

**REPAIR OF MIGRATED ABDOMINAL AORTIC ANEURYSM ENDOVASCULAR GRAFT WITH ZENITH RENU
BARNES-JEWISH HOSPITAL
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NARRATOR: Patients having received prior endovascular repair of infrarenal abdominal aortic aneurysms and suffered from migrated abdominal aortic aneurysm endovascular graft now can be treated with the first medical device specifically designed for secondary endovascular intervention. Today, vascular surgeons will show and discuss repair of a migrated abdominal aortic aneurysm endovascular graft with the Zenith Renu in a roundtable setting. Your hosts for today's discussion will be Dr. Samuel R. Money, Program Director and Professor of Vascular Surgery at Ochsner Clinic in New Orleans, Louisiana; Dr. Luis A. Sanchez, Vascular Surgeon at Barnes-Jewish Hospital; and Dr. Juan C. Parodi, Professor of Surgery at Washington University School of Medicine and Barnes-Jewish Hospital. Now, your host, Dr. Samuel R. Money.

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SAMUEL R. MONEY, MD: Thank you for joining us for this web broadcast. Joining me on the podium are Dr. Luis Sanchez and Dr. Juan Parodi, both from Washington University and the Barnes-Jewish Hospital Center. I'd like to thank you for joining us today. We're going to discuss a new advance in endovascular treatment of aortic aneurysm and that's the Zenith Renu device system. In addition to discussing the new devices, we're also going to view two cases that Drs. Sanchez and Parodi performed last week.

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I would like to start by introducing you to these new devices. These are the Zenith Renu devices. Endograft migration is a real problem. As you see from this slide, this patient has been followed for 36 months. The patient had an AneuRx graft placed. If you notice at 12 months, the graft functionally is at the bottom of the L1 interspace. Over time, you see the migration occurring. If you look at 24 months, the graft is starting to bow outward and there is some migration occurring. However, look at 36 months. The graft has migrated a full vertebral body down. Notice the extensive migration. This led to a significant endoleak.

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What is the rate of migration at two years? Well, that's difficult to define because some authors have defined migration at 5 mm, whereas the SVS and other authors have defined it at 10 mm. If you look at this graph, you can see the data reported for two years migration, both in papers and to the FDA for follow-up. The AneuRx graft reports a 5.3% rate of migration at two years. It's not clear whether they had defined it as 5 or 10 mm in their paper. If you look at the Excluder and Zenith, they're both at approximately 2%. Remember, these are in controlled studies where the patients were very well screened before primary implantation of endografts occurred, so actual migration in the real world may be significantly higher.

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The Zenith Renu device has received an indication from the FDA as an ancillary graft for secondary endovascular intervention in patients who have received prior endovascular repairs. The problem they're solving is inadequate proximal fixation or seal, or what we tend to think most of the time will be migration problems. There are two types of Zenith Renu grafts. There is the Renu main body extension and the Renu converter. The main body extension is simply a small extension or cuff that fits between the lowest renal artery and the bifurcation, whereas the converter actually converts the old graft with the use of an occluder into what would be an aorto-uni-iliac. We'll spend a few minutes talking about both types of devices. Generally, we suggest that you obtain a thin cut CT scan with 3 mm slices, evaluate where the pre-existing old graft or the primary endograft is, note the dimensions of the old graft, and note the dimensions and the diameter of the aorta. It's important to note the distance from the lowest renal orifice to the pre-existing bifurcation or flow divider because that's where your new graft or your Renu graft, we should say, is going to sit. Obviously there are some general indications for any

type of endovascular graft. You need adequate iliofemoral access so you can deliver your device. Angulation is a problem. You need an angle of less than 60° relative to the long axis of the aneurysm. We also suggest an angle of less than 45° relative to the axis of the suprarenal aorta. Let's spend a minute talking about the main body extension. The main body extension comes in two sizes, a 43 and a 62 length. Again, this fits simply as one would picture, a cuff with a suprarenal fixation and the suprarenal fixation looks familiar to most of you. This is the standard Zenith suprarenal fixation.

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Again, the working length must be a minimum of 43, so again, from that lowest renal to the bifurcation or flow divider must be 43. We suggest at least one Z-stent seal, 17 mm of seal in length. We would like the pre-existing graft to be less than 30. The aortic aneurysm neck or the neck of the aorta that you're treating should be 18-28 so you can get adequate oversizing.

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This little diagram will show you how to deploy it. Basically you verify your position, make sure you're fine with the renals. You deliver the graft up there and first you will release the graft and we'll see how Dr. Sanchez did it in his cases with Dr. Parodi. Then we suggest putting a balloon in to mold graft after you have released your suprarenal stents. Again, then you go on to your final angiogram and confirm that you have taken care of this Type 1 problem.

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The converter is a little different. Again, as you can see, it does have those Zenith suprarenal fixation devices. It also has a stent graft at the top that is full sized and then it tapers down to 12 mm. This can be used with an iliac limb or an iliac extension and it also be used to be placed inside of the old graft or more distal in the iliac artery. How do you place the converter? Again, the first thing to realize is that you have to have adequate length for the full superior portion of the stent graft to be deployed. Therefore, the length from the lower renal to the bifurcation should be a minimum of 37 mm and we'd like the aortic diameter to be 18-28 mm. When is the converter used? Basically we suggest that if there's a graft of PTFE material, recommend that you should use the converter. In addition, most people would recommend that you use an iliac leg graft in it so that you've covered the whole area of the PTFE with Dacron. The main body length, the top of the graft to the bifurcation, must be at least 17 mm proximal graft. If the graft is greater than 30, you cannot use just a little cuff for the extender because that doesn't give adequate oversizing, so you have to use a converter so that you can seal in the neck. Obviously you need appropriate oversizing to place this graft.

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Again, when you want to use an iliac limb or an iliac extension with it, there are some things you have to keep in mind. First of all, you have to keep in mind whether you want to land inside the distal end of the other graft or you want to land above the iliac bifurcation. We suggest that you use 10 mm of length with your landing zone that looks like stable vessels. We also suggest that the diameter should be no less than 12 mm because the distal end of the converter is 12 mm. Obviously we want at least one Z-stent placed and the diameter should be no less than 12 throughout the entire graft, not just in the landing zone.

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Here's a little diagram to show deployment. You see the balloon deploying the graft there. Here's a little schematic. This one has an iliac limb that's been used. Notice the left distal common iliac artery. An occluder has been used there and this patient would probably do better with a femoral-femoral bypass, so functionally you have converted a failed or failing endograft into an aorto-uni-iliac and then a femoral-femoral bypass is placed. Over the past few years, Cook has made available to some physicians custom-made devices, sort of the frontrunners or the pre-Renu devices. A registry was obtained from 69 patients. This took place in 13 countries throughout the world. These patients were treated for proximal fixation failures. Six different grafts were the primary grafts placed: Zenith, Talent, AneuRx, Vanguard, Stentor, and a custom-made device. The physicians elected to place approximately 85% main body extenders, using converters in the remaining 15%. The outcomes? The implant was functioning fine at a mean duration from implantation of 26.3 months. Surgical conversions occurred in 5 of 69 patients. We'll discuss those a little more in depth a little later on. Eight of 69 patients expired and one patient was lost to follow-up after a 26-month follow-up visit.

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Let's look at surgical conversions. There were two acute conversions. There was one conversion at five months post-implant, probably secondary to an endoleak, one at 12 months post-implant, and one was converted and

the physician who responded to the registry was not exactly certain of the time of the conversion. The mortality in this group was eight patients. Three of the eight patients expired within 30 days of implantation. One expired prior to implantation, but as a device had been created for the patient, using intention to treat protocol, we thought it would be correct to keep this patient in here and report the mortality. One patient died secondary to a perioperative myocardial infarction and one patient died of sepsis secondary to a pneumonia postoperatively, day 28. Five of eight non-aneurysm related deaths completes the eight patient mortality. There is one patient that I think bears discussion. This patient died 36 months post custom made device implantation. The patient had an attempted surgical conversion and they expired. The physician reported that it was a Type II endoleak that caused the continuous expansion and endoleak. I have some personal questions about that, but according to the registry, it was reported as a Type II endoleak, not a direct failure of the device. The overall aneurysm-related mortality was 5.8%. This includes the patient who never had the device implanted, using the intention to treat protocol. If we exclude that patient, our mortality drops to approximately 4.5% in a group who already had previous endografts placed and had failure of those endografts. In conclusion, I think the use of the custom-made devices, sort of the forerunners of the Renu devices, to treat patients with proximal fixation failures of the primary endografts, was quite successful. A majority of the patients did well, and again, this is a fairly difficult clinical problem. We're going to turn now to a little animation that shows how the converter is placed. We've gone to the converter because Dr. Sanchez and Dr. Parodi placed the converter in two of their patients. What you see here is the device going up and you see that the graft has migrated down from the area of the renal significantly. The graft is being deployed into the iliac limb. After the graft is deployed, the suprarenal fixation device is deployed. The delivery device is removed. An iliac limb is deployed. A balloon is placed to mold proximal. Luis and Juan, I would tend to mold the whole thing with the molding balloon. What do you do in St. Louis here?
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LUIS ARTURO SANCHEZ, MD: That's what we usually do. We prefer to mold the complete device, from the proximal sealing zone all the way down to the distal sealing zone, to make sure that the device has the best shape possible throughout its entire length.
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SAMUEL R. MONEY, MD: Great. Why don't we spend a few minutes talking about the first patient that you did and maybe you can take us through that case, the two of you. We'd appreciate it. Luis, do you want to tell us about the patient while they're seeing the video of you working?
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LUIS ARTURO SANCHEZ, MD: The first patient, that was treated last week, was an 81-year-old female who presented originally to our institution in March 2001 with an enlarging infrarenal abdominal aortic aneurysm. At that time, she was successfully treated with an AneuRx endovascular graft and her anatomy was quite reasonable. She did very well over the ensuing few years, having follow-up at least yearly. At her most recent follow-up, a few months ago, she was noted to have a graft that had migrated from her proximal attachment site due to some anatomic difficulties of her proximal attachment area. She developed a Type I endoleak in addition to the migration of the proximal graft.
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SAMUEL R. MONEY, MD: Lou, do you want to sort of take us through where you are now?
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LUIS ARTURO SANCHEZ, MD: In the tape that you are watching, in the left side we have placed a sheath already to be able to have a pigtail catheter and you can see the initial arteriogram there.
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SAMUEL R. MONEY, MD: Pretty impressive leak.
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LUIS ARTURO SANCHEZ, MD: Exactly. You can see the Type I leak with the graft migrated from the level of the renal arteries approximately 2 cm. In this particular view, we see the renal arteries, but we don't see them perfectly. You can see the Type I leak on the side of the graft there, extending down into the aneurysm. In the right side, which we planned to be the ipsilateral side, we had already placed a Lunderquist wire, over which we were planning to place the first device. We changed the angle of the fluoroscopy unit to be able to better visualize the renal arteries. On this angiogram, you can better see the left renal artery extending down and to the left side of the patient, and the right renal artery being somewhat higher, giving us a landing zone which had somewhat of a reverse taper, but a landing zone nonetheless to be able to seal this graft. We thought this particular graft was

the best option for this patient to be able to get her completely excluded once again, short of having to convert her to open repair.

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SAMUEL R. MONEY, MD: Juan, you probably have more experience than just about anyone in the world. I mean, you basically invented the endograft. How much migration have you seen?

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JUAN C. PARODI, MD: It depends on what device. In the last year, we were using the Cook and the Excluder and we have seen very few, but in the past we have used the Vanguard. We try to use all of them. Vanguard, Talent, and AneuRx we have seen more. As you mentioned initially, this is a big issue, not only migration, but also, you know, we have seen damage to the wires, separation of the wires, and initially with the Vanguard it was a perfect system for two years. After two years, we started to see material fatigue and leaks of all kinds. We are seeing that also now with the AneuRx, a little later, obviously after more than two years, but migration and separation of seals and microleaks we are seeing very often now.

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SAMUEL R. MONEY, MD: Will you take us through what we're seeing now? It looks like you're delivering the converter.

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LUIS ARTURO SANCHEZ, MD: Yes, the decision was made that the patient would be best treated with the converter device and the pigtail catheter is from the left side. The device was advanced successfully with minimal difficulty through the right side. It was positioned at the level of the renal arteries and we maintained the pigtail catheter in position so that we could inject and reposition the device exactly to where we wanted. The patient had a proximal neck that we wanted to make sure we sealed very well right below the renal arteries to have a good long-term result. You can see in that injection the level of the renal arteries. The markings on the device are just below the level of the left renal artery, which happens to be the lowest one in this particular patient. We do usually short injections to continue to visualize the renals as the deployment happens. You can see at this point the sheath is being retrieved in the device. The sheath now has a marker on the tip and this is brighter, so you can see the sheath being retrieved. You know what level you're at. We're getting to the point of the first covered portion of the converter device being exposed there. You will see the device starting to open and flare into position. What we usually do is after the initial flaring of the device, right around the level of the renal arteries, as you can see there, we repeat the arteriogram, make sure that we're exactly in the right position where we want, before completing the deployment of the device and deploying the transrenal or open portion of the device.

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JUAN C. PARODI, MD: That was a very short neck, so this case was not easy at all. In addition, we positioned it in order to be octagonal. You can see the proximal marks at the same level. That's very crucial when you're dealing with very short necks because the deployment is octagonal and you take advantage of this device, that you can reposition and move it. As Dr. Sanchez mentioned, we do a small injection of 7 cc at a rate of 40 per second, so we don't use a lot of contrast medium, but we are very precise and you can be very precise in very short necks with this device.

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SAMUEL R. MONEY, MD: Do you always do craniocaudal? Do you go 10 to 20 and kind of move right to left when you have a very short neck?

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JUAN C. PARODI, MD: Most of the time.

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SAMUEL R. MONEY, MD: Yeah. We sort of have a joke in the OR that I start at 18 and my partner starts at 20 on craniocaudal.

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LUIS ARTURO SANCHEZ, MD: In this particular case, it ended up that right around 20 was the appropriate angle to be able to get the best visualization in this case. In other cases, as you've mentioned, it can be a much more significant angulation that you require, but that's one of the other advantages of the device. Those marks you can visualize very clearly and decide what angle.

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SAMUEL R. MONEY, MD: I'm going to interrupt you for a second. It looks like you're doing your suprarenal fixation.

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LUIS ARTURO SANCHEZ, MD: The device, the converter has been fully deployed at this point. We have released the safety wires and at this point the transrenal portion has been fully deployed. At that point you lock it in place. You don't want that crown to catch on any of the other metal components. You can see at that point the hands of the operator getting ready to lock it and leave it in position. He's pulling the second safety wire, which will release the lower end of the converter device. After that, then we can retrieve the introducer system for this particular device.

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SAMUEL R. MONEY, MD: Whose hands are whose over there? Who's the fellow getting yelled at by right now is what I want to know?

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JUAN C. PARODI, MD: He's receiving the direction of the senior guy.

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SAMUEL R. MONEY, MD: Sometimes the fellow gets confused when there are too many senior guys in the room.

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LUIS ARTURO SANCHEZ, MD: At this point you can see that the introducer system has advanced back to be able to capture that caudal portion of the device where the transrenal portion was housed, to be able to protect that as it would be retrieved, very much like the system of the bifurcated Zenith device.

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SAMUEL R. MONEY, MD: I think, as you said before, it's very important to remember you want to go up and, as we say, fetch the cap, but you want to do it away from the suprarenal fixation. Not that we know anything from experience that we've run into in that situation.

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LUIS ARTURO SANCHEZ, MD: At this point, after the two opponents are well opposed, you can retrieve the whole introducer system, leaving your guide wire in position for further manipulations as you're planning to complete the procedure. You can see the introducer system being retrieved completely. The field is very dry with the new valve that this device has, compared to the other devices.

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JUAN C. PARODI, MD: I think Cook has been very successful with this last valve because we always have problems with the valves, so we are very happy that finally we have a very effective valve.

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SAMUEL R. MONEY, MD: What I remember is when we started doing EVT in the original trial, we used to call it dial-a-crit. If you didn't have your finger on the valve, you could dial the crit down as low as you really wanted it to go.

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LUIS ARTURO SANCHEZ, MD: Sam, you can see here that after retrieval of the Introducer system, as we mentioned before, we like to mold the device completely, especially that area, where it's going to have the seal proximally. You can see also the wire from the contralateral side that has been retrieved and left inside the body of the AneuRx device, which will serve us later to be able to place the Occluder on the contralateral side in the appropriate sheath. We usually mold the whole device as it comes down. You can see the balloon there being used to mold the device.

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SAMUEL R. MONEY, MD: Did you use an iliac extension on this?

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LUIS ARTURO SANCHEZ, MD: Yes, in this particular case the limb of the original device was approximately, I think it was a 15 mm limb. You'll see us measuring what the limb is at this point and we did do an extension. As you mentioned before, this device, its distal portion is around 12 mm and if the limb of the other device being salvaged is around 12 or smaller, this will seal, but the vast majority of them that have been used, the limbs are larger than 12 mm, so I think it would be very common that you would require an iliac extension in the majority of the cases.

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SAMUEL R. MONEY, MD: Actually, someone just handed me an email question and it's, I guess, for Dr. Parodi. What devices have you been using up until now for migrating grafts? What have you done before the Renu became available?

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JUAN C. PARODI, MD: With a migrating graft, the only devices we could use were cuffs from AneuRx, from Talent, from Excluder. Initially those cuffs were effective, but Dr. Sanchez just completed a review of those patients and after a few years we learned that that was not a very effective and durable procedure, so we were happy initially, but following those patients, we learned that was not the right treatment for migration.

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SAMUEL R. MONEY, MD: Great. I think a lot of us have suffered the same reality, that the previous devices we tried to use for this just made us feel good for a few years, but after that—Luis, what are you doing now?

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LUIS ARTURO SANCHEZ, MD: At this point, you saw the limb being measured. In this particular case, the ipsilateral limb measured approximately 13-14 mm in diameter and a 16 mm iliac extension from the Zenith device is being advanced into position to overlap into the converter and we would overlap right to the end of the limb of the AneuRx graft. This particular limb of the AneuRx graft had good position inside the iliac and it extended to just above the hypogastric artery so that the new extension of the Zenith device that we are placing right now we wanted to extend to cover the complete limb of the AneuRx graft, but we did not want to extend it further down and that way we would preserve the hypogastric on the right side. You can see the system being retrieved at this point. We would mold the system in position, just like we did the converter.

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SAMUEL R. MONEY, MD: Great. Let me just speak to the audience out there. We are accepting email questions and we've got a few that are coming in, but please ask if you have any questions that you'd like to pose to Dr. Parodi, Dr. Sanchez, or to myself, please email us in. Luis, you're getting ready, you're molding right now.

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LUIS ARTURO SANCHEZ, MD: Yes, you can see the balloon right now. We're just molding the ipsilateral limb in position, just to make sure you take out any folds and wrinkles of the device to have the best possible result and avoid any problems with kinking of the limbs or compression of them, especially since you're inside another device. Here you can see the balloon taking a nice shape there and accommodating the device very nicely. At this point we remove the molding balloon and, in this particular case, you have to be ready to do the opposite side. You can see our technician at that point measuring the contralateral limb so that we can decide what occluder will be the most appropriate. Just like you mentioned before, whenever the converter is used, for the vast majority of patients we need to do two things: reperfuse the contralateral lower extremity and you need to occlude the contralateral common iliac or the limb of the other device to prevent retrograde flow into the area of the Type I leak or the area of migration of the device. You can see at this time the appropriate sheath being advanced into position to be able to get the appropriate size converter, occluder. In this particular case, since the limb was 18 mm, the occluder chosen was 20 mm. This sheath was able to be advanced into position without any significant difficulty. You can see the dilator being retrieved. After the dilator is retrieved, the wire would be removed. That's the cartridge that carries the occluder in position. The cartridge is positioned and you will advance the occluder to the location that you're interested in deploying it and you'll see in a minute how it's being deployed.

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SAMUEL R. MONEY, MD: The thing that you always have to remember is there's no wire that's left in there because this is an occluder. It shuts everything down.

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LUIS ARTURO SANCHEZ, MD: Correct. And it's very important to know that, that you cannot advance the occluder out of the sheath. You want it deployed by an exchange because you have no wire access at this time.

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SAMUEL R. MONEY, MD: Luis, that was a great case. I think that if we can go to the slides we have here, this shows the final angiogram and the postoperative CT scan. Then I have another email question. So if we can go to the slide.

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LUIS ARTURO SANCHEZ, MD: On the slides, you can see on the left hand side the completion arteriogram at the time of the deployment of the device and you can see complete exclusion of the other device and the Type I leak, good perfusion to the kidneys, and flow only down the ipsilateral right iliac system. Both the hypogastric and the external iliac arteries are widely patent. At this time, on the middle panel, the patient two days postoperatively underwent a three-dimensional CT scan, a spiral CT scan, and you can see complete exclusion of the prior AneuRx device and the aneurysm. You can also see the femoral-femoral bypass at the bottom of the image and retrograde flow up the left external iliac artery, maintaining patency of both hypogastric arteries. The third image just shows you sort of the metal of the device itself inside the original AneuRx device. The patient tolerated the procedure well and went home within a few days of the original reconstruction.

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SAMUEL R. MONEY, MD: Luis, just one question. Do you think you used enough PTFE in that fem-fem bypass? I just want to make sure you have enough there. Okay, someone slipped me a question here and it says how many patients are out there who you really think can use this type of graft? Well, I think Dr. Parodi sort of

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JUAN C. PARODI, MD: I think endograft is an evolving technique. We should mention this because if you'll remember, the mechanical and aortic valves, they had to go through nine generations until they reached an acceptable level. I think we're reaching a very good level now, very acceptable and durable, but we had to go through several different devices before coming to this point and everybody's learning now, so we have plenty of patients who had the other systems that were effective initially but now we're starting to see them failing. Most of the cases were done initially to treat high risk patients. That means that the survival rate is very, very low. At least in my experience that was positive in terms of not having to treat many patients because those patients had a very short life expectancy, but since the FDA approved the devices and many people are using these, we are going to see people surviving enough time to see the failures and we need to be prepared to help those patients. I think this is a device that can be very effective doing that, not only to treat migrations, but also to be able to reline the whole graft and treat Type III, Type IV endoleaks or that kind of problems that can require eventually a conversion, so we need to prevent conversions and I think this is a good way to do it.

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SAMUEL R. MONEY, MD: I think that people have to remember that the risk of an open conversion is so much greater than a primary aneurysm repair. It sort of changes the whole equation so if you can get by with relining it with a converter graft or even an extension, it's a whole different magnitude of morbidity and mortality for the patients.

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LUIS ARTURO SANCHEZ, MD: Initially many of these patients, as they were treated with endovascular devices, the decision was made, because they were not great candidates for open repair to start with, now they're 4, 5 years from the original procedure, they're not getting any younger or any healthier and this particular technology may really help a lot of these patients if we can avoid having to convert them to open repair.

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SAMUEL R. MONEY, MD: Great. Why don't we go on to the second case. Dr. Sanchez, do you want to tell us a little bit about this patient?

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LUIS ARTURO SANCHEZ, MD: I'm going to tell you a little bit about the second case. His anatomy was a little bit different. The patient's a 78-year-old gentleman. He was treated originally in the year 2000 with aortoiliac aneurysms. He had the left hypogastric excluded and the AneuRx device extended well into the left iliac system. He had a successful repair but returned in 2001 with a problem with a Type I endoleak. At that time, he was treated with a proximal cuff, which was 7 cm in length, successfully with excellent overlap of the proximal attachment of the main device, and he was subsequently followed. He did well for a number of years and has returned most recently with a pulsatile abdominal mass and a CT scan that shows a Type III endoleak with separation of the components that were well overlapped at the secondary procedure in 2001, over time. So this patient, we're trying to figure out what would be his best option for reconstruction and we also thought that this patient would be best treated using a converter device. On the images, you can see this patient's anatomy was somewhat more difficult. You can see the tortuosity and some difficulty getting the converter device into position. You can see the multiple components of the AneuRx device that we used originally for this patient. He had a single renal artery

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SAMUEL R. MONEY, MD: What wire did you use to get up there?

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LUIS ARTURO SANCHEZ, MD: In this case, we started with an Amplatz Superstiff. It did not support us enough. We ended up using a Lunderquist wire. We got much better support. Even then, it was a little difficult to get the device up, basically because of the anatomy that we were trying to traverse. The combination of the tortuous iliac arteries, a tortuous main body device that was fairly loose in the bottom of the aneurysm, and two cuffs that were serially traversed by the device and the wire. In this particular case, like in the other one, we want to know exactly where the renal arteries are. He only had a single kidney on the right side and somewhat elevated renal function with a creatinine of 2.5, so what we decided to do was to use gadolinium to visualize the renal artery. As you can see here, we're using a catheter to try to cannulate that right renal artery. It's somewhat difficult trying to get over the ridges of the AneuRx cuff.

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SAMUEL R. MONEY, MD: Did you use gadolinium for your original CT scan?

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LUIS ARTURO SANCHEZ, MD: In fact, this patient on his original evaluation was evaluated by a CT scan without contrast and we combined that with an MRA to be able to evaluate flow and we avoided the use of ionated contrast for his complete evaluation.

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SAMUEL R. MONEY, MD: We've done a few patients where we've actually placed the pigtail into the pararenal aorta and then shot a CT scan with the gadolinium under power injection. It's just a good little trick to get good visualization. So you're trying to intubate the renal artery now.

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LUIS ARTURO SANCHEZ, MD: Exactly, and you can see the catheter being used to cannulate the renal artery because of his anatomy. As you can imagine, it was somewhat difficult. We decided to move the device down, just to make it a little bit easier to get into that renal artery, as we wanted to visualize it well, make sure we knew where it was, and we wanted to be very close to it so that we would have the best possible stability of the device long-term. We changed catheters a few times until we were able to get into the renal artery. You can see the cannulation there. The renal artery is cannulated with the appropriate catheter and wire. At this point, all we did was just leave the catheter in position, leave the wire in position, knowing where the renal artery was, and planned to deploy the device exactly below it and avoid any further use of ionated contrast.

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SAMUEL R. MONEY, MD: So this was really a high risk patient.

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LUIS ARTURO SANCHEZ, MD: Yeah. He had a few other considerations. This particular patient, in fact, we did under regional anesthesia. He had severe COPD and was on oxygen originally at home. He has been using it off and on at this point, but we did not think that he would tolerate general anesthesia either, so even through the procedure, you'll see that the patient is breathing fairly hard and we kept him awake through the procedure. Some of the visualization also makes it a little more difficult if the patient cannot hold their breath perfectly for us. We thought that getting a wire into the renal artery would be the safest way of knowing exactly where it was as the images would continue to move to some degree because of some of the other difficulties.

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JUAN C. PARODI, MD: In this case, we wanted to mark where the renal artery was, but in case the neck is very, very short, we prefer to come from the upper extremity and to put a wire and be able to put a stent, in case we cover the orifice inadvertently. In this case, we didn't expect that and you will see that we found the right angle to separate and to see exactly where the neck was, so we had enough room here, we didn't need to put a sheath, in case we needed to put a stent.

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SAMUEL R. MONEY, MD: Have you had to bail yourself out a few times when you've inadvertently covered part of the renal and you've had to put a stent in?

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JUAN C. PARODI, MD: Yeah, we had some cases we had to. But you can predict that when you have angulated necks and short necks, it's better to have a wire inside and come from the left brachial.

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LUIS ARTURO SANCHEZ, MD: That provides you a little more access and, with the same system, the sheath and the wire already in position, you can go ahead and stent the renal artery if you need to. In this particular case, to get the best angulation for deployment and exactly know where that renal artery was, we had to go almost 300, compared to the prior case, to get the best angulation. You can see right there, the device is being just deployed. The first ring is getting close to being opened and you can see the sheath being retrieved. We're just trying to be just below that catheter in position.

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SAMUEL R. MONEY, MD: This is not for a proximal Type I leak here, is it? What kind of leak do you have? I want to just reinforce that.

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LUIS ARTURO SANCHEZ, MD: This patient had a Type III endoleak. That was what I was going to mention, wherein that proximal cuff of the AneuRx device, that is well seated in this particular neck, we still want to cover it completely and be very close to the renal arteries to have the best long-term result, but this particular patient, his problem was a Type III endoleak. When we go over the images on the sides, I'll show you what his preoperative study showed, that he had a very classic Type III endoleak disconnection of the components with total pressurization of the sac and enlargement to approximately 9 cm.

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SAMUEL R. MONEY, MD: So functionally, he did have a proximal migration problem, but the cuff had stayed in place and the main graft migrated down, so I guess do you call that a Type I leak or a Type III leak at this point?

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LUIS ARTURO SANCHEZ, MD: It's still a migration. I guess by definition it becomes a Type III leak, which is something that we've seen on these patients that we're very happy initially by adding other components and we thought we've sealed them now. We have another cuff, we're going to have a good result, and if the patients survive and are followed closely and it's long-term enough, many of these patients will come back with further separation of components or migration of the most distal component, leading to failure. You can see there, after the device was completely deployed, like the other converter, the transrenal portion was deployed and the introducer system is being retrieved. We capture the cap for that particular device, only this time we're going to completely retrieve it. In this case, compared to the other case, the patient's left hypogastric artery was already occluded. By placing the converter, the left iliac system was completely excluded, so we did not have to consider or need to place an occluder in the contralateral side. You can see the catheter on the left side, which is basically being pulled out. There's no sheath or anything else in the left iliac system. Very much like the first case, we're going to need to measure and see if we need an extension, an iliac extension. Here's the holding balloon going into position, molding the proximal portion of the device initially, making sure the device is fully open before we attempt to get any other introducer systems or other devices into the converter.

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SAMUEL R. MONEY, MD: Someone just handed me an email question. How many of these devices have been placed in patients? I can answer that. I believe it's about 130 have been placed by now. I think we're up to #6 in the United States, 5 or 6, and my guess is within a month we'll probably be up to 20 in the United States because patients are sending films in for review. Luis, why don't you take us through. I think you're almost done with your study here now.

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LUIS ARTURO SANCHEZ, MD: Yeah. We molded the device. We chose the extension. In this particular case, we decided to completely exclude the AneuRx device and bring the iliac extension to below the end of the original AneuRx device. The right limb of the device was attached to the proximal common iliac. There was no Type I endoleak there, but it was relatively short. The common iliac flared to approximately 19-20 mm, so we decided to use a Zenith iliac extension that would flare to 24 mm so we would have appropriate overlap and have good attachment into the right common iliac artery. You can see the device going into place there and extending just distal to the original limb of the AneuRx device. The limbs are being deployed and you'll see there's the very end of the iliac limb being deployed. The introducer system will now be retrieved. Following the steps of deployment of the device, at this time we'll mold this component into place, especially its distal attachment portion, just to make sure it's well secured into the common iliac artery and that the overlap of the components is appropriate.

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SAMUEL R. MONEY, MD: We're going to go to a molding balloon and then a completion angio?

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LUIS ARTURO SANCHEZ, MD: Correct. Here's the molding balloon. In this particular case, we saved all the contrast for the final angio. We didn't want to use it for the rest. We just used gadolinium to find that renal artery, as we were talking about, and we'll just have a completion arteriogram on that particular patient, just to make sure that we have a good result. This patient will likely be followed by CT scan and an additional ultrasound to be able to make sure that he does not have any endoleak and hopefully these aneurysms will decrease in size. You can see the molding of the iliac. At this time you're going to see the completion study going down, just on the ipsilateral side. The ipsilateral hypogastric is open. The ipsilateral external is open. The left system is not visualized at all, since the hypogastric was already occluded, embolized and extended. Then, following this, he underwent a femoral-femoral bypass and ligation of the very distal external iliac artery so there would be no retrograde flow into the left iliac system.

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JUAN C. PARODI, MD: This was very interesting to see this because you see an aneurysm of the distal iliac but that aneurysm is now covered, so we use the system in patients with iliac aneurysms. One wonders how an aneurysmal graft would behave. Obviously with this graft there, that aneurysm is not going to grow.

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LUIS ARTURO SANCHEZ, MD: In fact, this patient, that dilatation of the right common iliac, that's the way he's been from the original deployment. HE has never dilated over a period of approximately six years, that common iliac artery, which is 19-12 mm in diameter, interestingly.

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SAMUEL R. MONEY, MD: So that's remained stable. I've got a few email questions that came in. The first one I think Dr. Parodi, you'd probably be the best to answer this. What type of anatomy have you experienced the most graft migration in?

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JUAN C. PARODI, MD: Patients with conical necks, short necks, and angulated necks, so those cases should be excluded, at least initially, from the practice of this endoluminal treatment.

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SAMUEL R. MONEY, MD: I think personally the bad neck is the worst prognostic indicator of failure of the graft, but what if you have to place an endograft? The patient has a 7 cm aneurysm, bad COPD, and you just feel you have to place an endograft? Can I push you? What do you do different to try to reduce that migration?

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JUAN C. PARODI, MD: That's a good question because we see that kind of patients often and what we have been using is a combination of an endograft and the extra large pulmastent. We started to use the extra large pulmastent in 1990. Actually, we were producing that and then Johnson and Johnson started to produce the extra large. We designed the pulmastent, which initially was up to 12 that you could open, and the one we designed went up to more than 40. I think it's a good combination because I should say, answering the first question, in terms of using cuffs, in the cases we use cuffs and extra large pulmas, those cuffs are still together, so it's a way to lock those cuffs. To use a malleable system, like a pulmastent, a balloon-expandable malleable system, you can adapt to different angles and even hourglass shaped necks. We don't have to do that often, but from time to time we have patients, as you said, that we need to push the envelope and fix their aneurysm endoluminally, even if the anatomy is not an appropriate one.

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SAMUEL R. MONEY, MD: Okay. We've got a few more questions. Luis, this may be a good one for you. How do you minimize the chance of graft migration?

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LUIS ARTURO SANCHEZ, MD: Clearly the most important part to try to minimize graft migration is to have very good patient selection. Unfortunately, a lot of times we're placed in the situation that you just mentioned, that the patient may not have the best possible anatomy. They're not a great candidate for other options for treatment, including open repair, and then it's a matter of what component or what device we choose to try to minimize migration and failure of the proximal attachment site. Some other things that we commonly do is use a device that has transrenal attachment to try to minimize the risk of migration. At the same time, we need to make sure that the device seals very well proximally. Many of them, by molding the device is enough. If that is

not enough, the concept that Dr. Parodi was just mentioning, using some more radial force in that location with a pulmastent or some other large stent will help us seal the device in position, but having a transrenal fixation device usually will help us to try to avoid the issues of migration in the vast majority of patients. There's always anatomies that will make it very difficult. It doesn't matter what we try to do.

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SAMUEL R. MONEY, MD: Actually, Chip Sternberg, who is my partner, looked at this and we have clearly concluded that graft migration is obviously device-specific and I think we're all saying that we all sort of like suprarenal fixation and stuff like that. I think we have 1-2 more questions. This one says when would you decide to use a main body extension versus a converter? Which one do you like better? Tell us about these.

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LUIS ARTURO SANCHEZ, MD: I think in general, for the vast majority of patients, I think we have the tendency of using a converter if we have it available. Now that it's available, I think we'll use it the most. If a patient's device has already migrated distally, what we've found, using other cuffs and other even transrenal cuffs, in particular the Talent cuffs, AneuRx cuffs, Excluder cuffs, really any of the aortic cuffs, it's hard to get them appropriately overlapped when the devices have a relatively short body. We have a very good short-term result, but we're starting to find out that at 2-3 years and even further, as these patients are surviving longer and longer, the risk of migration is still there and it's not the whole device, but the bifurcated portion of the device that will continue to separate from the proximal cuff that has been placed and you end up with a Type III endoleak, still a migration problem. A converter, I think, would give you much better long-term stability. The other components in specific situations will be helpful, but I think the converter will be used the most.

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SAMUEL R. MONEY, MD: Juan, do you have anything you'd like to add to that?

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JUAN C. PARODI, MD: Yeah. I think Luis made the point that when we treat the patient with an AneuRx, the main body is 3 cm, so you don't have room for overlapping. Perhaps that device could be used in the few cases we see of migration of the Zenith device, so you have a long main body, so you can overlap more, but I agree with Luis that the tendency is to go into one of the limbs until Cook develops a bifurcation or something like that.

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LUIS ARTURO SANCHEZ, MD: Ultimately, one of the things, if you can accommodate another full bifurcated graft, it would be an advantage, a transrenally attached, fully bifurcated graft, so you maintain a full bifurcation on the patient. I think that would be the best goal. But most of the bifurcated devices, if you include the body and the contralateral limbs, the systems are so long that you cannot accommodate most of the migrated devices. As you said, the distance between the renal arteries and the bifurcation of the device that has migrated is a crucial piece of information to be able to treat this problem and it's usually shorter than 7 cm, so for most bifurcated devices out there, we can accommodate them as a salvage type situation.

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SAMUEL R. MONEY, MD: I think we have to remember that if there's a PTFE graft that's been placed, we have to use the converter, rather than just a body extension cuff. At this point I'm going to turn the floor over to you two. Do you two have anything you'd like to add at this point, before we close up?

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JUAN C. PARODI, MD: Sometimes I am amazed at the explosion of this technology, but I strongly believe that we're helping patients and actually, when we started to think about this minimally invasive treatment, the reason was that the main procedure we used and still use, open procedure, is a very good one, very effective, but also very traumatic. When you start dealing with patients over 80 and with a lot of comorbid conditions, I think we are on the right track and this should help us to save the problems we had with other devices or even with the Cook device, so this is absolutely welcome because we need it. We need it, no question.

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LUIS ARTURO SANCHEZ, MD: Yeah. I think it's really going to help us deal with some very difficult situations that we encounter and get a lot of patients through, hopefully with the least possible problems in the perioperative period.

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SAMUEL R. MONEY, MD: Great. I think that the two of you have sort of summarized our feelings. This is going to help, potentially, a fair amount of patients who have this problem and reduce the morbidity and mortality from

conversions and redo redo cuffs, etc., etc. With these final remarks, I thank you two. Thank you very much for spending time with us this afternoon.

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NARRATOR: Thank you for watching the webcast discussion of a repair of a migrated abdominal aortic aneurysm endovascular graft with the Zenith Renu. To make an appointment, make a referral, or request more information on the procedure, please click the buttons on the screen. For more information on the Zenith Renu from Cook, Inc., Endovascular Therapy Products, please go to www.zenithstentgraft.com.