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Preservation Matters

Clinician and patient perspectives from the first bilateral iliac branch endoprosthesis procedure in the United States.

WITH SHARIF H. ELLOZY, MD, AND JOHN GRIECO

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When John Grieco, a competitive triathlete, was diagnosed with aneurysms in his abdominal aorta and both iliac arteries (Figure 1) in January 2015, he thought he would never compete in a triathalon race again. Only 48 years old at the time, he was concerned about the potential lifestyle-limiting effects of the reduced lower-extremity bloodflow that was a likely outcome if he pursued the initial repair options presented to him. Just when he thought he was out of options, he was referred to Sharif H. Ellozy, MD, who told him about the GORE® EXCLUDER® Iliac Branch Endoprosthesis (IBE), a device undergoing clinical investigation in the United States at the time.

Endovascular Today met with Dr. Ellozy and Mr. Grieco to talk about this unusual case and how bilateral branches impacted his post-procedure quality of life and preserved his ability to compete.

Mr. Grieco, tell us about your lifestyle before your diagnosis.

Mr. Grieco: My lifestyle was very active. My wife Melissa and I both really enjoy cycling, swimming, and running, so we took up the sport of triathlon. We were typically doing those activities for 10 to 14 hours in a given week.

How did your lifestyle affect how you sought treatment?

Mr. Grieco: Figuring out how to take corrective measures and continue that lifestyle was a big factor in the process. Of course, I was hoping for a 100% solution—I didn't just want to have surgery and a process that kept me alive. After my first doctor did his examination and explained the surgery, he looked at me and leaned in and said, "You may never run or cycle again." I wasn't ready to throw in the towel, so I looked back at him and asked, "Are there any other options?"

What were your sources of education on endovascular and open repair?

Mr. Grieco: I didn't know anything other than what an aneurysm was—I knew nothing about the locations of my aneurysms or the treatment for my specific issue. When I started to research, I got a bit more depressed because I came to realize that I could possibly have a very different lifestyle after the surgery. I did a lot of Internet searches, naturally, trying to find reputable sites for the doctors' qualifications, looking up abdominal aortic aneurysms (AAAs), endovascular aortic repair (EVAR) and understanding what that meant, understanding what the risks were associated with either treatment option. At the same time, I went to see some solid doctors at a couple of different hospitals. I also called a doctor friend of mine who I'd known for a number of years, and I asked him to direct me through medical care, the selection of a surgeon, and making good decisions.

What informed your decision to ultimately select endovascular therapy?

Mr. Grieco: It was a kind of process of elimination. I originally had a vascular surgeon suggest that open surgical repair was the best option because I was young, healthy, and active, so the typical risks of a more substantial operation were less significant. He recognized the fact that there wasn't a complete solution with traditional EVAR. I then saw another doctor, Dr. Michael Marin, who also confirmed that traditional EVAR wouldn't be a complete solution. I was almost in denial accepting the truth that there was a medical issue without a perfect solution. But, lo and behold, he said that there was a study that may address my issues.

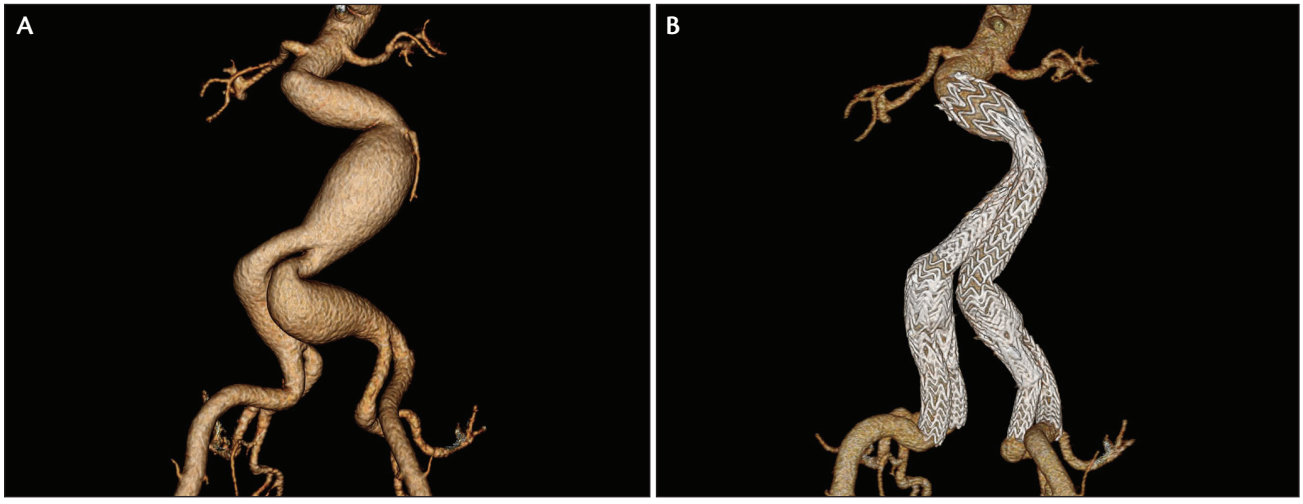

Figure 1. Pre-implant (A) and 1-year follow-up (B). Courtesy of Sharif Ellozy, MD, and Darren Schneider, MD, New York Presbyterian/ Weill Cornell Medical Center; New York, New York.

When I met with Dr. Ellozy, he walked me through my condition and how the bifurcated iliac stents could address my specific diagnosis. Melissa and I looked at each other, and we immediately knew that we were in the right place, and we were extremely fortunate to have all of the elements—a great hospital, a great doctor, and a procedure that appeared to be a solution.

What was recovery like? How long before you could resume normal activity?

Mr. Grieco: I was diagnosed in January of 2015 and had the procedure in February of 2015. By March I was starting to cycle a little bit and starting to get on the treadmill to walk a little bit. By the end of March, Melissa and I went out to Tucson, Arizona, and that week I cycled 300 miles.

All of 2015 was a rebuilding year, and I was so grateful that I could still cycle and still run long distance without having any pain or discomfort—that was just incredible.

Before my diagnosis, we had set out to do several IRONMAN® triathlons the year that I had the surgery. I put that in the back of my mind and assumed that may not happen. Once I started to cycle again, I realized that I could still participate in the triathlons. I couldn't race them, but I could certainly show up and complete them. So that's what we did—we completed four IRONMAN® races the year (Figure 2) that I had the surgery, which is an incredible amount of training and racing even for someone who didn't go through the surgery.

What is your lifestyle like now?

Mr. Grieco: This year, my goal was to try to get back to 100%, and my wife and I just completed a race this past November, and we qualified for the half IRONMAN® world championship in our respective age groups, which will take place next August 2017 in Penticton, Canada.

Dr. Ellozy, how did Mr. Grieco's age and lifestyle factor into your treatment decision?

Dr. Ellozy: John came in to my office with a picture of himself on a bike, and he had angles calculated, the

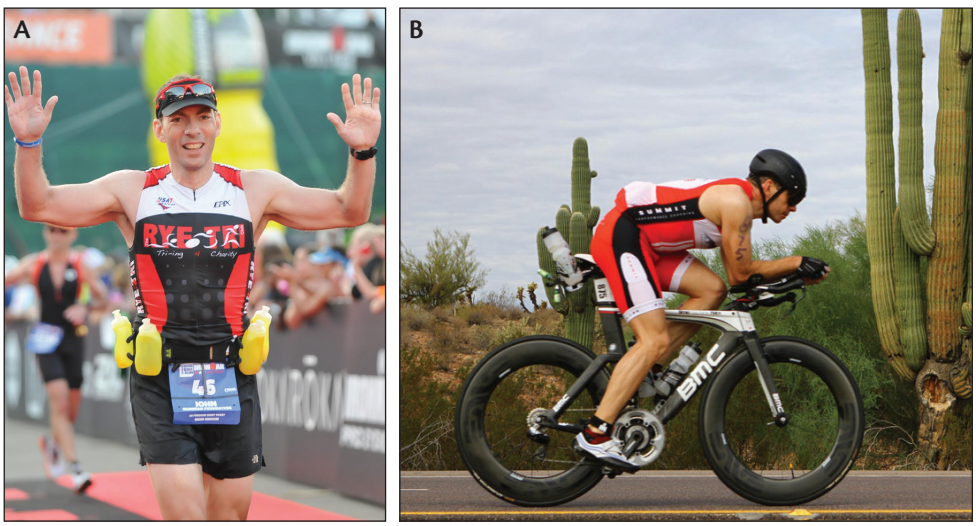

Figure 2. Each year, John Grieco participates in several triathlons across the country. He competed in the July 2015 IRONMAN® Lake Placid 5 months after surgery (A) and the November 2015 IRONMAN® Arizona 9 months after surgery (B). Images courtesy of John Grieco.

position that he'd be sitting in, asking if it would be stressful for the device. There were a lot of considerations that I hadn't run into with my typical AAA patients before then because most of them are not triathletes.

He is not a typical patient because he's much younger and healthier, and his anatomy was a little more tortuous than most aneurysms. There is always a certain amount of patient input into therapeutic choices, and when we met, I offered the possibility of open surgical repair. Listening to what was important to him, however, I thought that enrollment in the trial would be a good solution for his problem.

What influenced your decision to choose this device?

Dr. Ellozy: We had a couple of options. To pursue an endovascular approach, we could do embolization and extensions to the external iliac arteries, but then we would lose the benefits of pelvic perfusion. We had access to two iliac branch devices in two different clinical trials, but only the GORE EXCLUDER Iliac Branch Device was allowing for bilateral repair, and there is about a 20% incidence of buttock claudication in unilateral embolization.

There are off-label uses such as a sandwich technique, but when there is a device that's designed for this, I think you're much more likely to get a durable result than if you have an off-label use of a device or a modification of a device.

What concerns did you have as the treating physician about long-term outcomes, based on the data that exists?

Dr. Ellozy: Durability is going to be a concern in any patient, but especially for the younger patients. For a patient who is athletic, you may put the device under more strain than someone who doesn't have such an active lifestyle, but there's no real way to test for that. These devices are put through lifecycle testing to see if they will endure, but at some point, you have to make a decision based on judgment and experience.

Although this was an investigational device, it was based on the same platform as the GORE® EXCLUDER® Device, which has been time-tested, and the iliac branch device is essentially a smaller GORE EXCLUDER Device. The system is a little different to allow for tracking the internal iliac component to it, but we know that it performs well and it's durable, so that gave me more comfort than if it had been a totally new platform.

What was unique about this case?

Dr. Ellozy: There are some patients who are endurance athletes and develop iliac aneurysms, but it didn't really look like that because there was an aortic component as well. Similarly, a connective tissue disorder is always a concern, but it wasn't that either. This was more tortuous than most aneurysms. When aneurysms dilate, they get longer, but this got a lot longer (Figure 1A).

The iliac component was well within the instructions for use (IFU), but the aortic component also had to be within the IFU for the GORE EXCLUDER Device, and there was more tortuosity there. There was a significant angle at the level of the renal arteries, but a straighter portion just proximal to the first bend where the device would land nicely. We believed that there was a normal segment beyond the first bend, and that wouldn't fit within the IFU. That had some implications in terms of where it was okay to deploy the device.

What is the plan for long-term follow-up?

Dr. Ellozy: We will continue to do CT scans according to the clinical trial protocol. This is an MR-compatible device, so ultimately my goal is to use MR or ultrasound surveillance so that we don't have to use any radiation. The 1-month, 6-month, and 1-year (Figure 1B) surveillance were CT scans. In an older patient, the implication of repeat CT scans is less because of the potential for oncogenesis. In a younger patient, if you can avoid the radiation, it's better. Once a year is not a lot, but we only do what's necessary for surveillance.

As surgeons, you always think about the outcomes and you always anticipate managing complications. I think with this device, if there are failures in the future, it is a little easier to handle than with some of the other devices.

As physicians we are always concerned about surveillance and making sure that the repair is intact, even more so on a young, active patient, but so far we are good, and 2-year follow-up is coming soon. ■