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The SoloPath Balloon-Expandable Sheath

Dr. Erin M. Moore discusses a better way to place thoracic and infrarenal aortic endografts with potentially less vessel trauma, which may increase the patient potential for minimally invasive treatment.

How did you first become aware of the SoloPath device (Terumo Interventional Systems, Inc., Somerset, NJ), and what led to your interest?

A few years ago, I had a couple of cases involving marginal surgical patients who were EVAR candidates but required either unilateral or bilateral conduits for graft placement. A friend of mine and I both commented, "I really wish we had a sheath that would go in at one size and get a little bit larger. I just don't know how you'd get it back out." About 6 months later, we were having the same conversation, and he said he heard there was a device like that on the market. I did some research and actually saw the first mockup of the sheath in *Endovascular Today*.

I started using the SoloPath device in a few cases at my previous practice, then continued here in Jacksonville. We had a few cases with issues regarding access—both for infrarenal aneurysm repair and for thoracic aneurysm repair. I mentioned the device to my current colleagues as a way to avoid getting into what was essentially reoperative territory for some of these patients. From there, we kept it on the shelf and started using it on a more regular basis.

Can you describe your experience incorporating SoloPath in your cases?

As with many things in vascular surgery, necessity is the mother of invention. You find yourself in a situation where you have a need, you find that there is already a device available, you bring that to your practice and see if you can use it to help your patients. The same was true with SoloPath. Our group found that we had more than a few patients with infrarenal aneurysmal disease who we wanted to treat with an endograft, but they had very difficult access vessels and a lot of calcium and narrowing. Because of the sheaths that were required for that particular procedure, the size

Figure 1. SoloPath: folded distal segment.

was prohibitive unless there was some sort of preoperative or preplacement angioplasty, and/or stenting of the iliac segment, to get into the aortic sac and up to the infrarenal neck for treatment.

For us, that's where SoloPath became very helpful. We could go into the vessel at a much lower profile size, achieve access through the area more easily, and get our device in a place where we were happy. My main concern was that once you get the device in the right spot and it's inflated, how easy will it be to bring the sheath back out again?

That's where the learning curve comes into play. There is an understanding that the kind of disease you're looking at can be prohibitive. That is to say, a patient with iliac occlusive disease who has circumferential calcification—a sort of "lead pipe" type of vessel—can be very daunting and dangerous if you're not careful when you go in and dilate. Whether it's with a sheath or a stent, or even a stent graft, you have to be prepared that you might end up injuring the vessel to the point of having leakage, and you need to be able to handle that effectively.

Initially, we were pleased that the device went in quickly and effectively. The instructions called for dilation to 20 atm and keeping it inflated for 60 seconds. We also followed the instructions for use to remove

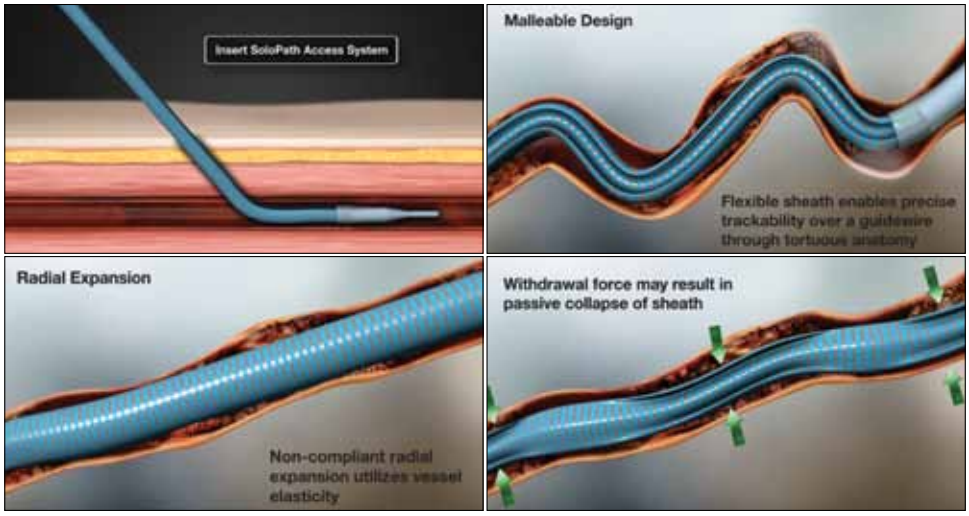

Figure 2. SoloPath: mechanism of action.

the device using steady backward traction. With each SoloPath sheath removal, we have not had any problems with undue traction on the vessel.

This is obviously done over a wire to maintain wire access, so that if we need to do a repair, we can. In regard to sheath removal, we were very grateful that the device came out just as it was designed.

Which grafts have you delivered through SoloPath? What considerations would you share with colleagues regarding delivery of those grafts through SoloPath?

My main graft of choice for AAA repair is the Excluder (Gore & Associates, Flagstaff, AZ). Before they came out with their own proprietary sheath, we were using a sheath made by Cook Medical (Bloomington, IN). Neither sheath is hydrophilic. The SoloPath sheath and the Excluder device have functioned well together in our experience. I would encourage anyone that before using SoloPath for the first time in a case, to get one in your hands and learn how it works ex vivo. It's probably in your best interest to try a demo model of your endograft of choice, as far as type and size for that particular case, and decide whether the device will fit into the SoloPath versus a standard sheath. How will it work? Will it fit and pass through the sheath easily? How is it going to look in relation to the markers on the graft device versus the markers on the SoloPath? You should know how it's going to behave before you begin the procedure.

Another factor to consider is vessel tortuosity. The SoloPath is a pretty useful device in that it will take turns very nicely around fairly tight or tortuous C-loops while maintaining its structural integrity to allow for endograft passage and placement.

What clinical advantages do the low profile, malleability, and radial expansion of SoloPath provide you?

The device itself is fairly slick because it has a lubricious coating that makes it easier to insert. It starts out in a "W" conformation and then expands to a full circle. When you are initially putting it in over the wire, it tends to travel fairly quickly. The expectation is that you are going to have a little bleed back along the W-shaped channel until you get to the actual hub of the sheath, at which point the conformation becomes more cylindrical and gives you the seal in the arteriotomy to seat the sheath in place and be hemostatic.

You have to account for vessel tortuosity and make sure that you choose the right wire, whether it is an Amplatz wire (Cook Medical), a Lunderquist wire (Cook Medical), or another rigid wire.

As far as the radial force, with the first balloon expansion, the balloon is cylindrical, and the sheath itself will be cylindrical. When you take the balloon down, remove the balloon introducer, and start working through it, it's not perfectly cylindrical; it takes on a different conformation shape, almost a loose, rounded-off diamond shape. Radial force grants the ability to hold the vessel open enough for me to get the graft in place. This speaks again to the fact that you need to know which device you are going to use to make sure that it's going to fit into that particular size of SoloPath. The ability to place the sheath initially without dragging it across the iliac anatomy and "dottering" the vessel helps to avoid significant intimal damage in an area that may not be covered by the endograft after completion of the case.

I think it's important to be able to easily place a sheath into an otherwise diseased vessel while avoiding a significant amount of drag and traction against the intimal surface. Radial force applied for inflation as might be applied during standard balloon angioplasty is far better tolerated than the axial load from an oversized sheath in a small vessel.

Case in point, we performed thoracic endograft placement in a patient who had already undergone

Figure 3. The SoloPath balloon-expandable transfemoral access system.

infrarenal open aneurysm repair and had fairly tight external iliac arteries. Our concern was having to perform an open, retroperitoneal conduit placement in reoperative territory in a patient who was elderly and not in the greatest shape from a pulmonary standpoint. It's tremendous if we can avoid that. In this case, we were able to take the thoracic device, which was indicated for a 22-F size, and pass the 34-mm thoracic endograft through the 21-F SoloPath without any difficulty and complete our case.

So to reiterate, in our experience, SoloPath provided the radial expansion and the radial force we needed to place the graft but did not grip the wall so aggressively that we couldn't get it back out—that's what I like about this sheath (Figure 1).

What effect might this balloon-expandable sheath have on your patient selection?

Our main focus was on patients who had pretty significant common and external iliac occlusive disease with an associated infrarenal aneurysm. But what I think is really remarkable and advantageous is the use of this device as it relates to placing thoracic endografts. Thoracic endografts, by and large, are bigger grafts, and they tend to require a fairly large sheath size (between 20 and 24 F), depending on the graft size.

It is well documented that a very significant portion of these thoracic aortic aneurysm patients require some sort of adjunctive conduit to be sewn somewhere in the aortoiliac segment just to get a sheath and device in place; the literature implies between 18% and 20%. In my experience to date, I feel that if we can use a device that can potentially reduce the need for a conduit, that can make a significant difference. So this device is not only for treating infrarenal aneurysms but, more importantly, thoracic aneurysms as well.

What additional applications would you consider for this new technology?

This device gives you the ability to take on the entire aortic segment—from the thoracic aorta all the way down. There has been some talk as to whether there would be a problem when ballooning around the sheath and cracking, damaging, or rupturing the iliac vessel. Theoretically, that potential exists, but there are bailout options to treat on the way out. For example, you can slowly bring the sheath back while placing covered stent graft material out of the end of the SoloPath as you come back through. Ultimately, for us, this has not been an issue to date. Knowing that I can access that anatomy with an endograft and treat it confidently is fantastic.

In your experience to date, describe your use of SoloPath and the need for endoconduits.

For thoracic endografting, we probably take on between 12 and 15 procedures per year, give or take. It has been our experience that the statistic holds true that between two and five of those patients will require some type of conduit, whether it is open or endovascular.

When you are dealing with infrarenal aneurysmal disease, you're typically faced with performing balloon angioplasty to prep the iliac vessel because you have to land in that same segment as opposed to a thoracic graft. With thoracic devices, even vessel prep with angioplasty is often inadequate to accommodate the larger sheath requirement. SoloPath may obviate those problems.

I do not have specific data regarding endoconduit placement reduction by using SoloPath yet, but our incidence of conduits has definitely been reduced. If I can avoid using a conduit, believe me, I'm going to try anything to avoid doing so, and SoloPath has worked well for us (Figures 2 and 3). ■

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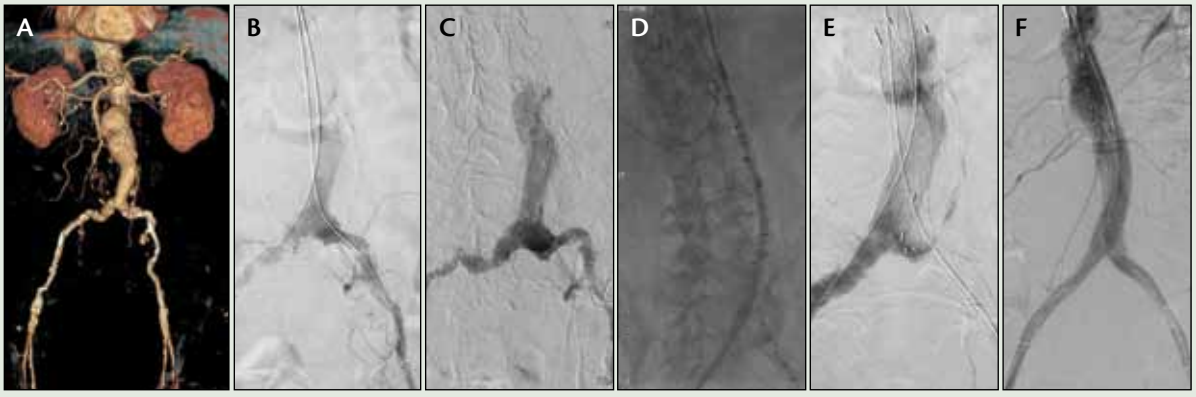
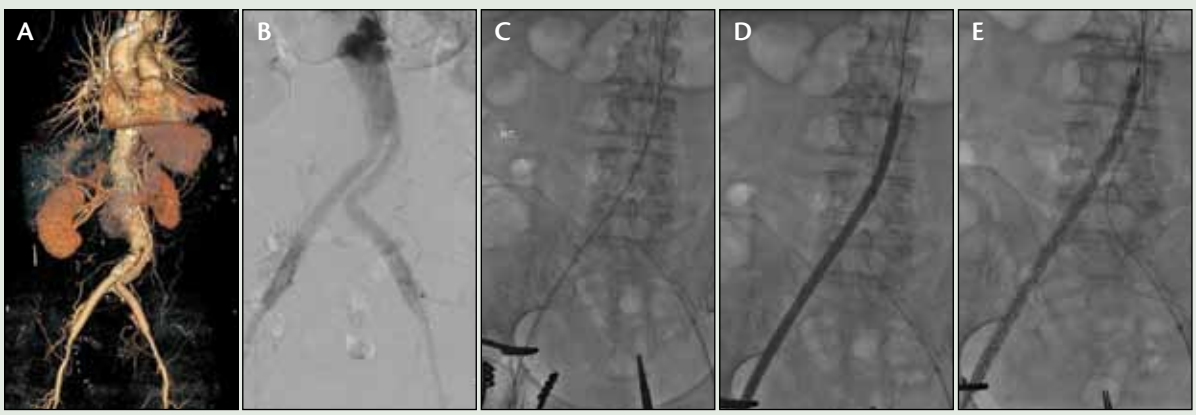
SoloPath Case Studies

Case 1



Three-dimensional reconstruction of a AAA showing calcified and stenotic iliac access (A). Angiography of the infrarenal aorta with diffusely stenotic iliac access (B). Initial iliac access imaging on infrarenal EVAR (C). Excluder C3 device through the SoloPath (D). Retrograde angiography through the SoloPath after partial withdrawal (note the dilation of common iliac compared to initial angiography) (E). Completion angiography with SoloPath in distal right iliac (F).

Case 2



Three-dimensional reconstruction of a TAG case (note the small iliac vessel access for standard 22-F sheath requirement) (A). Initial angiography showing tight iliac access for a > 20-F sheath requirement (B). Initial insertion of the SoloPath (C). SoloPath balloon introducer inflation (D). The TAG graft inserted in the 21-F SoloPath (E).