
Best Interventional Therapies for TASC C/D Lesions in the Femoral-Popliteal Arteries

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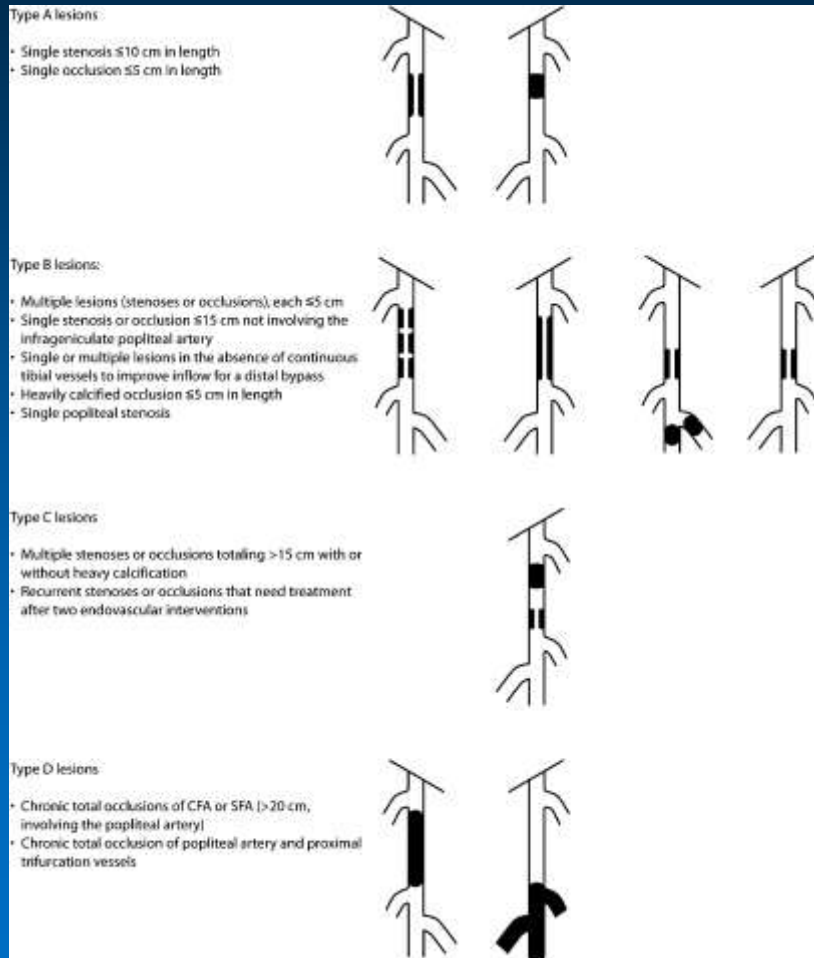
Faculty Disclosure

Robert M. Bersin MD, MPH, FACC, FSCAI

Abbott Vascular C, P, SB
Ablative Solutions EI
Boston Scientific AB, C, EI, P, SB
Cook Medical, Inc. C, P
Cordis Endovascular C, EI
Covidien, Inc. C, P
Medtronic Vascular C, P
Omeros Corp, EI
QT Vascular, EI
Sapheon, Inc. EI
St. Jude Medical C
Transverse Medical AB, EI, SO
Vatrix Medical EI
W.L. Gore C, P

AB: Advisory Board
C: Consulting Relationship
EI: Equity Interest
GS: Grant Support
P: Proctor or Training Course Sponsorships
SB: Speakers Bureau
SE: Spouse Employee
SO: Stock Options or Positions

TASC II Recommendations for Infringuinal Interventions and Surgery



TASC C: >15 cm lesion or restenosis
TASC D: >20 cm CTO

Recommendation 37

Treatment of femoral popliteal lesions

- TASC A and D lesions: Endovascular therapy is the treatment of choice for type A lesions and surgery is the treatment of choice for type D lesions [C].
- TASC B and C lesions: Endovascular treatment is the preferred treatment for type B lesions and surgery is the preferred treatment for good-risk patients with type C lesions. The patient's co-morbidities, fully informed patient preference and the local operator's long-term success rates must be considered when making treatment recommendations for type B and type C lesions [C].

Pooled Analysis of Infrainguinal Interventions and Surgery

“Vein has better long-term patency than prosthetic in the infra inguinal region (Table F7).”

Table F7b. Randomized trials of types of conduits²⁰⁶⁻²⁰⁹

<i>Above-knee femoral popliteal bypass</i>	<i>5-year patency</i>
Vein	74-76%
PTFE	39-52%

PTFE – polytetrafluoroethylene graft.

206. Green R et al. Prosthetic above-knee femoropopliteal bypass grafting: five-year results of a randomized trial. *J Vasc Surg* 2000; 31: 417-25.

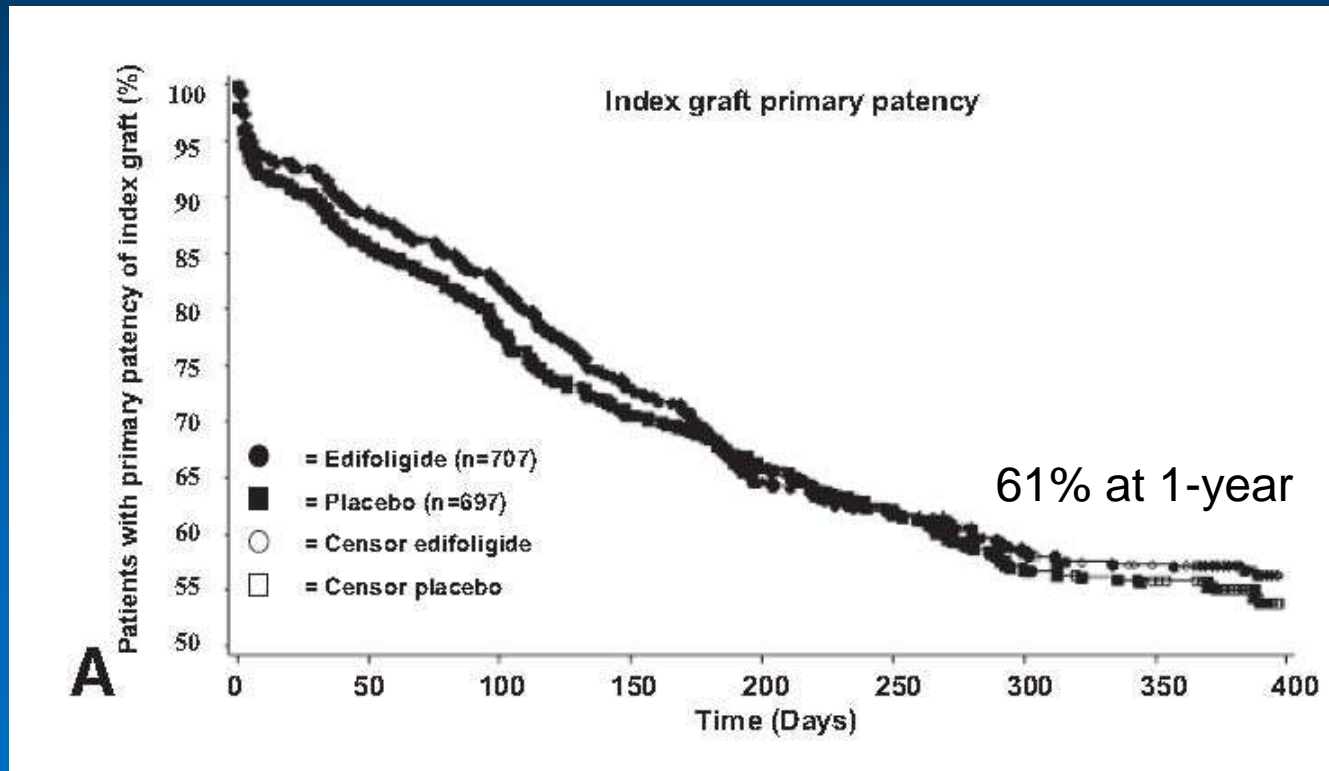
207. AbuRahma AF, et al Prospective controlled study of PTFE versus saphenous vein in claudicant patients with bilateral above knee femoropopliteal bypasses. *Surgery* 1999; 126(4): 594-601.

208. Johnson WC, Lee KK. A comparative evaluation of PTFE, umbilical vein, and saphenous vein bypass grafts for femoral-popliteal above-knee revascularization: a prospective randomized VA cooperative study. *J Vasc Surg* 2000; 32(2): 268-77.

209. Klinkert P, et al Polytetrafluoroethylene femorotibial bypass grafting: 5-year patency and limb salvage. *Ann Vasc Surg* 2003; 17(5): 486-91.

PREVENT III Trial

Autologous vein bypass graft primary patency at 1-year (N=1,404)
(PSVR < 3.0 or PSV < 300 cm/sec)

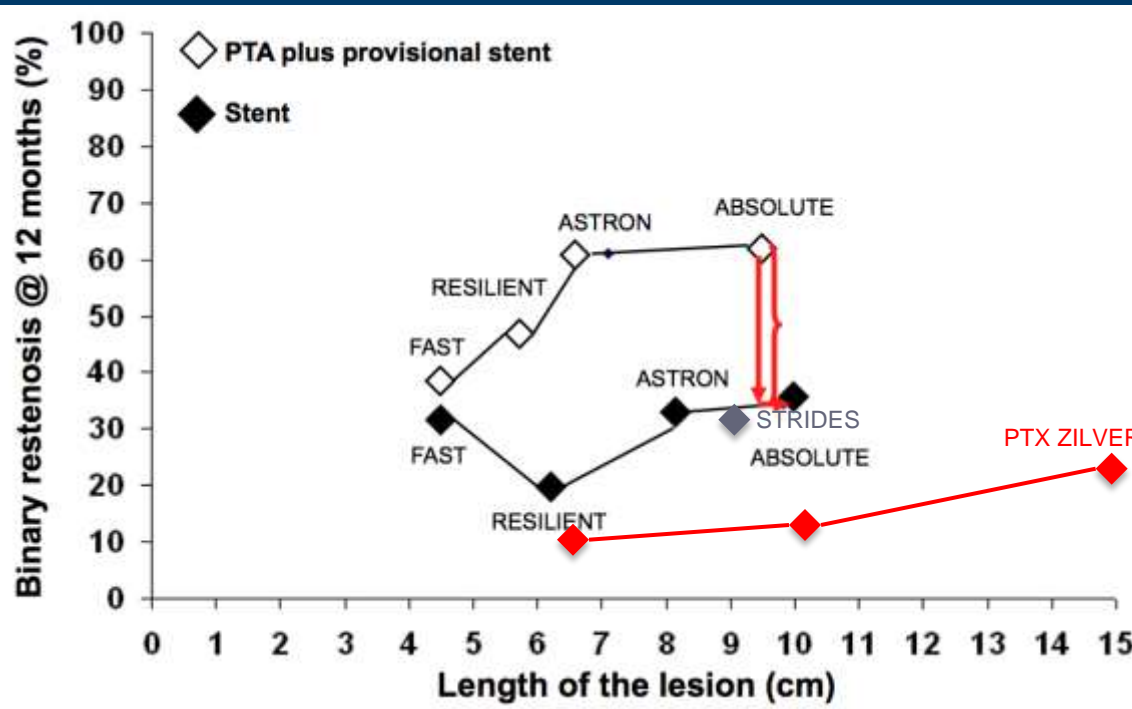


Re-intervention rate 33.4%

Restenosis with Infringuinal Nitinol Stents



Re-Entry PTA



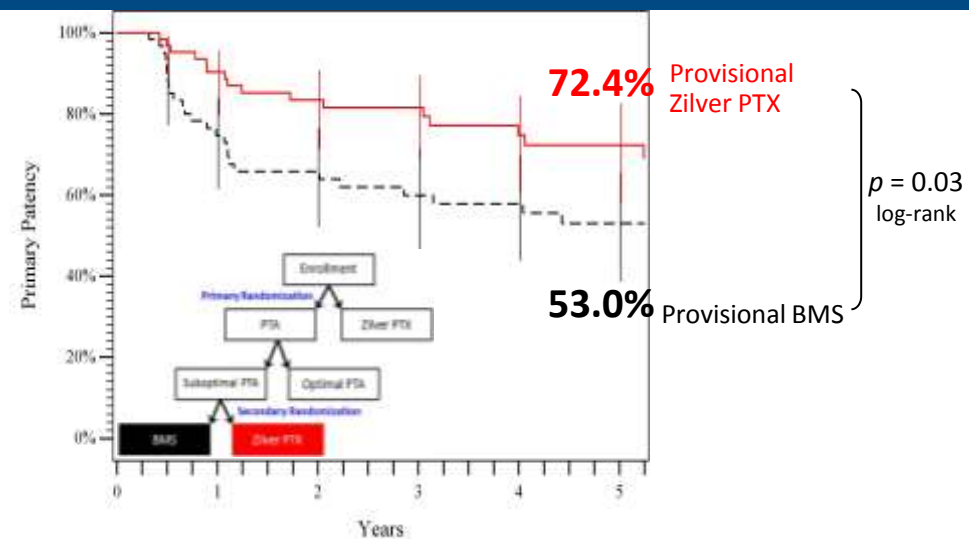
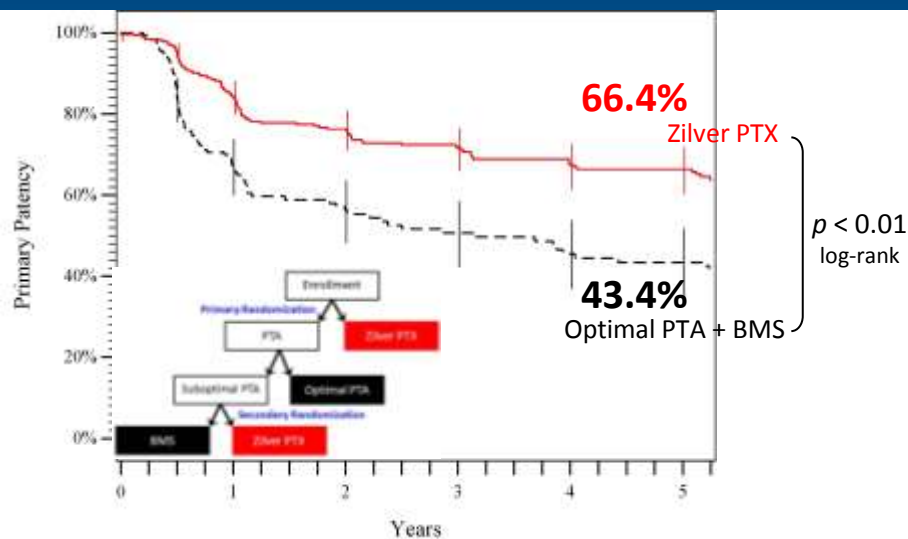
Post Stent

PTX Zilver 5-Year Primary Patency



Primary Randomization

Provisional Stenting PTX vs. BMS



PSVR < 2.0

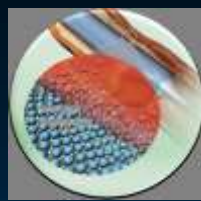
BMS and DES in TASC C/D Lesions

	Zilver PTX RCT ¹	Zilver PTX SAS ²	Zilver PTX SAS LL ³	Zilver PTX Longer Lesions	Durability 200 ⁴
Patients	236	787	134	45	100
Lesions	247	900	135	45	100
Lesion length (mm)	66 ± 39	100 ± 82	226 ± 44	189 ± 91	242
Diameter stenosis (%)^a	80 ± 17%	85 ± 16%	97 ± 9%	95 ± 11%	N/A
Total occlusions	30%	38%	84%	82.2%	N/A
1-year Primary Patency	82.7% (PSVR < 2.0)	86.2% (PSVR < 2.5)	77.6% (PSVR < 2.5)	86.1% (PSVR < 2.0)	64.8% (PSVR < 2.4)
1-year Freedom from TLR	90.8%	89.3%	85.4%	86.1%	68.2%
1-year Fracture Rate	0.9%	1.5%	2.1%	0.0%	6.0%

^a Angiographic core lab assessment for RCT and longer lesions Zilver PTX

1. Dake MD, et al. *Circ Cardiovasc Interv.* 2011;4:495-504.
2. Dake MD, et al. *J Endovasc Ther.* 2011;18:613-23.
3. Bosiers M, et al. *J Cardiovasc Surg (Torino).* 2013;54:115-22.
4. Bosiers M, et al. *JVS.* 2011;54:1042-1050.

DCB in TASC C/D Lesions



IN.PACT Admiral DCB Global Registry



Pre

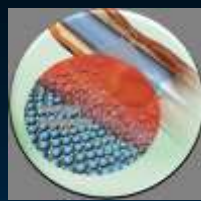
DEB

Post

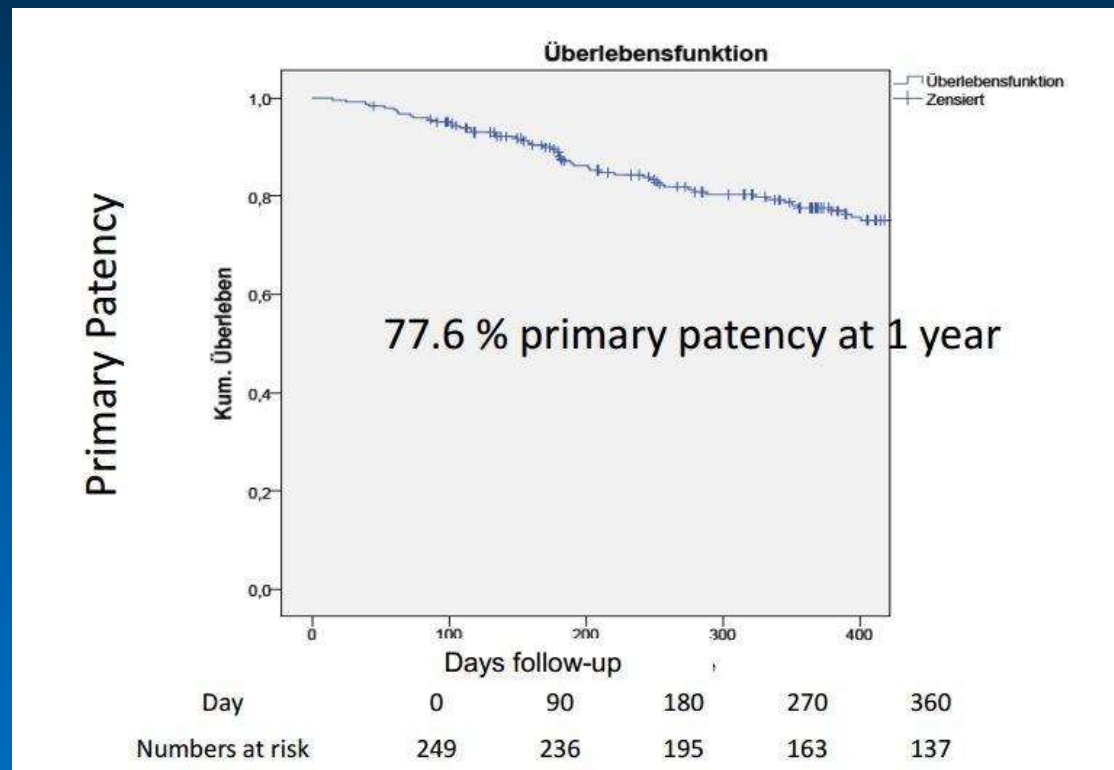
6-mo

1-year TLR rate for lesions >15 cm 11.5% (N=191)

DCB in TASC C/D Lesions



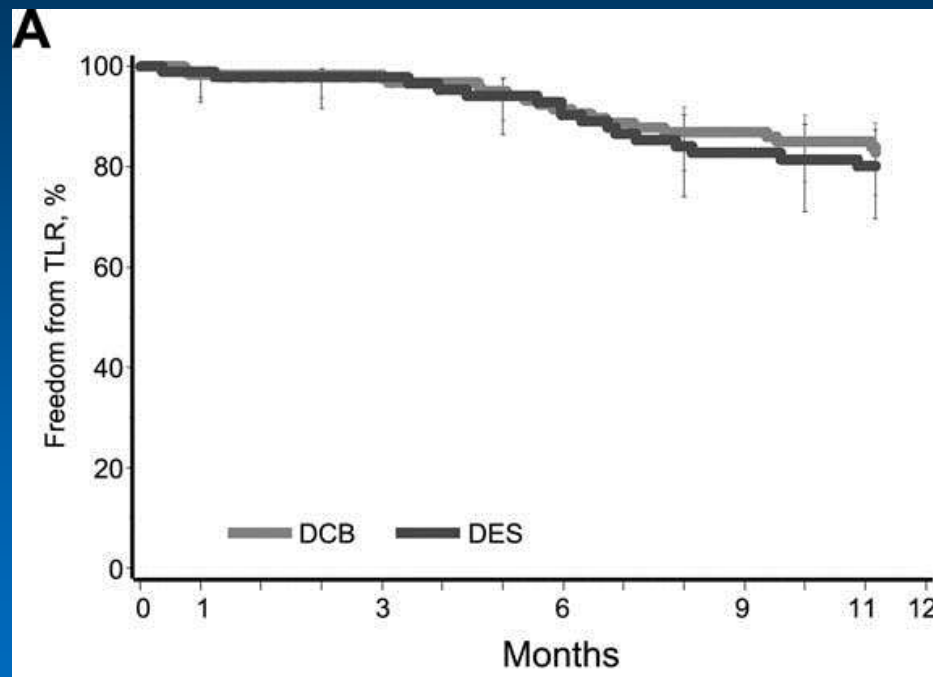
Leipzig Long Lesion DCB Registry (N=249)



DCB plus bailout BMS
1-year PP 77.6%
Ave LL 20.0 cm

DCB vs. DES in TASC C/D Lesions

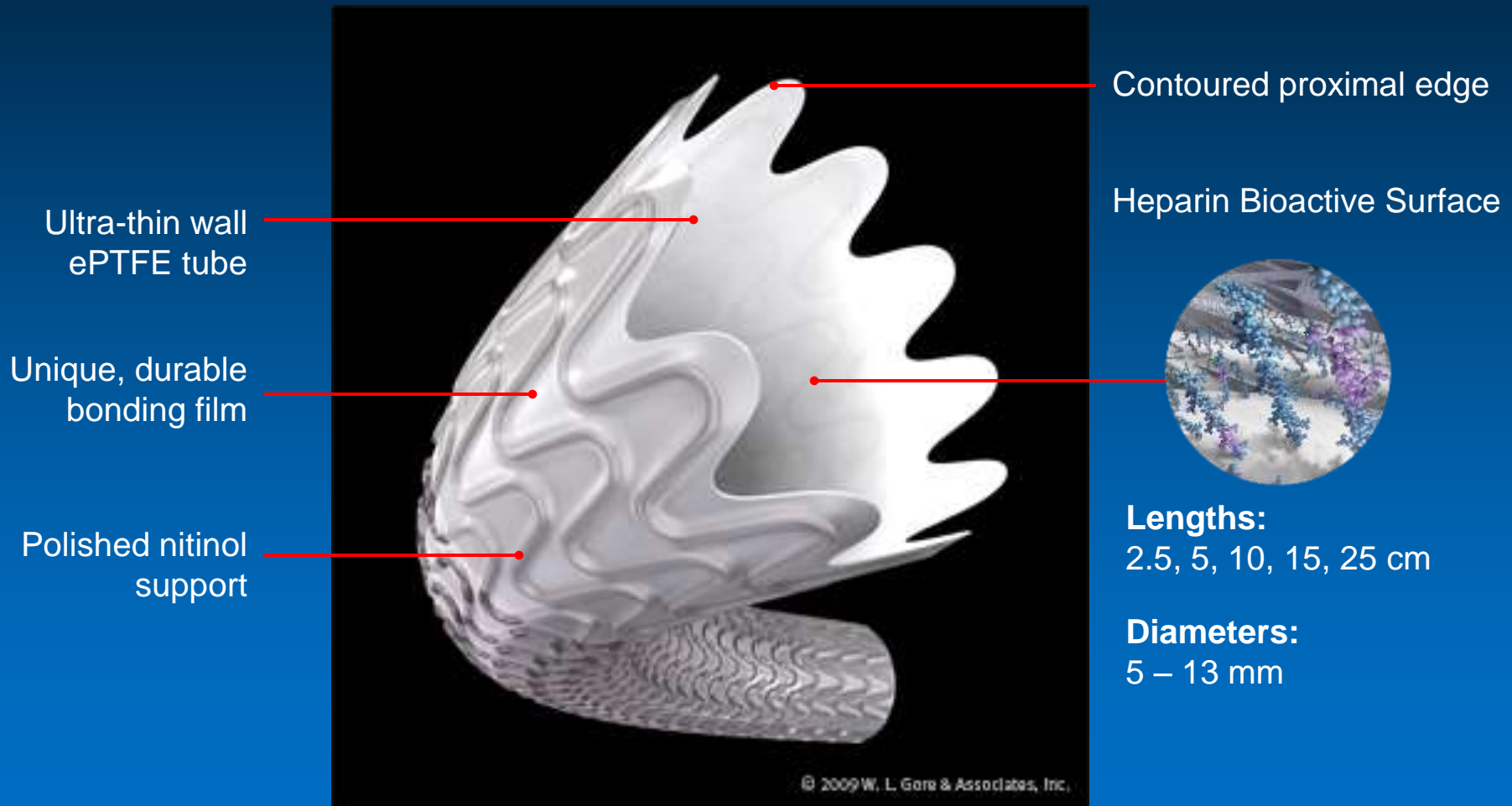
Retrospective 2-center study with propensity score stratification (N=228)



DCB
1-Yr PP 76.1%
Ave LL 19.4 cm

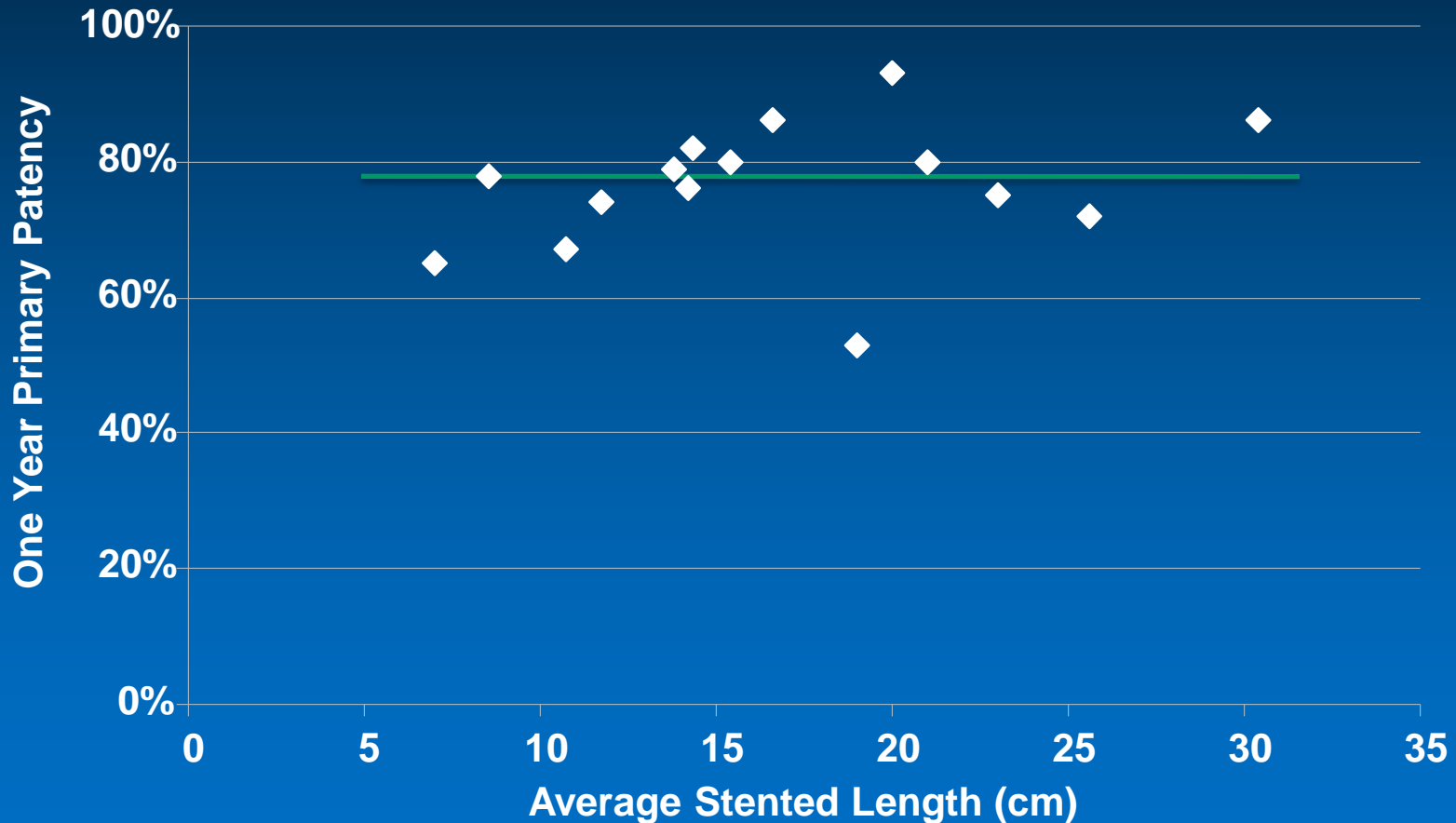
DES
1-Yr PP 69.6%
Ave LL 19.5 cm

Gore Viabahn Description



GORE® VIABAHN® Device One Year Primary Patency in the SFA Based on Lesion Length

More than 1,100 Limbs in 17 Independent Studies*

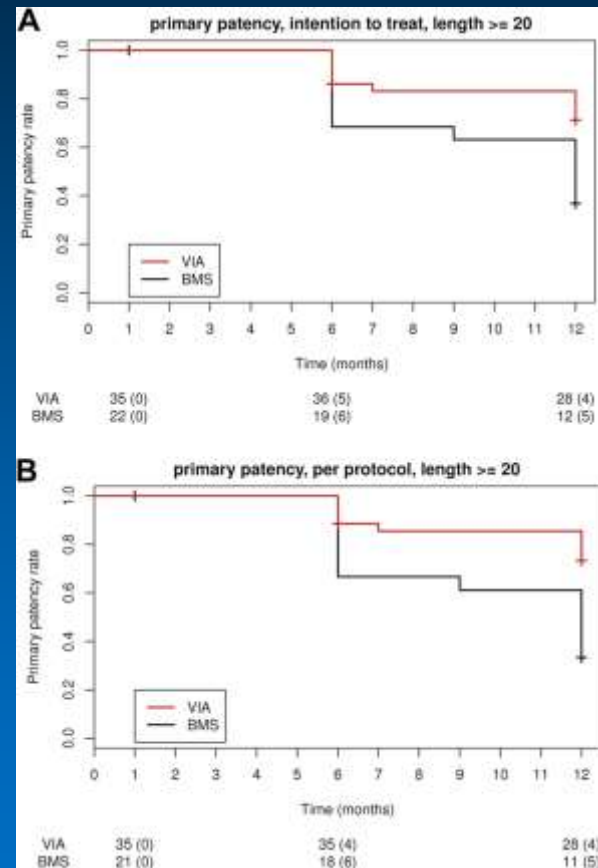
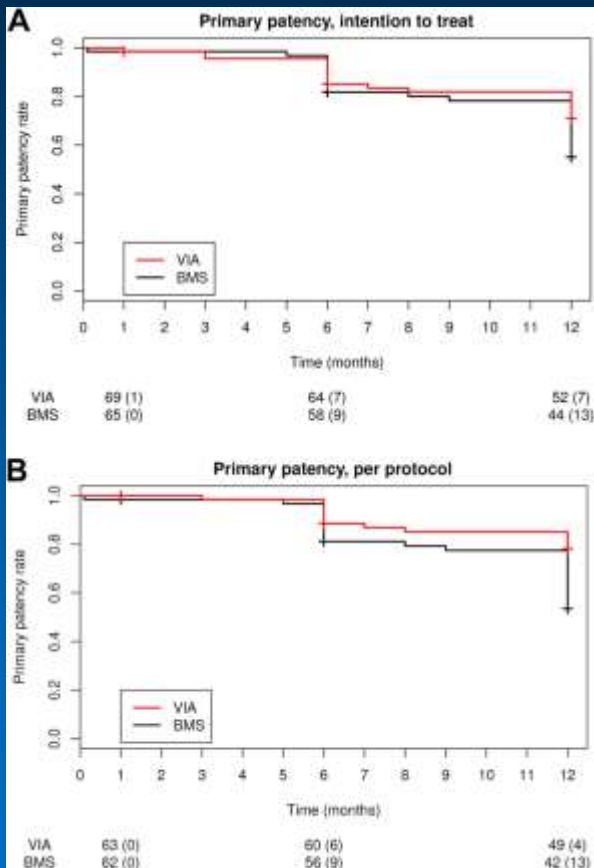


* Patient demographics, lesion characterization, and patency definitions may differ among studies. Studies include at least 30 limbs. Coats, et al., and Rabellino, et al., did not report lesion length

VIASTAR Randomized Trial

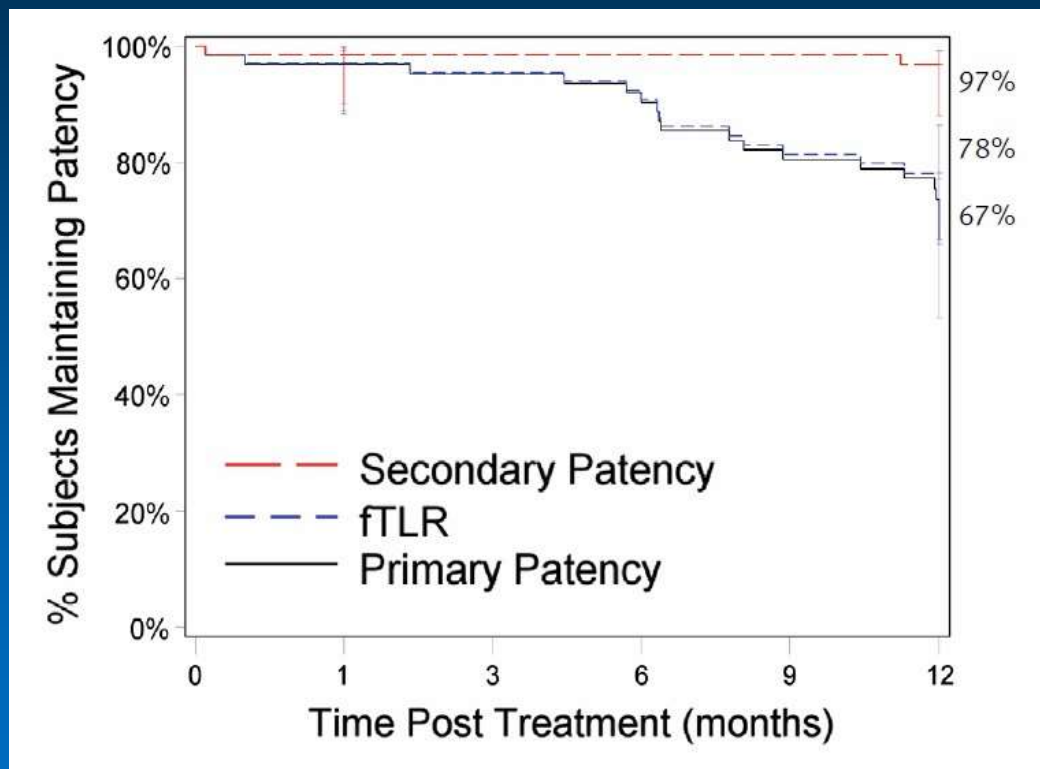
All lesions

Lesions ≥ 20 cm



1-year PP 78.1%
Ave LL 19.0 cm

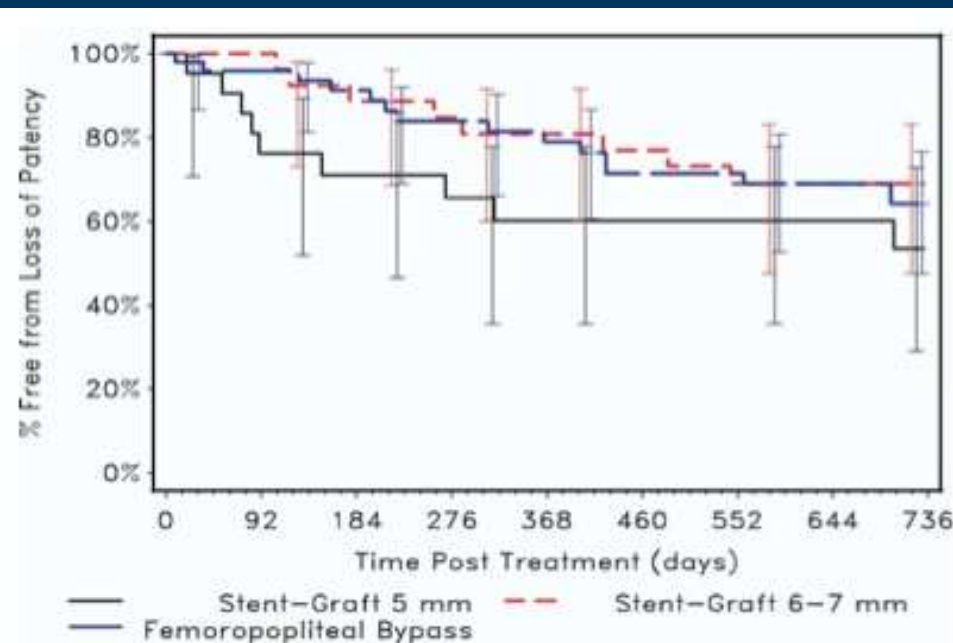
TASC D 25cm Viabahn Study 12-month Primary Patency and fTLR



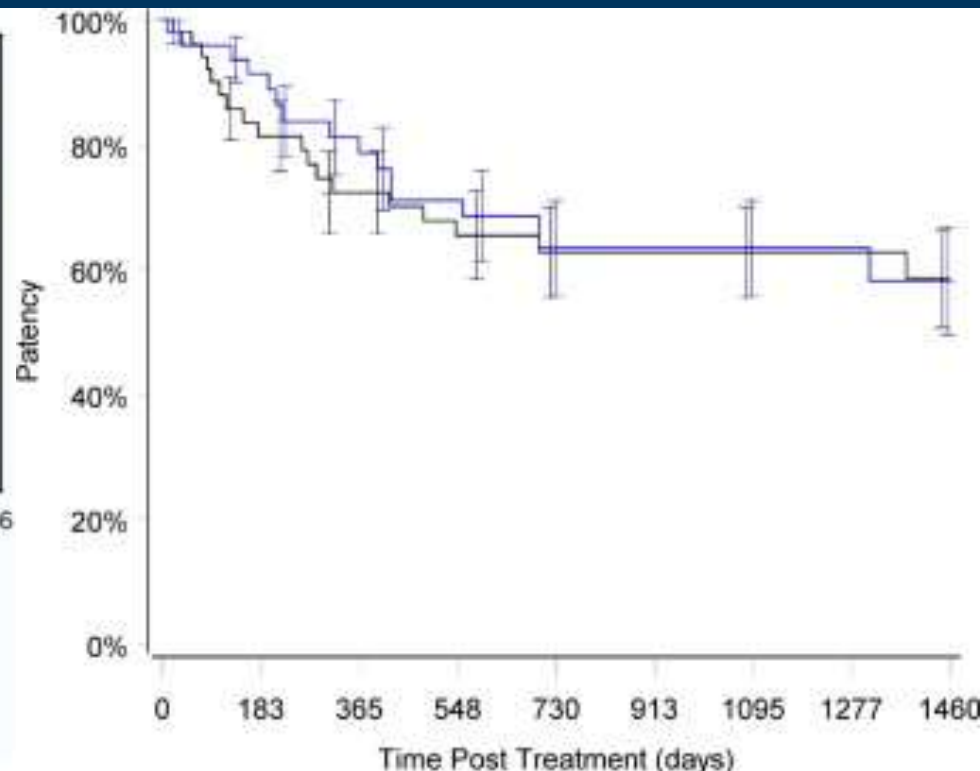
92% CTOs

1-year PP 67%
Ave LL 26.5 cm

Endografts vs. Prosthetic Fem-Pop Bypass Graft Surgery



N Left (days)	0	31	137	228	320	410	593	730
Stent-Graft 5 mm	21	20	15	13	11	11	9	8
Stent-Graft 6-7 mm	29	29	24	23	21	21	17	14
Femoropopliteal Bypass	50	45	41	34	33	31	28	26



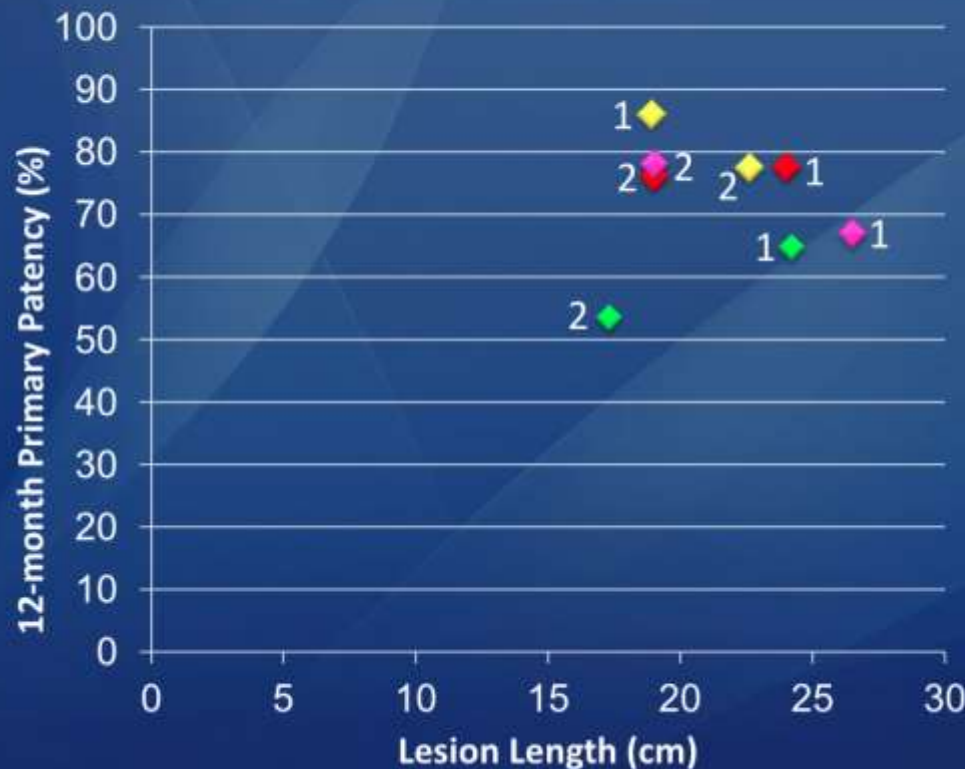
Ave lesion length 25.6 cm

McQuade K et al *J Vasc Surg* 2009; 49: 109-116

McQuade K et al *J Vasc Surg* 2010; 52: 584-591

Primary Patency of Interventional Therapies in TASC C/D Lesions

TASC C & D – evidence



DCB

1. Leipzig registry
2. Zeller registry

BMS

1. DURABILITY 200
2. VIASTAR: BMS

DES

1. ZILVER PTX registry
2. ZILVER PTX single arm study

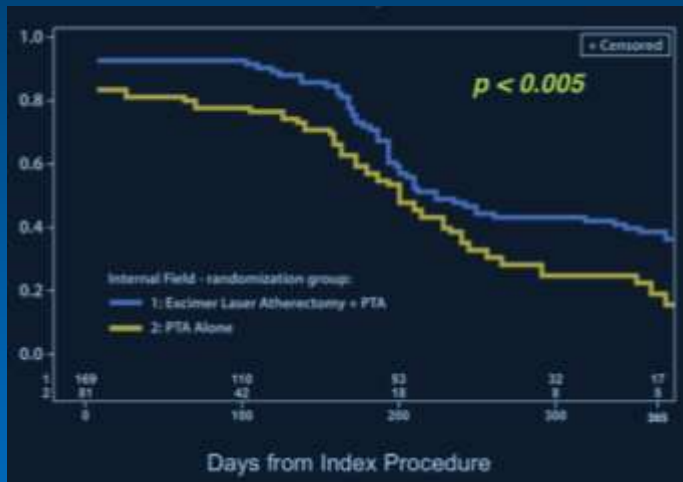
Covered Stent

1. VIABAHN 25CM
2. VIASTAR: Viabahn

TASC II C ISR Lesions

Randomized Trials

Laser



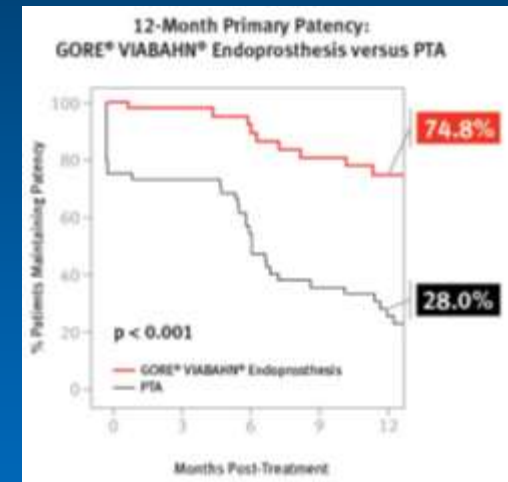
EXCITE ISR Trial
1-yr PP 40.0%
Ave LL 19.6 cm

DCB



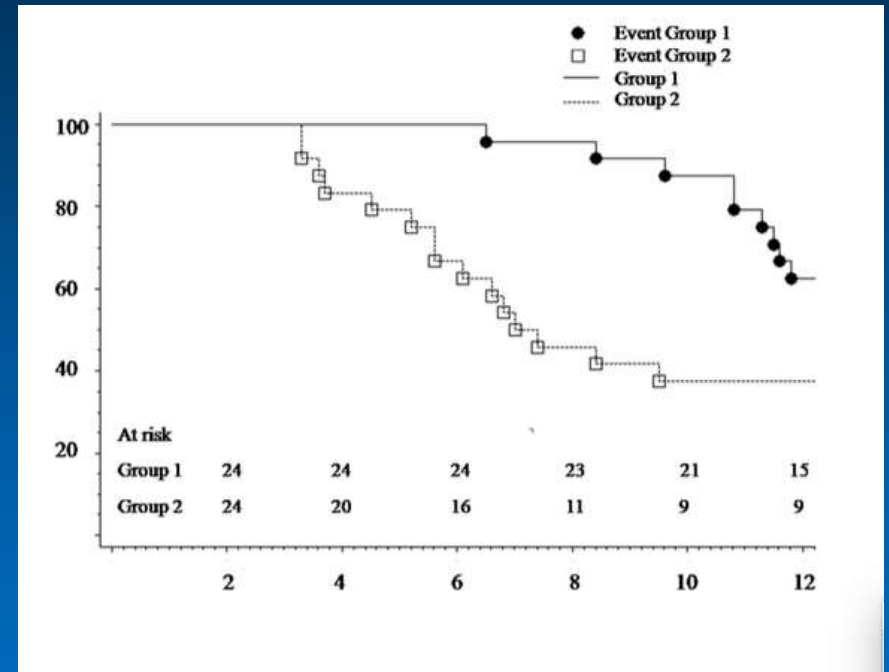
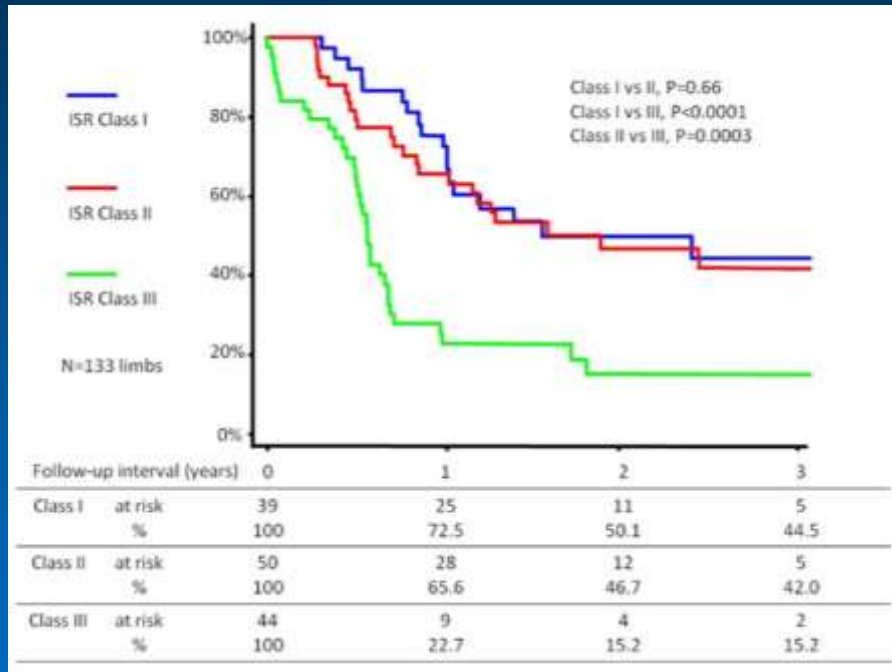
FAIR Trial
1-yr PP 70.5%
Ave LL 8.2 cm

Viabahn



RELINE Trial
1-yr PP 74.8%
Ave LL 17.3 cm

TASC II C Stent Occlusions



PTA Alone Class III
1-Yr PP 15.2%
Ave LL 19.8 cm

DCB Alone
1-Yr PP 37.5%
Ave LL 21.2 cm

Laser plus DCB
1-Yr PP 66.7%
Ave LL 20.0 cm

Conclusions

- The 1-year primary patency of autologous vein bypass grafts is only 50-60% when studied in rigorously controlled, prospective clinical trials.
- Intervention is preferred today for TASC II type C lesions >15 cm given the superior outcomes with drug eluting stents, DCBs and endografts.
- The results of intervention appear to be equivalent to surgery for TASC II type D lesions (≥ 20 cm occlusions and of the distal popliteal trifurcation), even when autologous vein is used.
- The data would support the use of endografts for TASC II type C ISR lesions, but whether DCBs are as good needs further study as only short ISR lesions have been shown to have good outcomes in DCB ISR trials.
- Laser atherectomy improves the results of PTA in the treatment of TASC II type C ISR lesions, and may also improve the results of DCBs and the Viabahn in ISR lesions, but this requires further study.