ENDOVASCULAR REPAIR OF DESCENDING THORACIC AORTIC ANEURYSM
WITH GORE TAG ENDOPROSTHESIS
UNIVERSITY OF NORTH CAROLINA HOSPITAL, CHAPEL HILL, NORTH CAROLINA
Broadcast December 15, 2005

00:00:16.000
NARRATOR: Thoracic aortic aneurysms are diagnosed in approximately 15,000 people annually. An aneurysm can cause the aorta to grow to several times its normal size. Left untreated, the aneurysm can rupture, resulting in internal bleeding and, in most cases, death. Endovascular repair is a relatively new procedure for the treatment of TAAs. During this live webcast, Dr. Mark Farber will perform a descending thoracic aneurysm repair with the GORE TAG thoracic endoprosthesis. The procedure will be performed at the University of North Carolina Hospital.

00:00:56.00
ROBERT MENDES MD: Welcome to Chapel Hill, North Carolina. I am Dr. Robert Mendes with the University of North Carolina Endovascular Institute. I’ll be today’s moderator for the webcast. If you have any questions, please click on the MDirectAccess button on your screen. Today you’ll be watching a live webcast of an endovascular repair of a descending thoracic aneurysm. We will be using a GORE thoracic TAG endovascular prosthesis to repair this aneurysm. Dr. Mark Farber will be the primary surgeon performing today’s procedure. Dr. Mark Farber, can you please introduce the OR staff?

00:01:35.000
MARK FARBER MD: Thanks, Bobby. This afternoon we are going to proceed with a thoracic endovascular repair on this gentleman. I have several people that are helping me. To my immediate left is Dr. William Marston. Across the table from me is Dr. Laura Kissel. I have one additional assistant at the table. That would be Dr. Peter Ford. We have two other individuals in the room that are essential for performing these endograph procedures. That is the surgical scrub nurse, Karen, and our fluoro technologist, Scott. Now, Bobby, we have just a few more minutes of work to do to get the wires in place, so if you’ll go ahead to the brief summary of thoracic disease while we finish getting the patient ready, that would be terrific.

00:02:15.000
ROBERT MENDES MD: Okay, Mark, thank you. Today we’re going to give a background on thoracic aortic aneurysms. The thoracic aorta is the largest blood vessel in the body and can become weakened over time, resulting in a bulge or an aneurysm of the vessel. The incidence of aneurysms in the United States range from 15,000-25,000 people per year. The occurrence of aneurysms in patients is approximately 60% found in men and 40% found in women. To go over the basic anatomy of the heart and the major blood vessels that arise from it, the heart, as you understand, is located in the center of the chest. The major blood vessel coming from the heart is the thoracic aorta. After providing blood to the upper extremities and to the head, the aorta descends along the back, close to the spine, before it comes to an area around the general location of your belly button, to split into the iliac arteries. Thoracic aneurysms are found in between the left subclavian artery, which is the last vessel coming off to the left arm, and the diaphragm, which separates the thoracic cavity from your abdomen. A normal diameter of the thoracic aorta ranges from about 1 to 1.5 inches, or 2-4 cm. A thoracic aneurysm could rupture if it’s left untreated. The risk of rupture increases with aneurysmal size and with the rate of growth and with increased blood pressure. Ruptured aneurysms are frequently fatal. A descending thoracic aneurysm, as you can see here, is located between the left subclavian artery and the diaphragm. You can see a diagrammatic picture of it on the left, and on the right you can see an angiogram, which is an injection of contrast into the blood vessel through a catheter. An angiogram will evaluate or illuminate the inside of the blood vessel to be able to identify where the aneurysm is located. Patients who have aneurysms are frequently asymptomatic, not having any presentation or any pain or any difficulty from this. That occurs about 75% of the time. When symptoms do
occur, they usually are from pressure on adjacent structures. Chest pain, shoulder pain, or back pain are frequent presentations. Sometimes the aneurysm compresses different types of vessels, such as the bronchus or on a nerve, which can cause coughing or hoarseness. Pain can vary from severe to mild. It can be detected during a routine physical, but more commonly an aneurysm is found during an imaging study, either a CT scan, chest x-ray, MRI, or catheterization. The risk factors for thoracic aneurysms are usually multifactorial, but things that play a role include vascular disease, smoking, high blood pressure, high cholesterol, genetics, and trauma. The treatment is based upon the size and location of the aneurysm. When small, medical management with reduction of risk factors are primary to therapy, including blood pressure reduction and smoking cessation. However, if an aneurysm is large or is rapidly growing, surgical intervention may be required. The classic treatment options include an open surgical repair. These are frequently performed through an open incision in the chest and replacement of the affected or diseased aorta with an artificial artery. The recovery, including hospitalization and rehabilitation, can take as much as 3-6 months. Not all patients can tolerate this type of open procedure. An endovascular repair, which you will be seeing today, is a new procedure that is less invasive. It is created by inserting a new lining inside of the diseased artery. The patients are hospitalized for only 1-2 days and fully recovered within 1-2 weeks of the procedure. This, however, requires regular follow-up visits to monitor the success of the repair.

You can see on the right of your screen an example of some of the devices that we will be using today. This is a GORE thoracic TAG device and it is a wired stent that is covered with PTFE. It is then wrapped and placed on the catheter, which will be inserted into the vessel and placed and deployed in an area where the aorta is aneurysmal. Here is an example of an aneurysm that has been repaired. On the left, you can see an aneurysm of the descending thoracic aorta with a large bulge from its normal pathway. On the right, you can see after it is repaired with an endovascular device, that the aneurysm is present but is no longer receiving blood.

Let's move on to an animated description of what we will be performing today. The GORE thoracic TAG device is a device that is placed through the arteries located in the legs. A catheter is brought up through the major blood vessel of the aorta. As you can see on the diagram in front of you, a wire will pass into the ascending aorta. The device is then brought up to the area of the diseased vessel and then is deployed. In slow motion, you can see once again that the wire access is obtained and the device is deployed from the center, moving outward. The catheter is then slowly removed and, as you see, the inner lining is now smooth, with no evidence of bulge from inside of the vessel. After the device deployment has been removed, a tri-lobed balloon is brought up to the distal aspect of the stent, where the stent is lowest in the vessel. The balloon is then inflated to press the stent against the wall of the aorta. After it is ballooned, it is rotated and a second balloon is performed, then the balloon is brought up to the proximal end, or the top part, of the stent and once again repeated, first with ballooning once, rotating, and a second ballooning procedure. This is a unique balloon in that it still allows passage of blood around the balloon without totally occluding the blood vessel. After the balloon is removed, the wire is removed and inside you know have normal flow of blood from the top to the bottom.

Dr. Farber, we just finished going over the animation of the endovascular repair, are you ready for us to start coming over to take a look at what you have?

MARK FARBER MD: Just give me about 30 seconds, Bobby. I need to just make a little nick here in the artificial artery that we put in this gentleman and then we'll be just about ready. If you have a question from the audience, that would be great.

ROBERT MENDES MD: That sounds pretty good. What we're going to do first is just remind the audience to go ahead and send in any questions that you may have at any time during this webcast. Simply press on the MDirectAccess button, email your question to us, and we will answer your questions as they arrive. How are we doing right now? Are we getting closer toward being ready?

MARK FARBER MD: Yes, Bobby. I'm just bringing the sheath up into place. Let me just make sure I can get it into the artery appropriately.
ROBERT MENDES MD: Alright, Mark, what we'll do is go ahead and answer some simple questions that have already come across to us. The first question that was brought to us is what type of patients are appropriate for endovascular technique? That is a good question that is often asked. Traditionally, patients that have aneurysms have been repaired through an open procedure, as I described earlier. This procedure does have quite a bit of stress on the body. If patients don't have a strong heart or have multiple other illnesses, they oftentimes cannot tolerate this type of procedure. We now have taken patients that have previously been unable to have an aneurysm repair, because they have been sick or otherwise unable to go through an open operation, and now we can provide those patients with the care that they were not able to receive.

A second question. Dr. Marston, you're in here with Dr. Farber. I don't know if Dr. Marston can hear us or not, but how do you choose the GORE TAG device for this type of patient?

MARK FARBER MD: Bobby, how are the questions coming?

ROBERT MENDES MD: Right now we were asking how do we choose the GORE TAG device for this type of patient?

MARK FARBER MD: The GORE TAG device is really currently the only device that is approved for insertion and treatment of thoracic aortic aneurysms in the United States currently. Let me just make sure I can get this sheath in. There we go. Do you see that go in there, Bobby? I don't know if the audience can see that go in. So that is the only one currently used. Here at the University, we do have several clinical trials that are examining all of the current devices, but this is the one that's currently approved.

ROBERT MENDES MD: Good. Actually, Mark, that brings us to a question that was just asked to us. What is our experience with endograft and thoracic aneurysm repair?

MARK FARBER MD: Over the past 3 years, we have performed about 130 of these procedures. 130 thoracic endograft procedures for fixing aneurysms, so that comes out to approximately 40-50 a year. That's a fairly large experience. Most institutions in the United States have not performed more than 1-2 of these procedures in a short period of time and probably less than 10 overall, so that really shows you that here at the University we've been very active in this, since the late 90s, in treatment of patients for this disease process and that is because our mentor and current Chief of the Division of Vascular Surgery, Dr. Keagy, has had an active interest in thoracic disease since he started here, doing open repairs. Bobby, to make sure we get this procedure all on tape for everyone, I'd like to go ahead and show the individuals where we currently are with the procedure. You can see that this gentleman has had a coronary artery bypass graft, because he has those wires in place. You see we have two wires. One has some markers on it and that is actually a catheter, not a wire, and a second wire in place. On top of one of these wires, we're going to insert the device. So the first thing we're going to do is remove the cap and put the device cap, and at the same time we're going to get the device ready on the back table. Scotty, let's pan up and make sure our wires are at the appropriate position. Good. That wire is a little coiled, but he's very tortuous at the top - that means he curves a lot at the top of those sternal wires. Come on back down, Scotty. So those of you who are not familiar with looking at x-rays, that is his heart right there in the center of the screen and you see those wires there, where they did his heart bypass several years ago.

ROBERT MENDES MD: Dr. Farber, what are those markers or those dots that we see in the middle of the screen?

MARK FARBER MD: Those markers are on a catheter that tells us distances inside the blood vessels. Right now we're working inside the thoracic aorta, so the purpose there is that we are able to see where we implant the device, see how much room we have and so forth. Currently that noise you hear is us unpackaging the sterile device. The device has several aspects to it that are really critical for its use. This device is extremely flexible. It can handle curves very easily. You'll see how this device does go around the corners at the top. This device has little caps on it and a little wire that keeps it from bending while it's in the delivery system. Well just remove those so we can make sure there's no air inside the device when we insert it. It's critical that you ensure that that's the case because, if not, the air can get into the patient's arterial system and cause problems. So Karen
and our other assistants, Dr. Marston and Dr. Ford, will just push all the air out. You can see the air coming out of it. Once we’ve ensured that that is in place, you can see the device is mounted here and you can see the fabric and the metal wires are all constrained. You’ll see it much better when we get it inside the patient and look at it under fluoroscopic imaging.

Now, this particular gentleman has a fairly extensive aneurysm which is about 4-5 cm, which is about 2 inches down from the artery to his left arm. The plan is to put this device distal, or more close to his feet, to his left arm. Once we’ve done that, we’ll put 3 sections in to treat his aneurysm.

ROBERT MENDES MD: So Dr. Farber, you were mentioning that you’re going to be basically covering the entire thoracic aorta.

MARK FARBER MD: Yes, we’re going to cover just about 2-3 cm distal, or a couple of inches distal to his left arm artery and then all the way down to the arteries to his intestines. There you see the device going up in an appropriate position. Now, Scotty, if you’ll rotate to 30° and Dr. Passamanti, at the head of the table, can you rotate the patient about 20°, right side down, left side up. What that does is that puts the aorta in a position where I can see it. You’ll see under this that the distance has changed. We thought those wires were crossing and now they look pretty good. Let’s shoot our first angiographic run. We’re using a little dilute contrast today because this gentleman has some renal insufficiency or kidney problems, so we’ll reduce the amount of contrast we give him, but we’ll still be able to see fairly clearly what we’re doing. The first thing you’ll see is that catheter sitting in the aorta, where the vessels to the brain and the left arm sit. We’ll get a good idea if our device is in the appropriate location. If it is, we’ll be able to deploy it appropriately.

ROBERT MENDES MD: Mark, while you’re reviewing that arteriogram, I’m going to ask you a couple of questions that have been sent to us. One of the questions is why is an open repair so much more dangerous than an endovascular repair of an aneurysm?

MARK FARBER MD: An open repair is significantly more dangerous because of the open incision and the stress on the heart and the lungs when you have to clamp the major artery after it leaves the heart. That puts a lot of stress on the heart and that is the biggest issue.

WILLIAM MARSTON MD: The other thing, of course, Bobby, is the large incisions required for the open repair cause a lot of morbidity and take many months for full recovery, whereas this procedure typically a couple of days in the hospital and recovery in 1-2 weeks.

ROBERT MENDES MD: So even though you cover the entire thoracic aorta, the risk of paralysis is still lower.

WILLIAM MARSTON MD: It is lower and it’s mainly because you have much less problems during the procedure and are able to keep the spinal cord better perfused. Less hypotension and other similar things that cause risk for paralysis.

ROBERT MENDES MD: Today we’re going to be repairing an aneurysm, but are there other emergent situations when we can use the endovascular device to help a thoracic aortic injury?
WILLIAM MARSTON MD: There are other situations, such as traumatic injuries of the thoracic aorta, such as motor vehicle crashes. We are able to repair ruptures from traumas such as gunshot wounds as well.

ROBERT MENDES MD: Very good. How are we coming along, Mark?

MARK FARBER MD: Getting ready to deploy the device. We're just reconfirming where we are and that's a good position. We're going to deploy the device. Bill, if you'll deploy the device here. Scotty, we'll do this under fluoro. You need to watch fairly closely. This happens fairly rapidly for the patients.

ROBERT MENDES MD: Would it be possible to point out where the aneurysm is located?

MARK FARBER MD: Here goes the device. There's the device deploying. Good. Let's get the next device up, which is going to be a slightly larger device, 34 x 15.

ROBERT MENDES MD: So as Dr. Marston was mentioning earlier, one of the unique things about an endovascular repair is that during the entire procedure, the flow to the rest of the body is not stopped. The flow continues through the aorta and through the stent, and the stress on the heart is significantly reduced.

MARK FARBER MD: I'm just going to move this catheter back down to the aorta, where I need it.

ROBERT MENDES MD: So Mark, as you are right now watching on the screen what is going on down in the groin, you have access to both arteries, one from each leg. The catheters and wires are used to gain access to the ascending aorta, which is actually above where the stent is located, and through those access sites you are able to run catheters, wires, sheaths, and balloons to perform your procedure. Dr. Farber right now is bringing the catheter down. That little hook shape, or the shepherd's crook, that you can see on the lower part of your screen is the catheter that is used to inject contrast or dye to be able to evaluate the inside of the aorta.

MARK FARBER MD: You see there, that little ring that's on the distal aspect of the previous device. Now I just need to be careful that, as I bring this device up, I don't move that proximal piece too much. There you go. You can see that that fits in there very nice. We're going to make sure we have enough overlap on these pieces. This device is made to fit inside one another and that looks very nice there.

ROBERT MENDES MD: Dr. Farber, while you are going ahead and rotating and getting the patient in an appropriate position, a question I have for you is the presence of aneurysms and open repairs, how long of a procedure is it when you're doing an open repair compared to an endovascular repair?
gentleman, it would require replacing almost his entire thoracic aorta, all the way down to the vessels to his intestines, which means you have to open up not only his chest, but his belly, in order to do that. That sometimes can be a long, arduous procedure during the day, 6-8 hours, and then it takes a lot of care in the ICU for several days to get the patient through that. You have to deflate one lung during that procedure and during that deflation, the patients can go on to get pneumonia and have other issues.

00:25:22.000 ROBERT MENDES MD: Dr. Marston, one of the questions I have for you would be actually the follow-up that is required for an endoprosthesis device. How do you follow these patients after they've left the hospital?

00:25:34.000 WILLIAM MARSTON MD: We've been using these devices for various aortic problems for 6-7 years and we have a pretty good idea, at least for the abdominal aorta, that they last relatively well, but we need to follow the devices routinely. Our experiences earlier were in the thoracic aorta, but we do know that patients must come back at least 6 month intervals for a CT scan for the first 2 years and then yearly thereafter. So if a patient is not prepared to do the follow-up, then they should possibly not consider this procedure.

00:26:10.000 ROBERT MENDES MD: One of the questions I have is what exactly are we looking for when we follow them up and are getting those CT scans?

00:26:14.000 WILLIAM MARSTON MD: What we've found is approximately 5-10% of patients may develop a leak around the graft that may require a subsequent procedure to dilate the graft or put a new piece in. We think that is going to be less common in the thoracic aorta. The other things that could happen would be if a piece of the device twists or gets a kink in it, it might need to be dilated to reopen it.

00:26:41.000 ROBERT MENDES MD: I also have some more questions that have been brought to us through the email system. One of the questions is that Dr. Farber had mentioned that you guys started off by creating an artificial conduit, or sewed on an artificial artery to be able to gain access to this vessel. Why is it that they had to sew a conduit or an artificial artery in?

00:27:01.000 WILLIAM MARSTON MD: Well, the devices that we use for this are 6-8 mm in diameter and the iliac artery, which is the artery extending from the aorta down to the leg, oftentimes is not large enough to accommodate the device, so we make a small incision just above the groin and sew a larger artery up just below the aorta to allow us to have access.

00:27:26.000 ROBERT MENDES MD: So the lower limit at which we would use a femoral artery or the lower limit before we have to sew a conduit on is about what size, would you say?

00:27:37.000 WILLIAM MARSTON MD: I'd say about 7 mm. If it is less than that, we would worry, particularly if it is diseased and calcified.

00:27:45.000 ROBERT MENDES MD: Let me ask you another question about just the endoprosthesis device itself. When it is sitting in the aorta, what are the risks of blood clots or actually blood clots forming on the material itself?

00:27:57.000 WILLIAM MARSTON MD: In a well placed endograft, where it is sealed up against the wall and there are no major kinks or problems, it is very low. We thought that would be a common complication during the development of these devices, but with the level of technology the manufacturers have now, it is been quite rare.

00:28:25.000 MARK FARBER MD: Let's go back to that last run so I can show people what I'm looking at on the screen. At the bottom part of the aneurysm, you see there is a lot of branches coming off. Those are the vessels that feed this gentleman's spleen and liver and intestines. So I want to make sure this device doesn't come down and cover those because he does need those to preserve his intestinal function, so we've marked on the screen where we need to place the bottom end of the device. Generally this device will move just a little bit when we place it, so I've allowed for that. Now we'll just get one last view. You see how the device is positioned inside the previous device. Good.
Let's see that run one last time to make sure I've got the device in the last correct position. This last piece is slightly bigger. We'll seal off the bottom end of his aneurysm. You see the device is floating on the top in there, just where we need it. So I've positioned that device right on the area where I want it to land. I'm happy right there. Now you can see how that device is constrained on the bottom. That tells me that it's sealed there right at the right position. If I look at the marks that we put on the screen, you'll see it's right at the celiac artery. We've come down exactly to it. The last thing I'm going to do is pass this catheter up.

The last thing we'll do is do one final run and then we'll take some additional questions. At that time, I may show you one additional technique we use in patients with limited renal function, like this gentleman. We use a sound wave machine inside his arteries and that gives us an idea of how things look. Good. That looks pretty good. Let's do the proximal run and we'll see what that looks like. That covers most of his thoracic aorta. Let's move this patient up so we get a bigger picture. Good. That's just about the whole device. We're missing the very bottom, so we'll do a final projection at the bottom to make sure.

ROBERT MENDES MD: Dr. Farber, what are you looking for with this arteriogram?

MARK FARBER MD: I want to make sure that now the flow is just within the device I inserted. You saw before that the aneurysm was quite large and you saw contrast outside it. Now we should see flow just within it, if things look terrific. Now we'll go back to the very first run we did and you'll see the difference in these images. You see how big that artery is there, Bobby. Now let's go to Run #9.

ROBERT MENDES MD: When we see that the artery is enlarged, even from the inside that looks smaller than what the CT scan looked like. How come that's the case?

MARK FARBER MD: As arteries get enlarged, blood flow tries to maintain a lamina or simple stream, not a bunch of turbulence or eddies. When it does that, blood clots on the side walls of the artery. Let's do one final run at the bottom. Good. Regular fluoro now. Let's go back to that AP position so it'll look just the same.

ROBERT MENDES MD: Dr. Farber, you keep mentioning AP and oblique. What exactly are you meaning by that?

MARK FARBER MD: Those are instructions to Scott about what position I want the radiograph to be pictured from, whether it's from the patient's side, whether it's from his belly or from his back. AP stands for anterior-posterior, which means the x-rays are going through the patient's belly. The other degrees, 30o means I'm shooting from the side. That looks pretty good. Let's come down a little bit and we'll do one final run there.

ROBERT MENDES MD: While we're doing that run, as the people out in the world start to look at these images, if you have any further questions, just go ahead and click on the MDirectAccess button and email us your questions and we'll answer them to the best of our ability.

MARK FARBER MD: Good. That looks nice. You see we still have flow to those intestinal vessels. There's a little bit of the wall of the device that's not on the posterior wall, but we don't see any flow up top into the actual aneurysm. It's staying all within the device, so he has two sections of seal there. Sometimes we'll come and balloon that. I think that's probably what we'll do today, just balloon that up just a little bit and touch that up on the bottom end.

ROBERT MENDES MD: Dr. Farber, you were just talking about leaking around the graft. That's one of the concerns that we always have when we're placing an endovascular device. What exactly is an endoleak? People that get these procedures are going to be hearing that word quite often, iendoleak."

MARK FARBER MD: In this particular case, when I say leak, it doesn't mean blood is leaving his blood vessel. It means blood is going around the end of the device and it's not completely against the wall, and that's just because this artery curves there. So in most patients, a leak does not mean they've ruptured. It just means the
blood is not all within the device. Now, there are some patients who have these repairs that if the repair is not working, they can pressurize their aneurysmal wall and then rupture. Now, that type of situation means blood is leaking outside the artery, so that's why we refer to one as a leak and one as an endoleak.

00:36:13.000 ROBERT MENDES MD: These endoleaks, do they cause the aneurysm to grow more afterwards? Is it a major concern?

00:36:19.000 MARK FARBER MD: Endoleaks can cause the sac to grow and that's why the patients need to get monitored. In this case, you'll see, Bobby, I've positioned the balloon inside the device and we're going to insufflate it. Now Peter, you use about 20 cc of insufflation of that balloon. You'll see, Bobby, that trilobed balloon has been designed by the company W.L. Gore for this device. You'll see it's got three lobes there. We'll blow that up because we just want to improve the seal on the bottom end. You see the device is all constrained. It's not sitting perfectly against the walls, so we're just going to smooth everything out and then you'll see on the final run that things look pretty good. Let's desufflate there and then we'll do one more balloon insufflation.

00:37:04.000 ROBERT MENDES MD: Okay. As you're ballooning there, one of the main questions that I guess is going to be asked is why not just place one long piece in there, instead of having to angioplasty or balloon all those segments and the interconnections between those stents?

00:37:19.000 MARK FARBER MD: You can do that. However, the current devices are set at certain size limits, 10, 15, or 20 cm in length. That allows us to do a couple of things. In this particular gentleman, these are 3 different sized devices so I can custom tailor all of the devices to the patient's anatomy as needed. That allows me to custom fit these devices. Not everybody is the same. They need different pieces at the top and the bottom. You can do one piece. In patients with short aneurysms, that's exactly what we use, one piece, but this gentleman has a little bit larger aneurysm in terms of the length of the aneurysm and it is very hard to do that with a single piece. The company will be coming out with longer and more varied sizes of devices and tapered, but as the first device is approved, it's important to have gotten this out into the FDA approval so that we can use it in patients and treat them, and then we will continue to modify it and improve its outcome.

00:38:22.000 ROBERT MENDES MD: I just noticed in this patient that you placed your endograft starting at the top and working your way distally. Do you always do it that way?

00:38:30.000 MARK FARBER MD: It depends on the patient's diameters. In this case, he was small up top. If each piece is a little bit bigger, I put each piece inside the other one. In some cases, it's just the opposite. When they're small at the bottom and big at the top, then I do just the opposite; I start at the bottom and work my way up. You have to be careful when you put these in because if you have a very tortuous or curved aorta, sometimes the second piece you put in cannot accommodate the curvature because the device itself stiffens things up, so those are the issues that we consider in everyone.

00:39:02.000 ROBERT MENDES MD: One of the situations you had mentioned earlier is this patient has renal insufficiency. Being that he has renal insufficiency, how do we follow up this patient with CT scans afterwards if contrast media could be a problem?

00:39:32.000 MARK FARBER MD: CT scan is not the only way in which we can follow patients. We can use magnetic resonance angiography. If you like to use CT scan because of the better imaging in terms of spatial resolution, you can use a special contrast called gadolinium and we can get very good images with gadolinium when we do that. So this gentleman actually had a gadolinium CT scan when we saw him in clinic several weeks ago and that's exactly what he had. For the aneurysms in bellies that we do, you can also use ultrasound to follow these patients, but in the thoracic area currently it's difficult to ultrasound image that. The one last thing that you can do and is coming down the pipeline is pressure sensors. Recently there has been a pressure sensor that's been approved during implantation for aneurysms in the belly and it is my thought that eventually that will be approved for use in thoracic aneurysmal disease and that will help follow patients potentially as a chronic method, although it is not currently approved by the FDA for that.
ROBERT MENDES MD: So Dr. Marston, let me ask you, being that the endovascular device is placed, will the aneurysm shrink around the device or does the aneurysm just stay the same size?

WILLIAM MARSTON MD: Well, we like to see some shrinkage of the aneurysm, but that depends a lot on how much old clot is inside and some other factors. The majority of them will shrink some and some will just stay the same size. Clearly we get worried if there is any growth and we look to see what might be the cause of that.

ROBERT MENDES MD: When the aneurysm is actually shrinking, can the device move or migrate?

WILLIAM MARSTON MD: That was a large problem with some of the early devices used for aortic aneurysms, but with the current strategies, that’s pretty rare. It depends a lot on how good the proximal and distal fixations are and we work very hard to get good fixation of the device so it won’t move over time.

ROBERT MENDES MD: Another question that has been asked to us is what happens if a stent or graft accidentally covers an artery that we didn’t wish for it to cover (for example, the left subclavian or the celiac artery)?

WILLIAM MARSTON MD: Well, it depends on the artery, clearly. We’ve found with experience that the majority of the time the left subclavian artery, or the one that serves the left arm, can be covered and most often the patients are not symptomatic, so we don’t need to do anything in that case. We worry more about the celiac artery. If we think we’re going to need to do that, we may choose to do a bypass graft to that artery prior to the repair.

ROBERT MENDES MD: Dr. Farber, how are things coming along there?

MARK FARBER MD: Good, Bobby. We just did that final injection and you can see the device comes very close. With the marker catheter in, we’re within 1 cm of the arteries to his intestines. You see the device is sealed now. We ballooned it and we have no leaking up proximally into the sac. That’s a big difference from what we started with, especially you noticed it during that second piece, which is at the top of your screen there. All the contrast doesn’t extend up above that area and it all stays within the sac wall.

ROBERT MENDES MD: Dr. Farber, I think you had a good example of a leak earlier on that is now sealed off. Is it possible to show the previous angiogram so they can see what we’re talking about?

MARK FARBER MD: Yeah. We’ll go to image #10 and you see a little bit of contrast flow there at about 10:00 or 11:00 position. It’s very faint but you can pick it up. Now, as you move, you no longer see that that is there. The contrast now stays within the device, so that shows you a much better result by the ballooning that we do there. Now, we have a few minutes left, Bobby. If you want to take some questions, we’ll see about getting an IVUS catheter up here and doing a little IVUS work. I’m going to show you first, before we go there, the proximal difference. That’s his aneurysm as it extends down. You see that little curved knob. You see no flow in the aneurysm at the top and then go one more run there.

ROBERT MENDES MD: Dr. Farber, I’m seeing a stenosis in that celiac artery. Is there any need to fix that or take care of that at this time?

MARK FARBER MD: No. Some people like to fix patients who are asymptomatic, but when the patient is not having any symptoms, especially for something like a vessel to the intestinal arteries, there’s no need to fix it. You actually have 3 vessels to your intestinal arteries. The celiac artery was mentioned when the question was asked, your superior mesenteric artery, your inferior mesenteric artery, as well as collaterals from your internal iliacs or hypogastric arteries, so if patients aren’t complaining of pain after they eat or severe weight loss, then you do not fix those. Most patients, that artery can be completely occluded and you will never know that there’s an issue with that.
ROBERT MENDES MD: Once again, I'd like to ask anybody that's out there, if they have any questions, to go ahead and click on your MDirectAccess button to enter your questions. Send them in to us and we'll answer them to the best of our capabilities. Dr. Farber, you were just mentioning that you're going to pass an IVUS machine into the aorta. What exactly is IVUS and what is it used for?

MARK FARBER MD: IVUS is an acronym for intravascular ultrasound, which means that it's a little, small catheter that has an ultrasound probe. We'll be able to pass that up, turn on the ultrasound machine, and look at this artery from the inside. It'll give us an idea if the device is against the wall, how much it is against the wall for, if the device is moving at all. As well, we can see how close, specifically, we are to the vessels that go to this patient's intestines.

ROBERT MENDES MD: Is the IVUS a good modality to use for other issues, like dissections or other issues that you want to fix in the aorta?

MARK FARBER MD: Yes, IVUS is very good. Currently devices for dissections are not approved by the FDA, so we only do it in experimental trials, but it is very critical to know where you are. As you see on the fluoroscopic image, you can see that little catheter there. IVUS is up. Now you see the IVUS catheter and now you see we're inside the artery. That's that dark circle. I'm going to just move the catheter up and down some and you're going to see that things change.

ROBERT MENDES MD: It definitely requires a trained eye to look at what you're looking at there, Dr. Farber. Seeing that you've done so many, can you just describe what you're looking for? What exactly can you see?

MARK FARBER MD: Let me just get to the end of the device, Bobby, and then we will look at everything. Now, you see what changed there. You have that nice, bright ring around the outside. That's actually the device. Then, if we shoot fluoro, you see where that little dark bullet is in the center of the screen, Bobby, you see we're right at the device and that corresponds to what we see on the screen.

ROBERT MENDES MD: Right at the bottom of the device?

MARK FARBER MD: Yeah. Do you see that little bullet moving there, Bobby? That's where the IVUS catheter is. Now let's go back to the IVUS machine. You see on the IVUS machine there's a little dark speck in the center. That's that catheter we have up, but on the outside of the little feet of the device, as we come down, you see we lost them on the 12:00 to 6:00 position of a clock and they're still there on the 6:00 to 12:00 section, so that's just at the end of the device. As we come down, you see at 11:00 there's a little artery taking off. I'll show you that again. I'll come up and you see all of the device. As we come down, we're only moving about 1 cm. There's the artery leaving right there at 11:00, Bobby, so the device is coming down. The feet or the fingers of that device are right at the celiac artery. We're within 5-7 mm of where we have an ideal implantation. That's pretty good, seeing that we're working with catheters that are several hundred times longer than that. Precise deployment is very critical. Now, as we come down, you'll see other vessels and you'll see this gentleman's native artery. We'll see if I can show you the kidney arteries here, if we can get a good picture. Sometimes there we go, you see on the top of the screen, Bobby, the renal vein, which goes right along the artery, right there at the top, this little black shadow there at 11:00-12:00. As you come up, at 9:00, Bobby and the audience, there's a small right renal artery. As I move down, that artery will move away from the big circle. There it is, moving away at 9:00. Now it's at about 8:30. There's a little spot there. That's his right kidney artery. So we get a look at things. Now I'm going to go up into the device and just make sure, by IVUS, that the device looks completely open. There you see the ring, completely open. I'm making sure I don't have to do any more ballooning or anything. Sometimes it is important to do ballooning for the whole device. In this case, we can test it with IVUS. I tend to like this method of looking at the device to make sure it's completely open. We're at the junction. As we keep going up, you see that all of the device is a big circle. It's not infolded on one another. Now, as you see, Bobby, we lost that ring, and the audience. We're outside the top of the device.

I'm going to come back through the device one last time and we'll record this as we come through so we have a recording.
ROBERT MENDES MD: Dr. Farber, what do you mean when you say fluoro?

MARK FARBER MD: Fluoro is the x-ray equipment. The ultrasound catheter we're using inside the artery is one thing, but I'm also looking at the x-ray image to know where my catheter sits, so that's a type of imaging modality, just like a CT scan, just like an angiogram. When you have a cardiac catheterization or an angiogram, you're actually using fluoroscopic imaging, which I abbreviate by the word fluoro.

ROBERT MENDES MD: You also have asked anesthesia a couple of times to suspend respirations. We have had some concerns about what that actually means.

MARK FARBER MD: This gentleman we currently have intubated, so he's on a breathing machine. That allows us avoid any movement of the artery. You can imagine if I'm trying to implant this device within 1 cm or so. If he breathes in the middle of me deploying this device, it can change the adjustment a couple of cm, so therefore I like to have the patient's breathing stopped. He gets stopped for about 15 seconds. It's like holding your breath. Then we start the machine back up, breathing for him. So it doesn't cause any problems. He's still getting oxygenation through his breathing tube. We just stopped his chest and diaphragms from moving so that we can see exactly where we are.

We're done with that IVUS catheter now. You saw that we're right where we need to be.

ROBERT MENDES MD: I have some questions for you, Dr. Farber. You said that your experience here has been very extensive. Where should people go to find out how to have the procedure done if they have this kind of problem?

MARK FARBER MD: That's a very good question, Bobby. There are some websites to go to. You can go to OR Live, www.or-live.com, which you're currently on, and get our address. You can go to W.L. Gore's website, www.goremedical.com, who actually manufactures the device, and get someone who is in your local area. Now, our area here is probably a regional area. There is probably about 10 centers that have extremely extensive experience with various devices in this technique and other centers that aren't. Like I mentioned at the beginning of this webcast, this is a fairly new technology and most physicians and most patients are not aware that this minimally invasive technique exists. In general, these types of patients will go home in 1-2 days after their procedure, as you talked about at the beginning of the webcast, Bobby, and usually within 5-7 days they are fully recovered. Some patients who are a little older may take as much as two weeks to recover.

ROBERT MENDES MD: What kind of medications do patients have to be on after they leave the hospital? Do they need blood thinners of any type?

MARK FARBER MD: No. Most patients do not need to be on a blood thinner. In general, as you're older, most patients are on aspirin. They take an aspirin a day, which is good for the heart, so therefore, that's all they need. This device has a large amount of flow through it. It does not cause blood clots and there has not been an issue with that. If you need to take blood thinners, you can also do this device in patients that require blood thinners and then you just need to stop it for a short period of time to do the procedure and then restart the blood thinners once that's completed.

ROBERT MENDES MD: Just to go over some more questions that we have been emailed. Emails are coming pretty frequently and rapidly now. One of the questions that has been brought to us is what are the risks of this procedure during the operation? Is there a risk for stroke? Is there a risk for paralysis? What about you, Dr. Marston, what do you think?

WILLIAM MARSTON MD: Well, there certainly are some risks, a small risk of stroke and the incidence has been in the 1-2% range, which is also lower than with an open repair, and there is the small risk of paraplegia that we
discussed before, but overall, when you look at all of those risks compared to open surgery, with the exception of the contrast-related risks, they are less with endovascular repair.

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ROBERT MENDES MD: One of the other questions I have for you is what type of learning curve is there for placing these endovascular devices?

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WILLIAM MARSTON MD: That is a great question and I think that most people who want to do these procedures start with basic guide wire and catheter skills, so it means if you’re a vascular surgeon or a cardiothoracic surgeon that has never done any guide wire catheter-related procedures, you need to start with basic procedures, work your way up to doing other types of aneurysm repairs and then the thoracic aneurysm repair has its own set of challenges and thought processes. So it is not a simple approach to step directly into this.

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ROBERT MENDES MD: Who do you think should be placing these endografts? Should it just be vascular surgeons or are other disciplines also included?

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WILLIAM MARSTON MD: I think there is a wide range of people that can participate in this. I think the best teams are those that have multispecialty input in the procedure.

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MARK FARBER MD: Bobby, if I can add to Dr. Marston’s comments, I think there is two things that you have to consider. When we started these procedures, we started in 1996 and now we’ve done over 500 endovascular procedures just to treat aneurysms. That doesn’t include all the other small stents and everything else we’re placing. That is very critical. You need a lot of experience to know how these devices function. Once someone has those experiences, to do a new device or something new with a different company or if something else is approved, it will take you approximately 30 cases before you get facile with that device and get comfortable with it, how it performs, when to use it and when not to use it. I think those are issues that need to be looked at in everybody. I think once the team has those skills to do that, then it is fairly safe for the patients to undergo that procedure.

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ROBERT MENDES MD: I think a good thing to point out also, Dr. Farber, is that in placing these devices, it is good to have the experience, but it is also good to have the capabilities to take care of problems if they should arise. For example, how would you take care of an aneurysm rupture while you were trying to get this taken care of?

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MARK FARBER MD: If it ruptures while we’re here, many times we can just move along a little bit faster and exclude that area where the artery has broken. Rarely has that ever happened with the actual procedure itself. What happens is some patients come to us and already have ruptured and are brought into the operating room after the emergency room very rapidly. We can actually use this device to fix the ruptures and have had a little bit better success with that, so that’s how we do it. The other thing I think is important, Bobby, is not only here do we treat these disease processes with this minimally invasive, but we also do the open procedure, so that puts us in a position where we can look at all aspects of the patient, whether they’re a good endovascular or good open repair candidate, discuss that with them and have them help us make a decision about how their aneurysm needs to be treated, what their lifestyle is like, and so forth. I think that is all aspects that need to be considered by the patients that need this procedure. It will affect what they do and how they live. In general, this procedure they get over very quickly and they can do everything they want to do without a problem.

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ROBERT MENDES MD: How are we going along with the procedure right now?

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MARK FARBER MD: We’re done. I just need to pull out the wires. I had about two minutes left, so I wanted to give you the rest of my time before I pulled the catheter wires out. All we do is just pull the catheter wires out and I sew up this small incision. Then I can just take out the little retractor there. That is an incision about the width of your hand, as you see, for that incision. That is all it is done through in this particular gentleman, with small arteries, so we’ll just do that and we’ll sew this little tube off and tuck it on the inside of him and it won’t cause him any problems and we won’t need to use it anymore.

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ROBERT MENDES MD: Once again, just to bring back the question of the femoral arteries, what size is too small for you?

MARK FARBER MD: It depends on the actual device Iím inserting. This device needs three different sheaths, based on its size, so if Iím using the smallest devices, that can go through a 6-7 mm artery. If I need to put the big sheath in, like this gentleman, itís more in the range of 7-9 mm, so that really dictates it. Not only is it the size, Bobby, but its the presence of calcium, whether the calcium goes all the way around the artery, and how tortuous or curved the artery is and whether I can get this big sheath through it. Iíd rather do a simple procedure like this through my hand incision, instead of an incision half that big, and ensure that I donít injure the artery going in or coming out and that the patient doesnít have any added bleeding because thatís part of the safety of the procedure, very minimal blood loss so patients can get out of the hospital and back to full activities fairly quickly.

ROBERT MENDES MD: Weíre getting to about only two minutes left in the webcast and Iíd like to ask you two more questions, if I could. First of all, what about the size of the aneurysm? Does that make a difference?

MARK FARBER MD: The size of the aneurysm comes into play as to whether youíre going to treat it to begin with. In this particular gentleman, his aneurysm was 6.2 cm in diameter. That gives him a rupture risk of approximately 20% per year, which means that 1 in 5 people, if they all had a 6.2 cm aneurysm, 1 of those 5 would rupture within the next year. The problem is itís difficult for us to predict which of those 5 people will rupture. Obviously those that are having symptoms, we are more concerned than those that are asymptomatic and thatís what makes the decision difficult. 75% of patients donít have symptoms, as you mentioned in the beginning of this webcast, Bobby.

ROBERT MENDES MD: Patients oftentimes are they awake or are they always put under general anesthesia for this procedure?

MARK FARBER MD: Most of my patients are done under a regional block or a local block to just numb the area around the femoral artery where I go in, but this gentleman needed an incision a little bit higher up. Since he was thin, we thought it was safe to put him to sleep. He will have the breathing tube taken out at the end of the procedure and go right to the floor. He will not have to go to the intensive care unit.

ROBERT MENDES MD: How long did this procedure take? This wasnít a very long time.

MARK FARBER MD: We started approximately 20 minutes before the webcast was broadcast and itíll take us maybe 10 minutes to close this, so roughly youíre talking about an hour and a half, maybe an hour and 45 minutes between when we make the incision and close the incision, and this is a gentleman who had to have 3 pieces put in. If itís a single piece insertion, you can imagine we can cut off another 20 minutes and shorten that procedure some. It can go very rapidly compared to the 6-8 hour type procedures for open repair.

ROBERT MENDES MD: Thank you. Dr. Marston, thank you. Dr. Farber, thank you. The OR team, Iíd like to thank you very much. If anybody else out there has any further questions or would like to contact us in any way, you can do that through the OR Live website, www.or-live.com, or you could just contact the University of North Carolina and ask for the vascular surgery service. Once again, this webcast can be seen again through the archives in approximately about an hour from now. Thank you very much for joining us today.

MARK FARBER MD: Thank you.

NARRATOR: This has been a live webcast of an endovascular repair of a descending thoracic aortic aneurysm with the GORE TAG endoprosthesis, from the University of North Carolina in Chapel Hill, North Carolina. For more information, to make a referral or make an appointment, click the buttons below.