The Future of Health Care Delivery
CLI Centers
What Do You Need to Know

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ACV Advanced Cardiac & Vascular Amputation Prevention Centers

Talk Outline

- Virtual CLI Centers
- Center Requirements
- Quality Metrics
- Case Selection

Virtual CLI Centers

- CLI expertise require particular set of skills
- CLI centers have to be proficient in evaluating CLI patients

Virtual CLI Centers

- Access to evaluation: 24-72 hours policy
- Assessment to revascularization: 24 -48 hours

Virtual CLI Centers

- Non invasive testing: ABI's are not useful in evaluation of CLI patients

Lack of Association Between Limb Hemodynamics and Response to Infrapopliteal Endovascular Therapy in PatientsWith Critical Limb Ischemia

- ABI's remain a poor tool to evaluate CLI Patients
- Depending on ABI's may delay care For patients who require immediate attention

MUSTAPHA, ET AL.

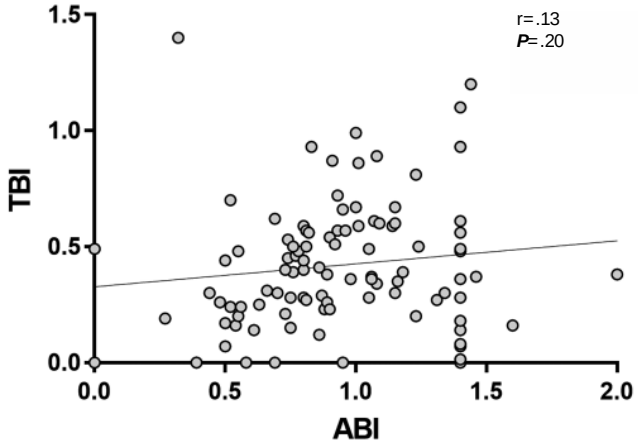

FIGURE 1 Relationship of ankle-brachial index (ABI) and toe-brachial index (TBI) prior to endovascular therapy in patients with critical limb ischemia.

HyperView™ - Visible Light Hyperspectral Imaging (VL-HSI)

- Visible light hyperspectral imaging (VL-HSI)
- Quantifies approximate levels of OxyHb, DeoxyHb and O2Sat in superficial tissue
- No patient contact, no contrast, no ionizing radiation
- Point and shoot convenience
- Outputs DICOM files and PDF reports
- Image capture < 0.6 seconds
- Correlates to TCPO2 in published literature

https://www.sciencedirect.com/science/article/pii/S089050961200057X
http://www.jvascsurg.org/article/S0741-5214(17)30930-8/abstract

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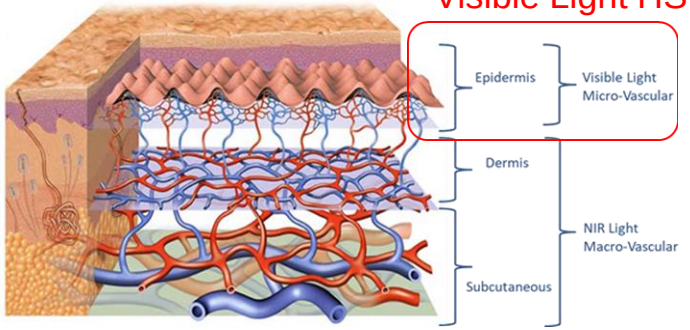
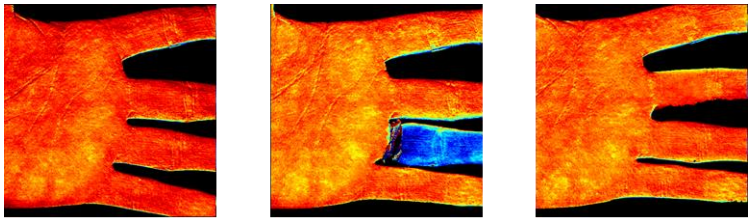
Visible Light Hyperspectral Imaging (VL-HSI) Overview

- Hemoglobin imaged with visible light
- OxyHb and DeoxyHb absorb light differently
- Visible light (versus near infrared) limits depth of penetration to capillary bed
- No veins or arteries shown in image
- Avoids signal from arteries and veins in deeper tissue where O2 Sat is different

Visible Light HSI

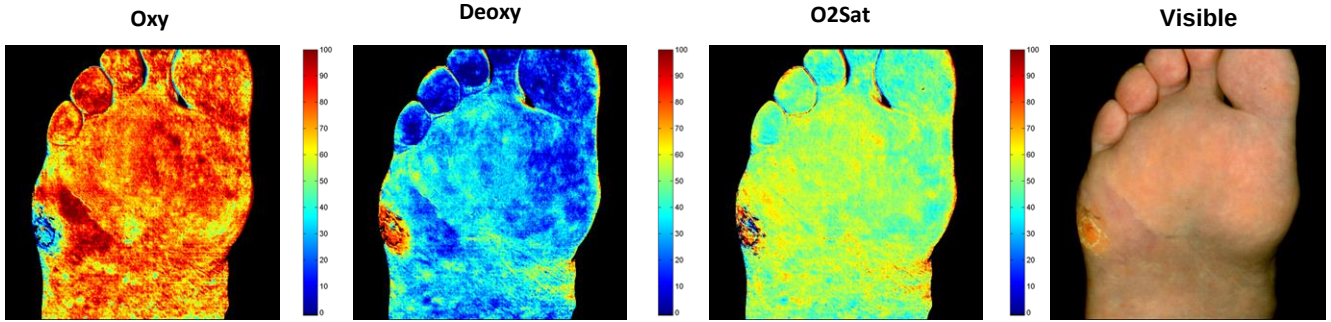




Pre-Occlusion | ~ 100 Seconds | ~ 200 Seconds

Clinical Relevance of VL-HSI

- Image contains OxyHb, DeoxyHb and O2Sat data at each pixel
- Areas of ischemia can be identified leading to understanding of tissue viability
- Areas of tissue re-generation show elevated Oxy and Deoxy levels vs. adjacent normal tissue. while O2Sat remains similar in new and old tissue
- Note pre-debridement area shows little to no Oxy and Deoxy values



1 Images shown from HyperView Clinical Testing

VL-HSI Correlates to $TcPO_2$

Transcutaneous Oximetry ($TcPO_2$)

- Features
  - O2Sat values
  - No OxyHb or DeoxyHb measurement
  - Contact probe heats skin
  - Oximetry at 1 point per contact probe
  - Slow, i.e. 45 minutes
  - Not easily used for screening due to complexity and time requirements

Visible Light Hyperspectral Imaging (VL-HSI)

- Features
  - O2Sat values
  - Quantifies OxyHb and DexoyHb
  - No contact, no heating of skin
  - Over 1 million points per image
  - Fast, i.e. 5 minutes
  - May be useful as a rapid and easy screening tool in front line clinics

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1. https://www.sciencedirect.com/science/article/pii/S089050961200057X
2. http://www.jvascsurg.org/article/S0741-5214(17)30930-8/abstract

Gender: Male
Foot/Metatarsal/Right/Plantar

DISCUSSION

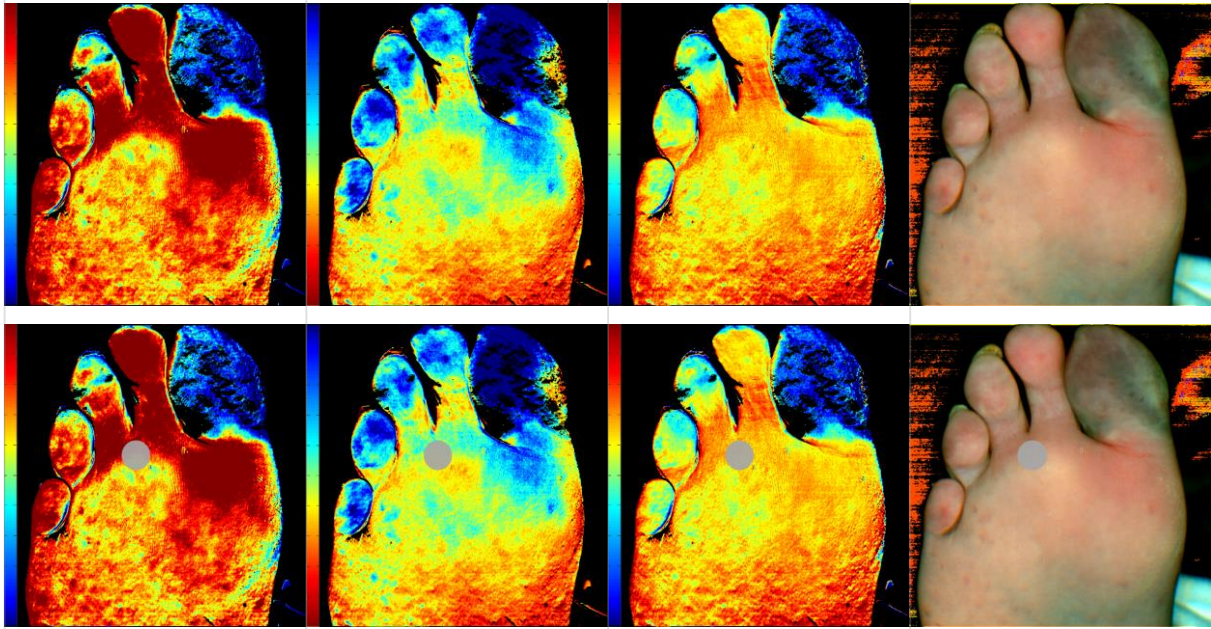
- Aortogram with bilateral runoff with catheter place in suprarenal and infrarenal position.
- Selective angiography of the right lower ext with the catheter placed in the right SFA.
- Successful deployment of embolic protection device spider filter at the trifurcation of the tibial vessels.
- Self expanding stent placement at the popliteal artery.
- Aspiration artherectomy with Jetstream device of the right SFA and popliteal arteries followed by balloon angioplasty.

Visualize Arterial Delivery
Oxy

Visualize Venous Return
Deoxy

Visualize Vascular Exchange
O2Sat

Photographic Reconstruction
Visual



OxyHb: 78
DeoxyHb: 42
O2Sat: 65%
Analysis Area: 78 mm²
Second Area:

User: admin
Date: 11/14/2018
Time: 06:49:05 AM
Temp: 22.8°C / 73.0°F

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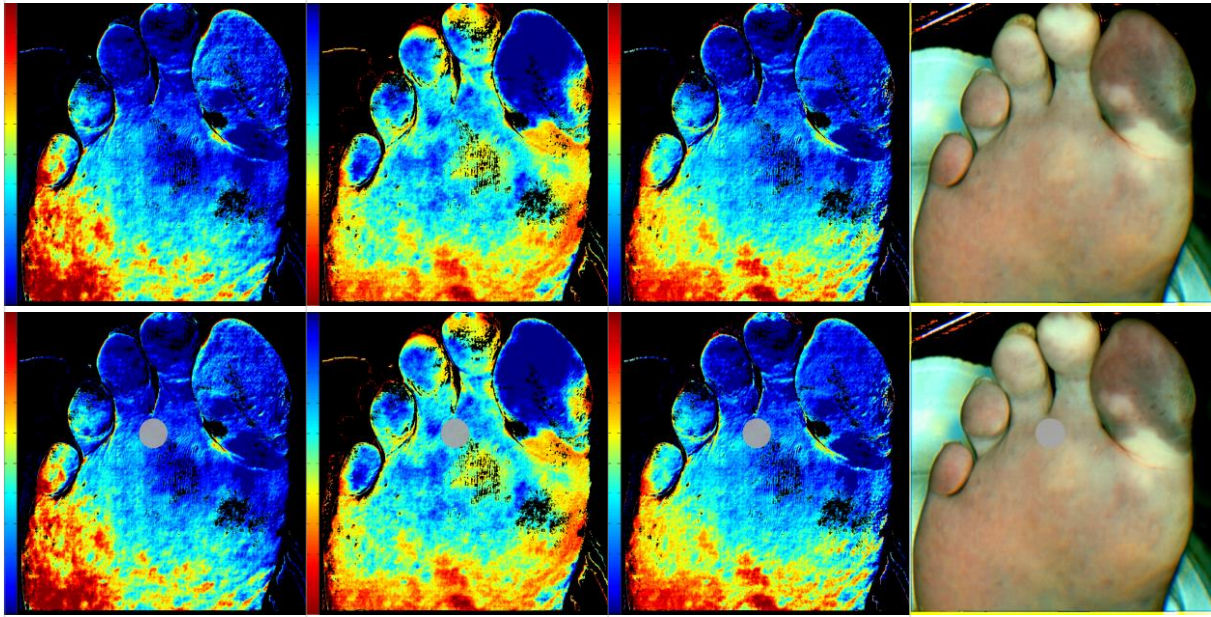
DISCUSSION

Visualize Arterial Delivery
Oxy

Visualize Venous Return
Deoxy

Visualize Vascular Exchange
O2Sat

Photographic Reconstruction
Visual



OxyHb: 19
DeoxyHb: 64
O2Sat: 23%
Analysis Area: 71 mm²
Second Area:

User: admin
Date: 11/14/2018
Time: 09:59:17 AM
Temp: 22.2°C / 72.1°F

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DISCUSSION

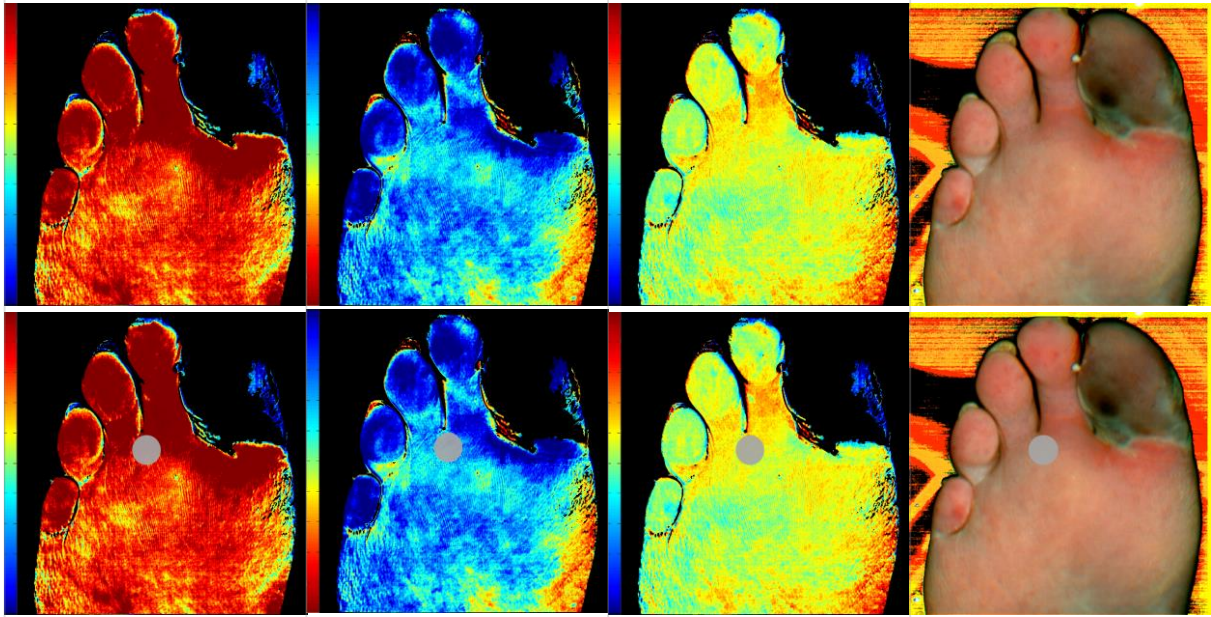
Patient has undergone RLE endovascular interventions with excellent flow to the right foot. However, the ischemic right great toe has now progressed to gangrene. TMA was preformed.

Visualize Arterial Delivery
Oxy

Visualize Venous Return
Deoxy

Visualize Vascular Exchange
O2Sat

Photographic Reconstruction
Visual



OxyHb: 98
DeoxyHb: 69
O2Sat: 59%
Analysis Area: 78 mm²
Second Area:

User: admin
Date: 11/19/2018
Time: 09:48:10 AM
Temp: 31.2°C / 88.1°F

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Virtual CLI Centers

- Patients Follow up and assessment
- Two way communication
- Identify team members that understand and compliment what you do

Clinical Presentation

- 75 y ted
  with d
  rest ft
  lowe

AV Reversal

Complex Wound Care

7 days

30 days

2 years

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Center Requirements

- Staff Requirements
- Equipment Requirements
- Revascularization Modalities

1. Scr
2. Inte
US Tec
3. Ph
4. Sedation RN
5
6
7

Interventional US Tech
Extra Vascular Ultrasound (EVUS)

1. Arterial Access
2. CTO Crossing
3. Complication Evaluation
4. Closure Management

Antegrade Access

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An official publication of the ISEVS

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Chronic Total Occlusion Crossing Approach Based on Plaque Cap Morphology: The CTOP Classification

Fadi Saab, MD[1], Michael R. Jaff, DO[2], Larry J. Diaz-Sandoval, MD[1], Gwennan D. Engen, BSN[1], Theresa N. McGoff, BSN[1], George Adams, MD[3], Ashraf Al-Dadah, MD[4], Philip P. Goodney, MD[5], Farhan Khawaja, MD[6], and Jihad A. Mustapha, MD[1]

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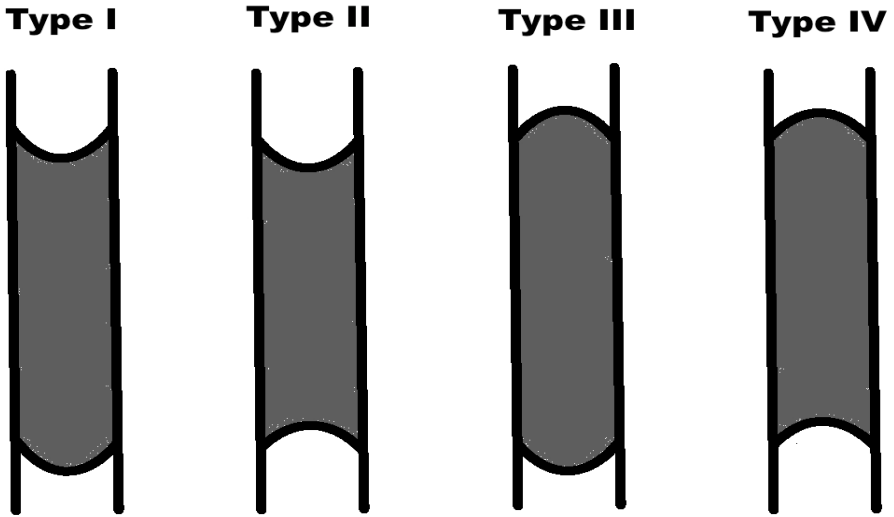
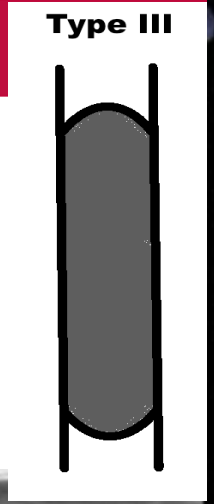
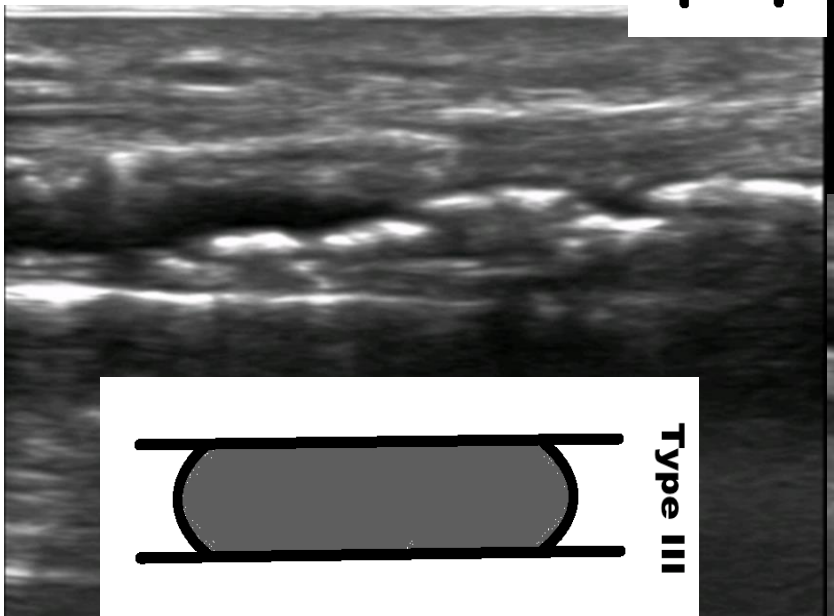
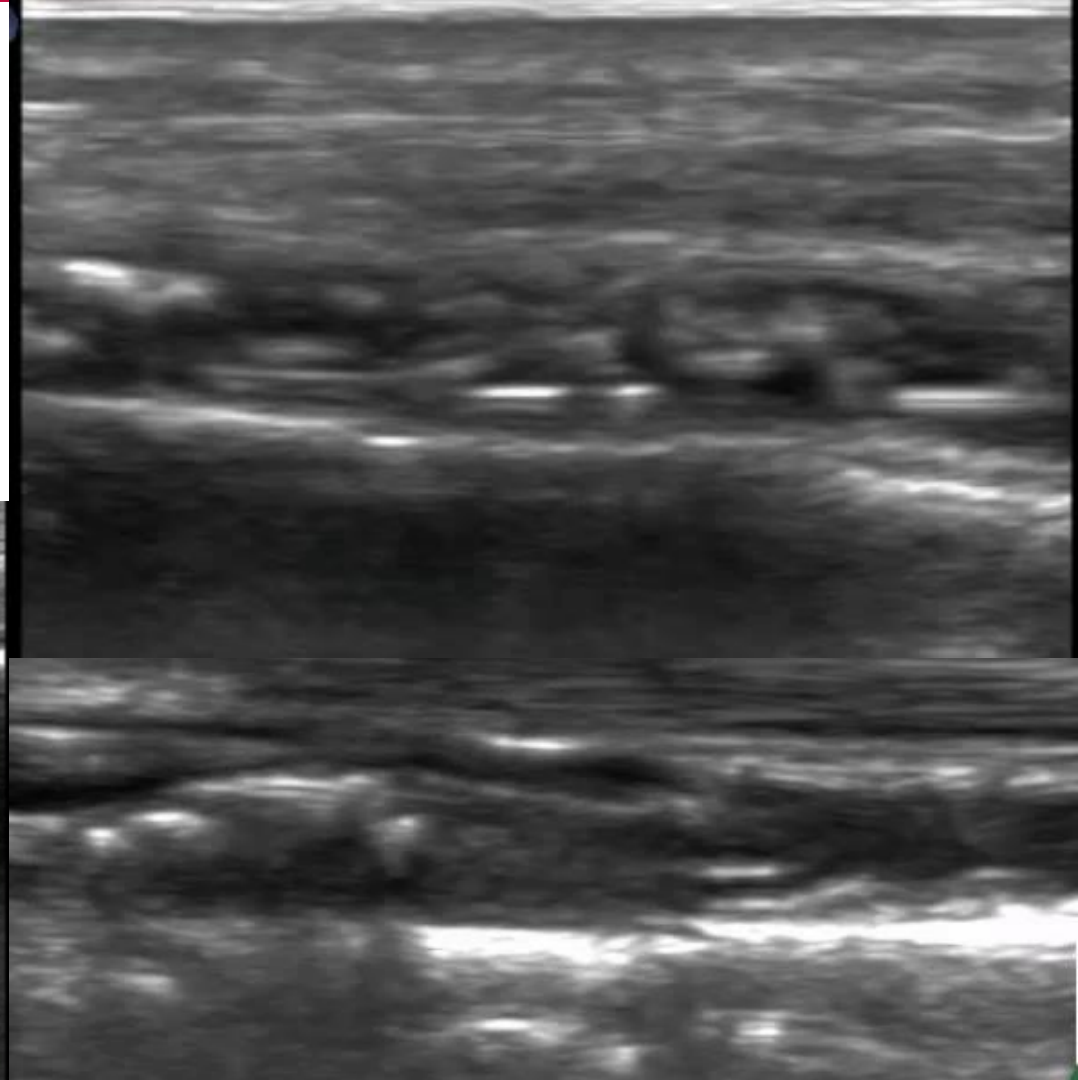


CTO Crossing

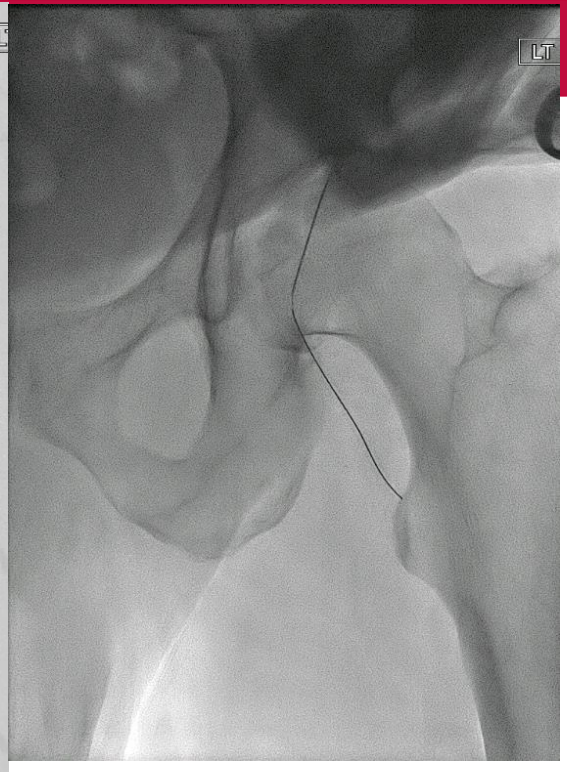






Assisted TAMI

- 69 Year old male with Aortic-Bifem Bypass
- Rest pain bilaterally, RF class IV
- Diastolic heart failure with EF 60%
- DM, CKD and HTN
- ABI 0.3 R, 0.5 on the L
- Radial approach is limited secondary to device length



- Low profile Antegrade Sheath (3 French)
- Type II CTO that would require antegrade and retrograde access
- Need to cross the antegrade CTO cap

Clinical Investigation

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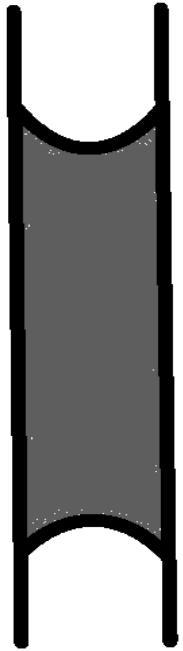
Type II



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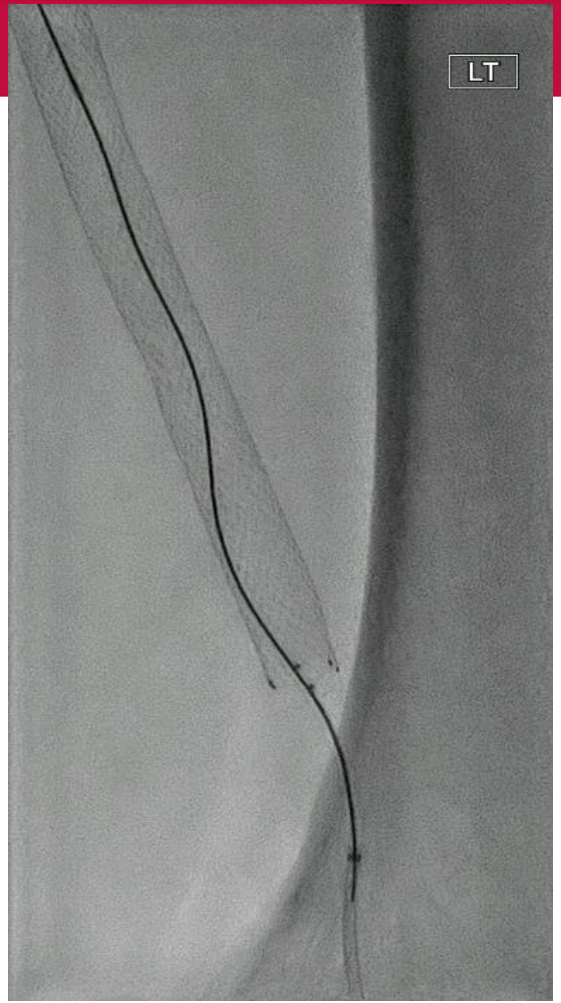
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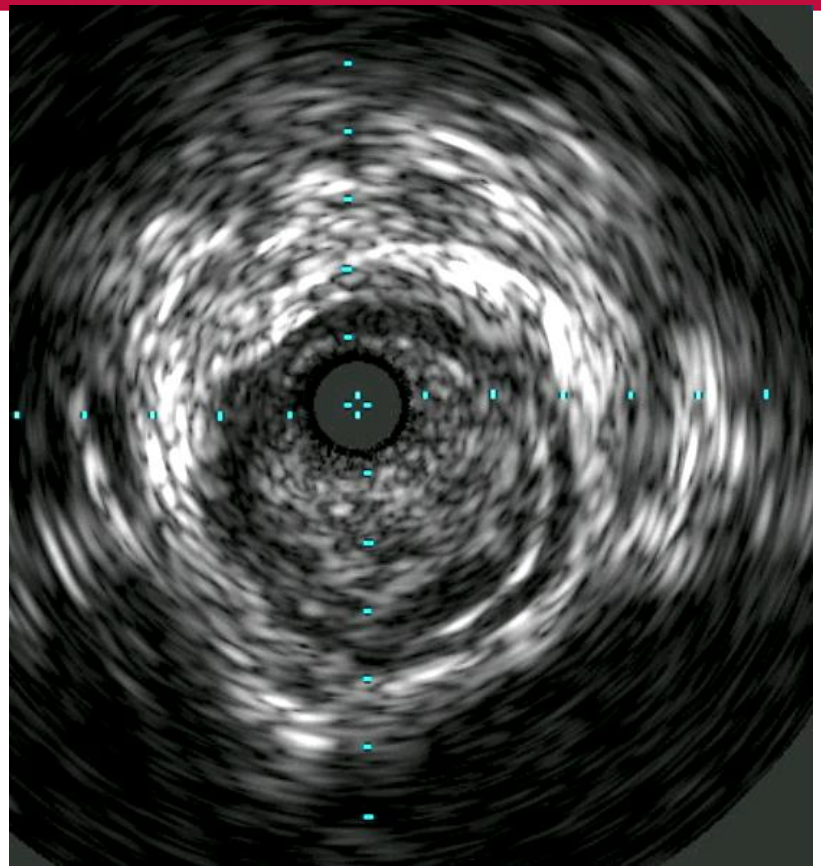

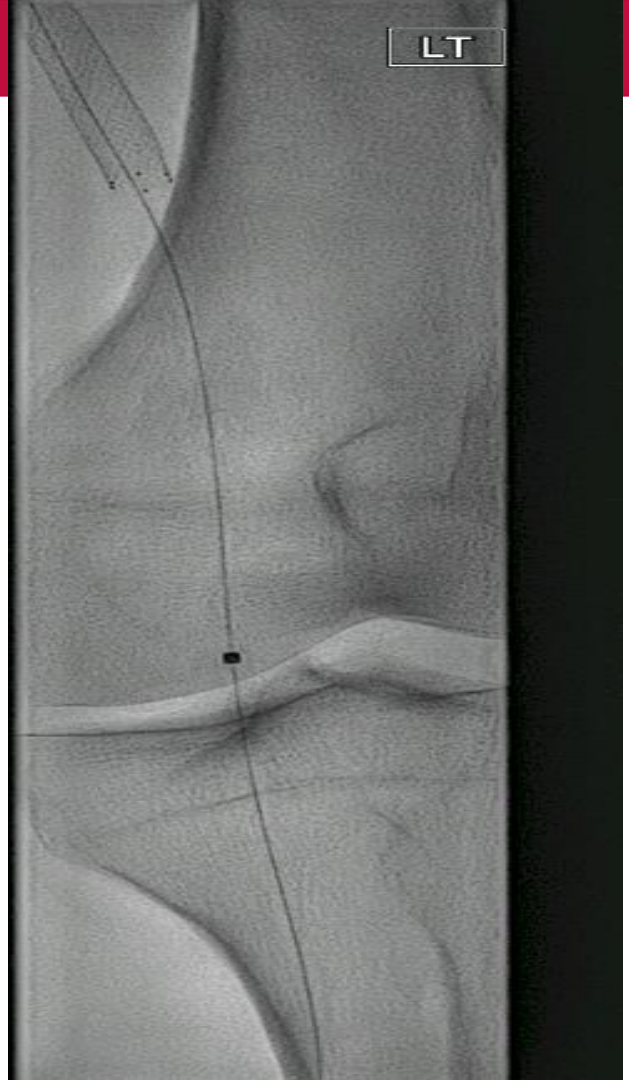
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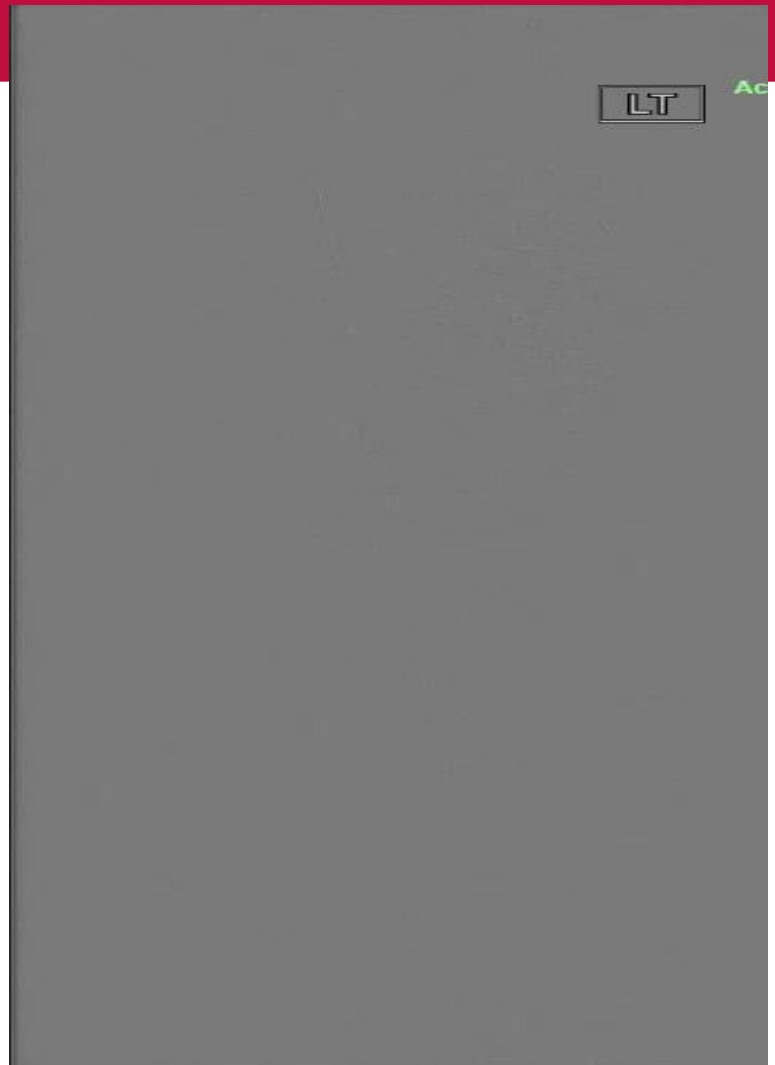
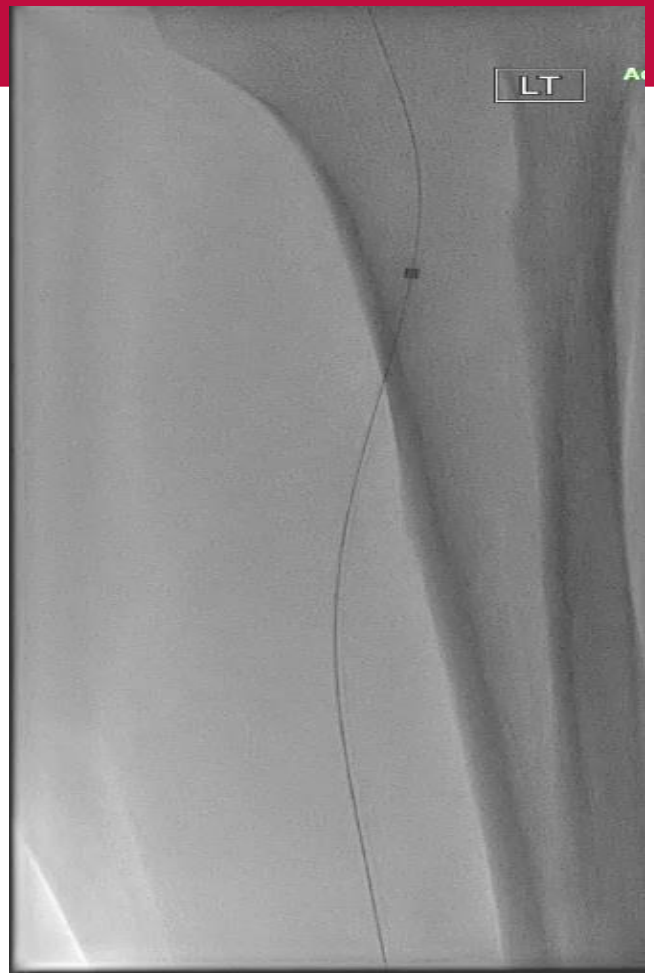
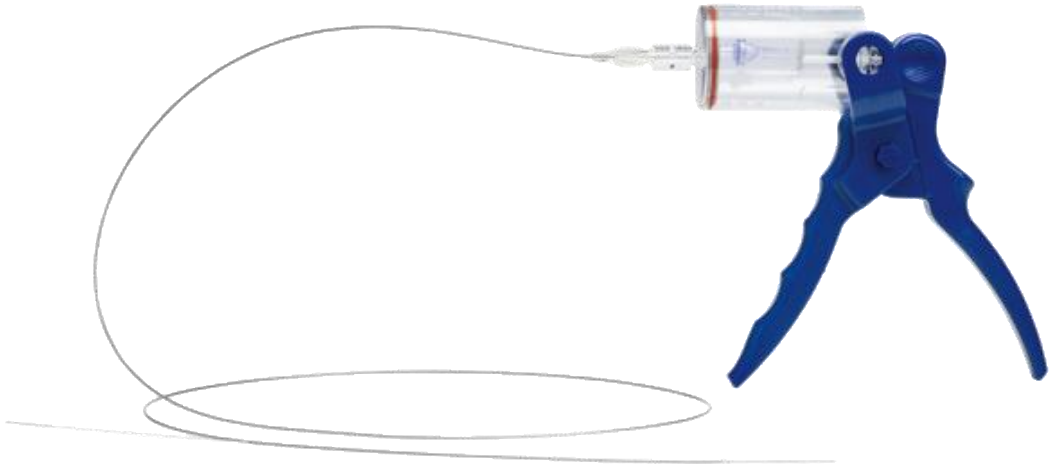


Acute Occlusion of the PT



Aspire Retrograde Thrombectomy

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Quality Metrics

- Track patient presentation
- Intra Procedural Outcomes
- Post Procedural Outcomes
- Wound Management and Amputation Free Survival

Patient Demographics

G	H	I	J	K	L	M	N	O	P	Q	R
AGE AT PVI	SEX	COURSE	IF TAPED, #	RUTHERFORD	HTN	DM	HYPERLIPIDEMIA	SMOKING	CAD	DIALYSIS	CKD ≥ Stage 3
81	MALE	No	No	RC5	YES	NO	YES	NO	YES	NO	NO
84	FEMALE	No	No	RC5	YES	YES	YES	NO	YES	NO	NO
87	MALE	No	No	RC5							
67	MALE	No	No	RC5							
86	FEMALE	No	No								
66	FEMALE	No	No	RC5	YES	YES	YES	NO	YES	NO	YES
61	MALE	No	No		YES	YES	YES	FORMER	NO	NO	NO
81	MALE	No	No	RC5	YES	YES	YES	NO	YES	NO	YES
74	FEMALE	No	No	RC5	YES	YES	YES	FORMER	YES	NO	NO
67	MALE	No	No	RC5	YES	YES	YES	NO	NO	NO	NO
71	MALE	No	No		NO	NO	YES	CURRENT	NO	NO	NO
50	MALE	No	No		YES	YES	YES	CURRENT	NO	NO	NO
93	MALE	No	No	RC5	NO	NO	NO	NO	NO	NO	NO
84	FEMALE	No	No	RC5	YES	YES	YES	NO	YES	NO	NO
83	FEMALE	No	No		YES	NO	YES	NO	NO	NO	NO
77	FEMALE	No	No	RC4	YES	YES	YES	FORMER	YES	NO	NO
71	MALE	No	No	RC5	NO	NO	YES	UNKNOWN	YES	NO	NO
88	MALE	No	No	RC5	NO	YES	YES	FORMER	NO	NO	YES
81	MALE	No	No	RC5	YES	NO	YES	NO	NO	NO	NO
87	MALE	No	No	RC5	YES	YES	YES	NO	NO	NO	NO
73	FEMALE	No	No	RC3	YES	NO	YES	FORMER	YES	NO	NO

Intra Procedural

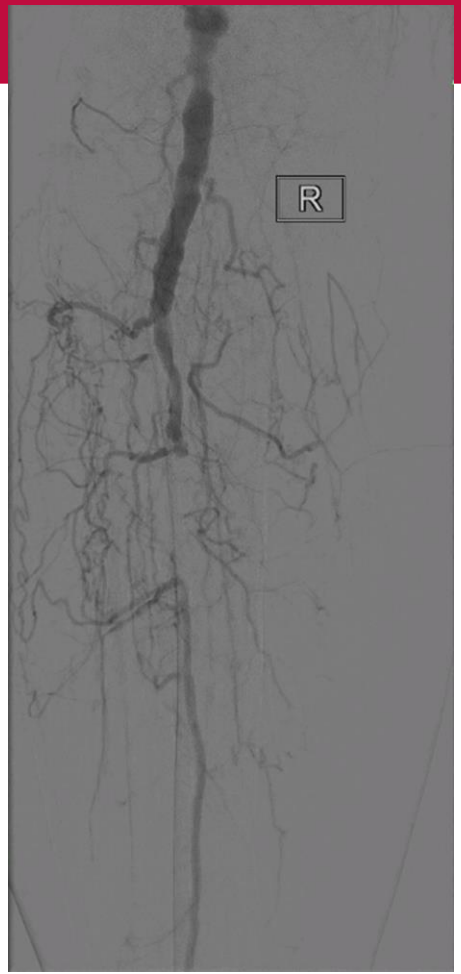
F	G	H	I	J	K	L	M	N	O	P	Q	R	
OPERATOR	CFA	SFA	TIBIO-PEDAL	BRACHIAL	RADIAL	TAMI	DUAL ACCESS	FEMORAL SHEATH S	TP SHEATH SIZE	FAILURE TO CROSS	LIMB TREATED	ILIAC	CF
MUSTAPHA	Yes-Retrograde	No	Yes-Retrograde	NO	NO	NO	Yes	5F	2.9	POP	LEFT	NO	NO
MUSTAPHA	No	No	No	NO	NO	YES	No	NA	4	No	RIGHT	NO	NO
MUSTAPHA	Yes-Antegrade	No	No	NO	NO	NO	No	5F	NA	No	LEFT	NO	NO
SAAB	Yes-Retrograde	No	Yes-Retrograde	NO	NO	NO	Yes	6F	2.9	No	RIGHT	NO	NO
MUSTAPHA	Yes-Antegrade	No	Yes-Retrograde	NO	NO	NO	Yes	5F	2.9	No	RIGHT	NO	NO
MUSTAPHA	No	No	Yes-Retrograde	NO	NO	YES	Yes	NA	4	No	LEFT	NO	NO

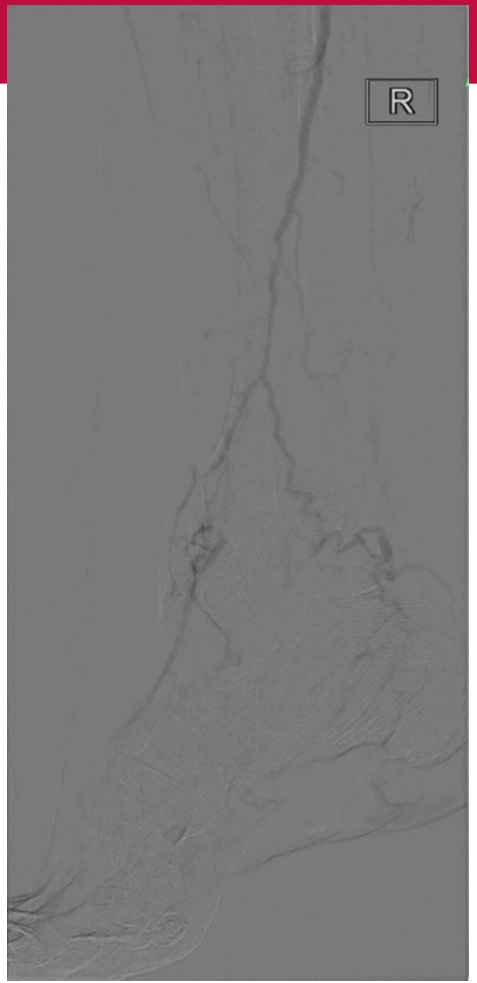
Complications

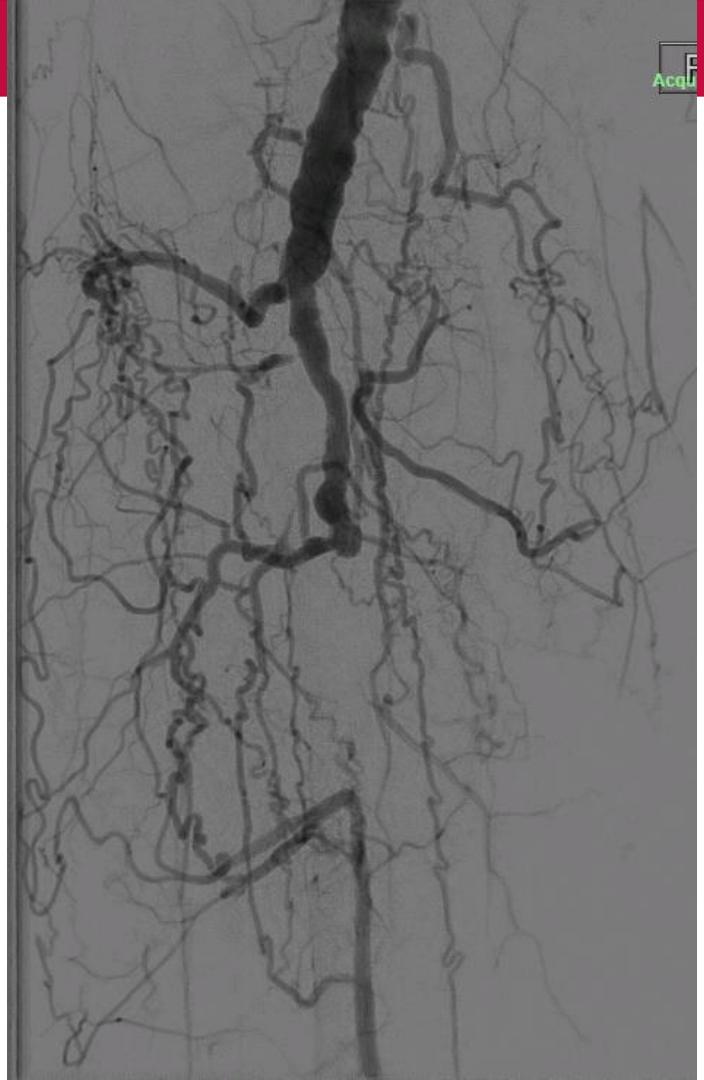
G	H	I	J	K	L	M
VISIT WINDOW END	DATE OF EVALUATION	ACCESS SITE COMPLICATION	CIN	HOSP R/T PROCEDURE	DEATH	COMMENTS
04/18/18	03/05/18	NO	NO	NO	ALIVE	
04/18/18	03/28/18	NO	NO	NO	ALIVE	
04/18/18	03/30/18	NO	NO	NO	UNKNOWN	
04/19/18	03/20/18	NO	NO	NO	ALIVE	
04/19/18	NA	NO	NO	NO	UNKNOWN	Indiana patient-No post labs done, no f/u U
04/19/18	04/09/18	NO	NO	NO	ALIVE	
04/20/18	NA	NO	NO	NO	UNKNOWN	Pt had 30 day PV protocol on 3/23 but cance
04/20/18	03/16/18	NO	NO	NO	ALIVE	
04/20/18	04/17/18	NO	NO	NO	ALIVE	
04/21/18	03/19/18	NO	NO	NO	UNKNOWN	No post labs done and no f/u past the 30 da
04/21/18	03/22/18	NO	NO	NO	ALIVE	
04/25/18	4/16/18 @ Metro	NO	NO	NO	ALIVE	
04/25/18	04/13/18	NO	NO	NO	ALIVE	
04/25/18	03/28/18	HEMATOMA	NO	NO	ALIVE	Pt has had all subsequent PVI at Metro
04/26/18	08/28/18	NO	NO	NO	ALIVE	OOA patient
04/26/18	03/12/18	NO	YES	YES	ALIVE	Pt was admitted to Metro after OV 3/12/18
04/27/18	04/26/18	NO	NO	NO	ALIVE	
04/27/18	03/22/18	NO	NO	NO	ALIVE	
04/28/18	03/05/18	NO	NO	NO	ALIVE	
04/28/18	03/30/18	NO	NO	NO	ALIVE	
04/28/18	04/12/18	NO	NO	NO	ALIVE	
05/02/18	04/09/18	NO	NO	NO	ALIVE	
05/02/18	04/12/18	NO	NO	NO	ALIVE	

Case Selection

- 69 year old male that presented with RF class 5 and rest pain
- Risk factors: HTN, DM, CKD stage III







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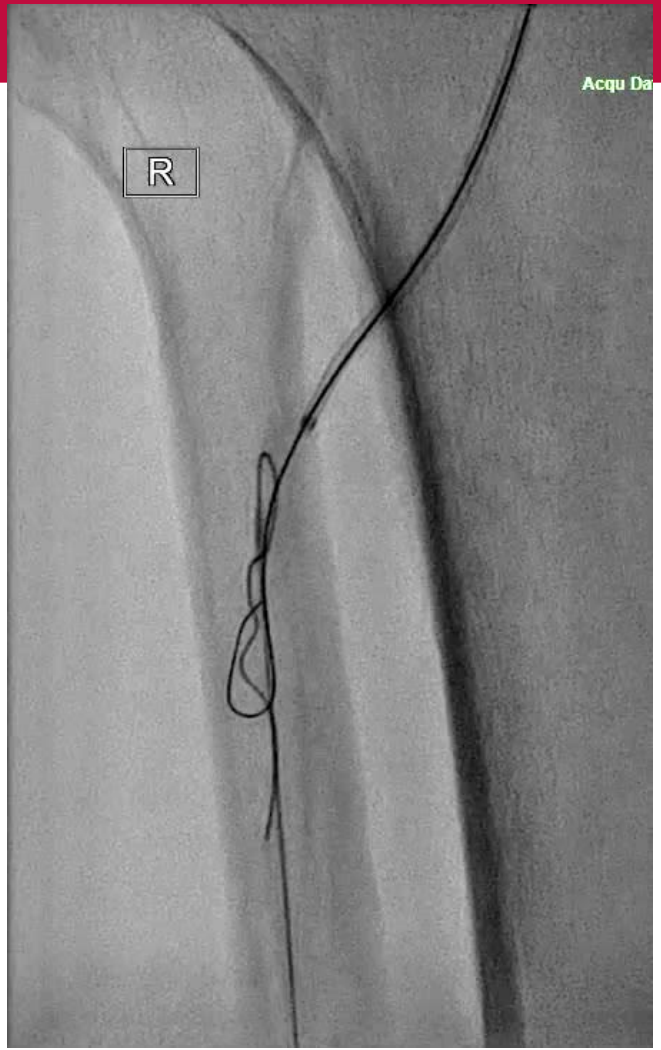
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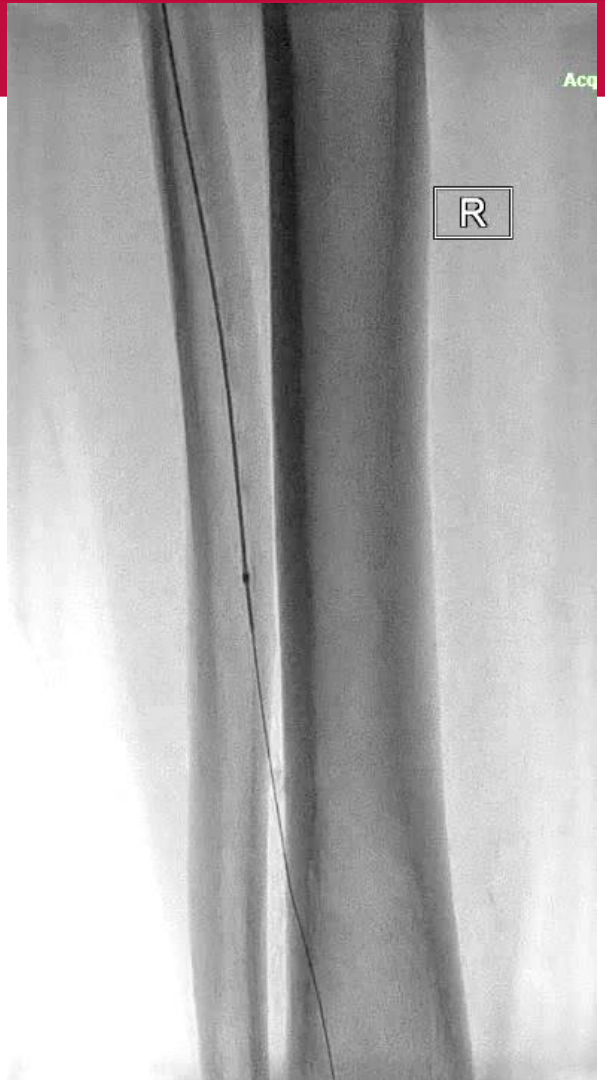
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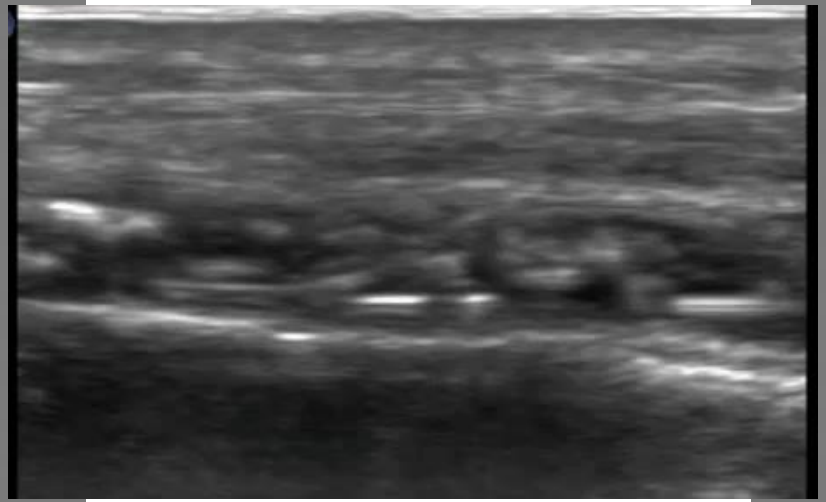

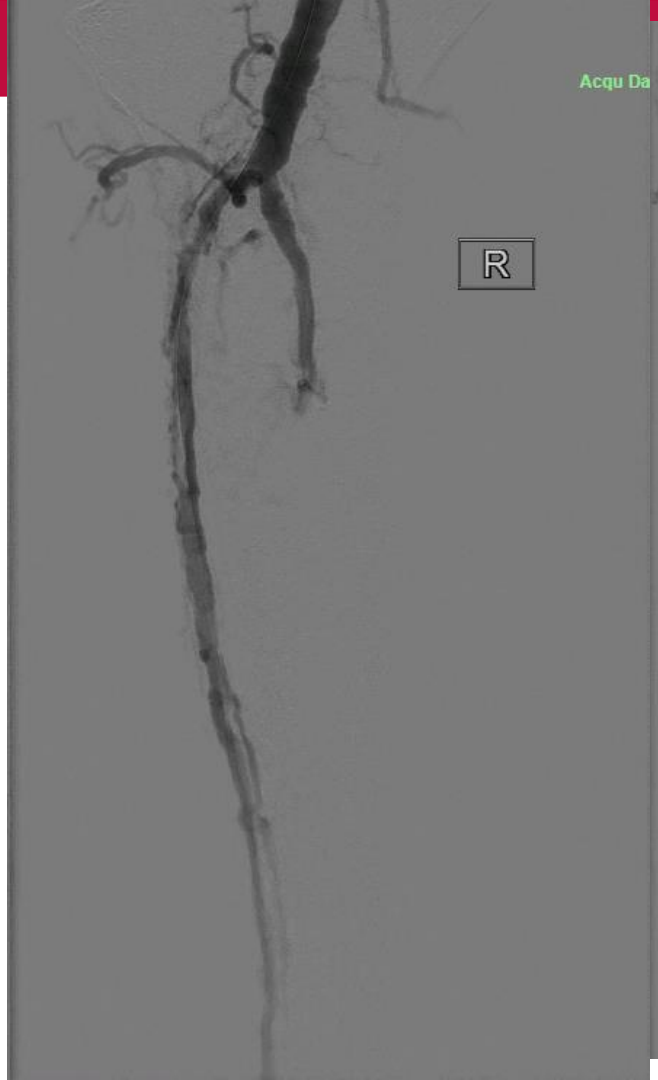
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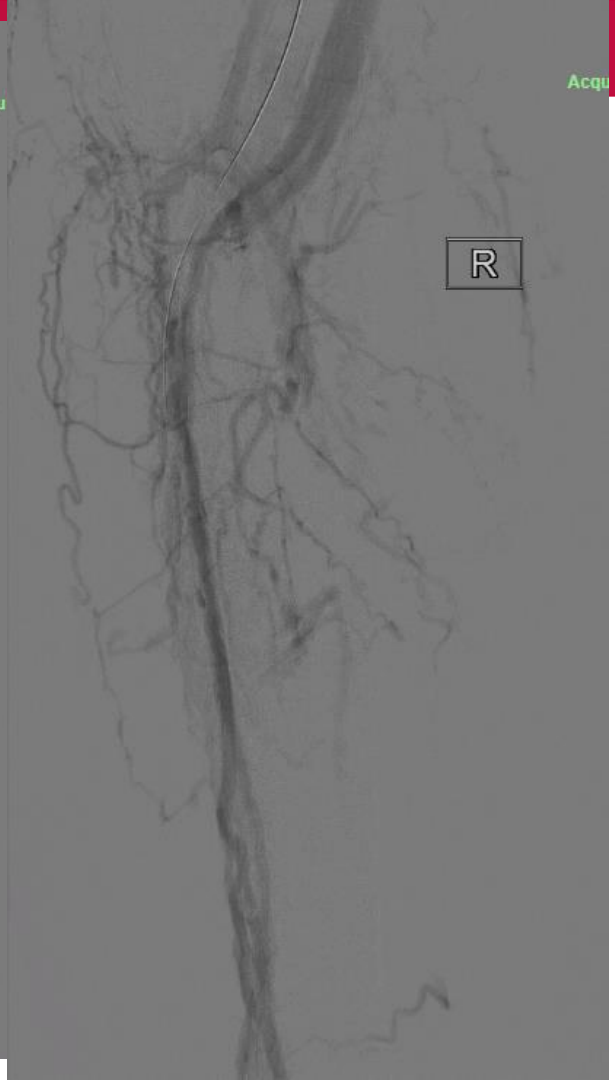
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Primary Endpoints

SAFETY

Freedom from Major Adverse Limb Events (MALE) & All-Cause Perioperative Death (POD) at 30 Days

★ ***Amputation (above ankle)***
★ ***Major re-intervention***
- New bypass graft
- Jump/Interposition graft revision
- Thrombectomy/Thrombolysis

EFFICACY

Composite of Limb Salvage and Primary Patency at 6 Months

★ ***Defined as freedom from the composite of above ankle amputation, target vessel occlusion, and clinically-driven target lesion re-intervention.***

Primary Endpoints (30-Day Safety*)

	DCB N=287	PTA N=155	Difference in Response % (95% CI)	P-Value
Free from Primary Safety Event at 30 Days	99.3% (283/285)	99.4% (154/155)	-0.1% (-3.9%, 3.8%)	<.0001

*Freedom at 30 days from TVR, major index limb amputation, and device and all cause death.

Jihad Mustapha, MD

Primary Endpoints (6 Month Efficacy*)

	DCB N=287	PTA N=155	Difference in Response (95% CI)	P-Value
Free from Primary Efficacy Failure at 6 Months	73.7% (196/266)	63.5% (87/137)	10.2% (-0.2%, 18.7%)	0.0273

*Freedom at 6 months from major index limb amputation, target lesion occlusion and TLR.

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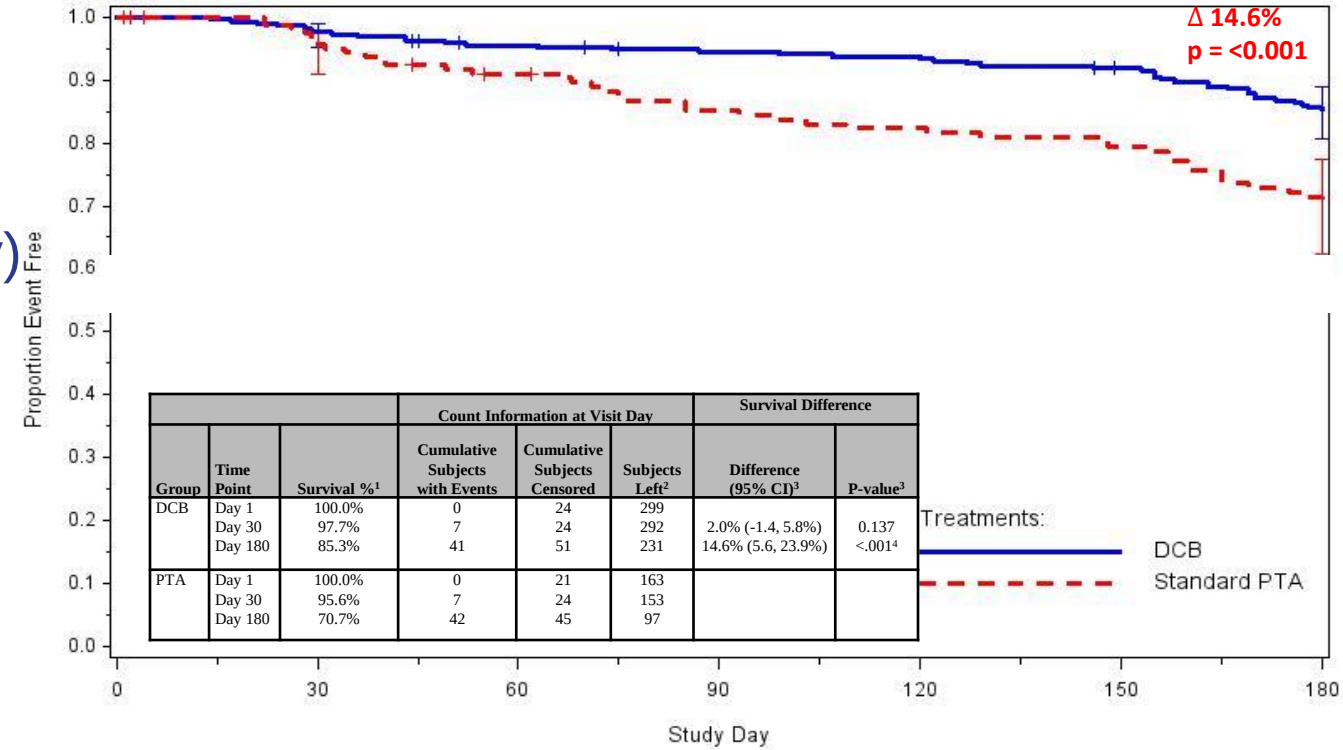
Primary Endpoints
(KM 6 Month Efficacy)

Figure 14.2.2.1
Kaplan-Meier Estimates for Full Pathway Primary Effectiveness Endpoint Event Free Survival
Intent-to-Treat



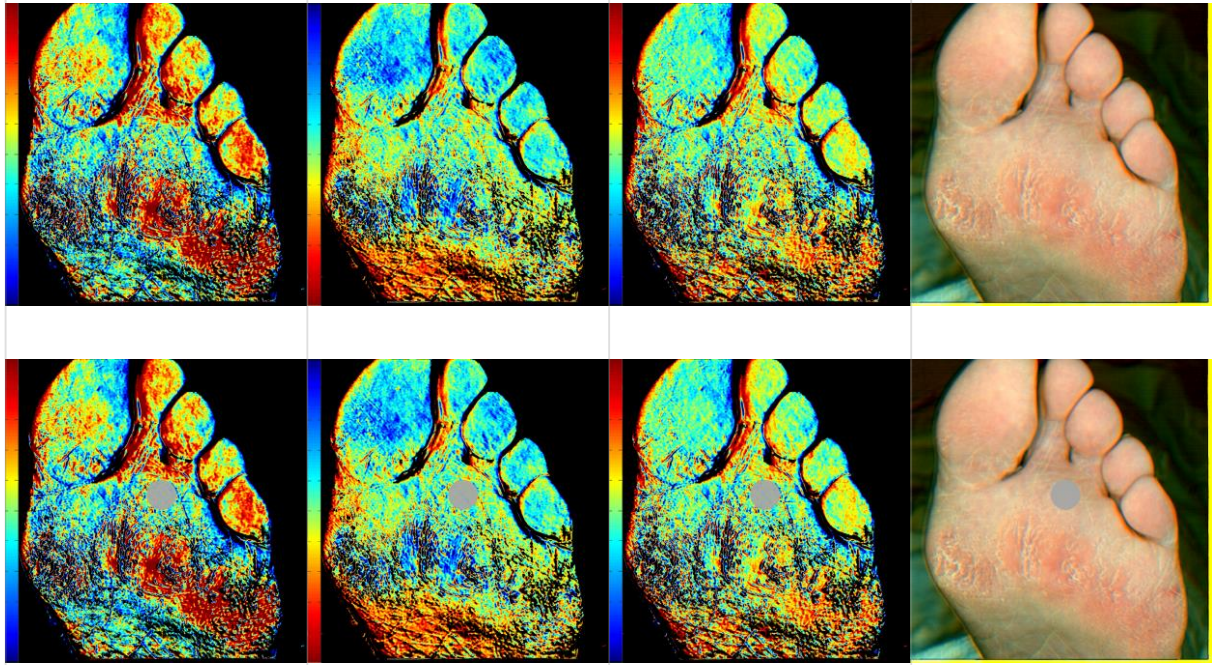
			Count Information at Visit Day			Survival Difference	
Group	Time Point	Survival %[1]	Cumulative Subjects with Events	Cumulative Subjects Censored	Subjects Left[2]	Difference (95% CI)[3]	P-value[3]
DCB	Day 1	100.0%	0	24	299		
	Day 30	97.7%	7	24	292	2.0% (-1.4, 5.8%)	0.137
	Day 180	85.3%	41	51	231	14.6% (5.6, 23.9%)	<.001[4]
PTA	Day 1	100.0%	0	21	163		
	Day 30	95.6%	7	24	153		
	Day 180	70.7%	42	45	97		

[1] Kaplan-Meier estimate of proportion of subjects without a composite failure event at the visit day
[2] Subjects ongoing without an event at the visit day
[3] 95% CI for difference and p-value for one-sided test that DCB response is less than or equal to Standard PTA response obtained from Kaplan-Meier estimates and standard error estimates from Greenwood's method
[4] Statistically significant

DISCUSSION

PRE IMAGE

Visualize Arterial Delivery	Visualize Venous Return	Visualize Vascular Exchange	Photographic Reconstruction
Oxy	**Deoxy**	**O2Sat**	**Visual**



OxyHb: 47
DeoxyHb: 48
O2Sat: 49%
Analysis Area: 78 mm²
Second Area:

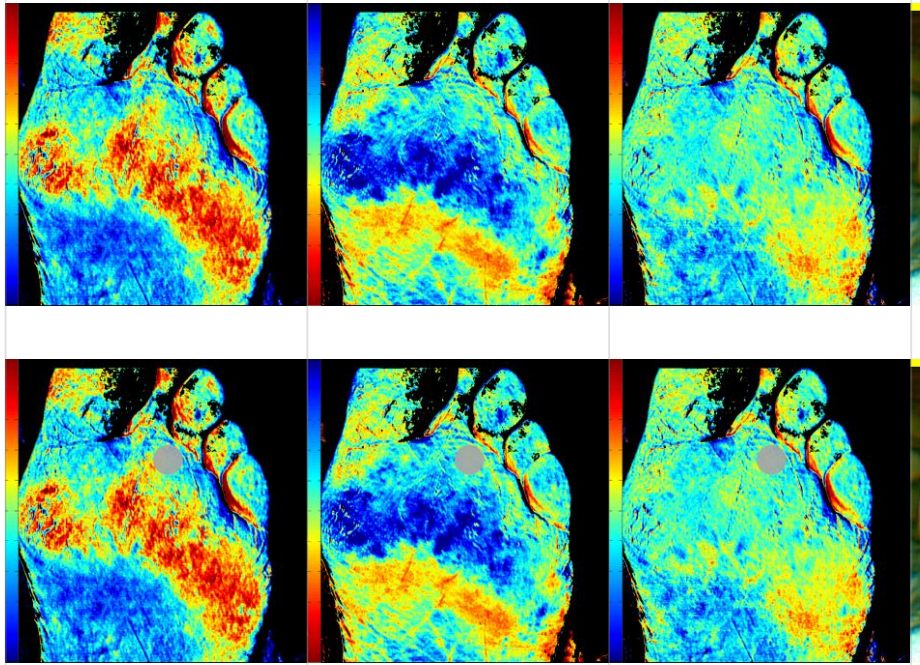
User: admin
Date: 02/12/2019
Time: 10:36:09 AM
Temp: 23.8°C / 74.9°F

CONFIDENTIAL

DISCUSSION

POST IMAGE #1

Visualize Arterial Delivery	Visualize Venous Return	Visualize Vascular Exchange	Photographic Reconstruction
Oxy	**Deoxy**	**O2Sat**	**Visual**



OxyHb: 44
DeoxyHb: 54
O2Sat: 45%
Analysis Area: 78 mm²
Second Area:

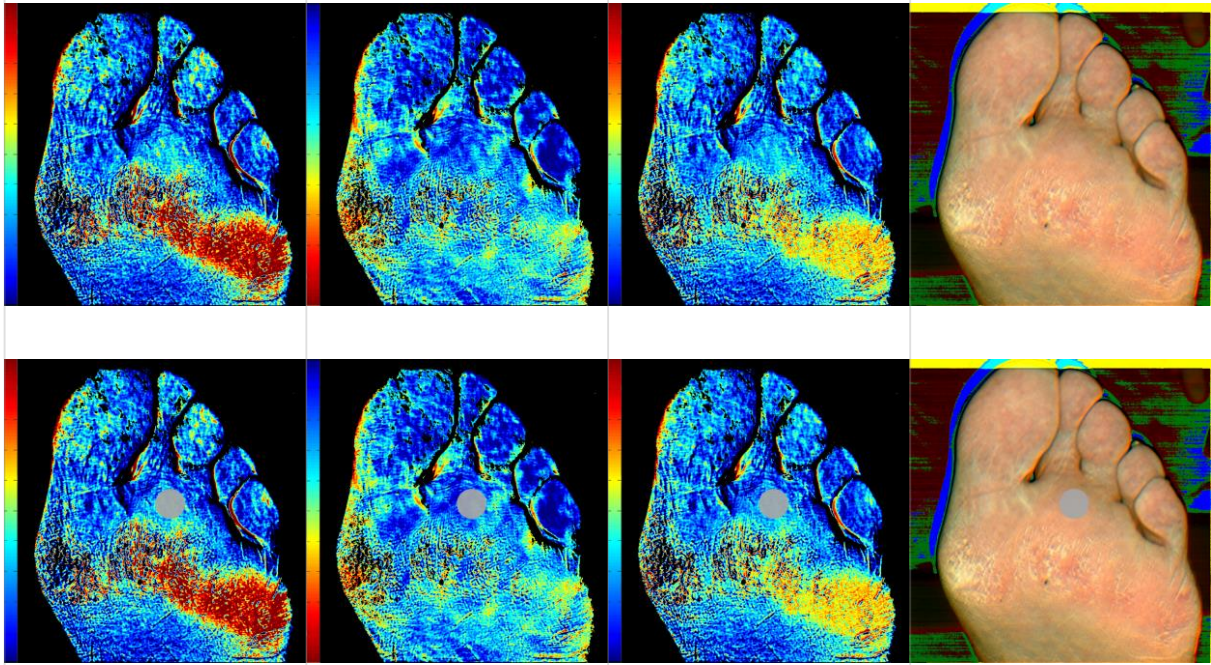
User: admin
Date: 02/12/2019
Time: 02:04:18 PM
Temp: 27.2°C / 81.0°F

CONFIDENTIAL

DISCUSSION

FOLLOW UP IMAGE 33 DAYS POST OP- LEFT

Visualize Arterial Delivery	Visualize Venous Return	Visualize Vascular Exchange	Photographic Reconstruction
Oxy	**Deoxy**	**O2Sat**	**Visual**



OxyHb:	35	**User:**	admin
DeoxyHb:	74	**Date:**	03/15/2019
O2Sat:	32%	**Time:**	10:09:36 AM
Analysis Area:	78 mm²	**Temp:**	26.0°C / 78.7°F
Second Area:			

Conclusion

- Building a CLI center requires incorporating multiple departments beyond revascularization
- We believe that building an out patient CLI Centers affords the health care system the ability to focus on what matters

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