STENT GRAFTING PROCEDURE
MASSACHUSETTS GENERAL HOSPITAL, BOSTON, MA
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NARRATOR

Thank you for joining us to view the live stent grafting procedure to treat thoracic aortic aneurysms from Massachusetts General Hospital in Boston. Dr. David Brewster and Dr. Christopher Kwolek, both of the Division of Vascular and Endovascular Surgery at Mass. General and the Thoracic Aortic Center will perform the procedure.

DAVID BREWSTER, M.D.

An aneurysm basically is a weakening of the blood vessel wall and it bulges out like a bubble in a garden hose or a weak spot in a tire tube. The major danger of an aneurysm is that the bubble will become too weak and thin and rupture or bursting of the blood vessel will occur, so the goal is to repair the aneurysm, either remove it by open surgery or in this case cover it over with a stent graft within the blood vessel itself, exclude this weakened portion from the circulation, and thereby avoid any possible bursting or rupture.

CHRISTOPHER KWOLEK, M.D.

We take a tube in combination with some type of support material, so a combination of stents, which are already available, and graft material, which we have already used for open repairs, combined the two, decreased their size, and allowed us to slip them into place inside the area of the weakened wall, so the concept is to take a new tube or a new device, a new sleeve, if you will, and slide it up within the old weakened or enlarged sleeve and then expand it into place. I think one of the analogies that patients appreciate is that of a Chinese finger trap, something that’s very tiny when it’s stretched out, but when it opens, it expands and widens.

NARRATOR

Dr. Richard Cambria, Chief of the Mass. General Division of Vascular and Endovascular Surgery and Co-Director of Mass. General’s Multidisciplinary Thoracic Aortic Center, will be your host and answer your email questions during the live webcast. The Thoracic Aortic Center at Mass. General is one of only a few groups in the northeast to perform this type of procedure and the Center’s surgeons have the largest regional experience to date. The Thoracic Aortic Center is participating in all three clinical trials evaluating thoracic aortic stent graft repair.
RICHARD CAMBRIA, M.D.

For a conventional open operation of a thoracic aortic aneurysm, the patient would usually be hospitalized for 7-10 days and then ordinarily spend a minimum of several months in functional recovery, until they attained their preoperative functional status. In the case of a stent graft repair of an aneurysm, the patient is generally hospitalized for two days and within 10 days of surgery is generally back to their preoperative function status.

NARRATOR

Now your host, Dr. Richard Cambria.

RICHARD CAMBRIA, M.D.

Good afternoon. My name is Richard Cambria, representing the Division of Vascular and Endovascular Surgery and the Thoracic Aortic Center here at the Massachusetts General Hospital. Welcome to our live web broadcast of an innovative minimally invasive surgical procedure known as thoracic aortic stent graft repair for an aneurysm involving the descending thoracic aorta. The format of our program this afternoon will be didactic, demonstrative, and interactive; didactic in that we’ll start with a short presentation, laying the background, the development of this type of surgery, and how we plan for it in terms of assessing patients; demonstrative in that the bulk of the program will, of course, be devoted to our live surgical performance, performed by my colleagues, Dr. Brewster and Dr. Kwolek; and finally, interactive in that during the surgery you are invited to send in online email questions which we will do our best to answer during the course of the program.

So we’ll start with a short presentation that involves a PowerPoint presentation of the background of this type of surgery. Displayed on the screen is, in fact, the concept of what we are doing. This is a cartoon displaying what an aneurysm is and that’s the bulge that you see in the cartoon on the left. Inserted up through the arteries itself is the stent graft and you see it first partially deployed and then completely deployed in the panel on your right. This accomplishes the same goal as open surgery, where we would, in that case, sew this graft into the aorta, replacing the aneurysm. You physicians in the audience, bear with me. Since we do have a mixed lay and professional audience today, we are trying to gear the presentation to the entire audience. This is indeed a timely and hot, if you will, topic. Displayed in this cartoon are some covers from some very recent vascular journals, characterizing thoracic aortic stent graft repair, indeed, as the next frontier in endovascular therapy. We’ll give a brief overview about the spectrum of pathology involving the thoracic aorta, the very important distinctions in stent graft repair of the thoracic aorta when compared to the now commonly performed stent graft repair in the abdominal aorta, a little bit about the results of treatment so far in the literature, and finally, a little bit about the next frontier beyond, indeed, the treatment of aortic dissection.
Unlike the abdominal aorta, where we are almost exclusively talking about degenerative aneurysms, the spectrum of pathology in the thoracic aorta, which can be either focal, as shown in the cartoon in the upper right, or involving the entire thoracic aorta, includes aneurysms, acute and chronic dissections, intramural hematoma, penetrating ulcers, acute traumatic transections, pseudo-aneurysms of all types, and the so-called source of atheroembolic shaggy aortic syndrome. Potentially all of these pathologies are amenable to stent graft repair.

An important distinction from repair in the abdominal aorta is referable to anatomy. This is strictly an anatomy-driven procedure. Some patients’ anatomy permit it, whereas others do not. Whereas, as shown in the black and white cartoon, extreme angulation in the so-called neck of the aneurysm would be a relative contraindication to stent graft repair, in the thoracic aorta this angulation is a constant, where the transverse aortic arch proceeds into the descending aorta. Indeed, the spectrum of anatomic configurations of the distal aortic arch is an important anatomic variable in the evaluation of patients for potential stent graft repair. The other important distinction, of course, with repair of abdominal aortic aneurysms, has to do with what I refer to as the morbidity quotient of surgery. In this hospital, open repair of abdominal aortic aneurysms is typically carried out with a less than 1% operative mortality. Displayed on the slide is a report from our own institution, that is an MGH series, and eight reports from the literature with, as you can see, a large number of patients. As you can see, the mortality for open repair of descending thoracic and thoraco-abdominal aneurysms continues to run in the near 10% range. Thus, the availability of a minimally invasive procedure for repair of thoracic aortic aneurysms is likely to have a major impact on the morbidity of surgical repair.

Another particular complication of operation on the thoracic aorta is the potential for spinal cord ischemia. This, of course, relates to the intercostal vessels off the thoracic aorta. Whereas spinal cord ischemia remains an unsolved problem with open repair of descending thoracic aortic pathology, the initial experience with thoracic aortic stent grafting has indicated that the incidence of this devastating complication is substantially lessened in stent graft repair as opposed to open aneurysm repair.

Stent graft repair anywhere in the aorta is strictly an anatomically driven decision. One needs an area of so-called seal zone of relatively normal aortic caliber above and below the aneurysm, although the potential seal zone for thoracic aortic stent grafting proximally runs throughout the area of the aortic arch and it may be necessary to re-route or divert blood flow into the subclavian and even left common carotid arteries to permit an adequate proximal seal zone for the aneurysm.

Since this is an anatomic-driven planning, we take great care and go to great lengths to utilize the latest in axial imaging modalities. Displayed in these slides are some so-called MMS 3-dimensional reconstructions of a complex thoracic aortic aneurysm. I’m going to take you now to a different screen, displaying the MMS reconstruction for this patient. What you see on this screen is a cartoon three-dimensional reconstruction of a CT scan data set, which we can rotate through any plane and at the same time that we’re looking
at the 3-dimensional reconstruction, we can scroll down a perpendicular aortic slice. This type of sophisticated imaging equipment allows for very accurate topographic assessment of the aorta. It allows precise measurements of aneurysm and proximal and distal aortic diameters, and there are a variety of manipulations that we can do with this so that we can show the blood flow line in the aorta and I’m going to attempt to show you right now by subtracting some elements in the cartoon that you see.

Okay, I think our operators are now ready to proceed directly to the procedure itself.

DAVID BREWSTER, M.D.

Good afternoon. I’m Dr. David Brewster. I’m joined by Dr. Chris Kwolek and our fellow, Dr. Patrick Casey. We’re pleased you could be with us. We started the procedure a few minutes ago by gaining access to the vascular system in the right groin by a limited open incision. I hope you can see that on the overhead camera. That’s the extent of open surgery, if you will, so it certainly reinforces Dr. Cambria’s point about the minimally invasive nature of the procedure and it’s certainly a remarkable contrast as opposed to standard open repair of a thoracic aneurysm.

On the contralateral side here, on the patient’s left side, we have accessed percutaneously; that is, without any incisions, just with a needle. Through the needle, we introduced a guide wire. Over that guide wire, we have placed a sheath that has a valve that lets us work without blood loss.

Over this wire, we then have a catheter that we will obtain an angiogram. Hopefully you can see this going up and you may note that there are a series of radio-opaque metal markers on the catheter that, once it’s in the body, will allow us to observe those markers, make measurements, and so forth. So we’re going to pass that over the wire. Maybe we can switch to the fluoro screen at this point and watch it go up through the abdominal aorta, into the region of the thorax. You can see it coming up there. I think if I stop, you can see those radio-opaque markers that I mentioned. We’ll pass that around the aortic arch, into the ascending aorta, and then Dr. Kwolek removes the guide wire and we now have a catheter in the thoracic aorta that will allow us to inject contrast or dye and obtain an aortogram or a road map from which we can work.

CHRISTOPHER KWOLEK, M.D.

I think it’s important to note as well that we’re working in a fully functional endovascular suite here. We actually have a ceiling-mounted system that you can see that allows us to have basically state of the art imaging right in the operating theater. This has a 16” eye and both digital subtraction and road map capabilities that allow us to do virtually any type of endovascular procedure in the operating room. Now what we’re going to do through the groin, that we’ve opened through a small oblique incision, we’re going to access the common femoral artery. This will be the side that we have chosen to introduce our stent graft through. Again, we’ll advance a second wire up under fluoroscopic guidance and you’ll again be able to appreciate the image on the screen. You can see our
second wire coming across. We’ve chosen a little bit stiffer wire. What we’re going to do is switch out for another catheter now. We chose a long 125 cm catheter. Anything over the length of about 90 cm should suffice. Again, we just want to direct our wire around the aortic arch and then we’ll exchange this out for a relatively stiff guide wire, which should give us better trackability in terms of delivering the device into the transverse thoracic aortic arch.

DAVID BREWSTER, M.D.

So again you see the basic principle of the guide wire, with the catheter going over it. The same will be used for the delivery of the advice itself. Inserting things over the wire is obviously important to keep the device, the catheter, in the middle of the blood vessel and avoid the possibility of injury.

The need for a small open incision is obviously necessary because of the fairly large caliber of the device that will be apparent to you in a moment.

CHRISTOPHER KWOLEK, M.D.

Now on the screen, on the monitor, you should be able to notice our catheter and guide wire around the aortic arch, so essentially we have two catheters now, our marking pigtail catheter and our second catheter. The second catheter we’re going to use to deliver an Amplatz super stiff guide wire around the arch and then that’s the wire we will also use for the delivery.

In the meantime, what we’re going to do is, on our side table, we’re going to open up the proximal first portion of the device and go ahead and prep it, flush it with Heparinized saline solution. We’ll also use some lubrication.

RICHARD CAMBRIA, M.D.

Dr. Kwolek and Dr. Brewster, we have some email questions coming in, so I’m going to take the first of these. One of our physicians has inquired about the general availability of this procedure. Is this procedure available at all types of hospitals and across the spectrum of geographic regions? The answer to that is, at the present time, all thoracic aortic stent graft technology in the United States is available only in the form of FDA-approved clinical trials. There are now three such open clinical trials and we hope that we will be rapidly gathering the information available to prove the worth of this technology. There’s very little doubt in the minds of most of us that this technology will prove to be a major advance forward and there may be a commercially FDA-approved device as early as mid-2005.

I believe that Dr. Brewster and Kwolek have the device now ready to insert.

DAVID BREWSTER, M.D.
If we can go back to the overhead camera, we’ve just taken the wrappings off the thoracic endograft. You can see here, the device is of fairly large caliber; hence the need for the open incision. Dr. Kwolek is flushing some Heparinized saline to prep the device, prep the guide wire lumen. It has a tapered cone tip here that allows passage, streamlined passage up the blood vessels. The device itself is contained within this sheath. You can see here there’s a component of bare mental stent here. The endograft then sits here. This device usually will come in several pieces, using a so-called modular concept where one piece is inserted and then another piece is tromboned and overlapped into that and that allows more precise anatomic confirmation of the device to the anatomic and measurement needs.

CHRISTOPHER KWOLEK, M.D.

The other issue is that most of these devices range in size somewhere between 22 to 25 French, so what we’ve found is often, if you can make a little transverse arteriotomy in your artery, that will help you with repair afterwards. We have found that most often you can do a primary repair, believe it or not, the vast majority of the time with these cases. Occasionally you will have to do a common sternal artery repair and endarterectomy, but again, we’ve been fairly happy that most of the time we can do a primary repair after removing the device. Now what you’ll see us do is leave that wire in place, which is seated well around the arch. We’re going to apply a clamp

RICHARD CAMBRIA, M.D.

While Dr. Kwolek is preparing to open the artery for the insertion of the stent graft, we’ll take another question. One of our listeners wants to know how do you determine a patient’s candidacy for a stent graft? Well, this is strictly an anatomy-driven decision. At the moment, some 50-60% of thoracic aortic aneurysms that we see are anatomic candidates for stent graft repair. However, that is very much a shift in baseline. If we can use the analogy and draw conclusions from the experience with abdominal aortic aneurysm repair in the early stages of the evolution, particularly as these devices are inserted in the form of clinical protocols, the anatomic criteria are somewhat restrictive. With time, a larger percentage of patients will eventually be treatable with this technology.

CHRISTOPHER KWOLEK, M.D.

One of the other things we’ve found is, particularly when you’re going around the aortic arch, you’re fighting that angle or the genu of the thoracic aorta, as Dr. Cambria mentioned. If you take a look at the preoperative imaging, you can see there’s quite a bend there. What we’ve found often is that using a second wire for support, an Amplatz or Lunderquist wire, can make a significance difference in terms of going out.

DAVID BREWSTER, M.D.
As we’re getting ready to get this situated, it may be a good time to go back to Dr. Cambria for any further questions from the internet.

RICHARD CAMBRIA, M.D.

Alright. We do have some questions coming in from our listeners and viewers today. One viewer wants to know, if physicians at one center have said that a patient is not an appropriate candidate, does that rule it out or would it be appropriate to have this reviewed in another environment or another hospital? The situation with who is and who is not a candidate for stent graft repair, as I previously mentioned, is very much an anatomy-driven decision. In current practice, it may or may not be necessary to do a procedure known as a diagnostic arteriogram to continue the evaluation. At the present time, it is fair to say that there are not many centers with much experience in stent graft repair of the thoracic aorta. At our hospital, we do have the luxury of the multidisciplinary team in the Thoracic Aortic Center for thorough evaluation of these patients. At the present time, our total experience with thoracic aortic stent graft repair numbers nearly 100 patients.

Let’s check back on the procedure to see how we’re doing.

CHRISTOPHER KWOLEK, M.D.

Alright. We’re just exchanging wires at this point.

RICHARD CAMBRIA, M.D.

Dr. Kwolek has prepared the femoral artery. As you heard mentioned by Dr. Brewster and Dr. Kwolek, very stiff working wires are used to introduce this device because a constant in patients with thoracic aortic aneurysms is significant buckling and turning of the aorta, often below the aneurysm, in addition to the turn of the transverse aortic arch into the descending aorta, something we refer to as the genu of the distal transverse aortic arch.

You’re watching Dr. Kwolek do a catheter and wire exchange through the left femoral artery. As we exchange out for the stiffer wire, what it did was kick our catheter back down and we were not happy with our ultimate wire position, but I think we’re well over now. I think it’s an important point, if you end up losing your position, what we ended up doing was going back through a directional catheter, going back to a very floppy-tipped wire to gain access in the ascending aorta. Now, once again, we’ll switch out to either a Lunderquist or an Amplatz Super Stiff. It’s important for people, particularly starting off with these procedures, if you realize that these stiffer guide wires are not something that you necessarily want to lead with, so rather than take a chance and causing perforation or difficulty with negotiating that aortic arch, it’s always better to come out and be safe, put your catheter back in the ascending arch or ascending aorta, and then again exchange out, as you’re watching Dr. Brewster do, so we have excellent access now. We’re going to come back out with our catheter. We have the wire in place.
The other thing that we’ve found helpful is that we’ll often mark the position of our wires fluoroscopically in the ascending aorta and we’ll actually mark them on our table with a little marker so that we know relatively where our wire position is.

DAVID BREWSTER, M.D.

While we’re on the subject of stiff guide wires, Chris, say a word about isolated transfemoral as opposed to through-and-through wire access from an upper extremity access artery.

CHRISTOPHER KWOLEK, M.D.

Occasionally we have found that what you can do is, through a brachial approach, do a body floss technique, where you’re bringing a relatively stiff wire through and through all the way from, say, the left brachial position. The potential caveats with that are, (1) you need a long enough wire, usually 300+ cm. Second of all, you have to be very careful as you’re using these wires across the origin of the vessels in the arch that you don’t saw through the vessel. The other thing we’re going to do as we go up, you’ll notice that our position is such that we don’t have the arch completely open. What we’re going to find is we’ve put this patient in a prone, supine position, but we’ll also put a roll underneath his shoulder and now we’re going to oblique our image intensifier so that we actually open the angle of the arch as we’re coming up and that will help us to negotiate things a little better.

RICHARD CAMBRIA, M.D.

Now we’re watching the initial stages of the stent graft insertion into the common femoral artery and we will follow it.

DAVID BREWSTER, M.D.

The other thing that’s important now, with this big device, is to make sure it’s going through the vessels satisfactorily.

RICHARD CAMBRIA, M.D.

With this large bore hardware, as Dr. Brewster emphasized...

DAVID BREWSTER, M.D.

You can see it in the iliac artery now. It seems to be passing very nicely.

RICHARD CAMBRIA, M.D.

Now you can see that aortic arch opening up.
CHRISTOPHER KWOLEK, M.D.

Dr. Cambria may have mentioned that we have found not infrequently that in an LAO oblique position, when you open up that arch, your endotracheal tube tends to be a very, very good marker for where the subclavian and other arch vessels come from. Now what we’re going to do is remove that stiff wire, now that we’ve delivered our graft to the approximate position, and we’re going to hook up our power injector so that we can actually perform a contrast arteriogram. For this, we’re going to go to the subtracted image on the right screen. Obviously we’ve systemically Heparinized this patient prior to performing this.

DAVID BREWSTER, M.D.

We will typically introduce the device, as we’ve done here, prior to obtaining our mapping arteriogram because of course introduction of the device itself can change the conformity of the thoracic aorta.

CHRISTOPHER KWOLEK, M.D.

We’re going to stay with our live image on the left and once we get ready to do our subtraction run, then we’ll go to our subtracted image on the right. That actually shows it very well. You can see where our catheter is. We can appreciate where our graft is. Okay, we can go to the subtracted image and that lines up about perfectly, so in fact, as we said before, that endotracheal tube lines up almost perfectly with the distal aspect of the origin of our subclavian artery on that left side.

DAVID BREWSTER, M.D.

I think you can see the very beginning of the aneurysm. The end of our view piece of the device is more or less right at the beginning of the aneurysm. Hence, we’ll have to use and sometimes even three pieces with the modular concept in order to achieve an endograft of adequate length to exclude the aneurysm from circulation.

CHRISTOPHER KWOLEK, M.D.

One of the debates we had as well in deploying this device is should we just try to land distal to the genu of the area of flexion. With this device, there’s a fair proximal component and we thought it would be safer, in terms of getting a seal and not having any issues with our proximal attachment, to come around the curve if we could and again deploy right there.

We’ll stick right at the subclavian. I think we can get a little further around. Craig, can we get a road map image on that and let’s go ahead and mark our monitor too.

DAVID BREWSTER, M.D.
As Dr. Kwolek mentioned, I think the endotracheal tube is really quite a good marker, just by happenstance, of the origin of the subclavian artery and the proximal extent of where we probably would want to start the endograft deployment.

RICHARD CAMBRIA, M.D.

While we’re readying the screens for the initial deployment, we’ll take one more question from our viewers. There’s a very important question and it’s a bread and butter question. What is the typical size that an aneurysm of the thoracic aorta has to be before repair is recommended? 6 cm is the typical size threshold for intervention in the descending thoracic aorta. We’re back live on the fluoroscopy screen now.

CHRISTOPHER KWOLEK, M.D.

You can go ahead and answer that question, Rich. We’re just going to do our final positioning here. We’re opening up our second piece as well. I’m going to stay a little bit here. We do have the capability of doing a road map subtraction image on this as well. Again, with the markers that we have, we have found that it’s helpful to mark something on the screen or the patient. There’s a little bit of initial resistance to overcome with that deployment, but then you’ll notice the first part will flower and then we’ll do our final positioning.

DAVID BREWSTER, M.D.

You can see the two radio-opaque markers that denote the beginning of the covered endograft.

CHRISTOPHER KWOLEK, M.D.

You can also see how this is required to make a fairly sharp turn or bend. Our last component of the device is opening now. Again, we still have our wire access across. Dr. Brewster, when we pulled away, had pulled the pigtail catheter back, so now what we’ll do...

DAVID BREWSTER, M.D.

I think you can see the stent components. There’s the bare mental stent, the uncovered portion, proximally. That’s meant for fixation. Then the radio-opaque markers denoting the beginning of the Dacron cloth covered device.

CHRISTOPHER KWOLEK, M.D.

Now we’re marrying the components so the profiles improve. We’re going to pull this back some, but we’ll leave the whole sheath delivery system in place until we have the second piece available. The one thing we want to make sure is that we keep the wire in
place so we don’t lose wire access across our stent graft, so that we still have access for our second component.

RICHARD CAMBRIA, M.D.

That looks very nice, Chris. I’m really pleased with that sealing in the distal transverse arch. While that fluoroscopy image is up that, it is not advised to try and seal, particularly to have a graft end at the genu of the transition from the arch to the descending aorta because you tend to get bending and inadequate apposition of the stent graft to the aortic wall. We’d like that proximal component, as you can see it in the distal arch now, nice and parallel and well apposed to the aortic wall.

DAVID BREWSTER, M.D.

This is a good illustration of the endovascular suite, with a carbon floating top table. Dr. Kwolek is able to readily control that and move the table as necessary for imaging.

RICHARD CAMBRIA, M.D.

So the first component of the stent graft has been delivered and now we are preparing to load a second component into place. While Drs. Kwolek and Brewster work, I’ll take one more question. The question is, is stent grafting being done on the ascending thoracic aortic aneurysms? Well, when one considers frontiers, that is as yet a frontier that has not been traveled, other than a rare individual case in phase 1 studies. The ascending aortic topography is obviously much more difficult to deal with, since it is immediately beyond the jet of ejection from the left ventricle and one needs to deal with anatomic features like the coronary artery ostia and the sinus of Valsalva. I do, however, believe that as technology and development proceed, that eventually even ascending aortic lesions will be treatable with this modality.

An important question here has been asked about the size of the iliac vessels required for the device we use and what preoperative imaging techniques do we use to evaluate that? This patient had both a CT scan, CTA, and an arteriogram. Since the descending aorta is proportionally much larger than the abdominal aorta, the size of the hardware required for delivery systems is substantial, ranging from 24 all the way up to 27 French, depending upon the size of the particular graft that is used. Stated differently, a 22 diameter graft might be deliverable with a 22 French introducer system, whereas a 40 mm diameter graft, which is much more bulky, would require up to a 27 French introducer system, so one needs to have an absolute minimum of 8 mm in the external iliac artery. Indeed, because of the size of the hardware, iliofemoral access issues are a constant when dealing with thoracic aortic stent graft.

CHRISTOPHER KWOLEK, M.D.

We’re ready to go with the second piece. What we’re going to do is float down and take a look at the abdominal component. You’ll notice that we still have our marking pigtai
catheter, although we have not put our second Lunderquist wire back up. We’re now going to deploy in the relatively straight portion of the descending thoracic aorta, so hopefully, since we’re not going to negotiate that arch, we shouldn’t need the same level of stiffness to get up and around. What we’ll do is float the table as we come up.

Now, one of the keys we’ve found over time is that we actually like to have a not insignificant amount of overlap in terms of these devices so there’s not potential for either leak or detachment later on down the road. You can almost appreciate on fluoroscopy image where the aneurysm sac is and we’ve found that close to a 50% overlap is probably what we want to aim for. I’m going to try just a little more in and then we’re going to start with the deployment by slowly pulling back.

DAVID BREWSTER, M.D.

Let’s have the overhead camera for a moment so you can appreciate how the deployment occurs. The device is here. This component is called a pusher or a stabilizer. This will be fixed to maintain the device. This component will then be pulled back over there to uncover, by pulling back this sheath, to uncover and deploy the stent graft component, so as you can see here, Dr. Kwolek will fix that and then withdraw the sheath with the other hand.

CHRISTOPHER KWOLEK, M.D.

Again, we’ve gone a little bit far up, at least to overcome the initial pull and you’ll see as we start to flower, we can make any final positioning changes again. We’re going for a significant amount of overlap, so we’re going to go ahead and accept that. We have a third piece here and I think we’ll probably end up using that, at least by looking at our distal aspect, we probably have a little more of the aorta that we want to cover. There’s a little pusher device here that you’ll notice. I’ve pulled my sheath back. What we’ll do is pop that back and you’ll see the final part deploy right there. Let’s watch our wire and make sure our wire is all the way around so again we don’t lose access to that. What we’re going to do is, as we keep our wire in place, we’re going to pull our whole nose cone device back in, marry the two pieces, lock that, and again we’ll bring the device out.

RICHARD CAMBRIA, M.D.

As mentioned, this is a nice case for illustration, since fluoroscopically one can see the mass of the aneurysm. Alright, while we’re loading up the third component of the stent graft, we’ll take a few more questions, which are pouring in on our email circuit. One questioner obviously understands some of the potential complications of this procedure. What percentage of postoperative brain complications? Indeed, in the first series of thoracic stent grafting, because of the extensive manipulation in the aortic arch, intraoperative stroke is a potential complication. We’ve done well with that, with a less than 5% stroke rate in our stent graft patients. I do, however, think it’s important to take a very careful look at the qualitative aspects of the aortic arch. If extensive mushy mural
thrombus is seen in the aortic arch, those patients clearly are at higher risk for intraoperative stroke and one may choose another strategy.

One surgeon in the audience has asked, if we’re using multiple devices, wouldn’t it have been wiser to build up from the bottom, rather than down from the top? That is, in fact, a strategy which is used in certain patients, depending (a) on anatomy and (b) on the particular device construct. This particular 2-3 piece component device construct is designed to deploy from proximal to distal so that we can have appropriate size overlapping of the interlocking components. There are circumstances, in particular when the distal seal zone is more precise or more limited, where one would build from the bottom up, but in practice, the overwhelming majority of our thoracic cases have been built from proximal to distal because it is the proximal seal zone that is often most limited, most crucial, and most subject to problems with deployment accuracy.

CHRISTOPHER KWOLEK, M.D.

Rich, I think the time that makes a difference is if you’re planning to go all the way down to the celiac and perhaps put a bare stent across the celiac, then often what we’ll find is that putting that celiac piece in and then building back in between two different devices is the way to go. One of the other problems we’ve also found is that, in terms of trackability, if you’re always building from distal to proximal, sometimes with these devices you’ll have difficulty tracking through the previously deployed devices more proximally.

What we’re doing now is we’ve had a little bit of kinking with one of our wires. That’s another not uncommon problem. These are fairly stiff and rigid wires. If you bend them, you can often have problems with trackability and deliverability of the devices, so in fact, what we’ve done now is we’ve deployed our first two devices. We’re going to attempt to place another catheter up over this wire, not losing our access What we’re trying to do is get an unobstructed fresh wire to pull through this. Since this wire has kinked and frayed, we’re going to have to cut it and I don’t think we’re going to have any success putting the device over this and we may not even be able to get another catheter over it, so we’re going to again work with the catheters here for a minute, get our access back across the aortic arch, make sure we’re within the lumen of the graft, and again, these are self-expanding grafts so they approximate to the wall very well and after that we’ll have a final piece to deploy, then we’ll proceed with balloon dilatation along the overlap sites and in our proximal attachment zone and then a completion angiogram.

RICHARD CAMBRIA, M.D.

While we get a new wire in, we’ll answer a few more questions that are pouring in. One viewer wants to know, is there a limit to the size of the aneurysm that can be treated? The limitation is not really on size or diameter of the aneurysm, but rather the extent of the aneurysm proximally and distally in the thoracic aorta. The most common pattern that we see in our referral practice through the Thoracic Aortic Center here is a patient who, after all is said and done, has true thoraco-abdominal extent of the aneurysm. Stated
differently, it is an extensive aneurysm proceeding into the visceral aortic segment, which is the single most common anatomic limitation to stent graft repair, but there’s no finite limit of the size of the aneurysm that can be treated.

One of our physicians wants to know what the role of thoracic aortic stent grafting is in patients with aortic dissection. That is a very different pathology than we’re dealing with today and it is yet to be studied in any substantial number of cases or clinical trials in this country. One needs to talk about both acute and chronic dissection because the roles and goals of stent grafting in the two circumstances are quite different. In the acute phase of the disease, stent graft deployment can be used to seal an entry tear, for example, of a distal dissection, correct early malperfusion syndromes and, in theory, prevent the single most common late complication of the procedure, namely aneurysmal dilatation of the outer wall of the false lumen. Clinical trials will eventually be held in the various phases of aortic dissection, but to date, there is very little experience with use of stent grafts in a circumstance of acute and chronic dissection.

One listener wants to know what are the contraindications to this procedure? Well, the contraindications to the procedure are primarily anatomic. If a patient does not have adequate proximal and distal seal zones above the aneurysm, that represents an anatomic contraindication. As previously stated, extensive mural debris in the transverse aortic arch does make the risk of stroke intraprocedurally higher and constitutes, in our view, a relative contraindication.

DAVID BREWSTER, M.D.

Okay, we’re about to put the final component over the wire here. You can see it being loaded on. Again, a very stiff wire.

CHRISTOPHER KWOLEK, M.D.

Again we’re going to float down. Watch as this comes up, we have our wire marked in pen. We’ll go to our live fluoro screen. You can watch the device coming up. You can see it’s just approaching the second piece that was deployed. You can see the radio-opaque markers. Now it’s being overlapped again, by about 50%. We’ll pull our marking catheter back. You can see where the diaphragmatic pleura area. You can also see the patient’s valve in place. We have about a 50% overlap. I think we’re well down below that previous aortic aneurysm segment. Is everybody happy with that position?

DAVID BREWSTER, M.D.

Yes.

RICHARD CAMBRIA, M.D.

Any need at this point, Dr. Kwolek, to check the position of the celiac access or are you comfortable that we’re still well above it?
CHRISTOPHER KWOLEK, M.D.

I think we’re comfortable we’re still well above it, but that’s an important point, particularly if you’re not used to doing these routinely. I think it’s always wise to double check. You can see where the genu is. You can see where the sac is relative to everything else. Our wire is up and around by the valve, so again, I think we’re in pretty good position here. I think we’ll start a little bit high, deploy down, and then we’ll come back and go ahead and do balloon angioplasty for our final component.

RICHARD CAMBRIA, M.D.

We’re deploying the third component now.

DAVID BREWSTER, M.D.

You can see obviously these are so-called self-expanding stents, where once the sheath is removed, the metallic memory forces the stent to expand on its own.

CHRISTOPHER KWOLEK, M.D.

Now this is a large enough sheath size that when we take this delivery system out, we will exchange it out for a Cook 18 French sheath, which will allow us to do any further manipulation and angiograms as well as our balloon dilatation.

RICHARD CAMBRIA, M.D.

Chris, say a word about the desirability and necessity of balloon inflation after the stent graft is deployed.

CHRISTOPHER KWOLEK, M.D.

Well, theoretically the fixation is as you explained, with the self-expanding stents due to the continuous outward radial force. Most of the devices that we’re currently using or considering using are designed to be placed with at least 15-20% oversizing, so from a theoretic standpoint, the device itself should be sufficient to seal. Nevertheless, we have found that when we’re trying to mold that graft, particularly at the proximal attachment site and, in addition, at the overlap junctions between the graft components, we’ve found that it has been very helpful to go in with a fairly large, compliant balloon. The difficulty, as you might imagine, is finding balloons that are large enough and compliant enough to mold to the aortic anatomy.

DAVID BREWSTER, M.D.
A large working sheath has now been placed in the femoral access site. This will allow us to work through it, as Dr. Kwolek said, with the balloon and subsequently a final angiogram.

CHRISTOPHER KWOLEK, M.D.

You’ll watch as the balloon tracks over. We’ve found, in fact, it often takes two syringes with fairly dilute contrast and a little bit of hand strength to be able to sufficiently inflate this. We’ll let our anesthesia colleagues know that we’re getting proximal inflation.

DAVID BREWSTER, M.D.

You can see the balloon being inflated. The concept here is to mold the endograft to the contours of the aorta and further enhance the seal.

CHRISTOPHER KWOLEK, M.D.

Again, we’re not necessarily using an endo-inflation device for this. This is more looking at the contour and our radiographic images. We’ll bring that down, then move it back and hit the overlap sites further. One of my colleagues here is holding that in place, so obviously there’s a temptation for that to fall back and be carried distally, just with normal aortic flow. Again, we’ll mold this here, proximally, at the fixation site. Again, you can see how that molds rather nicely.

RICHARD CAMBRIA, M.D.

I’m really pleased with that length of proximal fixation we have because we know from our preoperative imaging studies that we had 4 cm above the aneurysm and 2 at the genu. Drs. Kwolek and Brewster made the decision to carry that seal zone around to the transverse arch.

CHRISTOPHER KWOLEK, M.D.

One might argue that we went a little bit far distally, although if you look at where that second piece seems to end the aneurysm shadow that you see, you want at least a good 20 mm or 2 cm and I think we’ve achieve that, perhaps a little bit more. Again, depending on the segments that you choose and the types of pieces that you choose, with this design you have the option of having a bare stent distally. Again, that’s designed more if you’re going to be very close to the celiac access and you’re concerned about potentially needing a seal right there.

DAVID BREWSTER, M.D.

Now, balloning in this segment, obviously we’re in the aneurysm, but what we’re aiming to do is to make sure the overlap of those pieces forms a good seal within the endograph conduit itself.
I think that’s important, as has been mentioned throughout the broadcast, because early on I think ourselves and some of our colleagues, at least across the States here, if not internationally, have noticed that if there’s less overlap, with the confirmation changes in these aneurysm sacs over time, you can, in fact, get dislodgment or separation of components with a delayed endo leak and then the necessity to come back and add an intervening segment and re-seal the aneurysm sac.

While the sequential balloon inflations are occurring and, in particular, as you come down to the distal seal zone in that lower descending aorta, Chris, one of our viewers wants a comment on intercostal vessel occlusion and the risk of spinal cord ischemic injury. I did address this somewhat in the initial presentation and early in our experience, indeed, we wanted to treat that distal seal zone as short as possible so as not to occlude intercostal vessels in the critical intercostal segment, that is between T9 and L1. However, experience has shown that the single most important factor is getting a good seal and we certainly don’t hesitate to cover intercostal vessels in the lower descending aorta. Certainly our distal seal piece in this case, right where you see the balloon going up now, is certainly in the T9, T10 region of the lower descending aorta.

Another technical question about the incidence and risk of perforation during this procedure. Thankfully, both in our experience here and internationally, perforation of the aorta occurs rarely during this procedure.

Okay, I think that’s probably enough balloon, so we’ll insert the angiographic catheter up and hopefully take a final picture showing good exclusion of the aneurysm. Also what we’ve found is if we’ve molded it well and the catheter’s not been in too long, hasn’t softened up, we can actually, as Dr. Brewster is doing, pass it back proximally into the ascending aorta. Again, we have a little bit of a tricky angle there, where we may need a wire.

While Dr. Brewster and Dr. Kwolek prepare to perform the completion arteriogram, one of our viewers wants to know what makes the care in the MGH Thoracic Aortic Center so unique. The Thoracic Aortic Center here at the Mass. General is a multidisciplinary group, including participants from our own Division of Vascular Surgery, colleagues in the Division of Cardiothoracic Surgery, and the Department of Cardiology here at the MGH. This multidisciplinary approach allows a multifaceted evaluation of patients with these often very complex thoracic aortic problems to be seen and evaluated comprehensively and in one sitting by multiple disciplines and bringing all of those
forces to bear together, we think, affords a unique opportunity for management of patients with so-called complex thoracic aortic pathology. Are we ready for our angiogram?

CHRISTOPHER KWOLEK, M.D.

We have a pigtail catheter again back in the aorta. We’re trying to see if we can catch this entire field of view with a 16” II and I think with a couple different maneuvers we can do it.

RICHARD CAMBRIA, M.D.

What exactly are we looking for on this completion arteriogram, Dr. Kwolek?

CHRISTOPHER KWOLEK, M.D.

A couple different things. 1, we want to make sure that our proximal head and neck vessels are intact and we haven’t created any trauma in either the transverse arch or ascending aorta with either our wire or catheters with the manipulation. Second of all, we also want to take a look at that proximal seal, which I think will be fine, and make sure we have a good seal, that there’s no proximal endo leak. Finally, we want to make sure our overlap zones and our distal attachment site are intact as well. I would predict that we’re not going to have a significant amount of flow into that aneurysm sac.

DAVID BREWSTER, M.D.

Alright, we’re suspending respirations.

CHRISTOPHER KWOLEK, M.D.

Breath hold. We’re going to the subtracted image on the right screen.

DAVID BREWSTER, M.D.

Looks terrific.

RICHARD CAMBRIA, M.D.

I like that picture.

CHRISTOPHER KWOLEK, M.D.

Again, we could have run out the length of our subtracted image a little bit longer, but I think you can appreciate on that, you see our subclavian vessel is widely patent. We’ve sealed nicely proximally. There’s no flow in our aneurysm sac. We’ve certainly got a good, intact distal attachment zone. Again, we’re still up in the chest there.
RICHARD CAMBRIA, M.D.

Very nice, gentlemen.

DAVID BREWSTER, M.D.

Okay, so the procedure will be concluded by removal of the devices, primary repair of the femoral arteriotomy site, withdrawal of the sheath in the contralateral groin, and compression.

CHRISTOPHER KWOLEK, M.D.

Again, just a minor point, but we don’t like to pull catheters back across the stent graft if we don’t have to. You’ll notice our pigtail catheter has a bit of a curve on it, so we’ll preferentially put a wire back up there and remove it over a wire, rather than taking a risk of having that becoming entangled in part of the stent fixation system. Essentially we’ve finished here. What we need to do now is remove our right femoral sheath, go ahead and primarily repair, hopefully, that common femoral artery site. Then we’ll let that Heparin drip down and just pull the left femoral sheath and hold direct pressure.

RICHARD CAMBRIA, M.D.

Alright. I think we’re ready to go to our few wrap-up concluding remarks. At this point, we’ll finish the presentation with just a little bit of wrap-up of what the experience to date across the world has been with this procedure. As mentioned, in this country we are currently in phase 2 FDA-approved clinical trials, but summarized in the graphic on your screen are some of the major series to date, including our own and reports from Stanford Mt. Sinai and Eurostar, which is the largest series, refers to a collective group in Europe accumulating and combining their experience. As you can see, the technical success of implantation runs relatively high, in the over 80% range, but if you look at the mortality column, you will note that this is not necessarily a benign procedure and it reflects the fact that many of these patients are treated in urgent, desperate circumstances where there is no other treatment option. The final column, SCI, refers to spinal cord ischemia, which has been in the less than 5% range in most of the major series.

I think we can summarize by saying that the technical results to date have certainly been acceptable with this procedure. The procedural mortality is largely referable to the clinical circumstances. A number of our patients are treated for frank ruptures, erosion into the tracheobronchial tree, and so forth. The mid term follow-up results really reflect the evolution of the design concept. We certainly believe that this will be a viable, if not preferred, option for many patients with thoracic aortic aneurysm. We don’t really have time to talk too much about the nuances of aortic dissection, a very complex sort of pathology which will be the next frontier, as illustrated in this cartoon. We do have a particular experience and interest in this disease and we have put together some series over a long period of time, indicating that many patients with distal aortic dissection do
have vascular complications that require treatment and these complications contribute significantly to mortality. The largest series, again, comes from Europe, with results in dissections indicating that the technical success runs about the range where we see in degenerative aneurysms and short-term follow-up has been favorable. So the outlook, we think, is very promising for this new technology. It’s an exciting time to be involved in its application. There is very little question in our minds and in the minds of people involved with stent grafting that, similar to the rapid evolution and acceptance of this technology for treatment of abdominal aneurysms, a similar evolution will be seen in the thoracic aortic realm. Its utility in the treatment of degenerative aneurysms seems assured, but separate trials in other pathologies will be required to clarify the ultimate role of this technology in aortic dissection, intramural hematoma, and so forth.

It’s time for us to end our presentation now. We’d like to thank you for joining us today. We hope you found this an educational experience. Thank you for your attention.

NARRATOR

Thank you for watching a live stent grafting procedure to treat thoracic aortic aneurysms. To obtain more information, make an appointment, or make a referral, please click the buttons on the player window or the web page.