Michel S. Makaroun, MD Details the Gore Suite of Aortic Branch Stent Grafts

Interview by Jennifer Ford

At the 2014 VEITH symposium, Michel S. Makaroun, MD, presented data on his case experience along with clinical trial updates for Gore’s new thoracic and iliac branch stent grafts. Gore has recently grown its selection of products in its aortic branch portfolio undergoing evaluation.

A feasibility trial of the Gore TAG Thoracic Branch Endoprosthesis in the treatment of thoracic aortic aneurysms that require coverage of the left subclavian artery (LSA) was started in 2014 under an investigation device exemption (IDE) from the FDA. Gore also recently gained approval to begin an early feasibility study of the same branched device through the FDA’s Innovation Pathway Program to assess the treatment of aortic arch aneurysms in zone 0/1. Gore has also been developing a new device to treat aortic aneurysms involving visceral branch vessels, the GORE EXCLUDER Thoracoabdominal Branch Endoprosthesis. Vascular Disease Management spoke to Dr. Makaroun about these stent grafts.

Q: Could you tell us about your clinical experience with the Gore thoracic and iliac branch stent grafts?

A: Maybe we should start by saying the Gore TAG is a thoracic graft with a stent that has been in existence, tested and released more than a decade ago. The Gore TAG started clinical testing in the late ‘90s and was approved by the FDA in 2005. It was the first thoracic endograft approved by the FDA and has been in use for a long period of time, with the next generation, the Conformable GORE TAG device approved in 2011. The new product that we were presenting on today is the Gore TAG Thoracic Branch device, which is a generation down the line that allows us to actually cover parts of the aorta containing branches, which in this case is the arch of the aorta. The limitation of current technology using simple
tube endografts is that you can only cover aortic segments without branches that are essential for the perfusion of important organs. The new devices being introduced into the Gore family of products that we are now working with have side arms that can maintain blood flow into important aortic branches allowing us to treat more pathology directly.

One of them is part of the thoracic family and is called the thoracic branch endograft, TBE that has a single branch that has been designed to allow blood flow to go up one of the branches of the arch. There are three branches of the arch: the first one is the subclavian that goes to the left arm, then the left carotid that goes to the left brain and then the innominate artery, which goes to the right arm and to the right brain. So depending on where the aneurysm is or where the pathology of the arch is, the concept is that you can use that branch to perfuse one of those arteries and then if needed, a bypass is performed in the neck to connect that artery to the other arteries that are now covered by the stent graft. The way we have been dealing with this pathology until now required a bypass to provide blood flow to all the branches we cover. For example if we want to cover all the arch branches, then the only way now is to split the sternum and do the bypass from the ascending aorta to the neck which is certainly a much more invasive procedure. So this branch system now allows us to go all the way over to the innominate and not to have to open the chest to do the more invasive procedure.

So this is the first application of this branch system in the arch now being tested and so far we are in the feasibility portion of the study. We are just making sure it works well and it actually keeps that branch open. There have been 11 patients so far that have been entered in the arm of the study that evaluates the system in the subclavian artery, which is the first branch, and we started there because that is the least problematic in case something goes wrong, the patient will not suffer. Now, as we’re gaining more confidence, we’re moving to the other 2 branches and those feasibility trials are about to start.

Once we are comfortable that the system works well, then we will probably go into a phase 2 study, and that will be the study that will allow the FDA to approve it for general commercial release.

**Q:** How would you say the use of this device could change everyday practice for vascular clinicians?

**A:** It’s going to allow us to treat sicker patients that could not, for example, tolerate the sternotomy. In certain cases, let’s say in the subclavian artery, it will allow us to avoid any surgical procedure completely by actually having that branch perfused by a stent graft. So it will reduce the invasiveness of what we have to do to treat patients with aneurysms that are involving the arch.

This is clearly one more step in advancing the endovascular technology to treat a variety of pathologies that impinge on those blood vessels and it’s not the only area of the vasculature that is limiting. The other area is the abdominal aorta, next to the arteries of the kidneys, the small bowel and the liver and spleen, or the visceral arteries.

There’s another product that bridges the gap between the thoracic Gore and the abdominal Gore
product, and that’s called the TAMBE. The first 2 patients have been enrolled in a study of that device in Brazil. Those patients had the procedure done in late 2014 and both have been very successful so far. And the third anatomic location that has been addressed with these continuing branch developments is the internal iliac artery, which provides blood flow to the pelvis and to the muscles of the buttocks. In the past, we would occlude this artery.

The downside of this is that about 30% to 50% of patients will develop buttock pain when they walk, which is a symptom that is clearly bothersome to a certain number of patients. It’s not bothersome to some, depending on their level of activity, but the availability of the iliac branch or the IBE will allow us to also provide flow to that internal iliac artery and minimize the postprocedure symptoms that can limit the activity of many patients. So the branch technology now is gradually reaching all of the beds that previously were not easily accessible with endovascular therapies.

**Q:** As for the 11 patients who have been treated with the TAG device, are you able to describe one of those cases?

**A:** We have done 2 of the 11 and both of them on the same day. Both of them went very well technically. They are both past 6 months and have completely normal activities. Both were discharged in a couple of days from the hospital with only a small incision in the groin, so the clinical behavior and course of those patients has been very uneventful. The 11 patients at 30 days had no deaths and no major complications, so thus far, it’s very early in the course of the development in the trial but the outcomes have been very encouraging.

**Q:** How many patients will be enrolled and what is their inclusion criteria?

**A:** The enrollment allowed by the FDA for the feasibility trial is between 20 and 40. This is just a phase 1 to be sure that it works. The protocol is not finalized yet for the pivotal phase 2 trial, so we don’t know exactly how many patients will be enrolled, but it will probably be more than the phase 1 trial.

**Q:** Is there anything else that you wanted to add about the devices and how you think they will change practice?

**A:** All of the devices are becoming like a family of products with branches. There are additional developments in the works but these are the 3 that have already been tried in humans, that have already been implanted in patients and the results so far have been very encouraging.