

# Hypogastric Preservation With the GORE® EXCLUDER® Iliac Branch Endoprosthesis\*

How the potential technical benefits of the device may help navigate tortuous anatomy.

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**D**ilatation of one or both common iliac arteries (CIAs) is a major anatomic challenge of endovascular aneurysm repair (EVAR) and is estimated to occur in 20% to 40% of EVAR patients.<sup>1-3</sup> Ectatic or aneurysmal CIAs are often anatomically inadequate for effective distal seal and fixation, which can ultimately compromise the effectiveness and viability of the EVAR procedure. One option for CIA repair is hypogastric occlusion followed by endograft extension into the external iliac artery. However, hypogastric occlusion can lead to ischemic complications, commonly resulting in buttock claudication in up to 50% of patients,<sup>4</sup> sexual dysfunction in up to 40% of patients,<sup>4</sup> and more rarely can result in severe morbidity and mortality caused by bowel or spinal ischaemia.<sup>5</sup> Bifurcated iliac side branch devices represent a valid alternative technique to preserve pelvic blood flow while providing adequate distal seal and fixation with EVAR. Experience with the COOK® ZENITH® Iliac Branch Device (Cook Medical, Bloomington, IN) showed that this technique is feasible and safe, with promising results.<sup>6</sup>

## DEVICE AND DEPLOYMENT

The recently introduced GORE EXCLUDER Iliac Branch Endoprosthesis<sup>7</sup> (Gore & Associates, Flagstaff, AZ) is based on the design of the GORE EXCLUDER Abdominal Aortic Aneurysm (AAA) Endoprosthesis. The major design differences in the GORE EXCLUDER Iliac Branch Endoprosthesis compared to the AAA device center around alterations in device dimensions (overall length and distal iliac limb diameters) for suitability within the iliac artery anatomy. There are certain morphological characteristics required of the native arteries, the most important of which is the minimum diameter of the CIA, and the procedure should be completed using the standard GORE EXCLUDER Device for the abdominal aorta. There are several advantageous design aspects of the device. The first is that the GORE

EXCLUDER Iliac Branch Endoprosthesis is compatible with a 16-F introducer sheath, which is intended to allow for improved vessel access. The second is that the device design is based on the current GORE EXCLUDER AAA Device, which has high conformability in the limbs to offer good adaptation even in tortuous iliac arteries, avoiding flow-limiting kinking.

Furthermore, several features represent important technical innovation in the deployment of the GORE EXCLUDER Iliac Branch Endoprosthesis. This device is designed to offer repositionability using a simple, two-stage deployment mechanism via a nested deployment knob. The outer deployment knob initiates deployment of the GORE EXCLUDER Iliac Branch Endoprosthesis to the level of the internal iliac artery (IIA) gate, similar to how deployment of the GORE EXCLUDER AAA Endoprosthesis featuring C3 Delivery System initiates deployment to the device's contralateral gate. At this point, if the IIA gate is deployed slightly higher than the intended final position, then the GORE EXCLUDER Iliac Branch Endoprosthesis can be rotated up to 90° in either direction to facilitate access to the hypogastric artery, and gently moved distally as needed for optimal alignment with the IIA ostium. The inner deployment knob initiates deployment of the EIA leg, completing the deployment of the device as a final step.

The second novel technical feature of the GORE EXCLUDER Iliac Branch Endoprosthesis is the removable guidewire tube, which is intended to provide a small channel within the constrained device for the introduction of a second guidewire to precannulate the IIA gate. This guidewire is a bifemoral, up-and-over through wire, captured via a snare catheter from the contralateral groin and is established before the introduction of the device. The GORE EXCLUDER Iliac Branch Endoprosthesis is guided through the introducer sheath over both the aortic wire and the through wire. The intended purpose of this, aside from precan-

nulating the side branch channel, is to easily advance the contralateral introducer sheath into the device gate, which can facilitate catheterization of the IIA and provide stability to the contralateral sheath for delivering the internal iliac component.

Finally, the third important characteristic is the internal iliac component, which is a dedicated, self-expanding stent-graft for the hypogastric artery that is based on the design of GORE EXCLUDER Device iliac legs. With maintenance of the through wire, it is not necessary for the sheath to go inside the hypogastric artery, but it is instead stabilized inside the side branch of the device.

### FIRST EXPERIENCE

Two of the first three implants of the GORE EXCLUDER Iliac Branch Endoprosthesis in Europe occurred in Rome, Italy on November 4, 2013. In subsequent days, other centers began using the graft throughout Europe. This device is undergoing a clinical trial in the United States.

Patients identified as having challenging anatomy that could potentially benefit from the device design and features were chosen for these first cases. The first case involved a patient with a straight stent-graft in the infrarenal aorta (previously implanted at a different hospital), and a 39-mm CIA aneurysm. The procedure was performed with a percutaneous approach. The IIA take-off angle was quite steep, and the repositionability of the device aided in hypogastric artery cannulation. Postprocedure computed tomography (CT) scans showed good blood flow through both the external and internal legs of the stent-graft. The second case involved bilateral, saccular CIA aneurysms as well as a saccular aneurysm in the aorta.

Again using percutaneous access, we elected to place the GORE EXCLUDER Iliac Branch Endoprosthesis in both CIAs in a bilateral configuration. The completion angiogram showed excellent flow in all iliac branch vessels, with both sides accommodating the GORE EXCLUDER Iliac Branch Endoprosthesis. The follow-up CT at 1 week showed the same. In both cases, there were no proximal or distal type I endoleaks seen on postoperative CT scans, and all branch vessels were fully patent.

### DISCUSSION

Iliac side branch devices can be considered the first endovascular option in patients with aortoiliac aneurysm

and suitable anatomy. The major disadvantage of this technique is the technical feasibility related to anatomical requirements. In our experience with the Cook platform, the majority of technical failures were related to severe vessel tortuosity or iliac anatomies not totally fulfilling the criteria for application. The presence of small or tortuous EIA or the concurrence of large IIA were the main negative predictors of outcome.<sup>6</sup> In our initial experience, the GORE EXCLUDER Iliac Branch Endoprosthesis may be an optimal endovascular option in this scenario. The stent-graft appeared to conform well to accommodate the difficult anatomies experienced in these first cases. We found the deployment to be intuitive and easy, aided by the ability to precannulate the IIA gate and stabilize the contralateral introducer sheath with the bifemoral through wire. The ability to reposition the GORE EXCLUDER Iliac Branch Endoprosthesis is designed to provide clinicians with the ability to realign the device for easier hypogastric cannulation, which may reduce operative time and achieve optimal device positioning. Further data on the GORE EXCLUDER Iliac Branch Endoprosthesis performance will be collected as part of the post-market GREAT registry in Europe. The device is also in clinical study in the United States. With EVAR becoming the common, preferred option over open surgical repair, technological improvements such as those offered with the GORE EXCLUDER Iliac Branch Endoprosthesis are needed to continue expanding the treatment options and performance in the face of difficult anatomy. ■

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