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Cochlear Americas Commitment to Educational Outreach

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>> Melissa: Let me know you can hear my voice and we're good in the particular pod. Thank you so much, Chris. Make that box a little bit smaller so the presenter can see his slides pretty big. For those of you that need the captions you can click in the caption pod. You will notice a small carat, looks like a arrow on a horizontal bar, hide the menu of the box to make it a little bit larger for you. For those of you that need scrolling captions today.. I see that Donna Sorkin has arrived.

>> George: Test, one, two. Test, one, two.

>> Melissa: George, if you can hear me, could you have -- I've not sure if Donna tried to activate her microphone at all, but if she could go on her screen to microphone button and select to disconnect, I don't want to get any feedback between speakers and the two computers in that room.

>> Donna: We will get her to turn the speaker off.

>> Melissa: Thanks.

>> Donna: Hello, this is Donna Sorkin cochlear program. He's audiologist with Cochlear Americas, George Cire. We will be starting at the top of the hour and ten minutes until the start time, so everyone, you still have time to get some tea or water until we begin the session today. We will be offering CEU's today from American Academy of Audiology, ASHA, and AG Bell LSLS program and you also may receive a cert of participation. If you download and fill out the feedback form. The feedback form is in the left side of the screen. Look in the file share area, there's a feedback form is on the top and the second handout is the PowerPoint that George will be using, so you can go ahead and download both of those right now. Please remember where you kept it. And we do take about two weeks to return the certificate, so please keep that in mind. It is free to get a certificate of participation. We also ask that you fully fill that out and demonstrate active learning. Just to remind everyone, we have over 100 recorded courses in the archived area of the HOPE website, including a number we have done on single sided deafness and conductive hearing loss and solution for that. We have one on soft band for young children, so if you are interested in this topic, and the use of the Baha device, there are a number of other courses up there in the archived area. So going to take just a little break here and we will be back in a few minutes. This is Donna Sorkin from Cochlear Americas HOPE program. We are putting polls up for you. We would love to know who you are and also how you found out about our HOPE site and also we are interested in knowing whether you're using the captioning today.

Thanks, everyone. Looking at the results of the polls, just over half of you have taken recorded HOPE Online, half of you never taken a recorded version of HOPE Online, and I want to remind you that we actually have over 100 recorded courses, and those are available with mostly CEU's. If they're older than a year you can't get the ASHA but you can get the AG Bell. Take a look at the recorded online and I think there's many you may have missed. We're just about ready. You can take those down, Melissa. I think we're just about ready to begin.

>> Donna: Hello, everyone, I'm Donna Sorkin from Cochlear Americas HOPE program and welcome you to Understanding Single Sided Deafness with Dr. George Cire, audiologist with Cochlear. This is part of the regular series on HOPE Online programs. We really try to cover the range of issues in hearing loss and the technologies that can resolve that bolt cochlear implants and the Baha device. We also talk about -- hearing aids and other technologies. George Cire is clinical manager with Bone Anchored Solutions and fellow of the American Academy of Audiology and American Sign Language and Hearing Association and won an award for continuing education from ASHA and over 30 years as audiologist in both the private practice and industry, and he's kindly shared his e-mail there with everyone if you have additional questions. So with that I'm going to turn the program over to George who's sitting right behind me here in Denver.

>> George: Thanks to everybody who is taking time out of busy schedules to join us today on our HOPE Online series. Just as a

matter of disclaimer, I am going to be talking today about a number of devices that Cochlear does not manufacture or distribute because the respiratory of this was to show the landscape of what's available for patients with single-sided deafness, so the information I will share with you on products that are not distributed or manufactured by Cochlear are information that I gained from the public domain as a student of this particular segment of audiology and hearing rehabilitation. I guess a good place to start today is to define what single-sided deafness actually is. And the slide that you're now looking at states that the single-sided deafness is defined as a condition where an individual has a nonfunctional hearing in one ear and receives no clinical benefit from amplification in that ear with the contralateral or opposite ear possessing normal audiometric function, and we define that as hearing thresholds that are no greater than 20 dB hearing level for pure tone levels of five, one and 23-kilohertz. The nonfunctional ear can be but not limited to profound hearing loss. The key factor is that the poor or bad hear has not or will not receive benefit when traditional acoustic amplifications applied. This is only -- only hearing good ear must really have pure tone average that does not exceed 20 dB hearing loss across the pure tone range. And this next slide you will notice kind of unusual nomenclature, big K with 021837. This is actually the 510K clearance definition because single-sided deafness is defined, and it is defined relative to Baha, and you will notice, and this is lifted directly from the language that the use of a Baha heard for SSD is intended to improve definition and single-sided deafness is definition for Baha hearing aid for patients who suffer again from unilateral deafness on one ear and other ear

having normal hearing, and define normal hearing like we did earlier, no greater than 20 dB. And Baha in all caps and word hearing aid. Over the evolution of this product and because of changes in classification for reimbursement purposes, we no longer refer to Baha as a hearing aid. We refer to it as osseointegrated implant system and this is actually defined and before there was single-sided deafness what we lived with was the description of unilateral sensorineural hearing loss and usually in the profound category, so the term single-sided deafness was actually coined by the predecessor company Antic when they offered Baha for single-sided deafness and introduced that term and become very widely used in the industry to describe the condition of a complete sensorineural hearing loss in one ear. So when we talk about that we really want to differentiate with someone that may have a conductive loss in one ear like you would see in patient with matricia and people with single-sided deafness have such damage to the ear, traditional amplification does not provide them any benefit. And we want to define the type of problem that is created when one is presented with this type of a situation. First you lose the ability to have spacial hearing. What we traditionally think of is localization in the horizontal plane. Auditory system is very oriented toward using very special cues to allow to localize sound and two channel or two ear input to make that kind of thing happen. So when one ear taken out of the creation it creates some confusion with localization. And the same time we have addition of the Head Shadow Effect which is a scenario where the dead side or the side where there is a nonfunctional ear actually is -- in the acoustic shadow of the good ear on the opposite side of the

head and we are going to talk about how that works and impacts, and what ends up happening is accumulative effect this presents difficulty with speech intelligibility in the presence of background noise and often most prevalent when the speech target is presented from the dead side and signal having to cross over and be heard by the only hearing ear on the opposite side, so it creates some communication problems, and it also creates some decrement and quality of life and quality of listening. So what we do know about two ears is that spatial hearing is very important to us and one of those qualitative features of the auditory system that allows us to be able to identify both near and distant sounds as well as where those occur 360° around our head. So as a result it is quite an important thing. What we understand about spatial hearing is there are features that we use when we have a normal functioning two channel system where normal ears are present in the patient and we utilize several different attributes here to allow us to have spatial hearing. One is interaural time difference or delta IT, and that's typically a lower frequency phenomenon. And allows the two ears to be compared against one other and small differences in time in the lower frequency domain, that can be measured and told and if the sound coming from left side of the head, 128 stimulate the left ear or head of the side opposite and those timing differences can be decoded in scenario where two ears are involved, and predominantly again low-frequency phenomenon. Look in frequency above 1600 Hertz, also deal with the interaural level differences. This is a scenario where the sound is actually occurring and slightly louder on the side that is presented to, and again the intricate connections in the auditory brainstem and

lower auditory system actually allow us to look at those differences, and this gives the brain information about where sound comes from and we call that the delta IL or interaural level difference. And then the last one you see on the slide is required or described as spectral difference or delta S and these three attributes allow us to have spatial hearing, so you can imagine if you lose one of the channels and you have no input, this gets thrown off. Doesn't completely destroy all the cues but modifies them in a way that creates some confusion. So the loss of spatial hearing is usually the motivating factor that would move a patient to look for treatment of SSD. It is not the only fantastic but -- only factor but if you work with patients with SSD, especially patients acquired SSD, this is the thing they notice right away, and they will also report this loss of balance between the two ears, and you lose this ability to have stereophonic or stereo hearing, so again, this is a motivating factor when this occurs that creates them to look for a solution. The loss of spatial hearing will not only -- communication concerns but create safety concerns as well because you can imagine if you have completely impaired ear on one side and have some auditory confusions, you're at more risk when you're a pedestrian of stepping in front of a car or a bus that may be coming that you might not hear, so these are real issues that can impact one's quality of life everyday. We usually evaluate spatial hearing. When you think about the types of hearing test and evaluations that we currently provide, we very rarely ever evaluate how patient hears in especially hearing domain, but it is a very important part and take largely for granted, and then finally spatial hearing is not equal to localization, but what I would say is

localization a component of spatial hearing, and we're going to talk about what to expect when we're doing these various treatments for individuals with complete loss in one ear. The Head Shadow Effect is really one of the major mechanisms that's widely studied and understood and with the loss of auditory function in the unilateral configuration sounds that originate from that same side where the impaired ear is present will actually fall in the shadow of the head. For long wavelength sounds or low-frequency sounds, these sounds because of the long wavelength have been very readily around the head and largely unaffected, so the head is actually transparent to the lower frequency sounds that might be present, but when we deal with the higher frequency sounds that have shorter wavelengths, these sounds tend to be reflected or baffled by the head in that shadow. And they get attenuated and that creates some difficulty. When one considers consonant sound with the meaning of English speech occur in the higher frequency domain, the Head Shadow Effect can be the primary or root cause for the difficulty of communication, especially as it relates to speech understanding in the presence of background noise. This graphic here kind of demonstrates what we said verbally in the previous slide. You can see the blue line representing lower frequency and wavelength sounds that tend to bend around the head but higher frequency short wavelength bounce off and create a shadow effect and you see the red X demonstrating the graphic illustration of where the ear is nonfunctional and the ear opposite is the ear that is normal hearing. So there's this combination effect that I describe here that talks about the loss of spatial hearing and the Head Shadow Effect create that



third problem of hearing in the presence of background noise. This is probably the other key factor that motivates one to seek some treatment when they have an acquired sensorineural hearing loss on one side. Speech recognition and noise is also confounded by the fact -- or lack that you don't have binaural summation and using the full capacity of the central auditory system but when we have a unilateral loss in one ear, we lose that summation effect which creates an additional confounding factor. And the use of any kind of CROS system, and we will define that in just a moment, generally will have no effect in terms of helping the binaural summation effect, and it is a very challenging scenario we deal with when we deal with this problem. So what causes single-sided deafness? This is not inclusive list by any means, but one of the causes that we know about is the presence of an acoustic neuroma or space occupying lesion in the angle. Typically these types of tumors are benign and slow growing but the surgical removal modifies or creates a damage to the auditory nerve rendering the patient completely deaf on that ear, and it is quite important that the space occupying lesions be removed so that they don't create other types of health problems and the side effect, of course, is many cases the patient is left completely deaf on that side. The larger problem is what -- is the second bullet which we call sudden idiopathic hearing loss, and usually due to viral infections, but this is the sudden loss of hearing for no really good explained reason. And it is usually inflammatory process that occurs in the cochlea and the virus infects the cochlea and causes localized swelling and culminates permanent damage to the hair cells in the cochlea and the patient doesn't get any recovery and left without any

hearing in one ear. Of course, you can have blunt trauma that might reverse create a Transverse fracture of the temporal bone and renders the cochlea completely inoperable at the time and have vascular insults that can occur to the vascular structures in the brainstem that damage the auditory pathway and leave one ear completely damaged. Meniere's Disease is process which fluid overpressure in the ear long-term damage to the cochlea and renders nonfunctional and can be congenital or genetic loss of hearing and unilateral presentation, and we know from early intervention and early screening programs that there are children that are born with unilateral loss and perfectly norm hearing in another ear. Again, this is not a complete list, but gives you kind of a flavor for what can potentially cause single-sided deafness. So what are our solutions? Well, unfortunately for a number of people the do nothing solution is what's offered because there's oftentimes a fairly cavalier attitude presented if you have one good functional ear, then you should move through life and just learn to live with the fact that the other ear will not contribute much, and believe it or not for some segment of that population of SSD patients, that's exactly what they do, and some of them never miss a lick as a result of that. We can offer what we call a CROS system which I will define in a moment and various bone anchored systems which we will talk about today as well, and there are options here that can be exercised for SSD. So what is CROS. CROS is contralateral routing of signal and see nice depiction of scenario where the patient's ear, and I will get my pointer here to point that -- this is the dead side of the ear, and notice that a microphone has been placed on the dead side and signal is routed to

amplifying system on open tube fit on the good fit side. This particular scenario we are able to contra laterally route the signal. This original work was described by Harford and Barry, where they have done early experimental work and this is the main treatment, and traditionally think of the main treatment as CROS or contralateral routing of signal. The early devices that Harford and Barry report are the older style of eye glass CROS hearing aids in the '60s where they were able to build most the electronics into the temple piece of the eyeglasses and use earmolds or open tube fittings to allow the signal to cross over and able to bury the wires that carried the connection from the connection to the amplifier in the frames and fitting these on individuals who didn't even have actual hearing loss and using plain glass to conceal and make it a more cosmetic scenario, but that is where the particular technology developed. We have now moved from CROS scenario that requires hard wires to something showing you on the slide now which is the latest Phonak CROS system with the size similar to the Audeo SMART hearing aid and built in the ear product as well as behind the ear product, so we have come a long way. The early CROS devices were hard-wired devices and you can imagine there were cosmetic push back from some patients that did not want to have this type of solution. Another company that offers a wireless CROS configuration is Audifon which is a German based product and also use real-time streaming methodology which provides a very broadband width signal and represents traditionally what we have had in CROS hearing aids. Now, there's another way to accomplish the CROS scenario and the transcranial CROS and described in the early 1990s and actually where canal hearing aid

that was acoustic hearing aid was fitted to the poor or dead ear and sound pressure in the residual volume was loud enough to allow pathway -- auto tympanic transmission of sound to cross from the bone of the dead side to the good ear on the contralateral side. So the poor or dead ear must be able to handle the high level of sound pressure level without any tolerance or recruitment issues, and that was the limiting factor for some patients who didn't have a completely dead ear on that side. This was not a good treatment option, but patients were able to use this, and again you will see in the next slide, we were using the small completely in the canal hearing aids and that was fitted in the canal of the dead ear with a lot of power to transmit the sound across, so it was just a different pathway that would allow for signals to cross over, and it was quite cosmetic because these things were largely invisible once they were inserted into the ear, and still some clinicians that use this technology. Again, it is highly variable by patient but good option for people that want a solution for the SSD. And again, we are going to move now into some discussion around how we use bone conduction solutions to accomplish that contralateral routing of signal, and notice in this particular slide you see the high and low-frequency wavelengths, but now what you see here is Baha or bone anchored product has benefited behind the ear on the dead side, and that's created the ability of the patient to have the signal routed through the bone in the skull and stimulating the cochlea on the opposite side. So we use these bone solutions in the same way but using the pathway of bone conduction. When we talk about bone conduction, bone conduction hearing enhancement devices came from the 1790's, physician

named Paledino in Italy developed largely a metal rod with the stirrup and simple distinction, speak to the patient we can transmit the vibration or raw vibration from the laryngeal output on the road and place on the patient's teeth or bone behind the ear and create a bone conduction pathway. There were obvious limitations to this technology but it was pretty sophisticated for the 1790's. And when we fast forward now into the modern electronic age where you see a cross-sectional view of bone conduction oscillator called the B71. This is largely electromechanical device that allows for a coil to stimulate a magnet core and when you apply an alternating current to the electromagnet, the movement of the armature in the center up and down creates vibration which can be transmitted through the skin and into the bone to create this bone conduction pathway. So this particular device was instrumental in creating bone conduction hearing aids in the electronic age and this is what a bone conduction hearing aid traditionally looked like, a manufacturer would simply take an air conduction hearing aid and modify the air conduction hearing aid to drive a bone conduction oscillator and it worked quite well. The problem with this is steel head band that you have to wear this on is not really comfortable for all day or long-term use and quite a bit of adjustment, and it wasn't the most cosmetically acceptable option, but it was still used and still used today in some situations. It is a little bit more difficult and lots of folks were not using this for SSD because of the amount of complexity and discomfort. Here is another depiction of a bone conduction device, made by the Starkey Corporation where there was actually a hearing aid circuit built into this -- get this working here. Built into this device here, and you can

see that it pictures the sound up through the microphone and there's a battery on this side and there's a wire in this head band. And this is the bone conduction oscillator that does the actual transduction of sound to the cochlea through bone conduction pathway. So this is the area. Bone conduction devices that we lived with. So there was the opportunity then to use what we call the bone conduction pathway in a device sent the TransEar which is a device that's produced in a company based in Tennessee, and then this particular depiction you got a behind the ear hearing aid attached to what you have seen before, but what's attached is not acoustic ear mold. It is a Lucite ear pace that encases or holds a bone conduction vibrator. And if you look at the length or dimension of this, you will notice this will be quite long. If you think back to the anatomical features of the external ear and external auditory meatus, the back one-third of the tube that defines the auditory canal is actually the skull bone and it is a bony feature. So if you are able to get the earmold seeded into the second bend of the ear canal so the tip of this ear mold is in contact with the bony ear canal, you can produce bone conduction signal through the ear piece and late the pathway through the skull and transfer the sound to the opposite side. So this is an option for folks that the don't wish to have surgery but when they have SSD there are some limiting factors in terms of the size of the ear canal and the comfort, but overall this product is met with some success and certainly an option for individuals who are considering treatment for SSD. So a new device that you may be hearing about is device by Soundbite by Sonitus Medical in California. This is interaural device and retainer device with a vibrator or bone conduction oscillator and

stimulator package with internal battery. This is actually worn in the mouth and snaps on the back of molars and the device that's shown in the middle here is the ear or receiver package which is actually a microphone and transmitter that is actually fitted to the deaf ear, and what goes into the ear is actual microphone so that you can use the actual bone conduction cues and these devices allow for the sound to be transmitted and amplified, and this is clipped on and off, much like a retainer would be. This is a relatively new device. We don't know a lot about it, other than the fact it has had clearance and is now commercially available but participates and works in the very same way in sound being picked up by the microphone, amplified and transmitted by the bone and the bone pathway allows the good ear on the opposite side of the deaf ear to be stimulated and product is another bone conduction device that doesn't require a surgical intervention but does require dentist to fit and take the impression and audiologist to fit that. Now we're going to move into a discussion about bone anchored solutions. This is the topic that's near and dear to my heart because this is what I work with pretty much everyday, and we will give you overview of what's available in the arena as well. One of the devices that's current to the market is device that's marketed by the Sphero corporation of Boulder, Colorado and was first found in Germany and manufactured in the United States. Particular slide, implant package here which is couple rare earth magnets encased in titanium carrier implanted underneath the skin and similar to the hearing aid and picking sound up and creating vibrational signal, and there's actually a magnetic plate that's attached to the back of this and transmission of sound is across the skin barrier what

we call transcutaneous pathway, so it is a bone anchored device and implant is anchored under the skin but nothing protruding through the skin. Two magnets attach on either side of the skin barrier and sound submits across the transcutaneous barrier and stimulates the sound through the bones in the skull and again the option is to transmit the sound to the ear opposite the deaf ear so that can be CROS hearing or contralateral routing of signal. This is relatively new and clear and available and then we will talk again about some of the other devices available here as well. Oticon Medical is a company that's developed a bone anchored solution. This is a picture of the sound processor, the Ponto pro, and this is the abutment and implant with the connecting screw that's all blown out in expanded format. And this basically picks the sound up. This is what we call a para cutaneous opportunity because there's a small metal snap that fits through the skin, and then this is the implanted component that's in the skull. So this is one of the options that's available. This is a relatively new company to this particular treatment. And then of course Cochlear has been involved a long time with the Baha System, and this is a picture of the Cochlear system and like the Oticon Medical system there's an implant and there's a -- an abutment that protrudes through the skin and that abutment allows for the processor to be attached to the -- to the abutment to get the sound transmitted into the bone directly by bone conduction and this is a photograph of the sound processor that's used. What we can say about the Baha System as it relates to Cochlear's involvement is it has been around since 1977. This was when the treatment was first introduced into the European market,



and it was the first implanted hearing system that worked by virtue of what we call direct bone conduction. Remember the Sophono device that we showed you earlier does not have the direct pathway because the sound has to travel through the skin, but the implanted Baha allows the sound to go to the bone and bypass the outer and inner ear and stimulates the cochlea in that fashion. So from a historical perspective the original work on Baha was done in Sweden and it was identified and the underlying property of osseointegration was identified by Professor Brånemark who discovered that titanium or the element titanium if implanted in bone and left undisturbed formed a bond that would strengthen over time, and Dr. Brånemark coined the term osseointegration and also involved with dental implants, so he knew quite a bit about biomaterials technology. And the technology was developed for aural implant retention and very rapidly progressed to ability to fix craniofacial and other types of anchoring systems and in the late 1970s Brånemark partnered with Anders Tjellström and it has developed since 1977, and again what makes it unique is it is a surgical procedure but allows for direct bone conduction pathway to be accessed and it makes a very stable long-term and predictable success story. This photograph you see here is actually the surface of a Baha implant where osteocytes are bonding to the implant and over time this comes with the bone and creates the pathway that's so important that we call direct bone conduction. This works again independent of the ear canal and allows for direct transmission and gives very clear and natural sound. The other really nice thing about these types of devices is that preoperative testing can be done and the patients have very high wearing comfort. We don't have

these hard spring steel head, and actually the surgery that's involved in placing a Baha is very straightforward and quite safe and has known a 30 year history of predictable outcome. So in this arena for bone anchored solutions Cochlear and Oticon are the ones available for this type of treatment. And this kind of gives you an overview of how it was dealt with in the United States. Both -- lots of these devices are scrutinized by the Food and Drug Administration because surgeries involved and cleared at the level of 510K and we mentioned in earlier slides that the device of the Baha -- original Baha device was available in 1977. It wasn't until 1995 that the device actually obtained clearance to be treating mixed and conductive hearing losses, and in the red I have marked the brake water year for Baha and that was in 2002 when the FDA gave clearance to the Baha System for use in single-sided deafness and this is why we're having the discussion today, and same year we also introduced a soft band that allowed us to treat children under the age of five. So with that said there was a long history of this particular thing, and we have been adding signal processors and digital signal processors and improved along the way, so a lot of growing interest. Frequently now people ask us I didn't -- a lot of people surprised to know this has a 30 year history but it is a really good treatment option. And wrap up some of the last slides here we talk about the win-lose scenario and it was talking about Baha on SSD and it could actually be relative to any type of CROS scenario, and bring the pointer down here and try to show you -- I could make that work. There we go. What we have here is person who has a Baha on their right ear and a good hearing ear on this -- sorry on the left ear and

speech presented where there's Baha mounted. Noise being presented from the front or noise and so this particular situation we call that the win situation because the performance of the Baha is much better when the speech is the primary signal that's on the side that the microphone is mounted to, and then we contrast that to the lose scenario where speech is actually in front of the patient and now noise is being presented predominantly to the Baha side, so now what's crossing over is the noise. So if we use a full bandwidth signal and we don't modify or roll off some of the low-frequency energy, when patients get in this type of a situation, they actually have more difficulty and perform worse with the Baha, and sometimes patients learn a very valuable lesson and when noise is predominant signal on their Baha side, instead of turning the volume of the Baha up, reducing the volume will oftentimes improve the ability to hear speech, so there's no free lunch here. Win and lose scenario and keep in mind this is true of the CROS technologies as well because if we replace the graph with a microphone here and transmitter or amplifier in the ear opposite, you would still have the same basic effect, and again, when speech is present at the microphone of the processor, that's when you have the best potential benefit. So this gives you sort of a graphic illustration of an audiogram that you might see where there's a patient with a good potential to be helped by Baha or any other type of a CROS system. The right ear audiogram shows nice normal thresholds, and you can see the left ear audiogram is sort of corner audiogram and there's no cochlear function measured by mass bone function so it is essentially called a dead ear and in that situation they have had acoustic neuroma in the

left ear and rendered left ear nonfunctional. So what do we do when we talk about the indications. So when we talk about Baha, we talk about the indications for Baha or the Oticon Medical Pontus system. The patient needs to be at least five years of age for implantation, and we define normal hearing and the only hearing or contralateral ear is thresholds no better -- greater than 20 dB for five, one, two and three. Notice that nowhere in this description does it describe what the level of hearing loss has to be in the poor ear but does state that the functions via transcranial routing of signal. So children under the age of five can use Baha on a soft band until they reach the appropriate age. Important thing for audience to realize and kids under the age of five due to the immature structure of the bone and osseointegration may not take place in the timeframe, they typically do not implant kids under the age of five. So from a single-sided deafness perspective, what do we try to accomplish with bone anchored system? Amplification to overcome the head transfer function. That's the ability to get the sound across the skull and the additional force that's available in the sound processor may be required to overcome a larger head function. The unknown for a lot of patients is the fact that their heads may be more or less dense or have more or less mass and if there's any hearing loss that is acquired after implantation due to aging there's to add additional force to overcome some of that effect. The common difficulties for adults with SSD are again like we talked about earlier, hearing and background noise, localization and what I like to call spatial hearing and being able to understand individuals who are situated near or on their deaf side. And the common experiences that occur when we

talk with children with unilateral deafness is you can see speech and language delay in difficulty and noisy environments and difficulty in localizing sound. This is part what we reference here is talking about the deleterious effect in school. We know kids with hearing loss are 30% more likely to repeat a grade than their normal hearing peers that have two good hearing ears. So this type of problem is not only experienced by adults but also by children, and so these are things to consider when you start talking about treatment options for these individuals. This is an audiogram that shows you how that particular patient did with the Baha, and in this particular situation the patient had very normal hearing in left ear and had the dead ear on their right side. So the aided audiogram that you see in this panel right here shows bone conduction aided sound threshold and placed on the patient's right side and left ear plugged and muffled and you can see it was picked up by the sound processor, easily crossed the skull and stimulated the cochlea on the left side and now seeing a very nice aided result relative to the speech articulation area. So the idea of being able to do contralateral routing through the bone pathway does seem to work quite well. Here is a nice photograph here of an actual abutment that has been placed. This is a patient who has had the Baha surgery. There's a small bald spot here and you can see the small implant is exposed, and next slide you will see the sound processor that's attached to the abutment with patients with longer hair, particularly female patients, can be a very cosmetically acceptable solution for SSD. So when we talk about this, we talk about this crossing effect that occurs and transcranial attenuation does occur. Many of you studied audiology probably remember

assume study of clinical masking and translated to a generic myth that there is no attenuation of sound once it is stimulating the skull, but the average skull actually has about a ten dB attenuation factor as sound crosses from one side to the other. And this is really one of the more important things to understand and be aware of as you're working with these bone anchored devices, especially with SSD patients. So this is a procedure, this is a block diagram of a procedure that Cochlear introduced with the BP100 processor called BC direct. It is NC2 audiometric testing protocol where we actually can take the software that programs the Baha and we can turn it into an odometer. We can actually produce pure tone signals and direct them to the Baha on the abutment and ask the patient to respond just like they would respond in a normal hearing test. The advantage here is that we're able to see how the device interacts with the skull and how the signal is affected as it crosses the skull. And so the particular slide that you see here is basically some data that talked about the -- this is the study that was done that described the average transcranial attenuation at ten dB. I can tell you if you can look at the slide and scrutinize it, you will see that in this particular situation there are some patients here who actually have as much as 30 dB of attenuation or loss of signal as the signal crosses the skull. So we know that there's a lot of individual variability in terms of how these devices interact with the skull, so bone conduction director NC2 measurement quite important. Oticon Medical is now using this particular process. They call theirs NC2 audiometry to do a similar kind of thing, and really enlightened an audiogram where there's little or no transcranial loss of signal and then this particular situation the

little thin line, which probably more visible to you than it is to me is the actual bone-conduction threshold and thick line where you see the blocks here, thresholds that were measured as a function of going through the abutment doing the measurement. This particular patient didn't have a great deal of difference and as a result didn't have much in the way of transcranial attenuation. If you look at the next slide, you can see that's a little different because you can see that the bone-conduction threshold is here based on what you did in the audiometric booth and this was what was measured. So this patient had for whatever reason a lot more loss of signal, and so the software that fits the device takes us into account and can add additional gain to make the device more effective as the signal crosses the head. So as a result you will see that this particular process makes a great deal of sense for improving the fitting of Baha. So I'm going to go through, we have some questions here, and I'm going to go through them. We have some time for those. I wanted to finish my slides by talking about some upcoming HOPE events. Donna Sorkin was talking about what's going on. On seventh of December we have sound foundation for babies and toddler, a habilitation resource that's going to be presented by Nancy Caleffe-Schenck and highly recommend and January 10<sup>th</sup> auditory comprehension will be given by Ashley Garber and keep an eye open for these in the HOPE series and workshop 1 day introductory workshop on cochlear implants on words and music and sites in San Diego and Washington D.C. and see how to register and who to contact at cochlear for those types of workshops if you are so interested in that type of situation. From a standpoint of contacting

me happy to field any questions that I don't get to. E-mail me at [gcire@cochlear.com](mailto:gcire@cochlear.com) and if you have any other inquiries, Donna Sorkin's is here as well. I will open up the questions and start at the top and move down. Jesus, I will try to answer your question. You say what about 800 to 1600 Hertz? You're talking about the middle frequencies that aren't covered. That's a good question and what that deals with is those are the theoretical boundaries. There's actually quite a bit of overlap in those two scenarios and use those as scripters in terms of what has come out of the psychoacoustic literature but my general understanding that you kind of draw a line right in the middle and differences between interaural time and level difference is overlap in the central area, and I HOPE that answers your question. Then you had what is the actual lag time of the signal from the poor ear to the normal cochlea? Also an excellent question but in this particular situation the actual lag time is surprisingly not what you would think because you're going from an air conducted median to bone conducted median because the bone has much more density to it. The signal crosses very quickly through the bone structure and so there are not the types of disturbances that you would think you would have. As a matter of fact, it is quite effective in terms of sending the signal through the bone because of the density of the skull. And Mohamed asked the question why years of age? I think we might have covered that, but in this particular situation we're talking about the fact that the bone has to really be in a position to create the osseointegration, and we had to draw the line somewhere, and it is typical. In Europe, for instance, where they actually implant kids under the age of five, there's a much higher probability of failure



of fixation of the fixture of which then can result in further surgery and follow-up, so we take a very conservative stance here in the United States and largely due to the maturity of the bone. We answered that one. Jeanette said is there sufficient research on and what does the research say about the success of Baha in children ages five to six? A very excellent and interesting question. There is what I would describe as a paucity of literature that's specific to Baha in this particular age range. When we talk about the actual application of the Baha. There are some children that are fitted. I was just advising on a case today that came in by e-mail where there was a child that had been identified with a congenital hearing loss was now age five and were they a good candidate for Baha, and my question was well, what was the -- what's the net effect of the unilateral hearing loss? I have worked with some colleagues that have done quite a few children with SSD and Baha, but the typical age range that they start implanting these kids is usually between the ages of ten and 13 where they allow the child to actually participate in the decision. When you think about the fact early age children often educated more in a visual channel and not so much in an auditory channel, they got one good hearing ear and good, good speech and language development and don't have any problems there and probably okay. But as the curriculum changes from more of a visual learning scenario to one of auditory learning and dealing with adverse effects in the classroom, that's where children oftentimes break down. And it is not kids in the five to six or seven year age range can't benefit but this needs to be more systemically studied, especially as we live into an age of evidence based practice, so it is nice that you brought that

up. And there are some studies underway, so helpful we will see more in the peer review literature regarding that. So what do patients say about Baha? People born with no hearing on one side and patients had normal binaural hearing and lost hearing in one or the other of the ears? Good point typically that's two very different things. If someone has a congenital hearing loss and lived with it a long time, they don't know any better, and if they didn't have any deleterious effects of that that affected the speech and language development, sort of in the category of do nothing, actually had the opportunity to work with a patient that was in her 50s who had a single-sided deafness for as long as she can remember, probably was born with it. One of the very good friends had hearing loss and successfully implanted with a cochlear implant and she urged her friend,ed who the single sided deafness who was my patient, to go forward with a consult because she thought she could benefit from the wonderful technology. She wasn't a cochlear implant candidate but she was a Baha candidate and she elected to have the Baha, and she made a comment that it made -- she was surprised at the difference that it made. So again, it has to do with what kinds of problems. If it is not creating a communication problem or there's a pain point about a communication breakdown, it becomes harder to get motivated to do anything about it, so I would have to say that individuals that acquire hearing loss who had normal hearing are much more probable to pick up the phone and make an appointment and evaluation for someone who had this for long-standing time but if this has been a long-standing problem and struggle for them, the Baha can be quite, quite good in the particular situation. Is there

sound problem? Getting lots of echoing. HOPE not. Is FM recommended with Baha when used with SSD? Absolutely. Again in situations in schools where there's poor acoustics, the Baha can make a big difference but oftentimes see, and I have been in communication with educational audiologists who see some additional improvement when the Baha is on, but when they apply the FM when the child is having some attention deficit issues or learning on FM system with SSD and Baha does make quite a bit of difference and works very, very well. What would you comment on the use of two Baha Softband for bilateral? Again, outside the scope of this particular discussion and happy to answer the question, and in this particular situation when you got a bilateral microtia or atresia, it is a really good idea to apply the Baha bilaterally if you can. What age is it important? Typically you identify these kids at birth and know you have the problem, but you have the Bahas mounted behind the ear so the microphone is in close proximity to the ear in order to give them the full benefit of bilateral presentation. But there are some studies that have been in the literature that demonstrate that kids with bilateral microtia atresia and symmetrical cochlear function actually develop and enhance the localization ability, and that's the main thing. What we try dot is use bilateral Baha on soft band when the child has sufficient head control and can sit up. When they're an infant laying down most the time, it is more difficult to manage the situation. Is Baha a latest technology? I think we talked about the fact that the technology has been around for about 30 years, so it is not brand-new, but I think we're much more aware of it and certainly more opportunity for this to be obtained in a variety of different

settings. Are you seeing CROS hearing aids for children? That's sort of all over the place and kind of goes back to the question that was earlier presented regarding the issue of when do you apply a Baha in that five-year-old range? A lot of it has to do with the individual, so I would have to say yes, I have seen them, but again, CROS hearing aids are sometimes difficult. Now we have the difficult ones across and more easier to wear, that may change the scape to some degree. Can I expound on preoperative testing, you mentioned? Absolutely. Preoperative testing we can actually apply Baha on hard head band or soft band and place the patient in a sound room with speakers and do testing before the patient makes any determination that they actually want the surgery, and actually provide a very good demonstration of how the Head Shadow Effect is lifted, and we can also do speech and noise measurements and if the patient is sufficiently impressed with that, they usually get a better result once they're implanted because when you're using a Baha on head band or soft band, having to deal with the transcutaneous and skin issues as well. I work with eight infants and toddlers with Baha or Pontiff head bands. Families don't notice a difference and kids do not seem to like it. I keep trying to encourage them, what would you say to them? I know the science may be about the auditory pathways and need of stimulating early is possible, however, a reality and curious how you would respond. This is the common challenge, especially when in the trenches actually trying to manage and keep this stuff on kids, and a lot of times it requires really patient set of -- not only care providers and conscientious care providers but also requires very good family support and you support. If the thing is

only being worn when the kids at school or being allowed to be mishandled or bounced around, it creates the challenge. So when we're talking about applying the soft band technology to the kids, you really want to look at what the net effect of the loss is that they have. Whether it be SSD or conductive or mixed loss, and typically if the child is getting benefit from the technology, you can extinguish some of the behaviors but I would be the first one to agree with you this can be a very challenging thing, and does require the village, if you will, to make all of this work. Recently received recommendation for student with SSD to be fitted with system on her ear. Would it be beneficial to the student who has noise and distance issues? Actually it would be. The problem I have with FM systems is they're great for the classroom and if there's a specific problem in this kind of scenario, then it would make all the sense in the world to apply that, and because the eye senses receiver in the canal type of configuration, it doesn't occlude the ear. The only hearing ear, but begs the issue of what happens when the child goes home because these are typically purchased by the school districts, and it is really a difficult thing to apply an FM system when you're not in a classroom environment because you have to involve somebody else with the microphone. It lends itself to the educational situation to a large degree where you can actually have the teacher wearing the microphone, but for the kids that would be having trouble in distance and noise, absolutely an option for those kids. Are most developing age appropriate speech-language. That again is something that's under study and looked at. We have talked to some -- especially some kids with microtia and atresia using soft bandwidth unilateral configuration in

addition to the improvement in localization and spatial hearing ability, early intervention specialists are reporting that they are improving the sign language development at younger age especially with a soft band technology in those situations. What is better -- what is better, cochlear implant or Baha for SSD? They're typically not employed in SSD largely because there's unknown in terms of how electrical signal on one side is going to fuse in the brain with acoustic signal coming from the only hearing ear on the opposite side. In that situation there are studies underway in Europe right now looking at cochlear implants but in the United States it is not being done and in the United States it is not for SSD. Got just a few more here. What would you recommend for implant for patient who is 86 and acquired SSD 15 years ago? Again, that would be totally up to what the patient's communication difficulties were under what kinds of problems they have. Again, like to fit patients and not audiograms, so patient would have to tell me pretty compelling story about what's happening in order to help me make that particular decision. I could not resist asking the question. What about CI for the nonfunctional ear? I'm sure there are patients somewhere who agreed to insertion to help them and that goes back to the research that's been done in Europe. There are some patients in Europe who have benefited with cochlear implant on dead side and normal hearing on the other ear. Typically patients who have unilateral tinnitus on the dead side and electrical stimulation. That is under study right now in Europe and it is a hot bed of study activity, so wouldn't be surprised to see studies launched here at some point in the future. Baha being used when mixed bilateral loss when traditional hearing aids cannot be used.

Absolutely. Contraindication to use Baha in the scenario and is Baha needs rehabilitation program for implantation. Again, depending upon the patient for SSD typically acquired situations I would say not, but there are some studies underway where there's potential to actually improve the ability of localization with practice, and I have one last question and we will have to go. Does Baha provide any tinnitus suppression? Generally speaking no it does not. Amplifying system and it doesn't generally do a very good job as a tinnitus. I'm at the top of the hour. Melissa, I HOPE everybody enjoyed the presentation. You have the handout presentation and do not hesitate to contact me by e-mail if you have any further questions and great pleasure to spend this hour with you. Have a nice day.

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