



i-MEET
NEXT GENERATION
Multidisciplinary European Endovascular Therapy

Lithoplasty for vessel prep (rationale,
evidence and clinical case)

Erwin Blessing

Karlsbad, Germany

Disclosure of Interest

Disclosure

Speaker name:

Erwin Blessing

- I have the following potential conflicts of interest to report:
 - Consulting
 - Employment in industry
 - Shareholder in a healthcare company
 - Owner of a healthcare company
 - Other(s)
- I do not have any potential conflict of interest

Case presentation

64 year old male patient

Rutherford 3 right leg

Previous recanalization right SFA with PTA/stent 2017

ABI: right leg: 0.4

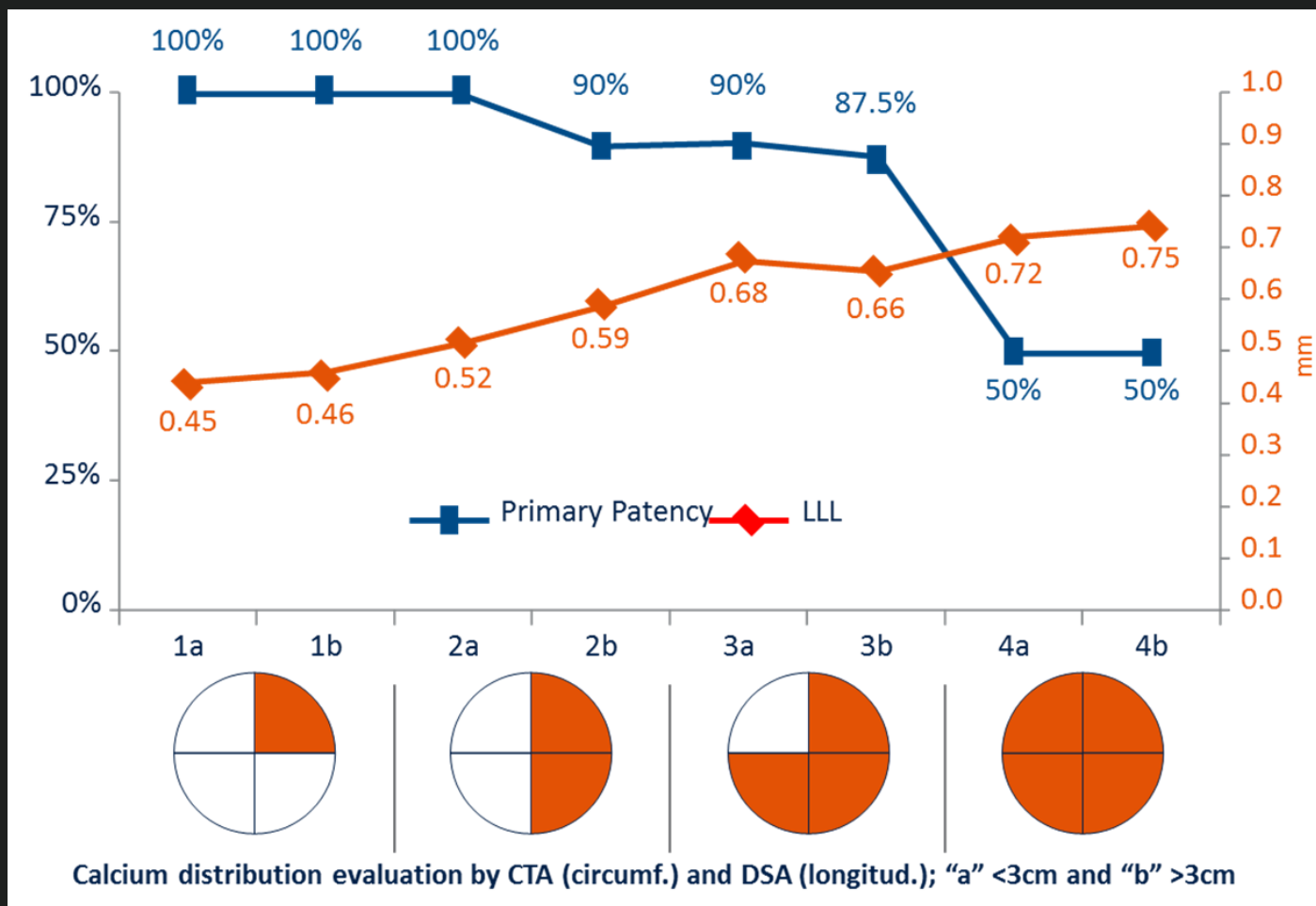
CVRF: smoker, art. HTN, HLP

Duplex: Calcified subtotal occlusion right CFA,
occluded right Profunda

Case pres

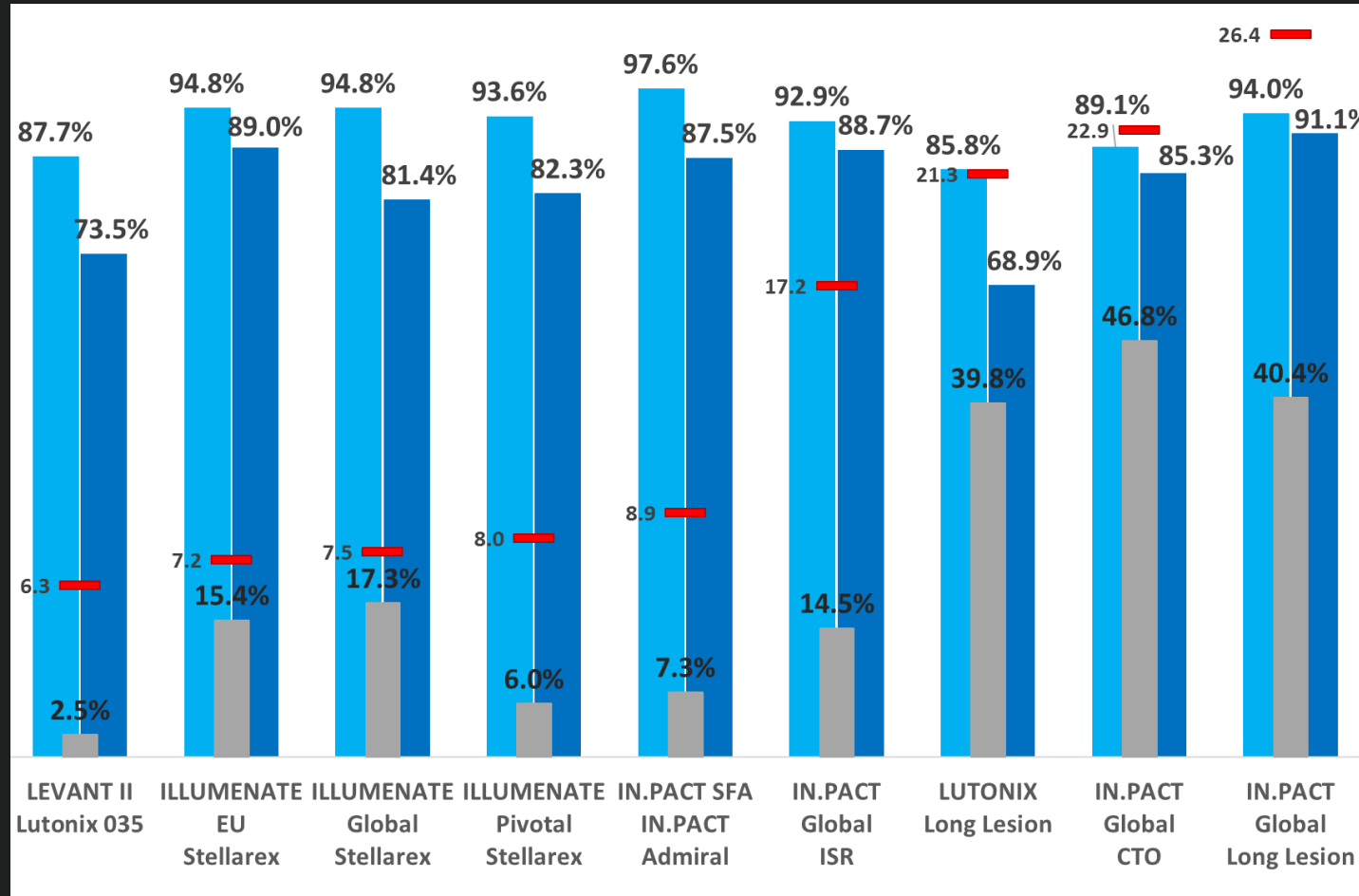


Limitation: Calcium



- Calcium is a potential barrier to optimal drug absorption
- Calcium distribution and severity may affect late lumen loss (LLL) and primary patency

Limitation: High provisional stent rates



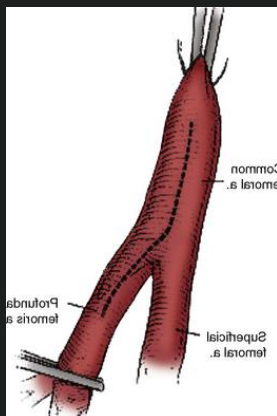
- DCB use in real-world registries enrolling more complex disease is associated with increased provisional stenting

• Provisional stent rates of 40-47%

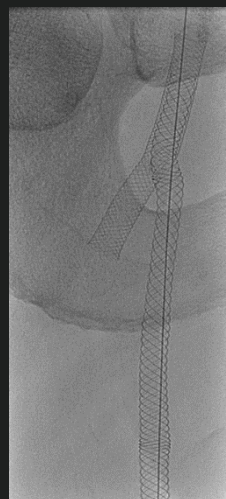
1. Rosenfield K, et al. New Engl J Med 373:145-53 (2015).
2. Presented by Brodmann M, AMP Chicago, USA 2016.
3. Presented by Zeller T, LINC Leipzig, Germany 2017.
4. Presented by Lyden S, TCT Washington DC, USA 2016.
5. Tepe G, et al. Circ 131:495-502 (2015).

6. Laird J, et al. J Am Coll Cardiol 66:2329-38 (2015).
7. Presented by Brodmann M, VIVA Las Vegas, USA 2015.
8. Bard Lutonix Instructions for Use, BAW1387400r3.
9. Presented by Tepe G, Charing Cross London, UK 2016.
10. Presented by Scheinert D, EuroPCR Paris, France 2015.

Treatment options?



Surgery



Supera

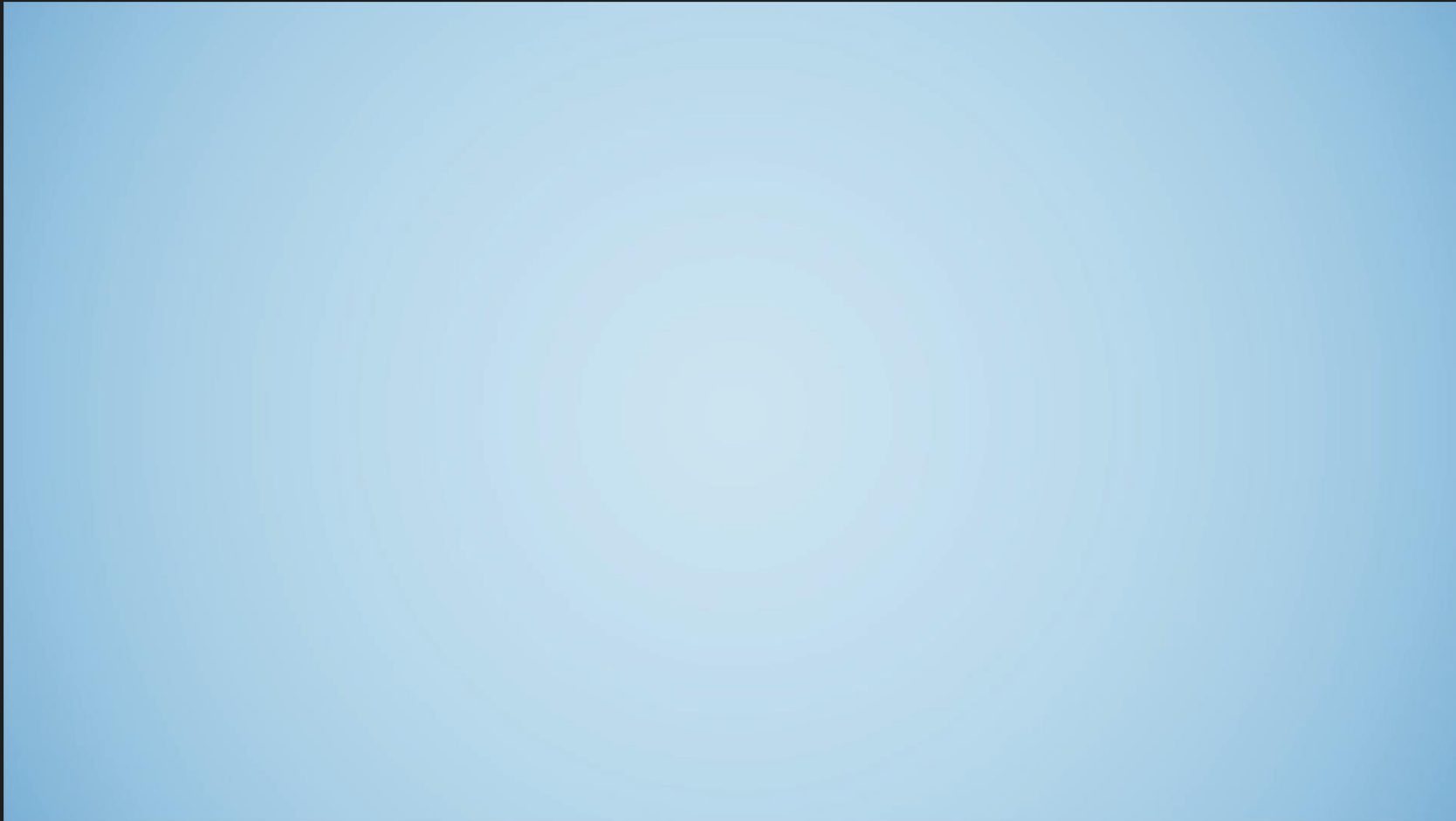


Specialty
balloon

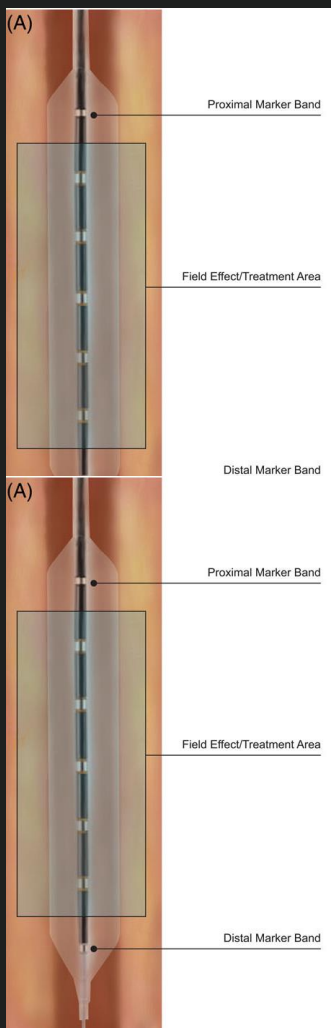


Atherectomy

Intravascular Lithoplasty



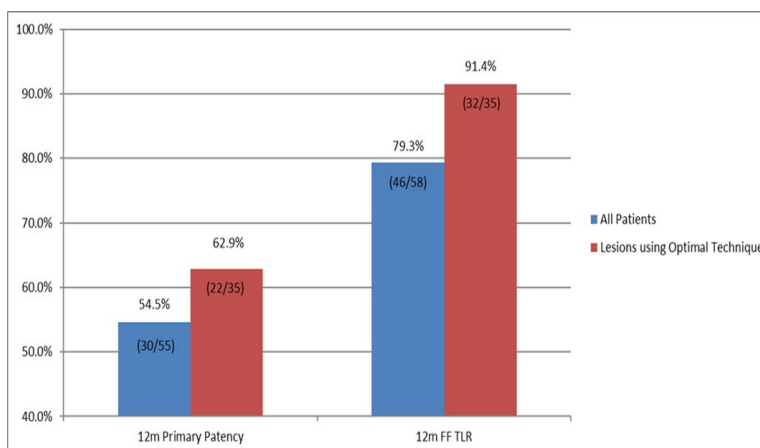
Clinical evidence: Lithoplasty



Summary: Disrupt PAD II 12-Month Results

1st and only core lab adjudicated, long-term study exclusively enrolling heavily calcified lesions

- Typical baseline characteristics except increased age, diabetes and renal insufficiency
- **85% severe calcification (by PARC)**
- High acute gain (3.0mm), low residual stenosis (24%), and minimal complications
- **Primary patency: 54.5% for intent-to-treat versus 62.9% for those with optimal technique**
- **Clinically-driven TLR: 20.7% for intent-to-treat versus 8.6% for those with optimal technique**



Post-Procedure N=60	
Dissections D ⁺ /E/F	1.7% (1)
Perforations	0% (0)
Abrupt Closure	0% (0)
Slow/No Reflow	0% (0)
Thrombosis	0% (0)

†Guidewire induced through recanalization of a CTO which was resolved with stent placement

Courtesy of
A. Holden

Clinical evidence: Lithoplasty

Disrupt PAD Clinical Programs

	Disrupt PAD I	Disrupt PAD II	Disrupt BTK	PAD III RCT	PAD III OS
Status	Completed	Completed	Completed	On-going	On-going
Target Lesions	Severely calcified, SFA/pop lesions	Severely calcified, SFA/pop lesions	Severely calcified, SFA/pop lesions	Severely calcified, SFA/pop lesions	Severely calcified peripheral artery lesions
Study Design	<ul style="list-style-type: none"> • Single-arm • Safety and effectiveness 	<ul style="list-style-type: none"> • Single-arm • Safety and effectiveness 	<ul style="list-style-type: none"> • Single-arm • Safety and effectiveness 	<ul style="list-style-type: none"> • RCT • IVL+DCB vs PTA+DCB 	<ul style="list-style-type: none"> • Single-arm • All-comers
# Patients	35	60	20	400	1000
Enrollment Period	Jan 2014 – Sep 2014	Jun 2015 – Dec 2015	Jun 2016 – Mar 2017	Feb 2017 - present	Nov 2017 - present
# Sites	3 (EU/NZ)	8 (EU/NZ)	3 (EU/NZ)	54 (US/EU/NZ)	26 (US/EU/NZ)
Study Conduct	<ul style="list-style-type: none"> • Independent Angio Core Lab • Independent CEC 	<ul style="list-style-type: none"> • Independent Angio Core Lab • Independent CEC 	<ul style="list-style-type: none"> • Independent Angio Core Lab 	<ul style="list-style-type: none"> • Independent Angio Core Lab • Independent CEC 	<ul style="list-style-type: none"> • Independent Angio Core Lab

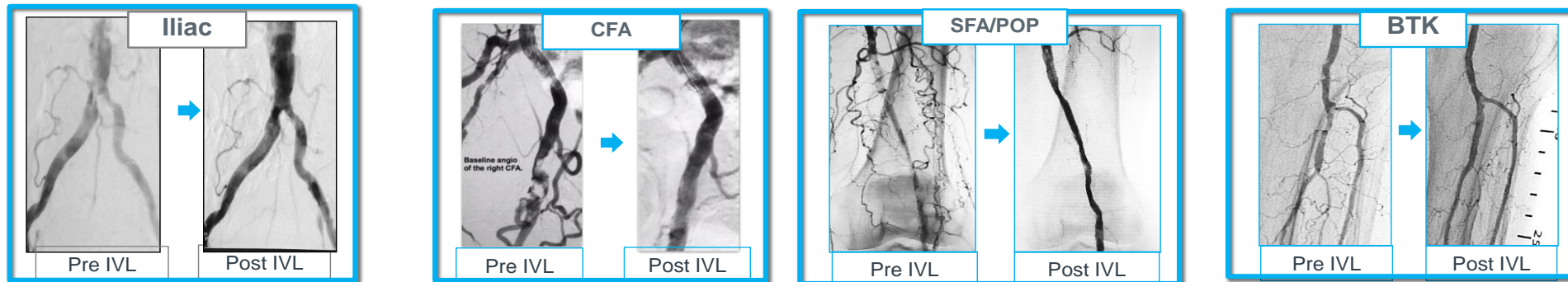
Courtesy of
A. Holden

Clinical evidence: Lithoplasty

Disrupt PAD III: Observational Study

Objective: assess the real-world acute performance of the Shockwave Medical Peripheral IVL System in the treatment of calcified, stenotic, peripheral arteries

- Planned enrollment of 1000 subjects at the same 60 sites as RCT
- Real-world claudicant or critical limb ischemia (CLI) population

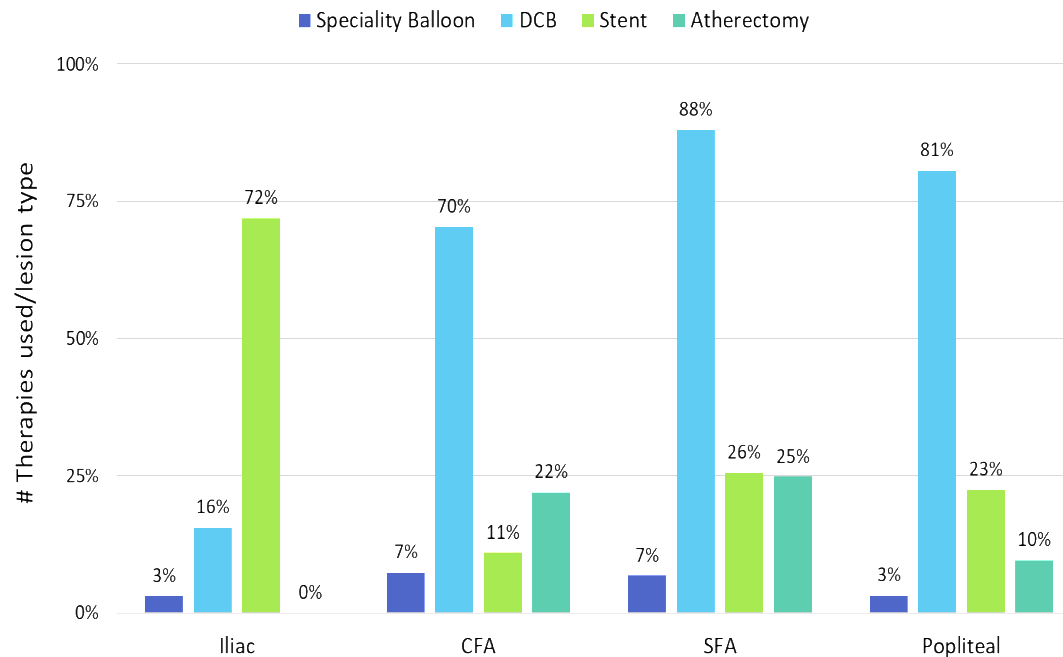


Subjects who do not meet the inclusion/exclusion criteria for the randomized study may satisfy the eligibility criteria for the observational study

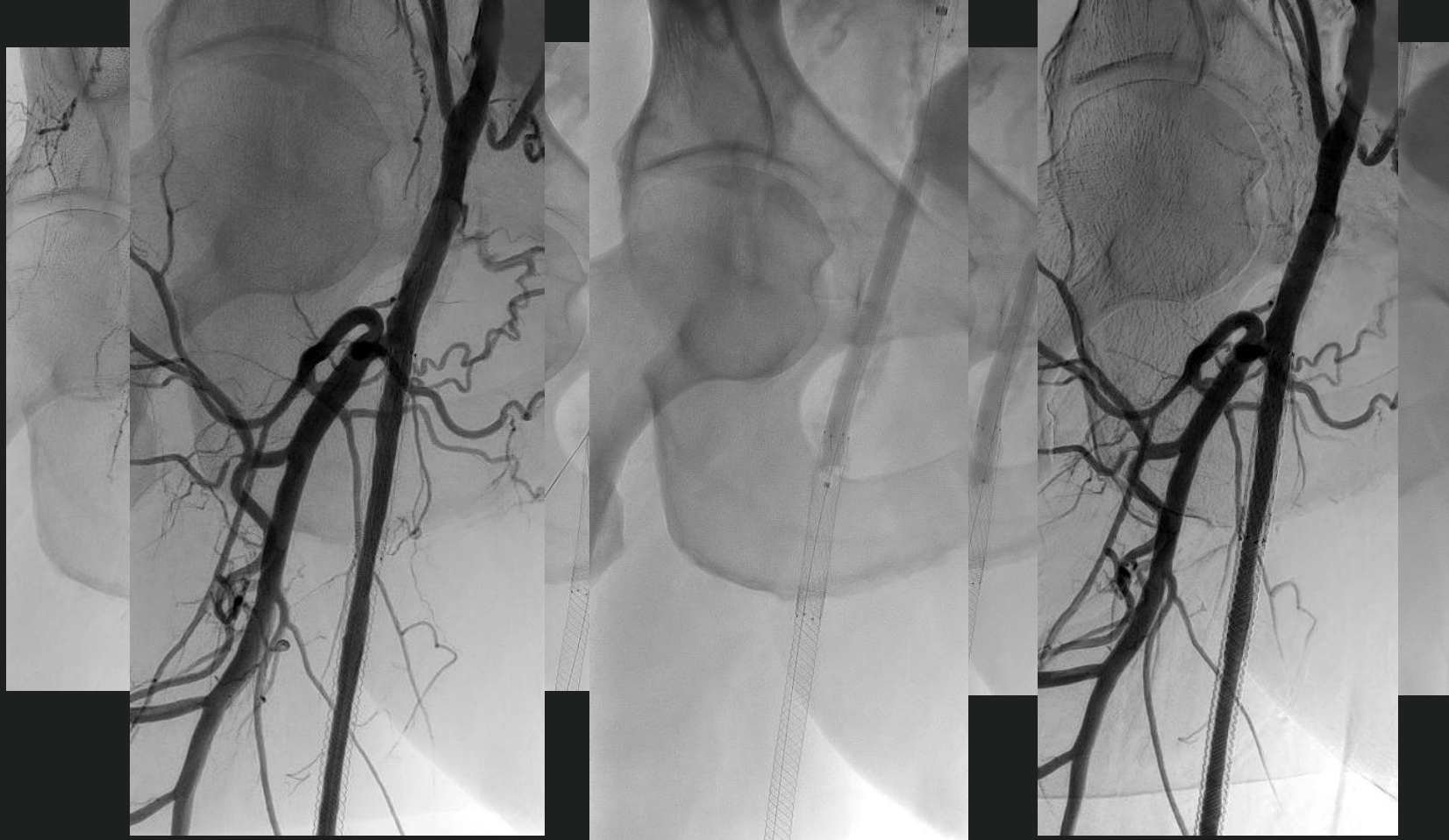
Clinical evidence: Lithoplasty

Adjunctive Therapy Use by Vessel Bed

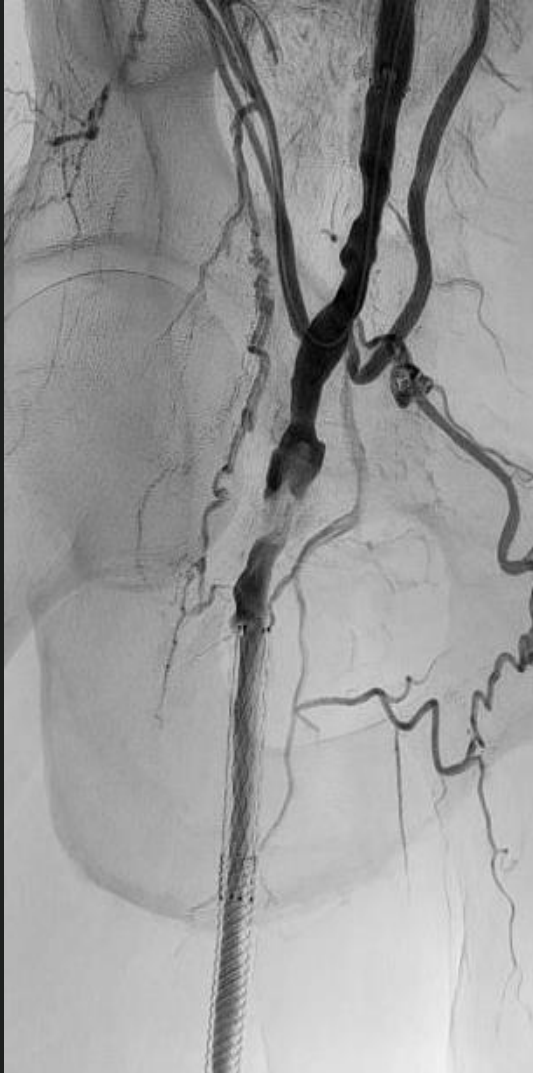
- DCB was used across all vessel beds
- Majority of atherectomy was used in SFA
- Majority of stenting was done in the iliac and SFA vessel beds



Clinical Case



Clinical Case



10:17

10:49



Conclusions

- Intravascular Lithoplasty is safe, easy to use and effective in calcified lesions in all vascular beds (high technical success, low bail-out stent rate)
- Primary patency and TLR depends on optimal technique
- Lithoplasty alone (without adjunctive therapy) with suboptimal patency in single arm trial (DISRUPT II)
- Ongoing trials (DISRUPT III RCT) and observational studies (PAD III OS) to help clarify the future role of Lithoplasty