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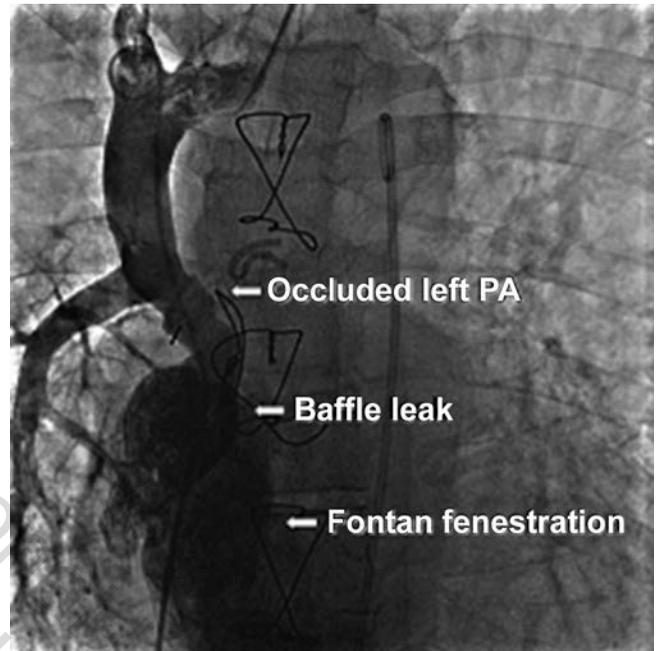
Customized Covered Stent Graft for Percutaneous Closure of Fontan Baffle Leak

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ABSTRACT: We report the innovation of both a partly-covered and completely-covered, variable-diameter, balloon-expandable stent that was custom-designed by NuMed, Inc for percutaneous closure of a baffle leak after total caval pulmonary connection (TCPC). A 50-year-old patient, born with tricuspid atresia, who had undergone TCPC, developed severe persistent cyanosis due to a right-to-left shunt through a TCPC baffle leak. Re-operation was deemed too high risk. Therefore, considering his complex anatomy, a custom-made, partly-covered, tapered, balloon-expandable stent was designed and successfully deployed. Months later, the shunt recurred at the junction of the covered to uncovered stent cells; subsequently, a second fully-covered, custom-made, tapered stent was implanted with an excellent outcome. The use of covered or partly-covered customized variable-diameter stents for closure of baffle leak after TCPC is feasible and resulted in marked clinical improvement. Customized balloon-expandable stents may be superior to traditional cylindrical stents because of better anchoring and apposition.

Right-to-left shunts after total caval pulmonary connection (TCPC) surgery may be intentionally left by creating a fenestration from the TCPC baffle to the systemic atrium to ensure sufficient cardiac output (fenestrated TCPC).[1] However, shunts may arise as a complication caused by baffle dehiscence.[2] In both situations, the right-to-left shunt may require closure, which may be performed percutaneously with atrial septal defect (ASD) occluders, patent ductus arteriorus (PDA) occuders, coils, or covered stents.[2-7] The literature on the use of covered stents in patients with complex congenital heart disease is limited[8,9] and the marked change in diameter of the involved structures can hamper the use of cylindrical stents. We describe the use

Figure 1. *Angiographic assessment of baseline anatomy: there is a marked change in vessel diameter between the atrial portion of the baffle and the connection to the pulmonary artery. Note the occluded left pulmonary artery.*

of novel, customized, tapered, balloon-expandable covered stents for occlusion of a large baffle leak in a patient with complex anatomy.

Methods

Patient. A 50-year-old male patient, born with tricuspid atresia, underwent a Glenn procedure (connection of the superior vena cava with the right pulmonary artery) in childhood and a Blalock-Taussig shunt (connection of the subclavian artery to the pulmonary artery) at the age of 20 years. Later, at the age of 25 years, a fenestrated TCPC was performed, using Hemashield grafts. A 5 mm fenestration to the systemic atrium was placed in the pericardial baffle. Shortly after TCPC surgery, the Hemashield graft to the left pulmonary artery occluded and two percutaneous attempts to re-open it were unsuccessful.

After doing clinically well for a number of years, the patient developed progressive shortness of breath and cyanosis. An angiogram showed a patent Glenn shunt, chronic occlusion of the left pulmonary artery, and a large residual
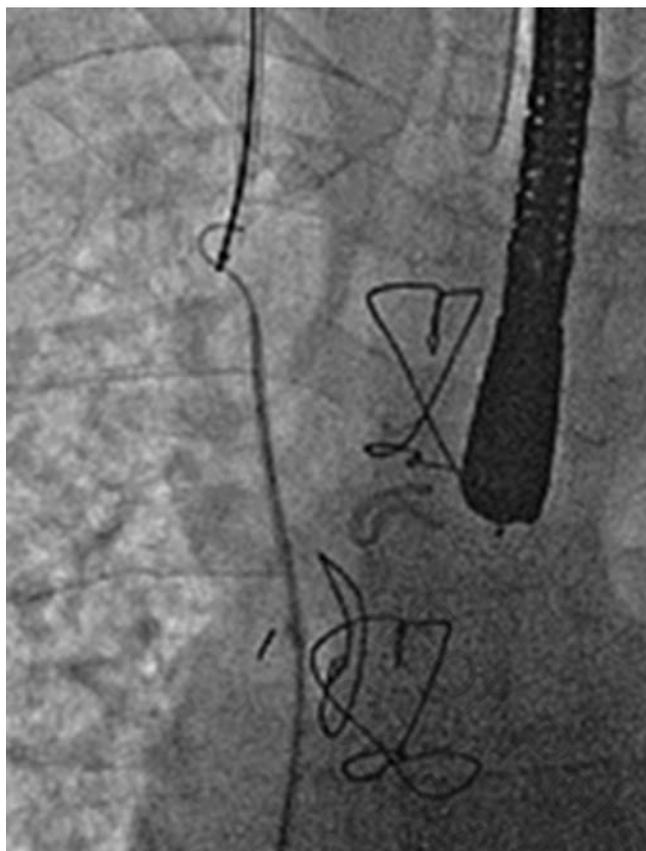
Figure 2. *Snaring of the Amplatz extra-stiff wire from the jugular access site.*
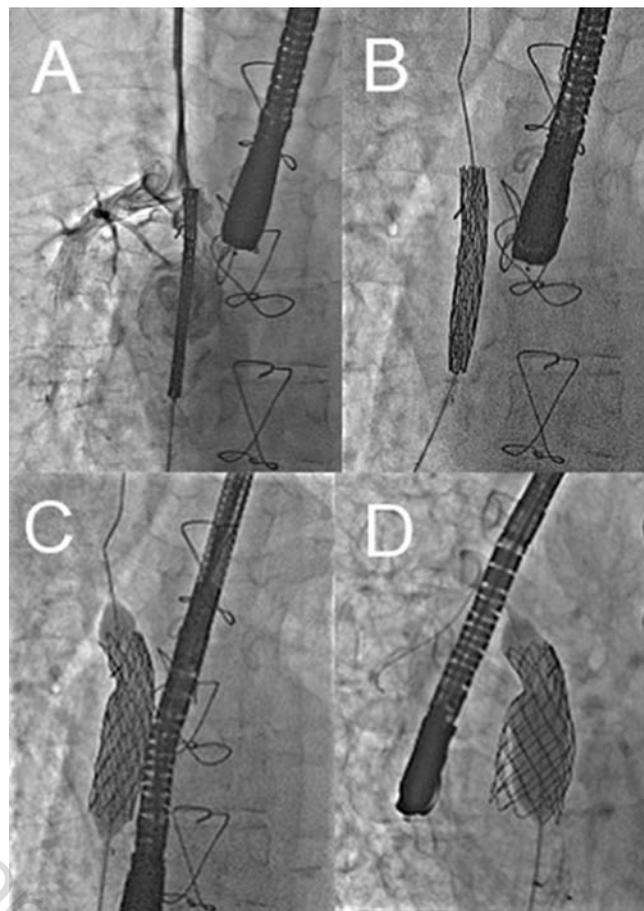

Figure 3. (A) *Positioning of the stent.* **(B)** *Inflation of the inner balloon allowing final positioning.* **(C)** *Inflation of the asymmetrical outer balloon with a bigger diameter at the caudal 4 cm and smaller diameter at the cranial 2.5 cm.* **(D)** *Postdilation of the caudal (not shown) and the cranial part of the stent in order to achieve approximately 20% oversizing.*

shunt from the TCPC to the systemic atrium along the superior edge of the pericardial baffle. In addition, the intentionally created 5 mm fenestration was a second source of right-to-left shunting.

Multidisciplinary discussions considered further therapeutic options with surgical correction deemed very high risk and percutaneous closure of the significant right-to-left shunt was deemed preferable.
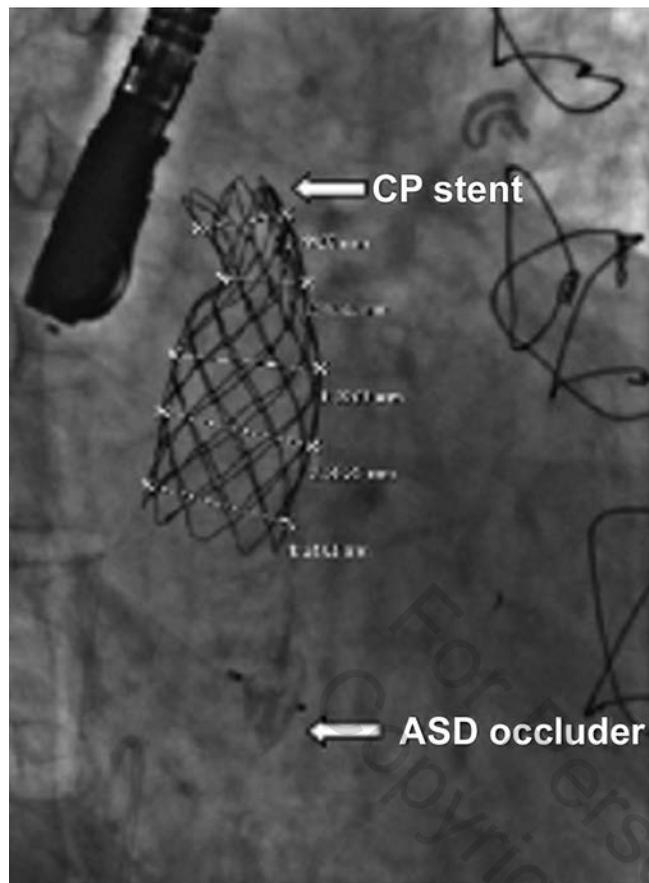
Anatomical and physiological considerations. On echocardiography, the left ventricle was markedly dilated with a mildly depressed systolic ejection fraction of 50%. The peak gradient across the fenestration was 9 mm Hg. The site of the baffle leak appeared to be in the medial aspect of the tunnel. The baffle measured 22 mm in diameter at the leak site and 11 mm at the attachment to the right pulmonary. In order to fully cover the leak and to sufficiently anchor the stent in the right pulmonary artery, a total stent length of about 60 mm was required (Figure 1).

Effective percutaneous closure was felt to require a partly-covered custom stent design to secure reliable placement and anchoring given the marked change in diameter between the actual baffle and the right pulmonary artery. Since the only source of blood supply to the lungs was the right pulmonary artery, it was crucial not to compromise flow into the right pulmonary artery.
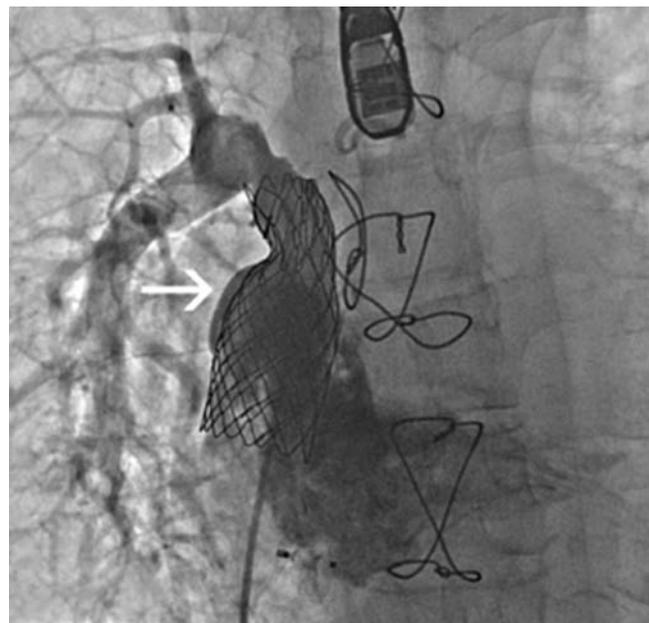
Stent and delivery system design. In collaboration with the company engineers, the stent design was based on a modified covered Cheatham Platinum (CP) stent

(NuMed Inc). The CP was an expandable polytetrafluoroethylene (ePTFE) covered stent, with a 90% platinum and 10% iridium frame and a strut thickness of 0.013″. The stent configuration consisted of 10 strut cells, allowing expansion up to 30 mm. The novelty of this system was the balloon-in-balloon delivery catheter (NuMed Inc). The inner balloon measured 6 cm x 8 mm and the outer balloon was asymmetrical with the cranial 2.5 cm of the outer balloon expanding to 16 mm (2.5 cm x 16 mm) when fully inflated and the caudal 4 cm expanding to 22 mm (4 cm x 22 mm). The ePTFE covered only the caudal 40 mm of the stent. As this stent expands, it progressively shortens; hence, it is necessary to accommodate greater shortening of the larger diameter portion of the stent (anticipated to be 15%) than at the smaller distal part of the stent. Inflation of the inner balloon would lead to partial expansion and anchoring in the narrower cranial portion. This would result in minimal ability to adjust the position prior to inflation of the outer balloon for final deployment.

Procedure. The procedure was performed in the catheterization laboratory under general anesthesia and transesophageal echocardiographic imaging. Right femoral (18

Figure 4. *The stent is well expanded and safely anchored in the pulmonary artery. The Fontan fenestration is occluded with a 5 mm atrial septal defect (ASD) occluder. CP = Cheatham Platinum stent.*

Table 1. Baseline measurements and final stent dimensions.

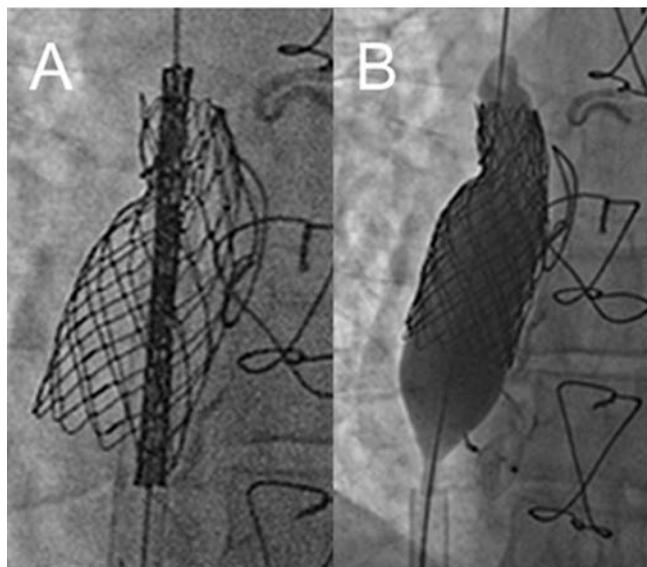|	Right PA	Common PA	Leak site
Baseline first stent (mm)	11	12	22
Final dimensions first stent (mm)	15	14	26
Oversizing first stent (%)	36	16	18
Baseline second stent (mm)	14	14	24
Final dimensions second stent (mm)	15	14	24
Oversizing second stent (%)	7	0	0
PA = pulmonary artery.			

Fr, Cook Canada, Inc) and jugular venous (8 Fr) and left femoral arterial (5 Fr for pressure recording) accesses were obtained.

An Amplatz extra-stiff wire was introduced from the femoral vein and snared (35 mm loop Gooseneck snare; eV3, Inc) from the jugular access site as previously described[2] (Figure 2). The endovascular stent and delivery system were inserted via the 18 Fr sheath and positioned to accommodate the anticipated shortening. Positioning was guided by contrast injections through the jugular sheath (Figure 3A) and after partial inflation of the inner balloon (Figure 3B) the position was adjusted and the stent was fully deployed by inflating the outer balloon (Figure 3C). Postdilatations were performed using a 25 mm Nucleus balloon (NuMed, Inc) for the caudal part of the stent and an 18 mm Z-med balloon (NuMed, Inc) for the cranial part of the stent (Figure 3D).

Results

Despite aggressive postdilation, a small residual shunt at the baffle leak persisted. Therefore, we decide to occlude the intentional TCPC fenestration with a 5 mm ASD occluder (AGA Medical Corporation; Figure 4). The final stent dimensions were slightly oversized by approximately 20% as compared to the baseline measurements (Table 1 and Figure 4). Procedural success was documented by marked reduction in right-to-left shunt and an increase in arterial blood saturation (preprocedural 76%, postprocedural 95%). Venous and arterial sheaths were removed and entry sites manually compressed. There were no procedural complications and the patient was discharged the following morning. He was given aspirin and clopidogrel for 3 months in addition to chronic warfarin therapy.

Despite initial clinical improvement, the patient presented 1 month later with worsening dyspnea. His oxygen saturations had again gone down to 83%. Venograms of the TCPC and superior vena cava showed a recurrent leak around the transition of the covered to the uncovered portion of the stent, causing recurrence of a clinically significant right-to-left shunt (Figure 5). It was felt that a second

Figure 5. *Contrast injection in the stent shows the leak at the junction from the uncovered to the covered stent cells with a significant shunt to the common atrium (white arrow pointing at the contrast outside and around the covered stent portion).*

Figure 6. (A) *Positioning of the second stent, which is still inside the sheath.* **(B)** *Deployment of the second stent (both deployment balloons are inflated).*

percutaneous procedure placing a fully ePTFE-covered stent inside the first stent would exclude the shunt.

Second procedure. Since the first stent in place constituted a radio-opaque landing zone for the second stent, there was limited value in transesophageal echocardiography guidance and general anesthesia was not used. A second modified custom stent with a complete ePTFE covering (NuMed, Inc) was produced. It was designed to inflate in the larger portion up to 24 mm and in the upper narrower portion to 14 mm. The procedure was carried out using an approach similar to the first procedure. The initial venogram in the Fontan circuit demonstrated immediate flow of contrast from the baffle into the systemic atrium (Figure 5). We placed the second stent within the preexisting stent in the Fontan circuit (Figure 6A). A marker band on the delivery catheter aided localization of the transition point in the stent diameter. We then sequentially hand inflated the balloon-in-balloon device to fully deploy the stent (Figure 6B). It was very well positioned and measured 15 mm in the upper narrower portion and 24 mm in the lower portion. A postprocedure venogram demonstrated no contrast from the Fontan to the atrium (Figure 7), with transit through the lung to the systemic atrium in a delayed fashion as intended. The systemic oxygen saturation increased to 97% and the patient was discharged home the next morning reporting marked improvement in his dyspnea.

When seen 6 months later, the patient reported continued improved symptoms (New York Heart Association class II). His exercise capacity during cardiopulmonary exercise testing had considerably improved from 45% of the age-predicted maximum preprocedure to 54% at 6 months postprocedure.

Discussion

Although freedom from re-operation after TCPC surgery is high,[10-12] re-operation in these patients carries a

Figure 7. *Contrast injection in the stent shows no shunt from the Fontan circulation to the common atrium.*

high mortality risk.[1,3,14] Percutaneous procedures are lower-risk alternatives to re-operation, but abrupt changes in vessel diameter may hamper a good result for conventional cylindrical stents. Self-expanding nitinol stents partly account for these diameter changes, but at the price of lower radial force and greater risk of stent migration compared to balloon-expandable stents.[15,16]

In this case, we used a novel customized stent delivery system to better accommodate the marked changes in baffle diameter. This new stent and delivery system have the potential for better apposition and anchoring as compared to cylindrical stents. The first stent was designed to only cover the larger diameter portion to exclude the leak at the dehiscence and reduce the risk of placing the covered portion too cranial, avoiding obstruction of the right pulmonary artery. However, ineffective sealing occurred at the superior border related to changing diameter and angular configuration of the connection to the right Glenn or due to dislocation

of the ePTFE covering. The second fully-covered stent enabled complete exclusion and coverage of the transition zone where the stent diameter change was essential.

Alternative approaches might have been to place a fully-covered cylindrical stent either initially or on the second attempt, anticipating that the smaller diameter portion would simply be underexpanded. We chose to avoid a significant rupture risk by constructing the stent with variable diameters. A second concern with using a cylindrical stent was the potential for caudal displacement, since the cranial portion of the balloon would be markedly oversized for that portion of the vessel. Other approaches could include placing 2 separate overlapping stents with different diameters at the outset; however, this would add additional complexity and have similar challenges in dealing with the transition point.

Conclusions

The use of covered or partly-covered customized tapered stents for closure of baffle leak after TCPC is feasible and resulted in marked clinical improvement. Customized balloon-expandable stents may provide a good alternative to traditional cylindrical stents with potential for better anchoring and apposition in complex anatomies.

References

1. Bridges ND, Lock JE, Castaneda AR. Baffle fenestration with subsequent transcatheter closure. Modification of the Fontan operation for patients at increased risk. *Circulation.* 1990;82(5):1681-1689.

2. Hijazi ZM, Ruiz CE, Patel H, Cao QL, Dorros G. Catheter therapy for Fontan baffle obstruction and leak, using an endovascular covered stent. *Cathet Cardiovasc Diagn.* 1998;45(2):158-161.

3. Hausdorf G, Schneider M, Konertz W. Surgical preconditioning and completion of total cavopulmonary connection by interventional cardiac catheterisation: a new concept. *Heart.* 1996;75(4):403-409.

4. Daehnert I, Hennig B, Wiener M, Rotzsch C. Interventions in leaks and obstructions of the interatrial baffle late after Mustard and Senning correction for transposition of the great arteries. *Catheter Cardiovasc Interv.* 2005;66(3):400-407.

5. Boudjemline Y, Bonnet D, Sidi D, Agnoletti G. [Closure of extrocardiac Fontan fenestration by using the Amplatzer duct occluder]. *Arch Mal Coeur Vaiss.* 2005;98(5):449-454.

6. Marini D, Boudjemline Y, Agnoletti G. Closure of extracardiac Fontan fenestration by using the covered Cheatham Platinum stent. *Catheter Cardiovasc Interv.* 2007;69(7):1002-1006.

7. Sommer RJ, Recto M, Golinko RJ, Griepp RB. Transcatheter coil occlusion of surgical fenestration after Fontan operation. *Circulation.* 1996;94(3):249-252.

8. Butera G, Piazza L, Chessa M, Abella R, Bussadori C, Negura D, Carminati M. Covered stents in patients with congenital heart defects. *Catheter Cardiovasc Interv.* 2006;67(3):466-472.

9. Nietlispach F, Leipsic J, Wijesinghe N, Webb JG, Carere RG. First-in-man use of a tapered endovascular stent graft for treatment of aneurysm after coarctation repair. *Catheter Cardiovasc Interv.* 2010;76(7):1035-40.

10. Ono M, Boethig D, Goerler H, Lange M, Westhoff-Bleck M, Breymann T. Clinical outcome of patients 20 years after Fontan operation — effect of fenestration on late morbidity. *Eur J Cardiothorac Surg.* 2006;30(6):923-929.

11. Kim SJ, Kim WH, Lim HG, Lee JY. Outcome of 200 patients after an extracardiac Fontan procedure. *J Thorac Cardiovasc Surg.* 2008;136(1):108-116.

12. Nakano T, Kado H, Tachibana T, et al. Excellent midterm outcome of extracardiac conduit total cavopulmonary connection: results of 126 cases. *Ann Thorac Surg.* 2007;84(5):1619-1625; discussion 25-26.

13. Monro JL, Alexiou C, Salmon AP, Keeton BR. Reoperations and survival after primary repair of congenital heart defects in children. *J Thorac Cardiovasc Surg.* 2003;126(2):511-520.

14. Wells WJ, Blackstone E. Intermediate outcome after Mustard and Senning procedures: a study by the Congenital Heart Surgeons Society. *Semin Thorac Cardiovasc Surg Pediatr Card Surg Annu.* 2000;3:186-197.

15. Grenacher L, Rohde S, Ganger E, Deutsch J, Kauffmann GW, Richter GM. In vitro comparison of self-expanding versus balloon-expandable stents in a human ex vivo model. *Cardiovasc Intervent Radiol.* 2006;29(2):249-254.

16. Dalainas I, Nano G, Bianchi P, et al. Aortic neck dilatation and endograft migration are correlated with self-expanding endografts. *J Endovasc Ther.* 2007;14(3):318-323.