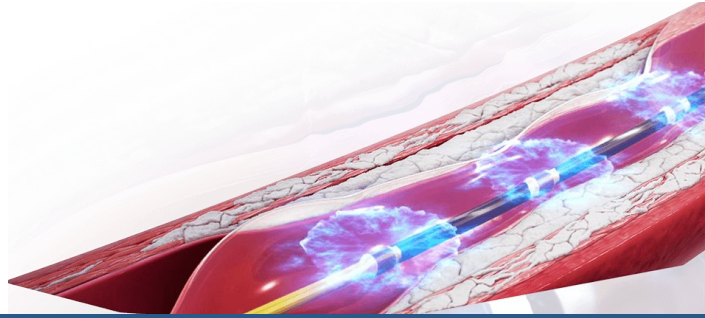
SIPROTEC

SHOCKWAVE | IVL

Características y Beneficios



MINIMIZA EL TRAUMA

Minimiza el trauma en los tejidos blandos, fracturando de forma segura el calcio de la íntima y la medial

OPTIMIZA LOS RESULTADOS

Reduce las complicaciones y los de costos de los procedimientos

PROCEDIMIENTOS SIMPLIFICADOS

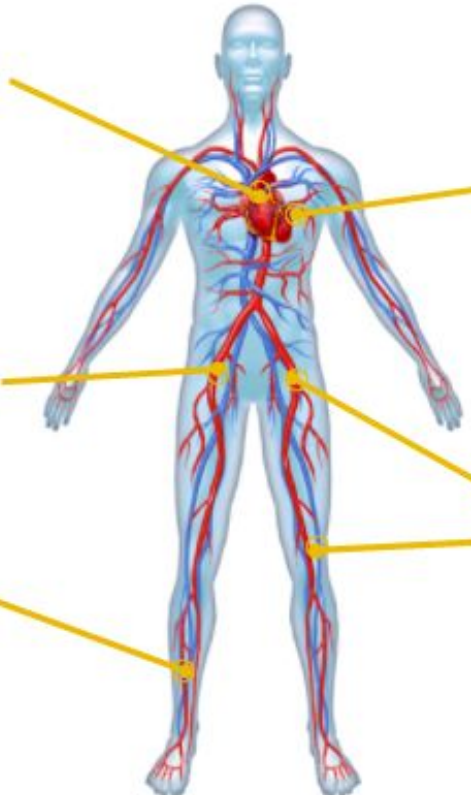
Sistema simple e intuitivo que hace que los procedimientos calcificados complejos sean más predecibles.

Calcificación severa : Un gran problema en el sistema cardiovascular

Válvula Aórtica
Calcio representa gran problema

AAA, TAVI.
Accesos complejos debido al calcio

Arterias infrapatelares
≤ 75 % presentan calcificación moderada/severa



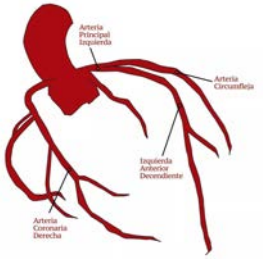
Arterias coronarias
≤ 25 % presentan calcificación moderada/severa

Ilíacas, femorales
≤ 50 % presentan calcificación moderada/severa

SHOCKWAVE

CORONARIO

Shockwave C2



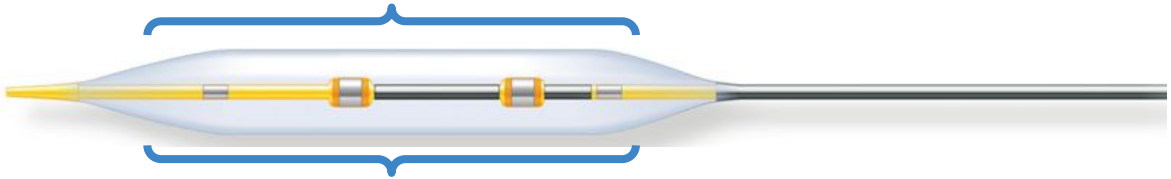
PERIFÉRICO

Shockwave S4 (Infrapatelar)

Shockwave M5 (Suprapatelar)

C2

2 emisores



12 mm de longitud

Sistema RX, compatible con guías 0,014
de 190 a 300 cm
80 pulsos de entrega máxima.
138 cm de largo

Diameter (mm)	Length (mm)	Max Pulse Count	Guidewire Compatibility (in)	Guide Catheter Compatibility	Working Length (cm)	Crossing Profile Range* (in)
2.5	12	80	0.014"	6F	138	0.044 +/- 0.002
3.0						
3.5						
4.0						

M5

5 emisores

60 mm de longitud

Sistema OTW, compatible con guías 0,014 de 300 cm
300 pulsos de entrega máxima.
110 cm de largo

M5 CATHETER SPECS

Catalog Number	Diameter (MM)	Length (MM)	Sheath Compatibility	Working Length	Pulses/ Cycle	Cycles	Pulses (Max)	Crossing Profile
M5IVL3560	3.5	60	6F	110	30	10	300	.054
M5IVL4060	4.0	60	6F	110	30	10	300	.057
M5IVL4560	4.5	60	6F	110	30	10	300	.058
M5IVL5060	5.0	60	6F	110	30	10	300	.062
M5IVL5560	5.5	60	6F	110	30	10	300	.064
M5IVL6060	6.0	60	6F	110	30	10	300	.066
M5IVL6560	6.5	60	7F	110	30	10	300	.068
M5IVL7060	7.0	60	7F	110	30	10	300	.073

S4

Sistema OTW, compatible con guías 0,014 de 300 cm
160 pulsos de entrega máxima.
135 cm de largo

IVL CATHETER SPECS

Catalog Number	Diameter (mm)	Length (mm)	Sheath Compatibility	Working Length	Pulses/ Cycle	Cycles	Pulses (Max)	Crossing Profile
S4IVL2540	2.5	40	5F	135	20	8	160	.048
S4IVL3040	3.0	40	5F	135	20	8	160	.048
S4IVL3540	3.5	40	5F	135	20	8	160	.048
S4IVL4040	4.0	40	5F	135	20	8	160	.050

CONSOLA:

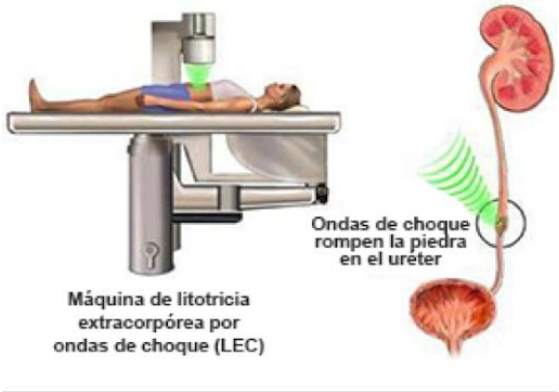
Portátil, recargable.
Configuración rápida y sencilla

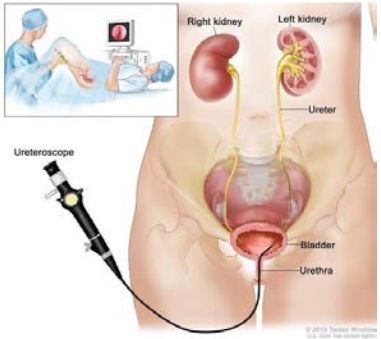
CABLE CONECTOR:

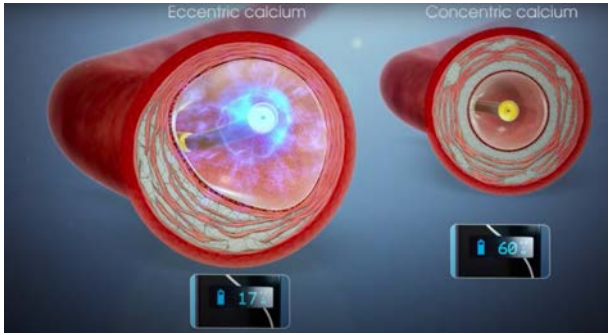
Conexión magnética.
Boton pulsador On/Off

DIFERENTES MODALIDADES DE LITOTRICIA

	Extracorpórea	Intracorpórea	IVL
Fuente de E	Fuera del cuerpo	Dentro del cuerpo	Dentro del balón
Liberación de E	Anisotrópica	Isotrópica	Isotrópica
Profundidad de penetración	150 mm	10 mm	7 mm





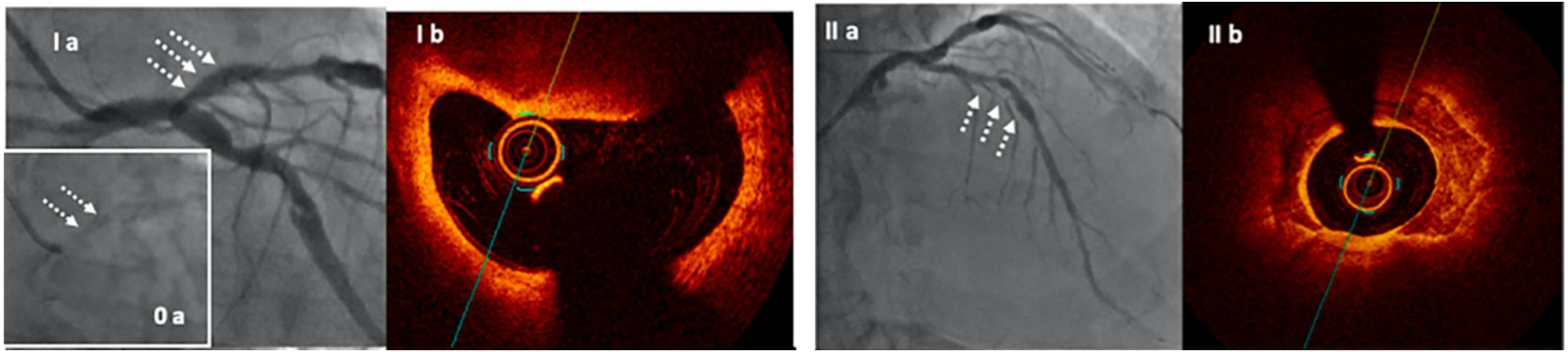


Intravascular imaging to guide lithotripsy in concentric and eccentric calcific coronary lesions

Alessio Mattesini [1], Giulia Nardi [1], Antonio Martellini, Carlotta Sorini Dini, Brunilda Hamiti, Miroslava Stolcova, Francesco Meucci, Carlo Di Mario *

Structural Interventional Cardiology, Careggi University Hospital, Florence, Italy

https://doi.org/10.1016/j.carrev.2020.04.016



Conclusions

with RA. Lesions treated with IVL followed by IVUS/OCT guided second generation DES implantation delivered excellent immediate procedural results and short-term patient outcome, both in concentric or eccentric calcifications.

Características y Beneficios

1

Minimiza el trauma

Fractura el Calcio mediante US evitando el daño en la pared arterial

2

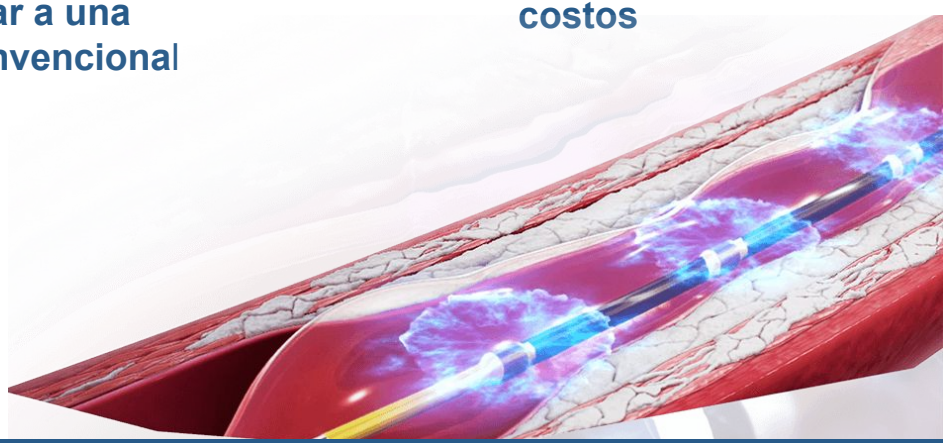
Procedimientos Simples y seguros

Curva de aprendizaje rápida, técnica similar a una angioplastia convencional

3

Resultados Óptimos

Reduce complicaciones y costos



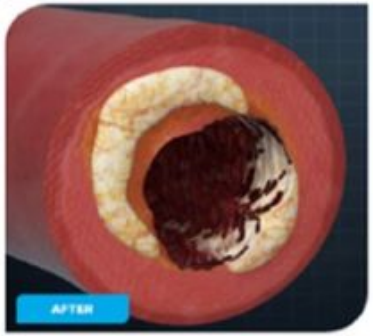
SIPROTEC

MINIMIZA EL TRAUMA

Las onda de ultrasonido atraviesan el tejido sano, sin dañarlo y al llegar al calcio lo fracturan a nivel de las capas arteriales **íntima y media,** devolviendo la complacencia a la arteria

SIPROTEC

Angioplastia con balón utiliza alta presión constante para superar la resistencia de la placa.



Los dispositivos de aterectomía eliminan la placa aterosclerótica superficial sin diferenciar entre placa y tejido blando

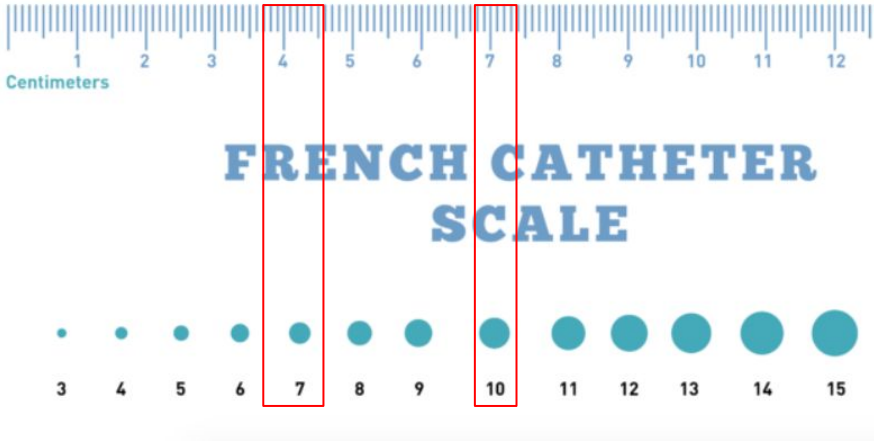
IVL utiliza ondas de presión sónicas que atraviesan los tejidos blandos y fracturan el calcio en las capas íntima y medial.

FRENCHAJE DE ACCESOS

Burr & Catheter Sizing

Guide sizes are based on larger lumen catheters.

Burr (mm)	Diameter (Inches)	Minimum Recommended Guide Catheter Internal Diameter (Inches)*	Recommended Guide Catheter†,‡	Recommended Burr Speed
1.25	0.049	0.060	6F	160,000 – 180,000
1.50	0.059	0.063	6F	160,000 – 180,000
1.75	0.069	0.073	7F	160,000 – 180,000
2.00	0.079	0.083	8F	160,000 – 180,000
2.15	0.085	0.089	8F	140,000 – 160,000
2.25	0.089	0.093	9F	140,000 – 160,000
2.38	0.094	0.098	9F	140,000 – 160,000
2.50	0.098	0.102	10F	140,000 – 160,000

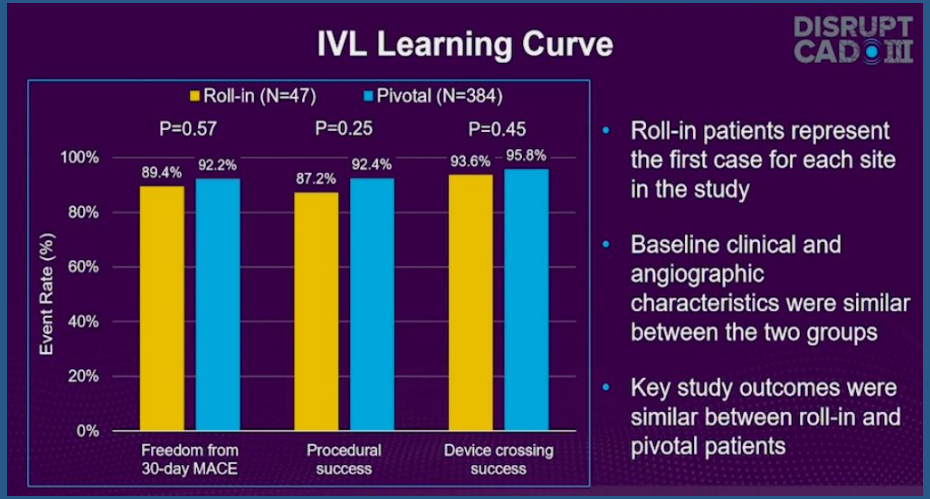


C2 — 6fr

M5 — 6fr / 7fr

S4 — 5fr

PROCEDIMIENTOS SIMPLES Y SEGUROS



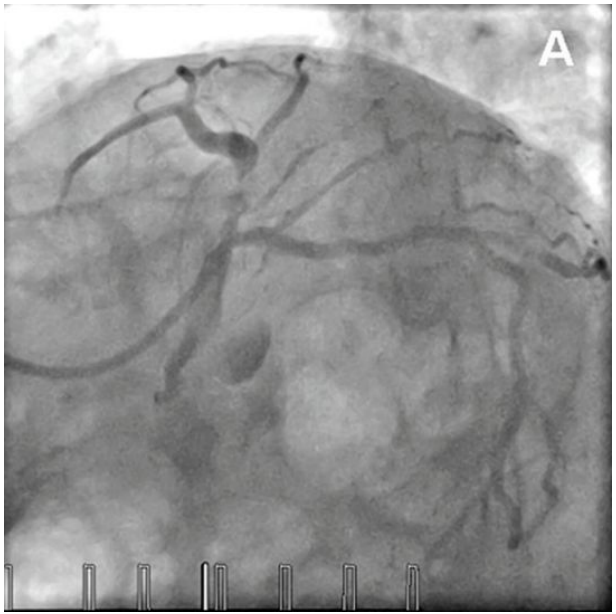
DISRUPT CAD III: A Deep Dive on the U.S. Pivotal Study for Coronary IVL, Sponsored by Shockwave
FACULTY: Jonathan Michael Hill, Matthew J. Price, Dean J. Kereiakes, Howard C. Herrmann, Richard Shlofmitz, Robert F. Riley

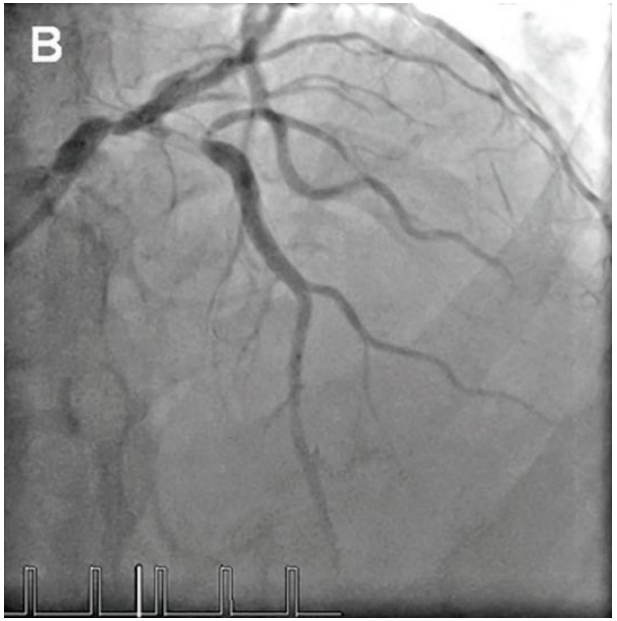
SIPROTEC

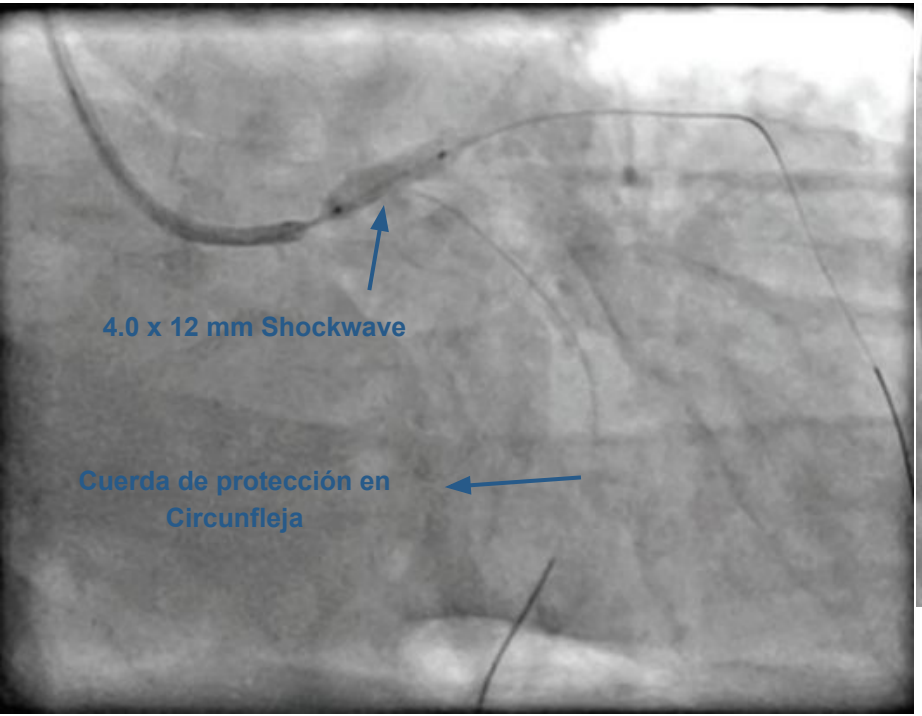
Tratamiento de la enfermedad de tronco coronario

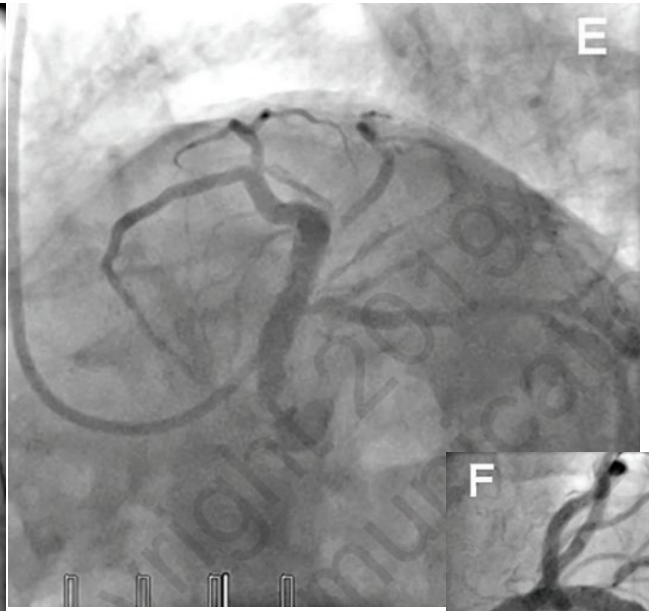
Treatment of Heavily Calcified Unprotected Left Main Disease With Lithotripsy: The First Case Series

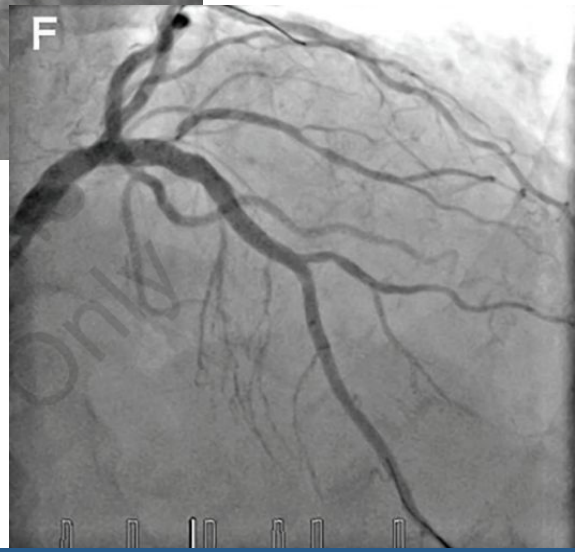
Bernard Wong, MBChB; Seif El-Jack, MBBS; Ali Khan, MBBS; Ruth Newcombe, DCR; Timothy Glenie, MBChB; Aleksandar Cicovic, MBChB; Guy Armstrong, MBChB









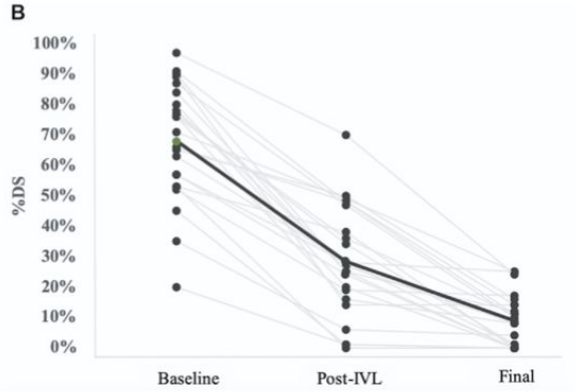


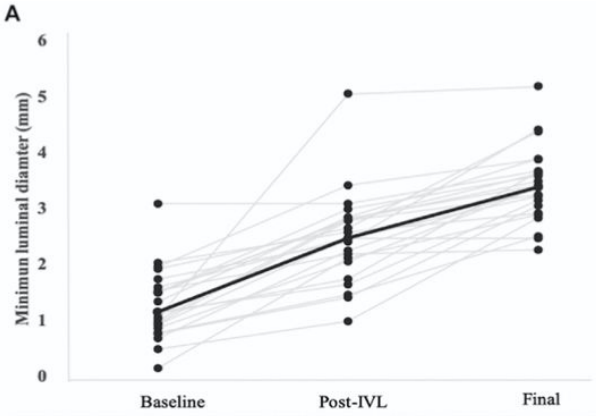
JACC: CARDIOVASCULAR INTERVENTIONS VOL. 13, NO. 14, 2020
JULY 27, 2020:1723–31

RESEARCH CORRESPONDENCE

Feasibility, Safety, and Efficacy of Intravascular Lithotripsy in Severely Calcified Left Main Coronary Stenosis

https://doi.org/10.1016/j.jcin.2020.04.022





1)La terapia se aplica mediante un catéter-balón, motivo que lo hace relativamente simple, con una cueva aprendizaje corta

2) A diferencia que con los dispositivos de aterectomía rotacional, **la guía en la rama lateral se puede mantener durante la IVL**.

3) IVL **fractura la placa**, pero no genera **desprendimiento** de placa, lo que hace que la aparición de **no reflow** sea poco probable

El no reflow es una de los complicaciones importantes asociadas con la aterectomía,y en el contexto de la enfermedad de tronco puede conducir a eventos adversos importantes

REDUCCIÓN DE COSTOS

Minimal below-the-knee vessel recoil after IVL

In this case study, **Peter Soukas** demonstrates the benefits of IVL in a below-the-knee vessel, including decreased resource utilisation, cost-effectiveness, and reduced length of hospital stay.

Case study — Emerging value of IVL

Simple IVL-facilitated EVAR access

Mazin Foteh discusses the clinical and economic value of IVL for endovascular aneurysm repair (EVAR), concluding that the technology has "revolutionised" his approach to aortic procedures.

Reduced rates of dissection and recoil seen with IVL result in decreased resource utilisation by limiting the need for bailout stenting. Unlike atherectomy devices that typically require the additional costs of embolic protection devices, IVL may be used as standalone therapy, or combined with DCBs.

Moreover, additional interventions for distal embolisation or perforations seen by atherectomy are largely avoided with IVL, limiting those costs. In spite of often complex calcified disease, most patients treated with IVL are predictably discharged the same day.

eries.

sty was endoconduit by placing covered stents in

eal of the the iliacs, but this adds tremendous cost

e iliacs and does not eliminate the risk of rupture.

o

al

Mazin Foteh

An open conduit is anatomically not an option and would not solve the issue with limited access. In an era of medicine in which cost has become omnipresent, cost effectiveness is now one of the very first considerations when designing a plan for complicated cases. IVL allows for the elimination of between US$6,000 and US$10,000

e past, the in additional cost.

EVIDENCIA CLÍNICA

C2

M5

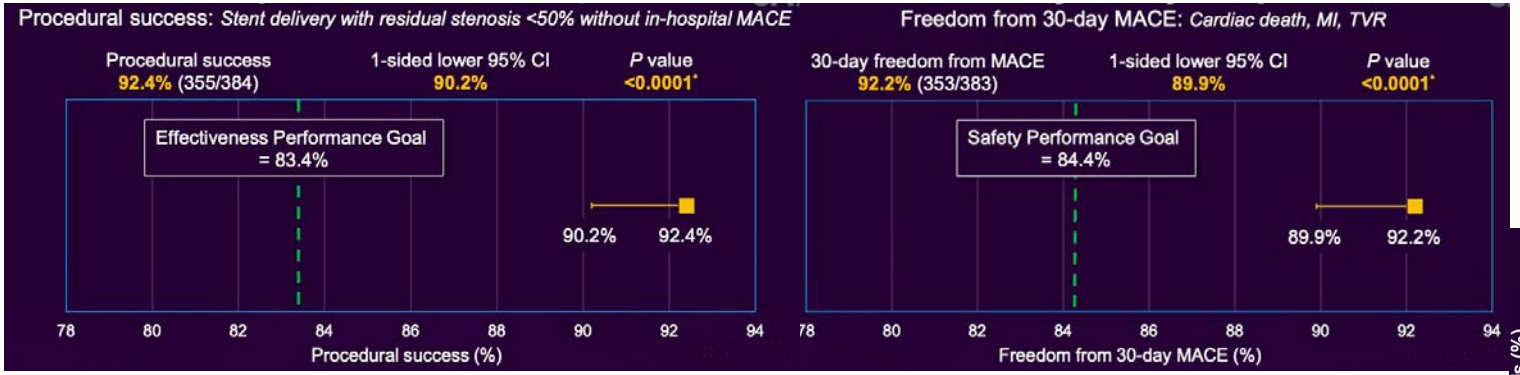
S4

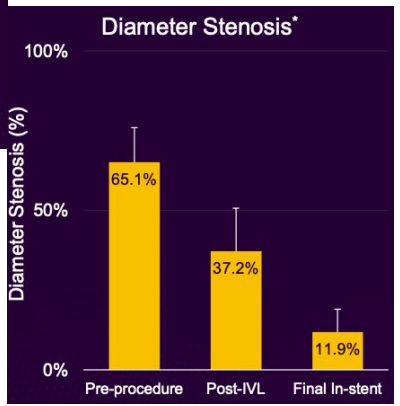
DISRUPT CAD III

Intravascular Lithotripsy for Treatment of Severely Calcified Coronary Artery Disease: The Disrupt CAD III Study

Brief Title: Disrupt CAD III Study

Jonathan M. Hill, MD[a *], Dean J. Kereiakes, MD[b *], Richard A. Shlofmitz, MD[c], Andrew J. Klein, MD[d], Robert F. Riley, MD[b], Matthew J. Price, MD[e], Howard C. Herrmann, MD[f], William Bachinsky, MD[g], Ron Waksman, MD[h], Gregg W. Stone, MD[i]





DISRUPT PAD III

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Journal of Endovascular Therapy
1–8

DOI: 10.1177/1526602820914598
www.jevt.org
SAGE

Intravascular Lithotripsy for Treatment of Calcified Lower Extremity Arterial Stenosis: Initial Analysis of the Disrupt PAD III Study

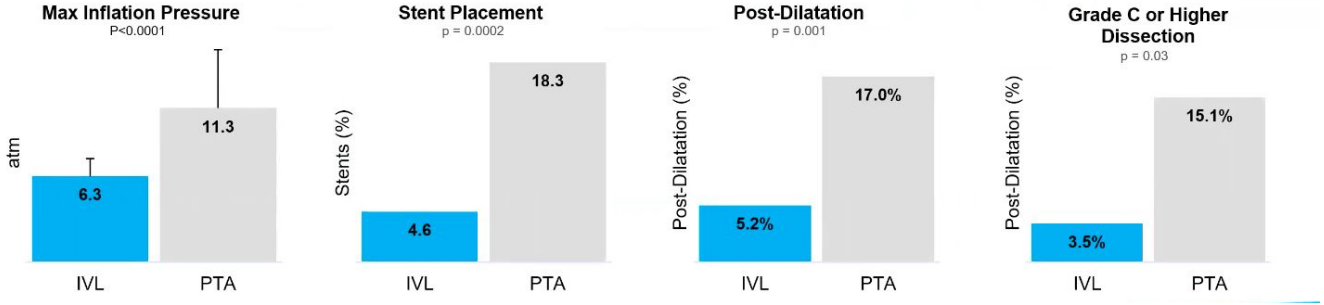
George Adams, MD, MHS, MBA[1], Nicolas Shammas, MD, MS[2], Sarang Mangalmurti, MD[3], Nelson L. Bernardo, MD[4], William E. Miller, MD[5], Peter A. Soukas, MD[6], Sahil A. Parikh, MD[7], Ehrin J. Armstrong, MD, MSc, MAS[8], Gunnar Tepe, MD[9], Alexandra Lansky, MD[10], and William A. Gray, MD[11]

⬇ 40%
Lower pressure to achieve better results with IVL

⬇ 75%
Reduction in provisional stent placement risk with IVL

⬇69%
Reduction in need for post-dilatation with IVL

⬇77%
Reduction in Type ≥C Dissection with IVL



SIPROTEC

DISRUPT BTK

Clinical Investigation

JOURNAL OF ENDOVASCULAR THERAPY

Journal of Endovascular Therapy
1–5

DOI: 10.1177/1526602818783989
www.jevt.org
SAGE

Safety and Feasibility of Intravascular Lithotripsy for Treatment of Below-the-Knee Arterial Stenoses

Marianne Brodmann, MD[1], Andrew Holden, MD[2], and Thomas Zeller, MD[3]

20
Patients from 3 sites

100%
Moderately/severely calcified lesions

75%
Rutherford Category V

95%
Procedural Success

0%
Perforations, Embolization, Slow/No Reflow, Abrupt Closure

26%
Final residual Stenosis with an acute gain of 1.5mm

0%
Major adverse event at 30 days

100%
Freedom From CD TLR at 30 days

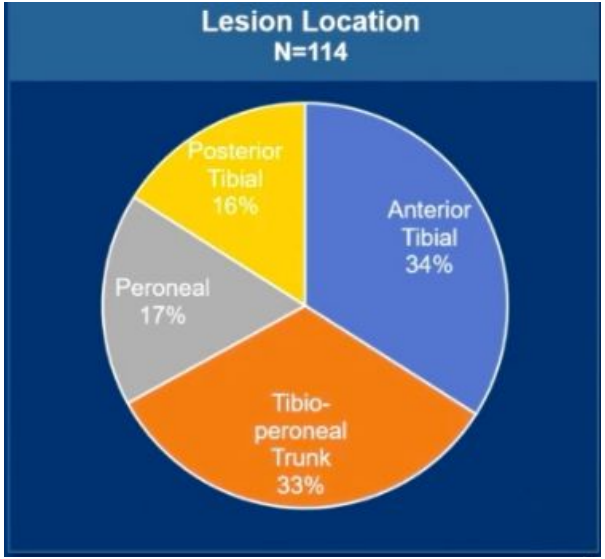
SIPROTEC

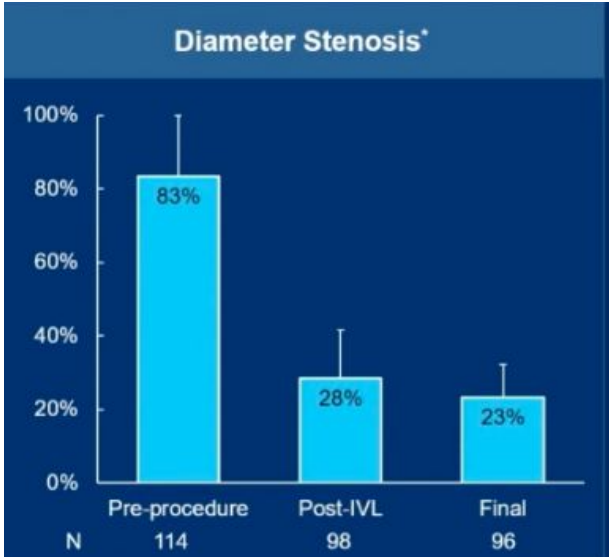
Intravascular Lithotripsy for Treatment of Infrapopliteal Lesions

Results from the Disrupt PAD III Observational Study

PAD III OS Sub-study:
IVL treatment of calcified infrapopliteal arteries
Heavily calcified *de novo* infrapopliteal lesions
IVL +/- adjunctive therapy*
July 2018 – Aug 2020
N = 101 patients; 114 BTK lesions; 15 global sites

Sub-study objective: Assess 'real world' peri-procedural outcomes of S[4] IVL treatment of calcified BTK lesions†





¡MUCHAS GRACIAS!

SIPROTEC

SISTEMA INTEGRAL DE
PROVISIÓN DE PRÓTESIS