Physician Modified Low Profile Endograft for Endovascular Repair of Juxtarenal Abdominal Aortic Aneurysms in Patients with Small Access Vessels

Gustavo Paludetto a,*, Stefaan Van der Meulen b, Kenneth Ouriel c, Roberto Patarca d

Division of Endovascular Surgery, Santa Lucia Hospital, Brasília, DF, Brazil
Syntactx-Europe, Denderleeuw, Belgium
Syntactix, New York, NY, USA
Cordis, a Cardinal Health Company, Miami Lakes, FL, USA

WHAT THIS PAPER ADDS

Branched or fenestrated aortic stent grafts allow endovascular repair of juxtarenal abdominal aortic aneurysm in patients at high risk for open repair; however, they are expensive, 18–20 F in diameter depending on endograft diameter, not widely available in most countries, and require three to four weeks in urgent cases and up to six to eight weeks for graft customisation. Physician modification and implantation of a standard 14F stent graft with a 16F sheath is described for endovascular repair of juxtarenal aneurysms in patients with small access vessels.

Introduction: Urgent or emergency treatment of patients with abdominal aortic aneurysms that are anatomically unsuitable for conventional repair because of short proximal necks, small diameters and access vessel calcification, and high risk for open repair can be performed with commercially available branched or fenestrated aortic endografts or physician modified stent grafts.

Report: A technique is described for modification and successful implantation of a commercially available standard aortic stent graft with a low profile main body in two patients at high risk for open repair, with small access vessels and requiring uni- or bilateral renal artery fenestration for juxtarenal aneurysm repair.

Discussion: Based on two case experiences, the use of physician modified off the shelf endografts appears to be a feasible and effective alternative to fenestrated endovascular repair in patients with juxtarenal abdominal aortic aneurysms at high risk for open surgical repair. Studies comparing effectiveness of the different options, including chimney/snorkel technique and debranching, are warranted.

© 2021 The Authors. Published by Elsevier Ltd on behalf of European Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

Article history: Received 11 July 2020, Revised 2 March 2021, Accepted 30 March 2021.

Keywords: Abdominal aneurysm repair, EVAR, INCRAFT, Modified endograft

INTRODUCTION

If fenestrated endovascular repair (FEVAR) and open surgical repair are not feasible as first choice treatments for juxtarenal abdominal aortic aneurysm (AAA) because of procedural or clinical outcome considerations,1,2 options include debranching of the visceral aorta with subsequent aortic stent grafting and “snorkel” or “chimney” techniques that have been associated with lower morbidity and mortality.3 However, broader use of branched or fenestrated aortic endografts is limited by cost, availability, endograft diameter, and time required for graft customisation. Another option is physician modification of commercially available standard stent grafts and reconstrained stent graft after deployment and repositionable platform.4,5 Two cases are described in which physician modified endovascular aneurysm repair using low profile (14F), a 16F sheath, and partial deployment of a commercially available stent graft allowed treatment of patients with a small access and juxtarenal AAA.

REPORT

Two patients were treated. First, a 71 year old man who had a 6.7 cm juxtarenal AAA arising 4 mm below the lower edge of the left renal artery (LRA). He had severe chronic obstructive pulmonary disease and coronary artery disease
with myocardial revascularisation 10 years ago without follow up. The echocardiogram showed an ejection fraction of 30%, dilated cardiomyopathy, and atrial fibrillation using an oral anticoagulant which rendered open repair high risk. The patient had persistent and important bleeding from a prostatic lesion with haemodynamic symptoms needing transfusion, despite best medical treatment and continuous irrigation using a triple lumen urinary catheter. He needed radical prostatectomy surgery to remove the cancer and stop the persistent bleeding. The aortic diameter was 25 mm at the level of the upper renal artery (right) and 28 mm at the level of lower renal artery (left). The distance from the bottom of the right renal artery (RRA) to the top of the AAA was about 2 cm. The distance from the LRA to top of the AAA was 4 mm. There is no thrombus or calcification of the AAA was about 17 mm without thrombus or calcification. The AAA was about 2 cm. The distance from the LRA to top of the AAA was about 17 mm without thrombus or calcification.

Both patients had a <6 mm diameter access of both external iliac arteries. Because of the non-availability of a commercial fenestrated endograft at the institution, the risks and benefits of open and endovascular aneurysm repair with a physician modified stent graft were discussed with the patients, who consented to the latter on a compassionate use basis6 (Table 1).

### Endograft modification

A 30 mm diameter Incraft was chosen for the first patient, oversized about 5%—15%, 20 mm long, and 25—28.2 mm neck diameter. For the second patient a 26 mm diameter Incraft oversized about 20% to 30%, 17 mm long, and 20 mm neck diameter was chosen.

Under strict sterile conditions on a back table, the Incraft (Cordis Corporation, FL) aortic endograft was partially unsheathed, and the first and second covered rings were partially opened, leaving the main body partially closed. The “free flow stent” was constrained by the release wire. The locations for the fenestrations were pre-marked on the body of the stent graft using the measurements obtained from centreline analysis on computed tomography angiography (CTA), in which the distance to the visceral branches from the superior extent of the landing zone and size of the branch orifices were identified using axial images and clockface orientation. These modifications allowed a proximal landing zone of 20 mm for the first patient and 17 mm for the second patient.

The fenestrations were made with a no. 11 blade; enlarged with a 6 mm diameter balloon (which helps make them perfectly round); sutured circumferentially with 0.014” PT® wire (Boston Scientific, MA) using 6-0 Prolene for reinforcement and to make them visible under fluoroscopy; and pre-cannulated with 0.018” hydrophilic wires (one and two, respectively, for male and female cases) to the main body and pulled out from the proximal stent of the main body separately. The stent graft was partially reloaded retrogradely into the sheath (Table 2).

### Endograft implantation

The main body was introduced by the largest femoral access, and the contralateral limb was placed by the contralateral femoral access. A 16F DrySeal (W.L. Gore and Associates, AZ) sheath was introduced. No pre-dilation was needed probably because the largest diameters of the external iliac arteries in the patients were 5.95 and 5.93 mm, very close to the 6.1 mm diameter of the DrysealFlex. The reconstrained main body was then introduced through the femoral sheath.

The top of the covered part of main body was positioned right below the RRA in the first patient, and just inferior to

| Patient | AAA diameter (cm) | Aortic diameter at level of renal artery (mm) | Distance from lower edge right renal artery to beginning of AAA (mm) | Distance from lower edge of left renal artery to beginning of AAA (mm) | Distance lowest renal to aortic bifurcation (cm) | Diameter of right external iliac artery (mm) | Diameter of left external iliac artery (mm) |
|---------|------------------|---------------------------------------------|-------------------------------------------------|-------------------------------------------------|-----------------------------------------------|------------------------------------------|------------------------------------------|
| Patient 1 | 6.7              | 28.2                                       | 21.6                                            | 4                                               | 10.66                                         | 5.93                                      | 5.22                                      |
| Patient 2 | 7.9              | 20.3                                       | 0.0                                             | 1                                               | 10.38                                         | 5.39                                      | 5.95                                      |

AAA = abdominal aortic aneurysm.

---

6. Gustavo Paludetto et al. (2023).
the SMA according to the lateral aortogram. Via brachial access (single on first and bilateral on second case), the pre-cannulated wires were captured separately using a snare at the thoracic aorta. A 7F Ansel Flexor (Cook Medical Inc., Bloomington, IN) slide on a through and through system was used for crossing inside the top edge of the partially released proximal stent without any trouble and selectively cannulating one/both renal arteries. After angiographic confirmation, the wires were exchanged for Rosen wires (Cook Medical Inc., IN). After accessing both renal arteries, the aortic endograft was deployed and the proximal seal zone fully expanded with a Coda balloon (Cook - W. L. Gore & Associates, Inc). The iCast covered stents (Atrium Medical, NH) were deployed into left renal (male case)/both renal arteries (female case) and flared proximally with a 12 mm angioplasty balloon. The contralateral gate was then cannulated, and the contralateral limb was deployed in the standard fashion.

**Procedural outcomes**

The completion angiogram and intra-operative 3D computed tomography and follow up CTA 12 months after the procedure (Figs. 1 and 2) demonstrated SMA patency, both renal arteries, and no evidence of endoleak. No reinterventions, occlusions, or ischaemia were detected. Follow up of two subsequent cases performed without the use of pre-cannulated wires is near completion.
DISCUSSION
Because customised endografts are not suitable for patients who need urgent or emergency juxtarenal aneurysm repair, different techniques can be applied, including parallel grafts, and branched or physician modified endografts. An off label use of a physician fenestrated Incraft stent graft appears to be a viable alternative for patients with small access vessels, at high risk for open repair, and in urgent or emergency cases. The technique (summarised in Table 2) might allow the limitations of branched or fenestrated aortic endografts, such as cost, availability, endograft diameter, and time required for graft customisation to be overcome. Larger studies the comparing use of physician modified off the shelf endografts with chimney/Storkey techniques and debranching for repair of juxtarenal aneurysms in patients with small access vessels is warranted.

REFERENCES
1 Schwarze ML, Shen Y, Hemmerich J, Dale W. Age-related trends in utilization and outcome of open and endovascular repair for abdominal aortic aneurysm in the United States, 2001-2006. J Vasc Surg 2009;50:722-9.
2 Steyerberg EW, Kievit J, de Mol Van Otterloo JC, van Bockel JH, Eijkemans MJ, Habbema JD. Perioperative mortality of elective abdominal aortic aneurysm surgery: a clinical prediction rule based on literature and individual patient data. Arch Intern Med 1995;155:1998—2004.
3 Donas KP, Lee JT, Lachat M, Torsello G, Veith FJ, on the behalf of the PERICLES investigators. Collected world experience about the experience of the snorkel/chimney endovascular technique in the treatment of complex aortic pathologies. Ann Vasc Surg 2015;262:546—53.
4 Oderich GS, Ricotta 2nd JJ. Modified fenestrated stent grafts: device design, modifications, implantation, and current applications. Perspect Vasc Surg Endovasc Ther 2009;21:157—67.
5 Starnes BW. Physician-modified endovascular grafts for the treatment of elective, symptomatic, or ruptured juxtarenal aortic aneurysms. J Vasc Surg 2012;56:601—7.
6 Starnes BW. A surgeon’s perspective regarding the regulatory, compliance, and legal issues involved with physician-modified devices. J Vasc Surg 2013;57:829—31.
7 Oderich GS, Greenberg RK, Farber M, Lyden S, Sanchez L, Fairman R, et al. Results of the United States multicenter prospective study evaluating the Zenith fenestrated endovascular graft for treatment of juxtarenal abdominal aortic aneurysms. J Vasc Surg 2014;60:1420—8. e1—5.
8 Kinstner C, Teufelsbauer H, Neumayer C, Domenig C, Wressnegger A, Wolf F, et al. Endovascular repair of thoracoabdominal aortic aneurysms with a novel multibranch stent-graft design: preliminary experience. J Cardiovasc Surg 2014;55:543—50.
9 Sobocinski J, d’Utra G, O’Brien N, Midulla M, Maurel B, Guillou M, et al. Off-the-shelf fenestrated endografts: a realistic option for more than 70% of patients with juxtarenal aneurysms. J Endovasc Ther 2012;19:165—72.
10 Ricotta 2nd JJ, Tsilimparis N. Surgeon-modified fenestrated-branched stent grafts to treat emergently ruptured and symptomatic complex aortic aneurysms in high-risk patients. J Vasc Surg 2012;56:1535—42.