



**MINIMALLY INVASIVE PROCEDURES FOR IMPROVING CIRCULATION TO THE
LEGS
SENTARA NORFOLK GENERAL HOSPITAL
NORFOLK, VA
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ANNOUNCER: Welcome to Sentara Norfolk General Hospital in Norfolk, Virginia. Over the next hour, see minimally invasive procedures to improve leg circulation. Peripheral vascular disease is caused by buildup of a fatty material within the vessels. It's a gradual process in which an artery becomes blocked, narrowed, or weakened. Risk factors for this disease include cigarette use, high blood pressure, or elevated cholesterol. If left untreated, gangrene or stroke can occur. To treat the condition, doctors can use a range of tools from lasers to stents and ballooning. In just moments, you'll see some of the latest minimally invasive procedures used to open up the arteries and improve circulation, all without the complications associated with traditional surgery. 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 in the endovascular suite.

00:01:17

MARC H GLICKMAN, MD, FACS: Welcome to Sentara Health Care System's first live webcast of two or hopefully three procedures to revascularize the lower extremity in patients with significant vascular disease. We are live from the endovascular suites at Sentara Norfolk General Hospital, where we have certified technologists helping my two partners, Dr. Gordon Stokes in room one and Dr. Jean Panneton in room two, performing live procedures using minimally invasive techniques to restore circulation to the lower extremities. I'm Marc Glickman, vascular surgeon and director of vascular services for Sentara Health Care System, both in the south side and peninsula. In room one is my partner, Dr. Gordon Stokes, who trained at Medical College of Virginia. And he'll be performing an innovative technique to restore circulation in a 70-year-old lady with an ischemic ulcer to her left fifth toe. In room two is my other partner, Dr. Jean Panneton, trained at the Mayo Clinic at Rochester, Minnesota. He is going to be working on a 70-year-old gentleman with hypertension, coronary artery disease, hyperlipidemia, who has disabling claudication to the lower extremities. We are Sentara Health Care System. We are 118-year-old not-for-profit health care system providing services in southeastern Virginia. We serve over 2 million patients by seven hospitals in the local Southampton Road area. We are presently at Norfolk General Hospital. We provide services in the peninsula at Williamsburg General Hospital and Sentara CarePlex. In the south side, we provide services at Sentara Virginia Beach, Sentara Leigh, Bayside, Norfolk General Hospital, and Obici Hospital in Suffolk, Virginia. We're going to be describing today minimally invasive procedures that will hopefully improve circulation to lower extremity not using any type of surgical -- open surgical technique. These are new and exciting and innovative techniques established here in Norfolk, Virginia, and elsewhere in the United States and in Europe. These procedures are totally minimally invasive. They do not require any incisions, but just a needle stick in the groin or the arm in order

for us to deliver new, innovative techniques and equipment to restore circulation to the lower extremity. Surgical revascularization sometimes is utilized, but in the majority of cases, we can restore circulation using these new techniques. The purpose of an endovascular procedure is to really to optimize circulation in a quick and efficient manner, and today, we -- I hope to present these cases to you so you'll be able to see it with your own eyes. We started using endovascular, or the minimally invasive, techniques back in 1997. At that time, only 10 or 15% of our procedures were being performed using the minimally invasive techniques. Today, over 85% of our procedures are being done in this fashion, in a minimally invasive almost outpatient procedure for the majority of our revascularization procedures. This really made the change in 2001 and 2002, as you see by this slide, and the slide and difference continues to grow year after year. We've been able to perform these at our endovascular suites both located in all of our hospital systems, especially Norfolk General, the CarePlex, and Virginia Beach General. When we compare subintimal angioplasty, the techniques you'll be seeing today, to bypass surgery, we see that the subintimal angioplasty, or the minimally invasive procedure, really only requires often an overnight stay or can be done as an outpatient. It's all done percutaneously. No pain; the patient is awake during the procedure with minor complications and a very low mortality and morbidity. And this we compared to our open, long-standing surgical procedures, which often require a three to five day hospitalization, anesthesia, multiple incisions, significant postoperative pain, and often can be fraught with wound complications in the 15-20% range. And as any procedure that is performed using surgery, it carries a mortality and morbidity in the 3-5% range. There are several lesions that we'll be looking at today, and I want to educate you with these lesions. The first lesion is what we call a TASC A lesion. This is a lesion in the superficial femoral artery, which is the artery in your thigh, in your upper thigh. And a TASC A lesion is a narrowed lesion not totally blocked. A TASC B lesion is the same artery that has multiple blockages, near occlusion, but not totally blocked. A TASC C lesion is a lesion that is blocked but only for a short distance. And a TASC D lesion, one that you'll be seeing today, is a lesion that -- of the superficial femoral artery where it's totally blocked. We have to recannulize or re-channel that blood vessel to restore circulation to the lower extremity. Some of the methods that you'll be seeing today includes the subintimal angioplasty technique, and this is where we provide -- place wires through one of the layers of the blood vessel to open up or make a new channel in that blood vessel. In our hands, which you'll be seeing later today, has been very successful with good long-standing results. And we're proud to show these to you this afternoon as well. This is a picture of the subintimal technique. Again, going through one of the layers of the blood vessel, bringing wires, then balloons, opening up the blood vessel so that a new channel or new opening can be created in the blood vessel to the lower extremity. This is a TASC D lesion in an 85-year-old lady with total occlusion of the superficial femoral artery, or the artery in the upper thigh, with reopening of the artery in the lower leg. Using the subintimal technique which you'll be seeing today, the entire blood vessel is reopened. The patient goes home the next day or that day without any complications or problems. This is one of my patients, an 85-year-old female, that I performed this procedure prior to her going to the National Dancing Championship in Columbus, Ohio, this year in which she won the championship for the samba. She was able to ambulate six to eight hours after the procedure. She was discharged home that day on Plavix and aspirin regimen and with clinical follow-up in three to five months. We are excited today to show you these procedures. In room one is Dr. Gordon Stokes. Dr. Stokes, please tell us where you are and what you're doing today.

00:09:09

GORDON K. STOKES, MD, FACS: Thank you, Dr. Glickman. We are here today -- my patient has an ischemic ulcer on the foot, and the artery is clearly occluded. We started out in the right groin, but a skinny needle, a micropuncture needle into the groin, into the femoral artery. We threaded a wire up into the aorta, which is major to -- from the heart down to the legs. And we passed a catheter over the top, over the aortic bifurcation, down into the left leg. We've taken a picture, and it shows the occlusion, which was what we predicted based on the non-invasive studies done in the non-invasive laboratory where the waveforms, instead of being nice and peaked with high amplitude as they are in a normal artery, were dampened severely. And that's a major threat to the leg. The leg has an ischemic ulcer on it, the toe is a threat. So our goal here is to cross this lesion. I'm considering different options for treatment. It looks like we may consider the laser, but I'll be able to tell more as I get into the case. So at this point, I'm going to try to pass my wire. I have the subintimal wire, and Skip is going to hold that catheter. Pop it back. And if you can keep your eye on the wire tip, you can see that it's traversing in the plane.

00:10:49

MARC H GLICKMAN, MD, FACS: One of the things that you're seeing with Dr. Stokes' performing is he has a loop within his guide wire, and this is allowing him to go into the subintimal plane. And so he's established himself in the subintimal plane with that loop, and that's the hallmark to know that he's getting into the right area and hopefully will reenter into the true lumen down the perineal blood vessel.

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GORDON K. STOKES, MD, FACS: So it's a little bit diseas-- it's terribly diseased, actually, and so I'm going to take a picture to try to outline our target. You see how terrible the blood flow is. There's a tiny wispy vessel which is our target. It should be a nice, open vessel about the size of my pinkie, and there's nothing there because it's filled with plaque. That's the hallmark of arterial occlusive disease, which causes claudication, which my patient has, but it's a worse level than that; it's threatening the leg by an ischemic, or poor blood supply, ulcer to the foot. So my job is to get through there...

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MARC H GLICKMAN, MD, FACS: Open that up and try to restore a new channel in that blood vessel to bring blood down to the lower extremity.

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GORDON K. STOKES, MD, FACS: Skip is doing a good job holding that in place. And so advance that a little bit more. All right, hold right there. let me just take this.

00:12:17

MARC H GLICKMAN, MD, FACS: These are live cases going on right now, so we're going to be patient as Dr. Stokes tries to reenter or get into that small blood vessel called the perineal artery in the lower leg. As you can see that loop as it goes down there, that's the loop that's dissecting within the planes of the artery in order for him to try to hopefully try to get back into the -- that small vessel, the normal lumen. What he has here is he has a catheter at the end of his loop that's helping him guide into this space. And what he's going to do here next is take another picture just to see exactly where he is in this. There he goes.

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GORDON K. STOKES, MD, FACS: Okay, I'm right at the origin of the perineal. I'm knocking at the door, so to speak, so it is right there. so you have to be delicate because these vessels are pretty small.

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MARC H GLICKMAN, MD, FACS: And calcified.

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GORDON K. STOKES, MD, FACS: Don't push it.

00:13:44

MARC H GLICKMAN, MD, FACS: And what Dr. Stokes now is into that perineal subintimal spot -- plane -- and trying to get into the true lumen of that area. While Dr. Stokes is working in room two, let's switch to -- room one -- let's switch to room two to see Dr. Panneton. Dr. Panneton.

00:14:15

JEAN PANNETON, MD, FACS: Well, Mark, we're -- we're getting ready here. We already have gained access into the femoral artery on the right side. What we intend to do with this nice gentleman here is to treat lesions that are on the left -- in the left leg. He's a 70-year-old patient, as you mentioned, who has extremely disabling claudication of both lower extremities, the left one being the worst, with a decrease in circulation down to approximately in the range of 65-70%. So that clearly is enough to really be disabling. It's not enough to lead to critical ischemia and threaten the limb, but enough to really be a major problem for daily activities as simple as walking. We already have the -- a large sheath that is into the aorta right now. We've already taken also the -- an angiogram of the left lower extremity showing that he does not have occlusive disease to the point where it's a total occlusion, but what he does have is some stenosis of the superficial femoral artery. That's the main thigh artery, as you mentioned already. He has a very high-grade stenosis near the ostium at the very beginning of the artery as well as another one further down into mid-thigh. So the key to minimally invasive treatment is always access. We already have access from the right side, but we now need to bring a sheath on the other side so that we'll be able to deliver the technology that we've elected to use for this patient. So we're going to go live right now and bring that sheath down into the left femoral artery from the right side.

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MARC H GLICKMAN, MD, FACS: And the purpose of the sheath is so that it's a -- allows for Dr. Penneton to bring his balloons and wires without damaging the art-- the inside of the arteries of this patients vessels.

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JEAN PANNETON, MD, FACS: So we have the sheath here that's advancing, and you can see on the screen that there's a little black marker that is now right at the level of the -- of the femoral head, which really is what you would like to have. That mean-- that way we have a real good controlled access to the contralateral artery. We're now going to remove the dilator and what we're going to do now is we're going to have to cannulate selectively into the femoral artery, which is the vessel that we need to get into to proceed with the next part of the procedure, which will be to actually open up the vessel with the stenosis. Now, in this patient, because he does not have an actual occlusion of the vessel, a total occlusion, we don't need to use a subintimal technique, but we're going to use something that's called a SilverHawk atherectomy device, and I'm going to let you expand on this a little bit further later, but the concept is going to be to de-bulk the lesion. So while we get this ready, I'm going to pass it back to you, Marc.

00:17:06

MARC H GLICKMAN, MD, FACS: Great. What we're going to be talking about, what Dr. Panneton's going to be using in room two is an atherectomy device, or a removing of the plaque, usually minimally invasive techniques. There are different ways of dealing with plaque. One is balloon angioplasty, one is removing the plaque, and this is a fairly new technique. A company, FoxHollow, developed this atherectomy device in removing the -- the plaque or the blockage within the -- within the vessel. This is what Dr. Panneton will be utilizing today. This is the -- the SilverHawk device. And you can see that what the device does is chews up or removes the plaque with this rotating head as we skive and open up the plaque so

that the plaque is totally excised and removed from the blood vessel. As you see from our slides, you can -- and from the previous study, a case I did several weeks ago that you saw on the live webcast -- you can remove lots of plaque from these patients, up to 380 milligrams of plaque if you get a significant diseased blood vessel. Again, this is the way we work with this. We deliver the FoxHollow to the area, we use the cutting area and skive and remove as much plaque as possible during the procedure. We do this throughout the entire blood vessel on the areas of narrowing in order to remove and to restore a normal-appearing lumen, or inside of the blood vessel as much as possible. This device was cleared by the FDA in 2003, and we have a very large and extensive history with this device with a lot of excellent results in looking at -- for outcomes in using this device and restoring circulation to the lower extremity. This is a close-up view of the device, of the cutting machine. It comes in various sizes. We can use it in larger vessels as well as small vessels within the calf as well. You have to use a very -- different-size device for each blood vessel that you use. Let's look to room two right now. Dr. Panneton, where are you right now?

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JEAN PANNETON, MD, FACS: Well, we have now selectively cannulated the superficial femoral artery, what we call in our own words the SFA. That makes it a lot easier. So the wire is now -- if you scan on the screen here, the wire is now -- goes all the way down toward the knee there. you might be wondering what this is here. Basically, this patient had a previous total-knee arthroplasty, and this is what you see on the screen here. But you can see that the wire is right all the way down to the level of the knee, which is what you want to achieve. With the safety of the wire like this, we can now introduce any devices that we'd like to -- to pick: balloon or, like in this patient, a SilverHawk FoxHollow device. So now that we have that done, we're going to advance the device. And probably what I'll do first is take one more picture of the stenosis. There is one that actually was a little difficult to cross, which is right at the mid-thigh. It -- it looked like at least a 98-99% stenosis, very high-grade, and it's only a very small wire. It's an 0.14 wire, that's the only kind of wire that I managed to get across that stenosis.

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MARC H GLICKMAN, MD, FACS: Okay. Before -- while you're doing that, Dr. Stokes, how are you doing in room one? How are we --

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GORDON K. STOKES, MD, FACS: This is a tricky -- there's a very tight lesion right at the perineal, and I'm fighting to get into the perineal.

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MARC H GLICKMAN, MD, FACS: I see that.

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GORDON K. STOKES, MD, FACS: I have taken a skinny little wire with a hydrophilic coat on the tip, and I'm trying to negotiate down into the artery. This is really the trickiest part of the case, and if we can get the wire into the proper position here, then we'll be able to open up the occlusion up above. So you have to have some patience in working with this type of a tibial vessel. And I use this catheter because it's -- this wire because it's lower profile than what I started out with. Now, Skip's going to take the larger catheter off, and we're going to put a skinny catheter down. And then I'm going to test with an angiogram to show me where I am because it's real important for Skip to leave the tip of the wire right where it is.

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MARC H GLICKMAN, MD, FACS: Which wire are you using now?

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GORDON K. STOKES, MD, FACS: This is a V-18.

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MARC H GLICKMAN, MD, FACS: V-18, that's your favorite. You may have gotten in there, I don't know.

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GORDON K. STOKES, MD, FACS: Yeah, I don't know, we're going to see.

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MARC H GLICKMAN, MD, FACS: It looks pretty nice. Dr. Panneton in room two -- if you look at Dr. Panneton's film in room two that's on the screen right now, you see a high-grade stenosis in that mid-thigh area, the mid-blood vessel, and you can see that's about a 95 -- 95% shelf blocking that blood vessel down there, and that looks like a lovely lesion for the atherectomy device, Dr. Panneton.

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JEAN PANNETON, MD, FACS: Yeah, indeed, that's what's most appealing. It's very -- what we call an eccentric lesion, very high-grade lesion, and it clearly is very appealing to de-bulk the lesion by removing the plaque instead of simply pushing the -- the plaque aside with a balloon. But the other thing that makes this patient actually quite disabled by this high-grade SFA stenosis is the fact that the profunda femoris artery, which is the vessel that you see next to it on the screen, also has a high-grade stenosis. So usually the profunda is a vessel that gives good collateral further down the leg, but in his case, he does not have that because he also has a tandem lesion in his profunda, so I think that's why it makes him even more disabled by this lesion. So by this point in time we have the SilverHawk atherectomy device all prepped. It's on the wire, and now we're going to bring it across from the right side into the left side over this wire.

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MARC H GLICKMAN, MD, FACS: Dr. Panneton, in your room, you're very lucky. You have three great people. You have Tony San Antonio, who's been with the center, the endovascular center, since it's creation, and he's your floating nurse helping you with this. You have John McMillen, who's scrubbed with you, was trained here and has extensive peripheral vascular training, and you're lucky to have these two people really at your side as well as Stephanie, who's running the monitor and getting all the data for you.

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JEAN PANNETON, MD, FACS: I can tell you, the beauty of working in this environment here is you have to speak very little because these are -- these folks are so experienced and so good at what they do that we don't even need to talk. They know -- they know exactly what we're going to need and they have it ready before even having to ask and wait for it. And the combined experience of all the techs that we have to work with here is purely phenomenal. We have, you know, decades and decades of experience in here, so it is -- it is a true blessing to be able to do those procedures with the kind of help that we have.

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MARC H GLICKMAN, MD, FACS: I want to go to room one for a second. Theresa, can you run that last film? As we noticed last -- with Dr. Stokes, I thought he had gotten in to the true lumen, and here he is, he has successfully gone through that blockage of the popliteal and just the superficial femoral artery, and now he's back into the lumen. He was able to do that with great wire skills and great technique. Nice job, Gordy.

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GORDON K. STOKES, MD, FACS: I'm pretty happy because that vessel was pretty bad and pretty fragile, too.

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MARC H GLICKMAN, MD, FACS: And very small.

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GORDON K. STOKES, MD, FACS: And that's the thing that we've learned. This patient's had some vein taken out of the leg, so the bypass options are limited. We've had a great experience with minimally invasive approach. We know when we operate on these vessels, they're tiny, they're fragile, it's a big operation. We have to go deep in the leg. This -- this is the deepest blood vessel in the leg, and it's her lifeline to keeping her leg going, so I'm happy we're into it. We have some more work to do, we're going to exchange out for an even thinner wire, we're going to heat the laser up, and I believe this is a good one to de-bulk with the laser. And then after that, we'll probably have to balloon it and take a look and see whether we need any further therapies.

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MARC H GLICKMAN, MD, FACS: So it looks like for Dr. Stokes in room one, he is through the -- the entire lesion, and that's really great. And he's going to be using a laser to open that up, and we're going to be talking about that in a couple minutes on that. Dr. Panneton, room two.

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JEAN PANNETON, MD, FACS: Yeah, Marc, we have the SilverHawk ready here, and you probably can see on the screen here, this component that's in my hand is -- is the actual engine that will activate the blade that will cut the plaque and remove it. And now if you go back to the screen, on the -- on fluoroscopy, you can really see the mouth of the SilverHawk. And if you look at it now live, you're going to see that the mouth of the SilverHawk can really be adjusted, and you can see how we can twist it in order to really shave the plaque in multiple planes inside the vessel in order to really de-bulk as much of the plaque as possible. But that is really the beauty of this device is how directional it is despite the fact that we are working from the right groin into the left groin. So now we're going to actually start the shaving of the plaque, and Tony here will activate the device.

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MARC H GLICKMAN, MD, FACS: Before you do that, can we go into the slide that I have now, please?

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JEAN PANNETON, MD, FACS: Sure, we can do that.

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MARC H GLICKMAN, MD, FACS: Slide, please. This is a slide of really what we have on our hands when we have blockages. How do we deal with this blockage? And what we're seeing today in these two cases that, instead of doing a subintimal dissection, we're going to be using the SilverHawk or the laser atherectomy. That's the skill and that's the beauty of being at a center that you can change your approach to these patients as long as you have these things at your hand and have the experience. So every lesion is different. Both these gentlemen are using two different types of methods in order to open up their blood vessels and deal with their blockages. Let's go back to room two.

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JEAN PANNETON, MD, FACS: All right, Marc, we are ready now. Tony will activate the device, and so we are now open, and we're going to do a few passes in the plane here in order to really shave the plaque. Off. Now that we've done one pass in one plane, we do a little bit of a -- of a change in the direction. Activate. And we're going to come and shave the other way here. The plaque that we shave is actually collected inside a small collecting chamber that's at the very tip there in order to not have any piece of the plaque to travel downward.

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MARC H GLICKMAN, MD, FACS: So what you see here is Dr. Panneton is taking the device, the eating device, and moving it up and down not the entire length of the blood vessel, but just that area that's blocked so he can remove plaque without destroying the remaining part of a blood vessel, take -- eat up, remove that plaque, and then we'll take that plaque out and then we'll see what he has -- what he's been able to remove from this patient's leg. And what he's basically doing is trying to do in 360 degrees to remove this concentric plaque, just not in one -- one area but really to pass it in various different planes so that we're eating up the entire -- opening up the lumen in the entire fascia throughout this blood vessel.

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JEAN PANNETON, MD, FACS: One more.

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MARC H GLICKMAN, MD, FACS: All right. Dr. Panneton, are you also going to be working on the ostial lesion as well, or...

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JEAN PANNETON, MD, FACS: Yeah, after I'm done with this more distal lesion, I will go back to the ostium, and I may also consider doing the profunda femoris, which also has the high-grade stenosis and treat -- treat both vessels. I think that's what probably will result in the best relief of claudication for him. The -- the collecting chamber now appears to start to be a little full because of the plaque de-bulking, so we're going to withdraw the device, empty the collecting chamber, flush it, clean it, and then we're going to reintroduce again for another -- another series of passes to provide more plaque de-bulking.

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MARC H GLICKMAN, MD, FACS: Great. We'll want to see what you remove, but I do want to remind viewers that we -- that we're willing to take your e-mails. On the bottom of your screen, all you have to do is hit "e-mail" and please send your requests and questions to me, and I'll be happy to answer them. I'd like to answer Tom's from Florida, from 34235. He rec-- he asked the question: I have recently been diagnosed with peripheral vascular disease of the popliteal artery. Thinking of cryoplasty or other new procedures. What you're seeing here today is that I can't give you one answer. You need to be able to go to a center that has multiple approaches to your -- to your disease. Subintimal may be the proper approach, you're seeing Dr. Panneton is using the atherectomy device, or the laser device. It all depends what your blockage looks like and how facile your surgeon or interventionalist or specialist is in dealing with those issues. Let's go to room one. Dr. Stokes, how are you doing here?

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GORDON K. STOKES, MD, FACS: Good. I'm in good position to tackle the lesion. We're through it, I've confirmed. The important step is to document that you're in the position that you want to be down in the lower leg. So the wire's through, the wire's shifted out, the laser is heating up, and they've opened the -- the laser probe. This is a cold-tip laser, and it's -- does a nice job. It de-bulks the lesion, opens the channel. If there is any thrombus, it tends to eliminate that, and it'll allow me to get a more durable result for her arterial lesion.

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MARC H GLICKMAN, MD, FACS: I have the laser atherectomy tip in front of me now, if we can get a slide on that. This is the tip of the laser atherectomy. This is what Dr. Stokes is using, and the cold laser atherectomy -- the cold is going to be delivered through the tip, and we'll be seeing this in a minute. If we switch to the slides, I want to just go over what the concept is of the laser atherectomy. As Dr. Stokes said, it's the cool excimer laser. And many of you may say, "well, years ago, I heard that lasers didn't work." Well, they didn't work years ago. Spectranetics has a new

laser which is a cool excimer laser, and we were one of their studies for FDA trials in recannulizing lower extremity vascular disease. And we've had a lot of success with this device. This laser is the cold laser, and as you can see, the difference in our previous lasers, they were infrared or hot laser, as you see on your right with the YAG coloration. What we're dealing with is in the ultraviolet scan, and that's the laser-- the excimer laser that we're seeing. Are you starting to laser, Dr. Stokes?

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GORDON K. STOKES, MD, FACS: We're just getting the laser heated up and they're calibrating it and working through the process.

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MARC H GLICKMAN, MD, FACS: Okay, well, keep me informed. As you can see, in studies, laser can be used in the superficial femoral artery, the popliteal artery, the inferior popliteal, and other vessels, and there really has been excellent results with using this. In a large LACI trial, there's been a 99% success rate. In our hands, it's about 97%. So we've been very pleased with the results in using this study -- this device. In fact, we were able to last year run a course for over 25 surgeons and interventionalists and cardiologists throughout the United States on the use of the laser in lower extremity revascularization at one of our hospitals, the CarePlex Hospital. You can see on our slide, here are some lesions that we've had in the past have opened up -- opening up these lesions with the laser. Dr. Stokes will be showing you how he uses this today in getting similar results in our patients. But here, these are some of the studies of patients in the past and what they looked like in opening up TASC D lesions or TASC C and B lesions as well.

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GORDON K. STOKES, MD, FACS: So, Marc -- don't pull it.

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MARC H GLICKMAN, MD, FACS: Are we ready? Let's go to room one. Dr. Stokes, is your device down there?

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GORDON K. STOKES, MD, FACS: I am -- Skip's holding the end of the wire steady, and I want to reiterate what you said a few minutes ago. We are very lucky. The hospital has invested a lot in all of this equipment, put it at our fingertips. A lot in training of the people around us. Skip and Nikki and Theresa are some of the best people in this in the world, and I am fortunate to be working with them. And they know exactly what's to be done in most of these cases. Okay.

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MARC H GLICKMAN, MD, FACS: Your scrub nurse is Nikki Sutherland, who was trained here, did a great job. Skip Dale Scanlon, who's been in the field for probably 10 years. And Theresa Downey, who was trained at our school here, is running the monitor. So you have a great team as well, Dr. Stokes.

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GORDON K. STOKES, MD, FACS: Okay, well, we're getting ready to crank the laser up right now. We're in perfect position.

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MARC H GLICKMAN, MD, FACS: Okay, what I want -- I want to tell the viewers, the top part of the screen, you see a black dot. That is the beginning of the laser machine. And Dr. Stokes now is over the wire with his laser device, and he's going to be turning the laser device on and you'll be hearing a noise that -- there it goes. That's the noise of the laser working as he slowly goes through the blockage to debulk it or vaporize -- evaporate the plaque within this lady's vessel. And he's going to take this all the way from the superficial femoral artery, the popliteal vessel, to the tibial peroneal vessel. And take a look at it. Dr. Panneton, let's quickly go to room two. Dr. Panneton?

00:37:04

JEAN PANNETON, MD, FACS: Hi, Marc. We've made progress. We've emptied the collecting chamber of the atherectomy device --

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MARC H GLICKMAN, MD, FACS: Great, look at that.

00:37:10

JEAN PANNETON, MD, FACS: And this is the kind of plaque. Now, it may not look like much when you look at it, but actually, these are strands of plaque that are coming from the inside of the vessel, and that's the true advantage of this device is the way that it can de-bulk the vessel and actually remove the plaque. So this has been four -- about four or five passes that we've done. I think it's been quite successful. We're going to reinsert the SilverHawk. It's already sort of in position right now to provide probably three or four more passes, and then after that we're going to repeat an angiogram to see what kind of residual lesion we have. If it needs to be touched up some more or if the de-bulking has been sufficient enough.

00:37:47

MARC H GLICKMAN, MD, FACS: Right. That -- what you're seeing, folks, is the plaque or the hardening of the arteries of the blood vessel. Hardening of the arteries is a complex disease phenomenon. It is cholesterol that has been layered into the inside lumen, inside part of the blood vessel, from years of high cholesterol, high lipids, perhaps cigarette abuse, hypertension, diabetes. And that's what we're removing today. And as you see in room two, Dr. Panneton is redeploying that device to remove more of that concentric plaque in that area, similar to what we saw before. Speaking of that, we've received an e-mail from Don from Michigan, 48858. Don wanted to know: how do you know the difference between arthritis of the knees or vascular insufficiency? Well, sometimes that's difficult. But a good noninvasive study looking at one's circulation at rest and with exercise can help you, Don, determine whether or not that is a -- whether or not your pain is from your arthritis or from blocked blood vessels to your lower extremity. Dr. Stokes, how are we doing in your room one?

00:39:09

GORDON K. STOKES, MD, FACS: We're doing good. we've lasered the popliteal artery, and I believe that at this point we're going to shoot a picture, and I think what we're going to have to do is hit it with a balloon.

00:39:26

MARC H GLICKMAN, MD, FACS: Are you going to do a picture now?

00:39:27

GORDON K. STOKES, MD, FACS: Yeah.

00:39:28

MARC H GLICKMAN, MD, FACS: You're doing the picture now, which means injecting dye into the blood vessel and to see what we're doing. So you have restored some, but you still have a little bit more work to do to get that lumen open on up.

00:39:42

GORDON K. STOKES, MD, FACS: We clearly do.

00:39:44

MARC H GLICKMAN, MD, FACS: Janice from Florida, 32701, e-mailed us to say: what is the FoxHollow technique? Do we use it in soft plaque or in hard plaque? Our experience really is a firmer plaque is really what FoxHollow is used for. The soft, pliable plaque really does not do as well as with -- with the FoxHollow technique as a firmer, calcified plaque that Dr. Panneton is working with now. So, Janice, your answer is soft plaque, I would use a different type of technique, perhaps the cryoplasty or balloon angioplasty. I would not use the FoxHollow in soft plaque to your lower extremities. Dr. Panneton, how are we doing now? Where are you?

00:40:32

JEAN PANNETON, MD, FACS: We've finished -- Marc, we've just finished a few more passes, about four more passes around the le-- the lesion itself, and we actually are -- just emptied the collecting chamber to see again a lot more plaque that we've just removed, if you want to focus on the -- on here. So we've got -- this is actually significant amount of plaque for a very focal lesion, so it clearly was a very high-grade lesion, and we're about to take a picture to see what it's going to look like pretty soon here. So we'll be back with you probably in a couple minutes.

00:41:06

MARC H GLICKMAN, MD, FACS: Okay, just look at these slides right now. You can see what Dr. Panneton has removed is similar to plaque that -- what we've removed in the past. For a very short lesion, he's removed a lot of plaque, and we're hoping that our completion angiogram will demonstrate an excellent result. And here it is. Look at room two. Slide to room two. Can we see it one more time? Stephanie?

00:41:35

JEAN PANNETON, MD, FACS: Yeah, Marc, we've just finished the angiogram right now, and here it is live and running, and you can really see -- and if you could compare to the previous lesion, there's really no plaque left now, no residual stenosis. This went from basically a 95% stenosis to a 0% stenosis. There's really nothing left that we can see here, so no need to touch that up with a balloon, no need to add a stent. This is just a complete removal of the -- of the offensive plaque.

00:42:08

MARC H GLICKMAN, MD, FACS: If we look at the slide that I have here, what you've done is really what this slide shows, is that you've removed the plaque without doing any balloon angioplasty that may create trauma to the intima of the blood vessel. And that's one of the advantages of using the SilverHawk device is that you can really remove plaque without doing perhaps the balloon angioplasty or the trauma that's due to the ballooning of the blood vessel. Here's a picture of what a balloon looks like for those interested. This is a balloon that we actually fill with some colored dye so that you can see it against my coat. But this is usually the size of the balloon that we place within the blood vessel so that you can see what it looks like. And we use an insufflator on this side here that we blow it up to a certain amount of pressure to reopen that blood vessel. But what you see from what Dr. Panneton did really did establish a lovely opening there of that blood vessel. If we look at room two again, he's now going to that origin of that superficial femoral artery. On different views, we saw a marked narrowing of that blood vessel as well as the one to the -- to the profunda, and he's going to be using, again, the rotating cutting device, atherectomy device, to remove this as much as possible.

00:43:31

JEAN PANNETON, MD, FACS: Yeah, Marc, we are -- we are in position right now to start the, again, the de-bulking by the atherectomy device of the -- the SFA stenosis. Now, I think the beauty right now is the fact that when you have an ostial stenosis, if I were just to inflate the balloon at that level, what it would risk to do is to jeopardize the other vessel next to it. So I think this is a very nice way to deal with the plaque at that level by again removing the plaque instead of trying to just push it on the side with the risk of losing the profunda femoris, which is quite an important vessel as well. So this is what we're about to do right now. We have the device in position, we're going to start the de-bulking right now.

00:44:12

MARC H GLICKMAN, MD, FACS: Great. And we'll watch you do that. And so what he's doing is going to be probably de-bulking this lesion as well as possibly the one to his profunda to really help this gentleman with his revascularization. And he's doing the same thing that we saw earlier, and we can use this, again, again to remove the

plaque in 360 degrees at various angles for this -- in this patient. Dr. Stokes in room one, how are we doing here?

00:44:51

GORDON K. STOKES, MD, FACS: Well, I think we're doing pretty good. We've got one balloon treatment to the perineal artery done. I was not as happy with the laser. It did a good job up top, but I didn't want to push -- push it too hard down low because the vessel was clearly very fragile. And so right now I've got a balloon in the popliteal artery.

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MARC H GLICKMAN, MD, FACS: And how big a balloon are you using?

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GORDON K. STOKES, MD, FACS: A four-by-twelve.

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MARC H GLICKMAN, MD, FACS: Four. So much smaller than what I showed the audience today. A smaller balloon, half the size.

00:45:31

GORDON K. STOKES, MD, FACS: And this is going to reopen the channel. You see how that artery is, it's just a very diseased vessel.

00:45:36

MARC H GLICKMAN, MD, FACS: As you notice when you look at this on the webcast, you can see how that -- that balloon is disfigured. That's the plaque that's being sent to the side of the blood vessel. So that plaque is being -- that channel is being opened up against the plaque with a new -- with a new opening to the blood vessel being established. Now, when one does this, the patient can develop some discomfort as that blood vessel gets re-expanded, and what we're giving the patient now is some medicine, some pain medicine to prevent some of that discomfort.

00:46:17

GORDON K. STOKES, MD, FACS: She had a brief episode of some discomfort in the leg, but it's better now. The artery -- I'm just going to let that stay up for a minute.

00:46:24

MARC H GLICKMAN, MD, FACS: Now, there are some questions about whether or not -- how long do you keep the balloon up? Some of us put it up slowly and stay for one minute or two minutes. There's really no science to it, but what needs to know is when everyone's -- when you've completed this process, you need to do a completion angiogram or a x-ray of the blood vessels to make certain that the -- that the lumen looks good. Gordy, what was the pressure that you used in that balloon?

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GORDON K. STOKES, MD, FACS: The burst pressure was 13, and we -- because it was a little bit disfigured, you saw that it took a lot to get that artery open. We pushed it all the way up to 13, and that's when she had some discomfort. So after it opened for a couple of moments, we backed the pressure off back to 10 atmospheres, and she did very well with that.

00:47:15

MARC H GLICKMAN, MD, FACS: And whose balloon were you using? What type of balloon was that?

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GORDON K. STOKES, MD, FACS: This is a -- no, I'm going to use it again. This is a EV3 balloon.

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MARC H GLICKMAN, MD, FACS: EV3 balloon.

00:47:22

GORDON K. STOKES, MD, FACS: And it's a nice one. It's long, it's a very good one.

00:47:25

MARC H GLICKMAN, MD, FACS: Great. If we look in room two quickly -- if we switch to room two, Dr. Panneton just did the FoxHollow in room two, and he just did his completion angiogram, and that's where he looked at the origin of that superficial femoral artery. That's the artery that goes down to the thigh. And did you get much out?

00:47:47

JEAN PANNETON, MD, FACS: Yeah, I got more plaque out, Marc. I think I'm going to do a little bit more of a touch-up. There's still a little bit we can get on the -- on the medial -- medial wall of the ostium of the SFA, so we're going to go back at it for a second -- a second shot at it with probably about two or three passes mainly on the medial part of the vessel.

00:48:08

MARC H GLICKMAN, MD, FACS: One of the things that the audience can take a look at, and these are two great patients, the different size of one's blood vessels. And I think that goes to the question that we were asked, popliteal artery. You can see in room one, Dr. Stokes' patient, he has a very small blood vessels that he's working with. This lady has small blood vessels. As opposed to your gentleman in room two, where the blood vessels are much larger and that when you remove the plaque, you're really left with a very large blood vessel in establishing a flow down to that lower extremity.

00:48:45

JEAN PANNETON, MD, FACS: Yeah, that's a very good observation, Marc. I'm pretty lucky right now. This gentleman is cooperating very nicely with us with the size of his -- of his vessel.

00:48:54

MARC H GLICKMAN, MD, FACS: One of the questions that we had and I didn't show it very well was that what happens to that plaque that you have in th-- that you remove? And what the FoxHollow has, if we shove a live picture to me, please, is that in the -- there's a basket that the plaque gets placed into so that when you remove -- so that when the plaque is eaten up, it's placed into a basket where it's prevented from going down through the lower extremity. So there is a basket portion to this device which captures the plaque and prevents it from being dislodged to the lower extremity. Okay, great. Let's go back to -- we're doing quite well here. We have actually two lovely cases. I'm pretty honored to be moderating two superb technicians with two neat cases here. Dr. Panneton's in room two again passing the device again through to --

00:50:02

JEAN PANNETON, MD, FACS: Yeah, Marc, we've finished four more passes of the ostium of the superficial femoral artery right now. We're going to remove the device one last time, and we're going to now empty the collecting chamber and see what else we -- we're going to obtain out of there. I have the impression that we're probably going to be okay with the SFA, and there's really no need to -- to remove more.

00:50:26

MARC H GLICKMAN, MD, FACS: Great. I have a couple questions. I have one from Tyrek from hotmail.com. He would like to thank us for this live broadcast and he would like to know about the advantages of the use of minimally invasive techniques for removing plaque or doing some of the work that we have been doing. What are the disadvantages? What type of problems occur, et cetera? And what I'll -- this is a great opportunity for me to really go into some of our results with this because I think that's really the key to this. How long does this work and how -- how successful has it been? And if we look to our slides now, please, we can see that from 2002 to 2003, we treated 105 limbs. We are going to be presenting over 600 --

our history of 650 limbs over a four and a half year period at the Society of Vascular Surgery in June in Baltimore, but we can see that we treated 105 limbs, and we have almost a 23-month follow-up for the mean patients of this. And you can see that the majority of these patients have hypertension, coronary disease, and a history of cigarette smoking. And the reasons for the indications for the procedure is claudication in 37, but the majority of these patients had non-healing ulceration, which means that their ischemia was quite severe. And the majority of the lesions that we have serviced or opened up are in the superficial femoral or popliteal vessel. And what we determine as technical success was passage of the catheter across the subintimal plane, and we achieved in our history, of 87%. And this is pretty spectacular, knowing that we are almost successful 90% of the time. And we did not use any reentry devices in our early study. Our complication rate has been very, very low. We've had three arterial perforations, one arterial pseudoaneurysm, but none of these required surgical intervention. And this is what our primary patency rate is, which means how long does this stay open without any further intervention? And at 24 months, or two years, 43% of these patients -- these vessels remained open without any further intervention. And that's almost comparable to bypass procedures. If we look at what our patency rates -- or how they remained open at 24 years with some type of intervention, it improves to 54%. And our secondary patency rate means that they occlude or may open, we have a 24-month 63% success rate. This is our data here at Sentara Norfolk General Hospital. So yes, these -- these procedures are quite successful. They may require another intervention. It's about .21 interventions per year. But their overall success rate is spectacular. At 24 months, patients with claudication, 74% of those patients have total improvement in their symptomatology. And that is excellent results with low mortality and morbidity. And most importantly, we have an 88% limb salvage rate. So those patients in that group that had gangrene or ulcerations, we were able to save 88% of these patients' limbs over a 24-month follow-up. Again, to rep-- these are successful procedures that result in excellent outcomes for our patients. Our overall limb salvage, 100% of our patients ended up with limb-salvage procedures, required no amputation of their affected limbs. So subintimal angioplasty and our techniques have been -- are feasible. Our success rate is high, our experience has been excellent, and it's a safe, few complications, no operative treatment is required, and we've not had to go to any type of bypass procedures. It's a durable procedure, it has excellent patency rates, low reintervention rate, and our patients have been bypass-free for over three years. So as we conclude this in a very short period of time, we'll take a look at room one with Dr. Stokes.

00:55:14

GORDON K. STOKES, MD, FACS: Well, Marc, I'm looking at the result, and I'm pretty happy. We may have to iron out that popliteal artery right behind the knee, but we've gone from absolutely no flow through this artery to a reopened channel. It's a typical appearance. The subintimal always-- the flow spirals around in the layer of the artery outside the plaque, and that's what you see in this vessel. But we've gone from completely occluded to wide open. I've considered putting a stent in. I don't think I need a stent because I've got a good result. I believe the durability in this location will be better without a stent at this time. So I'm pretty -- I'm pretty happy with the flow that we've restored to her leg.

00:56:03

MARC H GLICKMAN, MD, FACS: An excellent job, Dr. Stokes. You really did spectacular. I mean, this is -- this is modern innovative techniques in limb salvage. And room two with Dr. Panneton for a wrap-up, how are you looking here?

00:56:5

JEAN PANNETON, MD, FACS: Marc, we're doing very well. We've done the two high-grade lesions in the SFA, and if I can just show you very briefly here, this is the total plaque that we've removed in the -- in the superficial femoral artery. And if you go on the screen now, we -- we now have the wire into the profunda femoris artery, and we're going to go take care of this high-grade lesion that's present in the mid-profunda right below the femoral neck. So we've got the wire in place now, we're going to just bring our catheter there, do a wire exchange, and then treat that lesion in just a moment.

00:56:54

MARC H GLICKMAN, MD, FACS: Great. An excellent job, Dr. Panneton. Both you and Dr. Stokes have really done great on this today. Well, in conclusion, as we're nearly wrapping up, I want to talk a couple minutes today to thank both teams but also to let you, the audience, know that the science of vascular surgery has dramatically changed in the last five years. This improvement has allowed for more aggressive care for very complex patients. This care is being delivered through minimally invasive techniques in an innovative, thoughtful fashion. This is my e-mail if you want to e-mail me questions at any time or through the OR-Live website. I want to thank Sentara Health Care System for its support and thank its hospital facilities, its health care management facility in allowing us to show the public and our pure physicians, the excellent quality care that we can deliver for our patients. This is the number that you can call at any time to get more -- request more referral information, to get -- to ask for an appointment with any of our vascular specialists to help you with your vascular problems. I think we have showed to you excellent quality work in two very complex patients, and we're honored to share this new and exciting innovative techniques with you. Again, this is the number, 1-800-SENTARA. Ask for the Vascular Services, and we'll be able to give to you -- offer you an appointment at any of our offices. Or you can call our office directly at 757-470-5570. This production has been brought to you by Sentara Health Care System, which is a nonprofit health care system providing innovative and experienced care to patients in -- throughout the United States. Thank you very much for tuning in, and I appreciate the opportunity of sharing these innovations with you. Thank you very much.

00:59:18

ANNOUNCER: This has been a minimally invasive procedure to improve leg circulation performed at Sentara Norfolk General Hospital. 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.

01:00:02

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