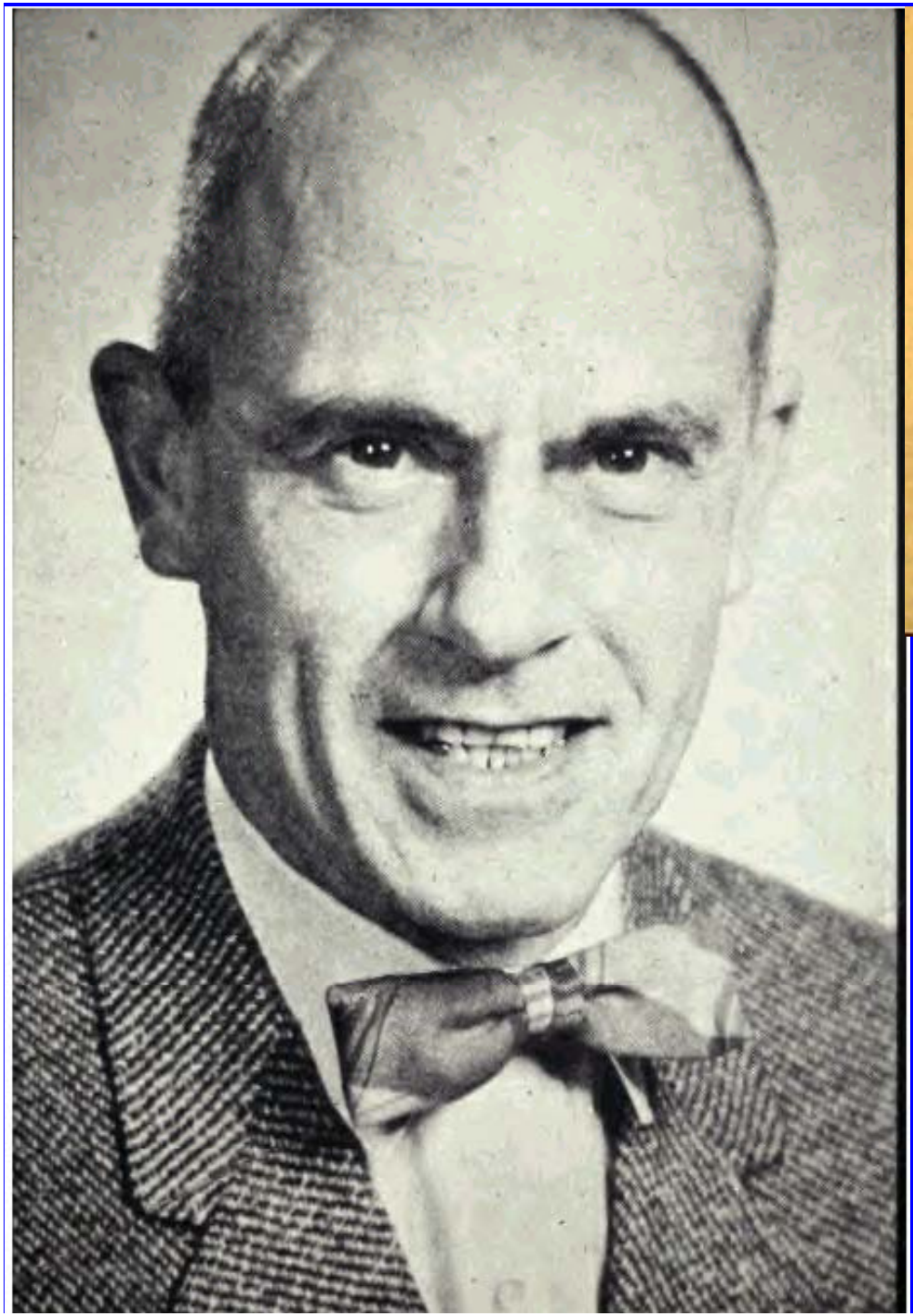
# How to Treat Femoropopliteal Artery Diseases in 2015

Amir Motarjeme, M.D., F.S.I.R



# Transluminal Treatment of Arteriosclerotic Obstruction

## Description of a New Technic and a Preliminary Report of Its Application

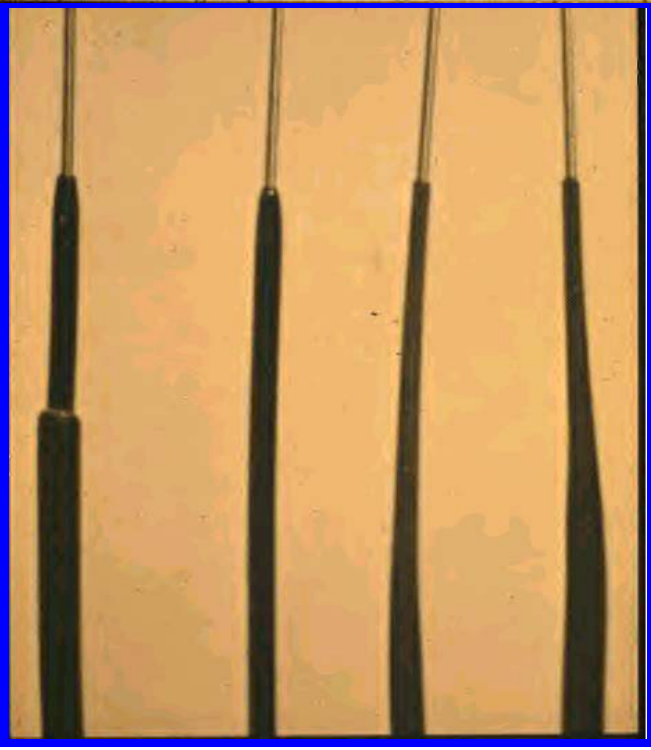
*By* CHARLES T. DOTTER, M.D., AND MELVIN P. JUDKINS, M.D.

DESPITE the frequency and importance of arteriosclerotic obstruction, current methods of therapy leave much to be desired. Nonsurgical measures, however helpful they may be, provide the patient little more than an opportunity to live with his disease. Consistent success in the use of surgical technics such as endarterectomy, angioplasty, and grafting has largely been confined to highly specialized vascular surgeons of whom there are far too few to cope realistically with literally millions of patients suffering the pain-

### Method

#### Procedure

Prior angiographic survey of the abdominal aorta, its iliac branches, and the leg arteries, including those beyond the suspected primary block, is best done by retrograde catheterization of the opposite femoral artery, thus insuring a hematoma-free femoral region on the side to be treated. If an attempt appears indicated, the procedure, including its present experimental status, is fully discussed with the patient and specific permission is obtained. Oral anticoagulant agents are discontinued and barbiturate sedation is given at an appropriate time. Local anesthesia was used



Reprinted from the Journal of the American Medical Association
October 7, 1974 Volume 230


# Transluminal Iliac Artery Dilatation

## Nonsurgical Catheter Treatment of Atheromatous Narrowing

Charles T. Dotter, MD; Josef Rösch, MD; Janice M. Anderson, MD; Ruza Antonovic, MD; Manfred Robinson

**• By means of a reinforced balloon catheter, percutaneous transluminal dilatation was used to treat 48 consecutive cases of atheromatous iliac artery narrowing. With no deaths and little increase in the time and risk of diagnostic arteriography, the procedure was successful in more than 80% of cases, giving immediate luminal enlargement and relief, as judged clinically, for up to six years, the maximum follow-up period. In properly selected patients, this technique should be used in preference to reconstructive vascular surgery.**

**(*JAMA* 230:117-124, 1974)**

INTERMITTENT claudication in legs and buttocks, pain at rest, gangrene of the feet, and sexual impotence are among the clinical manifestations of atherosclerotic iliac artery obstruction. Although supportive therapy and the development of collateral circulation may slow the progress of the disease, the best chance for relief has been through iliac artery surgery. This report describes the technique and gives the results of transluminal iliac artery dilatation, a nonoperative alternative to surgical revascularization in which luminal enlargement is effected by a special balloon catheter percutaneously introduced through the femoral artery.

### Therapeutic Rationale

The rationale of transluminal dilatation is based on the physical and biological properties of the obstructing atheromatous core.[1-3] Unlike hypertrophied muscle or fibrotic scar tissue, the noncellular substance comprising the bulk of the mature atheromatous lesion is capable of retaining an in-situ compression-remodeling that is achieved by forcing the lesion against the surrounding outer arterial wall (Fig 1). Early predictions that forceful catheter dilatation would cause prohibitive plaque dislodgement and thrombosis have not been borne out. Since transluminal dilatation is applicable to atherosclerotic narrowings that can be traversed by a catheter, but not to complete occlusions, an informed decision to use it rests on the arteriographic and clinical assessment of the individual patient.

### METHOD

### Caged-Balloon Catheter Dilator

Percutaneous iliac artery dilatation requires an expansile catheter dilator. Simple balloon catheters are not strong enough to achieve dilatation of most iliac artery stenoses. An early design provided the needed authority by means of a woven fiberglass sheath that encircled the balloon, but because of feared thrombogenicity, it was not used in patients.[4] A similar approach to balloon reinforcement was successfully put to clinical use by Pursmans[5] who expanded a balloon within a short segment of an outer catheter that had been slit longitudinally so as to form a reinforcing cage; in his words, a "Korsett Catheter." Our caged-balloon catheter dilatation system includes a thick-walled balloon mounted on a 60-cm long, 22-gauge metal cannula, terminated by a flexible, curved-tipped wire guide.[6] Insertion of this balloon cannula all the way into a preslit No. 8 French outer catheter automatically positions the balloon within its cage 6 cm from the end of the catheter (Fig 2), beyond which the guide projects another 6 cm.

Fig 1.—Mechanism of transluminal dilatation. Stenotic lumen (left) is enlarged, not by reaming, but by compressing atheromatous core against outer arterial wall (right).

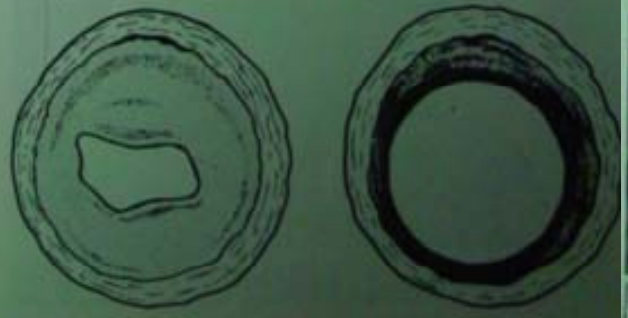
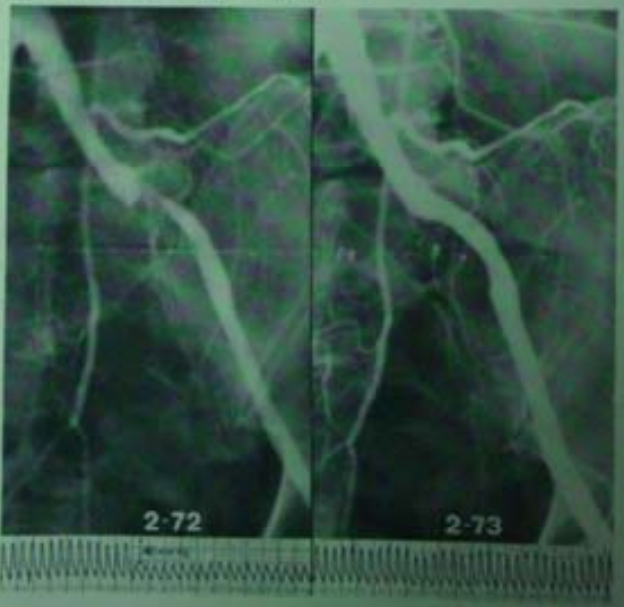


Fig 2.—Caged-balloon dilating catheter. Longitudinal slits in No. 8 French outer catheter (top) form a cage around expanded balloon (bottom), providing needed reinforcement and permitting up to threefold increase in diameter (3 to 9.3 mm, outside diameter).

Fig 3.—Common iliac stenosis, before (left) and a year after (right) percutaneous dilatation in 65-year-old man. Good luminal restoration with abolition of pressure gradient. Despite presence of complete superficial femoral artery occlusion, iliac artery dilatation was followed by complete relief of severe claudication and healing gangrenous toe. Records of pull-out pressure (below respective arteriograms) show disappearance of pressure gradient after dilatation.




### Procedure

The procedure is done under local anesthesia in the manner of retrograde diagnostic femoral catheterization. Up-to-the-minute control arteriograms are useful in planning. These can be obtained by a separate diagnostic catheter inserted through a patent opposite femoral or axillary artery, with the advantage that fluoroscopic contrast visualization can be used to facilitate the ensuing retrograde catheterization of the stenotic artery. Alternatively, control arteriography can be done through the symptomatic side, an approach requiring only one needle puncture, but calling for greater experience.

To begin the actual dilatation, a standard wire guide introduced into the femoral artery is gently manipulated upwards so as to traverse the stenosis. A small (No. 5 6 French) conventional polyethylene catheter passed over the guide can be used to measure the pressure gradient and, if not already done, to obtain a control arteriogram. It is crucial that the stenosis be negotiated without force, lest subatheromatous penetration result. Efforts to measure pull-out pressures are not made because of the risk of losing a transstenotic pathway gained with difficulty.

Next, following the prophylactic intra-arterial injection of 3,000 units of heparin sodium, the diagnostic catheter is exchanged over the guide for the No. 8 F cage-catheter. A thin sheath of polyester film placed around the cage keeps it closed during insertion and is then slipped back out of

From the Department of Diagnostic Radiology, University of Oregon Medical School, Portland.
Reprint requests to 3181 SW Sam Jackson Park Rd, Portland, OR 97201 (Dr. Dotter).

*Medical Staff Information Bulletin*

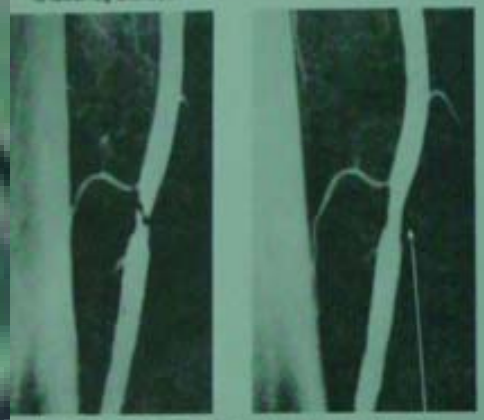
ST. ANNE'S HOSPITAL

4950 W. THOMAS STREET • CHICAGO, ILLINOIS 60651 • (AREA CODE 312) 378-7100

October, 1978

# St. Anne's First Chicago Hospital To Perform New "Balloon Catheter Procedure"

X-Ray shows right femoral artery prior to balloon catheterization treatment. Arrow points to plaque deposit obstruction narrowing the vessel to 2 mm and severely restricting circulation to lower leg and foot.



After balloon dilatation, plaque has been pressed into arterial wall and lumen has been widened to 5 mm at point of treatment. Blood flow has been increased to the extremity.

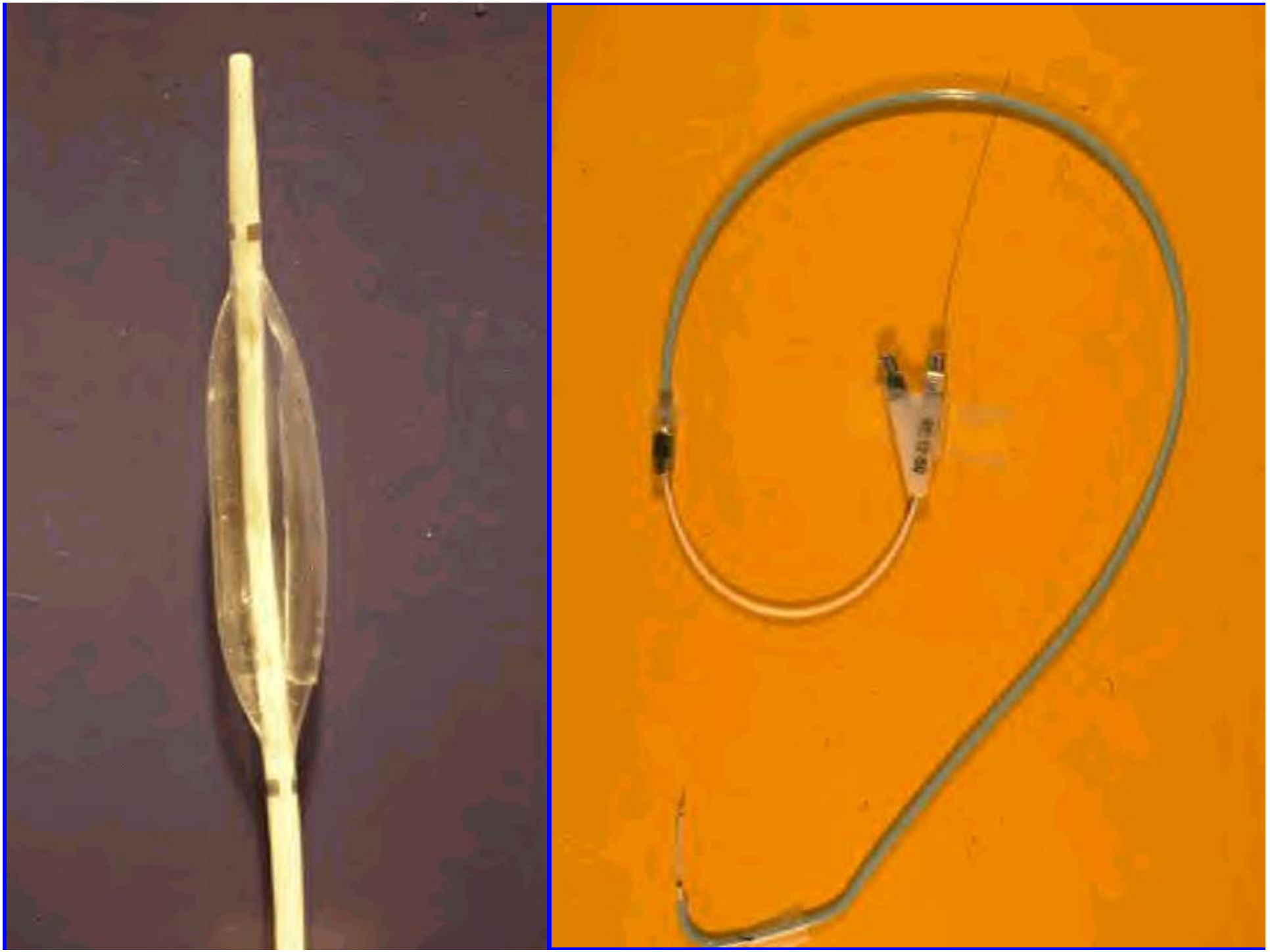
…mir Motarjeme, M.D., Chairman of the Department of …diology, successfully performed a percutaneous trans…inal arterial angioplasty of the right superficial femoral …ry on September 14, 1978 in St. Anne's Radiology …partment. It was the first time the procedure had been …e in the Chicago area, although much national publicity …been given to a similar procedure performed on coronary …eries at New York's Lenox Hill Hospital this past June.

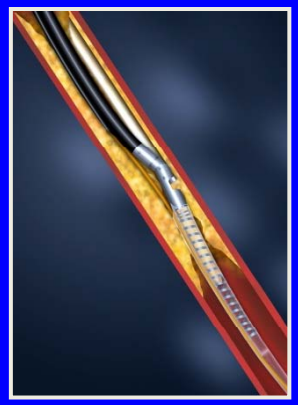
…r. Motarjeme accomplished the catheter dilatation treat…nt on Mrs. Ruth O'Grady, 73, a patient of Chester J. …uszka, M.D. with Paul Naffah, M.D. consulting. Mrs. …Grady's right femoral artery was 75% blocked by a plaque …ulting in severely restricted circulation to the extremity. …e patient complained of a cold right foot and a painful large …er of the right ankle.

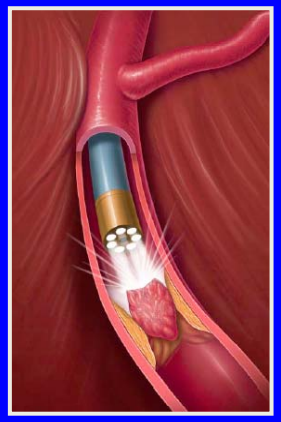
…s consultation, the three physicians determined on two …urses of action: either to attempt surgical arterial bypass or …empt a radiologic procedure of inserting a balloon catheter down the femoral artery to the point of blockage and inflating the balloon, thus pressing the plaque into the arterial wall. The latter course of action was decided upon and Dr. Motarjeme, in a 45 minute procedure, successfully dilated the artery from 2 mm to 5 mm in diameter increasing blood flow substantially to the lower leg and foot. The patient left St. Anne's Hospital on Friday, September 22, but Dr. Motarjeme reports a balloon catheter patient should be able to return home in 24 hours barring unforeseen complications. Mrs. O'Grady remained longer for observation of the dilatation and for treatment of her ulcerated ankle.

Radiologist Charles Dotter, M.D. of the University of Oregon, first introduced the idea of using a dilating catheter in angiography in 1963. Subsequently he reported successful dilatation of the stenotic arteries in many cases. In 1964 Dr. Dotter and an associate, Melvin Judkins, M.D., saved a leg destined for amputation by using the dilating catheter to overcome arteriosclerotic narrowing in the femoral artery, a case similar to, but more severe than, the O'Grady case. In fact, Dr. Dotter reported in one of his articles that 9 patients with 11 involved extremities had undergone transluminal therapy for arteriosclerotic ischemia of the leg. There were no deaths and 6 avoided amputations.

The procedure entailed administering a local anesthetic to the patient and inserting an angiographic catheter into the femoral artery. After injection of the Heparin the catheter is exchanged and a balloon catheter is inserted. The catheter is advanced until it passes the blockage area. The balloon is inflated pressing the plaque into the arterial wall and actually widening the arterial lumen. Experience in using this technique shows that the chance of dislodgement of plaque fragments and possibly causing embolization, is almost non-existent. Dr. Dotter suggests use of dilatation in many small and medium sized arteries and coronary vessels. Research at the University of Oregon found that the best candidate had a segmental superficial femoral artery occlusion with at least some portion of the popliteal artery and its branches open. Finally there appears to be few or no adverse effects from the procedure and serious bypass surgery can often be avoided. The chance for post-operative trauma, infection, circulatory complications and shock are reduced or limited. Recuperative time and hospital stay time are shorter and the total cost is approximately 10% that of by-pass surgery.







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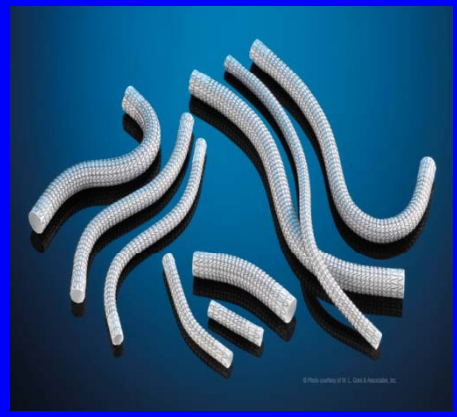

1974

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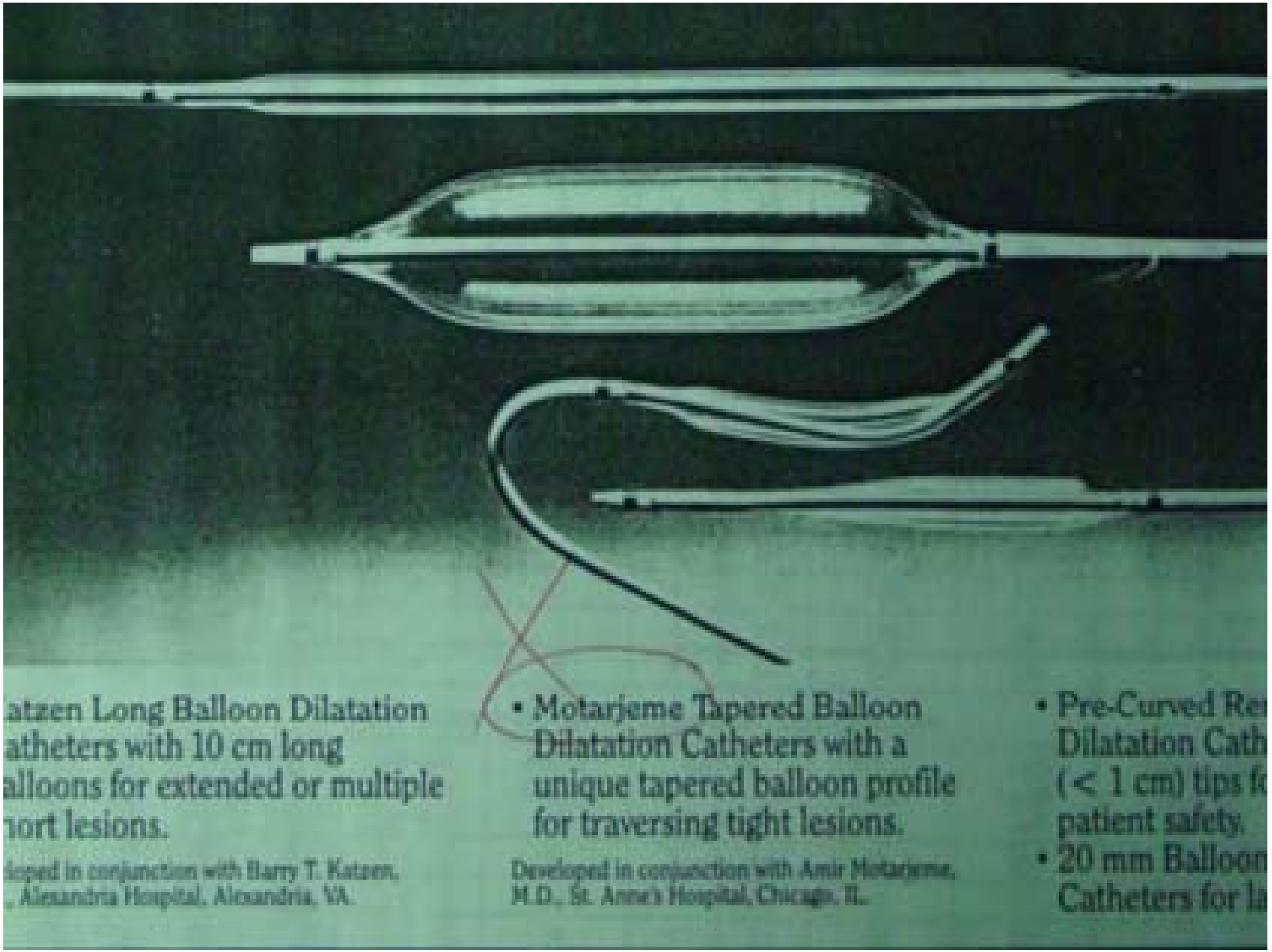


atzen Long Balloon Dilatation
atheters with 10 cm long
alloons for extended or multiple
ort lesions.

loped in conjunction with Barry T. Katzen,
, Alexandria Hospital, Alexandria, VA.

- Motarjeme Tapered Balloon Dilatation Catheters with a unique tapered balloon profile for traversing tight lesions.

Developed in conjunction with Amir Motarjeme, M.D., St. Anne's Hospital, Chicago, IL.

- Pre-Curved Re
Dilatation Cath
(< 1 cm) tips f
patient safety.
- 20 mm Balloon
Catheters for la

# Routine stent implantation vs. percutaneous transluminal angioplasty in femoropopliteal artery disease: a meta-analysis of randomized controlled trials.

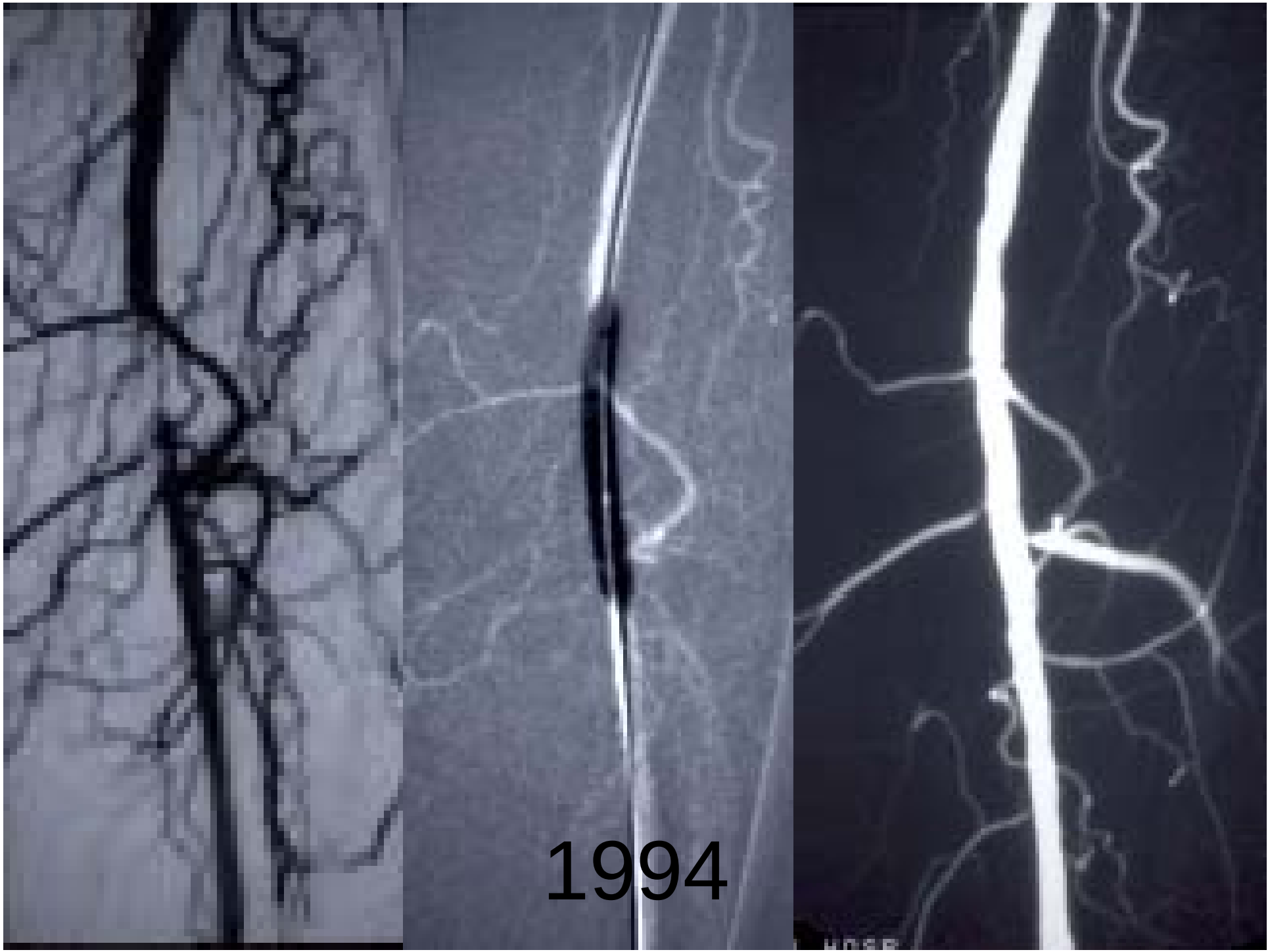
Kasapis C,Henke PK, Chetcuti SJ, Koenig GC, Rectenwald JE, Krishnamurthy VN, Grossman PM, Gurm HS.

# Ten Randomized trials
# 9-24 months follow-up

- Stents 724 Limbs
- Mean Lesion Length 45.8 mm.
- PTA with Provisional stenting 718 Limbs
- Mean Lesion Length 43.3 mm.

# Conclusion

Despite the higher immediate success, routine stenting was not associated with a significant reduction in the rate of restenosis or TVR. Our data do not support use of stenting as the primary endovascular treatment for short SFPA lesions.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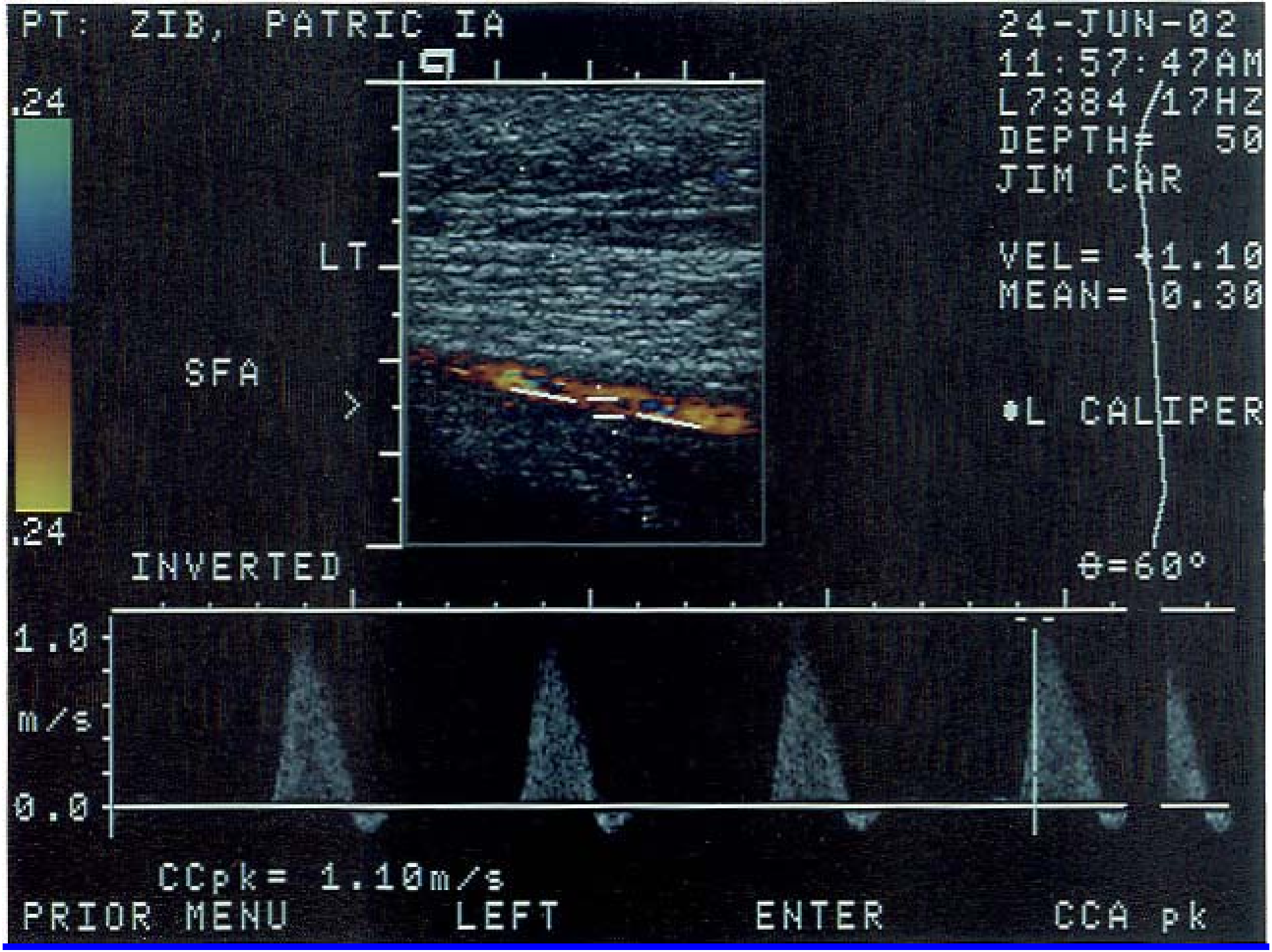
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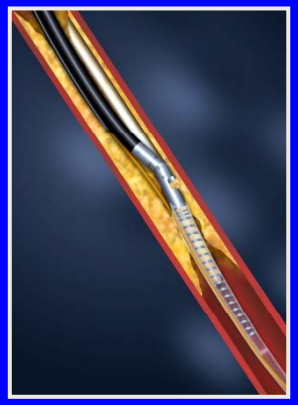
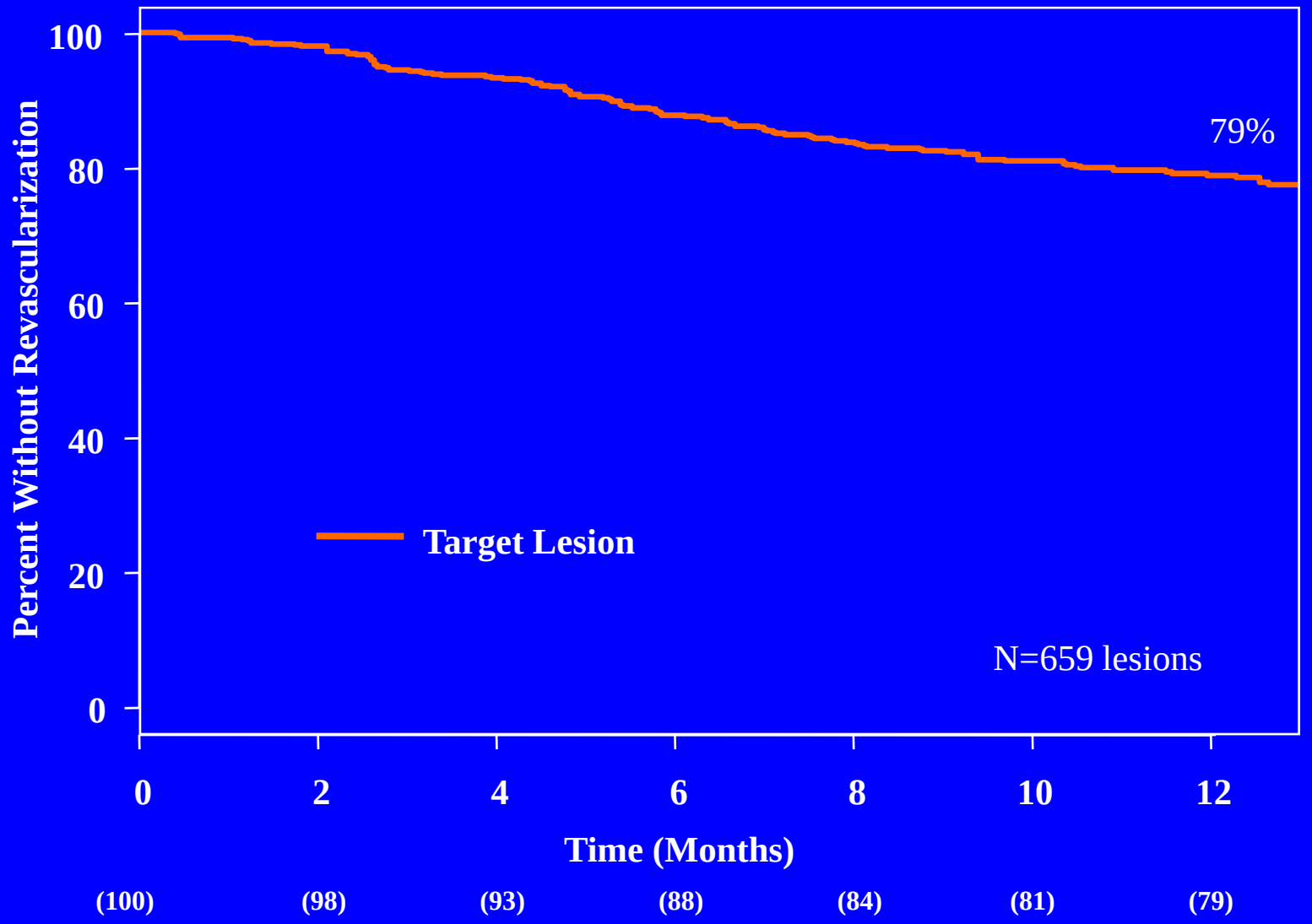


1985-
2003

PAD

# SilverHawk device

# 12-month Freedom From Target Lesion Revascularization



# DEFINITIVE LE Conclusions

- Largest independently-adjudicated study of peripheral atherectomy performed to date
- Directional atherectomy is safe & effective at 12 month

  -Effective for short, medium and long lesions in claudicants & CLI patients

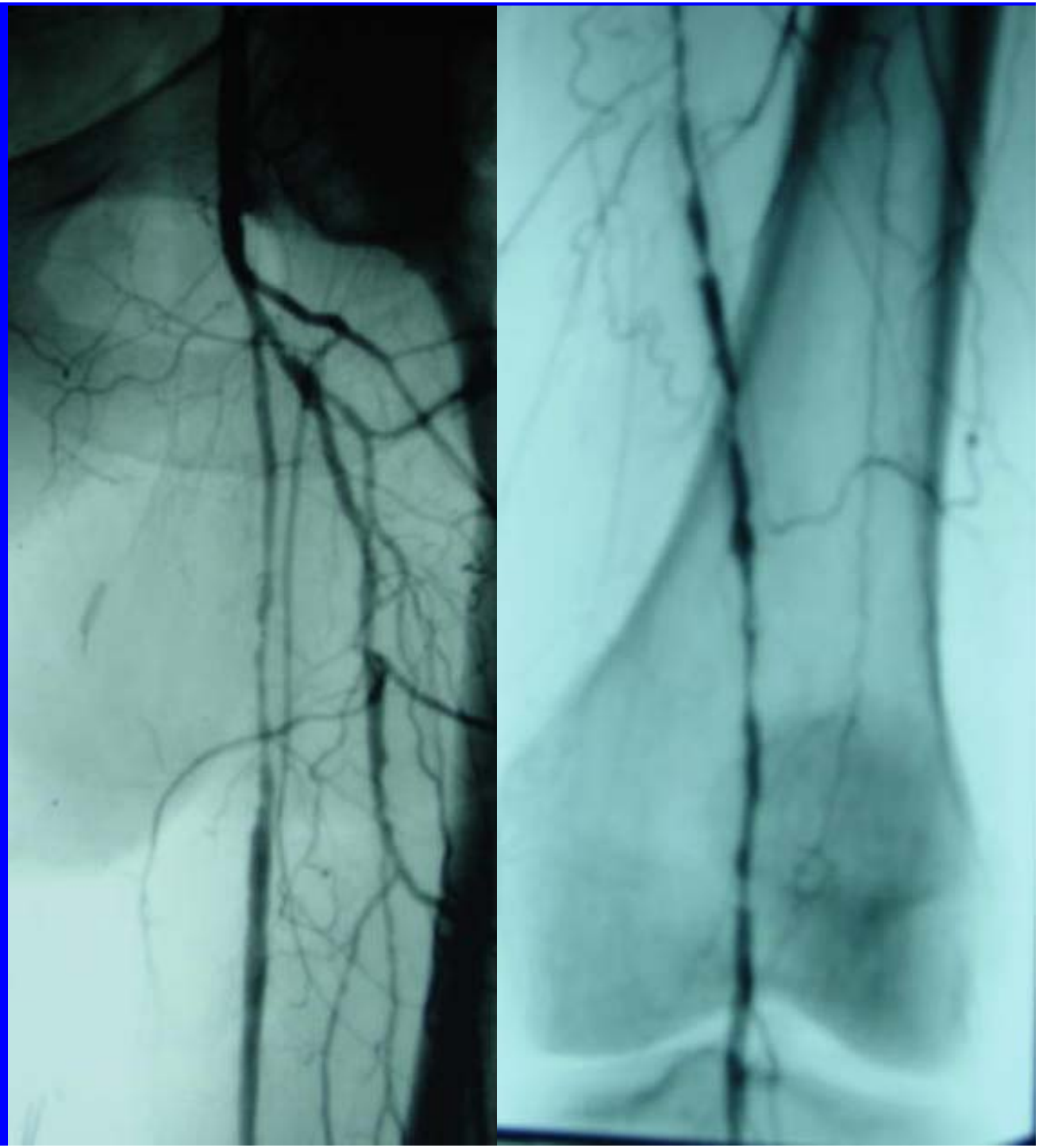
  -83% Patency in SFA (4-10cm) in claudicant patients

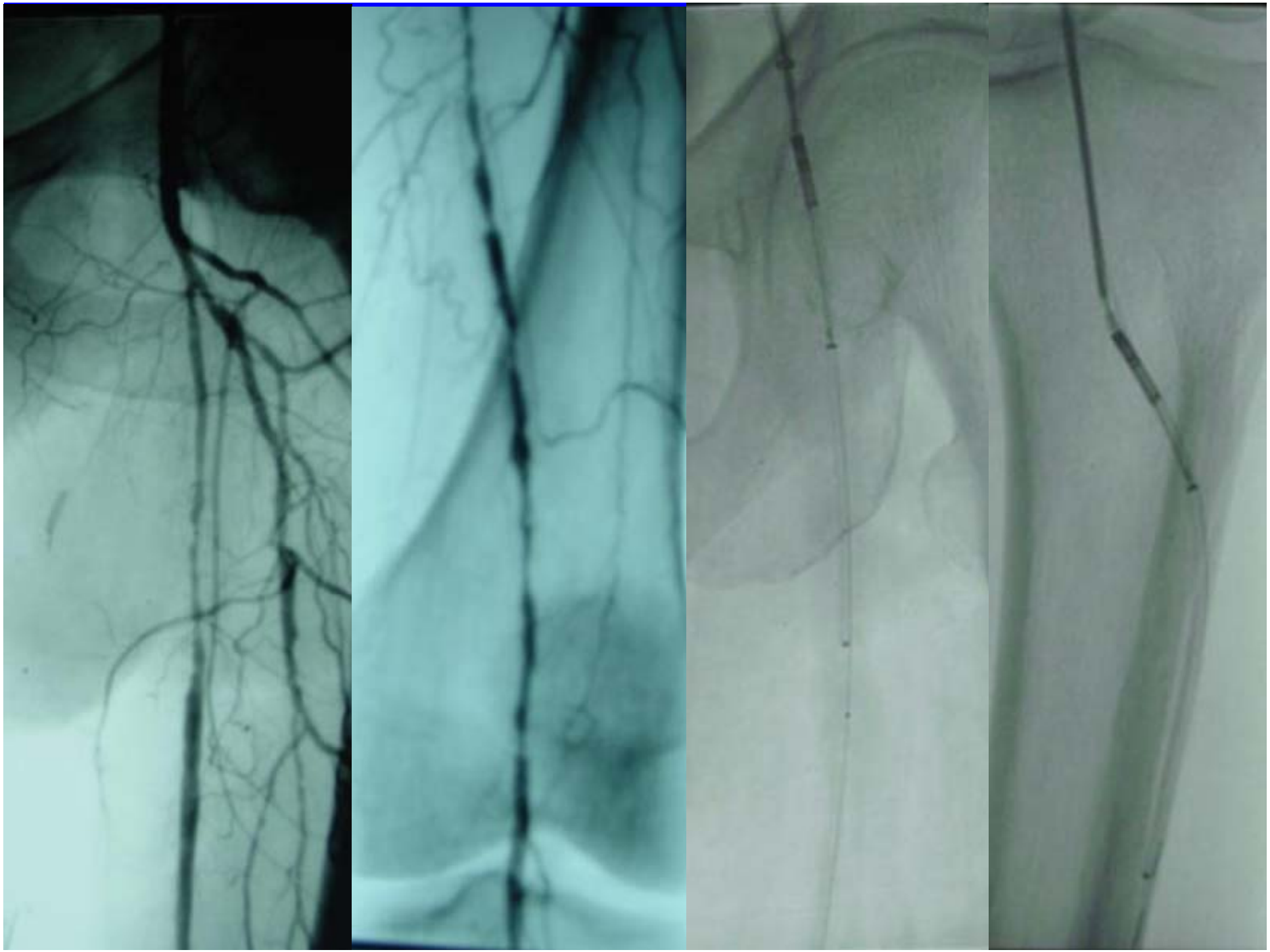
  -78% Patency in Infra-popliteal (6.0cm) in CLI patients

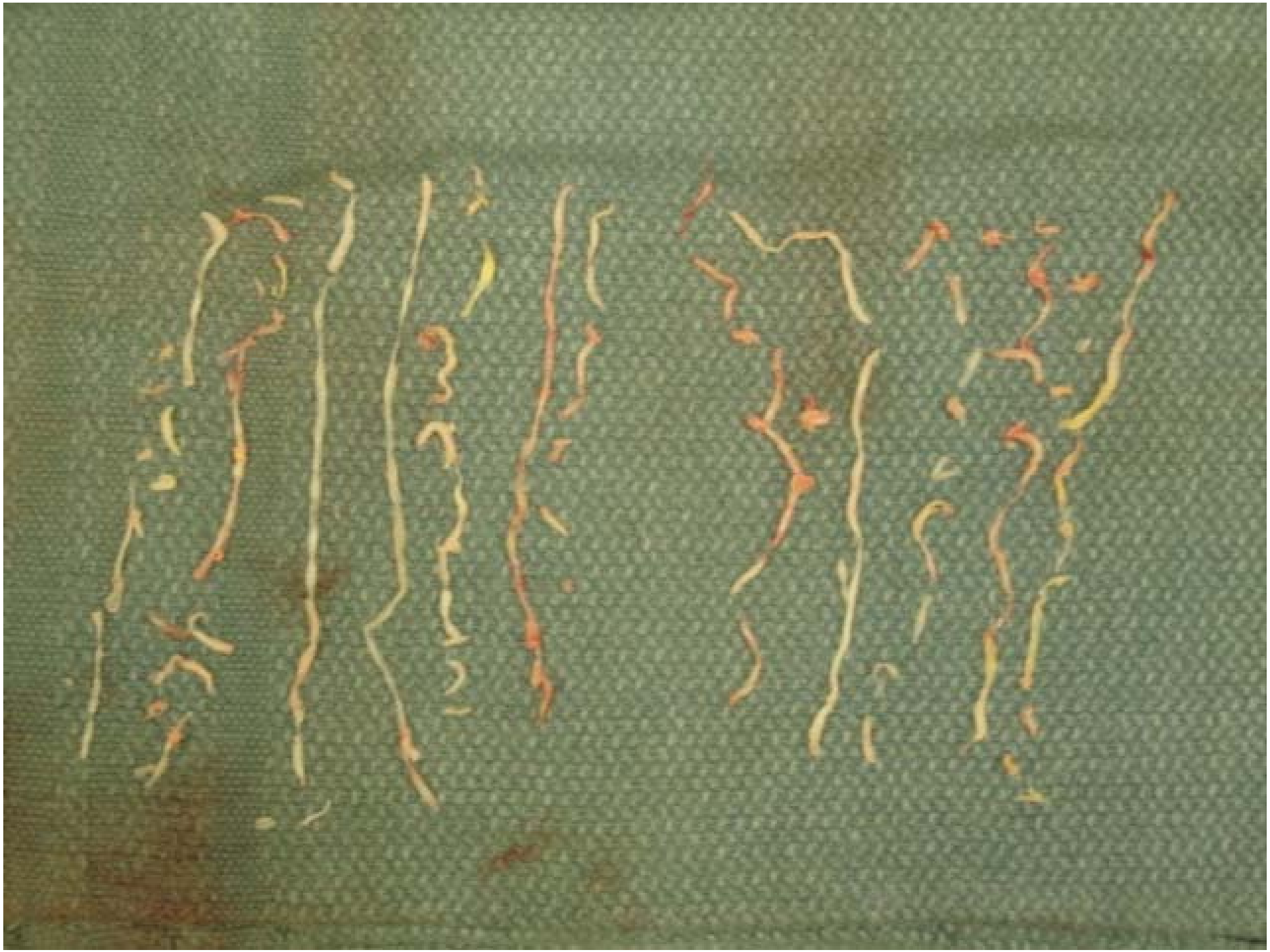
  -95% Limb Salvage in CLI patients

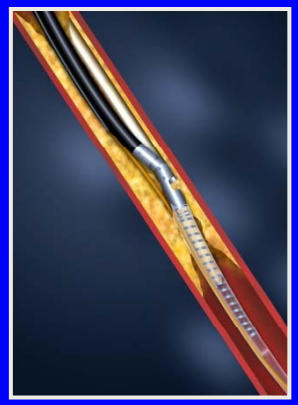
  -Distal embolization requiring intervention rate of 1.6% independently adjudicated is low and proves safety of SilverHawk for the treatment of infra-inguinal arterial disease. Further, all complication rate needing treatment is 7.6%.
- **Diabetics perform equally well when treated with directional atherectomy to non-diabetics for claudicants**

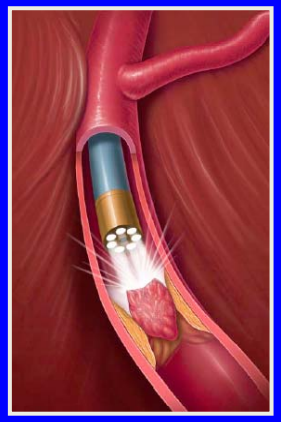
- 67 y/o diabetic woman
- with CLI, ischemic
- ulcer of the right
- foot.











1987

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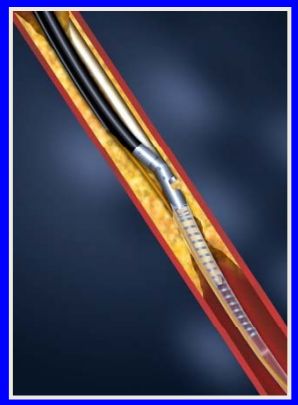
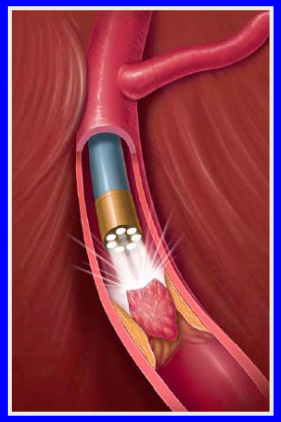




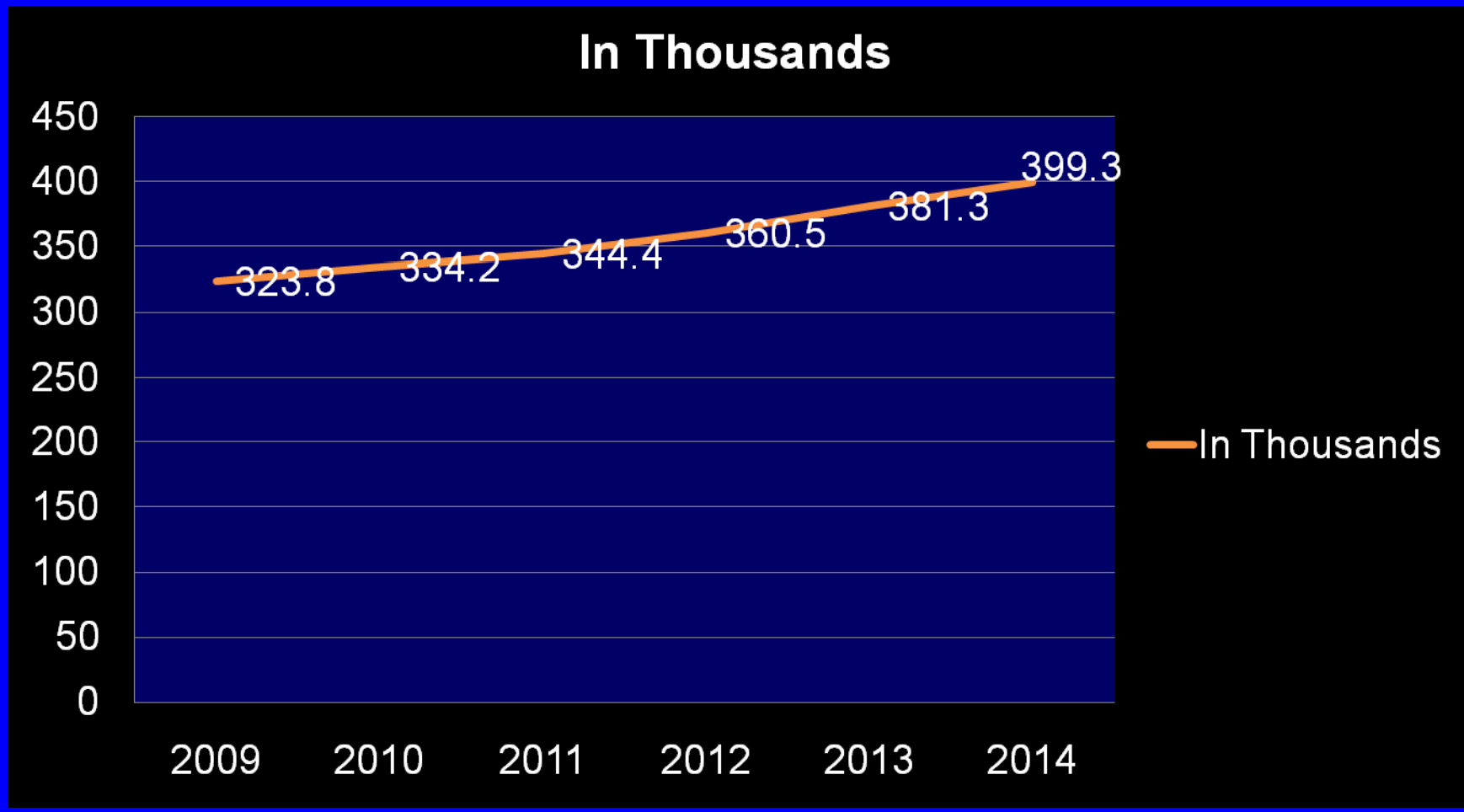
PAD

# Lower Extremity Arterial Stenting

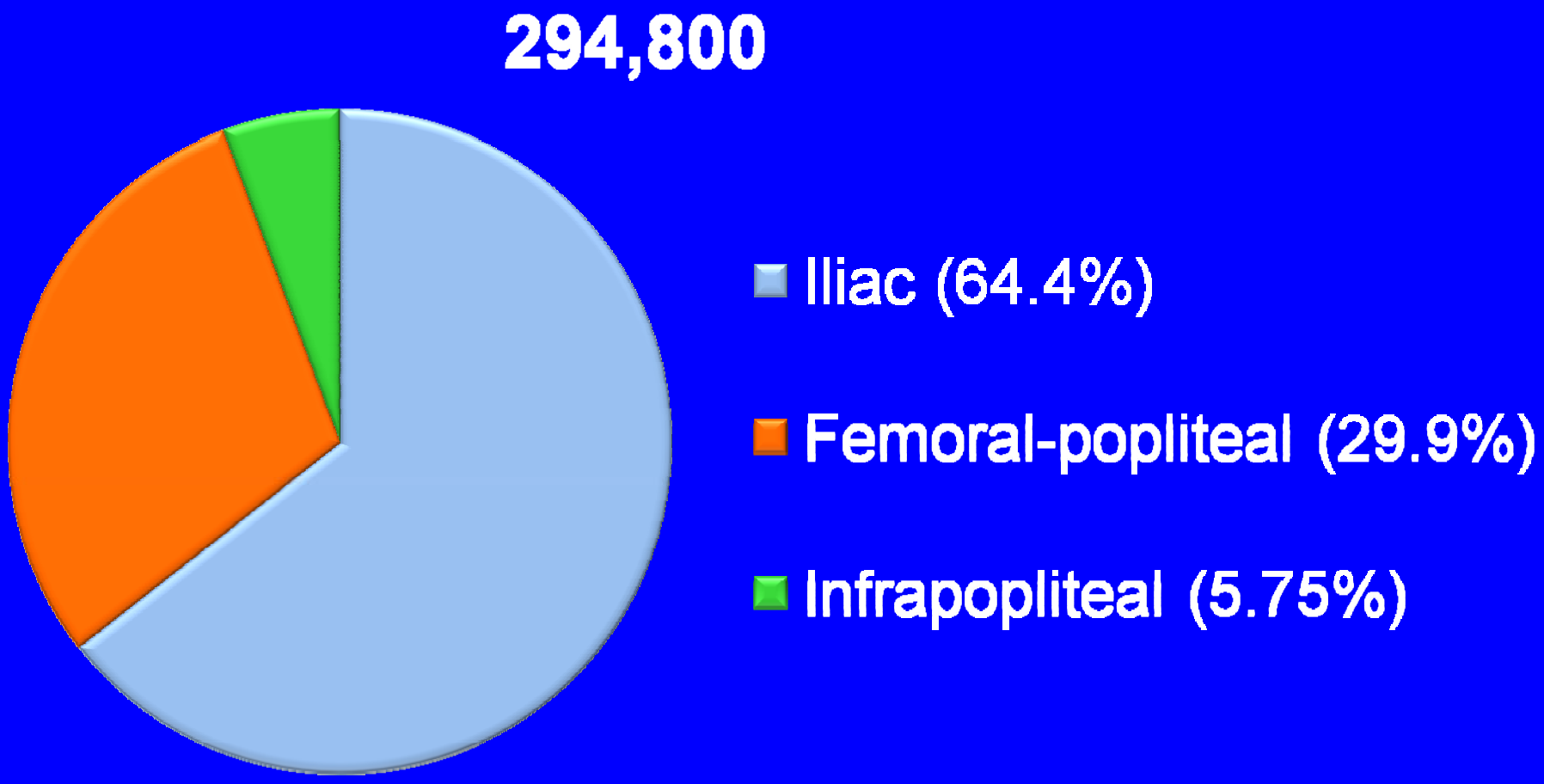
Stenting of the femoral-popliteal artery is increasingly being used in conjunction with other endovascular treatments

# Lower Extremity Arterial Stenting

## The procedure volumes forecast for lower extremity arterial stenting



# Lower Extremity Arterial Stenting



# SFA Trials

- Complete SE…… SE Stent (Medtronic)
- Superb …….. Supera (Idev)
- Durability II……Protégé (ev3)
- Stroll……Smart (Cordis)
- Viper……Viabahn (Gore)
- Vibrant ……..Viabahn & Bare Stent (Gore)
- Fast ……Luminexx (Bard)
- Fact……Conformexx (Bard)
- Resilient …… Life Stent (Edward)
- Zilver…….. Zilver (Cook)

# In-stent Restenosis

| SFA Trials | 1 Year | 2 Year | 3 Year |
|---|---|---|---|
| Complete SE | 23.3 % | - | - |
| Superb | 31.7 % | - | - |
| Durability II | 20 % | 36% | 53% |
| Stroll | 24% | 40% | - |
| Viper | 18% | 22.9% | - |
| Vibrant | 12% | 21.1% | - |
| Fast | 37% | 45% | - |
| Fact | 37% | - | - |
| Resilient | 21% | 33% | 43% |
| Zilver | 48% | 64% | 81% |

# Treatment Options For In-stent Restenosis

- Balloon Angioplasty
  - GOB
  - Cutting Balloon
  - Polar Cath (Cryoplasty)
  - Drug Eluting Balloons
- Laser
- Restenting (Drug Eluting Stent)
- Atherectomy
- **Covered Stent graft**

# Excimer Laser with Adjunctive Balloon Angioplasty and Heparin-Coated Self-Expanding Stent Grafts for the Treatment of Femoropopliteal Artery In-Stent Restenosis:

Twelve-Month Results From the SALVAGE Study

Laird JR, Jr., Yeo KK, Rocha-Singh K, et al.
Catheter Cardiovasc Interv 2012 mar 15.

# Salvage Study

| | | |
|---|---|---|
| Patients | 27 | 100% |
| Technical Success | 27 | 100% |
| Complication | 3 | 11% |
| Available for follow up | 23 | 85% |
| 12 month primary Patency | 11/23 | 48% |

Laird JR, Jr., Yeo KK, Rocha-Singh K, et al. Catheter Cardiovasc Interv 2012 mar 15.

# RELINE; Clinical Trial

Heparin-bonded Viabahn endoprosthesis
vs. standard angioplasty balloon
for treatment of in-stent restenoses

# RELINE Study

Randomization of 83 patients with In-Stent Restenosis to PTA alone (44) and Viabahn endoprosthesis (39)

M. Bosiers, M.D., Presented at LINC 2013, Leipzig

# The Reline Trial

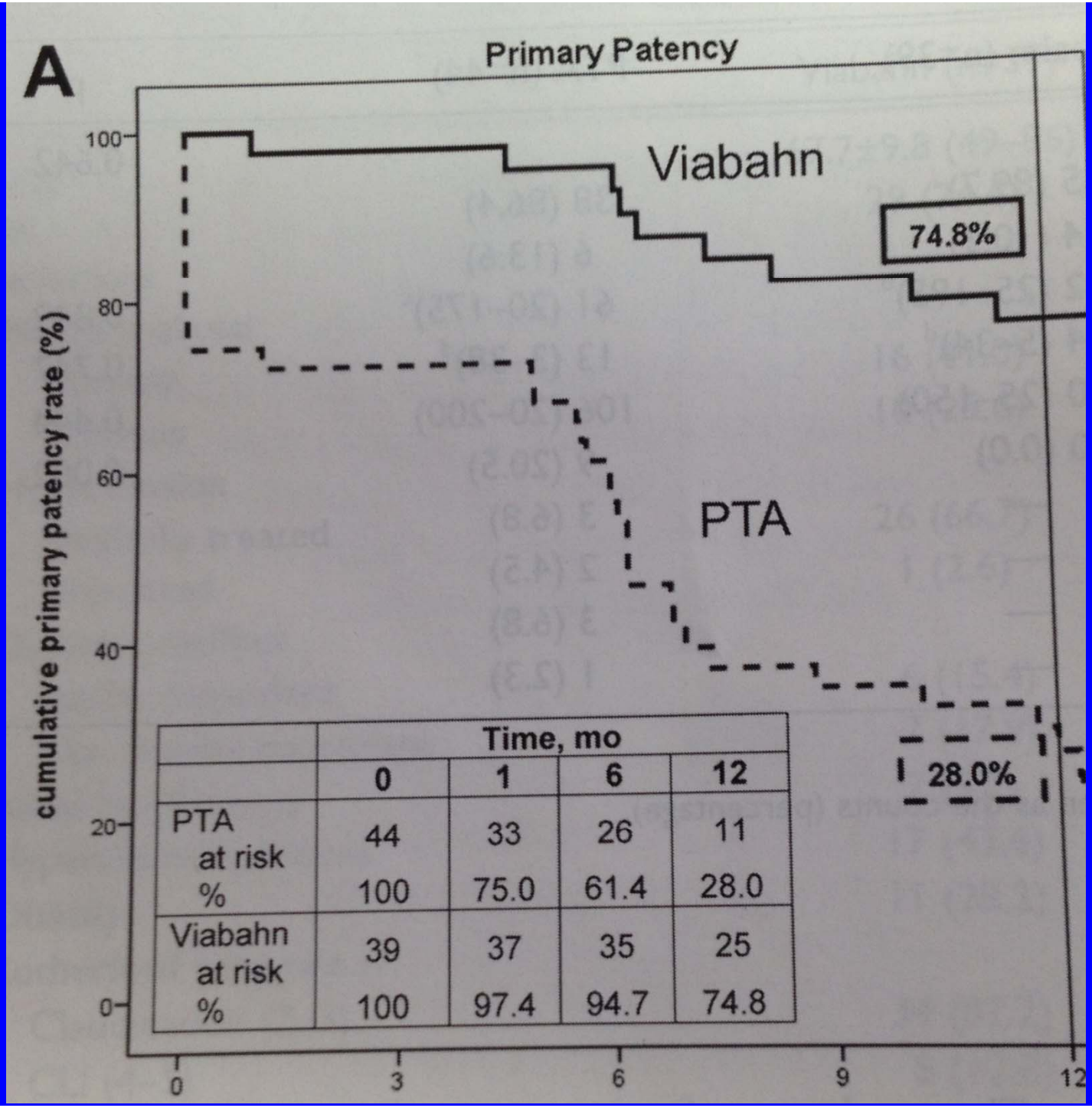
## 6 month Primary Patency

| | |
|---|---|
| Viabahn | 94.7% |
| PTA | 60.5% |

M. Bosiers, M.D., Presented at LINC 2013, Leipzig

# Superiority of Stent-Graft for In-Stent Restenosis in the Superficial Femoral Artery: Twelve-Month Results From a Multicenter Randomized Trial

Marc Bosiers, MD, Koen Deloose, MD, Joren Callaert, M.D., et al



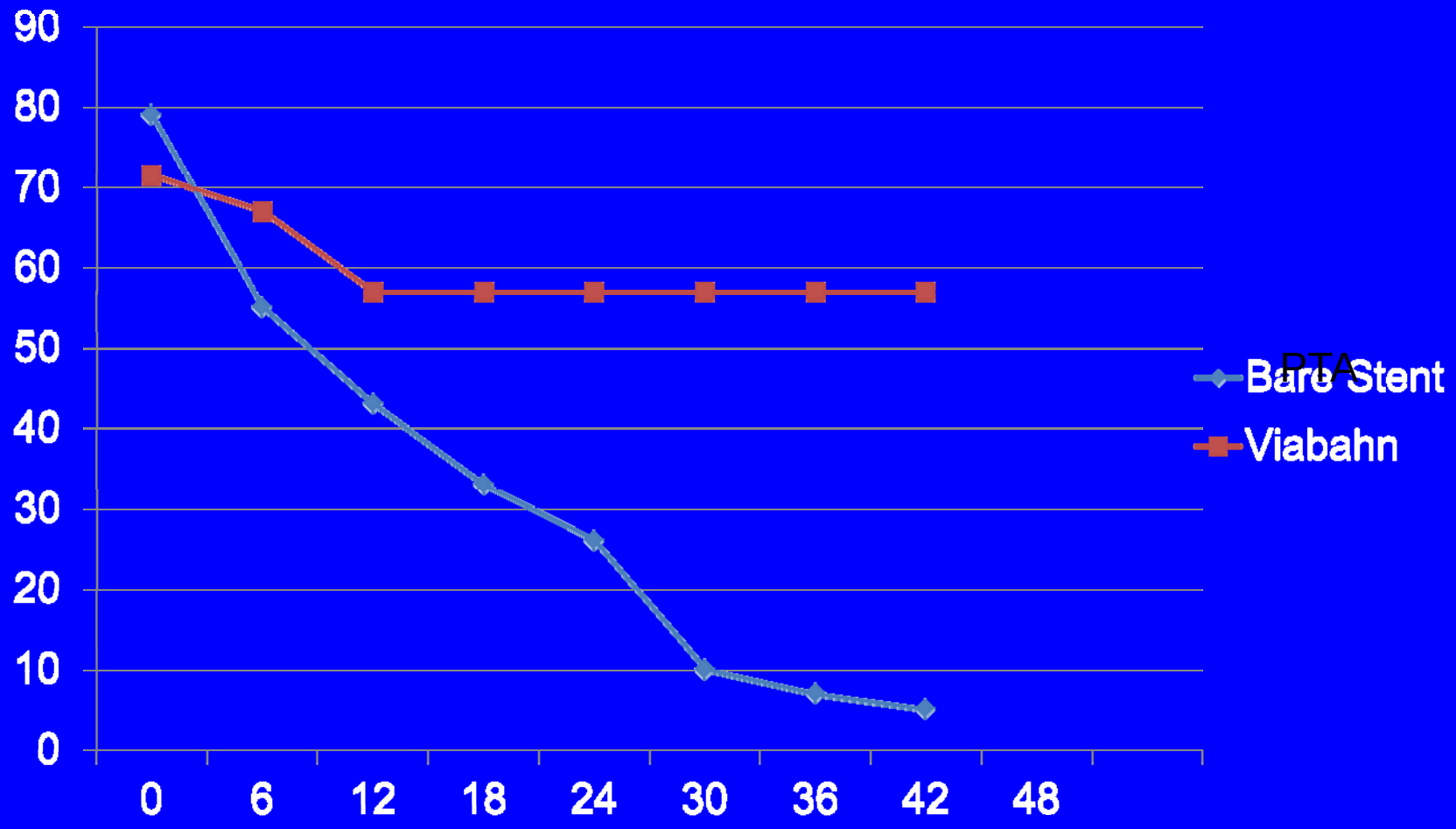

| | Time, mo | | | |
|---|---|---|---|---|
| | 0 | 1 | 6 | 12 |
| PTA at risk | 44 | 33 | 26 | 11 |
| PTA % | 100 | 75.0 | 61.4 | 28.0 |
| Viabahn at risk | 39 | 37 | 35 | 25 |
| Viabahn % | 100 | 97.4 | 94.7 | 74.8 |

# Lower Extremity Arterial Stenting

2005 – 2010

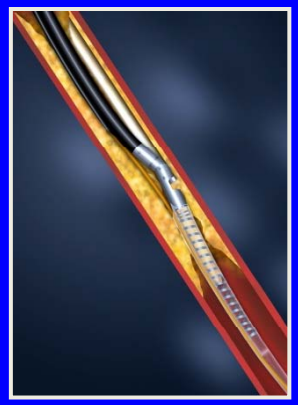
- Patients 599 100%
- Restenosis 176 30%
  - Treatments
    - » PTA 113 64%
    - » Atherectomy & PTA 63 36%

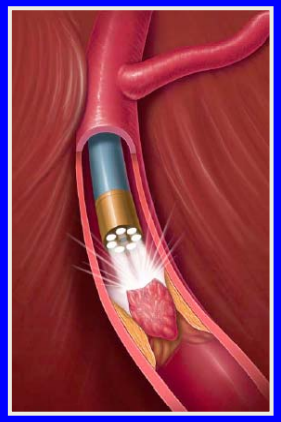
# Treatment of In-Stent Stenosis with Covered Stents



# Conclusion

- Treatment of in-stent restenosis with covered stents is associated with a patency rate superior to other treatment modalities, eg, PTA, Atherectomy and Restenting





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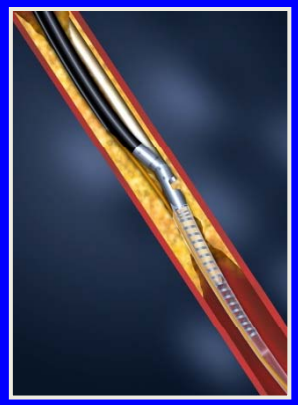
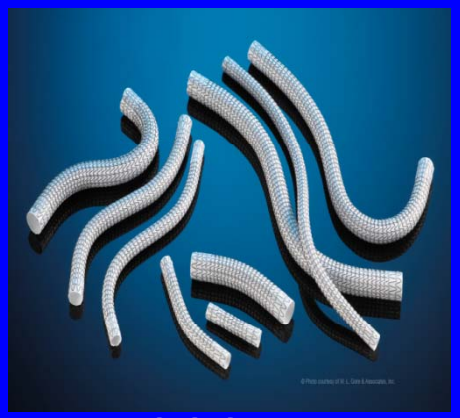
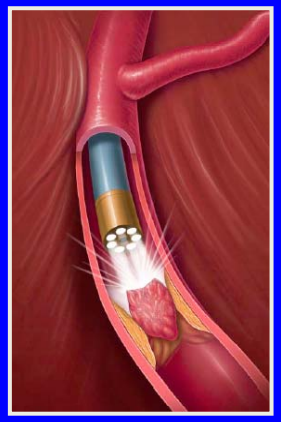


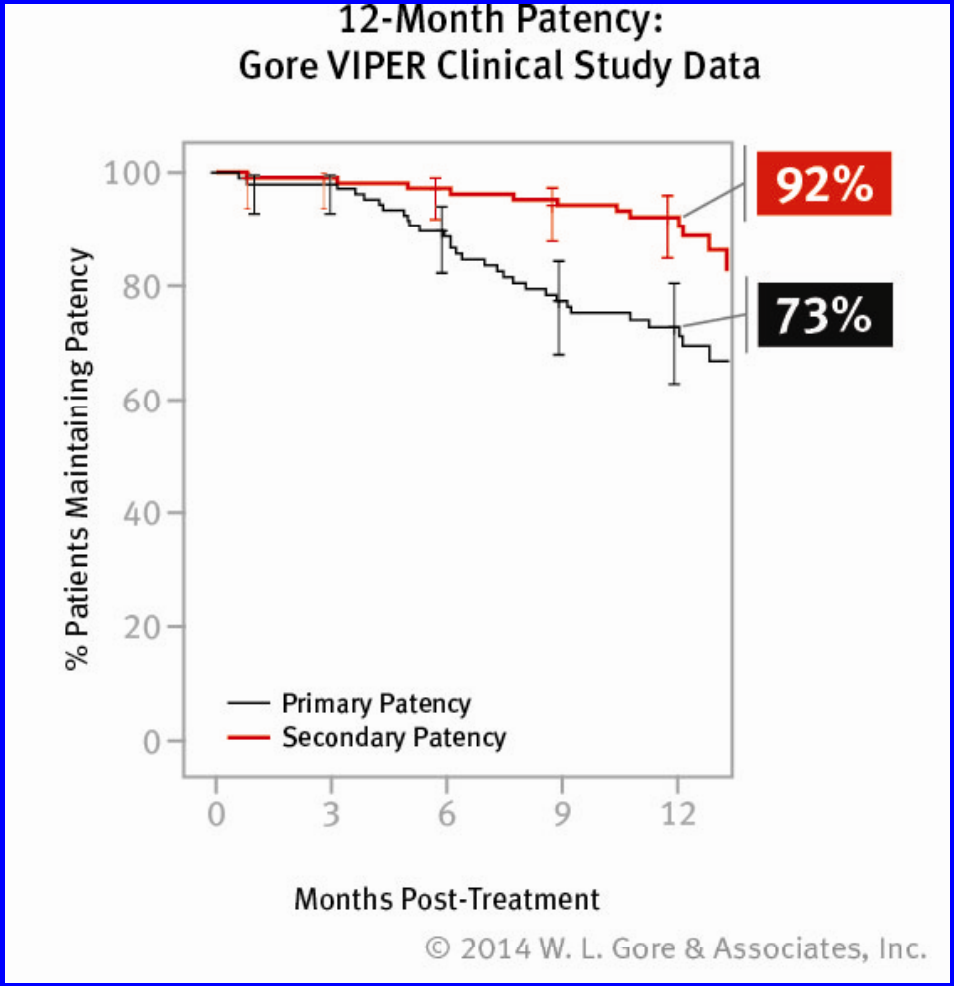


2005



# PAD

# One-Year Patency



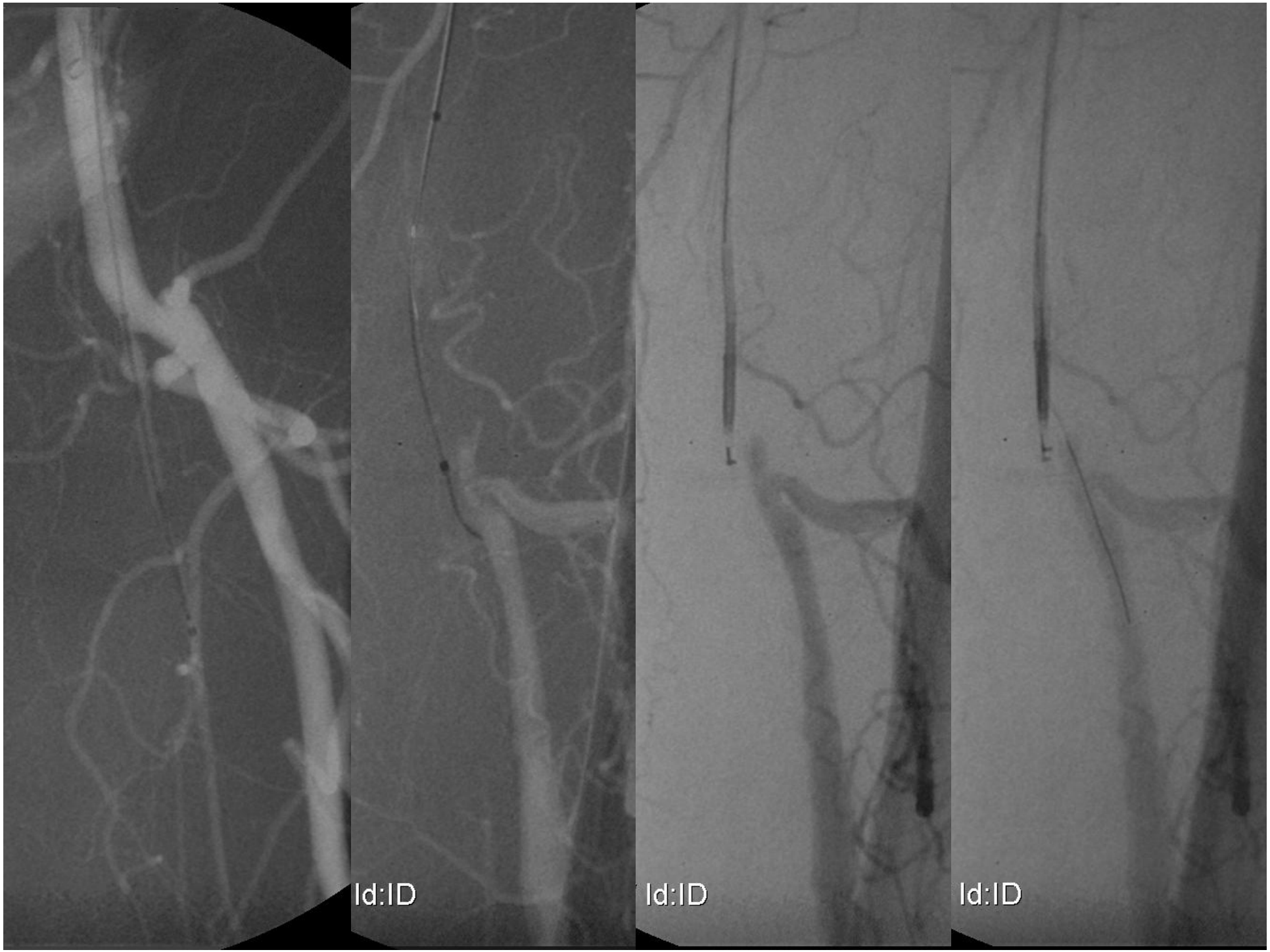

*103 / 119 limbs available for follow-up at 12 months*

57-year-old male

Complaining of claudication of the left leg

# Treatment Plan

- Atherectomy and PTA of pre-decided segment followed by implantation of the covered stent.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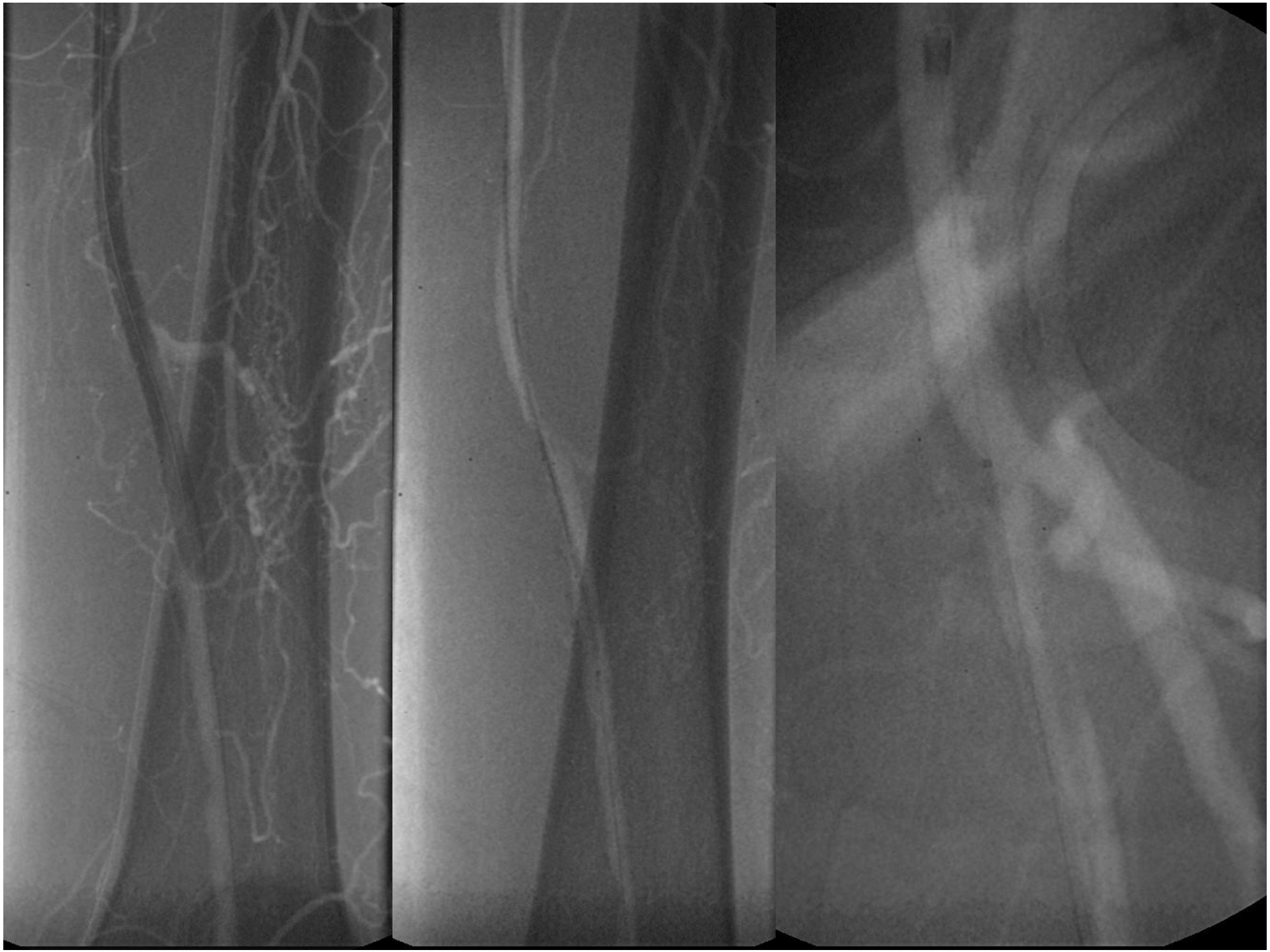
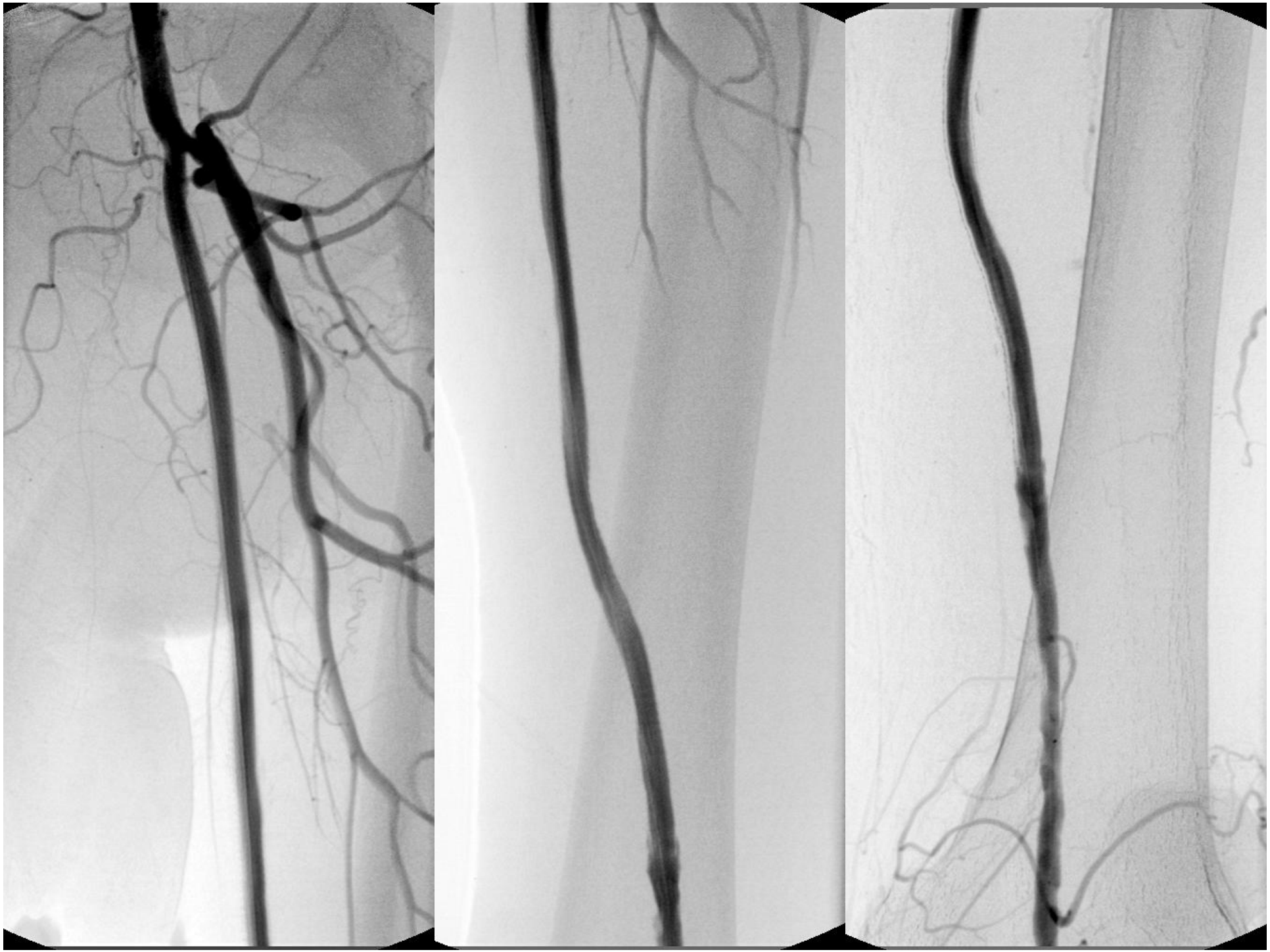
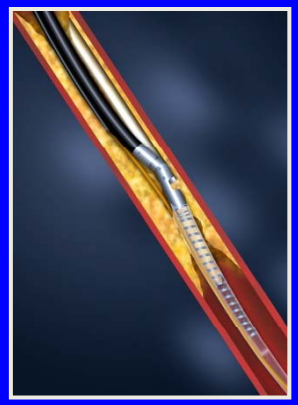
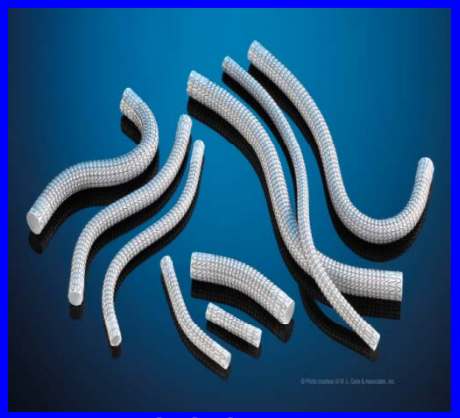
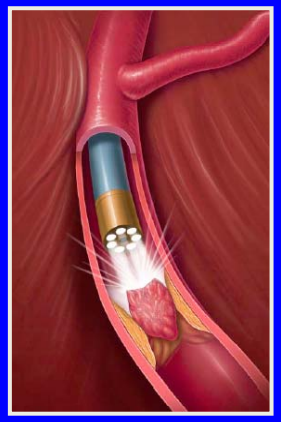






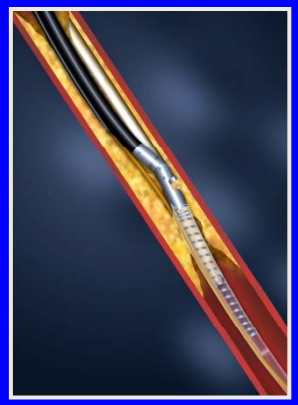


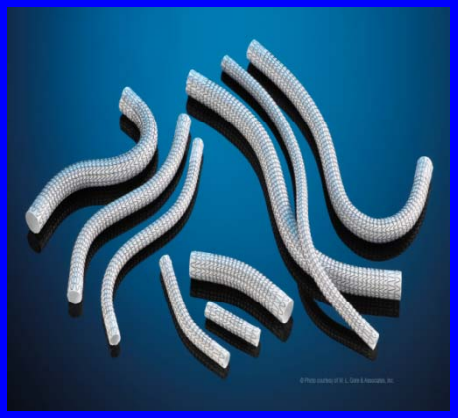
2005

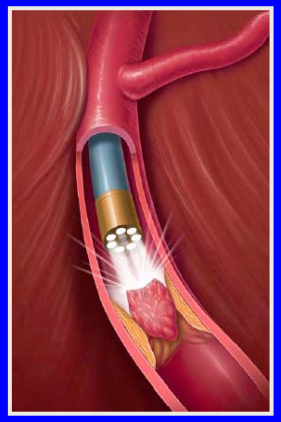


# PAD

2007







# PAD

2015

# Drug-Coated Balloon Versus Standard Percutaneous Transluminal Angioplasty for the Treatment of Superficial Femoral and Popliteal Peripheral Artery Disease

## 12-Month Results From the IN.PACT SFA Randomized Trial

**Conclusions:** In this prospective, multicenter, randomized trial, DCB was superior to PTA and had a favorable safety profile for the treatment of patients with symptomatic femoropopliteal artery disease.

DOI: 10.1161/Circulationaha.114.011004

Gunnar Tepe, MD; John Laird, MD; Peter Schneider, MD, et al

# Meta-Analysis of Drug-Eluting Balloon Angioplasty and Drug-Eluting Stent Placement for Infrainguinal Peripheral Arterial Disease.

**Conclusions: Drug-eluting balloon angioplasty and DESs demonstrated superior outcomes compared to PTA and BMS, with no difference in amputation or motality.**

J Vasc Interv Radiol.2015 Apr;26(4):459-473

Baeriocher MO, Kennedy SA, Rajebi, et. Al.

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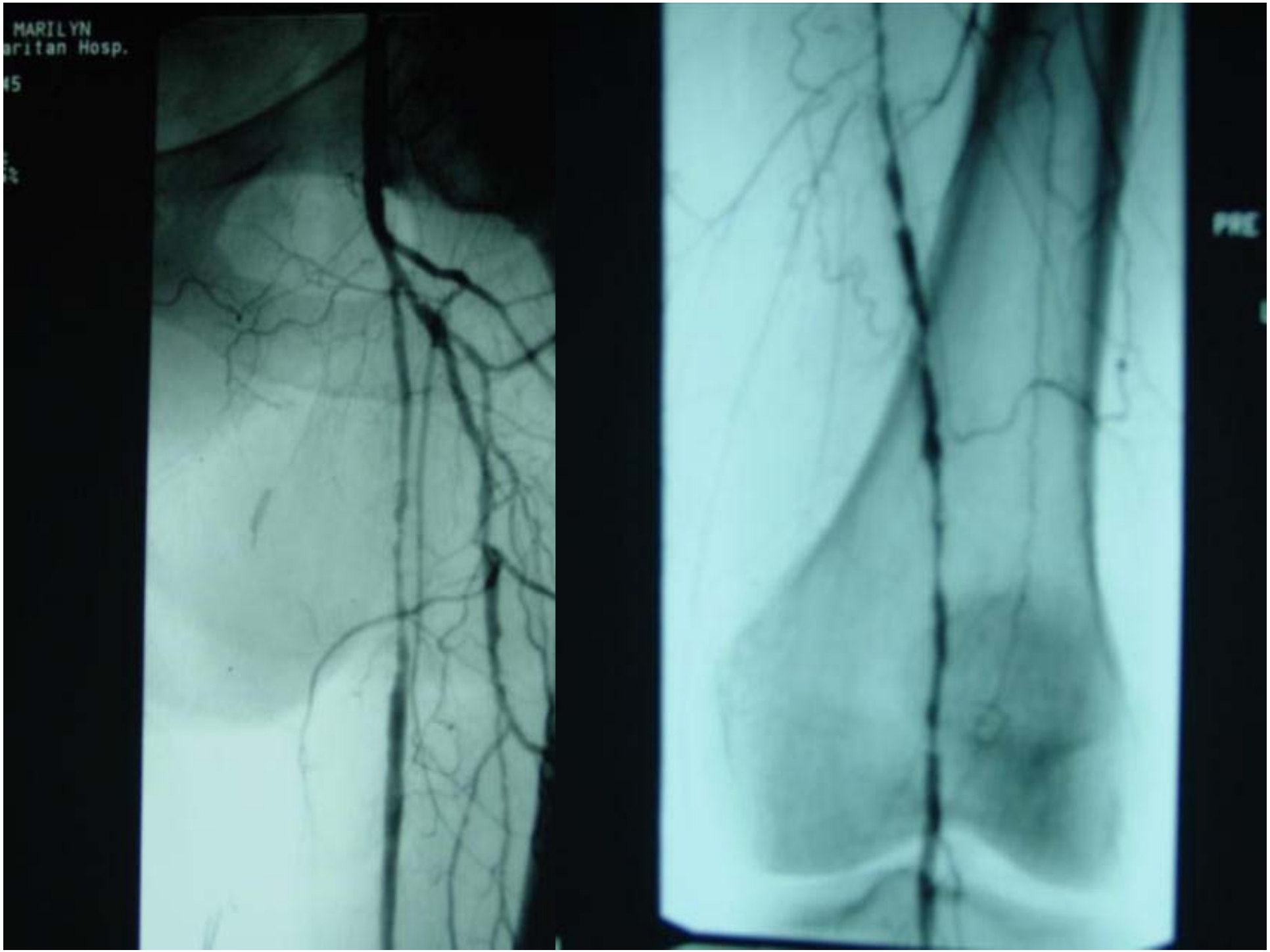
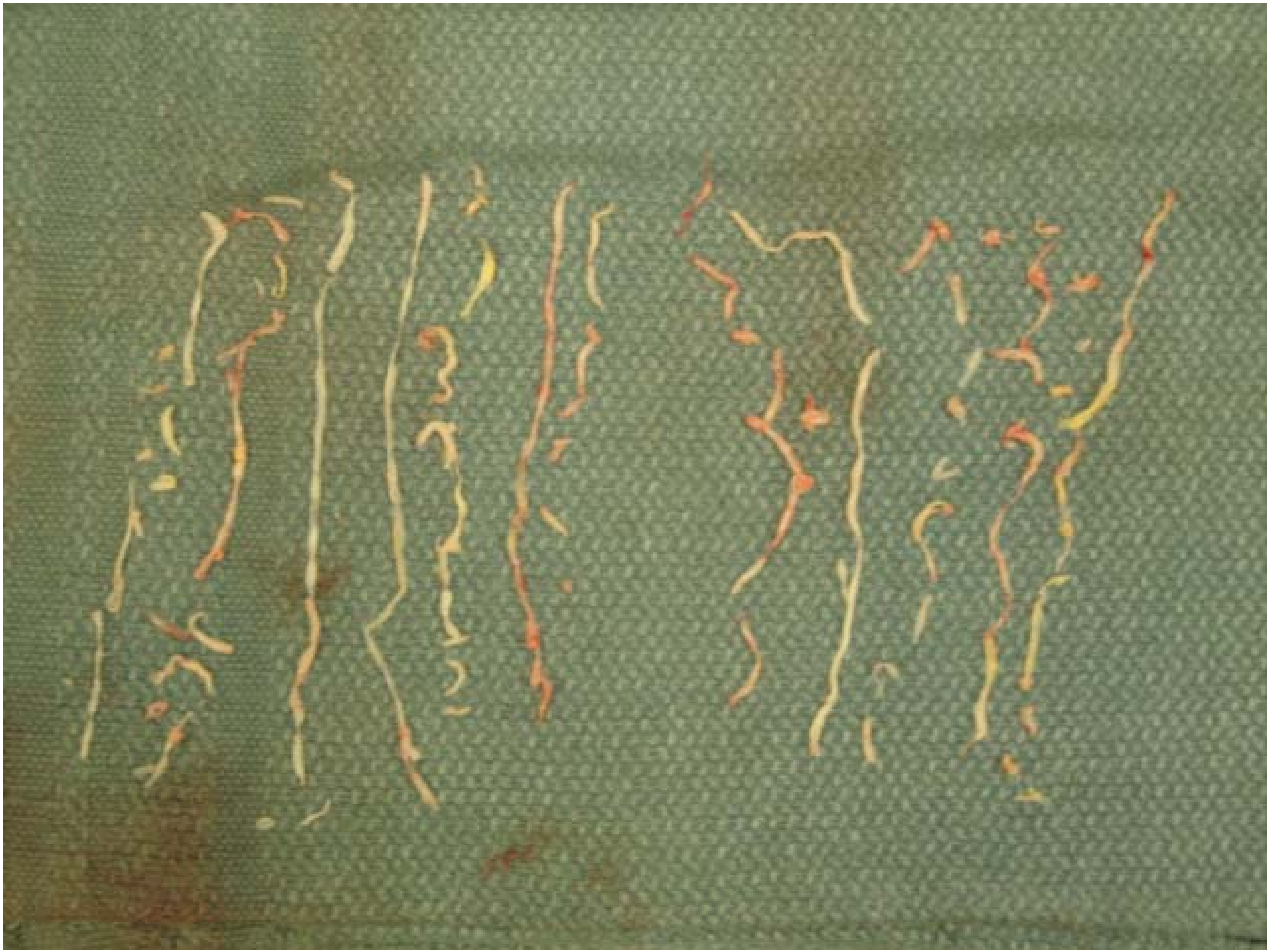
Gunnar Tepe, MD; John Laird, MD; Peter Schneider, MD, et al

# How to Treat Femoropopliteal Artery Diseases in 2015

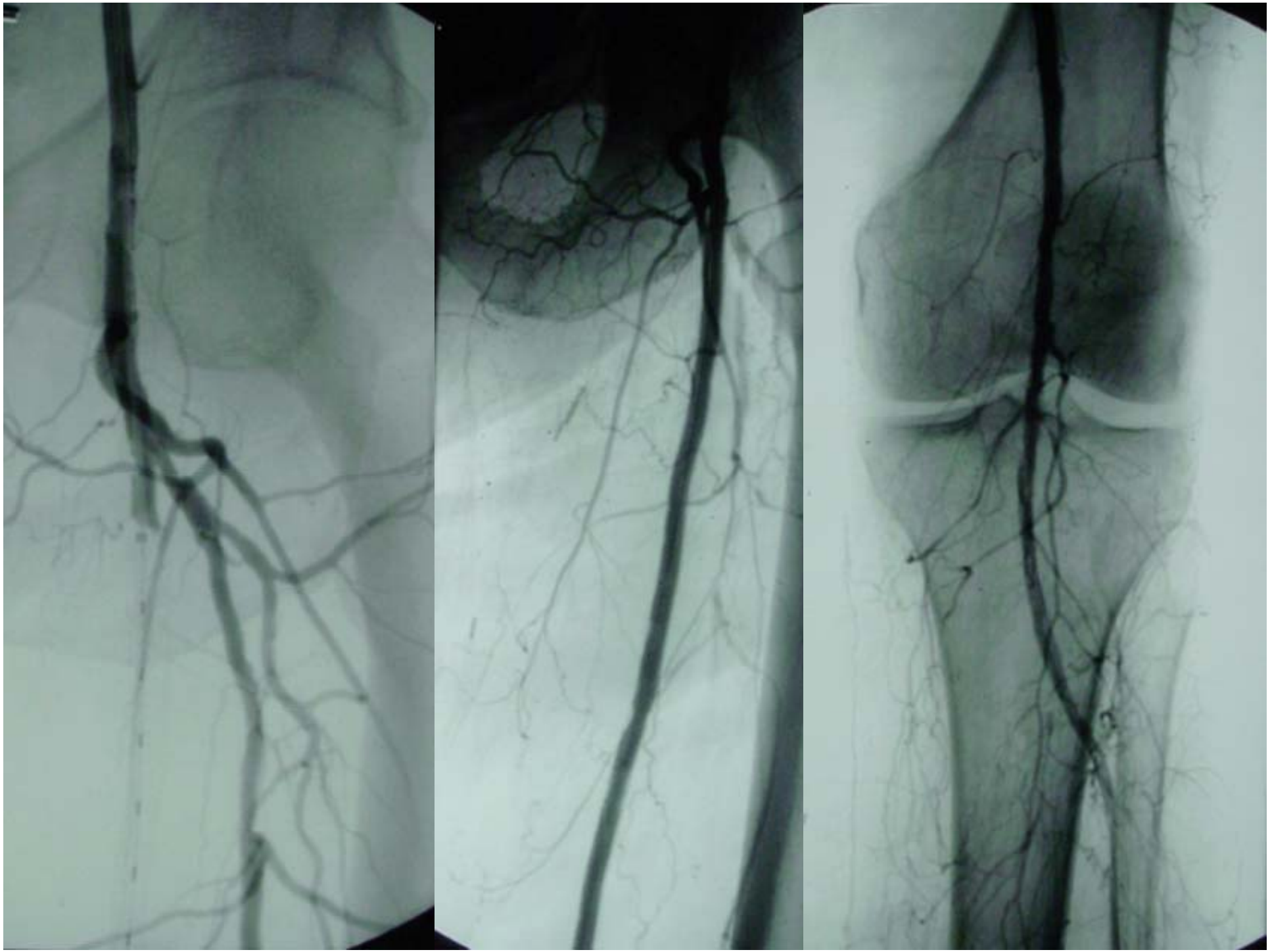
- 1 ) D C B  Angioplasty
- 2 ) Atherectomy + D C B
- 3 ) Atherectomy + D C B + Provisional Stent
- 4 ) Atherectomy + Balloon Angioplasty and
- Covered Stents


- Amir Motarjeme, M D. F.S.I.R.

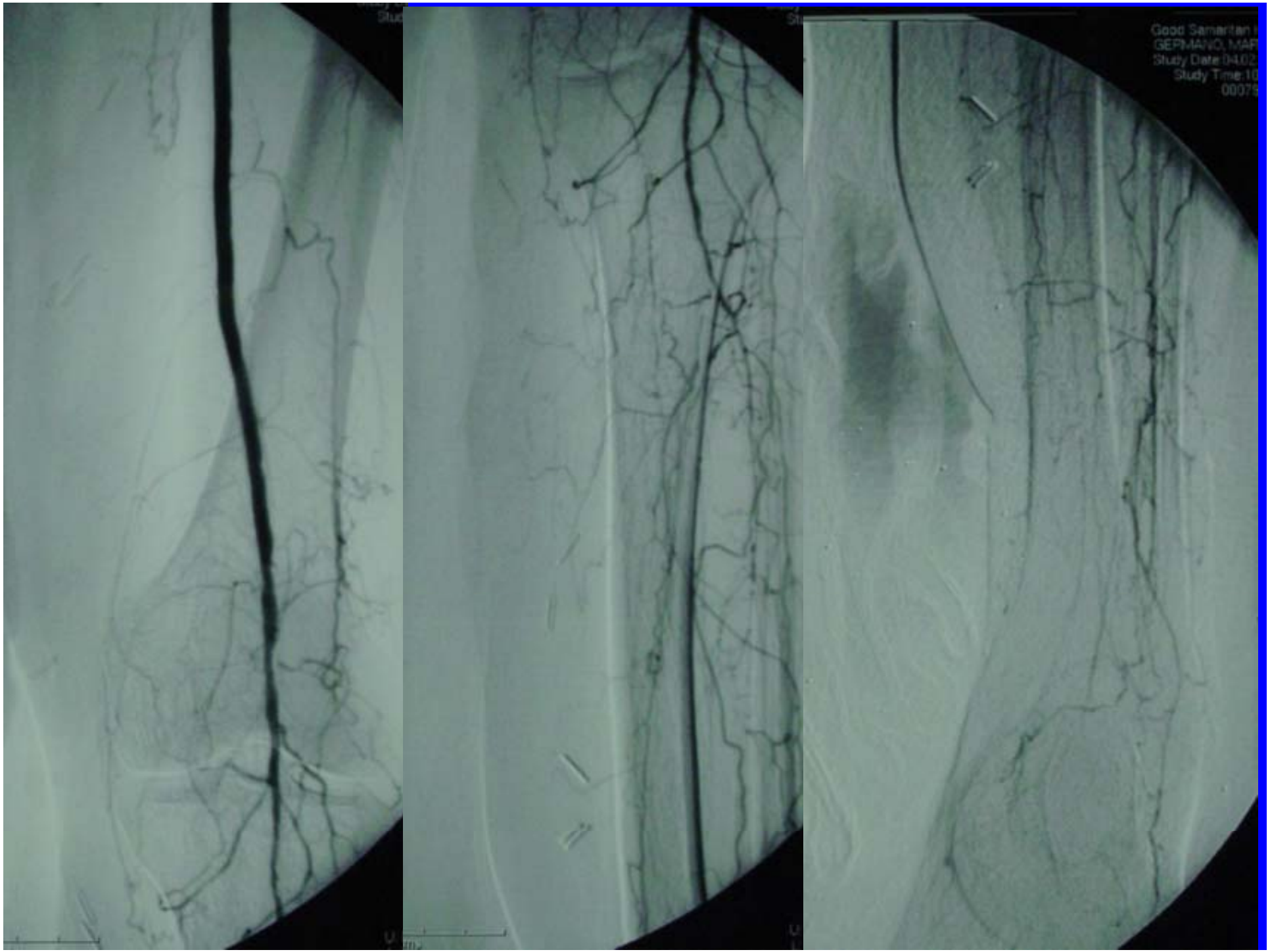

MARILYN
aritan Hosp.
45
PRE




POST ATH
JCM
LAO




5 cms


Good Samaritan
Study Date:0402
Study Time:10

# LT. SFA CTO

65 Y/O MAN, COMPLAINING OF CLAUDICATION OF THE LEFT LEG,

FOR THE PAST THREE MONTHS

# LEFT SFA CTO

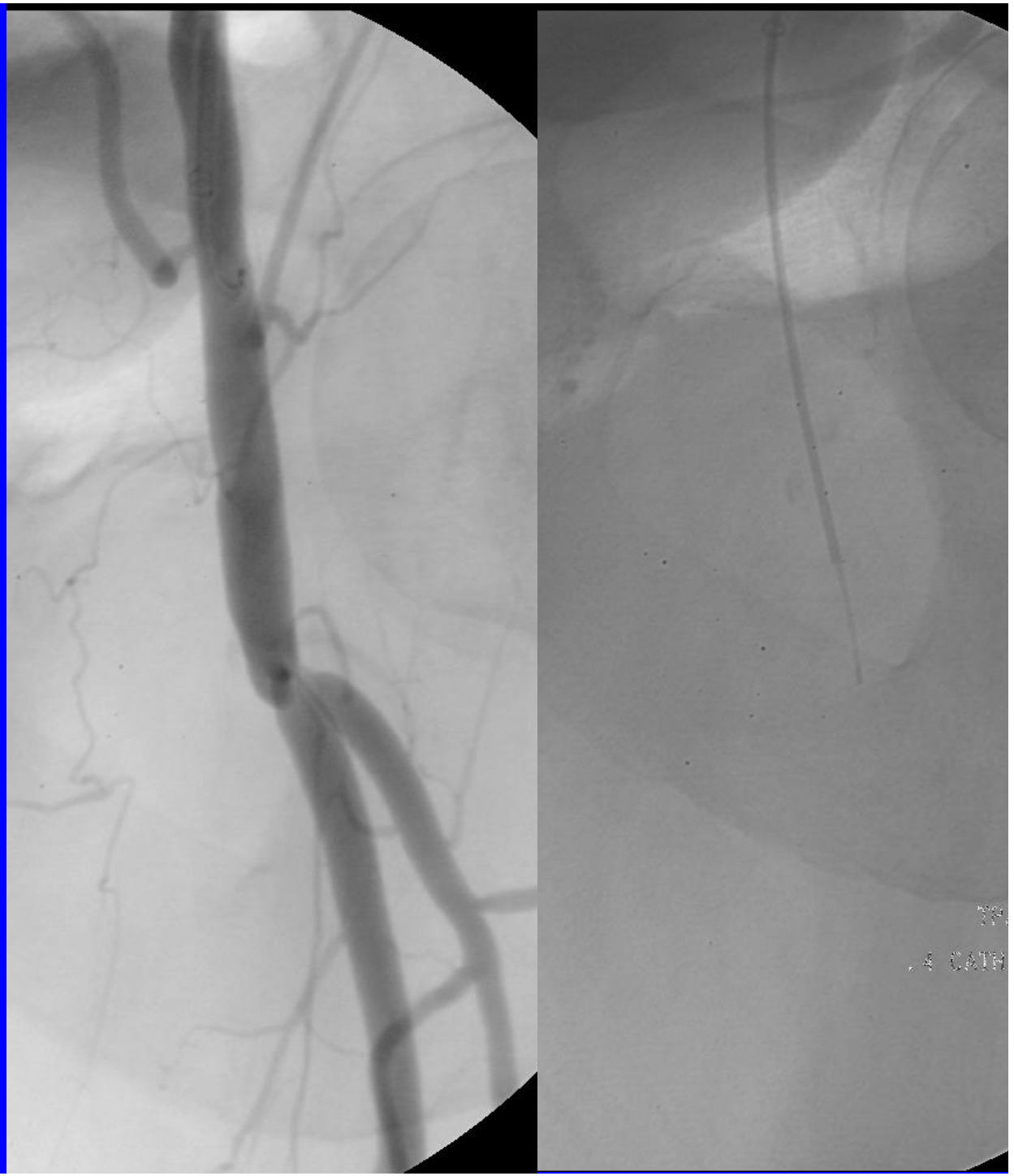
THE COLLATERAL ARTERIES ARE SMALL AND NOT WELL ESTABLISHED

.

THE DISTAL RUN OFF IS FUZZY AND

# LT. SFA CTO

AN INFUSION WIRE AND CATHETER IS INSERTED INTO THE SFA'S ORIGIN AND INFUSION OF tPA ONE MG/HR WAS STARTED.



# LT. SFA CTO

POST THROMBOLYSIS (12 HRS ) ARTERIOGRAM SHOWES CLOTLYSIS AND PATENCY OF THE SFA DOWN TO THE ADDUCTOR CANAL.

# LT. SFA CTO

ANGIOJET THROMBECTOMY IS USED FOR RESIDUAL CLOTS.

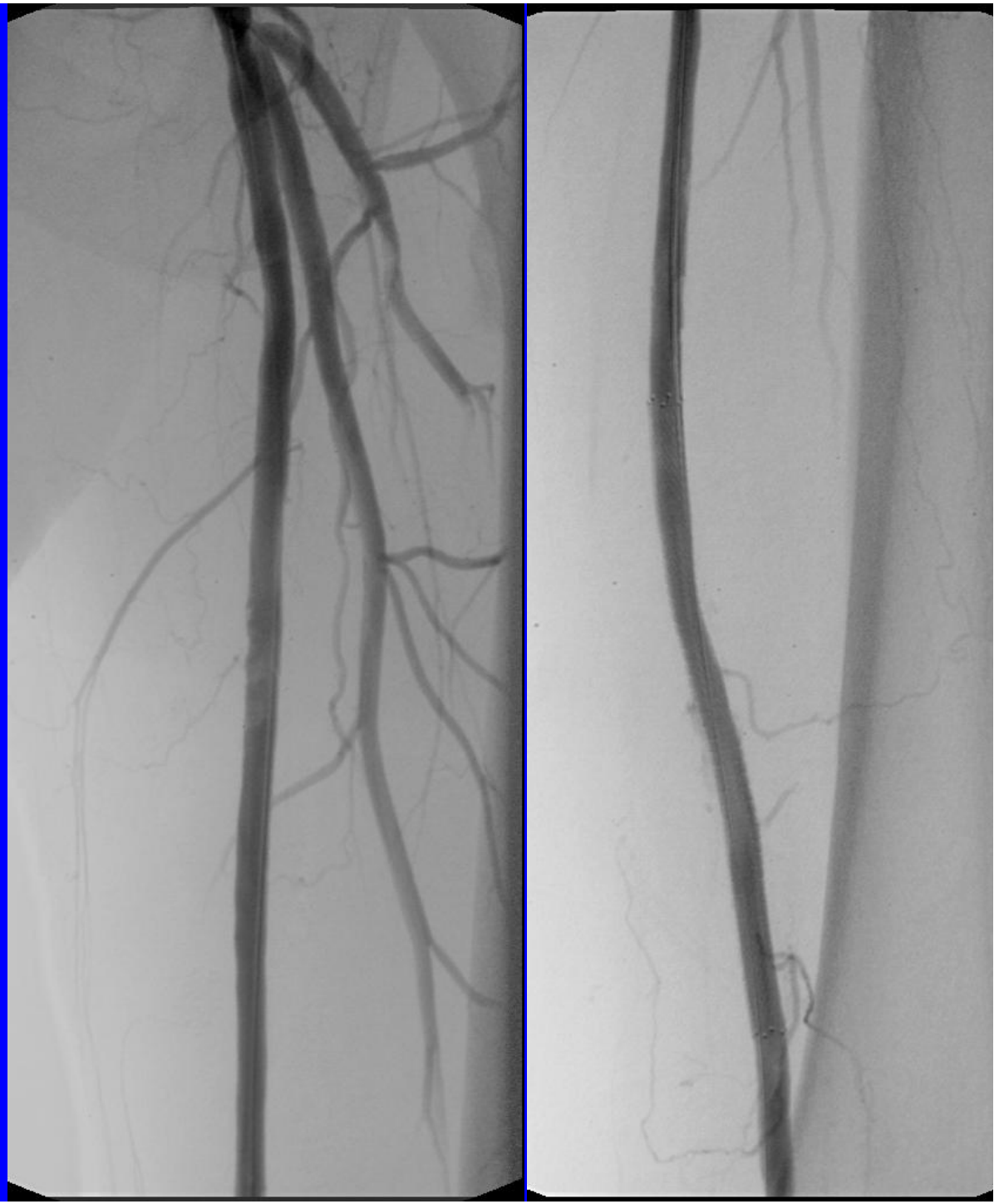
# LT. SFA CTO

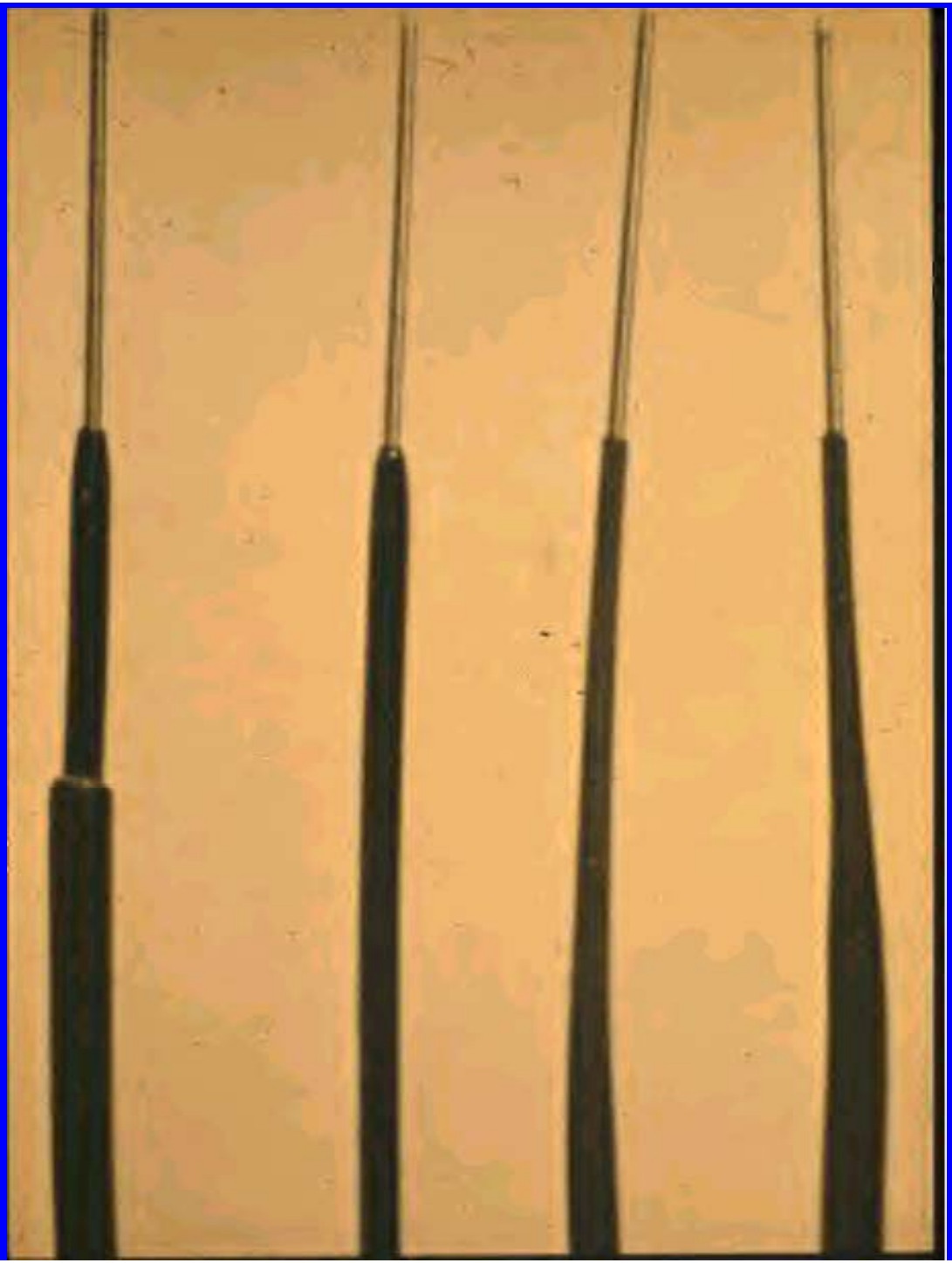
POST PTA ARTERIOGRAM AND STENT DEPLOYMENT

# LT. SFA CTO

A FINAL ARTERIOGRAM SHOWES PATENT SFA AND POPLITEAL ARTERIES

WITH LIMITED STENTING





# Transluminal Treatment of Arteriosclerotic Obstruction

## Description of a New Technic and a Preliminary Report of Its Application

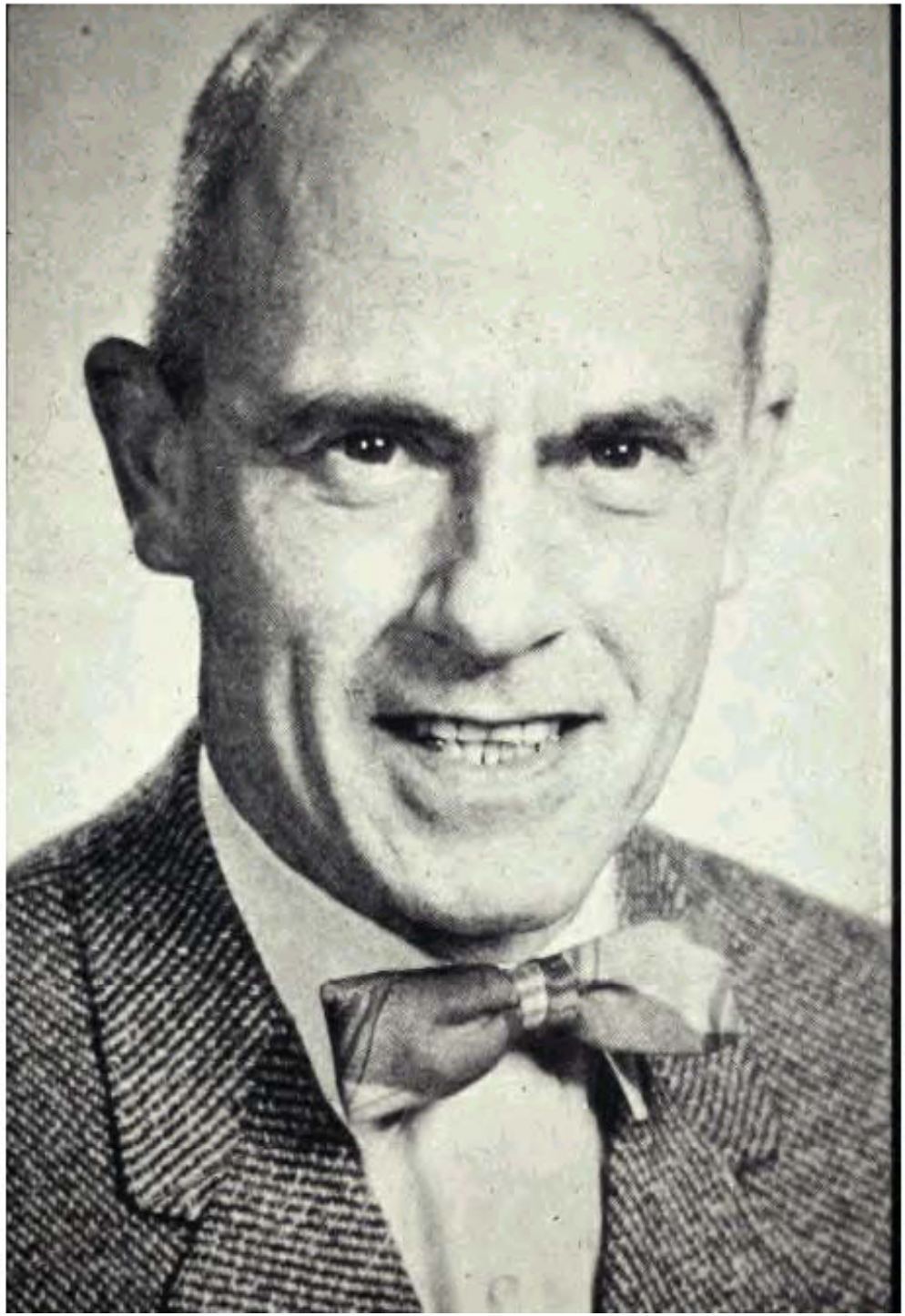
*By* CHARLES T. DOTTER, M.D., AND MELVIN P. JUDKINS, M.D.

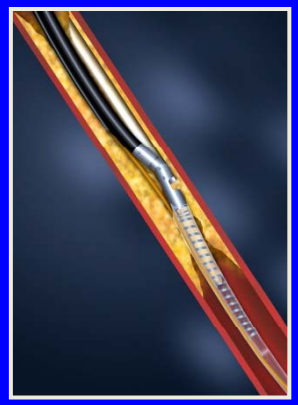
DESPITE the frequency and importance of arteriosclerotic obstruction, current methods of therapy leave much to be desired. Nonsurgical measures, however helpful they may be, provide the patient little more than an opportunity to live with his disease. Consistent success in the use of surgical technics such as endarterectomy, angioplasty, and grafting has largely been confined to highly specialized vascular surgeons of whom there are far too few to cope realistically with literally millions of patients suffering the pain-

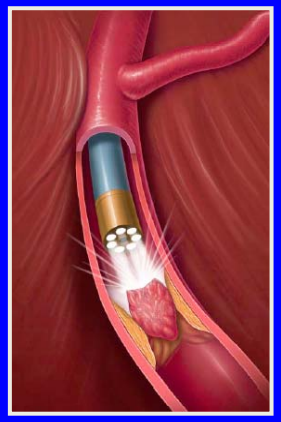
### Method

#### Procedure

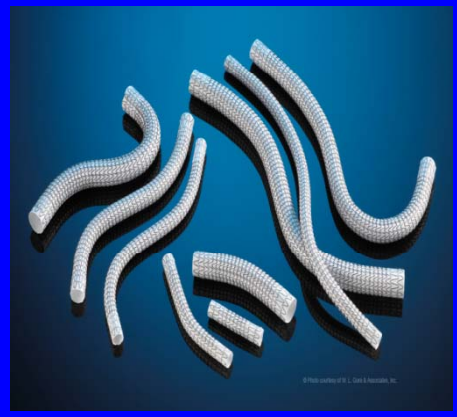
Prior angiographic survey of the abdominal aorta, its iliac branches, and the leg arteries, including those beyond the suspected primary block, is best done by retrograde catheterization of the opposite femoral artery, thus insuring a hematoma-free femoral region on the side to be treated. If an attempt appears indicated, the procedure, including its present experimental status, is fully discussed with the patient and specific permission is obtained. Oral anticoagulant agents are discontinued and barbiturate sedation is given at an appropriate time. Local anesthesia was used



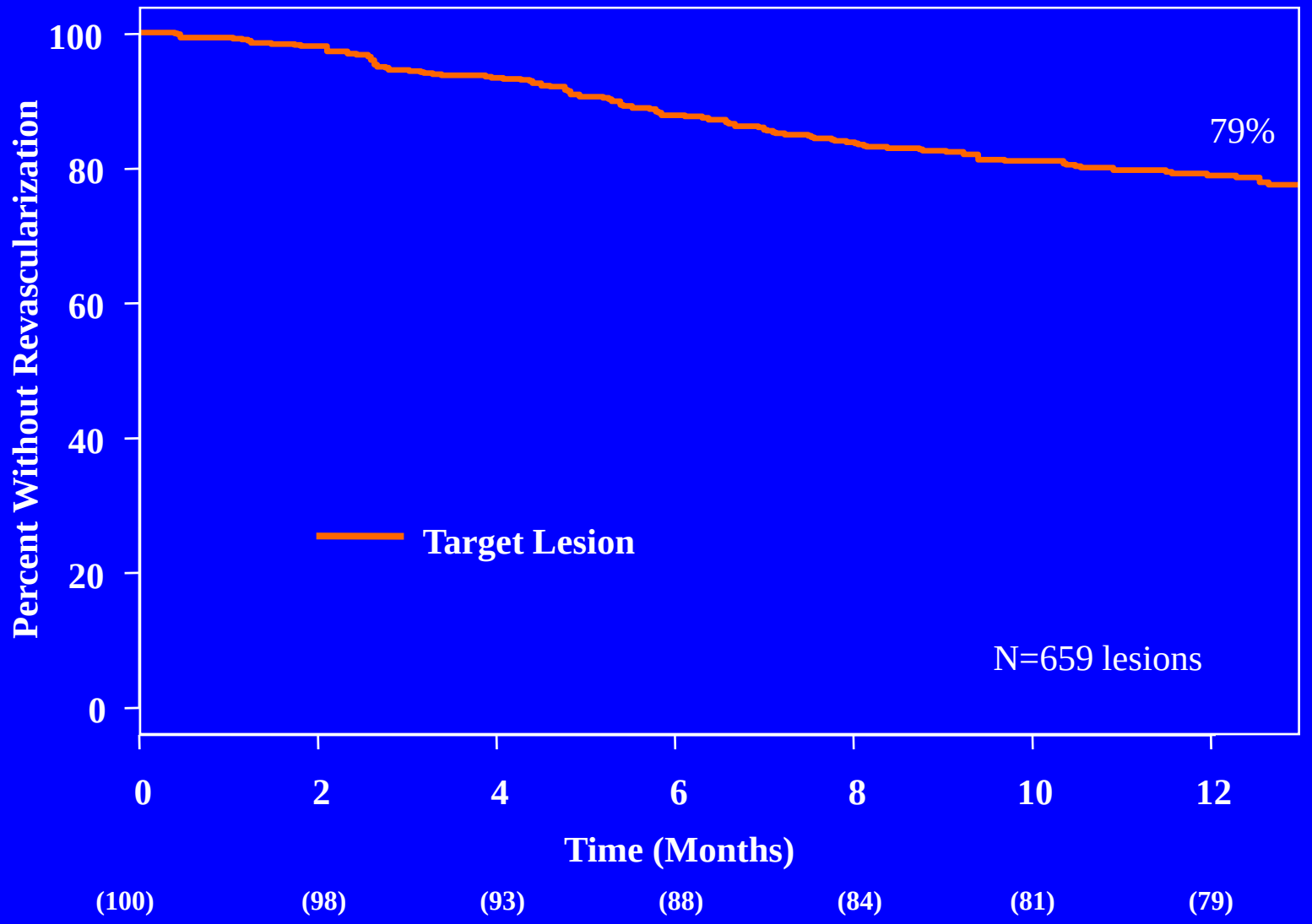




# PAD



# 12-month Freedom From Target Lesion Revascularization



# 10-15-1978

- 55 y/o female
- complaining of
- of intermittent
- claudication

# IN.PACT Amphirion Paclitaxel Eluting Balloon Versus Standard Percutaneous Transluminal Angioplasty for Infrapopliteal Revascularization of Critical Limb Ischemia: Rationale and Protocol for an Ongoing Randomized Controlled Trial

Trialsjournal.com Trials 2014,15-63

Zeller et al.

# Key Study Endpoints

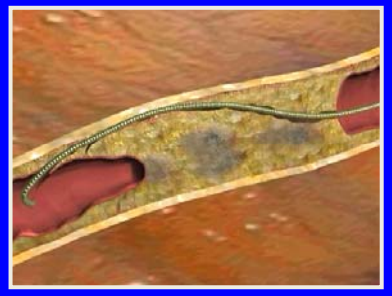
| Claudicants | Primary Endpoint: Primary Patency at 12 months (PSVR <3.5) | | Secondary Endpoint: Primary Patency at 12 months (PSVR <2.4) | |
|---|---|---|---|---|
| | Patency | LL (cm) | Patency | LL (cm) |
| All (n+743) | 82% | 7.5 | 78% | 7.5 |
| Diabetic | 80% | 7.6 | 77% | 7.6 |
| Non-Diabetic | 83% | 7.4 | 78% | 7.4 |

**CLI** Primary Endpoint:

Freedom from Major Unplanned Amputation of the Target Limb at 12 months

# Stent Placement vs. Balloon Angioplasty for Popliteal Artery Treatment: Two-Year Results of a Prospective, Multicenter, Randomized Trial

Alijoscha Rastan, MD, Hans Krankenberg, MD, Iris Baumgartner, et al



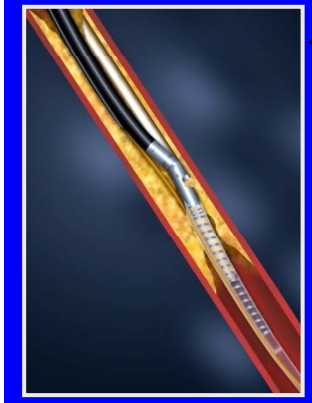
Subintimally dissect it

Balloon it

Stent it

PAD

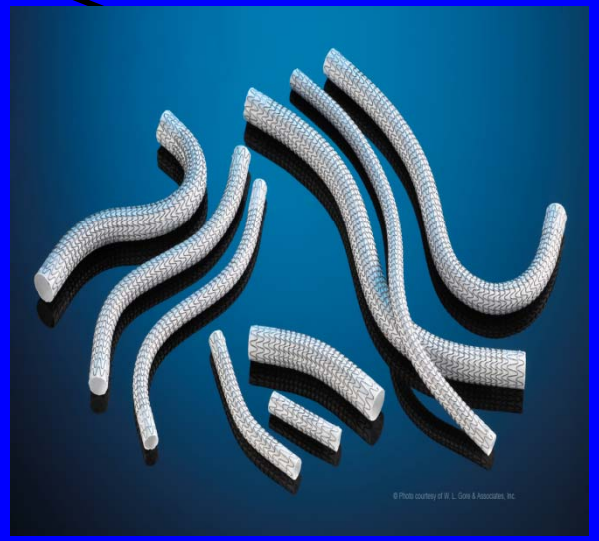
Sand it!!!



Excise it

Lace it

Freeze it



# Balloon Coated Balloon with Pactitaxel

Pactitaxel interferes with cell division after DNA replication, and the end result is a cytotoxic effect that limits intimal hyperplasia

# Meta-Analysis of Drug-Eluting Balloon Angioplasty and Drug-Eluting Stent Placement for Infrainguinal Peripheral Arterial Disease.

**Conclusions: Drug-eluting balloon angioplasty and DESs demonstrated superior outcomes compared to PTA and BMS, with no difference in amputation or motality.**

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Baeriocher MO, Kennedy SA, Rajebi, et. Al.

# Drug Eluting Balloon

# Atherectomy

- Indications
  - Stand alone treatment
    (short SFA and popliteal lesions)
  - Arterial bifurcations
    (saddle back stenoses)
    - Common femoral artery
    - Popliteal trifurcation
  - In-stent stenoses
  - Infrapopliteal arteries in CLI
  - Avoiding stent

# Treatment For In-stent Restenosis

- Patency after PTA
  - 1 – 19 month

    Midian; 6 month
- Patency after atherectomy
  - 2 – 28 month

    Midian; 12.3 month

Unpublished data of Midwest Vascular Institute of IL

# Treatment For In-stent Restenosis

– Patency after atherectomy

- Patency after PTA
  - 1 – 19 month

    Midian; 6 month
  - 2 – 28 month

    Midian; 12.3 month

Unpublished data of Midwest Vascular Institute of IL

# Treatment of In-Stent Restenosis with Covered Stents 2005-2012

| | | |
|---|---|---|
| PT | 42 | 100% |
| Male | 24 | 57% |
| Diabetics | 19 | 45% |
| Claudication | 24 | 57% |
| CLI | 18 | 43% |
| Stenoses | 14 | 33% |
| Occlusions | 28 | 67% |
| Atherectomy | 27 | 64% |

# Viabahn/Hemobahn Data From Studies Treating SFA Disease

| Study | SG-Treated Limbs | CLI, % | Oclusions % | Success % |
|---|---|---|---|---|
| Lammer 2000 | 80 | 62 | 62 | 100 |
| Bauermeister 2001 | 35 | 100 | 100 | 100 |
| Deutschmann 2001 | 18 | 28 | 28 | 94 |
| Railo 2001 | 15 | 66.7 | 66.7 | 100 |
| Bray 2003 | 59 | 53 | 53 | 95 |
| Jahnke 2003 | 52 | 82.7 | 82.7 | 100 |
| Daenens 2005 | 40 | 62.5 | 62.5 | 100 |
| Fischer 2006 | 60 | 87 | 87 | 98 |
| Kedora 2007 | 50 | NS | NS | 100 |
| Saxon 2003 2007 | 87 | 42 | 42 | 100 |
| Hartung 2005/Alimi 2008 | 102 | 62 | NS | 100 |

# Covered Stents in CLI

| | | |
|---|---|---|
| Patient treated with covered stent | 335 | 100% |
| CLI | 90 | 27% |

# Covered Stents in CLI

## Covered Stents

- Wallgraft (1997,BSC)
- Fluency (2003,Bard)
- Viabahn (2005,Gore)

# Covered Stent For Diffuse SFA Disease

## A RECIPE FOR SUCCESS

- Debulk the diseased SFA segments
- Avoid PTA of the popliteal artery
- Cover the immediate collateral arteries to eliminate competitive flow
- Do not leave any treated lesion uncovered
- Extend the covered-stent to the origin of SFA if it is needed

# Superiority of Stent-Graft for In-Stent Restenosis in the Superficial Femoral Artery: Twelve-Month Results From a Multicenter Randomized Trial

Marc Bosiers, MD, Koen Deloose, MD, Joren Callaert, M.D., et al

# Balloon Coated Balloon with Pactitaxel

Pactitaxel interferes with cell division after DNA replication, and the end result is a cytotoxic effect that limits intimal hyperplasia

# RELINE; Clinical Trial

Heparin-bonded Viabahn endoprosthesis
vs. standard angioplasty balloon
for treatment of in-stent restenoses

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Zeller et al.

2015

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2015

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