## Arterial Preparation Improves Outcomes of Drug Coated Balloon Angioplasty

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Objective: Angioplasty without arterial preparation can lead to complications including large uncontrolled dissections. Arterial preparation can mitigate these risks, providing a better lumen patency, limiting the use of stents, avoiding excess wall stretch from high pressure balloons, and decreasing the need for stents.

Methods: FLEX Dynamic Scoring Catheter, a non-balloon-based scoring device, prepares the lesion prior to drug coated balloon angioplasty (DCB). FLEX creates continuous, controlled-depth, longitudinal microincisions regardless of lesion length or morphology. During angioplasty the micro-incisions expand, resulting in improved drug delivery, while decreasing the occurrence of large dissections. The FLEX is indicated for use in the superficial femoral artery (SFA) or popliteal arteries (PA) as well as arteriovenous dialysis access.

Results: At Cantonal Hospital Fribourg, 15 patients with peripheral artery disease were treated with FLEX followed by a prolonged DCB angioplasty to recanalize an SFA or PA stenosis or occlusion. Estimated excellent acute results were obtained with zero stents placed. Technical success was 100%. In 8 patients at 2-month follow-up and 7 patients at 6-month follow-up primary patency has been observed. Two dialysis access interventions have also utilized the FLEX prior to angioplasty, resulting in optimal acute results, and permeability at 2 and 4-month follow-up. A multi-center, prospective study is scheduled to take place in Switzerland evaluating the FLEX with DCB outcomes.

Conclusions: Preparation by the FLEX prior to angioplasty improves drug-uptake and reduces the risk of dissection, when compared to angioplasty alone. Improved lumen restoration and reduction of stent use has been observed with FLEX plus DCB. Arterial preparation by the FLEX Scoring Catheter followed by DCB is a simple and favorable approach for all lesion types.

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