

# SFA Stenosis Treated With Cryoplasty

This technique may alter the cellular response to angioplasty, limiting neointimal hyperplasia and thus improving patency.

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**B**ypass grafting is an established method of treatment for femoropopliteal occlusive disease. Recently, however, catheter-based treatments are being used more frequently as an initial therapy with variable results.<sup>1-3</sup> The relatively poor results encountered with angioplasty alone have led some investigators to advocate routine stenting after angioplasty in hopes of improving patency.<sup>4</sup> Although stents may improve short-term patency results, stent placement may also incite a more proliferative healing phase that could contribute to failure related to neointimal hyperplasia. These endovascular shortcomings have created inferior patency rates compared to open surgical reconstruction. However, the limited morbidity of percutaneous treatment has led many patients to seek this modality, even accepting a shorter-lasting revascularization result. Most recently, the technique of cryoplasty has been developed as a potential way to improve long-

term clinical outcomes in the catheter-based treatment of arterial disease by limiting the injury response of the artery. Cooling is achieved by inflating the balloon with nitrous oxide to the optimum temperature of -10°C. At this temperature there is induction of an acute phase change that triggers apoptosis in smooth muscle cells. This technique may alter the cellular response to angioplasty, limiting neointimal hyperplasia and thus improving patency.

## CASE REPORT

A 57-year-old man with a history of diabetes and dialysis-dependent renal failure underwent right iliac stent placement 9 months prior to presentation. His ankle-brachial index was unobtainable due to inability to compress his tibial vessels. He had initial improvement in his right leg ischemic symptoms; however, he soon developed a recurrent ulcer with return of rest pain. Repeat

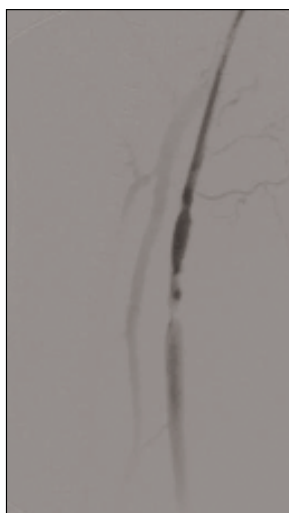


Figure 1. A proximal SFA lesion.



Figure 2. Inflation of the cryoplasty balloon.



Figure 3. Completion arteriography.

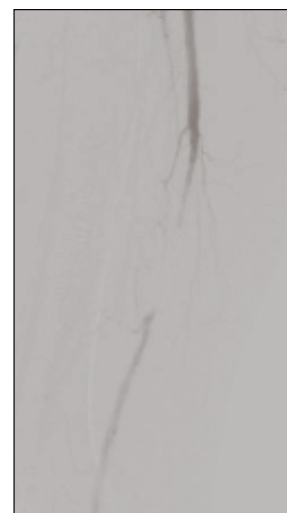


Figure 4. Distal SFA occlusion with popliteal reconstitution.



Figure 5. The popliteal artery after crossing the distal occlusion.



Figure 6. Cryoplasty of the distal lesion.

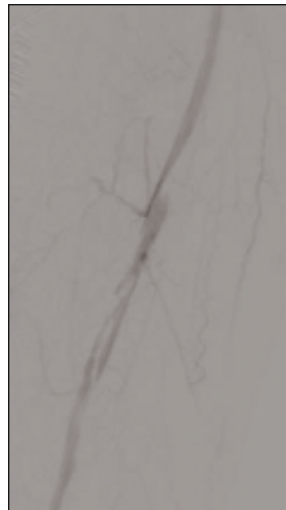


Figure 7. An arteriogram obtained after cryoplasty showing dissection.



Figure 8. A completion arteriogram obtained after repair of the dissection with use of covered stents.

arteriography showed good flow through his iliac stent, but progressive stenosis with occlusion of his right superficial femoral artery (SFA) (Figure 1). He had undergone previous saphenous vein harvesting for coronary revascularization as well as progression of his other medical comorbidities, and for this reason a catheter-based approach was chosen to treat his critical limb ischemia. He underwent cryoplasty with a 6-mm X 40-mm PolarCath balloon (Boston Scientific Corporation, Natick, MA) (Figure 2) with resolution of the proximal SFA stenosis (Figure 3). The distal SFA stenosis had progressed to occlusion (Figure 4) and, therefore, also underwent subintimal angioplasty (Figure 5) with the PolarCath balloon at the distal SFA (Figure 6). However, the subintimal dissection was flow-limiting even after the percutaneous transluminal angioplasty (Figure 7) and a 6-mm X 10-cm covered stent (Viabahn, W.L. Gore & Associates, Flagstaff, AZ) was placed to maintain patency (Figure 8). He was discharged the following day after dialysis, having resolution of his pain prior to discharge. Four weeks later, a duplex scan showed normal flow without significant stenosis and the ischemic ulcer had improved.

## DISCUSSION

Femoropopliteal angioplasty remains an attractive alternative for the treatment of some patients who require revascularization. Realizing that surgical bypass has maintained superior patency rates, endovascular therapies can be successfully utilized for those with limited disease or even for those with advanced disease.

Patients who are poor surgical candidates and have limited life expectancy may see improvement in symptoms and longer amputation-free survival with catheter-based treatments. Furthermore, those with limited disease and disabling claudication may gain additional health benefits with improved exercise capacity. Additionally, these treatments have better short-term morbidity when compared to surgical bypass, and infrequently affect the complexity of subsequent surgical revascularization.<sup>5</sup>

The relatively poor patency rates reported for percutaneous transluminal angioplasty in this setting have limited its use. The causes of this treatment failure are multifactorial and include vessel recoil, wall remodeling, thrombus formation, progression of distal disease, and neointimal hyperplasia. Some practitioners advocate primary stenting of long-segment stenosis in hopes of increasing patency.<sup>4</sup> Although the evidence is not conclusive, there are multiple reports of improved patency with the use of stents. However, stents may lead to intermediate failure secondary to neointimal hyperplasia.

The use of stents may improve the mechanical components, namely recoil and vascular wall remodeling, of the restenotic process. Vessel thrombosis can be limited by using antiplatelet agents. Neointimal hyperplasia, however, remains a frequent cause of in-stent restenosis. This hyperplastic reaction occurs because vascular smooth muscle cells accumulate in the intima and secrete matrix proteins. Numerous pharmacologic therapies including antithrombotics, antioxidants, vasodilators, lipid-lowering agents, and growth factor inhibitors have all been proposed as a way to limit neointimal

hyperplasia. These agents, however, have failed to consistently improve patency in other vascular beds, namely the coronary arteries, and have yet to demonstrate an improvement for lower-extremity occlusive disease.

The cryoplasty balloon has been developed to address the problem of neointimal hyperplasia. Recent reports have shown early results that are at least as good as conventional angioplasty.<sup>6</sup> The possibility of limiting the hyperplastic response and improving patency makes this technology promising even in face of the additional equipment required. The cryoplasty balloon does require a 7-F sheath for the introduction of the balloon and delivery of nitrous gas. There are, however, potential advantages to the idea of treating neointimal hyperplasia with an angioplasty balloon. Other pharmaceutical agents that might affect the injury response may be delivered to the arterial wall with this modality.

## CONCLUSION

The use of cryoplasty has the theoretical advantage of limiting neointimal hyperplasia and thus improving patency after lower-extremity balloon angioplasty. Furthermore, this technique can be used in conjunction with primary stenting and antiplatelet drugs. Although long-term data are not complete, the initial angiographic results appear equivalent to standard angioplasty. Considering the similar short-term result, the long-term data may predict the utility of this new technology in treating lower-extremity occlusive disease. ■

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