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Anatomy Based CI Fitting:
Matching the Natural Ear Like Never Before
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- Hi and welcome and I'm so glad to be able to share with you today some new information from MED-EL about anatomy-based fitting, a new feature that we're launching right now for our cochlear implant system and our MAESTRO fitting software. So just to share a little bit with you today about what we'll be covering. After this course, we want you to be able to explain the premise of anatomy-based fitting and also be able to implement it easily in MED-EL's fitting software. So I'll begin by introducing anatomy-based fitting and its companion, OTOPLAN. Katelyn Glassman will follow, she'll cover reducing spectral mismatch through anatomy-based fitting. And Josh Stohl will also then be sharing with you some detailed information about how anatomy-based fitting aligns with the natural function of the auditory system.

And we'll close with Barbara Foster, sharing with you how to apply anatomy-based fitting in our MAESTRO software. So over MED-EL's history, our goal has always been to achieve closer and closer to natural sound quality and hearing with a cochlear implant. And we've come such a long way over many years. And in the very beginning, back in the mid-nineties when we first came on the scene, we introduced our cochlear implant system with a 31 millimeter electrode. That was our first electrode that we developed and we developed that electrode based on the presumption or the assumption that the average cochlea is 32 millimeters in length. And so we felt from the very beginning that it was very important to cover as much of the cochlea as we reasonably could with an electrode array in order to get natural sound quality.

We also early on introduced a three to one compression ratio and roving AGC. And the idea was to match as closely as possible compression ratios, both in hearing aids and in the natural auditory system. A roving AGC allows the system to manage loudness without the patient having to make constant volume adjustments throughout the day and provide still a wide dynamic range of over 75 db. We also then introduced time domain filter banks, which allow us to cover up to 250 different spectral shapes. And so depending on the resolution of the patient's auditory system, they may be able to

hear many, many pitches delivered with just 12 electrodes. And that's some incredible magic that happens. We also introduced our fine structure coding strategies starting with FSP, fine structure processing, and then later with FS4 and FS4-P as coding strategies.

These are the only coding strategies available that provide a deliberate cue for fine structure. So rather than the traditional CIS concept, some of the electrodes in the apical region are providing time-based stimulation that is intended to trigger phase locking just as it is in the normal cochlea in the apical region. We also introduced bimodal hearing aid synchronization recently that allows us to match the timing of our system to a contralateral hearing aids onset timing. And we also then are bringing out now, anatomy-based fitting with OTOPLAN. And during all of this time, we've been expanding indications as well into populations, like the patients that are using electric acoustic stimulation where they have some reasonably good low frequency hearing that can still be used acoustically in combination with their cochlear implant and even patients with single-sided deafness.

And these patients have been really instrumental to taking us forward in this technology because they have a normal hearing ear and they can truly tell us what their cochlear implant sounds like. And this has been extremely useful in learning how to better match natural sound quality. So anatomy-based fitting is a unique approach to cochlear implant frequency mapping, and the idea is to align the frequency filters in the fitting map to the natural tonotopic place-frequency mapping of the cochlear based on where that person's individual electrode actually sits and where the contacts are located. So the idea is to identify first where each contact is, and we do that with imaging preoperatively or postoperatively, once the electrode is in place, of course.

And then we use that information to create a place-specific map with individualized center frequencies for each contact that's a closer match to the natural frequency

place. So let me tell you first a little bit about OTOPLAN, and we won't spend too much time on that today. It's a surgical planning software and it uses standard imaging. We import a CT scan or an MRI preoperatively and get detailed three-dimensional anatomy that allows us or a surgeon to measure the parameters of the cochlear in all three dimensions. Preoperatively, we can then visualize how each particular MED-EL electrode would fit in that cochlear. Based on OTOPLAN, choose appropriate electrode for each cochlear. Postoperatively, then we can look at where those contacts actually sit and make frequency-based decisions for anatomy-based fitting.

So all of you hopefully know that MED-EL makes a variety of different electrode lengths. We have a 31 millimeter electrode all the way down to a 20 millimeter electrode and even shorter if needed. And historically, we've always focused on the average cochlea being 32 millimeters and then if the cochlear is shorter than that, having an appropriate electrode to fit that cochlear. And one of the most fascinating things to me about anatomy-based fitting is now being able to really see how many cochlear are actually longer than 32 millimeters and many are. So a 31 millimeter electrode in some cases won't cover the entire cochlear if the patient has a very long cochlear duct. And so that's one of the things that I think makes anatomy-based fitting so exciting is that we can really now match the electrode to the cochlear and then match the pitches to where the electrode sits in the cochlear.

So OTOPLAN, this is a screenshot from the OTOPLAN software and it allows the surgeon to overlay different electrodes preoperatively on the patient's audiogram and which can be entered and then choose which electrode is the best fit for the cochlear. And the foundation of this information is based on extremely detailed anatomical data that's collected using the synchrotron-based contrast imaging approach. And this is a work of a variety of different organizations. There's no way that this incredible amount of data could have come together without all of the individual organizations that have been a part of this process. But this detailed information then allows us to tie together

the previous frequency place algorithms that are out there based on mathematical modeling, using individual real life data from each individual patient so we can determine exactly where each contact lies and what's the frequency tuning of the nearest nerve fibers.

So to give you some examples, here's an x-ray of a cochlear with a really nice insertion, a fairly deep insertion, and this is what we would call adequate cochlear coverage. In this particular picture, it's about 630 degrees, and that's a really great situation for anatomy-based fitting because it will adjust the frequency bands according to that natural tone of tonotopicity. And you can see the gray frequency bands here are the defaults and the rainbow-colored frequency bands are those that are chosen by anatomy-based fitting. Based on where the green dots are, you can see exactly where the electrodes sit in the cochlear. So in a really deep insertion and ideal situation, anatomy-based fitting can almost aim the frequencies towards exactly where those same tuned nerve fibers sit in the cochlear.

Now as the electrode insertion depth is shallower and shallower, then it becomes a different picture. So here we've got rather limited cochlear coverage. This is about a 540 degree insertion. An anatomy-based fitting is still possible, but it's going to require some deviation from the natural tonotopicity on the apical contacts in order not to compromise spectral resolution. In other words, the contacts aren't in that deep, and so we have to make some adjustments to make that work. Here we have a situation where there's quite limited cochlear coverage. We have about a 450 degree insertion and anatomy-based fitting is still possible here, but it's going to require some compression of low frequencies onto the apical contacts. And that will give us some reduced spectral resolution.

We'll still use all the channels and provide all the frequency range, but the system will have to make some compromises because there are not electrodes in that cochlea far

enough into the apical region to really match those to tonotopic nerve fibers. And then when we get into even shallower insertions, very short arrays are just simply too short. Anatomy-based fitting just can't overcome a very shallow insertion in a normal length of cochlear, even in a very long length of cochlear. There's just not enough natural frequencies covered by the electrode array. So to give you some idea of where we're going before we get into the details of the concept and the engineering of it, I wanna give you some idea about the use cases we anticipate.

Our results to date have indicated excellent acceptance by recipients as long as the insertion depth or insertion angle is deep enough as you've just seen, and while it can be used with any recipient, it can work with any MED-EL implant. The most promising use cases are those we think where the cochlear implant needs to be matched in some way to whatever's happening on the other side if there is any remaining hearing on the other side. So that could mean, for example, a bilateral cochlear implant recipient. You see an example here where we have a bilateral recipient that has different electrode array links on either ear. I think that can happen. And anatomy-based fitting allows us to align the frequencies between those two electrodes and that we hope will help preserve really important cues, not only for speech understanding, but also for things like localization and binaural fusion.

It's also important to recognize, and I think OTOPLAN is helping us to learn this for the first time really clearly, that there are actually quite frequently differences between the two cochleas on either side in one patient, the same way that you might have slightly different shoe sizes or my eyeglass prescription is different between my two eyes. Cochleas are different sizes even within the same person. And so allowing to accommodate for that is also one of the exciting things about anatomy-based fitting. Then the next example I've got here is SSD or bimodal patients, patients who have acoustic hearing on the other side. So here in this example, you could imagine that this patient has a very long cochlear duct length and maybe they have the most longest

electrode that's available, a 31 millimeter electrode, but let's say their cochlear duct length is 38 millimeters.

And so this will allow us to then align the cochlear implant stimulation and the frequencies that it's stimulating and where to the naturally hearing side. And that's really exciting for those users that have residual hearing. And even in a situation like EAS where we're using both electrical and acoustic stimulation in the same cochlea, this will now allow us to know really where each electrode sits and be able to better match between the acoustic region and the electric region. So anatomy-based fitting I think, is one of the most exciting things that's come along in cochlear implants in quite a long time and really excited to begin to bring it out in the United States and allow all of you to start using it. And with that, I'm gonna turn it over to Katelyn Glassman to share more information with you.

- Thank you, Darla. I think as we talk about anatomy-based fitting, one of the things that's most important is to really get into the understanding of why this is important for our patients. And so I'm gonna talk a little bit today about how we are reducing spectral mismatch through imaging using OTOPLAN software and how we're using that software to both select electrode arrays for our patients as well as to do anatomy-based fitting and MAESTRO. So what is spectral mismatch? Cochlear implants by default, when we take an array and we place it in a patient's cochlear are going to create a difference in the frequency information that's being transmitted electrically by each contact of the electrode array and the natural frequency information that's located adjacent to each of those contacts in the cochlea.

And so that difference between the information that we're transmitting electrically in terms of frequency and the natural frequency information being provided tonotopically in the cochlear is known as spectral mismatch. We know that that amount of spectral mismatch can be influenced by how deep a cochlear implant array is inserted into the

cochlear. And so in order to match that tonotopic map across the entirety of the cochlear, we need long electrode arrays that are able to more closely align with that frequency information or that natural place pitch. And so here you can see a picture of a cochlear. This is a cochlear that has two and a half turns, which is typically what we see as an average.

And you can see our MED-EL FLEXSOFT array as well as our MED-EL FLEX28 array and how they are able to extend well into that second basal turn. There's also two competitor arrays here that are only extending about a couple of degrees past that one full turn into the cochlear. So really only extending into that first basal turn. In gray, you can see what the natural frequency response at the adjacent location to where that electrode array is sitting on the average is. So these are spiral ganglion frequencies associated with the most apical contact or the deepest contact of each array. And so for our FLEXSOFT array, that frequency is around 185 hertz. For our FLEX28, because that array is a bit smaller, on average that's gonna be around 300 hertz.

And then for both of those competitor arrays, that natural frequency information adjacent to the cochlear implant array is sitting between 600 hertz and 650 hertz. So there's wide variability dependent on the length of the electrode array in terms of what natural frequency information is being stimulated by each contact. So is that a problem for patients? Traditionally, we've looked at this in normal hearing listeners listening to artificial stimulations of cochlear implants, and those are known as vocoders. And the reason that we've done that and used normal hearing listeners is that that allows us to control that degree or that level of spectral mismatch across a large group of users. And so these studies have found that when there is a large frequency shift imposed within one ear of greater than three millimeters, that can negatively impact speech understanding both in quiet and noise.

They've also looked into what if we impact the frequency information in one ear and we shift that information and have it in combination with another ear that hasn't been shifted. And when we do that, we see that we also see impacts on a patient's spatial hearing or ability to separate speech and noise in listening environments as well as sound localization. But we know that these vocoder studies are limited. Recently, there's been studies in single-sided deafness users that suggest that these vocoder models, while they're similar to cochlear implants, may not have the same sound quality that patients are perceiving. And these vocoder studies typically don't consider the impact of cochlear size on that degree of spectral mismatch that's being applied.

I think most importantly, these results are being obtained acutely, meaning that normal hearing listeners are going into a research lab, they're listening to these shifted simulations, and that shifted pitch for maybe 5 to 30 minutes and then they're being tested and they're leaving. But we know that's not what patients are typically going through after initial stimulation. They have months to listen to these spectral mismatches and try to adapt to their cochlear implant. So how have we approached spectral mismatch up to this point as clinicians? Historically, we haven't. We have given patients cochlear implants and provided frequency information that is mismatched from that natural frequency information, and we've asked them to adapt to that sound over time. And so this is the reason that many patients at initial stimulation come in and we turn them on and they say, hey, this sounds really cartoonish or very high pitched.

And over time we expect that sound to become natural and patients come in and say, this is sounding more natural to me. But more recently, we've had evidence suggesting that while previously we thought that that pitch was shifting lower, that the brain's ability to adapt may be limited when there's a very large spectral mismatch present for a patient. And more importantly, these pitch up shifts or that cartoonish sound quality that patients are perceiving, particularly our patients that are implanted with shallower

electrode arrays may be persistent for years after the patient receives the device. And so there's been several studies conducted looking at single-sided deafness users of cochlear implants to look at their perception of sound.

And we're finding that many of these patients, despite normal speech scores, are selecting matches to their cochlear implant that are much higher in pitch and that they're reporting these sounds as sounding natural, but we actually believe that something is happening cortically that's making those sounds go from unfamiliar to familiar and they're not actually perceiving a change in their pitch perception. So when we look back at some of those older studies that show that pitch changes over time that we've relied on, this is an example of cochlear users and the center frequency at their most apical channel or the deepest inserted contact is at 250 hertz. So we can see that two of those patients, one with about eight months experience and one with about four years of experience, have adapted to the pitch information that's being provided by their device.

But there's a large group of patients with anywhere from about eight months to two and a half years experience that are still perceiving sound as being much higher in pitch than what we're providing through their cochlear implant processor. So we know that cochlear implants by design create a spectral mismatch for users. We know that MED-EL long electro arrays on average are reducing the amount of spectral mismatch for patients, particularly when we look at those low frequencies. And so you can see on this figure here on the right, we're looking at frequency by that insertion angle or that depth of the electrode array in the cochlea with that natural hearing response in green. And those two longer MED-EL arrays shown in red are showing a much closer match to that natural frequency information.

We also know that large levels of spectral mismatch may have a long term impact on patient's sound quality as well as the potential to impact their patient performance.

And so we really think this is important when we think about patient's ability to use their devices on an everyday basis. But up to this point, the majority of data has looked at averages and they've looked at a group of users and one particular electrode array, and they haven't looked at this on an individual basis because we needed imaging data. And we know that that level of spectrum mismatch is going to be highly dependent on the patient's cochlear size, their electrode array length, the frequency allocations that we're assigning to each channel as well as their hearing configuration.

And so if you look, these are three different MED-EL electrode variance, and there's high variability in how deep we can get those electrode arrays based on the patient's individual anatomy. And so we've thought a lot as a company about how can we further improve individualization and reduce spectral mismatch for our users. So there's two different ways that we can reduce spectral mismatch. The first is preoperatively by choosing an electrode array that more closely matches the natural frequency characteristics of the cochlear. And so here on this Y-axis, you have an angle in degrees. So we're thinking about how deep is that electrode inserted in the cochlear going from zero degrees or at the level of the round window up to about 900 degrees at the level of the apex.

In green, we have that natural frequency response of the cochlear, and we can take an electrode. And so this is a electrode that's inserted to about 460 degrees, but we see a large mismatch between where that red line is sitting representing the electrode and that green line representing that natural frequency response of the cochlear. But what if we take that electrode and we insert it deeper into the cochlear? Now we see a much better match between that natural frequency information and the information we're transmitting electrically. So in order for us to achieve a closer match through an array selection, we need to know several aspects about our patient. We need to know their cochlear duct length as well as the estimated angular insertion depth of array options.

And that's gonna allow us to choose the electrode array that is most ideal for the patient's anatomy. So cochlear duct length is the size of the cochlear, it's the measurement of the basilar membrane from the level of the round window to the helicotrema, and that may encompass the hook region that goes around the round window as well. And so with recent imaging, if we have very high quality images, we can measure that CDL or that cochlear duct length directly, but we can also use lower quality images, CTs or MRIs to estimate that CDL through formulas. And so that's what we're doing in OTOPLAN software. We also need the angular insertion depth. So for patients that have already been implanted, this is where the patient's electrode array is sitting within the cochlear.

We can also estimate the angular insertion depth if we have a patient's CDL by looking at different electrode array variants again to determine the most appropriate array. And so angular insertion depth is typically reported as the location where the most apical contact of the cochlear implant is located within the turns of the cochlear. And so that's gonna be that deepest contact. And having that measurement allows us to make comparisons across different cochlear implant users. And so when we're talking about angular insertion depth, we're really talking about that 360 degrees, 450 or 720s, with 360 being one full turn in the cochlear and 720 being two full turns. So how are we getting this information? We're able to get this information through OTOPLAN.

And so when you do preoperative imaging through OTOPLAN, we're able to calculate a patient's CDL based on their own anatomy, and then we're able to look at different electrode array variants to evaluate what is the best array and which array provides the desired angular insertion depth for that patient. So this is what that looks like within the OTOPLAN software. And so this is a patient where we've already done some analysis on the patient's cochlear. And so you can see that we've defined the diameter, the width, and the height of the patient's cochlear, and that provides us the CDL measurement. And then we're also able to add the patient's audiogram information

within the software. This is particularly important for our patients with residual hearing, so we can look at that relationship of the electrode array selection and the patient's residual hearing.

And then we're able to visualize different electrode array variants based on the patient's individual anatomy as well as any audiogram information that's been entered. So Darla spoke earlier about how previously we've known that that CDL link sits around 31 or 32 millimeters. So how variable is CDL across most patients? We've actually learned based on more advanced imaging in the past few years that that CDL may actually be on average a bit longer, and that variability can range anywhere from about 28 millimeters to 40.3 millimeters with that average CDL now sitting around 34 millimeters. So we can look at patients with different size cochlear duct lengths going from a short CDL around 30 millimeters, up to a long CDL around 40.2 millimeters. And we can see where different electrode array variants sit within each of those cochlea.

And so I think it's really fascinating to look at where do our arrays sit, looking at that FLEX24 and seeing how far that patient with a short CDL that we're able to extend down to a frequency of around 260 hertz. But for a patient with a very long CDL that we're only reaching down to about 950 hertz, similarly, if we look at the FLEXSOFT array for that patient with a long CDL, it's only extending down to about 330 hertz, but that's the longest array on the market, and that's gonna provide the most cochlear coverage for that patient. And so really thinking about how anatomy influences the frequency information that our patients are hearing. There also has recently been studies looking into is there a limit in how much cochlear coverage is needed to provide an optimal benefit to patients?

And so a recent study looked at CNC performance at six months post activation, and then they compared that to the apical angular insertion depth, and they found that there was an increasing benefit for patients that had electrodes deeply inserted up to

about 600 degrees. And so we see increases in CNC scores as we approach that 600 degree point. And past that point, we see that those scores are stable. And so the author suggested that the optimal electrode array is going to be the one that at least reaches that 600 degree region of the cochlear. And so it's able to provide as much benefit as possible by providing that close match to the frequency information that's provided naturally. And if we look back at that short CDL, that average CDL and that long CDL, and we look at our FLEX28 ray, which is our most commonly implanted electrode array, we can see that that electrode array is extending in our average CDL to around 600 degrees.

And so really those long electrode arrays are providing that information that we need for optimal speech performance. The second way that we can reduce spectral mismatch for our patients is by relocating frequency. So this time, instead of looking at the insertion depth of the electrode, we're now looking at frequency going from low to high. Again, you have that natural frequency response of the cochlea in green, and we have that same electrode array extending up to about 460 degrees, but this time that array's already been implanted for that patient. And so we can't take that array and put it in further into the cochlea, but what we can do is reallocate the frequency information of that patient's processor through anatomy-based fitting.

And so what we're doing is we're taking that information and we're shifting the frequency content provided through the processor closer to that natural frequency response of the cochlea. But it's important to know that only long MED-EL electrode arrays are able to extend into the second basal turn allowing for more accurate low frequency information. And so we can look at our FLEXSOFT array here in red and one of the competitors arrays here in yellow. And when we look at the center frequency provided by the most apical or the deepest contact in the cochlea, the MED-EL array sits at 120 hertz and the other array at 250 hertz. So what if we took that shallower

insertion and we shifted the frequency information to provide more low frequency content?

We'll look at the relationship between what frequency information that array is providing and the natural frequency response of the cochlea. We've actually created more distortion and frequency information and a greater level of spectral mismatch. Alternatively, we could strictly match that natural frequency information through the frequency settings of the implant by taking that and shifting it closer to that natural frequency response. But in doing so, we have to cut out some of that low frequency information because extending that further down is creating more distortion. And so there's going to be a choice that has to be made. If you have a shallowly inserted array, you're either going to have to sacrifice that low frequency information or you're going to have to apply a lot of distortion in order to have a close match.

So in OTOPLAN, how do we access the information that we need to do anatomy-based fitting? We're able to automatically locate the contacts within the cochlea. And so I have another video for you. And so once we have already analyzed a patient's cochlear duct length, postoperatively using a CT scan, we can automatically detect where each of the contacts are within a patient's cochlear. And so this is happening in real time in the video. And once we have that information, we're now going to have angular insertion depths for each of the patient's electrode contacts. And we also have the ability to make manual adjustments if we want to. If you have done 3D modeling within software, you also are able to visualize exactly where a patient's electrode array is sitting within their cochlea, which can be great for talking with colleagues as well as counseling patients.

So what is OTOPLAN giving us? It's giving us frequency estimates and angular insertion information for each contact of the implanted array. And that's gonna be available both in the OTOPLAN patient report, as well as in an XML file. And that XML

file is what we're going to be able to import into MAESTRO to allow for anatomy-based fitting. And Barb will talk to you in a bit about our service, OTOPLAN On Demand, which we're really excited about, but this same information is going to be available to you through that service. So I'm gonna hand things over to Josh Stohl, who's going to be talking more about how anatomy-based fitting is actually being applied in our software.

- Great, great. Thank you, Katelyn. So as Katelyn mentioned, I'm gonna describe the anatomy-based fitting concept and its incorporation into our MAESTRO software. And first, I'll start at a very high level, which is to say that as we all know, cochlear implants are designed to restore the sensation of sound. This is amazing, but it also means that we're tasked with setting the minimum and maximum levels of stimulation. And in the MED-EL system, we're also giving you the flexibility to fit in the time domain, fit the timing of the stimulation that's coming from the cochlear implant. And now with anatomy-based fitting, we're giving you the opportunity to fit the place of stimulation or to align the frequency content with the place of stimulation in the individual cochlear.

And if we don't get all three of these dimensions lined up correctly, that's going to produce distortions to the acoustic information that's arriving at the microphone of the device. So what we've really tried to do is design flexible cochlear implant systems that can really be adjusted for every individual irrespective of their listening configuration. So just to review quickly, we'll talk about the three components of sound. What we see on the left is a spectrogram. This is one way to represent sound visually. This is the word being, and this spectrogram represents the three components of sound. The first component is intensity, which corresponds to loudness, and this is what you typically fit in cochlear implant software. Historically, setting the thresholds and maximum comfortable loudness levels which control how loud or intense or this visual representation, how bright the spectrogram is.

We've also recently introduced our hearing aid delay technology that allows you to control the time of arrival or the time that the information is delivered by the cochlear implant, so that it can be aligned with a hearing aid in the contralateral ear, for example, that might have a longer delay than the MED-EL cochlear implant system. And now we're introducing anatomy-based fitting, which allows us to make modifications in the frequency domain, and that might be an expansion or compression of the frequency information or an increase or decrease in where that information is presented. Again, based on the individual anatomy of the patient. And ultimately, all three of these components of sound need to be correctly fit so that the acoustic information is properly represented when we deliver it electrically to our cochlear implant users.

So as I mentioned, intensity is the classic fitting domain or the classic fitting dimension. Hopefully, this is something you're all familiar with. We're typically setting the thresholds and the maximum comfortable loudness levels or the maximum levels of stimulation on each electrode. And so this is really mapping acoustic pressure onto electric charge. As I mentioned, we've recently introduced our bimodal synchronization technology or through our hearing aid delay parameter. In the MAESTRO software, you're able to enter information about the hearing aid used by your bimodal patients and the amount of time that it takes those devices to process sound. And then the MED-EL system, which has a processing delay of about one and a half milliseconds, essentially can wait to start so that it's delivering sound essentially to the brain stems so that we provide good binaural cues at the same time as the hearing aid on the contralateral side.

Without any hearing aid delay applied, what we would see is an earlier time of arrival on the cochlear implant side in the right ear in this example. And that gives the impression that the sound is coming from the right side of the listener because it's arriving earlier to the brainstem, again, where the brain is comparing the inputs from the two ears. If we apply the patient specific hearing aid delay, then we have the arrival of

those sounds at the brainstem at the same time and the image is centered. Now we're introducing anatomy-based fitting, and that allows us to make modifications to the mapping of frequency information onto specific places in the cochlea. So we've already seen that even with one electrode array, and we have three examples here from our shorter FLEX24 to our 31 millimeter FLEXSOFT and standard arrays, even within one of these category of arrays, we see a wide variability of the apical insertion depth shown on the vertical axis.

And again, that's because we now understand that the variation in the cochlear duct length of patients plays a large role in where the electrodes ultimately are placed after surgery. The implication, if we look at the individual data points here on the horizontal axis, the implication of this variability in electrode array replacement is a mismatch between the default frequency allocation and the position of the electrodes. And so what we see here on the horizontal axis is that mismatch between the default frequency allocation given to all of these patients and the position of the electrodes based on images. And so 12 semitone mismatch would be about an octave mismatch, and ideally we would have zero mismatch so that the frequency information corresponds to the place of that electrode.

And what we see is as we reduce that mismatch, we see an increase in the CNC word score when the patients are listening monaurally at the six month mark. So we wanna align the filter frequencies to the place of stimulation monaurally because it's going to provide the best opportunity for good reception of this speech information. It's also important to align this information for the binaural system. Again, we need to get not only the time and the intensity correct, but we also need to deliver those cues to the correct places in the cochlear. The binaural system compares the two ears based on place of stimulation, and so we need to align the place of frequency content between the two ears so that the listener is able to accurately localize sound and has good fusion of those two inputs.

As you've already heard about, the first step to getting a good place frequency match is to select the correct electrode array at the time of surgery. And so you'll hear more about how we as an organization, are supporting you all in terms of providing this information to you based on a preoperative CT scan or an MRI so that you can get some estimate of the individual cochlear duct length per ear and make comparison of electrode arrays prior to selection to really ensure that we have the longest array possible for the given cochlear. And that's the first step in getting a good place frequency match. Once the electrodes are placed, as Katelyn showed us, we can get estimates of where the electrodes are within the cochlear, and that is the angular insertion depth of the AID of each electrode.

And that allows us to then incorporate that information into fitting postoperatively. This is an example of the kind of report you would get back from MED-EL if you've provided imaging data or that you could get from the OTOPLAN software if you do the analysis yourself. And you can see we get electrode numbers here, the angular insertion depth, and some different frequency estimates. As part of the service that Barb will describe later, MED-EL will provide this report as well as an XML file that can be imported directly into our MAESTRO software. It's very straightforward when you're editing the patient, you have the opportunity to import anatomy data. That's that XML file that we'll provide, and that gets directly imported into the clinical software.

And I'll show you in just a minute what that looks like. But first, let me remind you what is anatomy-based fitting and that's what we wanna do is use this anatomical information to fit in the frequency domain. So MED-EL is offering a new frequency allocation option. We have our classic logarithmic FS or logarithmic fine structure frequency allocation shown here in gray. But you can see for this patient who has a deep insertion, we have a little bit of mismatch between the estimated position of those electrodes shown in the green dots and the default frequency allocation shown in the

gray bars. And so what anatomy-based fitting is going to do is allow you to align those filters with the position of the electrodes within the cochlea so that we get a better delivery of the information monaurally as well as binaurally.

So when you import that data, when you import the XML file into MAESTRO with that one click, then you'll get these dots and you'll get a dot for each electrode that's inside of the cochlear. This example is a FLEX28 placed in an average 33.8 millimeter cochlear. The CDL of this cochlear is 33.8 millimeters, and you can see that the frequencies of the electrodes fall nicely within each of the filters. Now, when you import the data, you'll have a couple of options, and that's going to correspond to either an organ of Corti frequency map or a spiral ganglion frequency map. Those frequency maps correspond to two structures in the cochlear, the organ of Corti map, which is the default, because it provides the opportunity for the highest level of individualization corresponds to the basilar membrane, what we see here in green.

We also provide frequency estimates for the spiral ganglion, which are the target neurons that might be stimulated by the cochlear implant. Once you have that information in the fitting software, then the software will automatically align some frequencies, but it's not going to completely modify the fitting. That is to say only the filter spacing changes. We're not going to do any electrode deactivation and we're not going to modify the overall frequency range. Those are decisions that you as the provider will still have the freedom to make just as you always have. So where we are strictly mapping the filter frequencies to the tonotopic frequencies is between 950 hertz and three kilohertz where we know that speech frequencies are most prominent and it's most important to convey proper speech information for good format frequency representation, for example.

So the system will, by default, automatically align the filters to the electrode frequencies between 950 and three kilohertz. Below that, below 950 hertz. The system

will by default maintain a full frequency range and use our logFS spacing or logarithmic find structure spacing to extend that low frequency information down to 70 hertz by default. And above 3,000 hertz, we'll use a strict logarithmic distribution. Here we're really interested in discrimination of those basal electrodes, and rather than deactivate electrodes that might have a small tonotopic mismatch, we want to leave all of those channels available to the listener. We wanna avoid electrode deactivation and leave that to you as a clinician to make that decision. So again, I will revisit some use cases.

The idea here is that once we've aligned the filters to the electrode frequencies, we're moving these patients who have a relatively large frequency to place mismatch toward the zero line or towards a place where they have no frequency to place mismatch. And ideally, this will produce a monaural improvement in CNC scores, an improvement in quality of sound and other standard speech and outcome measures. But anatomy-based fitting also gives us the opportunity to align two inputs. And so you've heard about these use cases from Darla already, but I'll just go through them once more. If we think about bilateral cochlear implant users that might have electrode arrays that are either inserted to two different angular insertion depths or maybe similar insertion depths but are residing in cochlear of two different lengths, we can have a mismatch in the electrode positions and the characteristic frequencies of the ear where that electrode has been inserted.

And so if we apply anatomy-based fitting in both ears, that will align the frequency content between the two ears. Again, the goal being to get complimentary information to the brain stem at the same time from the same place with the same intensity. If we think about our patients who have acoustic input on the contralateral ear to the cochlear implant, our single-sided deaf and bimodal listeners, we have a natural representation of the tonotopic frequencies on the acoustic hearing side. And in the cochlear implant side, we can apply anatomy-based fitting and ensure that those electrodes are giving place appropriate information. In an EAS system, this provides us

the opportunity not just to create a continuous representation of frequency, but also to make sure that the place of stimulation is contiguous as well, that that electrode goes right up to the point where the acoustic hearing begins, but no further.

So in summary, we're always going to need to fit thresholds and maximum comfortable loudness levels. These are still our most critical parameters. Hopefully, you've already been exposed to our hearing aid delayed parameter for use of bimodal patients, and now we have the opportunity to fit in the frequency domain as well so that we can match filters to electrode positions. And again, I really hope that you take the message away from me that what we're trying to do at MED-EL is design flexible cochlear implant systems that can be configured for any hearing configuration. Thank you.

- Thanks, Josh. Now that we've covered the innovations in cochlear implants and how we've gotten to this next exciting step of individualized cochlear implant experience, I'm gonna review the steps in our OTOPLAN On Demand and the easy process of pulling in this information into the MAESTRO fitting software, making it easier than ever to customize the fitting for your patients. Our recently launched OTOPLAN On Demand is a free service we provide to you. Our team of experts will provide precise measurements for each of our electrode variants based on the pre-app imaging we receive from you, either a CT or an MRI scan. We then send precise measurements via a secure platform for how each of our electrode variants fits into that unique person's cochlear duct length.

Then your center will choose the best fit. Let's walk through the five steps in utilizing OTOPLAN On Demand. Step one, the clinic professional visits the OTOPLAN On Demand link they receive from their regional surgical account manager. Step two, the requester receives an email confirmation with a link to a secure file upload location. Next, the requester uploads the DICOM file. That's the CT or MRI image. Our team of experts will provide the OTOPLAN report within two business days of receipt. And

finally, your clinic will then select the best electrode length from our portfolio for that patient's individual cochlear duct length. And as you've already heard today, getting the best match preoperatively is a terrific place to start.

The next step would be to further customize the individual experience by importing a postop CT from OTOPLAN into the MAESTRO fitting software for fine tuning via anatomy-based fitting. So what is required for anatomy-based fitting? Two things. A postop CT scan and an XML file from OTOPLAN. Remember, the OTOPLAN software is not necessary to have if you use our OTOPLAN On Demand service, we will provide you with that XML file you'll need to import into Maestro. Anatomy-based fitting is easy to implement with just a few clicks in the MAESTRO fitting software saving you time. I'll show you a video in the next slide, which covers each of these steps. So first, you'd open up MAESTRO version 9.0.5 or newer.

Then navigate to the patient and select the patient name to open the patient editor. Select the internal implant and then choose import anatomy data. This will allow you to navigate to the location in which you save that XML file. Check to be sure you're importing the correct info. Then click save. Save and close that patient editor. And then you'd start the session. Of course, we'd run telemetry first, and I've already done that. So we're going to select the highlighted plus icon for a new fitting map. You can choose Art Fit or ESRT if you choose to. But to save time on this demo, I'm selecting an empty map. Navigate to the frequency bands tab and select anatomy-based OC, that's the default option.

This will display the OTOPLAN data in relation to the frequency bands as Josh just described. Then simply navigate to the levels tab and proceed with your fitting as usual. So does this anatomy-based fitting remove the need for fitting RCI recipients? No. What we've done is taken the next step forward by using imaging to visualize exactly where that electrode sits after implantation within the patient's cochlear. This

information is then used to individualize that recipient's map based on the precise location of each electrode contact. And that's information you know before you proceed with the fitting as you typically would. For the first time, audiologists are now able to best match the frequency settings to the natural pitch information unique to each patient's ear.

Anatomy-based fitting, as you saw, is really easy to implement with just a few clicks in the MAESTRO fitting software. Another innovation in MED-EL technology to allow our recipients to achieve their best possible outcome with their CI. This is a brand new tool to our market, and we're so excited to see this area of knowledge grow in the coming months and years. And what we've learned so far is anatomy-based fitting is no magic cure and really cannot fix that missing cochlear coverage, which is why the pre-planning is so important. And secondly, preliminary data in new users suggest good acceptance for anatomy-based fitting if the insertion depth or insertion angle is deep enough.

Continuing MED-EL's history of backwards compatibility, anatomy-based fitting can be used with any MED-EL internal device back to the COMBI 40+. That's over 25 years of internal devices, and it can be used with any aged MED-EL CI recipient using our latest processors. As you can imagine, anatomy-based fitting is most effective with new users who have not yet adapted to the frequency information provided by their CI. But as you also heard, this tool has a potential to allow for a better match between ears for experienced bilateral recipients, EAS recipients, SSD, or bimodal recipients. MED-EL has several resources available on all of our products and accessories to help support you and your hearing implant recipients with this or any topic on our products and services.

Our online resources include our website, professionals blog, our online learning platform, the MED-EL Academy, AudiologyOnline, and more. For more information on

anything you've heard today, please contact your regional MED-EL team. And if you're not sure who your regional team is, please contact us at medel.com or 888-MEDEL CI. We'd love to hear from you. Thank you.