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CODA Balloon Catheter

Use of this device as an adjunct to successful aortic endografting for disadvantaged anatomy.

BY MARTIN R. BACK, MD

The CODA Balloon Catheter (Cook Incorporated, Bloomington, IN) is a semi-compliant, polyurethane balloon used for expansion of abdominal (AAA) and thoracic (TAA) aortic aneurysm endografts and/or temporary occlusion of large vessels. The balloon is available in diameters of 32 mm and 40 mm, with maximum inflation volumes of 34 mL and 40 mL, respectively. The 32-mm balloon is mounted on a flexible 100-cm, 10-F catheter, whereas the 40-mm balloon is mounted on a 120-cm, 10-F catheter; both are compatible with a 14-F introducer sheath (Figure 1).

The proximal and distal segments of the balloon are identified by radiopaque markers located 36 mm apart on the 32-mm balloon and 38 mm apart on the 40-mm balloon. The balloon's shape and material allow for good conformability within anatomical regions of rapid diameter change. Distinct design advantages include short balloon shoulders that minimize inflation trauma to adjacent vessel, a more rapid inflation/deflation rate than other aortic occlusion balloons, and a low postdeflation profile with minimal winging.

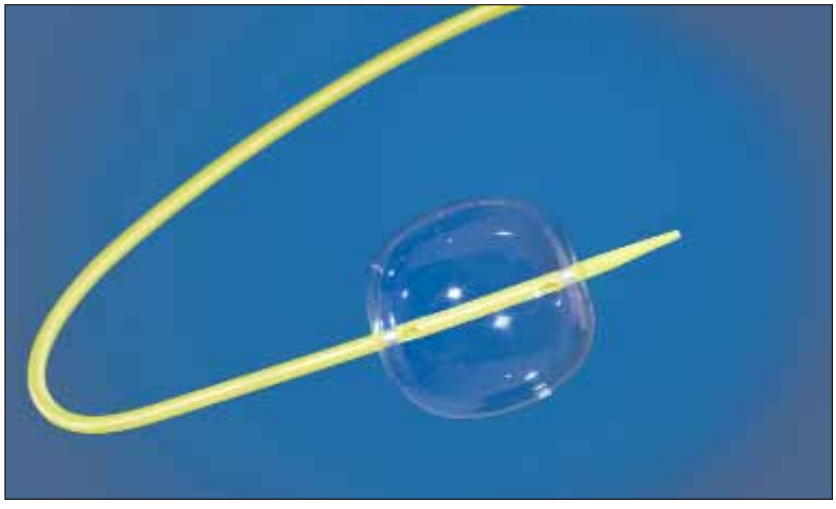


Figure 1. The CODA Balloon Catheter is mounted on a polyurethane bi-lumen catheter and indicated for abdominal, thoracic, and iliac applications. The polyurethane balloon conforms well to irregular aortoiliac anatomy.

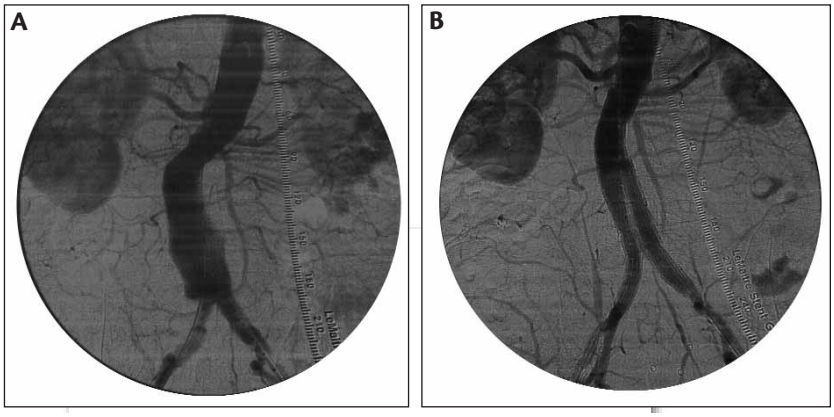


Figure 2. A patient with a AAA prior to endograft deployment (A). An angiogram obtained after balloon placement shows the graft well seated in the infrarenal neck, with no endoleak (B).

CASE EXAMPLES

We have found the CODA Balloon Catheter to be particularly effective in facilitating endograft placement in disadvantaged aortoiliac anatomy associated with aneurysmal disease in which it is often difficult to attain optimal seal and fixation. Figures 2 through 5 illustrate four such cases.

In the first case (Figure 2), imaging revealed an angled infrarenal neck with an irregular luminal surface and "bleb" formation along the right lateral aortic wall.

The second case (Figure 3) had a calcified aortic neck with an irregular luminal surface that resulted in a type I endoleak after device deployment. We increased radial force in the calcified region by deploying a cuff inside the upper primary graft and performing additional CODA ballooning for complete expansion and endoleak ablation. AAA regression of 10 mm had occurred by 6-month follow-up, with no endoleak detected.

In Case 3 (Figure 4), a proximal device migration and type I endoleak were found in a patient with a conical, angled infrarenal neck 2 years after initial endograft placement.

The fourth case occurred in a AAA patient with right proximal common iliac stenosis and distal iliac ectasia, which created an area of rapid vessel diameter change. The CODA Balloon Catheter was used to successfully dilate the stenosis after endograft placement and expand the distal portion of the endograft limb within the dilated iliac above the hypogastric origin.

In the fifth patient with an acute type B aortic dissection, which was complicated 1 month after presentation by a distal thoracic aortic pseudoaneurysm, a type III endoleak occurred after placement of three overlapping endografts. More aggressive device expansion at the lower endograft overlap site was accomplished with the 40-mm CODA Balloon Catheter, abolishing contrast leak between device components and the type III endoleak (Figure 5).

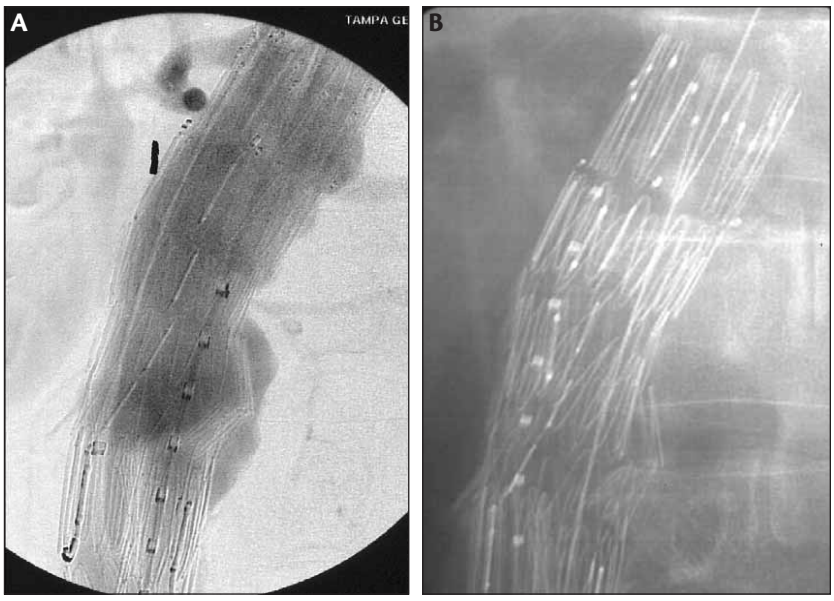


Figure 3. After initial endograft placement, the patient was found to have a type I proximal endoleak (A). A Zenith cuff (Cook) was placed inside the proximal segment of the primary graft, and additional ballooning was performed (B).

DISCUSSION

In cases such as these presented herein, the CODA Balloon Catheter has significant advantages over standard, noncompliant, constant-volume angioplasty balloons. Whereas angioplasty balloons maintain a constant shape with increased pressure, the CODA Balloon Catheter maintains a constant pressure while conforming to the shape of the vessel or endograft in which it is expanded, resulting in greater contact of the balloon with the inner surface of the endograft, more uniform application of distending pressure to the inner circumference of the endograft, and consequently better con-

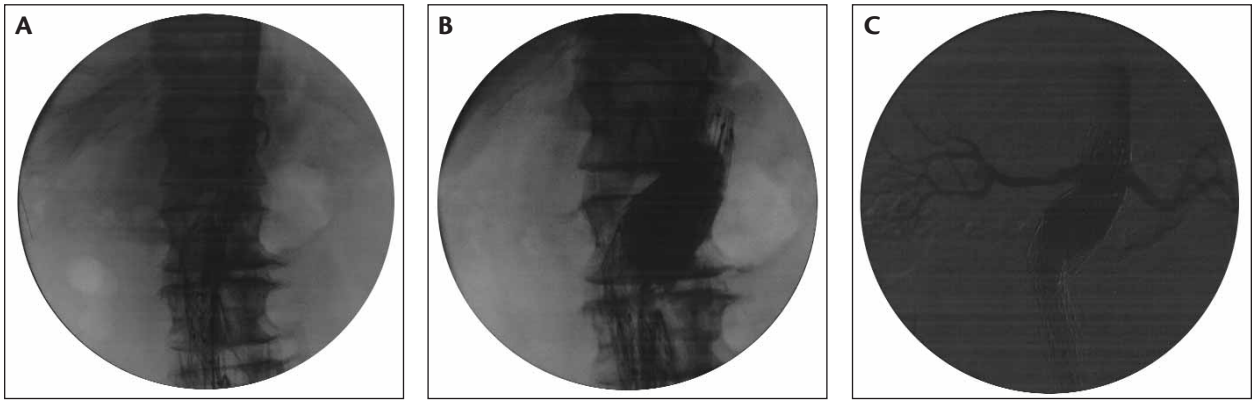
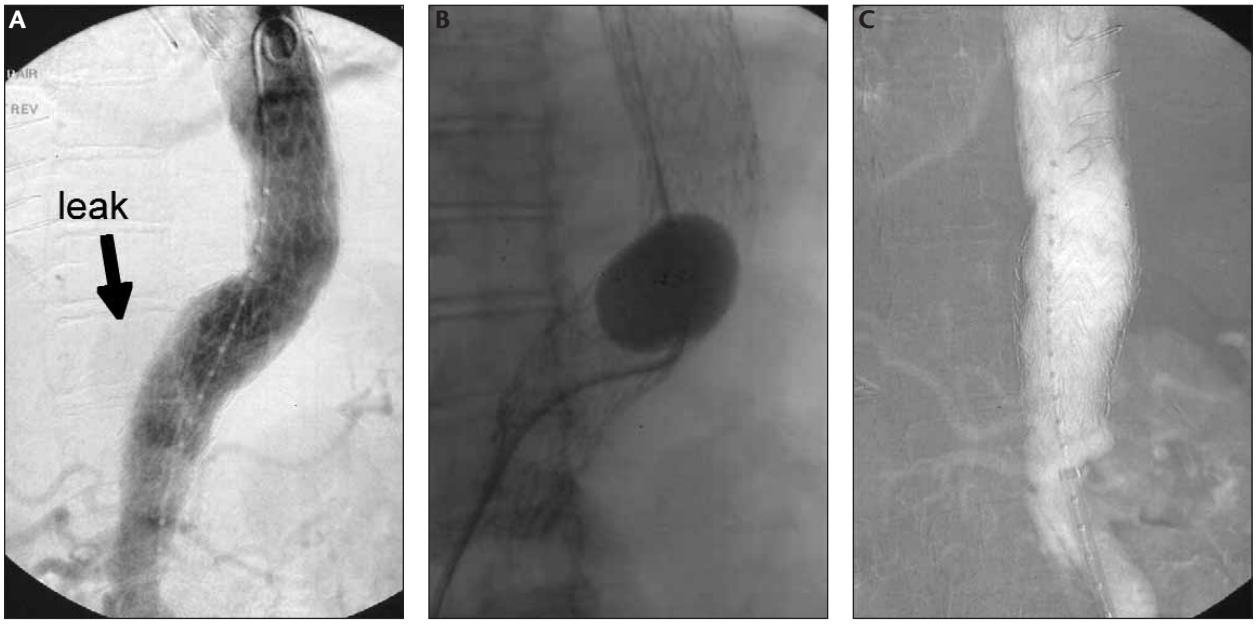


Figure 4. The device migration was repaired with a Zenith RENU aorto-mono-iliac endograft (Cook) (A). The CODA Balloon Catheter was inflated within the RENU graft to optimize expansion and apposition to the angled, conical infrarenal neck (B). Angiography performed after the procedure revealed successful exclusion of endoleak and repair of migration by establishing a new, secure proximal fixation site (C).



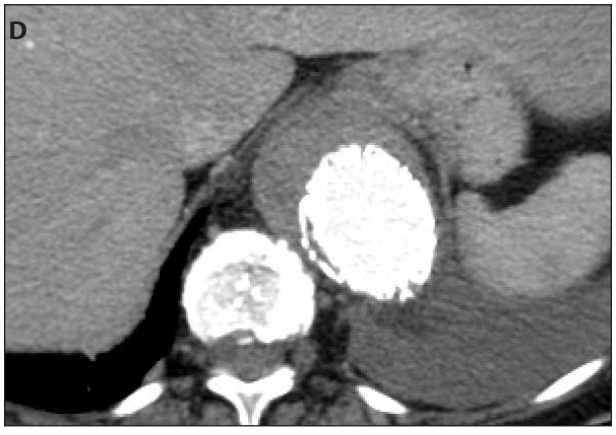


Figure 5. Residual type III endoleak after multicomponent treatment of a distal thoracic pseudoaneurysm and type B aortic dissection (A). CODA balloon expansion at device overlap site (B). Elimination of type III endoleak and exclusion of contrast flow between outer and inner endograft components during completion angiography and later confirmed by contrast-enhanced CT scan (C,D).

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formance of the endograft within disadvantaged aortoiliac anatomy.

The CODA is also less likely to cause trauma to either the endograft or the vessel. Angioplasty balloons, which typically have higher inflation pressures, can be overinflated within an endograft, rupturing sutures at the stent graft junctions and creating microleaks. When overinflated at the margin of the graft where the balloon shoulder comes in contact with the vessel wall, they can rupture the vessel. Because the CODA Balloon Catheter increases in volume rather than pressure, it is a safer choice for use in large-diameter vessels such as the aorta in which distending balloon pressures should not exceed 2 atm. The CODA Balloon Catheter's short shoulders also make vessel rupture less likely by reducing the likelihood of balloon-to-vessel contact at the graft margin.

Finally, the CODA Balloon Catheter yields significantly better results than angioplasty balloons during molding of irregular shapes and surfaces within an infrarenal neck. The frequently used "kissing" technique, in which two angioplasty balloons are inflated side-by-side, provides incomplete balloon-to-endograft contact. As a result, endograft circumferential expansion and apposition to the aortic wall may be insufficient to prevent endoleaks or later fixation failure and migration. The CODA Balloon Catheter attains much greater circumferential contact with the endograft, optimizing expansion and conformance within the vessel. ■

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