Transatlantic Perspectives on Vessel Preparation

Interventional experts from the United States and Europe discuss the current state of vessel prep and their experience with the **FLEX Dynamic Scoring Catheter®**.

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Vessel preparation is increasingly being cited and recognized as an important component of vascular interventions, especially in the era of drug-coated balloons (DCBs). What are your thoughts regarding vessel prep?

Prof. Zeller: Vessel preparation can allow for an improvement in the acute results such as increased luminal gain, improved vessel compliance, and a lower rate of dissections, so it is very important. In the era of DCBs, vessel prep should also improve drug uptake and transport into the vessel wall. This is necessary to achieve favorable long-term outcomes. Studies have shown that a residual stenosis > 30% will require reintervention sooner. We know that improving acute

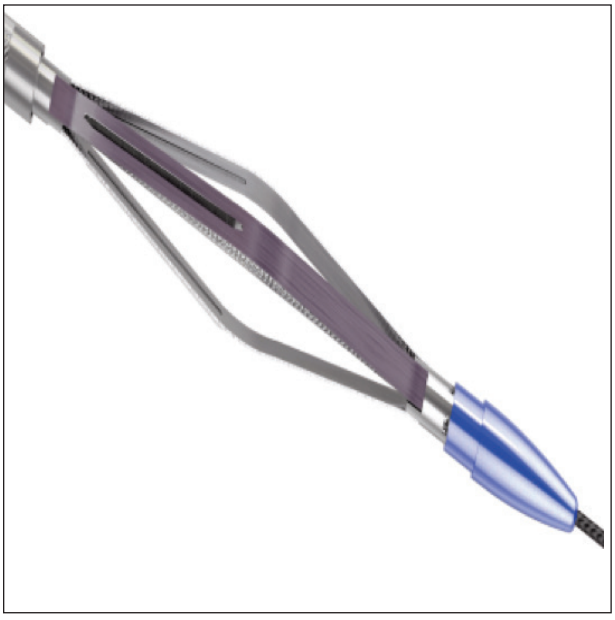


Figure 1. The FLEX Dynamic Scoring Catheter with scoring basket.

procedural results leads to better long-term outcomes. When coupling vessel prep with plain old balloon angioplasty (POBA) or a DCB, we rarely see residual stenosis to that degree.

In your experience, are you seeing a decrease in dissections with vessel preparation?

Prof. Hayoz: Yes, flow-limiting dissections are occurring at a much lower rate. Vessel preparation has created a shift in the standard of care, as we are now in the "leave nothing behind" era. In the past few years, in-stent restenosis (ISR) is the new challenge that has surfaced. If a stent is not completely apposed to the vessel wall, restenosis occurs and continues to be an issue. Prepping the vessel before stent placement improves the stent apposition, lessening the likelihood of reintervention due to ISR.

What are your thoughts on the numerous studies on the use of vessel prep with DCBs?

Dr. Montero-Baker: Early studies on DCBs found that when a lesion was predilated with POBA, the DCB performed better. These studies sparked an increase in the use of specialty balloons and atherectomy devices as vessel prep, as well as a need for innovation, such as the development of the FLEX Dynamic Scoring Catheter device® (VentureMed Group, Inc.).

Through innovations like the FLEX device, we hope to find improved longer-term results due to creating an ideal environment for the DCB. In my early experience with FLEX, I believe we are improving the vessel compliance, which is evident in the balloon inflation pressures. After prepping with the FLEX device, I have balloons effacing target stenoses at around 4 atm, which is significantly below nominal. Additionally, we can increase the amount of drug uptake and create a larger surface area for distribution.

Are there types of lesions in which you would not suggest the use of vessel prep?

Dr. Mouawad: No, vessel preparation can be used in all cases before POBA, DCB, self-expanding stents, and bioabsorbable scaffolds. The improvement in acute results is significant and the data suggest that vessel prep can be useful in many different types of morphologies. In my high-volume clinical practice, I have encountered challenging calcified lesions and observed that the FLEX device performs well there.

What are the advantages of using the FLEX Dynamic Scoring Catheter for vessel prep?

Prof. Zeller: FLEX is a single-insertion device and is very intuitive to use for femoropopliteal lesions. The device is advanced to the lesion, unsheathed by an actuator on the handle, and creates three parallel scores using retrograde pullback. You can score lesions of any desired length as well as treat any vessel diameter. This is truly a one-size-fits-all device. FLEX can be passed two to four times, yielding six to 12 microincisions. The nonballoon-based design also offers a new advantage, as you are not required to reinflate the device multiple times. When you need multiple balloons to treat one lesion, the procedural time is affected, and multiple balloon inflations can increase the potential for dissection.

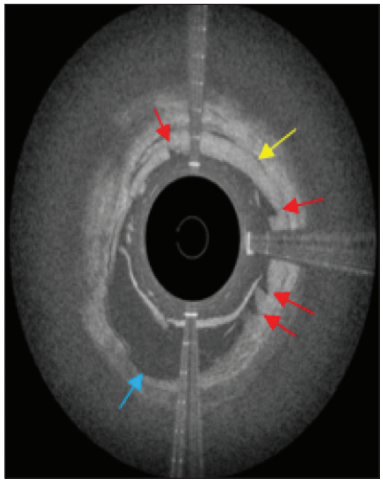


Figure 2. OCT imaging of a nonperfused human cadaver superficial femoral artery after vessel preparation by the FLEX Dynamic Scoring Catheter. The red arrows indicate FLEX microincisions, the blue arrow identifies calcium, and the yellow arrow indicates elastic lamina.

Can you explain the mechanism of action?

Prof. Hayoz: The FLEX device has three radial arms, each consisting of a skid and an atherotome (Figure 1). The skids follow the contours of the vessel walls, like a sled going down a hill, allowing the atherotomes to cut at a controlled depth. The atherotomes are 0.010 inches in height, are mounted perpendicular to the skid surfaces, and create three parallel microincisions. This ensures that the elastic lamina is not disrupted. There is a growing body of evidence that procedural disruption of the elastic lamina can contribute to restenosis, so FLEX, with its controlled-depth microincisions, may be advantageous. During angioplasty, the microincisions allow for improvement in the angioplasty results.

Can you see the microincisions created?

Dr. Montero-Baker: Yes, the incisions can be visualized using optical coherence tomography (OCT) or intravascular ultrasound (IVUS). The microincisions created by FLEX will appear like triangular cleaves. The operator can rotate the FLEX device after subsequent passes, creating multiple cleaves around the circumference of the vessel (Figure 2).

Do you suggest using OCT/IVUS with FLEX?

Prof. Zeller: No, it is not necessary because the device delivers very good tactile feedback. With each subsequent pullback, you can generally sense less resistance. In addition to the microincisions, the scoring basket interacts with a spring-like 1 atm of pressure to gently predilate the lesion.

What about the device costs for vessel prep?

Prof. Hayoz: Cost is an increasingly important part of peripheral interventions. The FLEX device appears to be a cost-effective option for this purpose. We want to maximize the effect of DCBs because they are considerably more expensive than a regular angioplasty balloon. Improved outcomes can certainly justify the cost of vessel prep devices. Also, in Europe, atherectomy has a challenging reimbursement scenario depending on the country. Having a cost-effective and safe option for vessel prep is imperative to our practice.

Dr. Mouawad: The unique design of FLEX allows a single catheter to be a one-size-fits-all device treating all femoropopliteal lesions. The inventory required for FLEX is significantly smaller than other vessel prep devices because it only has one SKU for the femoropopliteal device. You do not have to stock by diameter size or treatment length.

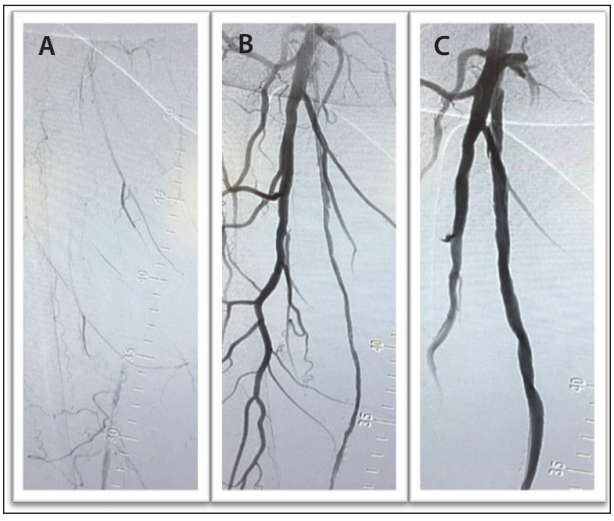
How does FLEX compare to other vessel prep devices in regard to safety?

Dr. Montero-Baker: There have been no flow-limiting dissections, perforations, or embolizations reported to date. Additionally, I have not encountered any safety concerns while using this device. I have had the device in the subintimal space and did not encounter any perforations. The FLEX was purposefully designed by an interventionalist with a patient's safety in mind. The low atmosphere predilation likely accounts for these findings.

What clinical data exist about vessel prep by the FLEX Dynamic Scoring Catheter?

Prof. Zeller: I presented the results of the FLEX device when used in 100 chronic total occlusions (CTOs) at the February 2018 International Symposium on Endovascular Therapy (ISET).[1] The FLEX device effectively recanalized all 100 vessels and performed well even in long or calcified lesions. No adverse events were observed, and a very low amount of minimal dissections occurred while maintaining below-nominal balloon inflation pressures.

Dr. Montero-Baker: Results of the FLEX device were compared across varying degrees of calcification at the Charing Cross Symposium this year, demonstrating that the results post-FLEX alone and postprocedure were impactful regardless of the severity of the calcification.[2] Calcified lesions are challenging and can limit the suc-



Courtesy of Sharat Koul, DO, FACC, FSCAI.

Figure 3. A CTO recanalized by the FLEX Dynamic Scoring Catheter and DCB. Preprocedure angiogram (A). Imaging after vessel preparation by the FLEX Dynamic Scoring Catheter (B). Result post-FLEX and DCB treatment (C).

cess of DCBs. These results support the FLEX as a prime vessel prep device.

Dr. Mouawad: Additionally, there was also a comparative review by lesion length presented at New Cardiovascular Horizons.[3] Over 300 real-world lesions were treated, with no flow-limiting dissections, perforations, or embolizations noted. Unlike the FLEX, most balloon-based devices require multiple inflations, especially for longer lesions, increasing the potential for dissections and perforations.

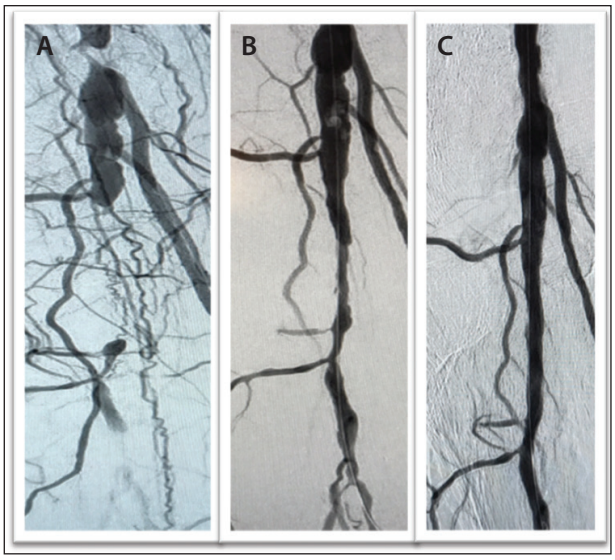
Prof. Hayoz: There is currently a lack of level 1 data for all vessel prep devices; however, I believe that there is utility in the registry data that are currently being compiled for the FLEX device. These are real-world cases involving more than 75 interventionalists in dozens of different hospitals with consistent results across the board. A review of physician-recorded case report forms to date has revealed a 25% to 30% improvement in luminal gain with use of the FLEX device alone before angioplasty. Additionally, in 75% of the cases, the FLEX device was used before the DCB. Many operators are skipping the intervening POBA step and are going straight to the DCB after FLEX because they believe that FLEX is adequately prepping the vessel.

Let's look at a couple of examples of cases treated with the FLEX Catheter. Prof. Zeller, can you please comment on the case shown in Figure 3, which is similar to the 100 CTO cases you presented at ISET this year?

Prof. Zeller: This is an example of a long CTO. In the ISET series, the average length of CTOs was > 19 cm and approximately half of the lesions were recorded to have moderate or severe calcification. These are difficult real-world lesions. The post-FLEX angiogram (Figure 3B) demonstrates that the FLEX device was able to recanalize the CTO with significant luminal gain. The final result shows a widely patent superficial femoral artery segment with restoration of inline flow after application of the DCB. This is a very acceptable result, as it avoids the need for stenting.

Based on your own experience with the FLEX Dynamic Scoring Catheter, can you comment on the recent case illustrated in Figure 4?

Dr. Montero-Baker: In CTO cases like this with calcification, there is a high risk of dissection. FLEX tracks easily through CTOs and tight, long stenotic arteries. The tapered-tip design and braided shaft allow for good pushability, so if a lesion can be crossed, there is a very high technical success rate with delivering the FLEX catheter. In this case, FLEX crossed the lesion with the final result showing no need for stenting.



Courtesy of Ian M. Gawich, MD.

Figure 4. A CTO recanalized by the FLEX Dynamic Scoring Catheter and DCB. Preprocedure angiogram (A). Imaging after vessel preparation by the FLEX Dynamic Scoring Catheter (B). Result post-FLEX and DCB treatment (C).

The FLEX Dynamic Scoring Catheter appears to be an innovative device to prepare lesions for angioplasty that is safe and easy to use. Is there an upcoming study that we should be looking forward to?

Prof. Hayoz: Yes, we are currently initiating a multicenter, single-arm, prospective study in Switzerland. The study will follow 150 patients through 12 months of follow-up. We will be collecting angiograms as well as duplex scans to be adjudicated through a core laboratory. The purpose of the study is to evaluate outcomes of using FLEX with a DCB. Our initial experience in following 50 patients after FLEX plus DCB revealed significantly improved results compared to the use of a DCB alone. Therefore, we are excited to study the FLEX catheter for improvements in both acute procedural results as well as long-term outcomes. ■

1. Zeller T, Lopez L, Pigott JP. Early clinical results utilizing the FLEX Catheter in 100 femoropopliteal chronic total occlusions. Presented at the International Symposium on Endovascular Therapy (ISET); February 2–7, 2018; Hollywood, FL.
2. Pigott JP. Real world results of a dynamic scoring device in calcified femoropopliteal vessels. Presented at Charing Cross International Symposium; April 24–27, 2018; London, United Kingdom.
3. Yoho J, Lopez L, Pigott JP. A comparative review of the FLEX Catheter in the treatment of femoropopliteal lesions of differing lengths. Presented at New Cardiovascular Horizons; May 30–June 1, 2018; New Orleans, LA.

Data on file. Please visit www.flexvesselprep.com for more information.