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Ponto 5 SuperPower - New Clinical Data
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- Hi, everyone, and welcome to this AudiologyOnline talk on Ponto 5 SuperPower, new clinical data and key elements of bone conduction devices. My name is Julie. I'm the Director of Product Management in Oticon Medical in Denmark, and I'll be taking you through this topic today. And I'll skip to the next. Yes. Just some information that you already know on your continuing education here. Then I also have a financial disclosure, as I am an employee at Oticon Medical, and I think that is what is to be disclosed. And today's learnings objectives. I will just read through them. Upon completing this course and have listened to me, you will be able to describe OpenSound Navigator and new speech intelligibility data that compares Ponto 5 SuperPower with Ponto 3 SuperPower.

You'll also be able to list three important elements in bone conduction solutions and as well as being able to describe the evidence behind patient preference for Ponto 5 SuperPower over Ponto 3 SuperPower. I will start off with a brief introduction, then some clinical data on performance, the speech intelligibility data that we have, some key elements of bone conduction devices and some key features, and then some new clinical data on preference between two SuperPower bone conduction devices. Let's get to it. So this is on the Ponto System, a great choice for patient, and a family of especially Ponto 5s that I will present to you has a bone conduction option that enables your patient to hear better. And of course, this is not something that you should just take my word for.

We will, in course of this, show you the proven data or the proven results behind this claim of better hearing. And then, on a different note, we released Ponto 5 SuperPower last year and Ponto 5 Mini the year before, and we were happy to see that the pace at which new patients are experiencing Ponto 5 and SuperPower sound has been incredible. And thank you for allowing a lot of patients to experience this SuperPower sound. It's a joy and something that we're very proud of. So let's get to the data. I will show you today data from two clinical studies that compare Ponto SuperPower

devices. Both studies are cross-over studies with within-subject control design. And what that means is, of course, that the groups of study participants are trying both devices.

Each person are trying both devices and comparing within their own experience with both devices. So it's not between groups, but it's within-subject control. And the main goals of these two studies were a comparison of the speech intelligibility of Ponto 5 SuperPower versus Ponto 3 SuperPower, and then it was the preference between Ponto 5 SuperPower and Ponto 3 SuperPower from this group of experienced Ponto users. The sites that did these two clinical studies were the headquarters of Oticon Medical in Denmark in Copenhagen, where we have test persons that come in and participate in trials with the bone conduction devices at their own free will. And then it's Dr. Susan Arndt and Dr. Thomas Wesarg at the University Medical Center in Freiburg in Germany who also did a study with Ponto 5 SuperPower.

The two study designs were slightly different. One was sort of a more classical, full clinical trial design, and that is the one that you see on your left, where all participants come in. They are current Ponto 3 SuperPower users. So they come in, and then they have this, I think we call it a washout period, where they are fitted with a device with no automatic settings whatsoever. It just has amplification, just has gain. And then they walk home with this device to set a new baseline for their listening experience. So they're not set into one or the other device, but they're sort of washed out for any preference, or at least we try to get them to a new zero.

And then, based upon some randomization, they either start a trial of two weeks with Ponto 5 SuperPower, and then they swap to Ponto 3 SuperPower, or the other way around. And within all these trial periods, they have visits at our headquarters, where we test them with objective measures, the speech intelligibility, as well as ask them about their preference at the end. So this is more of a clinical trial design with a

cross-over period. Then, at Freiburg, it's a different design. It's more the coming in for an update or an upgrade kind of trial, where you come in with a Ponto 3 SuperPower, and then you're fitted with a Ponto 5 SuperPower. You get to test it out on site, in the canteen, walking around, getting an experience with the device, and then you do the objective measurements test with the speech material for speech understanding, and then the participants give their preference towards one or the other device.

At the Copenhagen site, 12 users participated, and it was more a mix of users, also a mix of different hearing losses, from the bigger losses to actually slighter ones that are still SuperPower indicated and preferred, at least in the past. And then, at Freiburg, it was sort of the more classical SuperPower users with sloping losses that also challenged the upper end of the fitting range of the devices. So 12 users plus 8 users that we have. It was two sites and two different speech materials, but it's the same underlying test. In Denmark, we used it in the native language for the Danish test participants, and, of course, in Germany, it was in German for the native German participants. It's a word recognition test.

It's sort of a closed-set test, where you have a noun, you have a verb, you have a numeral, and then you have a color, and then you have another verb that's sort of mixed in a matrix. In US, it's called the matrix test, and it's validated in German, in Danish, and as well in American English. The SNR levels used at the two site differed slightly and something that we adapted when compiling the results afterwards. The test setup in terms of the speakers and the speech was the same at the two sites. You had noises coming from the back and coming from 110 degrees behind the user and then speech coming from the front. And the results.

Here, we see the two different test conditions that we tested in. We tested them in an omnidirectional setting and in a full help system setting. And of course, we tested wearing Ponto 5 SuperPower and Ponto 3 SuperPower in both settings. And on an

overall level, what we see is that users performed significantly better with Ponto 5 SuperPower than with Ponto 3 SuperPower. And that goes for both the omnidirectional setting and as well as one with the full help systems. Full help system for Ponto 3 means that the system, the system is in full directional. You have access to the full noise reduction settings that is in the device, in FreeFocus. And then, for Ponto 5 SuperPower, it means that the OpenSound Navigator is set to an automatic version, where they're able to do the full balance and noise removal that is possible with the device.

And of course, these features are disabled when you test in the omnidirectional setting. So significant improvement both when having all the bells and whistles turned on, the full help systems, and as well as when just testing the two devices against each other without the help systems. And of course, what we see in this noisy setup with all the automatic is that the OpenSound Navigator that has this selective noise reduction, where both balances and noise removes in complex environments, are really able to help the users get rid of the noise and improve their speech understanding. And what the difference is, what you see here in the difference in decibels in the speech recognition thresholds that we're able to measure, is that it converts to or it translates to 16% increased speech understanding when comparing Ponto 5 SuperPower to Ponto 3 SuperPower.

And I just have a bit of the technicalities around how can we translate this difference in SRT, as measured in a dB SNR difference, into a percentage difference between the two. And here, we use the psychometric function of the test. Because we know the slopes of the two test materials, both for the German and from the Danish test, where we're able to measure the steepness of the curve and translate into the dB SNR difference and then the difference in percentage in speech intelligibility correct measured. So the 1.1 dB translate into 16% difference between the two devices. That was the version where we had the full automatics, all the help systems enable, where

OpenSound Navigator really helped the Ponto 5 users in performing better than when wearing the Ponto 3 devices.

Same users, two different devices. So in the omnidirectional condition, where, again, same users wearing two different devices at different points, why did they perform better with a Ponto 5 SuperPower relative to a Ponto 3 SuperPower? And here, some of the reason is within the gain of the two devices. Ponto 5 SuperPower has the ability to prescribe more gain than the Ponto 3 SuperPower. So you have an additional 5 dB of stable gain when prescribing and when fitting with a Ponto 5 SuperPower. And that is both the whole difference between the two systems but also due to the new feedback system that is featured in Ponto 5 SuperPower. Ponto 5 SuperPower features OpenSound Optimizer, which is able to predict, make very fast calculations that predicts when feedback would be building, and thus, keeping that in check, not having to lower gain to kill feedback, and thus, provide more gain with no audible feedback along the way.

That was the first clinical data on performance on how going from a Ponto 3 SuperPower to a Ponto 5 SuperPower can significantly increase the speech intelligibility performance in both a setting with a very noisy setting with all automatic features and also even just having the basic of the device. And that is the segue into some of the key elements of bone conduction solutions. Here, we point to three key features. The first being the foundation of hearing aid treatment as well as hearing aid or bone conduction hearing aid treatment is audibility, so making sure that soft sounds become audible by amplifying the soft sound and providing gain to the user in their hearing. Then, after achieving audibility, which makes audibility, I guess, the sort of prerequisite to move towards the right on that figure, we're able to provide algorithms and signal processing that enhances speech understanding and lowers listening effort, so taking away some of the noise in noisy situations and increasing performance in noisy situations.

And then, as more of a special thing for bone conduction devices, we also need some maximum force output. Bone conduction devices are inherently challenged on delivering a lot of sound. We have a transducer that doesn't, or most users don't want it to be too big. We also want to operate on a smaller battery that has limited battery power, and we need to optimize everything within the device to provide as much power as possible to be able to reproduce all the dynamics in different environments and especially these louder ones where some devices may be challenged in reproducing the peaks of dynamic situations. So let's start with audibility, so the foundation of helping bone conduction hearing aid recipients in hearing better.

And here, SuperPower, and Ponto 5 SuperPower, in this instance, is not really comparable to other devices in terms of how much full-on gain it is able to provide the user. So here is a comparison of Ponto 5 SuperPower, Ponto 5 Mini, and Baha 6 Max, where you can see that the capability of the sound processors are quite different. The two smaller ones have a limit to how much gain they're able to provide. Whereas, a Ponto 5 SuperPower is able to provide more than 10 dB more gain across the frequency range. And part of this, both, of course, for SuperPower having more gain, having a more forceful transducer, but also some of this is in how we do the signal processing on feedback.

And this, of course, goes both for Ponto 5 Mini but also for Ponto 5 SuperPower, where it really had something extra, is that we have the OpenSound Optimizer technology. And what it is is a patented breaker signal. So it's what you see here on the schematic as a striated picture, where it breaks where feedback would otherwise build. So we're able to detect very speedily that something is building within a certain frequency range and then applied very fast, detecting it before it becomes audible, before it builds to the level of being audible both to the user and surrounding, and then break that path. And that is broken in tens of milliseconds, so 60 milliseconds. Then, of course, it

should be applied only precisely where there's a risk of feedback, where feedback would build, and then, of course, no longer than it's actually able to kill or sort of stop the feedback risk.

So it should be very precise and very diligently placed and should not be applied longer than is needed, which also means that the end result is that it becomes non-intrusively, or non-intrusive to the user because it's applied that briefly that it's effectively stopped the feedback and then has very minimal impact on the speech spectrum. So first, I showed you the technical gain measurements of these different devices, and then we have the OpenSound Optimizer technology that works on top of that, but how does that translate into accessible gain for the patients in real life? So we are now going from more of a product information view to a validation view or a verification view within a patient.

So here, you see three different gain curves. What you can imagine is that we have three different devices, Ponto 5 Mini, Baha 6 Max, and Ponto 5 SuperPower. And what we did is that we have one single patient with a given hearing threshold, we fit the three devices to set hearing threshold, then we do a feedback measurement on, again, on the head when worn by the patient, and then we increase the gain all the way up to the maximum capability of that device, so setting the device to the max after the feedback measurement has been done. Then we take it off the patient and then put it on the skull stimulator, put it in a verification box, an Affinity, and then we do the measurements of the output, the output of the devices.

And then, what do we then get? Because that's sort of the real-life challenge or the real-life situation where we see that the two parameters, gain and feedback, come into play. And when we overlay these curves, and I hope that your screens are able to reproduce this sufficiently. It's a bit light on mine. What you see here is that the Ponto 5 SuperPower, which is the top curve here, top curve here, is able to provide. Even with

this scenario where you have feedback measured and then you've actually fitted above that limit, you're able to get a lot more gain out of the device, especially in the high frequencies, than you are on the other two devices that are more comparable in their output.

So that was the real-life test on how it looks. Good. So that was the audibility part. Now, we're moving to the middle column, the signal processing. And signal processing, not that it's sort of the icing on the cake, because I think it is a very central part of things. But once achieving audibility, then the next part is actually improving the now audible signal. And here, we are using OpenSound Navigator and going down the path of having this very transparent and seamless system that is able to do very fast processing to the signal and change with the dynamic environment that the user is in. So here, OpenSound Navigator, as you know, it analyzes the situation, pinpoints where you have sound sources in the environment as a user.

After having pinpointed these and how they move, we do a balance or it does a balance on these sound sources based on the nature of them and also the position of them. Is it speech, or is it noise? Is it coming from the front of the user? Is it coming from the back of the user? Also trying to take in some of the intent of the head direction that the user has. So balancing out, focusing on the speech part, regardless of the direction, and taking out the noise part again, also regardless of direction. And then we have very fast noise removal that will remove the rest of the unwanted noise. And here, we have a very, very speedy system that works even between words.

We will be able to take away some of that steady state or some of that noise that can pop in between speech coming from the desired direction. And this is not, as said before, not just a fancy algorithm. This is something where we have, both in the past with the Ponto 5 mini, when comparing that to previous generations of sound processors, but also here between Ponto 5 SuperPower and Ponto 3 SuperPower, we

can see that having access to this new technology, we can increase the speech understanding with 16% for these users. And then the third leg of this being the maximum force output. So taking the loud sounds and making sure that these are reproduced and remain within the signal and give the dynamics that situations have.

And here, SuperPower is a category of itself because it's power-heavy. It's force-heavy when reproducing something that is really loud in the environment. And I have here a representation of a Ponto 5 SuperPower, orange one, a Baha 6 Max, the yellow one, and then the gray one being Ponto 5 Mini. And what you see is that from Ponto 5 SuperPower, we get more than 10 dB more maximum force output from the device, where we were able to capture some of the dynamics that would otherwise be lost in a distortion or in clipping from the device that the user will be wearing. So those are the three parts that we find are key elements or a necessity for providing good bone conduction sound.

And also, I guess, some of these are the ones that lay foundation to how the preference will be for the user trying the different devices. So, are things audible in noisy environments? Are the dynamics heard? And also, how much help do I get in noisy situations? Am I helped out? Can I focus on speech? Is it effortful or more effortless to listen to this device? So we're back with the clinical results from the two clinical studies that we did to see how these feature improvements or these device improvement translate into preference between the two devices for the participants. And after trying out both, so in one study, after having trial periods with both devices, the users are asked, "Which one would you like to take home?"

And for the one with the more trialing situation, where they have a one-day trial, they're asked afterwards, "Which one did you prefer? Which one would you rather choose if having the choice between the two?" And these are some of the statements that they give that they base their preference on. So the majority, vast majority, have either a

strong preference or indicate somewhat better preference for a Ponto 5. A few have no preference, and same amount, same little amount have a preference towards Ponto 3 SuperPower. And the reasons that they give are that the localization is better, that their feedback is better, or perhaps that the feedback isn't there, that they're able to wear a cap again, that they hear a more clear sound, and that it works better for them in noisy situations.

And that makes out to an overwhelming preference to Ponto 5 SuperPower. And I think an important point also of this, especially for the group that participated at the Copenhagen office, some of the functionality or the technology increases that are between the two devices, the Ponto 3 SuperPower to the Ponto 5 SuperPower, for example, being able to have Bluetooth wireless functionality, that is not something that we include in the test. So what they based their preference on is the sound quality of the device and what it sounds like when they're wearing it. It doesn't encompass sort of their full how do I connect to the world demands that they could also put into this. So despite not having the full wireless options as well, we see that 90% of the participants that trialed both devices prefer Ponto 5 SuperPower, even the ones that only trialed it for a short period of time and having just walked around a university hospital were able to make a judgment between the two devices.

So that leads to an encouragement to have patients try out Ponto 5. We have some clinical data that really proves and really puts into perspective how the benefit of choosing a next-generation, choosing Ponto 5 SuperPower over Ponto 3 SuperPower will enable the users to hear better. We have increased the feedback system in the Ponto 5 SuperPower to have more gain while having less audible feedback and both in terms of what it can technically do, but also what we hear from users, what is their experience when they're moving from one device to the next device, that the feedback is something that they find is a significant difference between the two devices. And then we have users that have a clear preference when they test out both, and they

have a tendency, a clear tendency to prefer Ponto 5 SuperPower over Ponto 3 SuperPower.

And these are users that I believe were quite satisfied even with their Ponto 3 device, so they were potentially hard to impress. I can't vouch for that in terms of the evidence of that, but they were quite clear in their preference of Ponto 5 SuperPower. And coming from having patients try it out, I will mention that, of course, Softband is ideal for trials. We have an updated Softband, a new Softband in Ponto 5, which is ideal for these trials. It's slightly wider than the Ponto Softband, the previous one, but the elastic is the soft elastic that you know from the previous one. We've updated the design of the features of the Softband. So it has a new connector, the butterfly shape.

It has a connector pad that could be used on the back to increase comfort while keeping the good transmission. Then we have a new safety release. We pulled it out from the connector, so these are now two distinguishable parts. And then we changed the length adjuster also to keep a good, tight fit that fits the full day of use. And the Softband comes in two sizes, of course, adjustable sizes for both small heads and larger heads. We also support, of course, both unilateral and bilateral versions, and different colors, from different hair and skin colors to more fun colors, perhaps towards pediatrics or more fun use. And then, of course, a connector pad that can be used for an even more comfortable fit.

And then, as I spoke to previously, that Ponto 5 SuperPower is, of course, part of this world of connectivity, where the user can stay connected by using direct streaming, using different accessories, and connecting to the world around them, using the ConnectClip to connect to computers or to PlayStations or gaming devices and connecting to everything that's around them. I think, especially for younger users, this becomes a necessity and something that opens the doors for taking in the device as part of this whole sphere of connectivity that surrounds young users. And of course,

this is not only for young users, also for older users. These are great additions to the Ponto 5. And here are the full portfolio of devices, from remote control to TV adapter, still something that a lot of people use, also because it then removes the volume level for the full living room of people, and you're able to make volume changes directly to your Ponto 5 device.

The ConnectClip for your hands-free option and working with any modern smartphone. Then both EduMic for the educational setting here. The ConnectClip can, of course, also be used as a remote mic for these situations where you would like the sound of the one that you're talking to or who is talking to you to move closer to you and have sound come directly to your Ponto device. And this concludes my talk. It's here for... So this concludes my talk on the Ponto System and the clinical data that is behind it. And just to sum up, these were clinical data that talked about the performance, how the Ponto 5 devices were better in clinical tests when testing speech understanding, both in an omnidirectional setting, in a setting without all the help systems, and also in a clinical setting with a noisy setup with all help systems enabled.

And we talked about some of the key elements where the SuperPower and the Ponto 5 SuperPower device both had the gain to increase audibility, to enable audibility, have the signal processing in OpenSound Optimizer to remove feedback and actually provide the gain that the device can give technically, and then the maximum output, where the device is powerful enough to provide the dynamics of situations, even loud ones. And then we have the preference data, where we asked patients who were currently using and happily using our Ponto 3 SuperPower devices to test out Ponto 5 devices and see what they preferred after having either tested them for a longer period or even just a short period of time. And that was overwhelmingly positive, with 90% choosing a Ponto 5 SuperPower over a Ponto 3 SuperPower. Thank you for listening in, and have a great day, everyone.