

# ***Optimal Treatment in Femoro- popliteal Disease with Misago***

## **Peripheral Self-Expanding Stent System**

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# Disclosures

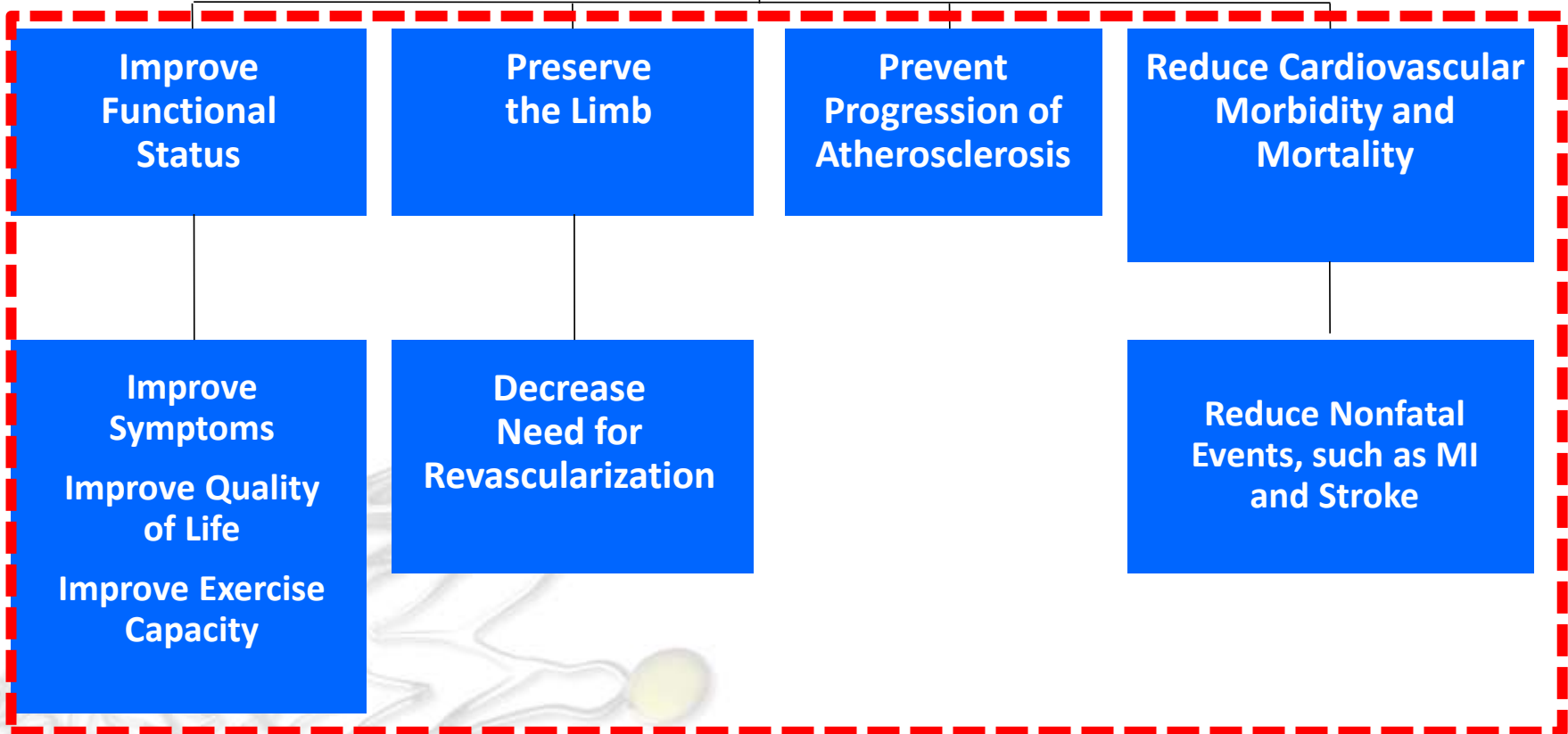
**Speaker:** Prof. [Seung-Woon Rha](#)

I have the following potential conflicts of interest to report:

- Receipt of grants/research support
- Receipt of honoraria and travel support
- Participation in a company sponsored speakers' bureau
- Employment in industry
- Shareholder in a healthcare company
- Owner of a healthcare company
  
- [I do not have any potential conflict of interest](#)

# Treatment Goals for the Patient with PAD

## Clinical Treatment Goals



# Balloons for PTA

|                  | 014            | 018        | 035                         |
|------------------|----------------|------------|-----------------------------|
| <b>Abbott</b>    | Armada14       | Fox cross  | Armada35                    |
| <b>Boston</b>    | Coyote         |            | <u>Mustang (NC)</u>         |
| <b>Cook</b>      | Advance 14 (M) | Advance 18 | Advance 35                  |
| <b>Cordis</b>    | Sleek (M)      | Savvy      | PowerFlex                   |
| <b>Medtronic</b> | Amphirion (M)  |            | <i>InPact (DEB)</i>         |
| <b>Covidien</b>  | Nanocross      |            | Evercross                   |
| <b>Bard</b>      |                |            | Rival, <u>Conquest (NC)</u> |

\*M; monorail type available  
NC; Non-compliant balloon  
DEB; Drug-eluting balloon

# Stents for PTA

| 014              |  | 035          |                          |
|------------------|--|--------------|--------------------------|
| <b>Abbott</b>    | Xpert (SES)  | Absolute Pro | Omnalink (BES)           |
| <b>Bard</b>      |  |              | Life                     |
| <b>Cordis</b>    | Precise (SES)-Carotid<br>Palmaz Blue/Genesis (BES)-Renal |              | <u>Smart</u>             |
| <b>Gore</b>      |  |              | Viabahn (Stentgraft)     |
| <b>Cook</b>      |  |              | Zilver, Zilver PTX (DES) |
| <b>Medtronic</b> | Maris deep (SES);014 & 018<br>Chromis Deep (BES)         | Complete SE  | Scuba (BES)              |
| <b>Boston</b>    |  |              | Wall Stent, Epic, Inova  |
| <b>Covidien</b>  |  |              | Protege                  |
| <b>Biotronic</b> | Pulsar (018)   |              | Pulsar (035)             |
| <b>Terumo</b>    |  |              | <i>Misago (Monorail)</i> |

## Misago (Osprey):

The English word for Misago is Osprey. Osprey is a bird more commonly known as the Sea Hawk or the Fish Eagle.

The naming comes from the quick and swift action of the bird when catching its prey and reflects on the quick action of the monorail system compared to competitors.



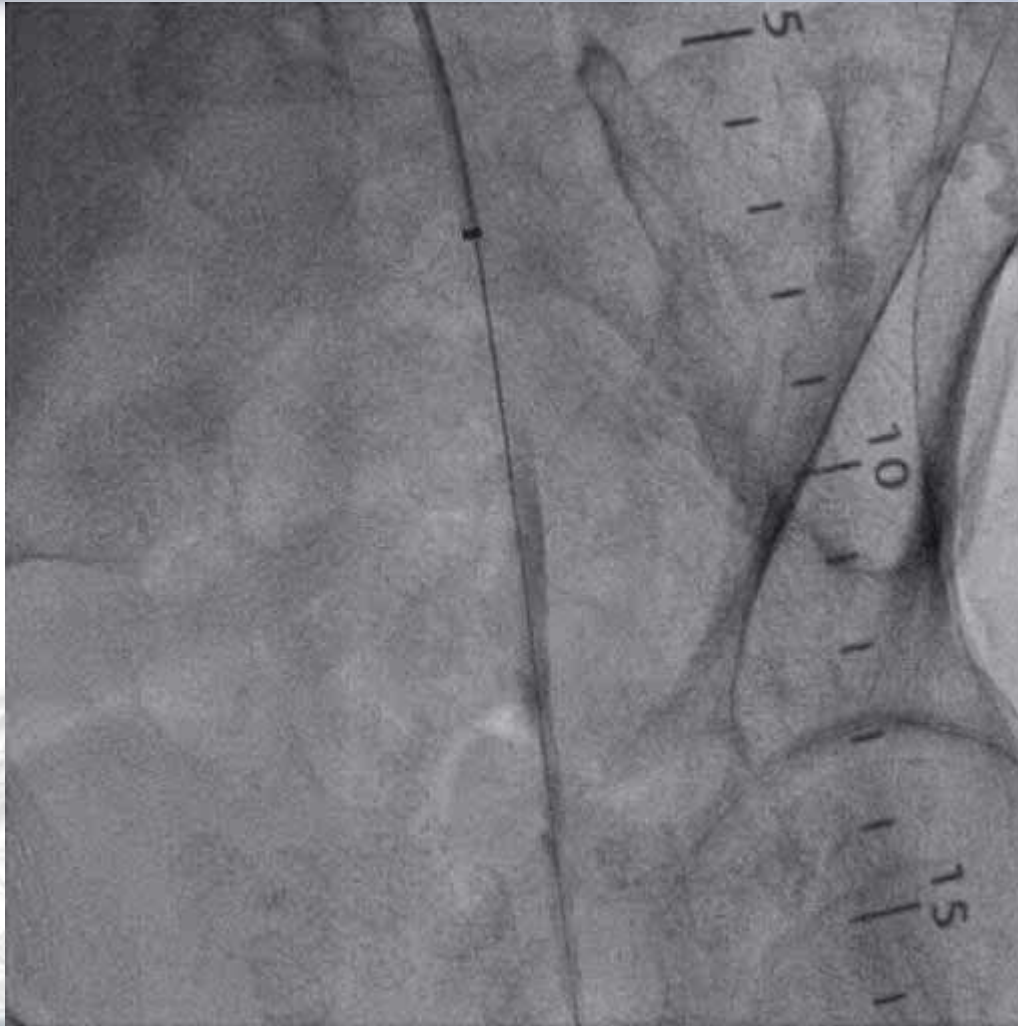
\*척추동물-조강-매목-수리과-물수리

\***Pandion haliaetus**

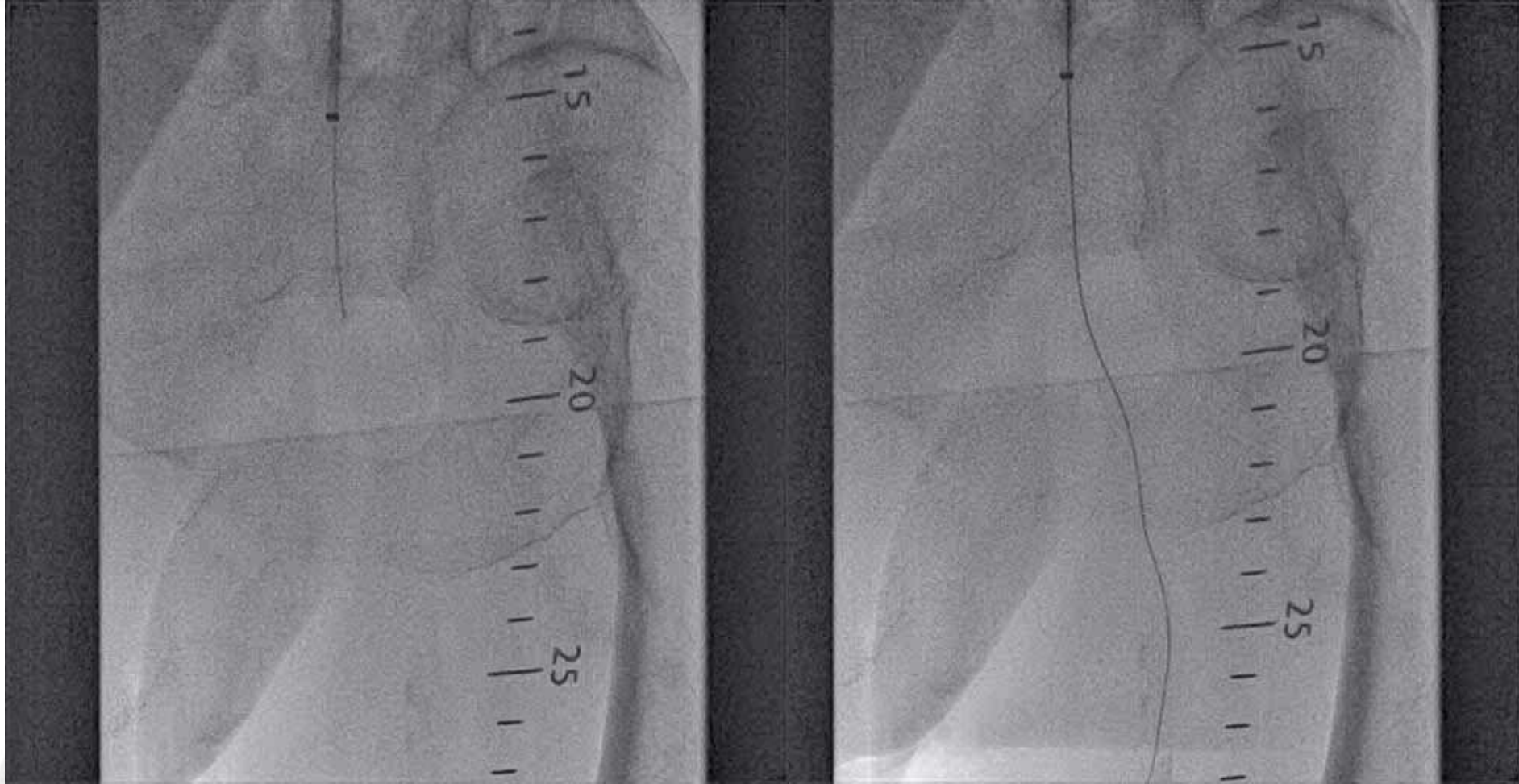
\*Size; 54-64cm, 2-4.2kg

# Misago SFA Case

M/58, CLI

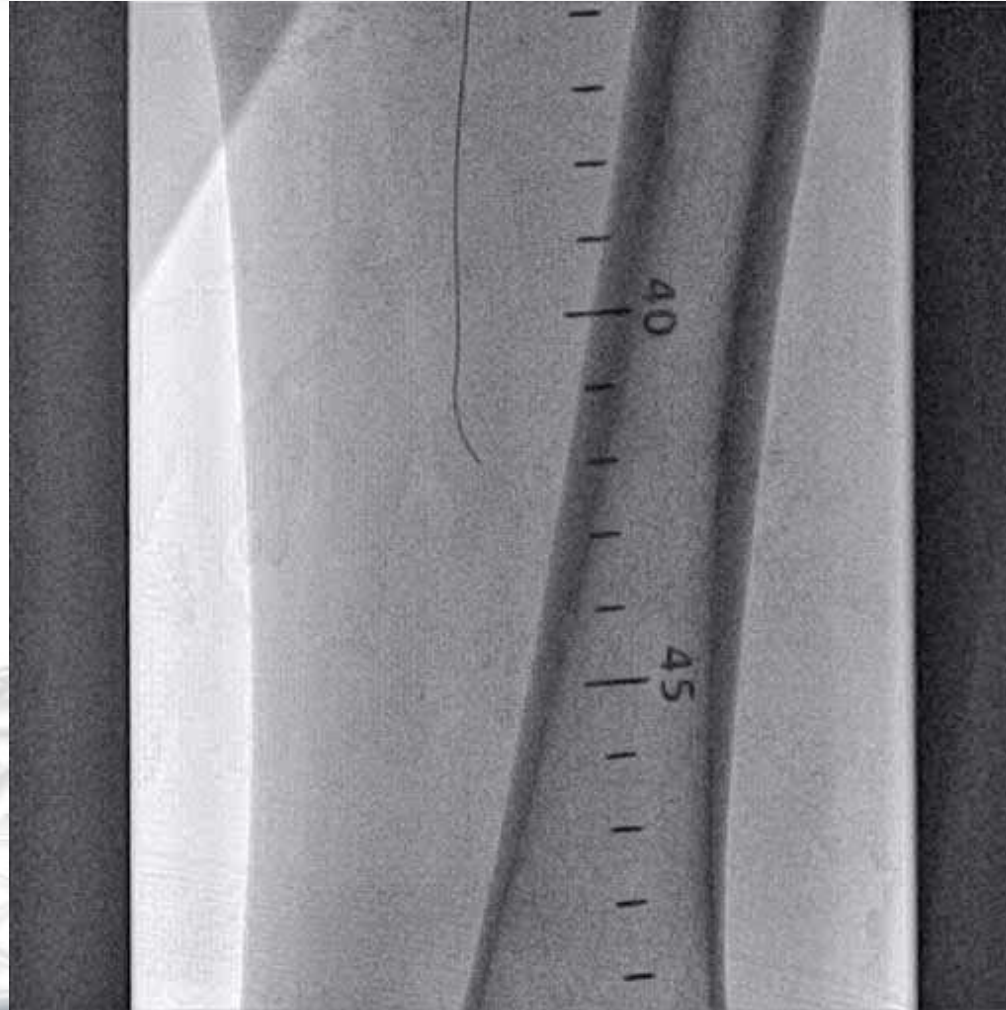


# SFA Wiring

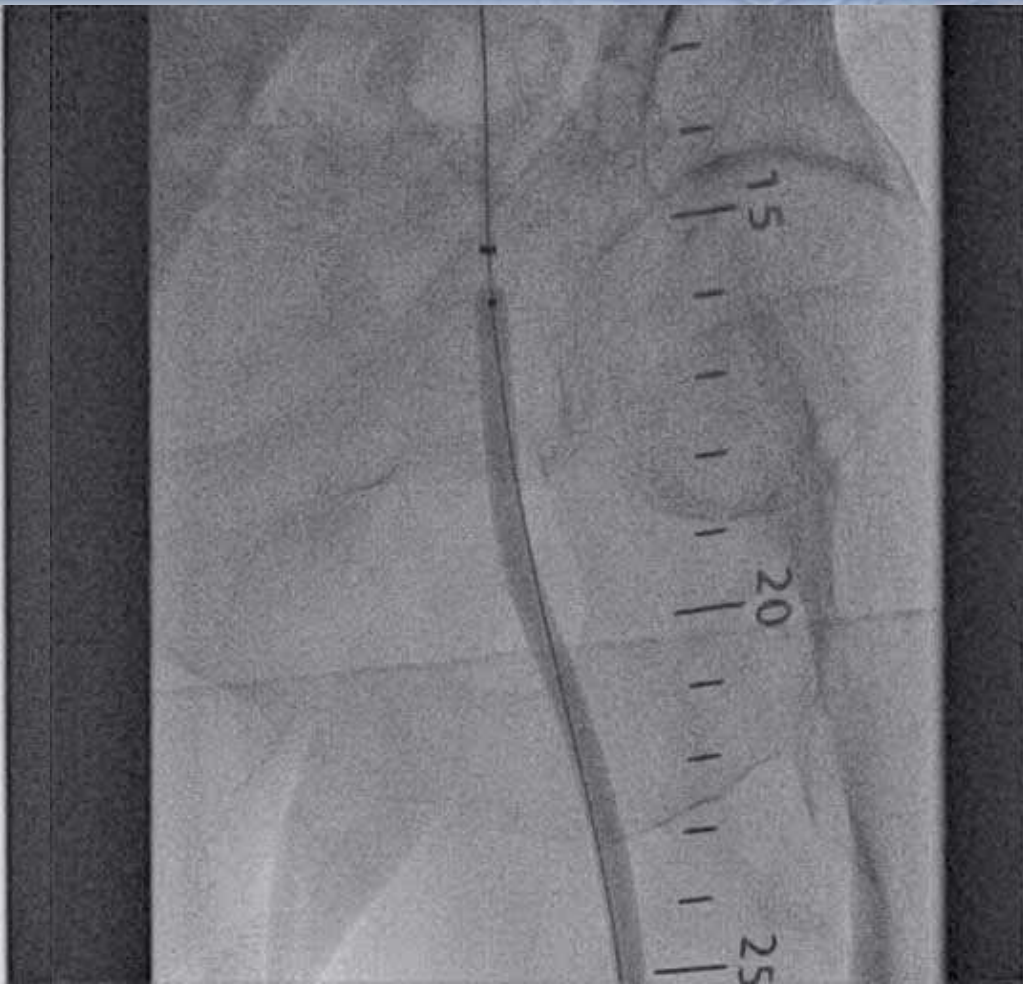




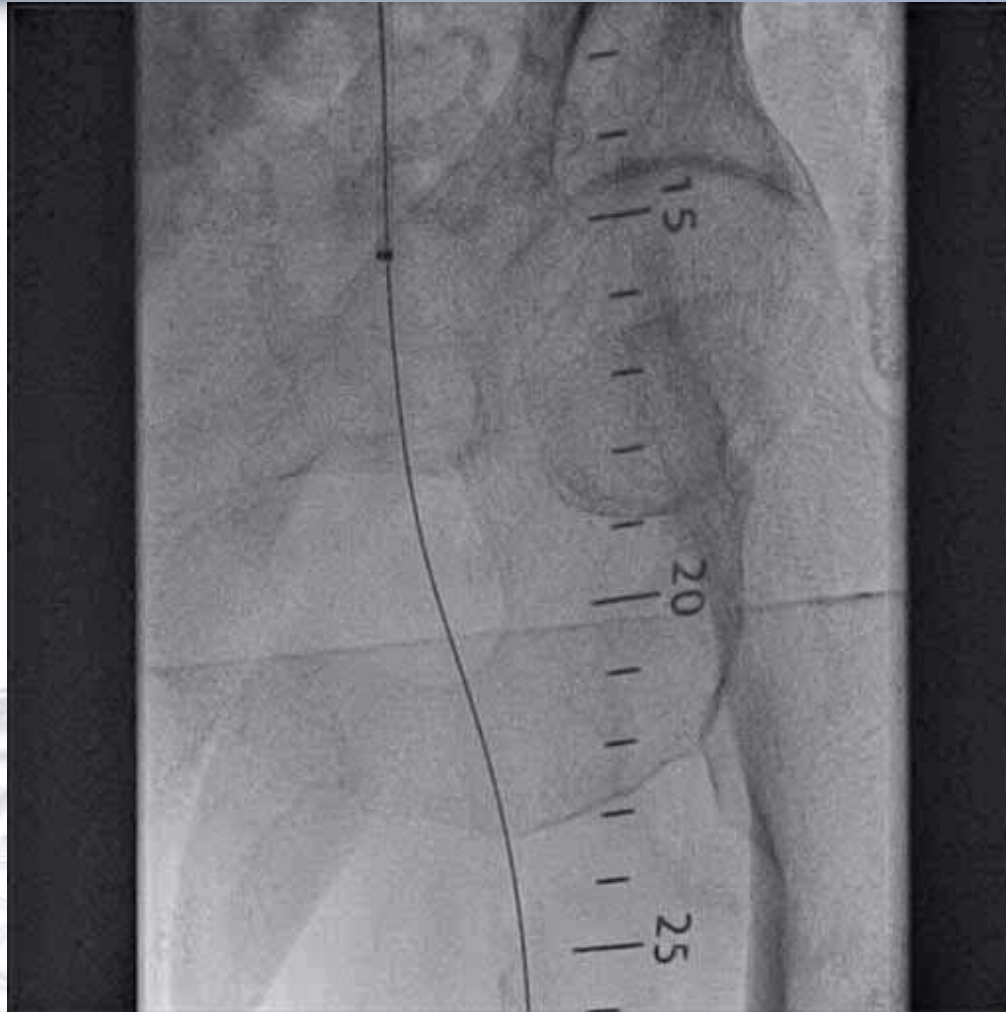
# Post SFA Wiring



# Balloon Dilation



# Post POBA

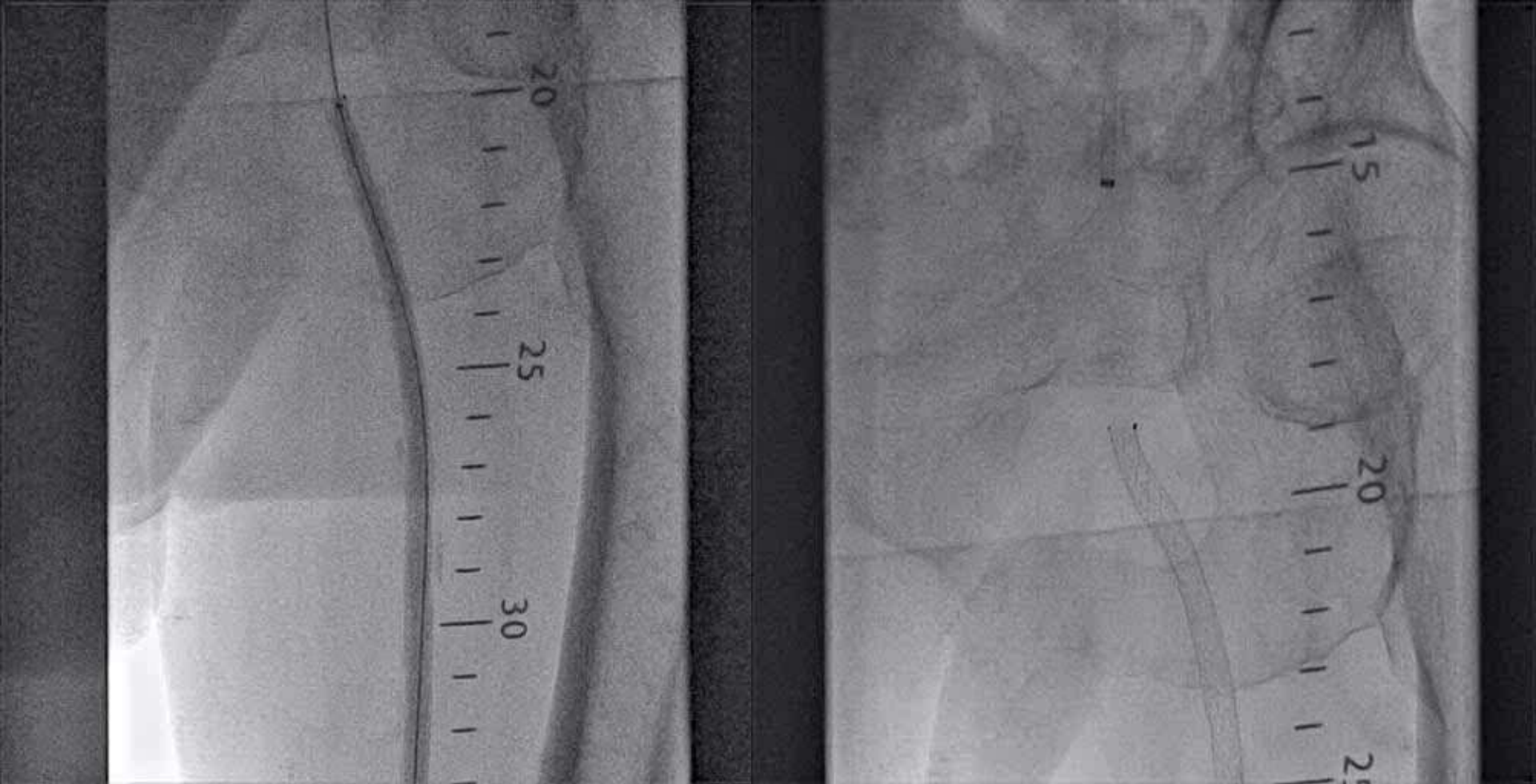


# Misago Stenting

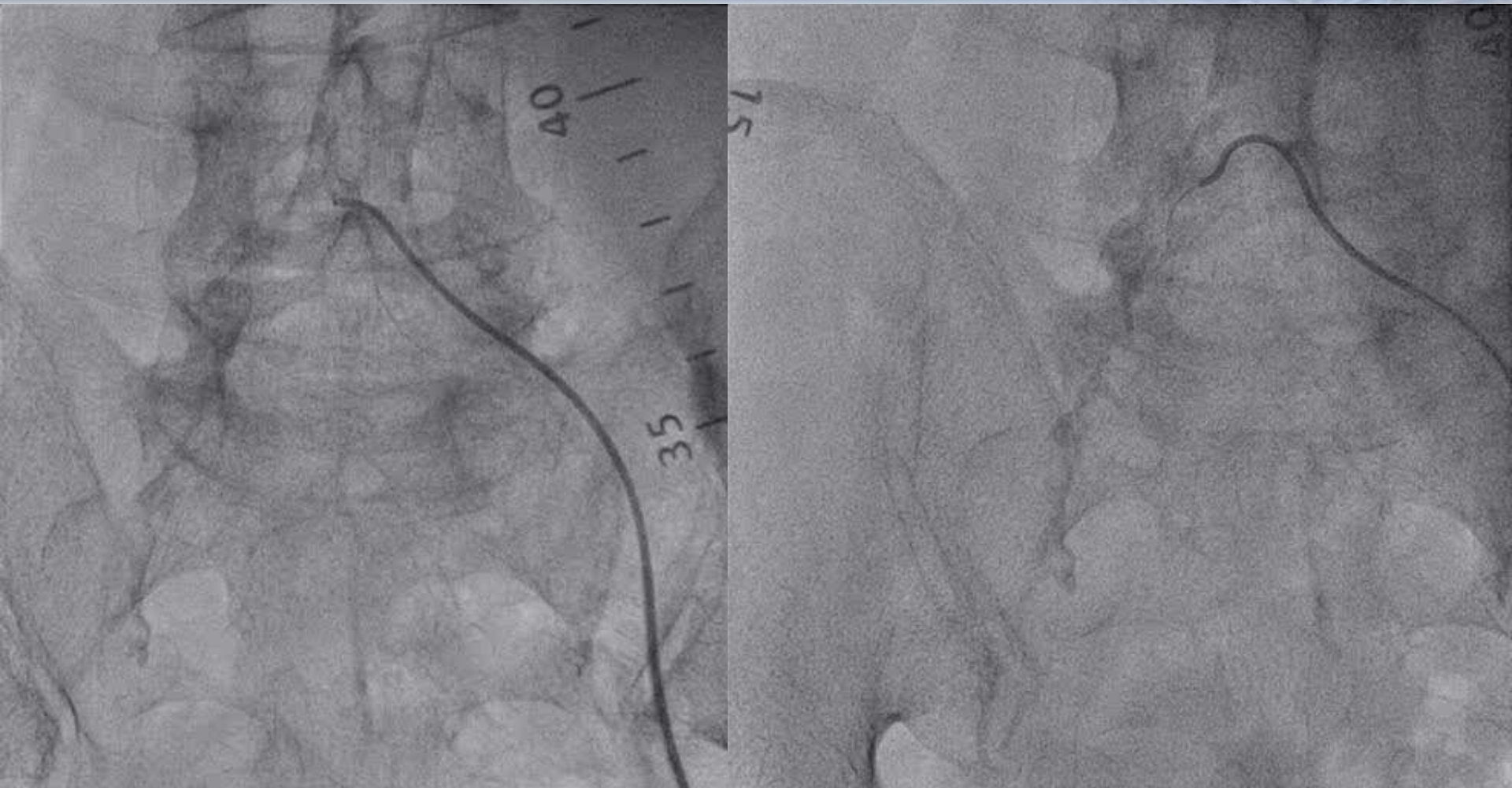




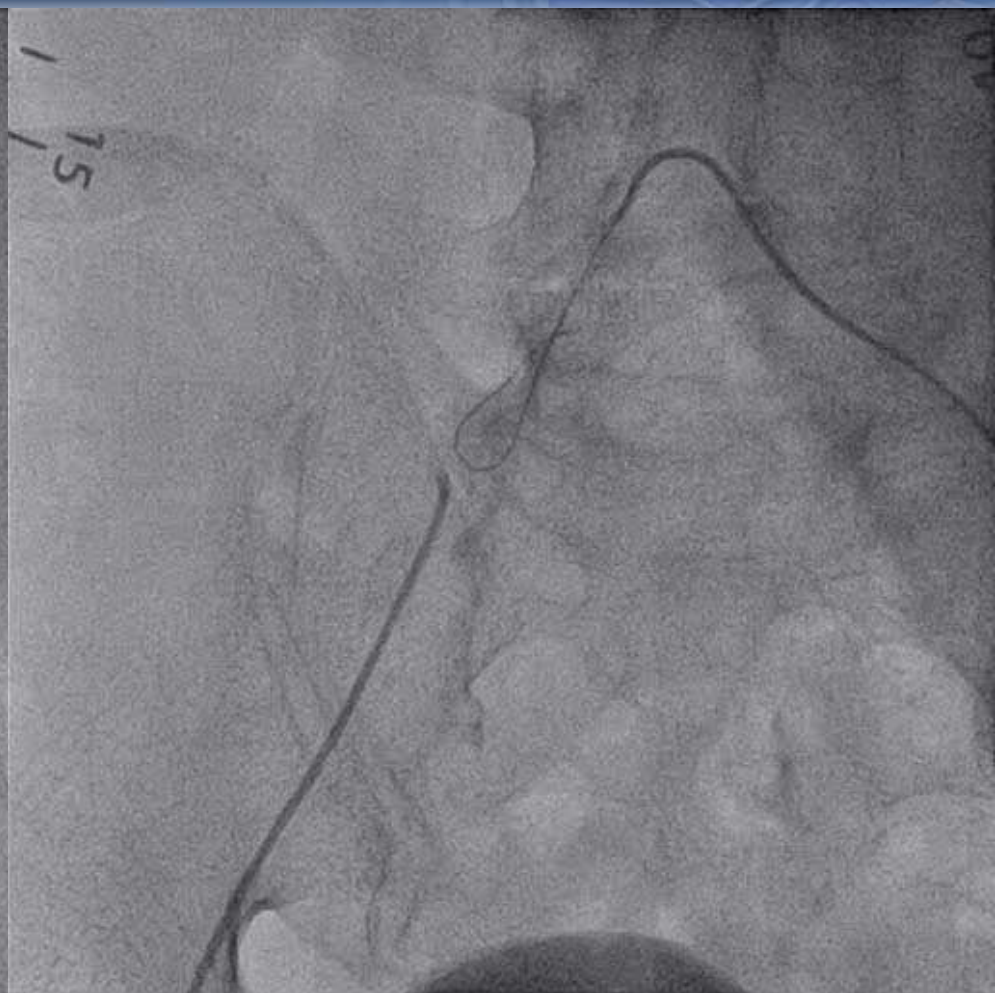
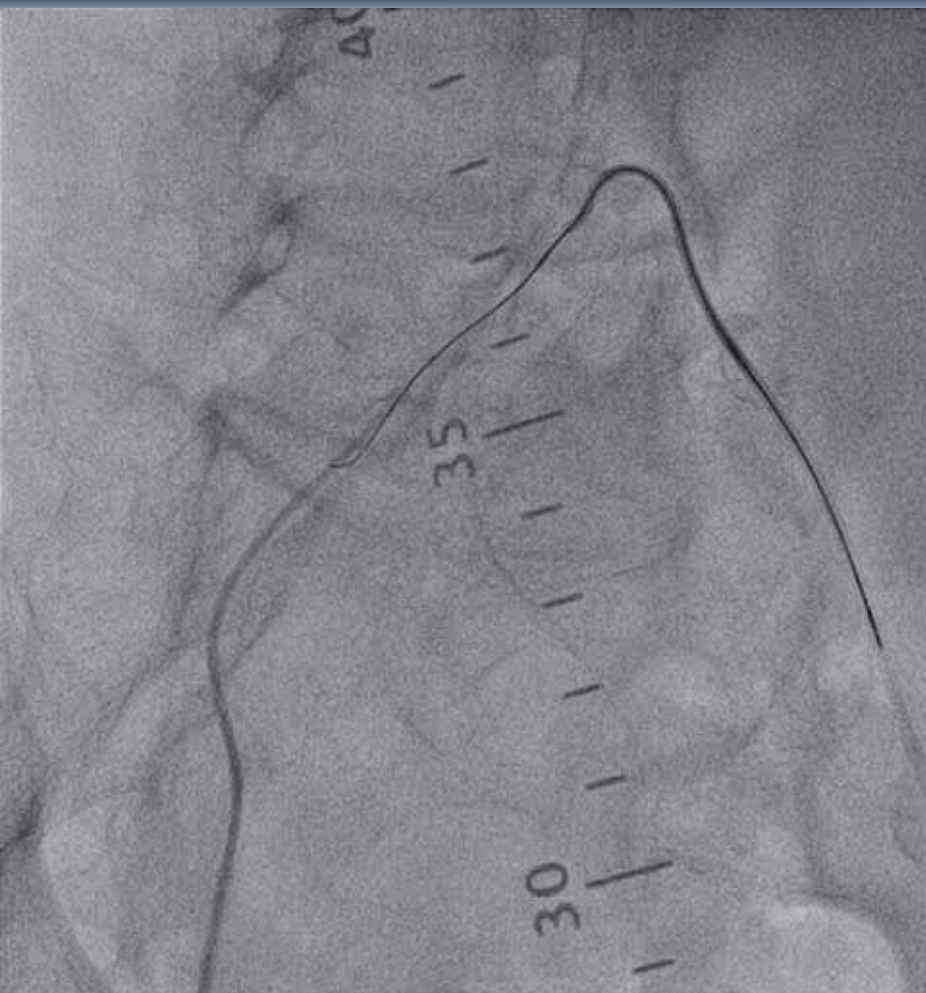
# Adjuvant Balloon and Final



# Misago Iliac Case

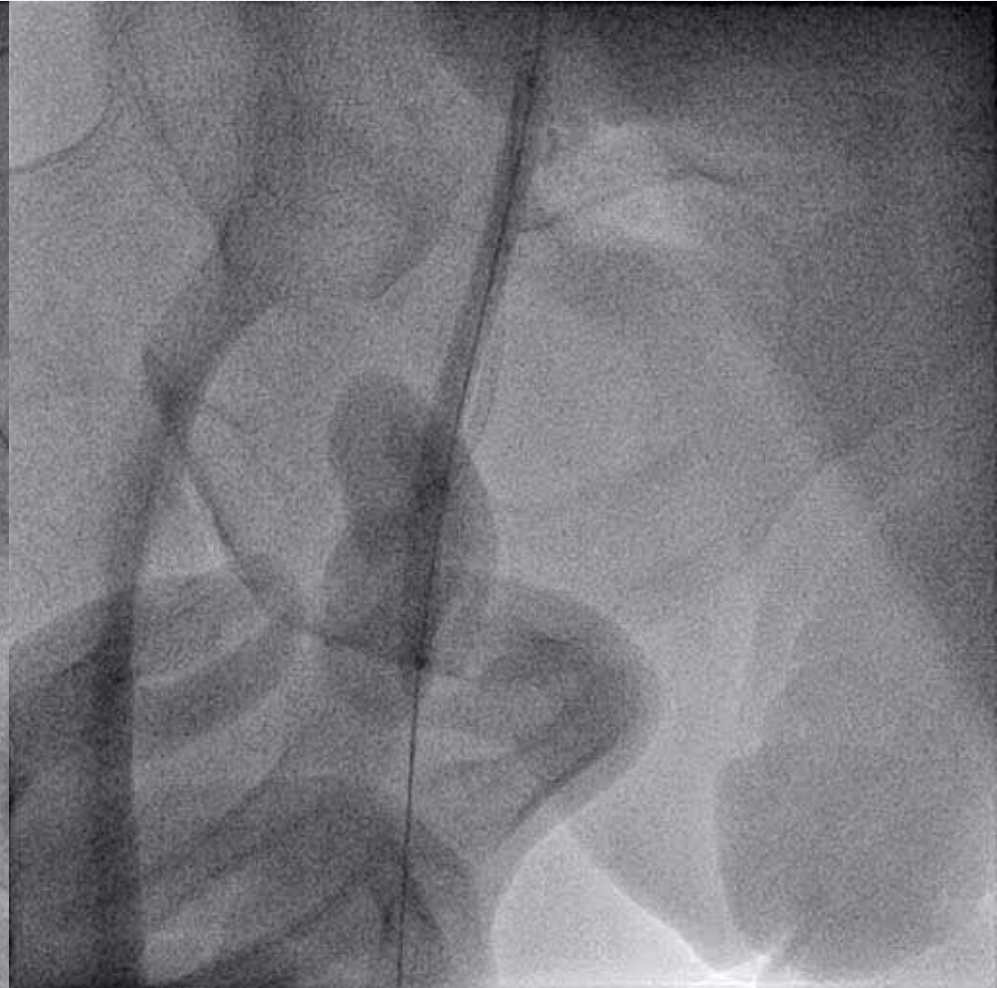
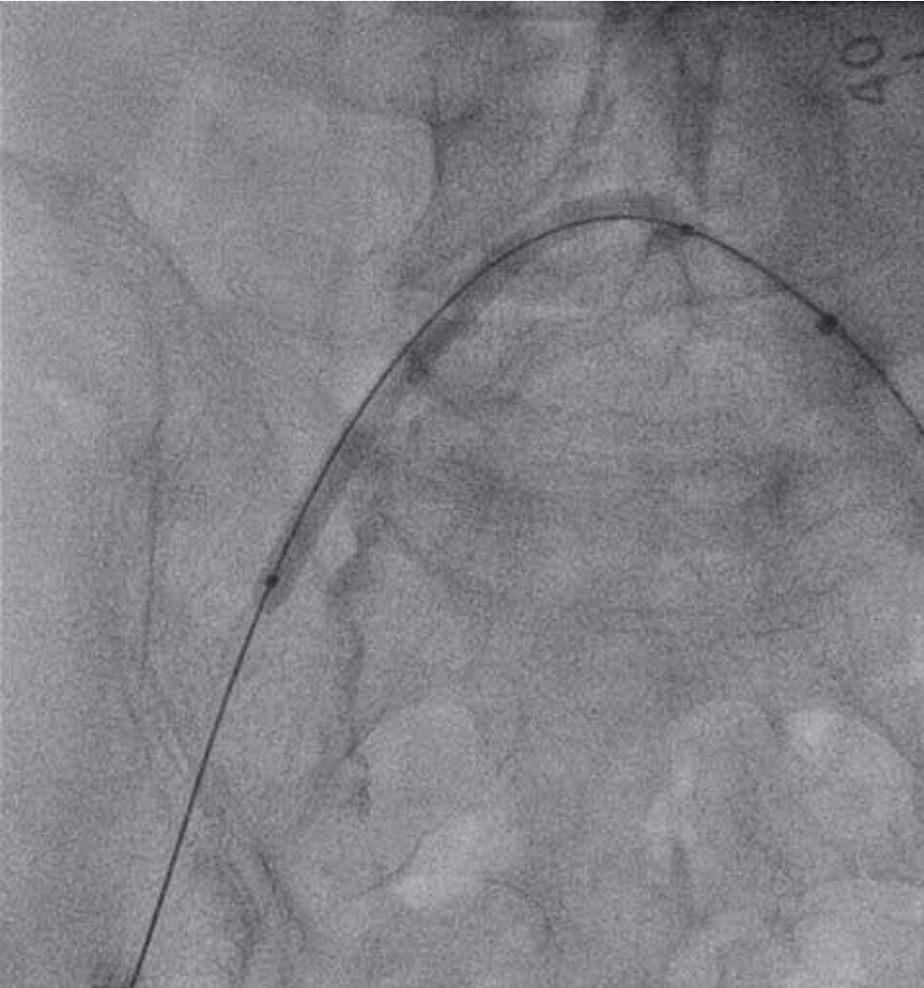


# Iliac CTO-Wiring

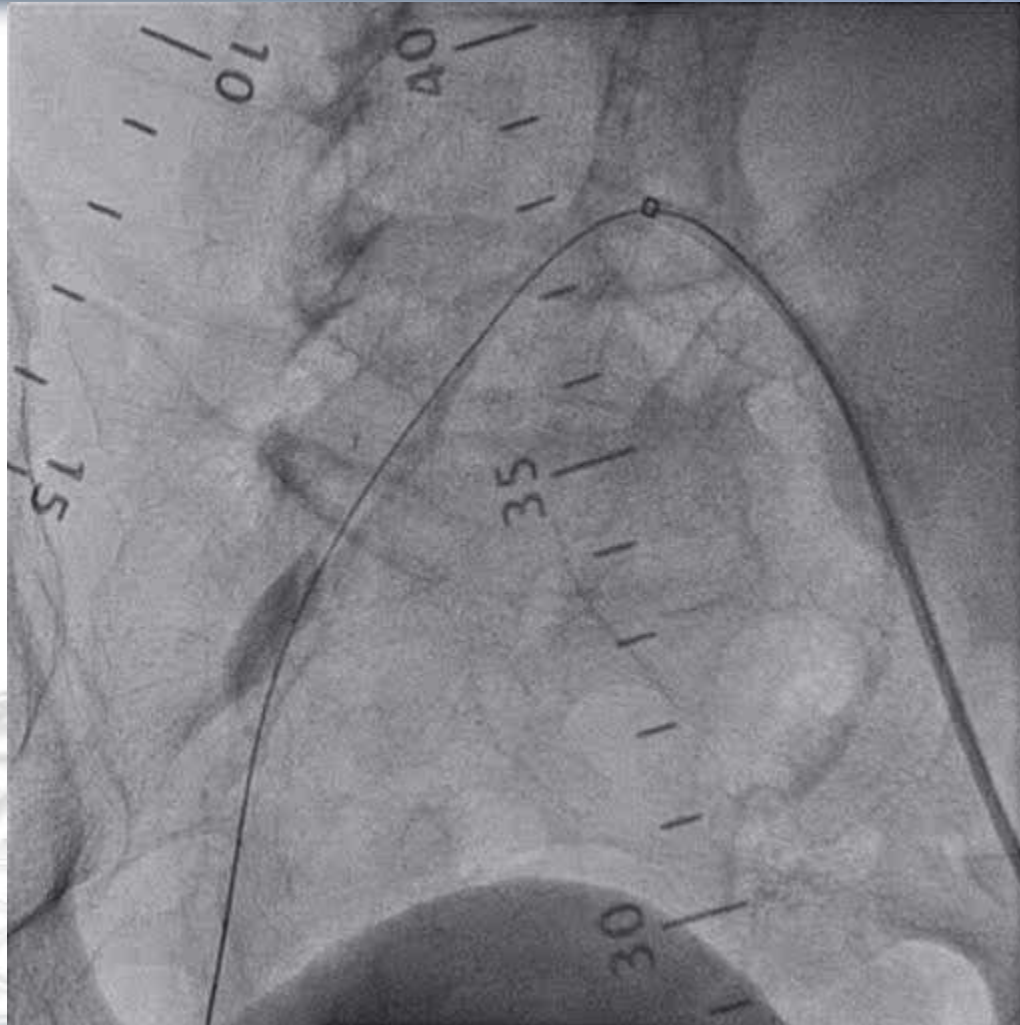




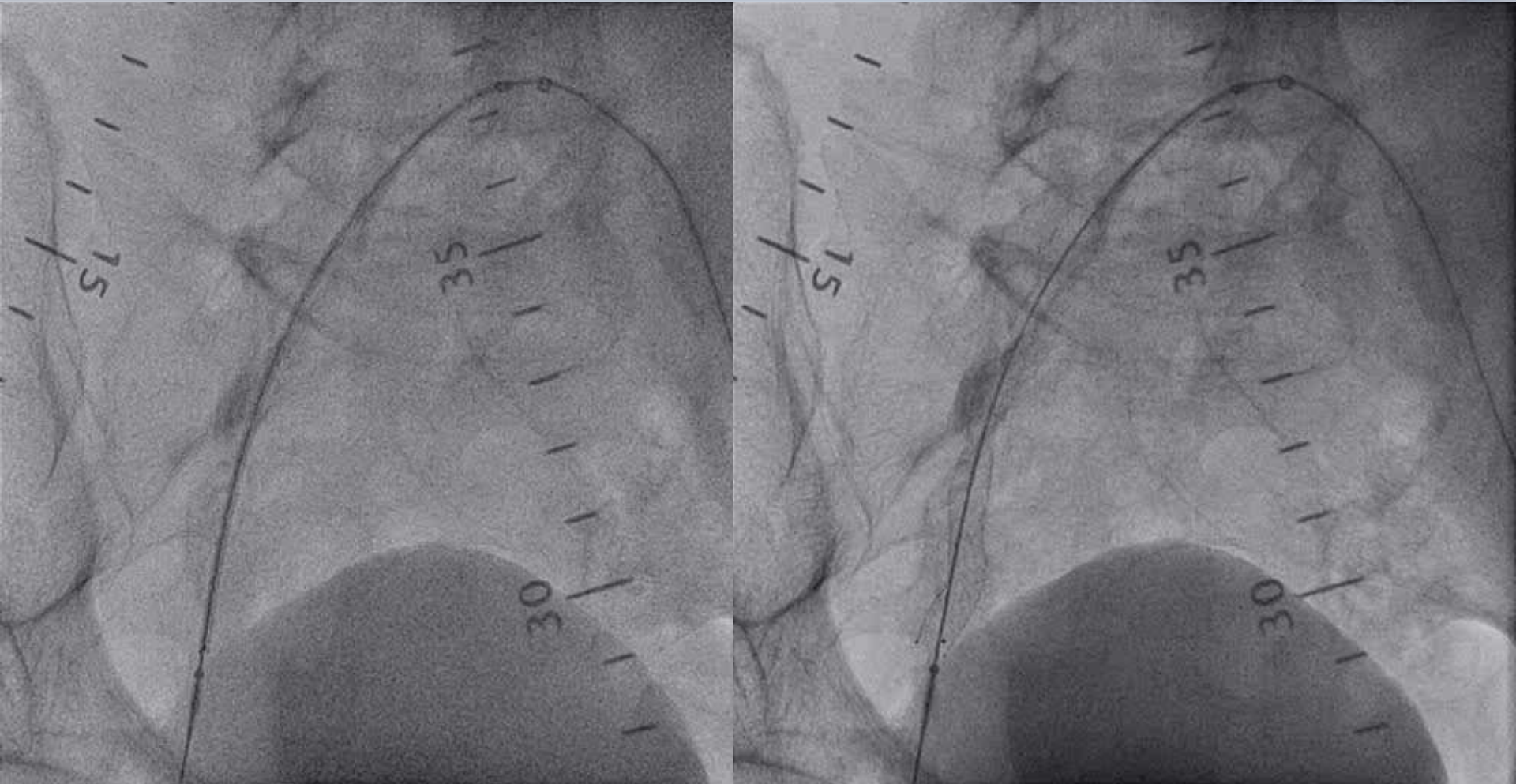
# Balloon Dilation



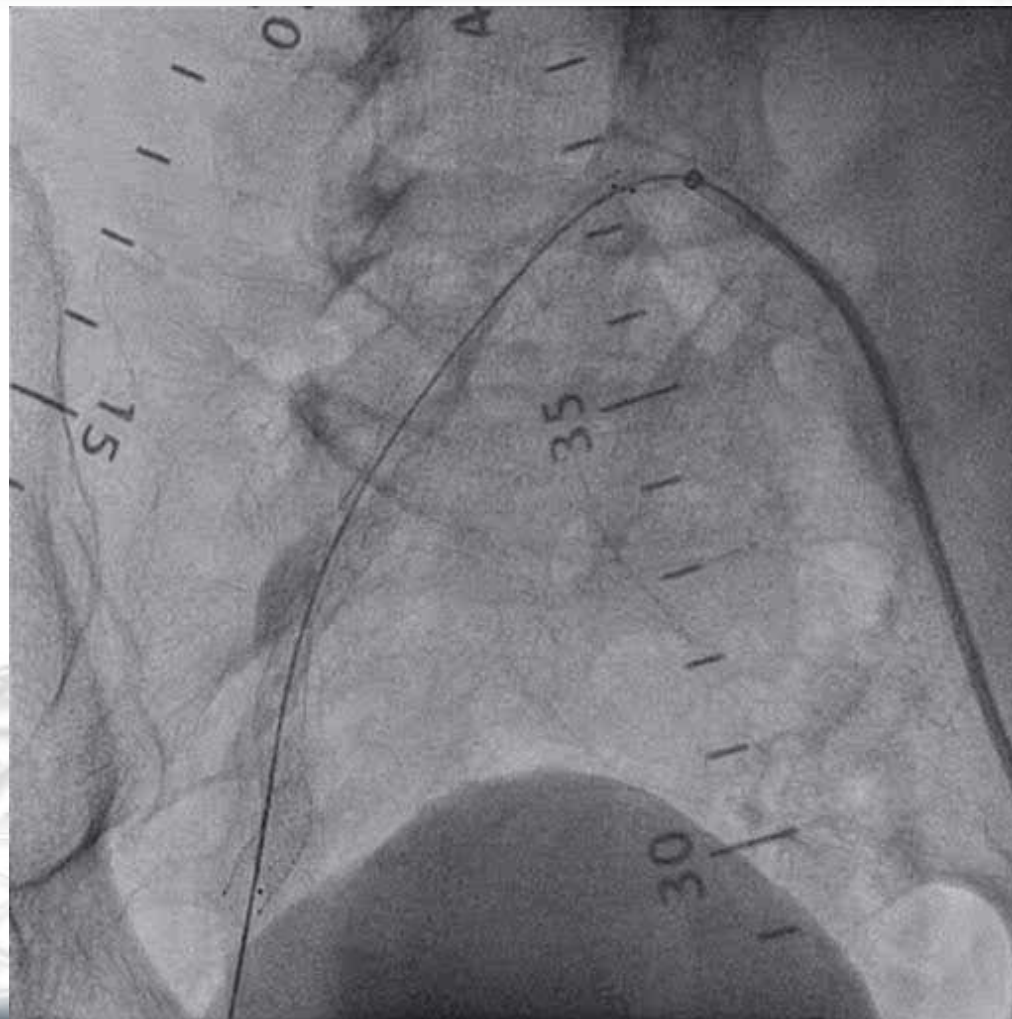
# Post POBA



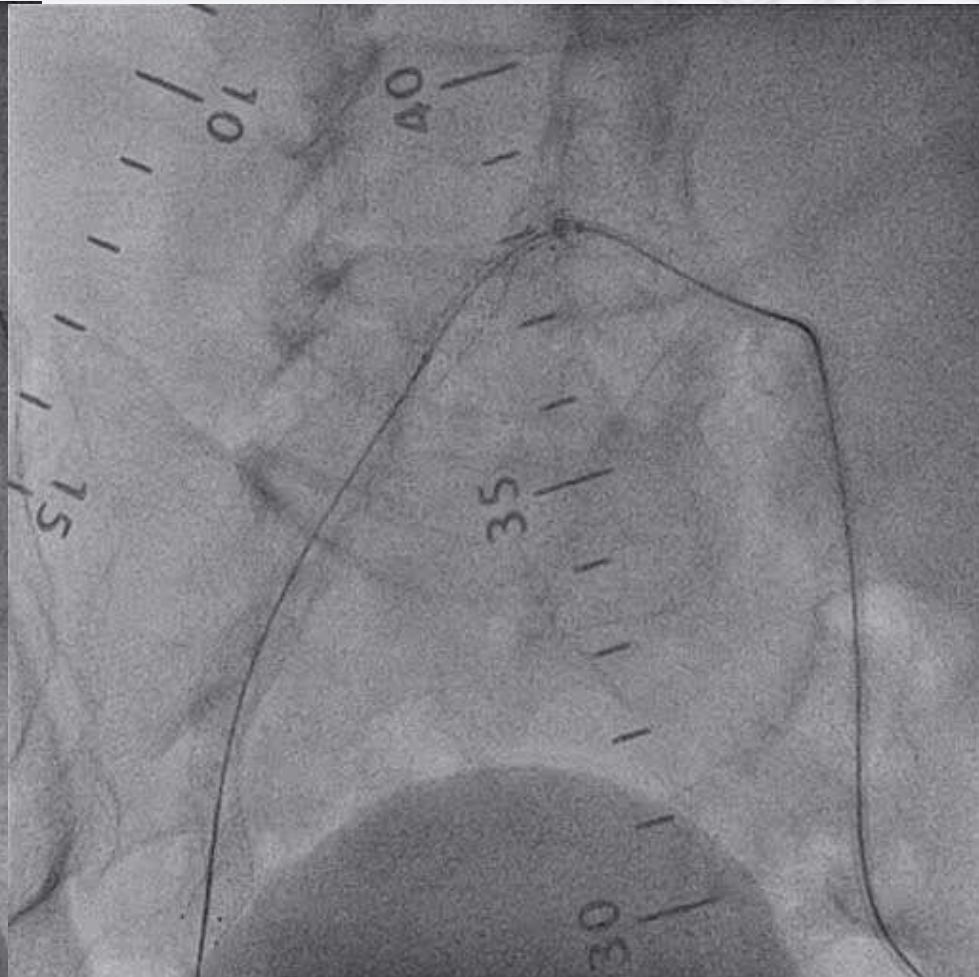
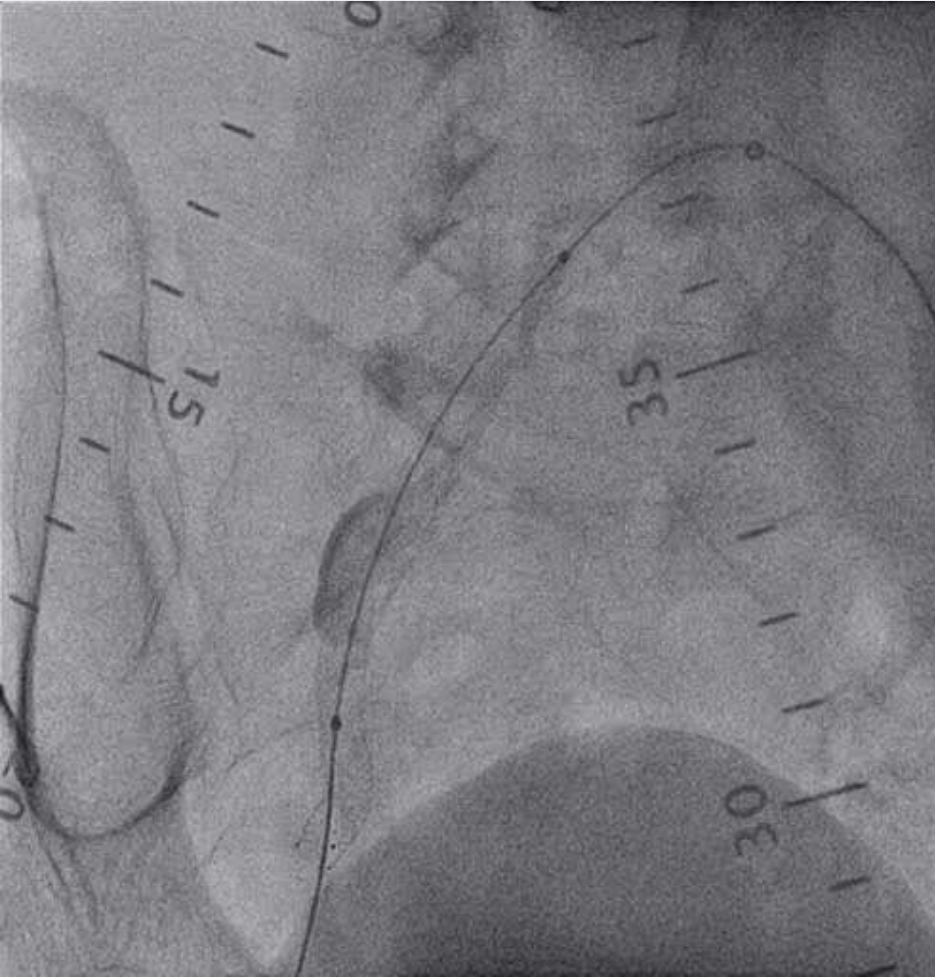
# Misago Stenting



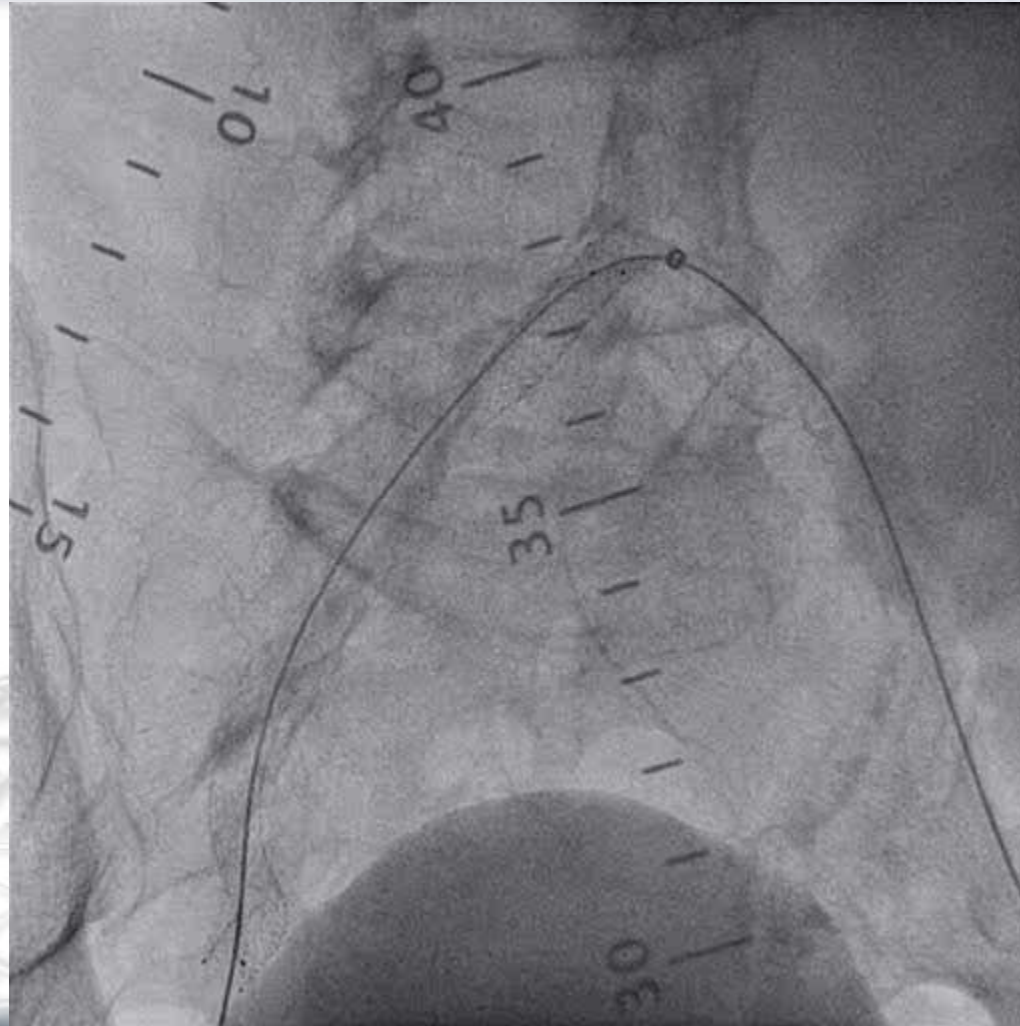
# Post-Misago Stent



# Adjuvant Ballooning and Stenting



# Iliac-Final Angiography



# Misago Stent



## Unique stent design

- ✓ Excellent conformability
- ✓ Low Fracture rate
- ✓ Long term patency



## RX delivery system

- ✓ Precise deployment of stent
- ✓ Fast catheter change, short wire

# Misago Product concept

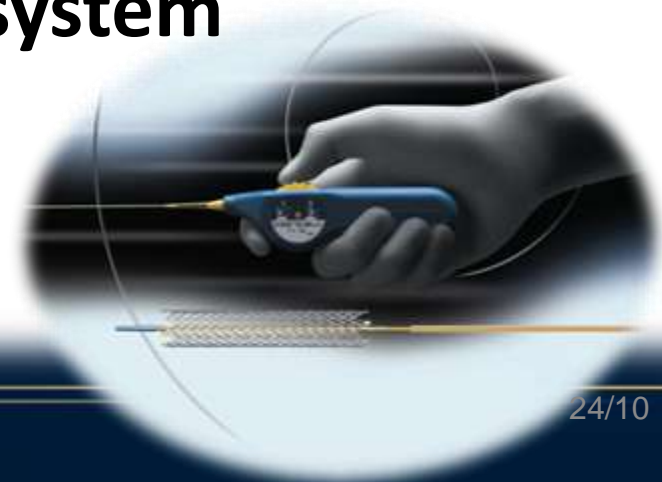
## ■ Long term patency

- Flexible stent design
- Excellent conformability
- Low fracture rate
- Moderate Radial Force



## ■ Easy and precise deployment system

- RX (monorail) delivery system
- Compact grip system

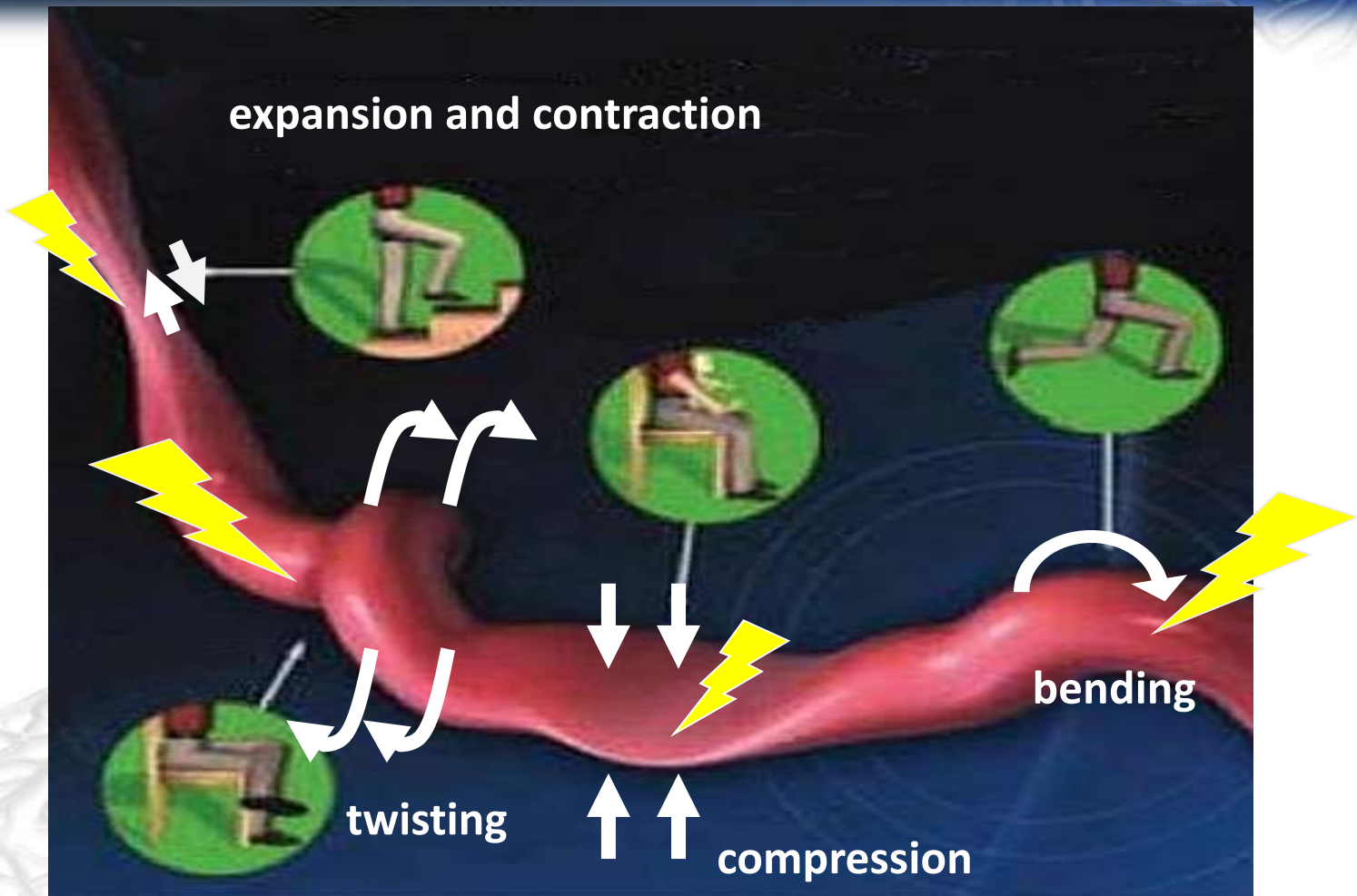




# Stent specifications

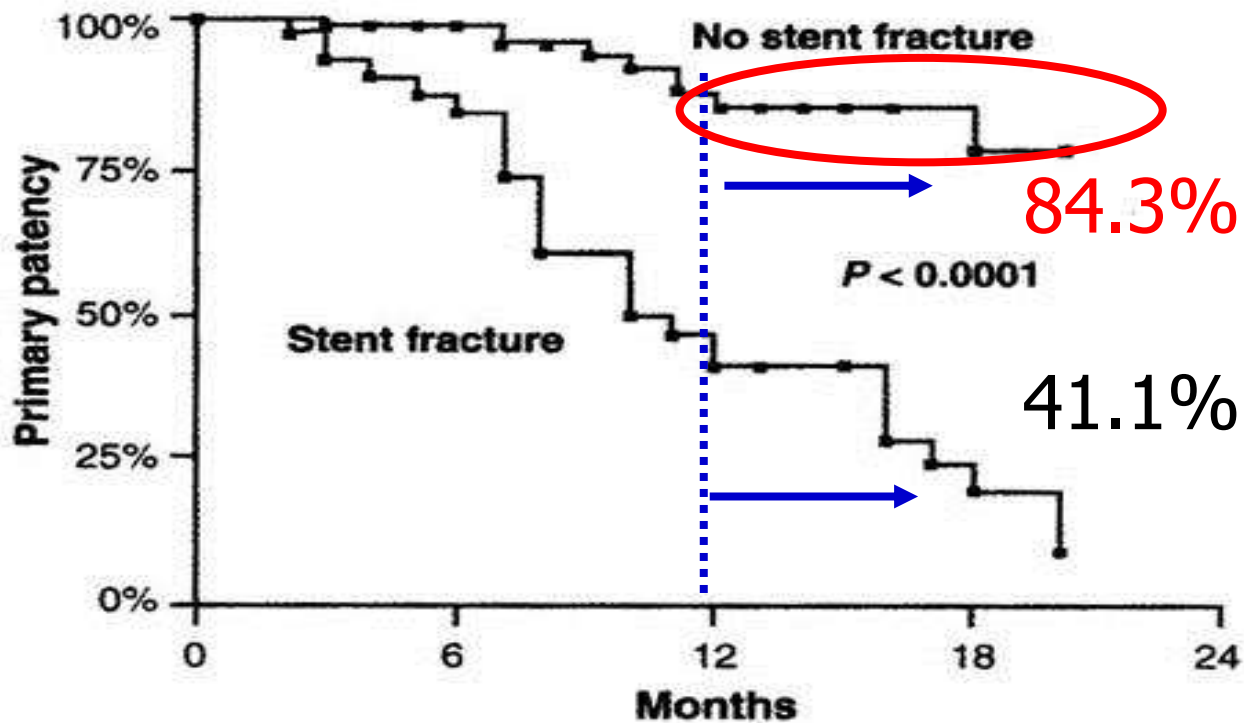
| Stent diameter<br>(Indication diameter<br>means stent ID) | Target<br>vessel | 40<br>mm | 60<br>mm | 80<br>mm | 100<br>mm | 120<br>mm | 150<br>mm |
|---|------------------|----------|----------|----------|-----------|-----------|-----------|
| 6 mm  | 4.0-<br>5.0mm    | ○        | ○        | ○        | ○         | ○         | ○         |
| 7 mm  | 5.0-<br>6.0mm    | ○        | ○        | ○        | ○         | ○         | ○         |
| 8 mm  | 6.0-<br>7.0mm    | ○        | ○        | ○        | ○         |           |           |

# Movements of SFA



**There are many kinds of force to the stent due to the many movements of the SFA vessel**

# How Stent fracture affects clinical outcome



Primary patency is obviously much better with stents with no fracture compared to the stents which fractured.

# History of the SFA stent

At first, when there were no stents especially for the SFA, stents made especially for the Iliac was used for SFA procedure.



As the Iliac has much less movement than the SFA, the Iliac stent is a hard stent with a very strong Radial Force



When the Iliac stent was used in the SFA, many fractures occurred as the stent was not able to withstand the movements of the SFA

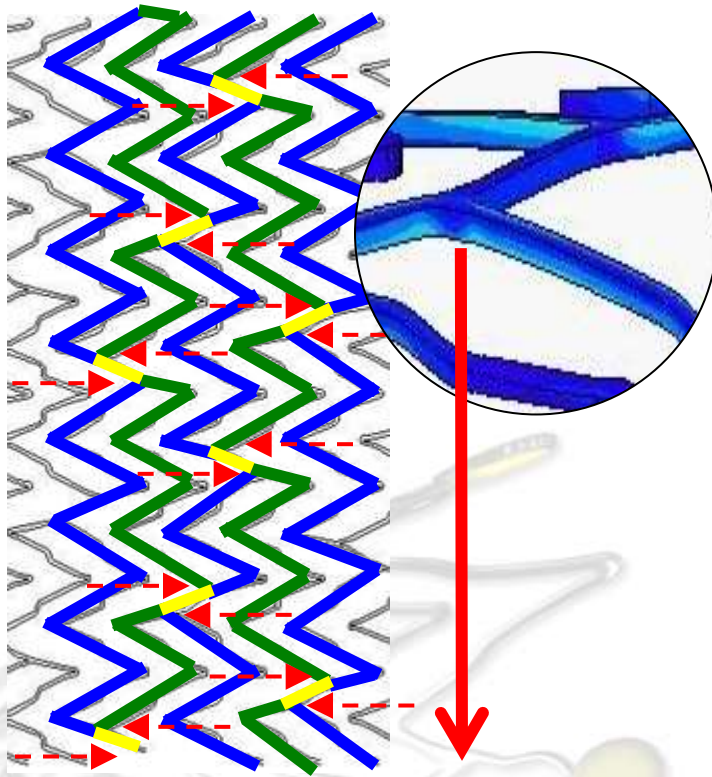


**Misago is a strong, flexible stent especially made for SFA for the purpose of achievement long term patency**

# Stent design

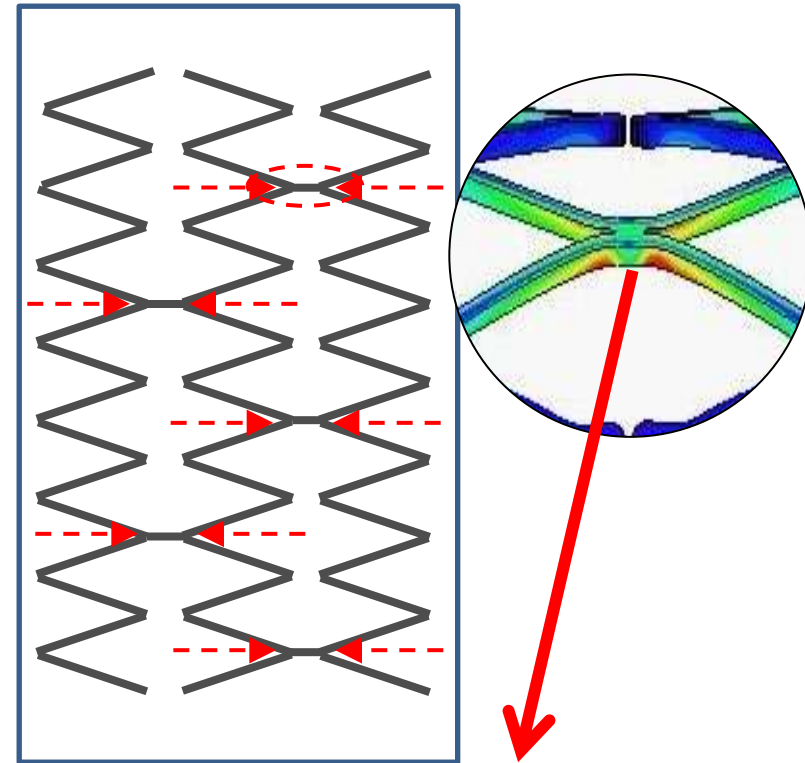
## Misago

Unique direct link design



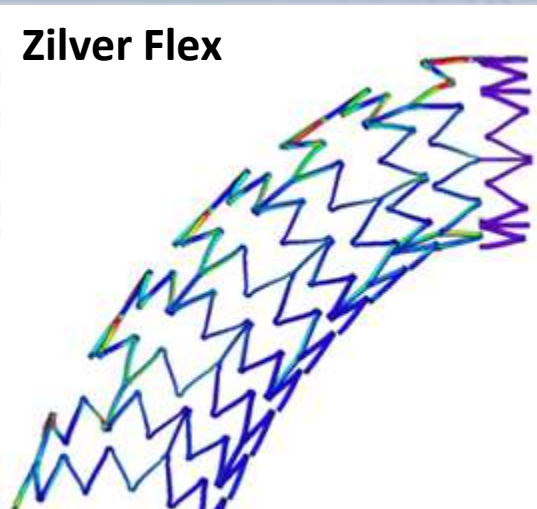
Misago's ZigZag design disperses the load caused from the outside movement.

## Other stents

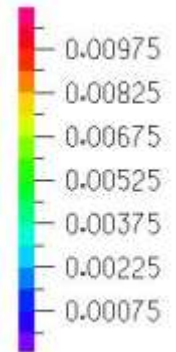


The junction of the struts is between the two points, concentrating the load leading to fracture

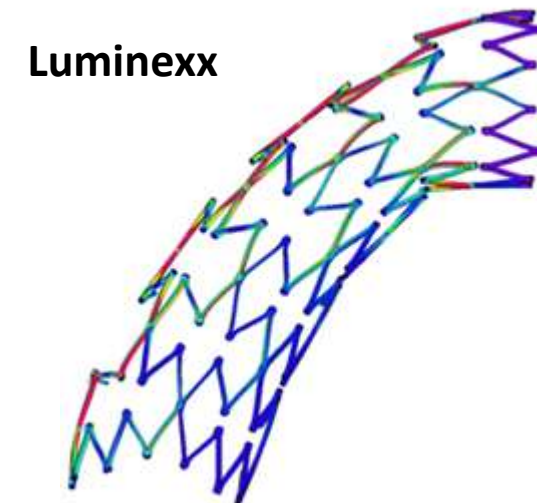
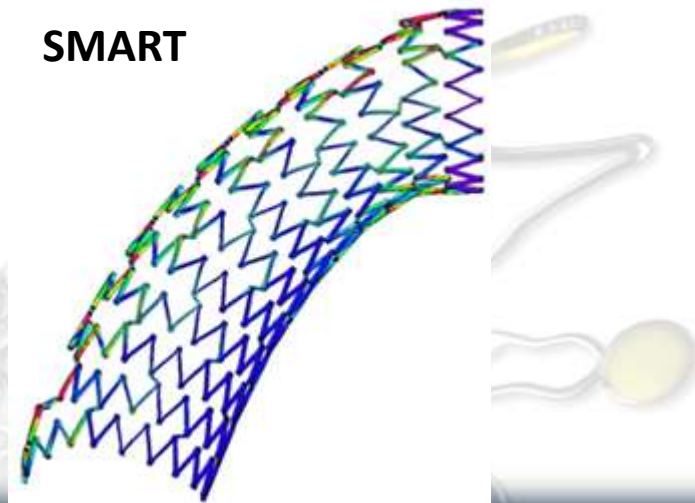
# FEM analysis - Bending -



Strain  
Hi



Low



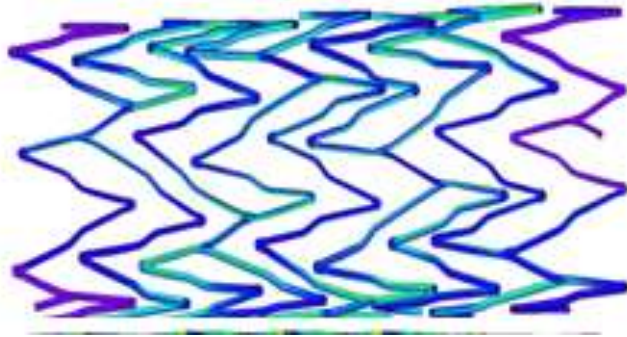
Bending : 12mm



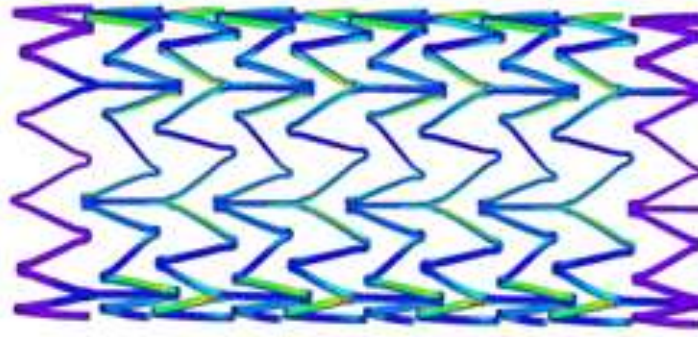
15mm

# FEM analysis - Compression -

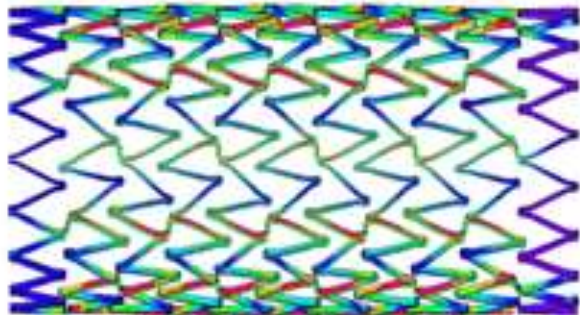
Misago



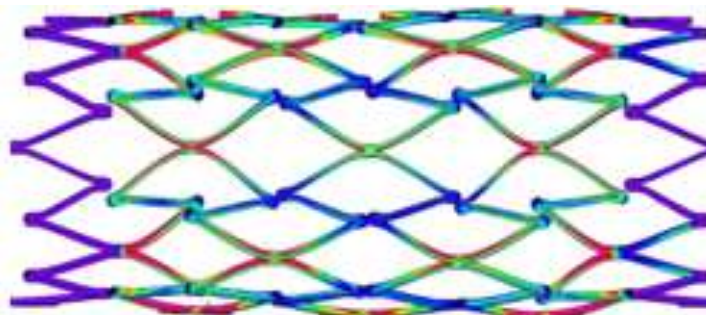
Zilver Flex



SMART

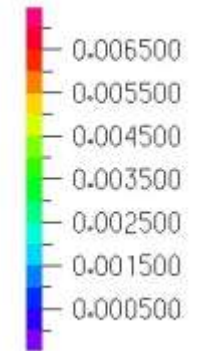


Luminexx



Strain

Hi



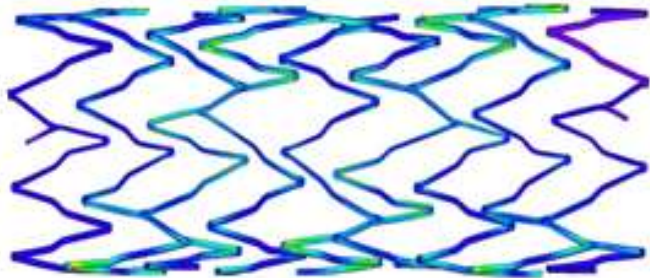
Low

20% compression

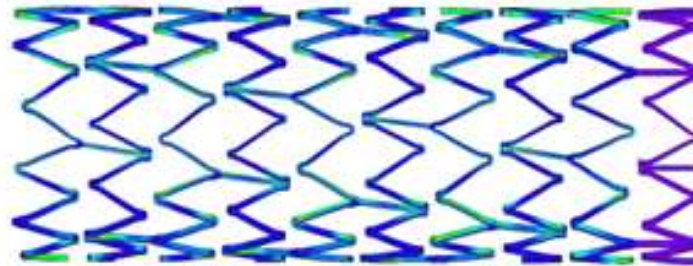


# FEM analysis - Torsion -

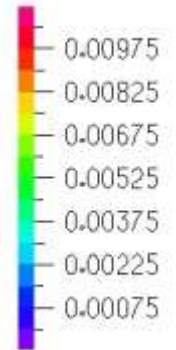
Misago



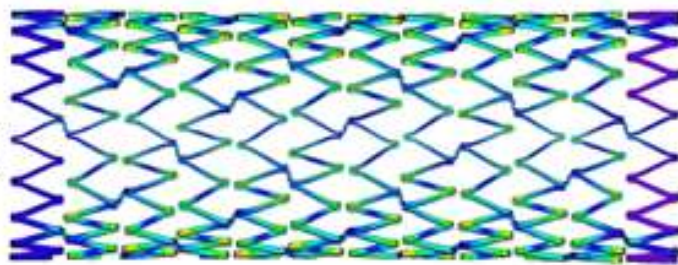
Zilver Flex



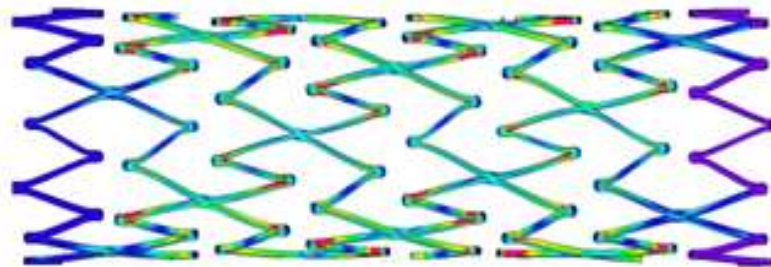
Strain  
Hi



SMART



Luminexx



Low

FEM; Finite Element Method

60 degree





# Stent Durability

Applied the each forces 650,000 times (10 years worth) and assessed when the stent fractured.



Compression



Torsion

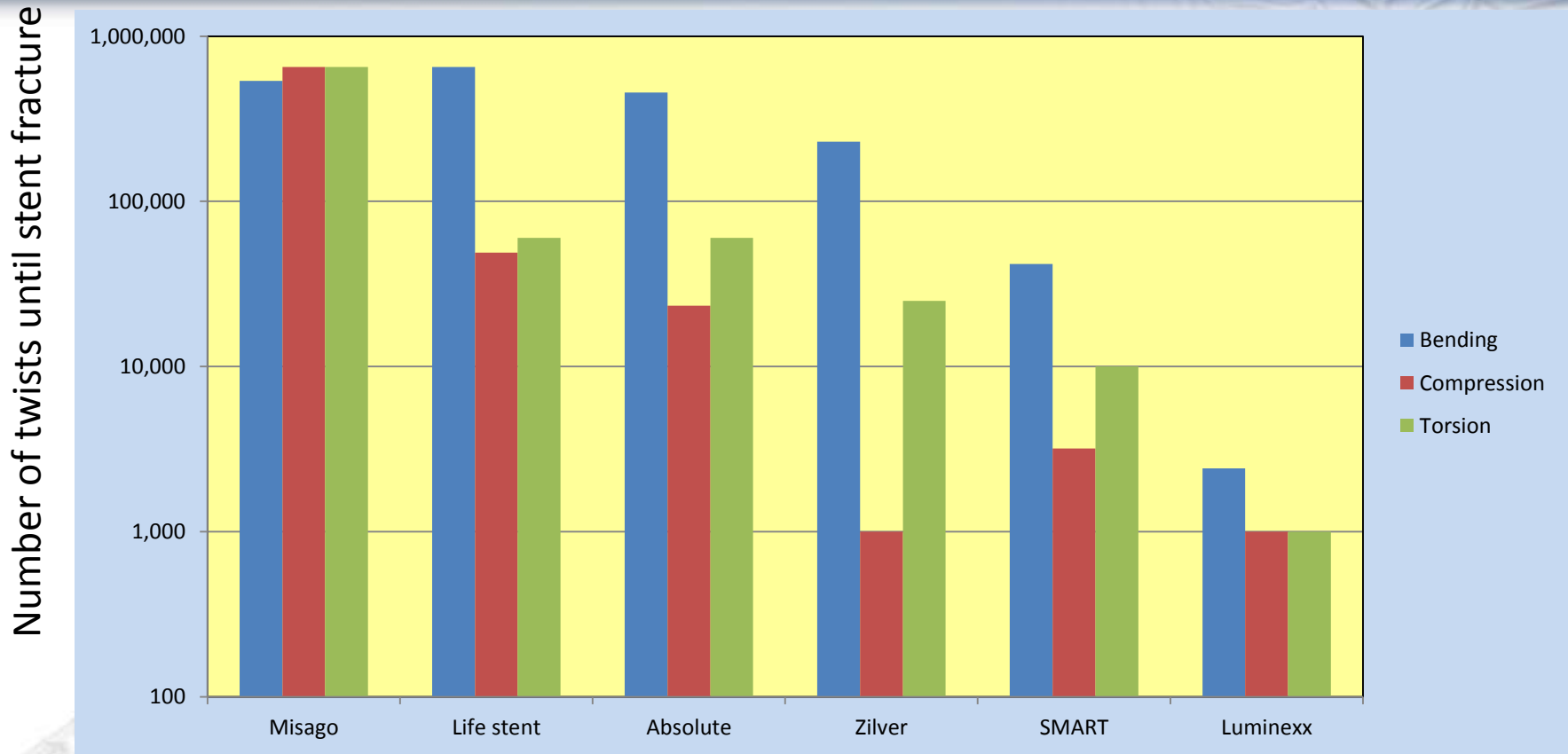


Bending

Temperature 37 °C

# Stent Durability

## - test results -



**Misago shows the highest durability**

RA Self-expanding Peripheral Stent  
**Misago**

EXPERIMENTAL INVESTIGATION

J Endovasc Ther 2010

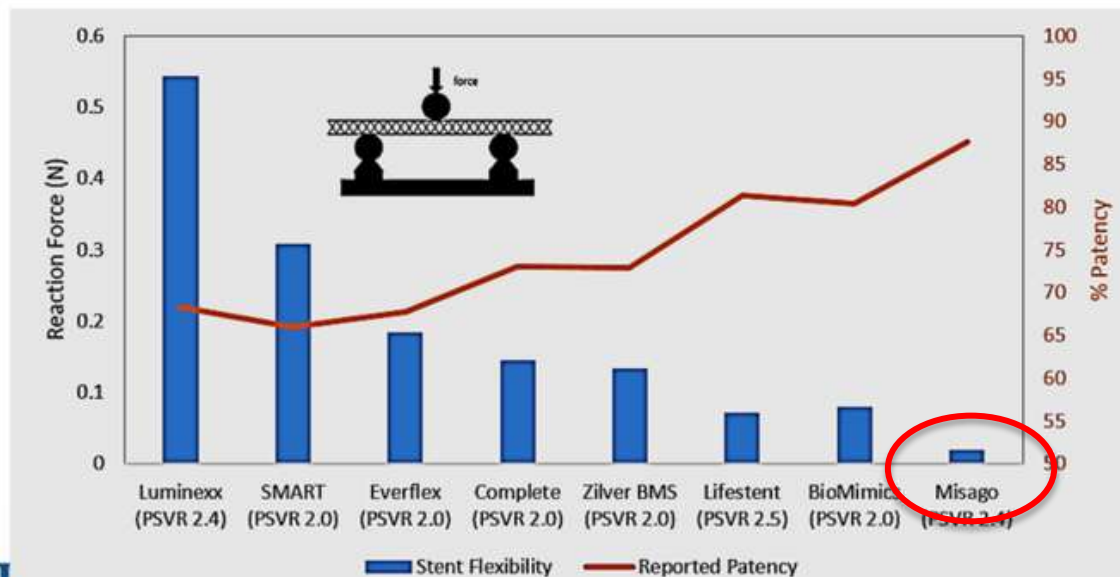
**Comparison of Second Generation Stents for Application in the Superficial Femoral Artery: An In Vitro Evaluation Focusing on Stent Design**

<sup>1</sup>Stefan Müller-Hülsbeck, MD, PhD; <sup>2</sup>Philipp J. Schäfer, MD; <sup>3</sup>Nikolas Charalambous, MD; <sup>4</sup>Hiroshi Yagi; <sup>5</sup>Martin Heller, MD, PhD; <sup>6</sup>Thomas Jahnke, MD, PhD

# More Flexible, Better clinical result

## Evolution of stent design

- Directly or indirectly- Stent design has evolved to accommodate axial compression and bending loads
- Are more flexible stents associated with improved patency?

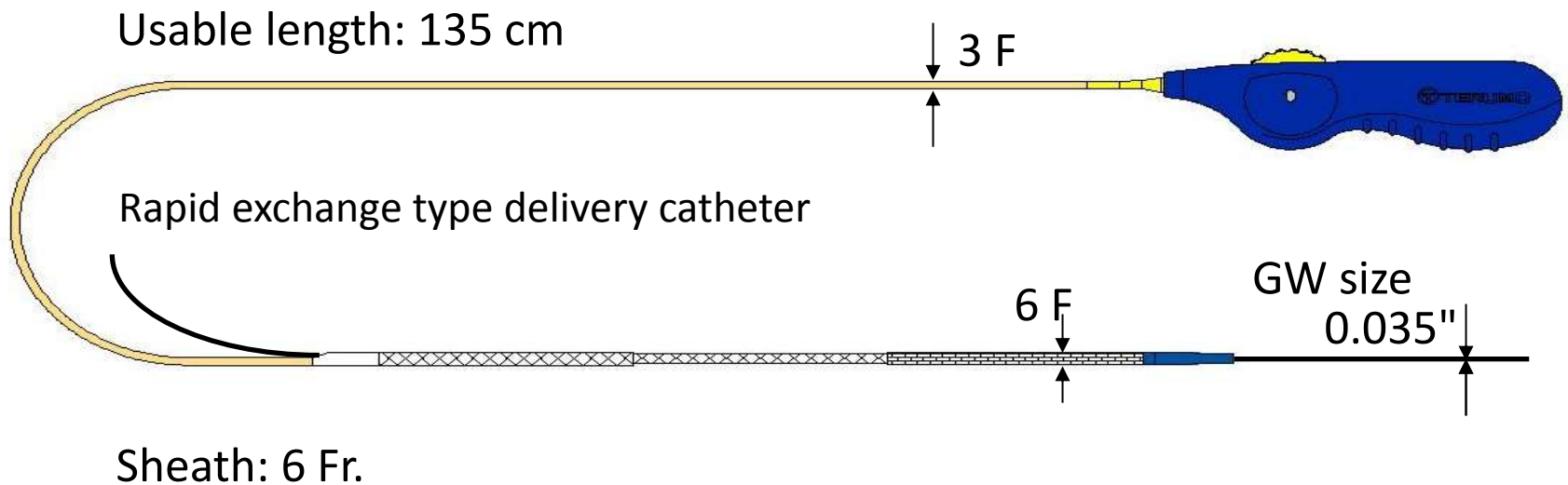


ISL

# Delivery system

The first ever RX delivery system for lower limb stent.

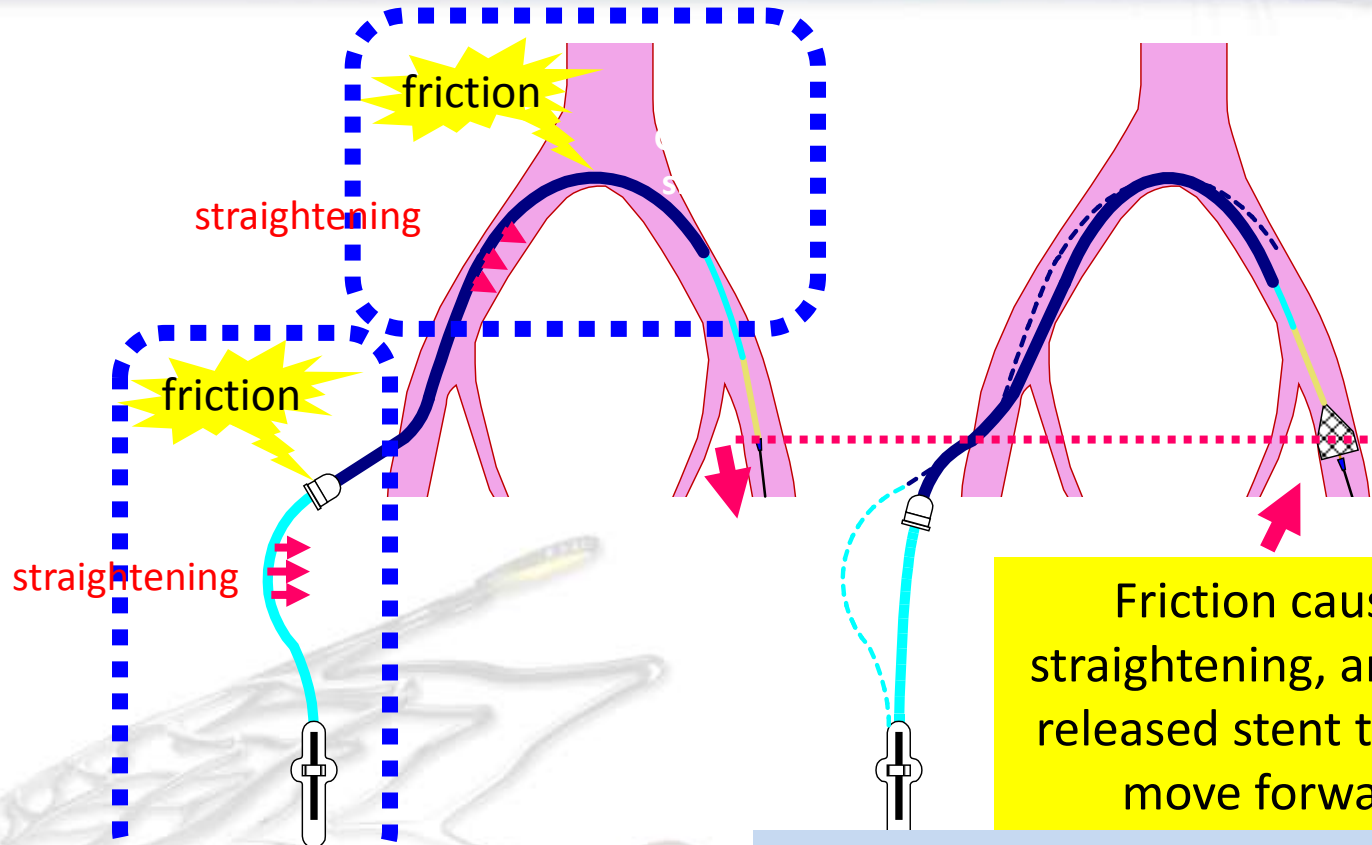
- Precise deployment of stent
- Can be used even if it is a single operator



# OTW systems are more prone to “Jumping”

OTW systems

Misago



The whole sheath moves when deploying the stent and so there is more friction with the vessel wall. The friction causes the stent to “Jump” forward at the time of deployment.

Misago is a monorail system and only the distal outer sheath moves when releasing the stent. The lack of friction from moving the sheath stops the stent from jumping.

# Operating suggestions to prevent shortening

Fix the delivery catheter firmly by hand  
at a proximal position.



# Misago clinical programs

|            |            |   |
|------------|------------|---|
| EU         | MISAGO1    | <ul style="list-style-type: none"><li>➤ First in man with 55pts</li><li>➤ Primary Endpoint: patency@6M</li></ul>                              |
|            | MISAGO2    | <ul style="list-style-type: none"><li>➤ European study with 744pts</li><li>➤ Primary Endpoint: Absence of clinically driven TLR@12M</li></ul> |
|            | E-MISAGO   | <ul style="list-style-type: none"><li>➤ Real world study with 3404pts in EU</li><li>➤ Primary Endpoint: Patency @ 12M</li></ul>               |
| JP<br>(US) | OSPREY     | <ul style="list-style-type: none"><li>➤ Clinical trial for JP/US application</li><li>➤ Primary Endpoint: Non-TLR @12M</li></ul>               |
|            | MISAGO PMS | <ul style="list-style-type: none"><li>➤ Post marketing surveillance in Japan with 295pts</li></ul>  |
|            | MIRAI      | <ul style="list-style-type: none"><li>➤ Real world study with 500pts in Japan</li><li>➤ Primary Endpoint: Patency @ 12M</li></ul>             |

7 월 20 일 (수)

R U 9 25 김 영 (F/62) CAG

R U 11 25 유 승 (M/60) CAG

R U 12 05 \* \* \* \* \* (F/70) CAG

O \* \* \* \* \* (M/60) CAG

④ R 박영준 (M/54) Spasm

당일 ① R 이영원 (M/56) Spasm - \* PCI

② P 임은준 (F/65) Spasm

③ P 하인선 (F/67) Spasm

② 9399 R 심영리 M/77 PTA G. 122 CTX

③ 9386 R 조경숙 F/42 PTA ST

④ 8399 R 나선표 M/77 PTA

✓ 4387 S 강요준 F/73 CAG/PCI

@ ICU2-3 R 이은수 M/40 CAG (found) 10

✓ 7283 N 원명화 F/43 CAG/PCI

⑩ 8048 R 신은희 M/50 PTA G. 102

⑤ 8154 R 정영희 M/64 PTA

⑦ 8157 R 김대성 M/61 PTA

⑧ 8281 R 기종남 M/73 PTA

⑤ 8388 F 이은 F/74 PTA

③ 태희 R 권순환 F/80 104/10



10000 ms

12000 ms

14000 ms

4:13:52 AM

7/21/2011

174 Days

4.1 GB





# EVT vs. PCI; Longer Procedure Time and Prolonged Gravity Burden to Operator's Spine



# Everything can be changed...but you need regular exercise!!



1985 Summer at KUMC  
(187cm, 85kg)

2011 Summer at KUMC  
(186cm, 108 kg)



Despite the risk of Injury (5 screws/1 plate), I cannot stop exercise; Higher Radiation → Bone Weakness



OS professor said, I can't trust this patient. Let's do the emergent surgery....

# Balancing Between Patient's Best Outcomes and Operator's Safety

## 1. Control procedure-related factors

- 1) Preventing contrast nephropathy in high risk patients  
; Sono-guided, CO2 angiography-guided, or Diluted contrast
- 2) Reducing radiation hazard  
; lower-dose (7.5 F/sec), Fluoroscopic storage, less oblique view, shorter procedure time, and radiation protection equipment

## 2. Consider operator's safety

- 1) Share the cases with your colleagues or juniors
- 2) Maximally reducing radiation hazard
- 3) Control the procedure time and adequate recovery time
- 4) Regular exercise for improving physical strength
- 5) Reducing stress with hobbies (Basket ball, Piano..) and others (Church activities, good friends...)

# Misago (Osprey)-Conclusion



- ✓ Excellent conformability
- ✓ Low Fracture rate
- ✓ Long term patency

- ✓ Precise deployment of stent
- ✓ Fast catheter change, short wire

# Thank You for Your Attention!

Korea University Guro Hospital, Seoul, Korea

