High pressure Non-compliant Angioplasty in real-world CLI

12 and 36 month results of JADE Registry

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CLINICAL INVESTIGATION

Early Recoil After Balloon Angioplasty of Tibial Artery Obstructions in Patients With Critical Limb Ischemia

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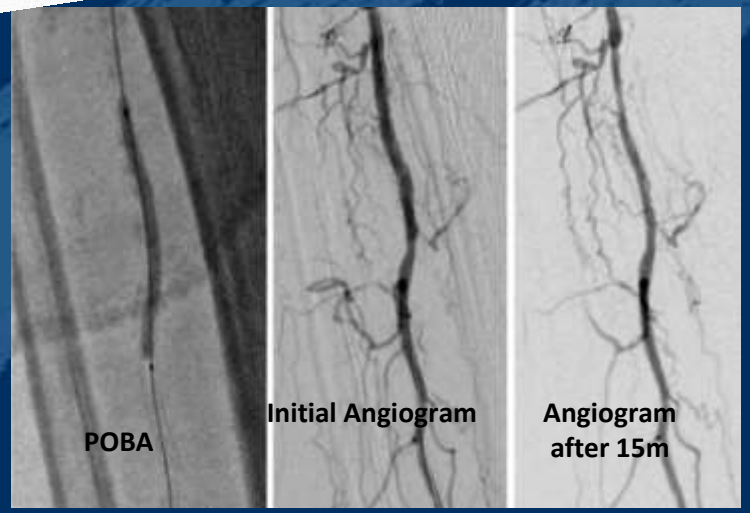
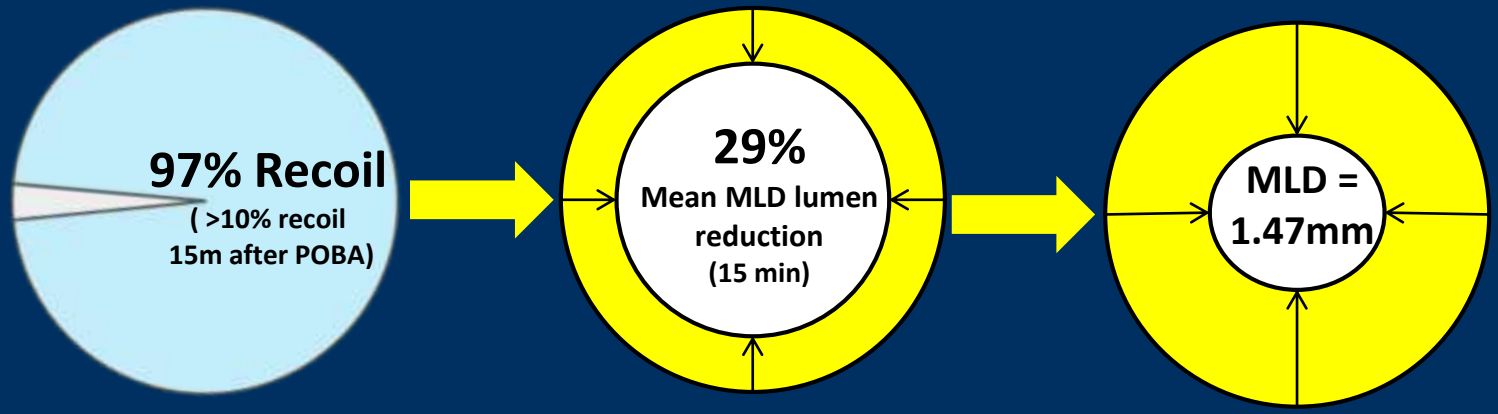
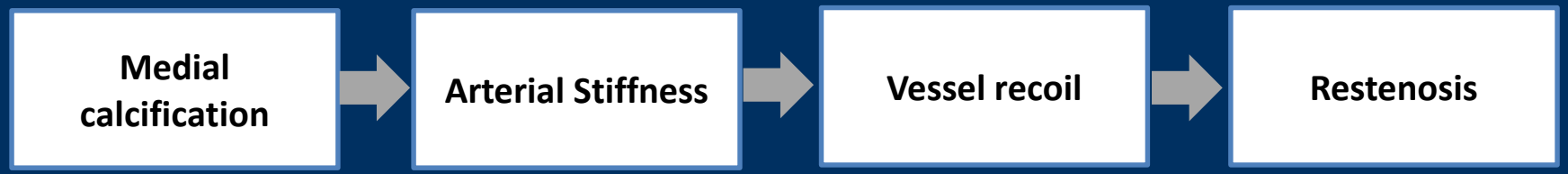
Most BTK vessels undergo significant elastic recoil following angioplasty



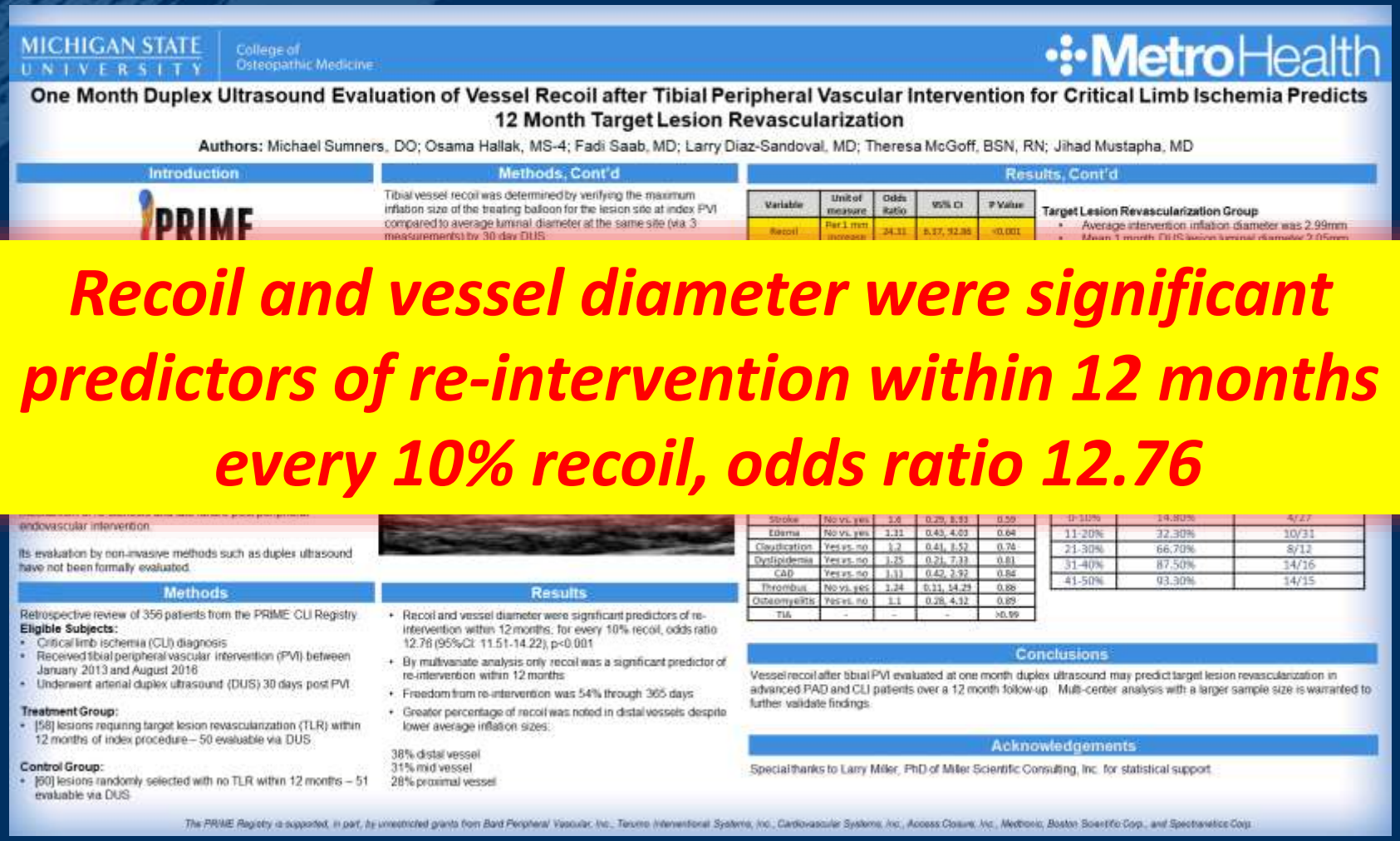


Medial calcification produces vessel recoil and restenosis[2,3,4]



1) Baumann et al, Early recoil after balloon angioplasty of tibial artery obstructions in patients with critical limb ischemia, J Endovasc Ther 2014
2) Guzman et al, Tibial artery calcification as a marker of amputation risk in patients with PAD, JACC 2008
3) Zettervall et al, Association of arterial calcification with CLI in patients with PAD, J Vasc Surg 2017
4) Mustapha et al, One-Month Duplex Ultrasound Evaluation of Vessel Recoil After Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12m TLR, AMP 2017

Tibial US after 1 month is predictive of reintervention at 12 months



MICHIGAN STATE UNIVERSITY College of Osteopathic Medicine

MetroHealth

One Month Duplex Ultrasound Evaluation of Vessel Recoil after Tibial Peripheral Vascular Intervention for Critical Limb Ischemia Predicts 12 Month Target Lesion Revascularization

Authors: Michael Sumners, DO; Osama Hallak, MS-4; Fadi Saab, MD; Larry Diaz-Sandoval, MD; Theresa McGoff, BSN, RN; Jihad Mustapha, MD

Introduction

PRIME

endovascular intervention.

Its evaluation by non-invasive methods such as duplex ultrasound have not been formally evaluated.

Methods

Retrospective review of 356 patients from the PRIME CLI Registry

Eligible Subjects:
- Critical limb ischemia (CLI) diagnosis
- Received tibial peripheral vascular intervention (PVI) between January 2013 and August 2016
- Underwent arterial duplex ultrasound (DUS) 30 days post PVI

Treatment Group:
- [58] lesions requiring target lesion revascularization (TLR) within 12 months of index procedure – 50 evaluable via DUS

Control Group:
- [60] lesions randomly selected with no TLR within 12 months – 51 evaluable via DUS

Methods, Cont'd

Tibial vessel recoil was determined by verifying the maximum inflation size of the treating balloon for the lesion site at index PVI compared to average luminal diameter at the same site (via 3 measurements) by 30 day DUS.

Results

- Recoil and vessel diameter were significant predictors of re-intervention within 12 months; for every 10% recoil, odds ratio 12.76 (95%CI: 11.51-14.22), p<0.001
- By multivariate analysis only recoil was a significant predictor of re-intervention within 12 months
- Freedom from re-intervention was 54% through 365 days
- Greater percentage of recoil was noted in distal vessels despite lower average inflation sizes:

38% distal vessel
31% mid vessel
28% proximal vessel

Results, Cont'd

Variable	Unit of measure	Odds Ratio	95% CI	P Value
Recoil	Per 1 mm increase	24.31	8.37, 92.86	<0.001
Stroke	No vs. yes	1.8	0.29, 8.33	0.59
Edema	No vs. yes	1.31	0.43, 4.03	0.64
Claudication	Yes vs. no	1.2	0.41, 3.52	0.74
Dyslipidemia	Yes vs. no	1.25	0.21, 7.33	0.81
CAD	Yes vs. no	1.11	0.42, 2.92	0.84
Thrombus	No vs. yes	1.24	0.11, 14.29	0.88
Osteomyelitis	Yes vs. no	1.1	0.28, 4.32	0.89
TIA	-	-	-	>0.99

Target Lesion Revascularization Group
- Average intervention inflation diameter was 2.99mm
- Mean 1 month DUS post-procedural luminal diameter 2.05mm

0-10%	14.80%	4/27
11-20%	32.30%	10/31
21-30%	66.70%	8/12
31-40%	87.50%	14/16
41-50%	93.30%	14/15

Conclusions

Vessel recoil after tibial PVI evaluated at one month duplex ultrasound may predict target lesion revascularization in advanced PAD and CLI patients over a 12 month follow-up. Multi-center analysis with a larger sample size is warranted to further validate findings.

Acknowledgements

Special thanks to Larry Miller, PhD of Miller Scientific Consulting, Inc. for statistical support.

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Recoil and vessel diameter were significant predictors of re-intervention within 12 months every 10% recoil, odds ratio 12.76

IS STANDARD POBA STILL EFFECTIVE?

	Lesion Length(mm)	Outcome	3 months	12 months
Schmidt 2010 **DM 90%**	180 mm (65% Occlusion)	**Patency**	31% (Reintervention 50%)	
		Clinical Outcome	76% [1]	
Iida 2013 **DM 50%** **Dialysis 50%**	96% TASC D (TASC 2000)	**Patency**	27% (Reintervention 40%)	18% (Reintervention 48%)
		Clinical Outcome	68% complete healing	85% complete healing

[1] clinical improvement = marked reduction of ulcer-size or rest pain

JADE Registry

-

Changi General Hospital Singapore

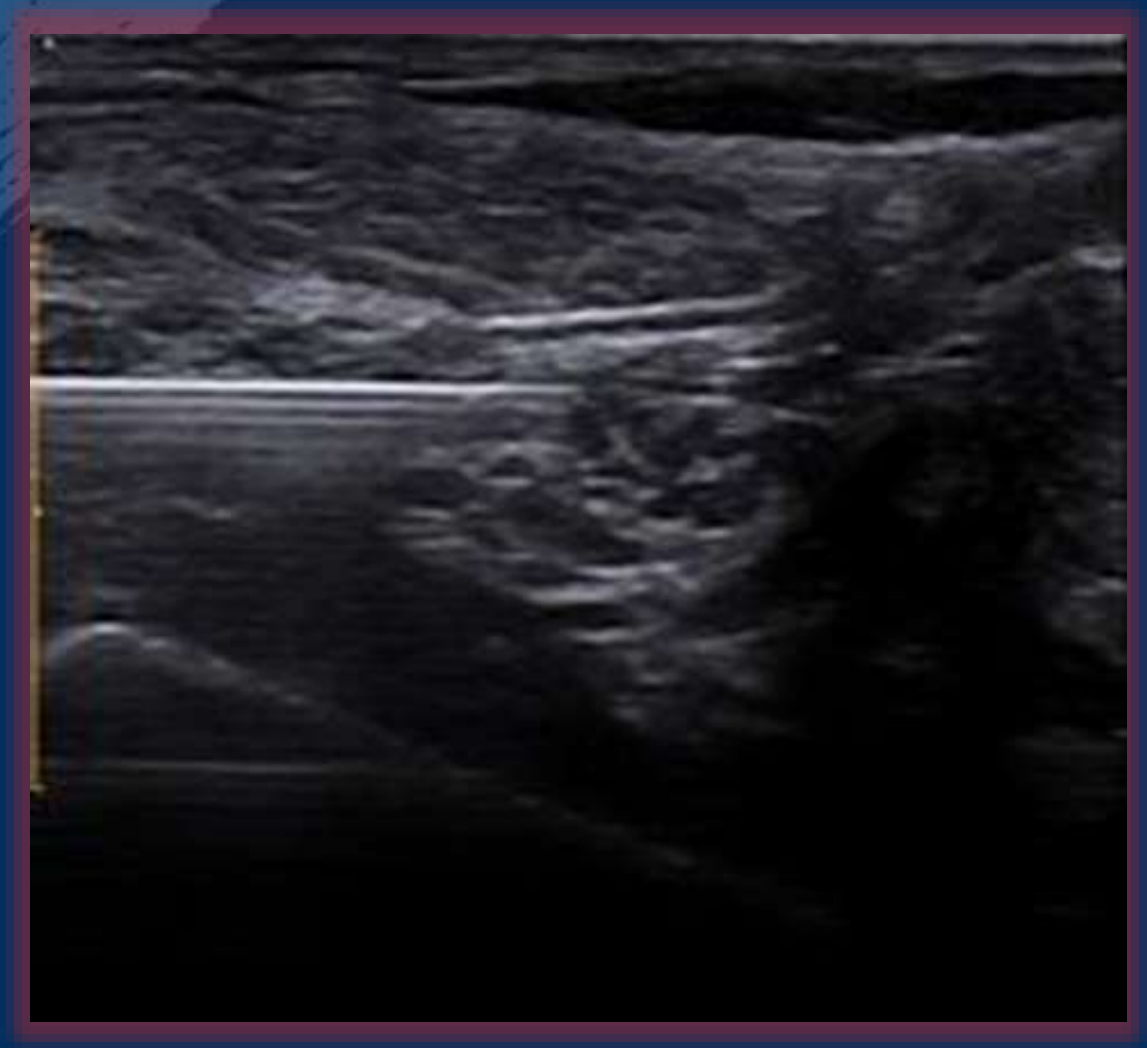
AIM

- To evaluate the safety, feasibility and effectiveness of high-pressure, noncompliant balloon angioplasty in the management of long infrapopliteal calcified lesions

Methods

- Retrospective Single centre
- Changi General Hospital, Singapore
- January 2016 and July 2016
- Consecutive patients with CLTI presenting with de novo infrapopliteal lesions that were treated with the JADE balloon (OrbusNeich, Hong Kong)
- *High-pressure, non-compliant balloon @ 22-24 atm for 90 seconds*

Popliteal Anaesthesia allows ***Painless*** HP POBA



Inclusion/Exclusion

- **Primary outcome**
  - technical success (immediate angiographic recoil or dissection < 30%)
- **Secondary outcomes**
  - procedure related complications
  - limb salvage
  - AFS
  - freedom from CD-TLR
  - Survival
  - resolution of CLTI (resolution of rest pain, and complete wound healing *without* TLR)
  - wound healing

Demographics

Table 1. Baseline characteristics

Variable	Number (%)
Patients	20
Limbs	21
Men	14 (70.0)
Age, years	65.90 ± 10.9
Left limb	12 (57.1)
Comorbidities	
Hypertension	18 (90.0)
Diabetes	**19 (95.0)**
Hyperlipidemia	16 (80.0)
Hemodialysis	**4 (20.0)**
Cerebrovascular accident	4 (20.0)
Chronic kidney disease	**10 (50.0)**
Smoking*	5 (62.5)
Laboratory results	
Serum creatinine (μmol/L)	117 (85-211)
GFR <30 (mL/min/1.73m^2)	6 (30.0)
Rutherford	
5	**18 (85.7)**
6	**3 (14.3)**
Mobility	
ADL assisted	3 (15.0)
Community ambulation	16 (80.0)

GFR = glomerular filtration rate,
ADL = activities of daily living.
Continuous data are presented as mean ± standard deviation or median (interquartile range).
Categorical data are presented as number (%).
*Rates do not match because of missing values.

Lesion Characteristics

Below the ankle > 40%

- 40 vessels
- 21 Limbs
- 20 patients

Table 2. Angiographic findings at baseline

Variable	Total
Vessels treated	40
Anterior tibial artery	19 (47.5)
Dorsalis pedis	**11 (27.5)**
Plantar arch	**5 (12.5)**
Posterior tibial artery	3 (7.5)
Peroneal artery	1 (2.5)
Plantar lateral artery	**1 (2.5)**
Lesions	23
Occlusions	**13 (56.5)**
Lesion length, mm	**374.8 ± 140.03**
Vessel diameter treated, mm	3.0 ± 0.15
PARC classification	
Focal	1 (4.8)
Moderate	4 (19.0)
Severe	**18 (78.3)**
TASC classification	
A	1 (4.8)
B	1 (4.8)
C	**10 (43.5)**
D	**11 (47.8)**

PARC = Peripheral Academic Research Consortium,
TASC = Trans-Atlantic Inter-Society Consensus Document .
Continuous data are presented as mean ± SD.
Categorical data are presented as number (%).

Therapy

- Mean diameter of balloon = 2.9 mm
- Mean length of balloon used = 106 mm

Results

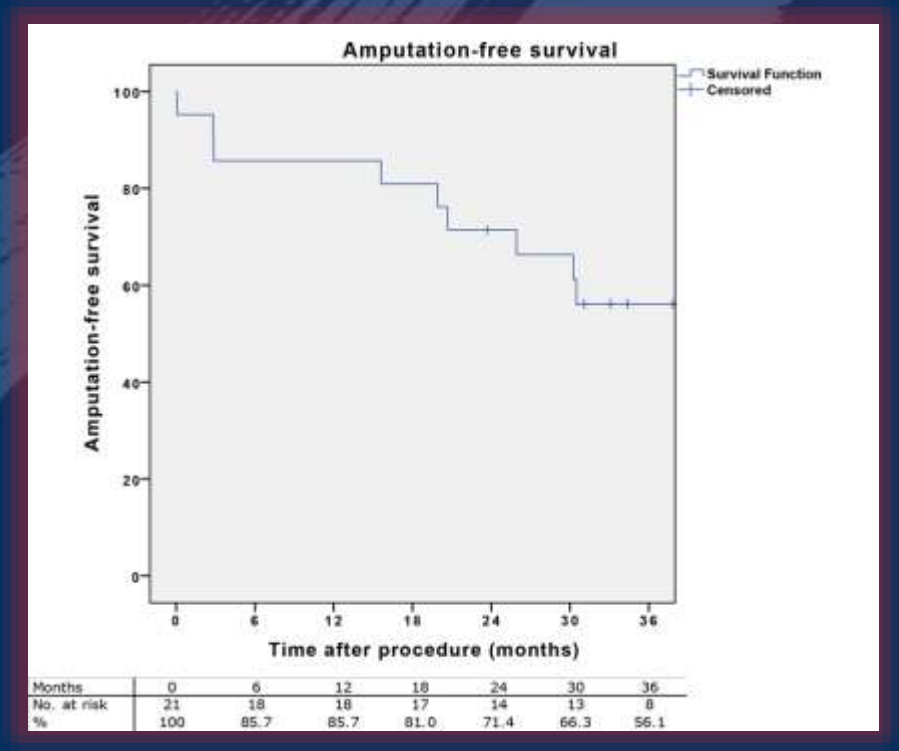
Technical Success

- Technical success (ie dissection/recoil < 30%) = 95.2%
- No Perforations
- No Bailout stents
- Improved runoff

Table 3. Runoff vessels pre- and postprocedural

Variable	Preprocedure	Postprocedure	*P* value
Runoff vessels	0.62 ± 0.67	1.57 ± 0.60	<0.001
Runoff vessels to the foot	0.19 ± 0 .40	1.14 ± 0.36	<0.001

AFS & Limb Salvage

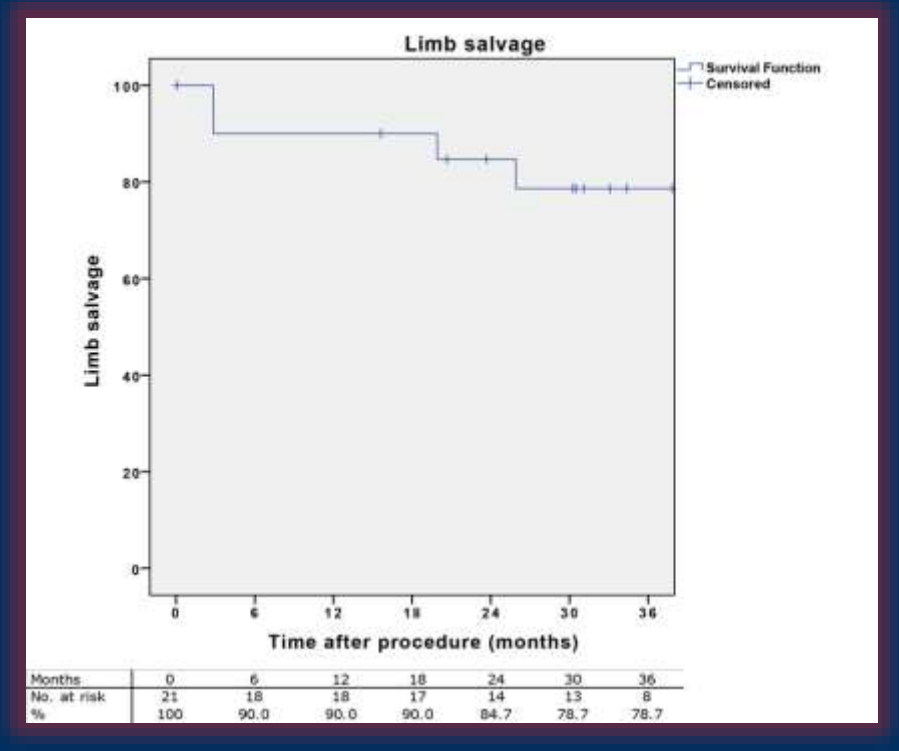


AFS

6 month = 85.7 %

12 month = 85.7 %

36 month = 56.1 %



Limb salvage

6 month = 90.0 %

12 month = 90.0 %

36 month = 78.7%

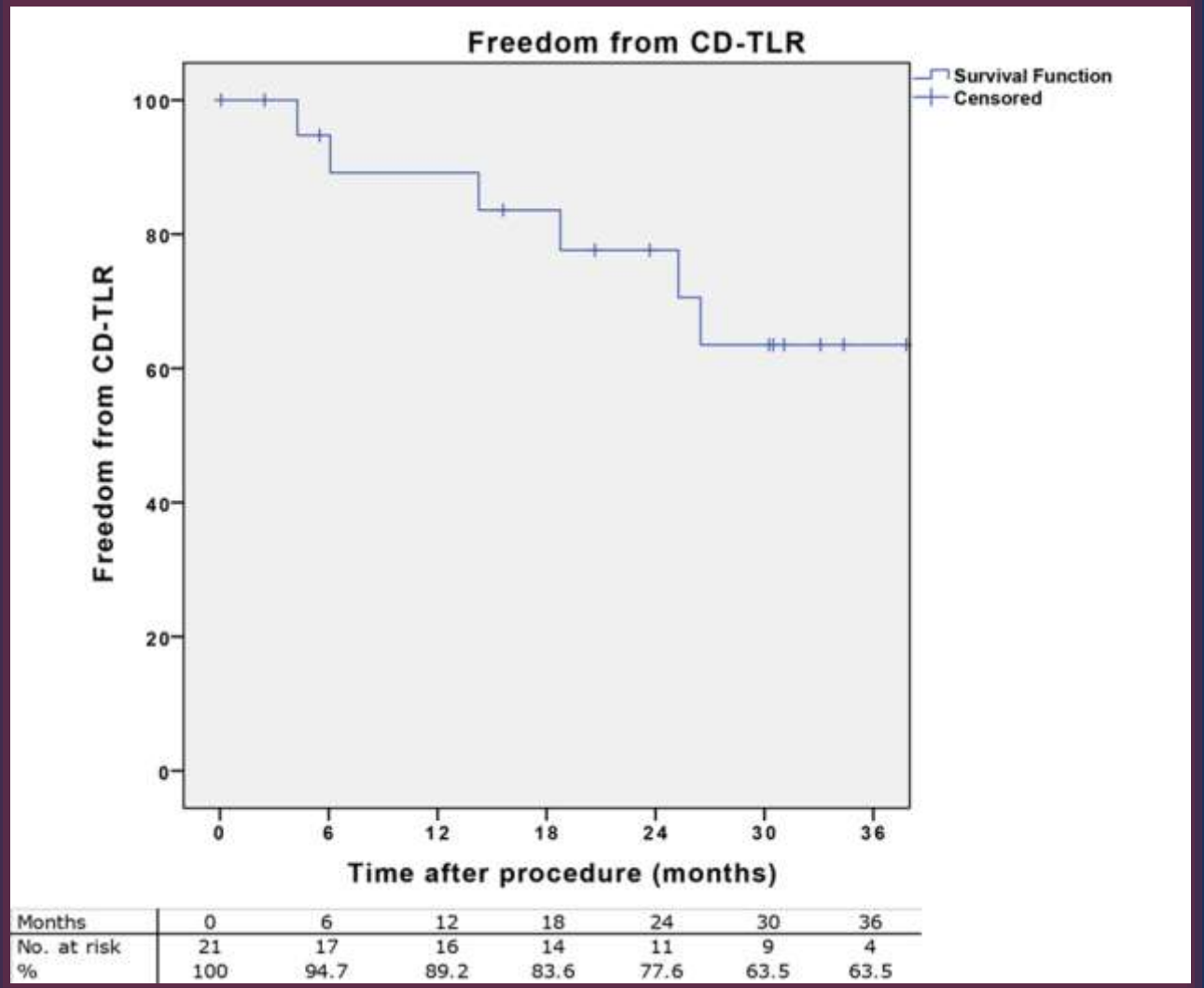
FF-TLR

Freedom CD-TLR

6 month = 94.7 %

12 month = 89.2 %

36 month = 63.5 %



Months	0	6	12	18	24	30	36
No. at risk	21	17	16	14	11	9	4
%	100	94.7	89.2	83.6	77.6	63.5	63.5

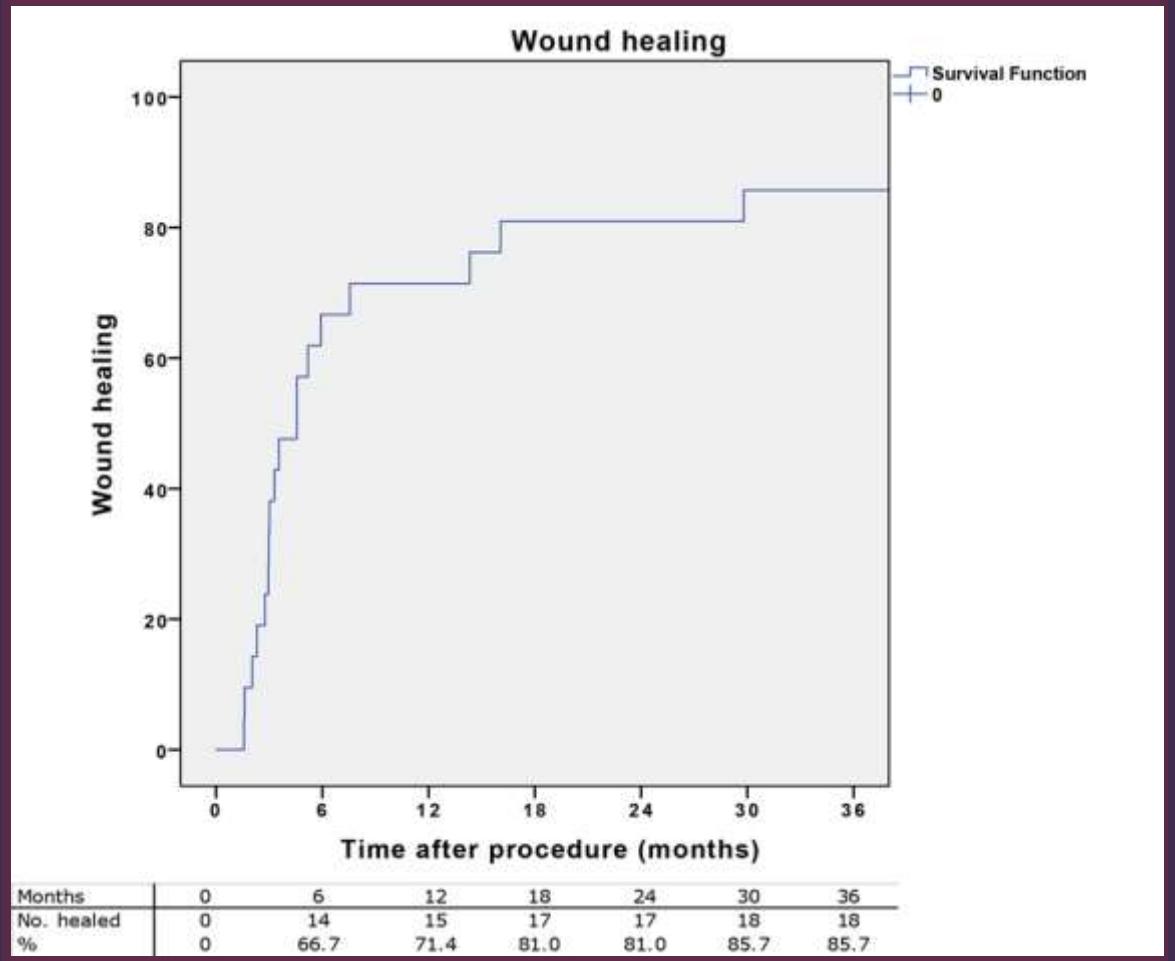
Wound Healing

Wound Healing

6 month = 66.7 %

12 month = 71.4 %

36 month = 85.7 %



Months	0	6	12	18	24	30	36
No. healed	0	14	15	17	17	18	18
%	0	66.7	71.4	81.0	81.0	85.7	85.7

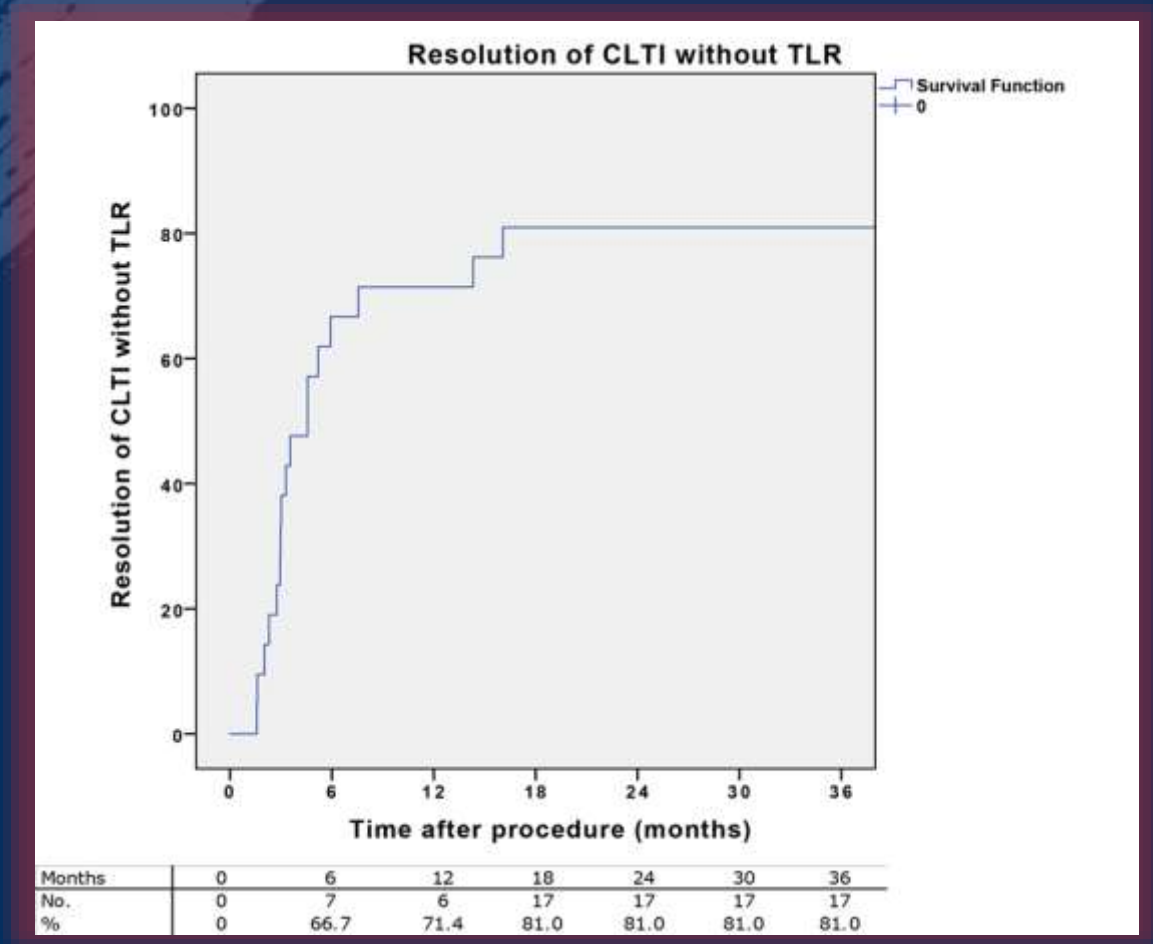
Resolution of CLTI

Resolution CLTI

6 month = 66.7 %

12 month = 71.4 %

36 month = 81.0 %



Months	0	6	12	18	24	30	36
No.	0	7	6	17	17	17	17
%	0	66.7	71.4	81.0	81.0	81.0	81.0

Resolution of CLTI =

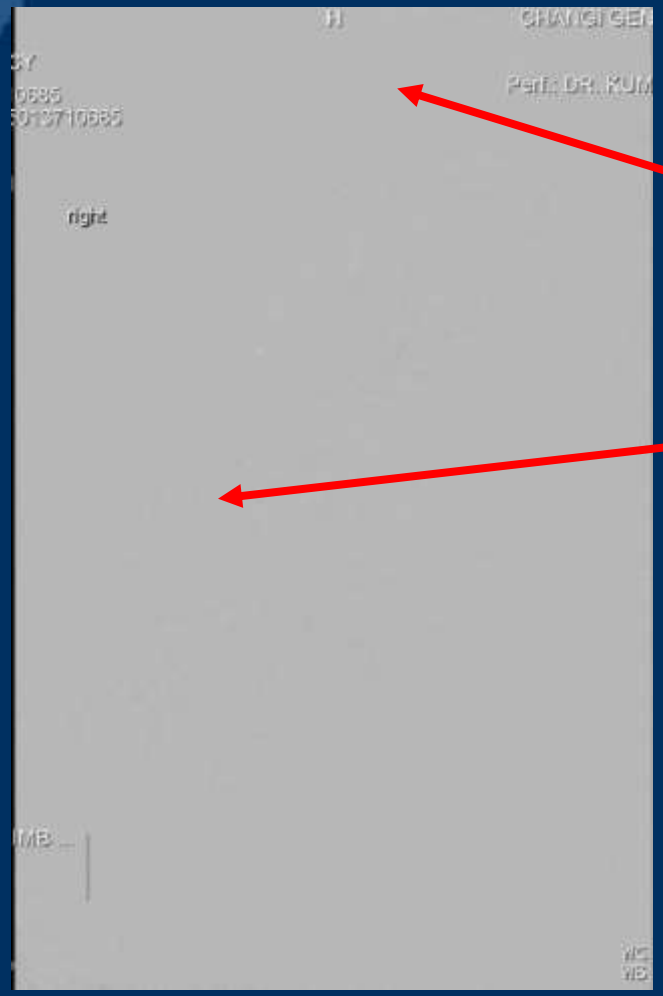
Resolution of rest pain, and complete wound healing without TLR

Case Examples

1.5 x 40

3 x 40 @ 14 atm

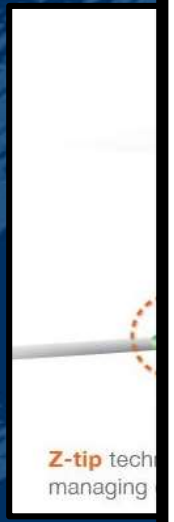
POST POBA

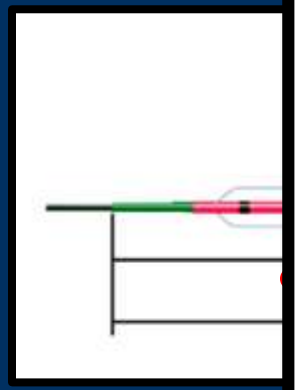


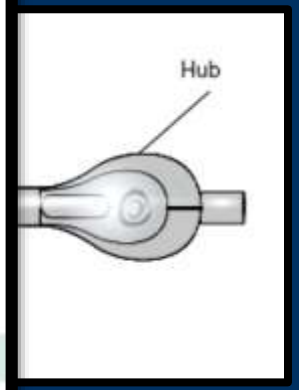
Dissection/Recoil

JADE

OrbusNeich™

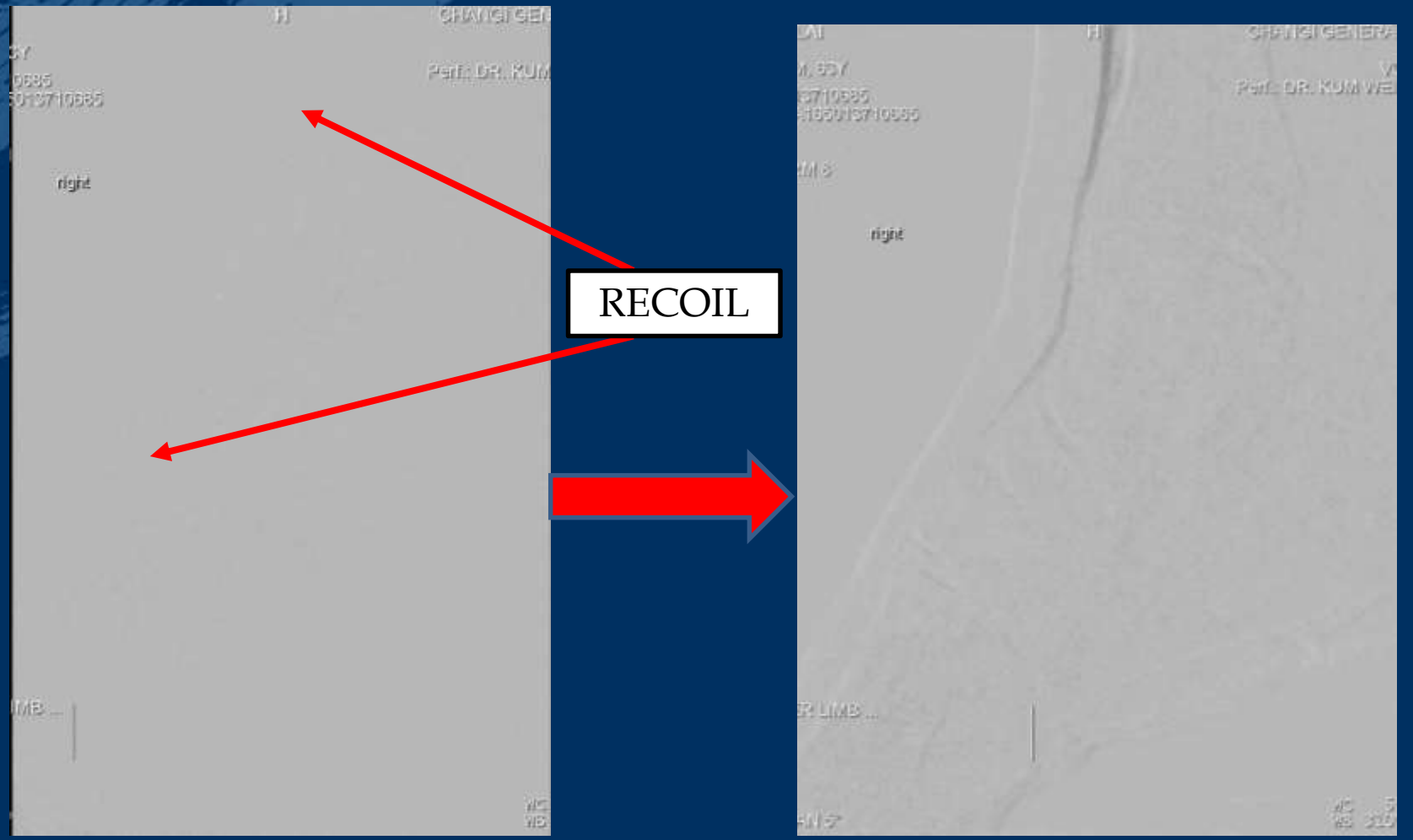




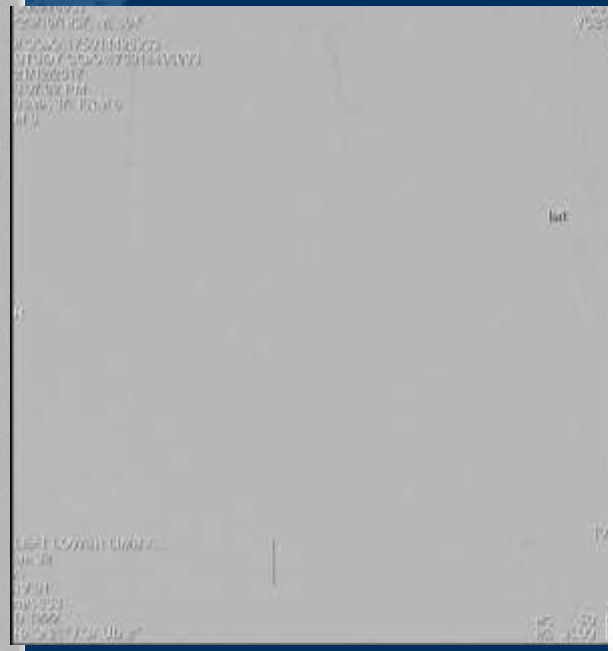


JADE NC 3 X 80 @ 22 ATM

BEFORE AND AFTER *HP POBA*



Another Example

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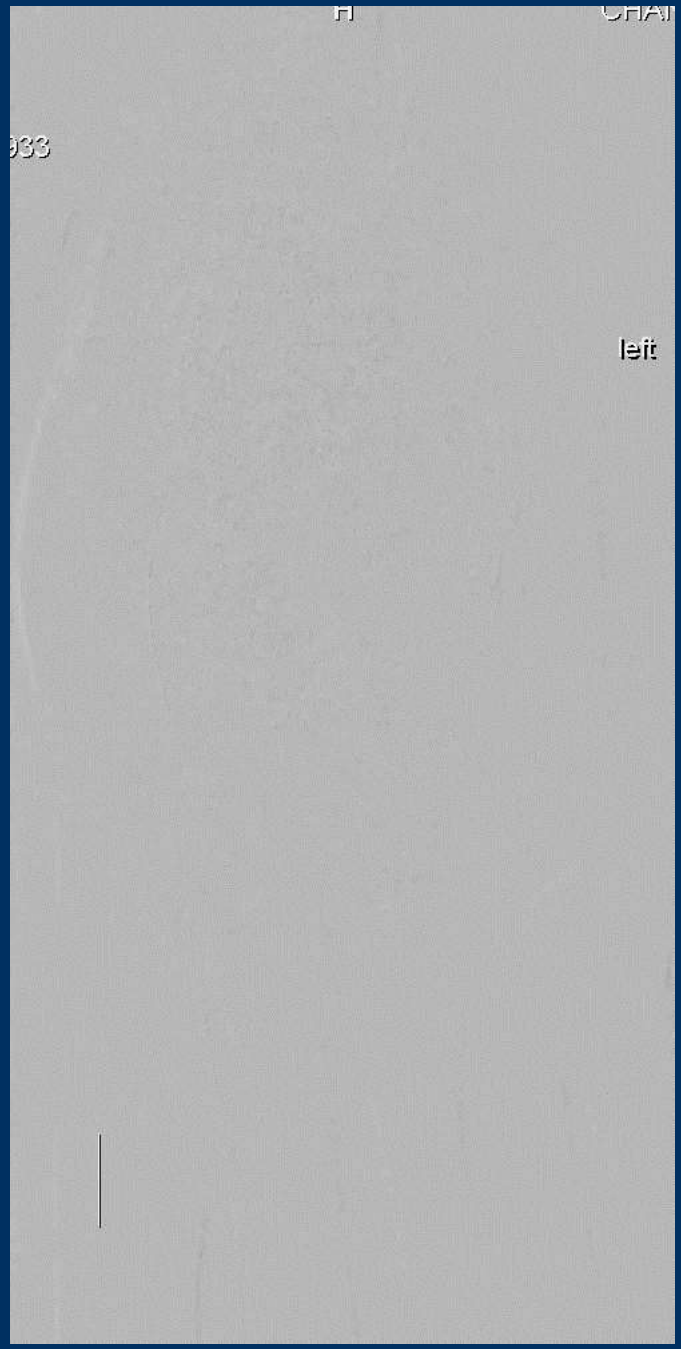
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Summary

- Recoil is a common occurrence in BTK interventions
- **High pressure, Non-compliant Angioplasty** ***effective in Long calcified BTK/BTA lesions*** in CLTI
- Safe and well tolerated in combination with Popliteal anesthesia
    - ↓ recoil, ↓ reintervention
    - Possibly ↑ perfusion, ↑ wound healing

High pressure Non-compliant Angioplasty in real-world CLI

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