

Utility of the FLEX Dynamic Scoring Catheter® in Peripheral Interventions

Dynamic scoring technology to improve outcomes in lower extremity intervention.

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The prevalence of peripheral artery disease (PAD) is increasing and is estimated to affect more than 200 million people worldwide.^{1,2} The safety and efficacy of peripheral interventions compared to surgical revascularization have been established.³

Standard practice for the treatment of PAD is balloon angioplasty, at times accompanied by adjunctive therapies to provide the optimal acute result for the patient. However, balloon angioplasty alone may result in flow-limiting dissection and increase the need for bail-out stenting.⁴ Additionally, there is concern for restenosis requiring repeat interventions. Dynamic scoring can be used to prepare a vessel and create an optimal environment for balloon angioplasty, decreasing the occurrence of dissections and the need for stenting.

CASE REPORT: CHRONIC TOTAL OCCLUSION IN THE SFA

A 72-year-old woman with Rutherford class 3 symptoms presented with a 410-mm chronic total occlusion (CTO) in the left superficial femoral artery (SFA). The lesion was accessed via a contralateral approach, and the vessel was prepped with the FLEX Dynamic Scoring Catheter® device (VentureMed Group, Inc.). Four retrograde pullbacks with the device were utilized with a 30°

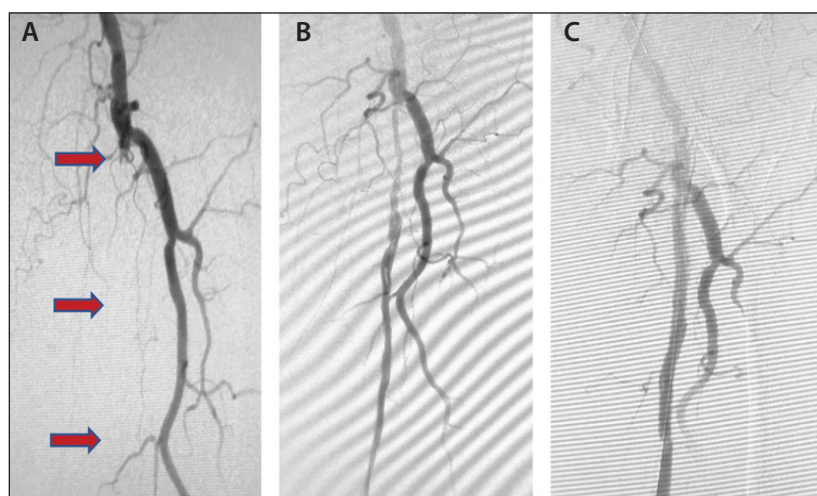


Figure 1. Initial angiogram. Arrows indicate a CTO in the SFA (A). Post-FLEX recanalization (B). Final angiographic result (C).

rotation between passes. Angiographic evaluation after treatment with FLEX alone noted recanalization of the SFA (Figure 1). The lesion was then treated with a 5- X 150-mm drug-coated balloon (DCB), with an opening pressure of 4 atm. The final angiogram revealed a widely patent SFA without recoil or dissection.

FLEX DYNAMIC SCORING CATHETER DEVICE

The FLEX Dynamic Scoring Catheter device was purposely engineered to enable vessel preparation prior to angioplasty. The FLEX is composed of a novel, sheathed, three-strut scoring basket that “flexes” to follow the contours of the diseased vessel wall, creating controlled depth microincisions. Laser-welded to each of the three

Courtesy of Dr. Oriowo, Promedica Joint Vascular Institute, OH.

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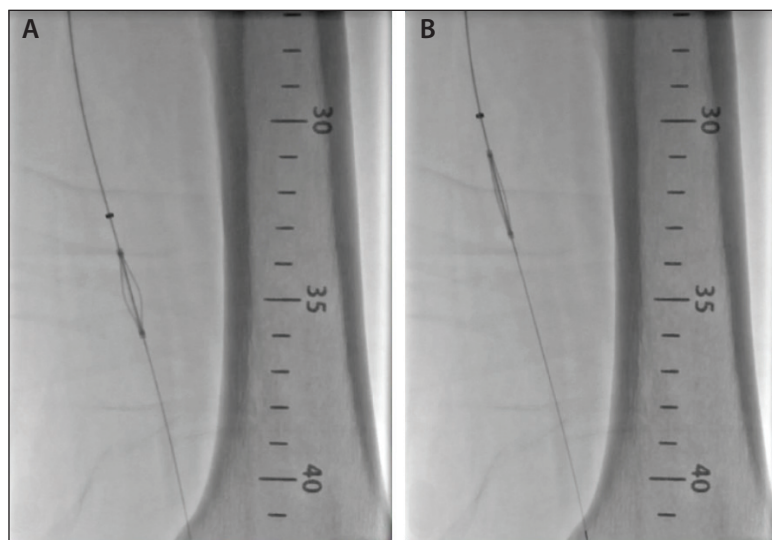


Figure 2. The FLEX Dynamic Scoring Catheter deployed with the scoring basket fully expanded (A). The FLEX scoring basket flexing to the contour of the vessel walls at the site of a high-grade stenosis (B).

scoring elements is a surgical atherotome, 0.010 inches in height, mounted perpendicular on a protective skid. The skids allow for the device to follow the vessel walls during retrograde pullback, controlling the depth of the atherotome incisions. Visualization of the device under x-ray is excellent, as the scoring basket is constructed from stainless steel (Figure 2). The FLEX can also be rotationally controlled to create multiple linear scores around the vessel circumference with repeated passes in a single insertion. A braided shaft provides a high degree of torqueability.

The handle contains two actuators—one to retract the sheath and the other to expand the scoring basket (Figure 3). The FLEX Scoring Catheter is 6-F compatible, can be used with a 0.014- or 0.018-inch guidewire, and is available in two working lengths: 40 and 120 cm. The device has a 2-mm crossing profile. CE Mark approval was received in November 2015 and US Food and Drug Administration clearance was granted in June 2016. The FLEX is indicated for use to facilitate dilations of stenoses in the femoral and popliteal arteries.

Mechanism of Action

Scoring balloons and angioplasty balloons use static or focused force to treat the lesions, requiring high pressures to engage the scoring elements.⁵ Additionally, balloon-based devices require multiple inflations to treat long lesions, increasing the risk of dissections.⁶ The FLEX Dynamic Scoring Catheter has a bimodal mechanism of action. First, the FLEX scoring elements exert approximately 1 atm of constant pressure against the vessel wall to gently predilate the stenosis or CTO. Second, the active movement of the blade across the vessel surface (Dynamic Scoring Technology®) allows the atherotome to incise the plaque at pressures much lower than balloon-based devices using static or focused force.

The FLEX Dynamic Scoring Catheter device creates parallel microincisions at a precisely controlled depth during retrograde pullback. Prepping the vessel with the FLEX device also allows the angioplasty balloon to fully efface stenoses or CTOs at significantly lower pressures as compared to vessels undergoing standard plain old balloon angioplasty (POBA). Human cadaveric SFA reveals consistent depth of microincisions in both histologic specimens as well as optical coherence tomographic (OCT) imaging (Figure 4).

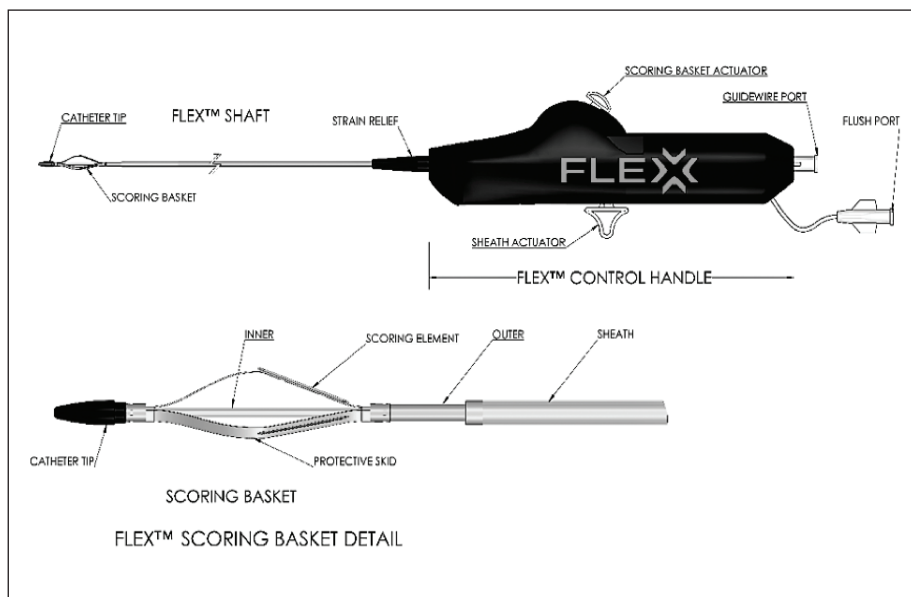


Figure 3. FLEX Dynamic Scoring Catheter schematic.

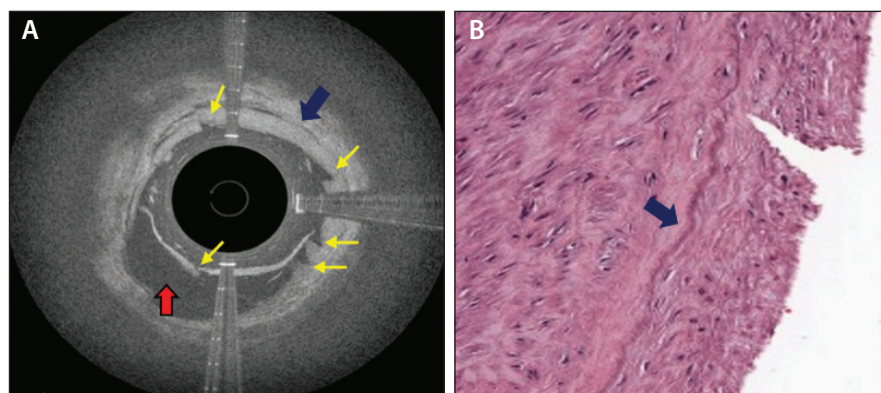


Figure 4. OCT image. Yellow arrows indicate microincisions, the red arrow indicates a calcium cleft, and blue arrows identify area of elastic lamina (A). Histology of microincision created by the FLEX Catheter in a human cadaver SFA (B).

Postmarket Clinical Results

Postmarket surveillance data have been collected from 352 real-world cases by 88 physicians in 57 health systems since December 2015 (Table 1). The average lesion length treated was 134.3 mm (range, 2–410 mm), with 218 (61.9%) cases longer than 80 mm. The average initial stenosis was 91.2% (range, 50%–100%); CTOs accounted for 160 (45.5%) cases. Moderate to severe calcification was recorded in 54% (191) of the cases. The FLEX Catheter alone prior to balloon angioplasty created an average luminal gain of 27.4%. There have been no flow-limiting dissections, perforations, or embolizations reported with use of the FLEX Dynamic Scoring Catheter.

Operators opted to use DCB in 258 (73.3%) cases, validating the FLEX Catheter as a vessel prep device prior to DCB. The opening pressure, defined as the lowest pressure required to achieve full lesion effacement, averaged 4.4 atm, which is significantly below nominal pressure. Improved vessel compliance is suggested in the low balloon opening pressures and is likely responsible for the low percentage of observed dissections. There have been no flow-limiting dissections, and 17 minor dissections (14 type A and three type B dissections per the National Heart, Lung, and Blood Institute classification system)⁷ reported post-FLEX and angioplasty. No adverse events have been reported to date, and the resulting residual stenosis after FLEX and any adjunctive treatment averaged 9.8% (range, 0%–60%).

Additional data from the FLEX Dynamic Scoring Catheter in real-world patients support that the device is effective in facilitating treatment in lesions with differing degrees of stenosis, lesion lengths, and severity of calcification.^{8–11}

Vessel Preparation

Other devices are being investigated for use in vessel preparation, including atherectomy devices. Atherectomy devices currently lack a method of depth control to minimize the impact to deeper vessel wall layers. There is a growing body of evidence that disruption of the elastic lamina and the accompanying inflammatory response of the vessel leads to restenosis.^{12,13} Directional atherectomy was studied in 116 patients, and histologic analysis identified adventitial injury in 53%

of the patients. Comparison of 1-year outcomes for patients without and with adventitial injury reported a significantly higher rate of restenosis in the latter group.¹⁴ Additionally, atherectomy devices are costly and can require a multitude of sizes. The FLEX device provides a cost-effective vessel prep alternative and is a one-size-fits-most platform, decreasing inventory carrying cost (budget and shelf space) and requiring only one SKU.

CASE REPORT: SFA PREPPED WITH THE FLEX DYNAMIC SCORING CATHETER

A 68-year-old woman with Rutherford class 3 symptoms (ankle-brachial index, 0.6) presented with a hemodynamically significant 30-mm-long stenosis at the origin of the left SFA. The lesion was accessed via a contralateral approach, and an initial angiogram confirmed a high-grade stenosis (Figure 5). The lesion was prepped with the FLEX Dynamic Scoring Catheter

TABLE 1. FLEX DYNAMIC SCORING CATHETER POSTMARKET SURVEILLANCE RESULTS

Case count	352
Average lesion length	134.3 mm
Percentage of chronic total occlusions	45.5%
Average luminal gain post-FLEX	27.4%
Moderate/severe calcification	54%
Average opening pressure	4.4 atm
Flow-limiting dissection	0%

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Courtesy of Dr. Ice, Deborah Heart and Lung, NJ.

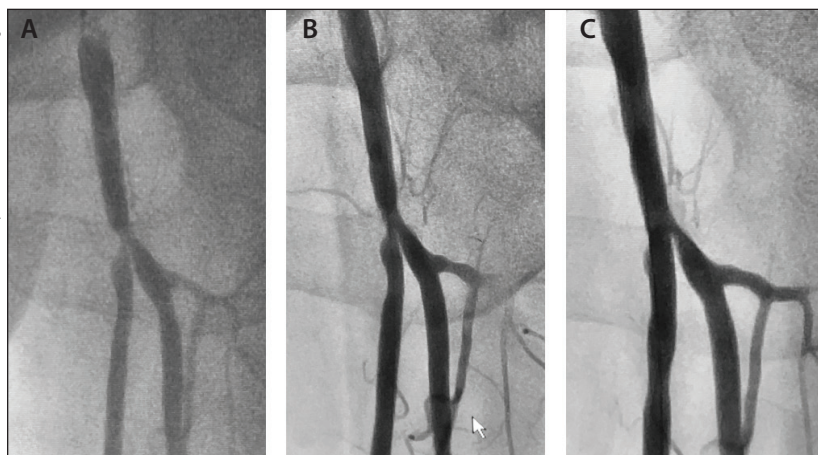


Figure 5. Preprocedure angiogram of a left femoral bifurcation stenosis (A). Post-FLEX recanalization (B). Postprocedure angiogram (C).

device with three passes rotated 30°. There was significant luminal gain noted post-FLEX treatment. A 6- X 40-mm DCB was subsequently used to treat the lesion at an opening pressure of 3 atm (maximum inflation pressure, 6 atm), resulting in a widely patent artery and restoration of pedal pulses.

CONCLUSION

The FLEX Dynamic Scoring Catheter is a vessel preparation device for endovascular intervention. Clinical data support that the device is safe and effective in creating luminal gain, increasing vessel compliance, and improving the overall results of balloon angioplasty. Physicians often use the FLEX device prior to a DCB, recognizing it as a vessel prep device. Vessel preparation with the FLEX Catheter creates an improved acute result, lowering the rates of dissection, and subsequently lessening the need for stents. This improvement may impact the long-term results of POBA and DCB use and will need to be further investigated. ■

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