
# Is connected stent the good option for TASC A → D SFA lesions ?

MD, PhD, FEVBS

Unit of vascular surgery
Bordeaux - France

**Disclosure**

Speaker name:

.....

I have the following potential conflicts of interest to report:

- ■ Consulting CORDIS
- ☐ Employment in industry
- ☐ Shareholder in a healthcare company
- ☐ Owner of a healthcare company
- ☐ Other(s)

☐ I do not have any potential conflict of interest

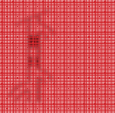
# TASC II GUIDELINES 2007

MEET 2015
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

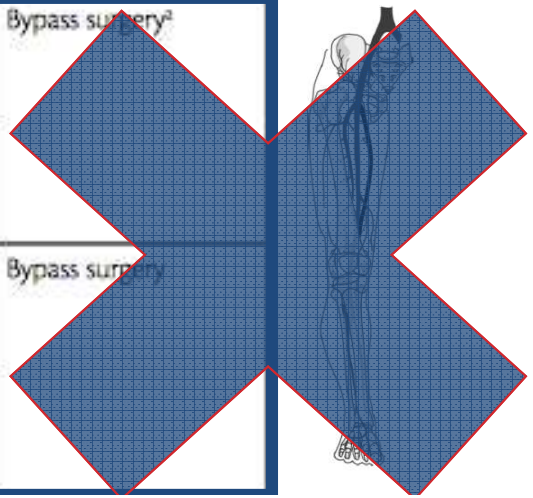
| | | |
|---|---|---|
| Type A Lesion  | Single occlusion ≤ 5 cm in length | Endovascular |
| | Single stenosis ≤ 10 cm in length | |
| Type B Lesion  | Multiple lesions (stenosis or occlusions), each ≤ 5 cm | Endovascular[a] |
| | Single stenosis or occlusion ≤ 15 cm not involving the infrageniculate popliteal artery | |
| | Single or multiple lesions in the absence of continuous tibial vessels to improve inflow for a distal bypass | |
| | Heavy calcified occlusion ≤ 5 cm in length | |
| | Single popliteal occlusion | |
| Type C Lesion  | Multiple stenosis or occlusion totalling > 15 cm with or without heavy calcification | Bypass surgery[a] |
| | Recurrent stenosis or occlusion that needs treatment after two endovascular interventions | |
| Type D Lesion  | CTO of CFA or SFA (> 20 cm, involving the popliteal artery) | Bypass surgery |
| | CTO of popliteal artery and proximal trifurcation vessels | |

# MORE AND MORE…

MEET 2015
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

| | | |
|---|---|---|
| Type A Lesion  | Single occlusion ≤ 5 cm in length | Endovascular |
| | Single stenosis ≤ 10 cm in length | |
| Type B Lesion  | Multiple lesions (stenosis or occlusions), each ≤ 5 cm | Endovascular |
| | Single stenosis or occlusion ≤ 15 cm not involving the infrageniculate popliteal artery | |
| | Single or multiple lesions in the absence of [illegible] to improve inflow for a distal bypass | |
| | Heavy calcified occlusion ≤ 5 cm in length | |
| | Single popliteal occlusion | |
| Type C Lesion  | Multiple stenosis or occlusion totalling > 15 cm with or without heavy calcification | Bypass surgery[2] |
| | Recurrent stenosis or occlusion that needs treatment after two endovascular interventions | |
| Type D Lesion  | CTO of CFA or SFA (> 20 cm, involving the popliteal artery) | Bypass surgery |
| | CTO of popliteal artery and proximal trifurcation vessels | |

ENDO FIRST



## THANKS TO Endovascular evolution

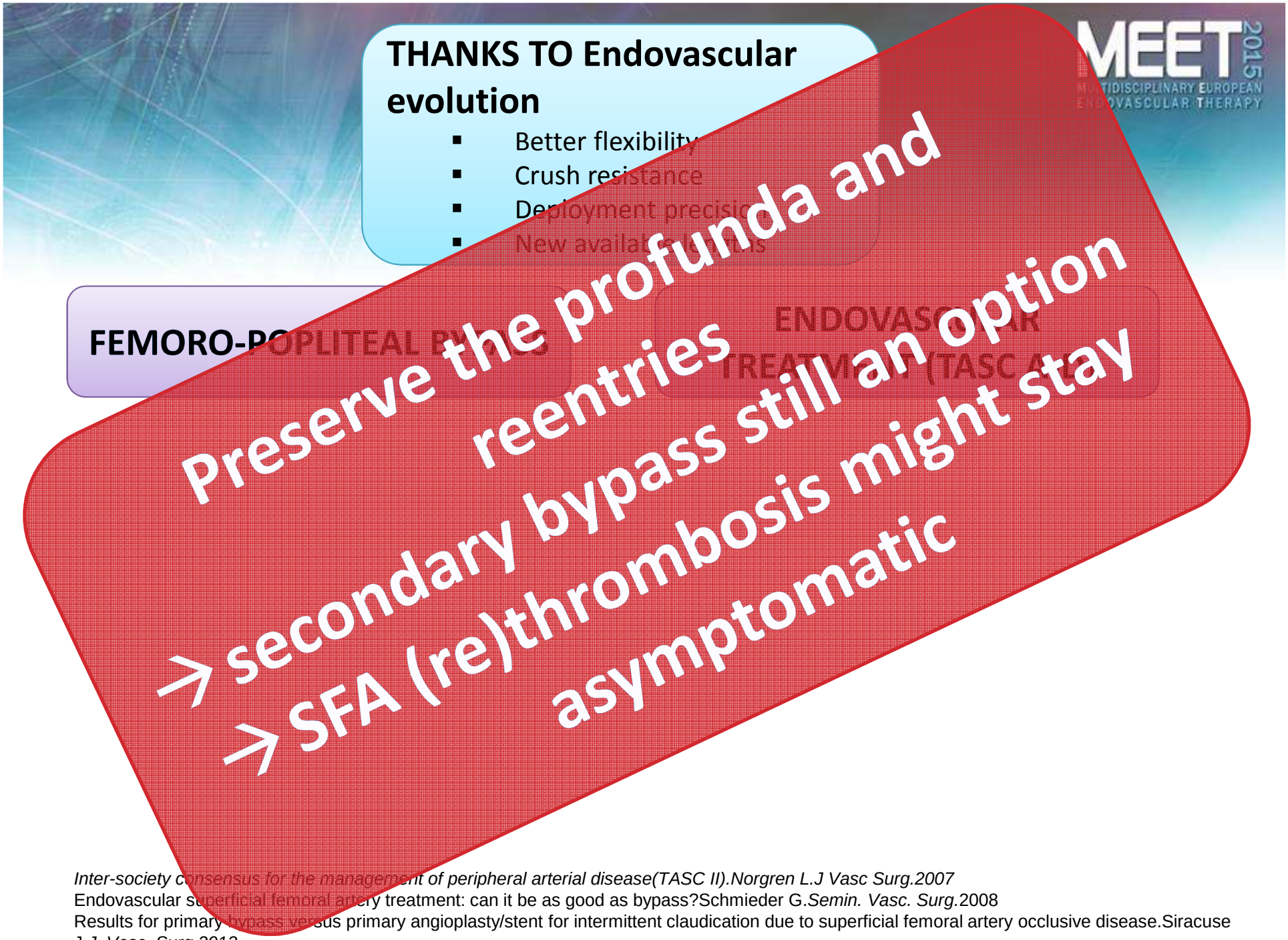
- Better flexibility
- Crush resistance
- Deployment precision
- New available lengths

## FEMORO-POPLITEAL BYPASS

- **Post-operative mortality :**
  - **0% - 2,7%**
- **Post-operative morbidity :**
  - **5% - 32%**
- **1 Year primary patency :**
  - **67%**
- **Freedom from TLR :**
  - **23% - 45%**
- **Limb salvage rate :**
  - **80% - 95%**

## ENDOVASCULAR TREATMENT (TASC A-D)

- **Post-operative mortality :**
  - **0% - 5%**
- **Post-operative morbidity :**
  - 2,2% - 10%
- **1 Year primary patency :**
  - **68%**
- **Freedom from TLR :**
  - **14% - 59%**
- **Limb salvage rate :**
  - **83% - 96%**




*Inter-society consensus for the management of peripheral arterial disease(TASC II).Norgren L.J Vasc Surg.2007*
Endovascular superficial femoral artery treatment: can it be as good as bypass?Schmieder G.*Semin. Vasc. Surg.*2008
Results for primary bypass versus primary angioplasty/stent for intermittent claudication due to superficial femoral artery occlusive disease.Siracuse J *J. Vasc. Surg.2012*

# RECENT TASC C & D STUDIES

- 2008: *Dosluoglu et al.* N=93 MI
  - 1 Year Primary patency for TASC C lesions : 80%
  - Results for TASC D lesions still in favor of femoro-popliteal bypass except in high-risk patients

- 2012: *Davaine, Goueffic et al. (STELLA trial)* N= 62
  - TASC C and D lesions (Median length 220 ± 160 mm)
  - 1 Year Primary patency 66% / Secondary patency 80.9%
  - 1 Year ABI increase : 0.58 to 0.94 (p = 0.001)
  - 1 Year In-stent restenosis : 19.3%
  - Stenting TASC C and D lesions : safe and efficient, high-sustained clinical improvement

- 2014: *Aihara et al.* N=263
  - Primary patency in favor of femoro-popliteal bypass
    - 82.1% vs. 67.8% at 1 year
    - 69.4% vs. 45.2% at 5 years
    - $p < 0.01$
  - But secondary patency did not differ significantly
  - Less complications with stenting (14.4% vs. 3.5%)

Stenting vs above knee polytetrafluoroethylene bypass for TransAtlantic Inter-Society Consensus-II C and D superficial femoral artery disease.Dosluoglu H *J. Vasc. Surg* .2008
Comparison of long-term outcome after endovascular therapy versus bypass surgery in claudication patients with Trans-Atlantic Inter-Society Consensus-II C and D femoropopliteal disease.Aihara H. *Circ. J. Off. J. Jpn. Circ. Soc*

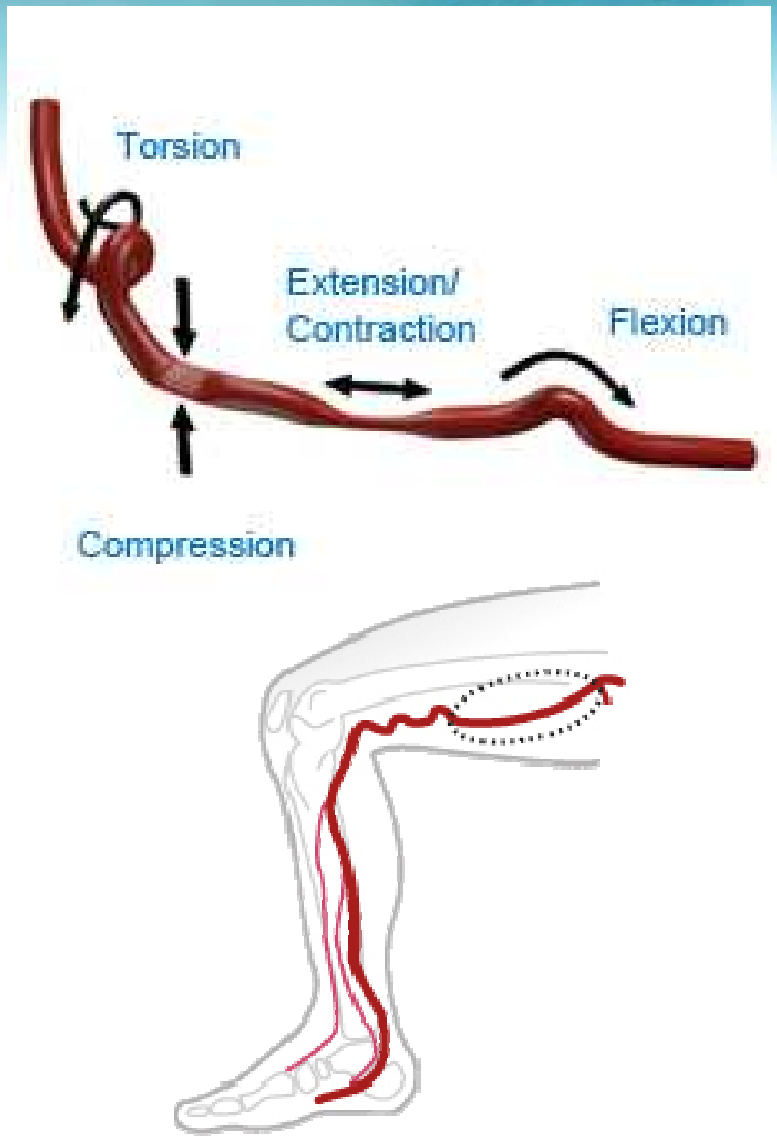
# DESIGN CONSIDERATIONS IN THE SFA

- **Unique forces in the human body :**
  - Compression,
  - Flexion/Extension
  - Torsion
  - Contraction
  - Fixation at both ends

  - Need for optimal stent combination to keep vessel's patency :

  - Radial strength
  - Flexibility
  - Longitudinal stability
  - Crush and Fracture Resistance

- Muller-Hulsbeck *et al.* Comparison of Second-Generation Stents for Application in the SFA: An In Vitro Evaluation. J ENDOVASC THER. 2010
  - Differences in stent design might play a major role in the appearance of stent strut fracture related to restenosis and reocclusion



# SOME PROBLEMS REMAIN…

MEET 2015 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

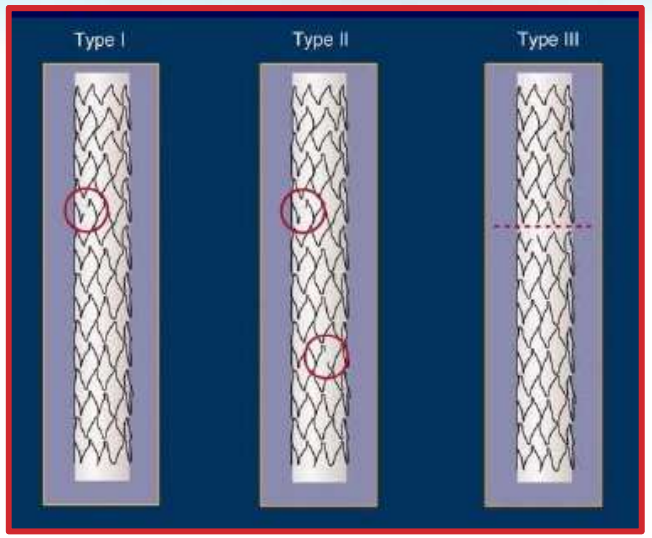
## Elongation

- Laird et al. RESILIENT Trial (Lifestent®)
  - Fracture rate :
    - 6 months : 1 (0.3%) type 4
    - 12 months : 9 (3.1%) fractures (4 type 1 and 5 type 4)
  - Stents with type 4 fractures were **all elongated** at deployment (118% to 143% of the nominal stent length)
  - 8 other cases of stent elongation did not result in stent fracture

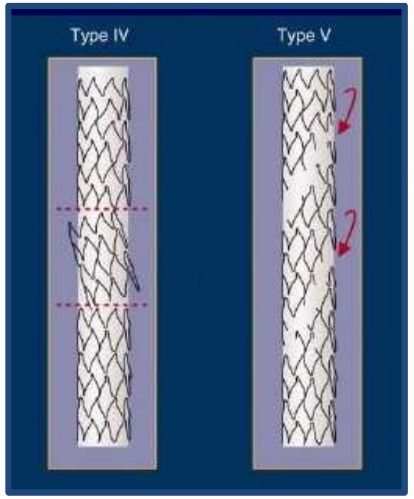
# High Rate of Stent Fracture

- Still controversial : significant association between stent fracture and clinical deterioration, in-stent restenosis, thrombosis or embolism?

**NO**




- Davaine et al.One year clinical outcome after primary stenting for TASC C and D femoropopliteal lesions (STELLA). Eur J Vasc Endovasc Surg. 2012
  - N= 62
  - Mean length : 240 ± 180 mm
  - 2.1 (1-4) Lifestent® (Bard)/patient
  - Stent fracture : 17.8%
    - 1 type I (asymptomatic)
    - 7 type II (2 restenosis)
    - 5 type III (asymptomatic)
    - 3 type IV (1 restenosis)
  - Symptomatology and in-stent restenosis rates did not differ significantly

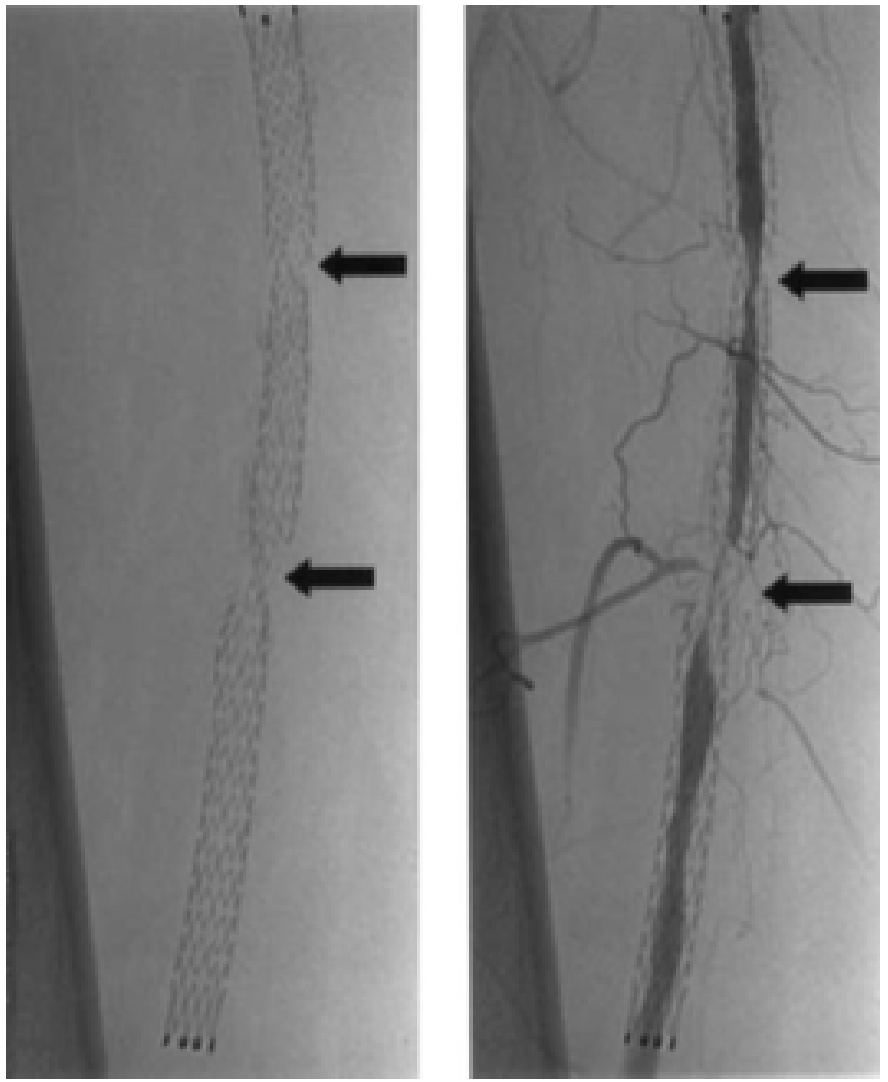



- Bosiers et al. One-year results with the Protege EverFlex 200-mm-long nitinol stent (ev3) in TASC C and D femoropopliteal lesions: DURABILITY-200study. J Vasc Surg. 2011

# YES

- Scheinert et al. Prevalence and Clinical Impact of Stent Fractures After Femoropopliteal Stenting, J. of the American College of Cardiology, 2005
  - Mean length : 157 mm
  - Stent fracture :
    - < 8 cm → 13.2%
    - 8 - 16 cm → 42.4%
    - > 16 cm → 52.0%

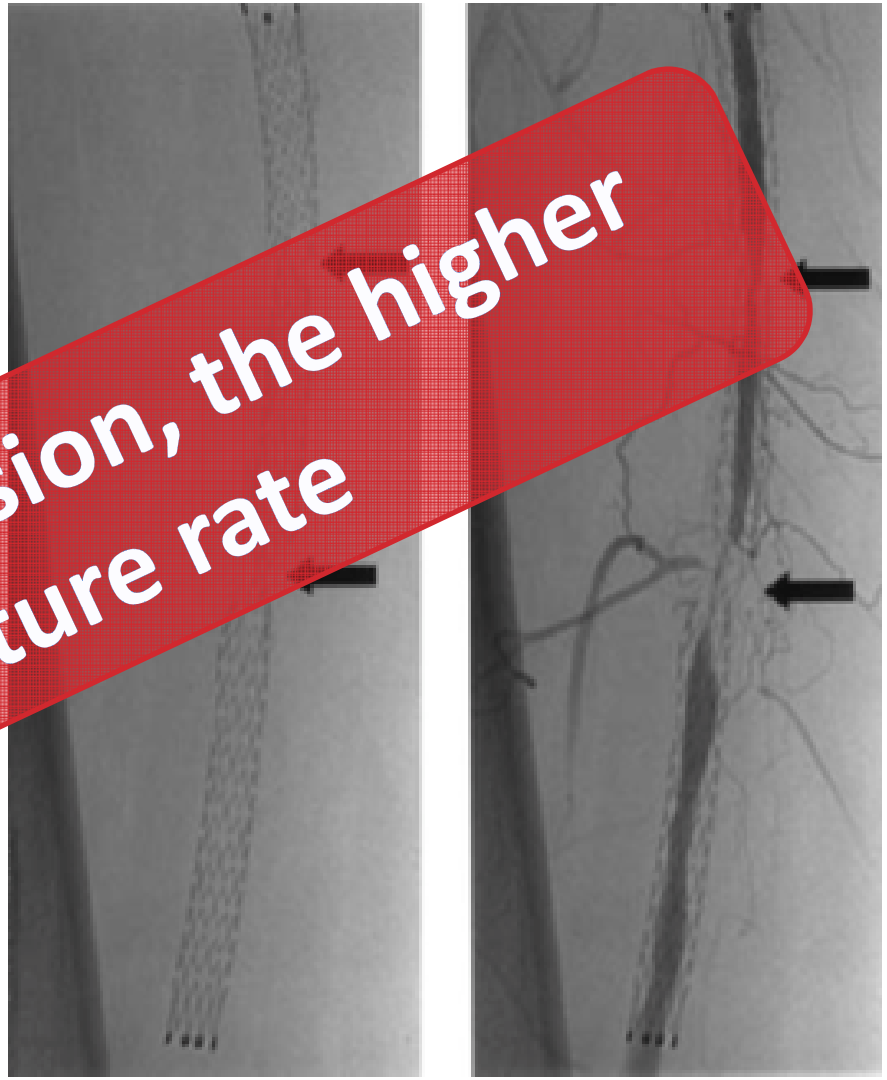
    - 31 type I (48.4%)
    - 17 type II (26.6%)
    - 16 type IV/V (25.0%)
  - 21 Binary restenosis (32.8%)
  - 22 Reocclusions (34.4%)
  - 1 year Primary patency (KM) significantly lower (41.1% vs. 84.3%, p=0.0001)
- Iida O, Nanto S, Uematsu M, et al. Effect of exercise on frequency of stent fracture in the superficial femoral artery. Am J Cardiol. 2006



# YES

- Scheinert et al. Prevalence and Clinical Impact of Stent Fractures After Femoropopliteal Stenting, J. of the American College of Cardiology, 2005
  - Mean length : 157 mm
  - Stent fracture :
    - < 8 cm → 13.2%
    - 8 - 16 cm → 42.4%
    - > 16 cm → 52.0%
    - 31 type I (48.4%)
    - 17 type II (26.6%)
    - 16 type IV/V (25.0%)
  - 21 Binary restenosis (32.8%)
  - 22 Reocclusions (34.4%)
  - [illegible] primary patency (PP) significantly lower (41.1% vs. 84.3%, p=0.0001)
- [illegible] exercise on frequency of stent fracture in the superficial femoral artery. Am J Cardiol. 2006

**The longer the lesion, the higher the fracture rate**



# STROLL TRIAL - Smart®

MEET 2015 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

- **Mean age : 68 years (2/3 Men)**
  - 50% diabetes
- **250 SFA/popliteal lesions**
  - 4-15 cm length (average : 8 cm)
  - 4-6 cm diameters
  - 1/4 CTO
- **Technical success (⃠ residual stenosis) : 100%**
- **No safety events at 30 days**
  - death, amputation, TLR
- **Primary patency (Kaplan-Meier) :**
  - 81.7% at 1 year
  - 74.9% at 2 years
- **Doppler US patency > 80% at 2 years**
- **Freedom from TLR > 80% at 2 years**

# STROLL TRIAL - Smart®

MEET 2015 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

- **Stent Fractures :**
  - 4/197 at 1 year (2%)
  - No further fractures at 2 years
  - Only type I (single connector fracture)
  - No association with loss of patency in this trial
- **Rutherford 2 - 4**
  - > 80% Rutherford 0-1 at 2 years
- **Mean ABI : significant improvement**
  - Baseline : 0.66 ± 0.15
  - Postprocedure : 0.98 ± 0.14
  - Durable to 2 years : 0.93 ± 0.18
- **No difference in safety, efficacy, or durability of results even in diabetes and CTO**

Gray et al. S.M.A.R.T. self-expanding nitinol stent for the treatment of atherosclerotic lesions in the superficial femoral artery (STROLL): 1-year outcomes. J Vasc Interv Radiol. 2015

# New Stent generation

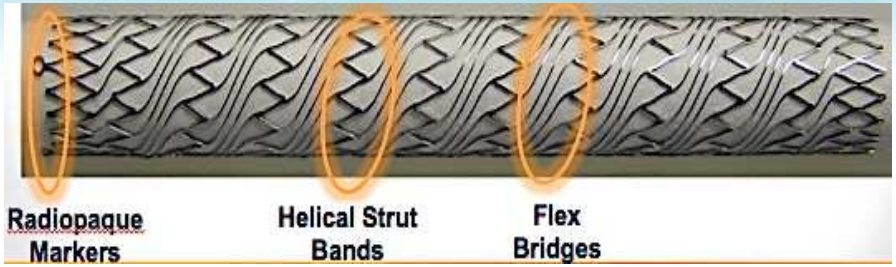
MEET 2015
MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

- ***S.M.A.R.T. ® Flex Stent is the only fully connected yet highly flexible self expanding stent***

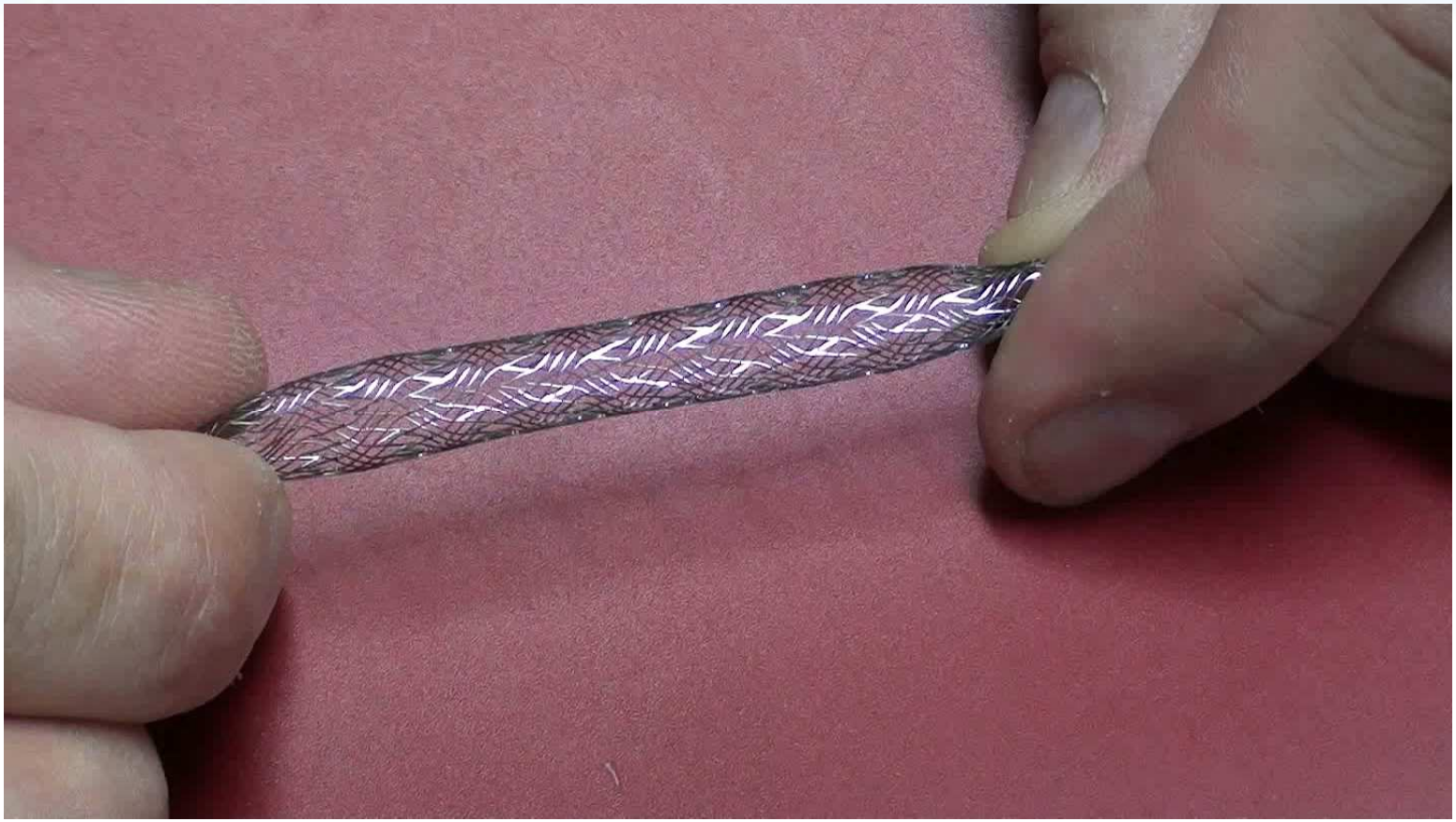
- **It has a heritage in Cordis/PALMAZ® Stent design**: The S.M.A.R.T.® Flex Stent shares a design heritage with the S.M.A.R.T.® Stent and was designed by one of the principal designers and developers of the S.M.A.R.T. ® Stent at Cordis.*
- **Combines the optimal features needed to treat Common and External Iliac, SFA and Proximal Politeal lesions**: Designed to optimize flexibility, fracture resistance and predictable placement while maintaining the tissue to metal ratio and radial strength of S.M.A.R.T. ® Stent, the S.M.A.R.T.® Flex Stent is the next innovation in peripheral stents.
- **It's not just a single product:** its design allows Cordis portfolio expansion.
- **It's approved/cleared and available for use**: The S.M.A.R.T.® Flex Vascular Stent System is CE Marked in Europe for the treatment of vascular disease common and external iliac, SFA and proximal popliteal and received 510(k) clearance by the U.S. Food and Drug Administration (FDA) for the palliative treatment of biliary strictures associated with malignant tumors.

# CARACTERISTICS OF S.M.A.R.T.® FLEX STENTS

- **Fully connected** and **highly flexible** laser cut Nitinol self-expanding stent
- Unique helical Strut Bands interconnected by Flex Bridges
- Radiopaque markers : 4 distally, 5 proximally
- 5 & 6 mm ø : 13 bridges, 26 struts
- 7 & 10 mm ø : 16 bridges, 32 struts
- Lengths **: 20-200** mm
- Offset peak-to-valley design → smooth lumen and stent contourability without strut overlapping or fish scaling
- FDA approval for the iliac in August 2003 and for the SFA and proximal popliteal artery in November 2012




# No elongation possible

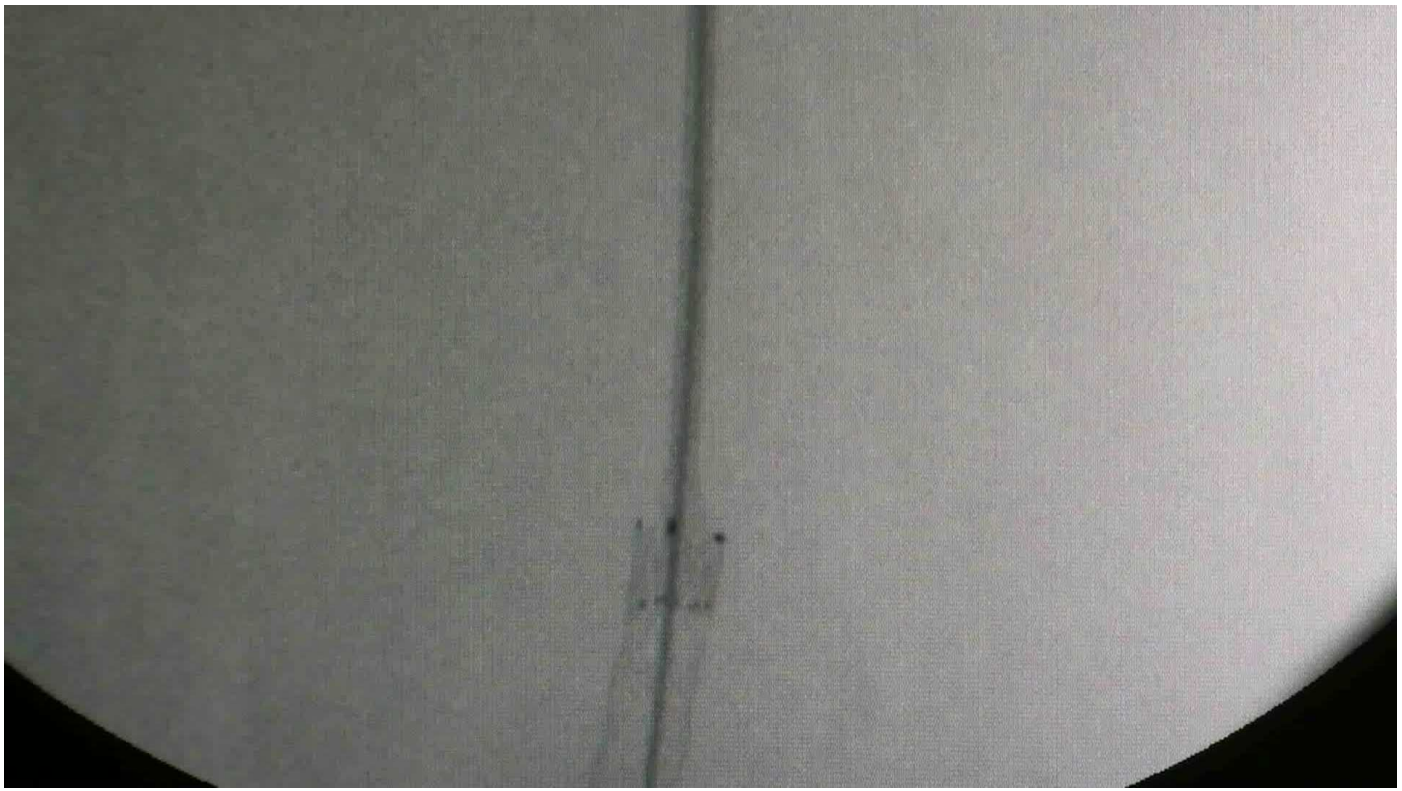


# Efficient stent delivery

- Particularly efficient for long lesions and/or cross-over delivery without possible elongation

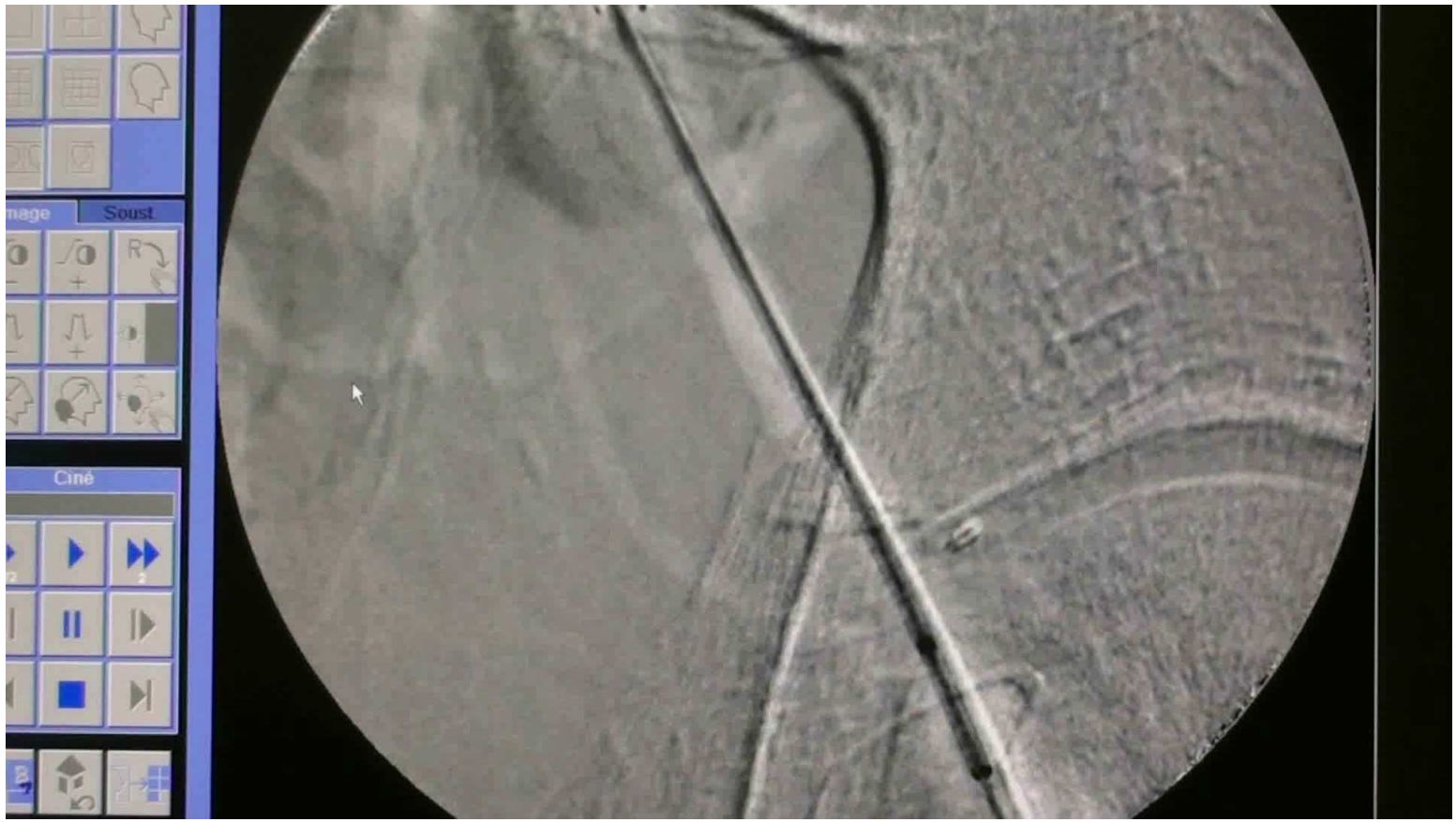
# Efficient stent delivery

- Particularly efficient for long lesions and/or cross-over delivery without possible elongation

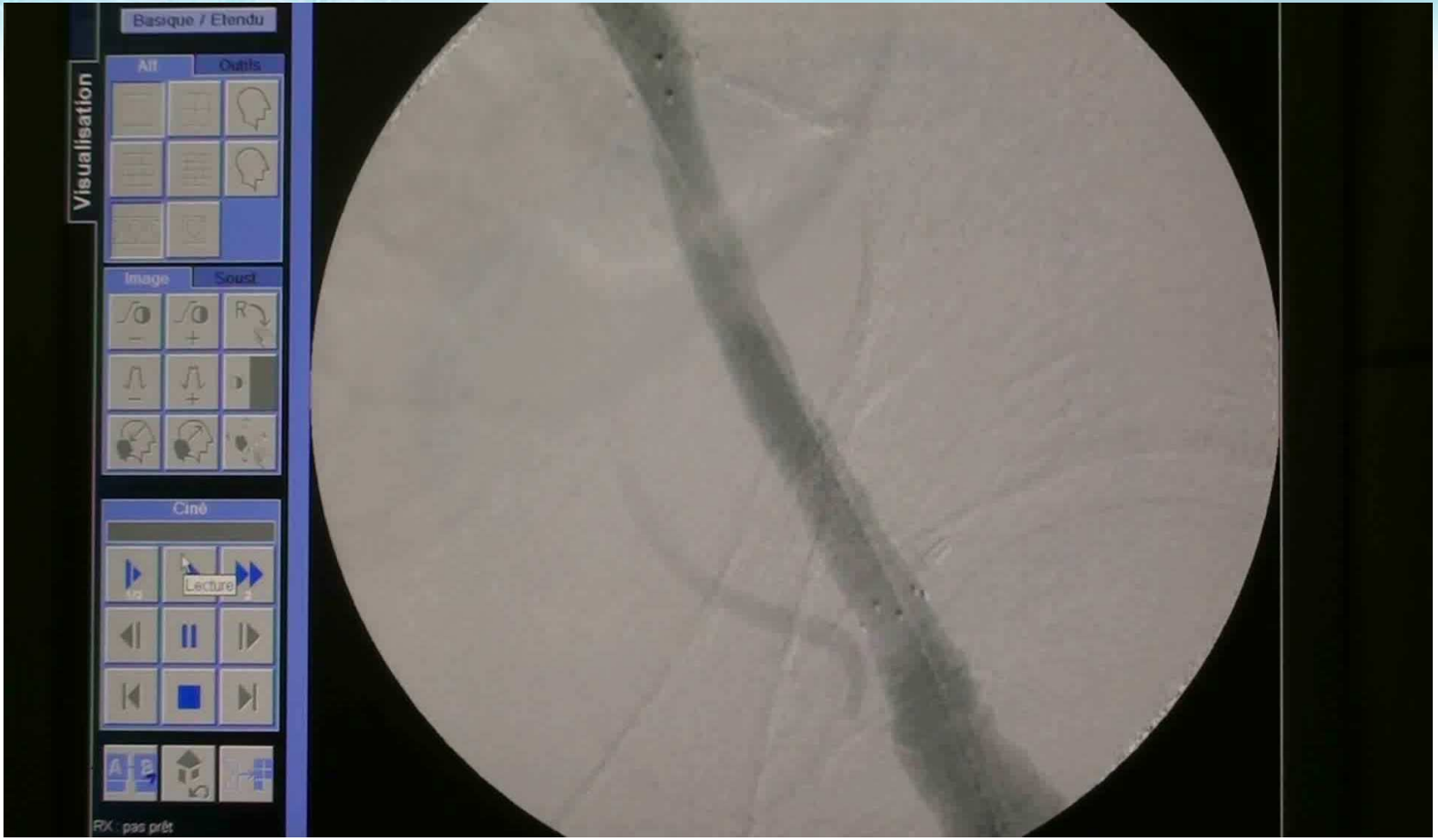


# Necessity of precise delivery

- Distal markers / landing markers



# Necessity of precise delivery



# TAKE HOME MESSAGE

MEET 2015 MULTIDISCIPLINARY EUROPEAN ENDOVASCULAR THERAPY

- Endo first in all TASC lesions
- Preserve the profunda and the re-entries :
  - Secondary Bypass still feasible
  - SFA (re)thrombosis might stay asymptomatic instead of having acute limb ischemia
- Need for specific stent caracteristics in the SFA (Compression-Flexion/Extension-Torsion-Contraction)
  - Long lesions/Stent elongation → stent fracture → risk of in-stent restenosis or thrombosis, clinical deterioration
- Close follow-up regarding the new generation of stent – Smart Flex® in all SFA-popliteal lesion (especially TACS C+D) and iliac arteries (EIA = important compression)