

**ENDOVASCULAR REPAIR OF DESCENDING
THORACIC AORTIC ANEURYSM
UNIVERSITY OF MICHIGAN MEDICAL CENTER
ANN ARBOR, MICHIGAN
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NARRATOR: Over the next hour, live from the University of Michigan Medical Center in Ann Arbor, Michigan, see an endovascular repair of a descending thoracic aortic aneurysm. An aneurysm can cause the aorta to grow to several times its normal size. Left untreated, it can rupture resulting in internal bleeding and in most cases death. In just a few moments you'll see how physicians use the GORE TAG thoracic endoprosthesis to create a new path for blood flow. The device is positioned through a small incision made in the patient's groin. OR-Live makes it easy for you to learn more. Just click on the "Request Information" button on your webcast screen and open the door to informed medical care. Now, let's join the doctors.

00:01:01

DAVID M. WILLIAMS, MD: Good afternoon. I'm Dr. David Williams from Ann Arbor, Michigan. I'm an interventional radiologist and we are in the operating room where we're going to treat a patient with a thoracic aortic aneurysm with an endoprosthesis, where the aneurysm is treated from the inside using only a small incision in the groin. The operating team consists of Dr. Himanshu Patel from thoracic surgery and Dr. Narsimham Daseka from interventional radiology. Dr. Patel, would you introduce the team please?

00:01:37

HIMANSHU J. PATEL, MD: Sure. Good afternoon everybody. I'd like to introduce the entire team. This is a...this is a team effort to get this type of a complex repair done. I'm going to start off by introducing Dr. Dasika to my left, one of my interventional radiology colleagues. Mr. [Tweeley?], one of our PA's. Dr. Howser up there is one of our anesthesiologists. And then we as well have Katie and Ann, who are in the OR assisting us as well. We're going to get started here. We...we have already made the going cut-downs in the...in the patient on one side to deliver the device that Dr. Williams will then...will discuss very shortly. And we have obtained percutaneous access on the other side with a five French Sheath. I'm going to turn it over to Dr. Williams.

00:02:34

DAVID M. WILLIAMS, MD: Thank you Dr. Patel. I think what we'll do first is go a little bit of the natural history and epidemiology of thoracic aortic aneurysms. And next show you in a cartoon form how this endoprosthesis, or endograft is deployed in a patient and then show you a tabletop deployment. At that point we'll be interrupting periodically to see how Dr. Patel and his team are progressing. Dr. Patel, please let me know when you're ready to put the sheath up so we can be sure to watch that part of it.

00:03:08

HIMANSHU J. PATEL, MD: Sure.

00:03:10

DAVID M. WILLIAMS, MD: If we can turn now to the laptop, we'll go through some of these figures on natural history and demographics. May I proceed with the laptop?

HIMANSHU J. PATEL, MD: Yes.

00:03:33

DAVID M. WILLIAMS, MD: Okay. The...This is Dr. Patel from thoracic surgery. This is myself and this is Dr. Dasika from interventional radiology who are comprising the implantation portion of the team here. An aortic aneurysm is conventionally described as any part of the aorta which is 1.5 times its normal diameter, or greater. You can see here in this picture of a thoracic aorta, this large bulge in the what's called descending portion of the...of the thoracic aorta, which is over the twice the diameter, as a matter of fact, of this aorta above it and below it right here.

The problem with thoracic aneurysms is that they are thin-walled and can rupture. There are approximately twenty thousand people in the United States who are diagnosed with thoracic aortic aneurysm annually, with about six thousand deaths per year due to this disease. Male to female ratio is about one to one. Average age of diagnosis is about seventy-five for women and about sixty to sixty-five for men. Five year survival in patients who are not treated from the time of diagnosis is anywhere from twenty to forty percent, depending, of course, on...at what stage the aneurysm is detected. Annual procedure volumes are around eighteen thousand for repairs and this includes not only the aneurysms, but other thoracic diseases like dissections and so on. The percent of patients with abdominal aortic aneurysms, which is more coming and gets more press, the percent of these patients who also have a thoracic aneurysm is about twelve percent, as you see here. Now, the problem with these aneurysms is that until they start to leak or...or show signs of impending rupture, they generally are symptomatic. Once in a while someone may get some symptoms such as hoarseness, or something like that, but generally it's completely asymptomatic. The five year accumulative probability of rupture, given one of these aneurysms at six centimeters or larger in diameter, is about twenty percent; one change in five it will rupture within five years. Over three-quarters of the patients who...who's aneurysms rupture die within twenty-four hours of the beginning of symptoms. So the overall fatality as a result of rupture is ninety-four to ninety-seven percent. So surviving a thoracic aortic aneurysm is a true near miracle. Risk factors of developing aneurysms include age, over sixty years of age, hypertension...high blood pressure, current or former smoker, hardening of the arteries – arteriosclerosis, and a family history of aneurysms in a first degree relative, blood relative.

00:06:34

HIMANSHU J. PATEL, MD: David?

DAVID M. WILLIAMS, MD: Yes, Sir.

00:06:35

HIMANSHU J. PATEL, MD: I think we're...I just wanted to show them the initial part here. This...So, as we'll show you in some of the animation schemes as well, but the device generally goes up through a single groin cut-down and we...we typically will percutaneously access the other artery, the other femoral artery, the other leg artery. And, what happens essentially, and you'll see this in the animation scheme, is the device will then go up through the...the blood vessels in the...in the pelvis in the abdominal aorta and then up into the thoracic aorta as you will see here very shortly. The...the way we...We have to deploy these things through a sheath that actually comes...It's about the size of your pinkie, for example. And in order to be certain that we can deliver the device as well as the sheath up through the narrow iliac arteries that exist down in the pelvis, we sometimes test the waters with a...what we call a hydrophilic dilator. It's a...It's a dilator that is hydrophilic, can slide in and out of the iliac artery. And...and that way can...we can...we can just be certain that we will have ready access into the terminal aorta with it. So the first one of these gray dial...hydrophilic dilators is a twenty French hydrophilic dilator. The sheath that is required to deliver this particular device for this patient is going to be a twenty-two French Sheath, so we will have that going up there relatively soon here. But this is a twenty French and then a twenty-four French dilator will then follow. So, Dr. Williams, I'll show them that in a second, if you want to proceed then.

00:08:23

DAVID M. WILLIAMS, MD: Okay. So, given a patient with one of these aneurysms, what are the options for treatment? There are two families of options now. One is open repair where the chest and abdomen are opened for implantation of a tube graft device. This is simply a fabric that's fashioned as a cylinder and sewn into the aorta, top and bottom. If branch arteries need to come off it, branches are fashioned to this and certain...and vessels are bypassed. The second option is one that's been around now for approximately ten years and consists of endo...what we call endovascular placement of it. And this is a...the device that we're implanting today. And I'll show you a little more features on that today, some...some of the technical features shortly.

00:09:15

HIMANSHU J. PATEL, MD: We're actually ready for the sheath, Dr. Williams.

00:09:17

DAVID M. WILLIAMS, MD: Okay. What we're going to do now is show you the implantation sheath, which is simply an access conduit which was placed up inside the patient's artery that allows passage of one or more endografts.

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HIMANSHU J. PATEL, MD: For this particular patients, as you will see shortly, we are going to deliver one single endograft that will go through this sheath. It comes with an introducer within it that then has a nice taper to it to allow for us to place this within the patient's iliac artery. And this is slowly advanced into the terminal aorta, as we will see here shortly. And then once we have situated this sheath into the terminal aorta, we will then withdraw this introducer and place these clamps on there to prevent any blood loss out through the end of the device.

And I think at this point we are...we're probably ready to shoot our initial angiogram, which we will do here very shortly. And then subsequently then deploy our device. We have typically made sizing measurements of the aorta and the aneurysms to determine which size endograft we should be using for each particular patient. Obviously, they're different because patient's aortas are different and the aneurysms that we're treating are different. And so what we essentially have to do is we have to...because this is a repair from within where we are relining the aorta, we have to have...and the graft is not sutured in like with an open surgical approach, we have to have what we call adequate necks on either side of the aorta. So... or, on either side of the aneurysm, excuse me. And essentially what it is, is the...the endograft then sits or fixates within these what we call landing zones on either side, these necks on either side of the aneurysm, and we size the...the device to the necks because then the endograft will situate and fixate in the...at the necks, both proximal and distal beyond the aneurysm itself. And this has actually been done before. You know, we have sizing measurements. Actually, Dr. Williams or Dr. Dasika and I will sit down and usually go through these CT Scans with 3-D reconstructions before to determine what is the most appropriate size endograft to utilize to treat the patient's thoracic aneurysm with. And for this particular patient, we have estimated from her previous 3-D imaging that the...the size of endograft that we will be using will be a thirty-four millimeter device and it will be a ten centimeter long piece, which we will prep and show you here very shortly. So, the first thing we have done is through the percutaneous access on the left groin, we are essentially ready to shoot the angiogram. And then through the cut-down on the right groin we will then deploy the...the device through this sheath that we have passed up. So I think we're just going to get connected up here, David.

00:12:54

DAVID M. WILLIAMS, MD: Yeah. Himanshu, tell you what, while you are putting your device alongside the...the catheter for the preliminary let me just give the audience a preview of what's going to happen so they'll recognize it all as it happens in progress. If we can go back to the laptop in this case that I'm showing here, you'll see...This is a before and after of an endograft. This is actually what we're putting in. The final device is this one

right here depicted in this funny little sigmoid curve. This is a device as it is compressed and fixed to the delivery catheter. It is such a device as this that runs up over a guy-wire. You can see this little tip here. This runs on a guy-wire which we've put up and which is actually in the patient there, that [unintelligible] that you saw earlier. When this is put into place, the deployment thread is...is retracted and then this device here spontaneously opens up and assumes this form right here. And what happens then is that...is a...in practice is that a guide wire is put alongside this catheter. This is a catheter through which x-ray dye is injected and pacifying the whole aorta along with the aneurysm and the descending aorta. The descending aorta in this patient actually starts right about here. And then this device is put up alongside it over a second guide wire. The device is released. It pops open. Like a spring it pops open and simply conforms on the inside. Dr. Patel was talking about landing zones. The landing zones in a patient like this would be in this area right here where the aorta is normal. And also in this area right here where the aorta is normal. And the way this device stays in place, rather than sliding down out of the aneurysm, is that the device is chosen to be slightly longer in diameter than this normal caliber landing zone below it and above it like here. And then once this device is put in, again, you can see with the contrast injection showing nice deployment of this endograft with exclusion of that large aneurysm. And how if we could show the animation to show how the device is actually deployed. So we now have this animation here. The heart is rotating here to show you a aneurysm here in the proximal...in the descending aorta. Here is a guide wire which has been threaded up through the aneurysm. The device is now in place, ready to be deployed. The string is pulled and you can see this opens from the middle outward to both ends. There you see it again in a little slower motion. And now the aneurysm has been excluded from circulation. Now in practice, of course, we have another catheter up there to show the inside of the aneurysm and those branch vessels so that we can position it appropriately. Once we do that we want to...these things just pop open spontaneously. We want to seal it on the top and the bottom, so we're going to go up there with a special, cleverly designed balloon here. This is a Tri-lob balloon. You see it has three lobes and there's a little space in-between the lobes as it dilates that lets blood go through, otherwise this is like opening...opening a spinnaker in a thunderstorm; the blood flow would just take that balloon and carry it down distally. So we're bringing up. We first dilated at the bottom. We're now going to dilate it at the top. And the same thing, the balloon is inflated, deflated, rotated about sixty...about thirty degrees and then re-inflated and the whole thing is then sealed.

At this---

00:16:39

HIMANSHU J. PATEL, MD: David?

DAVID M. WILLIAMS, MD: Yes, Sir.

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HIMANSHU J. PATEL, MD: Can we just break just for a second? I just want to show the preparation of this device. So, as you can see this device comes packaged essentially with a... with...about smaller than your pinkie. And it had a mandrel within it that we...we removed, and we will remove these as well. Dr. Dasika has flushed it to de-air out through the...through the tip of it. And essentially what happens is...and you'll see this on the animation as well as when we're deploying it, as well that the deployment knob will be released and the device will then... will then deploy to the center out to...to deploy within the aorta itself. But this thing is now essentially ready for delivery into the...into the aorta via that sheath. So, back to you Dave.

00:17:32

DAVID M. WILLIAMS, MD: Thanks. I think what we'll do now is show...since you saw the little cartoon there that depicts how this happens...this is done is we'll show you a little tabletop deployment of a device and then the...then we'll proceed to the actual implantation. This is a larger version of the device then we're actually going to implant in this patient. The one we're going to implant is about half as long and slightly smaller in diameter. This is

the very largest device that we have and fits out to an aorta that's approximately thirty-seven millimeters in diameter, which is quite large for a normal aorta. You can see that this device has...You can see these little sinusoidal ribs on this device. These are nitinol metal, and that's what gives this thing some rigidity and allows you push it and pull it, and so on. This is a heat sealed...The metal is heat sealed with a little Gortex ribbon on the outside. Heat sealed to this inner composite of a couple of layers of Gortex material, which is... already had a long history of use in...in the vascular system. You can see it's got these little open webs on the inside to allow some confirmation to the curvature of the aorta. This is the deployment device for a smaller version of the endograft that I just showed you. This is the tip that rides over the guide wire right here. This is the device itself, which is wrapped tightly around the catheter; the inside of the sheath on the catheter, with this little Gortex thread. And then through a deployment mechanism down on the other end of the catheter. So this first end, of course, is inside the patient. This end of the catheter with the two hubs is on the outside of the patient. One is a guide wire loop...channel that allows you to position it where you want through this guide wire. And the second is this little deployment mechanism. Think of it as a ripcord that basically is unscrewed, loosened up and attached to a little thread. You can see the little thread right here, perhaps if I put my thumb behind it. See that little thread there. That thread is attached to a chain stitch that's on the outside of this device right here. As I pull this off, this chain stitch is removed and the graft will pop open. If you can aim this down on the table here and I pull on this, you'll see this thing deploy. Just go ahead and focus down tightly on that as you can. There you go. I'm going to start removing the rest of this. You can see the chain stitch moving away from center outward. Now, of course, in the patient we would do this much quicker, because you've got the whole cardiac output coming down that aorta and you want to be sitting there with this thing occluded.

So here the device is. The little jacket is left behind in the patient and it's trapped between the device and the aortic wall. I think you should have a pretty good picture now of how this is deployed. Why don't we go ahead and put it in the patient.

00:20:55

HIMANSHU J. PATEL, MD: Yes. The device is in the patient. Yeah, the device is in the patient. If we can go to [Floro?] here for a second. If you can...If you can...If you see, the device is already situated within the patient. And there is one very long wire that goes up and around the arch. That's called the Lunderquist wire, a very stiff wire. That will...that is heavy enough to carry the...carry the device through the...through the access vessels to the site of delivery. Right next to it is what we call a pigtail catheter, and through that catheter we will shoot our initial angiogram with to identify and delineate the thoracic aortic pathology. And then after we have confirmed where the...where the device should sit, we will then deploy it. So, I think the first thing we're going to go do...I think...Are we ready, Kate, to shoot the angiogram?

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DAVID M. WILLIAMS, MD: Can we show them the [inaudible] device, because I don't know if they'll be able to see it.

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HIMANSHU J. PATEL, MD: All right. Okay. Are we all ready, Kate? Hold...hold ventilation, please.

00:22:08

NARASIMHAM DASIKA, MD: Hold the vent. Hold the vent, please.

00:22:25

HIMANSHU J. PATEL, MD: Okay. And...Thanks, Kate. And if we can go back and cycle this again. What is evident is that there is a lesion in the mid-descending thoracic aorta, sort of about halfway between where the graft is. And essentially what we are seeing is, is that we're seeing the...the aneurysm there. Part of it is thrombosed; that's why it's not larger than it actually would be, or that we can see on the CT Scan. And, actually, this is a great

example of aortography sometimes underestimates the...the extent of disease, because the CAT Scan will pick up the thrombus and will as well pick up other aspects that the aortogram itself wouldn't. If one were just looking at the aorta in this dimension one would think, well, the aneurysm is only about three or four centimeters; when in reality it is much...much larger because part of the saccular aneurysms that we're treating today is...is indeed thrombosed and doesn't receive any blood flow within it. So, I think we're going to go ahead and...and situate this device. The first thing we'll do is we will pull the...the pigtail catheter essentially out of the way. I think, you know...Are you happy with this? I think this looks pretty good.

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DAVID M. WILLIAMS, MD: Here is the...This is the proximal portion of the fully covered endograft. Ad you can see the distal portion right here. The total graft is ten centimeters long and that's going to be centered on this aneurysm.

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HIMANSHU J. PATEL, MD: So I'm just...If we're still on [Floro?], I'm still pulling the...the pigtail catheter essentially out of the way. And I think we're ready to deploy the device. And if you just pan down to the device here, we'll be able to show you how this...this device is pulled. There is a deployment knob that is situated right here...could...that...that Dr. Dasika is going to go ahead and pull the cord with and unfurl the device, as you've seen in the animation video. So, Dr. Dasika, if you could do the honors here. And essen...with...with the way this device deploys, it deploys from the center out to minimize what we call windsocking, which would carry the device more distal than the intended target location of where we would...where we want...we want to deploy it. So, the device actually deploys from the center out. And we typically leave the...the patient's blood pressures at about a hundred to a hundred and ten systolic, which is where...where it is during this thing. For some of those other devices with...that open from the front end, we would want to decrease the arterial blood pressure; otherwise, the device can sail downstream. But I think we're...we're probably ready to...to deploy it, Dr. Dasika.

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DAVID M. WILLIAMS, MD: There you go, deployed. Do you want to save the [Floro?] for this?

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HIMANSHU J. PATEL, MD: Save the [Floro?]. And then maybe we can go to [Floro?] here and it will show you...So this...Katie, can we have the [Floro?] go...Yep. All right, great. So this shows the device being deployed there. And it opened and situated itself exactly kind of where we wanted it. And effectively is...has presumably sealed off the aneurysm. And, what we're going to do at this point is we're going to go ahead and...[Floro?], here. Live [Floro?]. And we'll pull this device out.

00:26:12

DAVID M. WILLIAMS, MD:

Now we're going to pull the deployment catheter through the device. The device stays behind, of course. Here we are in the proximal descending aorta. And you see now that the...bring... there's the completely covered ring up on top and the completely covered ring on the bottom. And the question is, of course, have we...have we excluded the aneurysm. So the next step will then be to take that tri-low balloon that I showed...that you saw in the animated cartoon and then seal first this distal part of the...of the cath...of the endoprosthesis and then the proximal part of the endoprosthesis.

00:26:54

HIMANSHU J. PATEL, MD: Are we ready with the balloon, Kate? David, did you show them the balloon?

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DAVID M. WILLIAMS, MD: Just on the cartoon. I haven't shown---

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HIMANSHU J. PATEL, MD: Okay. Yeah, we can show them the balloon. We...go back from Floro to live here and we'll show them the balloon. So this is a Tri-low balloon, as...as you've seen from the animation. And what Dr. Dasika is doing is he's inflating with some saline. And, essentially, it's got three lobes – one, two and three. And the way this balloon then opens, it'll... it'll...it'll un-pleat the device within the aorta. But, at the same time, if you can look at it end on, it will allow for flow to persistently go through while this balloon is...is inflated. So, we just prepare the balloon this way and deflate it here. And I think at this point it is ready to be passed up into the...into the aorta. David?

00:27:53

DAVID M. WILLIAMS, MD: Yes. If we can go back to the laptop. What I'm doing here is showing the approximately treatment zone in this patient. And I want to also show you the CT Scan on this patient that gives you a little better idea of the...it gives you a little better idea of the aneurysm than you can get from this...from the angiogram...aortogram that we just shot. Okay, this is the patient's...a picture of the patient's thoracic aorta. This is all compiled from a CT Scan, a CAT Scan, that's performed in the usual fashion with slices very close together. And you can see that this picture gives you a panoramic view of the aorta all the way from the heart down to the...to the groin. All...both the top and the bottom part of this are important to us. In this patient's case, you can see this eccentric bulge in the mid-thoracic aorta. This would be about the level of the...where the abdomen, the transition between the chest and the abdomen. So you can see this as sort of mid-chest level. There's this eccentric aneurysm. It's about twice the diameter of the adjacent aorta, top and bottom. And this is approximately the ten centimeter segment of aorta that we treated. If we move up into the region of the aneurysm itself, you can see that...This is the region of the aneurysm. And this is where you saw that eccentric bulge of contrast material on the aortogram.

00:29:24

HIMANSHU J. PATEL, MD: David, we're actually ready to balloon dilate the landing zone. So, if we can go to Floro here for a second. Are we on Floro? Okay. So, we're going to go ahead and...What we do is we un-pleat the device in the distal landing zone first, so we're going to go ahead and inflate the device here. And essentially what I'm doing as...as Dr. Dasika is inflating the balloon, I am just maintaining forward tension on the...on the balloon so that we don't drag the device back through the aorta down distally. And, because it's a Tri-low balloon, we have to do it actually in two separate motions here; one rotated from the other so that we un-pleat the entire device. And what we...We do what's called balloon dilating essentially to profile. So we go to the edges of the device, so that we un-pleat the device without tearing the aorta. So that's the distal landing zone that was balloon dilated. And I'm going to advance this balloon now into the proximal descending thoracic aorta and we will inflate the balloon here. So you can see it's going up in the proximal landing zone to let the sealing cuffs meet the aorta nicely. So that was in one projection. And then we're going to rotate the balloon. And we're going to do this again in the second projection. And each time we do this the blood pressure will go up, so we're just cognizant of that; watching that while we're doing typically...If it is high, then we'll try to get the blood pressure down to avoid dragging the device down. And then we watch this balloon as it comes down through the graft. And we actually leave it situated in the terminal...descending thoracic aorta here for a little bit, at which point I think we'll be ready to advance the pigtail catheter through the endograft into the distal arch. And, I think at this point we're ready to shoot a completion angiogram. I think---

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DAVID M. WILLIAMS, MD: So the money area to keep an eye on is this area right in here, which is where the aneurysm is. Now, when we do these aortograms following prosthesis...you know, placement of a prosthesis we're, of course, very careful to look at the vessels that are adjacent to it to make sure they're still well perfused. And then, of course,

in addition to that we want to see if there's x-ray dye which escapes from the prosthesis into the aneurysm sac. Are we ready for the aortogram?

00:32:35

HIMANSHU J. PATEL, MD:

All right, ready. I think we're ready to...Will you hold ventilation, please? Could you go to Floro, please. Could we go to Floro, please? Okay. Hold that, please.

00:33:05

DAVID M. WILLIAMS, MD:

Okay, you can hold it.

NARASIMHAM DASIKA, MD: Okay, good. Ventilate, please.

HIMANSHU J. PATEL, MD: Go ahead and ventilate, please.

00:33:14

DAVID M. WILLIAMS, MD: Now, these bulges that you saw initially are simply the endoprosthesis which is bulging into the aneurysm sac. The top and the bottom, of course, is constrained by the normal wall, but it's not constrained here where the...you know, the aorta itself bulges out.

00:33:41

HIMANSHU J. PATEL, MD: What do you think of the angiogram, Dr. Williams?

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DAVID M. WILLIAMS, MD: Well, what do I think of it. It...the patient, of course, is lying on her back so we see some x-ray dye that sort of lingers here on the dependent part of her aorta. There is a little bit of...it almost looks like x-ray dye that's getting outside the device right here. The question is how it could be filling. We'll notice that even though the graft goes from here to here, we're seeing all these intercostal arteries. These are the arteries that supply the muscles by the ribs on both sides. We see these filling. So, we have a good seal on the top and a good seal on the bottom, so it's hard to believe that the leak...if this x-ray dye in the aneurysm sac, it's hard to believe it's coming up alongside it. So my feeling is it's probably coming from these intercostal branches which are filling from collaterals. This is what would be called an endoleak, if it's contrast material. In a minute we're going to look at this angio in non-subtract mode to see if that...make sure that's not misregistration artifact. But, if it turns out to indeed be contrast material, I think it would be a Type II endoleak. Do you agree with that Nara?

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NARASIMHAM DASIKA, MD: Yeah, I think so. It's coming to the [unintelligible], so it's a delayed endoleak.

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DAVID M. WILLIAMS, MD: Yeah. Dr. Dasika agrees with that. Can we run this non-subtract, please? It's a little harder to see. But it looks like there is something there showing up late. Right there. So, if there were any question of, you know, of having marginal adherence of the endograft to the aorta on the top or the bottom, I'd recommend redilating there, but this...this looks adequate and I think this is just a Type II endoleak; most of which will seal spontaneously in the coming days. And, Dr. Dasika just brings up a good point. That this patient, of course, has his blood...her blood thinned considerably with some heparin, which delays blood clotting. And once that heparin is reversed at the termination of this procedure, she'll probably clot off this portion around the...around the endoprosthesis. If I could...if we go back to the laptop, I can finish up with a few more....Is there anymore points you want to make onto this, Dr. Patel?

00:36:21

HIMANSHU J. PATEL, MD: Well, I think...I think one of the things we may just want to do is just to be certain we've got adequate seal in here. I just wonder whether we go ahead and just balloon dilate the landing zones again, all within the...you know, the part that's within the graft, just to be certain that there is no...no Type I. Although, I think if you look at the angiogram there's sufficient length above and...above and below where the aneurysm neck

is...or, the aneurysm lies, rather. And I suspect that that's probably not the case, but I think it would be okay if we just went ahead and balloon dilated since it's not...it's not any added....

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DAVID M. WILLIAMS, MD: Right. We're in there and it's no added risk to the patient just to put that balloon back up and dilate.

HIMANSHU J. PATEL, MD: Right.

00:37:02

DAVID M. WILLIAMS, MD: While you're doing that, we can go back to this slide presentation. The...Okay, the GORE...or, device which we just put in is the only FDA approved device at the present time. There are several others that are on the pathway to approval, but it is the only one that's currently approved. It...It's approval was on the basis of...It's approval was on the basis of a controlled trial where a number of patients underwent either deployment of the device to...or, underwent open repair. In this particular study, there was a fifth of the paraplegia and paraparesis. Paraparesis is simply spinal cord signs, tingling and numbness and so on. One fifth the rate in the patients who had the endoprosthesis compared to the open surgical group. This actually, this percentage here is quite high. Most large aorta centers that do a lot of open repair actually have a smaller rate like this. The rate is more like three to five percent. And the rate now of endoprosthesis is down around one to three percent. One-sixth the operative mortality in the endoprosthesis group. None of the patients had an aneurysm rupture at three years, nor did any of the control patients. We're certainly not impugning the long term good record of open repair and the grafts that are put in, but...you know, the suspicion always rise...arises that in this new device...is the new device a durable fix for an aneurysm. In any case, three years is a short period of time and, of course, we want to...interested in ten years, twenty years and thirty years even. Lower aneurysm related death throughout...up to two years and in the time around the procedure itself much less smaller blood loss – half a liter versus two and a half liters. Shorter average stay in the intensive care unit – one day versus three average hospital stay and faster recovery and return to normal activity. Now, there is a mechanism for the audience to ask...submit questions. And I will answer them myself or I'll direct them to Dr. Patel as the topic suggests. Now, the way you can access these is there is a little button, I think, that's on your web page that's called MDirectAccess button. If you will click on that it will give you a little page where you can e-mail a question.

00:40:08

HIMANSHU J. PATEL, MD: David, if we could just go back to Floro here. We're going to take another aortogram here. And, we have actually changed the projection on which we are going to do it. So this is almost ninety degrees orthogonal to the first angiogram that we had done. So essentially what we're going is we're getting biplane angiography. What we just did was we just balloon dilated that distal and proximal landing zones again to be certain that we have adequate...that we have adequately achieved a seal, both proximal and distal to the...to the aneurysm. And, as Dr. Williams had suggested, it's really not increasing the risk, particularly to the patient, because we're...we're already in there and we've already got the balloon in there so it's really generally not a big deal to slide the balloon up there. So we're going to go ahead and shoot another angiogram here. If we could hold ventilation. Katie, are we ready? Hold ventilation, please.

00:41:01

NARASIMHAM DASIKA, MD: Okay, shoot.

00:41:20

HIMANSHU J. PATEL, MD: Okay, hold. Go ahead and ventilate, please. Well, what do you folks think of the...what do you...David, what do you think of the angiogram?

00:41:30

DAVID M. WILLIAMS, MD: Well, I'm not sure I see anything. There is some...a busyness over here that I'm not sure is real or...or simply misregistration. This...Can we run this non-subtract, please? And, is it possible to lighten it up a little bit?

00:41:52

NARASIMHAM DASIKA, MD: [Unintelligible] build up, please?

00:41:59

DAVID M. WILLIAMS, MD: We'll adjust it a little bit so that we can see it. Well, the other...That's better. Okay, run this. Go ahead, run it. Just keep it running and cycling. You see this little area you actually see moving between...you know, even before the x-ray dye is there. So, it's not x-ray dye getting out there. I think it's just a little misregistration artifact. Right, from soft tissue structures. Yeah. Yeah. You can see the intercostal arteries right here. These are the source of the endoleak when they're present, because...you know, they refill from collateral pathways that are always in place and always ready to pop...you know, break into action here when their neighbors are in trouble, as they are here with the endograft in place.

Any other points you'd like to make about this particular case here? This patient's anatomy?

00:43:35

HIMANSHU J. PATEL, MD: I don't think so. I think we're...I'm sorry?

00:43:40

DAVID M. WILLIAMS, MD: In some ways this patient had very favorable anatomy for this. The iliac...the arteries in the pelvis were nice and large. The...the aneurysm itself was remote from critical branch arteries. It was in a relatively straight portion of the aorta. So she was an ideal anatomic candidate for the device. Not everybody has all the anatomic features that really allow this device to...to shine, and sometimes it's difficult to place. In some patients, of course, it's impossible to place. I...At this point I'm going to review a few of the questions from the audience and answer them to the...First question is from someone who asks, is this condition hereditary? Our mother had an aneurysm on her aorta two inches from her heart. The doctor told her it was hereditary. Aneurysms are hereditary. It's not...You know, it's not a straightforward inheritance like the color of your eyes, but they are hereditary. And if you have a first degree relative who had an aneurysm in the chest or the abdomen, you are at higher risk. And, certainly, when you move into the age group or if you've had longstanding high blood pressure, you're a chronic smoker, and so on, your chances of having the aneurysm are enhanced.

In cases like that, you could go to...to your physician. And there are some very benign screening tests that would allow for examination of the aneurysm. What complications can arise during this type of surgery? Dr. Patel, would you like to address that one?

00:45:37

HIMANSHU J. PATEL, MD: I think so. I think...you know, what I generally tell patients is that virtually the same complications that can occur with an open operation can occur with an endovascular repair. The...I usually tell them the five biggest risks that we worry about - bleeding or infection. Any time we do an operation, the risk for stroke, because we're often working near the arch vessels where the...where the patients have their blood vessels supplying the brain. There's a risk for paraplegia as...as was explained earlier, some of these blood vessels will communicate with the...with the spinal cord. And then there's a risk for dialysis as well. The risks for each one of these things, in our series that we've previously published a lot of...a lot of our patients that we've treated over the years now is...have been patients that have been not really considered suitable for open operation. And those patients, even in these very high risk patients, the rates of each one of these things ranges from about one to four percent, including the risk for mortality, or passing from the operation. And I think when we look at our open series we...we know that there are certainly some patients who would likely have a prohibitive risk for open operation. But in those patients in whom we have endografted, they have had...we have had good success

getting them through this operation, treating their pathology and as well providing them with a relatively low risk alternative to open...open surgery.

00:47:13

DAVID M. WILLIAMS, MD: The next patient I'll direct to you too, Dr. Patel. Is hoarseness the only symptom a patient might notice? And at what point might they notice that? In other words, is rupture imminent once the hoarseness occurs?

00:47:26

HIMANSHU J. PATEL, MD: Hoarseness can be a...a worrisome symptom of a...of a patient having aneurysm. Typically, patients don't have symptoms from aneurysm disease until a complication has happened. The reason the patients get hoarseness from a descending thoracic aortic aneurysms is that one of the nerves that supplies the vocal cord actually wraps around the aorta and the distal arch just beyond where the left subclavian artery comes off. And in those patients when the...when the aneurysm either expands over time or expands rapidly, and it can happen either way, they can present with hoarseness as their only symptom. And those particular patients, we attempt to expedite their workup and if they have anything concerning on their CAT Scan or in their other symptomatology that suggests they've had acute expansion, then in those patients we will typically perform more expedited repair; either with an endovascular or with an open approach.

00:48:25

DAVID M. WILLIAMS, MD: I notice that, you know...you know, virtually we're done with the case now and we could even close up. How long would a case like this take if you were doing it open?

00:48:37

HIMANSHU J. PATEL, MD: It...it depends on whether we have to use certain adjuncts, including what we---

DAVID M. WILLIAMS, MD: Let's say this patient here.

00:48:42

HIMANSHU J. PATEL, MD: So this particular patient would probably require a four to...four to six hour operation in total. The typical length of stay in the hospital would include a...perhaps a one to two day hospital...or, hospital ICU stay. And then, I suspect probably on the order of seven to ten days. Now this particular patient whom we did this procedure on was actually a bit prohibitive in terms of risk for an open approach. And so we...we...if we had no endovascular option, we would likely not have offered her anything other than medical therapy, which constitutes blood pressure management and is associated with a relatively dismal prognosis.

Patients with an endovascular approach, in contrast to open repair, we have seen and other centers as well have reported that these patients will go home within about two to five days. And then their total convalescence time, including that at home or...or elsewhere, is on the order of two to four weeks as opposed to open surgery which will typically take two to three months.

00:49:49

DAVID M. WILLIAMS, MD: There are a couple more questions which I'm going to get to. Dr. Patel, though, before I get to those questions, we've put in...What's our total number at this point?

00:49:59

HIMANSHU J. PATEL, MD: I've sort of lost count, but I think we've done probably over...over a hundred of these from a time span of 1993 to this year.

00:50:09

DAVID M. WILLIAMS, MD: So in that time why don't you address some of the really common questions patients ask about the device and then I'll get into the last two questions here.

00:50:15

HIMANSHU J. PATEL, MD: Well, I think one...Of course, one of the issues is since this is a newer type of therapy, is this something that that's...that's durable. And it really depends on...on the patient. You know, aneurysm disease typically occurs in older patients. And what we do at our center is we look at the patient's physiologic condition, their age and determine what their most suitable option is. If there is a patient such as this, who is really a...an appropriate anatomic candidate, because she's got a, you know, mid-descending thoracic aneurysm that is saccular in nature with very... very regular landing zones or necks on either side, even if they were younger and otherwise relatively healthy we would suggest this as a suitable option for the patient. In contrast, in some of these aortic aneurysms, the...there can be some difficulty with deciding what...what the best option is, particularly in some of these patients in whom the...the aneurysm is a bit more complex and spans either the...the total descending thoracic aorta and includes, perhaps, a distal arch. Because in...in those patients sometimes anatomically it may be a bit more difficult to proceed with an endovascular approach. But, it's really decided on a case by case basis, looking both at the anatomic requirements for an endovascular repair, as well as the patient's physiologic condition. If patients are not really candidates for an open approach, then we definitely won't proceed with an open approach, as would make sense. But, at the same time, if somebody is considered a suitable anatomic candidate for an endovascular approach, if they are extremely young sometimes we will suggest that we perform an open repair because of its very...because of its known long term durability. And those are really the decisions that we're making to be certain that we have the right...we can offer the right choice to the patient.

00:52:23

DAVID M. WILLIAMS, MD: All right. I'll go to the last two questions that we have. The first one is, how long does the endograft remain in the patient? And, I think our attitude is that basically it is going to remain in the patient for life, if we do not at this point always plan to remove the case. I guess there is an exception in some of the off-label uses, the non-FDA approved uses of the device where we may put it in as a temporizing device, let's say in somebody for trauma or something, who's young and we don't really expect this to last a lifetime but the patient is in no shape to really have an open operation. In cases like that, we will sometimes place an endograft, planning at some point in the future to take it out. Now, in general, once a device like this is put in, the actual operation required to take it out and replace it with graft material is usually more complicated because the aorta where it's put in usually is not in good shape and so a larger portion of the aorta has to be treated. So, it's not a trivial thing but it is possible, of course, to take these out. And, you know, if they get infected, which is rare but possible, then they, in fact, have to be taken out. Otherwise, we plan... especially in the patients over sixty, we plan that they stay in for life. The final question is a little more complicated. From Ron, from extra...from New Zealand. Welcome Ron. You must be...[Inaudible – someone accidentally pulled the mic off the doctor's mask]. Twenty years ago I had an MVA...which....Can you still hear me? MVA which resulted....[Looking for microphone]

00:54:20

HIMANSHU J. PATEL, MD: Yep. What we're going to do is we're actually essentially done with the procedure with the sole exception of needing to fix the...the femoral artery. So this is the last part of the...the procedure and...and essentially what this involves is...primary closure of the femoral artery. So as you can see....And then finally closure of the...the...the groin as well. The...the....On the other side, where the percutaneous sheath is placed, we will typically just hold pressure there for twenty to thirty minutes and...Can you hear me? And then...then essentially be done with it. And these patients will then go back to our ICU where they will stay...Another stitch please.

00:55:08

DAVID M. WILLIAMS, MD: Okay. Do I have time for this last question?

00:55:11

HIMANSHU J. PATEL, MD: The patients will then stay in the ICU, hopefully just overnight, or perhaps two days if we have used a...a lumbar drain, which is used to protect in some patients in whom we're doing extensive coverage, the collateral flow to the spinal cord. And, for some of the...for some of those patients, they will stay in the ICU perhaps a bit longer, but they can often go home straight after they leave the ICU. So, as I said before, I think it's...it's...Another stitch, please. It's associated with a three to five day hospital stay. If we're doing a limited segment coverage and the patients are in the...in the...can be in the hospital for as little as one or two days. So...

00:56:01

DAVID M. WILLIAMS, MD: Okay, Dr. Patel, I have one final question. I had a little microphone...technical snafu there. But, Ron from New Zealand asks, twenty years ago I had an M...a motor vehicle accident which resulted in the insertion of a Dacron graft in my thoracic aorta to treat a thor...an aortic rupture. In case I develop an aneurysm around the existing graft, can this new device be inserted in...in the area of injury or would additional surgery be required?

00:56:30

HIMANSHU J. PATEL, MD: That's...that's a great question, Ron. And, it can be treated. It... Again, endovascular repair really is an anatomic treatment. And, what we have to do is we have to be certain that...that your aorta would...would conform to accepted anatomic criteria. But it is very feasible to treat patients with a endovascular approach, if they have had...if they have had a previous aortic repair.

00:57:04

DAVID M. WILLIAMS, MD: Thank you, Dr. Patel. And, thank you Dr. Dasika. Thanks to the rest of the team. We are wrapping up this case right now. They are almost closed. The groins are almost closed. I want to thank the audience for their participation and thank GORE and the film crew for their work as well. I'd like to remind everybody that an archived version of this placement of the endoprosthesis in this patient, an archived version will be available within the hour at this website that is giving you access to this live presentation right now. Thank you very much.

00:57:47

HIMANSHU J. PATEL, MD: Thanks a lot everybody.

00:57:50

NARRATOR: This has been an endovascular repair of a descending thoracic aortic aneurysm performed from the University of Michigan Medical Center in Ann Arbor, Michigan. OR-Live makes it easy for you to learn more. Just click on the "Request Information" button on your webcast screen and open the door to informed medical care.

00:58:17

[END OF WEBCAST .]