

COMPARING VESSEL PREPARATION USING THE FLEX VESSEL PREP SYSTEM AND DIRECTIONAL ATHERECTOMY DEVICES IN PATIENTS WITH LONG ATHEROSCLEROTIC LESIONS IN INFRAINGUINAL ARTERIES

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Introduction

Adequate vessel preparation (VP) improves technical and clinical outcomes of angioplasty with uncoated balloon (POBA) and drug-coated balloon (DCB). In severely calcified vessels, VP provides additional luminal gain, increases vessel compliance, and minimizes incidence and severity of dissections. The aim of this study was to compare results of using the FLEX Vessel PrepTM System (FVP) with atherectomy devices for vessel preparation prior to POBA and/or DCB.

Study Design

Retrospective comparative analysis of results of vessel preparation in patients with atherosclerotic infra-inguinal lesions longer than 8 cm, using data from SVS VQI Peripheral Vascular Intervention module and the Jobst Vascular Institute (JVI) a single center cohort using FLEX Vessel Prep.



FLEX Vessel Prep System

- Creates longitudinal micro-incisions in any length lesion
- Works in all lesion morphologies
 Controlled incision depth .01"
- Controlled inclsion depth .01"
 Flexes to follow the vessel contour



OCT Image FLEX Micro-incisions in Human Cadaver SFA

Results

The average opening balloon pressure after using FVP was 5.08 +/- 1.64 atm, showing improved vessel compliance.

Luminal gain >40% was observed more frequently in the FVP group.

Fewer re-interventions were required in lesions treated with FVP.

There was no difference between the two groups in: age, sex, diabetes, use of antiplatelets

	VQI	JVI
Number of patients	3499	112
Luminal gain >40%	2.5%	21.2%
Lesion length	22.7cm	14.7cm (p<0.01)
Improved ABI	48.9%	75.6%
Procedural complications	15.5%	10.0% (not significant)
Re-Intervention	21.5%	4.7% (p<0.001)
Smoker	35.2%	25% (p=0.03)

Luminal Gain and Lesion Length





Conclusions

The FLEX Vessel Prep[™] System is similar or superior to atherectomy devices for vessel prep in patients with long lesions in infrainguinal arteries.

Improved vessel compliance evidenced by low opening balloon pressures was demonstrated using FLEX, as well as increased luminal gain and lower rates of reintervention when compared with atherectomy.

This study was limited by the data available in the VQI registry (e.g., lack of information of technical outcomes for vessel preparation, poor follow up rates).