Candidacy for a Bone Anchored Hearing System in the Adult Population

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- - [Jackie] All right, hello everyone! Welcome to the Audiology Online webinar, today's course will be on, "Bone-Anchored Hearing System Candidacy", and also, the "Evaluation of an Adult Patient". So, just a brief introduction before we get started, my name is Jackie, I'm an audiologist, at the Michigan Ear Institute. MEI is a neurotology clinic, that's located in Southeastern Michigan. We have nine neurotologists, 16 audiologists, and one audio technician, so it's a pretty large practice, and as an office, we do see many implant patients; last year, we activated 96 osseointegrated devices. So, I'm excited to share with you, some information today, about the bone-anchored hearing system candidacy, and the evaluation process, in our clinic. So, this course, here, I'll provide you with an overview; of the candidacy criteria, the evaluation process, and the post-operative follow up, for patients that are pursuing a bone-anchored hearing system. We're also going to briefly discuss some of the data, on one of our single-sided deafness studies, currently going underway, right now, at Michigan Institute. So, here's the agenda for the afternoon, we'll review the bone-anchored hearing system, how it works, discuss some of the candidacy criteria, considerations for implantable devices, what's typically done during the evaluation, and again, the standard fitting and follow up, and then a little bit on that SSD research, as I mentioned before.

So, before we dive in, here are some of the course objectives, to keep in mind throughout the presentation. At the end, you should be able to; list the main components of a bone-anchored hearing system, discuss the audio metric candidacy criteria, for a bone-anchored hearing system, you should know the difference between a percutaneous and transcutaneous system, and list at least three things that should take place, during the evaluation process of a BAHA candidate. So, let's get started, here first, with that overview of the bone-anchored hearing system, and how that works. Bone conduction hearing, works by bypassing the outer and middle ear, and stimulating the inner ear directly, as most of us already know. When the

bone-anchored hearing system is worn, the external sound processor takes the acoustic sound signal and transforms that into vibrations. The processor is attached to an abutment, which is connected to an implant, that's secured in the bone of the skull, and that contact transfers the vibrations through the skull bone, to both cochlea, to give the patient the perception of sound. This way of hearing is possible, through a process called osseointegration, a term that I'm sure most of us are familiar with, and this is where the bone itself, begins to grow on to the titanium implant, and creates a strong connection between the two. The bone cells naturally want to integrate with the implant, and as a result, a direct route for sound is established. So, typically, around the six-week mark, osseointegration is near complete, and it's safe to begin using a processor on the abutment. At our clinic, we do typically, program the patient's bone-anchored hearing system approximately six weeks after surgery, unless it's a revision surgery, or an abutment replacement, then the physicians will usually request, that the delivery be postponed, until closer to 12 weeks, to avoid possible failure of complete osseointegration. So, there are a few different types, of osseointegrated systems, out there, that I'm gonna talk about, your typical bone-anchored hearing system, on a post, is a percutaneous direct-drive system.

So, with this type of device, the sound is transmitted, directly to the skull, from the processor, via an abutment, that's penetrating the skin. That abutment is attached to an implant, that's osseointegrated in the temporal bone. So, the Oticon Ponto, and Cochlear Americas' BahaConnect, are two of the examples that are commonly seen, that are known as direct drive systems. With skin drive systems, also called transcutaneous bone-anchored hearing systems, the vibrations are transmitted across the skin, to the skull bone, so Cochlear Americas' Baha Attract, is one example of a skin drive system. More specifically, it's a passive transcutaneous bone-anchored system, which just means that, the processor generates that stimulation outside of the skin, and the sound is then attenuated by the skin, before reaching the bone. Direct drive systems typically result in the most efficient transfer of sound, between those two

types. Some research has shown that there's a significant high-frequency attenuation, when the sound is transmitted across the skin, compared to the direct drive system, that transmits directly to the skull. When you're talking about output, a traditional bone-anchored hearing system, on a post, is best, followed by a magnetic solution, and then, finally, a non-surgical option, such as a soft band, or a sound arc fitting. And one other thing I did want to mention, is just the Osia, which is a newer device, from Cochlear Americas, that utilizes something called a piezoelectric transducer, and that transducer is situated in the implant, under the skin, which is different from the typical electromagnetic transducer, that sits in the processors of the other bone-anchored hearing systems we discussed, such as the Ponto and the Baha Connect and Attract. The candidacy criteria is a little bit more strict for the Osia, compared to a traditional bone-anchored hearing system. So, for the sake of this presentation, I'm not really going to focus specifically on that device, but I did wanna mention that, it's a different type of system that is available.

So, here are the components of a percutaneous bone-anchored hearing system, which as I mentioned, is the type that is most commonly seen in clinic. So, these components include the sound processor, the coupling, the abutment, the screw, and the implant. The implant sits internally, and the abutment penetrates the skin, the processor sits just outside of the skull. So, for the transcutaneous bone-anchored hearing system option, the processor is attached to an external magnet, and that attracts to an internal magnet, to hold that processor in place, rather than having the abutment. So, now that we've had a brief overview on the bone-anchored hearing system, and how it works, we're going to spend a lot of today, focusing on the candidacy, and seeing what our typical, bone-anchored hearing system patient looks like. So, these candidates can be patients, that have single-sided deafness, conductive hearing loss, or mixed hearing loss. So, as we're all aware, patients with single-sided deafness, have essentially unaidable hearing, in one ear, so the options for treatment of these patients, commonly include; either doing nothing, wearing a CROS unit, or utilizing a bone-anchored

hearing system. So, just a reminder, the CROS and the bone-anchored hearing system, are truly, not aiding that poor ear, in these cases, but instead, the devices are routing the signal to the better-hearing-ear, either via wireless transmission, with the CROS system, or via bone conduction, with an osseointegrated device. Your patients with conductive, and mixed hearing losses, have outer, and/or middle ear issues, that are causing an air-bone gap on your audiogram, and the bone-anchored hearing system, effectively closes that air-bone gap, by completely bypassing the outer and the middle ear spaces, and stimulating the inner ear directly.

So, this is a great treatment choice, for patients that have any of these types of hearing loss. Listed here are just some of the potential causes of hearing loss, that you may see in your patients, who are bone-anchored hearing system candidates, single-sided deafness may be congenital, it could be caused by the presence, or the removal, of an acoustic neuroma, may be a result of a viral infection, or even severe or long-standing Meniere's disease. Patients with conductive and mixed hearing losses, might have conditions such as; otitis media, otosclerosis, tympanic membrane perforation, or congenital defects, such as; microtia or atresia. So, here's the audio metric criteria, that we look at for bone-anchored hearing system candidacy, specifically, for patients with conductive, and mixed hearing losses. So, your patients with air-bone gaps, have good, or, at least, better nerve function, since the cochlea is intact, so, really, what they need most, is simply more volume. And as I mentioned before, the bone-anchored hearing system, effectively closes that air-bone gap, because it's bypassing the problematic area of the ear. So, to determine candidacy, for a bone-anchored hearing system, first and foremost, you wanna look, at the bone conduction pure-tone average, which should be at, or better than 65 dB, for the patient to be a good candidate. Second, we're also looking at the amount of air-bone gap that's present, so, we typically look for an average, of about 30 dB or greater, when strongly recommending a bone-anchored hearing system to a patient, over hearing aid, but this is not a hard and fast rule, at least in our clinic, by any means. Some research, that's out there, has

shown that, the larger the air-bone gap is, the more likely it is, that the bone-anchored hearing system, will outperform a traditional hearing aid. So, in cases when you see this on the audiogram, maybe we need to give greater consideration to the bone-anchored hearing system, over a traditional hearing aid, even when there's no contraindication for wearing a standard hearing aid. So, this figure, that you see up here, is actually from an article that's available on audiologyonline.com, and what it's showing, is the decline in reported benefit, when the patient has an air-bone gap of 30 dB, or greater. So, your large air-bone gaps, can create difficult hearing aid fittings, when the loss is severe, you could run into issues with feedback, you may run into issues with lack of headroom, and distortion to the patient.

So, these are some of the considerations to take into account, when you you're evaluating a bone-anchored hearing system, and recommending a treatment option, for a patient that fits this criteria. And when you have a patient with conductive, or mixed hearing loss, and you're considering a bone-anchored hearing system, which side do you fit, if not both sides? We know that two ears are better than one, however, for a bone-anchored hearing systems patients, to actually achieve true binaural benefits, it's important to have symmetrical, bone conduction thresholds between ears. So, according to both major bone-anchored hearing system manufacturers; Oticon Medical and Cochlear Americas, this means an average of 10 dB or less, and no more than 15 dB, when you're looking at individual frequencies. The bilateral fittings, have been shown to provide the patient with binaural summation, improve speech and noise understanding, and they may even assist in sound localization. So, if the patient has bone conduction thresholds, that do not meet the outline candidacy criteria, they may still benefit from a bilateral fitting, in terms of achieving better audibility, and I know, at least, in our clinic, this is something that has been done in the past. For patients that have a symmetrical bone, typically what we're doing, is fitting the side with the best bone conduction threshold, and then recommending hearing aid use, on the opposite ear, if bilateral bone-anchored hearing systems, aren't considered. So, you want the

patient to have the best hearing with the device, especially, if one is all that they're going to be getting. And since there's some attenuation of sound, on the opposite side of the fitting, if you're implanting the bone-anchored hearing system on that poor side, it'll work more like a CROS device, than an actual hearing aid in these cases. But, you may also need to take into consideration, things like; drainage, inflammation, recurrent ear infections, and things like that, when choosing a side to fit, it may not always be a straightforward decision. In terms of your audio metric results, for single-sided Deaf patients, rather than looking at the bone conduction threshold, of the ear to be implanted, as you would with conductive or mixed hearing loss patients, you'll wanna be looking at the thresholds of the better-hearing ear. Remember, in these situations, the bone-anchored hearing system is taking that sound, and routing it over to the better hearing ear, via bone conduction.

Traditional single-sided Deaf patients, have profound hearing loss in one ear, and normal hearing in the opposite ear, defined as a pure-tone average of 20 dB, or better, at five, one, two, and three. With the advancements in the processor power, you can now fit patients, who have some degree of hearing loss, in their better ear as well. Both Cochlear and Oticon, can have regular power, power, and super power devices, that are available, and you can fit patients with up to 65 dB of hearing loss, so it's quite a wide range. For your single-sided deaf cases, where the patient also, has a significant amount of hearing loss in the good ear, historically at our office, what we've recommended, is use of a BiCROS system, over a bone-anchored hearing system, so that the patient can achieve the best audibility from using a hearing aid on that better ear, along with the benefit of the crossover, that's provided by the transmitter. But I did wanna mention here, an interesting research study, that was completed in 2016, it's cited at the bottom for you, what they did, was, they looked at unconventional bone-anchored hearing system recipients, with mild to moderate hearing loss, in their better-hearing ear, and what they found, is that these non-traditional patients, performed poor on the speech and noise tasks, that they were administered, but they

had improved quality of life measures, and, they noted a similar perceived benefit, to those patients that had true SSD, so this is also a very good option for those patients. Here are just some of the potential advantages, of a bone-anchored hearing system, over other options that may be available to your patient, and these may become points of discussion, during the evaluation process. The bone-anchored hearing system, is going to leave the ear canal open, and it only requires wearing one single device, compared to a traditional hearing aid, the bone-anchored hearing system, would require significantly less gain, because there's no conductive component, that you have to overcome, in the programming. It also may require less adjustments, as we know, the air-conduction thresholds, of patients with conductive or mixed hearing losses, tend to fluctuate, depending on the status of the outer and middle ear, and this can require constant programming changes, while wearing a traditional hearing aid. So, since your bone-anchored hearing system is completely bypassing that part of the ear, that's causing the air-bone gap, the programming is only done, when the patient's neural function changes. For single-sided Deaf patients, the CROS unit requires wearing a device on each ear, and that sound is being transmitted to the healthy ear. The sound that's being transmitted over, is filtered through the receiver of the hearing aid. So, if you have a true SSD patient, that has normal hearing on the opposite side, it might sound strange to them, to have artificial sound quality transmitted through a completely normal hearing ear.

So, again, just some things you may wanna take into consideration. So, here we're going to focus on the evaluation process, of patients who fit that candidacy criteria, that we just talked about. So, I've listed here just some things that should be done, during the evaluation, for a bone-anchored hearing system candidate, you'll notice that I started the sound field testing. At present, this is only part of our evaluation process for research participants at our clinic, however, we are looking into changing this, and making it a standard part of our evaluation protocol, for all bone-anchored hearing system candidates, the biggest challenge, at least in our clinic, is the time that it takes

to complete this kind of testing, and the fact that, currently, all of our bone-anchored hearing system, simulation appointments, are no charge to the patient, which is an hour of time, that we are billing nothing to insurance, and nothing to the patient for. During the evaluation, I feel, really, that it's most important to demo the device. I truly believe that the demo, of the bone-anchored hearing system, is powerful. Many patients rely on that demo, to give them an idea of what to expect after surgery. Plus, you actually have the ability to show a patient what the device sounds like, which is unlike other surgical options, such as a Cochlear implant, so you might as well, utilize that. It's easy enough to complete an in-office demo, of the device, you can also choose to give the patient a more real-world experience, such as having them take the processor to lunch, maybe walk around the atrium in your facility, or even take the device on loan, for a weekend-long trial, or on a vacation.

In our clinic, we're always doing a demonstration, during the appointment, and any additional time with the processor is given, if the patient requests it, or if they're on the fence, about whether or not, they have perceived any benefit from it, during that quick demonstration. So, we're mostly seeing these extended trials, with our single-sided Deaf patients, as they don't typically have the wow factor, that many patients with conductive hearing loss have, when they first hear through a bone in your hearing system. Your demos can be done on a test band, using a test rod, or placed on a soft band. So, typically, we're using a test band, which as most of us probably know, looks and fits similar to the bone conductor, that you're using in everyday audiometry. So, in terms of the programming, you can choose to program the processor, for demonstration purposes, in a few different ways. If you have the time, it's best to complete BC Direct, through the software, with the bone-anchored hearing system on the patient, using that test band, or a soft band. So, this is essentially, like running an in-situ audiogram, in a hearing aid, which I'm sure most of us have done in the past. The patient will tell you when they hear the beeps, and the processor becomes programmed, based on those results that you've inputted. You can also choose to

keep your bone-anchored hearing systems pre-programmed, for quicker demonstrations, in our office, if the physician adds on an evaluation that we're doing more on the fly, we have our different devices, pre-programmed, so that we can complete the demonstration, without actually needing a computer that has the NOAH software available, to complete BC Direct. So, for example, you can set program number one, for a patient with conductive hearing loss, maybe set two, for a patient that has a mixed hearing loss, and use program number three, for your single-sided Deaf patients. So, even though these settings aren't unique, to each and every patient that you're going to see, for these quick demonstrations, it'll still give them some idea, of the bone-anchored hearing system's benefit, which is the goal of the demonstration. So, something that I wanna mention here, is that, we are always demoing each manufacturer's power device, even if the patient is a regular power candidate, and that's because, obviously, there's no osseointegration at this point, and as we know, the gain is attenuated, without having that direct drive, particularly in the high frequencies, and the mid frequencies, which are important for speech, and we want them to perceive benefit, during trial, on the device, so we are always using that power processor.

So, I just wanted to give you some example demo settings here, if you are choosing to complete demonstrations using pre-programmed bone-anchored hearing systems, here are the examples, of how our devices are set for patients. We have three programs for each manufacturer's power device, and we input a test-patient into NOAH, with bone conduction thresholds just between 10 and 15 dB, at all frequencies, to create program number one. Program number one, we use for patients with conductive hearing loss, programs two and three, are modified based off of program number one. Program two, we use for patients with mixed hearing loss, and here what we've done, is just added overall gain to the settings, I believe around five units. For program number three for our single-sided Deaf patients, we've taken program number one, and we've just added five units of high frequency gain, to compensate for that

attenuation from crossover. So, if you're new to bone-anchored hearing systems, the programming is very easy to do. All you have to do is, go into the manufacturers program settings, add a program, and modify the gain, from the fitting screen. It's also a nice way to navigate the software, and familiarize yourself with the programming, without a patient in front of you. So, for sound field testing, once your device or devices, if you're demoing different options, have been programed, either, using that preset gain or BC Direct, you can choose to complete sound field testing, to determine any potential benefit, from the bone-anchored hearing system. So, this is new to our clinic, and still kind of in the trial phase, as I mentioned before, it's currently only a standard part of the evaluation process, if the patient is enrolled in one of our SSD research studies. So, if you choose to do this, as a part of your evaluation, you should be completing unaided testing and aided testing, on your potential candidates in the sound field.

And it can give you an idea of speech perception ability, with and without the bone-anchored hearing system, that you can use for comparison purposes, so what was that patient's aided, benefit, with this device. And really, there's no standard for this, you can use whatever speech material that you have available to you, you just wanna make sure, that the patient can complete the test unaided, but, you wanna make sure that they won't hit the ceiling, in the unaided condition as well, because it will leave you no room to show any benefit, when using a device. So, for SSD patients, which are those who are completing the testing at our clinic, currently, we're typically seeing the largest benefit during the aided condition, when noises towards the patient's good ear, and speeches coming in towards the patient's bad ear. So, like I said, this testing can give you an idea of post-operative benefit, with the bone-anchored hearing system, which is why it's really important to do, if you have the time, and of course, if you can bill for that time, which I'll talk about in just a few minutes. And, these results of your sound field testing, can help to guide your counseling with the patient, when it comes to choosing a treatment option with them,

at the end. So, I just wanted to give you an example testing condition, and currently, this is the setup that we're using for our research patients. So, as I mentioned, there's no standard procedure for this type of testing, so you can modify it to your preference, and use what materials you have available in your clinic. Currently, we're using the QuickSIN speech material, in the separated-speaker conditions, so, for testing the presentation level, for the speech, is 50 dB HL, and that competing speech babble, is adjusted with each sentence, going from a signal to noise ratio, of 25 dB, all the way to zero, which is a really, really tough condition, as most of you are aware, if you've done it with your hearing aid patients, or even taking the test yourself. So, speech is presented at a zero-degree azimuth, and noise is presented at 90 degrees towards the better ear, and then we're also presenting noise towards the poor ear. Testing is completed, unaided first, using two separate QuickSIN lists, for each of those conditions, and then we are doing aided conditions, just the same. So, you get an SNR loss, for each condition, and what we're looking at, is the difference in the unaided and the aided conditions, as well as those with speech towards the poor ear, and speech towards the better ear.

So, again you're typically going to see the largest benefit, for single-sided Deaf patients, when noise is towards the patient's good ear, and speech is coming in towards the patient's bad ear, or speeches coming in head on. So, as you can see, just from the settings here, and the setup, the testing is fairly simple, but it can be pretty time consuming, depending on what your test protocol includes. And as we know, time is money, especially in today's climate, so the big question is always, how do you bill for this testing? So, if your clinics doing any cochlear implant evaluations, you are likely billing the CPT codes; 92626, and possibly, 92627 in addition to the 626 code. The codes are actually not specific to cochlear implants, but according to ASHA, they can also be used, when evaluating patients for hearing aids, osseointegrated implants, like in this case here, middle ear implants, and even auditory brainstem implants. So, these are time-based codes, and, at least to my understanding, you must spend a minimum

of 31 minutes, of the 60 minutes, for the, 92626, at least 31 of those minutes, needs to be spent evaluating the patient, which includes testing and counseling. The add-on code, 92627, can be used in addition to 92626, for any of your evaluations, that might be lasting longer than 60 minutes, but you cannot bill, 92627, without 92626. So, if your evaluation is shorter, and there's another option that I'll talk about, but before that, I wanted to mention that, for the 92626 code, the average reimbursement for 2019, when I spoke with our billing department, was $59.70. So, $60, for the hour-long appointment, it isn't much, but it's better than nothing, and again, we're in Michigan here, so, those reimbursement rates may be different, in your state. So, yeah, it's not a whole lot, but, if you can streamline your testing protocol, and complete your evaluation, with sound field testing, in an hour or so, it's not bad! So, if you're doing an evaluation that's less than 30 minutes, you can choose to build a 92700 code, which this code stands for, an unlisted otorhinolaryngological service or procedure.

So, that billing code requires you to send in supporting documentation, and that documentation has to detail the need for service, the time it takes, the effort it takes, the equipment that's necessary to provide the service, and still, your reimbursement may be questionable. So, we have actually used this billing code at our practice, in 2019, we were using it for video head impulse testing, because there's currently not a CPT code available for that. And, when we were billing vHITs, under the 92700 code, even with supporting letters, and all that documentation that was requested, we were receiving many rejections, and those rejections would require appeals to even consider payment, and even then, a lot of them resulted in poor reimbursement, despite over and over trying to appeal them, by sending in more and more documentation. So, this can be time consuming for you, it can be time consuming for your billing department, if you're fortunate enough to have one in your practice, so it can be something to try, but we had actually switched our video head impulse testing, to a private pay service, in January of this year because it was just too time-consuming, to be billing out the 92700 code, wait for a rejection, submit an appeal, and kind of go back and forth, with

the insurance companies. So, I just wanted to mention that. So, nearing the end of the evaluation process, you come to the device selection, so, your patients have many options at this point; are they going to go untreated, will they use a CROS, if they're an SSD candidate, will they use a traditional hearing aid, if they have a conductive or mixed hearing loss, did they like the bone-anchored hearing system? This part of the process can be really overwhelming, and require a lot of discussion, on the pros and cons of each option, before the patient actually decides. So, you always wanna ask the question, of whether or not, the patient found benefit during the demonstration, and if so, which device did they prefer? So, it could lead to discussions of cosmetics, wearing one device versus two, the sound quality of a bone-anchored hearing system, versus a traditional hearing aid, or a CROS, and the connectivity options that are available, which, in today's day and age, pretty much any option, has a Bluetooth, so... For sound field testing, if the sound field testing was completed, you can also discuss which option, the patient performed best with.

And something else I just wanna note here, is that, if the patient perceived benefit, during the non-surgical demonstration, of a bone-anchored hearing system, it's likely that they will feel even more, after surgery, as more gain will be available, once you have that post in place. So, the demo, actually underestimates, the device benefit. So, finally, if the bone-anchored hearing system is in fact chosen, is the patient going to use the percutaneous system, so, having a post, or are they going to be using a transcutaneous system, having that magnet, holding the bone-anchored hearing system, in place, You'll wanna consider this, because the transcutaneous system, will likely require a more powerful processor, because you're going to have that attenuation from the skin. So, those cases, in cases where we have patients who have progressive hearing loss, or if their thresholds are borderline, we tend to lean towards choosing a more powerful processor, so that we have increased headroom, because you're not upgrading a bone-anchored hearing system, very often, it's usually every five years, or later. So, wrapping up the appointment, typically includes; discussion with the patient,

and that discussion's about, what they've learned, about the devices that are available to them, what they've experienced during the demonstration. So, during the evaluation, you really wanna determine, what the patient's goals are, for treatment. Then you wanna discuss how those different treatment options are gonna help the patient achieve those goals, and then just make sure, that the patient has realistic expectations. So, to get this information, you can use formal methods, informal methods, or a combination of formal and informal. The American Academy of Audiology, recommends the use of formal hearing handicap inventories, such as using the COSI, or the APHAB, which we're all likely familiar with, because it's also best practice, to use for your hearing aid patients, so it's good routine, to get in to start using it, on your bone-anchored hearing system candidates as well.

So, nearing the end of the appointment, you wanna make sure that the patient also understands the process, and what to expect after a treatment option has been chosen, and reviewing that timeline with them, of how long this will take. How long is it gonna take for surgical scheduling, to contact them, when is their surgery going to be? How long after that, will they see you? And then making sure that they're visiting with their physician as well, so that the physician can answer any questions, about the surgical procedure itself. So, in terms of the post-operative follow up, I'm just gonna briefly review, what usually happens, with our bone-anchored hearing system patients. As I mentioned before, the patients are typically seen, approximately six weeks after surgery, unless there were complications with healing, or if the surgery was a revision, then it's closer to the three-month mark, and that's really dependent on what the physician says. So, the fitting, at our office, is a one hour-long process, and the bone-anchored hearing system kit, is mailed to our office. So, once it's mailed to the office, we have audiology assistants, that are reviewing the packing list, and cross-checking things, so, making sure that, not only the appropriate device was sent out, but that the patient also has all of their paperwork, and all of their manuals, ready at hand, as well. So, I've outlined down here, the checklist that we typically follow,

during our delivery appointment, which is always starting with checking the implant site, to make sure that it looks healthy. One nice part about working in a neurotology clinic, is that there are always physicians, and fellows, available, if something doesn't look quite right to you, in terms of the site. So, maybe you see a little bit of skin overgrowth, or there's oozing at the implant site, you want the patient to be medically cleared, before you're fitting the processor to them. So, after that clearance, we are programming the processor using BC Direct, we're always doing a detailed fitting during the delivery, we never express-fit it, at this point, after the patient has had surgery, and is taking that device home, for the long term. So, after we complete BC Direct, we're making any gain, or programming adjustments, to the patient's liking, adding any additional programs, changing any fitting formula, anything like that, and then, we're also paring any accessories that were received, for those of you, that are already doing bone-anchored hearing systems, you know that the orders come with an accessory, so we're always discussing that, at the evaluation, and then, at the delivery of the bone-anchored hearing system, we're pairing the accessory for them, and showing them how to use it.

We're also reviewing items of their kit with them, and spending a lot of time practicing with the processor, which seems to be the most difficult for the patients, just the orientation, getting it on the abutment, and practicing with it, because many of them are really hesitant to do so. So, we're showing them on how to change the battery, how to put it on and off the abutment, and all of those different things, how to use their accessories, how to activate that streaming. And most of our bone-anchored hearing system patients are really happy, and they require minimal follow up. So, typically, once that processor's fit, once it's programed, and the patient oriented, we don't schedule a return visit, unless it's requested by the patient. The patients, really, only call to come in, if something has broken, or if their hearing has changed, and the programming is warranted at that point. Sometimes, when they're coming in to see the physicians, the physicians will send them over, for a quick boning for hearing system

check, where we'll just take the processor, clean it up, we place it through the electronic drying cycle, make sure that everything sounds good on a test rod, and ask them if they're having any difficulty with the processor, and then, at that point, if things come up, we are scheduling visits for them. But I would say overall most of our patients, who are using osseointegrated devices, are really happy with them, we've been really fortunate with that. So, I hope that I provided you with a decent overview, at least on the candidacy guidelines, and what should be completed during the evaluation process, of a potential candidate for a bone-anchored hearing system. Like I mentioned at the beginning, I just wanted to briefly touch on one of the studies, that's being conducted here, with our single-sided Deaf patients, we currently have two going on, I'm only going to touch on one today though. So, this particular study that I'm gonna talk about, is focused, primarily, on device selection, for single-sided Deaf patients. So, what are these patients choosing if anything, are they not doing anything, in regards to their single-sided deafness, are they choosing a CROS unit, if so, which manufacturer? Are they choosing an osseointegrated device, if so, which manufacturer? Are they using percutaneous, transcutaneous, or did these patient patients choose the Osia, which I mentioned at the beginning of this presentation.

So, for these participants, that have agreed to be in the research study, prior to their evaluation appointment, the front desk is giving the patient, a Hearing Handicap Inventory for Adults, the HHIA, the Tinnitus Handicap Inventory, the THI, and a questionnaire that was developed, at Michigan Ear Institute, with some assistance, and that purpose was trying to determine, what factors are influencing the patient's treatment choice. So, for the survey, we used a Likert rating scale, where the patient's choosing their level of agreement, to each other 25 statements, along a five-point scale, and that five-point scale, ranges from, strongly disagree to agree. So, we had developed questions, for the device selection questionnaire, that relate to motivation, and perceived level of handicap, surgical versus non-surgical intervention, and characteristics that are related to the device model itself. So, all 25 questions were

grouped, into those categories, there, that I mentioned. So, what we're currently working on, is examining relationships, between the ratings on each statement, and which treatment option the patient chose. So, at present, this study hasn't been going on very long, and then we have the whole COVID pandemic, so it was a couple month hiatus in between, but we only have approximately 35 surveys completed, right now, that they've completed all three questionnaires, that we've asked, and we know who the patient is, so that we can track which treatment was chosen. So, our goal is, really, to get at least 50 of these patients, hopefully closer to 75 or 100, before we really start to dive into the analysis. So, one thing that I found interesting, and did wanna mention is that, during the preliminary analysis of the device selection survey, so, that 25 item questionnaire, we found several questions, that elicited a homogenous response, across all of the participants. And all of those statements are listed up here, so of each of those eight statements, they all had an average rating of four or higher, across all of those participants, all 35 of them.

So, we're currently analyzing the answers, to these statements, and again, like I said earlier, which device was chosen. So, I did mention at the beginning, that the patients were also given two questionnaires, in addition to this 25-items survey, most of the focus on the study, is on the device selection questionnaire, however, we're also going to be looking at the correlation, between the HHIA scores, and the THI scores, and particular questions that were asked, in the device selection survey. So, so far, we are seeing a correlation with the HHIA score, and question number one on the survey, which states, "I feel handicapped by my single-sided deafness", this is something that we expected. Interestingly, we are seeing no correlation, between a high THI score, and question number 17, on the survey. Question 17 on the survey states, "Relief from my tinnitus is my main motivation "for seeking treatment." So, at least now, it appears that tinnitus relief, is not the primary goal of treatment, even though these patients are reporting a severe handicap, from the tinnitus, that they are experiencing. So, this could be just the way that the question was worded, as to why we're not getting the

correlation that we've expected, at least so far. So, hopefully, I'll be able to share more of these results, from this study, at a later date, with you, so stay tuned. And finally, I just wanted to say thank you, for joining me this afternoon, to discuss the bone-anchored hearing system candidacy, the evaluation process, and the post-operative course, for an adult patient. I did just wanna give a special thank you, to Robby, at Oticon medical, for inviting me, Melissa, with Audiology Online, she's been really supportive throughout all of this, and then, Christine, from Oticon Medical as well, who has helped with the SSD study, that I touched on, from a consultancy standpoint. So, I do want to share my email with you, if you have any additional follow up questions, that you can think of today, I forgot to put it on the slide here, but if you have a pen handy, my email is, jrenker@michiganear.com So, thanks again, I really appreciate it. Alright, so any questions that anybody has, you can type them in your question box, at the bottom, and I'd be happy to answer those for you, or do my best to answer them for you. A lot of what I talked about today, was specific to our clinic, here, and if you guys are doing the bone-anchored hearing systems already, your protocol may be a little bit different.

So, I have a question here, "The bone-anchored hearing system, "will be implanted behind my poor ear, "is this true or false, and can you explain this more?" So, the bone-anchored hearing system, in most cases, is implanted behind the poor-hearing ear. So, for your single-sided Deaf patients, you're implanting it behind the poor-hearing ear, and that signal is being routed to the better-hearing ear. So, that's true, and then, typically, with cases of conductive or mixed hearing loss, it's also the poor-hearing ear, when you're looking at air-conduction thresholds, but like I said in the presentation, that may vary. So, what we're typically doing, is implanting the ear with a better bone, which typically does have the poor air-conduction threshold, so I hope I answered that for you. "It looks like from your illustration, "of speech and noise testing, "that four speakers are required, is that correct?" No, so that was two separate, I can go back here for you. So, on the testing conditions here, it's actually

two speakers, so if you read at the top, we're just changing whether the noise, is going towards the patient's better-hearing ear, or whether it's going towards the patient's poor-hearing ear. So, only two speakers are required, for the sound field testing. You can have them set up like this, and I know some booths, also have the patient sitting in the middle, facing towards the window, and they have a speaker to the left and to the right, so that the sound is actually going into one ear, and then sound from the other speaker, is going in the other ear, not necessarily facing a speaker. Another question's here, "Are infections or complications with the implant rare?" So, because there are 16 of us, that are seeing the bone-anchored hearing system candidates, at our clinic, I'm not sure about other audiologists, and what their experiences have been, but I think out of all of the bone-anchored hearing patients that I have activated, I have maybe had one patient, that we've had to postpone it for. And then, from a surgical standpoint, I know our physicians are typically telling the patients that, it's a very quick procedure, the complication, and infection rate, is pretty low.

They're telling a patient it's about 45 minutes, and usually, they're seeing them, for two post-op appointments, after or before we are seeing them, so I would say that the infection and complication rate, is pretty rare with the bone-anchored hearing system. "So, can you explain more about the benefits "of a bone-anchored hearing system, "for a patient that has atresia?" So, these patients, a lot of them cannot use a traditional hearing aid, so when you test patients, who have atresia, microtia or both, you're going to get, pretty much, a maximum conductive component on your audiogram, and many, many times, your patient has really good nerve function. So, the bone-anchored hearing system, can be a really good benefit for your atretic patients, it may also be their only option. I know a lot of the patients, that we're seeing in our clinic, especially kids, are children that have atresia and microtia. "Do you believe that, "the distance between the implant and the ear canal, "is important for better sound transmission?" So, this is a really good question, the distance between the implant and the ear canal. This is not something I've heard of before, as an audiologist, at least in our clinic, we

are not discussing with the patient, exactly where that implant is going to be placed, in the temporal bone, the physician is placing it, and so, I don't really know, if there is importance to that placement. So, "How old must patients be, in the United States, "for a bone-anchored hearing systems, "and can you talk more about pediatrics, "and what you see, in-clinic?" So, in the United States, your patients must be five years of age, to be implanted with an osseointegrated system, but before this time, you can be doing non-surgical bone-anchored hearing systems with them. So, you can have them using the device on a soft band, or using the device on a sound arc, and a sound arc is sort of like a headband that's available, that Cochlear Americas uses, with their bone-anchored hearing systems.

So, you can use those, up until five, and then, the patient is eligible for surgery, at five years of age, in the United States. So, in terms of pediatrics, I am not a pediatric audiologist, and see very, very few kids, I know that there was a presentation last week, on pediatric fittings, so what I would recommend, is just looking back at the presentation that was given, on June 2, that way, you can learn a little bit more, about those options that are available for pediatric patients. Another question that I have here, "Are adults wearing bone-anchored hearing systems all day, "or all waking hours?" I would say most have our patients, are wearing the bone-anchored hearing system, pretty much, all waking hours, and what we typically tell patients, just like you would tell those that are wearing a hearing aid, is to get used to that sound quality, and to get used to having something on, that they're not used to, as you want to try and wear it, as much time as you can. So, I don't know what the average data logging looks like, in our clinic, for bone-anchored hearing system patients, but, there is good acceptance of it, and patients are reporting wearing them very often, except if they're going swimming, taking a nap, or if they just need a physical break from the device, maybe they're outside doing yard work, wearing a hat, things like that. "Is age a concern for older patients, "for example, a 90-year-old, given that, "they're medically, a fairly good candidate?" I would say no, we have patients, we have kids as young as

five, and we have patients that are in their 90s, using bone-anchored hearing systems with success, I think, with older patients, at least for what I've experienced in the delivery of them, not necessarily do they have issues with the surgery, but they tend to have more trouble, getting the processor on and off. So, that's kind of been my experience, as the patient gets older, is that, they have a little bit of a tougher time, getting used to putting it on and off the post. And typically, in our clinic, we are fitting most of our bone-anchored hearing systems on a post, we have very, very, very few patients, who are using that skin drive option, that's held on by a magnet. So, most of our patients are in either; an Oticon Ponto implant, or a Cochlear Baha Connect, very, very few, in the Cochlear Baha attract. "Can you share some real world discussions, "that you've had with patients, "that are bone-anchored hearing system candidates, "and what their expectations might be?"

So, I think the biggest thing when we're counseling, the bone-anchored hearing system candidates, and giving them those realistic expectations, especially for patients that have single-sided deafness, is that the bone-anchored hearing system, isn't necessarily going to restore your localization at all. If your patients, bilaterally fit, with a bone-anchored hearing system, and they are meeting the criteria for 10 or less, as a PTA, 15 or less, at all frequencies, they may have decent localization with a bone-anchored hearing system, but in a case where the patients fit unilaterally, this is not something that's going to help at all. And a lot of your single-sided deafness patients, their main complaint, especially if they're a true SSD patient, with normal hearing in one ear, is, "I can't tell where sounds are coming from!" And because the bone-anchored hearing system is not stimulating the poor-hearing ear, and, in turn giving the brain those cues, of timing differences and level differences, localization is something that a lot of patients come in, expecting to get from a treatment option, and that they're not going to receive, no matter whether they choose a CROS, or, whether they choose a bone-anchored hearing system. So, that's the biggest thing, I think, that we discussed, in terms of realistic expectations, is localization with it. We've also

discussed, so some of the things that I talked about earlier, when the patient has a really large air-one gap, we tend to push more of a bone-anchored hearing system, over a traditional hearing aid. We're also considering the patient's medical history; do they have tympanic membrane perforations, do they have draining ears, have they had reactions to ear molds in the past, that have caused inflammation and stenosis of the ear canal? So, these are all things that we've discussed with patients, in this, kind of real-world setting, of the evaluation process? "How long do bone-anchored hearing system devices last?" I think this is probably dependent on, how well the patient takes care of the device, but typically, around the five-year mark, is when our patients are coming back in, for upgrades to their processor.

So, after this time, the technology has been upgraded, the patient's device is out of the manufacturer warranty, and the manufacturer warranty, for a bone-anchored hearing system, is two years, so, it's out of warranty at this point, newer technology has come out, the new processor, probably has better sound quality, so we're typically seeing our patients, around a five to six-year period, but I have seen patients who have had the same bone-anchored hearing system, for 10, 11 and 12 years, so I think it's really variable, on how long it will last, kind of like with hearing aid patients. "Can you discuss the counseling that you've had, "regarding cosmetics, "when working with young adults and teens? So, this is something, in terms of the cosmetics, of a bone-anchored hearing system. I think this is something, that's being more and more accepted, especially, by the younger population, because people are always using some type of headphone, either in their ear, or now, there either bone conduction headphones behind the ear, or that you can wear on the temporal bone, and listen to music through that. So, I think in terms of cosmetics, it's not really a big deal for the younger patients, we have, at least in my experience, I've had some older patients, that have said, "I don't wanna look like Frankenstein!", with that post, out of their head. So, with those patients, if it's something that they're really, really against, that you think, they truly will not wear, the bone-anchored hearing system, because they have that post sticking

out, even though with most patients, you can't see it, when, or when they're not, wearing the processor. This may be something where you consider the Attract option, or using that transcutaneous option, that way, when the patient's not wearing the processor, you can't see any evidence, of having that implant site there. so working with younger adults, and working with teens, I don't feel like we really have to defend the cosmetics, or the way that the device looks, anymore, both manufacturers have nice color options for the processor, and the processors are a really sleek design. And I think for your younger patients, that are teenagers, and young adults, most of them are using smartphones, and their processors have Bluetooth capabilities, so being able to tell them that, there are all of these other great things about the processor, even if they don't like the way that it looks, that the advantages, kind of outweigh those things that they don't like. So, "For patients with mixed or conductive hearing losses, "your bone conduction threshold should be where, "to utilize a bone-anchored hearing system?"

They should be 65 dB, or better, let me go back here. So, this photo you have here, and you should have it in your printout as well, so, both Oticon and Cochlear, have this regular power, power, and super power option available, and that cutoff criteria is the same. So, 45 dB HL, your bone conduction should be at, or better than that, to use the regular power processor, 55 dB HL, for the power processor, and 65, for the super power processor. And one thing here, if you are not familiar with the bone-anchored hearing systems, or had not done a lot of these super power options, is, the Oticon Ponto is just that single unit processor, with that same 65 dB cutoff, and Cochlear Americas super power, looks a little bit more like a cochlear implant, where it has the processor and the actuator, on it, and that's connected by a cord. So, I know, at least in my experience, in fitting the super power bone-anchored hearing systems, for patients that are riding that 60-65 dB line, is with the Cochlear processor. This is where placement has come, I guess a little bit more into play, because the processor and the actuator, can sit so close behind the ear, if that implant site is sitting a little bit more forward, you may run into issues of feedback. So, if your patient is going to move

forward, with a super power option, and they choose Cochlear Americas' device, what we have been asking our physicians to do, is place the abutment a little bit further back, in the temporal bone, so that there's more space, between the actuator and the processor, and we don't run into issues of feedback. But if it's too late, there are also different ways that you can wear the processor with a longer cord, by clipping it to the shirt, or hooking it underneath the ear, that can help to reduce that feedback as well. So, 65 dB is going to be the worst bone that you can have, to utilize a bone-anchored hearing system. So, follow up, "Are cosmetics harder for older patients?" I would say in my experience, yes. More older patients, I think, are more accepting of a traditional hearing aid, and not having a processor, "sticking out of their skull, "and having that post there all the time". So, in my experience, I think that younger adults, and teenage patients are a little bit more accepting, of the way that things look, compared to the older crown. But again, this may vary, depending on the age range that you're seeing, and your patient population. So, do I have any other follow up questions? I think we went over a lot, with the presentation, and a lot with the questions, and like I said, if you think of something after the fact, you have a patient coming in, or you have a follow up question, that you didn't think of today, please feel free to send me an email, like I said earlier, my email is jrenker@michiganear.com. Okay, I don't see any other questions coming in, so, again, thank you all, for your time, I really appreciate it, and please feel free to reach out, with any follow up, have a good afternoon.