

# Endovascular Repair of Hemodialysis Graft-Related Pseudoaneurysms

An alternative treatment strategy in pseudoaneurysm exclusion using endografts.

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The prevalence of end-stage renal disease (ESRD) and the number of patients who need maintenance hemodialysis have risen steadily during the past 2 decades. According to recent data from the US Renal Data System, more than 300,000 patients with ESRD in the US undergo maintenance hemodialysis annually.<sup>1</sup> Surgical procedures for hemodialysis access have become the most common vascular operation in this country today. The leading causes of morbidity in the ESRD patient population are related to both vascular access placement and the resultant complications associated with the prosthetic arteriovenous graft (AVG).<sup>2</sup>

Several complications are associated with prosthetic AVG placement and include graft thrombosis, infection, and pseudoaneurysm formation.<sup>3</sup> The development of an AVG pseudoaneurysm is in part from the repetitive puncture during the hemodialysis sessions at the same graft location, which result in thinning of the prosthetic graft material (Figure 1). With chronic hemodialysis, the weakening of the prosthetic graft fabric ultimately leads to the pseudoaneurysm formation. Moreover, pseudoaneurysms can also occur from poor puncture technique of the AVG before it is fully matured. The traditional treatment of choice for an AVG pseudoaneurysm is resection or ligation of the AVG pseudoaneurysm, followed by interposition graft placement. Often, despite a successful surgical repair, the newly placed interposition AVG may require a period of 3 or 4

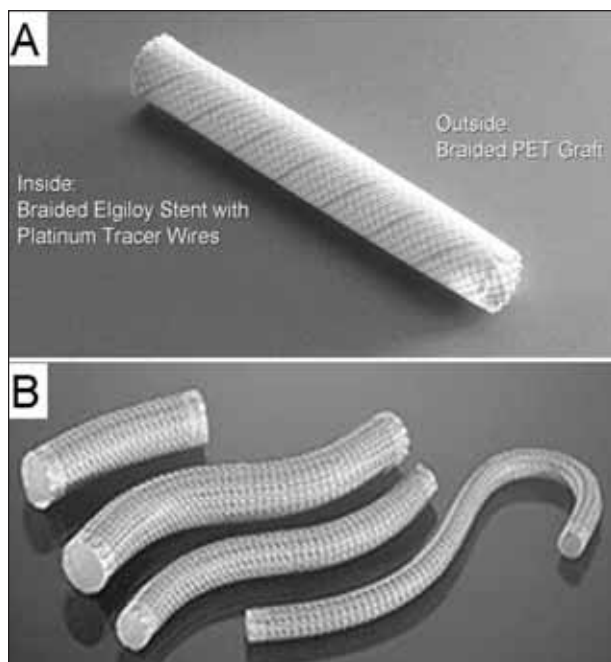


Figure 1. Representative image of a forearm AVG pseudoaneurysm due in part to chronic venipuncture for hemodialysis.

weeks before it is matured for dialysis access. Furthermore, with these surgical revision procedures, available access sites in the upper extremities will become scarce. Use of alternative strategies to maintain continuous hemodialysis access in the treated AVG pseudoaneurysms becomes important. We present our clinical experience with endoluminal stent graft exclusion of AVG pseudoaneurysms.

## METHODS

Sixteen patients (14 men [88%]; overall mean age,  $53 \pm 5.6$  years) with AVG pseudoaneurysms underwent endoluminal



**Figure 2.** Endograft used to exclude AVG pseudoaneurysms. The Wallgraft endoprosthesis consists of a braided, multifilament, textured polyethylene terephthalate yarn graft on the outside covering a flexible braided Elgiloy stent with platinum tracer wires on the inside (A). The Viabahn endoprosthesis is an ePTFE/nitinol self-expanding stent graft (B).

stent graft exclusion. Treatment indications included large AVG pseudoaneurysm size (n=5; mean diameter, 4.6 cm), localized pain over the AVG pseudoaneurysm (n=4), impending superficial skin breakdown (n=3), and enlarging AVG pseudoaneurysm (n=4). All endovascular AVG pseudoaneurysm repairs were performed under local anesthesia (n=10), conscious sedation (n=3), or general anesthesia (n=3). All patients underwent follow-up assessment, including ultrasound duplex at 1 and 6 months.

## Stent Graft Devices

In 14 patients (88%), the Wallgraft endoprosthesis (Boston Scientific Corporation, Natick, MA) (Figure 2) was used to exclude their AVG pseudoaneurysm. The Viabahn endoprosthesis (Gore & Associates, Flagstaff, AZ) (Figure 2) was used in two patients (12%) in our series. The Wallgraft device consists of a braided, multifilament, textured polyethylene terephthalate yarn graft on the outside covering a flexible, braided Elgiloy stent with platinum tracer wires on the inside, which were manufactured separately. The stent is coated with Corethane adhesive (Boston Scientific Corporation), which bonds the graft throughout its entire length. In contrast, the Viabahn device consists of a nitinol



**Figure 3.** A venogram demonstrates an AVG pseudoaneurysm (A). Completion venography showed a fully excluded AVG pseudoaneurysm by the Wallgraft endoprosthesis (arrow) (B).

self-expanding stent exoskeleton with an expanded polytetrafluoroethylene (ePTFE) graft attached to the inner stent structure. It is noteworthy that both Wallgraft and Viabahn endoprostheses are approved for clinical application in tracheobronchial strictures. The Viabahn endoprosthesis also received clinical application in superficial femoral artery lesions in patients with symptomatic peripheral arterial disease. The application in AVG pseudoaneurysm exclusion followed by venipuncture for hemodialysis in this study represents an off-label use of these endoprostheses.

## Treatment Technique

All patients underwent routine venography of the AVG before the endograft exclusion procedure. The location venipuncture for venography was selected to allow insertion of a Wallgraft endoprosthesis during the same venography session without requiring a new puncture site. A .035-inch Bentson wire (Boston Scientific Corporation) was inserted through a Seldinger needle puncturing the AVG. A 10-F Pinnacle sheath (Boston Scientific Corporation) was then placed over the wire under direct fluoroscopy. The patient was given 3,000 units of heparin intravenously. The diameters of the proximal and distal segments of the AVG were measured using a calibrated guidewire. The Wallgraft or Viabahn device was oversized by 15% to 20%, as recommended by the manufacturer, and this was based on the size of the normal-caliber graft diameter adjacent to the pseudoaneurysm. The Wallgraft or Viabahn endoprosthesis was carefully positioned and deployed. The delivery device was then removed, and a completion angiogram was obtained (Figures 3 and 4). After ensuring presence of no endoleak and no filling of the pseudoaneurysmal sac, the sheath insertion site was closed with a purse-string suture, and the sheath was removed.

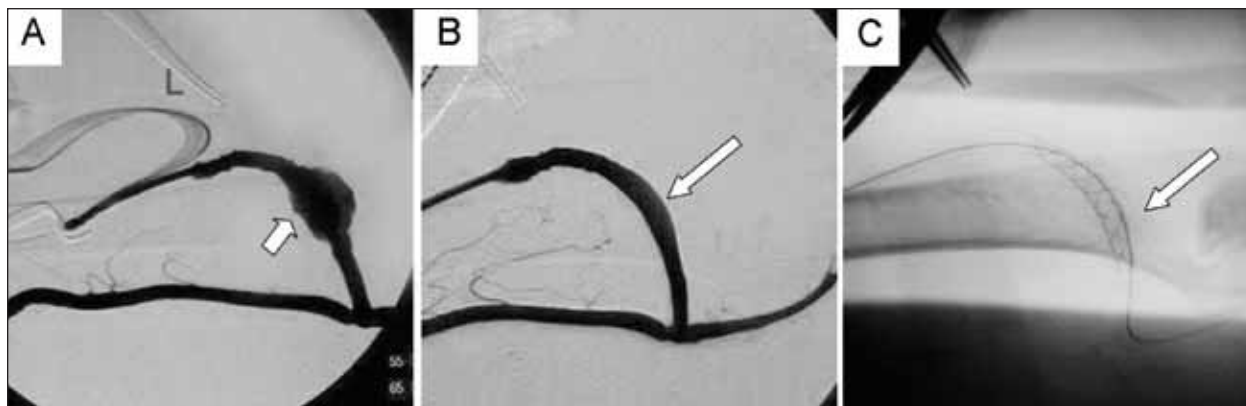


Figure 4. A venogram demonstrates an AVG pseudoaneurysm (short arrow) (A). Completion venography showed a fully excluded AVG pseudoaneurysm by the Wallgraft endoprosthesis (long arrow) (B,C).

## RESULTS

Technical success was achieved in all 16 patients (100%). Thirteen patients (82%) required only one endograft component to fully exclude the AVG pseudoaneurysm, whereas three remaining patients (19%) required two endograft devices for complete AVG pseudoaneurysm exclusion. All patients underwent hemodialysis with needle venipuncture through the endograft-excluded AVG pseudoaneurysm on the next postoperative day. Three patients (19%) underwent surgical revision at 21 days, 45 days, and 49 days due to either return of AVG pseudoaneurysm pulsatility ( $n=1$ ) or persistently large AVG pseudoaneurysm size ( $n=2$ ). The mean diameter of the AVG pseudoaneurysm in these three patients was  $4.3 \pm 1.5$  cm. The relatively large size of these AVG pseudoaneurysms precludes safe needle venipuncture during hemodialysis, even though two of these patients had complete AVG pseudoaneurysm exclusion by the Wallgraft endoprosthesis. Three patients developed thrombosis of the endograft-excluded AVG pseudoaneurysm at 17 days, 29 days, and 43 days. Among them, two patients received the Wallgraft device, whereas one patient received the Viabahn endograft. One procedure-related complication occurred in a patient who received two Wallgraft endoprostheses to exclude his AVG pseudoaneurysm; stent graft separation developed within the pseudoaneurysm. This event occurred 6 weeks after endograft implantation. This patient underwent AVG pseudoaneurysm excision and bypass graft interposition using a prosthetic graft. Eight patients (57%) developed complete resolution or marked decrease in the size of their pseudoaneurysms after Wallgraft endoprosthesis exclusion. Two of these patients died from heart failure and pneumonia at 5 and 6 months, respectively. Six patients underwent subsequent interventions after Wallgraft endoprosthesis insertion; their AVG primary patency ended at 55 days, 68 days, 72 days, 79 days, 95 days, and 168 days. These six patients were able to receive hemodialysis three times

per week with routine needle venipuncture through the Wallgraft-excluded AVG. The mean follow-up period in our patients was 8 months (range, 5 to 7 months). Serial ultrasound surveillance at 1 month and 6 months showed no endoleak outside the Wallgraft endoprosthesis. In all cases, pulsatility could be detected within the AVG pseudoaneurysms for at least 1 or 2 days after endograft exclusion, despite the absence of endoleak on completion venography. The primary patency rate of the endografts after AVG pseudoaneurysm exclusion was 25% at 6 months (Figure 5).

## DISCUSSION

Pseudoaneurysm formation is a well-known complication after AVG or fistula creation, and incidence rates range between 2% and 10%.<sup>4-6</sup> The traditional treatment approach is surgical excision or ligation of the pseudoaneurysm, followed by interposition grafting with a prosthetic conduit. The possibility of treating an AVG pseudoaneurysm with a stent graft device for pseudoaneurysm exclusion provides a less-invasive treatment alternative, along with several advantages. First, it permits continuous hemodialysis access of the AVG without the need of temporary dialysis catheter placement. Second, no surgical incision is necessary for stent graft placement, which may be associated with decreased blood loss. Last, it preserves the patency of the same AVG for continuous hemodialysis without the need for searching for potential sites for new AVG placement.

The application of stent graft devices in the management of AVG-related complications is not a novel concept. However, its application has been largely limited to the management of venous anastomotic stenosis or occlusion. Other studies have shown that stent graft device use is beneficial in treating venous outflow stenosis by providing a scaffold to maintain the outflow patency.<sup>7-9</sup> Researchers have also postulated that the stent graft may

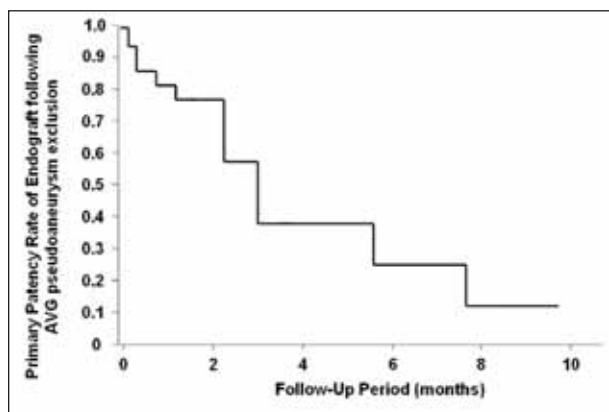


Figure 5. Primary patency rate of endografts after AVG pseudoaneurysm exclusion.

provide a theoretical advantage of reducing restenosis by excluding the anastomotic stenosis from direct contact with the procoagulant elements in the circulation.<sup>8,9</sup> Several studies have similarly reported various endovascular strategies for AVG pseudoaneurysms. Selby and colleagues described percutaneous placement of a detachable balloon to induce pseudoaneurysm thrombosis but with varying degrees of success.<sup>10</sup> Others have created homemade, stent graft devices using a Palmaz stent (Cordis Endovascular, a Johnson & Johnson company, Miami, FL) and polytetrafluoroethylene graft to exclude AVG pseudoaneurysm. Such a treatment strategy has not been widely embraced because of the risk of crushing the balloon-expandable stent from external arm compression.<sup>11,12</sup> Hausegger and colleagues reported their experience with Cragg Endo-Pro stent grafts (Boston Scientific Corporation) to exclude AVG pseudoaneurysms and noted that repeated puncture of the stent graft may lead to delayed pseudoaneurysm recurrence from degenerative breakdown of the graft materials.<sup>13</sup>

FDA approval in 2001 of the Wallgraft endoprosthesis for clinical use created new treatment strategies in endoluminal exclusion of peripheral arterial aneurysms, including AVG-related pseudoaneurysms. The first reported application of the Wallgraft endoprosthesis to exclude AVG pseudoaneurysms involved use in 10 patients who were able to receive continual hemodialysis after Wallgraft endoprosthesis exclusion of an AVG pseudoaneurysm.<sup>14</sup> In that study, all patients were able to resume hemodialysis in the Wallgraft-treated AVG site within 48 hours, and postoperative duplex scanning showed successful exclusion in the AVG pseudoaneurysms without endoleak. Similar reports of the technical feasibility of stent graft exclusion of AVG pseudoaneurysms with subsequent successful hemodialysis were reported by many researchers.<sup>13,15,16</sup> Vesely used the

Viabahn stent graft to successfully exclude AVG pseudoaneurysms in 11 patients.<sup>16</sup> Among them, six patients (55%) underwent reintervention after stent graft exclusion, with primary patency rates of 39 days, 40 days, 63 days, 104 days, 120 days, and 327 days. Two patients were deemed to have treatment failure with AVG pseudoaneurysm exclusion and had to undergo surgical repair.<sup>16</sup> In contrast to the report by Vesely, we used the Wallgraft endograft in 88% of our patients. The primary patency rate in our series was 25% at 6 months, which was similar to his findings.

Besides the Wallgraft and Viabahn endoprostheses, the Fluency Plus stent graft (Bard Peripheral Vascular, Tempe, AZ) is a comparable device that similarly received FDA approval for tracheobronchial application. However, we have no experience in using this device in excluding AVG pseudoaneurysms. Moszkowicz et al reported on 28 stent placements in 16 patients with hemodialysis access pseudoaneurysms or areas of graft degeneration using the Fluency Plus, with follow-up performed at an average of 3 months after stent placement. Four patients exhibited complications after stent deployment; three of these four experienced endoleak, and one had a stent migration. The investigators found that true pseudoaneurysms responded more favorably than did areas of degradation, with the former requiring placement of a single stent and the latter requiring two or more. They concluded that the use of stent grafts in treating clinically significant pseudoaneurysms appears to be a viable option for patients who might not be capable of undergoing further surgery to create a new fistula or are unable to undergo further surgical revision of their grafts.<sup>17</sup>

“... [using] a stent graft device for pseudoaneurysm exclusion provides a less-invasive treatment alternative, along with several advantages.”

Since the publication of studies reporting the technical feasibility of using stent grafts to exclude AVG pseudoaneurysms,<sup>7,14-16</sup> debates have arisen with regard to the safety of needle puncturing across the stent graft for hemodialysis. A study by Ryan and associates, who used Wallgraft endoprostheses for AVG pseudoaneurysm exclusion, demonstrated that these posttreatment AVG pseudoaneurysms can tolerate immediate needle puncture for immediate hemodialysis on the day after the Wallgraft endoprosthesis placement.<sup>15</sup> Additionally, they reported no recurrence of the pseudoaneurysms or dis-



tortion of the covered stent, and the grafts remained patent during their follow-up period. The follow-up period in this study, however, was short (3 to 11 months), and the study was limited to four patients. In a similar report by Rhodes and associates, who assessed routine venipuncture of Wallgraft-excluded arteriovenous fistula pseudoaneurysms, the authors noted that the Wallgraft endoprosthesis can withstand routine venipuncture for hemodialysis without flow-limiting distortion.<sup>18</sup>

To further investigate the device durability of the Wallgraft endoprosthesis after venipuncture for hemodialysis, we performed an *in vitro* study that examined the structural integrity of the Wallgraft endoprosthesis after hemodialysis in an AVG pseudoaneurysm model with duplex scanning to assess peri-Wallgraft endoleak.<sup>19</sup> Using a porcine femoral AVG model, which was excluded with the Wallgraft endoprosthesis, we showed a transient peri-Wallgraft endoleak within 6 hours after conventional hemodialysis. This transient endoleak was due to the needle track placed across the Wallgraft endoprosthesis. When we placed an explanted Wallgraft endoprosthesis in a flow circuitry analysis, we showed that the Wallgraft endoprosthesis was durable to withstand the hemodialysis at a flow rate of 600 mL/min. This finding underscored the durability of the endograft device to withstand the physical fatigue endured from routine hemodialysis-associated venipuncture.

## CONCLUSION

Pseudoaneurysm formation is a known complication after AVG creation. Although surgical revision remains the mainstay treatment strategy, endovascular repair with stent graft exclusion represents a minimally invasive treatment alternative. Numerous clinical reports have demonstrated short-term clinical efficacy for maintaining continual hemodialysis and prolonging the life expectancy of AVGs. Our *in vitro* analysis demonstrated that this treatment modality permitted repeated needle puncture for continuous hemodialysis. Our study supports further clinical evaluation of this device in the treatment of pseudoaneurysm exclusion. ■

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