Why should we adopt the “leave nothing behind” approach in the SFA?

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Why should we adopt the “leave nothing behind” approach in the SFA?

1. Mechanical problems in SFA-POP tract: the bad conduit
2. Global overview of SFA-POP solutions according to localization and length of lesion
3. The real world of ENDO treatment: a single center experience
4. Patency rate according to type of treatment

1.

Catheterization and Cardiovascular Interventions 74:787–798 (2009)

Quantitative Assessment of the Conformational Change in the Femoropopliteal Artery with Leg Movement

Andrew J. Klein,[1] MD, S. James Chen,[1] PhD, John C. Messenger,[1] MD, Adam R. Hansgen,[1] BS, Mary E. Plomondon,[2] PhD, John D. Carroll,[1] MD, and Ivan P. Casserly,[1*] MB, BCh

Conclusions

Significant changes in length, curvature, and twist occur in the PA and significant but more modest changes in length and twist occur in the SFA during movement from the straight-leg and crossed-leg position

Angiographic study on pts with PAD

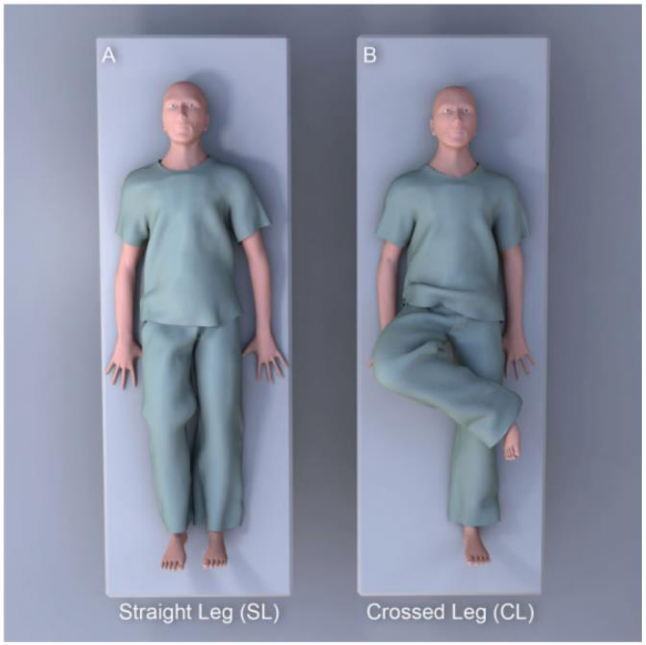


Fig. 2. Demonstration of the straight-leg (SL) and crossed-leg (CL) positions. [Color figure can be viewed in the online issue, which is available at www.interscience.wiley.com.]

2.

Journal of Biomechanics 47 (2014) 2249–2256

Contents lists available at ScienceDirect

Journal of Biomechanics

journal homepage: www.elsevier.com/locate/jbiomech
www.JBiomech.com

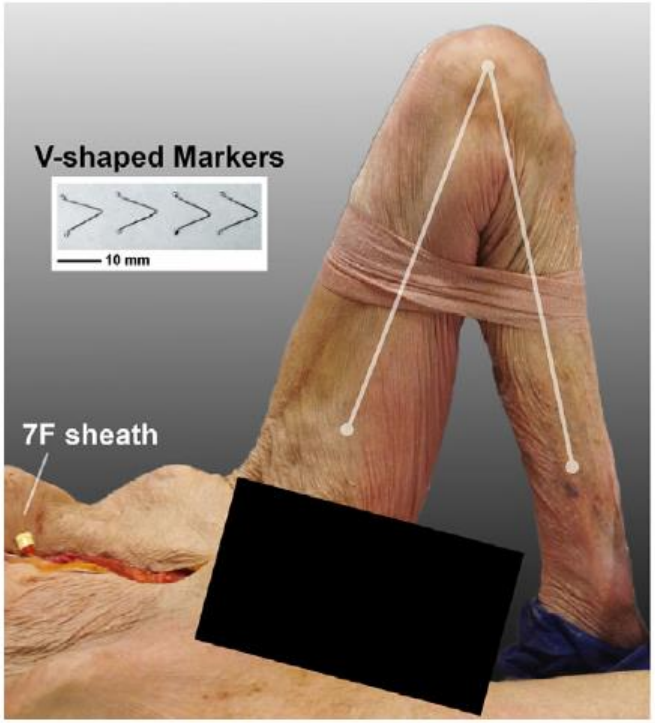
Three-dimensional bending, torsion and axial compression of the femoropopliteal artery during limb flexion

Jason N. MacTaggart [a,*,1], Nicholas Y. Phillips [1,a], Carol S. Lomneth [b], Iraklis I. Pipinos [c,a,e], Robert Bowen [d], B. Timothy Baxter [a], Jason Johanning [c,a], G. Matthew Longo [a], Anastasia S. Desyatova [e], Michael J. Moulton [a], Yuris A. Dzenis [e], Alexey V. Kamenskiy [a,c,e,*,1]

Conclusion

3D arterial bending, torsion and compression in the flexed lower limb are highly localized and are substantially more severe than previously reported

Cadaver study



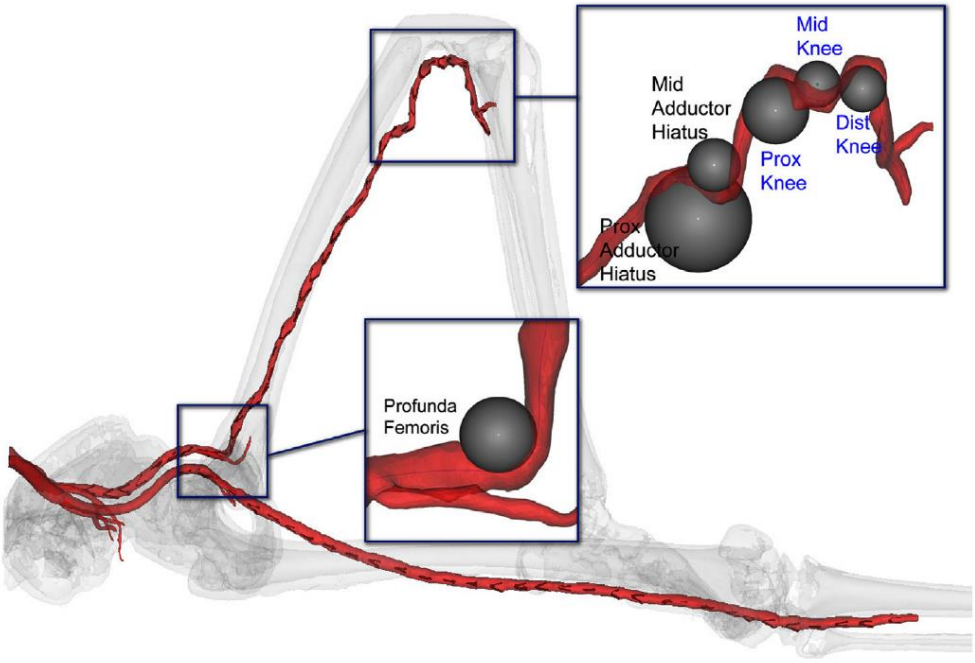


Fig. 3. Representative measurement of 3D bending as radii of inscribed spheres.

3.

828 J ENDOVASC THER 2013;20:828–835

◆CLINICAL INVESTIGATION ◆

Quantification of Popliteal Artery Deformation During Leg Flexion in Subjects With Peripheral Artery Disease: A Pilot Study

Can Gökgöl, MSc[1]; Nicolas Diehm, MD, MBA[2]; Levent Kara, MD[2]; and Philippe Büchler, PhD[1]

[1]Institute for Surgical Technology & Biomechanics, University of Bern, Switzerland.
[2]Clinical and Interventional Angiology, Inselspital, University Hospital Bern, Switzerland.

Rotational angiography study

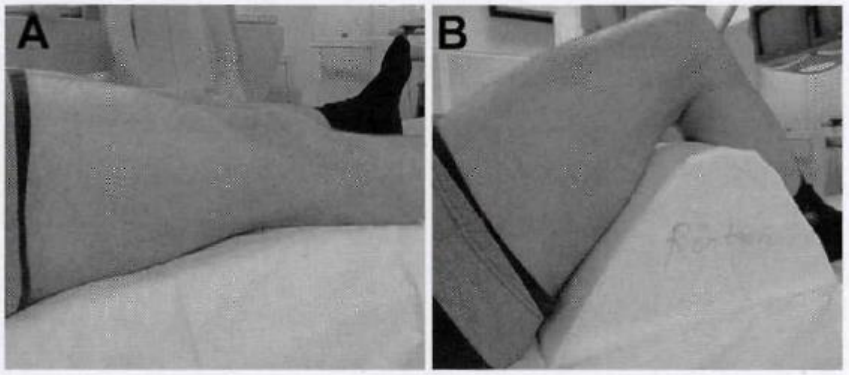
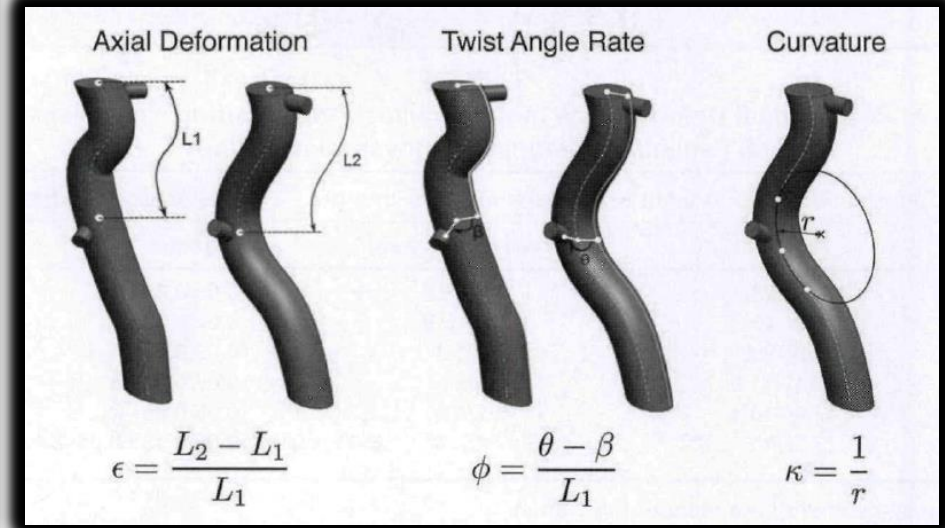


Figure 1 ◆ Positioning of the leg during 3D rotational angiography: straight (**A**) and flexed (**B**) with the help of a cast designed to simulate the walking condition.

Conclusion

- The popliteal artery is exposed to significant deformations during flexion of the knee joint
- The severity of calcification directly affects curvature, but not arterial length or twisting angles



4.

REVIEW ARTICLES

Richard P. Cambria, MD, Section Editor

Design considerations for studies of the biomechanical environment of the femoropopliteal arteries

Farzana Ansari, MS,[a] Lindsay K. Pack, BSE,[b] Steven S. Brooks, MD,[b] and Tina M. Morrison, PhD,[b]
Berkeley, Calif; and Silver Spring, Md

J Vasc Surg 2013;58:804-13

Review of the available literature = 12 relevant article

Conclusions

- Heterogeneous study designs that confound interpretation
- Different physiologic settings: young/mature, with/without disease, and cadavers
- Although this work has been valuable and significant, there are many limitations with the currently available data such that ***all we know about the SFA/PA environment is that we don't know***

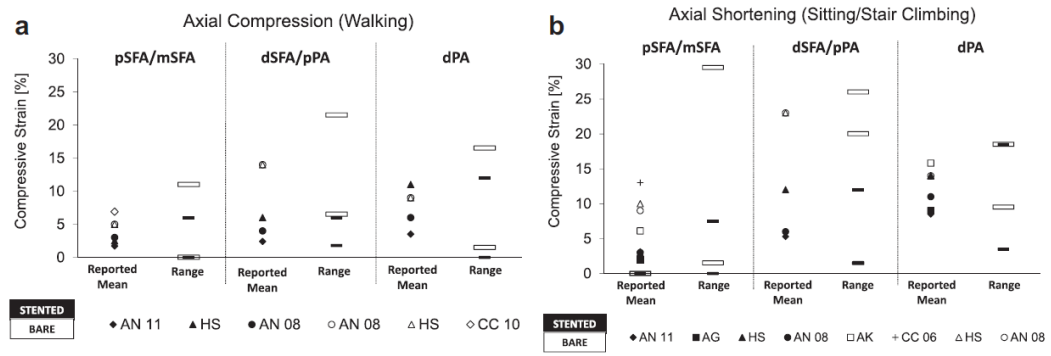
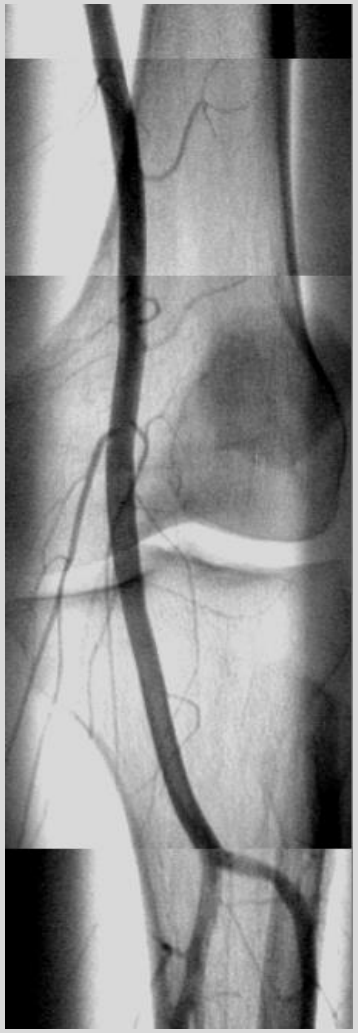
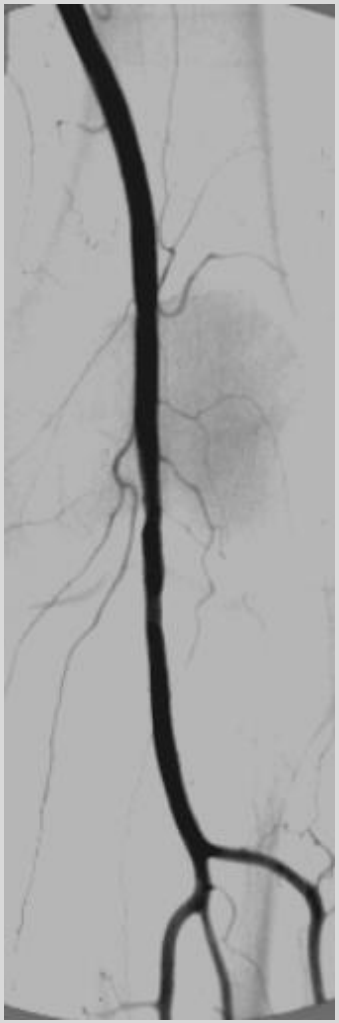


Fig 4. Summary of axial shortening data for (a) walking and (b) sitting/stair climbing positions from the literature database reports values from each article, as well as the maximum value for stented and bare artery data from the entire literature database. See Table I for the author acronym key. *dPA*, Distal popliteal artery; *dSFA*, distal superficial femoral artery; *mSFA*, midsuperficial femoral artery; *pPA*, proximal popliteal artery; *pSFA*, proximal superficial femoral artery.

36 yy



62 yy

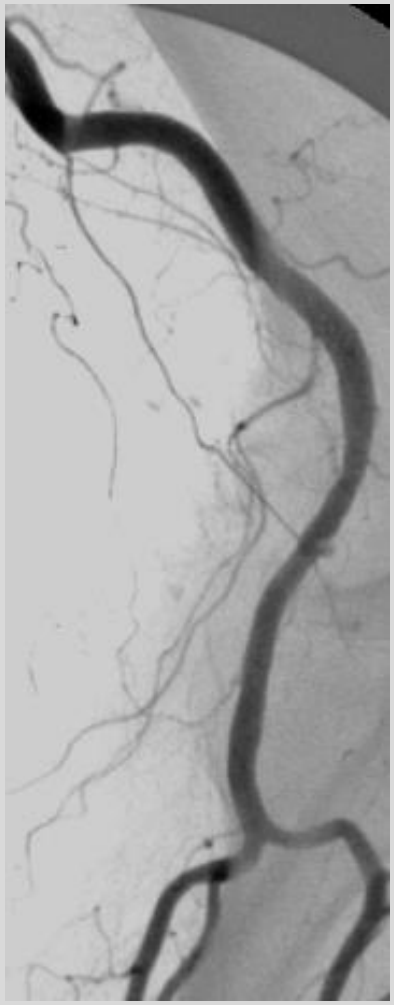


75 yy

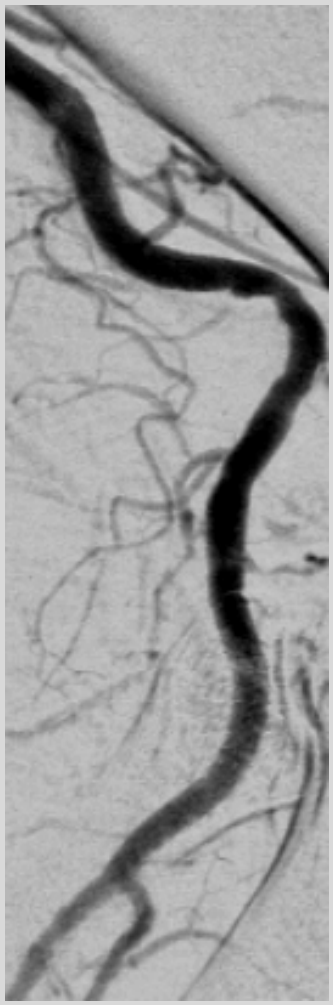
84 yy

36 yy

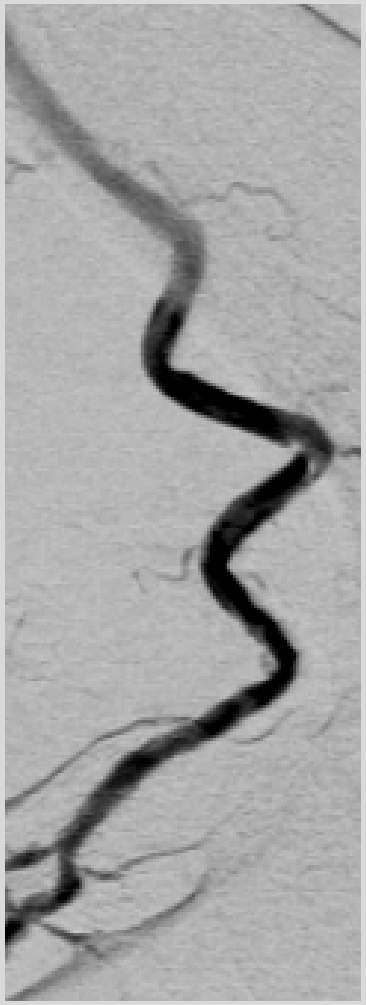
62 yy

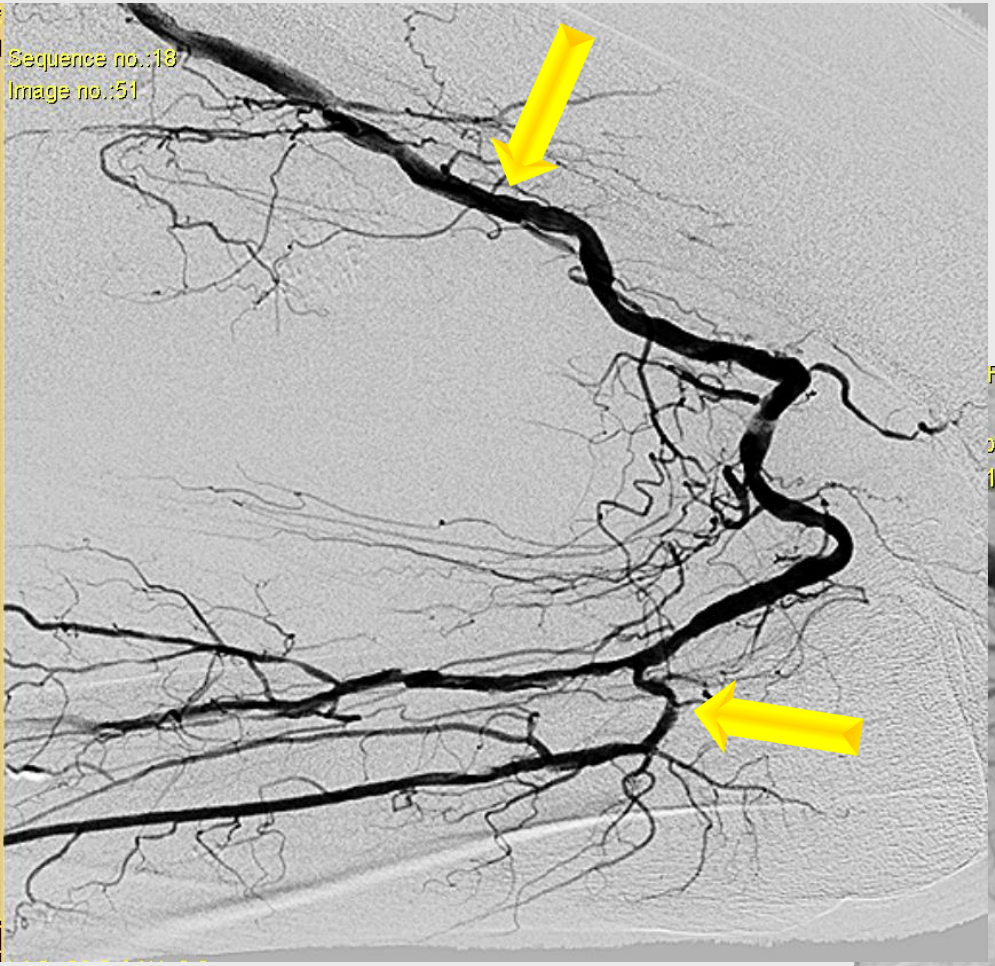


75 yy



84 yy

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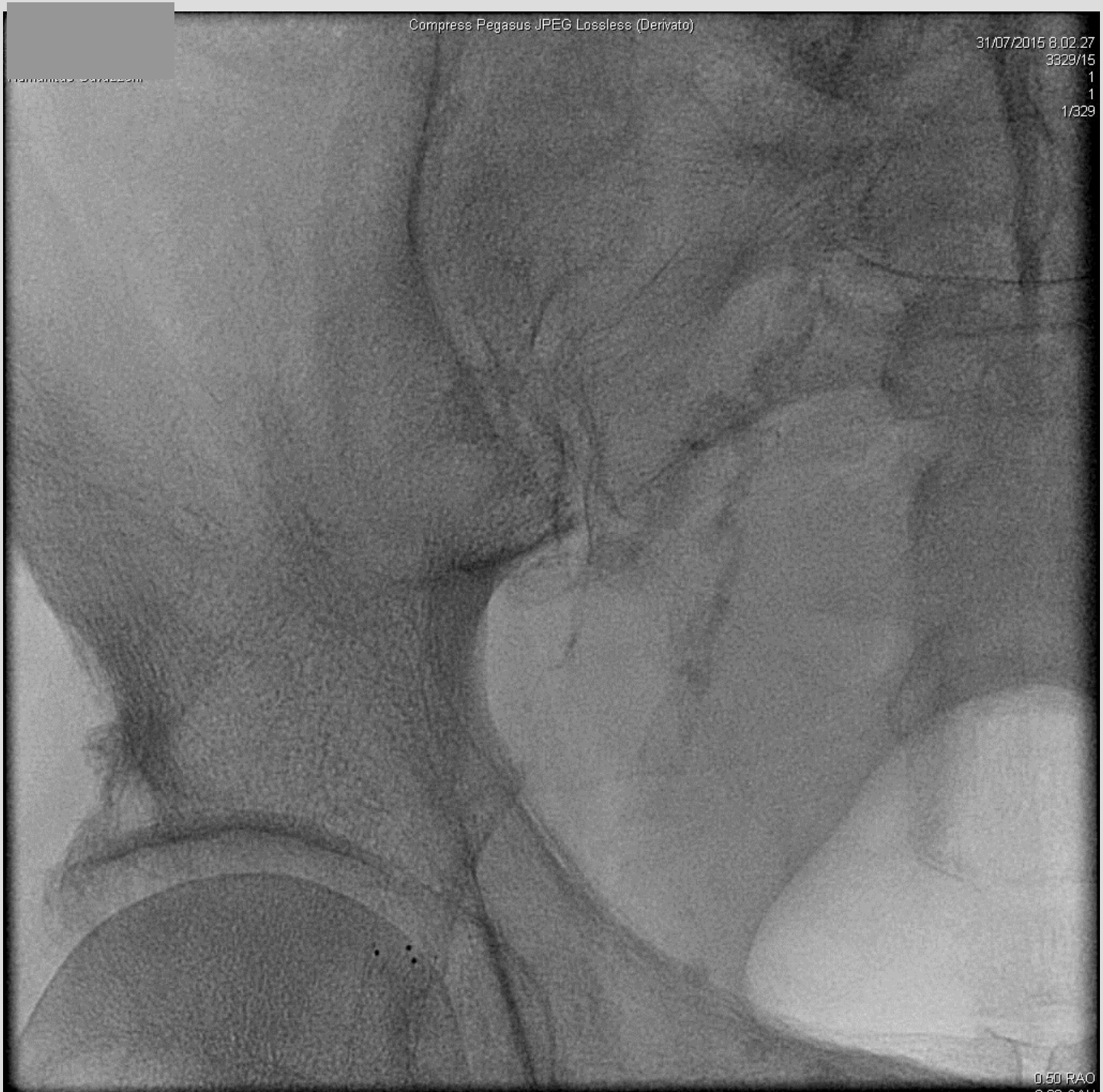
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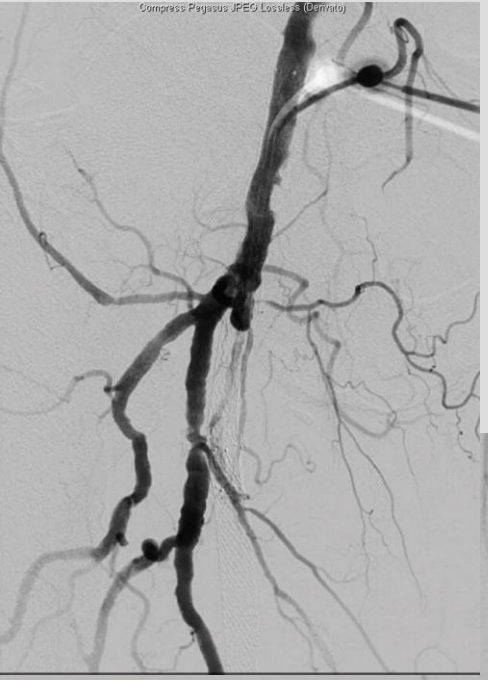
31/07/2015 8.02.27
3329/15
1
1
1/329
0.50 RAO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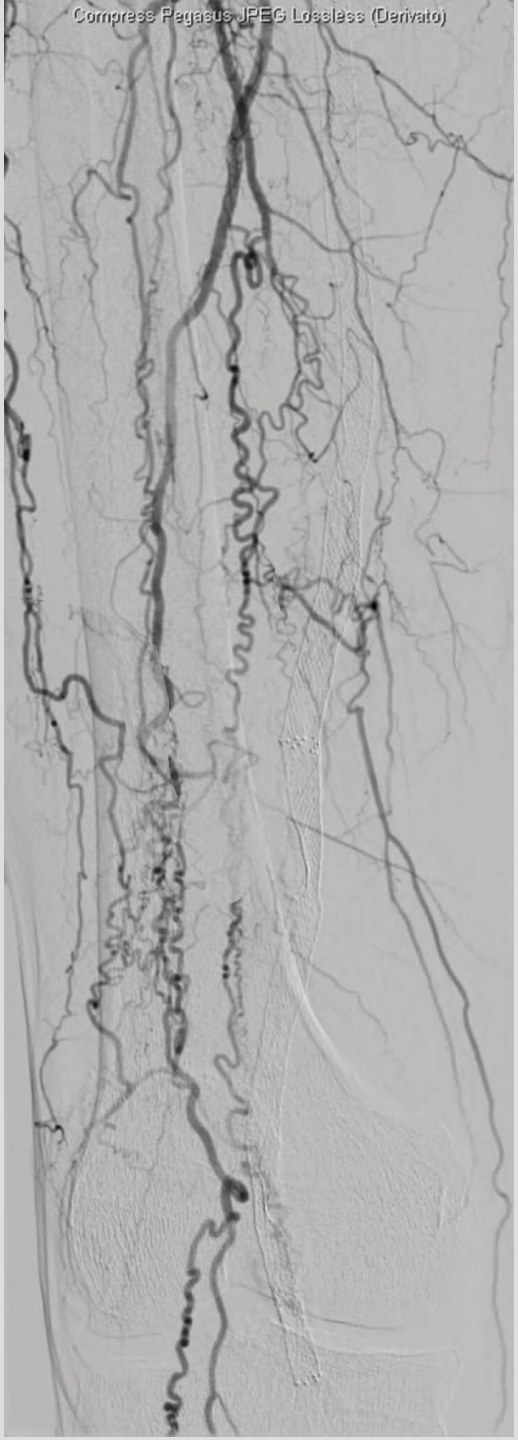
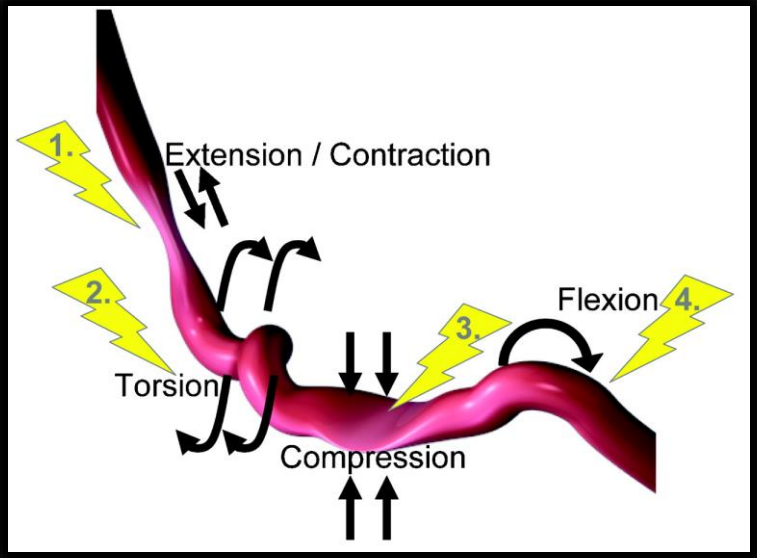

Compress Pegasus JPEG Lossless (Derivato)

Compress Pegasus JPEG Lossless (Derivato)



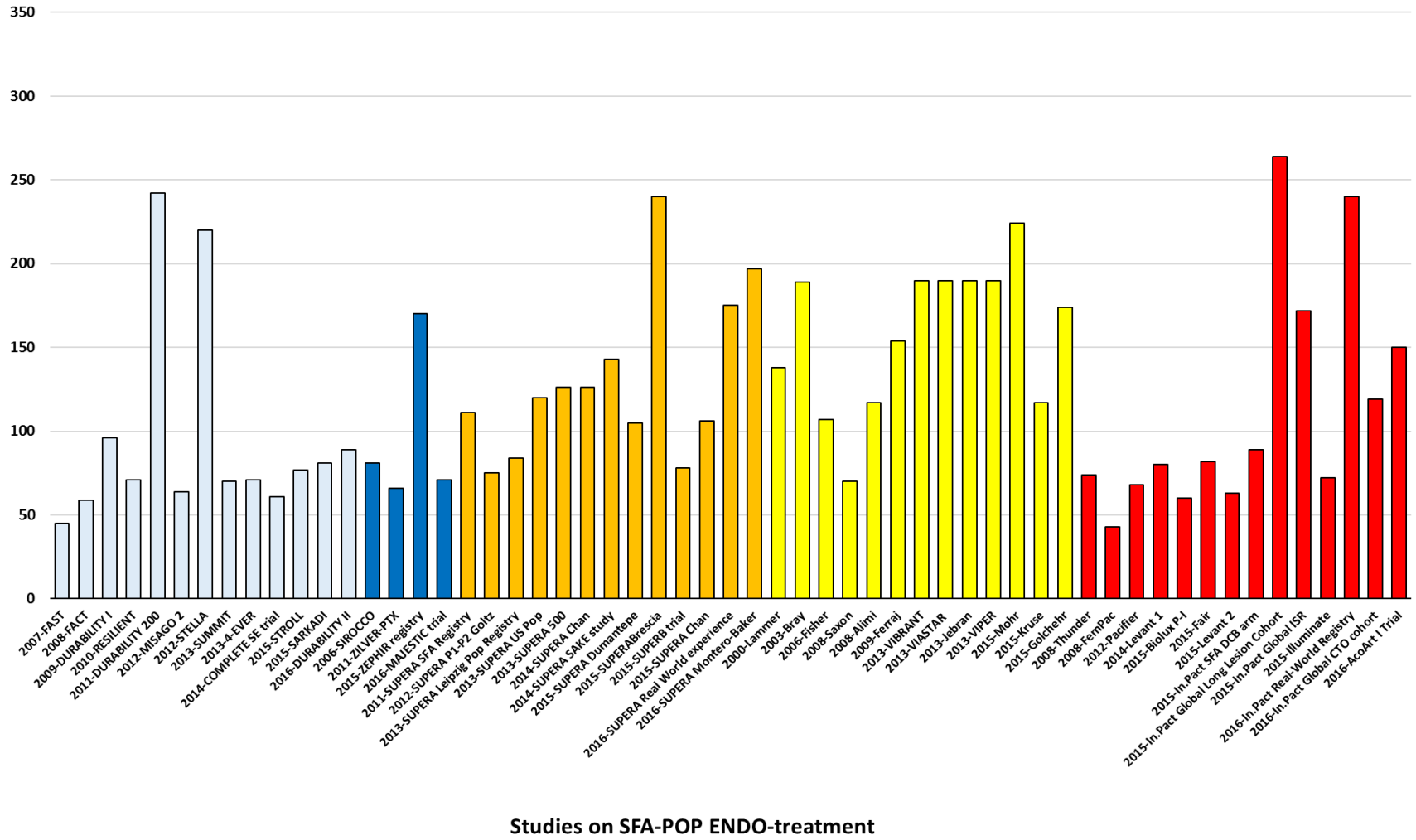
1. **The FEM-POP segment is subject to continuous and important mechanical forces that need to be carefully considered, as they weigh heavily on the outcome of endovascular treatments**

2. **Stenting means to interfere with the SFA-POP geometry and to impose a mechanical burden that leads to chronic mechanical stress. “Leaving nothing behind” is my first strategy**

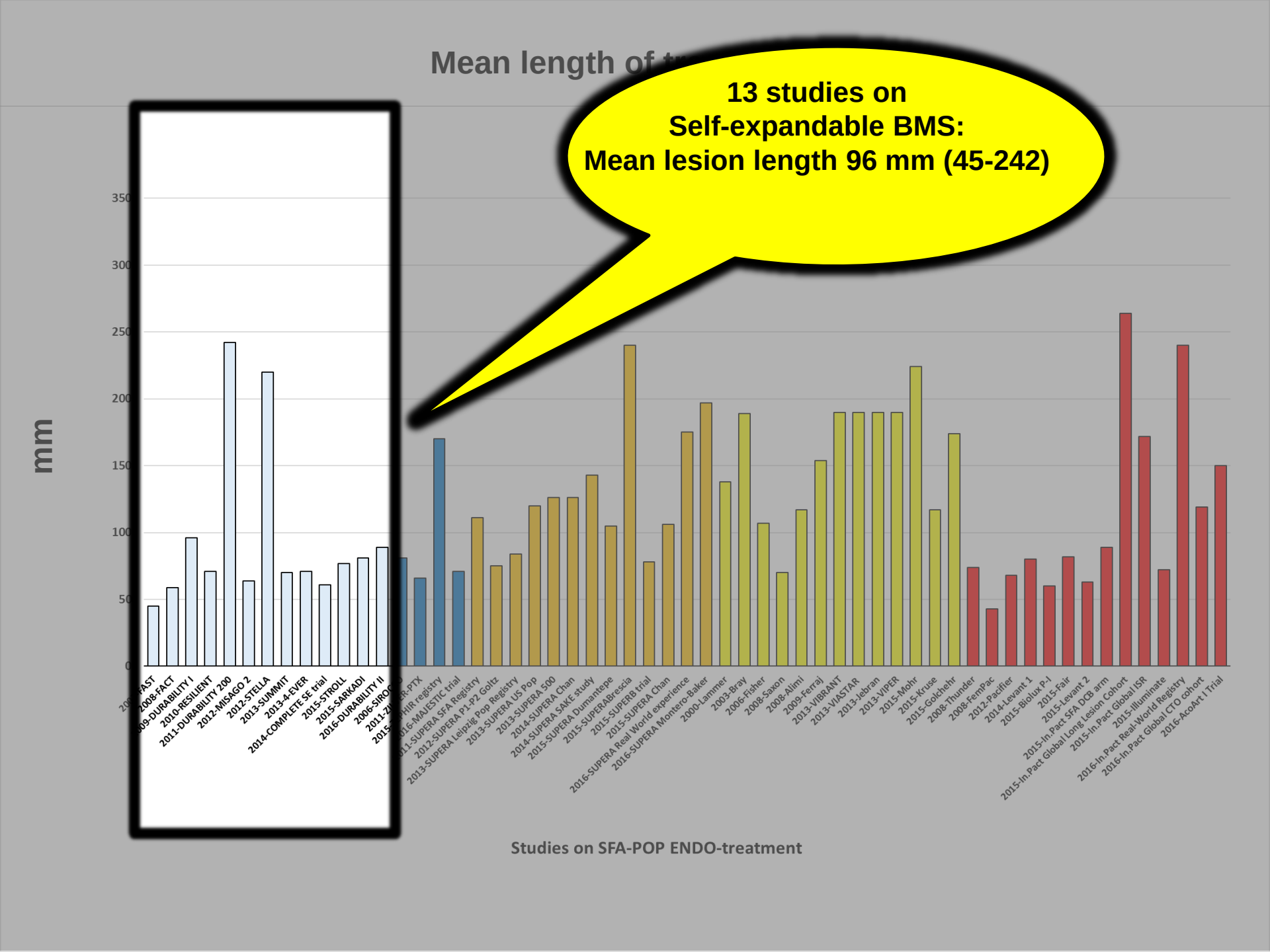
Why should we adopt the “leave nothing behind” approach in the SFA?

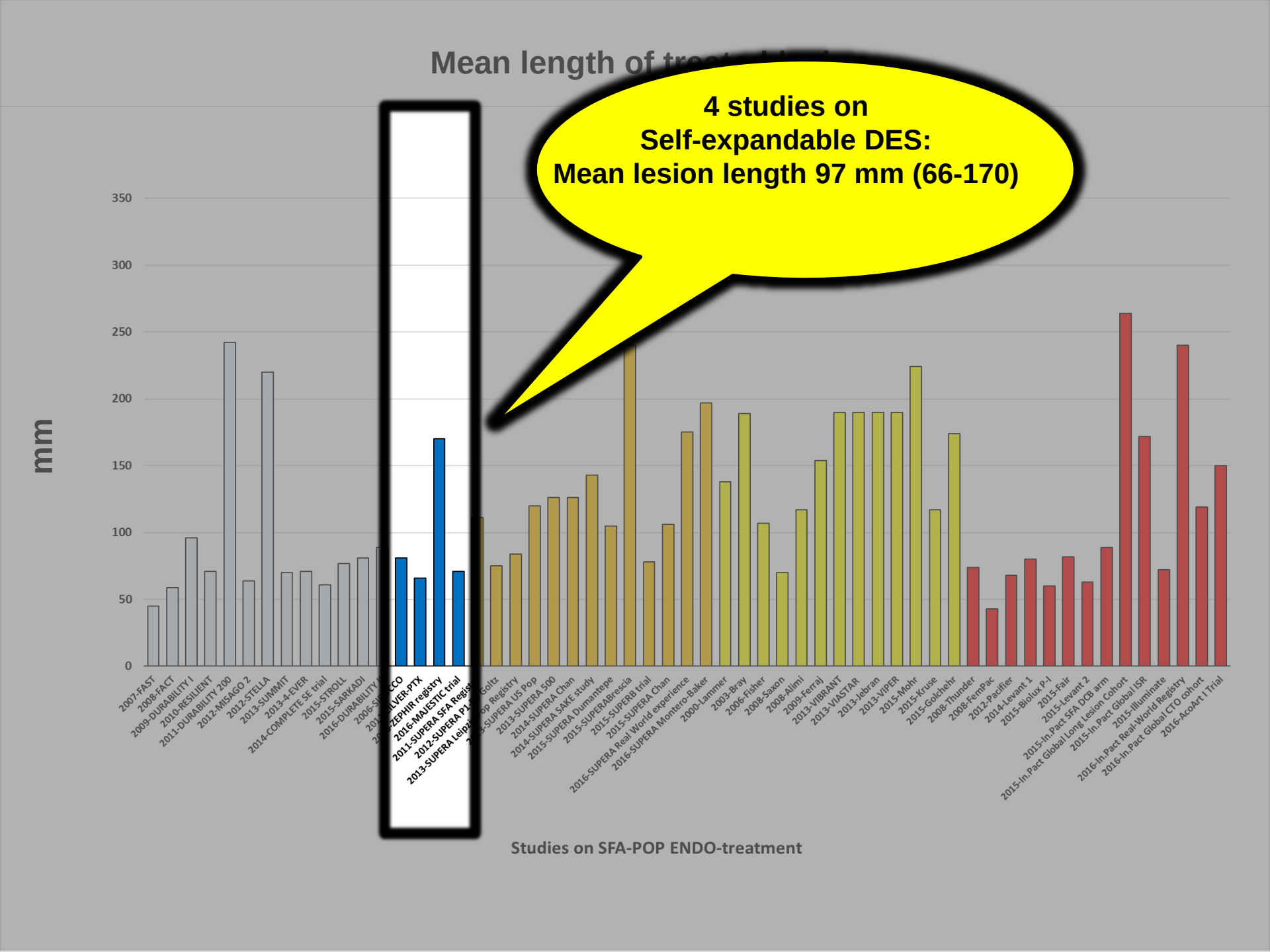
1. Mechanical problems in SFA-POP tract: the bad conduit
2. Global overview of SFA-POP solutions according to localization and length of lesion
3. The real world of ENDO treatment: a single center experience
4. Patency rate according to type of treatment

Mean length of treated lesion



Studies on SFA-POP ENDO-treatment


Mean length of
13 studies on
Self-expandable BMS:
Mean lesion length 96 mm (45-242)
mm
350
300
250
200
150
100
50
0
2008-FACT
2009-DURABILITY I
2010-RESILIENT
2011-DURABILITY 200
2012-MISAGO 2
2012-STELLA
2013-SUMMIT
2013-4-EVER
2014-COMPLETE SE trial
2015-STROLL
2015-SARKADI
2016-DURABILITY II
2006-SIROCCO
2011-ZILVER-PTX
2016-PHIR registry
2016-MAJESTIC trial
2011-SUPERA SFA Registry
2012-SUPERA P1-P2 Goltz
2013-SUPERA Leipzig Pop Registry
2013-SUPERA US Pop
2013-SUPERA 500
2014-SUPERA Chan
2014-SUPERA SAKE study
2015-SUPERA Dumantepe
2015-SUPERABrescia
2015-SUPERB trial
2015-SUPERA Chan
2016-SUPERA Real World experience
2016-SUPERA Montero-Baker
2000-Lammer
2003-Bray
2006-Fisher
2008-Saxon
2008-Alimi
2009-Ferraj
2013-VIBRANT
2013-VIASTAR
2013-Jebran
2013-VIPER
2015-Mohr
2015-Kruse
2015-Golchehr
2008-Thunder
2008-FemPac
2012-Pacifier
2014-Levant 1
2015-Biolux P-I
2015-Fair
2015-Levant 2
2015-In.Pact SFA DCB arm
2015-In.Pact Global Long Lesion Cohort
2015-In.Pact Global ISR
2015-Illuminate
2016-In.Pact Real-World Registry
2016-In.Pact Global CTO cohort
2016-AcoArt I Trial
Studies on SFA-POP ENDO-treatment


Mean length of
4 studies on
Self-expandable DES:
Mean lesion length 97 mm (66-170)
mm
350
300
250
200
150
100
50
0
2007-FAST
2008-FACT
2009-DURABILITY I
2010-RESILIENT
2011-DURABILITY 200
2012-MISAGO 2
2012-STELLA
2013-SUMMIT
2013-4-EVER
2014-COMPLETE SE trial
2015-STROLL
2015-SARKADI
2016-DURABILITY
2016-MAJESTIC trial
2011-SUPERA SFA Regis
2012-SUPERA P1
2013-SUPERA Leipzi
Goltz
Registry
SUPERA US Pop
2013-SUPERA 500
2014-SUPERA Chan
2014-SUPERA SAKE study
2015-SUPERA Dumantepe
2015-SUPERABrescia
2015-SUPERB trial
2015-SUPERA Chan
2016-SUPERA Real World experience
2016-SUPERA Montero-Baker
2000-Lammer
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2006-Fisher
2008-Saxon
2008-Alimi
2009-Ferraj
2013-VIBRANT
2013-VIASTAR
2013-Jebran
2013-VIPER
2015-Mohr
2015-Kruse
2015-Golchehr
2008-Thunder
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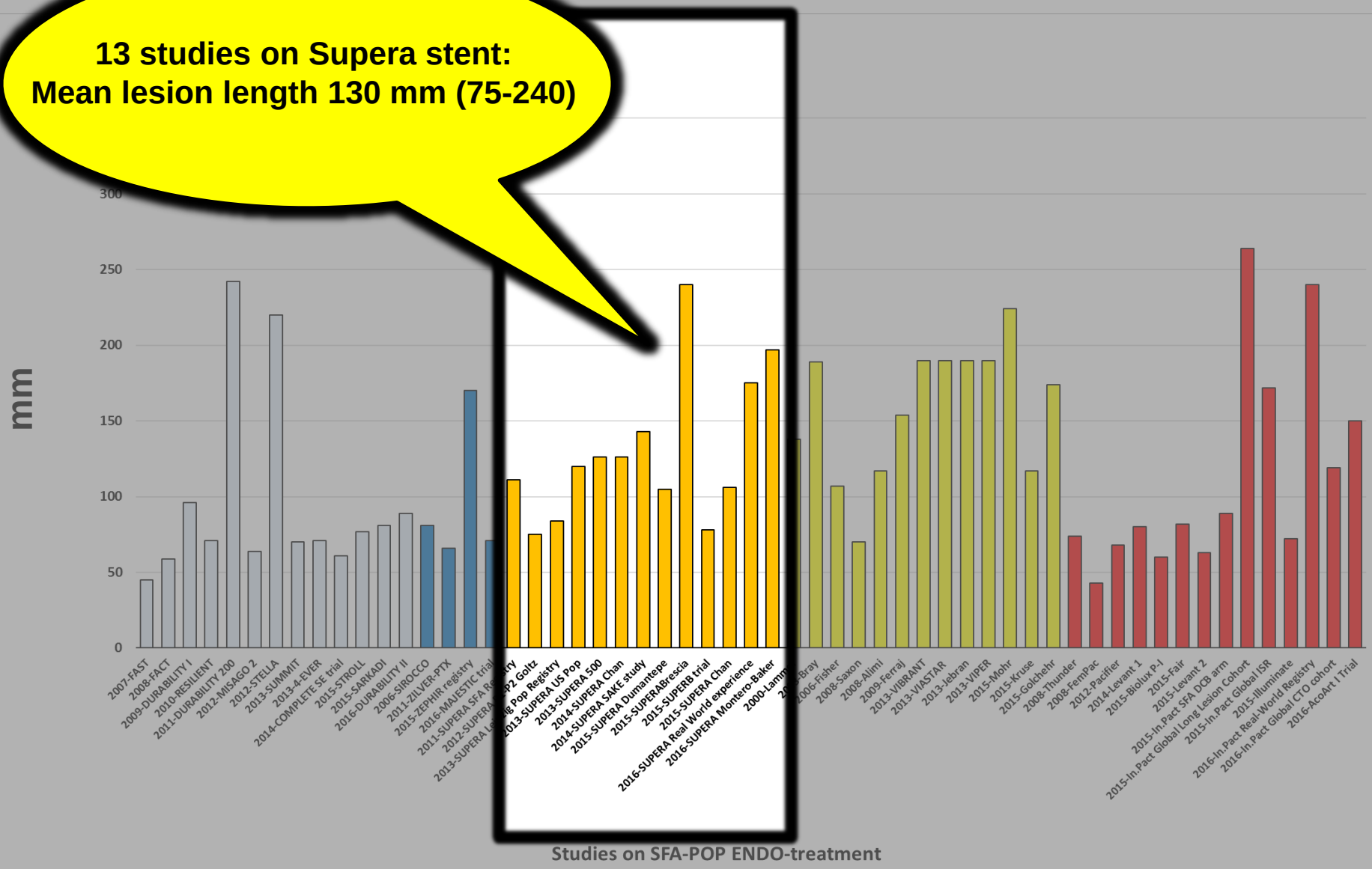
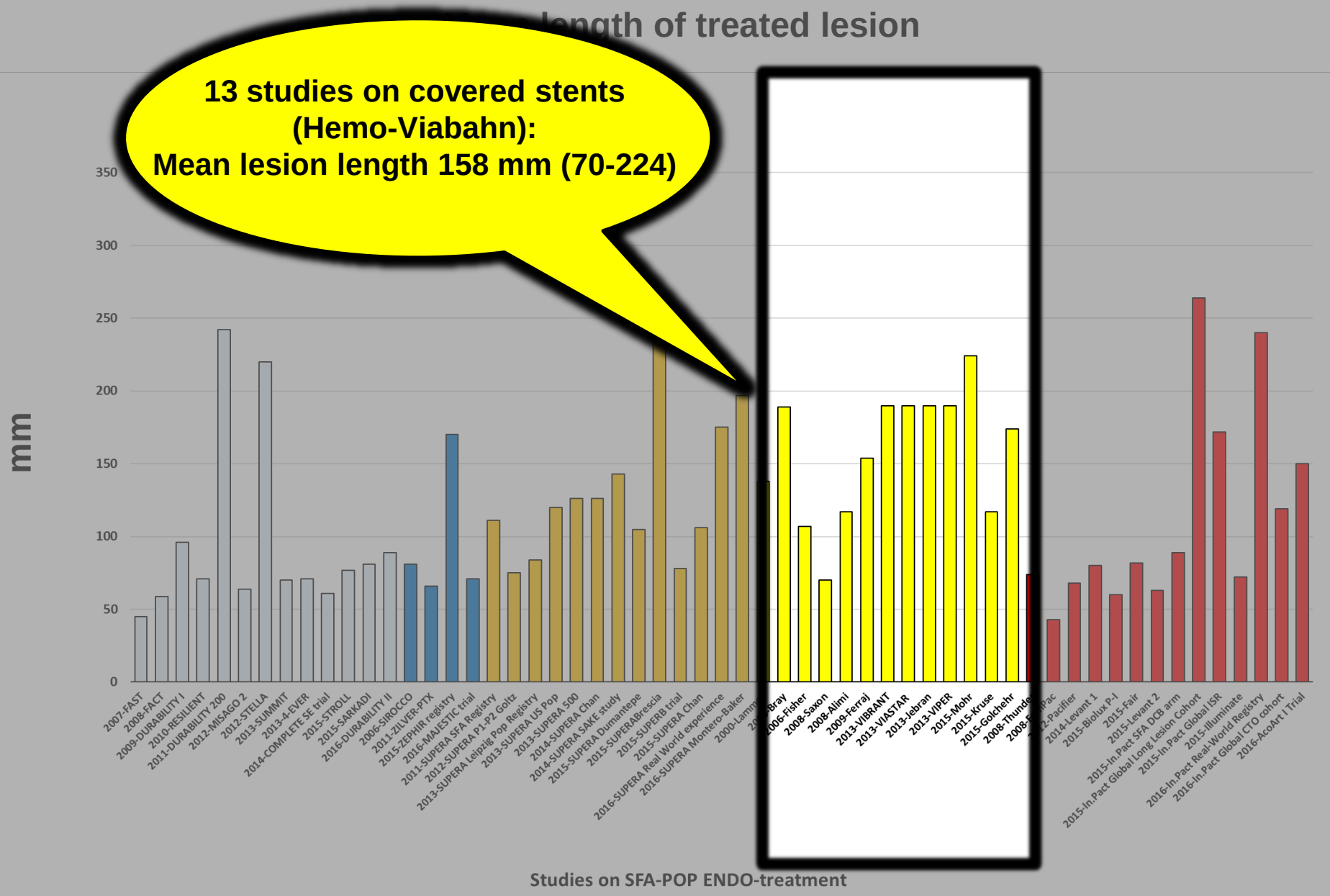
2012-Pacifier
2014-Levant 1
2015-Biolux P-I
2015-Fair
2015-Levant 2
2015-In.Pact SFA DCB arm
2015-In.Pact Global Long Lesion Cohort
2015-In.Pact Global ISR
2015-Illuminate
2016-In.Pact Real-World Registry
2016-In.Pact Global CTO cohort
2016-AcoArt I Trial
Studies on SFA-POP ENDO-treatment

Mean length of treated lesion

13 studies on Supera stent:
Mean lesion length 130 mm (75-240)



Studies on SFA-POP ENDO-treatment


length of treated lesion
13 studies on covered stents
(Hemo-Viabahn):
Mean lesion length 158 mm (70-224)
mm
350
300
250
200
150
100
50
0
2007-FAST
2008-FACT
2009-DURABILITY I
2010-RESILIENT
2011-DURABILITY 200
2012-MISAGO 2
2012-STELLA
2013-SUMMIT
2013-4-EVER
2014-COMPLETE SE trial
2015-STROLL
2015-SARKADI
2016-DURABILITY II
2006-SIROCCO
2011-ZILVER-PTX
2015-ZEPHIR registry
2016-MAJESTIC trial
2011-SUPERA SFA Registry
2012-SUPERA P1-P2 Goltz
2013-SUPERA Leipzig Pop Registry
2013-SUPERA US Pop
2013-SUPERA 500
2014-SUPERA Chan
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2015-SUPERABrescia
2015-SUPERB trial
2015-SUPERA Chan
2016-SUPERA Real World experience
2016-SUPERA Montero-Baker
2000-Lamm
2006-Fisher
2008-Saxon
2008-Alimi
2009-Ferraj
2013-VIBRANT
2013-VIASTAR
2013-Jebran
2013-VIPER
2015-Mohr
2015-Kruse
2015-Golchehr
2008-Thunde
2014-Levant 1
2015-Biolux P-I
2015-Fair
2015-Levant 2
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2015-Illuminate
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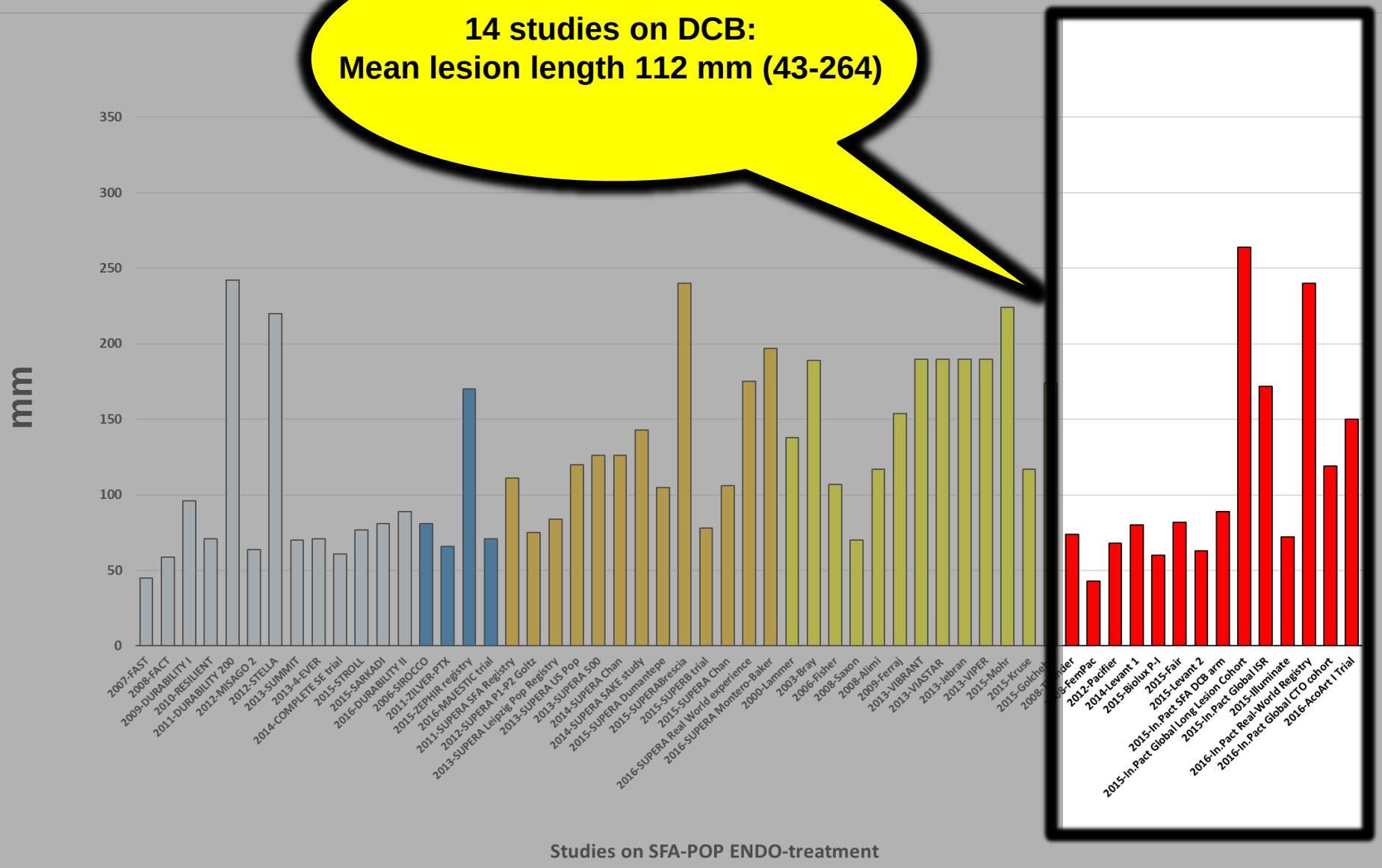
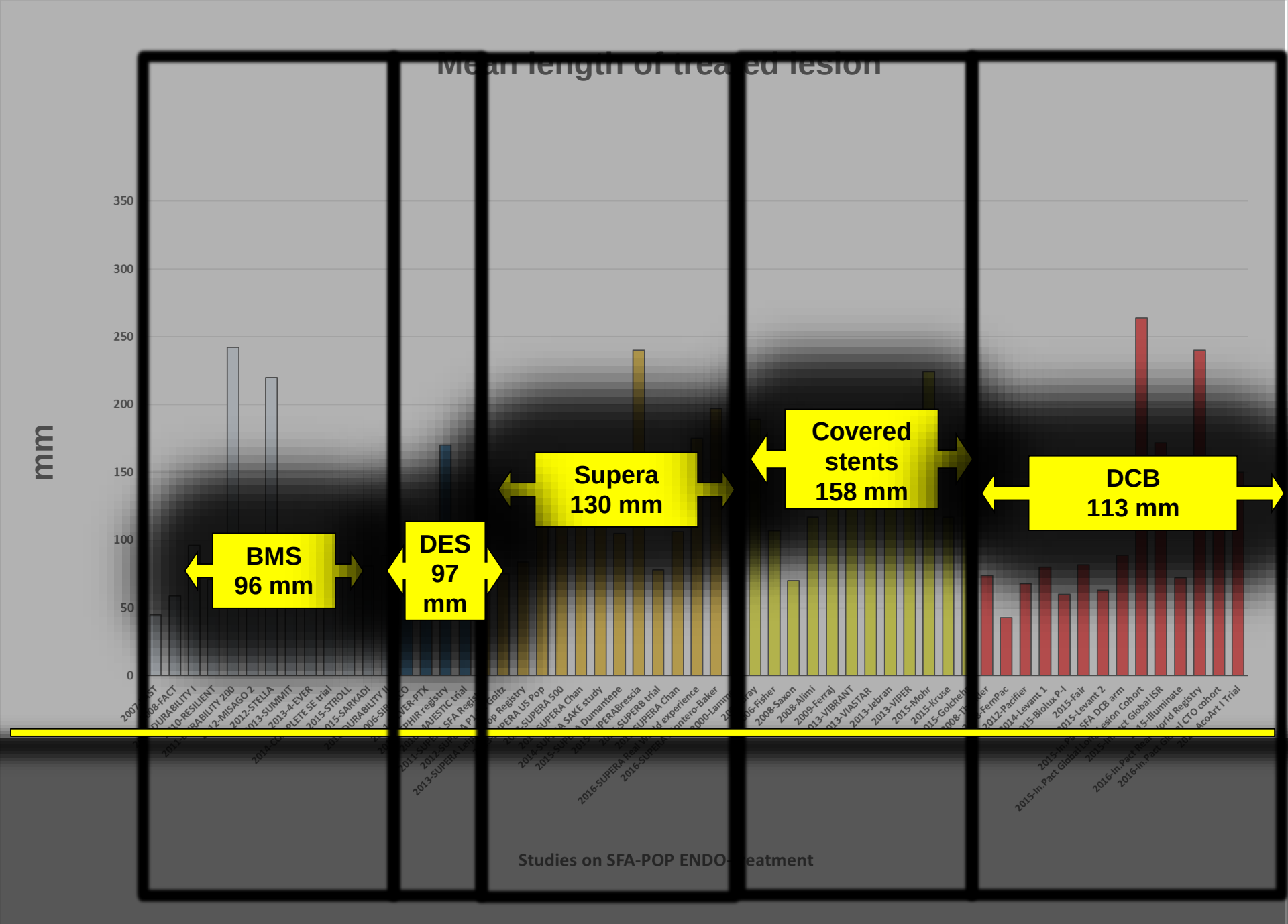
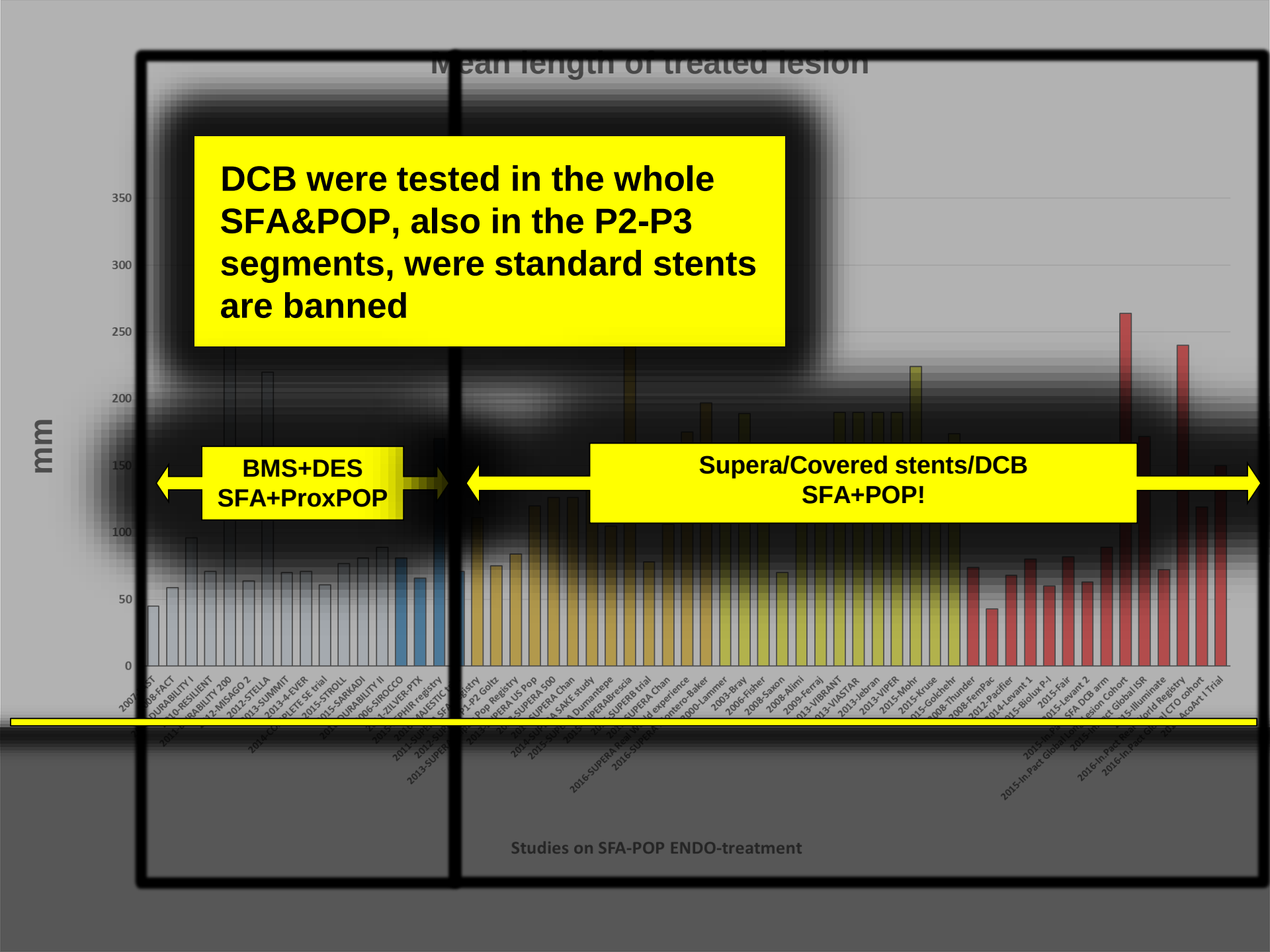
2016-In.Pact Global CTO cohort
2016-AcoArt I Trial
Studies on SFA-POP ENDO-treatment

14 studies on DCB:
Mean lesion length 112 mm (43-264)



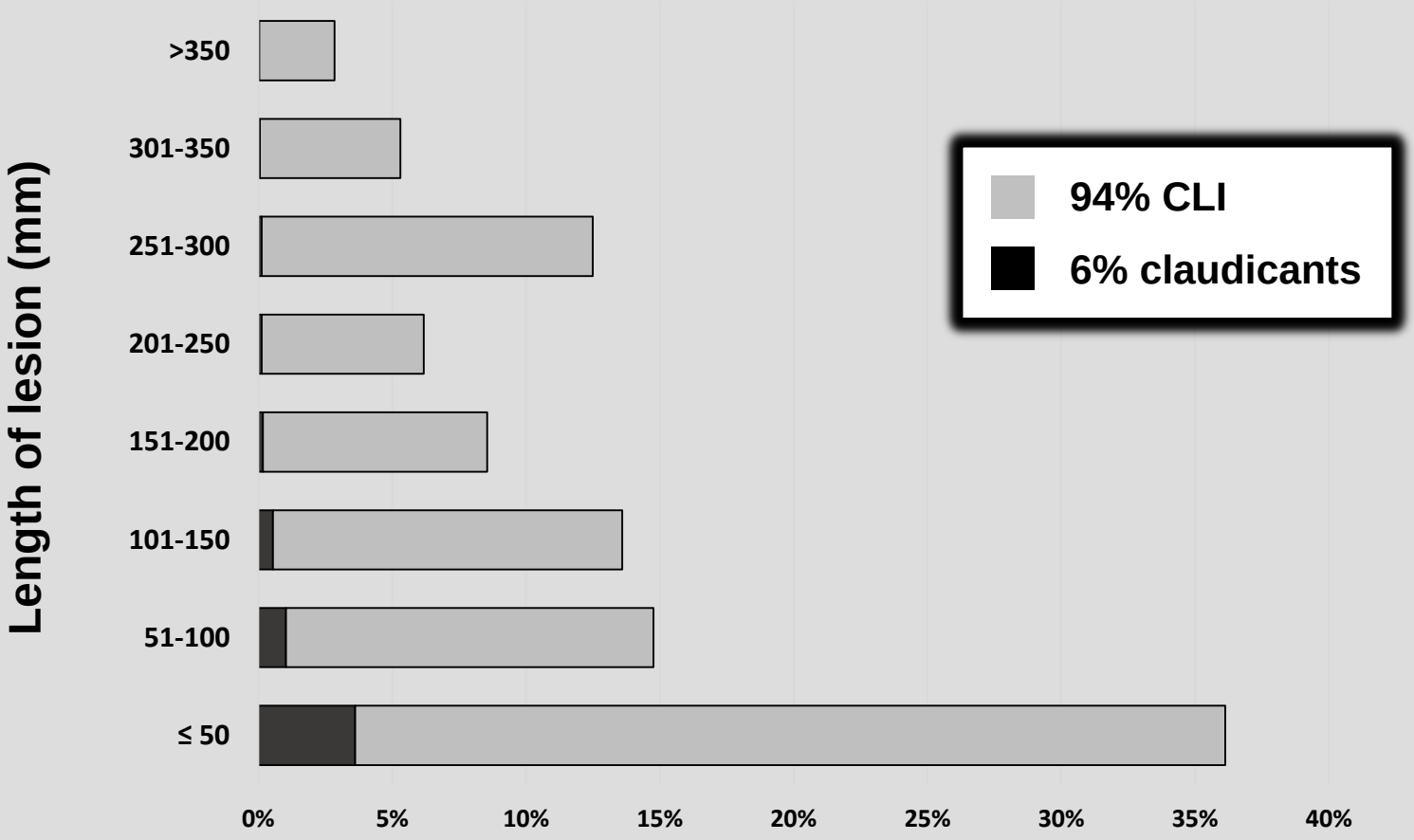

Mean length of treated lesion
mm
350
300
250
200
150
100
50
0
BMS
96 mm
DES
97
mm
Supera
130 mm
Covered
stents
158 mm
DCB
113 mm
Studies on SFA-POP ENDO-treatment


Mean length of treated lesion
DCB were tested in the whole SFA&POP, also in the P2-P3 segments, were standard stents are banned
mm
350
300
250
200
150
100
50
0
BMS+DES
SFA+ProxPOP
Supera/Covered stents/DCB
SFA+POP!
Studies on SFA-POP ENDO-treatment

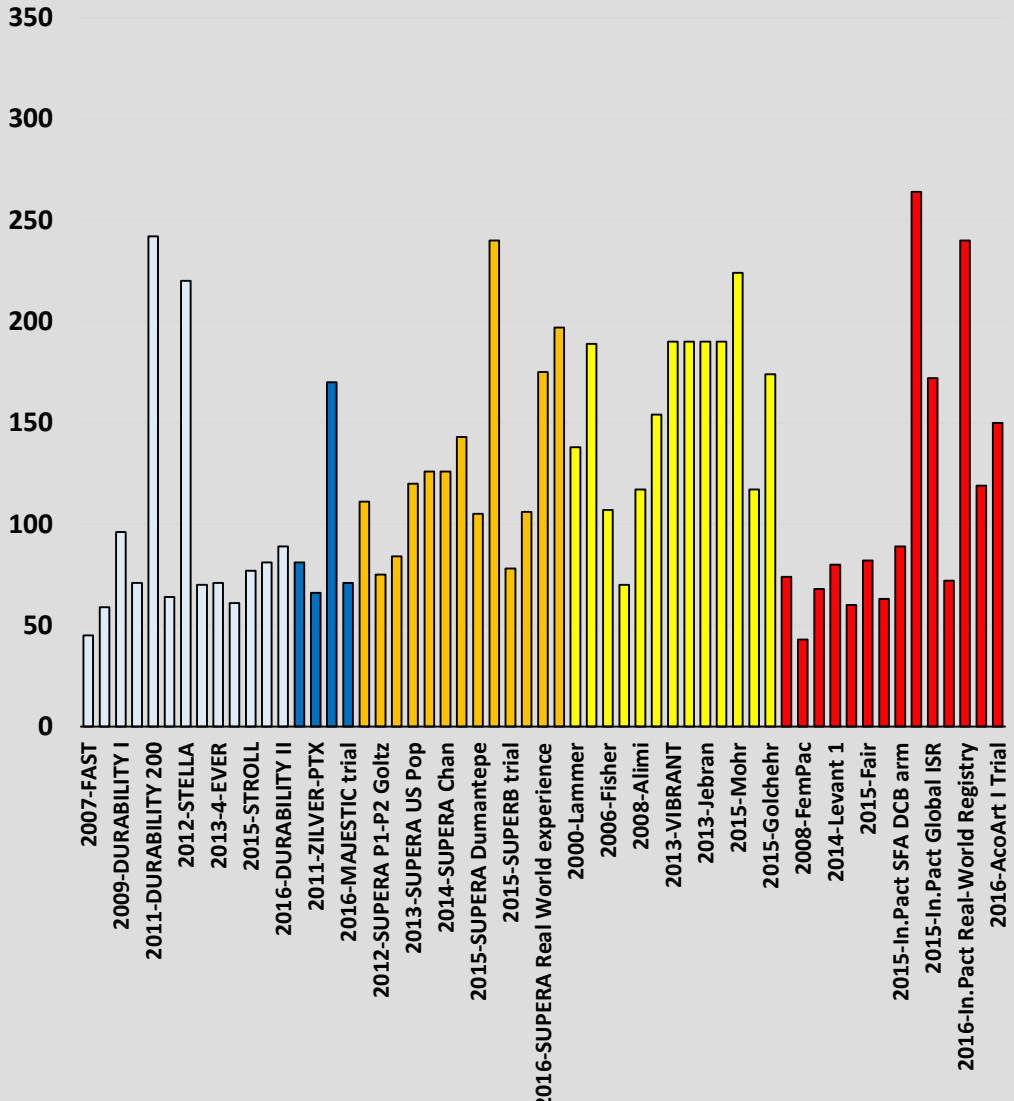
Why should we adopt the “leave nothing behind” approach in the SFA?

1. Mechanical problems in SFA-POP tract: the bad conduit
2. Global overview of SFA-POP solutions according to localization and length of lesion
3. The real world of ENDO treatment: a single center experience
4. Restenosis rate according to type of treatment

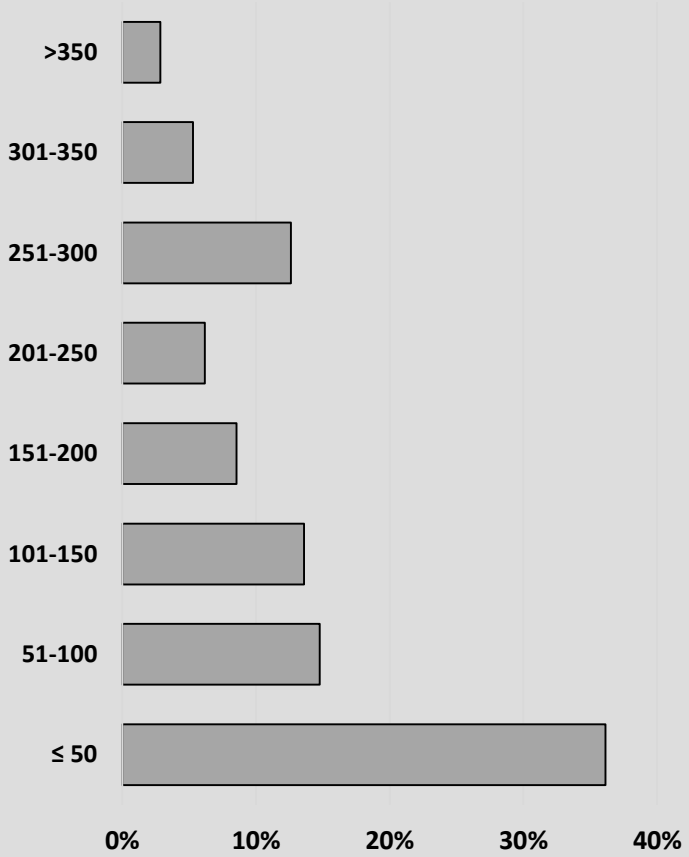
Length of successfully treated lesion
3089 SFA-POP lesions (2009-2014)

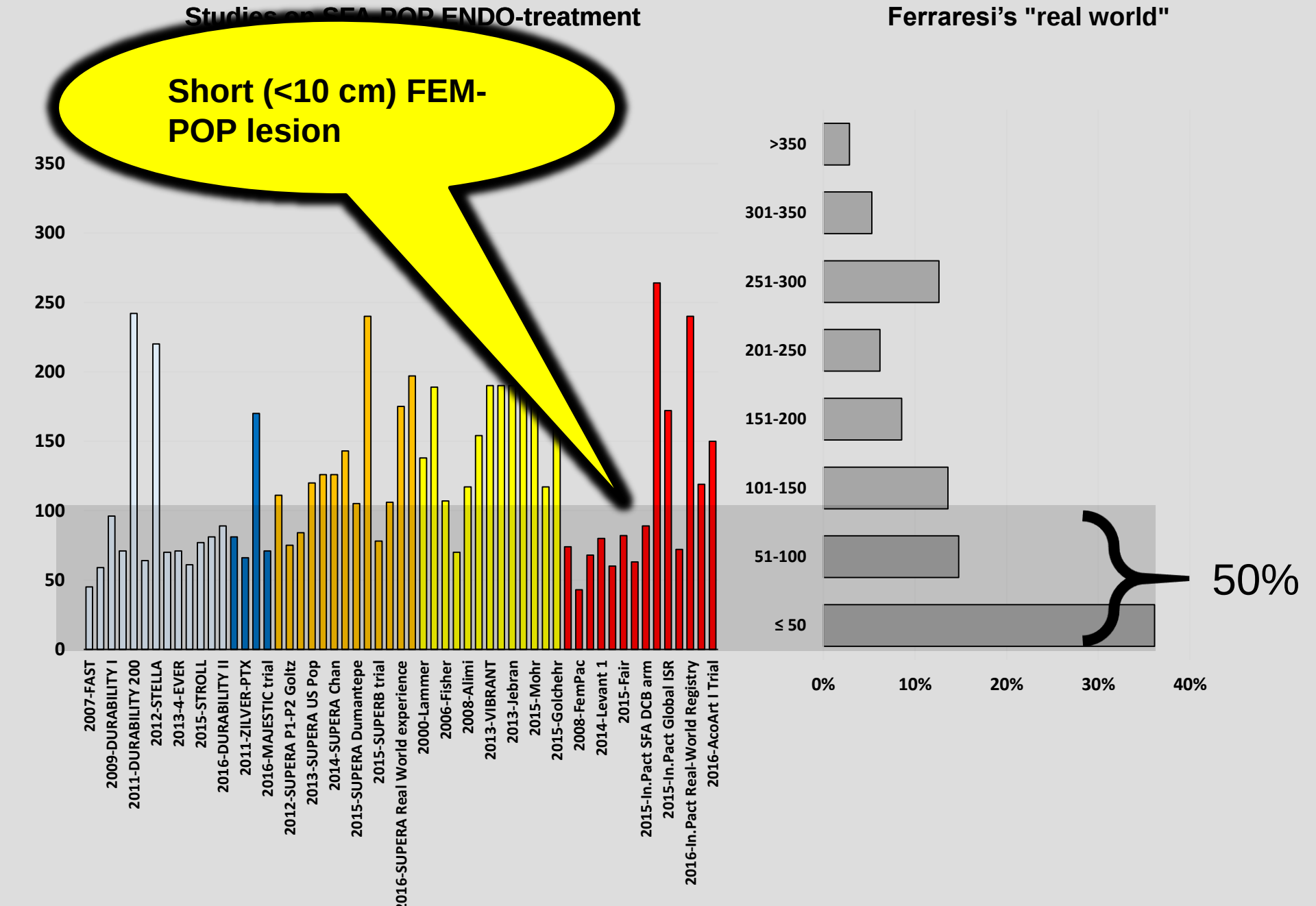


Studies on SFA-POP ENDO-treatment



Ferraresi's "real world"




Studies on SFA POP ENDO-treatment
Ferraresi's "real world"
Short (<10 cm) FEM-POP lesion
350
300
250
200
150
100
50
0
2007-FAST
2009-DURABILITY I
2011-DURABILITY 200
2012-STELLA
2013-4-EVER
2015-STROLL
2016-DURABILITY II
2011-ZILVER-PTX
2016-MAJESTIC trial
2012-SUPERA P1-P2 Goltz
2013-SUPERA US Pop
2014-SUPERA Chan
2015-SUPERA Dumantepe
2015-SUPERB trial
2016-SUPERA Real World experience
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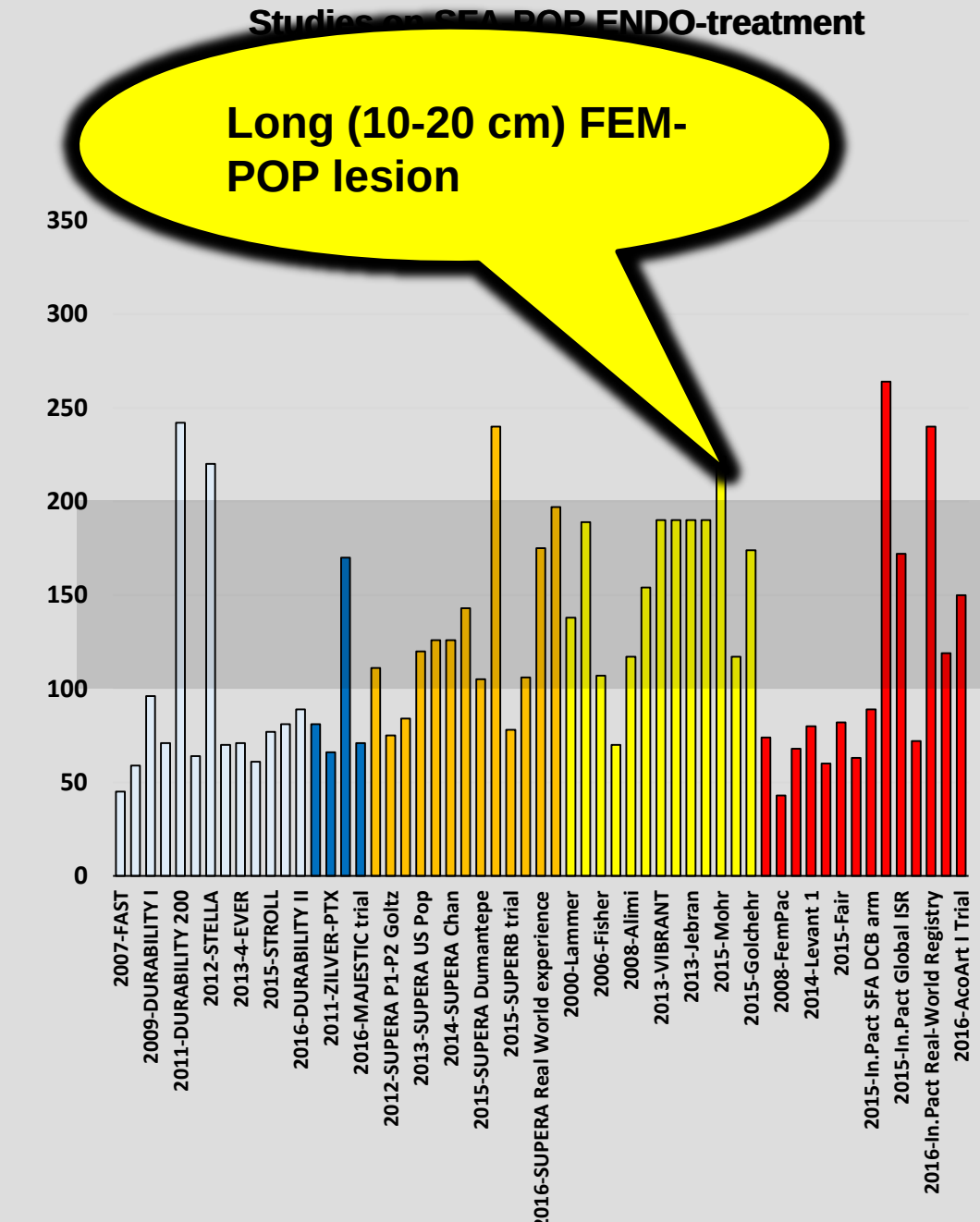
2008-Alimi
2013-VIBRANT
2013-Jebran
2015-Mohr
2015-Golchehr
2008-FemPac
2014-Levant 1
2015-Fair
2015-In.Pact SFA DCB arm
2015-In.Pact Global ISR
2016-In.Pact Real-World Registry
2016-AcoArt I Trial
>350
301-350
251-300
201-250
151-200
101-150
51-100
≤ 50
0%
10%
20%
30%
40%
50%


Studies on SFA-POP ENDO-treatment
Long (10-20 cm) FEM-POP lesion
350
300
250
200
150
100
50
0
2007-FAST
2009-DURABILITY I
2011-DURABILITY 200
2012-STELLA
2013-4-EVER
2015-STROLL
2016-DURABILITY II
2011-ZILVER-PTX
2016-MAJESTIC trial
2012-SUPERA P1-P2 Goltz
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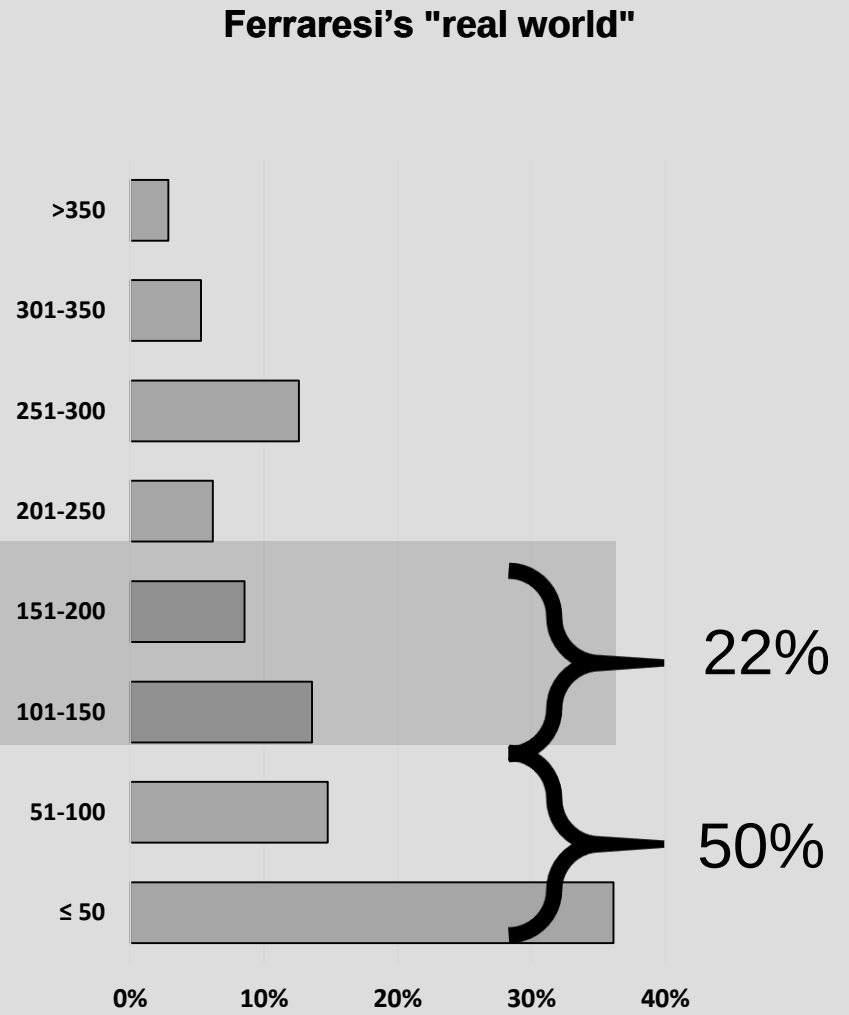
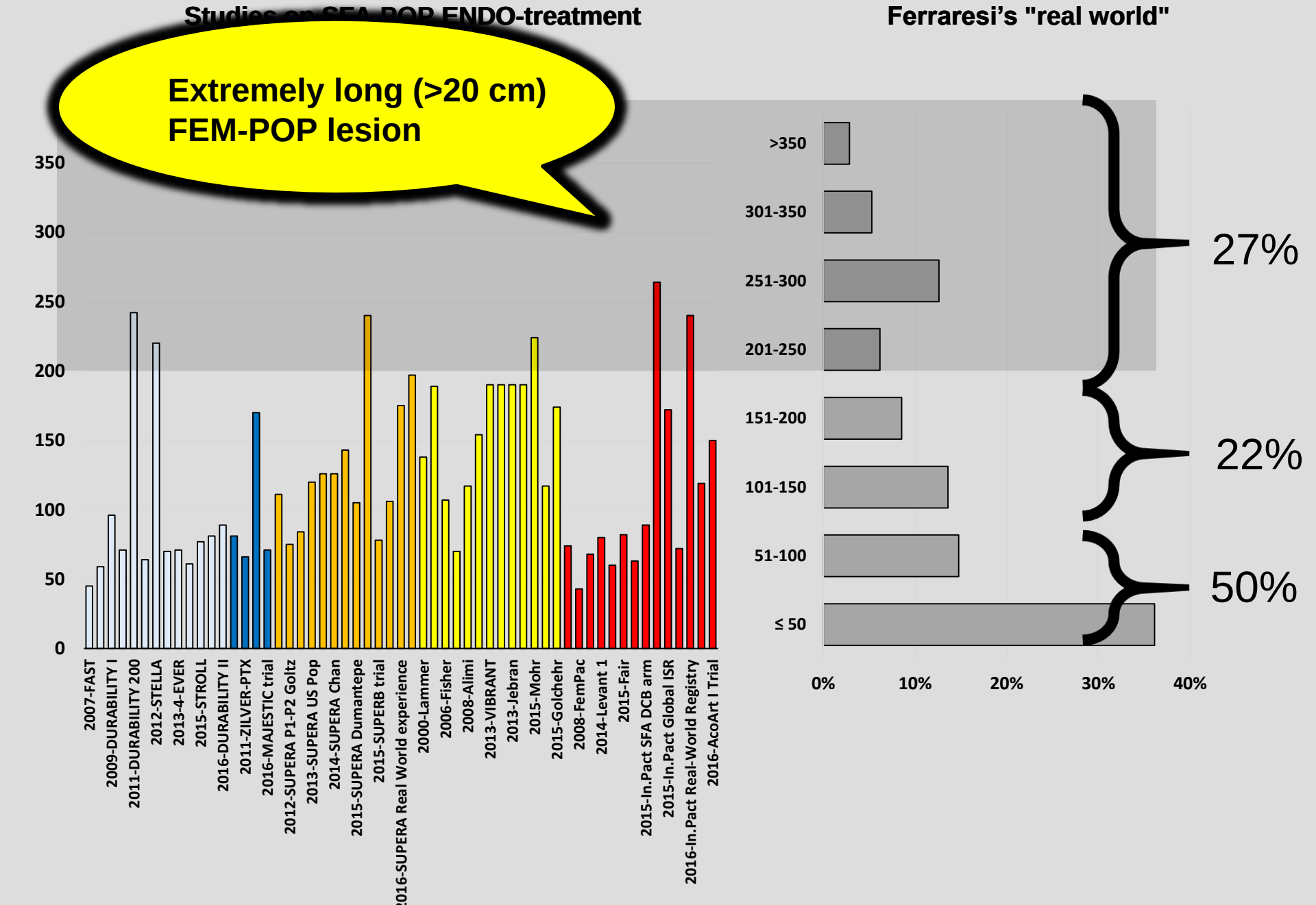
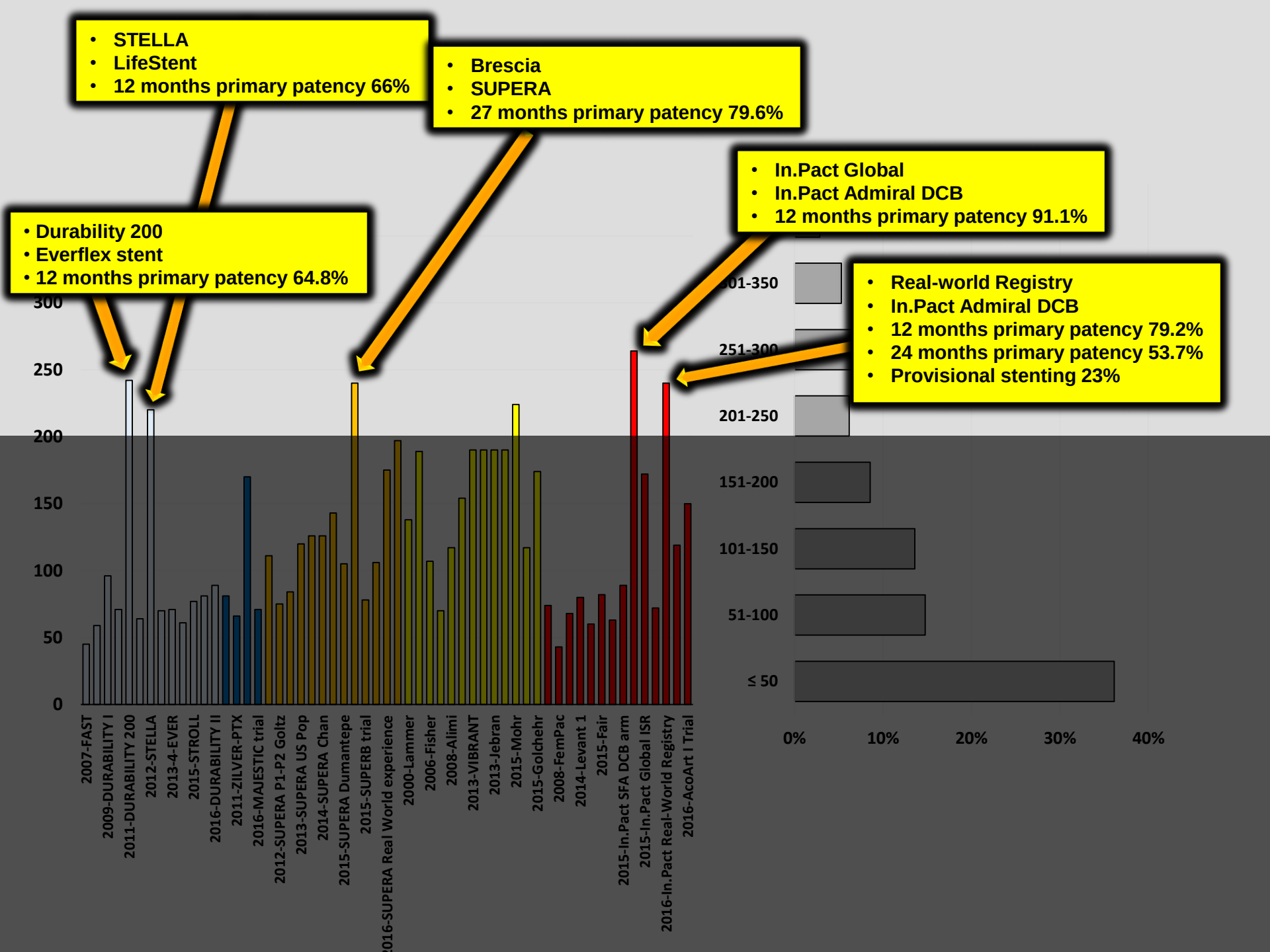

Ferraresi's "real world"
>350
301-350
251-300
201-250
151-200
101-150
51-100
≤ 50
0%
10%
20%
30%
40%
22%
50%


Studies on SFA-POP ENDO-treatment
Extremely long (>20 cm)
FEM-POP lesion
350
300
250
200
150
100
50
0
2007-FAST
2009-DURABILITY I
2011-DURABILITY 200
2012-STELLA
2013-4-EVER
2015-STROLL
2016-DURABILITY II
2011-ZILVER-PTX
2016-MAJESTIC trial
2012-SUPERA P1-P2 Goltz
2013-SUPERA US Pop
2014-SUPERA Chan
2015-SUPERA Dumantepe
2015-SUPERB trial
2016-SUPERA Real World experience
2000-Lammer
2006-Fisher
2008-Alimi
2013-VIBRANT
2013-Jebran
2015-Mohr
2015-Golchehr
2008-FemPac
2014-Levant 1
2015-Fair
2015-In.Pact SFA DCB arm
2015-In.Pact Global ISR
2016-In.Pact Real-World Registry
2016-AcoArt I Trial
Ferraresi's "real world"
>350
301-350
251-300
201-250
151-200
101-150
51-100
≤ 50
27%
22%
50%
0%
10%
20%
30%
40%


• STELLA
• LifeStent
• 12 months primary patency 66%
• Brescia
• SUPERA
• 27 months primary patency 79.6%
• In.Pact Global
• In.Pact Admiral DCB
• 12 months primary patency 91.1%
• Durability 200
• Everflex stent
• 12 months primary patency 64.8%
• Real-world Registry
• In.Pact Admiral DCB
• 12 months primary patency 79.2%
• 24 months primary patency 53.7%
• Provisional stenting 23%
300
250
200
150
100
50
0
2007-FAST
2009-DURABILITY I
2011-DURABILITY 200
2012-STELLA
2013-4-EVER
2015-STROLL
2016-DURABILITY II
2011-ZILVER-PTX
2016-MAJESTIC trial
2012-SUPERA P1-P2 Goltz
2013-SUPERA US Pop
2014-SUPERA Chan
2015-SUPERA Dumantepe
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2000-Lammer
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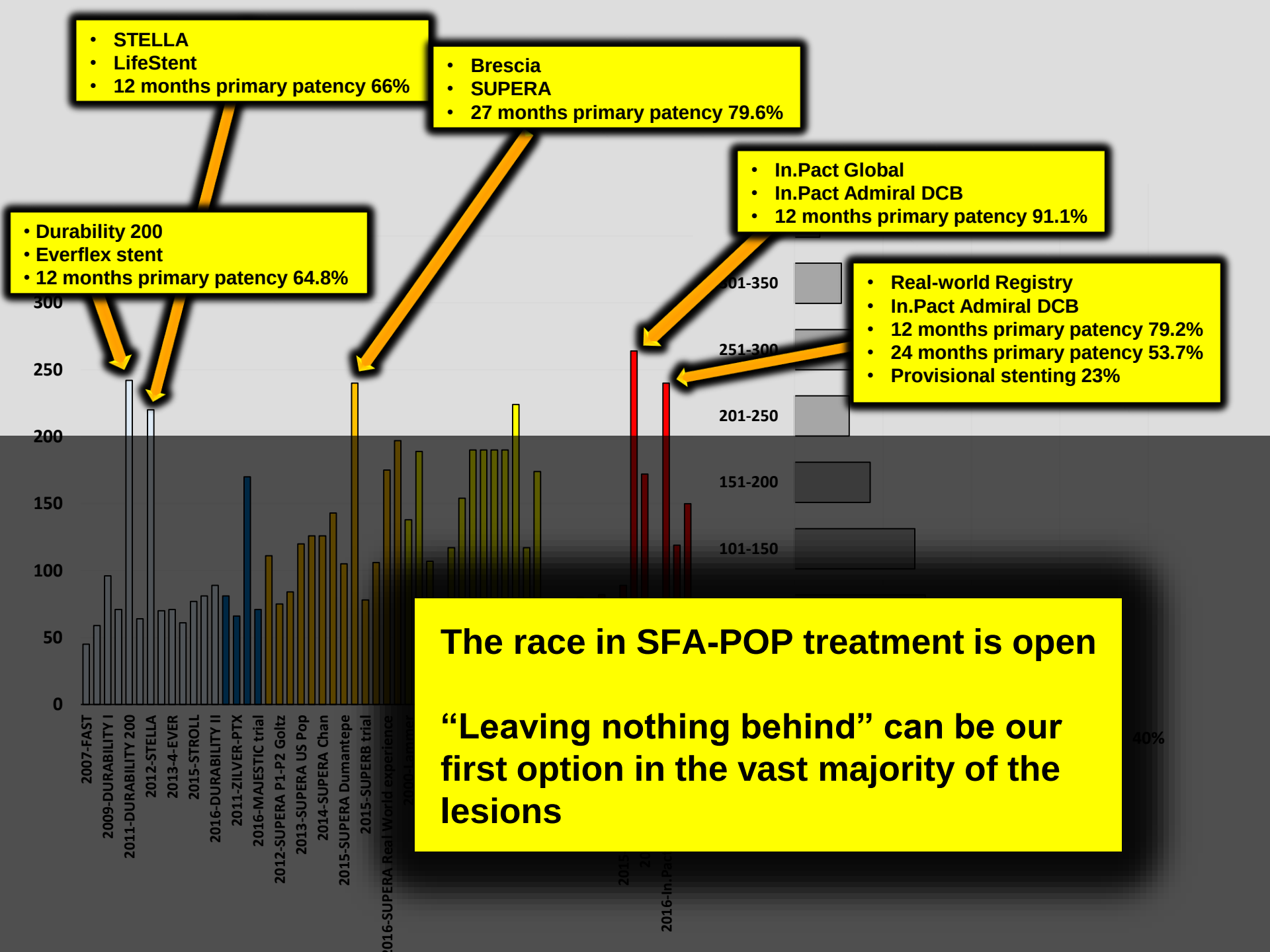
2015-In.Pact Global ISR
2016-In.Pact Real-World Registry
2016-AcoArt I Trial
01-350
251-300
201-250
151-200
101-150
51-100
≤ 50
0%
10%
20%
30%
40%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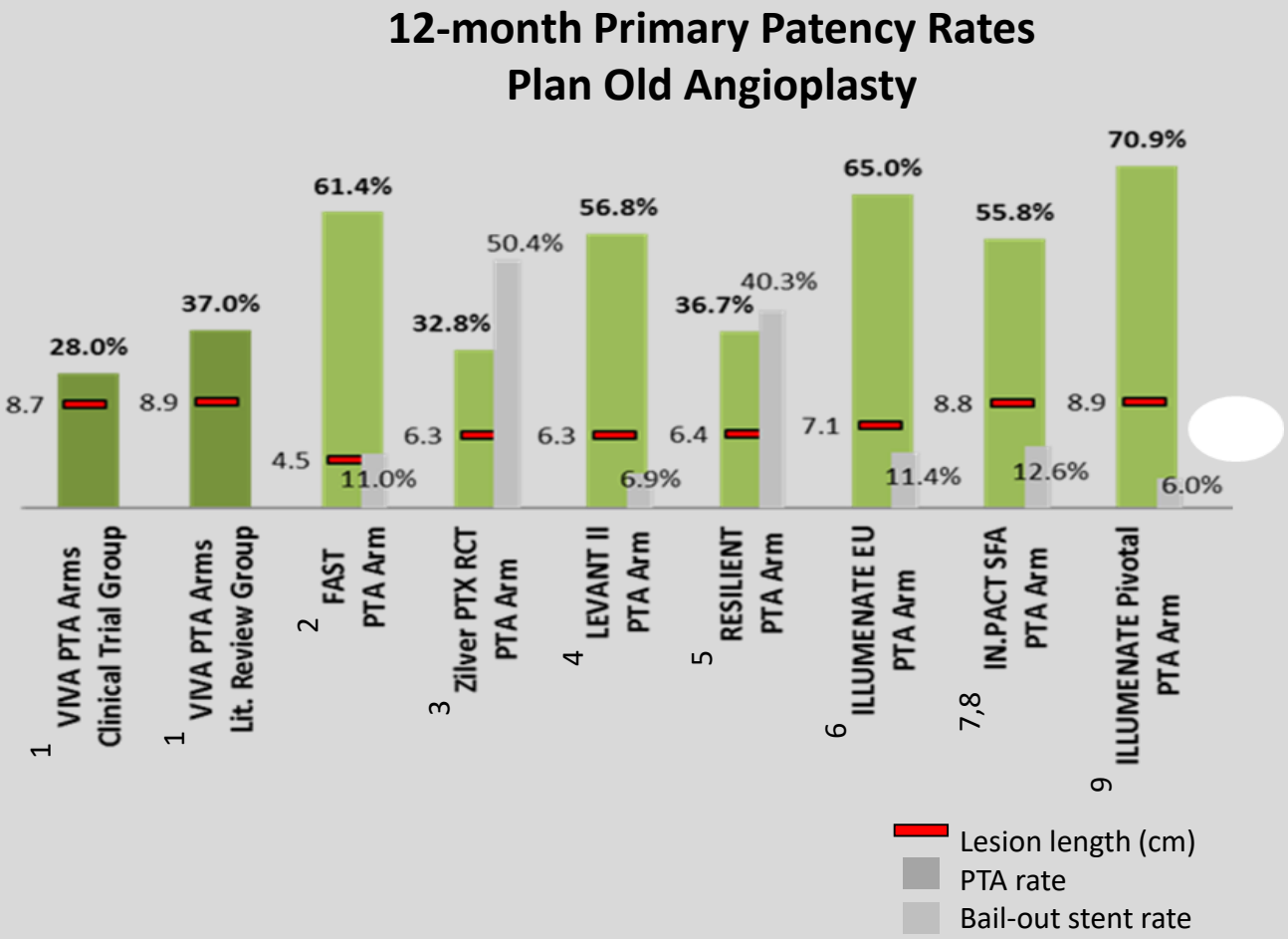
• In.Pact Admiral DCB
• 12 months primary patency 79.2%
• 24 months primary patency 53.7%
• Provisional stenting 23%
The race in SFA-POP treatment is open
“Leaving nothing behind” can be our first option in the vast majority of the lesions
300
250
200
150
100
50
0
301-350
251-300
201-250
151-200
101-150
40%
2007-FAST
2009-DURABILITY I
2011-DURABILITY 200
2012-STELLA
2013-4-EVER
2015-STROLL
2016-DURABILITY II
2011-ZILVER-PTX
2016-MAJESTIC trial
2012-SUPERA P1-P2 Goltz
2013-SUPERA US Pop
2014-SUPERA Chan
2015-SUPERA Dumantepe
2015-SUPERB trial
2016-SUPERA Real World experience
2016-In.Pact

Why should we adopt the “leave nothing behind” approach in the SFA?

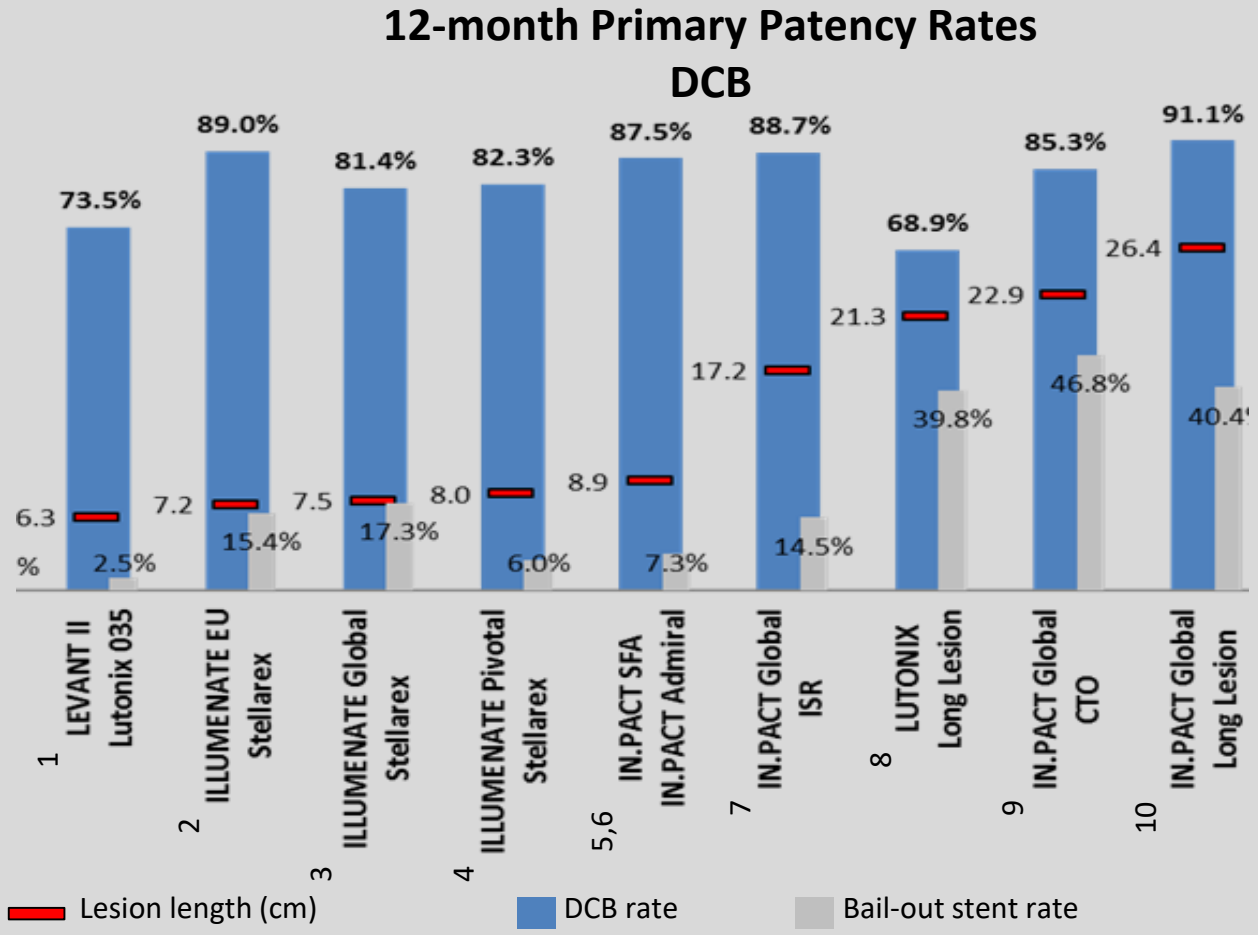
1. Mechanical problems in SFA-POP tract: the bad conduit
2. Global overview of SFA-POP solutions according to localization and length of lesion
3. The real world of ENDO treatment: a single center experience
4. Patency rate according to type of treatment

Patency rates after POBA → 28-71%



1. Rocha-Singh K, et al. Catheter Cardiovasc Intervent 69:910-9 (2007).
2. Krakenberg H, et al. Circ 116(3):285-92 (2007).
3. Dake M, et al. Circ Cardiovasc Interv 4:495-504 (2011).
4. Rosenfield K, et al. New Engl J Med 373:145-53 (2015).
5. Laird J, et al. Circ Cardiovasc Interv 3:267-76 (2010).
6. Presented by Brodmann M, AMP Chicago, USA 2016.
7. Tepe G, et al. Circ 131:495-502 (2015).
8. Laird J, et al. J Am Coll Cardiol 66:2329-38 (2015).
9. Presented by Lyden S, TCT Washington DC, USA 2016.

Patency rates after DCB → 68-91%



1. Rocha-Singh K, et al. Catheter Cardiovasc Intervent 69:910-9 (2007).
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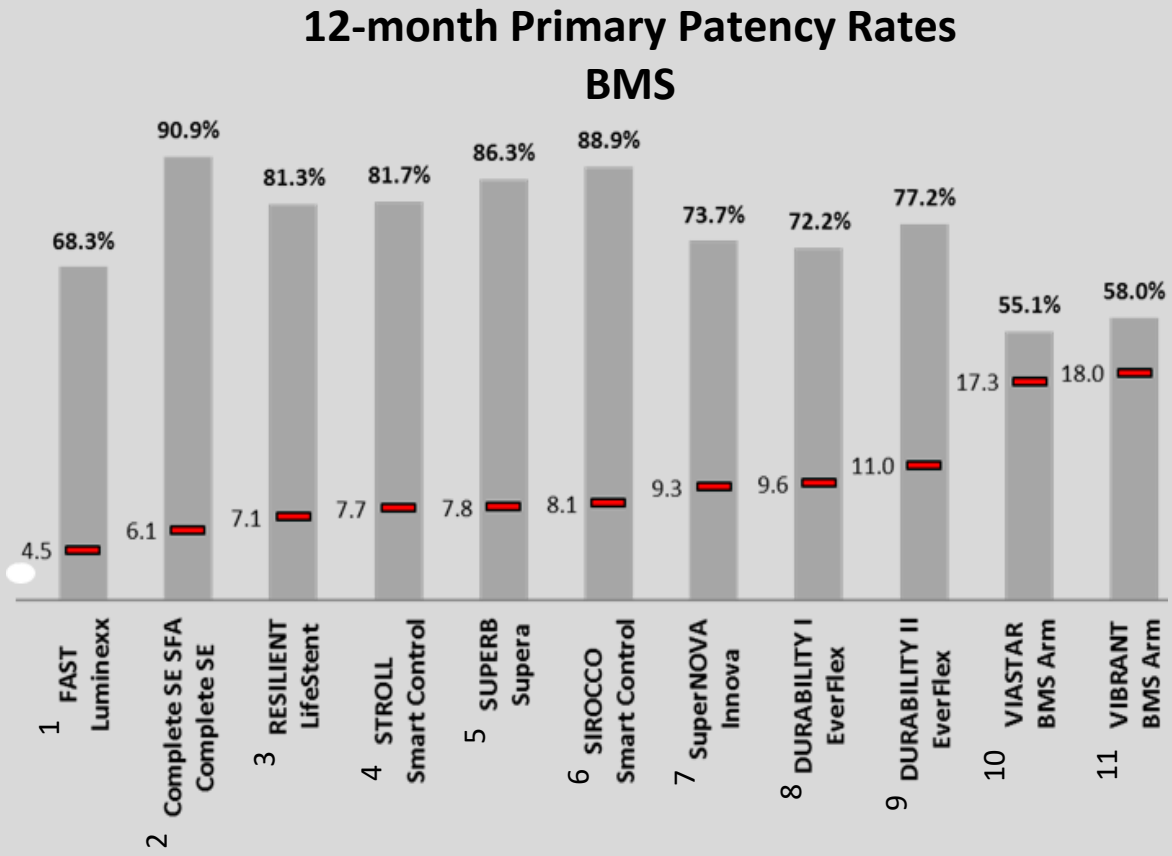
8. Laird J, et al. J Am Coll Cardiol 66:2329-38 (2015).
9. Presented by Lyden S, TCT Washington DC, USA 2016.

Patency rates after atherectomy → 54-78%

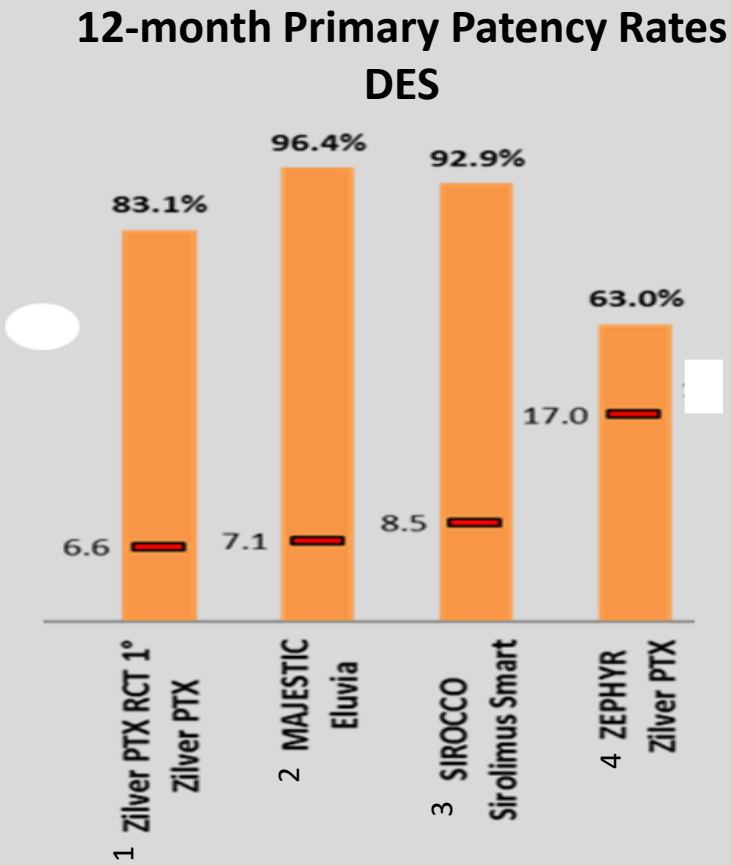
1. Zeller T, et al. J Endovasc Ther 16(6):653-62 (2009).
2. Dave R, et al. J Endovasc Ther 16(6):665-75 (2009).
3. McKinsey J, et al. JACC Cardiovasc Interv 7(8):923-33 (2014).

Patency rates after BMS → 55-91%



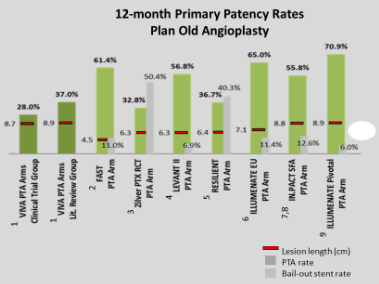
1. Krakenberg H, et al. Circ 116(3):285-92 (2007).
2. Complete SE Instructions for Use (Medtronic).
3. Laird J, et al. Circ Cardiovasc Interv 3:267-76 (2010).
4. Gray W, et al. J Vasc Interv Radiol 26:21-28 (2015).
5. Garcia L, et al. Circ Cardiovasc Interv 8(5): e000937 (2015).
6. Duda S, et al. J Endovasc Therp 13:701-10 (2006).
7. Innova Instructions for Use (Boston Scientific).
8. Bosiers M, et al. J Endovasc Ther 16:261-9 (2009).
9. Matsumura J, et al. J Vasc Surg 58:73-83 (2013).
10. Lammer J, et al. JACC 62(15):1320-7.
11. Presented by Ansel G, VIVA Las Vegas, USA 2009.

Patency rates after DES → 63-96%

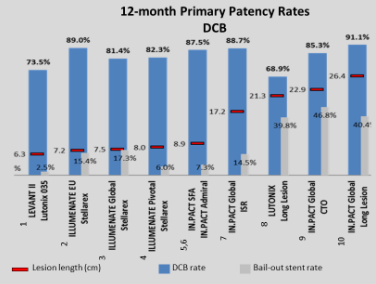


1. Dake M, et al. Circ Cardiovasc Interv 4:495-504 (2011). Dake M, et al. JACC 61(24):2417-27 (2013).
2. Müller-Hülsbeck S, et al. J Endovasc Ther 23(5):701-7 (2016).
3. Duda S, et al. J Endovasc Therp 13:701-10 (2006).
4. Iida O, et al. JACC Cardiovasc Interv 8(8):1105-12 (2015).

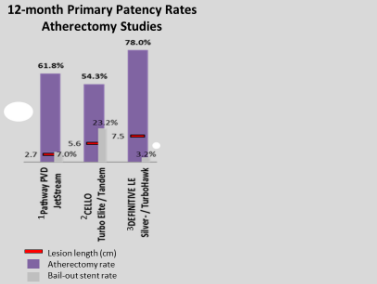
Patency rates after POBA → 28-71%



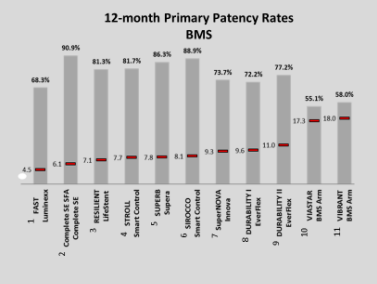
Patency rates after DCB → 68-91%



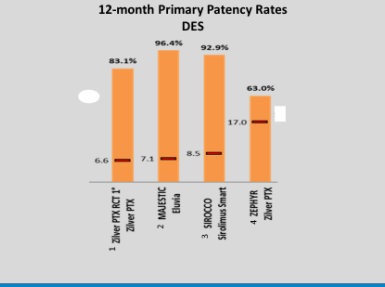
Patency rates after atherectomy → 54-78%



Patency rates after BMS → 55-91%



Patency rates after DES → 63-96%



- **SFA-POP artery is a "bad conduit" with unique mechanical problems**
- **Restenosis persists irrespective of the modality used, retreatment can be complicated by implantation of stents**
- **Antirestenotic therapies like DCBs have significantly improved outcomes with sustained benefit through 4 years (IN.PACT DCB)**
- **Reserve use of scaffolds for complicated situations like dissection/persistent recoil**