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WOLVERINE™

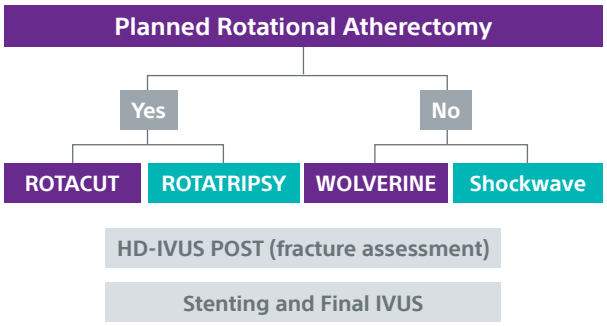
Coronary Cutting Balloon | The ShortCUT Trial

The ShortCUT Trial demonstrated WOLVERINE Cutting Balloon is non-inferior to Shockwave IVL with regard to MSA at the site of maximum calcium in moderate-severe calcified coronary lesions within the total study population.

Presented by Dr. Suzanne Baron, TCT 2025

ShortCUT Study Design

Randomised, non-inferiority trial of N=413 patients at 21 US sites with moderate-severe calcified lesions



Primary Endpoint (non-inferiority):
MSA at site of max calcification

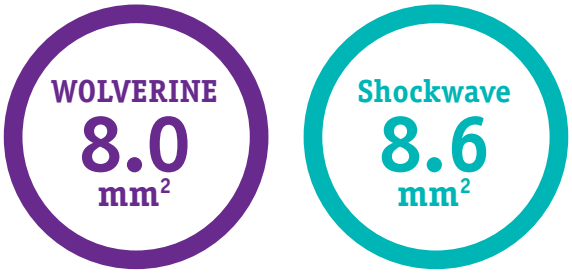
Key Secondary Endpoint (superiority):
Total procedural cost

Key Lesion Characteristics

	WOLVERINE N=212	Shockwave N=218
Reference Vessel Diameter	3.4 mm	3.5 mm
Target Lesion Stenosis	89%	87%
Median Max Calcium Arc	338°	347°
Nodular Calcium	25%	25%
CTO	13.5%	12.5%

WOLVERINE demonstrated non-inferiority to Shockwave in regards to MSA as site of max calcium. The ShortCUT Trial showed no differences in stent expansion and presence of calcium fractures in the total patient cohort.

MSA at site of max calcium
in total cohort



P-value (non-inferiority) = 0.007

Secondary Endpoints

Stent Expansion at site of maximum calcium

WOLVERINE	Shockwave
97.7%	97.7%

P-value = 0.99

Calcium Fracture

WOLVERINE	Shockwave
78.9%	77.4%

P-value = 0.72

Cost

Total procedural costs were significantly lower with WOLVERINE, showing it is a cost-effective strategy for IVUS guided PCI procedures.

Safety

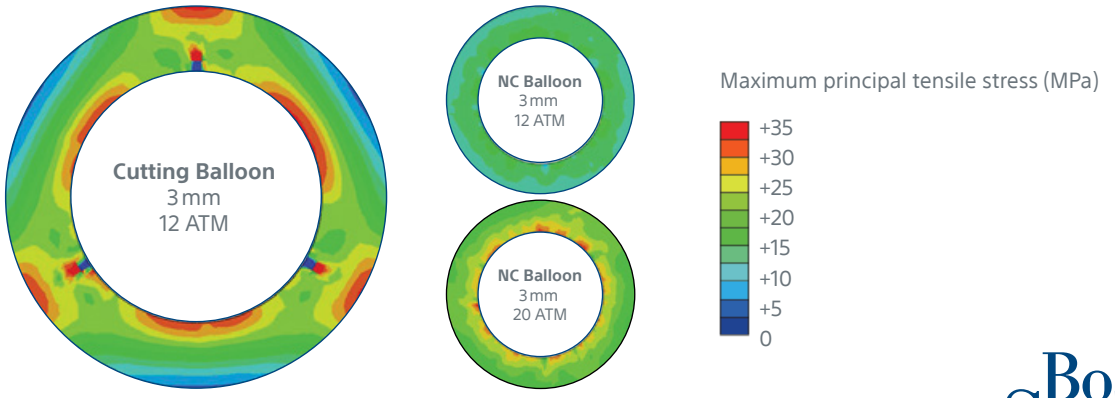
There were no significant differences in complication associated with randomised device, intraprocedural adverse events or MACCE through 30 days, validating WOLVERINE's comparable safety to Shockwave.

Endpoint	WOLVERINE N=206 Patients	Shockwave N=207 Patients	P-Value
Complication associated with randomised device	5.5%	4.0%	0.34
In-Hospital MACCE	1.0%	1.0%	1.00
30-Day MACCE	2.9%	2.9%	1.00
Intraprocedural adverse events	1.0%	1.0%	1.00

- ShortCUT trial protocol called for WOLVERINE Cutting Balloon to be sized 0.5 mm smaller than reference vessel diameter and inflated to high pressures (16–20 atm). Average pressure used for WOLVERINE based on protocol was 17 atm.
- HD-IVUS was strongly recommended prior to randomisation and mandatory after randomised device use (pre-stent implantation) & at procedure completion.

Wolverine's Unique Mechanism of Action

Superior outcomes at lower focused pressures
3x the stress, focused at the atherotomes for controlled cracking



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