Setting a New Benchmark with the Slim Modiolar Electrode

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- [Wade] Welcome everyone to the AudiologyOnline webinar titled Setting a New Benchmark in Hearing Performance with Slim Modiolar. Thanks for joining. We are excited to share with you some exciting new information on the latest electrode, the Slim Modiolar. My name is Wade Colburn and I am joined today here by Amy Popp. So just a little bit of a background on who both of us are. I'm the product manager for Nucleus Implants and I am a biomedical engineer by training and have had experience working with Cook before joining Cochlear as an engineer. And I'm happy to be on the webinar today. And then I'm also joined by Amy Popp who is an audiologist, who serves as the senior manager of Clinical Training Services. Her past experiences includes being a clinical applications specialist here at Cochlear and before joining Cochlear was the coordinator of the Cochlear Implant Center at Manhattan Eye, Ear, and Throat. She received her audiology degree from Central Michigan University. And as you have likely gathered, we both do work for Cochlear so that is our primary disclosure today.

So now let's jump in to what we're gonna cover today in this course. So from a learner outcome's perspective, after this course, participants will be able to illustrate to their colleagues the clinical evidence supporting the use and performance of perimodiolar electrode arrays, list all the different audiology considerations with the Slim Modiolar array, and elaborate on the new multicenter trial and the performance and bimodal benefits associated with that trial of the Nucleus 7 with Slim Modiolar system. So with a little deeper dive into what we're gonna cover today we're gonna be focusing on the Slim Modiolar electrode which is the latest electrode offering from Cochlear. We'll start the webinar with looking at the historical perspective of perimodiolar electrodes and then switch to an overview and introduction of that Slim Modiolar electrode or you may hear it referred to as the 532 or the 632. We'll then switch gears to focusing on some of the audiological considerations of using Slim Modiolar, as was the broader perimodiolar array offerings. And finish up with showcasing some of the data from our latest multicenter trial. For those that have had exposure to perimodior arrays, this will both provide a recap onto some of that historical perspective as well as provide new information on the latest offering. While those that are new to perimodiolar arrays, it will hopefully provide you a nice introduction to what to expect with perimodiolar arrays and the data that surrounds them. So with that, let's jump in. So first I'll focus on the history of perimodiolar arrays and try to walk you through some of those design elements and the thought behind them. And what kind of led Cochlear to the development of this category of electrodes. When we think about cochlear implants, there have been lots of innovations, both on the internal and external portion of the system. While we recognize that the complete system is needed, this slide looks at the developments over the years of the implants in particular. You'll see that we've had six distinct generations of implants.

You can also see the year of the release of each of those implants. While implants have become smaller and more reliable, we've also been able to advance the electrode offering on the electrodes. Historically, the electrode arrays were straight arrays. But in the early 2000s, Cochlear developed the first commercially available perimodiolar or pre-curved array. You will see that the Contour series was the first perimodiolar array that was created. And then the Contour Advance was an improvement over the Contour electrode. Then, most recently in 2016, we introduced our latest perimodiolar array. Today, most patients are receiving our sixth generation Profile Plus series, which comes with the three electrode variance. The Slim Modiolar, which is a perimodiolar array, Contour Advance, also a permidiolar array, and the Slim Straight, which is a lateral wall electrode. While we offer a portfolio of electrodes with both lateral wall and perimodiolar electrodes that are used for various different reasons and have general preferences depending on the surgeon or the audiology involved. All in all, about two-thirds of the recipients of our new Cochlear products end up with one of two perimodiolar electrodes. So the Contour Advence or Slim Modiolar. With more and more receiving the latest electrode technology in the Slim Modiolar which we're gonna talk more about today. Before we jump into that, it's important to kind of make sure we understand the distinction and the differences in a few key categories between a lateral wall and a perimodiolar electrode. So the key things that we'll talk about are kind of the approach from a surgical perspective between those two categories, how thin or soft those electrode arrays are, the optimal length of the array, the consistent scale placement and the history behind that, and then the distance from the outer hair cells. So when we look at lateral wall electrodes, the general perspective is that they can typically be implanted via all surgical approaches. They're known to be thin, atraumatic, soft. They vary in lengths with lateral wall electrodes so in general they typically have appropriate lengths available to cover all the different frequencies. They are known to have consistent scala tympani placement. But we do recognize that they are along the lateral wall and so therefore they are against the outer hair cell. So, this is kind of, this slide in particular was generated in the context of kinda from a preservation perspective, but I think it's also important from just an approach that because you're along the outer wall, you are making contact with those outer hair cells.

Then when we look at perimodiolar electrodes and we look at Contour Advance, there was some limitations in terms of the approval with Contour Advance or surgical approach. It wasn't necessarily known as the thinnest and softest array. It does have an optimal length so perimodiolar and lateral wall electrodes do have different lengths, but because of the trajectory that they're taking, it does cover all the appropriate frequencies. It had a historical perspective that it may not necessarily be in the scala tympani and half trans locations largely related to the stylet, if you've seen the array before and just the technique that's involved with that. But it does avoid those outer hair cells and it takes that inward trajectory. And then when we look at Slim Modiolar, you'll see that we are able to get all multiple surgical approaches similar to a lateral wall. Thin and soft array. We are able to still achieve that optimal length. We're able to achieve consistent scala placement and we're still able to avoid the outer hair cells and take the inward trajectory with that modiolar hugging array. So this just gives you a little bit of differences between those in terms of the lateral wall and perimodiolar and we'll dig into that a little bit further. Before we dig into that and we kind of look deeper at perimodiolar arrays, we've shown you some of those fundamental design differences but now we need to ask the question and begin to answer that question of, does placement impact performance? So, we talked about the difference between a lateral wall and a perimodiolar array. But the natural question is, does that placement matter and does it drive improved performance? So, set another way or looking at it another way, the difference and to better understand the difference between a lateral wall and a perimodiolar electrodes, we have to distinguish the difference between those groups. So lateral wall electrodes are obviously on the outer wall of the cochlea, whereas a true perimodiolar electrode is in very close proximity to the modiolus, thus having the closest proximity to the spiral ganglion cells. You can see in this image that with lateral wall electrodes, there is a greater spread of excitation from the electrode.

While with perimodiolar, there's more focused stimulation where you can use the electrode to stimulate a small section of the spiral ganglion cells. We'll dig deeper into the data behind this and other considerations. But for now it's important to understand the fundamental difference between these two designs in terms of how they're made and sort of the design rationale behind them. Now that we understand the difference between the designs, let's look at some of the data surrounding electrode design and continue to answer this question of, does placement matter? There have been a few different papers that have assessed patients that have received a cochlear implant to try and draw out major factors that influence cochlear implant performance. The Blamey and Lazard papers took a retrospective, multicenter approach with an extremely large data set. Looking at the results, they found that the greatest patient, looking at the results, they found the greatest patient and design factors. Holden et al followed a similar design with patients at Washington University. Out of these studies came a slew of different correlations, including patient factors and design factors. The patient factors that rose to the top were things like age, duration of hearing loss, and etiology of hearing loss. But today, we're going to focus on the four main design factors that were identified as having an impact on performance. So the four design factors that came out as having the largest impact included greater number of electrodes within scala tympani, absence of translocation from scala typani to scala vestibuli, a not excessively deep insertion, and reduced distance to modiolus. On the question to answer does placement impact performance, we'll highlight two of these: absence of translocation from scala tympani to scala vestibuli and reduced distance to the modiolus. Along the lines, and looking at the first element of does placement matter, we'll focus in on does scala tympani placement matter and does that lead to better performance? So this table is retrieved from O'Connell et al, and it looked at kind of a wide range of papers that have been studied over the years and what you'll notice is that on the left it'll talk about each individual paper and then on the right it talks about the number of implants and the findings.

And what you'll see is that there is a substantial data set suggesting, and they think this is pretty well understood across the industry, that scala tympani, in general, does drive to improve performance. While we recognize that there are lots of different patient variabilities that can come to fruition, that is also what the Blamey and Lazard and Holden papers also found was that scala tympani and not translocating did drive performance. So I think that ultimately when we talked about electrode designs, this becomes something that is of high importance to ensure that you can get in the scala tympani. And then the goal from there is trying to look at does the placement matter beyond the scala tympani in the sense of proximity to the modiolus? So I think that from the data set, it does appear, you know, and there's been lots of different groups that have studied it, that scala tympani placement does in fact lead to improved performance. One other study that's recent and it's actually available in one of your handouts, is being referred to as the Shaul et al paper, so this is out of the University of Melbourne, and they took Contour Advance patients, 57 patients that were post-lingual in matched groups, and they were looking at this very question of, does the location relative to scala tympani, a pure scala vestibuli or a translocation, does that impact the performance? And you can see that at the 12 month time point, post-op with phoneme scores, that there was a significant difference in terms of performance. So you didn't see that significance necessarily at the three month, but you did see it over that long-term, 12 month perspective. But even at three months, there was still a trend that is in similarities to that 12 month time point. So I think that all in all, I think it's safe to say that, and it shouldn't come at a huge surprise that scala tympani does lead to better performance, in general. So the natural question is if we've proven that scala tympani placement does, in fact, matter, then does placement close to the hearing nerve or have a modiolar hugging electrode, does that impact performance? And does that matter? So there's been a wide range of studies that have been done over the years that are looking at these, this very question.

One of those papers is the Holden paper. And this graph on the right of your screen showcases this paper and a graph from that paper. And essentially, what it's looking at is it's comparing the wrapping factor which looks at just how close to the modiolus and electrode is. So a lower wrapping factor would be, mean that it's more perimodiolar, whereas a higher wrapping factor means that it's more lateral wall. And so that's along the x-axis. And along the y-axis is the CNC scores. And you can see that there is a trend that, as you become more perimodiolar, that there is an improved performance. So that was a paper that was looking at Contour Advance electrodes of a well placed versus maybe a poorly placed array and just seeing that there is a trend towards if you have a well placed perimodiolar array, that there was an improved performance. Some other studies that have been done have looked at just the rationale behind perimodiolar arrays and we know that with a perimodiolar array, you can have focused stimulation that leads typically to lower current levels to elicit the neural responses and then in similar fashion, reduce channel interaction as measured with the ECAP. So that was shown in just a few different papers. And there's a couple different papers that are being referenced that are more recent that are available in your handout with those links that are associated with it. So there quite a few different studies that support there are programming and performance benefits with a perimodiolar array. And Amy's gonna talk further about that here in a little bit as well as showcase some of the performance differences with the Slim Modiolar array relative to even our historical perimodiolar arrays. So ultimately, you know, we were on this quest of, and I started the conversation with, does placement matter? And that's obviously placement within scala tympani, but also proximity to modiolus. But in similar fashion, Vanderbilt University was looking at answering this very question, as well. And trying to drive, what about the electrode design itself drove towards improved hearing outcomes? And so they looked at a wide range of studies, or a wide range of implant manufacturers and different electrode arrays. And we're trying to do a comparison between, say, lateral wall arrays and pre-curved arrays on what are the most significant things that drive performance based off their data set?

And what they found was is that with a perimodiolar array, the two most important drivers of performance were scala tympani location as well as proximity to the modiolus. So not only that it's important to be within the scala, but actually how close you are to the modiolus and how well placed you are to drive performance. So that speaks to this idea of the importance of having that true perimodiolar array and being as close as you possibly can to the modiolus. Whereas with a lateral wall array, they showed that the key driver to performance was the overall length so the depth of insertion did drive that in terms of the length. Now it's important to recognize that depth or length is not equivalent for a perimodiolar versus a lateral wall because of the trajectory of their taking is different. So it's not something that you compare in that manner, but that it does drive those differences. But if you read this paper, which again, it's in your handout as a reference, you will see that they look at those categories, the lateral wall and perimodiolar compared to one another and there is a trend that the perimodiolar arrays from a performance perspective did outperform the lateral wall arrays. So in general, the conclusion out of this was that our results confirmed the significance of electrode positioning in audiological outcomes. The most significant positional predictors of outcomes for pre-curved arrays were scala tympani insertion and modiolar distance. While for the lateral wall arrays, the depth of insertion was the most significant factor. So now that we've done a little bit of a historical look at perimodiolar arrays, let's dig deeper into the Slim Modiolar in particular and draw out some of those design goals as well as those design specifications, which help in understanding the data and the considerations that Amy is gonna speak to. So first off, when we talked about the design of Slim Modiolar, it's been on the market for a couple of years, but obviously it was in development for quite some time and there was really four main goals when we designed or sought to design this electrode. The first one was to try and create and thin, atraumatic electrode.

So, historically perimodiolar arrays had lots of, great data suggests that there was improved performance, but there were situations where people were concerned about, as we were moving to preserving that structure and more and more hearing, making sure that we can create a thinner, atraumatic electrode. So that was one key design goal. The other two design goals were related to that idea of placement. So we sought out to make more consistent scala tympani insertion, as well as have consistent proximity to the modiolus. And so it's really the key word there is consistency piece. So with Contour Advance, there's lots of people still utilizing it and having good results with that perimodiolar array. The biggest differences is just across the world and ensuring that we can have as consistent as scala tympani and proximity as we possibly can. And then the final piece is from a preference or a surgical perspective is making sure that this electrode can be inserted via all three surgical approaches based on a patient's anatomy. So it was really taking what was great about Contour Advance and maximizing that to add some of the benefits of lateral wall like thinness and atraumaticity and ensuring that we can kinda get the best of both worlds in that regard. So that was ultimately what the design goals with Slim Modiolar were. Now the question obviously becomes, were we successful in doing that and achieving these design goals which were set out early in the development process? So when we look at the Slim Modiolar and the specific specifications, there's a few things to take note. The first is is that obviously it is a pre-curved array and so in doing so, you can see the curvature of the electrode. The one thing to be, kind of as an obvious, is in order to get that end of the cochlea, obviously there has to be some mechanism to straighten out the electrode. So, how do we do that? The real potential for that is you either need to straighten it within the inside of the array or on the outside. And so Contour Advance has a stylet based straightener, which kind of runs through the middle. And with this, we were able to create a sheath base. So on the right side of the screen, you can see the orange sheath. And the biggest thing there is that that allows you to straighten out the electrode array. And that's important because, because we're able to straighten it from the outside, we were able to greatly reduce the overall size of the electrode. So we're able to make it less traumatic and ensure that we can get the best possible size.

So a couple of things just to be of note that are important from a design perspective, is that length of that sheath, so you can see sheath tip to sheath stopper 5.5 millimeters. The reason why that's important is that when we talked about consistency of being in the right scala and making sure we get the best possible placement, that was designed based off the, kind of the average basal turn of a cochlea to make sure that we can get consistent results across different recipients. And so for us, that is something that really drives the performance and drives the insertion and the overall design. The other thing that I'll call your attention to is that you can see on the left image, the three white markers and so that's important for surgeons as they insert it, our recommendation is to be able to see all three white markers following the insertion. And the reason why that's important is that is the best way to maximize that proximity to the modiolus. So we talked about the importance of even within a cochlea, which is really a small space, how important it is to get the best possible results, is to get as close to the modiolus as possible. And so that's, you know, if for some reason it's over-inserted a little bit, pulling that back a little bit and really tightening up that electrode allows it to get even closer to the modiolus. So that just gives you a little bit of an overview of some of the key elements of the design which are important to consider when we talk about audiology considerations, it's also important to understand how the array is designed to just understand why if you experience something, what that rationale or the potential cause could be in that regard. So I talked about the design in the sense of a stylet versus a sheath-based. And so what you'll see on this image is just kind of the proof from a dimensions perspective on both the apical and basal ends of the arrays where the yellow, or the orange-ish color is the Slim Modiolar. Whereas the black is the Contour Advance. And so we talked about this 60 percent reduction in volume. That's really driven from allowing that straightener of the sheath to be on the outside versus with the Contour Advance, where the straightener and the stylet is on the inside. So that's really driving that ability to reduce the volume.

The other key design element was obviously to try and make a very atraumatic electrode. And so in our temporal bone studies, leading in the design, no intracochlear trauma was evident in 98 percent of the specimens. So that's very exciting in that regard in those initial designs. And so in doing so, we're able to take that inward trajectory be close to the hearing nerve and the spiral ganglion cells, but also avoid the outer wall hair cells. So we're kinda being able to achieve both that atraumaticity perspective but then also maximize that location of the array. So when you have a thinner design, that's also driving in terms of overall proximity to the modiolus. This shows that proximity, in the sense of what those differences are, say, between Contour Advance and Slim Modiolar, so you may be saying, okay, but these are all perimodiolar arrays. But I mentioned that, because we're able to get thinner, that we're also able to get close to the modiolus than ever before, right? So this looks in a temporal bone labs, so if you see the purple is the Slim Modiolar first insertion. It is able to be reloaded so the bluish color is the second insertion of the same electrode after it was reloaded. And then the orange is the Contour Advance electrode inserted. So from those temporal bone labs, we saw that 92 percent of the Slim Modiolar electrodes had more contacts position medially compared to the Contour Advance, meaning that it's closer to the modiolus. And I think what's most significance is that because it's reloadable, if for some reason you don't like the location, you can pull that back, reinsert it, and there's largely no difference between those first and second insertions. So when we look at the length, obviously with the lengths are the same between Contour Advance and Slim Modiolar, but you're able to, because you're able to get that tighter curl, you're actually able to get closer and also ensure that the best possible stimulation in that regard. So one recent paper, which is also linked in your handout that I alluded to earlier about the scala tympani is that results and the importance of scala tympani is the Shaul et al paper from the University of Melbourne. So in addition at looking at does scala tympani matter, they also looked at a comparison of matched groups within the perimodiolar family.

So you look at Contour Advance and then Slim Modiolar and essentially in this group, they looked at the 12 month mean post-op phoneme scores and they showed a significant difference. A little bit about those groups though, is that they were matched, so they were post-lingual, there was a nonsignificant difference in the pre-op scores. And they all had full scala tympani insertion. So the thought is, okay, well why are we seeing this? Well, as we saw in that Chakravorti article from Vanderbilt as well as some of the others, things that I've shown you from a temporal bone lab, we do know that Slim Modiolar is able to get closer to the modiolus. And so the logic is that by maximizing that location and that proximity, we're actually also maximizing the performance. So what they found, and I think they're continuing to work on a larger data set from what I understand. But what they found in this, the data set, was that essentially the top 75th percentile of the Slim Modiolar were above the bottom 75th percentile of Contour Advance. And you did see a significant difference. So while these are matched groups and it's always hard to compare across patients and electrodes, we are seeing that trend that Slim Modiolar is maximizing that performance. And that's something that we're seeing across multiple studies that are coming out over the last couple of months that they're maximizing performance over Contour Advance, but then also over lateral wall electrodes. So within a compared data set, Slim Modiolar patients did perform significantly better at that 12 month time point. So really when we look at Slim Modiolar, we mention this idea of the importance of those design goals of thin, atraumatic electrode, the consistent scala tympani insertion, consistent proximity to modiolus, and then also the ability to insert via all three surgical approaches. And hopefully we've shown some of the data to suggest that we have been successful on this. And Amy's gonna continue to show a couple of more data sets from our multicenter study that demonstrate this, as well. But when we began this question of, does placement matter and does that drive performance, it really boils down to that scala tympani placement as well as that proximity.

And so from our data set, it does appear that the consistency in placement with the Slim Modiolar will drive to overall improve performance. So I mention that there's been a plethora of new studies that have come out and I've highlighted a couple of those recent ones within your handout. So certainly take a look if you haven't already. I'm giving you the links to obtain those from PubMed. But just to kind of highlight a few of those studies that have come out on Slim Modiolar and then obviously we're waiting the release of our multicenter study information, as well, which Amy will talk to. But some of the recent studies have been, one such one was coming out of the University of Vanderbilt, looking at a matched cohort and showing a superiority of pre-curved arrays. And that's with the Slim Modiolar. Then we look at the Shaw paper out of the University of Melbourne that looked at the importance of scala localization as well as how perimodiolar electrodes drive improved speech outcomes and the differences between Contour and Slim Modiolar, which I had shown you in the previous slides. And then also from NYU, they have a large data set from their early experience with Slim Modiolar. 200 plus patients that were implanted with that and then varying followups looking at that. So it's a really great publication there. And then some work being done out of Germany looking at some of the early findings from a European Slim Modiolar study and looking at just a wide range of both performance, audiological and then quality of life measures with that Slim Modiolar array. So we're continuing to see more and more data come out and obviously that's something that's exciting to us when we first launched the product, we had lots of different temporal bone and we had lots of historical perimodiolar data and we're continuing to see more and more specific to Slim Modiolar and showing how that's maximizing that performance. And Amy's gonna touch more on that, as well as some of the considerations from an audiology perspective. So with that, I will hand it over to Amy to kind of go over both those audiological considerations and then dig deeper into our large multicenter study focusing on that performance as well as those bimodal benefits.

- [Amy] Thank you, Wade. And with the review of the electrodesign completed as we'd mentioned, will now explore some of the audiologic consideration with the Slim Modiolar array. And so when we discussed perimodiolar arrays, we tend to see three areas really consistently demonstrate the benefit of this design. The first is that with the perimodiolar array, there is that focused stimulation that reduces the likelihood of channel interaction. And this is especially beneficial when it's paired in conjunction with our 22 unique electrode contact points. Because that combination allows for greater spectral resolution and the control of that spectral resolution. And due to the close proximity of the perimodiolar array to the modiolus, we also see lower and more stable impedances, which lead to lower T and C levels. And again, the pairing of those two factors often lead to better battery life as well as the ease of programming because you're staying within the compliance limits of the system and not having to make additional changes to the settings of the map parameters that you're using. As Wade mentioned, there have been a number of recent studies that have looked at the benefits of the Slim Modiolar array and he mentioned one of the Vanderbilt studies and how that suggests that, with a well placed perimodiolar electrode, there may be some additional programming method that can enhance the performance of the system. And that data will be presented in depth as part of a separate webinar. But something that, if you're interested in, you should stay tuned to hopefully gather that additional information. When we're discussing impedances and the status of a specific electrocontact, it's really important to remember how impedance is measured. So this graph really illustrates that the impedances are measured by RF first that are being sent from the processor to the implant. And the implant then returns coded information to the programming system about the voltage developed on the electrode during the simulation. And these voltages are measured at the four points over time indicated in this image. And those four pairs or impulses are encoded and the other information that comes into play is the time interval that occurs between each pair being proportional to that measured voltage. What we know is that the voltage reaches the neural elements and spiral ganglion cells. But body tissue and changes in the purulent fluid impedes the passage of that charge between electrodes. And that information about the resistance is read back through the telemetry function. And as you may have remember, when an electrode array is implanted, the body reacts by forming a layer of proteins on the surface of the electrode and the formation of a fibrous sheet around the electrodes within the cochlea.

And this is what causes the impedances at activation or after extended period of non-use to be much higher than impedances measured at subsequent visits after consistent device use. And a key implication of an increase in electrode impedance is a subsequent increase in power requirement to generate higher electrical stimulation that excite those neural elements of the cochlea. So ideally, we want a low impedance environment in the implanted cochlea. But we also know, from a historical perspective will all devices is that given the body's response to implantation and the various biological changes that may occur with age, growth, lifestyle, changes of electrode impedances are expected. And that's why it's important to consider different factors when interpreting electrode impedance information. As you can see from this list, there is a number of reasons that we know impedances change. Probably the most common are the hormonal changes that have been observed clinically for many, many years, changes that occur either immediately prior to or following vertigo attacks or episodes of dizziness as well as infections at any point in the body. And so while we recognize that the impedances giving quite a bit of information on electrode function, it's also providing insight into other physiologic changes that may be occurring systemically within that recipient's body. The key factors that we've observed that relate to changes in impedance levels are broken down into these four categories. On the environment in which the electrode is and making sure that there is good fluid content and not in a fibrous or ossified environment which would result in much higher impedances. Certainly the medical or pharmaceutical and hormonal changes that can occur as well as turning off electrodes or using CIS-type programming strategy when mapping can also affect the impedances due to the conditioning of the electrode so you may see changes in that as specific channels are turned on and off. And then the time of day that the measurements taken depending on the wear time that the individual has had prior to that.

So, many times when I was working in the clinic in New York City, parents would put their kids in the car very early in the morning to bring them into their appointments and they not put their processor on until they walked into the clinic. And so by not properly have that conditioning of the electrode, those early morning appointments sometimes would have higher impedances than we would see if that child had been seen later in the day. So how does this impact the way that we program and why are we talking about it now? And really it has to do with those differences in lateral wall versus perimodiolar electrode arrays and how they interact with the cochlea and the other systems that are involved in measuring impedances. One of the other factors is that with lateral wall electrodes, we tend to have smaller electrode contacts, which can also result in higher impedances. And so when you pair that with the fact that those electrodes are also further from the modiolus and have a lot more interaction with the fluid within the cochlea and the other biological changes. The combination of those two tend to lead to higher impedances or lateral wall electrodes than what we're seeing with perimodiolar arrays. And when we look at the studies that have been done comparing the impedance values of the Slim Modiolar array to the Slim Straight array, the average impedances for the Slim Modiolar were significantly lower than the Slim Straight. And the specific information is shown here in these graphs. But certainly goes along with what we've seen from a clinical application perspective of programming the devices. That's also why you'll see, within the systems, because those lateral wall arrays tended to have higher impedances and would require more current to elicit the same amount of charge. There are differences in the pulse width that is being utilized when programming the systems. And the goal of programming is really to keep those current levels and stimulation below the compliance limit that's been calculated for a given individual. And another way of thinking about this sort of taking it out of the realm of electrical stimulation, is we're trying to maintain the amount of charge that we're presenting, but having it dispersed across a different amount of space.

So it's very much the same as if you think about two structures that are both 2700 square feet, but one's a townhouse and one's a ranch. So the narrower pulse width would be more analogous to the townhouse and the wider pulse width would be the ranch. Where we're still providing the same amount of current, we're just allocating it a little bit differently within the system. What makes it even easier is that custom sound software keeps track of that for you so that for the perimodiolar arrays, which are shown at the top of the screen, the default pulse width when you're creating a new map will be 25 microseconds, whereas the lateral wall arrays shown at the bottom of the screen have the default pulse width of 37 microseconds. Similarly as we looked at the threshold and comfort levels with the Slim Modiolar array, we're also seeing consistently lower T and C levels when compared to other devices, which again leads to that improved battery life and better power consumption for day-to-day use. I'm now gonna take just a few minutes to share with you the outcomes of the US multicenter study for the Slim Modiolar array. This was a very comprehensive study that was completed with the participation of 13 sites, 26 surgeons, and 37 audiologists. And collaboratively, all of those professionals enabled 100 subjects to utilize the Slim Modiolar array and complete this study which is one of the largest multicenter studies that's been conducted in quite some time. Before we showcase the results, it's always important to take a look at the demographics and what you will notice here is that these are still very traditional cochlear implant patients with a pure tone average at 500, 1000, and 2000 Hertz of 85 dB. The duration of hearing loss continues to be quite substantial of 27.1 years. This was a slightly different gender mix than previous studies where we had 65 percent of the participants as male, just as it happened. And also, interestingly enough, both the pre-implant CNC word scores and AzBio scores were 15 percent on average. As Wade mentioned, one of the key components of perimodiolar array is really confirming what that electrode position is. And what you're seeing here is a report from the 3D reconstruction that was a component of the Slim Modiolar study. And it really assesses what that electrode position is within the cochlea, what the location is, and which scala, and also for calculating the wrap factor that Wade also discussed.

And so what we can see on this one, is we have a wrap factor of 49.7 percent and in this section here in the center, all of the electrodes are located within the scala tympani. And that consistent placement was a key outcome and proof of the design goal of the Slim Modiolar electrode, where within this study, with 26 different surgeons, we had 89 percent of the electrodes that remained within scala tympani. And just as a reference, historically those levels with other perimodiolar arrays have been between 27 and 53 percent. So this is a significant improvement in that regard. That consistent wrap factor in addition to the consistent position really comes into the analysis of the performance of these study subjects and one of the contributing factors to that improved performance. And so again, when we looked at those 3D reconstructions, the wrapping factor is calculated by taking the length of the electrode insertion and dividing that by the lateral wall length. So lateral wall electrodes tend to have higher wrapping factors, usually in the 80 percent range and perimodiolar arrays that are well placed tend to be much more in the 60 percent range. And this study fell right within that well placed range of having an average wrap factor of 59.6 percent, which gave us the opportunity to demonstrate that these electrodes work closer to the modiolus than we have previously seen before. From a speech perception perspective, we also saw significant improvements with the study subjects where there was four times improvement in understanding of CNC words when compared to the hearing aid only score pre-implants. And one of the other observations that occurred with this study was that at the three month test interval over 50 percent of the subjects were performing over 60 percent on the CNC words. And it was quite astonishing when we compared that to previous studies that had been run with very similar demographics. And, looking at how quickly they reached that same level, that 60 percent word understanding. And while we recognize that some of the patients in the Slim Modiolar study did start with more residual hearing, what we also found was that there was not always a one-to-one connection between how much residual hearing they had and where they ended up.

And so we're certainly seeing some better performance faster with the Slim Modiolar array. And looking at it from an overall perspective at both the three month and the six month test intervals, you can see how the Slim Modiolar array in gold compared to our Contour Advance and Freedom Systems that are shown in the dark and light gray. Certainly testing a noise is also something that we wanted to look at and what we can see is that that performance more than doubled comparing that pre-implant AzBio end noise with the cochlear implants alone. And additional improvements were also noted from a bimodal perspective and so part of this study included all of the subjects being fit with a ReSound hearing aid and maintaining that bimodal system and bimodal testing throughout the evaluation period. And what we looked at from an outcome perspective with the hearing aid was first confirming that their pre-implant hearing aids were all fit to target and optimally programmed. And then looking at the changes in speech perception using just the ear that was implanted versus bilateral. And assessing what their satisfaction rate was with their hearing aid or, in this case, dissatisfaction, where 91 percent of them were very dissatisfied or dissatisfied with bilateral hearing aid performance. When we look at the improvements from a bilateral hearing aid versus a bimodal system, again, we see significant improvements for these study subjects where the, in both CNC words and AzBio sentences in quiet and, sorry, AzBio sentences in noise. And then we also included some patient reported information and questionnaires. So with, on an SSQ, there was also significant improvements in their perception of benefit in a bimodal condition than in a bilateral condition across all of the subscales of the SSQ.

And finally, we used a quality of life measure in a health utility index to rate their general health status. And you can see the different classifications as they look at a range of health domains. The green is pre-op and the yellow is changes post-op at six months following implantation. I think it doesn't come as any big surprise that the most significant increase was in the speech and hearing domain. And it was enough of a significant increase that it actually changed the total HUI outcome and it was an increase of .19. And since a lot of these health utility indexes and quality of life measure aren't something we typically use in audiology, we went to compare what that .19 improvement correlated to or what some other aspects might be and that is along the same lines as a hip replacement. Actually, more of an improvement than cataracts and in line with some previous studies that also looked at cochlear implants and quality of life changes. It certainly helps to have a lot of the conversations with the candidates and recipients who were part of this study to not only have this speech perception measures to give them some of that information, but also really looking at that satisfaction information, we look at the pre-implant satisfaction. There's not one area that has a satisfaction score greater than 13 percent. And when we go to the bimodal satisfaction post-implant, again, we see a very dramatic improvement of that satisfaction, with all of them being above 50 percent and the total hearing performance and satisfaction rate being closer to 95 percent. So we hope that this information that we have provided you has helped identify the pieces of and benefits of the Slim Modiolar array and demonstrated how the placement of the implant can certainly impact performance as well as some of the tips on how we've been programming the devices. And we hope to continue to provide even more information as we learn more and gather more details. And we have a few minutes if there's any questions, we're happy to tape some of those. I saw a raised hand. Do you want to try and talk? I think I enabled your microphone. Or if you want to type it into the question box. So there's the question box in the lower left-hand corner. The question was wanting to know what the Slim Modiolar array was. And so that Slim Modiolar array is either the CI532 or the CI632. All right, well it does not look like we have any other questions. So we thank you for your time and appreciate your attendance.