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Baha in Young Children

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>> Donna: Good afternoon, everyone, this is Donna Sorkin from Cochlear America's HOPE program and we're glad to have a nice large group with us today. We're using Baha in young children, clinical and research implications for early intervention specialists.

Our speaker today is George Cire from Cochlear Americas. Before we start I would just like to remind everyone that we do have a handout for today's session in the file share area on the left side and you can download that PowerPoint now as

well as the feedback form. If you could just save those to your computer now, you'll have them.

We will be offering CEUs from the American Academy of also and ASHA and we also offer a Certificate of participation for all those who provide a completed feedback form.

So with that, I think we're ready to begin our session. I would like to go ahead andintroduce our speaker today but first say a few words about our HOPE program at Cochlear. For the past 3 years we have focused this program on professionals who work with children and family with hearing loss and I'm very delighted to let everyone know we will be expanding our online program to also serve parents and adults with hearing loss. So watch for those announcements in the fall, and please let your patients know that we will be having some sessions that are specifically for them starting in September.

Our speaker today is George Cire. George is the Clinical Manager at Bone Anchored Solutions at Cochlear. He's a Fellow at the American Academy of Audiology and a member of the American Speech Language Hearing Association as well. He has received many awards for his service in the field, including one from ASHA for continuing education. He served as a member of the Texas Board of Examiners in Speech and Audiology, and he has over 30 years serving as an audiologist in both private practice and industry. We think his service now

at Cochlear is his best gig ever. With that, I'm very, very happy to turn the floor over to George Cire.
>> George: Thank you, Donna, I appreciate the introduction and I'd like to welcome everybody and thank you for your time to participate in our program this afternoon. I wish you greetings from a snowy Denver, Colorado. We're having one of these freak snowstorms. As I'm looking out my window it is coming down quite hard.

What I would like to do is by giving you a little snapshot of the agenda that we would like to cover today in our hour together. And we really want to gear the talk toward young children in the early interventionist activities and the kinds of things that can help you make a decision as you guide individuals towards rehabilitation.

We'll talk a little bit about how the ear works just to get some common ground and describe the types of hearing loss we deal with in audiology. And then we'll also discuss briefly the audiogram because that tends to be our hinge pen or our map to work with. And we'll talk about causes of the -- each type of hearing loss and also what kind of treatment options are available. And we'll begin to discuss about Baha and how it works, and then talk about fitting and management considerations. And then the important thing I'm going to recognize this individual a couple of times, but I want to in advance thank my colleague Dr. Lisa Christiansen from

Arkansas Children's Hospital in Little Rock. She's graciously shared some key studies on children that she has worked with using the Baha. And I think that will be interesting for you to see.

And we'll end up talking about areas of potential research going forward, because this is a relatively new area. And then we'll allow time for some questions. So with that said, we'll begin and we'll move along in the slides.

When we talk about the -- this whole process we want to make sure that everyone understands that there are three parts to the ear, the outer, middle, and inner ear. The outer ear is the most visible thing that you see, and that tends to be the thing that we hang our eyeglasses on and our earrings and that kind of thing. And it acts largely as a collector of vibration and sound and your energy from the ear molecules that are around us. And the outer ear actually is made up of that thing that we see hanging on our head and the ear canal itself.

We move down into the ear, we talk about the middle ear. And when we talk about the middle ear we're actually talking about the eardrum and the ossicular chain and the three small bones that connect the outer ear to the inner ear and the inner ear, kind where was the rubber meets the road, so to speak. It's where all the hearing transduction takes place.

So if we look at a photograph here -- and I'll put the pointer up so I can guide you to that -- we use the collecting device here to recognize that sound is basically a series of air particle vibrations. And this is a nice collector. And then as the sound waves generate into the ear canal, they strike the eardrum and vibrate, the same phase. Connected to the ear drum are three small bones, the anvil, hammer and stirrup, and this strikes the mechanical transduction of that vibration to go down to this last bone, which is the stirrup or the stapes, and that fits in the overall window. The shell device here is the inner ear or the cochlea, and this is where most of the hearing takes place.

Everything from this point outward is basically a conductive mechanism. It moves sound from the outer part where it is outside down to someplace here where it can be converted into electrical signals. And that is done very elegantly by a series of things called pair cells that are in the snail shelled area here that I like to think of as a very simplistic level of switches. And what happens is the electrical impulses are encoded and set up the thing to the brain which is the auditory nerve. So the actual process of hearing is fairly involved when you think about all the things that could go wrong and what could happen.

Then one thing I wanted to point out were the areas here as many of you know the ear also controls the balance function

and these are the semi circular canals here that actually control the balance mechanism. We talked about the types of conductive hearing loss that are -- types of hearing loss that we can have. Conductive being the first one we want to discuss and we have sensorineural hearing loss and mixed hearing loss and I'm going to step backwards one more time and look at the slides here and when we talk about the conductive hearing loss, we talk about anything that can occur from this point outward and, so, typically what happens is something blocks the transmission of this sound energy from getting to the inner ear. When the problem exists or resides in this area here, we typically call this a sensorineural hearing loss and there are two components. The sensory organ is the actual cochlea and it is the nerve and the of two those things combined are the sensorineural element. As we're looking at this and we talked about losses we can have a conductive loss and we can have a sensorineural loss or we can have a mixed loss which can be some combination of the two devices. The two systems working together.

Again here are the topics that we've just discussed. And so we would move on and we'll talk about the audiogram. And with the audiogram what we want you to understand is that this again is the map that the audiologist uses and many of you are probably conversing in this particular thing. What I wanted to point out to you was across the top here we have these vertical lines with numbers assigned to them and these

vertical lines actually create the different tones that we test or the different tunnel frequencies that we work with in the inner ear from low frequency to high frequency and long the axis on this side of the chart we go from minus 10 to 120. This is the level of hearing or decibel hearing level that we record. So typically when a diagnostic audiological test is done it is done with an earphone over the ear which allows to for the testing of both the outer and middle and inner ears, or all three, and a threshold is then obtained in which it is recorded along this. This particular depiction we see the red circles which is the right ear occurring at O or five (audio difficulties). And we describe a conductive hearing loss what we describe is something blocking the transmission of these airborne sounds from moving down the ear canal and striking the ear drum. And the more simple outer ear conductive types of problems can be the most simple thing is earwax or debris which is lodged in the outer part of the ear.

You can also have conditions that will either create a malformation, which will also block the ear and one of the more common things that people run into when testing is being done, especially in school-age children, is the collapsing ear canal which is a scenario where the pressure of the earphone on the outer ear creates an actual collapsing or tweaking of the ear canal to the point where it creates a blockage of sound. The sound can't effectively trans-- the ear canal and it cannot strike the ear drum. Sometimes that will

be illuminated or alleviated by the insert of earphones or an astute clinician making sure they check for that. That is one of the thing I always like to do when I test a patient or before I test a patient is to touch their outer ear and look at how compliant that is and look at what it does because oftentimes just by doing that you can determine whether you may have that potential problem.

We talk about additional kinds of conductive hearing losses we talk about things that can occur and tympanic membrane perforation or a hole in the ear drum is one way the system becomes inefficient and will not allow sound to transmit through the system and into the inner ear.

Ex-the next term on the slide is tympanosclerosis and this is a condition where scarring occurs on the ear drum. If they're recurrent and chronic ear infections that cause acute fluid build up oftentimes these things can cause spontaneous ruptures of the ear drum or the tympanic membrane. When that happens a -- kind of an irregular jagged type of rupture occurs and when it heals back in some individuals there is a scarring that occurs and actually causes sclerosis or hardening of parts of the ear drum. And again when that is not flaccid enough to move properly you end up with a situation of not good sound transmission through the system. So tympanosclerosis is definitely something that you can see. Oftentimes when a physician or ear, nose and throat specialist

will look in an ear they can see kind of a white plaquing on the ear drum and that is usually the tell-tale sign of the tympanosclerosis.

Cholesteatoma is a condition that occurs as a secondary fallout to middle ear problems or ear infections. And this is actually a tumor-like growth that grows out of cells (inaudible) that occur and it usually occurs in what we call the upper part of the tympanic membrane and it creates a very erosive condition and oftentimes when it is seen in very young children it can be erosive to the point where it goes to the mastoid air cells and destroy the ossicular bones that we talked about earlier and it can create havoc. When it gets to that point a surgeon has to be called in and there has to be some modification or some removal of this particular growth and that oftentimes involves a procedure called a mastoidectomy where they have to surgically alter the ear to get that out of there.

The good news is we don't see that as much any more due to the fact that we have good antibiotic therapist that are now available. So cholesteatoma, it is something people still see, it is not as predominant as it was once with the advent of antibiotics.

Any time the bones or disconnected or disarticulated or malformed that sound cannot transmit through the middle ear.

This is another cause of conductive hearing loss. Again we mention the fact that surgical alteration of the middle ear is usually what is done for disease management in this.

The only other item I did not put on the slide but it is well worth mentioning because it is the most common cause of conductive hearing loss is serous alteration and the fluid stays behind the ear drum and kit cause a fairly substantial conductive hearing loss. We know that when children are in that critical period for speech and language development that it is -- that the whole system needs to work. If there is fluid behind that ear drum, that system is not working at the optimum level and can cause hearing loss that will oftentimes if it stay in a chronic condition, it will actually create the delay in speech and language development because the child is actually functioning optimal any that circumstance.

And it is controversial from a standpoint of how we treat it. A common surgical intervention to this would be the presence of PE tubes, or pressure equalization tubes and evacuation of the fluid by a procedure called an tympanocentesis and they place it in the opening there and it has equal pressure and no fluid present back there.

Oftentimes because very common childhood illness is an infection in the ears, the physician that is treating the child will often use antibiotics therapist and we do know that there

oftentimes are chronic conditions where the conductive hearing loss can remain over a long period of time and that will have some bearing on discussions we'll have later today as we go through the rest of the slides.

So when we talk about sensorineural hearing loss now, we talk about the fact that mechanical vibrations are entering the inner ear or cochlea but the hair cells, sensory structures that are in the cochlea are damaged and vibration is not converting correctly to the electrical stimulation that the pathway will require. Common causes of sensorineural loss or the most common cause in our adult population is the presence of industrial noise, military noise, rock-n-roll music, a lot in the press lately about the indiscriminate use of iPods and that kind of thing. So noise induced hearing loss is the No. one sensorineural cause and we can have meningitis and cyclomeningitis that cause them to die off or not be functional. Other toxic agents, pharmaceutical agents that are used for various types of treatment that actually have a nasty side affect of destroying the sensory tissue in the inner ear. The good news is oftentimes those are only used in very, very extreme cases where one is trying to preserve life or in the case of anticancer agents such as cysplatin where they're given to destroy cancer cells and the good news about that, there are ways and we're getting much better at monitoring how the hearing is holding up and these agents can be titrated over time or given over time as opposed to a massive dose.

We try to monitor that when possible. But other ototoxic agents can be used.

There can be factors and things that occur in the process or genetics of the child or the family that we don't understand that oftentimes relate to sensorineural and, of course, then we also have acoustic nerve tumors which are very, very rare. When you look at the overall population, acoustic nerve tumors only occur in 2% of the general population. But these are oftentimes -- these are benign tumors that grow on the hearing nerve and actually putting pressure that will destroy the hearing nerve eventually and oftentimes they have to be removed because they cause other problems and that usually ends up with a complete deafness.

So we go back to our friendly audiogram. We look at a different audiogram depiction. In this particular situation, you'll notice that we have two kinds of marks here. We still have our little zeros here and this is a right ear depiction but now we have a hearing loss that starts about 40 decibels in lower frequency and end up 90 decibels in the higher frequencies. What you want to notice is that we have got these carrots or a rows that follows and when an audiologist does an exam when they place a vibrating device behind the ear in this particular patient heard the same way through the earphone, as they did through the bone conduction mechanism and that is the Hallmark or indication when we have a sensorineural loss.

Had this been a conductive hearing loss these is rows would have within up here somewhere around five or 10, all the way across the board. That would have indicated to the person that had done the test or reviewing the test results that when sound is passed through the entire system there is an impairment but when sound is directed to the bone directly into the inner ear, the hearing appears to be normal. So that helps us to understand that there is a conductive loss versus a sensorineural hearing loss.

There are other tests that we do in terms of middle ear measurements and otoacoustic measurements that help with us this but this is the basic test that we rely on. This is the sensorineural loss on the audiogram.

So when we deal with mixed hearing losses we're dealing with a combination of both the interruption of vibration passing to the outer and middle ear and also in the hearing cells themselves. In this is a case we mentioned earlier the cholesteatoma with massive destruction and infiltration into the cochlea can cause both of a conductive pathway problem and inner ear problem. General malformation can occur in both areas and there can be damages -- damage due to the ossicles and temporal bones, head trauma, and oftentimes that conducts a myriad of mixed hearing loss.

So then again woe go back to the audiogram and see exactly

that in this hearing loss. We see that now when we have done the bone conduction testing it is not normal actually 30-40 dB but by air conduction we're down at the 60 to 90 dB range and we have a combination of both types of hearing loss present at this time.

So how do we do these treatments? In terms of conductive hearing loss we talked about medical/surgical treatment. When we talked about earwax or foreign body removal that is a fairly straightforward thing. If there is some type of malformation of the canal a thing called a canalplasty can be done. This is actually where a surgeon will reconstruct an ear canal and open it up. The myringotomy with vent tubes and we talked about that earlier and that is a very common surgical medical treatment for conductive hearing loss. Tympanoplasty is actually building a new ear drum and covering up a perforation in the ear drum. This is a very successful process and works quite well and can make the system efficient again.

Mastiodectomy is actually a procedure that is done when there is a great deal of disease process present and the infected process does not respond well to the antibiotic therapy that the surgeon is using. They'll actually have to go in and drill that area out and clear that area out. Oftentimes that creates problems that we can see with conductive and mixed conductive losses in that circumstance.

When there are problems in the middle ear there are oftentimes very talented surgeons that can do middle ear reconstruction where they go in and actually replace or rebuild the bones or replace them with prosthetic devices and make the ear work as it was originally designed. This is always a good thing when you can have that happen because a normal functioning ear is always better than one with some type amplification.

And then amplification, a way to conduct hearing aid fitting and it is only observed in circumstances when there is some reason why there can't be any surgical intervention to the ear. We'll also talk later today about cranial facial anomalies and the fact that sometimes people don't have ear canals or they have a bone plate in place and conventional hearing aid won't work. But amplification is going to be dependent upon the middle and outer ear and if there is an infection this will contraindicate the use of a air conduction hearing aid because if you work with that type of device you're dealing with a situation where you have to plug up the ear canal and that ear canal then causes drain and other types of medical problems.

We talk about sensorineural loss, the root loss is in the nerve and hearing amplifications are the treatment of choice. We have losses mild through severe. But severe and greater we have seen great uptake in cochlear implant and cochlear

implant technology has improved. Significantly with great outcomes and this is providing electrical stimulation to the hearing nerve directly and it has been quite effective.

When we have ear hair damage, it depend upon what the Cochlear can tolerate when it comes to the louder sound. This is where the audiologist has to make some decisions about how that particular device is going to work and set up.

The mixed hearing loss we can apply application of acoustic amplification for mixed loss but we have to consider both the conductive component which is that blockage of sound and the damage that occurs in the inner hair cells or inner hair cells and cochlea in a mixed loss.

An audiologist will often use some type of formula to derive how much gain or how much compensation they need to apply and typically in straight conductive hearing losses we look at 100% compensation even if we have a 60-decibel hearing loss we need to apply that equivalent amount of gain to that conductive hearing loss and we can overcome that.

When we deal with damage in the inner ear hair cells with the sensory hair loss we see all the rules based on 50% compensation. If we have a straight sensory or neuro-type hearing loss at 60 dB usually we look for about 30 dB of gain or about 50% compensation and again that is dictated by how

the ear can tolerate the loud sound because oftentimes when the sensorineural hearing loss is present you have an abnormal growth of loudness or a condition called recruitment which causes an interruption of our ability to apply too much gain without it becoming uncomfortable and distorted.

This is a case here that I wanted to just show you that it is actually a child with a mixed loss. Not a terribly significant sensorineural component but one in a young child that could be problematic from speech and language point of view.
15 decibels and at this point right here and I want to make it -- here it is. It drops down to 30 here. You notice we have quite a bit of hearing loss. When the child is listening through this particular ear, this is the loss that we have to deal with. This is down here about the 85-decibel level. So if we look at this we have got about a 20 dB and we pick out 1000-hertz which is right here. We look at the fact that we have a 20-decibel hearing level at this point. We have an 85-decibel by air conduction here. We're dealing with a total of, you know, 65 plus 20 being 85 decibels of hearing loss. If we go back to the earlier slide that talked about that we're going to use about 10 dB of gain to overcome the sensorineural component because that is half of 20. We're questioning to have to use about 65 dB of gain to overcome the difference between this point here and this point here which is about 75 dB. That is a very powerful haring aid and it -- hearing aid and it has to be that way because we're using an acoustic system to drive through

here. The bone conduction loss is only 20 dB.

The next slide is interesting because this is showing you some aided threshold on this same particular patient. Again with the pointer up we can show you that the curve marked HA represents an audiogram that was captured in Soundfield or in Soundfield testing that shows the loss of hearing with the hearing aid in place and then we look at what happened when a bone conduction hearing aid was placed and you can see that this good hearing is at the top here. You can see that we have a nice improvement over that. So this particular individual was much better served with the bone conduction hearing aid.

When we talk about mixed hearing loss we always want to make sure that the air conduction device to be effective needs to be a high powered device and that usually requires that a tight fitting earmold be used to create the blockage of feedback and creates other types of potential problems.

When we talk about bone conduction amplification the thing I want to really mention is that bone conduction amplification is not something that is me, it is quite old. It has been around a while. In this next slide we see a photograph or slide of bone conduction hearing aid.

What you see is a traditional ear conduction hearing aid that

has been converted and instead of having normal hook, sound hook and earmold on this side, this wire comes out and transmits the electrical signal that the amplifier is providing, the head, and this device here which is a bone conduction isolater. This is placed against the head and it has to vibrate the sound through and into the inner ear by bone conduction. It works quite well. As you can imagine, this could be quite an uncomfortable device to wear because the spring steel device has to be warned with it. It has to be a fair amount of pressure that is placed against the skull to hold this in place so that the vibration can go through.

Consider the fact that the inner ear is intended in bone and the fact that is vibration has to pass through both skin and bone to get there, it is not a terribly efficient system but given the fact that if someone has good normal inner ear hearing this thing works well. The downside is that compliance is quite poor because it is uncomfortable device. We have not seen a lot of them used very much because of that. It again is an air conduction hearing aid or power device that has been modified and this tight fit results in a lot of discomfort and I'll mention that again in another slide.

So due to the configuration and bone connection devices the long-term compliance has been a problem. People that wear this will wear it as long as they need to. we use energy across the soft tissue it is not an efficient system.

What I want to mention is the Baha System or the bone anchored hearing system and this was developed back in 1977, about the time I became an audiologist. Work done in Denmark by Professor Branemark and Tjellstrom. It was using technology that was developed by the dental industry but it uses a condition called osseointegration where a Titanium fixture is surgically implanted in the skull and it has a way for vibration to transmit to the bone. Part of that fixture that penetrates through the skin called an abutment and the actual vibrating device can attach to that.

This is a photograph here of that osseointegration principle. This is actually if you look at the gray area here, this is actually the implant itself. This material here is actually osteocytes are new bone growth. When these types of fixtures are placed into the bone it actually becomes one with the bone. It creates a very, very nice bond and we're able to bypass some of that soft tissue and get good vibration into the ear.

Here is a photograph of the system. What we're dealing with here is the sound processor which is actually powered by a battery and picks the sound up through microphone and provides a vibrational input through this snap couplilng. This system here is the abutment which is it comes through the skin in this small area here that looks like threads on it which are exactly that. This is surgical fixtures that is implanted into

the bone. That is where the osseointegration occurs. The whole system when it is connected allows for sound to transmit through the bone and into the inner ear.

Hires a schematic of one in place. We kind of shattered it out so you can see this place back here on the temporal bone itself and the sound is now being transmitted directly to the inner ear and in a very effective way.

This is actually a photograph of an adult patient that has the surgical fixture and abutment placed behind their ear and then this is the actual sound processor attached. When the hair is dropped over this, it is a very cosmetic solution for that individual.

Here is the one for kids, this recipient must be 5 years or older and have healthy bone. This is the criteria that is currently in place in the United States. That has to do with the fact if you remember when we looked at the earlier slide of osseointegration occurring that immature bone, this takes a large period of time. Children under the age of five really are not candidates to have this surgical procedure done.

It is a fairly and simple straightforward procedure. But what we have been able to do is modify the device so it works quite well.

I skipped over here. When we look at the Baha System from the standpoint of the surgery the child needs to be equal to or greater than 5 years old. They have to have 45 dB or less pure tone average. We're dealing with a device that doesn't go or loss in the sensory area that is not in excess of 45 dB. We can also do this bilaterally when there is symmetrical bone thresholds.

The sound processor can be mounted on a steel test band or a Softband, for a potential candidate to be evaluated. This is one of our shining examples here is unlike a cochlear implant where we have the decision to make that can't be tested until the actual surgery occurs. This Baha we can actually place the -- can actually place the device on a Softband or on one of those spring steel band like I showed you earlier and we can actually do some testing over a short period of time to determine how the device will perform and do behavioral testing. For children under 5 years of age this can actually be applied to the Softband which will show you a picture inform just a moment. This can be or continued to be used until the child is old enough to have the implant done.

The bone anchored solution provides a better functional gain. And the results Bone Anchored Solutions have to do with the direct bone conduction that occurs. It is a very favorable treatment. The other really nice thing about Bone Anchored Solutions and the Baha in particular is that we can actually

attach some devices to it like FM, Phonak MicroLink goes well with the Baha. There is a telecoil that is available in an adapter player and music can be inputted into the Baha.

When a conventional hearing aid is converted to a bone conduction hearing aid this uses up the audio input position on most hearing aids and these types of devices don't work well with that conversion but we can do it with the system.

In summary direct bone conduction gives us the ability to have the ear work independently in the ear canal and the middle ear. Direct transmission gives a clear and natural sound because it is an effective coupling of the vibration and energy and you don't have to have the amount of power and that is less of an issue. We can pre-operatively test this one and it gives a patient a very high wearing comfort. The surgery is actually safe and minor and this will provide a very predictable outcome over time.

This is the photograph that I happen to get to, to show you the Softband. This is actually an elastic Velcro band and the Baha attaches to a coupling that fits behind the ear. We still have the same issues because in this situation you do have to transmit that sound through the tissue into the skull but due to the design of this we oftentimes get much better wear. This can be moved around. One felt things I like to tell patients about this or tell folks about this particular child is that we were

told that when this child was placed in a car seat, for instance, the child had a habit of leaning her head up against the car seat which would have actually been about -- if you want it to work I'll show it to you -- about right here. You touch this because it is a vibrating mass it oftentimes provides a mechanical feedback. So Mom discovered right way that if you -- if Euro stated this in the car seat and put the Baha up here on her forehead there was no feedback and she could actually hear her Mom quite well when she was in the car seat or behind so this Softband really provides a very nice solution for individuals that are wearing this.

Especially with kids.

So let's talk about kids in particular. Let's talk about some of the conditions that we would run into. This is something that maybe you guys are going to see a lot of in the early intervention area is the fact that kids are born with aural atresia. This is a child that has no ear. And because there is no place to put an acoustic hearing aid, there is oftentimes when these children are tested, the actual inner ear is normal or working properly and there is just a thick growth of bone or tissue where the ear canal would have been.

These are oftentimes they occur, this is a photograph of a child or an individual , an older child with Goldenahar's Syndrome that has a classic low-set ears and asymmetrical

development, cranial facial bones. Oftentimes we'll see a noses or lack of an ear canal. This individual has nice pinnas but no ear canals present and usually a complete conductive hearing loss due to that.

But this is a Treacher Collins patient and both of these Treacher Collins patients are wearing a traditional bone conduction type device that fits on a spring steel band. I guess from my early train engine working with cranial facial patients that was one of the first thing. You can almost see it here this time individuals back in the day oftentimes started wearing these types of devices when they were quite young, when they were infants. Because of the pressure that is involved and the fact that the skull bones develop, you oftentimes will see a divot or deficit and you can notice in this patient there is a distinct ridge here where the headband was and I actually witnessed this firsthand when I was a graduate student audiologist, they had a very, very -- it had a distinct impression on me. The individual I was working with was about 9 years old and had this ridge where the bone conduction pinna helped him out. When high interviewed him he said it helps me to know where this thing goes. He says I have to tell you I wear this all day. But by the end of the day because of the pressure that has to be placed against the skull here oftentimes it gives me a headache and I have to take it off when I get home and break away from it but it makes all the difference in the world. And again with this type

of a syndrome, oftentimes the inner ear is completely normal or very normal and a little bit of vibration and energy will direct the hearing loss to a point where these folks here --

That is going to bring me into some discussions here in terms of these case studies and I think this is what we can find most interesting. Again I want to reiterate my appreciation to Dr. Lisa Christianson at the Arkansas Children's Hospital who provided these particular case studies because they're quite interesting.

So in their particular program they're following approximately 100 kids using Baha for some permanent hearing loss condition.

They have about 60 kids that have begun with the Softband and as these children grow old enough they have the fixture and abutment place and that happens and they're treating a range of etiologies, both conductive, unilateral and bilateral and also single sided deafness. This is a big uptake for us in the adult market. This is folks that have no hearing whatsoever and won't use a hearing aid for functional purposes and have normal hearing in the opposite ear. You place a Baha behind the core ear and place the microphone in the Baha, the sound is picked up and vibration transmitted to the only hearing or good ear and creates a nice affect and patients can oftentimes get lateral affects.

This is going to have some implications of a standpoint what was we're going to do. There is an awful lot of school kids and children that are identified with unilateral hearing loss. You know from studies done at Vanderbilt and other places, these folks oftentimes be retained more frequently and have academic difficulties and they're currently being placed in situations where there is Soundfield FM or other types of things. But a potential way to treat this would be to use a Baha and single sided deafness configuration.

So these cases you're going to see are going to represent a fairly large range of the children that serve there.

This first case here is -- let me get you some background. This particular child failed a newborn hearing ceiling and rescreening and seen by a doctor after the rescreening and the diagnosis was canal atresia and auditory brainstem test was done to determine the integrity of the inner ear and the lower Baha device was fitted on a Softband and there was no family history after trees I can't or hearing loss and the child actually had normal pinnas but the ear canal on both sides were stenotic. Meaning they were present but nothing was there that you could place a hearing conduction into.

The blue line represents the flesh hold that the patient measured when they tried to put earphones over the normal

shaped pinnas or outer ears and it was a fairly large conductive hearing loss. This was again identified by ADR by bone conduction.

The red line here represents aided Softband was applied and you can see -- I should also mention for those of you that are familiar that the zone here represents an area where most sound in English occur and again good hearing is up and poor hearing is down and when we're fitting these and depicting these types of outcomes I always like to see the aided outcome to be above or very near the top of this range because this ensures that it is good audibility of the speech sound and sounds cannot be intelligible and understood unless they're heard and in this particular situation this child was very well served by being able to hear through the Baha and a Softband at this particular level.

At least two -- this is a child that had Treacher Collins Syndrome. Cranial facial condition. Was adopted at age 2 from Korea. The child wore behind the ear hearing aids since moving to the United States and had fair looking pinnas or outer ears and one good ear canal on the right side. There had been several attempts to do what is called a canalplasty or surgery on the left to keep that ear canal open. And when the -- behind when a behind the ear hearing aid was fitted to the child in that ear there were terrible feedback issues and because of the numerous surgeries and problems with the

hearing stressing the family out. And so at age 12 the child tried a Baha on a Softband and the results were garnered here. So again let's go back and look at the actual measured threshold, the blue line here. We're talking about a fairly maximum conductive hearing loss.

The orange line was what the hearing aids were doing for the child in both ears. But there were problems because in order to even get to this level HAs were quite prone to feedback many that was largely due to the fact that the child had very small to ill-formed canals and the canals had been surgically modified but there had never been any great success there. When the child applied or the Baha was applied on the Softband in the test situation, this was a result that was obtained. This is quite, quite good. And it is my understanding that the child actually was eventually fitted with the surgical appliances, the fixture and abutment and now wears the because gnaw a traditional surgical implanted mode and the important thing to recognize about that is that if you look at those results very often we see even about another 5-10 dB of improvement by direct phone conduction.

See there is a couple of questions here and I'll get to those in a second. I want to move through the rest of the slides here.

We go back to case No. 3. And in case No. 3 we are talking about a child that had Goldenahar's Syndrome with microsha.

This is a small malformed external ear and they got transferred to the Arkansas Children's Hospital neonatal intensive care unit shortly after birth. The child failed ABR and a conventional bone conduction was done. So in that circumstance at the time there were no Baha's available and they used this device I showed you earlier in the slide which is a conventional hearing unit converted.

So what you're seeing the measured threshold here, the yellow curve demonstrates how the child was hearing through a bone conduction hearing on a steel band and this shows what mapped when we put the Baha on a Softband. We have some improvement here as well. We oftentimes will see that but because of the ability to more precisely place the device in a comfortable place we can oftentimes pick up aided additional gain over traditional bone conduction.

The fact that there is a much more comforting compliance really applies well in that particular situation. Moving on to case five.

Now, in case five it was a failed newborn hearing screening in another hospital and child was transferred to Arkansas Children's in the outpatient -- actually came in the outpatient clinic to be screened. No diagnosis from birth at the hospital but just failed newborn screening in both ears. Examination 1 year was completely no canal and the other ear was at a

very small underdeveloped pinna.

After genetic consultation and testing the patient actually was diagnosed with a fairly mild penetrance of Treacher Collins Syndrome. There was no history of this syndrome and it is believed to be a spontaneous case which I understand is fairly unusual.

The AVR indicated and confirmed that the child had a bilateral conductive hearing loss and she got fitted with a loaner Bahas on a Softband and she is fit with permanent Bahas later.

What we can see here is a scenario where you have again a relatively large conductive hearing loss present and we get very nice results with the Baha applied to the Softband. Again any time we're getting these kinds of results above this you can be happy that you're doing a good job.

One of the common things that we hear especially from older children and adult patients who have the experience of both being acoustic hearing and the Baha will oftentimes report a much clearer and crisper sound because of the direct bone conduction that occurs and due to the fact that the device is not -- doesn't have to be so powerful and it is not driving its inefficient system and it creates less need for power and usually less feedback which is present.

So in terms of areas for research, we really have to learn a lot in the area of single sided deafness. I mentioned that earlier because we do know that children that are identified and with universal newborn hearing screenings we often see kids, identify kids at an early age with unilateral hearing loss i is not simply okay any more to write those kids off and explain that they have to have preferential seating in the classroom. There are numerous study that point to the academic difficult teaspoon of kids and what they have with this time

Single sided deafness Baha is a benefit and again the nice thing about Bahas is the fact that one could actually hook up a Baha to a Softband and have a child tested or used over an extended trial period before anybody to do make any determinations about whether a surgery was involved and if you get good outcomes and you can move forward that.

So there is lots of work that I think needs to be done and we would welcome, you know, folks to consider that in terms of SSD or single sided deafness, sicly in the pediatric population. In the adult population it has become one of the larger treatments of choice. And we just feel like we can see some better uptake and get results.

As far as bilateral fittings are concerned, one of the things that occur with bilateral fittings is the fact that microphone placement, especially in some of the cranial facial cases

where there is bilateral conductive hearing loss, we have been able to measure and know there is asymmetry to the hearing in both bone conduction measurements. There is some real advantages to having microphone on both side of the head so there is better localization and there is not what we call a head shadow affect which can attenuate or muscle the higher frequency sounds that are coming from the side that is not amplified. We do know from study when is we're stimulating that both cochleas are being stimulated but again there is a proximity affect that occurs. If there is a child with a bilateral connective hearing loss and Baha on the side, the Baha closest to the ear is going to -- the ear that is closest to the Baha is going to receive the lion's share and they point to nice lateral results and this is less controversial. It is conventional head bands and then again we're seeing -- we would like to see some more results and there have been some nice studies that have come out of Europe, particularly in the Netherlands that show that they have been able to document improved thresholds and ability using the Softband versus conventional headband. And there are other areas but again because of the fact that the Baha has the ability to take direct auditory input we can put FM into this and this is really a real boom for us in terms of how we can do interventions in a pediatric population and get a good outcome.

That concludes my -- I think I may have skipped one other slide. Just curious to see if there is any questions here and I'll

try to answer these questions here and Carolyn, the above question refers to three-year-old using Softband. Is it already to keep the Baha unit on the forehead? Certainly it is okay to do that if that is where the child has to wear it. Sometimes just by necessity you have to do that because by doing that you're getting pretty equal distribution of the sound in both ears. What we do recommend when we are using a Softband is that you do move it around because just like the spring steal headband that is in a conventional hearing aid that is converted to bone conduction you can get some pressure there. And then if you ask him a question are we currently recommended bilateral Bahas for the patients and yes we are. The criteria is that we really need to know that there is some symmetry and mixed conductive loss and normal threshold and the other ear if the bone conduction thresholds are greater than 10 dB between ears that is considered a symmetrical and we're still not sure what happens in this situation so we tend to use that as a guidance but we do see and get reports from that.

William just asked a question do, we have any experience fitting Baha's to babies with unilateral unilateral microtia, and we have in that due to the fact that the child has this we're dealing with a shadow affect and even in a young child or a young baby speech and language abilities are quite good. Typically in a young child with -- where the parents are involved and the speech and language model is close, you

could argue the point as the child moves into the toddler area here in their -- their sound are coming from the side where the unilateral microtia and we know a lot of the mean speech occurs in the high frequency sound area so we have seen some experience there.

Let's see, our daughter got her first loaner Baha today. We're happy. Four months. But there is a delay in getting -- hold on just a minute. I'm having trouble here. Anything about when this will be resolved? Changing product out.

That would be an issue in terms what was the current stock levels are. I think if that is the question you're asking. Getting Softband, yeah. There is a delay. We're working on that at the moment. There are some back order conditions with certain products. So I can only ask that you be patient in that regard.

I'm going to try to get all these questions answered here. Jane asked any medical complications from surgery and/or long-term use in young children? Other than the fact that with the Softband application, we want to make sure that your child doesn't have any -- there is not any sore spots being developed and you can move it around. When the actual implantation occurs the only other criteria that is important is that the child have good hygiene or there be good hygiene support available because you have to keep the abutment site

clean and in some situations that can be problematic and that is one of the selection criteria. Next question is do you have a set policy in place of decontamination Baha units? Summerly we're recommending that Baha units be wiped down with an alcohol pledget and looking at other types of things. You can actually keep that clean. The most important thing to keep clean what we like to instruct patients to do is to use the -- use the -- a brush if you will and brush that snap coupling so you get any debris off of there and acetylside or the audiologist's choice that is the type of thing that can work for that. Alcohol can sometimes contaminate the plastic but we have looked at a 40% isopropyl and alcohol being okay for that.

What incidence of failure to occio-integrate young children? Right now we're only seeing -- we don't have any specific breakout at the moment of children versus adults but we see across all Baha that we only see 2% of osseointegration failures and one of the things that has to happen and we're looking at in Europe looking at whether or not you can load these things or do this implantation earlier and there is some evident that we're going to be able to do that and if that occurs we're going to have to provide that.

We're going to have to be able to prove to the FDA to be able to do that. Good questions, all. Hernanda. Would a child -- would a child with a following characteristics benefit from a Baha? Moderate hearing loss in one ear managed with a

hearing aid and doing great. Other ear is total loss. That particular child is relatively outside at 50 dB would be outside the fitting criteria if that is the level of bone conduction with the opposite ear mask and that is guided by our five 10K and what we have in our fitting indications or guy lines.

We're just about out of time many these are great questions and let me see if I can pick up a couple more. This is a question Barbara presented. Do we find that the abutment can loosen over time? We have a child who loses his Baha on the playground. Abutment can loosen over time many there is a protocol in place or recommendation in place for follow-up. Typically it's set to a specific degree of tightness. One important thing is we want to make sure that the Baha is appropriately attached to the abutment and there is a rock on rock off procedure that creates the ability for that to stay on there. We have seen some indications of people not getting it completely engaged and is actually operating but it is not fully engaged. If you practice with that with a practice -- if you have got -- we do supply these practice abutments so you can kind of get the feel for that. It is a little odd the first time you do it on someone's head that is not your own. But there is a good process of snapping it on and that could be happening.

But abutments can be -- can loosen but that would create a different kind of a problem.

William asked do we CT scan for bone density in young children. Many pediatric surgeons that are doing Baha surgeries actually do that and look at the bone density by a CT in terms of making their decisions about the appropriate age. And that certainly is being done in experimental cases in Europe where they're doing it in kids as young as age 3. Currently 5 is the age here.

This is a common question. Contract indications for MRI contact sports -- certainly contact sports someone needs to be careful. I think the appropriate use of helmets cover that. Abutment need to be considered and we have heard in reports of trauma to the actual abutment causing it to fail. Fairly rare. As far as the MRI is concerned remember the fact that both the abutment and fixture made out of titanium and is a metal and will not be affected by the MRI but will cause some smearing of the MRI image so the recommendation then is that you can proceed with an MRI of the head. The only thyme we have to remove the abutment is if the area that the aid yawls wants to image with the -- radiologist wants to image with the MRI is in the plane of the abutment. You can actually remove the abutment temporarily and it will reduce some of the scattering of the image and be put on right after.

I'm going to go ahead and turn it back over to Donna. Donna I have got most of the questions answered, I think. We're just about out of time and I wanted to see if you had any closing

comments.

>> Donna: Thank you, George, that was a really great session. Everyone, I think, has probably seen the upcoming sessions. And just to remind everyone that we do have a HOPE e-news and if you did not get notice about this via that mechanism I really recommend that you sign up to receive that on a regular basis.

Here are our contact information for George and myself. And the hope feedback information as well. We are into questions and I don't know if anybody has any other ones for George but it look like we have another minute if anyone would like to shoot him one last question. Otherwise, it has been a really good session. Lots of interaction. And we thank you and see you online very soon. Thanks, George.

(Event has ended. Thank you.)