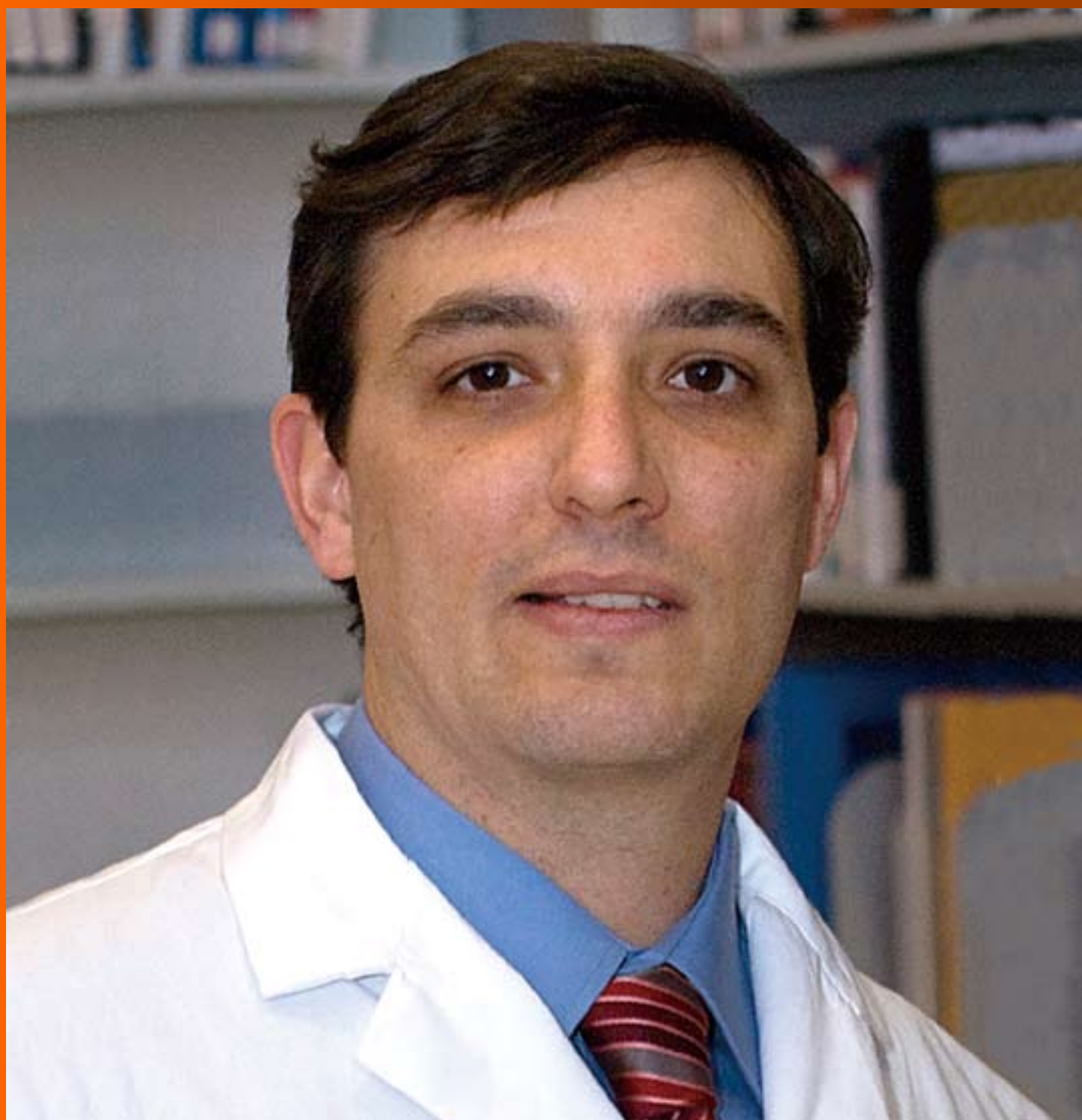


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## Revisiting endovascular treatment in below-the-knee disease. Are drug-eluting stents the best option?

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### Abstract

Patients with below-the-knee arterial disease are primarily individuals suffering from critical limb ischemia (CLI), while a large percentage of these patients are also suffering from diabetes or chronic renal failure or both. Available data from randomized controlled trials and their meta-analysis demonstrated that the use of infrapopliteal drug-eluting stents (DES), in short- to medium- length lesions, obtains significantly better results compared to plain balloon angioplasty and bare metal stenting with regards to vascular restenosis, target lesion revascularization, wound healing and amputations. Nonetheless, the use of this technology in every-day clinical practice remains limited mainly due to concerns regarding the deployment of a permanent metallic scaffold and the possibility of valid future therapeutic perspectives. However, in the majority of the cases, these concerns are not scientifically justified. Large-scale, multicenter randomized controlled trials, investigating a significantly larger number of patients than those already published, would provide more solid evidence and consolidate the use of infrapopliteal DES in CLI patients. Moreover, there is still little evidence on whether this technology can be as effective for longer below-the-knee lesions, where a considerable number of DES is required. The development and investigation of new, longer balloon-expanding or perhaps self-expanding DES could be the answer to this problem.

**Key words:** Critical limb ischemia; Infrapopliteal arterial disease; Drug-eluting stents; Peripheral arterial disease; Balloon angioplasty

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**Core tip:** The use of infrapopliteal drug-eluting stents

(DES) remains limited in clinical practice mainly due to concerns regarding the deployment of a permanent metallic scaffold and the possibility of valid future therapeutic perspectives. However, these concerns are not scientifically justified. Large-scale, multicenter randomized controlled trials investigating a significantly larger number of patients would consolidate the use of infrapopliteal DES in critical limb ischemia patients. Moreover, there is still little evidence on whether this technology can be as effective for longer lesions, where a considerable number of DES is required. The development and investigation of longer balloon-expanding or self-expanding DES could solve this problem.

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## INTRODUCTION

Patients with below-the-knee (BTK) arterial disease are mainly suffering from critical limb ischemia (CLI), the malignant expression of peripheral arterial disease<sup>[1]</sup>. Additionally, a large percentage of CLI patients with BTK disease are suffering from diabetes or chronic renal failure or both<sup>[2]</sup>. Specifically, patients with diabetes and CLI should undergo prompt revascularization, as the 5-year survival rate in such patients has been reported to be as low as 25%, while diabetes has been correlated with increased risk of limb amputation and repeat revascularization procedures<sup>[2]</sup>. These fundamental characteristics of BTK disease demarcate the therapeutic approach. More specifically, CLI sets the goal of treatment, which is limb salvage, rather than increasing walking distance, as in cases of intermittent claudication. Limb salvage is strongly related to direct, immediate and acute flow restoration to the foot, also described as immediate lumen gain.

The traditional endovascular treatment algorithm suggests the use of balloon angioplasty or bare metal stenting (BMS) as a bail-out option in cases of residual stenosis or flow-limiting dissection. However, diabetes and chronic renal failure contribute to the formation of an aggressive, hard, atherosclerotic plaque with marked calcifications that are resistant to balloon dilation, reducing the possibility of achieving an adequate acute luminal gain with the use of plain balloon angioplasty<sup>[2]</sup>. Therefore, in this specific population, the use of stents is, in many occasions, mandatory to obtain an acceptable immediate outcome. As outcomes of BMS in infrapopliteal arteries have been similar to those attained by balloon angioplasty and because short-term patency was not warranted, several studies, including multicenter randomized controlled trials (RCTs), investigated the use of infrapopliteal drug-eluting stents (DES) and the

**Table 1 Endovascular devices for infrapopliteal arterial disease**

Balloon angioplasty
Bare metal stents (balloon- or self-expandable)
Drug-eluting stents
Bioabsorbable stents
Bioabsorbable drug-eluting stents
Drug-coated balloons
Drug-infusion devices
Atherectomy devices
Lithotripsy

evidence in favor of this technology, which is widely used in coronary disease, began to accumulate<sup>[3,4]</sup>.

As a result, a significant volume of high-level evidence supporting the safety and effectiveness of infrapopliteal DES has emerged in the literature, motivating the Trans-Atlantic Society Consensus II update to endorse the use of DES in the treatment algorithm of CLI and establish endovascular treatment as a valid and successful alternative to surgery. Notably, the specific consensus document supports the use of DES in short-length infrapopliteal lesions<sup>[1]</sup>. The endovascular devices currently available for the treatment of infrapopliteal arterial disease are summarized in Table 1.

In a 2013 meta-analysis of five RCTs (611 patients), Fusaro *et al*<sup>[5]</sup> found that infrapopliteal DES use significantly decreased major amputations and reinterventions compared to plain balloon angioplasty or BMS.

In a recent network meta-analysis of 16 RCTs (1805 patients), Katsanos *et al*<sup>[6]</sup> demonstrated that both DES and drug-coated balloons (DCBs) had significantly better results compared to plain balloon angioplasty and BMS with regards to vascular restenosis, target lesion revascularization and wound healing. Moreover, DES had also significantly better results when compared with DCB for the most important, strong clinical endpoint of amputations. The Infrapopliteal Drug-Eluting Angioplasty Versus Stenting (commonly known as IDEAS) trial by Siablis *et al*<sup>[7]</sup> is the only study so far that directly compares these state-of-the-art technologies in BTK disease. Despite the fact that DES demonstrated significantly less binary restenosis at six months follow-up, late lumen loss was similar between the two technologies. An in-depth analysis revealed that this was attributed to the superior acute luminal gain obtained by DES compared to balloon dilation. In the case of small-caliber BTK arteries, even a few millimeters of initial gain are significant, as a larger initial vessel diameter requires superior volume of hyperplasia to reach the critical point of clinically significant restenosis. Therefore, the current data demonstrate the superiority of DES technology for the management of BTK disease (Table 2). Nonetheless, the penetration of this technology in everyday clinical practice has been poorer than expected, due to several issues that remain to be addressed.

First of all, the implementation of a permanent metallic scaffold in such small-caliber vessels as the



**Table 2** Randomized controlled trials for infrapopliteal drug-eluting technologies

Study	Yr of publication
Falkowski <i>et al</i> <sup>[22]</sup>	2009
BELOW. Tepe <i>et al</i> <sup>[23]</sup>	2010
ACHILLES. Scheinert <i>et al</i> <sup>[24]</sup>	2012
YUKON-BTX Rastan <i>et al</i> <sup>[25]</sup>	2012
DESTINY Bosiers <i>et al</i> <sup>[26]</sup>	2012
DEBATE-BTK. Liistro <i>et al</i> <sup>[27]</sup>	2013
IN.PACT DEEP. Zeller <i>et al</i> <sup>[28]</sup>	2014
IDEAS. Siablis <i>et al</i> <sup>[7]</sup>	2014
BIOLUX P-II. Zeller <i>et al</i> <sup>[29]</sup>	2015
PADI. Spreen <i>et al</i> <sup>[30]</sup>	2017

tibial arteries raises the issue of whether an occlusion would be re-accessible. Spiliopoulos *et al*<sup>[8]</sup> performed a retrospective analysis on the recanalization of occluded DES in BTK vessels. Within a period of seven years, a total 367 patients were treated with infrapopliteal DES and the re-occlusion rate was 11.4%. Notably, the success rate of endovascular recanalization of DES occlusions was 90.7% (49/54 cases), while endovascular recanalization was rarely technically demanding. Failure to recanalize the occluded stent(s) was associated with tandem popliteal stent occlusion and stent fractures. This concern of fracture or deformation that compromises patency and re-intervention options has been addressed in another retrospective analysis by Karnabatidis *et al*<sup>[9]</sup> in which the incidence and clinical implications of DES fracture was evaluated. In 63 CLI patients and 191 lesions, 369 stents were deployed. The follow-up period was 15 ± 11 mo. Only one (0.3%) severe stent fracture and eleven (3.0%) stent compressions were noted. The authors concluded that stent fracture or severe compression is rare and occurs in specific anatomical locations, mainly the distal anterior tibial artery. The authors recommended avoiding stenting in the specific anatomical location, as fractures lead to patency loss and inability to recanalize the occlusion<sup>[9]</sup>. The cost-effectiveness of DES was also a concern considering their higher price compared to plain balloon angioplasty and their short length, which leads to the deployment of a significant number of stents for the treatment of the characteristically long BTK lesions. This was also addressed in a cost-effectiveness study by Katsanos *et al*<sup>[10]</sup>, where they concluded that the higher DES direct cost is counter-balanced by the smaller number of re-interventions required for limb salvage. Considering that the price of DES has decreased, longer stents could further diminish the direct cost and optimize the cost-effectiveness of infrapopliteal DES use. Finally, some physicians advocate that the deployment of infrapopliteal DES could compromise future surgical options. According to the authors' opinion, stenosed or occluded BTK arterial segments are not a suitable target for surgical reconstruction. Nevertheless, stent placement should always be performed with a view to future treatment options and should certainly respect

non-diseased arterial segments that could be used for bypass surgery.

DCBs have been successfully used for the treatment of superficial femoral artery lesions and granted themselves an established role in the treatment algorithm, while there is already increasing evidence for their role in the treatment of dysfunctional dialysis access<sup>[11-16]</sup>. The use of this technology transformed treatment into a two-step procedure, with an initial step of mechanical treatment required to treat the immediate problem of vascular stenosis, while DCBs are implemented to slow down the process of restenosis using the cytotoxic drug paclitaxel. Several up-to-date tools are available in both the superficial femoral artery and dialysis access to perform vessel preparation<sup>[17,18]</sup>. However, in BTK vascular disease, the evidence supporting the use of DCB is rather controversial, as two large multicenter RCTs studies have failed to demonstrate the superiority of these devices over standard percutaneous transluminal angioplasty<sup>[19]</sup>. It is the authors' opinion that this disadvantage in BTK vessels is due to the deficient initial treatment vessel preparation step, which is not required when using balloon-expandable DES. Hence, it remains to be tested whether new technologies dedicated to vessel preparation and minimization of dissection will improve outcomes of infrapopliteal DCB angioplasty.

To conclude, although available data support the use of infrapopliteal DES for short- to medium-length lesions, the use of this technology in everyday clinical practice remains limited, mainly due to concerns regarding the deployment of a permanent metallic scaffold and the possibility of valid future therapeutic perspectives. However, in the majority of the cases, these concerns are not scientifically justified. Large-scale, multicenter RCTs investigating a significantly larger number of patients than those already published would provide solid evidence and would strengthen the use of infrapopliteal DES in CLI patients. Moreover, there is still little evidence on whether this technology can be as effective for longer BTK lesions, where a considerable number of DES is required<sup>[20,21]</sup>. The development and investigation of new, longer balloon-expanding or perhaps self-expanding DES could be the answer to this problem.

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