
Serranator Balloon for Vessel Prep
Current Status

Steven Kum, MD
 Mount Elizabeth Novena Hospital / Changi General Hospital
 Singapore


Disclosure

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below

Affiliation/Financial Relationship	Company
<ul style="list-style-type: none"> Research Support Consulting Fees/Honoraria Advisory Board Equity 	<ul style="list-style-type: none"> Boston Scientific, LimFlow/Inari LimFlow/Inari, Acelyt, Abbott Vascular, Boston Scientific, Orbus Neich, Bypass Solutions, PEDRA, Xeltis Abbott, Boston Scientific, Xeltis, LimFlow/Inari, Fastwave, Corflow, VCD, Bypass Solutions, Protexa LimFlow/Inari, Mercator, Cagent, PEDRA, Xeltis, Fastwave, Corflow, VCD, Bypass Solutions, Protexa, R3

Serration Technology

A Disruptive Innovation to Angioplasty



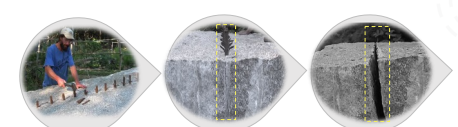
Available Sizes			
Balloon Diameter (mm)	Balloon Length (mm)	Guidewire Compatibility	Sheath Size (F)
2.5, 3.0, 3.5	40	0.034"	6
	80		
4.0, 5.0, 6.0	120	0.038"	6
	150		

Indication for Use:
 The Serranator PTA Serration Balloon Catheter is intended for dilation of lesions in the iliac, femoral, iliofemoral, popliteal, and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulas. Not for use in the coronary or neuro-vascular.

1,000X point force of POBA

Serration Technology: Based on Physics Principles

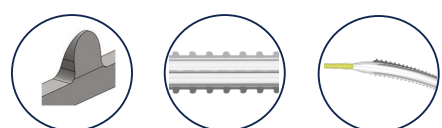
Mechanism of Action: Serrated Material is More Responsive to Directed Energy



- Short individual wedges are placed intermittently along a line
- Minimal energy is exerted on wedges to create deep fissures, below the surface
- 26,000 lb. granite opens in a predictable, controlled fashion

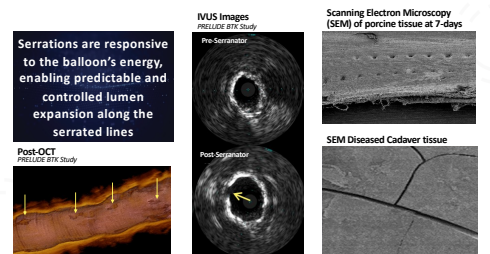
Unique Serration Angioplasty Achieves Lumen Gain

Mechanism of Action



- Point Force**
Serranate with 1,000x more Point Force compared to POBA
- Stainless Steel Serration Strips**
Effective in all lesion morphologies with arterial expansion along the serrated line
- Low & Slow Inflation**
4 ATM for 60 seconds
6 ATM for 60 seconds

Mechanism of Action: Serranate with Serration Angioplasty



Serrations are responsive to the balloon's energy, enabling predictable and controlled lumen expansion along the serrated lines

IVUS Images PRELIMINARY Study: Pre-Serranator vs Post-Serranator

Scanning Electron Microscopy (SEM) of porcine tissue at 7-days: SEM Diseased Cadaver tissue

IVUS Imaging of Posterior Tibial

Pre-Intervention vs **Post-Serranator**

Pre-intervention imaging showed diffuse circumferential superficial calcification (A-D). Post-Serranator angiogram showed slits (yellow arrow) in the superficial calcium enabling enlargement of lumen without any dissection (A'-D').

Dr. Akiho Marchard, Director, Intravascular Imaging, Core Laboratory and IRT, Core Laboratory, CRF

IVUS Imaging by Dr. K. Herzig



Prelude SFA and BTK

Prelude ATK Study Data² (n=25)
 • Final Residual Stenosis: 22.7%
 • Maximum Pressure (mean): 8 ATM
 • Bailout Stent Rate: 4%
 • Freedom from CD-TL/R/WR at 6 months: 100%

Prelude BTK Study Data³ (n=53 lesions)
 • Final Residual Stenosis: 21.8%
 • Maximum Pressure (mean): 6 ATM
 • Bailout Stent Rate: 1.9%
 • Freedom from CD-TL/R at 6 months: 97.7%

1. A. Hildner, et al. Prospective Study of Serranator Angioplasty in the Infrapopliteal Arteries Using the Serranator Device. PRELUDE BTK Study. Journal of Endovascular Therapy 2021.
2. A. Hildner, et al. PRELUDE Prospective Study of the Serranator Device in the Treatment of Atherosclerotic Lesions in the Superficial Femoral and Popliteal Arteries. Journal of Endovascular Therapy 2019, Vol. 22(12): 14-26.

POBA vs. Serranator in BTK

- Single-center
- Core lab adjudicated
- BTK sub-analysis

- 49% GREATER ACUTE LUMINAL GAIN** in residual stenosis. Greater acute luminal gain using Serranator[®] provides increased blood flow.
- 2.4x GREATER BLOOD FLOW**. Greater volumetric blood flow using Serranator[®] versus POBA.
- 62% HIGHER FREQUENCY OF RESIDUAL STENOSIS TO CTCS**. Serranator[®] outperformed POBA by an even wider margin in the most severe disease.
- 5ATM HIGHER PRESSURE USED WITH SERRANATOR**. Lower average pressure was used with Serranator[®] (5ATM) compared to POBA (9ATM).

3. Gavetti K, Mester V, Schwagerl L, Tang W, Patel K, Brodtkorn M. Standard Balloon Angioplasty Versus Serranator Scorpion Balloon Angioplasty for the Treatment of Below-the-Knee Artery Occlusion Disease: A Single-Center Subanalysis From the PRELUDE BTK Prospective Study. J Endovasc Ther. 2022 Nov 26.

Recoil Study: Serranator vs. POBA

Recoil Study: Serranator vs. POBA
 N=40 lesions

Serranator mean LL 85.5mm vs POBA mean LL 83.7mm

6% MEAN RECOIL ACROSS ALL LESIONS AT 15 MIN vs **55%** for POBA.

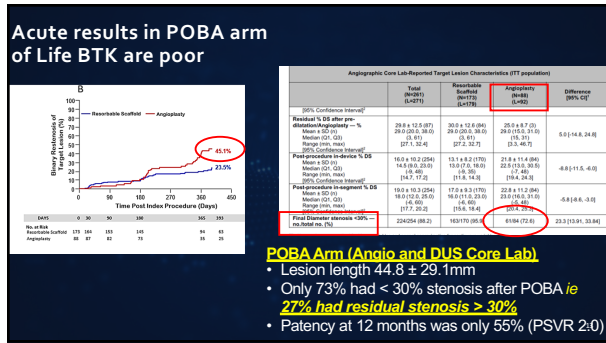
89% IMPROVEMENT OVER POBA IN RECOIL

Herrero-Gil A, Castano J, Schneider PA, Diaz-RB, Lichtenberg M, Szlachetka L. Serranator Angioplasty is Associated With Less Recoil in Infrapopliteal Arteries Compared With POBA. Balloon Angioplasty. J Endovasc Ther. 2023 Dec 7;35(6):802-812. doi: 10.1177/15268082231212294. Epub ahead of print. PMID: 38694662

Recoil Study Results

Outcomes	Serranator [®] (n=20)	POBA [*] (n=19)	P value
Mean recoil across all lesions at 15 min (\pm SD)	6% (+/- 25)	55% (+/- 69)	p = 0.009
Recoil	Serranator [®] (n=20)	POBA [*] (n=19)	POBA/ Baumans ^{**} (n=30)
% of lesions with recoil defined as $\geq 10%$ lumen compromise at 15 min	25% (5/20)	63% (12/19)	97% (29/30)
Clinically Relevant Recoil (CRR)	Serranator [®] (n=20)	POBA [*] (n=19)	
% of lesions with recoil (CRR is defined as $\geq 30%$ lumen compromise at 15 min)	10% (2/20)	53% (10/19)	

*Angiographic Core lab ** No Angiographic Core lab



Serranator PTA Serranator Balloon Utilized Below-the-Ankle

N=41 vessels
*Preliminary data

97%

FREEDOM FROM MAJOR AMPUTATION @ 5-MOS

0

PERFORATION, EMBOLIZATION, SIGNIFICANT DISSECTION

42%

PATIENTS IMPROVED TO RCC-0

89%

WOUND HEALING AT 5-MOS

Median Rutherford Improvement: 2 Levels

- Retrospective, Multi-center
- Below-the-Ankle
- Additional enrollment underway

Novel study on first Specialty balloon use in pedal arteries

1. Givell K, Muehler V, Schwagerl S, Tang WC, Patel K, Bradshaw M. Standard Balloon Angioplasty versus Serranator Serranator Balloon Angioplasty for the Treatment of Below-the-Knee Artery Occlusive Disease: A Single-Center Subanalysis From the PRELUDE-BTK Prospective Study. J Endovasc Ther. 2023;36:20

Preliminary Pre-Clinical Data: PK Analysis

Drug-Uptake Study: Animal Model

Admiral Xtreme™ PTA balloon

INPACT® Admiral® Pacilitaxel-Coated Balloon

Serranator™ PTA balloon

INPACT® Admiral® Pacilitaxel-Coated Balloon

Results: Up to 3x Drug-Uptake compared to POBA*

*Based on PK analysis from animal model study.



Serranator Effective in Severe Calcium

Above-the-Knee: Distal SFA

Pre-Procedure

Significant stenosis with severe calcium

Inflation

6.0mm x 40mm inflation to 11 ATM

Post-Serranator Treatment

Residual Stenosis: 24.07%
Dissection: No

Core lab adjudicated data

RVD: 6.12 mm
% Stenosis: 26.59 %
Lesion Length: 30.04 mm
Calcification: Severe

PRELUDE-SFA Study, read by Dr. Andrew Hildner

Lumen Gain. No Atherectomy. No Dissection. No Stent.

Below-the-Knee: Anterior Tibial Artery

Pre-Procedure

Stenosis: 100%
Lesion Length: 11.8.15mm

Inflation

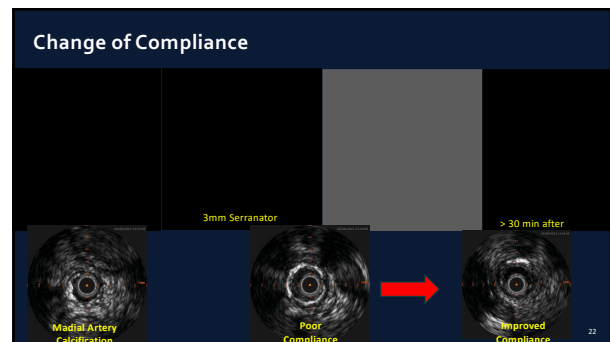
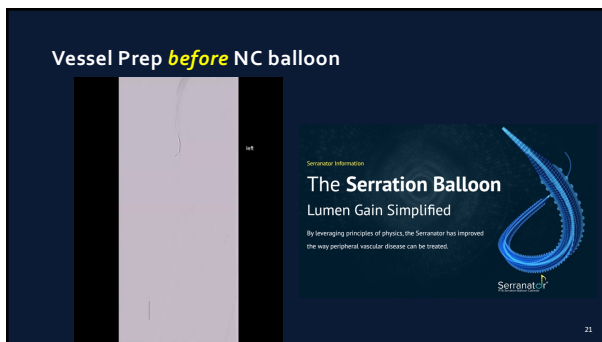
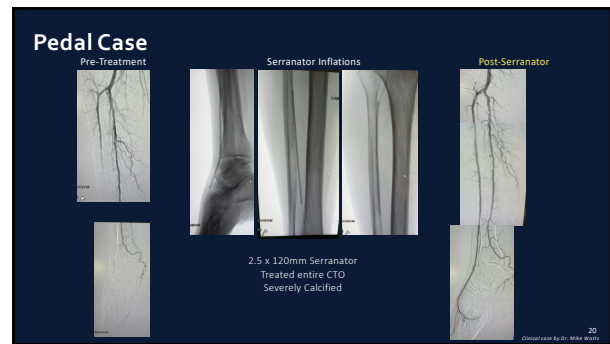
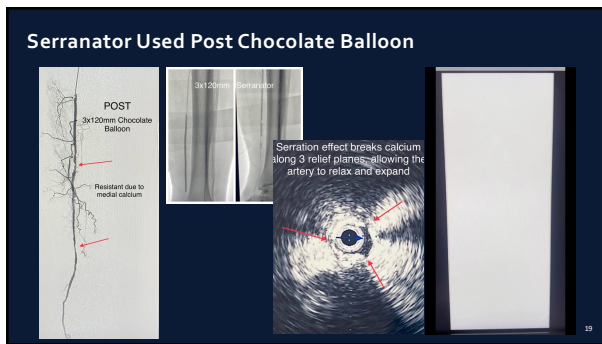
2.5 x 120 Serranator Max ATM: 4

Post-Serranator Treatment

Residual Stenosis: 35%
Dissection: No

Core lab adjudicated data

PRELUDE-BTK Study, read by Dr. Massimo Brancaccio



Summary

- Dedicated devices need to address recoil and dissection for acute lumen gain may be considered as standard of care
- Device needs to be
 - Deliverable
 - Effective
 - Cost effective
- Serranator balloon may addresses most of these needs

23