BRIAN DOWNS: I'm Brian Downs. I do facial plastic and reconstructive surgery here at Wake Forest. And you might ask yourself, why is a surgeon here talking to you all about non-surgical treatment? And that's an interesting question. As a facial plastic surgeon, part of my practice of course is facial reconstruction, including ear reconstruction. And so as I've decided on the trajectory of my practice and the building in my practice over the past 2 and 1/2 years, it came to my attention that this is an area in our geographic region that's relatively under treated or under served. And so I felt like, number one, it was important to discuss and then number two, I felt like that would dovetail nicely with not only my practice but also perhaps your patients.

And I think that it's interesting-- ear deformations, or "dee-formations," those are not malformations. And as not a pediatrician but as a parent, I know that oftentimes these are not life threatening. They're not overall going to be detrimental to health. And certainly for us as parents, we were just happy when the whole process was over and there was a baby. And so this is something I think that clearly is elective in nature, but at the same time, something that can, I think, have an effect positively as the child grows and develops.

Really my disclosure is I'll be primarily presenting this morning industry slides. These are not my slides and I, more importantly, have no vested interest in EarWell, which is the commercial system that I'm going to discuss with you in the context of ear molding early on in life. I'll come back to this at the very end because I think my personal bias is that there is perhaps a better and, as you'll see, more financially feasible way to treat these ear deformations for newborns.

The goal and the idea behind ear molding early on in infants is that circulating maternal hormones, specifically estrogen, create this malleability of auricular cartilage. And this effect lasts really anywhere from one to three or four weeks depending on the specific case. And in this time period, the external ears of newborns are susceptible to molding and sculpting and really creating what we recognize as a normal external ear.

What we're talking about, and I think this is important to understand, is a "dee-formation"-- a deformation-- and not a malformation. So a malformed ear is one that you all, I'm sure, are familiar with. And we will be talking about grades one, two, or three microtia where all of the parts are not there. This is in contrast to really the idea today, which is we're talking about a deformed ear. And the idea is that all the parts of the ear are there but that there have been external forces in utero that have created a change in the shape of those parts. And that's what is manifest by the deformations that we'll talk about today.

The deformational zones that we recognize commonly-- and this is overall a review of ear anatomy, but also these are the areas in red that are susceptible to these external forces that we see in utero. One is the helical rim. Also the scaphoid. The antihelix as well as the superior crus-- The superior crus is the area of the antihelix that extends up in kind of a Y shape, and that's the convexity, that's the superior limb, of the Y. The helical crus as well as the concha-- The conchal bowl is the concavity that leads to the external auditory canal. And that is also susceptible to changes in compression in utero.

The inferior crus, the tragus, and the lobule in white-- Those are areas that typically are not affected by these extrinsic or external forces in utero. And so those areas are less likely to be affected and less likely to be amenable to any change in molding or treatment.

Deformities oftentimes are heterogeneous and mixed and so they often co-exist. And so a pure conchal crus, for example, may not be as common as lidding plus a conchal crus. And so just a review of these deformities, not that the deformity name necessarily is as important as recognizing that there is a deformity.

On your left, lidding is where the superior aspect of the helix is folded down. This results in a hooded or a lidded shape, as well as decrease in the vertical height of the ear. That oftentimes co-exists with what's called a conchal crus. And you can tell in the picture on the left how the helical crus extends down and extends horizontally over to the antihelix.

And we'll go back and look at the normal ear again. And the crus helix, or the helical crus, really should end and taper off just superior and posterior to the external auditory canal, whereas in a conchal crus that helical crus extends across almost to the antihelix.

Prominent ears are also susceptible to deformation. It's hard to see on the lateral photo here. But that's when the actual projection of the ear is increased in the lateral dimension from the surface of the head, or the mastoid.

Stahl's ear is kind of a Spock ear or a pointed ear superolaterally. And that can also, as you can see on the right, co-exist with a conchal crus as well as lidding. And so this is just, again, to outline that oftentimes these deformations are not isolated in nature but oftentimes mixed. Again, another view of Stahl's ear, or Spock's ear, where that superior crus extends up and really goes to the margin of the helix. And we'll go back again and look at what should happen in what we call a normal auricular anatomy situation where the superior crus really extends into that scaphoid concavity before the helical prominence, whereas in Spock ear, or Stahl's ear, that crus extends up out to the helix and gives kind of a pointed and certainly phenotypically-malformed ear.

Helical rim deformities are also common. These can result in what we call the constricted ear. And studies have shown that these result from extrinsic compression either in a horizontal or a vertical fashion. And so that contributes, again, to these heterogeneous deformities that are not always isolated in nature. Two other representations of that phenomenon.

I think the point really is that specific identification of each of these deformations is not as important as recognizing phenotypically that the ear isn't normal. And so, granted, there are lots of concerns immediately after birth. And I think, again, just the relief of having the process at a completion point and having a healthy baby and other issues oftentimes will detract attention away from this. But I think that the point being that if this sort of normal situation is imprinted for us that we can better, perhaps, identify the abnormal situation.

What does the literature say about ear molding? And again, there is a time-sensitive nature of this where maternal estrogen makes that external auricular cartilage susceptible to molding. For 100 consecutive births at Baylor, a tertiary study, they identified 39 infants with 58 deformities. At one week, 2/3 of these deformities were still present. And if you extrapolate from these study results, approximately up to a fifth of births would be candidates for molding.

Now, the other caveat to this is that this is at a tertiary care center where perhaps it's more likely that pregnancies and gestations could be complicated by other factors. And so you could argue that this rate is perhaps higher than what one would see in the community. But nevertheless, this gives representation of the relatively high prevalence of this phenomenon.

I think the urban legend or the conventional wisdom over time is that these ears self correct. And I think that we have enough information from the literature now to say that that doesn't occur. This study from Canada looked at 200 newborns with auricular deformation. A hundred were treated with molding. A hundred were left untreated. Ninety percent of the treated ones were corrected to some degree, whereas 70% remained uncorrected. And so I think that this plus other studies are enough at this point to show us that the ears do not over time self correct if at birth a deformation is present. Same sort of thing here. Another study that showed that among the control group with deformities, there was no self correction.

So when to mold? Again, the first seven days is an important time to identify and consider initiation of treatment for newborns because those circulating estrogens will decrease rapidly after that time. If started after three weeks, there is a less than 50% possibility to correction as the cartilage becomes much less malleable. And so I think the conclusion from looking at this is that it's well established and apparent that this teaching or belief that infants will self correct is wrong but also can lead us to sort of miss this window that may preclude moldings and successful non-surgical treatment.

So a management rationale which I would propose would be to diagnose and alert parents early on in the initial newborn exam. I think that like many things, especially what I do, a picture's worth a thousand words. And so I think that having a photo and then, in two dimensions, a photo of a normal, or what we consider a non-deformed ear, and comparing that can oftentimes be enough to demonstrate the deformation. And then a follow-up exam early on is important if self correction has occurred-- which I don't want to say never happens-- but if it has occurred, then that's great. If not, then consider molding or consider referral for possible molding.

Now, here's where I'll branch over and talk about this commercial system that is available, the EarWell system. And it is actually a brilliant commercial adaptation of what we know works from a practical standpoint. And so what this company has done is designed a posterior conformer, which is basically a plastic mold that has a piece of adhesive on the back of it that sticks to the side of the infant's head after a little bit of hair has been clipped. That is coupled with what's called a conchal former.

Remember, the conchal bowl is that concavity that leads to the external auditory canal. And so that will fit into the conchal bowl to help with things like the conchal crus. And so remember, that conchal crus is the, on your left, is that extension of the helical crus that extends across to the antihelix. And so that conchal former fits into the conchal crus and helps to reform that concavity.

Retractors-- the mini retractor and the medium retractor-- both help to form that antihelix in the scaphoid fossa to help reform those concavities and convexities along the helix. And then an anterior shell is placed over with clips that clip into the posterior conformer. So stepwise, the hair is clipped, the posterior conformer is placed next to the head, retractors are placed, the conchal former is placed, and then the anterior shell is placed. And this is essentially a painless procedure.

But the key really is close follow up. The average duration of each application is two to three weeks, range 14 to 21 days. If the device loosens earlier, consider that we haven't clipped enough hair or that the child is just overly active and so interventions may be needed to help with that. Parents can reinforce this at home. Typically, Mastisol can be given as a skin adhesive to help re-stick the posterior conformer because that's really the part that is more likely to peel off.

On average, range of treatment total is four to six weeks. These ears may attain the shape in two weeks and it's tempting at that time point to go ahead and take the device off. But I think it's important until that malleability window closes for the most part to continue the conforming treatment. We think breastfeeding may increase the duration of treatment. Not that breastfeeding should be discontinued, but a word of caution that conforming treatment may be needed for a little bit longer.

A few before and afters again. These are commercial industry photos but reasonable expectations of what can be achieved with ear molding. So fairly dramatic. Here's a child with the conchal crus. You see on the left that helical crus extending all the way across the conchal bowl. On the right, morphologically, a much more normal ear. Again, there are also helical irregularities and abnormalities superiorly on your left. On the right, morphologically much more normal.

This is a constricted ear. You can see on the left the superolateral aspect is pushed in and the smooth contour and convexity of the helical crus is disrupted. On the right, morphologically much more normal.

Similar thing here. Deformed, constricted ear on the left as well as a bit of conchal crus. On the right, morphologically better. Similar here. A little bit of a Stahl's ear as well as a conchal crus. Vertically deformed ear. On the right, morphologically much more normal. Similar thing here. Just another before and after.

So nothing is without complication, right? So that's what we always tell patients before and after surgery and also before and after non-surgical treatment. Milia or monilia benign skin condition can be caused, we think primarily, because of moisture that is trapped underneath the conformer. Should be a self-limiting situation or condition.

Conchal erosion-- This is probably the most feared of the complications. Basically, a pressure sore associated with the skin tightly coapted against that cartilage. We see this as a dreaded complication rarely, fortunately, in otoplasty surgery with our head banding post-operatively. Here, this is primarily because that conchal conformer was tightly adherent and created a pressure sore on the concha. Fortunately, this can be treated and generally resolves without sequelae long term, but does require discontinuance of the conformer. And so usually at that point, the effect that you've achieved is really what you're going to get non-surgically as the conforming has to stop.

This is an episode, a condition of skin erosion and necrosis over the superior crus you can see on the right and on the conchal bowl from a tight conchal conformer on the left. Again, fortunately doesn't result in long-term sequelae, but the conforming has to, at that point, be discontinued.

In conclusion, early diagnosis is important and early referral is important if this is a condition that parents and you all feel like it is worth treating. I think having pre-conforming photos as well as normals to compare and show parents because again, oftentimes this may not be something that's easily picked up on or appreciated by them. Early application is best, if possible, five to seven days. And this can be easily done in a clinic. Doesn't require anesthesia.

And here's really the catch-- and this is where I want to go back around to where I started at the very beginning-- is the cost. Historically, the billing for this procedure has been done using a CPT code for custom auricular prosthesis. And that's what-- if you go on the internet or if you talk to this company, if you talk to EarWell-- that is how they encourage our getting paid for this unless it's done as a flat cosmetic fee as a cosmetic surgery.

Recently-- and I mean in the last 6, 8, 10 months-- there has been some backlash against that CPT code because this is not a custom auricular prosthesis. If you think about it, the intent-- really the letter as well as the spirit of that code when it was developed-- was for practitioners who are making their own molding prostheses in their office. So a patient comes in. It would be like getting a palatal prosthesis or a nasal prosthesis. A patient comes in and there is a custom-making process for the mold using what the patient comes in with and then some process of going to the lab or to the back table and carving or sculpting or making a custom prosthesis.

In the strict sense of the word, especially from a biller's standpoint and probably, realistically, from an ethical standpoint-- certainly not making any judgments-- but realistically, that code is probably not best used for this procedure. So what are our alternatives for custom molding? Well, I think, number one, is there a demand for this or is this something you all see? But number two, can we get this result or get these results using custom methods in a way that is cost effective for our patients?

And now the last thing, part of what I do is elective reconstructive and cosmetic surgery. And so the last thing I want to find myself in this situation is where we've done a procedure that we assumed incorrectly was going to be covered by insurance. And then the patient gets a huge bill because of this. And so I think that to do this, we should really, really, really make sure that we are not putting, not only ourselves, but really our patients in that situation.

So a review of the literature shows that there is a very effective custom way that we can do what the EarWell system does using Silastic tubing as well as Steri-Strips and Mastisol to, again, recreate those concavities and convexities that are present in the normal ear. And I like to think that, based on our training, we're a pretty creative lot. And part of what we do is, for our training, is see a deformity and figure out a creative way to fix it.

And so I would submit to you today that we can comply with the spirit and the letter of the CPT code that's available and custom treat these auricular deformities for children while at the same time making sure that we get not only the results we want but also do the right thing for patients and parents so that we don't put them in a bad spot. And so this is just an example of a way that we can do this safely and effectively for them.