FLAIR™
ENDOVASCULAR STENT GRAFT

Clinical Experience

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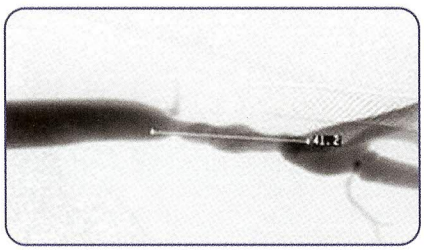

FIGURE 1: Recurrent venous anastomotic stenosis

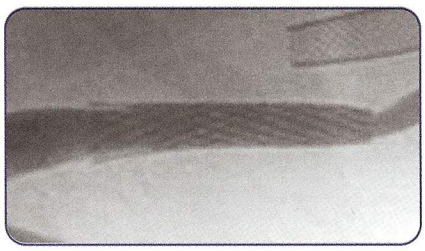

FIGURE 2: Ten month fistulogram of FLAIR™ Endovascular Stent Graft

FIGURE 3: 35 months after placement of the FLAIR™ Endovascular Stent Graft

A 62-year-old patient with hemodialysis-dependent end-stage renal disease for 6 years, Type-II diabetes mellitus, peptic ulcer disease, and moderate obesity underwent multiple catheter interventions and Wallstent placement in the left forearm AV graft until surgical revision of the graft was ultimately performed in October 1999.

Two months later, in December 1999, the access clotted. Function was successfully restored with percutaneous catheter thrombectomy and angioplasty. Nine months later, in September 2000, the patient was seen for increased venous pressure in the arteriovenous graft and underwent 8 mm diameter balloon angioplasty of a venous anastomotic stenosis. The patient did well for almost nine more months. In May 2001, the patient was again seen for recurrent elevated venous pressures in their access circuit. Once again, a venous anastomotic stenosis was demonstrated by fistulography and treated with 8mm diameter balloon angioplasty. Almost nine months later, in February 2002, the patient was again seen for increased venous pressure in their access and reduced clearance during dialysis. Fistulography demonstrated a 60-70% recurrent venous anastomotic stenosis (Figure 1).

The patient was enrolled in the BARD® stent graft clinical trial and randomized to the FLAIR™ Endovascular Stent Graft Group. The venous anastomotic stenosis was treated with 8mm diameter balloon angioplasty followed by placement of an 8mm x 50mm FLAIR™ Endovascular Stent Graft with a flared configuration across the site of angioplasty.

Interval fistulogram studies, per the study protocol, were performed at 3 and 10 months (Figure 2). The entire arteriovenous circuit, including the stent graft, was patent and dialysis was uneventful.

In January 2005, thirty-five months after placement of the FLAIR™ Endovascular Stent Graft, the patient returned for evaluation of the arteriovenous graft due to poor access performance during dialysis. Fistulogram showed that the FLAIR™ Endovascular Stent Graft remained widely patent (Figure 3) but a focal severe intragraft stenosis had formed within the arterial cannulation segment of the graft (not shown). This was successfully treated with angioplasty. Angiographic study of the access 3 months later confirmed that the stent graft, as well as the entire access circuit, remained patent.

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Clinical Experience

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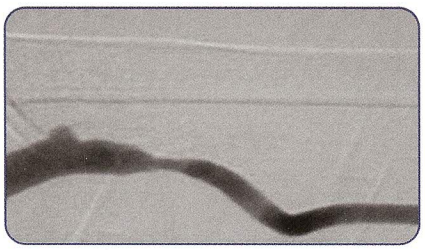

FIGURE 1: Venous outflow stenosis

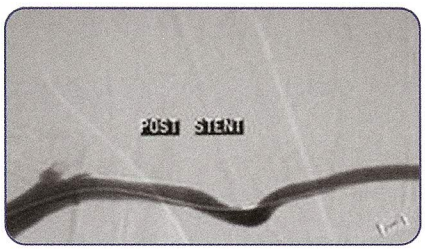

FIGURE 2: After treatment with a FLAIR™ Endovascular Stent Graft

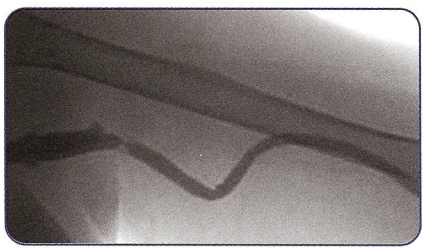

FIGURE 3: Stenosis 16 and 28 months after stent graft placement at the stent graft end

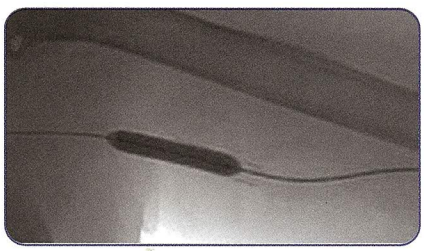

FIGURE 4: Treatment with an 8mm diameter balloon angioplasty

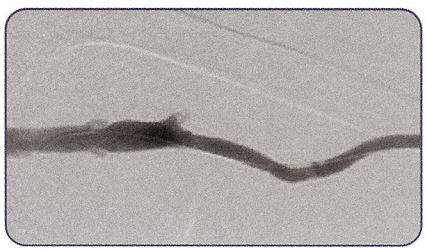

FIGURE 5: Thrill restored post angioplasty

A patient with a left forearm loop graft, including an extension to the axillary vein, presented high venous resistance in November 2001. A venous outflow stenosis was found (Figure 1) and treated with a 8mm x 40mm BARD® FLAIR™ Endovascular Stent Graft in a flared configuration as part of a clinical trial. Thrill was restored (Figure 2).

The graft remained patent without further intervention until March 2003, when it thrombosed. The area was treated with mechanical thrombectomy. A "candy-wrapper" type stenosis was found at the central end of the stent graft. This was treated with 8mm diameter balloon angioplasty as was the accompanying intragraft stenosis.

One year later, in March 2004, elevated venous resistance was again noted. The graft was pulsatile on physical examination and fistulography revealed restenosis in the same location at the central end of the stent (Figures 3 & 4) and treated with 8mm diameter balloon angioplasty. Thrill was restored in the graft and the patient resumed dialysis (Figure 5).

In August 2005, the patient moved to another state and was lost to follow-up. The FLAIR™ Endovascular Stent Graft was fully functional at that time and required no further intervention.

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Clinical Experience

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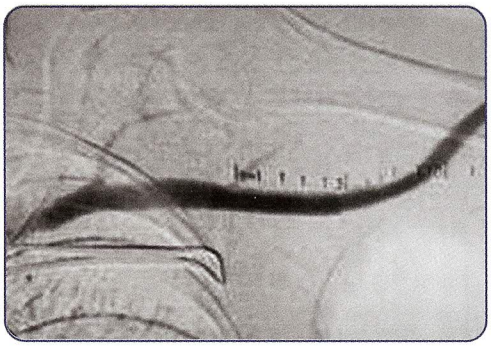

FIGURE 1: Fistulogram 2 months following placement of the FLAIR™ Endovascular Stent Graft

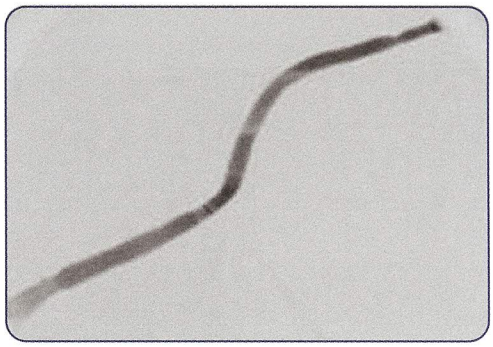

FIGURE 2: Fistulogram 29 months after placement of the FLAIR™ Endovascular Stent Graft

A 75-year-old patient has been maintained on hemodialysis via a left upper arm prosthetic graft for one year. Since placement, the patient had undergone fistulograms with venous angioplasties at 7, 9 and 12 months. The patient was included in the pivotal trial of the BARD® FLAIR™ Endovascular Stent Graft and randomized to the stent graft placement group. The individual had a recurrent 75% stenosis in the proximal venous outflow adjacent to the venous anastomosis. This was treated with 9mm diameter balloon angioplasty. Subsequently, a 9mm x 30mm FLAIR™ Endovascular Stent Graft in a straight configuration and overlapping 9mm x 40mm length FLAIR™ Endovascular Stent Graft with a flared configuration were implanted.

Figure 1 illustrates the appearance of the treated segment obtained at the fistulogram procedure 2 months following placement of the stent grafts. Two months later the patient had coronary artery bypass grafting and aortic valve replacement. After hospitalization their arteriovenous graft thrombosed. At the time of graft thrombectomy, the venous anastomosis and stent graft segments were noted to be widely patent. Graft failure appeared to be due to intragraft lesions. The arterial end of the graft was replaced.

Twenty-nine months later, the patient was referred for a fistulogram due to a dysfunctional access. At that time, the only lesion noted was a mild stenosis at the junction of the axillary and subclavian veins. The treated segment of the venous outflow containing the stent graft devices had a mild "candy-wrapper" effect stenosis at the distal end of the stent graft (Figure 2).

The access was eventually abandoned due to recurrent central vein stenosis 6 years after its original placement. The patient had early venous anastomotic stenosis that recurred 3 times after treatment with balloon angioplasty. However, the FLAIR™ Endovascular Stent Graft remained free of any evidence of recurrent stenosis for 5 years after its placement.

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