

**PARACARDIOSCOPIC EX-MAZE PROCEDURE
HEART INSTITUTE AT FIRSTHEALTH MOORE REGIONAL HOSPITAL
PINEHURST, NORTH CAROLINA
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ANNOUNCER: Welcome to the Heart Institute at FirstHealth Moore Regional Hospital in the world-famous golf resort of Pinehurst, North Carolina. Over the next hour, you'll be able to see a live paracardioscopic Ex-Maze procedure for treatment of atrial fibrillation. You'll also learn how this minimally invasive procedure has evolved with the help of Dr. Andy Kiser and his colleagues. OR-Live makes it easy for you to learn more. Just click on the "Request Information" button on your webcast screen and open the door to informed medical care. Now, let's join the doctors.

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ANDY C. KISER, MD: Good afternoon and welcome to the Heart Institute at FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. I'm Dr. Andy Kiser, Medical Director of the Arrhythmia Center at the FirstHealth Heart Institute. We're pleased to have you here this afternoon to present a case of a paracardioscopic Ex-Maze procedure. With me is Dr. Gerhard Wimmer-Greinecker. He's Professor of Surgery at Frankfurt University and Chief of Cardiac and Thoracic Surgery at Bad Bevensen in Northern Germany. Dr. Wimmer-Greinecker, welcome.

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GERHARD WIMMER-GREINECKER, MD, PhD: Thank you, Dr. Kiser. It's my real pleasure to be here. Thank you.

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ANDY C. KISER, MD: Atrial fibrillation is a disease that affects a lot of people in the United States and across the world. It actually is an arrhythmia that starts in the upper two chambers of the heart. The atria in the top of the heart beat irregularly because of an erratic electrical signal in the heart that causes the atria to quiver. When it quivers, it doesn't empty that blood in the atrium very well and it causes the ventricle to beat irregularly.

If we can go to the slides, you can see an EKG of someone on the top, with the red arrow, who has atrial fibrillation. Notice the steep peak, which is an irregular ventricular response, which means that the pulse is irregular. On the bottom, you can see a distinct small wave that the purple arrow is pointing to, which is a P wave. That means that that patient with the EKG on the bottom has sinus rhythm. If you go to the next slide, you can see that atrial fibrillation is a very debilitating condition. Again, it's an erratic electrical activity in the heart, in the upper two chambers of the heart, that causes a disruption in normal sinus rhythm. Most of the time, atrial fibrillation is caused by structural heart disease: coronary artery disease, mitral valve disease, aortic stenosis. That type of

problem can cause atrial fibrillation. These patients who have atrial fibrillation often have reduced cardiac output and have symptoms like shortness of breath, or lethargy, sometimes chest pain, and most commonly palpitations. The complications with atrial fibrillation include stroke, which is the most debilitating one, and also congestive heart failure. Atrial fibrillation is a disease that affects mostly the older population, someone who's over 65 years of age will have an increased instance of atrial fibrillation, as you can see by the blue bar graphs here in this slide.

Actually, atrial fibrillation can be divided into two different types: the focal atrial fibrillation, which affects about 17 percent of all people with atrial fibrillation, and then a wavelet type of atrial fibrillation, which affects the remaining portion of the population. This is a real problem with people who have atrial fibrillation, because there's about five million people in the United States who have atrial fibrillation, and of that, four million have that wavelet type of atrial fibrillation. In other words, they have more than one focus of atrial fibrillation in their heart. The patients with focal atrial fibrillation have a single area in their heart that stimulates the atrial fibrillation. Oftentimes, that can be treated with sometimes pulmonary vein isolation, or catheter procedures. The wavelet A Fib population is very difficult to treat with that procedure because there are so many locations to cause the atrial fibrillation. The very small portion of atrial fibrillation that are paroxysmal can be treated successfully sometimes with catheters and with clamps.

We go to the next slide, you can see that again the population of people who have atrial fibrillation is about five million, and those people that have non-structural heart disease, in other words, the people who have isolated atrial fibrillation, sometimes have focal atrial fibrillation. That, again, is sometimes treated with medicines or catheters. The population that we're more concerned about today are the patients with structural heart disease and those patients with wavelet atrial fibrillation. These patients have had atrial fibrillation for a long time, sometimes more than two to three years and have very large left atriums. These patients are difficult to treat with simple medications and often times don't have a good treatment opportunity because of their prolonged disease and because of the amount of atrial fibrillation that's in their heart. In the next slide, you can see that of the patients that have atrial fibrillation, over five years about 75 percent of these people will become refractory to drugs, so those people in the blue that responded to drug therapy will move into the more lighter blue area of these patients that really have no good treatment for their atrial fibrillation.

On the next slide, you can see on the bottom left of your screen is a pattern that Dr. Jim Cox first described many years ago. It's called the "Cut and Sew" Ex-Maze procedure, the Maze III procedure. In this the procedure, Dr. Cox describes a pattern that he creates by cutting the heart and then sewing it back together. That pattern that he described has been the gold standard to treat all types of atrial fibrillation, but specifically those with this wavelet type, this chronic type of atrial fibrillation. The Ex-Maze procedure, which we have been working on for quite some time, is a procedure that mimics that pattern that Dr. Cox described many years ago. The difference is this procedure is performed on the surface of the heart. In other words, the heart doesn't have to be stopped. It can be done while the heart is beating, and therefore the risk is somewhat minimized, but it is a very

similar procedure to that that Dr. Cox described many years ago. However, in the pattern you see on the right, that is an open-chest pattern. That's the procedure that we perform when we're doing concomitant procedures. In other words, patients who have that type of procedure, have other types of heart disease that require surgery.

The next slide, you can see how we've compared the pattern with the open-chest Ex-Maze pattern on the left to the minimally invasive paracardioscopic Ex-Maze pattern on the right. This pattern is one that's very similar to, again, the Cox Maze III procedure, but also on the open-chest Maze procedure that you see in this slide. Dr. Wimmer-Greinecker has been involved with this pattern actually since the initiation of the entire development of the procedure. Perhaps you can give us some comments about how we've progressed along the development of the Ex-Maze.

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GERHARD WIMMER-GREINECKER, MD, PhD: Well, it was really interesting to take this procedure from an open-chest procedure to a totally endoscopic procedure and I've been involved in the development of a lot of robotically-enhanced procedures and we created a lot of new procedures. One of those procedures was a totally endoscopic closure of an ASD, and there are a similarities between this procedure and the approach we're talking about now, and it was really fun and it was really interesting to develop the procedure we will be seeing in a minute.

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ANDY C. KISER, MD: If we can go back to the slide, I think we'll show you an animation of the procedure so that you can understand better the way we're talking about doing this procedure. This is actually a video animation of an Ex-Maze procedure done totally endoscopically. The pattern you see goes around the pulmonary veins and then crosses across the left atrium to include both the left and the right pulmonary veins, and again crosses onto the right atrium. The key fact in this procedure is that we treat and put ablation patterns on both the left atrium and the right atrium. That's very important in people who have chronic atrial fibrillation, who are having a stand-alone atrial fibrillation treatment.

If we can go to the video, we'll go to the operating room and actually see an Ex-Maze procedure being performed totally endoscopically. We can see here in the operating room, there are three people at the table, the nurse, the assistant, and the surgeon. I'll begin to mark out on the patient where we'll put the ports to enter the right thorax, the right chest, to do this procedure around the right part of the heart. There are three small incisions made in the right chest to give me direct visualization of the heart. Unique to this procedure is actually an access to the heart, through the abdomen. An incision is made and you can see the direction of a cannula that's positioned to go through the abdomen and then through the diaphragm, into the pericardium. This incision is made and you can see, we can actually feel the heart beating on the diaphragm through this small incision in the abdomen.

With this small incision placed, I place small trocars in the abdomen, much like you would use when you are doing a colesistectomy, minimally invasively. These ports are directly placed over a finger inserted in the abdomen to prevent any chance of injury to

anything inside the abdomen. These ports allow us the ability to use the same instruments one would use if we were going to perform a laparoscopic colesistectomy or any other laparoscopic procedure. The port is again placed into the abdomen and then a second or third port is actually placed through the incision that we made in the middle of the abdomen. Through these ports, we're able to place a camera, a laparoscopic camera, that you can see here. When that camera's in place, we can see inside the abdomen. What you're looking at in the bottom of the screen is the left lobe of the liver. You can actually see the heart beating through the diaphragm. You can see the heart beating, the heart is sitting right on top of the diaphragm, on the other side of it.

Now you can see, if we'll pause the video right here. You can see the room is situated, which is very important in this procedure. Over my left shoulder, you can see two cameras – the two cameras in the top of the screen that show both of the images that we see during the procedure, as well as the abdomen and the instruments that we use. Here you'll see the monitor that monitors the patient's vital signs and heart rhythm, and here you can see the monitor that monitors the energy that we're delivering to create the ablation pattern. If we can go back to the video, you can see how we can use the assistance of someone holding the camera while I use these very small instruments to open a very small defect in the diaphragm to gain access to the heart.

Here, these instruments that we use are a small scissor and a small grasper. Make a very small hole in the diaphragm and you can actually see the heart and one of the coronary arteries beating inside the pericardial sac. Next, we'll open that pericardial sac, which is a sac of fluid that the heart sits in. Once it's open, you can see some fluid come out, and see how we can now gain access to the heart, through the abdomen. By removing that fluid, we can see the back of the heart because of the position of the hole in the diaphragm and in the pericardium. At this point, if we can pause the video for a second and go back to a slide, the slide will demonstrate the paracardioscopic cannula that we use to perform the procedure through the abdomen.

So, if we could go to one of the slides, please. This is a diagram that shows how we position – a picture of how we position the cannula through the abdomen, through the diaphragm, and then you can see how it sits behind the heart, just underneath the heart. With a camera in this position, I can see the heart, but the unique advantage to this is the patient is asleep, but both lungs are being ventilated and the heart is beating. The heart's maintaining the patient's blood pressure throughout the procedure.

The next slide, you can see the way this paracardioscopic cannula looks. The small balloon on the end. Actually, the device you can see going through the end of the cannula with the radio frequency coil, which generates the lesion. This device can be placed over the guide wire to position the device under direct vision inside of the chest. If we go back to the video, you can see that we removed that middle port and placed the cannula through the abdomen and over the liver and then we'll position it through the defect in the diaphragm. The cannula is very soft, it's very atraumatic to the heart, and once we slip it through that defect in the diaphragm, it enters the pericardial space. Once it's inside the pericardial space, we can again place a camera through that cannula and look behind the

heart. This is right in front of the spine, but behind the left atrium. Again, what's unique about this is this patient's heart is beating. It's maintaining the blood pressure that the patient requires to be alive and be stable. The patient is being under general anesthetic but both lungs are being inflated.

What you see in the middle of the screen is the inferior vena cava. As you push the cannula in a little further, you can actually see now the right inferior pulmonary vein, that leaves the pericardium. You can see it just as it leaves the pericardium, about three o'clock on your video. Immediately above that is the entire back of the left atrium. As you rotate your cannula over and move over to the patient's left side, you'll begin to see the left inferior pulmonary vein as it leaves the pericardium into the pleural space on the left side. The pleural space is the area where the left lung is. So you can see now how easily you can see the cardiac structures of the heart that are important when you're doing ablation procedure. If you rotate that cannula a little more and pull back, you can actually see another very important structure while we're doing ablations and that's the coronary sinus. It comes into view there at 12 o'clock. It's the purple structure. Now that we've identified all these structures, we use the ablation device. If you can pause the video there, you can see that ablation device enters over that guide wire and into the paracardioscopic cannula.

If we can go to the slides, we can actually show you an animated video, or a slide, that demonstrates how the VisiTrax ablation device works. It's a suction device. It actually sucks up to the surface of the heart and keeps it in consistent contact with the heart. Because we do that, the energy can be directed into the heart and create a transmural lesion. That means the lesion goes from the surface to the inside of the heart. There is saline that goes across the surface of the heart to help keep it cool on the surface so the energy is uniform when it goes through the heart. But most importantly, this device allows a creation of visible lesions. Because we can see lesions, and they're transmural, we can create the pattern that Dr. Cox described years ago, that's very important, that inhibits the propagation of those erratic electrical activities in the atrium.

If we can go back to the video now, you can see how we positioned this device through the paracardioscopic cannula and then behind the heart. It goes over the wire, through the abdomen, and then right behind the heart. Again, the camera's inside the cannula so we can see what we're doing. With the aid of the wire and the cannula, we can rotate the device, rotate the VisiTrax device, rotate the cannula, and get it into a perfect position just beneath the left inferior pulmonary vein. Once it's into position, we can apply suction and begin ablation. So, here we have a good position of that, just at the bottom of the left inferior pulmonary vein, suction's been applied. You can sometimes see saline being aspirated through the device, and now energy's being delivered to create a lesion.

I want you to notice the left atrium, how there's two beats to the left atrium. It's not in a uniform pattern. You can almost convince yourself that it's beating in two different locations. So, if you'll watch, the heart will pause and reset. That patient just converted from atrial fibrillation to sinus rhythm while we were doing the procedure, while we were creating this ablation line. So patient's rhythm with atrial fibrillation and during the

creation of this ablation line, converted from atrial fibrillation to a sinus rhythm, to a normal rhythm. We often see that while we're doing this procedure. Again, because the heart is beating, there's no incision in the heart, and we can monitor the rhythm on the electrocardiogram.

This is a video again showing how the energy is applied and we'll show some more of that later in the video. You can see the ablation, the pale part of the heart there, and because we can see it, reposition the device and extend that ablation line from the left inferior pulmonary vein across the back of the left atrium, over to the right inferior pulmonary vein. This creates a lesion that connects the pulmonary vein lesions together to create a pattern. Again, get it into position, make sure that the energy is directed into the heart, apply suction, and then apply energy. Once again, that ablation line is created. Again, reposition it, now more towards that right inferior pulmonary vein that you can see there. You can see the end of the previous lesion at the bottom of the inferior pulmonary vein.

Again, advance the VisiTrax device into the paracardioscope, get it into position underneath that pulmonary vein and apply suction. As you can see there, it sucks the heart into approximation with the coil and then apply energy. When the energy is applied, you create the lesion. You can see that ablation line. Now we're going to create one that comes down from the inferior pulmonary vein, onto the inferior vena cava. Again, position the device, apply suction, and apply energy. This is all under direct vision. I'm very comfortable that the energy is being transmitted into the heart and not into another structure, like the esophagus, which is behind the pericardium there. At this point, we're going to create a lesion, again, that starts at the left inferior pulmonary vein and goes down towards that coronary sinus that we saw earlier in the video. So, again, we position it, apply suction, apply energy, and create an ablation line.

With the completion of that line, we've completed the posterior part of the paracardioscopic Maze pattern. Now we'll take the paracardioscope and look at all the lesions and make sure that we can see that they're all connected. In other words, we'll make sure that each lesion ever created touch the next lesion. You can see this lesion is very close to the coronary sinus. It comes from the coronary sinus, underneath that left inferior pulmonary vein, crosses the back of the left atrium, over to the right inferior pulmonary vein, and then over from the right inferior pulmonary vein down the inferior vena cava. There is the right inferior pulmonary vein and the vena cava lesion comes down and crosses over the oblique sinus onto the inferior vena cava. Now we've used a paracardioscope to verify that all these lesions are in contiguity. They're all connected and we know they're transmural.

We now go to the chest, let the right lung be deflated and place three small ports through small incisions and you can see how we operate now on the heart through the chest with the very same instruments that we used inside the abdomen. Again, I have all the monitors right in front of me, so I can see everything that I'm doing. With these instruments, we open the pericardium. The pericardium again is the sac that the heart sits in. We open it up towards the aorta, which is that white structure you can see moving

there. As we open the pericardium, it gives us access to the right heart, but also the right pulmonary veins. This again is done under direct vision and we're very careful to retract the pericardium away so that we don't injure the heart. As we open the pericardium now inferiorly, we're going to open it down towards the diaphragm, towards, the inferior vena cava. As we open it further, you can see how we can gain very good exposure to the right heart so we can complete the Ex-Maze pattern. We will retract the pericardium and actually place an endostitch in the pericardium and retract that out through the chest wall to help give us better exposure of the superior vena cava, which is the structure you can see there in the middle of the screen. Once the stitch is positioned, we can use that to retract the pericardium out and look right behind the superior vena cava. We're now looking over the pericardium inferiorly, down towards the diaphragm, through the right chest.

So, we have a camera in the right chest and we're using these very small but long instruments to open the oblique sinus. The oblique sinus is the space between the inferior vena cava and the right inferior pulmonary vein. As you begin to open that fine film of pericardium there, you'll begin to see the ablation lines we created on the back of the heart, through the abdomen. Once you open this space, you we can gain access to the back of the heart and see the lesions we created back there to connect those to the lesions we created on the front of the heart. Now you can see that the pericardial space is open. You can see that pale line of ablation that we've created there just in the middle of the screen.

Once this space is open enough to pass an instrument through there, we'll now open Waterson's groove. Waterson's groove is the space between the right atrium, which is immediately above the instruments, and the left atrium, which is immediately behind the instruments. The left atrium is where the blood comes back from the lung and a very important part of the ablation procedure because that area is where a lot of atrial fibrillation can initiate. We'll open the epicardium, which is just the fine film of tissue on the surface of the heart, down to the inferior pulmonary vein, where we've previously opened the oblique sinus. Once that's opened, we can that retract that fat that's on top of the pulmonary veins and created a space so that we can get a good ablation location on the antrum of the pulmonary veins. It's very important. You can see the lesion there where the scissors are pointing to the previous ablation line, to make sure that you can see that lesion so you can connect your other lesions to that. Now we'll use a small kitner to elevate that fat off the pulmonary veins. We want to stay well away from the pulmonary veins so we don't cause pulmonary vein stenosis with our ablation catheter, with our ablation device.

We're now behind the superior vena cava and you can see a fine filmy tissue that we opened bluntly to gain exposure to the left pericardium. As you open the left pericardium, the first thing you'll see will be the left atrial appendage which will be moving there in the film. You can see the kitner's pointing just to the base of the left atrial appendage, just on top of the left superior pulmonary vein. So now through the right chest, with the camera assisting me, I can see behind the aorta, on top of the left atrium, and identify the left atrial appendage. It's very important now because I'm going to pass a red rubber

catheter through the right chest, behind the superior vena cava, and then onto behind the left atrial appendage.

We can actually pause the video for one second and go back to the slides. We have an animation that will demonstrate how to position the device a little better. This is the animation that demonstrates the catheter, the device, going through the right chest, through the transfer sinus, behind the superior vena cava, and be in position, through the abdominal cannula, along the left anterior pulmonary veins. This is very important because it positions the device so that we can see it on the front of the left pulmonary veins instead of placing it blindly.

So now we'll go back to the video. You can see that we'll place that red rubber catheter behind the left atrial appendage but on the front of the left pulmonary veins in the left pericardial space. Once we've verified that it's in appropriate position, behind the left atrial appendage – as you can see there, it just went behind the left atrial appendage – we'll then place a guide wire through that red rubber catheter, through the right chest, behind the superior vena cava, through the transfer sinus, behind the left atrial appendage, and in front of the pulmonary veins, and then we'll grasp that and bring it out through the abdominal cannula.

So this video is now through the abdominal cannula, through the paracardioscopic cannula, and that wire is now in front of the left pulmonary veins, and coming out the abdominal port, just like you saw in the animation. We can now position the VisiTrax device on that guide wire and position it now in front of the pulmonary veins and visualize it being in contact in appropriate position. The device is now over the guide wire and you can see the previous ablation line just at that black arrow. So now I can see my previous line, see the device is in appropriate position and oriented into the pulmonary veins, apply suction, apply energy, and now I can continue that ablation line around the front of the pulmonary veins. After that line is completed, we then pass the same VisiTrax device over the guide wire, through the right chest. You can see it going over the guide wire, into the right chest, through that very small incision. Now with the assistance of the camera and the instruments, I can position that device to do the ablation behind the left atrial appendage and in front of the left pulmonary veins. So here what we'll do is we'll again under direct vision see the left atrial appendage, see the ablation device, rotate it and position it in front of the left pulmonary veins, be happy, be satisfied that the orientation of the device is into the heart and not away from the heart into structures that we don't want to ablate, like the phrenic nerve or the esophagus.

Once we're satisfied with the positioning here, we'll go back to the abdominal cannula, identify the left inferior pulmonary vein and now we can see the device, see how it's oriented into the pulmonary vein and in contact with that previous lesion. Now we can see through this camera and through the other camera, through the chest, that it's in appropriate orientation and it's ablation the left anterior pulmonary veins. Once that line is completed, we go back to the right chest and you can see now how we can work with the assistance of a technician, a nurse, and myself, to position the device with the use of both cameras in the operating room. We can now use these instruments to grasp the

device and then position it just behind the left atrial appendage and extend that ablation line from the pulmonary veins onto the top of the left atrium, or the dome of the left atrium. Again this is just behind the aorta and the pulmonary artery. Once it's into position, apply suction and apply energy and create an ablation line. Here you can see the blue graph demonstrating the amount of energy that we deliver. On the right you see a thermostat which demonstrates how much energy is being delivered throughout the entire ablation procedure. We ablate for 90 seconds. During this 90 seconds, 50 watts of energy is applied. This creates a transmural lesion, which means that the ablation line goes through the heart, from the surface to the inside.

Once we're satisfied of the energy that's been applied to the ablation line, then we go back and we can look at the lesion. You can actually again see the ablation line on the surface of the heart and see that it continues around the back of the heart and along the front of those left pulmonary veins, just behind the left atrial appendage. You can see how that ablation line is very clearly seen and makes it easy to make sure that all these lines are connected. Once the top of the left atrium is completed, we can extend the lesion that just goes onto the right atrium, just behind the superior vena cava. There are some areas of ganglionated plexi here that this lesion helps to ablate. Once we apply this device, we can then look at the lesions on the back of the heart and on the top of the heart and make sure that we're happy with the location. You can again see how the ablation line extends onto the right atrium and across the top of the left atrium, behind the transfer sinus, into the left pericardial space.

Next, we'll go down to the oblique sinus and position the device, again through the abdominal port. This time we just simply place the device in the abdominal port and grasp it through the right chest. When we grasp it, we can pull it out through the oblique sinus and now with the instruments, using the thoracoscope, in the right chest, we can position along the right pulmonary veins. Because it's along the right pulmonary veins now, we can connect those lesions we created on the top of the left atrium, to the lesions that were created behind the heart. The device is placed appropriately. It's oriented into the left atrium. It's well off of the pulmonary vein orifices. Suction's applied and an ablation line is created. Once the ablation line is created, we can take a look at it and make sure that we're happy that that line connects to everything else and is contiguous, not only with the lesion on the top of the left atrium, but the lesion behind the heart, that we created through the abdomen. And you can clearly see how easy it is to see those lesions, those ablation lines on the surface of the heart.

Next, we can reposition this device again to make sure that everything is connected and extend that lesion up towards the right atrium. So now we've reoriented the device into the heart, crossing from the left atrium onto the right atrium. The next ablation line extends onto the right atrium, up onto the right atrium, towards the junction where the atrium joins the right ventricle. This lesion crosses from the left atrium onto the right atrium. The final ablation line extends from the inferior vena cava to the superior vena cava. This ablation line is then – all the ablation lines are then tested. We have here a bipolar pacing wire and we're pacing the right atrium. You can see we have a capture at the right atrium because you can see the heart rate has increased. When we remove it, the

heart rate goes back down to about 60 or 65. Now, notice as we test the pulmonary veins, we should not have capture of the right atrium, so the heart rate shouldn't change. But in fact it does. What that indicates is that there is a lesion somewhere, an ablation line somewhere, that's not contiguous. There's a gap that needs to be fixed. Again, you put the pacer wire on the pulmonary vein and because there's a gap, electricity is going across the ablation line and capturing the heart. In other words, it's making the heart beat. I can see that there was a problem at the bottom of the right inferior pulmonary vein. Reposition the device to make sure that that lesion behind the heart is actually connected to the lesion in the front of the heart. Reablate, apply suction, reablate that area and once we're completed with that, again look at the lesions, make sure that we're happy with the position of the ablation lines. This time we'll go back and look over the top of the left atrium, being very satisfied there, all the way back over to the left atrial appendage, that everything is contiguous, everything is connected. Even down into the oblique sinus behind the heart.

At this point, we'll take the pacer wire once again. You can actually see the patient's rhythm in the screen above. Now we'll pace the patient's pulmonary vein once again, and this time the pulmonary veins are not capturing. In other words, we're pacing the pulmonary veins and it's not being captured by the heart. The heart rate's remaining at 65. If you remove that pacer wire, the heart rate remains the same. If you go back and again place it on the pulmonary veins, again the heart rate doesn't change. What this demonstrates is that all the lesions that were created are through the heart, they're transmural and they're contiguous, so the pattern is complete. Just to verify this, we'll take that pacer wire and put it on the right atrium and you can see how the right atrium picks up the rate and you can see how the heart rate increases just by pacing the pulmonary veins. So this is a very good indicator that the ablation lines are transmural and contiguous. We then place and endostitch to close the right pericardium and the right chest is closed after placing a very small drain to remove any fluids from the right chest. Once that suture's tied we'll irrigate any fluid from around the right chest, let the right reinflate. Now you can see the closure of the diaphragmatic defect. This is the same hole we created to put the paracardioscopic cannula in. We put a stitch in that, closed that diaphragmatic defect by tying the notch there. Then the procedure's completed just by simply closing those very small incisions in the abdomen and the chest. Then at the completion of the procedure, we'll install some local anesthesia underneath the ribs and in the incisions to help control any post-operative pain.

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GERHARD WIMMER-GREINECKER, MD, PhD: Well, thank you Dr. Kiser. This was a really impressive and fascinating procedure you just showed us. So, for which patients would you think is this procedure? Which patients would qualify and which patient's would you accept for this kind of surgery?

00:34:58

ANDY C. KISER, MD: We actually have a slide that demonstrates some of these indications for the atrial fibrillation procedure. Clearly, there is a lot of patients who have focal and wavelet A Fib, but anyone who's undergoing heart surgery for open-heart procedures or having a heart operation, who has atrial fibrillation, is a candidate for this procedure, to have it while we're doing the other procedure. Another group of people are

those people who have isolated atrial fibrillation, without indication for heart surgery, and those people would benefit from a minimally invasive paracardioscopic Maze procedure, and they could really have atrial fibrillation of any duration or any frequency. Those patients have often required medical management to take care of their treatment, but have not had previous heart surgery. So, perhaps someone who is still having A Fib and is on medications, that patient would be a good candidate for the minimally invasive procedure. Other patients are people who've had a previous ablation procedure. Perhaps they have gone back into atrial fibrillation or remain in atrial fibrillation. Those patients again are good candidates for the minimally invasive Maze procedure.

00:36:04

GERHARD WIMMER-GREINECKER, MD, PhD: So, I remember the first cases we've done together back in Europe and I know you have extended your experience now, so could you tell us how many cases you have done by now and maybe could you give us some insights on the results of those patients?

00:36:16

ANDY C. KISER, MD: Certainly. We've actually performed over 50 patients worldwide and we have some slides demonstrating. Actually, one of the post-operative patients and some of the slides, some of the data. These are the results of the first 39 patients that we performed both in Poland, where Dr. Wimmer-Greinecker and I worked with the Polish surgeons to perform the very first minimally invasive paracardioscopic procedures, and here in Pinehurst. You can see that of the 39 people that have had the procedure, 18 patients are now out at six months. That purple line, the 89 percent of the patients are actually out of atrial fibrillation. What's most impressive is that at six months, 83 percent of patients are actually off their anti-rhythmic medications and out of atrial fibrillation.

If you go to the next slide, when you compare that to some of the other procedures, on the left, you can see patients that have had not treatment at all, no ablation procedures. About 40 percent of patients are free from A Fib. Only a very small percent, in the blue there, are free from A Fib and anti-rhythmic medications. The gold standard at six months, the surgical Maze 3 procedure, has a freedom from atrial fibrillation of almost 80 percent. Although our numbers are small, the initial six month data for the minimally invasive procedure closely reflects that of the gold standard, Maze procedure. If you look at all patients that we've done in the next slide, we've actually performed 81 procedures, both concomitantly, that means during other heart procedures, and minimally invasively, as a stand-alone procedure. We have 15 patients that are now at 12 months and all 15 patients are not only out of atrial fibrillation, but are in sinus rhythm and are in sinus rhythm without anti-rhythmic medications. A significant proportion of those people are out of atrial fibrillation and off their coumadin now. Clearly we have to work with cardiologists to make sure that we don't have a risk of stroke at that time, but our goal is to get someone out of atrial fibrillation, into sinus rhythm, and eventually off their coumadin.

00:38:25

GERHARD WIMMER-GREINECKER, MD, PhD: So, I guess those are the real important things that have to be known about this procedure. So it is the prevention of stroke. It is getting off medication. It is getting better quality of life, by not having to take so many medications, like anti-coagulation. As I see, you have been joined by a gentleman next to your side. Would you be so kind and introduce him?

00:38:49

ANDY C. KISER, MD: Actually this is Jon Woods. Jon Woods is one of our first minimally invasive patients here at Pinehurst. Mr. Woods has his own story to tell, but he has been watching our development of the procedure for many months and was again one of our first patients, has now had the procedure several months ago and perhaps he would have a few words to share with us.

00:39:11

JON WOODS: Well, I think the first thing I'd say is I'm in sinus rhythm. That's probably the most important thing I can say. Just recently, I got off coumadin. So from a patient's standpoint, those are big things. As you know, because you know a little bit about my history, I was not a happy camper in A Fib. I had a lot of symptoms. I accept the fact that not everybody does. It was very debilitating to me. There were a lot of things that I just couldn't do. Even simple things like shaving was tiring. Washing car windows, simple things. Anything where the hands were above the heart. I was on a ton of medicine, trying to slow the heart down and it certainly did that, but guess what? It slowed all the rest of me down too. I remember – just a little small thing and I'm not going to dwell on any of this very long – but maybe I could capture the essence of how I felt and what was going on. Every night, I would crawl into bed and I would say to myself, “I made it through another day.” It wasn't because I was worried about dying or that kind of thing at all, but because it was a struggle to get through the days.

When I found out about your technique, your procedure that you were developing, I was ecstatic. As you know, because I've told you this privately, I waited for you to perfect this technique because nothing else appealed to me, because I wanted to be fixed, not just perhaps fixed, temporarily, part of the heart being ablated, or medicine long-term, or that kind of thing. When you did the procedure, it was like literally flipping a switch. I went from feeling really worn out, tired, fatigued, almost all the time, to an enormous new sense of energy. Certainly I'd say anyone who's a candidate for this procedure should seriously think about having it done. I'm going to say one other thing, then I'll shut up because I tend to be long winded. I had a visit with my cardiologist two weeks ago. It was a six-month follow-up, that's when I got off the coumadin, and he said something very profound to me. He said, “You know, in my profession, it's very rare that I can tell somebody, ‘You're Healed’, and I'm telling you you're healed. All indications are that you are healed.” So, I'm definitely a happy camper now.

00:41:48

ANDY C. KISER, MD: Thank you for sharing your comments with us. There are a lot of patients out there in Mr. Woods situation who have a very emotional response to being treated from their atrial fibrillation. Some of you may have questions about what is it like and what do the incisions look like several months after. We actually have a picture, not of Mr. Woods, but a picture of a patient three months after the procedure and we'll show that to you here. That's a picture. Now, again you can hardly see the scars after the procedure is completed. Actually the incisions now are even smaller than that. We've really developed the procedure as Dr. Wimmer-Greinecker has been describing to become minimally invasive, heart beating, small incisions, and I'm sure Mr. Woods would agree, minimally invasive into their life. Because we can do this procedure with the heart beating and through small incisions, they don't spend as much time in the

hospital and they get back to their lives, so we don't take away their days recuperating from a big incision or other things.

00:42:50

GERHARD WIMMER-GREINECKER, MD, PhD: I would have a question to you, Mr. Woods. Coming from Europe, our system is a little bit different. So, what would interest me – we have heard now there have been 50 cases done. How did you get to know about this procedure? Did your doctor tell you? Did you read something about it? How did that work?

00:43:08

JON WOODS: Well, that's a good question. When I found out I was in A Fib, I went on the internet trying to find everything I could find out about what it was, the various types, and what was available in the way of options to have it treated in some fashion. I looked at websites where, in a lot of cases, university medical centers were doing some kind of ablation. They were better than nothing, but they didn't sound like a complete fix to me. So when I saw my cardiologist, I expressed that frustration. He happened to know that Dr. Kiser was working to develop this minimally invasive technique. So he was tracking it for me and then eventually there was a website. I kept checking that to see where things were at and ultimately my cardiologist felt that the technique was sufficiently developed that I ought to see Dr. Kiser, which is what I did. I might just quickly add that my cardiologist is a very conservative cardiologist, which is terrific. So I knew if he put his stamp on it that I should see Dr. Kiser, that he had great confidence that this was going to be something worthwhile for me. That's a long-winded way of saying how I found out about it.

00:44:27

ANDY C. KISER, MD: We'll take some questions from the audience, and let me also add that if you have questions for us, you can click on the website and there are directions of how to email your questions to us. I want to echo one thing that Mr. Woods has said. When we do this procedure, we really work in concert with your cardiologist to make sure that we're doing the right thing because the technique and the procedure is very individualized. So Mr. Woods might have one type of – the paracardioscopic procedure, but another patient may not be a candidate for that and might be a candidate for something else. So we work closely with your cardiologist to make sure that we treat the patient, not only pre-operatively, but post-operative, so it makes it easier for the patient to follow up and to get all the care that they need.

00:45:10

GERHARD WIMMER-GREINECKER, MD, PhD: Well, Dr. Kiser, I was just handed the first questions that came in during the program and actually I found two questions I should address to Mr. Woods because he would be the best person to answer this. One question coming from Kentucky is, “What is the recovery period?”

00:45:30

JON WOODS: [laughs] You know, my response almost always is to do that because it's the capsulation of what it actually was. I was in the hospital two and a half days. Two and a half days, that's pretty remarkable to me. You know what? I never felt any pain. I never had any pain.

00:45:46

GERHARD WIMMER-GREINECKER, MD, PhD: That was the second question, Mr. Woods.

00:45:48

JON WOODS: A little discomfort. I sleep on my right side. A little discomfort for a couple days, but I find that remarkable. I know from talking to people who have had more extensive, rigorous procedures that they didn't have that situation.

00:46:04

GERHARD WIMMER-GREINECKER, MD, PhD: Another question coming from Florida is, "What if I do not get out of A Fib?"

00:46:11

ANDY C. KISER, MD: If you do not get out of A Fib, clearly this is an operation where I can not promise and no one really can promise that this will cure your atrial fibrillation because it is surgery. I'll add, it's heart surgery. Although we're doing it through small incision and with a heart beating, there are risks associated with heart surgery. However, as Mr. Woods has described, the pain and the time in the operating room is minimal. If we do not get you out of atrial fibrillation and keep you out of atrial fibrillation, it does not prevent us from continuing to treat you with medications or even doing additional catheter ablations, because we've not done anything inside the heart. In fact, by doing this procedure and doing some of the pattern on the heart, it may in fact make it easier for the electrophysiologist to do a procedure that they can do through the catheter, inside the heart, because part of their procedure has already been completed. So when you hear about doing EP ablations for atrial fibrillation that take six, eight hours, a lot of the lesions they have to spend so much time creating have been created with the minimally invasive procedure and it makes it easier for them to do that. So there are other options even if this doesn't work.

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GERHARD WIMMER-GREINECKER, MD, PhD: I would absolutely agree on that and I can tell you that in Europe there is even already a center in the Netherlands that do both primarily because they believe that if you can do it with a catheter and if you can do it minimally invasively, then you will have the highest success rate. So, one question coming out of Louisiana is, "What is the risk of recurrence after doing this procedure?" Mr. Woods told us he's healed, so is everyone healed or can it come again?

00:47:53

ANDY C. KISER, MD: Well, I wish I knew the answer and I think only time will tell. Certainly we like to think that if you've been out of atrial fibrillation for six months to a year, especially people who have been in atrial fibrillation for years. Some of the people that we've operated on have been atrial fibrillation for more than 20 years, so for someone to stay in a normal rhythm for six months or a year really makes you feel good about a cure, but clearly until we have longer results, it's hard to say that you're cured of atrial fibrillation. But we are gathering that data. Everybody that we operate on, we're very careful to follow them along to make sure that we see how they're doing afterwards in case there is a recurrence. We want to make sure that we catch that and get them into treatment for that.

00:48:36

GERHARD WIMMER-GREINECKER, MD, PhD: Of course, the webcast is an international program, so we also have international questions and there is one coming

from Egypt. It asks, the person asks, “What is the difference between this procedure and the epicardial ablation, which I've seen on a previous webcast?”

00:48:59

ANDY C. KISER, MD: I would have to assume that the epicardial ablation is the one that we performed during the open-chest.

00:49:02

GERHARD WIMMER-GREINECKER, MD, PhD: I would assume so, too.

00:49:05

ANDY C. KISER, MD: The difference is that we don't have to open the sternum. Whenever someone has a heart operation, the bone has to be divided and an incision has to be made to gain access to the heart. What we have begun doing now with the Ex-Maze, during a concomitant procedure, is to actually do the Ex-Maze procedure, the epicardial procedure, before we stop the heart, so the heart's still beating and off bypass. Again, because we do that we can test the lesions and make sure that they are actually transmural and contiguous, the same way we did in the patient in the video. The difference between the open chest and the closed chest is – the patterns are very similar, but they're done without the incision in the chest and strictly with just cameras and very small instruments. There are some differences in the pattern of the open versus the closed, but those are made so that we can test them in the operating room and also for safety reasons. You can imagine trying to operate on the heart with long instruments through cameras can be quite challenging unless you're a cardiac surgeon and so we have to be very careful about the danger that we have because we have small incisions and if we were to have a problem, we have to be able to fix that problem at that time, which again is an advantage to this procedure because the patient's laying flat on their back. Some of the other procedures have to lay on their sides to have the procedure done.

00:50:30

GERHARD WIMMER-GREINECKER, MD, PhD: So, the second international question actually comes from a country that's a little bit closer. It comes from Canada. “I have A Fib and I've had it for almost three years now. I'm 39 years old and ablation attempt a couple of years ago was not successful and my condition is worsening despite the medication. Am I a candidate for surgery and,” now an interesting question, “how much is it? I live in Canada.” Another question coming from Michigan is “Will insurance pay?”

00:51:03

ANDY C. KISER, MD: I wish I could tell you how much it is. I think it varies from state to state and it varies from hospital to hospital. There are diagnostic related groups. This is the way that Medicare pays and defines payment for procedures like this. This is not an experimental procedure. This is a procedure that has a payment code and insurance pays for this procedure because it's been done for a long time. It's just a different way of doing the cut and sew procedure. I can't tell you how much it costs. I can tell you that the procedure is done in several locations in the country and ask me again about the last part there, as far as will the insurance pay for it. Yes, that's what we answered earlier. So, the insurers do pay for the procedure. Can people come and have it done? They can and actually we're getting people all over the country, surgeons all over the country to learn how to do the procedure so that they don't have to travel so far.

00:52:09

GERHARD WIMMER-GREINECKER, MD, PhD: One question coming out of New York, I guess I'm going to answer this because I've been with you in the first cases and they were the ones that lasted the longest, because as in every procedure there is a learning curve as we all know. The question is, "Don't your hands get tired and lazy using those clipper things?" My answer to this question is no, they don't. Actually, also in robotic surgery and in other totally endoscopic procedures we have performed, years ago we started to take down IMAs with those so-called clipper things. We call them shafted instruments. Actually, you can do this for hours, for four, five, six hours and no, your hands don't get tired and we don't lose quality in performing those procedures. One question coming from North Dakota. "After having an Ex-Maze procedure, should I be taking extended release or the regular verapamil?"

00:53:05

ANDY C. KISER, MD: I think that's strictly between the patient and the cardiologist. The extended release decreases the frequency you have to take your verapamil. People take verapamil for different reasons, blood pressure is one indication to do so. So as far as questions like that, we really work with our nurse coordinator here at the Arrhythmia Center in Pinehurst and with your cardiologist. So if you live in North Dakota and you have the procedure done here, we're going to work with the cardiologist there to make sure that we're agreeing and in concert with your post-operative care, be it medical or surgical or whatever.

I will say this, there was a question earlier, and I don't think I answered it, about atrial fibrillation and recurrence of atrial fibrillation. Everybody that has this procedure, I virtually guarantee you're going to have a little bit of atrial fibrillation afterwards because of the inflammation that occurs around the heart. There's about a 40 percent chance of having atrial fibrillation even with lung surgery. So, we keep people on coumadin for at least three months after this procedure. Now, again, we want to make sure that you're in sinus rhythm, so we will do some monitoring with Holter monitors and that type of thing to make sure that you're truly in sinus rhythm and not fooling us before we stop the coumadin. But we do keep you on an anti-rhythmic for at least three months because of the risk of going in and out of atrial fibrillation simply related to having the procedure done. I think that's real important, because what we don't want to have happen is stroke.

If you have had an ablation before, can you have this procedure? Absolutely, because the catheter ablations are done inside the heart. If you've had a previous heart operation it's very difficult to do through the minimally invasive approach, but the catheter ablation really doesn't hinder us from doing the procedure. In fact, we've had a patient who had a previous catheter ablation, his electrophysiologist sent him here to have this procedure done. He told us exactly where the problem was, we did that ablation, that one ablation, the patient converted to sinus rhythm immediately, and he told us where the problem would be and he was absolutely right and the patient stayed in sinus rhythm. So it's very helpful to work in concert with an electrophysiologist.

00:55:22

GERHARD WIMMER-GREINECKER, MD, PhD: So, Dr. Kiser, we've seen a fascinating procedure now. I know what I'm going to do. I hope I can take this procedure

back to Europe. We've seen your excellent results. We've seen a happy patient, so is there room for improvement or where do you want to take this procedure.

00:55:40

ANDY C. KISER, MD: There's always room for improvement. Clearly we want to continue to follow our data and see if the 100 percent at a year continues to work. Hopefully that will. We want to get more patients into the database. We want to follow people along and make sure that they're doing well and we want to continue to make the procedure less invasive, decrease the number of incisions, improve the device to make it a quicker procedure. There are all kinds of things we're trying to do to make the procedure better. Are there other things we can add? We talked about catheter ablations as part of this operation. We're clearly waiting to see how outcomes are, but if someone has atrial fibrillation, that's a good tool to have in our material when treating atrial fibrillation. So, yes, we're continuously trying to improve the procedure to make it less invasive and have better results.

00:56:32

GERHARD WIMMER-GREINECKER, MD, PhD: Great. I think before we wrap up and get to summary, we got in one more question, also a question only you can answer. "How many patients had atrial fibrillation for more than one year at the time of surgery?"

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ANDY C. KISER, MD: In those 39 patients that you saw there in that slide, the average length of time in atrial fibrillation was almost nine years. I can't think of anyone that we've done this minimally invasive procedure on who's had A Fib for less than two years. So, the majority of the people have had A Fib for a long, long time and it really doesn't matter about how long they've been in atrial fibrillation because the procedure treats both the left atrium and the right atrium, which helps treat those people with that wavelet, that chronic atrial fibrillation. So, I think that really is important in looking at that.

00:57:28

GERHARD WIMMER-GREINECKER, MD, PhD: I just heard that we can see the slide of this again.

00:57:31

ANDY C. KISER, MD: If we can go back to the slide, we can show you some of the results. Again, you can see this is just the 39 patients that have had only the paracardioscopic procedure. Like I said, look at the one month data. You can see how many people – actually, just a very few, only 49 percent were free from A Fib and drugs, but look how that number increases. Again, there's a transient time where people have atrial fibrillation and they require some medications to control their rhythms. By six months, you can see how those results improve. This is exactly what Cox found and anybody else who does a cut-and-sew procedure. There's a transient time with atrial fibrillation and then the results get better over time. Again, that's just six months and just a few patients, but you see how many patients are going to come along and we're going to keep an eye those and present that in forms and literature also.

00:58:20

GERHARD WIMMER-GREINECKER, MD, PhD: Well, thank you Dr. Kiser. It was really great that you have invited me here. As usual, it's great working with you and I've really enjoyed the cases we've done together. I guess it's time for you to give us your summary and to end the session.

00:58:35

ANDY C. KISER, MD: Well, again Dr. Wimmer-Greinecker, I appreciate all that you've done. We've worked together, not only in Germany, but in Poland, with some very important surgeons there in Krakow, to help improve this procedure and we'll continue to do so. Certainly your expertise has been very helpful and as we progress, I'm sure we'll continue to work together. If I had to summarize this procedure in just a few sentences, the most important thing I can say is that this procedure is for anyone who has atrial fibrillation. Clearly if you've had a heart surgery, that's difficult to fix, because we can't do it minimally invasively, but if you've had atrial fibrillation, especially if you've had atrial fibrillation for a long time, this procedure really treats that population and there's a lot of people out there who don't have that opportunity because there's not a good treatment option for them. It treats both the left atrium and the right atrium. It allows you to create the pattern that Cox has defined and it's the gold standard, at least as close as we can on the surface of the heart. I think most importantly because we can see the pattern, we can create the ablations, we do it while the heart's beating, we check our pattern at the end and we don't have to stop the heart, we don't have to cut the heart, and the patients can have very small incisions and it has a very minimally invasive portion, not only from a surgical standpoint, but into the patient's life. So we're very excited about the opportunity to continue to do this procedure and to continue to improve it, but we're very, very excited about what we've done so far. We've come a long way to go from an open chest incision to just very small incisions with a camera to do the procedure. So, thanks for joining us today to see the paracardioscopic Maze procedure. I'm very excited about the results so far and if you have any other questions, please log onto the OR-Live website and direct those questions or re-look at the video and send any questions to our website here at FirstHealth. Thanks for joining us.

01:00:34

ANNOUNCER: Thank you for watching this paracardioscopic Ex-Maze for the treatment of atrial fibrillation from the Heart Institute at FirstHealth Moore Regional Hospital in Pinehurst, North Carolina. OR-Live makes it easy for you to learn more. Just click on the request information button on your webcast screen and open the door to informed medical care.

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