

# Results of the U.S. Multi-center, Randomized Trial of the Bard ePTFE Encapsulated Stent Graft Versus Balloon Angioplasty in Patients with Failing Dialysis AV Access Grafts

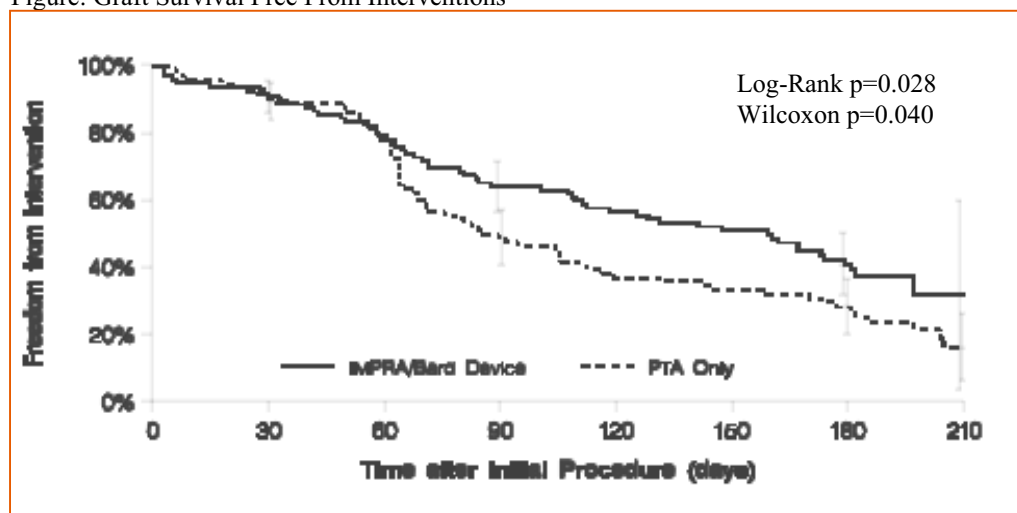
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**Purpose:** To assess the safety and efficacy of self-expanding ePTFE encapsulated stent grafts compared with angioplasty for the treatment of stenotic venous anastomoses in failing synthetic arteriovenous access grafts.

**Methods:** Prospective, 16 center, randomized enrollment of 190 patients. Enrolled upper extremity grafts had diameter stenoses >50% and obligate hemodynamic, functional, or clinical abnormalities. Patients were randomized to balloon angioplasty (PTA) alone versus PTA followed by stent graft. Functional and venographic assessments at 2 and 6 months with independent core lab analysis were performed. Endpoints were analyzed on an intention to treat basis with independent event adjudication.

**Results:** 97 patients received stent grafts and 93 PTA alone. There were no significant differences between stent graft and PTA cohorts for all criteria (e.g. demographics, graft age, location, size, prior treatments, configurations, anticoagulation, dysfunction criteria, presence of remote lesions). Device delivery success by patient was 99%. Anatomic success (<30% stenosis) was 94% in the stent graft group and 73% in the PTA group ( $p<0.001$ ). The binary restenosis rate (>50% stenosis) at 6 months was 27% in the stent graft group and 78% in the PTA group ( $p<0.001$ ). Treatment area primary patency (including the 5mm proximal and 5mm distal segment) was 80% at 2 months and 54% at 6 months (+30 days) for the stent graft group and 77% at 2 months and 29% at 6 months for the PTA group ( $p<0.001$ ). Access circuit primary patency (from arterial anastomosis to right atrium) was 80% at 2 months and 41% at 6 months for the stent graft group and 77% at 2 months and 26% at 6 months for the PTA group ( $p=0.031$ ). Time to reintervention was significantly shorter for the patients treated with stent grafts compared to the PTA group (Figure).

Figure: Graft Survival Free From Interventions



**Conclusions:** The Bard ePTFE stent graft is safe and provides clear 6-months primary patency superiority over balloon angioplasty for treatment of venous anastomotic stenoses in arteriovenous access grafts.