Single-Sided Deafness (SSD): Application of CROS, Bone Anchored Implants, and Cochlear Implants

Recorded Date: June 23, 2020

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AudiologyOnline.com Course # 34989
Partner: OticonMedical

- [Announcer] I am Director of clinical research from Oticon Medical US. I like to extend a very warm welcome to everyone attending today's session. Today's session is the fourth of a seven session series. And today's speaker is one of the most prolific researchers in our field, particularly in the CI space, with a long list of very noteworthy accomplishments. Many of us would have heard her speak at conferences or come across one or more of her many papers and there are over 110 of those. So she is no other than Dr. Rene Gifford. She's a professor in the Department of Hearing and Speech Sciences, as well as the Department of Otolaryngology, and the director of Cochlear Implant Program at the Vanderbilt Wilkerson, or Bill Wilkerson Center at Vanderbilt University. She has published over 110 peer-reviewed papers as I've mentioned, just a minute ago and authored a book now in its second edition entitled "Cochlear Implant Patient Assessment: Evaluation of Candidacy, Performance, and Outcomes." She is currently serving as the chair of the Research and Scientific Affairs Committee for ASH and is on the board of directors for the American Auditory Society. She was the 2015 recipient of the ASH Louis M. DiCarlo Award for Recent Clinical Achievement, as well as the 2017 recipient of the Vanderbilt Chancellor's Award for Research, both awarded for work in defining auditory outcomes. Following hearing preservation in cochlear implantation. So I'm really excited to have her speak today in our session, and I'm pretty sure all of you are equally excited. So without further ado, I'd like to pass the microphone over to Dr. Gifford. Thank you.

- [Dr.Gifford] Thank you for that introduction. It's such a pleasure to be here today to speak with all of you. Maybe be talking about some topics that are very near and dear to my heart, and see if I can get this to work. Perfect. Okay, so today we have a few learner outcomes, we're gonna be describing the underlying hearing mechanisms that drive spatial hearing abilities for individuals who have single sided deafness, or SSD. Who are using bone anchored implants and cochlear implants. We're gonna be contrasting the benefits of bone anchored implants and cochlear implants for SSD. As well as we gonna describe some of the preliminary studies from my lab that have looked at speech perception as well as lifting listening effort and reaction time for adults with SSD who use bone anchored implants. We're jumping in right now. So you might be thinking , okay why are we looking at apples and an orange? I was a child of the 70s and the 80s, and I spent most of my mornings watching Sesame Street. And I just really have to credit Big Bird and Cookie Monster for kinda giving me this love for psycho-acoustic experimentation. Specifically like the an alternative forced choice paradigm or which one of these is different than the others. And as you can see. You might be wondering. So we've got this cochlear implant researcher, this cochlear implant clinician, he's gonna be talking to us about CROS systems, bone-anchored implant systems. Which one of these is not like the others? And you might think yeah, okay, that would be me. I'm the possum at the cat party, but I do also wanna remind you that I'm still a practicing clinical audiologist. And I see a lot of both adults and children who are referred to us for audio logic intervention, due to single sided deafness. And so I'm gonna be speaking a lot of my background and binaural hearing.

My background and cochlear implantation and also relying a lot on my clinical experience with this population which is quite prevalent. I care about ensuring that my patients and of course my research participants are getting maximum auditory input. To ensure that they're getting auditory stimulation of their cortical auditory and auditory Association areas. And a really another very important consideration, of course is binaural hearing, which is a very important part of my research line. I'm not gonna go over this diagram, but I'm sure that you've seen this very one or something very similar to it, in your audiology education which really highlights the complexity of the binaural hearing system. And how important it is to be getting information, not just from a single ear but from both sides. So today, I'm gonna be talking about single sided deafness or SSD, and we're really talking about sensory neural hearing loss at this point. So we're not talking about cases who have unilateral hearing loss, where there's a conductive or a mixed hearing component. And so there are a lot of causes of SSD, many of which are idiopathic or we just don't know it happens suddenly, I'd say, I tend to see a lot of these in the clinic. We also know that there is potentially autoimmune component of course there's temporal bone fracture. Typically resulting from like motor vehicle accidents or motorcycle accidents. Many years disease can result in SSD, labyrinthitis, cause meningitis, cytomegalovirus, and enlarged vestibular aqueduct. So there are a number of underlying etiologies. Now, I'm gonna show you this picture here. So this is little over 60,000 individuals who had attended a Green Day concert in July of 2017 in Hyde Park, London. So, if you haven't seen this, this is such a great. It's on YouTube. It is such a an inspiring video because as they're waiting for Green Day to come out and they play music, they played Bohemian Rhapsody and the entire 60,000 person audience sang together and it was really just very cool. But why I've shown you this is that, it's estimated that approximately 60,000 people every year acquire SSD in the US. It's a very prevalent type of hearing loss that we encounter, and it's one that we as audiologists tend to struggle with, in providing you know, appropriate intervention. So that's what we're gonna be talking about today. And there are a number of intervention options of course for this population.

We can talk about remote microphone systems, we're not gonna be covering those today but there is a literature on that. We're gonna talk a little bit about CROS systems, bone anchored implants, cochlear implants, and of course, there is always the "Do nothing" approach. And for today we're gonna be focusing on these, with the greatest amount of our emphasis being placed on bone anchored implants and cochlear implants. We know that hearing with both ears is critically important. It's not just for speech recognition, not just for localization or telling where sounds are coming from, but also sound quality is dependent upon the ability for us to hear and integrate sound from both ears. Now in order to have true binaural hearing, and this is a quiz, potentially, an answer, we have to have access to interaural time differences and interaural level differences or ITD and ILD cues. And there are a number of phenomena, they're associated with binaural hearing that are resulting from some contribution of

ITD and ILDs. So for example binaural summation, simply adding a second hearing ear, head shadow. Now importantly head shadow is interesting because you don't necessarily need two hearing ears to benefit from head shadow. You simply need a head. Because even individuals who have one hearing ear can benefit from head shadow, provided that the noise or the distractor stimulus is originating from the poor hearing ear. Then of course there squelch or also referred to as binaural unmasking of speech. This is a combination of ITD and ILD integration, typically thought to be first occurring at the level of the brainstem. And then of course spatial release for masking which is simply when your noise and your signal are separated spatially and this is also a combination of both head shadow, as well as, ITD and ILD sensitivity. And spatial hearing is of course we know that in order to be able to tell where sounds are coming from, whether it be a static source.

So for example someone says, "Hey," And you're able to localize or tell where that person is located, or in the cases of auditory motion perception, such as a dynamic source like a cars driving by or someone on a bicycle is saying something to you as they ride by. This all depends on our ability to have hearing and integration of these cues from both ears. And then of course another really important thing that often gets overlooked is listening effort. So anyone who has hearing loss is gonna tell you that at the end of the day they can be absolutely exhausted from all the expended effort that's been put forth so that they can hear adequately and communicate effectively. And even individuals who have one normal hearing ear are still gonna be affected by listening effort, and of course sound quality. Okay, so I'm gonna do the first, "Do nothing" approach. I'm older than a lot of you here but I'm not that old. And when I was in school for my master's degree from my audiology degree, we were taught often that, you know, a lot of times you really only need a single hearing ear to develop speech and language abilities. And you know while we know that children are increased academic risk and there's greater fatigue and stress and all that. Provided that we have preferential seating or maybe remote microphone systems. These kids are gonna be just fine. Same thing goes with adults, they thought okay, adult you know who has one normal hearing ear. They had normal language development, they had normal binaural hearing development, they'll get by. I am gonna say the "Do nothing" approach is really no longer even a viable option in my opinion. There are so many options for our patients today and we're going to be talking about those. And then, why, oh, sorry about that. Okay. So why would we consider a cochlear implant for a patient with single sided deafness? This is actually a relatively newer intervention option, the first papers were published on this in the early 2000s, and it was originally an intervention to help with very severe tinnitus. Originally published from papers and from the Netherlands. But the thing about a cochlear implant is that we're going to be providing that patient for the potential to use binaural hearing cues, and specifically to be able to use interaural level difference cues or ILDs. We know that with having access to at least those ILDs that we can potentially provide better speech understanding for our patients, both in quiet and noise. Due to summation effects, having head shadow on both sides, as well as spatial release for masking. Now it is important to know that, currently there's no evidence that cochlear implant recipients who have SSD are using ITD cues at all.

The reason is that in order to be able to take advantage of these ITDs, you have to have access to a synchronous signal across the two ears with respect to the time domain. And we know that there's a couple of reasons why these patients can't use this. First of all the normal hearing ear, and the cochlear implant ear are not synchronous. They're not connected to one another, their time clocks or their phase characteristics are not linked. So that's one issue. The other issue is that the cochlear implant largely discards timing information, it presents signals at a single very high rate of stimulation, typically about 1000 pulses per second. Which is sort of largely outside the resolution limits for the temporal phase locking capabilities of our system. So, while it's possible that patients could potentially use our envelope ITDs. So in the envelope or the slow overall fluctuations of amplitude. It's really been shown that CI recipients who have SSD are largely relying on ILD cues. Of course, we know that, providing a cochlear implant in providing that potential for binaural hearing can improve one's spatial hearing abilities. Can potentially improve listening effort and improve one's quality of life. All of which we're going to talk about today. So, and of course tinnitus suppression, which is a huge part of this. In fact, in some ways, the cochlear implant is one of the most effective treatments for individuals who have very severe tinnitus. So we'll discuss that briefly today as well. So we're gonna talk about a brief literature review that has looked at cochlear implants, CROS systems and bone anchor implants for SSD. We're gonna be spending at this point, about half time on CI literature and about half the time on bone anchored implants and some of the newer very preliminary data that are emerging from my lab in this space. So in 2011 Arndt et al colleagues, they completed a study where they enrolled 11 adults who had SSD, and they wanted to look at the experiences of these individuals with CROS systems, bone anchored implant systems and cochlear implants ultimately. So you can see that these individuals had their range duration of deafness anywhere from four months to 110 months.

They had all tried the CROS system unsuccessfully, they'd used the bone anchored implant actually it was on a hard band it says. I always say soft band because of my pediatric audiology background. And what they did was they looked at localization so horizontal plane localization abilities, speech recognition and noise. And they did this for the unaided conditions so just one normal hearing ear, as well as for the cross system, bone anchored implant and cochlear implant. So we're gonna review some of the literature here and we're gonna focus on speech recognition and noise first. What they did was they presented a number of listening conditions. So here's an example of, you can see you're looking down on top of their listeners had, they had one normal hearing ear one SSD ear. They use conditions in which the speech was directed toward the normal hearing ear and noise to the poor ear. Of course, this would be easy listening environment for individuals in this listening configuration. They also then of course reversed it, where the noise was going toward the normal hearing ear. This would be a very deleterious listening environment for this population. And then of course they used the co-located speech and noise condition. Shown here you can see they're looking at, HSM sentence recognition, percent correct on the y-axis for different noise and speech configurations along the y-axis. So, speech for example let me grab my mouse. So you can see here we've got speech to the SSD ear, noise to the normal hearing ear, co-located in the middle and then speech to the normal hearing ear noise to the SSD ear. Now, each of the individual bars represents a different listening condition. So we've got unaided as the unfilled bars, the CROS system as the lightly shaded, bone anchored implant as the next dark shaded bar and then cochlear implant is on the right for each of these listening configurations. And so what you can see is that, first of all for the most part the cochlear implant yielded either equivalent or better speech recognition than the other conditions. Particularly relative to the unaided condition, but primarily in that listening configuration speech was coming to the poor ear and noise was coming to the normal hearing ear.

So not a very typical listening environment that one would put themselves in, if they had this hearing configuration. Another important finding was that, there was really no negative impact of the cochlear implant at least not statistically significantly so, on speech recognition as compared to the unaided condition. And then the CROS and bone anchored implant interventions were about the same as unaided for all of the conditions with the exception of this one over here on the right, on the left rather, where the most difficult listening environment, the CROS was slightly better than unaided. They also looked at a speech reception or receptive threshold or SRT. And so this is where you have an adaptive speech signal in the presence of a continuous background noise. So in this case, a lower score is actually better meaning that you can get about 50% correct at a more negative or more difficult signal to noise ratio. So we're looking of course at SRT on the y-axis for those three listening configurations described in the last figure. Now on this particular figure you're looking just at unaided and the CI conditions, and this was after the listeners had at least six months with their cochlear implant. And so what you can see is that in of course again the most difficult listening condition where speech was being directed to the poor ear and noise to the normal hearing ear, that there was a statistically significant and quite substantial improvement in the SRT. Nearly six dB improvement, when they had the cochlear implant. So this was a significant finding. You can also see that in the other listening conditions there was no benefit of the cochlear implant, as we wouldn't necessarily expect that in those listening conditions. There are other studies that have looked at this as well and so this is a more recent study coming out of the University of North Carolina Chapel Hill, so Buss et al from 2018. They were involved in a actual clinical trial looking at cochlear implantation for adults with SSD, or near SSD. Some of the individuals had a milder loss in the better hearing ear. This is a study that looked at 20 adults, you can see the range in age from 23 to 74, they had very pretty variable duration of deafness anywhere from about a half a year up to over six years.

All of them had been tested with bone anchored implant prior to the cochlear implant that is. And they had used of course the head band system so this was not the osseointegrated system which of course we know would provide you with much better gain and resolution. And two of them had tried bone anchored implant, and all of the others are gonna be tested acutely and the data will be shown in the next figure. Oh, I have some strange animation issues here. Okay, so what we're looking at here is, A-Z Bio sentence recognition in noise, percent correct on the y-axis, and then you can see that, we're looking at three different listening configurations. Very similar to what we looked at in the previous paper except in this case speech was always coming from zero or from straight ahead. And noise was being directed either toward the good hearing ear or the normal hearing ear to the front so this is the co-located cognition in the middle or the noise was directed to the poor ear. And so on this particular figure you're only seeing unaided, which is the gray bars in each of these listening configurations. And then with the cochlear implants signal across a number of different test points, going from one month postop activation, three months, six months, nine months and 12 months. On each of these also you're going to see a group of normal hearing control listeners, and those are in the unfilled bars, which are to the right of all the other bars. And so I think it's pretty clear from this figure that when you just look at individuals who are going from unaided to a cochlear implant over time, that in the most difficult listening condition where of course noise is coming to the good ear that there is a clear and significant improvement for speech recognition over time. However, they're still not achieving really what you would expect if you had two normal hearing ears. which of course is to be expected, I believe to some degree, particularly given that at least a portion of these participants had some degree of hearing loss in the better hearing ear. Now on this next we're gonna be figuring, we're gonna be considering tinnitus. So tinnitus is something that is heavily prevalent in even just the typical population it affects up to 15% of just adults.

And it's thought that up to 85% of individuals that have tinnitus have some degree of hearing loss. whether or not it's clinical, for example might be hidden hearing loss. and by hidden I don't mean necessarily cochlear cinematography, I mean that it might just be at higher frequencies that we don't typically test for clinical audiometry. And we know that while we don't know a lot about tinnitus, we do know that many forms of tinnitus are really thought to be caused by just auditory deprivation or lack of auditory input. And so as I mentioned earlier that cochlear implantation is really one of the most effective interventions for tinnitus suppression. And while we don't know exactly what the mechanism is there are some theories. The first thing is that we know that tinnitus is thought to be due to of course, a lack of auditory input or deafferentation. And so one thing we do know from animal models is that, when you have deafferentation there is a reduction in the inhibition that's provided from those thalamocortical feedback loops. And so when you have these loops and these neurons and these networks that are going from the thalamus up to the cortex, auditory cortex, there's this reduction of inhibition, which is thought to then provide an increase in gain that's provided at the synapses of the central auditory neurons. And the thought is that it's sort of like the auditory system is compensating for this lack of input right increasing the gain, which then results in an increase in the spontaneous firing rate of these underlying neurons which can be interpreted by our system as sound. And so if you're interested in getting a little bit more information about that, here are two. There are many papers, but these are two really good papers that provide a great description of that. And then the thought of course is that, the effects of this deafferentation can potentially be not necessarily permanently reversed by cochlear implantation, but can be suppressed at least while you're wearing the device. So such that electrical stimulation, one more regularly can actually help regulate neural activity.

Because you're providing this, instead of the deafferentation you're providing after input and so it's not gonna result in that increase in synaptic gain and increase in firing rate. And so you having a little bit of regulation. And so many of our patients, of course, who use cochlear implants, whether or not they have SSD or bilateral sensorineural hearing loss, they report a byproduct of getting the cochlear implant as gosh my tinnitus seems so much better. And of course, it can work here as well for this population. So we're going back to the first paper we described the Arndt Colleagues. And so looking here on the y-axis is the tinnitus strength or how severe the patient ranked the tinnitus. And then there are three conditions here along the x-axis; unaided, when the cochlear implant is initially switched on, and then when the cochlear implant is switched off after a period of time. And as you can see it's sort of this, it really shows you the importance of wearing the device in this case, because everyone, nearly everyone, showed a pretty substantial reduction in the strength of the tinnitus once the implant was on. But after the implant is switched off, that tinnitus perception increases again. So this is sort of showing you that yes this can be useful, but you have to wear the processor. Here's another study from 2008 Van de Heyning. And you're looking at tinnitus loudness here, so this is a visual analog scale which is VAS. And so of course a higher number represents higher disability related to the tinnitus or higher severity. And so we've got prior to the cochlear implant and then a number of time points following a cochlear implant activation. The squares here at the top of the graph show when the cochlear implant is off, and the bottom here these diamonds show when the cochlear implant is on. And I think it's pretty clear to see that, after the cochlear implants been fitted initially, there's a very substantial reduction in the perceived strength of the tinnitus, while wearing the cochlear implant. And in some cases it's also it persists for at least some degree when they're not wearing the implant but it's not as effective. And then here is a paper from from Vanderbilt that came out a few years ago, looking at specifically individuals of course again with SSD. They plot it the tinnitus handicap inventory their score of the THI as a function of the different time points relative to the cochlear implant.

Now I'm not gonna go over all of these grades of the THI but I do wanna point out that anything above a four is considered severe, in grade five all the way up here is considered catastrophic. So meaning like it is affecting all facets of one's life. And so what's interesting is that, prior to cochlear implantation over half of this sample had either a grade four or five tinnitus. Consistent with severe to catastrophic. And following cochlear implantation just a single patient remained at a catastrophic level, and every other participant out of all these 12 showed a significant reduction in their perceived tinnitus handicap. And then of course one more thing about tinnitus and one will finish with that, we're looking here this is from Dillon et al. So this is from the UNC group in their clinical trial of cochlear implantation for SSD. And you're looking at tinnitus severity here, again, for the THI grade four is up here with this horizontal dashed line. And you can see that the individual, so you've got individual data points as the circles and then the interquartile range and the median here with the bar in the middle. You can see a substantial reduction in tinnitus following activation of the cochlear implant that maintained over time. All right, so what about quality of life? So it's not just about necessarily speech recognition and noise, or tinnitus reduction. How does this potentially these interventions affect one's quality of life? And so shown here this is another figure from the UNC group. And you can see they're plotting here the APHAB in the course with APHAB higher score means more problems associated. And here is the global score, you've got preoperative, one month following cochlear implantation 12 months following cochlear implantation here for the global. And then here are the individual subscales. So ease of communication here, background noise reverberation, and aversiveness. And in all cases with the exception of aversiveness which is not uncommon. We're seeing a significant improvement following cochlear implantation on these subscales. As I mentioned the aversiveness scale is unique in that, sometimes or oftentimes even following hearing aid fittings, cochlear implant fittings, bone anchored implant fittings, we can sometimes see an increase or increase problems associated with aversiveness. Simply because people are hearing better they're hearing more of like alarming sounds.

So this trend is consistent with that. Here's another figure from the Dillion et al. Paper. so we've got SSQ, the speech spatial qualities questionnaire, and of course on this questionnaire, a higher score represents better outcomes or better perceived listening abilities. And the same data points are shown here, preoperative one month and 12 months. This is the overall SSQ score here on the left, and then here are the interquartile ranges in medians for the speech subscale, the spatial and the qualities. And as you can see that there are , very substantial improvements in both speech and spatial hearing abilities. As we could imagine following a cochlear implant and qualities. Actually spatial did still improve just not to the same degree as we would expect, particularly the spatial hearing abilities. Then here is the original paper we talked about the Arndt paper. Where they looked at both unaided, or they looked at unaided plus both CROS and bone-anchored implant and sort of the same thing. We're seeing that there's really little effect at least perceptually on a lot of these dimensions with the exception of the cochlear implant over time. So what about localization? So localization is something that I think about a lot. And our patients tend to think about a lot as well because they wanna know where sounds are coming from. It adds that stereophonic, perception adds to our listening experience. So here we are seeing, this is from the Arndt et al. Paper. We're looking at horizontal plane localization, a billion angles here on the y-axis. And in this case a lower score is better. Meaning that you can tell the difference between a smaller difference in asthma. And they have this for the unaided here, CROS system bone anchored implant on the headband in the cochlear implant. And of course because the cochlear implant provides the opportunity for binaural hearing, not guaranteed but provides an opportunity, we do see that the best horizontal plane localization was achieved with the cochlear implant system. Here is from the UNC group. And you're looking at RMS error, localization abilities this is sort of like your threshold. So the smallest asthma that you can tell the difference and here on the left side of this figure, these are the scores for these individuals in their unaided condition, as well as with the bone anchored implant. But of course keep in mind that it's bone anchored implant on head band.

And these are not significantly different from one another. Whereas once the individuals were fitted with the cochlear implant, we do see a significant improvement in localization abilities that in some cases is rivaling what we would expect from a group of listeners with normal hearing, which has shown over here on the right. And finally here is a figure from, Dorman et al. From 2016, showing the same thing RMS error, localization ability on the y-axis. And then there are a number of different participant groups here shown. So I wanna highlight this, okay, over here on the left we have normal hearing group. And then here is just individual with a single hearing ear. Now the individuals where you see the circle that's half filled, this shows performance for individuals with SSD who had had a cochlear implant, but when they were using just their normal hearing ear. And I want you to contrast that with this group over here, which is those same individuals, but are now using both their normal hearing ear and the cochlear implant. And it's obvious to see that, there is a substantial improvement in speech and, I'm sorry, and localization abilities once the cochlear implant was active. All right, so we've talked about speech perception. We've talked about tinnitus, we've talked about sort of a subjective benefit. We're finishing up the cochlear implant now, we're gonna move into bone anchored in just a moment. But first I wanna talk a little bit about neuroplasticity. And so this is basically the brains reorganization in response to a change in stimulus. And so this is an interesting paper, and I'll be honest until this paper came out, I was not a big proponent of cochlear implantation for individuals with SSD. We still don't have a ton of data on this, but this is a very interesting paper. This is a single case study, looking at a child who was nearly 10 years of age, but she started losing hearing in her right ear at about five years of age. Not sure why, she had tried CROS systems. She had an FM remote microphone system for the classroom. She didn't seem to find much benefit from it. She actually really wanted to get a bone anchored implant and her family pursued that. And really surprisingly insurance had denied that, but they approved a cochlear implant.

Which was really interesting because that was before any, FDA approval was granted for cochlear implants for single-sided deafness. All right, so what you're seeing here is, this is a current density reconstruction for a visual evoked potentials. And so this is for the single case study and we're looking at the neural activity in response to visual stimulation. The type of visual stimulation they were using is you simply there's no auditory stimulation. You would look at this figure and you see, it just kind of moves where it goes from circles to stars. What you can see is on the left here, this is her neural activation in response to visual stimulation prior to getting the implant. Now keep in mind the visual cortex is back here in the exhibital low. And you're seeing actually for this child, a lot of activity that's much closer to a primary auditory cortex and auditory association areas here in the temporal lobe. This is showing evidence of what we would call cross modal plasticity, such that in the absence of auditory stimulation from both ears this child was showing some cross modal reorganization or plasticity. But then following the cochlear implant over here on the right, you can see that this activation that was very much approaching the auditory area is sort of retreating away and making its way more to visual cortex. Which is really, to me very fascinating, particularly given that this child had a single normal hearing ear. Now here we are looking at, it's not just visual stimulation that can provide, CROS modal reorganization, but any other sensory systems. So here they used Somatosensory stimulation, which was simply like placing like sort of like your bone oscillator on the finger and just providing some sort of tactile stimulation to the finger. And so prior to the cochlear implantation, you can see that this amount of sensory stimulation provided pretty diffused activation, not only of somatosensory cortex which would be right here, but also sort of moving its way into auditory cortex. Or at least auditory association here, areas that are near the edge of this temporal lobe. Whereas following cochlear implantation, you're seeing that much greater somatosensory cortex is being activated. So again somatosensory stimulation is sort of retreating away again from auditory and auditory association areas. So the interesting thing is this really shows evidence of neuroplasticity following a cochlear implant for single sided deafness. But we don't know how much CROS modal plasticity is actually reversible. And we also don't know a lot about duration of deafness. So if this child had waited at 20, 30 years, would we have seen sort of this again, reorganization following a stimulation of both ears. I wanna focus now at this point, there are a lot of limitations of the SSD cochlear implant literature.

So I just presented about 15, 20 minutes of cochlear implant outcomes for SSD, but I'm gonna tell you, there are a lot of things to consider. So first of all, nearly all of these participants in every single study to date has used a bone anchored implant on a headband. And as I mentioned earlier, we know that this is not osseointegrated, it's not providing the maximum benefit that these systems can provide. Of course we also know that there's tremendous recruitment bias and experimental bias for these participants. I see this in my own laboratory because people that come to me, who have a cochlear implant and they have SSD, clearly they chose that intervention. So for whatever reason they did not, whether they might not have given a strong trial to a cross bone anchored implant system. And also the experimental bias here is that, the laboratory conditions that nearly all of these studies use, they're presenting noise directly to the normal hearing ear. Which we know is highly contrived. Because if you have SSD, you're not gonna situate yourself when there's noise coming at your better ear. you're simply not going to do that. And then of course we know that not all of these individuals had true SSD. So many of them had some degree of hearing loss in the better hearing ear. And most of the listeners, this is the key issue is that, they have very short durations of deafness. Which we know these are clearly the very best cochlear implant candidates. They've had less opportunities for sort of neuroplastic changes for this cross modal reorganization. And they had at least one point normal development of their binaural hearing system. These are some very serious things to consider because there's very limited literature on how successful these systems are for individuals who have congenital hearing losses. Which interestingly about 10% of the individuals who are referred to our cochlear implant center are adults who have congenital SSD.

And these are just about the worst candidates for cochlear implantation that you could imagine. I do wanna point out the labeled indications for SSD cochlear implant in the US. They are pretty restrictive at point of course, in some cases we can make a recommendation that may be off label. But we are right now as far as insurance goes, we can implant children age five years and older. And of course adults as well. They have to have very poor hearing in the poor ear. So basically have to have a profound hearing loss in the poor ear and very poor word recognition in that ear. Less than 5% or up to 5% CNC. And another very important thing is that, cochlear implantation for SSD is not covered by Medicare right now. So for adults who have a sudden idiopathic or meniere's disease or whatever might happen and have a resulting case of SSD a cochlear implant is not an option for those patients. Unless they want to pay out of pocket, which is extremely costly. Another important point is that, I'm a cochlear implant researcher. I work at a cochlear implant clinic, but I am always looking for the least invasive option for our patients. Of course that's what we do. And we know that cochlear implants aren't gonna be appropriate for everyone. So as I mentioned earlier, people who have very long durations of deafness where there's been considerable CROS modal plastic changes in the central nervous system are going to be less beneficial. A cochlear implant is going to be less beneficial for them. They have to be very motivated. This is something that is gonna take a lot of auditory rehab. Because presenting a signal, that's a very impoverished signal to the poor ear. And it's potentially competing with the signal from the normal hearing ear. And I can tell you that a lot of individuals, especially with those with longer durations of deafness, they just become non-users of their cochlear implant. And that's just a waste of our healthcare dollars. It's disappointing for the patient who now has a device implanted in their head and they're not using it. So that's a very important thing to keep in mind. There are also individuals that might have had vestibular schwannoma or other issues where they've had nerve resection on that side.

And then of course that those patients are not gonna be candidates for cochlear implants. They're individuals who have significant health concerns who are maybe not as healthy to undergo surgery with general anesthesia, which is the case for cochlear implants and is not the case for bone anchored implants which can be placed and are typically placed under a local anesthetic for adults. And as I mentioned on the previous slide, there are going to be some severe insurance restrictions, particularly for our Medicare patients who are just simply not gonna get coverage for this intervention. I want to discuss the option of bone anchored implant for SSD patients. I've been very interested in this particular for a research perspective, which I'm gonna show you some data. Because again we have so many people that are coming in and are really asking for our input, and there's just not a lot of really great definitive studies on this intervention out there. That I have really kind of looked at it, in comparison to cochlear implantation. Which is now of course FDA approved. What we wanted to look at is, do individuals with SSD who are fitted with bone anchored implant show improvement for speech recognition in noise in conditions that might not be entirely like those that have been in the literature? Where again, where noises only going to the normal hearing ear? And also we wanted to look at listening effort and quality of life potentially because again listening effort is something that these individuals really report as problem and would love to see if we can improve that with a less invasive option. So as I mentioned before, and I do also want to point out that, my co-investigator on these preliminary studies was Devin McCaslin. And he was at Vanderbilt at the time that we completed these studies. But he's now at the Mayo clinic. So as I mentioned before the previous studies had looked at co-located speeching noise, as well as, actually I'm sorry, this should have been, of course I see my errors after I've, proof-read this a million times. This should be noise coming to the SSD ear and then here noise coming to the normal hearing ear.

And of course this is another listening configuration that some of the studies have used where they have, speech coming to one ear noise coming to the other, which really wouldn't be a very ecologically valid listening condition with the exception potentially of, if you're driving, you have your window open, you have normal hearing in the left ear and your passenger is trying to talk to you. So again, not a very typical listening environment. What is very typical however, is this. So this is a snapshot of a scene from a breakfast at Tiffany's showing a cocktail party. And in this type of environment, people are talking and there's number of different individuals talking who may be taking turns and you have to be aware of where your signals are coming from. Another potential consideration is shown here. We all engage in family or group dinners, maybe not as much recently due to the COVID situation. But here you can have one person that's on your left that starts to speak. And then one on your right that starts to speak. And an individual with one normal hearing ear is really gonna be at a disadvantage here. So in this particular study, we wanted to really look at, what happens when the talker roves? In these cases like at a cocktail party or small group environment or a dinner party. I mentioned these data are preliminary. We only have three participants to date, but we do have goals to get more individuals recruited. We have a data for three individuals ranging in age from 25 to 44, all of whom had complete SSD. Completely normal hearing in one ear and profound hearing loss in the other. I do wanna point out that the individual here, that's 44 years of age actually did have an osseointegrated system and used a Ponto Power Pro. The other two here, we're not using anything. And so these two were fitted acutely with a headband option. That is something to keep in mind as we look at this data. What we did was we had the signal always where the signal would originate from the front in some cases. And then in some cases-- I'm gonna move along here for the sake of time. And then the signal would vary. And so the listener had to, just sort of, we asked them to keep their head pointed forward. And then on every subsequent sentence, the speech was varying from either zero or plus or minus 90. Now we did determine an individually, basically, individual SNR that was required to get them off the ceiling when the speech was originating from the front as shown here. And on average it was -2 dB SNR. We actually needed a zero dB SNR for one individual, and minus two for two of those individuals in the study. And what listening conditions we used was; we used unaided of course, and then we had the Panto Power Pro that was fitted.

Of course the one listener was a chronic user with her Panto and the other two were acutely fitted. And we had both an omnidirectional condition as well as a directional microphone condition. And the speech signal that we used were the TIMIT sentences, which if you're unfamiliar with this stands for; Texas Instruments Massachusetts Institute of Technology. And it's basically just a Corpus of sentences that were developed at least originally for speech recognition systems and have a number of different dialects and different speakers of different genders. And so it's a very rich speech Corpus. Shown here, what we're looking at, is the TIMIT speech perception in percent correct, as shown on the y-axis. And then we have data presented, mean data for the three listening conditions, for three different speech locations. So we had speech originating to the poor ear, speech originating from the front and then speech originating to the normal hearing ear. So this would be like zero degrees, and then of course, plus or minus 90 degrees, whichever ear was the individual's poor ear. We're looking right now at unaided data. And so you can see that in the poor ear, when speech was originating from the poor ear, these individuals, they would struggle. So like in a cocktail party or group dinner, this individual would miss that sentence, which is very difficult. Of course, when speech originated to the normal hearing ear they did great. When it was to the front, they did okay. And then, we looked at the bone anchored implant at it with an omnidirectional microphone. And what's really striking is that, keep in mind two of these three individuals were just fitted acutely. They show us substantial improvement in speech recognition when the speech originated to the poor ear and actually a little bit of a bump here even when speech was to the front, although it's likely not trending significant at this point. But could be individually significant for someone who's struggling for communication.

And then as might not be expected with a directional microphone in this particular situation where the speech is roving. In this particular case, omnidirectional was a much better situation for our listeners. But still even with speech originating to the poor ear, the directional microphone was a significant advantage over just unaided condition. So, it's not just though as I mentioned, it's not just speech perception. How much effort are these patients or these listeners expending to really make it through these listening configurations? And so what we also looked at was we wanted to see how these listeners perceive the difficulty of the speech in these different tasks. So after a run, so after they had listened to like a run with these roving noise surf sources, in their unaided, in their omni bone anchored implant and in their directional panto pro. We asked them to rate how difficult it was, ranging from one being no difficulty at all to 10 being the most difficulty imaginable. So what we show here is the listening difficulty based on that visual analog scale. Here is for the unaided condition, they're kinda at the upper range of being difficult. And then you can see, Oh yeah, I forgot my little animation, lower score is easier, with the omnidirectional bone anchored implant it got better. And it was substantially insignificantly better even with this preliminary data set.

So we saw a tremendous improvement in one's perceived listening effort for these very difficult listening configurations when fitted with a bone anchored implant. And then I wanted to show you the individual data. So you can see here are the unaided for the three listeners, with the omnidirectional and with the directional. And of course participant three is the person with the osseointegrated system Another way to quantify listening effort is to use response time sort of as a proxy. And here are a couple or a few studies that have done that and shown that that is a reliable proxy. And what I mean by response time is, when you're in a noisy environment, someone says something or maybe asks you a question, how long does it take you to either process that information or to respond or to basically repeat the sentence as is the case in this experimental condition? So here we looked at, we actually calculated for each one of these listing configurations.

We recorded it, we audio recorded it. And then we quantified how, what was the average response time from the time that the sentence ended to the time that the person started to repeat the sentence? And so here we're looking at obviously a longer reaction time would be associated with greater effort. And you can see in the unaided condition at range anywhere from just over a second up to two seconds. And then both the omni and the directional, which is interesting because this would not, this was surprising to me given that their speech perception scores weren't as good in the directional, but the reaction time was significantly shorter. So less effort required when they had their panto on, as compared to just the unaided condition. And what's really interesting and very cool to me is that, even the two listeners who were acutely fitted, keep in mind, longterm durations of deafness, we just fit them with that system and put them right in the sound booth. We are seeing significant improvements in the reaction time. And finally one more thing, I know we're getting close to being finished, but I wanna show you we did one additional listening configuration. We did A-Z Bio sentences, presented at a zero dB signal to noise ratio again diffuse noise and noise originating from 45 degrees all the way out to 315 degrees. And we see that in each case, we're seeing improvement in one's listening or speech perception abilities when going from unaided to a bone anchored implant fitted. And that's even when speech is always at zero, which wouldn't necessarily be considered to be a very difficult listening environment. Kind of wrapping things up. I also wanna point out that there was this study that did a systematic review of the bone anchored implant literature. And while they showed that there was no improvement at the group level for localization abilities, they did show that bone anchored implants show significant benefit for speech and noise. In many cases being significantly better than a CROS system. They also show that there was a significantly improved quality of life for individuals with SSD who had been fitted with bone anchored implants. And so again, I wanna really point out that the "Do nothing" approach for these patients really it's just not acceptable. We know that there's options out there that will improve their ability to communicate and to improve their quality of life listening effort, reaction time. If I were taking this quiz, I would say that, what's true of bone anchored implants and SSD is that there's potential for greater benefit for speech and noise as compared to CROS systems. So finish things up, you might be wondering, okay, what do I do from a clinical perspective?

I'm giving you just sort of an aggregate summary based on what the literature is telling us and based on my clinical experience. As I mentioned, we know that CROS systems and bone anchored implant systems, aren't preserving binaural cues. We still are leaving that individual with a single hearing ear. We're just directing information to the better hearing ear. So we're going to expect of course, that these systems are not gonna necessarily be providing us with benefit for localization abilities. We also know that single-sided deafness can result and will result in neuroplastic changes with the central system and can actually result in what has been termed aural preference syndrome. Karen Gordon from university of Toronto and Andre Krol from medical university of Hanover have described this extensively, both in children as well as in the animal model. These are things for us to keep in mind. If localization abilities are key

CROS and bone anchored implants aren't necessarily going to be the best intervention. On the other hand, we know that cochlear implants can provide access to high frequency ILDs, which we know results in better localization and can result in better speech recognition in complex listening conditions. We also know that there are qualitative reports of better speech recognition, abilities, and spatial hearing abilities, such omni SSQ and A fad. And of course we've discussed the option for tinnitus suppression with CI. Now, also important to keep in mind however, that bone anchored implant is much less invasive than a cochlear implant. And there are gonna be fewer insert insurance restrictions with respect to the age of the participant, their insurance provider. So these are very important considerations. Plus we know that bone anchored implants can improve speech recognition and noise, particularly when speech is being presented to the poor hearing ear. And even in those conditions when speeches randomly roved around as I showed from our laboratory. It's important to keep in mind that, we can see improved speech recognition as well as improved listening effort, improved listening difficulty, even when fitted acutely.

Which is to me really fascinating, particularly given that we have a lot, I mean, thousands, hundreds of thousands of adults out there who have congenital SSD, who could potentially benefit from this technology. Of course, cochlear implant is more invasive. We know there's gonna be some insurance coverage restrictions, particularly with respect to Medicare recipients. And are going to be, I will tell you not only from the peer reviewed literature but extensively from my clinical experience. Cochlear implants are not very effective for individuals who have long durations of deafness. And I wish I could tell you, okay here is this, you know, if they have greater than say seven years, then forget it, but we don't have the data to make that suggestion. But I can just say that, I know that those who have much longer durations of deafness, they don't use their device. They become non-users, they're not happy with that intervention. All right.So to summarize and bring this up. So what are the clinical recommendations? And this is actually what we do in our clinic as well. So for adults and for children who have SSD, we know that they have options. If we see very short durations of deafness, very poor spatial hearing abilities, and they're reporting significant difficulty with spatial hearing, and or if they have significant issues with tinnitus, especially this is the case for adults who have acquired onset SSD. We're gonna typically focus on the cochlear implant as being the best option for those individuals. On the other hand, when we have patients who have longer durations of deafness, her mostly saying, you know, I'm struggling with speech and noise, I'm tired at the end of the day. And especially if you pair those things with any potential concerns with insurance and or medical contraindications, we're really gonna focus more on, of course we provide a trial with the CROS system, but we are gonna push more for a bone anchored implant system. We can use that of course on a soft band for children, and with osseointegrated for our older children and adults. So I do want to just remind you that, we are potentially seeing up to 60,000 individuals just in the US every year who have acquired SSD. Now, not all 60,000 of them are gonna have longterm SSD.

We do know that at least a proportion of individuals, should they get immediate treatment, whether that be oral steroids or tympanic perfusion, they can have some reversal of those symptoms. But single-sided deafness is one of the most prevalent cases of hearing loss today and has been one of our most difficult interventions to provide effective audiologic intervention for. So I just want to finish up there and say that we have options. We have multiple options for these patients, and we have to look at it from an individual perspective. And so I wanna open it up. I know it's one o'clock and so we're essentially out of time, but if anyone has any questions, comments, suggestions, anything, I would love to hear it. No questions, everybody? Of course here's my email. If you've anything, I'm always really interested in to hear what people's clinical protocols are, for determining candidacy for the different options. This is something that's always a hot topic amongst our clinical providers and something that always gets a lot of attention at conferences. And so we're always constantly developing and improving those protocols.