

# BTK Stenting in Critical Limb Ischemia

A review of the data and practical techniques for below-the-knee stenting.

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Critical limb ischemia (CLI) is a serious condition affecting a growing number of patients worldwide, particularly as diabetes becomes a larger epidemic. A quarter million amputations are performed annually in the United States and Europe, and this number is even greater worldwide, resulting in a huge social and economic burden with a serious compromise in quality of life.<sup>1-5</sup>

CLI patients have extensive multivessel disease and challenging lesions, particularly in diabetic and renal failure patients.<sup>6</sup> The BASIL study showed that in CLI patients, lower limb bypass and balloon angioplasty were associated with similar outcomes in terms of amputation-free survival.<sup>7,8</sup> If untreated, CLI patients have a 1-year amputation rate of 50% or greater, with associated high morbidity and mortality rates. Limb salvage by surgery or endovascular techniques has improved the quality of life for patients, as well as 5-year survival rates. In CLI patients, endovascular techniques have been associated with lower morbidity and mortality rates than bypass surgery. Numerous endovascular techniques have shown limb salvage rates of > 90% in CLI patients.<sup>9-13</sup>

## BELOW-THE-KNEE STENTING

Below-the-knee (BTK) stenting is frequently used as a bailout technique for flow-limiting dissections after intervention, restenosis and elastic recoil, and suboptimal endovascular results. However, there are significant data showing that BTK stenting is an effective and durable primary endovascular strategy for CLI patients, which consists of balloon-expandable and self-expanding stents.<sup>14-17</sup>

## BALLOON-EXPANDABLE STENTS

The Paradise study investigated the efficiency and safety of balloon-expandable drug-eluting stents to prevent amputation in patients with BTK CLI. The 3-year cumulative rate of amputation was 6% ± 2%, and binary resteno-

sis occurred in 12% of the 35% of patients who underwent repeat angiography.<sup>14</sup> The Siablis study was a prospective registry investigating the performance of sirolimus-eluting stents versus bare-metal stents (BMS) in CLI patients.<sup>15</sup> The 3-year angiographic and clinical results showed improved patency with sirolimus-eluting stents over BMS.

A meta-analysis of 18 studies on 640 patients undergoing BTK stenting in CLI showed that (1) patients treated with balloon-expandable BMS have similar outcomes to those treated with self-expanding BMS, (2) sirolimus-eluting stents provided superior outcomes to BMS, and (3) primary patency was superior with sirolimus-eluting stents compared to paclitaxel-eluting stents in some studies.<sup>16</sup>

## SELF-EXPANDING STENTS

The XCELL study is the largest United States prospective multicenter registry of patients with CLI to evaluate the Xpert self-expanding stent (Abbott Vascular, Santa Clara, CA). Of the 120 enrolled patients, 21 patients (17.5%) were Rutherford class 4, 82 patients (68.3%) were Rutherford class 5, and 17 patients (14%) were Rutherford class 6. There were 76 patients (63.3%) with one-vessel runoff, 67% were diabetic, and the mean stented vessel length was 7.6 cm. The primary endpoint was 12-month amputation-free survival, and secondary endpoints were angiographic in-stent restenosis rates, stent fracture assessment, and the extent of wound healing.

At 6-month follow-up in 115 patients, interim data showed that there was a total of 36 target lesion revascularizations (31.3%), of which, 21 (18.3%) were symptomatic. There were seven major amputations (6.1%), six deaths (5.2%), four target vessel revascularizations (3.5%), and one access-site complication requiring transfusion (0.9%). Wound healing data showed that 68 wounds (53.5%) were 100% healed, 43 (33.9%) had significantly decreased wound areas, and 16 (12.6%) had increased wound areas at 6-month follow-up (Figures 1 through 3).<sup>17</sup>



Figure 1. Severe disease of the anterior tibial artery.



Figure 2. Angiogram after angioplasty and stenting with the Xpert stent.

## PRACTICAL TECHNIQUES FOR BTK STENTING

### Patient Selection

There should be adequate distal runoff below the ankle and in the foot, and the vessel caliber should ideally be more than 2 mm in diameter. The stented vessel should be the dominant vessel feeding the foot, constituting the pedal arch, and feeding the nonhealing ulcer.

### Vessel Preparation

Before stenting, the vessel should be adequately pretreated with balloon angioplasty—scoring balloons if the lesion is rigid and calcified—and debulked with atherectomy devices if the lesion is complex, heavily calcified, or if a long chronic total occlusion is present. This will allow for proper stent expansion and sizing and will help prevent stent elongation, which could increase restenosis and stent fracture rates.

It is important to adequately treat significant inflow and outflow disease before stenting. When stenting proximally in the tibial and peroneal arteries, make sure that there is good distal flow to prevent stent thrombosis. Selective administration of nitroglycerin (300–500 µg) should be administered into the culprit vessel to assess proper stent sizing.

When stenting distally, be sure that the distal stent edge is at least 3 cm above the ankle joint to avoid stent injury and preserve a distal bypass option. It is advisable not to stent across major branches, when the vessel caliber is 2 mm or less, and when the distal runoff below the ankle is poor.

### Tips and Tricks for BTK Stenting

It is important to make sure that the entire lesion is covered from healthy vessel to healthy vessel. When using balloon-expandable stents in bifurcated lesions, kissing stenting and coronary bifurcation stenting techniques can be used. It is always better to use one long stent than overlapping stents to decrease restenosis and stent fractures. When multiple stents are used, it is recommended to overlap them by 1 cm. Balloon-expanding stents should be expanded to a 1.1:1 ratio; for self-expanding stents, the stent size should be at least one size larger than the vessel diameter. For longer lesions, it is better to use self-expanding stents because of their longer length. Postdilatation for self-expanding stents is recommended with a balloon that is a half-size larger than the stent size.



**Figure 3. The Xpert stent.**

When deploying self-expanding stents, always advance the stent delivery system beyond the lesion and then pull it back to just beyond the lesion to offset the stored up torque in the delivery system. Deploy the stent slowly with a pin-and-pull technique to avoid elongation of the stent. Lastly, use road mapping while deploying the stents.

## DISCUSSION AND SUMMARY

Please note that BTK stenting with balloon-expandable and self-expanding stents, as described in this article, is an off-label use. This technique is primarily performed for flow-limiting dissections, restenosis, and inadequate results after other endovascular techniques. However, primary stenting for CLI patients should be considered as a first-line endovascular treatment based on the available data. Current limitations are the lack of available long stents and the expense of drug-eluting stents. In CLI patients, for lesions longer than 10 cm, atherectomy followed by low-pressure angioplasty should be considered with the limitation of currently available stent lengths.

Drug-eluting balloons will prove to be a great option for CLI patients. Further studies need to be done com-

paring drug-eluting balloons with and without atherectomy to longer BTK self-expanding stents with both bare-metal and drug-eluting stents. Sirolimus-eluting stents have shown improved durability and clinical outcomes compared to BMS. Interim data for self-expanding stents from the XCELL study have been very promising. Larger randomized studies are also needed to compare BTK stenting with other endovascular techniques in treating CLI patients with complex BTK multivessel disease. ■

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