

Novel Endovascular Devices and Techniques in the Management of Peripheral Arterial Disease



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Introduction

Endovascular management of peripheral arterial disease (PAD) has undergone a renaissance since the first angioplasty performed by Charles Dotter in 1964. The purpose of this study is to review the safety and efficacy of some of these novel devices and techniques specifically engineered to treat these complex lesions including atherectomy devices, specialty balloon catheters, helical stent technology, and dissection repair devices.

Serranator Alto PTA Serration Balloon Catheter

How it works/Specifications:

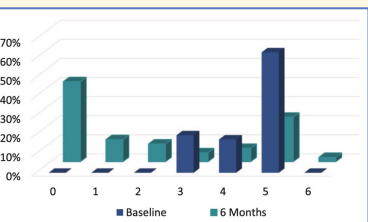
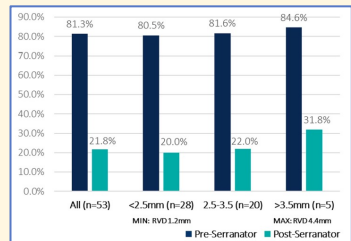
An over-the-wire balloon dilatation catheter with embedded serrated metal strips designed to create linear uninterrupted scoring to perform percutaneous transluminal angioplasty for peripheral vasculature. Indicated for dilation of lesions in the iliac, femoral, iliofemoral, and popliteal arteries.



Size	Guidewire Compatibility (in)	Catheter Length (cm)	Balloon Diameters (mm)	Balloon Lengths (mm)
6F	0.018	150	4.0, 5.0, 6.0	40, 80, 120

Prelude BTK Study Results/Conclusion:

The Serranator Alto balloon catheter was associated with high rates of technical and clinical success with low rates of dissection and bailout stenting.

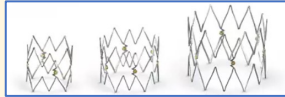


The bottom figure shows Rutherford category scores at baseline and 6 months.



Tack Dissection Repair system

How it Works/Specifications:

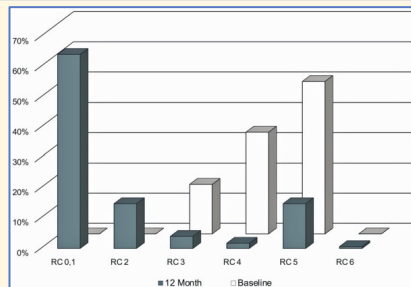
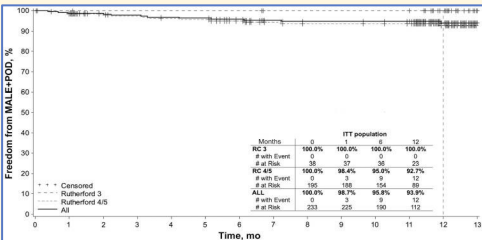


Endovascular System	Tack Implant Length (mm)	Catheter Length (cm)	Treatment Range (mm)	# of Tacks	Indications
4F	6	90	1.5 - 4.5	4	mid/distal popliteal, tibial and peroneal arteries
4F	6	150	1.5 - 4.5	4	mid/distal popliteal, tibial and peroneal arteries
6F	6	80	3.5 - 6.0	6	SFA + Popliteal arteries
6F	6	135	2.5 - 6.0	6	SFA + Popliteal arteries
6F	8	135	4.0 - 8.0	6	SFA + Popliteal arteries
6F	8	80	4.0 - 8.0	6	SFA + Popliteal arteries

The delivery catheter is preloaded with the four or six independent Nitinol self expanding implants with varying sizes to adapt to the patient's anatomy while maintaining a constant radial force to repair peripheral artery dissections.

TOBA II BTK Study Results/Conclusion:

The Tack dissection repair system was associated with up to 90% rate of dissection resolution above the knee and 100% rate of dissection resolution below the knee.



The top figure shows Kaplan-Meier curve for freedom from major adverse limb events + postoperative death in intent to treat subjects.

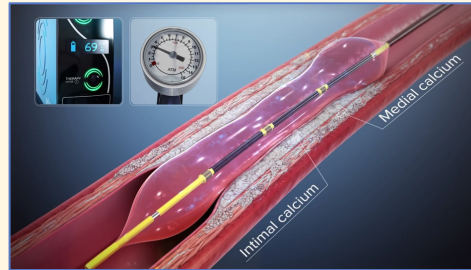
The bottom figure shows sustained improvement in Rutherford category (RC) status.



Shockwave Intravascular Lithotripsy System

How it works/Specifications:

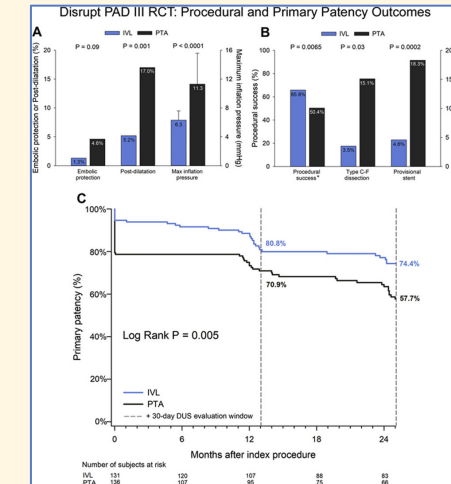
System consists of a generator, connector cable, and an intravascular lithotripsy (IVL) catheter that houses an array of lithotripsy emitters enclosed in an integrated balloon. The lithotripsy emitters break up calcifications, allowing for effective secondary device deployment.



Size	Diameter (mm)	Length (mm)	Guidewire Compatibility (in)	Working Length (cm)	Pulses (Max)
6F	2.5, 3.0, 3.5, 4.0	12	0.014	138	80

Disrupt PAD III Study Results/Conclusion:

The Shockwave intravascular lithotripsy balloon catheter was associated with lower rates of provisional stenting and high rates of primary patency at 2 years.



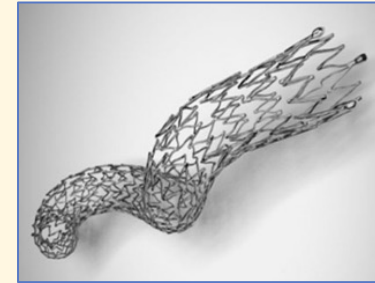
The figure shows primary patency was significantly greater in group receiving IVL treatment for lesion preparation than in percutaneous transluminal angioplasty (PTA) group.



BioMimics 3D Vascular Stent system

How it works/Specifications:

Consists of a unique 3D helical shape, designed to provoke swirling flow-mediated increase in wall shear stress to reduce atherosclerosis, restenosis, and stent fracture.



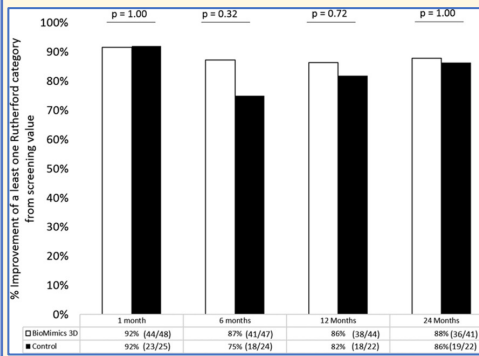
Stent Diameter (mm)	Stent Length (mm)	Reference Vessel Diameter (mm)	Stent Delivery System OD (inch)	Sheath Compatibility* Fr/minimum ID (mm)	Guidewire Compatibility (inch)
5	60, 80, 100, 125, 150	3.5 - 4.0	0.079	6FR/2.2mm	0.035
6	60, 80, 100, 125, 150	4.0 - 5.0	0.079	6FR/2.2mm	0.035
7	60, 80, 100, 125, 150	5.0 - 6.0	0.079	6FR/2.2mm	0.035

Stent material: Nickel-titanium alloy: nitinol

Radiopaque markers number and location: 3 distal and 3 proximal

MIMICS-3D Study Results/Conclusion:

The BioMimics stent was associated with high primary stent patency and low adverse events up to 2 years.



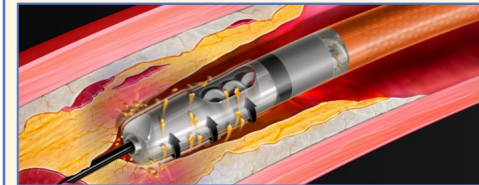
The figure shows the proportion of patients in each group that had improved by at least 1 Rutherford category through 24 months.



Rotarex Excisional Atherectomy & Thrombectomy System

How it works/Specifications:

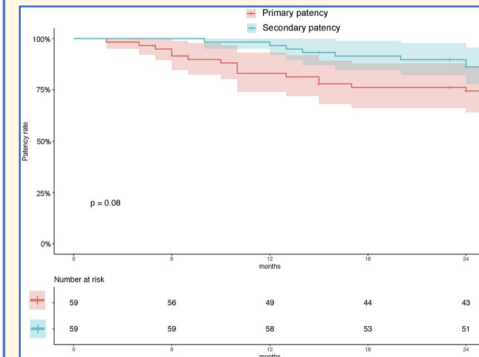
Catheter with a modified rotating beveled tip breaks down, actively aspirates, and transports material away. Indicated for atherectomy, thrombectomy, native bypass, artificial bypass, stent grafts, and in-stent restenosis.



Size	Length (cm)
6F	110, 135
8F	85, 110

PERMIT-ISR trial Results/Conclusion:

The Rotarex excisional atherectomy system was associated with high rates of target lesion revascularization, primary and secondary patency, and low rates of bailout stenting.



The figure shows primary and secondary patency rates were 82.5 and 92.5% respectively, at 12 months.



Reference/Contact Info

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