# The EXCLUDER-Centervasc Registry

A preliminary report from a 10-year efficacy and durability study on EVAR.

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The natural history of abdominal aortic aneurysms (AAAs) is well known. If left untreated, rupture and death is the expected outcome. Endovascular AAA repair (EVAR) was introduced by Parodi et al in 1990, primarily to treat high-risk patients, many of whom were unable to overcome the risks of open surgery.[1] After proving to be feasible in that decade, surgeons' worries were concentrated on the efficacy of the procedure, with special concern regarding the durability of the implanted devices and their ability to exclude AAAs.

Our experience with the GORE EXCLUDER Device (W. L. Gore & Associates, Flagstaff, AZ) began in December 1999. Through the end of 2010, 188 patients were treated at Centervasc (Rio de Janeiro, Brazil) with the EXCLUDER Device, with follow-up to 10 years. This is an independent prospective registry, and it has not been funded by either Gore or their distributor in Brazil. All endografts and hospital expenses have been paid for by either the patients themselves or by their health care supplier. All procedures have been performed under the supervision of the senior author, Dr. von Ristow.

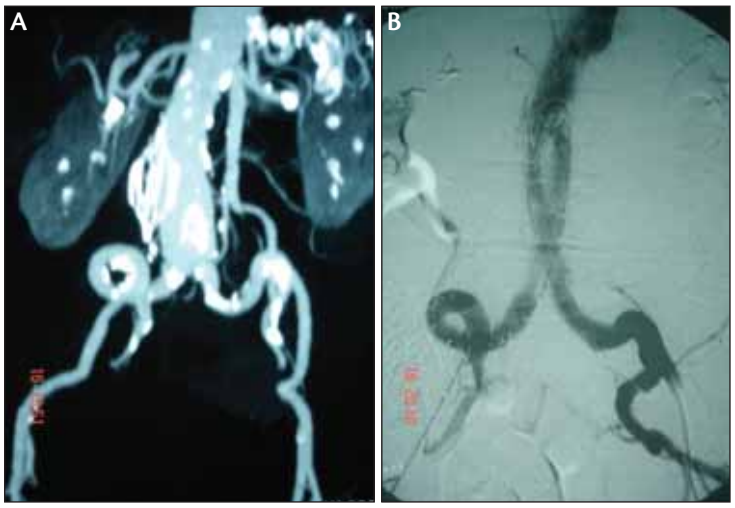


**Figure 1. CTA reconstruction of a AAA with 360º coiling of the right external iliac artery and severe tortuosity of left common iliac artery (A). Intraoperative conclusion angiogram after successful EVAR with the EXCLUDER Device (B). The challenging anatomy of the iliac arteries was managed with introduction of the sheaths over extra-stiff guidewires.**

## INDICATIONS, PLANNING, AND METHOD OF TREATMENT

Indications for treatment were based on the presence of symptoms and size of the AAA, as internationally accepted. Preoperative workup included carotid and coronary noninvasive studies in all patients, and operative risk was assessed according to the American Society of Anesthesiology. In the first 6 years of this study, EVAR was indicated only for high-risk patients, with strict criteria. Later on, as confidence was acquired with the EXCLUDER Device, EVAR was progressively indicated for lower-risk patients.

Although always based in computed tomography (CT), imaging considerably improved during the study period. Angiography with marked catheters played an important role in our early experience. Currently, multislice CT angiography (CTA) with multiplanar reconstructions has totally supplanted other methods.

The vascular surgery residents at Centervasc, assisted by senior staff members, performed all procedural planning. In this study, AAA cases with proximal necks of adequate length and an inner diameter ranging from 20 to 28 mm were enrolled. Thin thrombus at the neck, up to 25% of the circumference, was not considered to be a contraindication. Neck angle up to 60º was accepted. A diameter of at least 22 mm for the distal neck and a maximum of 18 mm for the iliac arteries was required, with a distal sealing zone of at least 10 mm.

The implantation was performed through surgical access to the femoral arteries. In the early cases, the EXCLUDER Device was released from its constraining covering using a quick deployment. With increased experience, release was performed slowly under full visual con-

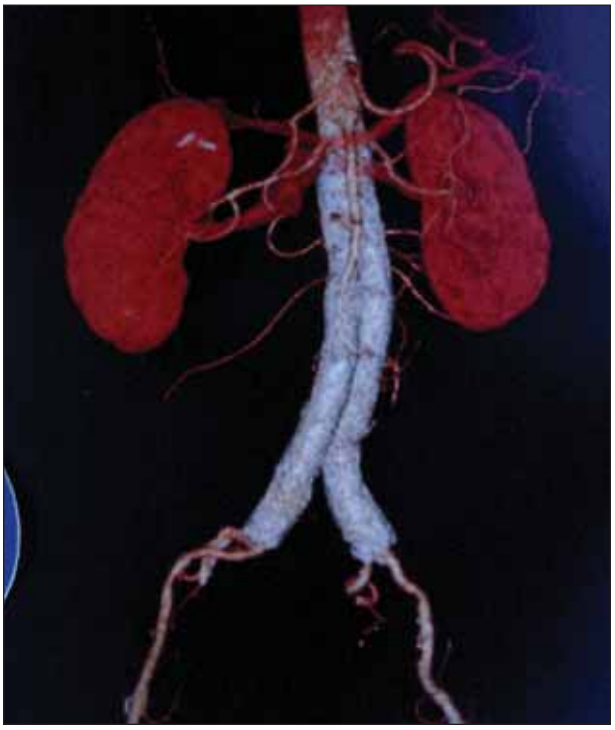

**Figure 2. Volume-rendering reconstruction of CTA of a patient treated in 2004 with bilateral bell-bottom EXCLUDER Device iliac limbs. In 2009, the iliac arteries have not enlarged, and both hypogastric arteries are patent.**

trol. The techniques we employed have been published in the Brazilian literature and by Minion and Jordan, respectively.[2-5]

The device has been extensively used in cases of tortuous iliac arteries, often along with extra-stiff guidewires to straighten them (Figure 1). In Brazil, many patients have small stature. The ability to use the EXCLUDER Device with crossed limbs was applied to prevent undesired hypogastric occlusion. Ectatic common iliac arteries (up to 18 mm) were treated with bell-bottom limbs (Figure 2). We have given extreme attention to the preservation of at least one hypogastric artery. Aneurysms of both iliac arteries with involvement of the bifurcation were usually treated with unilateral hypogastric exclusion plus surgical hypogastric revascularization in this series. In sexually active men, bilateral hypogastric preservation was the rule (Figure 3). In eight cases of nondialytic renal insufficiency, EVAR was performed without the use of iodinated contrast media. Fluoroscopy and duplex scan were used to guide the implant in these cases.[2] Whenever the diameter of the femoral artery allowed the concomitant introduction of a 7-F sheath, with the 12-F sheath used to implant the EXCLUDER Device contralateral limb in place, we filled

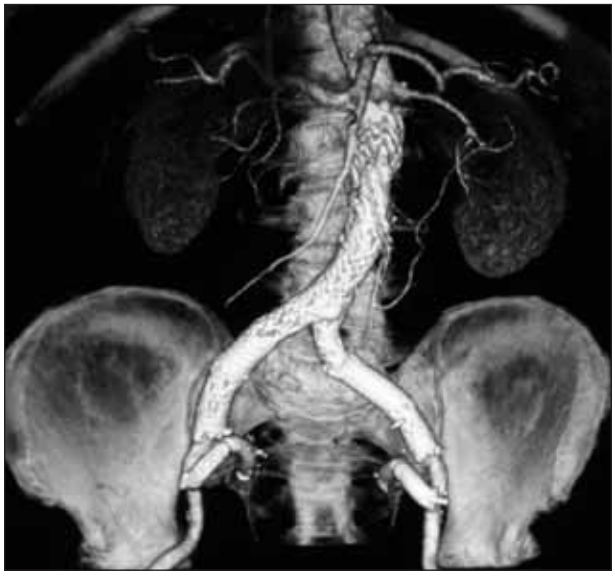

**Figure 3. EVAR with EXCLUDER Device in a patient with bilateral common iliac aneurysms. Late (6 years) CTA control of graft with bilateral polytetrafluoroethylene hypogastric artery revascularization.**

the aneurysmal sac with fragmented gelfoam sponge to reduce the occurrence of type II endoleaks.

## FOLLOW-UP

Patients were seen for follow-up consultations at 1, 6, and 12 months and yearly thereafter. Follow-up in the first 5 years of the study was based on physical examination and CT. Since 2005, our protocol has been based on an annual physical examination, duplex scan, and plain radiography of the abdomen and pelvis, complemented eventually by CTA.

### Early (30-Day) Results

Technical success was achieved in all cases, with no operative death. Thirty-day mortality was 1.6% (three patients had blood dyscrasia, pulmonary embolism, and myocardial

**TABLE 1. EARLY (30-DAY) RESULTS (N = 188)[a]**

| Results | n | % |
|---|---|---|
| Technical success | 188 | 100 |
| Mortality | 3 | 1.6 |
| Conversion | 0 | 0 |
| Type I endoleak | 1 | 0.5 |

*[a]Causes of early mortality: blood dyscrasia (1), pulmonary embolism (1), and myocardial infarction (1).*

**Figure 4. EXCLUDER Device stability in hostile anatomy: 2009 volume-rendering CTA image of an EXCLUDER Device implanted in 2002 within a 60° angulated neck.**

infarction, respectively). One type IA endoleak was observed. There was no conversion to open surgery (Table 1).

### Long-Term Results

One hundred eighty-five patients survived to 30 days and have undergone prospective follow-up (Table 2). One late migration in an angulated neck was observed, with development of a type IA endoleak, as well as one type IB endoleak due to enlargement of the iliac artery. Both endoleaks were treated by endovascular means—the type IA endoleak by transforming the bifurcation in a conical uni-iliac graft, with occlusion of the contralateral common iliac artery and femorofemoral crossover grafts. The type IB endoleak was treated with exclusion of the hypogastric artery with coils and implantation of an extension to the external iliac artery. Type II endoleaks were detected in nine patients (4.77%): two presented with spontaneous occlusions, two were treated by translumbar coiling, and five are under watchful observation, with no aneurysm growth. No structural failure (type III endoleak) has been observed.

We observed four patients (2.25%) that, after showing shrinkage of the sac, showed slow aneurysmal growth without a detectable endoleak, implying endotension. All of these patients underwent implantation before 2003. This occurrence is probably related to the expanded polytetrafluoroethylene permeability of the early device. To date, no sacs have enlarged to a size requiring further treatment.[6]

**TABLE 2. LONG-TERM RESULTS: ADVERSE EVENTS (N = 185)**

| Results | n | % | Remarks |
|---|---|---|---|
| Endoleak IA | 1 | 0.5 | Migration, treated |
| Endoleak IB | 1 | 0.5 | Iliac enlargement, treated |
| Endoleak II | 9 | 4.5 | 2 treated, 2 spontaneous occlusion, 5 under observation |
| Endoleak III | 0 | 0 | Structural defects have not been observed |
| Endoleak IV | 0 | 0 | None |
| Endoleak V (undetermined) | 4 | 2 | All under observation |
| Renal impairment | 0 | 0 | None |
| Limb kinking | 0 | 0 | None |
| Limb thrombosis | 3 | 1.6 | 1 treated (thrombolysis) |
| Late migration | 1 | 0.5 | Treated (same case as type IA endoleak previously noted) |
| Infection | 2 | 1 | Tuberculosis psoitis with endograft contamination |
| Secondary reinterventions of any kind | 8 | 4 | None |
| Late conversion | 2 | 1 | Both related to the infections previously noted |

**TABLE 3. ANEURYSM-RELATED DEATHS**

| Cause of Death | n | % | Remarks |
|---|---|---|---|
| Aneurysm rupture | 0 | 0 | None |
| Graft infection | 2 | 1 | All related to contamination of the graft by infection (Mycobacterium tuberculosis psoitis) |

In this series, we have not observed late renal impairment related to the presence of the endograft. Thrombosis of limbs were rare (1.6%), and only one required treatment. No main graft thrombosis occurred. There was one case of graft infolding in the external iliac artery. It has been observed for 3 years without thrombosis of the limb. Late graft infection occurred in two cases (1.1%) and both were due to contamination of the graft by contiguous infection by Mycobacterium tuberculosis of the left psoas muscle in very debilitated octogenarians. Both patients did not survive extra-anatomical axillary bifemoral grafting plus endograft explantation, although this is not representative of the overall findings because these were the only two aneurysm-related deaths in the series (Table 3). Aside from these two cases, no late conversion was necessary. Integrity and long-term stability, even in hostile anatomy, has been the rule with the EXCLUDER Device. We have not observed barb fractures or other device integrity issues.

## DISCUSSION

Results of the EXCLUDER Device for treating AAA have been widely published.[6-8] Several improvements were made to the EXCLUDER Device during the study period. Most important is the incorporation of a new low-permeability interior layer while maintaining the same luminal and abluminal stent graft surfaces, the addition of a 31-mm main body size, and iliac extensions up to 20 mm in diameter. The development of techniques that allow gradual and precise proximal graft release expanded the application of this unique device, which to date remains the only one that is mounted on a catheter, a feature that allows its use in severe iliac angulations without kinking.

In this series, we did not observe late renal impairment, which has been reported with the use of grafts with suprarenal fixation.[9] As well as efficacy, the durability of AAA exclusion has been a challenge to all grafts used for EVAR. Figure 4 shows an EXCLUDER Device that was implanted in a AAA with a 60º angulated neck and is perfectly stable 7 years after implantation. Long-term comparative outcomes after EVAR have been published, and all favor the EXCLUDER Device as an effective and durable device.[10-14] This 10-year follow-up study confirms outstanding results, situating the EXCLUDER Device in a privileged standpoint.

## CONCLUSION

After 188 EVAR procedures performed from 1999 to 2010 using the GORE EXCLUDER Device that were followed-up prospectively up to 10 years, we conclude that this device is durable and effective for the treatment of AAAs. ■

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1. Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg. 1991;5:491-499.
2. Ristow AV, Pedron C, Gress M, et al. Aneurisma da aorta abdominal-tratamento pela técnica endovascular. In: Brito CJ, ed. Cirurgia Vascular. 2nd ed. Rio de Janeiro, Brazil: Revinter; 2008: 1225-1304.
3. Minion D. Neck, seal, and fixation. Endovascular Today. 2009; 8(suppl):3-6.
4. Jordan WD. Accurate deployment with the Excluder endograft. Endovascular Today. 2009;8(suppl):7-9.
5. Minion DJ, Rodriguez CC, Moore EM, et al. Technique of slow deployment of Gore Excluder endograft improves accuracy of placement. J Vasc Surg. 2006;43:852-854.
6. Hogg ME, Morasch MD, Park T, et al. Long-term sac behavior after endovascular abdominal aortic aneurysm repair with the excluder low-permeability endoprosthesis. J Vasc Surg. In press.
7. Ghotbi R, Sotiriou A, Mansur R. New results with 100 Excluder cases. J Cardiovasc Surg (Torino). 2010;51:475-480.
8. Bos WT, Tielliu IF, Van Den Dungen JJ, et al. Results of endovascular abdominal aortic aneurysm repair with selective use of the Gore Excluder. J Cardiovasc Surg (Torino). 2009;50:159-64.
9. Böckler D, Krauss M, Mansmann U, et al. Incidence of renal infarctions after endovascular AAA repair: relationship to infrarenal versus suprarenal fixation. J Endovasc Ther. 2003;10:1054-1060.
10. van Marrewijk CJ, Leurs LJ, Vallabhaneni SR, et al; EUROSTAR Collaborators. Risk-adjusted outcome analysis of endovascular abdominal aneurysm repair in a large population: how do stent grafts compare? J Endov Ther. 2005;12:417-429.
11. Peterson BJ, Matsumara JS, Brewster DC, Makaroun MS; Excluder Bifurcated Endoprosthesis Investigators. Five-year report of a multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysms. J Vasc Surg. 2007;45:885-890.
12. Brown LC, Greenhalgh RM, Powell JT, Thompson SG; EVAR Trial Participants. Use of baseline factors to predict complications and reinterventions after endovascular repair of abdominal aortic aneurysm. Br J Surg. 2010;97:1207-1217.
13. Maleux G, Koolen M, Heye S, Nevelsteen A. Limb occlusion after endovascular repair of abdominal aortic aneurysms with supported endografts. J Vasc Interv Radiol. 2008;19:1409-1412.
14. Abbruzzese TA, Kwolek CJ, Brewster DC, et al. Outcomes following endovascular abdominal aortic aneurysm repair (EVAR): an anatomic and device-specific analysis. J Vasc Surg. 2008;48:19-28.