TRANSCATHETER REPAIR OF ATRIAL SEPTAL DEFECT
AKRON CHILDREN'S HOSPITAL
AKRON, OHIO
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Announcer: In a live broadcast over the next hour, you will learn about Akron Children's Hospital's program to treat children and adults who suffer from an atrial septal defect, commonly referred to as a hole in the heart. Cardiologists at Akron Children's hospital prefer to use the catheterization lab to treat the defect. The so-called trans-catheter repair is less invasive than the open-heart procedure. It also leaves the patient with less scarring, less discomfort, and a quicker recovery.
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Dr. Lane: Trans-catheter closure basically eliminates much of those potential drawbacks. We do this in a patient who is, in most cases, not under general anesthesia. So the amount of invasiveness is minimized from that standpoint. Patient's breathing on her own, the heart is beating.
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Announcer: And there is another benefit.
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Dr. Waight: We arrange it here at Akron's Children's Hospitals that once they're asleep that the A.S.D. will be closed. If we can close it in the cath lab, then I go ahead and close that A.S.D. If I cannot close it in the cath lab, we arrange to have the surgery done immediately afterwards.
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Announcer: You may e-mail questions to the physicians in the O.R. by clicking the MDirectAccess button at any time. This program represents Akron Children's Hospitals ongoing efforts to bring the latest developments in health care to the community.
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Dr. Smith: Welcome to this webcast, coming to you live from Akron Children's Hospital. This afternoon, we will be showing you a procedure to repair and atrial septal defect, commonly referred to as an A.S.D., or sometimes simply a hole on the heart. We will be showing you a novel approach to closing a hole in the heart that leaves the patient with no scarring, little if any discomfort, and a very short recovery time when compared to traditional methods using open-heart surgery. Hello, I'm Dr. Phil Smith, clinical director of the heart center and chief of cardiovascular surgery here at Akron Children's Hospital. Today, we will also show you how the cardiologists and cardiac surgeons here at Akron Children's Hospital work in a collaborative way to provide individualized care to both pediatric and adult patients with congenital heart disease. Before I introduce the members of our panel, a little housekeeping. At any time during this webcast, you can ask questions to our members here by clicking on the MDirectAccess button on the top of your screen. Now some introductions. First, I'd like to present my colleague, Dr. David Waight, the director of interventional cardiology and the director of the cath lab here at Akron Children's Hospital. David, thank you for being here. I'd also like to introduce the director of adult congenital cardiology, my colleague Dr. John Lane. John, thank you for being here. Finally, I'd

like to introduce Miss Desiree Lee. Miss Lee recently went underwent the procedure that you will be viewing during this webcast. That you for sharing your story with our audience and taking the time to be here with us today.
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Lee: You're welcome.
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Dr. Smith: Desiree, let's begin with you. Perhaps you could tell us, how did you find out you had an atrial septal defect?
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Lee: Originally, I had went to my PCP for just an annual routine checkup.
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Dr. Smith: Your primary care doctor.
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Lee: Yes. And she heard an irregular heartbeat, and she thought it would be a good idea for me to go and see an adult cardiologist.
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Dr. Smith: Now, when you were a child, had somebody told you that there was anything wrong?
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Lee: Actually, yeah, I was told that I was born with a heart murmur but I would actually grow out of it and there was no risk involved. So I've never thought anything else about it.
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Dr. Smith: Until your primary care doctor said something.
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Lee: Correct.
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Dr. Smith: So then you went to the cardiologist, and what happened there?
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Lee: He sent me for some tests. I had an echocardiogram, which came back abnormal. So then he sent me to have a T.E.E., and after he reviewed that, he thought it would be a good idea to see Dr. Lane, and after that, I actually went to see Dr. Lane, and that's how it all happened.
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Dr. Smith: Well, we'll talk a little bit more about your experience with it. David, perhaps for the audience, you could begin to tell us a little bit about what an A.S.D. is, why it's a problem.
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Dr. Waight: Well, an A.S.D. is defined as an opening or a hole between the two upper chambers of the heart. The upper chambers are usually separated by a membrane, which its called the atrial septum. If there are any holes in that atrial septum, then it's an atrial septal defect, and they can occur at various places and at various positions inside the heart. It becomes a problem because there's extra blood flow that comes from left side. That's blood that's full of oxygen and shout be going out to the body where the body uses up the oxygen, and then it flows back to the right side of the heart. That red blood, which is full oxygen, comes back across the atrial septum and puts extra blood flow into the right side of the heart and extra blood flow to the lungs. Essentially, it's blood that's getting pumped around in a circle and isn't providing any help to the body whatsoever.
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Dr. Smith: Is this a common problem?
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Dr. Waight: It actually is fairly common. The incidents, or the number of people, who have an atrial septal defect is fairly large. About eight out of 1,000 children are born with some form of congenital heart disease, and about 15% of those patients will have an atrial septal defect. So it's actually fairly common.
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Dr. Smith: How do these patients feel? I mean, what is it that brings them into the – to the care of the physician?
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Dr. Waight: Most of the patients with atrial septal defects may not notice any problems whatsoever or similar to Desiree's case. She didn't know she had any problem for a long time. Most of the children are actually diagnosed – again, similar to Miss Lee – they have a murmur, an abnormal heart sound when their pediatrician or their family doctor listens to their chest and listens to their heart. That murmur can be a number of different things, but with an atrial septal defect, it's fairly typical type of murmur that you hear with an atrial septal defect. Different than murmurs you hear that are normal murmurs or murmurs from other types of holes in the heart.
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Dr. Smith: Desiree, in retrospect, after you had this diagnosed, did you – were you aware of any symptoms that you may have had leading up to this?
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Lee: Well, not in general because I guess I've always had it, and I didn't feel anything out of the abnormal because I didn't really know what was normal and abnormal when I had this. But since I've actually had the procedure, I have noticed changes.
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Dr. Smith: So things that you might have – now that you – things have – the hole is closed, you notice – you might have in retrospect noticed that you were having symptoms.
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Lee: Correct.
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Dr. Smith: David, are there any other things that the patients with A.S.D.s experience?
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Dr. Waight: In childhood, they sometimes will have problems with a lot of respiratory infections, where they get colds that last longer than usual or more severe than they would be in people that don't have any heart problems. Rarely, there will be a child who doesn't grow well or has problems with exercise when they're younger. When children get in their teen years, they may be able to exercise quite as well as their – their friends or the other children on their sports teams. So they have what we call exercise intolerance or mild exercise intolerance. Occasionally, people will have abnormal heart rhythms. That becomes more frequent when they get in their 20s and 30s, and rarely, small number of individuals, they can develop something called pulmonary hypertension where they have severe problems with their lungs and they have very high pressures in their lungs. And that can be a potentially fatal complication.
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Dr. Smith: John, you take care of adult patients with congenital heart disease. If somebody has gone throughout their life without this diagnosis, what is the natural history of this problem? What happens to these people as they – as they get older.
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Dr. Lane: In other words, somebody's had an A.S.D. their whole life that hasn't been diagnosed and hasn't been recognized? Well, the majority of people actually remain quite well well into adulthood, into their 20s and 30s, and they're still actually going pretty well. If the defect is left uncorrected for years beyond that, that's what you start to develop more problems. You can have problems with the right ventricle, which is the pumping chamber that pumps the blood to the lungs, becoming overloaded and becoming dysfunctional, and you can develop congestive heart failure, pulmonary hypertension is kind of, typically, a late adverse outcome –
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Dr. Smith: And, thankfully, rare.
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Dr. Lane: And very rare.
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Dr. Smith: As a surgeon, I'm always faced with the situation in discussion matters with families about their children who have to have an A.S.D. closed, what it is that happens if this problem is left unchecked, and what I tell them is basically that we know from past studies that children with A.S.D.s who haven't had this – their defects fixed have a measurably shorter lifespan, living into their fifth decade and perhaps into the sixth as opposed to living into their seventh or eights, and this is an important factor. David, it is very important to convey to our audience that there are different types of A.S.D.s. Although it's a hole in the intra-atrial septum, there are different kinds. Perhaps you could expand on that.
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Dr. Waight: There are four types, three of which are more common, one of which is relatively uncommon. The most common types are the secundum A.S.D., which is about 60% of atrial septal defects. We've got a model here, and I can kind of show you a brief picture of the heart that will give you an idea of how the blood flows. Now, normally, the blood flows down from your head and your neck and drains into the right side of their heart through a vessel here called the superior vena cava, flows into the right atrium here through a valve down n the right pumping chamber here and then out through a valve that isn't on this model, and goes out to the lungs. Fills it up with oxygen, comes back into the left atrium. It sits kind of on the left side and in the back of the heart, collects in this chamber. It goes through a lower chamber to the pumping chamber on the left side, and that gets pumped out through a valve that, again, you don't see on this model out to the body. The body uses up the oxygen. It comes back in to the vein up here and the vein over here into the right side.
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Dr. Smith: And exactly where is the hole?
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Dr. Waight: The atrial septum is this membrane that separates the two upper chambers of the heart, and the hole is right in the middle of the atrial septum for a secundum A.S.D. The other defect are either higher or lower in the septum, and we can demonstrate some slides that actually have pictures of them. The first slide is of a secundum atrial septal defect, or a defect in the middle part of the septum. That type of defect is the one that's most amenable to closure in the cath lab with the trans-catheter technique. It's also, as I said, the most common one. So about 60% of the patients with A.S.D. are potential candidates for having it closed in the cath lab. The next most common one is called a primum atrial septal defect, which is at the bottom of the septum close to the valves that you kind of saw on the model there. That defect requires surgical closure. The third-most-common one is called a sinus venosus atrial septal defect. This is at the top of the heart near where the veins drain back from the lungs, and it's also associated with one of the veins being

abnormal and coming back more to the right side of the heart than the left side if the heart. This one requires surgery for closure and to correct the way that blood flows back into the heart. The fourth type is called a coronary sinus atrial septal defect, which is very rare.
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Dr. Smith: The – again, to emphasis this, the reason for identifying the different types is because it determines which – which approach we wind up having to take in order to – in order to close the A.S.D. Desiree, if I can ask you a question, how did you feel when you were – when you were told that you had a hole in your heart?
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Lee: Well, I was really depressed because the first thing that comes to your mind is, "Am I dying?" Because I know that, you know, you need your heart to live with, and I'm thinking a hole in my heart – is this going to kill me or, you know, I have a child to raise, and, you know, I was really depressed, but after speaking with Dr. Lane, he rest assured me that the hole could be repaired and with minimal side effects and that I could be out of the hospital in a day. And I felt really good about that. So after talking with Dr. Lane, I felt like this could be corrected.
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Dr. Smith: Making the right diagnosis is very important. John, maybe you can comment on how it is – how it is that we go about identifying the problem. How do we make the diagnosis?
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Dr. Lane: Typically the suspicion that an atrial septal defect or any type of heart defect is there is – is when you hear a heart murmur on a physical exam. A heart murmur is basically just an extra sound that you hear, and many things cause heart murmurs, atrial septal defects being just one of them. But that typically initiates a process whereby the heart is evaluated, and typically, the evaluation is a physical exam, an E.K.G., and an echocardiogram. Echocardiogram is an ultrasound of the heart, and that's really the best way to diagnose an atrial septal defect.
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Dr. Smith: Now, there are different kinds of ultrasound, and we've already referred to one, the one that Miss Lee underwent, but how are they use across different type patient – or across patient populations?
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Dr. Lane: Well, the most common type of echocardiogram is a trans-thoracic echocardiogram, and that's basically when the pictures are taken from the outside of the chest, and that's, you know, very easy to perform. It doesn't require any sedation of any kind of special preparations. Trans-thoracic echocardiograms are really idea for children, and we get, typically, very good images and can make the diagnosis, and that, typically, is all you need to do as far as the diagnostic workup. Adults are sometimes different. The adult echocardiographic images tend to not be quite as clear as what they are in children. And another test is called a trans-esophageal echo. This is something that Desiree mentioned. And this is a test that involves putting an ultrasound proud into the esophagus. The esophagus is the tube that connects, basically, the mouth to the stomach, and this runs right behind the heart, and it allows nice, clear ultrasound pictures of the heart. And so that's typically a test that is needed in an adult patient to confirm the diagnosis or to better characterize the defect.
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Dr. Smith: Desiree, you had a trans-esophageal echo done. Did you have anesthesia for that?
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Lee: Yeah, actually, I had what they call a twilight, so I do remember when they were putting a tube down in my throat, but I don't really remember anything after the tube went down, and it was really painless. So it was an easy procedure for me.
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Dr. Smith: So for children, this isn't usually necessary, but sometimes children don't co-operate. David, what are – what options do we have for a 3-year-old who doesn't want to hold still for the brief period of time needed to do the echo?
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Waight: Generally, for the echocardiogram, the technicians here at Akron Children's Hospital will deal with children who are – from very cooperative to extremely uncooperative. Typically, even in the uncooperative child, through methods of calming them down and dealing with their parents and the child himself, we can usually get the pictures. If it's impossible to get the images that we need, we can do a sedated echocardiogram. We'll give them some medicine so they get kind of sleepy, and essentially, they go to sleep, and then we get the pictures that we need. That's probably much less than one percent of the echocardiograms that we do on children.
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Dr. Smith: Is there any role for cardiac catheterization in the diagnosis of atrial septal defect?
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Dr. Waight: Cardiac catheterization is not needed for the diagnosis of atrial septal defect. It's only used to treat A.S.D.s and to close them.
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Dr. Smith: John, maybe you could comment. In adult patient populations, sometimes cardiac caths are performed for other reasons.
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Dr. Lane: Yeah, cardiac catheterization is done typically in the adult population to evaluate for coronary artery disease, which is basically blockages in the coronary arteries, and these are what cause heart attacks. So in some cases, as part of the diagnostic workup and evaluation of the heart –
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Dr. Smith: With a patient with an A.S.D.
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Dr. Lane: In a patient with an A.S.D., you may desire to do an evaluation of the coronary arteries, particularly if you're contemplating sending the patient for open-heart surgery. It's important to kind of know what you're dealing with before having a patient undergo surgery.
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Dr. Smith: David, one of the important things that we have to address with patients who are going to undergo a procedure, what's the indication for having the procedure. Why are we as physicians recommending to them that they have something done? In this case, what's the indication for closing an A.S.D.?
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Dr. Waight: The indication for closure of atrial septal defect is the presence of an A.S.D. that causes extra blood flow to the right side of the heart that's significant enough to enlarge the right side of the heart, and that's something that you can detect by the echocardiogram. You can get an indication sometimes from the electrocardiogram or the E.K.G. that's done, but the echocardiogram can actually measure it, and you can tell whether it's enlarged or not. Because of the risk of long-term problems, anyone who that has an A.S.D. that causes enlargement of the right side of the heart should have their A.S.D. closed.
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Dr. Smith: We have a non – or minimally invasive approach using the trans-catheter device closure, but what we'd like to do now is show the audience a bit about how we do this. David, you have a model here. Perhaps you can –
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Dr. Waight: I have this model that I demonstrated a few minutes ago supplied by the A.G.A. medical corporation that actually manufactures the devices that we use to close the atrial septal defects. The device is called the Amplatzer Septal Occluder. This is what the device looks like. It is a mesh of wires. They're nitinol wires, which is a nickel-titanium alloy. The device is formed in various sizes. This is a 15-millimeter device, which means the middle of the device, what we call the waist of the device, is 15 millimeters in size. There's a larger disc that goes in the left atrial side, and another one that goes in the right atrial side. Now, these are manufactured in various sizes, from 4 millimeters, which is very small for a very small A.S.D., up to 38 millimeters for a very large A.S.D. And this one is one the larger size of the small ones. It's 15 millimeters. Here's our model again. It shows the atrial septal defect right there. We do the cardiac catheterization, where we look at the heart, measure the pressure in the heart, measure the oxygen levels in the heart, and you'll see this all in the video, and then we cross the atrial septal defect and put the device in place. The device itself is screwed onto a delivery cable. The cable screws into the device. Make sure it's in good position. Attach it to the device. Make sure it's firmly on there. This is the shortened version for the demonstration of the catheter that we use to place the device inside the heart. The cable that's attached to the device is through the delivery cable or the delivery sheath. You pull back on the cable and it collapses the device inside the device. Now, a separate sheath similar to this one has been already placed through the vein in the leg, up into the right atrium, across the atrial septal defect into the left atrium. We're looking at this two different ways. We're looking at it with an X-ray image, which we call a cineangiogram, and also looking at it with the echocardiographic image, the echocardiogram, and that echo can be obtained a couple of different ways, and we'll talk about that in a minute. Once it's in position, we open up the left atrial disc, opens up in the left atrial side, and pull the whole system back to the atrial septum. Then bring the sheath back, which allows the right atrial disc to open. Put that against the septum. We push it a little bit, pull it a little bit, make sure it's in good position, evaluate both with the X-ray images and the ultrasound when it's shown to be in good position, and it closes the A.S.D. When we twist the cable, it releases the device from the delivery cable, then we pull the sheath back out through the femoral vein. That device occludes the hole with both the wires, and there's a mesh of fabric in there that causes the blood to form a little blood clot inside that that closes the hole, and then over the course of several weeks to a few months, the whole device gets layered with a normal layer of cells that are called epithelial cells, which line the inside of all the vessels and the inside of your heart. So in three to six months, it looks like normal tissue.
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Dr. Smith: We'd like to share with the audience now an actual example of one of these procedures being performed.
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Dr. Waight: The video images that you're going to see are from a 14-year-old who wanted to be completely asleep for the procedure. So he got general anesthesia. Here you see Dr. Lane placing the trans-esophageal echo probe down into the – can you freeze this? This is the image of the echocardiogram. The left atrium is up here. The right atrium is down here. They're measuring the atrial septal defect in this child, which was about 11 millimeters. We're now placing a small needle into the hip right over that vein. We find the vein, put a wire through the vein, put this device here, which is called a sheath into that vein, and then we can pass the catheter in

and out through this short sheath. There's the catheter. This catheter is used to measure the pressure inside the heart and to obtain small blood samples, which you see me doing there. That'll give us an idea of how much extra blood flow flows from the left atrium back over to the right side of the heart. Typical patient with an atrial septal defect has about 1 ½ to 3 to 4 times as much blood flow to their lungs as they have going out to their body, which limits their ability to increase their cardiac output or how much flow they have to their body when they exercise or they're under stress.
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Dr. Smith: And these samples allow you to determine that amount of extra blood.
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Dr. Waight: We measure that. The other thing we measure is pressure inside the heart. This is a catheter that is now in the right pumping chamber of the heart. Measure the pressure when it's relaxed and then when it squeezes and the pressure goes up what's called systolly. That's a normal pressure. Each one of these little marks is 4 millimeters of mercury. So that's a pressure of about 24 millimeters of mercury in the right ventricle, which is normal pressure. Then we pull the catheter back from the right pumping chamber to the right atrium, which is the receiving chamber at the top of the heart, and that pressure becomes very low, falls down to about 1 millimeter of mercury, which is normal. Then we can turn the catheter and push, and pushes across into the left atrium, and there you can see the pressure wave changed. Now the pressure is in the left atrium. And this whole procedure takes just a few minutes to do. We measure the oxygen level in the left atrium, which is why our pressure tracing goes away, and then the pressure tracing comes back. And now we've manipulated the catheter now into the left pumping chamber. It goes through the atrial septal defect in the left atrium and down into the left ventricle, and here's the pressure in the left ventricle, which is similar to what your blood pressure is going to be, at least from the top number, and the blood pressure here in the ventricle is 116. We pull it back into the atrium. Down here, you can see what the actual blood pressure is on one of the arms measured by a typical blood-pressure cuff, and the difference was here, 117 to 113 – no gradient or no pressure change from the pumping chamber out to the vessels to the body. So we can determine whether there's any abnormalities on the left side of the heart just going through the right side. Now we pull the catheter back through the left pumping – left atrium into the right atrium. Here, we're preparing for an angiogram, which is a picture inside the heart showing where the blood goes – manipulate a catheter where we want it here in the left vein. Stop this? Perfect. This catheter comes up through the vein into the right atrium, sits about here. The whole heart is here. It goes across the atrial septum, which is outlined right here.
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Dr. Smith: It's going right through the defect.
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Dr. Waight: It's going through the defect, and then we manipulate it up into the vein that's coming back from the right upper lobe of the lung. The dark stuff you see is the contrast. It mixes with the blood, goes wherever the blood goes. So this is the vein, comes back into the left atrium, which is here, and as soon as they start to play this again, you'll see of it come across here coming across the atrial septum. The rest of it goes down to the pumping chamber and out through this vessel that goes out to the body. Go ahead and let that play. You see the atrial septal defect is right about – it's actually right about there. Plays another time, and you can see that squirt coming across there is actually the shunt from the left atrium to the right atrium.
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Dr. Smith: Now, the angiographic picture also gives you an orientation of the septum so you understand it in three dimensions then?
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Dr. Waight: Right, so we have an image of the atrial septum in this plane so we know. We manipulate the actual cameras that we're looking at this with into a typical angle that we expect for this, and then we can look at it, and you see the hole right there. And the catheter goes through that hole, and the actual blood flow is coming across there. So we have both this image to look at and then the image from the ultrasound to both position the catheters and the device. Now we move the catheter in across the atrial septum, going up into the vein coming back from the left upper lobe of the lung. Now it's being – moving it around till they get to the right position. Once it's in the right position, we put a wire through that catheter. It goes out into that vein back from the left upper lung, sits inside the vessel, and we use that wire to direct the other catheters. First we're going to place a balloon catheter to measure the size of the atrial septal defect, and then we put what's called the delivery sheath that we actually put the device through that you saw in the demonstration with the model. The wire just slides through that catheter. It's positioned up here in this vein, comes back into the left side of the heart here and across the atrial septum and back down through the vein in the leg. The next thing you'll see is the sizing balloon. This is a very low-pressure balloon. It doesn't make things bigger. It just basically conforms to the size of the atrial septal defect. We slowly inject fluid in there until we block off all the flow. So there's a little bit of flow through the atrial septal defect in this ultrasound. Now I've inflated the balloon a little bit more. The flow essentially goes away. Once the flow goes away and there's no more shunt or no more blood flow through the atrial septal defect, then we can measure the size of the balloon. That gives us what's called the stretched size of the atrial septal defect or balloon size of the atrial septal defect. Here you can see a nice demonstration of the balloon inflated. The distance between there and there, which we call the waist similar to the waist on the human body, we measure that, and that's the size of the atrial –
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Dr. Smith: And that's what allows you to choose the size of the device that you want.
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Dr. Waight: We choose the size of the device to be the same size up to 1 to 2 millimeters larger than the actual measured size of the atrial septal defect. We measure this two ways. We measure it with the ultrasound, and we measure it with the echocardio—or the angiographic images. So we have two ways of measuring it, and we can correlate those two to make sure that they are the same size or close to the same size. Here's the setup with the long sheath. This is the catheter that's going to go across the atrial septal defect, over that wire. That was the delivery cable. There's the device. This is an 11-millimeter device. And the devices have a shaped memory property. So you can manipulate them, bend them, do just about anything to them short of cut them, and when you let go of them, they go back to the same size, which makes them perfect devices for going across the atrial septum through a small catheter and then having them enlarge and fill the defect. Here's the wire again that we're going to put the long delivery sheath over tat wire. And that goes through the same hole in the femoral vein in the leg. That slides up inside the heart. Just a little gentle pressure. Now we're loading the device into this little short piece of tubing which is called the loader. Once it's inside there, then we flush it with saline or salt water to make sure there's no bubbles inside there. Flush it back this way and then flush it forward. Once I'm sure that there's no bubbles in there so no bubbles can get inside the body, then we put it inside the sheath, which is across the atrial septum and advance it up through that catheter. This whole thing is

approximately 2 ½ to 3 millimeters wide. So it's actually very small. This is the trans-esophageal echo probe that's getting the ultrasound images.
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Dr. Smith: So you're using both x-ray images and ultrasound images to help guide you.
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Dr. Waight: This is the left atrial disc opening. Now we pull it back to the atrial septum here in just a second and… We're looking at this both ways; I'm pulling back to the atrial septum now, and I can see it up against the atrial septum, and now I'm going to pull the sheath back, which allows the right atrial disc to open and then the right atrial disc moves up to the septum to close the atrial septum defect. Now this is the same thing looped again, and here's the echocardiographic image. You're seeing -- The left atrium is up here, the left atrial disc of the device is there, right atrial disc is on this side, atrial septum comes in between it. You can -- Dr. Lane is manipulating the probe to try to get a good view of this, and there's a very nice view of the atrial septum coming to the middle of the device and coming out the other side of the device, the right atrial disc is here and the left atrial disc is there. Here's the delivery cable still attached to the device. If we don't like the position of the device, it's not perfect, we can pull it back, reposition it, put it back in. If it's the wrong-sized device for whatever reason, we can take it out and put a different one in. once we're sure that it's in good position -- And we do that by both looking at the device, looking at the atrial septum, looking at the veins coming back from the lungs -- this is one of the pulmonary veins coming back from the right side of the lung -- looking at the valves inside the heart to make sure that the device isn't so large that it's actually touching the valves, causing them to leak or causing any other abnormalities of the valves. There's the aortic valve, the valve that separates the pumping chamber from the body. This is the mitral valve that separates the left atrium from the pumping chamber on the left side, and that valve doesn't have any leak. You can tell that by looking at the way the color shows the way the blood flows. And this is the right-sided valve, or the tricuspid valve, that separates the right atrium from the right pumping chamber and the right ventricle, and that looks fine, so we determined it was in good position and we twist the delivery cable off, it stays in position across the atrial septum right behind the transesophageal probe. And then we look at it again after it's been released, and there's a trivial amount of flow still through the device in the first two minutes, and then usually over the course of 24 hours, that closes completely. Occasionally, it takes more than 24 hours for it to be blocked off completely, but most of the patients that have this device in have complete closure by about a month or two afterwards. This is a final picture injecting contrast in the right atrium with the device in position across the atrial septum. And you see it fill the right atrium here, and it fills the right side of the device, goes through the right pumping chamber out to the lungs, comes back and fills the left atrium here and fills the left atrial portion of the device but doesn't sc-- come back across the atrial septum in enough that you can see it. The ultrasound is very sensitive and it can detect just very small amounts of blood coming back across there. The procedure takes usually less than an hour; most of the procedures are 45 minutes or so from the time that we place the catheter until we take the catheter back out. I think Ms. Lee's procedure was, I think, 35 minutes. It's actually pretty short.
00:34:18
Dr. Smith: Desiree, maybe you could relate to our audience what your experience was like actually while the procedure was going on.
00:34:25

Lee: Actually, when I first went into the -- the room to have the procedure done, I was awoke and talking to the staff and everyone was really nice and after the anesthesiologist came along, I kind of don't remember anything after that until the actual procedure was over. And it -- it was just like I wasn't ever asleep. You know, I woke up and I start talking to him, and they actually told me that I wasn't asleep, but I don't really remember anything, and there was no pain or -- It just felt like I had went to sleep for a little while and woke up and everything was fine.
00:35:05
Dr. Smith: How long were you in the hospital?
00:35:08
Lee: I actually only stayed 24 hours. The procedure -- After the procedure was over, I had to actually lay flat for a few hours, and then after that, I could actually get up and walk around and I felt fine.
00:35:25
Dr. Smith: David, how long have -- has this procedure been around?
00:35:30
Dr. Waight: Well, the catheter method of closing the atrial septal defect was first used, you know, decades ago. The device that was used was a very large device, went through a catheter that's bigger than your finger, which was dangerous to the vein in the leg. And it wasn't well-received, and it didn't work very well, so there have been several devices that have been designed to try to improve on that in different methods. The device that we use is the AMPLATZER septal occluder, which has been in use for over eight years, but has been approved by the Food and Drug Administration, the F.D.A. in America, for use for approximately five years. It is the only device that's approved for A.S.D. closure in the United States.
00:36:10
Dr. Smith: This is -- This is not an experimental procedure, is it?
00:36:13
Dr. Waight: No, it's not. It's very commonly used -- The estimates are there's between 50 and 80,000 people worldwide who have had this device placed.
00:36:24
Dr. Smith: John, what do you advise your patients about the potential complications associated with this -- with this procedure?
00:36:31
Dr. Lane: Well, the procedure itself seems to be very safe, and I really try to stress that, although we have to mention the possible complications. Bleeding is probably the most likely complication, but in most cases that can be controlled with just fair-- fairly simple measures.
00:36:47
Dr. Smith: Bleeding from where?
00:36:48
Dr. Lane: From the leg site, typically, where the catheter goes in.
00:36:50
Dr. Smith: Are there any precautions that you take in providing care to the patients after the procedure to prevent that?
00:36:55
Dr. Lane: We keep them in bed for at least six hours, and we try to minimize any movement. The leg basically has to heal. There's a little -- a little blood clot that forms to block off the hole in the vein, and any movement or -- or, you know, activity could potentially pop off that clot, so we try to minimize activity. They have a tight dressing on that applies some pressure, so that helps to prevent bleeding problems. In most cases, even if it does bleed, it's easily controlled just with some manual or hand pressure applied to the site.

00:37:34
Dr. Smith: Desiree, how long before you were back up and around on your feet?
00:37:38
Lee: Same day, actually. After the six hours was over with, I was raring to get up out of the bed and there was a little soreness, but nothing out of the ordinary that I couldn't walk or anything. I actually got up and walked around a little bit afterwards. Not a whole lot because Dr. Lane didn't allow that, but just enough to move around and make sure everything was okay.
00:38:08
Dr. Smith: David, what are the reported risks that we -- that have to be considered?
00:38:15
Dr. Waight: The risk of the procedure itself is -- Bleeding is a small risk, and usually if it does cause a problem, it's at the site where the catheter goes in. You can get a bruise, and a bruise hurts. So although it doesn't cause serious problems, it's uncomfortable. That's a very low incidence, and it has more to do with whether people get up and move around early or try to do too much too soon. Usually don't let them go back to normal activity until the day after the go home, which is the next day. During the procedure, there's a risk of an abnormal heart rhythm; putting something inside the atrial septum can cause an arrhythmia or an abnormal heart rhythm. That can happen. It's uncommon, but it's usually something that's easily treated if it does happen. There's a risk of the device moving or going from its normal position across the atrial septum and doing something called embolization, where it moves either out to the lungs or out to the body. We have never seen that complication here at Akron Children's Hospital, but it's something that has happened to someone somewhere sometime. So when I talk to people, I say that that's a possibility. There's a risk of blood clot -- blood clots forming on the device itself, so everybody is treated with aspirin for six months after we've placed the device to help prevent any large blood clots from forming.
00:39:25
Dr. Smith: And that's just a baby aspirin?
00:39:27
Dr. Waight: For most children it's a baby aspirin, for adults it's either a baby aspirin or a regular 325 mg aspirin. And worldwide, the incidence of blood clots forming on this device is extremely low.
00:39:41
Dr. Smith: Desiree, how long before you were back to work?
00:39:45
Lee: Actually, I had took the week off, and I'm going to say it was about five days after I actually did go back to work. But after the procedure, the day that I went home, I actually felt like, you know, I hadn't even had a surgery, so I could've went back to work, but I took vacation.
00:40:10
Dr. Smith: We have an e-mail question that -- from one of our viewers. The question is: My 5-year-old has a heart murmur. Does he have an A.S.D.? John?
00:40:22
Dr. Lane: It's possible. Heart murmurs can be caused by a lot of different things and generally need to be evaluated. A.S.D.s are one of the things that cause a heart murmur, but there are other types of heart defects that can cause heart murmurs. Many heart murmurs in children are perfectly normal, so --
00:40:41
Dr. Smith: And how do you tell the difference? Desiree had a heart murmur which somebody said she'd grow out of, but that didn't happen. How do you tell the difference between something that's important and something that's innocent?

00:40:52
Dr. Lane: Well, that's our job. That's one of the things that we do as pediatric and adult congenital cardiologists is to try to define what's abnormal and what the abnormality is. So it's not always obvious. In some cases, it's -- it's unrecognized, and, you know, Desiree's a good example of that.
00:41:12
Dr. Smith: We have another question from a viewer: I'm 46 years old. Can I really come to a children's hospital for this procedure?
00:41:21
Dr. Lane: I guess that question's directed to me. In fact, we are, at Akron Children's Hospital, are not in the business of taking care of adult heart disease, but we take care of adults with a congenital heart disease, so we take care of a specific subset of adults, and adults with congenital heart disease have a lot of things in common with children with congenital heart disease, so we think it's -- it's kind of a natural association to take care of both of these types of patients.
00:41:49
Dr. Smith: David -- How -- Is there such a thing as a hole that's just too big?
00:41:56
Dr. Waight: Yeah. That's actually possible. We've had some patients who have been referred to us with an A.S.D. -- One of our other cardiologists, that's diagnosed an A.S.D., and they come to me and they say, you know, "David, can you close this A.S.D. in the cath lab?" And I can look at that and say, "Yes, that's one that should be relatively easy to close in the cath lab" or if it's a very large defect, I may say, "No, there's no way I can close that in the cath lab because the device that would be needed to close it is bigger than the atrial septum is that can hold it. As you saw in the image of the actual device itself, there's -- The discs on either side are larger than the middle of it, which is the size of the A.S.D., so occasionally a patient will have a more -- an A.S.D. that's too large to close, and I refer them to you and Dr. Spector to have it closed in the operating room.
00:42:45
Dr. Smith: Perhaps we could talk about the issues related to surgery and intervention. Either as competing options or complementary options. We work closely together in a collaborative way, and, David, you commented that we -- we set things up in a way that assures that -- that irrespective of whether it's done with a device or with surgery, that it's taken care of. Perhaps you can elaborate on that a bit.
00:43:18
Dr. Waight: I think this is one of the -- the most important thing that we do here at Akron Children's Hospital is to find the best way to treat the patient with congenital heart disease. It's not an option of "if I can do this, I should do this," it's an option of what's best for the patient. So a patient with an A.S.D. is fairly typical. We will look at their ultrasound, talk to their cardiologist, determine what's best for the patient, what's best for the family, what the family's choice is. If it's an A.S.D. that can be closed in the cath lab, I can say that, in our practice, all the cardiologists refer those patients for closure in the cath lab, and we present that patient at a group conference where the surgeons, the cardiologists, and anybody else who's interested in the care of these patients gets together and talks about that patient. Typically they go straight to the cath lab and have that done at a time that's convenient for the family. If it's an A.S.D. that's larger and it's unclear whether, when we do the balloon sizing or do another imaging study like a transesophageal echo, that we will determine that the A.S.D. is too large to be closed in the cath lab, we arrange things in advance so that when the patient comes to the cath lab, usually we'll start with the transesophageal echocardiogram, and these are usually children that have fairly large A.S.D.s, so they're going to want to be asleep or their family wants them to

have general anesthesia so they're completely asleep. We do the transesophageal echocardiogram; if the A.S.D. is too large, we can actually just stop the procedure, we don't put any catheters in, we don't do anything to the patient that's -- that's uncomfortable or causes any damage. They move across the hall to the operating room, about 25 feet, and they go ahead and have their atrial septal defect closed surgically at that time.
00:44:59
Dr. Smith: And when we -- we had the opportunity to design the -- the cath lab and the operating room, we purposely put them next to each other in the event that this sort of thing happens so that the -- the logistics associated with moving the patient are really quite minimal. Another question from a viewer: How many times -- the viewer asks -- How many times does a surgeon have to do this procedure to become proficient. I'm going to -- I'm going to assume they meant the interventional cardiologist. What process did you go through to learn this, and what are your thoughts about how many you have to have done in order to be proficient at it?
00:45:37
Dr. Waight: Officially, you have to be trained by a proctor from the A.G.A. Medical Corporation, and that involves working with someone who has done a lot of these, and there's a list of proctors across the country who have a big experience. And demonstrate that you both understand what's going on and understand how to do that before the company will even sell you the device or sell your hospital the devices to put in A.S.D.s. Typically, the people that do them are mainly pediatric cardiologists who have experience doing cardiac catheterization in children in the hundreds and thousands. In my experience, I worked at an institution that was part of the process to investigate this device before it was approved by the F.D.A., gathered all the data from the United States and helped put that together for a presentation at the F.D.A. before it was approved, so I actually started doing this back when it first came out. And, you know, have done greater than 300, 350 of these now, so I have a fairly large experience.
00:46:38
Dr. Smith: Next question from a viewer: Is there any need for anticoagulation therapy after the procedure? You did refer to the aspirin as -- but a perhaps the viewer's questioning about anything beyond that.
00:46:51
Dr. Waight: If there's another reason for a patient to need anticoagulation, they have a blood-clotting disorder or something else, then they can be treated with anticoagulation, but we do not give anticoagulation for just an A.S.D. device closure. We use aspirin, which is an anti-platelet agent, stops your platelets from working. Similar to anticoagulation, it's kind of a form of that, but not the type that typically causes bleeding or significant trauma bleeding from -- from -- basic trauma of childhood or normal activity. It doesn't cause those problems.
00:47:25
Dr. Smith: I think we should probably discuss the -- the issues in comparing surgery versus the transcatheter closure device, and I'm -- I certainly can speak to the matters related to -- to the surgical approach. Surgical closure of atrial septal defects has been something that's been done for decades, and it -- it stands as the gold standard for what needs to be accomplished in -- in A.S.D. closure irrespective of whether it's done by surgery or with a device. It is a procedure that is very safe, but in contrast to the minimally invasive aspects of what's done with the transcatheter approach, this does require a big surgical incision. In that case, it al-- In this case, it also requires the use of cardiopulmonary bypass, and -- and the use of a heart-lung machine. And the recovery is -- is quite a bit different. Typically, children and young adults undergoing AS-- surgical A.S.D. closure spend about two to three days in the

hospital, but the recovery can be a couple of weeks, and certainly the breastbone healing up can take anywhere from six to eight weeks depending on the age group. We -- We are -- The -- the safety and efficacy of surgical closure has been well-established, the mortality rates associated with A.S.D. closure are -- are certainly at very -- very low, certainly way less -- or far less than 1%. There have been series that have reported literally thousands of children that have undergone A.S.D. closure safely, and the complication rates typically are in the 1 to -- well, 1 to 2. -- 1 to 3% range. But the -- Certainly the -- For those select patients with sinus vinosus A.S.D.s primum atrial septal defects, coronary sinus atrial septal defects, or very, very large A.S.D.s, this is still the option that -- that -- that we have in place. Perhaps we could show the results of -- from Akron Children's Hospital -- for device closure and compare them with the results for surgery.
00:49:53
Dr. Waight: At Akron Children's Hospital since 2001, since the cath lab was first opened, there have been 84 patients who have had A.S.D. occlusion in the cath lab. The age range varies a lot. Most of our patients are, if they're children, are done between 5 and 8 years of age. The adults are done at presentation; whenever they have their diagnosis made, they can be done any time. The age range is from 3 to 89 years of age for any type of atrial septal defect. The typically older patients are Dr. Lane's patients, who actually have a different type of atrial septal defect known as a patent foramen ovale, and that's -- the indication for closure is different than for a typical A.S.D. that causes an enlarged right heart. The average hospital day is less than -- Or the average hospital stay is less than one day. Typically patients come in, they have their procedure, they stay overnight, they get a chest x-ray in the morning, they get an ultrasound in the morning, another echocardiogram, and they're home before noon the next day. We've had four patients who have been considered for A.S.D. occlusion in the cath lab who went on to have surgical closure. One of those patients had an attempt at an A.S.D. closure and the device could not be properly or safely positioned in the atrial septum, and took the catheter out and moved that patient over to the -- to the operating room, where it was surgically closed without any problems. Two patients were evaluated with a transesophageal echocardiogram and their A.S.D. was too large for a device that would safely close the atrial septal defect without causing any problems. An additional patient had a procedure started but we put the balloon sizing in for what looked like a fairly small defect, it turned out to be a defect that instead of being, you know, fairly round, was actually a long, oval in -- it was short this way, but very large this way, and when we did the balloon sizing, it came to be a very large A.S.D.. That's obviously an exaggeration, but it was too large to be closed with the device. So we've had four patients that converted to surgery.
00:52:03
Dr. Smith: We -- We had an opportunity, obviously, in each one of these four cases, to look at the atrial septal defect because eventually it was closed with an open operation, and in each case, it -- it -- the assessment was proven correct. This would have been something that would not have been amenable to closure with the device, and importantly, there were not efforts to try to make something work where -- where perhaps might have been unsafe. John, maybe you can comment about performing procedures like this on -- on octogenarians.
00:52:39
Dr. Lane: Yeah. We have a fair number of adults who get referred for P.F.O. P.F.O. is a small opening in the atrial septum or a potential opening, and in some cases, this is a risk factor for stroke. A subset of people with P.F.O.s actually have what is probably a good indication to close the defect, and that is if they've had a stroke or

recurrent stroke, and in particular, if they've failed conventional medical therapy. So -- so we do offer P.F.O. closure in addition to atrial septal defect closure.
00:53:18
Dr. Smith: And as indicated on the slide, there has been 100% survival associated with this. The minor complication rate at less than 1.5%, and long-term complication rate at 0%. David, what kind of long-term follow-up is required for these patients with a device?
00:53:34
Dr. Waight: The patients are, as I said, evaluated the following day after their procedure. They are typically seen again sometime in the first six months and then again at a year of -- a year post-procedure. At that point, if their A.S.D. is completely closed, they're not followed after that point.
00:53:53
Dr. Smith: Perhaps we can move to the next slide comparing the surgical outcomes. Just by way of reference, for the same time period, those patients undergoing surg-- the open surgical procedure were roughly the same: 79 patients. They aged in ran-- or ranged in age from 3 months to 39 years. And again, these are the patients that had the types of A.S.D.s that were not amenable to a device closure. The average hospital stay, as you might expect, was 2.4 days, longer to recover from the -- the -- the more extensive surgery. There's 100% patient survival and a minor complication rate of less than 2.5%. I have a couple of other questions from -- from viewers. Here's one: I train a lot. I assume this must be "exercise a lot." When can I go back to normal training after A.S.D. device closure?
00:54:47
Dr. Waight: We typically tell patients to, as we said, the day they go home to take it easy, the next day to take it fairly easy, after that they can go back to work or back to school. We ask them not to do vigorous exercise for at least a week or so and ask them not to do things like power lifting or isometric exercise like wrestling for at least two weeks.
00:55:10
Dr. Smith: Another question from a viewer: My 2-year-old has an A.S.D. and will probably have open-heart because the hole is too large for this procedure. And then she -- parenthetically, she says, "will she die with open-heart?" This case actually illustrates a lot of the issues related to the decision-making between surgeons and -- and interventional cardiologists. I think -- First of all, we can answer the second part of the question first. No, the likelihood of not surviving an open-heart operation for repair of an A.S.D. is infinitesimally small, so your child has a problem that can be fixed.
00:55:46
Dr. Waight: The important way to look at that is, in the group of eight cardiologists and two surgeons, none of us had ever seen any patient who had an A.S.D. surgically closed that did not survive.
00:55:56
Dr. Smith: What about a 2-year-old? Can you -- What are the issues for device closure?
00:56:02
Dr. Waight: For device closure, the main issue is first, does it need to be done now? And since children generally do very well and don't have any significant problems, we generally wait until they're larger; as they grow, their veins grow, their heart grows. The hole itself may not get larger or it may stay the same, it may get a little bit larger. In relation to their heart size, it won't change. If their heart is big enough to allow the device to sit in there and close the A.S.D., that's the most important thing. If they're very small, the catheters or the sheaths we need to put the device in are a

little bit bigger than we like to put in small children unless we absolutely have to. And since they're fine and clinically don't have any problems, we usually wait until they are 5 to 8 years old.
00:56:47
Dr. Smith: And that -- Perhaps that's the critical issue. Clinically, if children are having problems related to the A.S.D., then it has to be closed by whatever ch-- whatever route is -- is safest.
00:57:00
Dr. Waight: And it can be done in small children. We certainly have done it in very small children if they had a medical issue that put them at high risk for surgery. If you can't do it surgically and it's possible to do it in the cath lab, we would go ahead and do it in the cath lab. Whatever is best for the patient is what we want to do.
00:57:19
Dr. Smith: Another question from a viewer: Are they using this procedure at many other hospitals throughout the country?
00:57:26
Dr. Waight: The number of hospitals using transcatheter A.S.D. closure has increased over the last three years. It is primarily done at children's hospitals or hospitals that take care of patients with congenital heart disease. I don't know how many people are doing it. There's about 80 interventional cardiologists for congenital heart disease in North America; at least half of those are probably doing it. And this is somewhat of a guess, but probably 40 or 50 institutions in North America.
00:57:58
Dr. Smith: Another question from a viewer: What's the largest A.S.D. you've closed?
00:58:03
Dr. Waight: Here at Akron Children's Hospital, I think the largest device we've put in is probably 32 or 34 millimeters. The largest one I've ever closed, we put a 38-millimeter device in someone before.
00:58:18
Dr. Smith: I think if I can comment also, one thing that we wanted to emphasize in this broadcast is that it is -- The decision about surgery and -- or intervention is not a -- is not one of competing technologies. They are complementary technologies, and the -- the -- the ability of surgeons and -- and interventional cardiologists to understand that is very important in ultimately being able to choose the therapy that is best for your child. The -- the decision-making has to be made by looking at the objective evidence from echos -- the diagnostic information and then making a decision about whether or not the device as a first line of therapy can be used safely and effectively, and if not, then to -- to use the traditional open-heart surgical procedure. But they are very different modalities for treatment, and obviously we're very much interested in focusing on -- on the transcatheter approach today. Desiree, what would you recommend for -- having gone through this -- to the people in our aud-- listening in our audience? If they -- if they know that they have an A.S.D., what should they do?
00:59:42
Lee: Well, I would advise them to definitely seek a cardiologist. For me, it was a very easy procedure. Being a female, you don't want to have scars, and I don't have a scar, you know, and I felt like I could get up and move around the next day, it didn't -- It was no burden to me or my family that I couldn't, you know, survive or -- For me, it's like the risk factor is very low, and I have noticed changes since --
01:00:19
Dr. Smith: What sort of things have you noticed?
01:00:21

Lee: I've actually had it -- I actually sing in a choir, and the one thing I did notice is that I can hold a note longer than normal. And I really didn't realize that that was going to be a factor, but, you know, just things like that. I can actually walk longer and not feel as tired. I get up around 4:00 in the morning and start my day, and I just -- I just feel healthier. And for me, I would recommend it just, you know, for the low risk factors and it was a good procedure for me, so…
01:01:01
Dr. Smith: Well, we're all very glad to hear that you're -- you're -- things have gotten better for you. We'd like to thank our audience for joining us. I hope that this was informative and helpful to each of you who might be faced with the same sort of decisions that our -- Ms. Lee was faced with, and we want to thank you for joining us today and submitting your questions on -- to the panel on A.S.D. closure. And with that, we'll, on behalf of Dr. Lane, Dr. Waight, myself, and all of those here at Akron Children's Hospital, we want to say thank you and good evening.
01:01:45
Announcer: This has been a look at atrial septal defects in children and adults at Akron Children's Hospital in Akron, Ohio. To obtain more information or to make an appointment or make a referral, please click the button on your screen.

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