



# The PRELUDE Study

The PRELUDE Study (PRospective Study for the TrEatment of Atherosclerotic Lesions in the Superficial Femoral Artery and/or Popliteal Artery Using the Serranator Device) is a single-arm, prospective, multicenter feasibility study enrolling up to 30 subjects with superficial femoral or popliteal lesions. The first case was performed in February 2017. The primary objectives are to collect safety and efficacy data, and to perform 30-day and 6-month follow-up. A secondary objective is to assess the feasibility of using OCT and/or IVUS in a subset of 10 patients to evaluate the presence of serrations. Dr. Andrew Holden (Auckland, New Zealand) is the Principal Investigator of the study, and the coinvestigators are Drs. Marianne Brodmann (Graz, Austria), Marek Krzanowski (Krakow, Poland), and Przemyslaw Nowakowski (Chrzanow, Poland).

## PRELUDE STUDY: KEY INCLUSION/EXCLUSION CRITERIA

Inclusion	Exclusion
Resting ABI $\leq$ 0.9	Previously implanted stent
Rutherford 2, 3, or 4	Rutherford 1, 5, or 6
Lesions within the SFA or popliteal	CTO > 6 cm
Stenosis $\geq$ 70%	Acute total occlusions; evidence of acute thrombus
One long lesion or multiple lesions up to 10 cm	Severe calcification
De-novo, or non-stented restenotic lesions	Atherectomy

## CASE PRESENTATIONS

The cases presented here are five of the subjects enrolled in the PRELUDE study to date. The SFA and popliteal lesions (Cases 1, 2, and 3) ranged from mild to severe calcification. Each case demonstrates effective lumen gain with minimal injury and no flow-limiting dissections after the use of *Serranator*® Alto.

The IVUS and OCT images (Cases 4 and 5) demonstrate clear evidence of serration, disruption of intimal calcification, and acute lumen expansion.

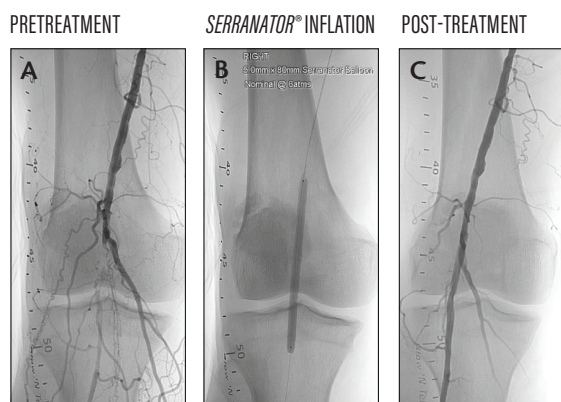
Angiography core lab adjudication was performed at Yale Cardiovascular Research Group under the direction of Alexandra Lansky, MD, and OCT/IVUS core lab adjudication was completed by University Hospitals, Harrington Heart and Vascular Institute under the direction of Hiram Bezzera, MD.

These early clinical results indicate that the effect of *Serranator*® Alto on atherosclerotic and calcified lesions, previously seen in preclinical bench, animal, and cadaver studies, is confirmed.

Enrollment in the PRELUDE study is ongoing. Six-month follow-up on all subjects is expected to be completed in Q4 2017. ■

## CASE STUDY #1

### Right Proximal Popliteal With Total Occlusion Performed by Dr. Andrew Holden



The reference vessel diameter was 4.19 mm; lesion length was 54.28 mm; percent stenosis was 100% (A). A 5 mm X 80 mm *Serranator*® Alto was inflated to 6 atm (B). After treatment, residual stenosis was 20.23% (C).

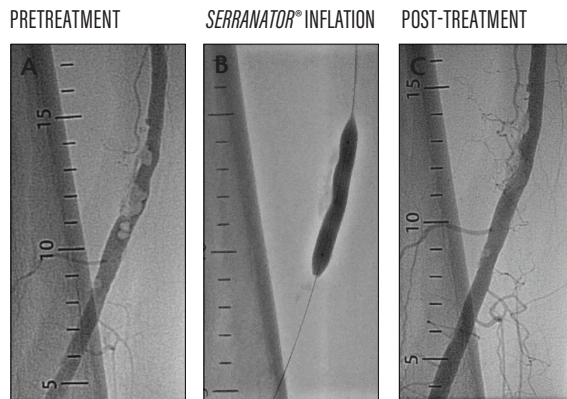


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## CASE STUDY #2

### Right Distal SFA With Severe Calcification

Performed by Dr. Marek Krzanowski

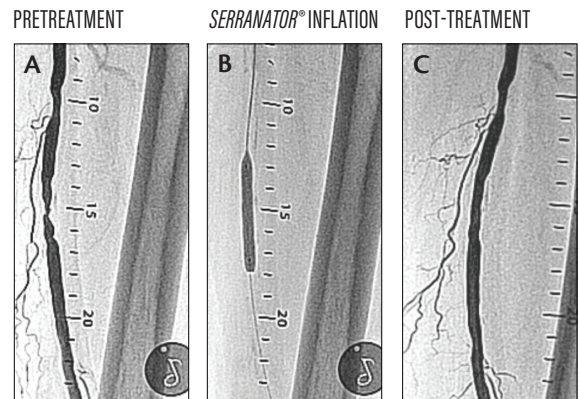


The reference vessel diameter was 6.12 mm; lesion length was 30.04 mm; percent stenosis was 94.59% (A). A 6 mm X 40 mm *Serranator*® Alto was inflated to 11 atm (B). After treatment, residual stenosis was 24.07% (C).

## CASE STUDY #3

### Left Mid SFA

Performed by Dr. Przemyslaw Nowakowski

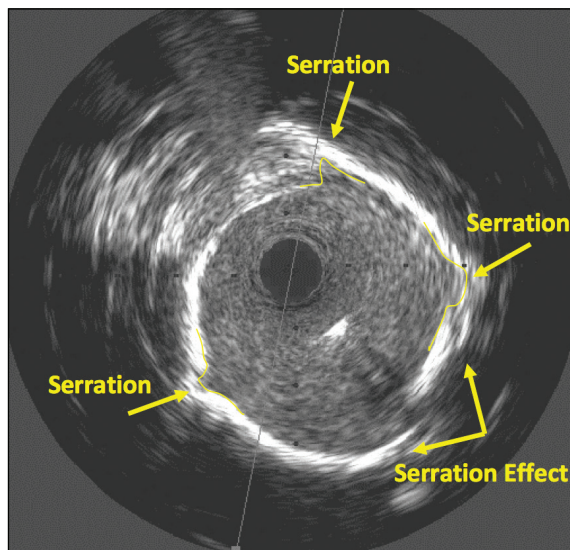


The reference vessel diameter was 5.15 mm; lesion length was 28.42 mm; percent stenosis was 77.02% (A). A 5 mm X 40 mm *Serranator*® Alto was inflated to 6 atm (B). After treatment, residual stenosis was 12.84% (C).

## CASE STUDY #4

### IVUS of Serration Effect in Mid-SFA Lesion

Performed by Dr. Przemyslaw Nowakowski



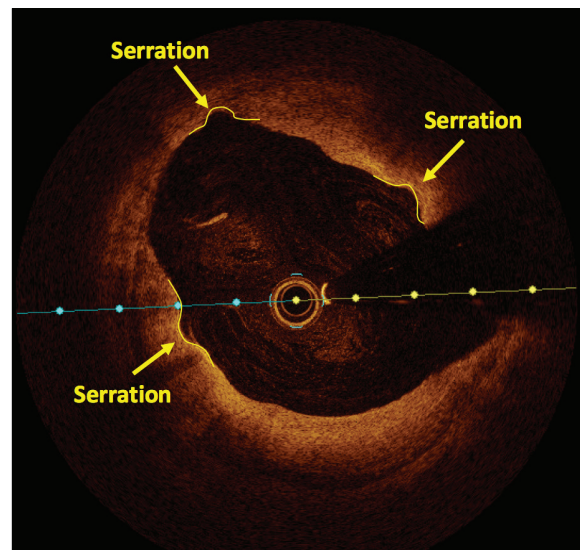
Controlled modification of severe intimal calcification by the *Serranator*® Alto. Note the controlled acute luminal gain of the impacted calcified intimal layer.

—J. Mustapha, MD

## CASE STUDY #5

### OCT of Serration Effect

Performed by Dr. Andrew Holden



The OCT image shows clear evidence of serration caused by the *Serranator*® Alto device.

—A. Holden, MBChB, FRANZCR, EBIR