

# Stenting With and Without Drug Eluting Technologies is Essential to Treat SFA Disease



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# Disclosure Statement of Financial Interest

A HEALTHIER WORLD THROUGH BOLD INNOVATION

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below.

Consulting Fees/Honoraria

Boston Scientific, Medtronic, Abbott, Covidien,  
Bard Peripheral Vascular, Volcano

Research Support

Atrium Medical, WL Gore

Scientific Advisory board/stock options

AngioScore, Angioslide, NexGen, Reflow,  
Endoluminal Sciences, Syntervention

Board Member VIVA Physicians

# SFA Stenting – A Few Facts

- SFA stents are getting better (long, flexible, fracture resistant)
- Excellent results with new stent designs, DES and covered stents
- For real world disease (long occlusions, diffuse disease, heavily calcified lesions), stents will provide the best results
- Quick, efficient, with predictable outcomes

# Evolution of Bare Metal Stent Technology

- Enhanced flexibility
  - Reduction of cell interconnections
  - Spiral orientation of interconnections
- Fracture resistance
- Novel designs
- Better delivery systems
- Longer stents
- Drug coatings



# The Evolution of Nitinol Stents

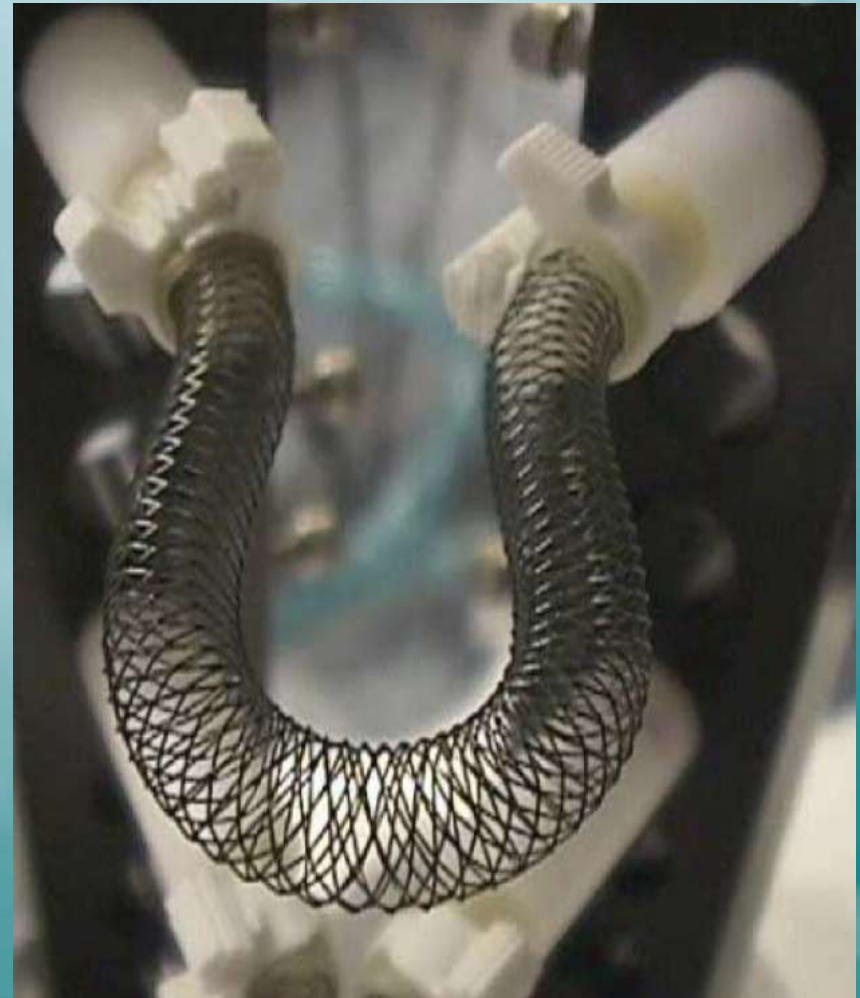
## Old Technology



## New Technology

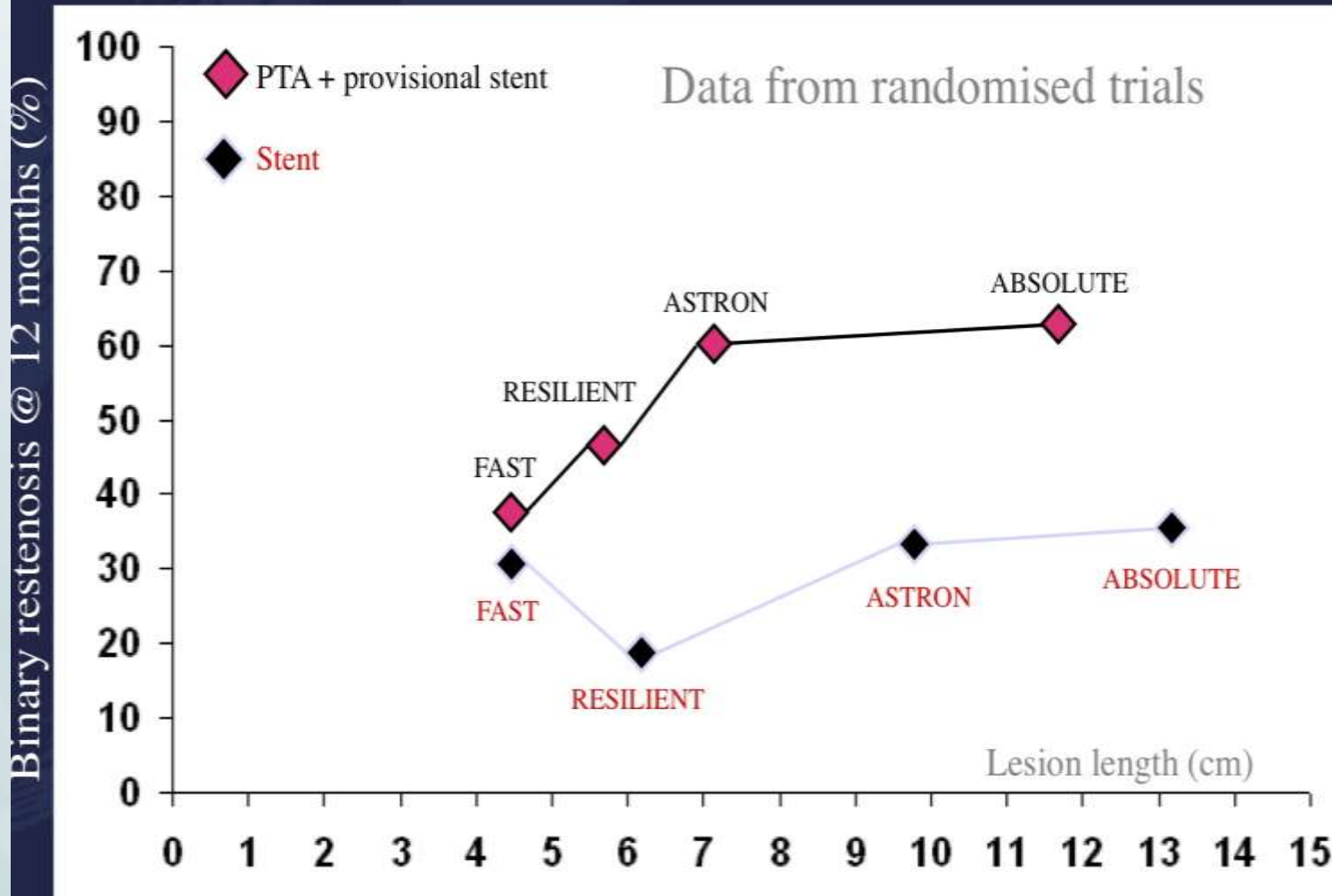


# Woven Nitinol Design



# Stenting is Clearly Better than POBA

12 months restenosis vs. lesion length



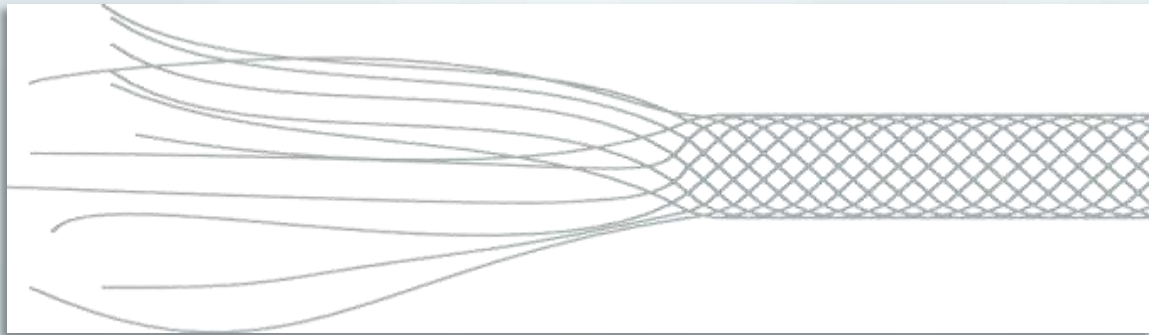
# The Growing Body of Evidence

- VIENNA (Absolute, Abbott)
- RESILIENT (LifeStent, Bard)
- DURABILITY 2 (EverFlex, Covidien)
- STROLL (SMART, Cordis)
- COMPLETE (Complete SE, Medtronic)
- ZILVER PTX (Zilver and Zilver PTX, Cook)
- SUPERB (Supera, IDEV)
- SUPERNOVA (Innova, Boston Scientific)
- OSPREY (Misago, Terumo)



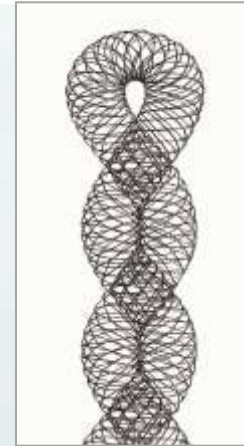
# Supera Technology Overview

- **Novel self-expanding nitinol vascular “mimetic” stent utilizing individual interwoven wire technology**
- **Provides increased flexibility, radial strength and resistance to fracture**



- **Standard nitinol stents (SNS) are made from a nitinol tube that is laser-cut**
- **Data suggests improved durability vs. standard nitinol stents (SNS)**

Supera



Standard Nitinol Stents (SNS)



# Increased Flexibility and Conformability in Tortuous Anatomy

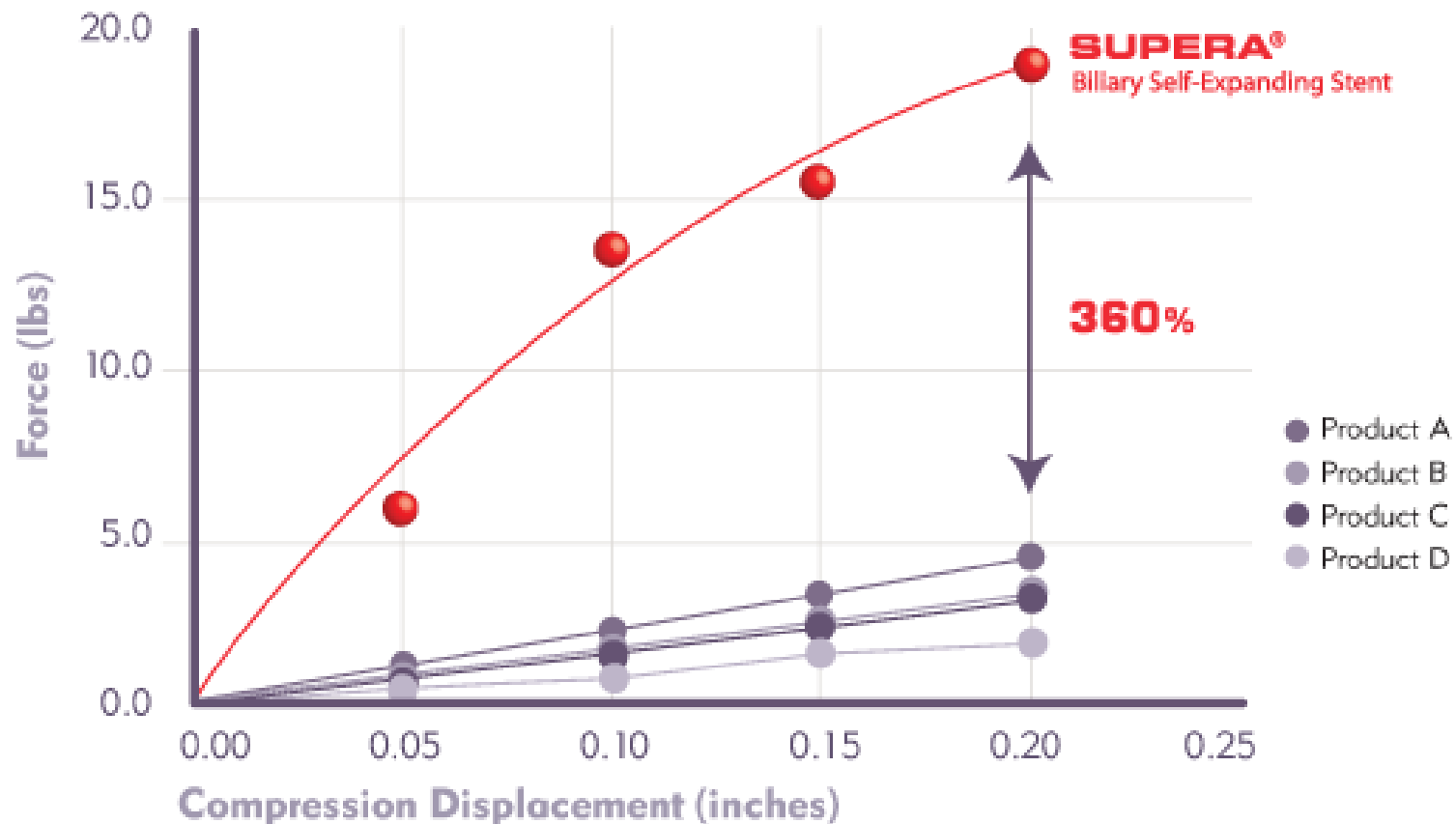


Courtesy of: Dr. Hans Biemans, Rivas Hospital Gorinchem, the Netherlands

Courtesy of: Dr. Thomas Zeller, Heart Center, Bad Krozingen and Dr. Dierk Scheinert, Park Hospital Leipzig - Germany

# Compression Data

## Crush compression data for 6 mm stents

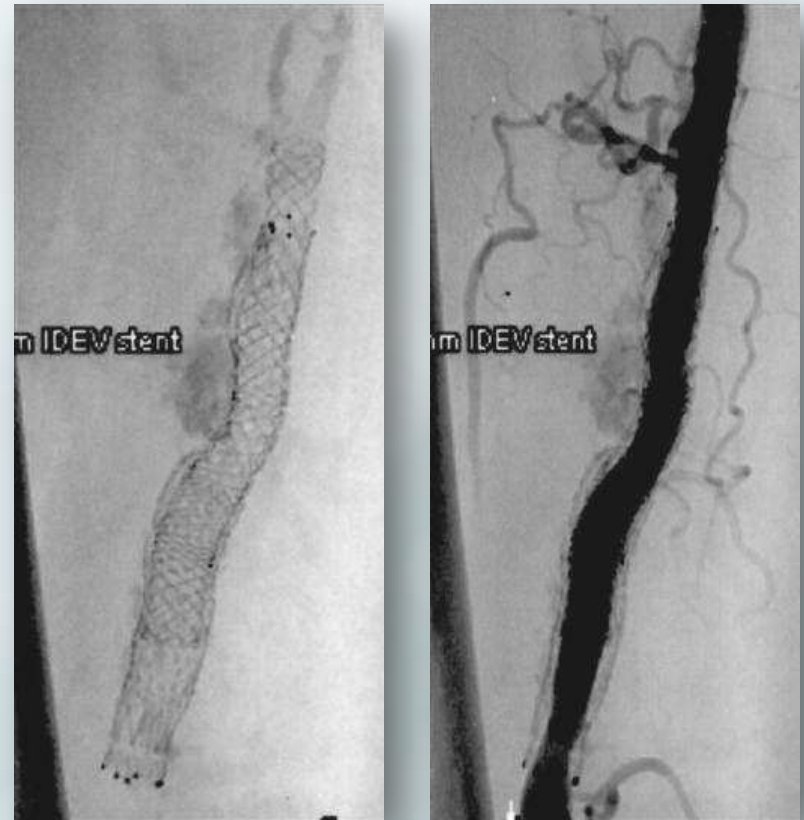


# Increased Radial Strength in Areas of High Calcification

**Pre Supera:**  
SNS deformation



**Post Supera:**  
Supera placed within SNS to restore patency

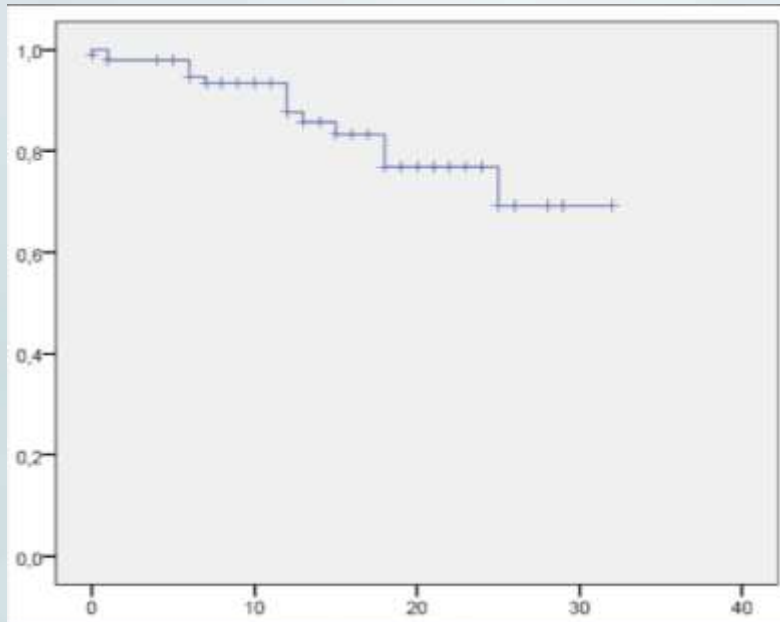


# Leipzig Supera Popliteal Registry

## N = 101

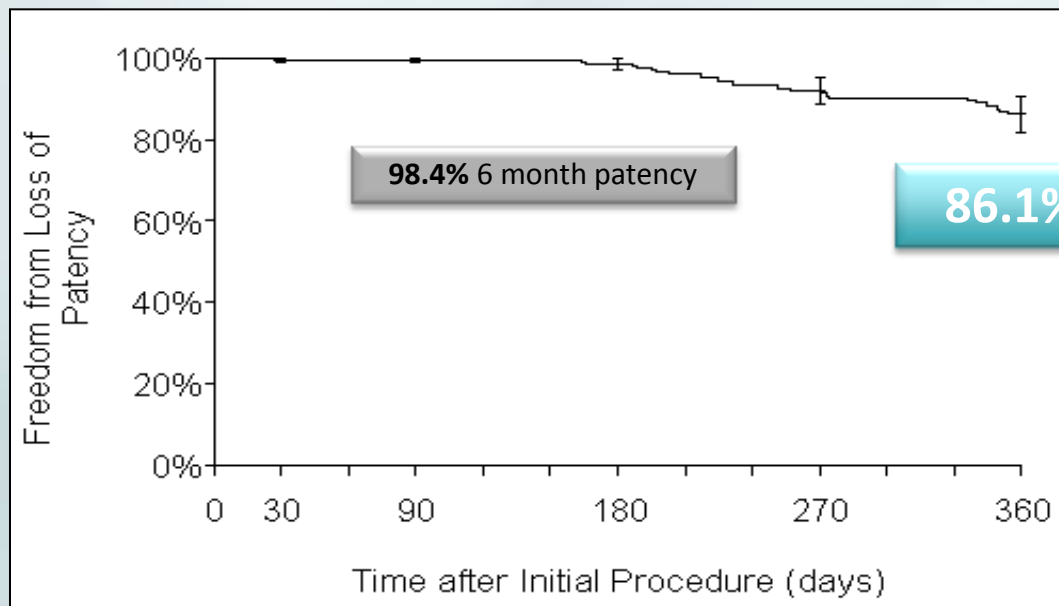
Primary Patency (PSVR < 2.5)

6 Month	94.6%
12 Month	87.7%
18 Month	76.9%
24 Month	76.9%

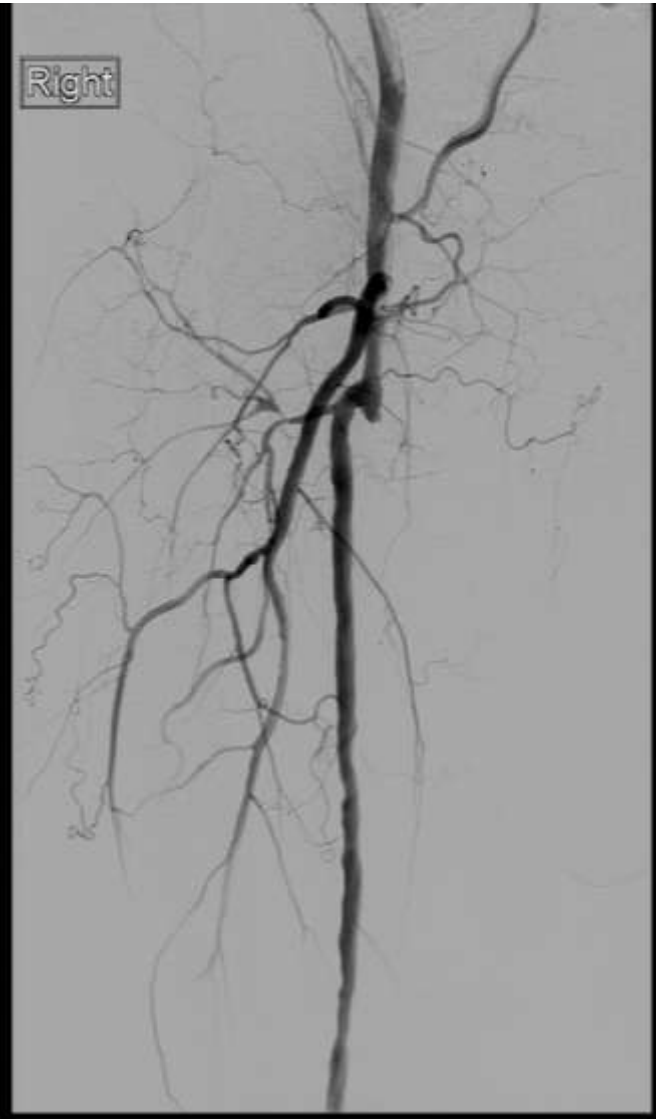


# SUPERB Trial Summary

- **Safety and efficacy endpoints were achieved at 1 year:**
  - Freedom from TLR of 90%
  - Survival Analysis primary patency of 86%
  - 0% (zero) stent fractures
  - Significant improvement in secondary endpoints including ABI/TBI, Rutherford-Becker scores, mean time and distance to claudication, and Quality-of-Life scores



# Diffuse Femoropopliteal Disease

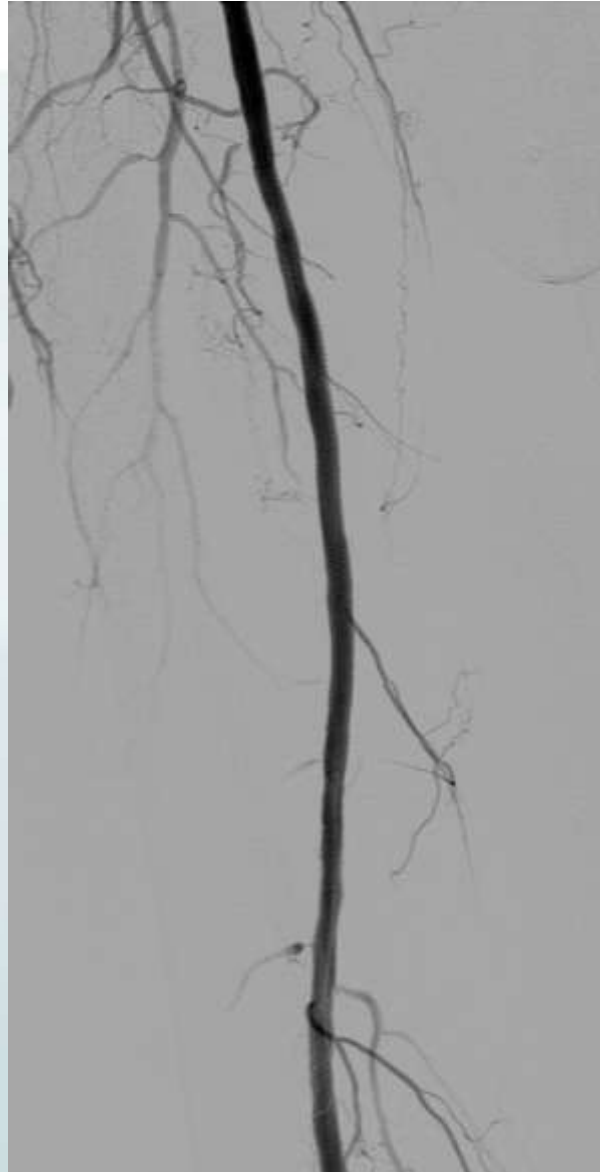


# 5 x 120mm Supera Stents (x2)

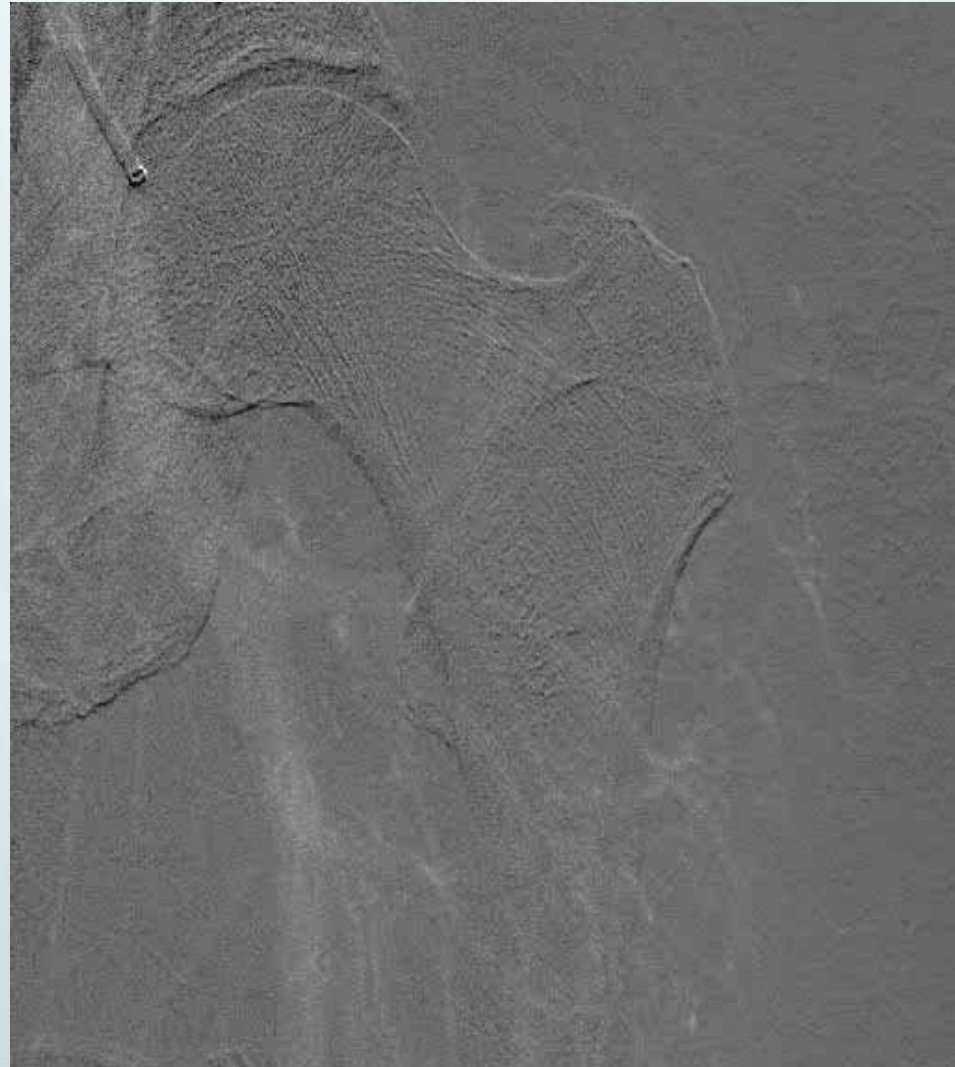




# Final



# Popliteal CTO: Interwoven Stents



# Bent-Knee Angio

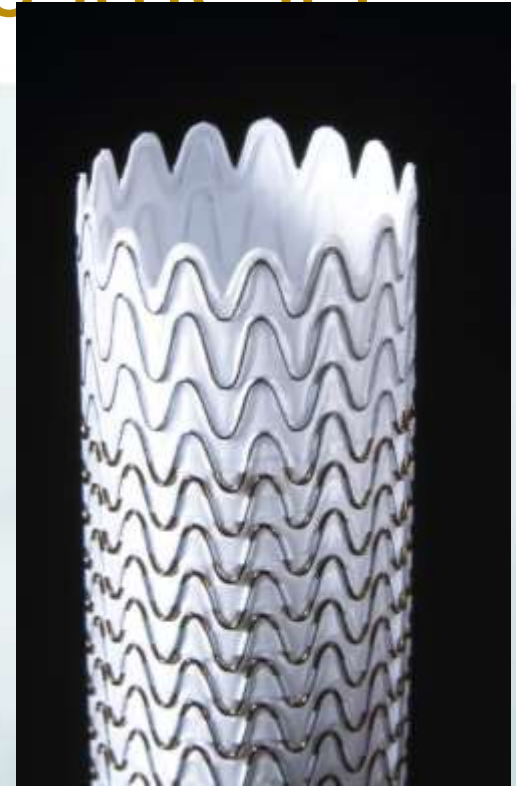


# Covered Stents



# GORE VIABAHN® Endoprosthesis

- Incremental improvements:
  - Lower profile
  - Proximal contoured edge to reduce the risk of proximal edge restenosis
  - Heparin Bioactive Surface



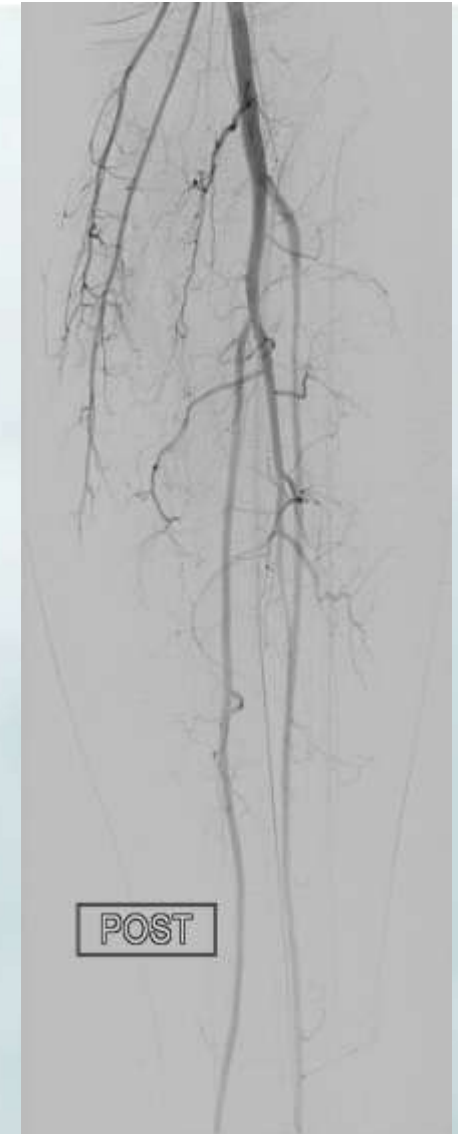
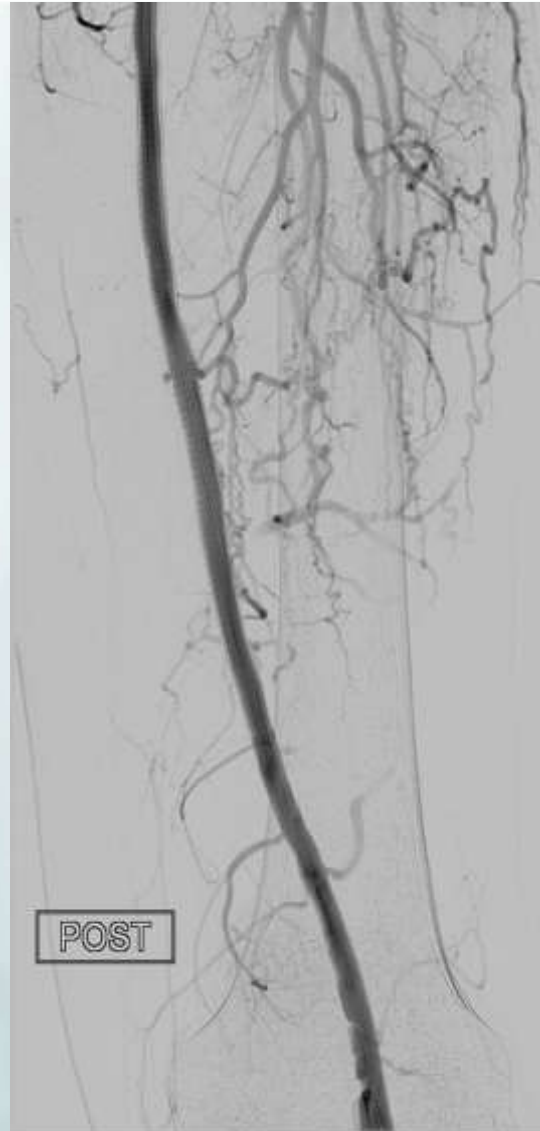
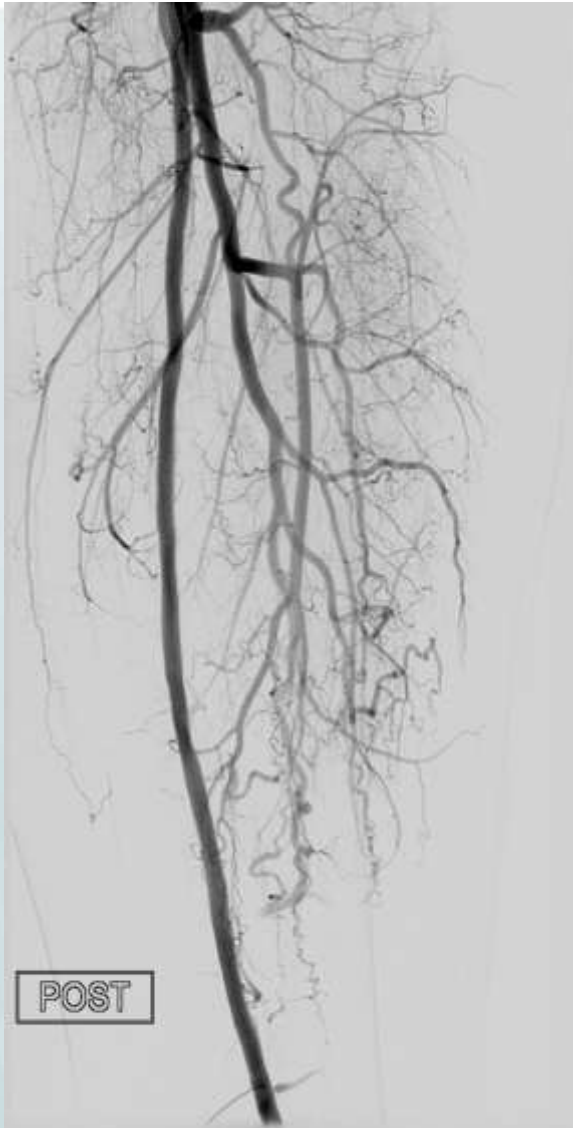
# Key Advantages

- Patency rate independent of lesion length
- Good results for long occlusions/stenoses
- When restenosis occurs, it is usually focal, edge restenosis
- Effective for instent restenosis

# Long SFA Occlusion



# Following Viabahn Covered Stents



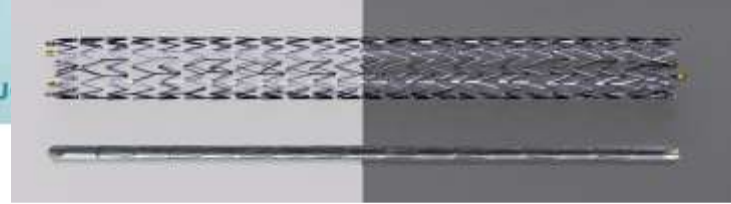


# VIASTAR Trial

- European randomized trial of Viabahn vs. bare nitinol stent for long SFA lesions
- Newest generation Viabahn endoprosthesis:
  - Low profile
  - Heparin bioactive surface
  - Proximal contoured edge
- 142 patients enrolled at 7 European Centers
- Rutherford category 2 - 5

# VIASTAR Outcomes

	VIABAHN™	BMS	P Value
Lesion length (cm)	19.0 ± 6.3	17.3 ± 6.6	P = 0.13
Occlusion	79%	70%	P = 0.21
12-month Primary Patency (all)	78.1%	53.5%	P = 0.009
12- month Primary Patency (> 20 cm)	73.3%	33.3%	P = 0.004
12-month Freedom from TLR	84.6%	77.0%	P = 0.37
Ankle-Brachial Index	0.94 ± 0.23	0.85 ± 0.23	P < 0.05



# What About DES?

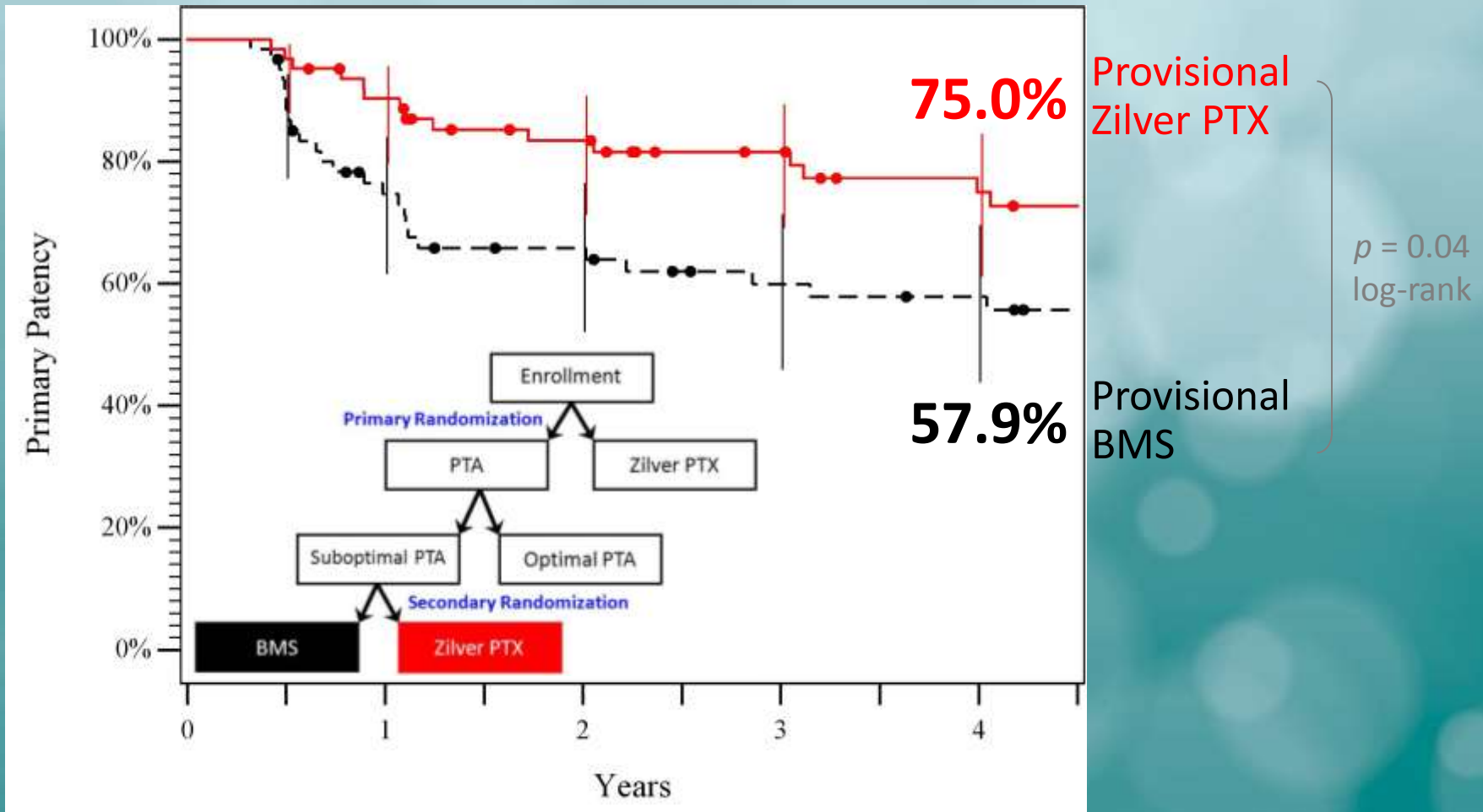
## *Zilver PTX*

- Paclitaxel only (no polymer or binder)
- Thin coating (less than 5 microns)
- 3 microgm/mm<sup>2</sup> dose density  
(maximum 880 microgm total dose, largest stent)



# Proven Drug Effect at 4 Years

## Patency (PSVR < 2.0): Provisional Zilver PTX vs. BMS



41% reduction in restenosis due to the drug

# Making Sense of it All

- Nitinol stents are superior to PTA for moderate length lesions in the SFA and proximal popliteal artery
- Better and more flexible stent designs, improved delivery systems and now DES
- Promising results with woven nitinol stent design (popliteal artery, heavily calcified lesions)
- Improving outcomes with covered stents



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