Innovations in Microtia Atresia Treatment: A 3D "Hearing" Ear in One Surgery

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- - [Melissa] Okay, I'm gonna go ahead and get us started. Welcome to today's course on, Innovations in Microtia Atresia Treatment: A 3D Hearing Ear in One Surgery presented by Dr. Sheryl Lewin. In today's course, you'll be able to explain how ear reconstruction has evolved over the past 20 years. Be able to explain how the 3D technology for microtia, creates a more realistic surgical outcome and be able to distinguish common 3D terminology used. Also be able to explain how a 3D hearing ear can be completed in one surgery, for those born with microtia and atresia. Thank you very much for joining us today. I now turn the presentation over to Dr. Lewin.

- [Sheryl] Hello, thank you very much. I am very happy to be here and I wanted to start by thanking Oticon Medical and AudiologyOnline for allowing me to give this presentation. Lemme they get my talk appear. Alright, I think we're ready to go now. So as Melissa said, we're gonna go over, Innovations in Microtia Atresia Treatment and I'm going to specifically discuss how we can get a 3D hearing ear in one surgery. So by way of introduction, I wanna tell you a little bit about myself. This is probably not the word you were looking to see when I started this talk but this word is actually very central to how I arrived where I am today. So I started my college years, not really sure what I wanted to do but I discovered architecture and decided that would be my career. So I completed my education in architecture and then I started to have a little bit of second thoughts about this career and actually decided to change gears and go into medicine. However, once I finished my first two years and started clinics, I really really missed both the art and the creativity of architecture. And so I was sort of perplexed how am I gonna get all of these things together, in one career and much by serendipity, it came to be that I discovered I can do surgery to create ears and it sort of fulfills all of my professional needs. So that's kinda a little bit of the background to how I ended up here. It wasn't really planned but it's been quite a blessing to me. So Lewin Ear Reconstruction was born. This is my practice, I started it in 2012, after working in children's hospitals and other hospitals. And we basically just do microtia

reconstruction. About 90% of what I do maybe, 95 now and it's been quite rewarding. So today I wanna introduce you to microtia which in literal terms that means little ear. This is a drawing of one of my favorite patients who was missing both ears and so after he got his first big ear, this was his self-portrait, I always love that. This condition affects about one in 6,000 to 12,000 babies and it seems to prefer boys more than girls about 60% boys and also about 60% right side more than left side. It occurs by laterally about seven to 22% of the time so much less common but actually a fair amount of the time, almost half of the time you can see this condition with other associated anomalies. And the two most common syndromes that we think of with microtia would be OAVS which is on a very large spectrum and Teacher Collins syndrome, also on the spectrum. We do know that the prevalence is significantly higher, in Asian, Hispanic and Native American cultures, although there's theories as to why but we do not actually understand why.

And this slide, I think, is really important because you don't just have microtia or don't, microtia is definitely a spectrum from just a small ear to nothing at all. And where you fall on this spectrum really determines, from my perspective, a little bit of your outcome and how difficult your case is gonna be and things that I need to be thinking about to do the best job possible. So this is a grading. It's a simplistic grading scale of how surgeons discuss microtia Atresia when they see it, this is specific to microtia. Goes from the most minimal grade one to the extreme grade for where there's nothing but really about 80% of microtia cases are grade three, probably what you might feel, like you've seen most commonly as well. Where there's a little bit of an ear lobe, a little cartilage nabbing above it and we call that grade three. So, of course, we all wish we knew the answer to what cause microtia. We get a little closer, we get a little better understanding over time when we find, for instance, genetic syndromes where we can identify the gene relating to it. But honestly most microtia is seen either isolated or not part of a genetic syndrome and therefore, it is a question that we haven't answered how much is genetic versus environment. But for those of you that work with any

families that have microtia atresia, I feel like this is such an important point. I actually include this slide in every single talk and often I'm speaking to parents. And this is just so so universal that it really is important to keep in mind that the guilt that parents feel when the baby is born and nobody knew and there's this newborn with a missing ear and/or ear canal. It's important to stress to the family that there was nothing that was done during pregnancy that caused this. It really, almost doesn't matter how much I say that. I still have crying moms in the audience every time because it just hits home that it's our natural instinct to think we did something wrong but it's important to educate everyone that that's not the case. Aural atresia, so when you're missing your ear canal, it can be complete meaning there's no evidence of a canal at all or it can be aural stenosis which means a smaller canal. But interestingly, the longer I'm in this field, you can get very, very unusual canal anatomy. In fact, just this week, we did a case for a patient with microtia atresia but he had this stenosis with a canal very close to his jaw line. So you really have to do a whole nother sort of treatment for that severe but these would be what's seen most commonly.

It's a little less common than microtia. One in 10,000 to 20,000 babies but it also primarily unilateral, primarily boys and preferentially also right side over left so similar in those respects. And there's three basic treatment options that we talk talk about. The Bone Anchored Hearing Systems which we're gonna go into more detail a little later, the Middle Ear Implants which are just starting to come to America and are not quite entrenched here. So I'm not gonna talk about those 'cause quite honestly I don't have enough, background knowledge for those specific systems, since they're not all here in the US. And then Atresia Repair which we'll touch upon as well. So I always found it kind of interesting, I guess I love ears but I found it interesting understanding the evolution of ear reconstruction. So it pretty much, it was fascinating that the initial ear reconstruction ideas, started an incredibly long time ago. And so how that evolution worked is a little odd 'cause it took a very long time to progress where we are today. And maybe one of the reasons it took so long is because it's very well kind of

understood and accepted that creating an ear is one of the most challenging operations that we perform. I think that is largely why I sort of fell in love with it 'cause I knew we had a long way to go and I had hoped in my career if dedicated to this one procedure I could make an impact there. So really long time ago, 6th Century BCE, was this famous famous surgical text and it was called the "Susruta Samhita" and this was literally when the first description of ear surgery occurred. Albeit not the form we do today and certainly simplistic but it was taking local tissue to create a part of the ear that was missing. And then you jump to the 16th century, when Tagliacozzi used tissue that was located behind the ear where we have a little more mobility and in that way could move that tissue around to repair traumatic ear deformities. So a lot of plastic surgery so he was famous for nasal reconstruction as well, is moving tissue from one place to another. And we've gotten much better at it today but it's fascinating the principles that they figured out so long ago. So we jumped to 1920, the very famous Sir Harold Gillies, is considered the Father of Plastic Surgery. And he had a pretty amazing idea to use the Rib Cartilage from a cadaver as well as Rib Cartilage from a mom to help reconstruct a baby's ear.

So unfortunately, as good an idea as it was at the time, it wasn't understood that the body would react against tissue that it saw as foreign and therefore all that cartilage was resorbed. But it laid the groundwork for the true father of cartilage ear surgery which is Dr. Tanzer and he's really, this is where ear reconstruction began. 1959 very long time ago, he presented a paper of his first several patients and it took six stages but he was able to make a rib from a patient's own rib. So he sort of put together that the body was rejecting mom's cartilage so let's use the patient's cartilage. And this has really been the basis of all future rib-based ear reconstructions. So then the thought came, well, maybe there's something like an implant that could be used to make an ear and so in 66 and sort of when breast implants, different implants were being thought of but we weren't really using silicone very frequently. We didn't understand it very well but they made a silicone ear and it looked great and here, you didn't have to harvest

the ribs. So it seemed like such a fantastic idea, however, over time what happened is most of these extruded and ultimately, even Dr. Cronin admitted that this was not a viable solution for ear reconstruction. We couldn't make the implant work. So basically, at that point really, everything focused on these Rib Cartilage ears and the most famous ribs surgeon in America, Bert Brandt. This is his framework and this was essentially the gold standard and what all plastic surgeons in America were learning. And just from the 70s to say 2000 or 2010 they were refining this procedure but it wasn't changing dramatically. They did fewer surgeries and kinda tried to minimize scars and minimize complications and pain. But the basic principle is you take three Rib Cartilages so you can see from the chest wall, it's quite a sizable piece 'cause you need to create an adult sized ear. And this created a safe, durable ear reconstruction. You had to carve this shape of a rib into something that looks more like an ear which is obviously quite more primitive than, the natural ear but it was sewing together, these multiple little stacked pieces with stainless steel wire or permanent suture and that got you this framework.

Then I'll go through a little bit of how that framework is used but basically because it's somewhat invasive, it requires inpatient hospitalization. As we said, multiple surgeries, it is somewhat painful so you can at least get special medications or IV medication or an epidural to help with that pain and that's a significant improvement. But one big issue is that you have to delay the surgery until the kid is grown large enough that those three ribs can create an adult sized ear and so in almost every country, rib surgeons have chosen about 10 years to get that, some really big kids, maybe you can go younger. In America, there's a little more pressure to do early reconstruction so they push it down a little but you have less rib to work with. For all types of ear reconstruction, a lot of experience is required to get consistent results. So a little bit of graphic videos, I apologize, close your eyes if it bothers you but simply put, they're gonna, this video is gonna show you a colleague of mine in Canada who does these type of ear reconstructions. Her framework is seen here on the left and she dissects

what we call a pocket. So a space where this implant can sit in the proper position to become an ear and here she is putting that implant into position so kinda goes in upside down and she turns it, gets it into position and then ultimately she will sew this together, put a drain in there, put the drain on section and when it's all sewn up it will look like this at the end of the day. So the section allows the skin to basically shrink wrap to the rib framework and then you can see the form of the ear. However, this technique, you have to kind of bury the ear framework under the skin so it doesn't stick out at all and that's why you need multiple surgeries. The next one or two surgeries will address, projecting the ear out. So these are the probably four most famous, Rib Cartilage surgeons in the world from, multiple different countries. And you can see that the frameworks are all a little bit different and a little, everybody has their, somewhat unique reconstruction technique but all of them because they have to withstand the pressure of that skin, compressing it, they're quite thick.

And if you're looking at a natural ear, the cartilage of a natural ear, you can see it's extremely thin, delicate and three dimensional and very curvy, like so very thin, curvy structure. These cannot mimic that because they would basically collapse under the skin. So they have to be sturdy, thicker and stronger and clearly that will affect the outcome. So when all these were put in their skin pockets, these are the same frameworks for these ears, this is what you see is the result of those reconstructions. And they all look ear like for sure but they also do not have the three dimensionality or delicacy of a natural ear. So this is something that I noticed and in my early ears when I did Rib Cartilage, it was a source of frustration that you can't, it doesn't look like exactly like the other side. One of the biggest issues is that even after the surgery to project the ear out, it doesn't always work and the rib ears tend to fall backwards. And so this girl had a rib ear that required removal and replacement with a new ear reconstruction. You can see with her other ear normal, it's quite obvious that they're not symmetric. This boy had a similar issue but his surgeon decided I'll just pin back the other ear but to not see any ears when you look at someone's face on is a very

unnatural appearance. So that's another significant issue that is not acceptable in my opinion. Finally, there are many surgeons out there making rib ears that really should never be touching patients with microtia atresia. I along with almost all microtia surgeons, people dedicated to this condition, feel extremely strongly that you cannot allow someone with little experience to do this procedure. It is incredibly challenging even for those of us that do it everyday. It's certainly not something that an occasional surgeon who just learned it and has done a few should operating and these are the results. So very much worse than the condition itself. So I'm a big proponent of if you can't make it to a very, very experienced surgeon who you see their results, then you just hold off on surgery. So my conclusion is that the Rib Cartilage technique cannot mimic how delicate and three dimensional a natural ear is. Which takes me to Porous Implant Ear Reconstruction. I call it PIER just as a short term but to tell you a little bit about how this implant came to be. The actual material is a high density porous polyethylene that was actually developed initially in the 70s but it wasn't really used clinically until the 80s.

And so, it's an incredibly light material 'cause it's made up of these pieces of the polyethylene with holes in between. Those are the pores and because it's about 50% air so it's very lightweight yet very strong. And one of the most important things is that of all the types of implants out there like titanium or silicone, this type of porous polyethylene tends to be the least reactive material, you can place in the body surgically and that's an FDA decided fact basically. So it's because instead of the body seeing this implant as a foreign body, it accepts the implant and grows into the pores and it's pretty fascinating. So, as one would imagine when we discovered this, we found all kinds of indications for its use which are still in use today as you can see all over the cranial facial skull and face. And extensive number of surgeries over many, many ears, have proven the safety of it. Certainly not as long as a Rib Cartilage ear but in 1982 this was the very first, ear reconstruction made using porous polyethylene. Dr. Alexander Berghaus lent me these pictures of his very first patient, the first one ever to

receive this technology done in Germany. Well, by the mid 90s, a company called Medpor, created this two piece Medpor implant made of this porous polyethylene and it is not terribly different than what you would buy today. There's been very little modification, it comes as a rim and a base. And here you can see in this video, you can size the rim to be bigger or smaller because it's in two pieces. And then once you decide your size, you use heat to melt the two pieces together and then you add a little more so you get strength but interestingly, it's the fact that it's two pieces is significant, when I started analyzing the results of these ear reconstruction. So here you can see a completed ear that I was using up until 2017. So I used these two pieces and what was fantastic about them is, their structure allowed the tissue to grow into the implants. So much so that if you, not that you would do this but if you cut this implant in half, once it was implanted in the body, the actual implant would bleed because the vessels and tissue grows into it. So in this, the positives were it could be very thin but very, very strong that it was biocompatible. And in 2015, a new company besides Medpor, started creating a Su-Por so I switched to Su-Por. That's why we call it PIER because there's multiple companies that make these. And the one thing to note is, even though it looks more realistic than rib, it is still not flexible, it's very, very hard. And for it to survive well in a body over your lifetime, it has to be covered 100% with your body's own tissue.

So very briefly, I'll show you kind of how we get that tissue to cover this implant which is sort of the magic that makes everything work. So this is a little three ear old boy so he's got a three ear old sized ear. So first, we have to envision what his adult sized ear would be and then take the opposite shape and position it symmetrically where we imagine his adult ear will go. You see that we have all these dots and dashes drawn on this little guy's scalp. Those represent arteries, the dots and veins, the dashes. So I sort of map out the blood vessels supply to the head here and I figure out the best tissue. I make an incision right here behind the ear. This is the only incision used, we don't make any incisions in the scalp, something that I started doing, shortly after

fellowship finished in 2006. Then I decide where do I wanna get the tissue that's gonna cover this implant. We call this tissue a fascial flap and it's literally a reddish pink color because of all these blood vessels so it's pulsing and alive. And the way that we're able to make this work is we keep this purple spot which is the blood supply to the flap intact. We don't touch that area 'cause that's where all the blood vessels are coming from. But we come all the way around from underneath the scalp through that white incision. We go all the way underneath, lift this up, come around and then we literally can pull it out from under the head and it just sits outside the body now, still connected by that purple area. So I'm gonna show you what this actually looks like and I'll try to warn you right before it occurs. But one thing I really want you to remember is sort of the magic of this surgery has to do with how this flap is dissected. It's really what is critical for, minimizing any future complications. It has to really be dissected perfectly. So after we get the implant made, the flap dissected, then we have to cover it with skin and so I find that it's best to cover the back of the ear with skin from either your tummy or your upper inner arm because you can get a nice piece with a thin scar. And then the front of the ear we use, skin from around the microtia and skin from the back of the opposite ear which doesn't change its projection but we can sneak a little skinny piece from there and those two together combine to cover the front of the ear.

So that the new ear is the proper color. So here's the part if you're nervous to see what the flap looks like, you can close your eyes for this part but here's the implant in place and then this is what the flap looks like over it. So now we've completed covering the implant with the flap and we're now at the point where we're gonna put section with this drain on. And so when we do that, you'll notice that the ear will gain a little more definition and it takes the form of the implant. So after that we're gonna put skin on, you can see these meticulous suturing to put the skin grafts just right and you'll see that we're able to use that skinny piece from behind the other ear and then from the around where the microtia was, that's our ears skin so that our ear has a proper color. If we didn't have quite enough, then we use the skin in the bowl and around the back

of the ear and that's from the arm or the tummy depending on the child. And then you can see, even though they're from different areas, even at seven weeks post-op, we still start to see kind of nice blending. There's a lot more healing to do. Obviously this is very early result but the skin colors tend to blend okay. So to summarize the difference between these two techniques, PIER and Rib Cartilage. PIER can be done as an outpatient because it's not very painful and therefore the kids wake up after surgery, doing quite well. They just take over the counter medications for pain. Unfortunately for Rib Cartilage, that harvest of the rib is painful. The PIER can be done in one stage, on occasion we need to do a small revision. Rib Cartilage is multiple stages, minimum of two but more commonly three or four. We talked about the difference in pain and the difference in age. So I used to do PIER at three ears but because we are wanting to get slightly larger flaps and be mindful of anesthesia in under four ear olds, I have made it now four ears is my earliest age and then Rib Cartilage much longer.

So why is that early time so important? I have sort of always believed that there's a much more significant psychologic component to this condition even in these young kids but I didn't understand just how big that component was. Or I certainly was persuaded to think harder about it when I treated this little patient. This is Trey, again he was only three ears old and he came to the OR with bunny bear, his best friend and you may notice or I will help you notice that there is this similarity with Trey and his bear in that both have, a little bit different looking left ear. And I thought, oh, I'm sure that's a coincidence. I kinda mentioned to the mom, like, I thought that was sort of funny and she's like, "Oh, no, that is no coincidence." And I had a little kid about Trey's age and I'm like, my kid definitely doesn't know, his right from his left or anything. He doesn't pay attention anything and I thought, I really doubt that there's any significant thing going on, he just happens to nibble on his bear dear. But then the mom sent me this picture and I was kind of blown away 'cause it is just hard to think that that is all simply coincidental. So the funniest part was we went on to give him his big ear and then his two ears looked the same so he gnawed all the other ears, right sided ears so

that the ears were now symmetric on all of his bears. It was pretty cute. But anyways, I just take a moment to say that there's a lot more going on, in these little kids minds about this stuff that we adults probably don't understand. And it's not a problem to do an ear at four because if you look at this graph of how ears grow over time, they're already 83% grown at four ears of age and 90% by seven ears. So I feel like certainly there's less anxiety and the little kids seem to experience less pain and not have, they bounce back from surgery quite quickly, say compared to a teenager. And that would lead them to have an earlier increase in self-confidence and less of a memory of the whole process if they can have their ear done, before kindergarten and hopefully one would imagine that would also be less teasing and bullying. 'Cause at least with two ears, although they may not be exactly the same, it is a little less noticeable than completely missing ear. So a post-op result of this two piece type of PIER technique is this little girl who was three.

So you can see her right ear had the microtia and when we reconstructed her right ear looks bigger which is what we want for it to be a little bigger 'cause she'll grow into it. This view is the best view to check symmetry 'cause you can see that they both project very similar and they're in very similar position. And when you look at her from this side, the ear itself looks like a pretty natural ear, the scars aren't too obvious. And then when you compare her she looks quite similar and that I believe is because her natural ear which is on the right side of the screen but it's her left ear, the natural ear is what I would call a very typical ear. So like kind of the common or ideal ear, if you can say there is one, it's just got very standard anatomy, from the surgeon's perspective. However, that's not everybody and I started to appreciate that like eyes and noses. Yeah, they're all basically the same but really, they all have their own personality. Kind of what makes each of us an individual we can identify and even ears have their own personality. These are all adult ears, adult sized ears and yet look how different their shapes are. So then this child I wanna show you also the same way as the last little girl, we did a two piece PIER reconstruction. However, if you look at his ear anatomy, it's a

little bit different than this example one that's kind of like, she's a mirror model. I got her off Google images for ears. I mean she has like very classic ear anatomy and the little boy's ear, the bowl is different, the top of the ear is different, the shape of the rim is different. So I tried to reconstruct him as best I could with this technique but it does sort of point out when you look at him from the front, he's got a very curvy natural ear, on the image on the right, it's the right side of the right image. But the reconstructed ear is not quite as curvy. It looks and not quite the same projection. Now, if you just look at the single ear, he has a nice reconstruction I believe and it looks very ear like. However, when you compare the two, that's when at least to my eye which I believe as a surgeon you should have a very critical eye. I very happy with his ear reconstruction but it doesn't look exactly like his other ear because these two piece they're kind of made to look like an ideal ear, like the last little girl. So when you have ears that are a little different, I'm challenged in a way that that type of an implant was too limiting.

So, I'm gonna show you why I think so. We get a close up view, it'll be a little easier to see this bowl, what we call the console bowl of the ear is not the same shape as the natural console bowl. And that sort of bothered me because in my world, I'd like them to be as symmetric as possible. And more than that, the rim for all these PIER ears, all these two pieces, they're very look like a machine made them, they're very, very kind of standard and all the same and almost so called too perfect but natural ears are never that perfect. They get wider or thinner, they bend a lot so that's why this kid's ear looked a little bit different. It was bendy. So I got to thinking, if everybody's ears are unique, it would be so great if we could make an ear reconstruction, exactly by replicating a patient's natural ear, if they're unilateral obviously. So when I looked at a natural ear compared to the two techniques available up till this time, I really decided I would push hard to see how can we do better than this. And in 2018, I was able to develop what I call a 3D Lewin Ear Implant and we got to the place where we could create an implant that essentially was well, in this case, an actual image but it would be a mirror image of the patient's ear. This was actually my employee, our first test

patient, just to see what we could get. But what really happened was this great breakthrough, when I found this wonderful scanner that allows me to very simply in two minutes, take a little tiny kiddo, four ears old here and create an actual image of her ear that is a essentially perfect match. So this is what that 3D scanner gives me, this view from every possible angle of all the intricacies of your ear which is so much more complex than sort of what I had thought. Until you start seeing these scans and models, it's very hard to appreciate that they're actually I consider them each, like a little miniature sculpture. So here's how that very first implant, matched the patient's ear. And you can see it really doesn't matter what angle we were finally able to get a very similar likeness. So basically, from that point on, I stopped using this style that is basically what the rest of the world is using and I just because it's the exact same material, I was free to use these new implants.

This company, this wonderful company Poriferous, makes these ears, it's called Su-Por, the material but it is the same porous polyethylene as Medpor but these are the guys that I worked with several ears to get to this technology and bring it to my patients. I was the first surgeon to offer this ear implants as by routine now, more than I'd say about, 95% of my patients are getting, either the 3D Lewin Ear Implants or the kind of 3D ideal ear implant that I use if you're bilateral. So almost everybody. This one piece implant is created much stronger and much more stable than the two piece implant and it does create this perfect match much better than any, I don't know how good a sculptor you could be but nobody can do as good as this little scanner that is to a ridiculously incredible accuracy. We've talked about bilateral patients, they get a 3D ear of a kind of an ideal ear scan that we did actually on the sibling of one of our patients. And over this past ear we've done 70 of these three 3Ds. We have I think, close to 100 already, on the books for next ear. The 3D scanning versus 3D printing. This is very a constant challenge, in understanding the differences between these so I do wanna spend just a moment, describing the differences. So scanning has to do with the imagery so it's the process of visually capturing a three dimensional object. And

this is the scanner I use, it's incredibly good. It uses just basically, all those little black circles are cameras and so you're taking all these images and the computer software is, building this three dimensional object. 3D printing is completely different. So that is the actual building of a particular physical object and it's using three dimensional inputs and usually that input is by probably software tells the 3D printer how to lay down layer after layer after layer to build an actual object. So many labs are trying to 3D print a cartilage ear. And I'm not sure but some I believe are trying to print even a porous polyethylene ear. Neither of those is what I'm doing 'cause I'm just using the scanning capability and we are creating a sterile porous polyethylene ear from that scan but not printing it. It's done in a kind of more of a mold type fashion. So we're not quite there yet, I don't know when we will be there for children. The first clinical studies haven't even been done, on adults yet. So it will be some number of ears before this is both doable, provable, sustainable and then practical meaning, is it affordable to do as a common front line treatment for microtia.

So when we compare the 3D versus the Medpor, we talked about these two piece implants, they can fracture because they had to be soldered together with heat. So there's an inherent weakness in the places where they are connected to the ear. And so the ear itself when it fractures, can appear like this and if you dissect out the implant, you can see that it's fractured. We can repair it with a 3D ear but this was a critical problem to solve because you have to do surgery to replace the implant. This is just showing you, this is actually a 3D printed model of a kid's natural ear and basically this video just shows that once we design this sterile implant for his microtia, how it heals over time. So first week, that's what they're supposed to look like, kinda crazy. And then by a month, it starts to get a little better but it really takes about a ear to fully heal but you'll see this child through about three and a half months after surgery. And at that point, it starts to look like an ear so here he is before and after. Before and after and again you can see his scars. You can see some redness because he's so early but we've basically been able to create a much more realistic looking ear by using this

technology. It's slightly bigger than his other ear because of his age, I think he's about five or six. And this just shows three dimensionally, we even can create the back of an ear with this technology. So here's another little girl about four months out, she also got a 3D ear. This is actually the little one that I was scanning and here you can see her ear reconstruction. And another example of an older boy more of a teenager, they have thicker flaps and he's not quite done healing, is about four months after. So his level of detail isn't quite there. But you can see pretty symmetric both front view and back view which is great if you're a boy and you wear your hair very short. So there are risks associated with PIER. Fracture we talked about, exposure which is a hole. Infection, there can be some injury to the nerve, to the eyebrow very, very rare and then failure meaning that the flap does not work. So fracture we talked about, these are just some examples but I have not seen, we've been doing these one piece ears, since 2017, the 3Ds since 2018 and none of them have fractured yet. Exposure is a hole, here you can see a little tiny bit of the implant is exposed. We do have to take the patient to surgery usually to fix that hole but then often they heal and they still do quite well. But they used to require surgery but more recently we've had a really great, experience using just a topical medicine to help these.

Moving on to infection. You can see this very red irritated ear, 10 days after surgery but then after just a week of medicine the infection resolves and that's because of the tissue has grown into the implant. And so the medicine goes into the tissue, into the implant and allows for treatment. So these are my complications from about the 2013 to 2018, over six ears. And you can see once we, the first column is all my ear reconstructions which is 395 versus just the Lewin Ear Implants, the one pieces. The most important thing to call attention to is the exposures are significantly lower and the fractures are zero, the rest are pretty similar. So now I'm gonna switch gears and talk about aural atresia. And we're gonna start with talking about the Bone Anchored Hearing System, BAHS or often called BAHA. We'll use that term BAHS. So it converts the sound into vibrations, that's the driving force that pushes from the sound waves

from the processor to the implant to the bone to the cochlea that allows it to bypass the canal and middle ear which are affected in atresia. This BAHA or BAHS creates excellent sound conduction and gets better sound localization for these patients. The two that I use surgically that I implant when we do ear reconstruction, are the Cochlear Baha and Oticon Medical Pontos. And in order to do it in a single stage we need a bone that's adequately thick which is usually about five ears of age and we'd like it to be greater than or equal to three millimeters. And then the abutment is size based on how big the child is and their thickness of soft tissue. So if you do at five, you're gonna need to change not their implant but the abutment out many ears later when the kid is grown. Then a two stage is if you have a bone that's either too thin or too soft which basically means it's less than three millimeters. And you just put the implant, then you put a little cover on this implant, like a little screwed cover and then you leave it under the scalp, you can't see it at all and you wait three to six months and then under local anesthesia, you can put the abutment on when, the osseointegration process has taken care of itself. But I think it's underestimated how important positioning is and it's very challenging if you don't have an ear, for a surgeon who's not doing the ear reconstruction to know where to put it.

So I really don't like BAHAS or BAHS being done prior to ear reconstruction. For this kid, we did it at the same time and you can see we placed our implant here, we put a sleeper which is basically something that if the first implant for some reason got knocked loose, we can use the sleeper. That's kind of like the way a two stage is done. And we position it based on the location of his ideal canal which you can feel when you're in surgery and that's about 50 to 55 millimeters away and in line with the top of the ear. So that's how our positioning works. I do this type of surgery with no additional scarring so you can see that we have an implant and a sleeper 'cause we were doing a two stage for him and he does not have any scars. So those are not without their risks either but they're very minor risks that I rarely see but you can't have bleeding, infection, healing issues are more common , particularly years ago, I find it

less common these days. A CSF leak is if you are drilling for the bone and you have a tiny little tear, in the covering over the brain, you get cerebral spinal fluid leak. I think I've seen it only once ever and it's very easily fixed by putting the implant in place and then poor osseointegration. So I do wanna spend a couple minutes, on Atresia Repair Surgery as well. And it's important that really only 50% of kids that have aural atresia are considered good candidates, for surgery, there's sort of a very complex way to assess how good a candidate you are. And it involves getting a CT scan and looking at the audiogram and the anatomy from the outside and then making that decision. This is an example of a kid who had an atresia repair and this is right before I did his, before he had it and then before I did his ear reconstruction. So one thing that I feel like is important to educate people about be it parents or audiologists or whomever is that this surgery I find to be not very predictable. And even if you have the best surgeon in world who did the best surgery, the improvement in hearing is not predictable. And we haven't got long term data to prove that the hearing that you gain early on will last.

It's important to know that there's a lifelong care to clean this canal so once you go down this road, you really can't go back. I came to know at an international conference that much of the world has actually abandoned this surgery. But still, there are a few spots that still do atresia repair and the US is one of those spots. We also are one of the country that doesn't have the latest technology as well. One of the reasons I have concerns is that two patients in the past year that I did reconstruction on long, long time ago that was successful, lost their ear due to complications from the canal. So to me that just added another level of importance in this decision making process for a family. So here's an example of a normal ear versus atresia repair. This is a kid that I did with a one piece implant and although I'm very happy with his ear reconstruction, I put this slide in to see that aesthetically there's really nothing you can do to remove the dark black hole of the canal reconstruction because that needs to be out there available for aeration in order to function. So it does affect, if you put your finger over that in your vision, it looks much more like an ear but that big black hole certainly is a

big signal that this is not an actual ear. And then there's a lot of risks to atresia repair and many of them require surgery but the ears can get smaller, they can get keloids, you can have a facial nerve paralysis or facial nerve injury if you're not an experienced, surgeon specializing in this. And then the issue of hearing loss over time is pretty significant as well. So the way I kind of look at this in order of trying to figure out how to compare these options, the attrition repair is more of a high risk with an unpredictable reward. But there's a big upside because you don't have to have a visible device and it's particularly significant, if you are missing both canals. The downside however is hearing gain may be minimal or it may be temporary. You may still require a BAHS and you may have a poor aesthetic appearance. Whereas the Bone Anchored Hearing System is a very low risk, it's high reward 'cause it's very frequently will get you so called normal hearing at least by audiogram. It's quite a minor surgery so very little risk and the processors are getting better and smaller and less noticeable which is fantastic.

So thank you, all of you. I know Oticon, I believe has the smallest, out there right now with their new Ponto 4. So all that technology is great and helpful but it is still a visible device and you can still have issues with infections over time. So all of this got us to where I am today. This is a fairly recent patient of mine who did come get a 3D Porous Implant Ear Reconstruction and we happened to do a Magnet BAHA 5 five for him with no scars in the scalp. So from where I started when I finished fellowship in 2005 to where we are today, I don't think we're there yet, I don't think I'm done but I think I'm very happy with the direction we're moving towards, advancing the treatment of this condition. Here's a little boy very similar, no scalp scars and he has the Ponto. Last thing I wanted to say has to do with our mission to educate families and audiologists about microtia and atresia. So every other year usually, we have conferences and bring together surgeons, ENT surgeons and Rick Carlisle surgeons and myself and we have conferences to teach everybody about all the specifics of this in much greater detail. So audiologists are welcome to join us and please look us up on our website and we

can get you more information to join us in August for our next conference in Los Angeles. Last little bit for the talk, please watch this little guy who was one of my favorite reactions to seeing his ear for the first time.

- I have two big ears. Thanks, mom, I have two big ears.

- [Woman] Yes you do.

- This ear is awesome.

- [Sheryl] All right, thank you guys very much, for your attention, I really appreciate that. Hopefully I'm still here.

- [Melissa] Okay, any questions, please go ahead and send those in, I'm gonna go ahead and copy them for you, Dr. Lewin right now.

- [Melissa] Families wants to know if you'll ever do, the middle ear implant surgeries?

- [Sheryl] Oh, I do not do the middle ear implants because that's really done by an otologist that specializes in that anatomy. So middle ear implants, like a Vibrant Soundbridge by MED-El. Those I have patients that have done them and it's done after the ear is reconstructed because if it's done first, it destroys the tissue I need for the ear reconstruction.

- [Melissa] Excellent, thank you that is. Okay, another question. Do you perform the combined microtia atresia surgery?

- [Sheryl] I used to do that when it first came out I believe 2007 was the first one and I was present for that surgery. But I did it after doing it for several years, it became

apparent that the results were better when, the surgeries were done separately. So my preference is to do the atresia repair first and then three to four months later, come and get the ear reconstructed.

- [Melissa] Excellent, thank you and if anyone has any other questions, go ahead and write those in. Dr. Lewin thank you very much for this course today. It was wonderful, absolutely fantastic.

- Thank you so much.

- [Sheryl] Wonderful, thank you very much. Thank you to AudiologyOnline especially and also thank you to Oticon Medical. I really appreciate it.

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