Savings Lives in Critical Limb Ischemia: The CrossLock™ Device in CLI Patients Who Have Failed Interventional/ Surgical Approaches

R. Heuser

Presenter Disclosure Information

Name: ***RICHARD R. HEUSER M.D.***

Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

- ***QuantumCor, Major Stock Holder/Medical Director;***
- ***Radius Medical, Avinger and Claret Medical, Major Stock Holder;***
- ***PQ ByPass, Founder and Major Stock Holder;***
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- ***Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium;***
- ***Medtronic, Abbott, AngioScore, Speaker;***
- ***Acist Medical Systems Grant; and***
- ***Verve Medical, Inc., Major Stockholder***
- ***Founder, Arizona Medical Systems***
- ***Owner/Inventor, ORACLE Thrombus Removal System***

Patents *-- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure, Vascular Access Patents*


We are trying to make
CTO PCI less mystical

- Our center performs same day coronary CTO discharge over 90% of the time safely and successfully
- Patients from all over the country are interested in this technology and we need more physicians to treat these patients with the CrossLock™ device

Why Use CrossLock in Coronary CTOs?

- Drastically reduce the need for the retrograde approach with its higher complication rate and procedure time…MD training radiation lab time
- Remember ~ 90% success rate should occur and CTO PCI is not proven

What about using a CrossLock™ for peripheral vascular disease?


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Stent Guide
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Guide Extension Catheter

What about using a "GuideLiner" for PVD…the CrossLock™ is unlike any other support catheter.

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Guide
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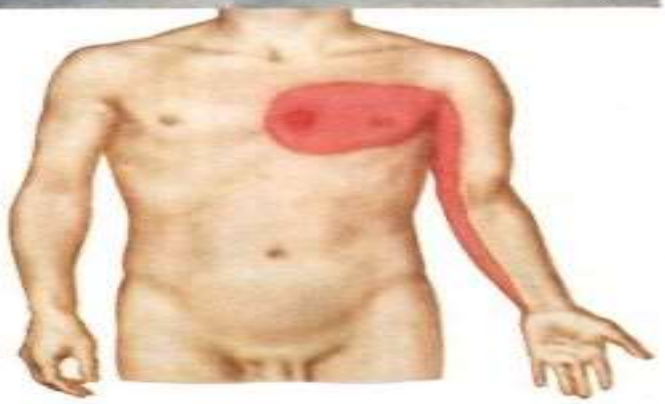
We do CTO PCI for only one reason…

COMMON PRECIPITATING FACTORS IN ANGINA PECTORIS: HEAVY MEAL, EXERTION, COLD, SMOKING



CHARACTERISTIC DISTRIBUTION OF PAIN IN ANGINA PECTORIS

PCI of CTOs

- Does it reduce myocardial infarction?
- Does it reduce mortality?

PCI of CTOs

- Are there interventional procedures that have the potential of reducing mortality?

The Centering Support Catheter for Improvement in Antegrade CTO Recanalization: The CrossLock™

- What is the mortality in CLI if amputation is necessary?

What is the Mortality in CLI if amputation is necessary?

- Perioperative mortality ~10%
- One year mortality ~25%
- Five year mortality ~75%

What is the Mortality in CLI if Amputation is Necessary?

- SO IF CLI INTERVENTION CAN PREVENT AMPUTATION, WE HAVE THE POTENTIAL TO REDUCE MORTALITY IN THESE PATIENTS.

A 63 year old diabetic female comes in with left pedal critical limb ischemia. She has hyperlipidemia, as well as known diabetes and chronic kidney disease with Creatinine of 1.8. A former smoker, she has had a left pedal ulcer on the dorsal of her foot for the last 3 months. We went in from the right groin.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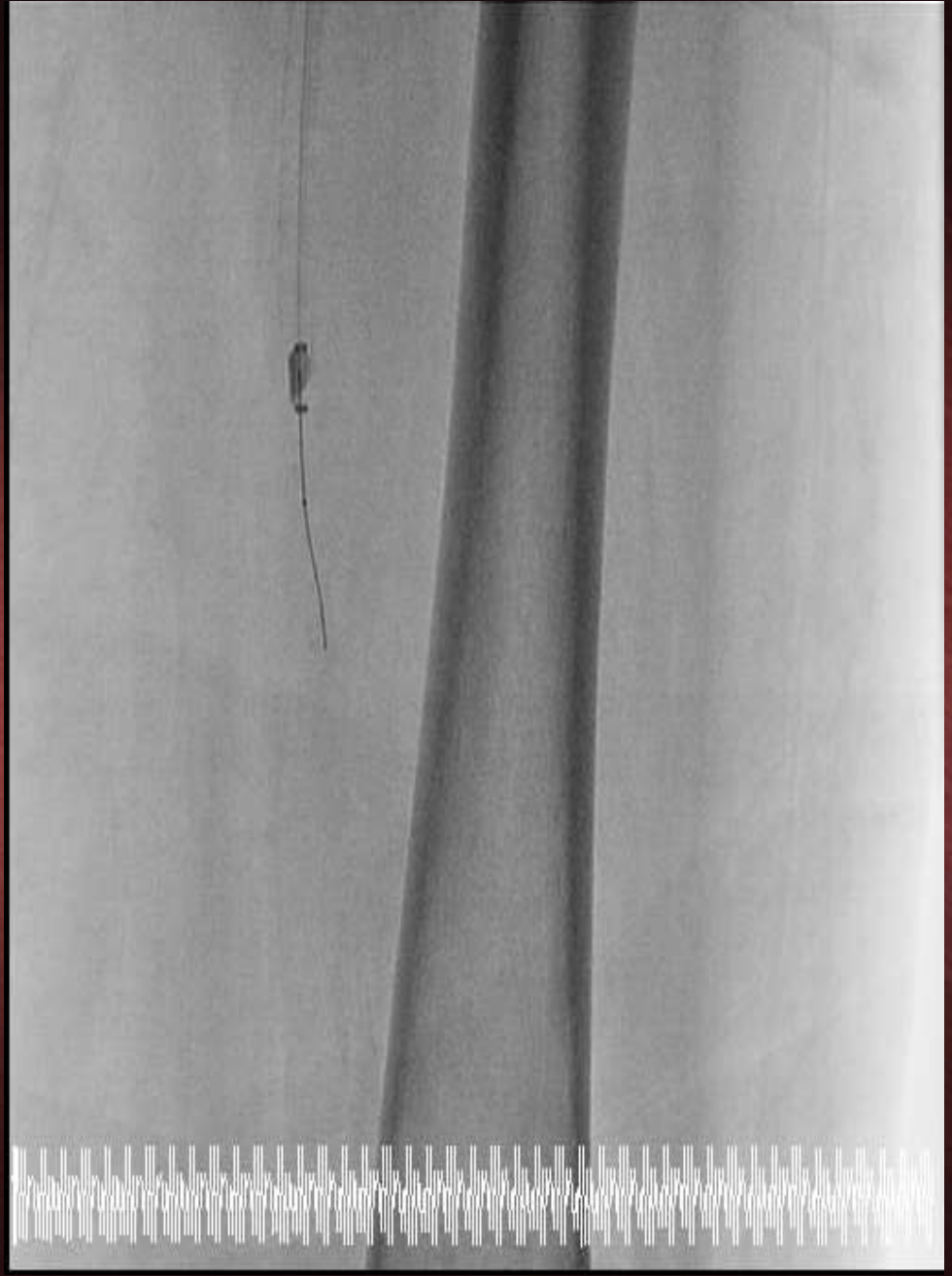

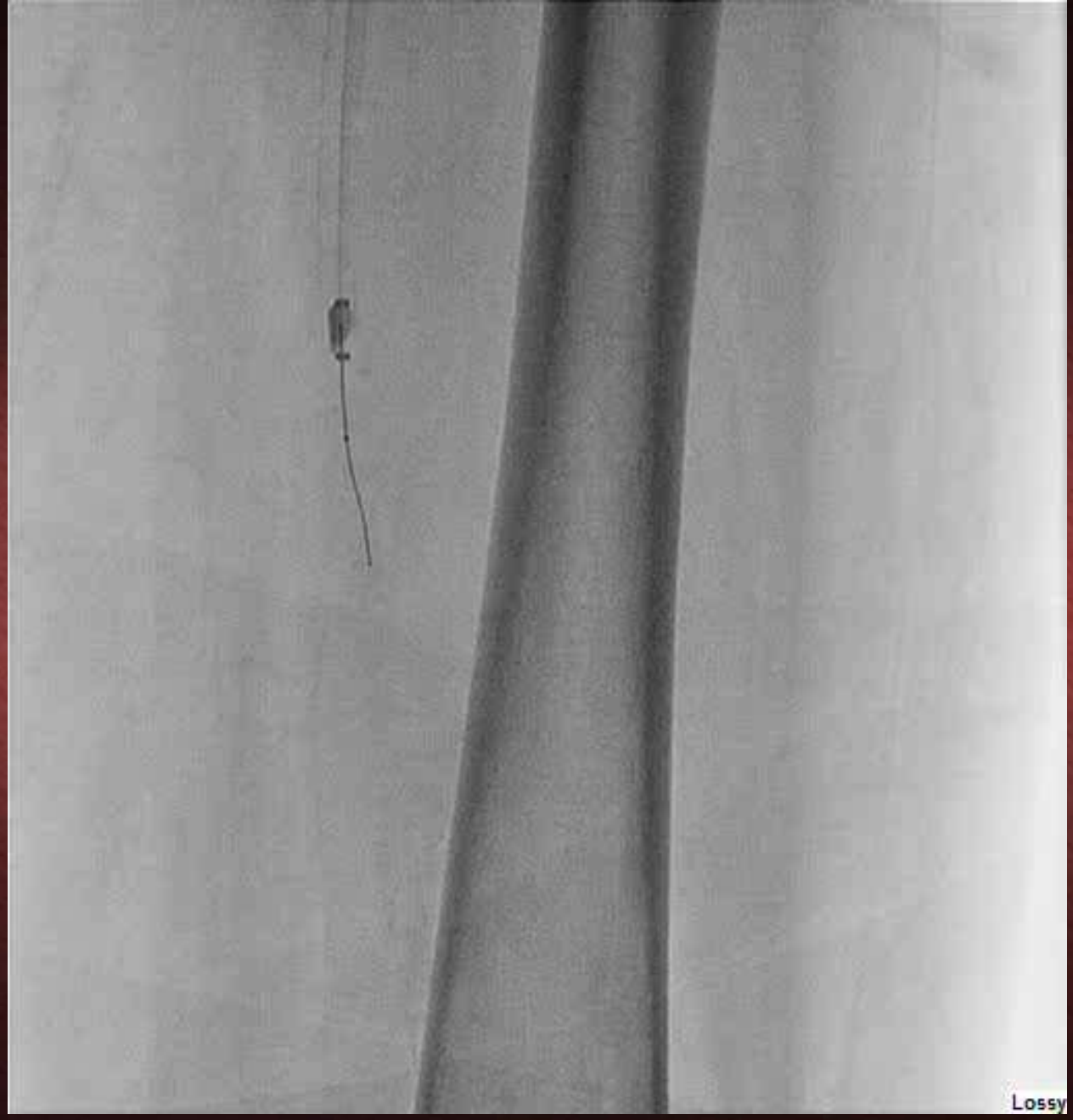
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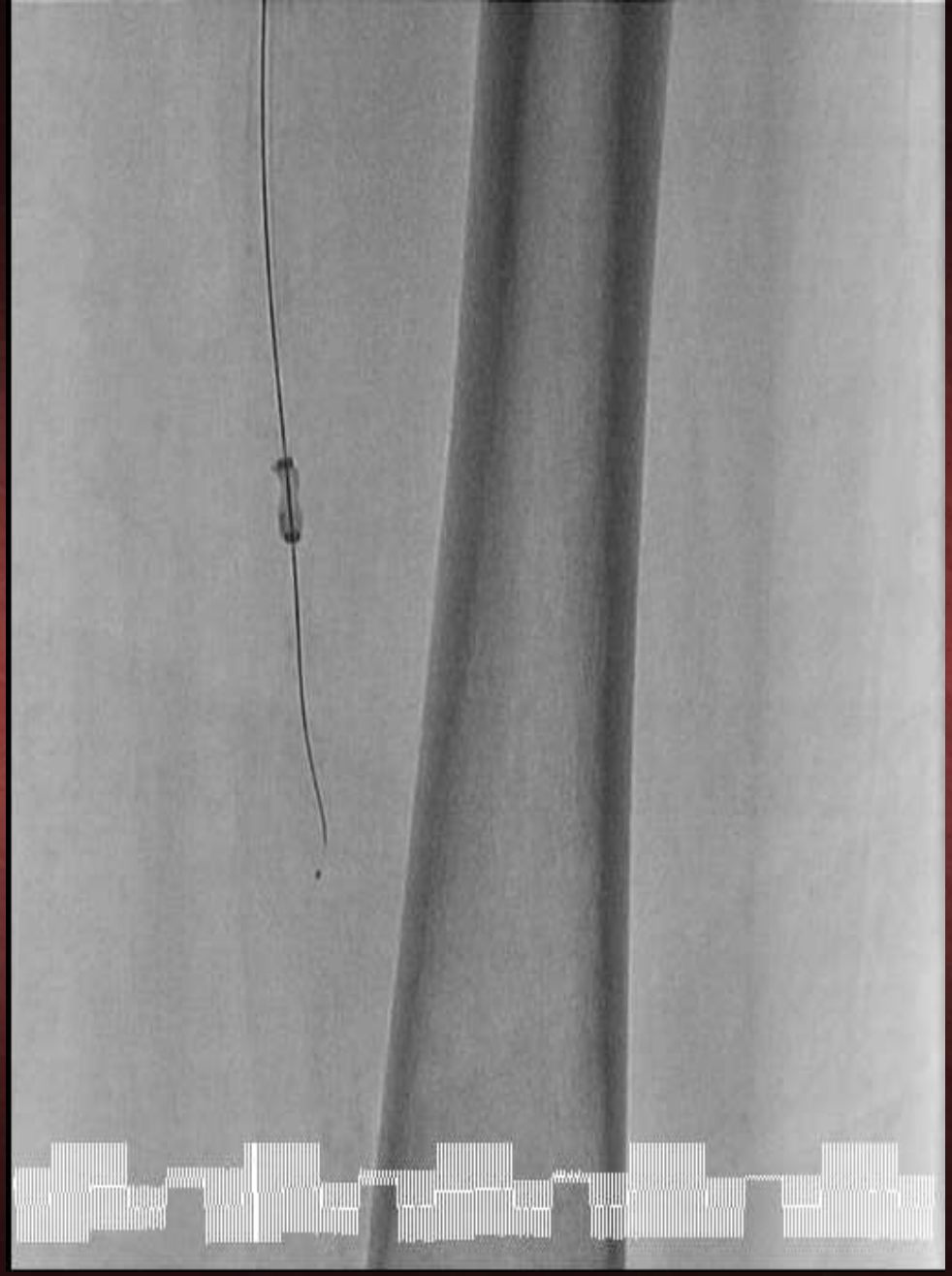

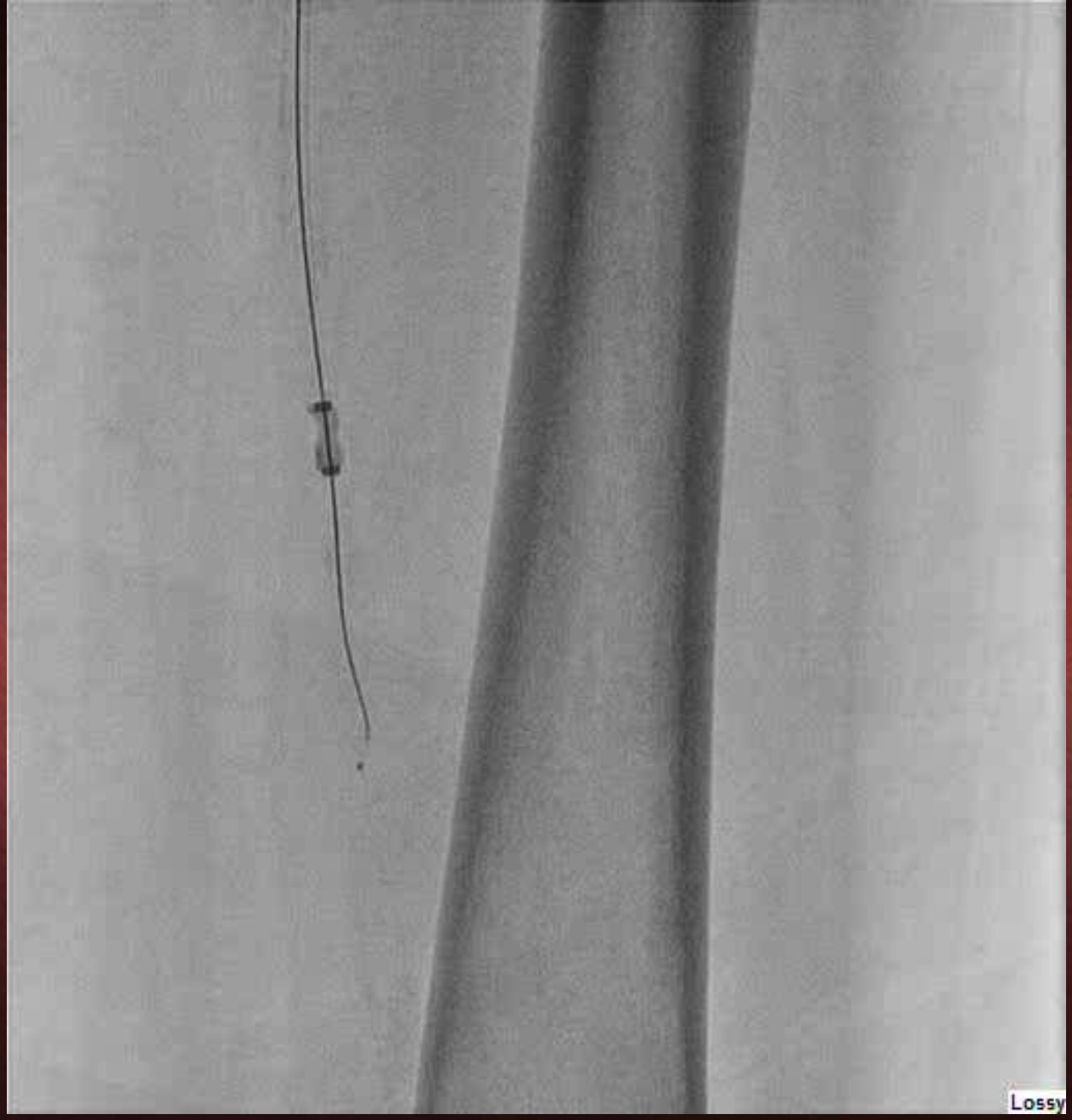
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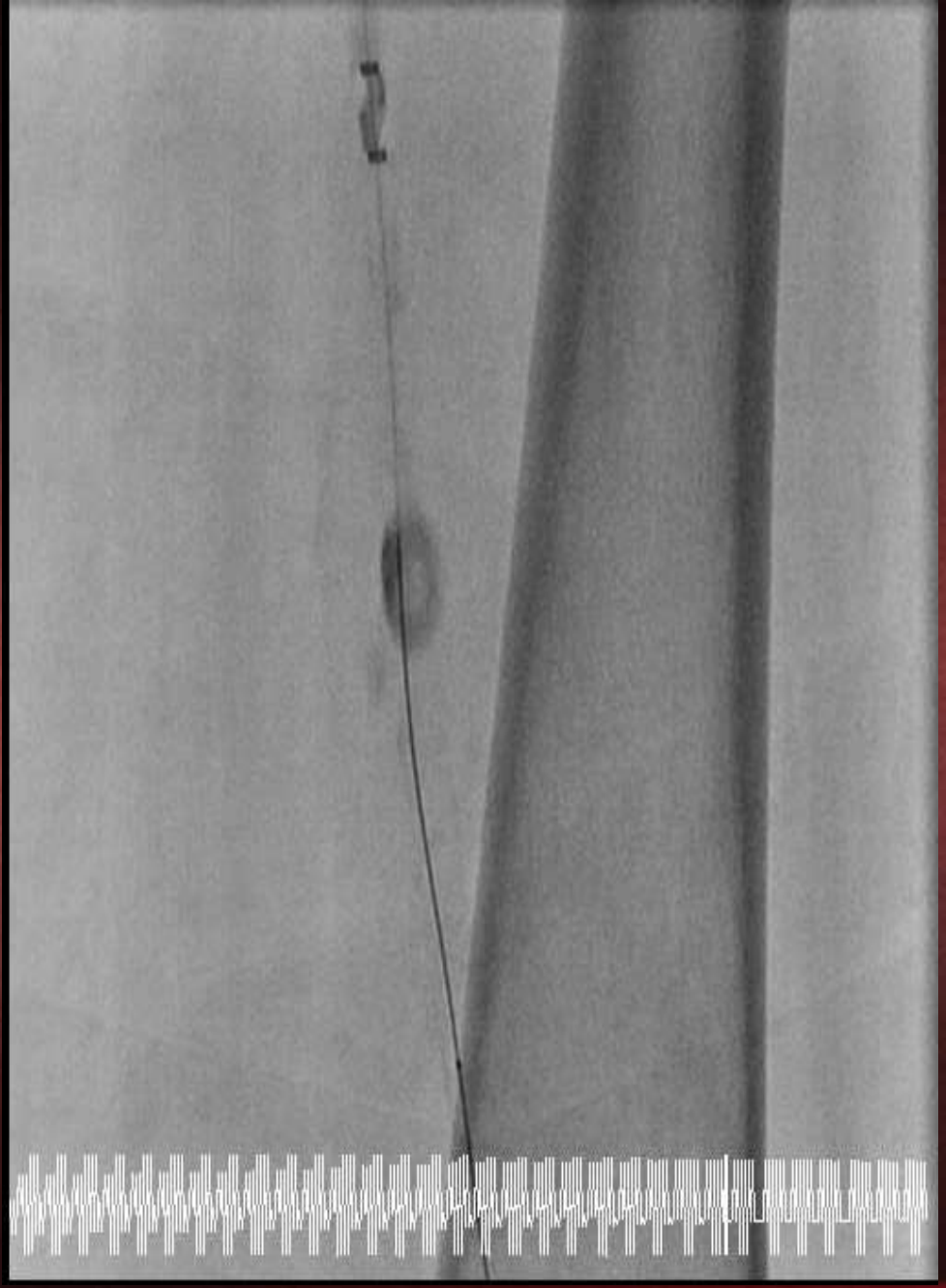

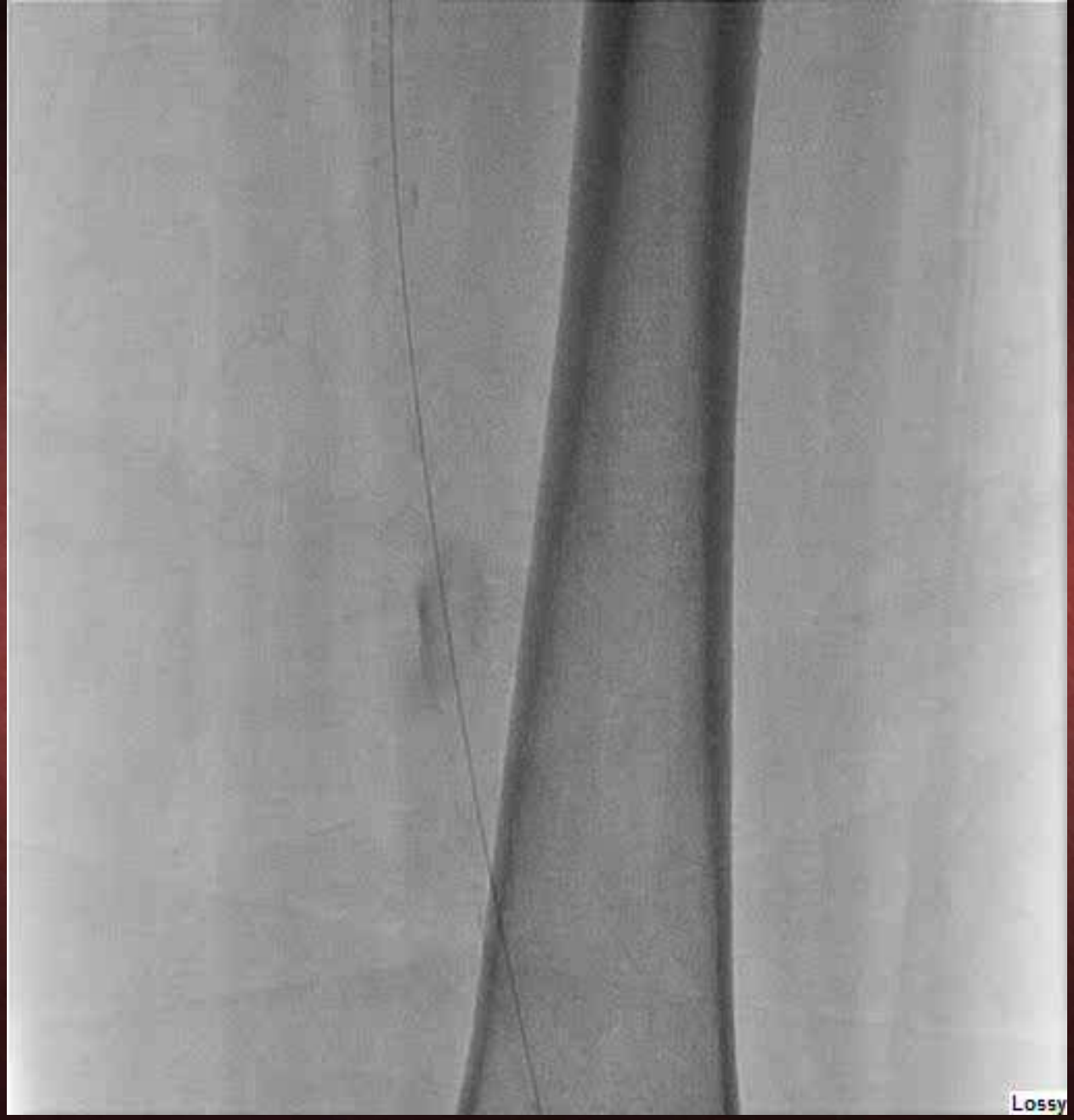
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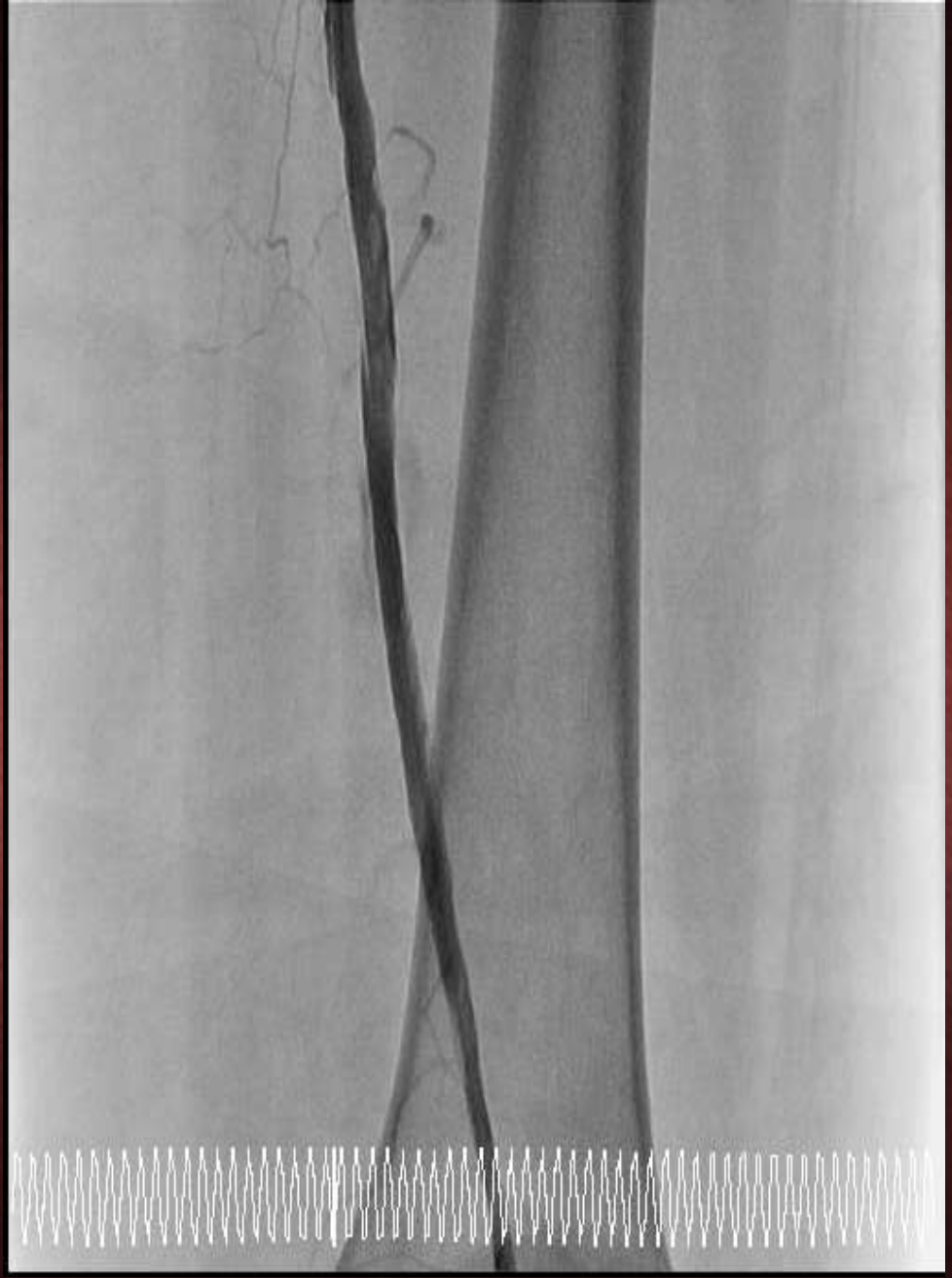

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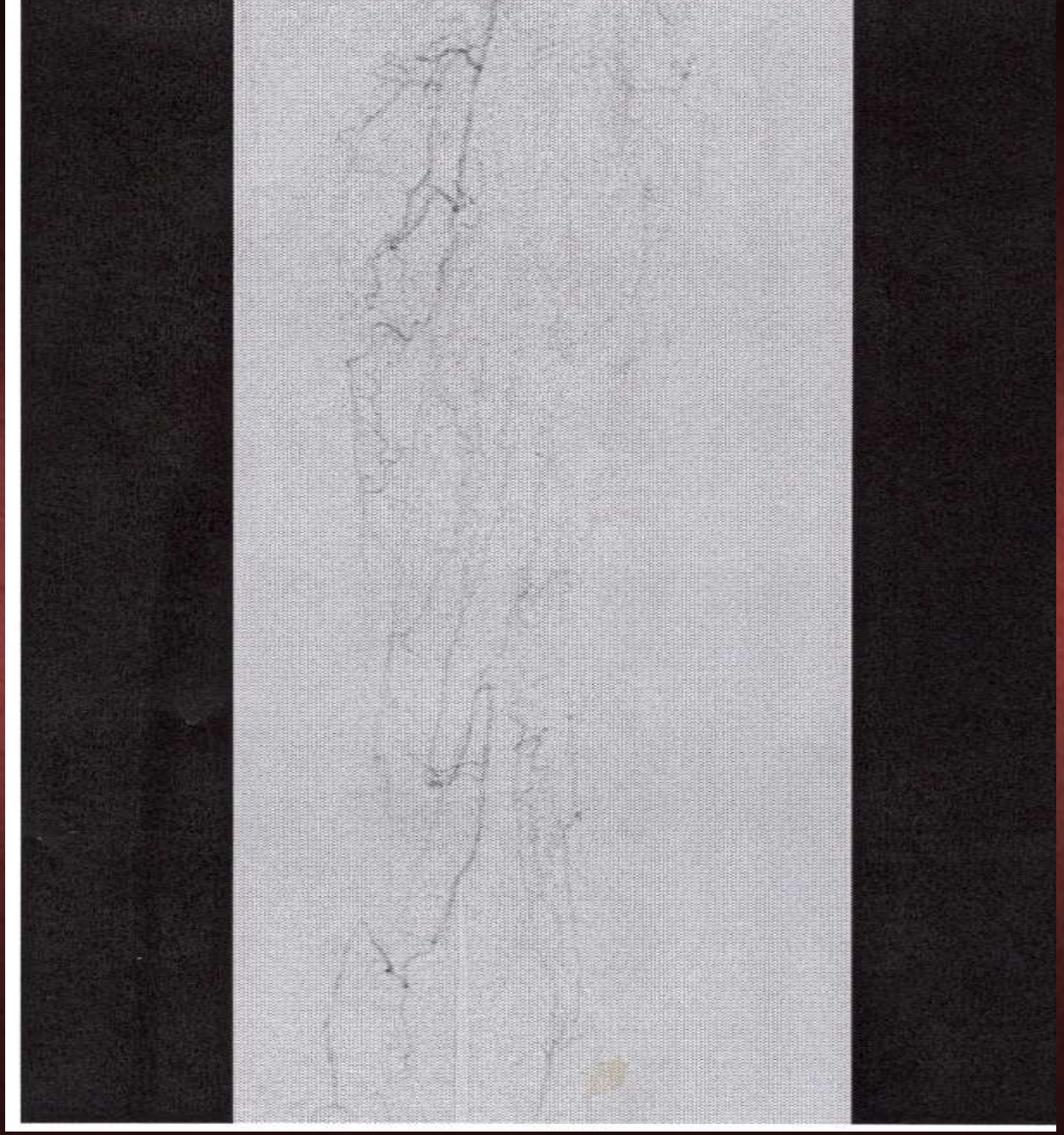
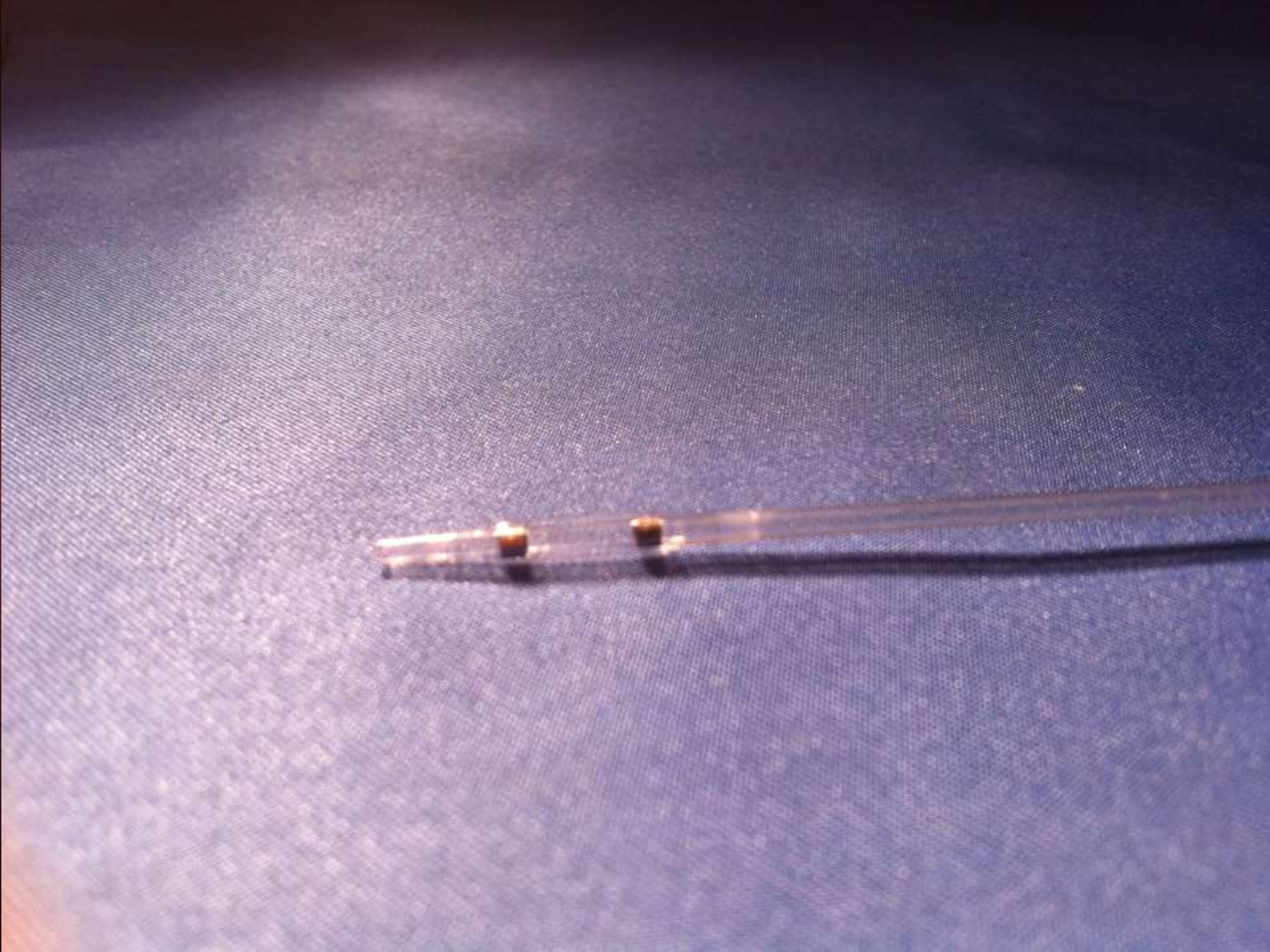
The patient presents with a dorsal foot wound with contemplated amputation





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FemPop Graft Failure: Resurrection with the CrossLock™LP

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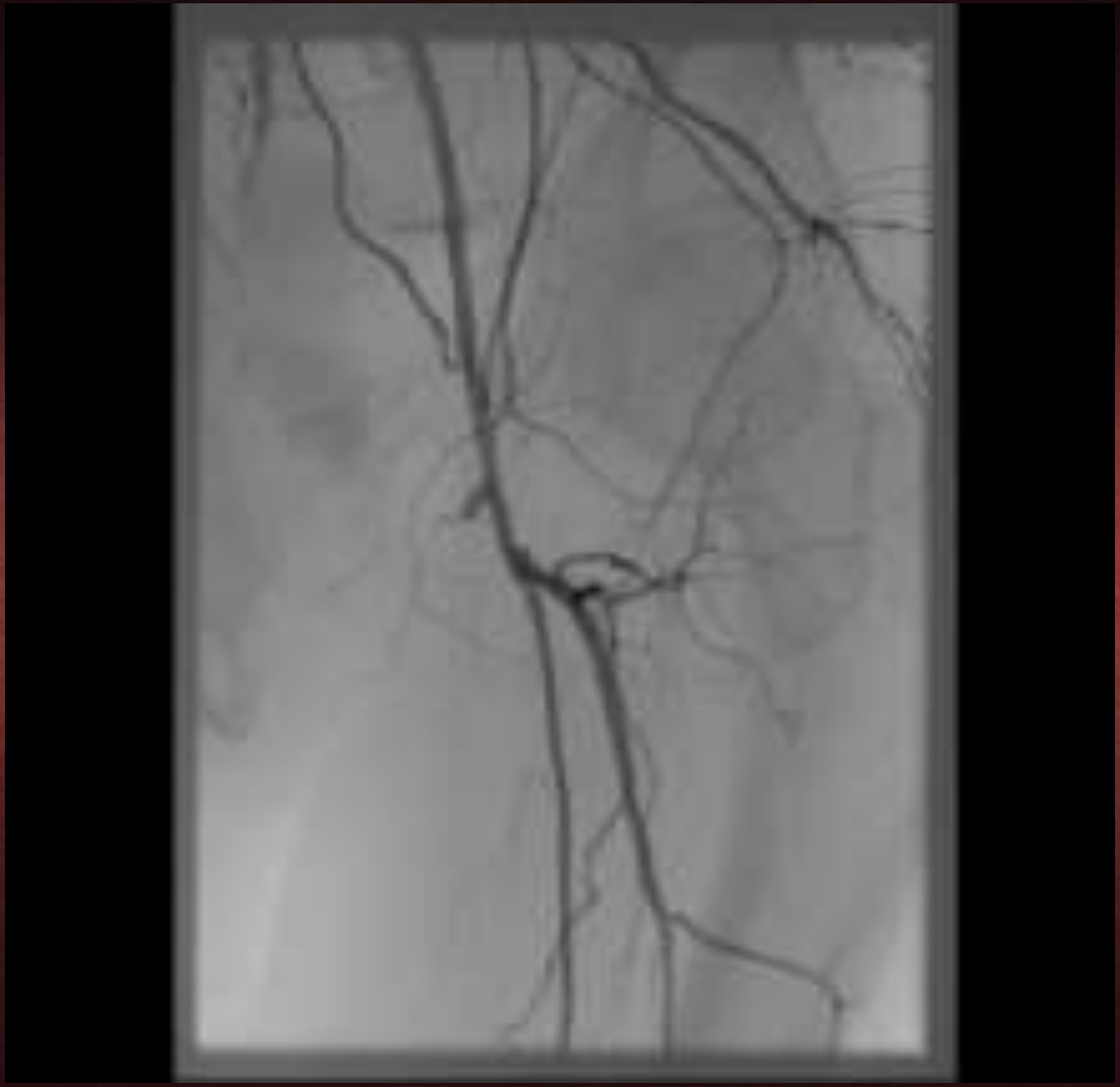
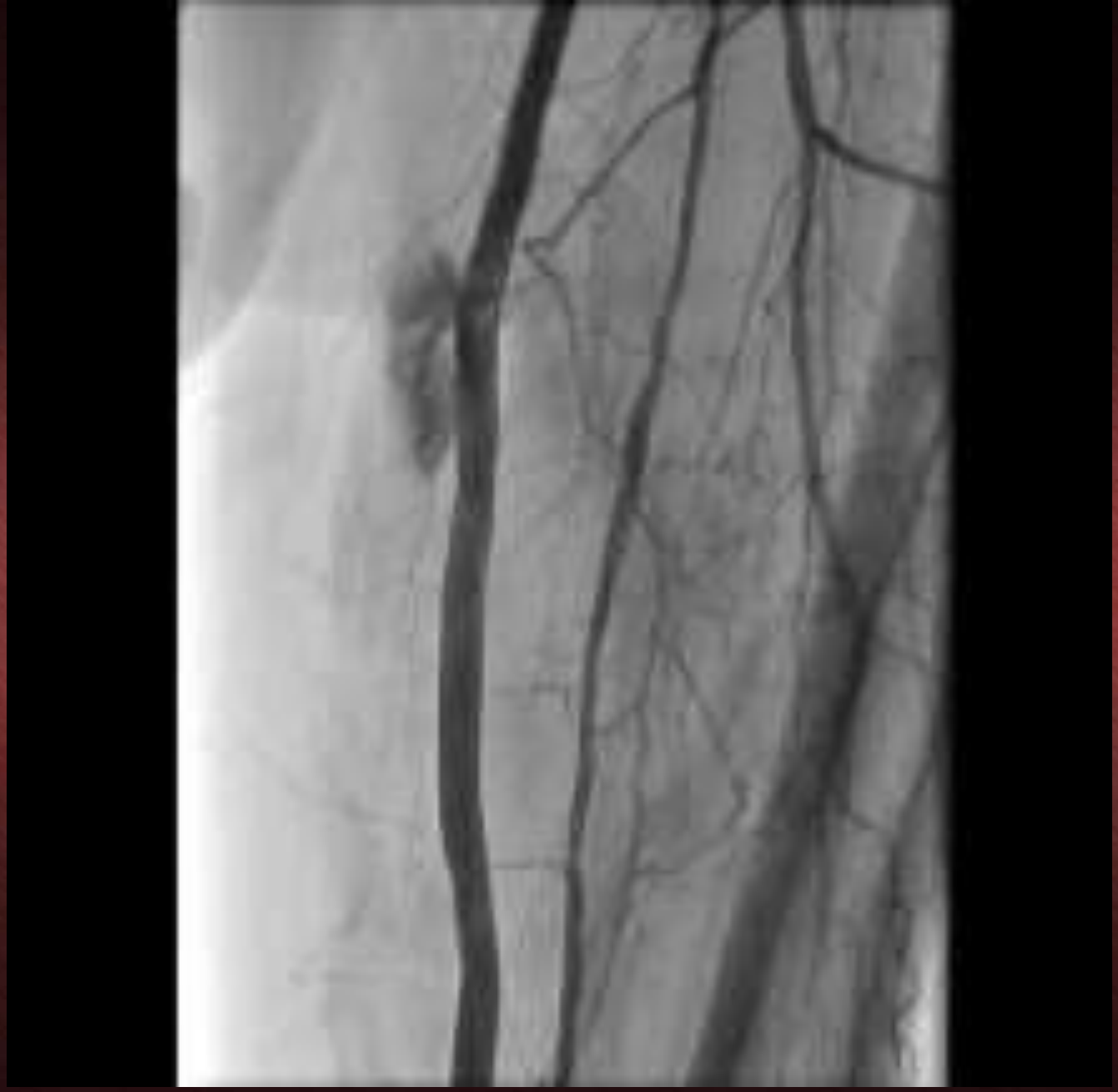
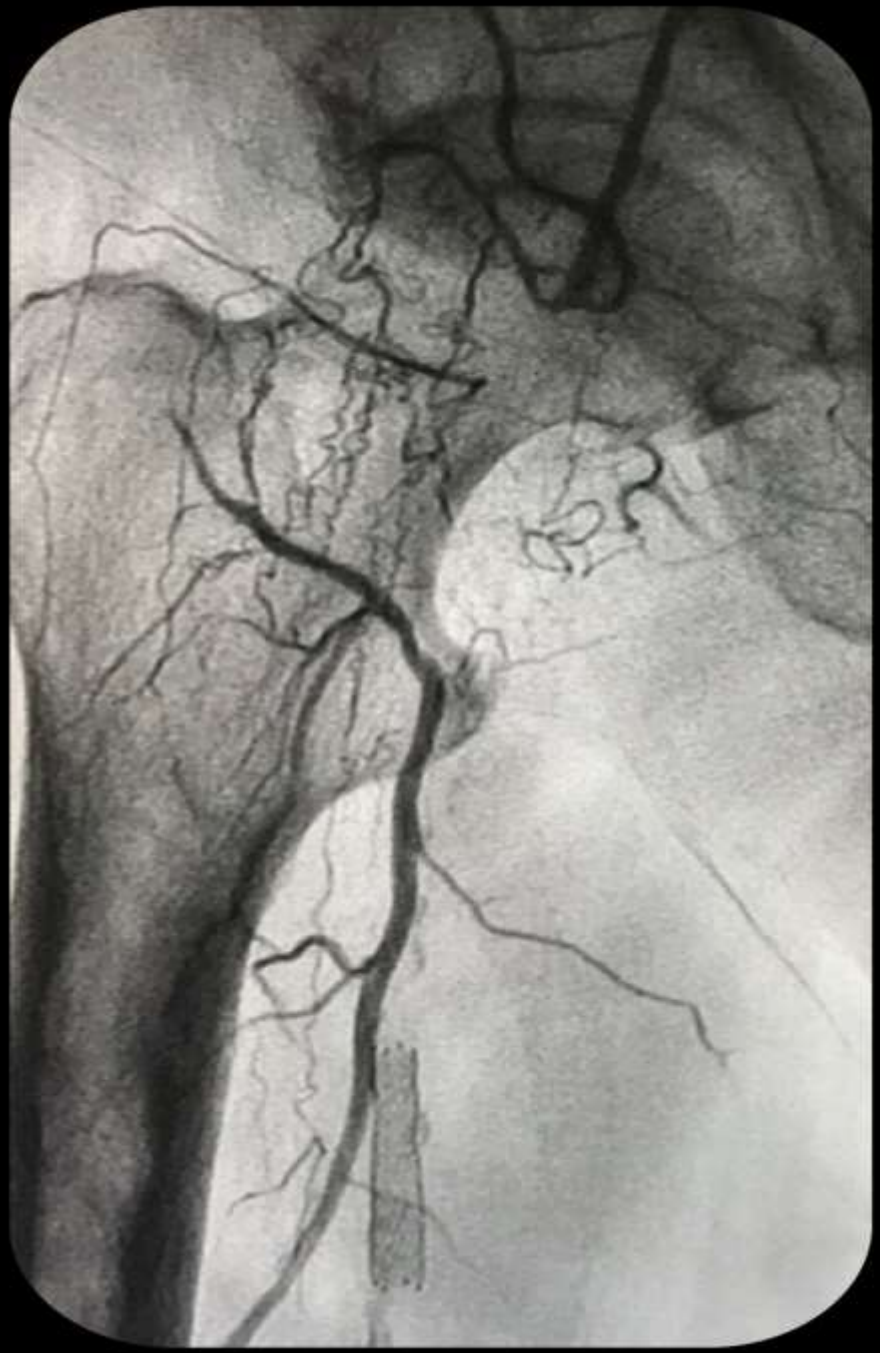
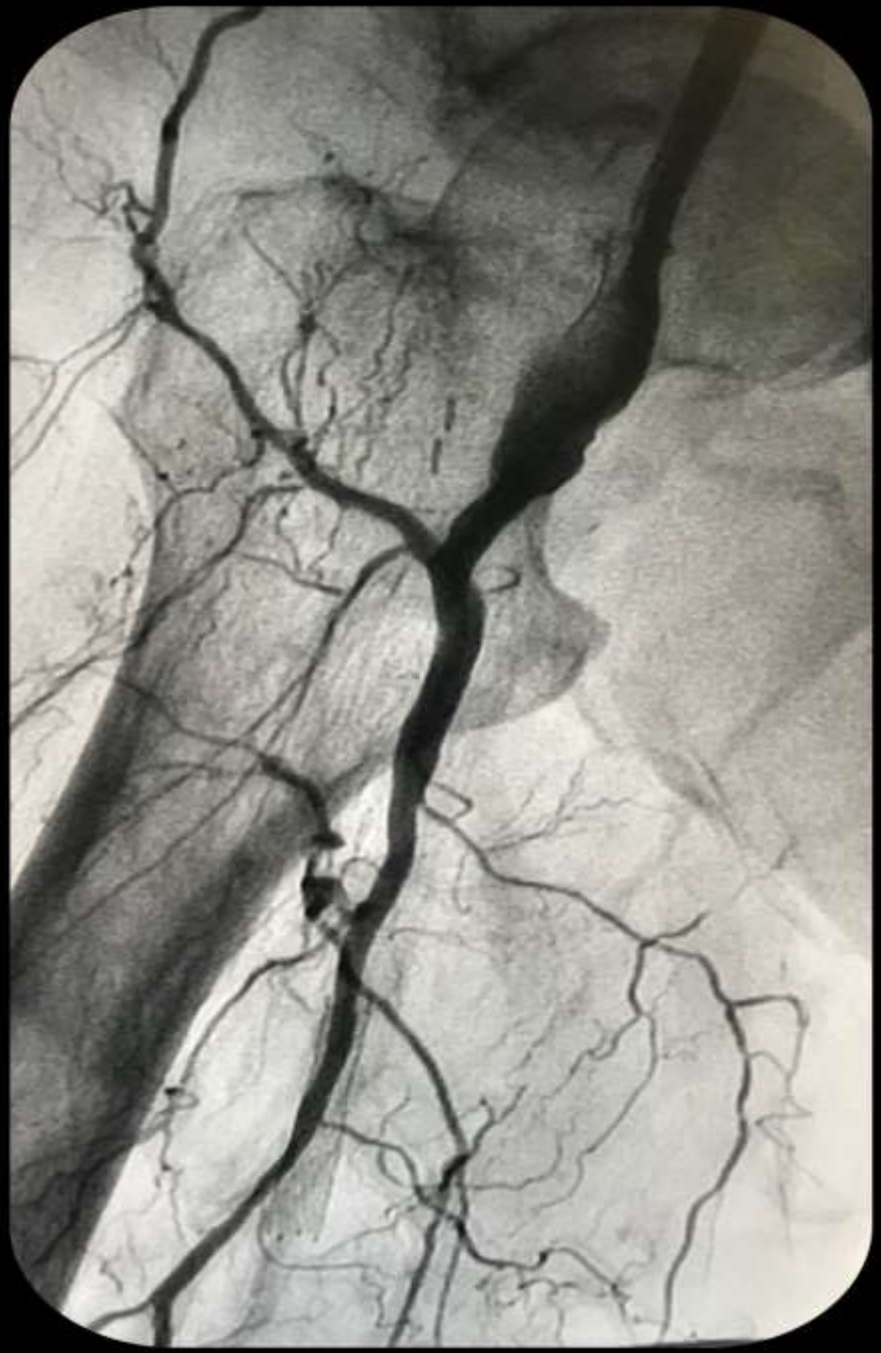
A 63 year old diabetic smoker has undergone 3 separate fem-pop surgery after failed intervention on his left leg. Twelve months prior to his visit, a self-expanding stent was placed in that fem-pop graft, but over the last 7 months, it is known to be occluded, and he has been told that he needs to have his foot amputated. He comes to see us.





A year later, the patient has no symptoms on his left leg, but now has 3 ulcers on his right leg, 2 below the knee and one right on the knee cap



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- 3 months post procedure the patient has no claudication and all 3 ulcers have cleared

A 90 year old woman also had had 3 fem-pop operations that had failed. Five months prior to seeing me, the vessel was known to be occluded and now she has a cold foot and was told by her vascular surgeon she should just go to hospice. She comes to see us.

- The patient had a cold foot prior to the procedure and the best we hoped for was a metatarsal amputation…she saw the orthopedic surgeon 2 hours after the procedure to set up this operation…he called me to tell me the foot was warm and she had posterior tibial and dorsalis pedal pulses and never required any surgery

73 year old female with smoking history. She has had multiple PTA procedures of her left SFA. Finally, 3 years ago, she underwent Fem-Pop grafting of her left leg. Following this procedure, her graft became infected requiring surgical removal of the graft. She presents with exercise limiting claudication.

Fig. 4. Frontrunner catheter with miniature hinged jaws (Image provided courtesy of Cordis, Freemont, CA).

A 64 year old gentleman presents with resting left leg pain. He has had multiple failures of fem-pop bypass on his left leg. Multiple attempts via the right groin wre not successful due to dissection on sheath placement. A radial approach even with the long Terumo sheathless guide is not possible because of equipment length. We decided to approach via the right brachial artery utilizing the Terumo sheathless 119cm catheter.


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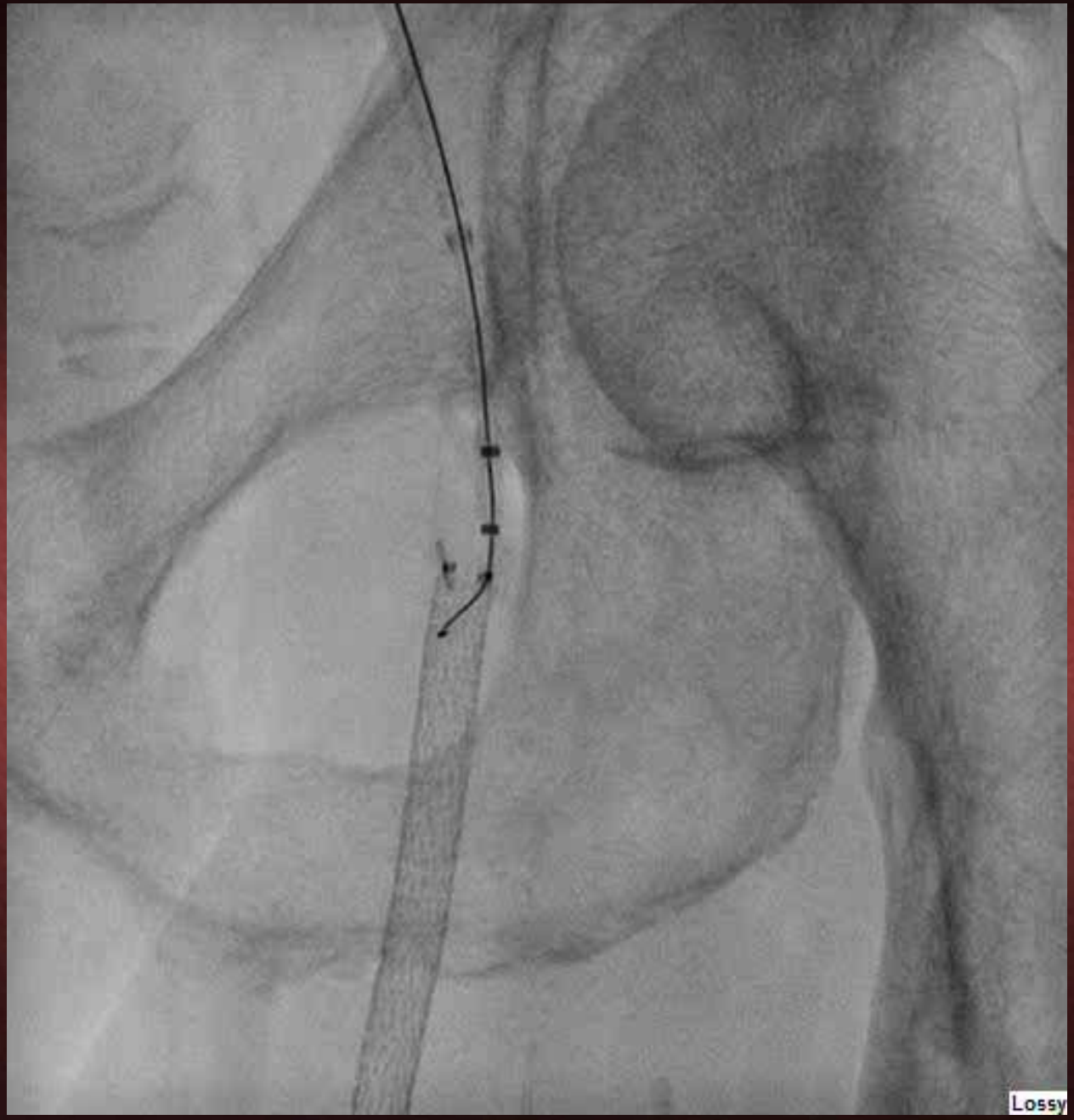
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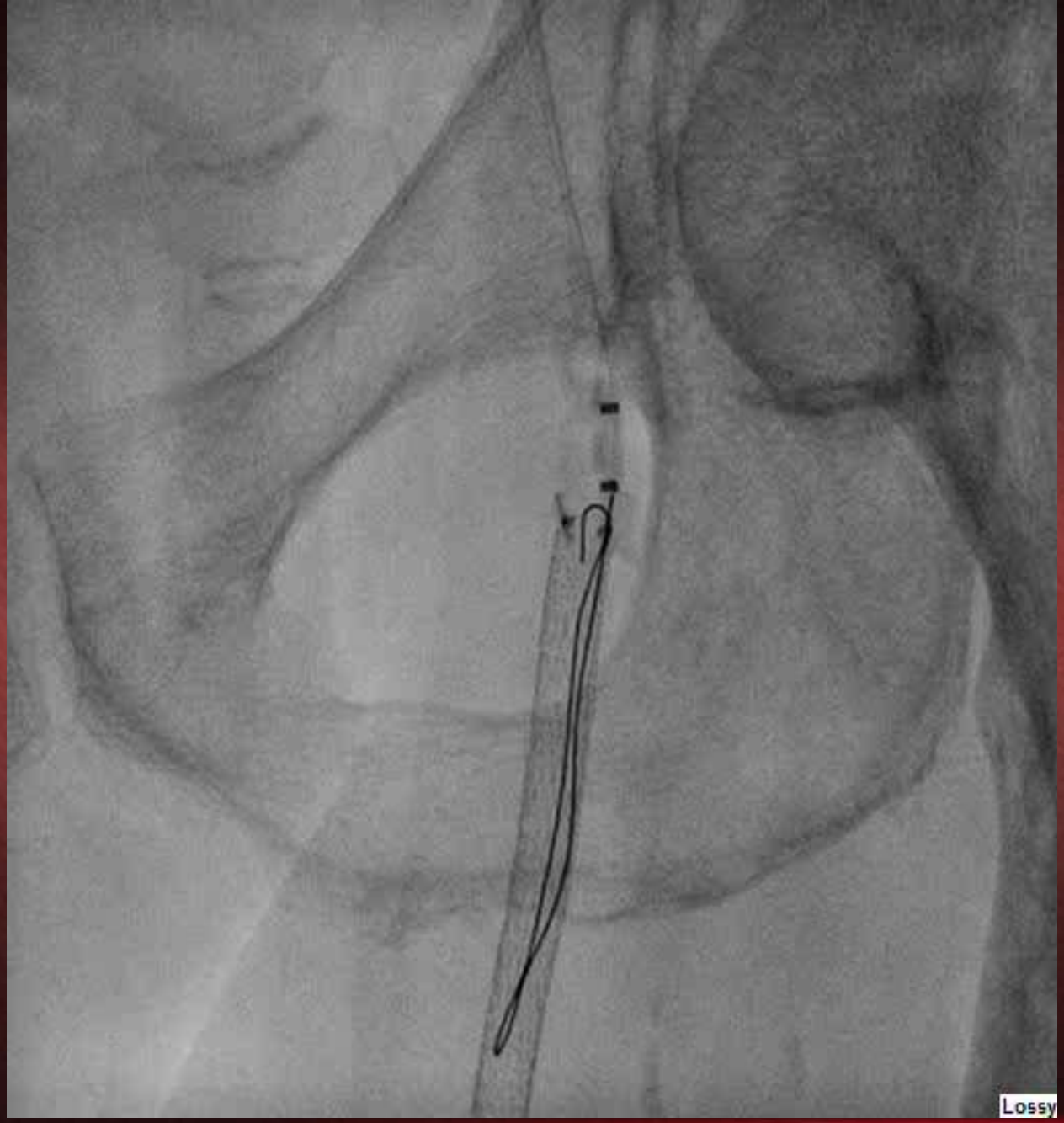
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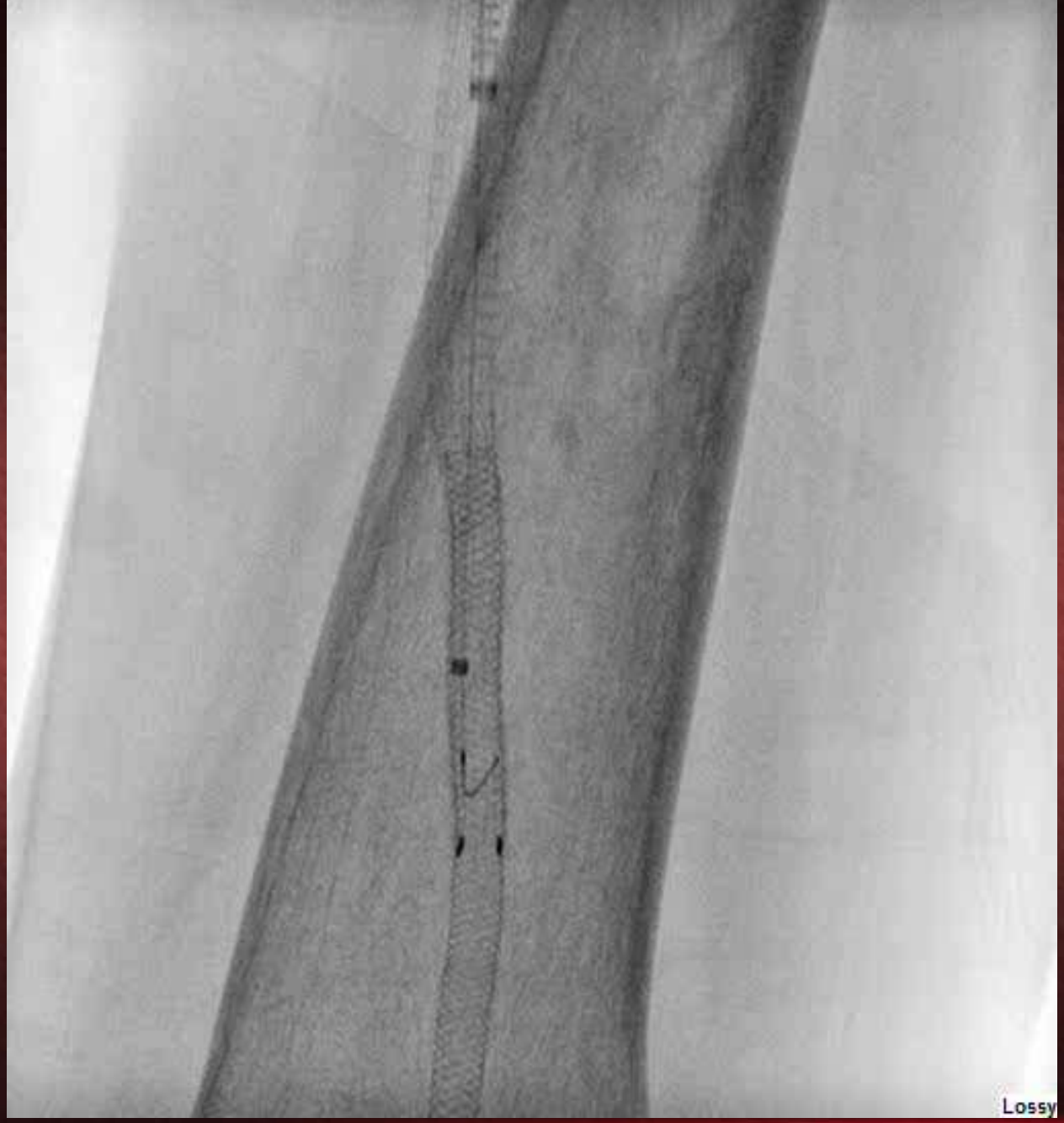
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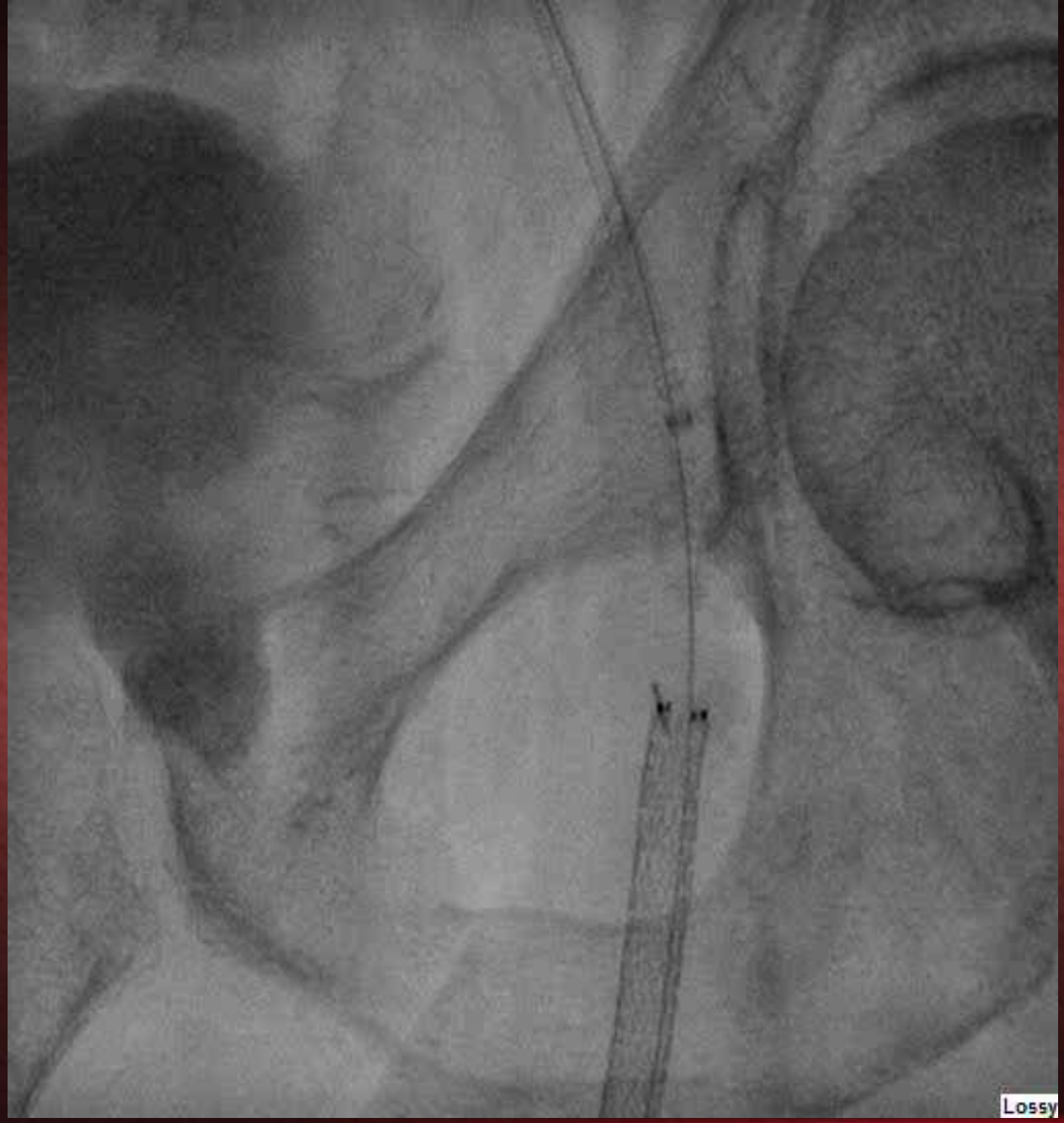
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Conclusion

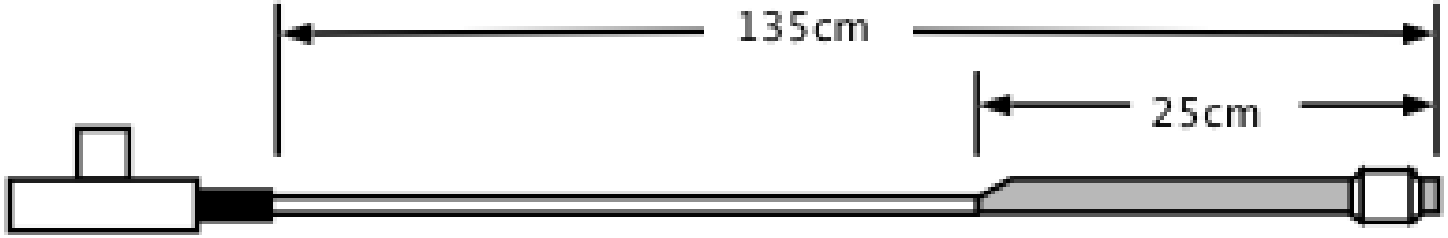
This case would never have been successful without the use of the CrossLock™ as well as the use of the Penumbra device. In the past, this patient would have had to have a long profusion of TPA, but his would have been difficult without the long sheaths and if this was performed via the brachial artery, the patient would have been at risk for forearm ischemia.

The CrossLock™ Device for Extra Support

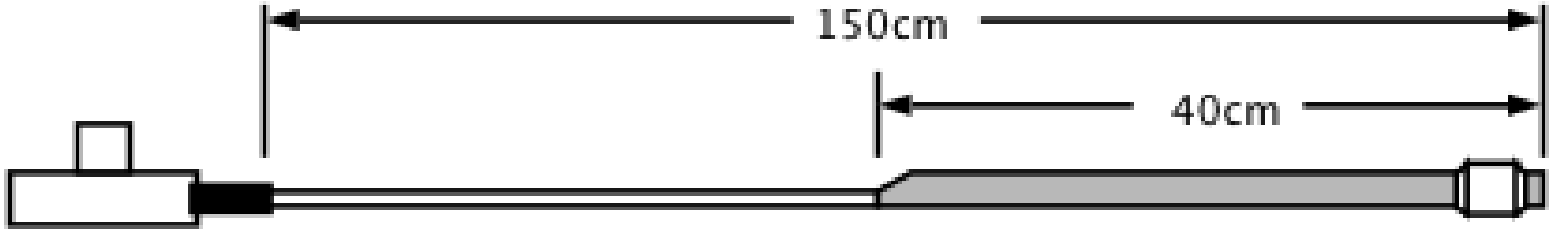
- The CrossLock™ can work with balloons, stents, the FrontRunner™, the Crosser, the Viance, the CrossBoss and the Laser.
- The CrossLock™ centers the lumen into the main vessel

The Centering Support Catheter for Improvement in Antegrade CTO Recanalization: The CrossLock™

- Intuitively obvious
- Does not require the presence of a sales rep
- Not exclusively coronary application
- Can be used in arterial and venous applications



CrossLock



CrossLock XL

CrossLock LP

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Leading the Way With a New Standard of Devices