

**CORONARY ARTERY BYPASS GRAFT FEATURING CARDICA C-PORT STAPLER
GENESIS MEDICAL CENTER
DAVENPORT, IOWA**

00:00:12

ANNOUNCER: Welcome to Genesis Medical Center in Davenport, Iowa. Over the next hour, you'll see a live panel discussion of a coronary artery bypass graft, featuring a Cardica C-Port stapler. In just moments, you'll learn how surgeons perform the coronary bypass surgery off-pump, meaning while the heart is still beating and without using the heart-lung machine. Hear about the recovery process from patients and some of the benefits of this exciting new procedure. 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 go OR-Live.

00:00:54

[RON ELKI]: Hello and welcome to Genesis Medical Center in Davenport, Iowa for our webcast of an off-pump, or beating heart coronary bypass graft, using the Cardica C-port stapling system. This is a new device that allows surgeons to attach the bypass grafts in a new way. My name is Ron [Elki], I work here at Genesis, and I'll be helping to guide the discussion of our webcast over the next hour. We do have a live audience present with us and we'll be able to take their questions later on in the webcast. If you're watching us from home on your computer, we'd like you to join in the webcast as well. You can email your questions to us by clicking on the link on your screen, the MDirect access link. Send us your email questions and we'll work those into the webcast later on, as well. Well, now I'd like to introduce to you the surgeons here at Genesis who perform this procedure. On my right, closest to me, Dr. Nicholas Augelli. He's a cardiothoracic surgeon who practices here at Genesis through our Genesis Heart Institute. He's been with Genesis since 2004. Welcome Dr. Augelli.

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NICHOLAS AUGELLI, MD: Welcome Ron.

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[RON ELKI]: To his right, Dr. Robert Fietsam, also a cardiothoracic surgeon who has been with Genesis since the summer of 2007. Hello to you, Dr. Fietsam.

00:02:04

ROBERT FIETSAM, MD: Thank you very much, Ron.

00:02:05

[RON ELKI]: I want to start with a very simple question because not everyone who's watching this webcast has a medical background and that question would be, "Why would someone need a coronary artery bypass graft?"

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NICHOLAS AUGELLI, MD: Well, most people, as you know – Heart disease is very prevalent in the United States and so most people over the age of 60 probably have some coronary disease. The need for coronary bypass grafting is determined primarily between the cardiac surgeon, the cardiologist, and the family practitioner who are caring for these individuals. Normally a patient will have some complaints of chest pain, fatigue, not feeling well for some time, they go get checked out, they end up on a cardiac catheterization table to identify the coronary disease, and then the next step is surgery.

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[RON ELKI]: So, they're basically on the path, Doctor, to a heart attack probably. Is that correct?

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NICHOLAS AUGELLI, MD: Correct, coronary artery disease will create closures of the coronaries, which are arteries on the heart that allow blood to nourish that heart muscle and sometimes you can have an angioplasty, which will dilate the vessel, and if there's a lot of disease, then those patients usually come in for surgery.

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[RON ELKI]: If that's not effective, it's the bypass thing that we have to go to at that point.

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NICHOLAS AUGELLI, MD: Correct.

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[RON ELKI]: Now, Dr. Fietsam, how generally does this operation work? What happens?

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ROBERT FIETSAM, MD: Well – Can I borrow that for a second? Basically, as Dr. Augelli pointed out, you have blockages in the arteries, and what we're doing is we create a conduit, either from an internal mammary artery or from a vein from the leg. We bring the blood flow from this aorta, this major artery, down to the coronary artery, bypassing the blockages that exist in the heart itself. That's why it's called "coronary artery bypass grafting."

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[RON ELKI]: All right. Dr. Augelli, what are some of the risks and potential complications from this procedure?

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NICHOLAS AUGELLI, MD: The major risk, of course, is death which doesn't happen all that often. The procedure's quite safe but you can expect a mortality anywhere between one and two percent nationally. In our hospitals, about 1.3 percent now. The other complications are such things as stroke, renal failure, pneumonia infections, and those are very rare or down on the list.

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[RON ELKI]: All right. Dr. Fietsam, there are two approaches basically to this procedure. One uses a heart-lung machine. The other is off-pump, or on a beating heart. Talk a little bit about those differences.

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ROBERT FIETSAM, MD: The machine, the cardiopulmonary bypass machine has been around since the 1950s. it's a standard way in which blood is taken out of the heart and goes to a machine which can cool the blood, give it oxygen, rewarm it, and then goes back to the aorta, and then goes to the rest of the body, to the brain, to the lungs, and to the kidneys. Now, that way you can stop the heart itself and all the blood going to the body system is circulated around the heart and the heart is not beating. We can directly on it. It's particularly important for working on valves. With the coronary artery bypass, using an off-pump system or beating heart, the heart actually maintains its blood flow to the rest of the body and brain while beating and we operate on one vessel at a time, slowing that area down so that we can do the bypass grafting that we talked about.

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[RON ELKI]: Dr. Augelli, are there determining factors to whether or not you use the off-pump method or use the heart-lung machine?

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NICHOLAS AUGELLI, MD: Yes, we evaluate each patient individually, but there seems to be an advantage of using off-pump technology in females especially. Women in general have twice the mortality rate and complication rate as men for same age and cohort of groups.

When you use the technology off-pump in them, especially if they have diabetes, you can actually normalize their mortality rates down closer to the male rates.

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[RON ELKI]: Any other advantages to doing it off-pump versus the heart-lung machine?

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NICHOLAS AUGELLI, MD: The blood utilization. There's less bleeding with the off-pump technique.

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ROBERT FIETSAM, MD: One of the main advantages that I've liked, I've been doing this for eight years, is that we can have patients having heart surgery in the morning. We've had them reading the paper or watching football games by Monday Night Football. Getting off the machine, the brain comes back, the kidneys do well. It's just a whole difference in terms of what we call "cognitive dysfunction". How well the brain thinks, its memory, and in the long run it seems to be working much better.

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[RON ELKI]: And as a practice, Doctors, you have decided to do these procedures off-pump, correct?

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NICHOLAS AUGELLI, MD: Yes, correct. Approximately 30 percent of the centers in the United States right now offer off-pump technique for a coronary bypass surgery.

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[RON ELKI]: The Cardica C-Port system, one of the things we're going to be featuring in this procedure, did that have any impact on your decision to do these off-pump?

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ROBERT FIETSAM, MD: Well, not me personally. As I've said, I've been doing this for several years and I've seen some excellent results with these patients. But the stapling device is a way in which we can create the anastomosis in approximately three minutes. The normal method of sewing these grafts can take 15 to 20 minutes. So this is a way to get much quicker through the operation and more standardized distal anastomosis, and we have some information that shows that it has a higher patency rate, or the grafts stay open longer after the surgery.

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[RON ELKI]: I'm sorry, from a time perspective, the quicker you can get in, do your work, and get out, that's better for the patient?

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NICHOLAS AUGELLI, MD: Correct. The other reason for using a stapler device is that it standardizes the procedure. You get an anastomosis that is defined, same size, same weight each time. When you have the human factor, there's the art of surgery and the science of surgery. So there is variability between the anastomosis, how those needles are passed, how the tissues come together. But with the stapler, it takes some of that guessing work out.

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[RON ELKI]: I'm going to grab one here and hand this to you, Dr. Augelli. This is one of the devices.

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NICHOLAS AUGELLI, MD: Right, this is a typical – It's called C-Port XA. This is one of the original devices. It's made out of – It's a regular stapler, only miniaturized. So there's a cartridge that carries the staplers. There is some levers here that help hold the tissues in place. Then there is the anvil that allows you to introduce the device into the arteries. The cartridge that holds the staple also will stabilize the tissue that you're going to be placing on the coronary. It's mounted on a shaft for the delivery. There's a piston here driven by gas that delivers the carbon dioxide which fires the staples. So the process is quite smooth. It

takes 15 seconds or less to fire the device. There is no motion when you're firing because it's gas driven. There's no levers that create any motion problems.

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[RON ELKI]: Or, if you're squeezing on it, it eliminates that.

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NICHOLAS AUGELLI, MD: Correct, it's a very smooth squeeze.

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[RON ELKI]: All right, so you've talked a little bit about this. We have some very nice animation from the Cardica Company showing how the C-Port stapling system works, so let's show folks that and explain to us what we'll be seeing here.

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NICHOLAS AUGELLI, MD: So, the vein is being brought in from below and is being positioned by the levers that come down and hold the tissue together. There is a side protector that helps the knife that comes in. Here's the punctures we made in the artery. The device is introduced. It's fired and then released. The stapler is removed out.

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ROBERT FIETSAM, MD: That's pretty much real time. That's about how fast it occurs, just like that. Boom. As Nick said, within 15 seconds it's stapled, you have 24 little clips that come around here and hold on to the vein graft to the artery, remove the anvil, and it's stapled together.

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[RON ELKI]: So now we have a sense of how the stapler works and we saw it loaded with a bypass graft or a vein on that. The question then becomes, "Where does that vein come from that you use in the bypass graft?"

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NICHOLAS AUGELLI, MD: The veins are usually obtained from the legs. The legs are surveyed and we used ultrasound to identify the quality and size of the veins and we choose either left or right depending on which one is better. And then we use an endoscopic system to remove the vein. We have helpers that help us do that. There's a trained nurse – they're called Registered Nurse First Assistants – that have training and they help us remove these veins endoscopically.

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[RON ELKI]: All right, we'll let's take a look. We have some footage of the vein harvest in this patient where the artery bypass graft was performed. So, Doctors, tell us what we're looking at here.

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ROBERT FIETSAM, MD: This has a conical shape at the end of a telescope basically, and you're looking right down the telescope. This is introduced through an incision that's about an inch long around the knee area of the vein. Then they push it in and you can see tissue is being separated out. That subcutaneous tissue, that little bit of collagen, and pretty soon you're going to get a visualization of the vein that we're trying to harvest out. The first part of this procedure is we're putting the conical telescope down the vein and following it up the leg. You can see there on the picture that it's a little bit better. The vein itself is this large whitish cylindrical object with the little red base of the suture over the outside of it. We continue loosening up that vein from the knee all the way up to the groin area, or from the knee down to the ankle area. Then after it's basically loosened from the tissue, we go back in a second time and there will be a probe. Then we're going to identifying the side branches of this vein and then dividing the side branches.

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[RON ELKI]: It's a great look at the vein there now.

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ROBERT FIETSAM, MD: Right. This is it. There's the 270 angular going around the vein, and this will help make sure that we're freed up from all the side branches and I think at this

point you're going to see a hemoprobe cautery come in. It will actually clip a side branch. It will divide it basically with heat cautery and you'll see smoke in the field and that is the smoke of the tissue burning inside the patient's legs. Very small and this is very well magnified.

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NICHOLAS AUGELLI, MD: The tunnel is created by allowing carbon dioxide to be introduced. Carbon dioxide is used because it's quickly absorbed by the body and removed through your breathing. But it creates that tunnel and compresses the veins so that the process is relatively hemostatic. You see there's not a lot of blood being lost here. It allows the transition to go very quickly.

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[RON ELKI]: How long of a length of vein do you normally take out for a bypass graft?

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NICHOLAS AUGELLI, MD: Approximately 20 inches or so.

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[RON ELKI]: And that depends on how many grafts you're doing and where those grafts are, how much of that you use?

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ROBERT FIETSAM, MD: Exactly, the size of the heart itself and where we're going to bring the grafts to. As we talked about before, we're taking the vein grafts from the aorta, bringing it down to either a diagonal vessel here or off to a circumflex vessel. The heart, on an average person is a bit larger than this, probably twice as large. So the vein that we'd need from this diagonal is a fair amount less than the vein we would need from going around to the circumflex vessel. Occasionally, we have to get to the right side of the heart, either to the right side itself or the bottom of it. Again, that varies with different patients.

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[RON ELKI]: Right. This vein harvest is going on while you are working in the chest cavity, getting ready for the grafts.

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NICHOLAS AUGELLI, MD: Correct. Most of the time we start by opening the chest and simultaneously we'll have somebody start with the vein. If there's any question, we'll always go back down and help. But our priority would be to take the left internal mammary artery from the chest wall as a separate dissection and we do that concurrently with the vein harvest.

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[RON ELKI]: We're doing that to shorten the total length of the surgery?

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NICHOLAS AUGELLI, MD: Correct. Just speed up the time. The less time the patient is under general anesthetic, the better they do, so we want to decrease the time of anesthetic and possible complication of lung operations.

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ROBERT FIETSAM, MD: Generally these operations used to be lasting like six to eight hours and quite frequently we were starting at 7:30 in the morning and we've had two done by three or four in the afternoon. So back-to-back heart surgeries in the same room. In part facilitated by the quick creation of the distal anastomosis with the stapling device.

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[RON ELKI]: It allows you get more done faster. All right, we've seen the stapler, how it work, through the animation. We've taken a look at the vein harvesting in the leg. We want to take you into the OR here in a second, but before we start showing you some of the actual surgery, Dr. Augelli this was your patient, so tell us a little bit about the background and the history of this patient before the surgery.

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NICHOLAS AUGELLI, MD: This gentleman was approximately in his mid 80s. He had been complaining of feeling a little tired. He was having a little pain after he finished his meals at dinnertime, just feeling like he was getting old and did not pay too much attention to it until the pain and discomfort became quite severe. He went and saw his family doctor, of course, and because of his complaints, a stress test was ordered, which was positive and he ended up seeing a cardiologist and a cardiac catheterization was done. Because of the number of disease vessels that he was dealing with, he was not a candidate for angioplasty and so he was referred for a surgical consultation.

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[RON ELKI]: Scheduled for us. So now let's show you a little bit of the surgery, some of the highlights of this surgery. Again, this is a three and a half, four hour surgery that we've taken some of the best parts to show you here. So, Doctors describe for us what we're seeing.

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NICHOLAS AUGELLI, MD: The skin has been incised already. The head is to the top of the screen, the feet are to the bottom of the screen. Dr. Fietsam is retracting the sternum which has already been divided. I'm placing a little bit of wax on the bone marrow of this bone, the sternum, to limit the blood loss. As you can see, we've just opened that area. We try to conserve blood as much as we can. We try to keep the field quite clean and neat. So the main emphasis right now is to control the bleeding and proceed with that. We use various techniques. The bone wax we just alluded to, and then cautery. We actually burn the little edges that are bleeding and you'll see that shortly. That's a suction device that is used to just harness all of the blood that's being formed. That blood is actually washed in salt water and then reprocessed because all the collections is still sterile and reintroduced to the patient later.

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[RON ELKI]: This entrance into the chest made in two stages. One through the tissue with a scalpel, and then what happens after that?

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ROBERT FIETSAM, MD: A jigsaw works very well.

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[RON ELKI]: I could imagine. Yeah.

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ROBERT FIETSAM, MD: Basically, you can see, Dr. Augelli did a great job with a straight line through that bone and that is an important thing. Staying out of the ribs themselves and going right down the center of the sternum. It's a pretty straight line. Basically it's a jigsaw that's sterilized so that we can use it on the field and usually it's either battery operated or gas-powered.

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[RON ELKI]: Okay. All right. Here we're getting a better look inside the chest cavity there now.

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NICHOLAS AUGELLI, MD: Yeah, the periosteum is what actually carries a lot of the blood flow to that bone and so we're burning the edges, literally. The current that is used is of a small intensity. You don't want to overburn because you don't want to kill that bone. It's got to heal back. We're very meticulous. Almost a point of cautery.

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ROBERT FIETSAM, MD: You can see the lung coming in and out of the field there for a second. That's something that we pointed out earlier and we'll see it again later on, I believe.

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NICHOLAS AUGELLI, MD: This is the retractor. It's a device that allows us to do the off-pump. It's a special retractor. There's a solid component and a more flexible component.

There's little compartments that allow you to put sutures to retract them and remove tissues out of the way. As you can see, it is quite brutal as we are spreading the chest open and now we're removing some of the tissues and opening the pericardium, which is the sac around the heart. The heart is not free-flowing in there. It is contained by a sac called the pericardium, and on top of that there's insulation with fat.

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[RON ELKI]: How long does it take you to get to this point in the surgery?

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NICHOLAS AUGELLI, MD: Usually 10 to 15 minutes.

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[RON ELKI]: Not that long.

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NICHOLAS AUGELLI, MD: No.

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ROBERT FIETSAM, MD: Our crisis – We've had a few patients come in that are currently alternating between opening the chest and pumping on the chest, in which case we can get to this stage in about 10 minutes. If you have to. We don't like that though.

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[RON ELKI]: Emergency situation. What are we doing here now?

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NICHOLAS AUGELLI, MD: We're cutting the fat pad that I was telling you about to expose the sac around the heart called the pericardium. There are some major structures we do have to look out for, closer to the head. That's toward that green towel that you just saw. Here the pericardium has been opened so you see the heart beating. The first structure you see is the right atrium and then that large structure north of that is the aorta, which is the blood vessel that carries the blood away from the heart to the body. Here we have an ultrasound probe that has been used to scan the aorta. The reason we do this is to identify any potential form of plaque that may be of concern when we apply clamps on the aorta that could be – plaques, calcium deposits could break off and cause strokes, so we're very cautious and we look for that beforehand.

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ROBERT FIETSAM, MD: Basically passing sound waves into that large artery, the aorta, and now on the echo cardiogram here we see pictures of the aorta itself and the vessel to the right of it is the pulmonary artery. We're looking for any calcium in that vessel that Dr. Augelli talked about and this case, his aorta was actually quite clear.

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[RON ELKI]: Good.

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NICHOLAS AUGELLI, MD: This is one of the devices we use to stabilize the heart, is being placed on the retractor. This is called a stabilizing fork and has little suction cups underneath that you can apply directly on the heart and then you tease the tissue upward a little bit and stabilize it. What the fork does, with the suction in place with arm stiffened, it will immobilize a small area, probably the size of a dollar, silver dollar, and render that area free from motion, while the rest of the heart as you can see is moving below it. This allows us to use this technique and be able to work on the heart while it's still beating.

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[RON ELKI]: Have we changed perspectives here now, Doctors?

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ROBERT FIETSAM, MD: We just now, we just did. Thanks for pointing that out, Ron. We're at the head of the bed now, looking down into the heart. The hand is in front of the heart, but we're working on the internal mammary artery, which is the artery we took off the back of the chest, and we're preparing that to sew it to the front part of the heart.

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[RON ELKI]: This is a standard in this operation. Why the left internal mammary artery?
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NICHOLAS AUGELLI, MD: The left internal mammary artery is a very special artery. It's not affected by atherosclerosis to the same degree as other arteries of the body. It's relatively spared. So it's always reliable. Also, there are studies that show that there's a survival advantage of placing this specific artery to the left anterior descending artery.

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[RON ELKI]: There's time involved here to dissect this. Are you basically redirecting the flow in that artery?

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NICHOLAS AUGELLI, MD: No, the flow, as it is, but it's mounted on a pedicle, so you basically are detaching the pedicle from underneath the chest wall and redirecting that pedicle flow directly onto the heart.

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[RON ELKI]: Okay, and you need to prepare the end of the artery there to be attached, right?

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NICHOLAS AUGELLI, MD: Correct. We're just removing some of the areolar tissue from around it and allowing the tissue to be more easily identified and attached to the coronary on the heart.

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ROBERT FIETSAM, MD: You want it cleared off as well as we can because if that artery's actually surrounded by a vein on both sides that we don't really need, and it also has tissue that is not going to be of any use to us. So, we want it to be as clear as possible, because we're going to use a very fine suture for this which is like fishing line. We want to be able to get a very clear view of the artery itself. Sometimes these arteries also have muscles within them that can spasm. This is a particularly difficult situation in younger men. So, we're going to inject some papaverine solution, which is basically a muscle paralyzing or a [unclear] dilator. That will allow us to keep this muscle open. The IMA, the internal mammary artery, has a significant advantage, as Dr. Augelli said, in long term survival. It also stays open much longer than other things that we have to use, such as veins or radial arteries. These arteries normally stay open for 98 percent of the time over 10 years.

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[RON ELKI]: You're doing the injection now?

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NICHOLAS AUGELLI, MD: Here you can see the papaverine being injected in the areolar tissue or the tissue surrounding the vessel. This medicine allows the vessel to relax so that it can be the maximum size or the largest size possible.

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[RON ELKI]: And easier for you to work with when you're suturing.

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NICHOLAS AUGELLI, MD: And easier for us to sew, correct.

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ROBERT FIETSAM, MD: I want to point out something that we haven't discussed earlier. The color of the heart is pretty well yellow. We're dissecting out the LAD vessel from the fat. It's not like the textbooks where they show nice red hearts and a nice pretty red artery. This is sort of a standard looking heart. Sort of a yellowish area, all of it's beating, and trying to distinguish the heart from the muscles and from the arteries is a very technical part of the procedure that we're seeing before us right now.

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[RON ELKI]: Just from a health standpoint, the more fat that's on that heart there, that probably decreases its functionality or not necessarily?

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NICHOLAS AUGELLI, MD: No, not necessarily. The amount of fat on the heart can be quite variable from individual to individual.

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[RON ELKI]: It's just more for the surgeon to get through to get to where you need to go.

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NICHOLAS AUGELLI, MD: Yeah, just think of it as insulation. But here we're exposing the vessel. We're getting prepared to puncture the vessel to gain access to the left anterior descending. A little cautery there to burn a little side branch, a vein. You can see really that fat tissue is actually literally involved in that artery, in protecting it. So you really have to open it, just to get access to it.

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ROBERT FIETSAM, MD: So again, this is a great view of the LAD is being stabilized, that part of the heart is not moving, and the whole rest of the heart around it is still pumping blood, getting blood flow to the brain, lungs, kidney, liver, all the rest of the body. That will continue throughout this whole operation.

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[RON ELKI]: So the heart's still able to do what it needs to do to get blood to the vital places?

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NICHOLAS AUGELLI, MD: Correct. As you can see here now, it's punctured the vessel. There's free flow of blood. We use a little device called Mr. Blower, which is a mix of carbon dioxide and salt water that comes in and removes with a gentle breeze, the blood. Here's the shunt going into the coronary. We do use intracoronary shunts that allow blood to flow past the level where we're working so that the vessel itself is not compromised. It takes a little juggling to get that in, but they're quite flexible, easy to put in. So now, we have that in place. You can see the field suddenly dries up.

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[RON ELKI]: I'm sorry Dr. Augelli, the little coin-like that's attached to the string there, is that just a marker so you know that it's there?

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NICHOLAS AUGELLI, MD: It is a marker. It allows us, in case the device should fall out and fall into the cradle of the heart, the pericardial sac, that we can readily retrieve it.

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ROBERT FIETSAM, MD: So this shunt is allowing the blood to go from the first part, or proximal part, of the coronary, the left anterior descending, to the distal part. Therefore, it's still supplying all the blood and oxygen that the rest of the heart muscle needs. Right in that particular area, where we're going to create our graft, does not have any significant blood flow through it. So, we can see clearly how we can do this, so we can do this anastomosis.

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NICHOLAS AUGELLI, MD: The left internal mammary artery has a catheter in it itself. This is placed in there to slightly dilate it and we actually zoomed in now on the coronary to show that more in detail. We're getting ready to attach the left internal mammary artery to the LAD or left anterior descending. This is done with sutures. It can also be done with the stapler. The decision of whether or not to use the stapler has to do with the size of the coronary and how easy it is to conform it and move it in position. There is some gyration you have to do with the stapler to get it placed correctly. Sometimes if the pedicle is not long enough or not enough slack or the heart is too stiff, it makes that difficult, in which case we do traditionally sew it back on.

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[RON ELKI]: So, there's some variables at that point?

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NICHOLAS AUGELLI, MD: There are variables.

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ROBERT FIETSAM, MD: There's variables not just with the sewing technique, but each artery is also a bit different. These arteries can have just as much calcification in them as the aorta can, which is what we were looking at earlier with the echo cardiogram.

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NICHOLAS AUGELLI, MD: As you can see, there is some motion of the heart, but you can work with it. The sutures are carefully placed in. We do use magnification to do the bypasses and so our field is quite larger than what you're actually seeing on the screen right now.

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ROBERT FIETSAM, MD: You can't even really see the string maybe, but it is a 7-0 Prolene, it's very small. Like I said, it's like fine fishing line. The magnification that we use on our eyes are three and a half power, usually. So this represents one third the size of what it would look like to us.

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NICHOLAS AUGELLI, MD: So, the process proceeds slowing but meticulously, and here the vessel is delivered, that left internal mammary artery is delivered to the LAD and then the vessel continues to be attached. Using the stapler, of course, this would have been done already. By the time you put the first two stitches and then you bring it down and deliver it, you're done. So, there is time saved in using the stapler. As we talked about before, there's also the consistency of the anastomosis. It's always the same size, always delivered. But, this technique works as well. We've used it many years and both Bob and I do a lot of our coronaries still this way as well.

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[RON ELKI]: Doctors, one of the questions that has been emailed into us is wondering about the staples actually increasing the chance of build-up in the artery and we're not finding that to be the case, at least at this point, are we?

00:29:00

ROBERT FIETSAM, MD: Right, for two reasons. There were staplers placed on the proximal aorta that did cause problems and that was about two or three years ago. These staplers were actually – you have the vein and the artery that goes with it. The staples are on the outside, basically holding the edges of the vein to the artery, so there is no material on the inside of this anastomosis. The suture goes all the way through and can sometimes create sort of a closed area of stomosis, of the anastomosis. The staplers are actually just holding the tissues together so that intima can develop over time and these staples are not on the inside of the vessels. They do not actually contact blood flow to any significant amount and therefore do not create any increased amount of disease down the road.

00:28:47

NICHOLAS AUGELLI, MD: The other reason that the staplers don't seem to create a lot of problems is because the cut is clean and it's quick. There's actually less tissue damage. You notice here, every time we come back and forth, we're actually touching both the IMA and the coronary with the stapler, just the one motion, one time. The anastomosis is actually interrupted, it's not continuous. So, in a sewn anastomosis, you can create a little purse string effect, it's called, where you narrow it as you tie it down. But in an interrupter anastomosis, that is not seen. Here we're preparing another coronary for the next bypass and this is the obtuse, or diagonal, I'm sorry, coronary that we're getting ready for the bypass.

00:30:33

[RON ELKI]: And I think this is the one where you actually show us the stapler.

00:30:36

NICHOLAS AUGELLI, MD: We'll show you the stapler on this one. This vessel was large enough, it was straight enough that it could accept the anvil and the clearance to allow the stapler to come in and deliver the vein was also quite favorable.

00:30:54

ROBERT FIETSAM, MD: This is beautiful magnification. This is very similar to what we're seeing with our loops. You can see that there is a purple line right above where Nick is dissecting off, and that is the vein. The artery is that pale cylindrical object right in the middle of his dissection, that probably measures about one and a half to 1.75 millimeters in size, which is about a sixteenth of an inch basically.

00:31:20

[RON ELKI]: It helps give us a little perspective on just how small.

00:31:23

ROBERT FIETSAM, MD: Right, take your rulers out at home and compare them to other things.

00:31:28

NICHOLAS AUGELLI, MD: If you look carefully, you can see that one of the suction cups is actually lifted off the heart as the heart is beating. That's not really a big deal when you're using the stapler because the anvil does also stabilize the vessel. Here's the stapler coming in. It looks quite larger than what you saw before with the magnification. That's how we see it. We're preparing the vein now, getting the vein ready. There is a little bit of preparation to be made. All the tissue that is kind of sticky has to be cleared off so that it doesn't entangle in the stapler. We also make sure this time that the side branches are quite hemostatic so they're not leaking. We remove any thickness or any valves at the tip and slice the vessel open and then we get prepared to load it on to the stapler.

00:32:27

ROBERT FIETSAM, MD: That little white light that's running around in the field, that's mounted on top of Dr. Augelli's head, so we can see what he's looking at, even though we can't see his eyes directly. That also helps in your illumination of the field because obviously lighting is very important to this procedure.

00:32:43

NICHOLAS AUGELLI, MD: The thickness of the vein is what allows you to use the vein or not in the stapler. The staplers are set up to only accept a certain thickness of vein. So when patients have really diseased vessels, it's very difficult to be able to use those veins. It's not just trouble for the stapler itself, it's also trouble for us when we actually try to sew them on. It makes the process all that harder. Here we're distending the vein. We are going to mark this vein. We put a purple line. This is a marker that's available to us. It's sterile and for whatever reason is always purple. The purple line is placed so that we can know the orientation of the vein once we load it.

00:33:29

ROBERT FIETSAM, MD: We're compressing that syringe with the papaverine and heparin solution, verifying that there's no leaks from any of the side branches of this vein. This is an important part of the operation so we don't have to come back later on and repair these things.

00:33:43

[RON ELKI]: Make sure that it's clean.

00:33:46

ROBERT FIETSAM, MD: This is an Xpose system, this little suction cup that we just saw and this helps lift the apex of the heart, or the end of the heart, on our model here. We put this suction cup on and we can actually lift the heart up out of the pericardium.

00:33:58

[RON ELKI]: Here we go, Doctor. Let's – Here we go.

00:34:02

NICHOLAS AUGELLI, MD: Here's the end that's been placed in the coronary, and as you can see, we make sure that the tissue is not obstructing the device and then the staple is going to be lowered. Here's Mr. Blower getting that area wet so that it can slide easier. That's how fast it it.

00:34:23

ROBERT FIETSAM, MD: That's it. Done. Stapled.

00:34:26

NICHOLAS AUGELLI, MD: You secure the vein and then remove the stapler.

00:34:30

[RON ELKI]: Now I noticed a little blood there. That's where the anvil enters the...

00:34:35

NICHOLAS AUGELLI, MD: Right. The anvil is not part of the anastomosis and so when you retrieve it, you can see that blood squirting. That is closed separately. It takes just one stitch to do a figure of eight and you control that little bleeding and that's it. You can see the bleeding's quite brisk and the vein has been distended by the blood.

00:34:56

[RON ELKI]: Again, it looks big there but this is very tiny.

00:34:59

ROBERT FIETSAM, MD: I was going to point that out.

00:35:00

NICHOLAS AUGELLI, MD: The puncture is one millimeter in size.

00:35:05

ROBERT FIETSAM, MD: It looks like a geyser of blood coming out of there but really it's just a one millimeter hole. It just has a lot of pressure behind it.

00:35:10

[RON ELKI]: You'll see here momentarily as we get the suture in place there that just like that it will stop.

00:35:18

ROBERT FIETSAM, MD: So, while we're sitting here thinking, "This guy's bleeding to death," in reality it's probably no more than a tablespoon of blood that's come out during this time period. That's it. Now it's dry. So he's going to tie that down and our anastomosis is complete. That's a significantly shorter time than it was for that hand-sewn anastomosis that we showed in the first screen.

00:35:46

[RON ELKI]: You can tell that vein is carrying a lot of blood already. You can see how it's expanded.

00:35:51

ROBERT FIETSAM, MD: The blood pressure in that vein is equal to basically the blood pressure of the patient. You have a patient who's blood pressure when he comes into the office at whatever, 140 over 80 millimeters of mercury. That's how much pressure is in that vein right now at that anastomosis.

00:36:06

[RON ELKI]: You could see, you could just a moment ago...

00:36:08

NICHOLAS AUGELLI, MD: Yeah, you can see the little staples. As you said, you can see they're on the outside, they're not on the inside. A lot of the problems that occur is if you actually have metal on the inside that can create trauma and abnormal healing.

00:36:24

[RON ELKI]: Okay. How do you – Do you need to get around to the back of the heart, and if so, how do you do that?

00:36:31

NICHOLAS AUGELLI, MD: Do you want to answer that?

00:36:32

ROBERT FIETSAM, MD: Yeah. Right at the beginning, right before we got to this anastomosis with the stapler, there is a suction cup we can put on the apex of the heart and lift it up, and basically lift the heart up out of the pericardium, so that we can get exposure to, in this case the diagonal vessel, and later on we'll get to a circumflex vessel, which is basically almost at the bottom of the heart. On the right side of the heart, when the heart's

sitting in the pericardium, the same suction device can be used onto the lateral edge, lifting it to the left shoulder and it gives us access down then to the bottom of the heart and to the right coronary artery.

00:37:05

[RON ELKI]: And then, there is a flexible stapler, too, that helps gain access to maybe difficult regions.

00:37:13

NICHOLAS AUGELLI, MD: Yes, and we actually have an example here if you wish to look at this. It allows you a little bit more flexibility because it doesn't have the stiff shaft.

00:37:21

ROBERT FIETSAM, MD: Before you go into that, Nick, can I just point out that this is the other end of that graft in anastomosis. We talked about being a bypass graft, bypassing from the aorta to the coronary arteries. We first did the distal part and now we're on to the coronary artery itself. Now we're bringing the vein around to the aorta. The aorta is that large artery coming out of the heart. At the bottom of your screen, you'll see a metallic object. That's a side clamp. It's basically taking the side branch of the aorta. We created a hole in it. Now we're sewing the vein graft to that hole in the aorta itself. That will complete the bypass graft from the aorta to the diagonal vessel that was already stapled.

00:37:59

[RON ELKI]: You can see the hole there, right?

00:38:00

ROBERT FIETSAM, MD: Yes.

00:38:01

[RON ELKI]: Just left of center on your screen.

00:38:05

ROBERT FIETSAM, MD: Right. That's the veins being moved around. That's the sutures. This was at one point – they asked earlier about the metallic staplers – they had a stapling device for these proximal anastomoses. Unfortunately, it did leave a fair amount of metal inside the aorta and subsequently did cause reactions and did cause closure at a little bit of a premature rate.

00:38:25

[RON ELKI]: Okay, so we suture this then?

00:38:27

ROBERT FIETSAM, MD: Currently. Although I'm sure there's a market out there for a stapling device coming down the road soon.

00:38:33

[RON ELKI]: Sure. I'll throw an email question your way. This patient we're seeing here today was an 80 year old, or in his 80s, mid-80s. Age obviously must affect the outcome of these types of surgeries.

00:38:46

NICHOLAS AUGELLI, MD: Actually, even in the octogenarians, or our patients that are older than 80, coronary bypass surgery now is well-tolerated. As you know, the population is getting older in general and so we operating on more and more patients in that age group.

00:39:05

ROBERT FIETSAM, MD: One of the big things that's become apparent though in studying these different age groups is that the stroke rate for patients that are in their 80s is significantly higher than in younger patients, with the use of the cardiopulmonary bypass machine. With that machine, there's a lot of blood circulating around, a lot of activation of clotting factors. With the off-pump system, we have noticed a significant decrease of stroke rates in these older patients.

00:39:30

[RON ELKI]: Here you're finishing.

00:39:31

ROBERT FIETSAM, MD: The side biters come off. The vein's been distended. There's a little white circular object in the middle that's used as a marking device, so later on if the cardiologist wanted to take this patient and recath them or look at his coronary arteries, he'll be able to find that through an x-ray machine with much more ease than otherwise.

00:39:51

NICHOLAS AUGELLI, MD: Here we're preparing another vein, getting it ready to be delivered.

00:39:57

ROBERT FIETSAM, MD: So, we have our XA stapling device. The vein's being put on it. The heel of the vein goes to the right in this picture of the stapling device. This is the solid bar, basically, Dr. Augelli was starting to show us the flexible one earlier, which is the ones we use to get further around to the back of the heart.

00:40:18

[RON ELKI]: Here's a good view of how you...

00:40:21

NICHOLAS AUGELLI, MD: There's a little hook that you have to anchor the heel of the vein to. Then you'll see a little plunger come down to puncture that and stabilize it. Then the vein is put in a little traction to stretch it. There's a shield that then is lowered and that shield is quite important. You'll see that being delivered in a second here. This is the shield. It's being lowered. This actually allows then – There's a knife that comes out that will cut the artery on which this vein goes in. This is the shield that prevents that knife from cutting the vein. Here's the levers that are being lowered to hold the edges away.

00:41:15

ROBERT FIETSAM, MD: 62 moving parts.

00:41:18

[RON ELKI]: It doesn't look like it could have that many.

00:41:20

ROBERT FIETSAM, MD: 62 moving parts in this device. It's pretty neat.

00:41:26

NICHOLAS AUGELLI, MD: So, now you can see the anvil, that's the most upper part, the plain part. That will go into the vessel, so now you're going to have the whole thing flip over. This is again showing us another device just to show you how it looks before the vein is loaded.

00:41:44

ROBERT FIETSAM, MD: The head is basically the same. It's just that this has a flexible arm to it that allows us to get to the back of the heart a little bit easier. Showing the anvil and back and forth and really how small. All this stuff is very small.

00:41:59

NICHOLAS AUGELLI, MD: The secret of all this was they were able to miniaturize the stapling device. We use staplers like this I general surgery all the time to bring bowel together, but nobody ever has made one this small. This is the loading of the vein onto a flexible device. You can see the shaft is being held by a little tonsil clamp, but mechanism of loading is the same.

00:42:30

ROBERT FIETSAM, MD: Vein goes down, gets open, the opening is secured by this little piece of metal, the side branches will go down and now it's ready to be stapled.

00:42:45

[RON ELKI]: Very simple. How many bypass grafts did you do on this patient, Dr. Augelli?

00:42:48

NICHOLAS AUGELLI, MD: On this patient, I had four bypasses.

00:42:52

[RON ELKI]: Okay. Is that pretty common?

00:42:55

NICHOLAS AUGELLI, MD: For us, three to four bypasses is the pretty common number of bypasses. It depends again on patient. You have to individualize. We've done as many as five or six and as few as one depending on what they need.

00:43:10

ROBERT FIETSAM, MD: A lot of patients with just single vessel disease are being very well treated with angioplasty and with stent placement. It's usually a larger number of vessels need to be bypassed when we come to the operating room.

00:43:23

[RON ELKI]: Okay. Here we go.

00:43:26

ROBERT FIETSAM, MD: Right, the bypasses have been completed. We're taking out our retractor. Again, you can see the sternum. This is from the head of the bed. Actually, I think we have turned our orientation around a little bit now. We're back at the foot of the bed here. Taking out the sutures that are holding the pericardium up. You see that that white sponge there has a little blue tag on it. The blue tag is also radiopaque, so that if we leave any of those in – that's one of the things about surgeries, we want to make sure anything that's left in can be identified if we're not able to find it later on.

00:44:05

NICHOLAS AUGELLI, MD: Here we're putting wires, these are regular stainless steel wires. They go around the bone, the sternum, and bring it back together. We have to do this well because our patients tend to sometimes lift more than ten pounds and so you have to make sure it's really well together so that it can heal.

00:44:28

ROBERT FIETSAM, MD: The sternum is basically a bone, and like all bones it takes about six to eight weeks to heal up. Normally, if you had a cast on arm, it would work well to stabilize it, but in this case we'll just use wires.

00:44:40

NICHOLAS AUGELLI, MD: Wire cutters are used to remove the wires. As you can see, we put them in a towel to contain them and protect ourselves as well as the patient. It goes rather quickly, the process.

00:44:52

ROBERT FIETSAM, MD: So, after about six to eight weeks, if they don't like the wires with knots underneath them, we can go back and take them out, but it's not usually a common procedure. They seem to like them.

00:45:00

[RON ELKI]: They don't usually bother the patient?

00:45:02

ROBERT FIETSAM, MD: No. After a while, they just kind of like them.

00:45:05

NICHOLAS AUGELLI, MD: Once or twice a year we have to remove. If people lose weight, some of those wires sometimes do bother them, if they lose a significant amount of weight on their chest wall, they can feel them.

00:45:18

ROBERT FIETSAM, MD: There are several layers of tissues that were reapproximating the pectoralis fascia, and after that we put together a derma layer and you don't see any staples on top of this. Pretty commonly, it used to be we'd close this all with staples and it would look like a zipper from a distance. Several places have zipper clubs known for patients who have had heart surgery.

00:45:38

[RON ELKI]: One of the things we didn't touch on was the endoscopic vein harvest. We had, in the old way, when you had to open the leg up to take that vein out, it actually – that wound bothered the patients more than the chest wound. Closing the chest up made me think of that. It's a big difference.

00:46:00

ROBERT FIETSAM, MD: Chest incision, may be 10, 20 centimeters at the most, but the previous leg incisions would be three times as long as that. It's quite common for patients to complain of the pain as well as the incision itself. They didn't look good in shorts, there were some other conflicts. Now the incision is about an inch long.

00:46:20

NICHOLAS AUGELLI, MD: But the main benefit of doing the endoscopic vein harvest has been infections. The number of infection in the lower extremities has significantly decreased. That used to be a major problem, especially in diabetic patients, when they had lower incisions in their legs with poor circulations and adding major infections. That would leave them in the hospital for two, three weeks longer than they needed to be.

00:46:44

[RON ELKI]: We've got a number of questions that have been emailed into us and we'll get to those. I want to ask you, what percentage of your bypass grafts now are you doing off-pump?

00:46:55

NICHOLAS AUGELLI, MD: We're 100 percent off-pump.

00:46:58

[RON ELKI]: 100 percent? Okay. Let's take a look at some of the email questions we have here. I had a beating heart bypass four – I'm assuming that was a quadruple bypass – about two years ago. I was in and out of the hospital in 31 hours. Is this common?

00:47:11

NICHOLAS AUGELLI, MD: It can be.

00:47:13

ROBERT FIETSAM, MD: That's pretty quick. Three days is not unusual. Four days is sort of an average. 31 hours would be just more than a day and a half or so.

00:47:22

NICHOLAS AUGELLI, MD: It's the advantage. He must have been quite fit before he had the surgery.

00:47:28

[RON ELKI]: 47, it says here.

00:47:29

NICHOLAS AUGELLI, MD: He must have had a great support system at home. In elderly patients, which is what we see a lot of, that would be pushing or stretching it.

00:47:40

[RON ELKI]: Is there a life expectancy of a grafted artery, and I believe you've touched on that?

00:47:45

NICHOLAS AUGELLI, MD: Yeah, there are defined patency rates for grafts and we're hoping that this stapler device will increase that. Normally for a vein graft, historically you're looking at 50 percent at 10 years. The IMA has the longest patency rate. They have 20 year data now with 93 percent patency rate.

00:48:05

ROBERT FIETSAM, MD: But, sometimes it'll last longer. I saw a patient today who's been 14 years out from his heart surgery. All four grafts were open still.

00:48:11

NICHOLAS AUGELLI, MD: There's a lot of patient variability.

00:48:13

[RON ELKI]: Why do females have a higher mortality rate during heart surgery?

00:48:17

NICHOLAS AUGELLI, MD: Nobody seems to know, but what appears to be the trend is that women tend to show up for their disease later in life with more advanced disease. They are the caretaker for the family and so they put their own needs aside. So, when they present

because they can't handle it anymore. They present with a later disease which is more aggressive.

00:48:45

ROBERT FIETSAM, MD: I think that the symptoms are a little bit different too. Classically people think, "Well if I have heart disease, I'm going to have chest pain. If I'm not having any chest pain, I must not have any heart disease." But coronary disease and heart disease like this can present with mild things like shortness of breath, dyspnea with activity levels, unable to tolerate a full meal without some epigastric abnormalities. And I think that those type of vague symptoms are more common in women, and are for the most part, as Dr. Augelli said, ignored.

00:49:17

[RON ELKI]: Wow. If you take a vessel from the leg, how does that area of the leg then get blood flow?

00:49:22

NICHOLAS AUGELLI, MD: Well, the body has multiple collateral flows and multiple access tissue. God made us in a way that we can take parts from one place and use them in other places. But there's at least three systems in the legs and so you're just removing one. There's two backups.

00:49:40

[RON ELKI]: You know, we'd welcome to take questions from the audience too if we have any. I'll keep plowing ahead here with questions that we've gotten in from email. This is from someone at a teaching hospital. It says, "General surgery utilizes staplers the majority of the time. What is unique about this device compared to general staplers?" and then "What prevents cardiac surgeons from adapting staplers as we do?"

00:50:05

NICHOLAS AUGELLI, MD: Well, this device is different because it's smaller. They've miniaturized it. So, if he is able to look at this device versus what he's using in general surgery, you'll notice that it's about a tenth of the size. They continue to miniaturize it more and the concept is to allow us to use these staplers to a port access so maybe one day we won't be opening the sternum, we'll be able to do this just with a beating heart with robotics, which is already happening in some centers in the country.

00:50:37

ROBERT FIETSAM, MD: This is really a good question, looking down the road outreach for this project because all bowel anastomosis we talked about were hand-sewn before. Now they went to stapling devices and pretty much stapling anastomosis is the standard. Well then we've gone to laparoscopic techniques where people don't have their abdomen open for these bypasses, for gastric bypasses [unclear] and we anticipate the same thing with the heart surgery. These staplers potentiate the use of a robotic system so that we can do heart surgery without having to cut open the sternum.

00:51:13

[RON ELKI]: Wow. Here's one. I've just learned our surgeons are using the C-Port stapler. They say it's better patency than hand-sewn. Do you agree? I think we've covered that.

00:51:19

NICHOLAS AUGELLI, MD: Yes. There's data to back that up.

00:51:21

ROBERT FIETSAM, MD: Absolutely.

00:51:22

[RON ELKI]: The females, higher mortality during heart surgery. You mentioned when a patient is put on a heart-lung machine, the blood is cooled, oxygenated, and then rewarmed before being put back in the patient. The question, "Why is the blood cooled and then rewarmed by the machine? Why not just maintain the temperature while it's being oxygenated?"

00:51:35

ROBERT FIETSAM, MD: When we stop the heart, we cross-clamp the aorta so the blood flow that would go out of the heart and back to the heart arteries isn't there anymore. We know that the tissue survives on oxygen and at lower body temperatures, as well as lower temperatures on the heart, it doesn't require as much as oxygen. So by cooling the heart, cooling the muscles, slowing down the metabolic needs of the heart and the rest of the body, it reduces the chance of heart attacks, heart ischemia, and other basic bad problems that could happen at higher temperatures.

00:52:10

NICHOLAS AUGELLI, MD: For every degree that you're able to lower your body temperature, there's about a ten percent decrease in metabolic activity, where normal temps are, and we tend to maintain a constant temperature, but that requires energy. We have to fuel that furnace. So by cooling down, it's protective of a lot of organs.

00:52:34

[RON ELKI]: Feasible that the Cardica device will be used in conjunction with minimally invasive robotic procedures? Yes, you guys talked about that. Fifth year medical student wanted to know "What are the indications for coronary artery bypass and the complications?" We covered those early but we can...

00:52:49

NICHOLAS AUGELLI, MD: The main indication for coronary bypass is angina, chest pain. You've got to have chest pain and you've got to have blockages that are greater than 78 percent stenosed. You have to have LAD disease, left anterior descending artery disease, or left main disease, or equivalent to left main.

00:53:10

[RON ELKI]: Okay. It seems the vein harvested was longer than necessary. What determines the length of the vein you harvest?

00:53:16

NICHOLAS AUGELLI, MD: The number of bypasses will determine the length.

00:53:19

ROBERT FIETSAM, MD: And which arteries that we're bypassing to also.

00:53:21

[RON ELKI]: Do you take enough for a backup graft if one gets compromised?

00:53:24

ROBERT FIETSAM, MD: No. If we need another we'll go back and get another one but this is the advantage of the off-pump system on the bypass, where you stop the heart. You really need all the vein graft and potential conduits ready immediately available so when you do the operation, you just continue through it. In this case, with the heart beating, there's no issue. If you get to the end and say, "Well, I'd like to bypass this other one too," or "I need a little bit more vein," the heart's beating, usually the patients are warm in the off-pump procedure, and we really have time as our luxury in this case.

00:53:58

[RON ELKI]: Can this be utilized with IMAs? I noticed you put a shunt and did hand-sewn.

00:54:03

NICHOLAS AUGELLI, MD: Right. Yes it can. It depends on the size of the IMA, the angle that you have to bring it down to. You have to be able to clear the stapler to deliver it properly, but yes it can be used with the IMA.

00:54:16

[RON ELKI]: This one says it's from Egypt. What is the difference between this device and the Octopus device being used before [unclear]?

00:54:23

ROBERT FIETSAM, MD: Yes, the Octopus device is made by Medtronic. The device we use for the off-pump system is by Guidant. They started at two ends of the curve and sort of have emerged very similar. The octopus system now is very similar to the Guidant system and its Xpose device. Before it used to have a 4-pronged star and it's changed its model.

Right now they're almost interchangeable, the two systems. The Medtronic system, which is called Octopus, and then the Xpose and Axius system made by Guidant.

00:54:55

[RON ELKI]: You said you checked for plaque so it wouldn't break loose, if you did see some, what would change about the procedure?

00:55:03

NICHOLAS AUGELLI, MD: Well, you do modify – You may not need to use a clamp at all. We do have devices that we can puncture a soft spot on the aorta, where there is no plaque. It's like an upside-down umbrella that maintains about a half centimeter concave area, a well, that we can sew the vein. It's got a little string that we pull out, de-air the vein, and then the whole thing just fills up with blood immediately. So, if we find that there is calcium and plaque that are not desirable, that don't make the clamping favorable, then we won't use the clamp.

00:55:45

ROBERT FIETSAM, MD: Yeah, that heart string device that Dr. Augelli talked about works great for certain spots in the aorta that need it. We've actually run across a couple places where even the aorta itself is so calcified, we have really two major options. One is to replace the whole aorta, which is a major undergoing. The other thing we've done is basically Christmas tree the vein grafts off the left internal mammary artery. So we still have the left internal mammary artery coming off and then the vein grafts coming off of that to bring blood flow to the heart.

00:56:15

[RON ELKI]: In cases in which more than one bypass is done, where are the blood vessels harvested? Generally it's the leg.

00:56:22

NICHOLAS AUGELLI, MD: The leg, or you can use radial arteries. You can use internal mammaries. There's two of them. We don't tend to use bilateral IMAs in diabetics, but if you're not diabetic and the conduits are good, we'll harvest.

00:56:36

[RON ELKI]: We've kind of touched on this one too. Any risk or danger in harvesting too much of one blood vessel for use in the bypass?

00:56:44

NICHOLAS AUGELLI, MD: Not really. We're very selective as Dr. Fietsam alluded, Bob alluded. We just take what we need and if we need more we go back. We want to be conservative on the amount of tissue we remove.

00:56:57

[RON ELKI]: Did you use different devices to perform [unclear] and SV to aorta? Did you use pure artery grafts for cavage?

00:57:10

NICHOLAS AUGELLI, MD: We do combinations of tissues. You can do total arterial revascularization. In some people that's not possible because sometimes the radial arteries are not adequate. They're calcified. This gentleman was elderly. The vein grafts are adequate for him in terms of his life expectancy and what the grafts can deliver. If it was a young person, we would try total arterial revascularization.

00:57:38

[RON ELKI]: We're getting close to the end of our time, so if we have any late email questions that come in, we'll answer those online obviously. Just a couple more questions, Doctors, and then we'll wrap things up. What kind of results are you guys seeing from using the stapling system?

00:57:57

ROBERT FIETSAM, MD: There's two issues. I think Dr. Augelli could address even the financial issues because he presented that to the Society of Thoracic Surgeons just last week, but one of the big issues is time savings, in terms of the operating room, as well as

consistency to the operation itself as well as we have studies – short term patency results are as good and in some cases better than the vein grafts.

00:58:23

NICHOLAS AUGELLI, MD: The reason we're using the stapler is that it is our belief that we can standardize this operation so that the human factor, which is the variable that's hardest to control, becomes a lesser fact. We will have more reliable anastomosis, which should increase patency down the road. The data from Europe is already indicating that in their centers that are replicating that data in the States.

00:58:48

[RON ELKI]: Should patients who are going to need a coronary bypass graft be asking their surgeons whether or not this is available to them?

00:58:55

NICHOLAS AUGELLI, MD: I don't think so. In this country, all the cardiac surgeons are very well trained. I would just trust the surgeon to deliver what they can offer for their patients. They have that patient in mind. They want the well-being of that patient. I think they should be able to use the tools that they are most comfortable with. This is a relatively new technology. Not everybody's going to jump on it. Some people will want to have more data for it. But, in all honesty, cardiac surgeons are very well trained and they will do the best for that patient.

00:59:31

ROBERT FIETSAM, MD: They need to work with what they're comfortable and familiar with. It takes about five years of research and data and long term results which, for heart surgery, is five to ten years, so we may not know in the long run, where this is going, but right now it looks like it's going great.

00:59:43

[RON ELKI]: Well Doctors, that's all the time we're going to take. We want to thank everyone who's tuned in for their interest in this procedure. Doctors, I want to thank you for sharing your knowledge and expertise with us on this procedure. We hope together we've been able to answer some of your questions about this surgery, particularly the benefits that are derived from performing this off-pump and using the Cardica C-Port Stapling System. For Drs. Augelli and Fietsam, our OR staff, and everyone here at Genesis, thanks again for tuning in tonight, and goodnight.

01:00:17

NICHOLAS AUGELLI, MD: Thank you very much.

01:00:20

ANNOUNCER: Thank you for watching this panel discussion of a coronary artery bypass graft, featuring a Cardica C-Port Stapler, from Genesis Medical Center in Davenport, Iowa. 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.

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