Repositioning the Future of EVAR

The first experiences with the new repositionable EXCLUDER stent graft.

BY ERIC VERHOEVEN, MD, PHD; ROLAND SIMMLER, MPH; AND MARK F. FILLINGER, MD

According to a report from the EUROSTAR registry collaborators, who studied endovascular repair of abdominal aortic aneurysms in Europe, all modern stent grafts perform reasonably well.[1] In their conclusion, the authors could not clearly identify one superior stent graft on the market. Instead, desirable characteristics and outcomes are dispersed among the varying stent grafts.[2] A comparison between third-generation devices is difficult because of the obvious clinical selection bias that is applicable to most large centers.[3] However, the differences in device design and introduction systems allow for tailor-made graft selection that suit the patient's specific anatomy.[4]

The EXCLUDER Endoprosthesis (W. L. Gore & Associates, Flagstaff, AZ) is a third-generation device that has performed well. Numerous studies have demonstrated the efficacy, safety, and durability of this device.[5,6] Strengths of the device include its original design, with a flexible, catheter-mounted delivery system and active infrarenal fixation. The limbs of the EXCLUDER Device are very flexible, are adaptable to most complex iliac anatomies, and have been implemented with great success for treating iliac aneurysms.[7] Although there is literature documenting extremely accurate placement based on pre- and postoperative evaluation,[8] accuracy of proximal deployment has been contested, and competing manufacturers have stressed that their system performs better in this regard. The microstructure of expanded polytetrafluoroethylene in the original device permitted selective permeability of serous fluid in a subset of patients,[9] but with the addition of a nonpermeable, very thin, highly durable fluoropolymer layer, this endotension has been obsoleted.[10,11]

DEPLOYMENT

The new C3 Delivery System (W. L. Gore & Associates) was developed by the company in cooperation with experienced users. The EXCLUDER Device itself remains unchanged, but deployment is now a three-step maneuver, including the option of reconstraining and repositioning the device. Adjustments for both the level of the device and orientation of the contralateral limb can be executed. If the position is believed to be too high or too low with regard to the renal arteries, the device can be easily adjusted to reach the ideal final location. Similarly, reorientation of the contralateral gate is possible, which makes cannulation easier and less time consuming.

Figure 1. The first deployment step opens the body of the graft and the contralateral limb.

Figure 2. A constraining wire allows for recapturing of the graft at the proximal end. The graft can now both be repositioned and reoriented.

In the first step, the body and contralateral limb of the device are opened (Figure 1). A constraining loop around the body of the graft allows for recapture and easy repositioning, if desired (Figure 2). After controlled positioning, the graft can then be redeployed, and the position can be controlled with precision. If positioning is satisfactory, the constraining loop is removed, and the ipsilateral limb is opened. Similarly, if the gate orientation is not in the ideal location for catheter access, the proximal trunk can be reconstrained, and the limb can be repositioned to a more convenient location (Figure 3).

FIRST EXPERIENCE

The first five implants of the EXCLUDER Device featuring the new C3 Delivery System in humans occurred in Nürnberg, Germany on August 25, 2010. In subsequent days, other centers began using the graft throughout Europe. This device is also FDA approved.

The first cases using the device were chosen based on challenging patient anatomy that was identified as potentially benefiting from the device features. The first case involved a patient with a short and angulated aortic neck, so the graft had to be repositioned both for level (lower/distally) and orientation (more left anterior, contralateral limb landed right anterior). The final position was excellent and was confirmed on a postoperative computed tomography (CT) scan (Figure 4). In two additional cases, the graft was repositioned for level (higher/proximally). The fourth case involved a long aortic neck within a bulging aneurysm. It was anticipated that repositioning would be necessary for orientation, but cannulation occurred instantly, making repositioning unnecessary. In the fifth case, the proximal position was ideal after the initial deployment, and cannulation was uneventful. Therefore, no repositioning was required, and the graft opened completely.

In all five cases, the graft remained in position (immediately below the renal arteries). There were no proximal type I endoleaks seen on postoperative CT scans, and all renal arteries were fully patent.

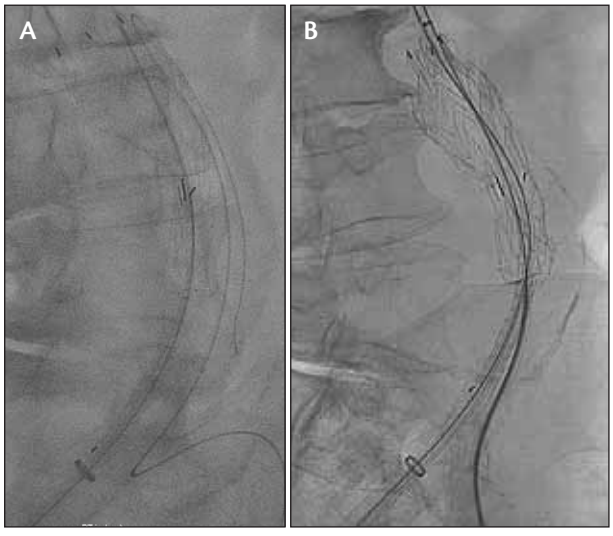

Figure 3. Position after initial deployment (A). Catheterization proved to be difficult due to left iliac artery angulation. Reorientation allowed for easier catheterization (B).

Figure 4. A postoperative CT scan showing the proximal position of the graft just below the renal arteries.

DISCUSSION

The EXCLUDER Device has been used very successfully in a wide array of cases, but as with any device, improvements are possible.[12,13] The current trend in most centers is for a larger percentage of patients to be treated with endovascular repair rather than open repair. As a natural result of this trend, clinicians gain increasing experience with more difficult anatomy and ask for device features that enhance performance in this challenging anatomy. The authors of this article have deployed a large number of original EXCLUDER Devices with a high degree of accuracy but certainly welcomed the idea of a repositionable device.[6,8,14] With any endovascular device, as aortic neck angles become more angulated or the neck length becomes shorter, the allowable margin for error decreases. The ability to reconstrain and reposition the EXCLUDER Device gives clinicians the ability to achieve optimal device positioning in difficult cases without the fear that there is only one chance to get it right.

The ability to reposition the device after initial deployment should also be welcomed by clinicians who are relatively new to EVAR or those with limited experience using the EXCLUDER Device. The ease of repositioning decreases the risk of suboptimal device positioning during the short but finite learning curve of using a new device. Also important to newer users is that the repositioning feature does not add complication to the deployment sequence. Retaining ease of use was a key feature for those accustomed to earlier generations of the EXCLUDER Device.

Although the ability to reposition the device within the aortic neck is the most critical aspect of the new deployment design, the ability to reposition the contralateral limb gate can be quite useful as well. Access to the contralateral gate is rarely an issue in simple anatomy, and the position can be simulated and planned preoperatively.[8] Nonetheless, any clinician with a large amount of experience has performed cases in which repositioning of the limb would have saved significant procedure time

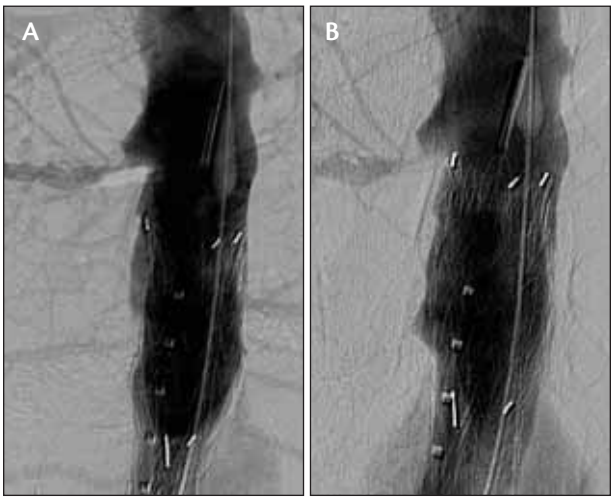

Figure 5. Intraoperative angiogram showing a proximal position that was too low after reorientation for cannulation in a dialysis patient with urine output (A). The graft was repositioned to land below the right renal artery (B).

and radiation dosage. Interestingly, in two cases with very tortuous iliac artery anatomy, we decided to use the EXCLUDER Device to its full extent (ie, to reorient the graft for catheterization before controlling the proximal position level). In both cases, reorientation was very useful in achieving catheterization, but the grafts equally needed proximal (higher) repositioning (Figure 5).

Finally, one further benefit from a repositionable delivery system may be cost savings. Although the percentage of EXCLUDER Device cases requiring aortic cuffs is low in our experience, any reduction in the use of cuffs will save on the cost of the component as well as the cost of the additional procedure time. Better device positioning on the first attempt should also decrease the number of balloon inflations in the neck, angiograms, or other interventions for suboptimal positioning and may decrease the need for subsequent reinterventions or additional imaging during follow-up. As previously mentioned, more rapid gate cannulation will contribute to time savings in a significant portion of cases. None of these aspects are trivial given the high cost of time in the operating room.

CONCLUSION

The new C3 Delivery System for the EXCLUDER Device enables easy positioning and repositioning, if necessary. In our first seven cases, the option to reposition the graft was used to adjust both the level and limb orientation with excellent results. This ability to reposition the device has obvious benefits, especially in cases with difficult anatomy. ■

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