ENDOVASCULAR ABDOMINAL AORTIC ANEURYSM REPAIR WITH GORE EXCLUDER
BIFURCATED ENDOPROSTHESIS

OKLAHOMA HEART HOSPITAL, OKLAHOMA CITY, OK
Broadcast June 22, 2005

NARRATOR

00:00:25:00 Abdominal aortic aneurysm rupture is the 13th leading cause of death in the U.S. During this live webcast, surgeons from Oklahoma Heart Hospital in Oklahoma City, OK, will perform endovascular abdominal aortic aneurysm repair with the Gore Excluder Bifurcated Endoprosthesis. This device is designed to be a minimally invasive treatment option for patients with abdominal aortic aneurysms, also known as AAA. The expected outcomes of this new treatment option include decreased procedural times and shorter hospital stays. At any time throughout this program, you may email questions to the physicians by clicking the MDirectAccess button on the screen.

LENNY STUBBS, M.D.

00:00:57:00 Hello and welcome to the Oklahoma Heart Hospital in Oklahoma City, OK. And also welcome to our live Internet broadcast where today you will have the opportunity to view the repair of an abdominal aortic aneurysm live in the operating room as the repair unfolds, using the latest endovascular techniques and technologies. Dr. Jim Melton, vascular surgeon of the Oklahoma Cardiovascular Associates here at the Oklahoma Heart Hospital will be performing the repair and you will have a chance and an opportunity to watch him perform this repair live in the operating room. My name is Dr. Lenny Stubbs, I’m also a vascular surgeon at the Oklahoma Cardiovascular Associates and I will be moderating the event today. I will also be providing some information about abdominal aneurysms as well as the history and the techniques for the repair, as well as some visual aids while the repair is taking place. Now, let’s turn it over to Dr. Melton and the operating crew live in the operating room.

JAMES MELTON, D.O.

00:02:05:00 Thank you very much, Dr. Stubbs, I really appreciate you moderating today and I look forward to your comments during the case. I’d like to introduce my OR crew today. Welcome everybody to Oklahoma Heart Hospital. This is Cathy, Colby, Steve, Johnny’s on the fluoro, Sarah and Becky are circulating. It’s a great crew we have here today and I look forward to a great case. Right now we’ve percutaneously accessed the patient. We have two sheaths in the patient. One is smaller on this side, one’s larger on this side. That’s for the main body device to go up here. The Gore Excluder device is what we’ll be using today and its distinct
advantage is a lot of the times we can do this percutaneously, without making an incision. We look forward to a good case here and welcome to Oklahoma City.

00:02:57:00 Right now we have the—we’d like to go to the fluoro and show the angiogram, if we can. The angiogram will be shot with some dye going through this catheter. You can see some markings on the catheter that demonstrate 1 cm markings throughout the length of the aorta. The aorta is the main blood vessel which supplies the legs and all the intra-abdominal organs. The aneurysm is just below the kidney arteries which we’ll be demonstrating here momentarily with the introduction of some dye into the patient’s body. So we’re going to take the angiogram and we’ll show you that on the fluoro machine. Johnny, you ready?

00:03:57:00 Right there you see the dye coming into the aorta and you see the large balloon formation just below the kidney arteries which we’ll demonstrate on fluoro here. The kidney arteries you can see going straight out like arms off of the aorta to two round objects there on each side of the screen which are the kidneys. The dilation of the aorta below that is the aneurysm and this lady has an aneurysm that’s almost 6 cm, which is very dangerous. We’re going to treat this, again, totally percutaneously without any incisions. Right now while we’re getting the device ready, I’m going to ask Dr. Stubbs to demonstrate with animation, angiography and the deployment of the graft and we’ll show you that live. Thanks.

LENNY STUBBS, M.D.

00:04:50:00 Thank you. Now we’re going to look at some animation of what’s going to transpire as far as the repair of the aneurysm in endovascularly. When we pull the animation up, I’ll go through the animation and the repair process. This is actually a shot, an animation shot of the aneurysm that he showed. It shows the wire access that he’s going to be using as he goes through the sheaths. Through that, he will deploy the device after positioning it just below the kidney arteries. When the sheath is pulled back, the device is exposed and you can see the device there in the aneurysm. The orientation of the device is done under fluoroscopy and you can see there he will be orienting the device and I’ll show you a little bit later what the device looks like outside of the body. Once this is done, the graft is deployed by simply pulling a string which unravels and allows the graft to expand. This is now an inside shot looking inside of the aorta at the graft with the wire in. Once this is done, a balloon is used to help smooth out the fabric and the wrinkles at the proximal end of the graft to help smooth out any irregularities in the graft when it’s deployed.

00:06:08:00 The next part of the animation involves getting wire access to the other side, or the contralateral limb and through this, the other side of the device is then deployed, in this contralateral leg of the device. That looks like the finished product and, again, this is inside the contralateral leg, or the opposite leg, looking at the device being deployed over the wire. That’s the animation. That’s what we’re going to be seeing unfold in the operating room.

00:06:43:00 A little bit about aneurysms again. Just like Dr. Melton had mentioned, it is a balloon-like enlargement of the artery wall that involves the entire wall. As the wall diameter increases, it weakens the wall which increases rupture risk and that’s why we get excited about doing these. I think we’re now ready to go back to the operating room. Dr. Melton is now placing the device for deployment.

JAMES MELTON, D.O.
00:07:13:00 Thank you, Dr. Stubbs. I appreciate that input there. I’m going to show you a few things about the graft here and how the graft comes in. As you saw in the animation, it comes in a main body with the entire neck of the graft and then one limb of the graft and then we insert the other limb through the contralateral, or opposite leg. This is the graft itself and it’s loaded on a catheter system. This graft is the Gore Excluder and one of its many advantages is it is low-profile and tends to be more applicable to the percutaneous approach than the other grafts that are out there. This is the graft itself. It’s flushed just with a simple catheter at the end of it. We flush it and make sure it’s all heparinized and that’s just a simple flushing system there. As you can see, the device has a flushing port here and has the end of the catheter where the wire comes through and then this part of the device is actually the deployment string that simply unscrews and it deploys in a proximal to distal fashion from this end to this end. It can be a controlled deployment or a rapid deployment, either one that you desire on this particular device.

00:08:47:00 So now we’re ready. We’ve got our angiograms, we have our kidney arteries marked which are very important within this procedure because the kidney arteries are exactly where we want to put the very top of the graft, this portion of the graft right here. We want to set that right at the level of the kidney arteries and deploy it there so we completely exclude the balloon dilatation just distal to that area. So we’ll work on getting the device up and then show this to you live, just like you saw on animation.

00:09:32:00 Now this graft is going over the wire that is already up and past the aneurysm. If you can give me some fluoro, shoot the fluoro, please. You can see the wire that’s up and you can see our marks on the fluoroscope machine there that show the level of the renal arteries of the kidneys. That’s our target mark for where we want to put the very top of the graft, this portion of the graft right here. We want to set that right at the level of the kidney arteries and deploy it there so we completely exclude the balloon dilatation just distal to that area. So we’ll work on getting the device up and then show this to you live, just like you saw on animation.

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Okay. I’m going to go to Dr. Stubbs so he can, again, go through the device real quick and then we’ll be back live in the OR for deployment.

LENNY STUBBS, M.D.

I wanted to show you the device again like Dr. Melton had done in the operating room, just to give you a little bit better view in the light. Again, there’s actually a packaged device that’s very small, low-profile. The graft—I will actually deploy this here so you can see actually how it deploys. Again, there is the string that deploys it, where you pull this string here and it will unravel the device as well as the flushing port back here. When it’s deployed, if you can see this shot here, when you pull the string, you unravel the string here and, if you get a shot of this here on the graft down here, you can see this as it deploys, this is what’s happening inside of the body. I’ll get the device here in a second and we’ll deploy this so you can see what’s happening inside the body because sometimes it’s hard to visualize. You can see this start to unravel and come open as it deploys and we’ll get a side shot of this as it deploys. You can see it unravel so that it actually expands, self-expands to take the shape that it wants to assume. The final product will look something like this. Why we call it a stent graft is it’s actually graft material with metal stents on the outside. That’s what also gives it this force to push up against the wall and then there’s these metal hooks that actually hold it in its place so it doesn’t migrate or move up and down. By doing this, it allows exclusion of blood flow from that sac so the blood flows only through the graft and that’s the repair. Let’s go back now to the operating room while Dr. Melton (inaudible)

JAMES MELTON, D.O.

Again, Dr. Stubbs, thank you for the look at the graft directly. It’s hard to demonstrate that when we have it here in the patient’s body. We’ve got the graft right at the level of the renal arteries, the kidney arteries and, again, this is a very critical portion of the procedure in that it’s very critical to get this right below the kidney arteries so you get a good seal, but not too high so you can, so you eliminate the blood flow to the kidney. We’re right here and we’re going to deploy very slowly. Go to fluoro, please, fluoro shot on the camera, please.

You can see it start to open up a little bit and the graft is opening as we speak and we’re going real slow to open the contralateral gate that you saw Dr. Stubbs demonstrate with the model. Now it’s open. We will stop there on the deployment and I’d like to go back to Dr. Stubbs for some discussion about aneurysms in general and about the contralateral gate wiring.

LENNY STUBBS, M.D.

Okay. We’re back and, again, we’ll get another shot. That’s what he actually deployed inside of the body and this finished product, this is the contralateral gate, or the opposite gate, for which eventually this other limb can go back into and fit inside the graft—you can get a shot of that—so that it fits inside and you get a nice seal zone on this contralateral gate. We’ll go over the animation here in a second. I want to flip to the slides here real quick and just show you a couple of interesting slides if we can.

One about rupture risk and size and why that’s important. We know that when these aneurysms enlarge and they approach 5 cm, for the viewing
audience, if you’re not familiar with centimeters, there’s about 2.5 cm in one inch, so we’re talking about a little under two inches. When it starts to reach that size, we know that historically the rupture risk tends to go up exponentially. So that’s why, number one, we get excited about fixing these and why we intervene to fix these. The other issue is that we know that over time these aneurysms expand, probably .5 cm per year, so about 10% expansion per year. So that’s why we tend to get excited about those. Again, Dr. Melton right now is actually trying to get a wire access. Let’s show the animation again, if we can, and run that so we can see wiring of the contralateral gate. We’ll run this animation again and you’ll see the full series.

00:17:12:00 Again, I will recap what he has done so far. Again, he has gotten wire access to the aorta, through the aneurysm for which he has now placed the trunk, or the main body device, and deployed this successfully. He’s opened it partially to allow him to gain wire access to the contralateral, or shorter, gate. In just a second here, after this is deployed, you will see what he is preparing to do now to complete the endograft repair. Again, this showing the main body deployment as it unravels and deploys inside of the aneurysm and now you will see this is actually the ballooning of the proximal to, again, iron out any wrinkles and give it a smooth profile for a good seal approximately just below the renal arteries. Okay. Again, now we’ll see the contralateral wiring, this is what he’s doing right now, getting the wire up in the contralateral gate so he can deploy this other limb to get the complete repair. And that’s the contralateral gate. Now let’s go back to the operating room where Dr. Melton has gained wire access and will deploy the contralateral limb.

JAMES MELTON, D.O.

00:18:40:00 Again, thank you, Dr. Stubbs for the animation; it’s very helpful. The contralateral gate has been wired without much difficulty. We got lucky on this one. It’s sometimes a little tricky to get this wire up, but it cooperated today. The catheter is up and we have a wire up where we need it. What we’re going to do now is I’m going to show you the other portion of the device, which is the limb that extends down in this patient into the left leg, again, percutaneously. This is a major advantage. This young lady’s 83 or 4 years old, but she’s extremely with it and independent and stays at her house by herself and everything. So she wants to get home and get back to her garden so this is better for her. Okay. This is the device that goes up the left leg and it’s, again—it looks the same as the other one except that it’s just the limb. It doesn’t have a body to it, it’s just a limb extension down into the left leg. Again, the same body components or the guts of it are up here. The flush hole and the end the wire goes out and then, again, the ripcord that deploys the graft. Again, this is all technology that’s very, very advantageous to the patient population because of all their other health issues that they have going on.

00:20:16:00 We’re going to deploy this up and we always try to use clean gloves and new gloves when we’re messing with the device here. We’ve all changed before we got the devices on the table. We’re going to go up with this sheath up into the gate, he can see it. Go to fluoro shot, please. You can see it up inside the gate, the dark area there. Then we will work on moving our device, again, over the wire and up into the contralateral or left-sided limb. This will complete deployment of the device and then we will work on, again, Dr. Stubbs mentioned, ballooning out the ends and making sure that they’re all nice and tight against the aorta. Can you mag up one, please, on the fluoro? Thank you.
I’m going to be putting this piece of the graft—you can see me moving it up and down—I’m putting it at this mark here. That tells me the area where I want to deploy it down into the left limb. Okay. Off mag, please? Again, we don’t have to worry about the kidney arteries anymore because we’ve already taken care of those above. We’re going to deploy this contralateral limb and we do that in a ripcord fashion. That’s done. Now we will come out with the device and leave the wire up. We will, please, go back to Dr. Stubbs for any, maybe some email questions that are available and we’ll be back to demonstrate exclusion of the aneurysm when he’s done. Thanks.

LENNY STUBBS, M.D.

Some of these email questions are actually very good and thank you to the viewing audience for sending in these very insightful questions. One of the questions was: how many endograft procedures has your practice done? In the last calendar year, the Oklahoma Heart Hospital has performed approximately 80 of these endograft procedures and Dr. Melton has performed over 400 of these cases in his practice to date. It also has been the leader from the beginning, or its inception, so there’s a vast amount of experience with these endografts at this hospital. It’s almost a common daily surgery. So we do quite a few of these here and we have vast experience from the OR staff all the way to the surgeons.

Another very good question: what evolutions are you seeing related to endografting and vascular surgery? Probably smaller delivery systems, number one. They continually become better and better as far as deployment, as far as fixation. As far as the delivery systems, they’re becoming much easier to deploy and we’re getting much better long-term results, so I think as time goes on we’ll see better graft material, better deployment systems. I think, also, coming up with aneurysms that occur in different areas of the body. Remember this is in the abdomen. Aneurysms that occur elsewhere, such as the thoracic aneurysm, and I mean the descending thoracic aneurysm, we have stent grafts that are becoming available for these repairs and this certainly will also make a difference compared open to endograft, as far as the morbidity and mortality of the procedure.

What advantages does it offer to the patient? If we go to the slide, looking at complications from open repair, certainly with open repair, there’s cardiac and respiratory problems, blood loss issues, potential for bowel obstruction and it’s also a very invasive procedure, when you’re talking about an open repair. This avoids all that, avoids the open repair, open abdominal surgery, the potential for bowel obstruction and bowel injury and both the cardiac, respiratory and even renal complications. Also, and even more importantly, with patient satisfaction, decreased amount of pain, discomfort, faster recovery time and faster operating room times, I think that is why this procedure has become so popular and probably eventually will become the standard of care. Let’s go back to the operating room now where Dr. Melton will be finishing the deployment of the endograft.

JAMES MELTON, D.O.

Welcome back to the OR and thanks again, Dr. Stubbs, for taking those questions. We have both devices right side and left side deployed. Again, percutaneously, I think, is a distinct advantage of, again, this graft, the Excluder. We’re now putting a balloon up at the top, there’s—you can see on fluoro, if you’ll pan to fluoro, please—you can see the balloon. It’s got two dots and I’m moving it up
and down around 56-58, if you can see the ruler. I’m going to balloon-dilate this and as Dr. Stubbs mentioned earlier, I’m going to seed the hooks there right below the kidney arteries. You can see this little kidney-shaped balloon there dilating and, again, compressing the graft against the aorta. We’re going to do a little bit more right there and you can’t overinflate these because you’ll—the aorta’s a certain size so you have to be careful as far as inflating the balloon too much. We’re also going to dilate the area where we put the gate in and make sure that it opposes the body well inside the graft. So that’s what I’m doing now with that colored object inside the graft. We’ll be taking the balloon down and taking the balloon out and then getting ready for our final picture to demonstrate complete exclusion of the aneurysm. I’d like to go back to Dr. Stubbs, if he has any more email questions or questions from the audience.

LENNY STUBBS, M.D.

00:27:01:00 They’re actually very good questions. One question was sent in by a viewer concerning candidacy for this endograft and whether risk factors like diabetes, hypertension or coronary artery disease might prevent them from having it. Actually, the candidacy is actually determined by the size and anatomy of the aorta as well as the iliac arteries and that’s usually done by CT scan by measuring prior to the operation and we use the arteriogram as an adjunctive measure. As far as the co-morbidities like diabetes, hypertension, certainly the risks of complications from diabetes, the coronary artery disease, high blood pressure, certainly much, much higher with an open procedure versus this endovascular procedure and that should not prevent you from having this particular procedure unless you have renal insufficiency, or kidney insufficiency might be one that might prevent you. However, even those patients do very well with this procedure.

00:27:58:00 Another question concerns—a patient sent in a question asking, her husband has a thoracic aneurysm or an aneurysm in the chest and is there a way to repair that? Again, yes, stent grafts are now available to repair these, what we call descending thoracic aneurysms. And, again, the candidacy is by size and anatomy. Yes, it’s certainly a much better procedure as far as complications versus open and that Gore right now has the only available, FDA-approved graft on the market for this. So, yes, that is certainly something that can be treated with this same technique and this is coming down the pipeline right now. Let’s go back to the operating room and watch him finish the deployment.

JAMES MELTON, D.O.

00:28:46:00 Thank you, Dr. Stubbs, I appreciate you, again, answering those questions. I might add to that one viewer that it’s not uncommon for Dr. Stubbs or I, either one, to do these procedures under local anesthesia, a patient awake if they need to be because of comorbid conditions including coronary artery disease or hardening of the arteries in the heart or bad lung disease, emphysema. It’s not uncommon for us at all to do these awake with local anesthesia, so this is just a tremendous benefit for patients, this percutaneous approach as opposed to the old aneurysm repair, which still needs to be done on occasion, depending on the candidacy. The thoracic graft question, again, I can add that Gore is the only graft on the market and many, many patients meet criteria for that, so I think that’s a very, very nice advance in technology that’s going to take care of a lot of patients and get rid of a very tough surgery open.
We're now ready to take the final picture and see how we did as far as exclusion of the aneurysm. Our catheter, our marker catheter, which we took the first angiogram with, is up and we're going to take a picture and see if we've got any leaks or anything we need to address as far as the aneurysm goes. Johnny, you ready?

You can see there, there's just a really nice post-picture there. These limbs that you see are crossed on the picture are done on purpose because of the length. We wanted to cross the limbs to get the correct length distally. That causes us no problems, no issues at all. The post-angiogram has absolutely no evidence of endoleaks whatsoever anywhere. I'm very happy with the end results here. We're going to now work on getting these sheaths out and showing you the end result of a 100% percutaneous approach with the Gore Excluder graft, hopefully. Yeah, we're going to do that and try to go from any incisions to just, again, percutaneous approach to this. I'd like to go back to Dr. Stubbs now for some more information regarding aneurysms and more questions.

Thank you, Dr. Melton. I'm going to go through more of the slide presentation now while he finishes up in the operating room. We hopefully will also get, like you said, the before and after pictures, which I think are usually fairly dramatic and show the difference in the repair. As far as treatment options, again, if they're small—and what do we mean by small? Well an aneurysm is actually defined as a 50% larger diameter than the normal artery. The normal artery usually measures 2 cm or under, so that would be 3 cm or above. If you're getting up toward 4, 4.5, 5 cm, that's when we start recommending intervening, especially with this endograft procedure if you're a candidate. As far as surgical repair, the open surgical repair, I'm going to go through some of these slides. This actually, again, involves an incision on the abdomen and going into the abdomen to do a direct repair of the aneurysm. Oftentimes it involves opening the aneurysm itself after clamping the aorta and the iliac arteries and doing what we call either a direct inline repair with a tube graft and/or even a bifurcated graft if the iliac arteries are either aneurysmal and/or if there is artery disease that narrows those arteries. Again, it's a very invasive procedure, it has the potential for complication, but it's still a good procedure and a gold standard.

Again, we'll go through the cardiac complications, respiratory complications like we talked about with the open procedure, it is a big stress to the body. The surgery time is usually longer and the recovery time is longer. The surgery time can be upwards of an hour and a half to two hours, the recovery time in the hospital can be, usually, five to seven to even nine days. The endovascular repair, as you've seen, is much less invasive. It's going through the femoral arteries. Those arteries are actually located in the groin area so there's no incision on the abdomen, you never have to enter the abdominal domain. It's much less invasive. It actually excludes the flow through the aneurysm sac, but it's not actually sutured in. Again, just like the open repair, it actually prevents the risk of rupture because there's no blood flow inside the aneurysm sac.

Just a little bit on the history. The first endograft that was deployed for the treatment of abdominal aortic aneurysm was done in 1991 by Juan Perotti in Argentina, so it's only been less than 15 years ago that these came about by Dr.
Perotti who decided to try to use a balloon-expandable stent sewn to a graft and from that idea was born the technology that we have today.

00:34:43:00 Again, we’ve gone over the candidacy and, again, the approach is through the femoral artery, so it’s in the groins and that’s the only scars that you’ll see. There’s no abdominal exposure. As far as follow-up is concerned, how do you follow these things, Dr. Melton mentioned leaks as far as the ballooning of the proximal-distal end of the graft. Usually we follow these endograft repairs with CAT scans, usually at 1 month, 6 months, 12 months after surgery and then annually after that. What the CAT scans do basically is monitor to see if the graft has a leak proximally or distally. Also to monitor the graft integrity itself as well as the aneurysm’s size. To go over endoleaks, basically we’re talking about leaking between the graft and the wall. If the anatomy is measured appropriately and we choose the right size graft, this is a very low risk. However, we still have to monitor these things.

00:35:44:00 One of the questions that was asked by one of our viewers was: what type of anesthesia was used during the case? This was a general anesthetic although we do have options as far as a regional anesthesia and/or even local anesthesia with sedation, which cannot be done with the open procedure, so there are several more options for anesthesia. If the general anesthetic is actually very stressful for this patient population then there are certainly other options if necessary.

00:36:18:00 Again, with the slide, again, it’s a shorter hospital stay, it’s a safer option for high-risk patients, patients with bad heart disease that can’t be treated, bad lung disease, such as COPD, and deconditioned patients. This is certainly a much better option for repair. Shorter operative times, the patient is much more comfortable postoperatively and the hospital stays are much shorter and they go home within 24-48 hours.

00:36:46:00 Now, let’s go back to Dr. Melton in the operating room and see how he’s progressing.

JAMES MELTON, D.O.

00:36:55:00 Stubbs, we’re continuing to close these percutaneous wounds here and sheaths and in a moment I’d like to recap kind of everything we’ve done and show you some before and after pictures and show you all these things. What we’re going to do now is we’re tying some of these percutaneous sutures down, if you can come on close-up on that for us. We’re tying some of those down and, again, these are all done through a poke wound that has—this patient has no incisions so far. Right now, everything’s going well with that. The other side’s done and we’re working on the right side, which is the large side. Again, in a minute, I’ll show you the before and after pictures and go through that with you. Again, we’re just tying these percutaneous sutures down. We can take a look at the fluoro machine, please, and show on the left hand screen, my left, there’s a before picture of the aneurysm. You can see the kidney arteries there, going down or out like arms and the aneurysm below that. And then you can see on the right side, you can see the finished product where the graft is inserted inside the artery and complete exclusion of the aneurysm has been accomplished. There is no evidence of leak whatsoever on this, neither from the top or the bottom or from the arteries that we call the lumbar arteries. This is a 100% exclusion of the aneurysm and we are very pleased with this result. This patient will receive a, again—more than likely will go home in the morning after
breakfast, will be eating supper tonight and will have a two-week follow-up appointment in the office and then be set up for a CAT scan at 3 months like Dr. Stubbs had mentioned. While we're doing this closure here, we'll come back in a minute and recap some things that we've done. Let's go back to Dr. Stubbs and see if he has any more email questions that he can answer.

LENNY STUBBS, M.D.

00:39:35:00 Thank you. Yes, one very good question involves is there any special training involved with this type of procedure? Yes. Vascular surgeons in general that do these procedures have fellowship training beyond their general surgery training and then there’s usually a course that we go to involving a certification for this as well as proctored cases prior to us actually doing these ourselves. So, yes, there’s some additional training as far as vascular surgery in general and then also for the graft itself. That was actually a very good question.

00:40:13:00 Again, talking about leak and exclusion, I'll go over real quickly the types of leaks, as far as the classification, how we classify and the things that we can do to fix these. In the operating room, when you talk about a Type I leak, that can either be at the proximal, or the upper end near the kidney arteries and/or down in the iliac arteries in the distal end. That's called a Type I leak and sometimes those can be fixed in the operating room with balloons to iron out the wrinkles in the fabric. Sometimes, if those persist, we can also use cuffs or extension devices, similar to—they look very similar to these type of devices like the one you see here, that I'll put down on the blue table so you can see. Sometimes we can use extensions that are a bit bigger and oversized to develop a seal so that you get a seal beyond this limb so that it would look something like this. Kind of a schematic representation, but extend it beyond, to get a good seal zone. And we can also do that up proximally. That's a Type I leak.

00:41:18:00 A Type II leak, like Dr. Melton had alluded to, involves blood flow from the lumbar artery and/or the inferior mesenteric artery, where it—actually that’s what we call backbleeding and it bleeds back into the sac. Sometimes those will occlude over time with watchful waiting, sometimes we have to intervene down the road with coil embolization, where we actually occlude these arteries so they don’t bleed back into the sac.

00:41:43:00 The Type III leak is actually a leak where these two joints actually come together, where the two different pieces can come together. Again, we can deploy, so the leak would be involved right here, where the graft actually is put together, those can be either—further pieces can be deployed in there to help create a seal, so again there is a fix for that type of leak.

00:42:06:00 And the fourth type of leak is a (inaudible) diffusion of blood through the graft material itself and the majority of the time when we see that in the operating room, once the blood thinner that we use for the procedure has worn off, that usually goes away. Those are the different types of leaks that Dr. Melton had alluded to and as you saw, the before and after pictures, that’s fairly dramatic that you don’t see any blood flow in the aneurysm sac which means it’s completely excluded and that blood flow is simply through the graft itself.

00:42:38:00 We have another set of email questions. Do you ever have to convert to an open procedure? The conversion rate is very small as far as percentages are
concerned. Yes, we always prep the patient as if they’re an open procedure. However, the conversion rate, again, is very small, but we do always advise our patients in the clinic that, if the deployment doesn’t always go right or if something happens in the operating room that we’re ready to intervene with an open procedure if necessary.

00:43:13:00 Okay, let’s go back and look at these before and after shots again. These are pretty dramatic-looking angiograms and if you can see on the left-hand side, we see the before or the beginning angiogram showing the aorta with its aneurysm and the iliac arteries. You can see the after shot on the right-hand side showing the graft, very successful graft deployment with exclusion of blood flow so that it’s only flowing through the graft. You don’t see any dye or contrast, which would be the black material on the screen, you don’t see any of that inside the sac, which means you have complete exclusion and no blood flow in the sac and that’s a successful repair. Like Dr. Melton had mentioned, we then follow these with CAT scans to make sure that that continues to be a good repair down the road.

00:43:59:00 Another email question involves closing the groins. Actually, Dr. Melton, with these percutaneous devices is using what is called a Perclose device. This is actually done over the wire so that no cut down has to be made and it actually is a kind of a purse-string type suture device that will actually close the holes so that all you’ll see at the end is just some band-aids over the puncture holes where the sheaths had been placed. Again, this is done strictly through the groin femoral arteries. One thing of note, we have to make sure that the iliac arteries and femoral arteries are of adequate size so these sheaths and devices can be deployed. I think Dr. Melton now is ready, we want to show you the closed groin and the finished product.

JAMES MELTON, D.O.

00:44:52:00 Dr. Stubbs, thank you so much for that and answering the questions there. I’d like to get a look at exactly what the wounds consist of. This is the left leg here and as you can see, it’s literally going to be closed with band-aids. The right side, the same, this is where the large part of the device went up. Again, just band-aids, so she’ll be, again, up tonight, she’ll be able to get up tonight and go to the restroom and eat dinner. Everything that you can’t do when you have it done the open way. Sometimes we have to make incisions in the groin to get the device up and that still consists of just a small incision so it’s not a whole lot of morbidity associated with it either. Either way, this procedure is very advantageous for most of the patient population with aneurysmal disease. The devices that we’re using today for percutaneous closure is the Prostar Perclose and what we do is on the big side of the device, which is the right side in this patient, we put two devices, one’s a 10 and one’s an 8 and on the contralateral, or small-limb sides we put a 10 Prostar on that side to close the 12-inch sheath hole. That’s what we’ve used today and as you can see, after having—let me have that sheath there, Steve, the big sheath, Colby—after having this size sheath on this side, you can see there’s—that’s the hole in the artery, that’s the size of the hole in the artery that would be created with this sheath. You can look at it, you know, you can see the hole size here, that’s a large hole and that’s been closed percutaneously and you can see we have no active bleeding. Let me see the other sheath. The other sheath side is smaller but, again, the same, it’s a large hole that would be created and that, again, is closed with no bleeding after it’s been pulled. We’ll reverse the blood thinner now and be ready to take her to the recovery room here momentarily. I’d like to thank OR-Live and Gore
as well as Prostar and all the participants today. I’d really like to thank my crew because they’re a wonderful group. They continue to perform on a daily basis in the operating room with these complex procedures. The procedures, I’d like to go over a little bit the graft again and how it’s set up as far as—this is the actual device, again. You can see that the graft is gone and, obviously it’s in the patient’s body, but it’s unsheathed by that ripcord-type delivery device and it is shelved here when we deliver it and, again, with the ripcord, it’s unsheathed at that time and deploys exactly right where you put it. This graft has a tendency not to move any when you put it at the level of the renals. Again, I would like to thank everybody that’s involved in today’s operation and thank the audience for coming and I’d like to go back to Dr. Stubbs for any questions that remain. Thanks a lot.

LENNY STUBBS, M.D.

00:48:31:00 Thank you, Dr. Melton. Again, as you saw, the very successful deployment of this endograft and, again, I’ll reiterate, the difference in the amount of time it actually takes to do this procedure is a very short amount of time and actually as we’re narrating it takes a little bit longer, but the procedure can take anywhere from 15 to 30 minutes as opposed to the open procedure that can take upwards of 2 hours. That, in and of itself, is a vast difference in the amount of general anesthesia needed. One of the questions that was sent in was: how do I know if I’m at risk for an abdominal aneurysm? That’s a very good question. If we can flip back to the slide that looks at AAA epidemiology, there are actually several risk factors for aneurysms. Hypertension, atherosclerotic or artery disease, smoking, diabetes, these are all risk factors as well as there’s genetic components. There’s some people that think there’s inflammatory causes, bacterial causes also, enzymatic theories as well. So there are several, several reasons that they think people have aneurysms. The infrarenal, or the artery right below the kidney arteries, is where it’s most common. Again, like I said, the time frame it took to do this was very short and so that actually demonstrates the difference between what would be an open repair where we’d just be getting started on doing the repair, versus the endograft repair. Those are some very good questions and I appreciate the audience for asking those. Again, you’ve just witnessed a live repair of an abdominal aortic aneurysm using the latest endovascular techniques and technology. I’d like to thank OR-Live and the local affiliates and crew and staff for allowing us to bring you these very fascinating images of a live repair of this aneurysm. I’d also like to thank the Oklahoma Heart Hospital and its staff for putting on this wonderful event and bringing you these wonderful images. I’d also like to thank the Gore Company for sponsoring the event and providing us with the products necessary to perform this repair. I hope this program has been helpful and very informative in showing you about aneurysms, how we do the latest and newest type repair and demonstrate just how fast and how beneficial this can be to this particular patient population. For all of us here at the Oklahoma Heart Hospital, from Gore, OR-Live and everyone involved with this program, we’d like to say thank you and goodbye from Oklahoma Heart Hospital.

NARRATOR

00:51:17:00 This has been a live webcast of an endovascular abdominal aortic aneurysm repair with the Gore Excluder Bifurcated Endoprosthesis from Oklahoma Heart Hospital in Oklahoma City, OK. For more information, to make a referral or make an appointment, click the buttons below.