Successful Treatment of an Above-Knee Femoropopliteal Bypass Anastomotic Stenosis with the aSpire Covered Stent
Bradley B. Hill, Rishad M. Faruqi, Christine E. Newman, Frank R. Arko, Thomas J. Fogarty and Christopher K. Zarins
Perspect Vasc Surg Endovasc Ther 2004; 16; 181
DOI: 10.1177/153100350401600306

The online version of this article can be found at:
http://pvs.sagepub.com/cgi/content/abstract/16/3/181

Published by:
SAGE Publications
http://www.sagepublications.com

Additional services and information for Perspectives in Vascular Surgery and Endovascular Therapy can be found at:

Email Alerts: http://pvs.sagepub.com/cgi/alerts
Subscriptions: http://pvs.sagepub.com/subscriptions
Reprints: http://www.sagepub.com/journalsReprints.nav
Permissions: http://www.sagepub.com/journalsPermissions.nav
Successful Treatment of an Above-Knee Femoropopliteal Bypass Anastomotic Stenosis with the aSpire Covered Stent

Bradley B. Hill, MD,* Rishad M. Faruqi, MD,* Christine E. Newman, RN,* Frank R. Arko, MD,† Thomas J. Fogarty, MD,† and Christopher K. Zarins, MD,† Santa Clara, CA and Stanford, CA

Prosthetic femoropopliteal grafts are commonly used for treating lower extremity arterial occlusive disease. Late graft failure may result from the progression of atherosclerosis or stenosis caused by myointimal hyperplasia at the sites of anastomosis. This report describes the use of an aSpire stent (Vascular Architects Inc. San Jose, CA) in the successful treatment of an anastomotic stenosis in a 64-year-old woman. The stent consists of a helical nitinol framework that is completely covered with expanded polytetrafluoroethylene. It is self-expanding and highly flexible with strong radial force, and offers the unique features of variable endoluminal coverage and the ability to maintain patency of important arterial side branches. In the case presented here, the stent successfully corrected the anastomotic stenosis and preserved both antegrade and retrograde blood flow into the above-knee popliteal artery as demonstrated by Duplex ultrasonography at 16 months and an ankle-brachial index of 1.0 and freedom from claudication almost 2 years after stent placement. The aSpire Covered Stent provides an alternative treatment option for correcting an anastomotic stenosis in a failing femoropopliteal graft.

Key words: aSpire stent, covered stent, peripheral arterial stent, femoropopliteal graft occlusion, anastomotic stenosis, side branch patency.

Introduction

Since the introduction of arterial substitutes in the early 1950s by Arthur Voorhees, arterial reconstruction by the use of synthetic graft material has become standard treatment in a variety of settings. Specifically, above-knee femoropopliteal bypass grafting using prosthetic grafts is widely performed for treating lower extremity arterial occlusive disease. While expanded polytetrafluoroethylene (ePTFE) grafts are reasonable alternatives to autologous vein grafts in the above-knee position with 5-year primary patency rates in the 50% to 70% range, graft failure can
occur because of intimal hyperplasia or the progression of atherosclerosis with resulting graft thrombosis.\textsuperscript{2-4} Current treatment options for graft occlusion include thrombolytic therapy, open surgical or percutaneous thrombectomy, percutaneous transluminal angioplasty (PTA) with or without stenting, surgical graft revision, or no intervention.\textsuperscript{5,6}

In cases of hemodynamically significant anastomotic stenosis, open surgical repair yields more favorable results than PTA alone or in combination with thrombolysis or thrombectomy.\textsuperscript{7} Another treatment option is the use of a covered stent to correct the stenosis. The aSpire Covered Stent (Vascular Architects, Inc., San Jose, CA) consists of a helical nitinol framework that is fully covered by ePTFE (Figure 1). The aSpire stent is approved by the U.S. Food and Drug Administration (FDA) for use in the tracheobronchial tree and is being investigated for use in the peripheral arteries. This report describes the use of an aSpire stent in the successful treatment of an anastomotic stenosis.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure1.png}
\caption{The aSpire covered stent is designed to be tightly "wound down" (A) for introduction and expanded (B) when released to provide vessel support without obstructing blood flow to collateral vessels.}
\end{figure}

\section*{Case Report}

A 64-year-old woman with a history of tobacco abuse, hypertension, and renal insufficiency, underwent a left above-knee femoropopliteal bypass for treatment of disabling claudication. Her ePTFE graft occluded 2 months postoperatively and again at 12 months. Graft patency was restored both times with catheter-mediated thrombolytic therapy. No stenosis or other arterial pathology was identified as the likely cause for the graft failure, and anticoagulation therapy with warfarin was initiated after the second graft occlusion. Eighteen months later the patient presented again, complaining of acute left lower extremity claudication.

The physical examination revealed a cold left foot with no palpable pedal pulses and a monophasic posterior tibial Doppler signal at the left ankle. The right foot was warm and pink in comparison with palpable pulses. Immediate angiographic evaluation revealed graft occlusion and catheter thrombolyis was initiated. Repeat arteriography the following morning showed a patent graft with greater than 50\% stenosis of both proximal and distal anastomoses. PTA was performed at the distal anastomosis. This resulted in a persistent residual stenosis greater than 50\% (Figure 2). Informed consent was obtained and the patient was taken to the operating room for graft revision.

After exposing the proximal graft anastomosis and gaining arterial control, the patient was fully anticoagulated with heparin and the proximal graft anastomosis was opened longitudinally. A 4F Fogarty thromboembolectomy catheter was advanced distally through the arteriotomy by using fluoroscopic guidance, and thrombus was retrieved, which resulted in reasonable back bleeding. An 8F sheath was inserted antegradely into the graft and hemostasis was achieved with a silastic vessel loop. The distal anastomotic stenosis was balloon dilated to 6 mm with 8 atm of pressure for 1 minute. This effectively predilated the distal anastomotic stenosis.

The balloon catheter was then removed and a 7-mm x 5-cm aSpire Covered Stent was introduced through the sheath and advanced over a 0.035\" guidewire to the distal anastomosis (Figure 3). The stent was expanded and angiography prior to releasing the stent showed obstruction of blood flow into the proximal popliteal artery that was previously patent (Figure 4A). The stent was wound down again and carefully repositioned and expanded a second time in a
manner that allowed retrograde perfusion of the proximal popliteal artery. A 6-mm angioplasty balloon was then expanded within the stent to even it out. Completion angiography demonstrated a widely patent anastomosis with both antegrade and retrograde blood flow into the popliteal artery (Figure 4B). The graftotomy was closed with an ePTFE patch to correct the proximal anastomotic stenosis. A posterior tibial pulse was palpable at the completion.

The patient's hospital course was uneventful and she was discharged to home on postoperative day 2. At 16 months postoperatively, ankle-brachial indices were 1.0 on the left and 0.7 on the right. Duplex ultrasonography at that time also showed a widely patent graft and distal aSpire stent without recurrent stenosis and normal blood flow into the popliteal artery with preservation of the retrograde flow into the proximal popliteal artery through the open gap of the stent. The patient takes clopidogrel (75 mg/day), follows a walking regimen, and is free of claudication symptoms at almost 2 years after graft revision.

Comment

The aSpire stent provided a favorable treatment alternative in this case because its open gap configuration corrected the stenosis and salvaged the retrograde blood flow into the proximal popliteal artery. By using a catheter-mediated approach, a more lengthy surgical procedure and distal incision were avoided. This facilitated the patient's early mobility and hospital discharge on postoperative day 2.

**Figure 2.** Angiogram shows stenosis at distal femoropopliteal graft anastomosis after initial balloon angioplasty (arrow).

**Figure 3.** aSpire stent in the “wound-down” state is introduced at the site of stenosis.
The ability of the stent to maintain blood flow into important arterial side branches made it ideal in this particular case. Another unique feature of the stent is that it can be expanded at the treatment site and angiography can be performed to check position before final deployment. If the position or side branch patency is in question, the stent can be wrapped down onto the delivery catheter, repositioned, and expanded again to confirm proper positioning before deployment. The ePTFE covering of the stent may also provide long-term advantages over alternative bare-metal stents by avoiding problems relating to material incompatibility when in contact with an ePTFE graft.

Unlike the device used in the above case, the newest iteration of the aSpire stent is compatible with a 7F sheath and 0.018” guidewire. The stent is available in lengths of 2.5, 5.0 and 10 cm with diameters ranging from 6 to 12 mm. A 15-cm long version is also available with diameters of 6 and 7 mm. All sizes are premounted on a catheter that consists of a proprietary controlled expansion delivery system.

Two FDA approved multicenter clinical trials began patient enrollment in August 2002 to assess the utility of the aSpire stent for treating stenotic and occluded iliac arteries (GALAXY) and suboptimal or failed PTA in stenotic or occluded superficial femoral and popliteal arteries (VALIANT).

Figure 4. (A) Angiogram after stent expansion prior to final release shows absence of blood flow into the proximal popliteal artery (arrow). (B) Completion angiogram after repositioning and release of aSpire stent. Note that the stent no longer obstructs retrograde blood flow into proximal popliteal artery (arrow).
REFERENCES


