

**SURGICAL VENTRICULAR RECONSTRUCTION
MONTEFIORE-EINSTEIN HEART CENTER
NEW YORK CITY, NEW YORK
February 13, 2008**

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NARRATOR: Welcome to the Montefiore-Einstein Heart Center in New York City. In just moments, you'll see an expert discussion concerning a surgical ventricular reconstruction. The surgery was performed by Dr. Robert Michler, with assistance from Dr. Richard Bello. The presentation will include a range of discussion topics, including a clinical discussion of the procedure and aftercare.

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ROBERT E. MICHLER, MD: We then opened the heart, looking and inspected and saw all of the scar. We repaired the mitral valve with a single valve stitch and then we performed a remodeling procedure, or surgical ventricular reconstruction by delineating the area of scar, putting a patch in and over-sewing the wall of the heart over the area of the patch.

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ROBERT E. MICHLER, MD: Good evening and welcome to the Montefiore-Einstein Heart Center. One of a few centers in the United States with innovations in the field of heart disease and heart surgery for the last fifty years. Tonight we are excited to present to you an operation to remodel and reshape the dilated diseased heart surgical ventricular reconstruction. My name is Dr. Robert Michler. And with me is Dr. Richard Bello. Members of the Department of Cardiothoracic Surgery at the Montefiore-Einstein Heart Center. Let us begin by discussing the patient that we will operate on, and Dr. Richard Bello will begin that discussion. Thank you.

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RICHARD BELLO, MD: Thank you, Rob. Good evening and thank you for joining us today. The patient we're going to discuss today is a fifty-five year old male with hypertension, Type II Diabetes and hypercholesterolemia, who presented to St. Barnabas Hospital in The Bronx with a non-ST elevation myocardial infarction. He underwent a preoperative workup which included an echocardiogram. This transthoracic echocardiogram demonstrated a low ejection fraction of approximately twenty-five to thirty percent. He had mild to moderate mitral regurgitation. And importantly, he had a ventricular aneurysm of the apex. The apex was akinetic. The adjacent regions of the myocardium were hypokinetic. He subsequently underwent a cardiac MRI, which further delineated his anatomy. This cardiac MRI demonstrated, once again, the thinned out apex with viability in the adjacent regions. He then underwent a cardiac catheterization, which we will discuss at the beginning of the video.

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ROBERT E. MICHLER, MD: Why don't we turn to the video now and begin our discussion from the operating room. And as we do, we'll begin to evolve our thinking and be at any point able to answer your questions from home regarding this operation. Remember that surgical ventricular reconstruction is an operation that we add to coronary bypass surgery. So, essentially what we're dealing with is a patient with ischemic heart disease and a dilated ventricle, with an area of asynergy. Either akinesia or dyskinesia. And our plan is to reconstruct that area of the heart in a way that will reshape and remodel the heart, reducing the stress and wall tension on the ventricle after we complete coronary bypass surgery. The concept being that revascularization will, in fact, provide new nutrient blood supply to the heart, reanimate areas of the muscle that have been hibernating as a result of the coronary artery stenoses. And then in addition to that, try to reshape this heart that has changed from the normal football shaped heart to a more dilated basketball shaped abnormal heart. So why don't we go into the operating room now at the Montefiore-Einstein Heart Center.

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In addition, there are three vessels down here, only one of which is probably graftable. And this patient is a left dominant circulation, so we're going to graft the left sided posterior descending coronary artery. The obtuse marginal. The anterior descending coronary artery, which fills the left to left collaterals. And then the question is whether this high diagonal is large enough to graft. So our plan is three, possibly four, bypasses and the remodeling procedure to reconstruct the ventricle. Sound like a good plan?

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RICHARD BELLO, MD: Sounds like a plan.

ROBERT E. MICHLER, MD: Ready?

RICHARD BELLO, MD: Good plan.

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ROBERT E. MICHLER, MD: Okay, let's go. Alright, Rick, let's get him cannulated. Is the vein out and we're sure the vein is good?

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So here we are in the operating room at the Montefiore-Einstein Heart Center. Dr. Bello is cannulating the patient. We're now on the heart/lung bypass machine. And the tubes that you see that are blood filled, are tubes that remove deoxygenated blood, take it to an oxygenator and provide oxygen back to the heart. Now looking at the top of the heart here, this is the left ventricle. And you see that at the apex of the ventricle there is an area that is not moving well. And once we open – and we're demonstrating that now. That's the left ventricle. But at the very apex of this heart there is an area that is dimpling. And you can begin to see that dimpling. Now as we return the heart to its anatomic position, we're indicating the right ventricle, the anterior descending coronary artery, which is the artery that we will bypass and, literally, the most important artery on the heart.

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And then the left ventricle. As we elevate the ventricle, you can see an area on the heart, the top part that dimples. It retracts. And we're showing that dimpling now. That is very important. That's something we recognized preoperatively and we understood to be a significant area of asynergy. And it...it's a soft spot. It's an area that retracts as the heart beats. And this is, in fact, the area that we will make an incision into and be able to remodel, or reconstruct the heart through that particular area.

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So this is a double bypass with vein. We mark the vein in blue so we maintain the proper orientation. That's the first obtuse marginal branch of the circumflex. Then it continues down to the second obtuse marginal branch of the circumflex. And we're showing the revascularization to both of those territories. And you can see as we deliver cardioplegia here that the cardioplegia is going in nicely. There are no areas of bleeding. And this area...or, these two areas of muscle, we fully expect to be reanimated with additional blood supply to the heart.

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We then have to take the internal mammary artery, which we harvest from the chest wall. Sometimes referred to as the internal mammary artery because it comes under the mammary, or breast. And we use that artery, which is a very robust artery and has a long term patency that's excellent, and we anastomose it to the anterior descending coronary artery. And here we're opening the anterior descending coronary artery, and we are preparing the mammary artery for bypass. We're clipping two veins that run on each side of the mammary artery. And this is a pedicle. It contains...it's embedded in muscle and fascia along the undersurface of the chest wall. We divide that muscle and fascia in both veins. We're clipping the second vein now. And then we incise...divide the mammary artery at a set location. And you'll see the mammary artery now being anastomosed to the anterior descending coronary artery.

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We use very, very fine suture for this work. In fact, it's barely perceptible to the television audience. But you can see that with this very fine suture we're able to connect these two arteries together in a manner that will bring new blood supply around an area of blockage.

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Remember, coronary artery bypass surgery is nothing more than fancy plumbing. You have a clogged drain at home, the plumber can come in and put a new pipe in, or rotorooter the pipe. In the heart, the arteries are embedded inside the muscle and fat of the heart and we can't replace them. But what we can do is take a artery, or vein, that has good upstream flow and go around, or bypass the blockage. So, the vein is now being sutured to the aorta, which is the largest blood vessel coming out of the heart. We've made a hole in the aorta and we are now suturing the vein to the aorta. This is done with fine suture as well, so that in your mind's eye you can see that new blood coming into this vein from upstream is going to go down the tube, or vein, and bypass those two blood vessels that you previously saw that we had bypassed.

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We have had a few questions from the audience. One is, what's the difference between this and a heart transplant. Rick, do you want to answer that question?

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RICHARD BELLO, MD: Sure. A heart transplant is meant for patients with end stage heart disease when there's no other options available. Unfortunately, the supply of donor organs is limited and we somehow...sometimes have to resort to alternative procedures. Some of the procedures that we perform are high risk mitral valve surgery. Previously, rather than the Dor Procedure, which is an alternative name for this procedure, the Batista procedure used to be performed. However, during the Batista procedure, viable myocardium which can perform useful work is removed. In this procedure we really perform a repair in the area of the scarred myocardium and we believe it to be a better procedure than the Batista.

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ROBERT E. MICHLER, MD: Now that's a very important point, Rick, because essentially what we're doing is restructuring the heart through an area of abnormal muscle, as opposed to the left

ventriculoplasty or Batista operation. Now let's look back at the heart. And what we're doing is trying to decide where to make an incision. And, we are feeling the heart, both with the forceps and our fingers. And we now place stay sutures in the muscle of the left ventricle. And, this is on the lateral side of the left ventricle. Then we'll place one medially. I like to use these sutures because it give me a firm area to work against, but it's also a marker so that in my mind's eye while I'm operating, I know the distances to different structures. I know the distance the anterior descending coronary artery and it also provides me with orientation.

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So, now we're going to make an incisions directly into the left ventricle through this area that is asynergic. And you'll see as we cut through it that this is actually an area intermixed with scar tissue, so it's quite firm. And as we...as we begin to cut you'll begin to see scar tissue, which is white, and that scar tissue is nonfunctioning heart. See all of that now? Do you see how thick that muscle is and how white it is? And in different areas it's a little thinner. So we're not incising directly up along the lateral side of the anterior descending coronary artery and down towards the apex of the heart. You'll see how thin it is now at the apex. These strands are fibrotic strands. These are not strands to any valve within the heart. We excise those. And now we feel in...feel inside. Very important to feel the ventricle. To feel the area of scar and thinning.

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And now as we proceed along the inside, we're looking to see where the scar tissue is. So the forceps are demarcating scar. Remember that the white tissue is abnormal scar. We also know from our preoperative studies where the extent of scar is. So while we operate, we're thinking back to all the images that we've looked at with the preoperative MRI as well as the echocardiogram.

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Now, in just a minute you'll see us delineate the edge of scar and we'll place suture around the edge of the scar to identify the transition zone between dysfunctional heart and what we think is normal heart. But before we do that, at this moment we are going to perform a valvuloplasty of the mitral valve. Rick, would you care to comment on how we perform this part of the operation?

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RICHARD BELLO, MD: Sure. It's not uncommon for this procedure to be combined with a mitral valve repair. As a matter of fact, in one of the observational studies that was performed on this procedure, approximately twenty percent of the patients received a mitral valve repair during the procedure. This can be performed through a separate incision in the heart. However, in this case we're performing an edge to edge, or Alfieri type of repair right through the ventriculotomy. What we're doing here that can't be visualized well is the fact that we're lining up the anterior and posterior leaflets to optimize that repair.

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ROBERT E. MICHLER, MD: What do we see there, Rick? What is it that we've just pulled into the heart?

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RICHARD BELLO, MD: Here, this is a left ventricular vent which has been placed through the left...excuse me...through the right superior pulmonary vein. This really helps to remove any blood from the field. However, we are repositioning it now because this vent travels through the mitral valve to get to the left ventricle and for our repair we are just repositioning it.

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ROBERT E. MICHLER, MD: Now, we've had a question from Hong Kong. And that question relates to the difference between the Batista operation and the Dor Procedure. And just to reemphasize that, this is the surgical ventricular reconstruction, or Dor Procedure, which in fact is a reshaping of the anterior segment of the heart. The Batista operation was a partial ventriculoplasty between the two papillary muscles on the lateral aspect of the heart, so almost directly behind where the procedure that we're performing today is located.

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Now, they were performed for very different reasons. And this is one of the important things that we wish to comment on with the surgical ventricular reconstruction. Now, one of the very, very important things to recognize is that this procedure is being studied currently in the largest surgical trial ever conducted by the National Institutes of Health and the National Heart and Lung Blood Institute, called the STITCH Trial, the Surgical Treatment for Ischemic Heart Failure. And that trial has now looked at over two thousand patients that were divided essentially into three different treatment groups. All patients enrolled in the trial had coronary artery disease that was amenable to coronary revascularization. And they had low ejection fraction, less than thirty-five percent. And a portion of those patients had dilated hearts. So the three treatment arms were medical therapy alone, bypass surgery, or bypass surgery with surgical ventricular reconstruction. This study is going to be a land...landmark study. And in all likelihood will influence therapy for the next decade.

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Rick, do you have a question there?

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RICHARD BELLO, MD: I do have a question. We have a question from the audience.

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ROBERT E. MICHLER, MD: But before we go to the audience, just for a moment. Right now what we're doing is identifying the area, the region of scar. And the forceps are showing the transition zone between a brown or reddish healthy muscle along the septum, which is away from you, or what you can see best, and the...and the anterior lateral wall. So this suture is going to be placed along that edge as a marker for the surgeon. It has an eponym called The Fontan Suture. And, this suture runs along the edge of transition zone where we will plan to the put the patch.

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Now, we also use a ventricular sizer and shaper that is appropriate for this patient's body surface area. And you will see that balloon sizer and shaper be inserted in just a moment to be certain that we're placing the apex in the right position in the ventricle, and also that our patch is placed in the proper position. So this suture can always be removed. But with experience, and we've done so many of these procedures now that we have a very good eye at determining where this transition zone is. And so, we can begin by placing this suture and then using the balloon to identify just whether we have placed it in the proper position. So, while we're placing this suture, why don't we take the next question.

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RICHARD BELLO, MD: So there's a question from the audience asking, is the asynergic area, or the scar, secondary to infarct? In fact, it is. This is a procedure for patients that have coronary artery disease with infarcted or scarred myocardium. They...these patients are usually in a Class

III or IV New York Heart Association heart failure. And not uncommonly have anginal symptoms as well.

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ROBERT E. MICHLER, MD: We have another question from Egypt. Which is better, the internal mammary artery or saphenous vein from the leg in bypass surgery? Well, the internal mammary artery is clearly recognized as the better conduit. It's an artery. It has a longer patency rate and is really the ideal conduit to use to bypass blood vessels. Wherever possible arteries are used. However, there's a limited supply of those. One can use both internal mammary arteries, the left and the right. The left is the most commonly used and it's most commonly used to bypass the anterior descending coronary artery, as we have done in this particular case. So, it is the vessel with the highest patency. One of the things we've been observing is that with the use of statin therapy after bypass surgery, we believe that the likelihood of restenosis of veins may even be less.

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So now we're tying down this suture and then we'll use the balloon to make sure that we have properly positioned and sized the new location of the apex. Remember, the entire operation as it unfolds has a singular purpose. And that singular purpose is to reshape the heart and downsize the heart, with the plan that we will create a more conical, elliptical shape to the heart.

Transitioning from the dilated basketball with an asynergic area, an area of dysfunction, to a more football shaped heart. And, that's the singular purpose of this operation. And that's what the STITCH Trial hopes to demonstrate. Rick, do you want to have another question for us?

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RICHARD BELLO, MD: Sure. We have another question asking, what is the role of stem cell therapy in treating these cases? Well, stem cell therapy is not a proven alternative yet. However, there are many studies and it's quite vigorously being investigated as an alternative therapy for patients with heart failure. So, it's not an active...It's not a currently used procedure, but definitely being studied. As a matter of fact, our lab is involved in research, investigating the role of stem cell therapy in heart failure.

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ROBERT E. MICHLER, MD: Let's come back to that question in just a moment, because I'd like to add a little something to it. But first I want to have our audience see that these...the... these sutures that are being placed along the edge of the Fontan Suture is effectively excluding the septal muscle. So, everything above where the suture is being placed will be excluded and not part of the tube, or lumen of the left ventricle. These sutures have a pledget, a little white felt that you see going down. And that little white felt is intended to prevent tearing of the suture through the muscle. So as those sutures come out through the septum, everything above that needle right there is going to be excluded from the chamber of the heart once the patch goes in and no longer will be in the blood contact surface. So, this is the very beginning of the exclusion process. Now, we take some sutures in a moment from the outside. But this is the purpose that we are seeing with the placement of these sutures.

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I want to return to the question of stem cell therapy. I think this is one of the most exciting areas in the entire field of cardiovascular diseases. We are deeply involved in this field. Very excited. And are extremely proud to have as one of our collaborators Dr. Piero Anversa, who is now at Harvard. Dr. Anversa and our team have been examining endogenous cardiac stem cells, identifying that these cells reside within each of our hearts. And the question that Dr. Anversa,

his team and our team is asking, is whether these cells could potentially, in the future, help to restore some of the dead muscle that has been...that has died as a result of a myocardial infarction.

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Now this is the balloon shaper and sizer. It will be filled to a predetermined volume that is specific for this patient's body surface area. So, you'll see that there's a flat base to this balloon, that the finger...index finger just touched. And then there's a apical portion where the saline is being infused. And as we insert this inside of the ventricle, the flat portion will be pushed up against the mitral valve, the balloon will be dilated with saline to the predetermined size. And this predetermined size is appropriate for this patient's new heart. And, we also are able to shape the heart around that new balloon sizer. And we also set the apex. So, this prevents us from creating a boxlike ventricle. Very important. The ventricle is shaped like, as I mentioned before, a football and we don't want to truncate, or flatten this part of the heart.

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So as we look carefully inside, the first thing we notice is are our sutures up tightly against where this balloon is indicating they should be for the proper size and shape of the heart. And, in fact, you can see that they most certainly are along the septal surface, which is the surface to the top of the screen. And then we're going to place sutures along the edge on the bottom of the...of the screen. That white material...that rectangular white material is pericardium from a cow. Rick, do you want to explain this portion of the operation?

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RICHARD BELLO, MD: Sure. So here, the sutures that are going to support the patch along the lateral aspect are passed from the outside of the heart. We use a bovine pericardium to provide support on the epicardial surface. And this bovine pericardial patch has a second function, and that is to aid in the closure of the ventriculotomy later on. We'll see that portion as we get to it. So right now these sutures are being placed with the sizer in place to make sure that we do not undersize or misshape the ventricle. As we put in the last few stitches we'll remove that sizer.

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ROBERT E. MICHLER, MD: As you can see, these needles are much larger than the needles that we had for the septal surface of the heart, because they must penetrate the lateral muscle of the heart which is a thicker area. Again, these sutures are coming out right where that initial Fontan Suture was placed. And we're using the balloon inside as a marker, as a guide. So, this operation, although it involves a fair amount of creativity on the surgeon's side, it has been systematized in this manner to provide consistent and excellent results. As you can see, we're not completing the apical portion of the suture line.

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Do you have another question there, Rick?

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RICHARD BELLO, MD: We have several questions. The first question is, what kind of troubles can one expect after a surgery like this? Well, I think the most obvious, looking at the operation, is in fact bleeding from this ventriculotomy. And we go to great lengths to make sure that this is a strong closure. And we'll see the closure of the ventriculotomy later on in the procedure. Some of the other complications that we can expect are---

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ROBERT E. MICHLER, MD: Rick, just a moment. Why don't we turn to the camera. And you see us cutting an elliptical patch here out of Hemashield, which is a thin...a synthetic woven Dacron material. We cut a nice little ellipse. And once you do this a few times, you can do it with essentially one cut, as we've done here. And we don't need to trim it any more. It's the right size. And, this is the patch that will be sutured over the top of...where the sutures have exited the heart. That will then lie...lay right inside the ventricle and will close over the top of that. So now you're beginning to see how this operation excludes the muscle.

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At this point we're deflating the balloon. The balloon had served its purpose. The sizer has helped us size the ventricle to the right volume. It has helped us position the apex and make certain that the shape of the heart is elliptical. So with that we will then remove this balloon and suture in the patch. So, Rick, why don't you go on to the next question.

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RICHARD BELLO, MD: So to continue with what kind of complications, the other major complication you can expect is cardiac insufficiency secondary to under-sizing the ventricle, or excluding too much muscle. And, again, this is pre...this is prevented by use of balloons such as this one. In general, what we see is the patient's ventricular function actually improves after this procedure, if done properly.

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We have another question, Rob, asking why aren't we removing more of the scar tissue that's still clearly visible in the field? And, again, what we're doing is not removing...the purpose of this procedure is not to remove, but rather to exclude. So, what you'll see is this patch will be sewn to the rim created by the Fontan stitch, which essentially creates a shelf. Now, outside, or external to that shelf is the nonviable myocardium that is effectively excluded from the ventricular cavity. We will then use this nonviable myocardium to close the ventriculotomy.

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ROBERT E. MICHLER, MD: So we're going to see that in just a moment. As we begin to tie this down and the audience is able to get a sense of the patch's location, I think that the answer to that question will become visually clear. Because everything we have done thus far in the operation is along the pathway of excluding muscle from the blood filled chamber of the heart in a way that resizes and creates a better shape for the left ventricle. So these sutures then go around circumferentially, proportionally, just as we place them, and I think the viewing audience will have a much better sense as we begin to tie these as to how we've excluded muscle from the blood contact surface of the left ventricle. I believe we have another question.

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RICHARD BELLO, MD: We do. Again, we have a question asking which is a better procedure, the ventricular reconstruction or heart transplantation. This particular viewer actually saw our previous video on heart transplantation. And to answer that question, they are both good procedures. The gold standard therapy for heart failure is, in fact, heart transplantation. However, not every patient is a candidate for heart transplantation. And in fact, some do not meet the criteria necessary to be listed for heart transplantation. In those cases we need to resort to alternative strategies such as this procedure.

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ROBERT E. MICHLER, MD: Well, very...Yes. And very importantly, this operation is usually done for patients with heart failure, but not a heart failure that is as profound as someone who requires a heart transplant. A heart transplant is really for end stage heart failure. Someone in

Class IV heart failure with ejection fractions of roughly twenty percent or less, who have biventricular heart failure and dilatation. This patient has left heart dysfunction and congestive heart failure. Is there another...

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RICHARD BELLO, MD: Yes, Rob, we have another question. What happens to the chordae tendinae when you put in the sizing balloon? And, in fact, because the ventricle is decompressed, the chordae are really not under any tension and simply collapse towards the posterior wall of the heart. These do not get in the way of the sizing balloon, as you saw earlier.

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ROBERT E. MICHLER, MD: I think you can see now the patch fitting inside of the chamber. So everything below that white patch is in the blood contact surface. Everything above it is no longer part of the chamber of the left ventricle. So, this has created a shelf, so to speak, but it's not a...it's a reshaping shelf and it is placed in a way that, as you have seen, reshapes the heart, but also reduces the overall chamber size. And, all the muscle that was above the white patch is now excluded and will be used to close over the white patch with separate suture line.

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This suture is being tied right at the apex of the new left ventricle. It's very important to place the apex properly. These sutures will then be cut and another suture line run over the top of the muscle to close this hole and close, essentially, the initial incision that we made, the ventriculotomy.

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Now what isn't actually apparent to the viewing audience is just how much muscle has been excluded. And it's quite a considerable amount. So we'll see in a moment whether we open up this ventricle to look underneath to see just how much muscle is actually no longer in the contact surface. This is a second piece of pericardium that's being run around the medial side, or the upper side of the camera. But we're now working under both sides. And as we lift up that heart muscle, you can see that all of that muscle above the white patch, which is a fair amount of muscle, has now been excluded from the blood contact surface. We have another question, Dr. Bello.

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RICHARD BELLO, MD: Yes. There's a question regarding the use of immunosuppressant therapy because of the use of bovine pericardial tissue. There is no need for immune... immunosuppressive therapy after this procedure, or in any procedure where bovine pericardium is used. This bovine pericardium has actually been fixed and is not immunoreactive.

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ROBERT E. MICHLER, MD: In fact, it's been treated. It's gluteraldehyde treated, which cross links the collagen and essentially makes it inert. You can see as we dip the sutures down through the muscle that there's a fair amount of left ventricle that has been excluded. And that is now forming the top of the closure of this ventriculotomy.

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RICHARD BELLO, MD: It's important to note, Rob, that you can get a sense as to how much force you're putting to pass the needles. And that's because this tissue is actually scar tissue, which is in fact being closed. So the scar tissue is never really removed, but simply excluded. And now, as you pointed out, really lies outside of the outside of the patch and excluded from the left ventricular cavity. As we finish up the closure here, we have another question.

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ROBERT E. MICHLER, MD: Rick? Before we go to that question, Rick, let me just comment on what you're seeing visually. This is the final closure. And you can see that it sort of looks like the top of a baseball. It's the weave of a baseball. It's used to secure the left ventricular...left ventricular closure. And, that's a watertight seal. This really rarely bleeds. We've become so experienced with doing this operation that bleeding is, fortunately, not a common issue that we have to deal with. We also place a little bit of glue. This is high grade medical glue over the top to just seal some of the suture line. But you can get a sense that we've converted that dilated ventricle into more of an ellipse.

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So at this point in time we've...we're going to take the cross clamp off of the aorta. The aorta dilates and now new blood...new blood is going into the heart. The bypasses should now reanimate some of the muscle on the heart and we should begin to see the heart muscle beating. You can see the internal mammary artery. We're not examining the apex for bleeding along the suture line, and there is none. And the heart now has started to beat nicely. We reexamine the suture line and you can see that that whole area is excluded. There is no bleeding from the suture line of the mammary artery to anterior descending anastomosis.

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We place right ventricular pacing wires on the undersurface of the heart. And those pacing wires allow us to temporarily pace the heart during the immediate postoperative period. This is the vent that went into the left ventricle and we're about to remove that vent. And in a moment we will see the completion of the operation, as the vent is removed.

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Now, Rick, why don't you tell us how this patient did after the operation and then we'll field some more questions from our viewing audience.

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RICHARD BELLO, MD: This patient's actually done fairly well. At the completion of the procedure, the ejection fraction had increased from a preoperative twenty-nine percent to approximately thirty-five percent. He's undergone a repeat echocardiogram which indicated slightly more improvement approximately two months after the procedure. He has not been readmitted for any reasons related to heart failure.

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ROBERT E. MICHLER, MD: He is no longer in heart failure.

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RICHARD BELLO, MD: He has not been readmitted with reasons of heart failure, and that's something that is commonly found. These patients have approximately an eight percent freedom from...eighty to eighty-five percent freedom from readmission for heart failure at approximately three years. And that's data from the Restore Group. Hopefully, the STITCH Trial will shed some more light on the result of this operation.

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ROBERT E. MICHLER, MD: Well, yes, indeed. And the importance of the STITCH Trial is that it is a randomized trial, unlike the Restore Group which was really just an observational study of how well patients did after surgical ventricular reconstruction and bypass surgery. I think there's tremendous enthusiasm and excitement around the world with regard to the results of the STITCH Trial, because it in fact is a randomized controlled study with strict entry criteria. And the sheer numbers of patients that have been enrolled in this trial will help direct therapy, in all likelihood, for decades to come. Remember, the very last study that even approached looking

at patients like this was the CASS Study, which was performed nearly thirty years ago and we are still delighted with the lessons we've learned from the CASS trial. You have another question, Rick?

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RICHARD BELLO, MD: Yes, I do. We have a question asking if there's any difference in the types of medication or the medical therapy that these patients receive after this operation? In fact, these patients have been treated for coronary artery disease and so the medications that they would expect to be on are what we would normally use after coronary bypass surgery, and that includes aspirin, lipid lowering agents and beta blockers. There's nothing in addition for these patients to receive because of the ventricular restoration. However, because they are frequently patients that came to us with heart failure, they may be on heart failure medications as well.

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ROBERT E. MICHLER, MD: We have another question, Rick. And this question is, how long after the procedure does a patient take to fully recover. This is a very good question, because it really deals with whether anything related to surgical ventricular reconstruction would add to the recovery period. And what we've found is that not to be the case. These patients really recover very much like a patient who has had bypass surgery. And, this is...this has been an average in the hospital of somewhere around five to six days in the hospital. These patients do extremely well from that perspective. And this patient, as you mentioned, did very well after his surgery.

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We do treat these patients with a standard therapy of beta blockers, statins and baby aspirin. It's very important. And some of these patients leave on ace inhibitors, or ARBs. And, that's Angiotensin Receptor Blockers. The reason for that is that some of these patients have mitral regurgitation in addition to their left ventricular dysfunction. And we've found this to be, obviously, a very important strategy in managing these patients.

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Another question we had is, how often do you require an intraaortic balloon pump in the management of these patients. Do you want to answer that question, Rick?

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RICHARD BELLO, MD: Well, looking at data from the Restore Group, again, this was a...this was an observational study of approximately 662 patients. In their data they found that fewer than one percent required an intraaortic balloon pump. But that is an important thing to consider, because these patients, in fact, have a low ejection fraction. It does improve pre-op...excuse me. It does improve postoperatively. But, nevertheless, this is an acute change and may take some time for the myocardium to recover.

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ROBERT E. MICHLER, MD: Excellent. Another question is whether there's a risk of the development of a ventricular aneurysm after this procedure. And what are the EC change...ECG changes, the electrocardiographic changes that can be seen in the patient after ventricular reconstruction?

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RICHARD BELLO, MD: You want to take a stab at that, Rob?

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ROBERT E. MICHLER, MD: Certainly. So, we do not see ventricular aneurysm formation after this operation. In fact, many of the patients who receive surgical ventricular reconstruction have a ventricular aneurysm. So the procedure in and of itself excludes or eliminates ventricular

aneurysm. And there are no specific electrocardiographic changes that are associated with performing the surgical ventricular reconstruction. We may see ECG changes related to coronary artery disease, and those are...and those we don't anticipate seeing because we're performing bypass surgery. So effectively this excludes, as you've seen, any left ventricular aneurysm.

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We have another question related to how often you monitor the patient after the procedure and how often you perform an echocardiogram.

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RICHARD BELLO, MD: Monitoring is standard after cardiac surgery. As I mentioned earlier, one of the important things we look for is bleeding. However, with a good closure that has not turned out to be a big concern. Certainly heart failure or cardiac insufficiency is important and that is something that can occur when the ventricle is undersized. With the use of the balloons, I think that is something that we avoid more and more. As Rob mentioned earlier, the balloons are specifically sized to the patient. Normally these balloons come packaged with normagrams relating the volume of the balloon that's used to the patient's body surface area.

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ROBERT E. MICHLER, MD: We do wish to repeat the echo's on a regular basis and follow these patients early on. Our first echo is about three to four months after the operation. And then serially thereafter at no less than about six month intervals. And then we do a complete evaluation on these patients a year after the operation.

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Another question relates to the use of blood thinners, or anticoagulants. Do you wish to comment on that, Rick?

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RICHARD BELLO, MD: Sure. After this procedure there's no specific need for the use of anticoagulation. However, if the patient develops atrial fibrillation or another reason, for blood thinners then they may be used without any problems.

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ROBERT E. MICHLER, MD: Some physicians around the world have elected to use anticoagulants in these patients who receive a patch. It remains unclear, though, whether that is absolutely necessary. We have another question that relates to how often one repairs the mitral valve in addition to surgical ventricular reconstruction.

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RICHARD BELLO, MD: Well, I'm not very familiar with the STITCH study. You can comment on that a little better. From the Restore Group, approximate...in their group of 662 patients, twenty-two percent required an intervention on the mitral valve.

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ROBERT E. MICHLER, MD: The mitral valve is an important valve to deal with in these patients. And we find that the larger the ventricles the greater the likelihood is that a patient will have some form of mitral valve pathology. Now if the valve leaks severely, or in some cases even moderately, but certainly moderately severe or severe mitral valve pathology requires a true mitral valve repair. And in those circumstances, we will not repair the mitral valve through the left ventricle as we did in this particular patient. All we did in this patient was a valvuloplasty, which sutured the anterior to the posterior leaflet of the mitral valve in the central portion. The anatomic location in our language of heart surgery is A2 to P2, so the central segment of the

anterior leaflet to the central segment of the posterior leaflet is, as Dr. Bello mentioned earlier, the operation that was done on this particular patient. And that helps when the leakage of the valve is mild.

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Now when we have severe or moderately severe leakage, we will actually enter the left atrium through the interatrial groove on the right side of the patient and perform a standard mitral valve annuloplasty with an annuloplasty ring to downsize the annulus in these patients who have had a very large dilatation of the heart.

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We have another question that relates to use a patch and when not to use a patch. Would you like to take a stab at that question?

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RICHARD BELLO, MD: Sure. What Rob is alluding to is either a ventricular restoration with a patch versus a linear plication where simply a ventriculotomy is made, or even without a ventriculotomy, the ventricle is essentially folded over on itself and sutures are passed, effectively excluding...effectively excluding a portion of the myocardium. The linear plication can be done when the scarred area is thin and it's small. But trying to perform a linear plication on a large scarred area of the myocardium can, in fact, cause distortion of the intraventricular anatomy as well as under-sizing of the ventricle.

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ROBERT E. MICHLER, MD: So I think the salient points that Dr. Bello is saying there is that when we have a dimension of the heart as large as the one we had in this case, I certainly prefer to use a patch. I will use a linear plication, as you said, for much smaller areas of akinesia or dyskinesia.

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RICHARD BELLO, MD: Absolutely.

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ROBERT E. MICHLER, MD: Any pearls that you would like to share with the audience in doing this particular surgery?

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RICHARD BELLO, MD: I think the most important thing to...in this operation is to think about it in the first place. Many times we have patients with the appropriate anatomy that come to us and we only consider performing a coronary bypass. I think if we are on the lookout for it and we recognize the anatomy, we need to consider this type of procedure because it can, in fact, improve the patient's quality of life, due to the improvement in ventricular performance.

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ROBERT E. MICHLER, MD: I think that's an extremely important point, Rick, and one that I hope our viewing audience recognizes. And that is that understanding the dimension and scope of the problem in patients with ischemic cardiomyopathy. Firstly, patients with heart failure should have coronary artery disease ruled out. And it's surprising how many patients with heart failure have not had a cardiac catheterization to determine whether they have ischemic heart disease. It's one of the messages, the public service messages that we're trying to communicate to the broad audience of physicians and patients, because this is a devastating disease. And remember, heart disease is this nation's number one killer. It kills more people than the most seven leading causes of death added together. And this is, in fact, one of the devastating components of heart disease.

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So, why don't we now just summarize what we've learned this evening from the surgical and technical perspective. And, we'll close with a discussion of that particular aspect of this operation. Remember that patients who are eligible candidates for this surgery are those who have coronary artery disease and poor left ventricular function. If a patient has poor left and right ventricular function and end stage heart failure, they are likely to be more of a candidate for heart transplantation or mechanical heart device implantation. Patients who have coronary artery disease, left ventricular dysfunction, and even if they have mitral regurgitation, are certainly candidates for surgical ventricular reconstruction and coronary artery bypass surgery, and mitral valve surgery. And on occasion, as we have performed, these patients also undergo a maze procedure to correct atrial fibrillation. To create a more regular and normal conduction from the atria, the upper chambers of the heart, to the ventricles, the lower chambers of the heart.

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So as we demonstrated with this operation, this patient underwent multivessel coronary artery bypass surgery with the intent of providing new blood to the heart, beyond the areas of coronary artery blockages. So the purpose of that was to restore new oxygenated blood to the muscle in an attempt to reinvigorate that muscle that, in fact, was dysfunctional and in some cases hibernating. But that's only part of what the intention of this operation is designed to do. So not only do we want to reinvigorate heart muscle, but we want to deal with the issues of wall tension in a dilated chamber. And in these patients, the heart dilates from the normal football shape to a basketball. And that basketball is abnormal. The heart does not like that. The patient does not like that. So the concept is can we reduce the size of the heart and restore a more normal shape to the ventricle, essentially restoring it closer to the ellipse, or football shape of the heart.

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In this case we did that by opening the left ventricle along the anterior surface, examining the ventricle, looking inside and feeling. Looking for the transition zone between scar and what appeared to be more normal functioning heart. We then used a balloon sizer and shaper to appropriately size and shape the heart, making sure that the apex was placed in the proper position. And then we placed sutures around the ventricle, excluding muscle. Not excising muscle, but excluding dysfunctional muscle, placing a patch over the top of that area and then reclosing the ventricle over the top of that patch. Essentially accomplishing both objectives, which were to reduce the size of the heart and also reshape the size of the heart.

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I think it's very...also very important for our audience to understand that the long term impact of this operation, we continue to examine and observe and expect that the results will continue to be very good. It is our hope that we can restore better functionality to patients. And, certainly, hope to avoid further deterioration of their heart function and their heart failure, and hopefully preventing patients from requiring mechanical device implantation or heart transplantation.

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Rick, would you like to add any final thoughts or comments?

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RICHARD BELLO, MD: No. I think you've summed it up well, Rob.

00:58:48

ROBERT E. MICHLER, MD: All right. Very well. Well, Dr. Bello and I would like to thank you for joining us this evening at the Montefiore-Einstein Heart Center in New York City. One

of the handful of centers that have been involved in innovations in cardiac disease and heart surgery for over fifty years. Thank you and good evening.

00:59:17

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