Stentgraft der unteren Extremität
Indikation & Ergebnisse

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77-jähriger Patient

KHK
St.p. PTCA/Stent RCA, CX, LAD
Herzschrittmacher
IDDM II
CNI kompensiert
CAVK, St.p. Insult
Hypertonie
Hypothyreose

St.p. iliacofemoralen Bypass re

pAVK IIb rechts > links

Reststenose > 30% nach PTA
flusslimitierende Dissektion

3 überlappende BMS 6/100

8 Monate später:
Resymptomatik
→ ISR

Re-PTA

3 Monate später:
Akute Ischämie
Stentverschluss

Fibrinolysis
Urokinase

- Pseudoneurysma
- Multiple Stentbrüche

Re- PTA und Re-stenting

PTA versus Nitinol Stents in der AFS

Randomisierte Studien

Vienna Absolute- Trial

- Absolute (Dynalink) Stent

Schillinger M et al. N Engl J Med 2006;354:1879-88

FAST

- Luminexx

Krankenberg H et al. Circulation 2007;116: 285-92

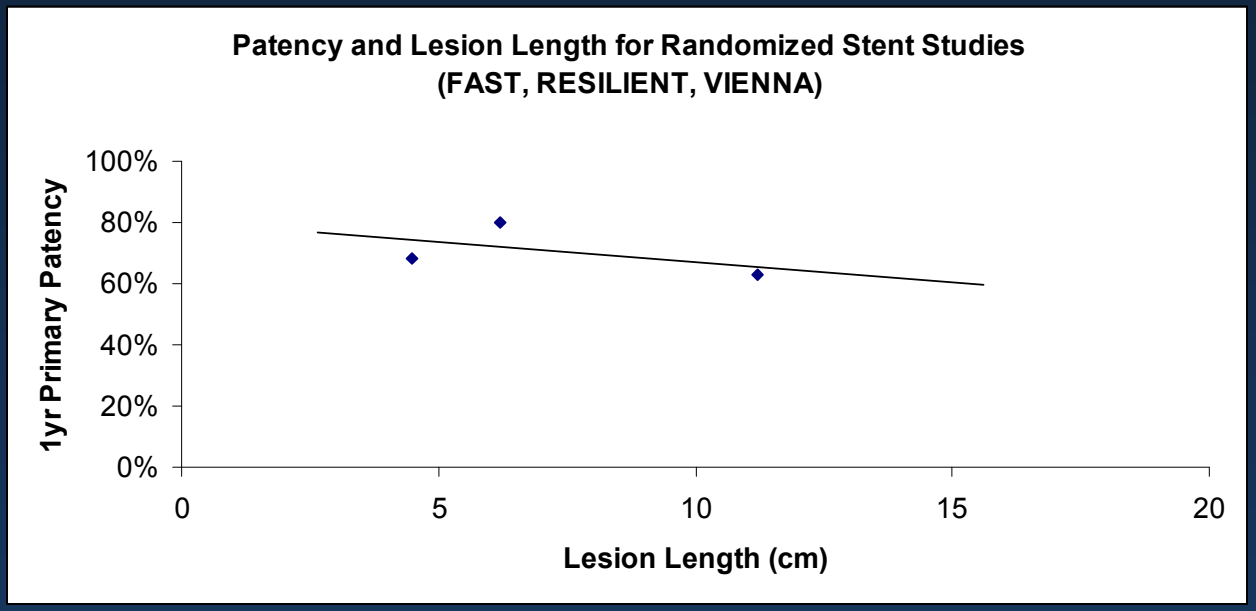
RESILIENT

- Lifestent

Laird JR et al. Circ Cardiovasc Interv 2010;3:267-76

Problem- Läsionslänge

	FAST	RESILIENT	ABSOLUTE
Design	Stent vs PTA	Stent vs PTA	Stent vs PTA
Länge (cm)	4,5	7,0 vs 6,4	13,2 vs 12,7
Verschlüsse	37% vs 25%	17% vs 19%	37% vs 32%
Prim. Offenheit 1 Jahr	67% vs 62,2%	81% vs 37%	63% vs 36%
Ergebnis	ns	signifikant	signifikant



Stentimplantation

Löst Probleme

- elastisches Recoiling
- residuale Stenose
- flusslimitierende Dissektion

und ermöglicht die Behandlung langer und komplexer Läsionen

Bringt Probleme

- intimaler Hyperplasie + ISR
- Stentbrüche

→ alternative Modalitäten

Erwartung an Stentgrafts

- Verhinderung von Gewebeinfiltration
- Unterdrückung der intimalen Hyperplasie
- Erhöhte Flexibilität
- weniger Stentbrüche
  (Stabilisation des Nitinolgerüstes durch ePTFE)

Offenheitsraten der Viabahn® Endoprothese in der AFS

Reported Patencies of GORE VIABAHN® Endoprosthesis / GORE HEMOBAHN Endoprosthesis (5-8mm) in the SFA (updated 2/14/07)

Author	Year	Journal Publication / Presentation	No. of Limbs	Lesion Length (cm)	% Occlusions	Primary Patency (years / %) 1	2	3	4	5
Kedora	2007	J Vasc Surg 45:10-16	50	26	NR	74	—	—	—	—
Chopra	2006	AIM Symposium, November 13 – 16	70	20	71	93	87	72	—	—
Kazemi	2006	TCT Meeting, Octover 23 – 27	65	12	39	90	—	—	—	—
Coats	2006	Endovasc Today, September	83	NR	47	89	—	—	—	—
Fischer	2006	J Endovasc Ther, 13:281 – 290	48	10.7	87	80	73	71	64	62
Saxon	2006	SIR Meeting, March 31	56	13.1	40	84	76	76	67	—
Zander	2006	SIR Meeting, April 3	31	16.6	NR	86	78	78	78	—
Panetta	2005	Endovasc Today, August	41	30.4	90	86	77	—	—	—
Hartung	2005	Eur J Vasc Endovasc Surg, 30:300 – 206	34	10.8	47	85	85	—	—	—
Bleyn	2004	Edizioni Minerva Medica, 14:87 – 91	67	14.3	100	82	73	68	54	47
Jahnke	2003	J Vasc Interv Radiol, 14:41 – 51	52	8.5	83	78	74	62	—	—
Turicchia	2003	Osp Ital Chir, 9:93 – 96	16	10	50	80	80	—	—	—
Railo	2001	Annales Chirurgiae et Gynaecologiae, 90:15 – 18	15	8	67	93	84	—	—	—
Lammer	2000	Radiology, 217:95 – 104	80	13.8	NR	79	—	—	—	—
Average / Total			**708**	**15**	**66**	**84**	**79**	**71**	**66**	**55**

NR = Not Reported

Selbstexpandierende Stentgrafts

Viabahn® Endoprosthesis (Heparin Bioactive Surface)

W.L. Gore & Associates

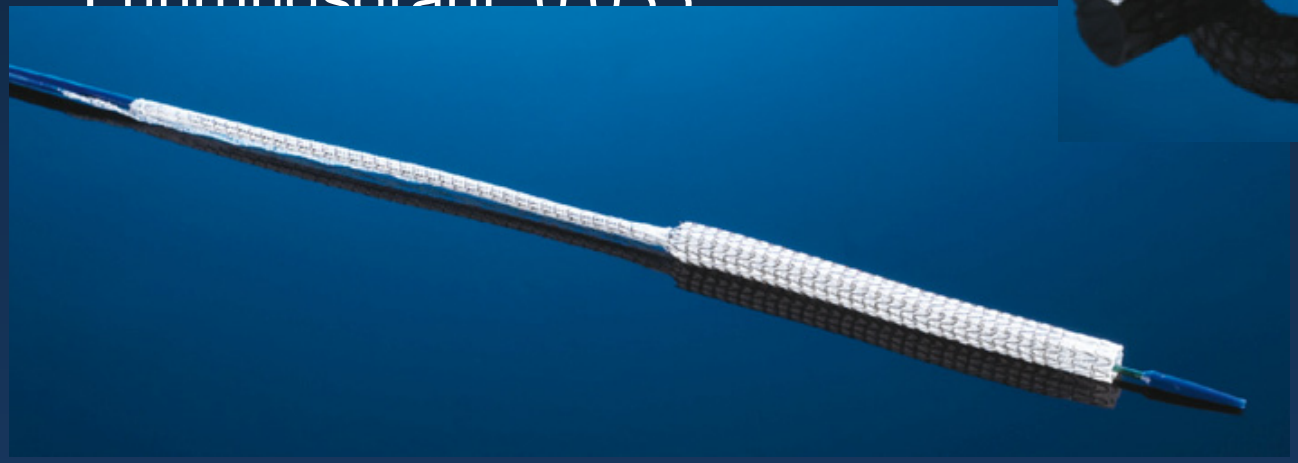
Nitinol, ePTFE gecovert

DM 5-8 mm, 7/8 Fr

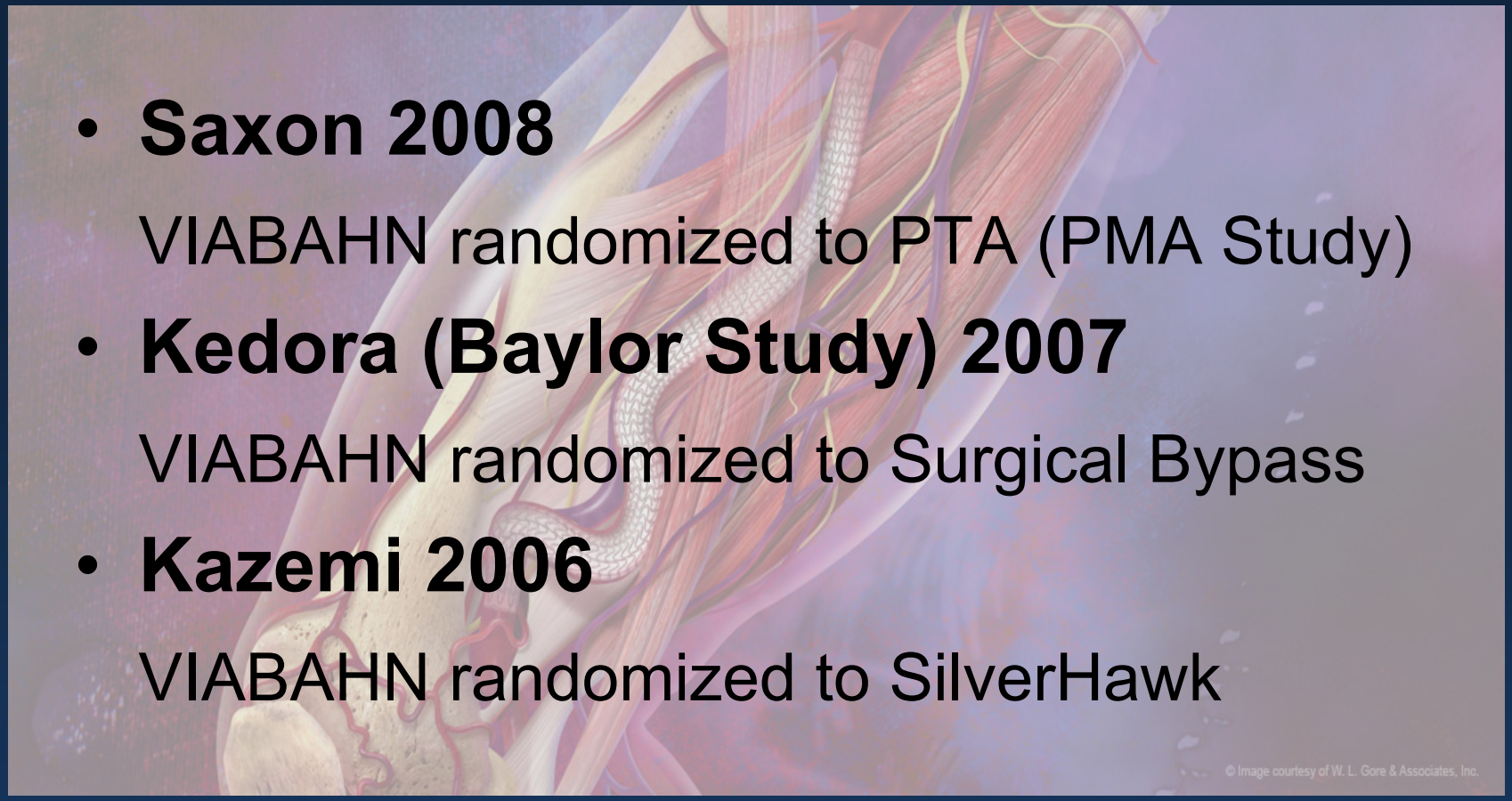
Länge bis15 cm (25 cm)

DM 9-13 mm, 9-12 Fr

Führungsdraht 0.035“



Viabahn – randomisierte Studien



- **Saxon 2008**

  VIABAHN randomized to PTA (PMA Study)
- **Kedora (Baylor Study) 2007**

  VIABAHN randomized to Surgical Bypass
- **Kazemi 2006**

  VIABAHN randomized to SilverHawk

Randomized, multicenter study comparing ePTFE-covered endoprosthesis placement with PTA in the treatment of SFA occlusive disease

Saxon RR et al. J Vasc Interv Radiol 2008;19:823-32

	PTA	**Viabahn**	**p**
Patients	100	97	
Claudication	88%	91%	ns
Resting ABI	0.67±0.18	0.74±0.17	0.005
Mean lesion length	7±4cm 0.4-13cm	7±4cm 0.5-13cm	ns
Technical success	66%	95%	<.0001
Clinical success	69%	84%	0.025
1-y primary patency	40%	65%	0.0003

Randomized comparison of percutaneous Viabahn stentgrafts vs prosthetic fem-pop bypass in the treatment of superficial femoral arterial occlusive disease

Kedora et al. J Vasc Surg 2007;45:10-16

		Viabahn	Bypass	p
Limbs		50	50	
Claudication		82%	62%	ns
TASC 2000	A	2	1	
	B	6	8	
	C	37	31	
	D	5	10	ns
Mean covered length		25,6±15 cm		

Randomized comparison of percutaneous Viabahn stentgrafts vs prosthetic fem-pop bypass in the treatment of superficial femoral arterial occlusive disease

Kedora et al. J Vasc Surg 2007;45:10-16

		Viabahn	Bypass	p
Primary patency	6 mo	82,0%	81,8%	
	12 mo	73,5%	74,2%	ns
Sec. patency	12 mo	83,7%	83,9%	ns
Limb salvage	12 mo	98,0%	89,6%	ns
Mean hospital stay (day)		0,9±0,8	3,1±1,8	<.001

Viabahn - Long-term follow-up

Saxon RR et al. J Vasc Interv Radiol 2007;18:1341-49

87 limbs; mean lesion length 14,2 cm

	primary	assisted primary	secondary patency
1-yr	76%	87%	93%
4-yrs	55%	67%	79%

Primary patency was independent of lesion length and TASC but dependent on device diameter

4-yrs primary patency 82% in diameter $\geq$ 7 mm (n=21)

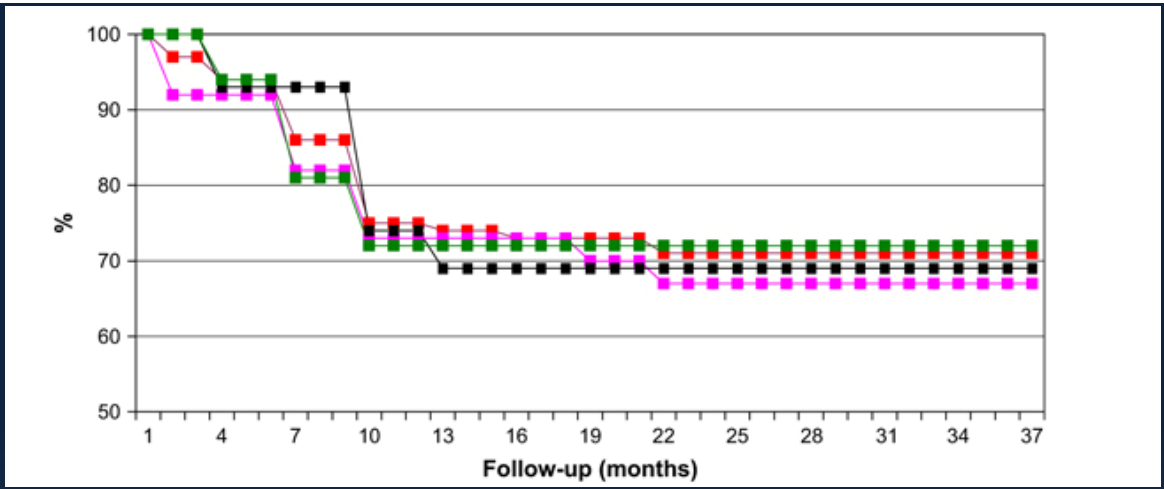
Viabahn - Long-term follow-up

Alimi YS et al. Eur J Vasc Endovasc Surg 2008;35:346-52

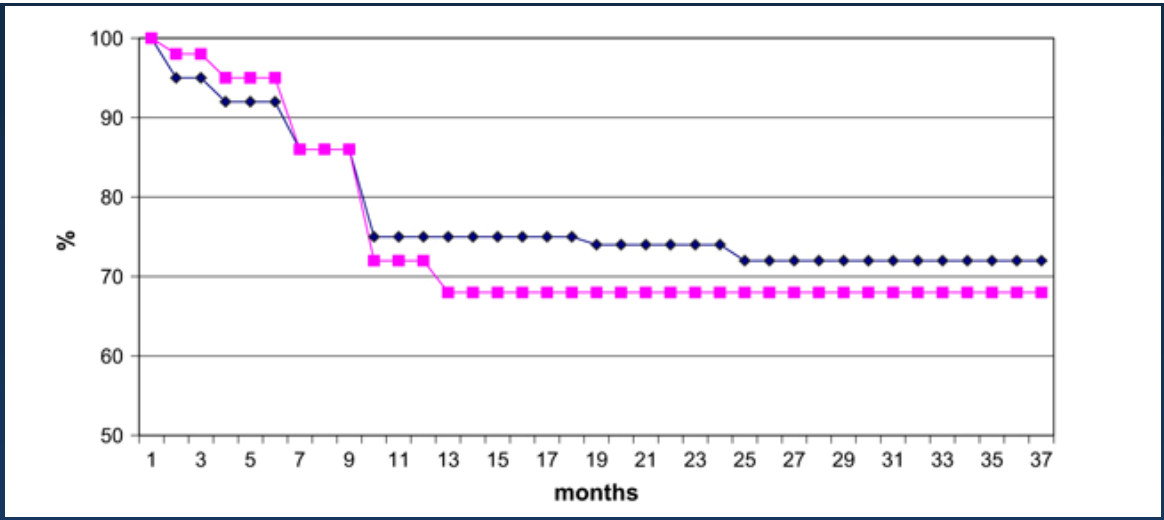
	Claudication (n=50)	**Critical LI** (n=31)	**Acute LI** (n=18)	**Total** (n=99)
Mean lesion length (cm)	11,6	12,4	10,8	
≤ 1-vessel runoff	18%	69%	55%	
TASC II				
A	12%	3%	10%	9%
B	44%	44%	30%	41%
C	28%	25%	30%	28%
D	16%	28%	30%	22%

Alimi YS et al. Eur J Vasc Endovasc Surg 2008;35:346-52

Actuarial primary patency for all limbs and according to preoperative symptoms (p=0.88)

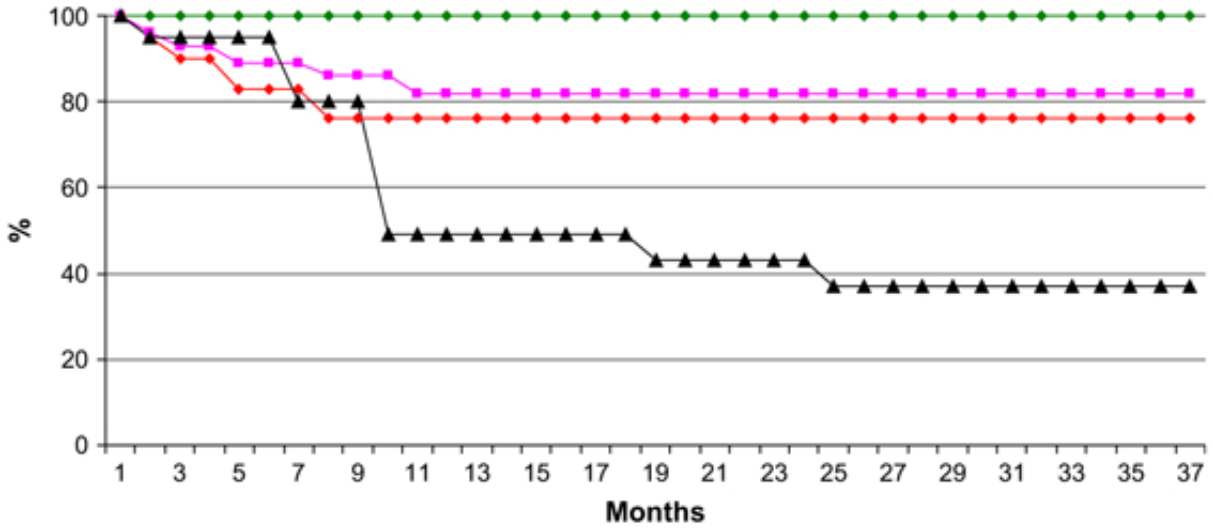


Actuarial primary patency according to preoperative outflow (p=0.94)



Alimi YS et al. Eur J Vasc Endovasc Surg 2008;35:346-52

Actuarial primary patency according to preoperative SFA lesions(p< 0.01)



TASC A

TASC C

TASC B

TASC D

3-yrs primary and secondary patency significantly different between TASC C 84% & 87% and TASC D lesions 39% & 57%

Lesion severity, rather than preoperative symptoms or runoff status should be the main consideration for Viabahn therapy

Patientin 69 Jahre; Hypertonie, Hyperlipidämie, Raucherin
Rutherford 3; ABI 0,69

Reguläre Ein- und Ausstromgefäße
Referenzdurchmesser 4,5mm

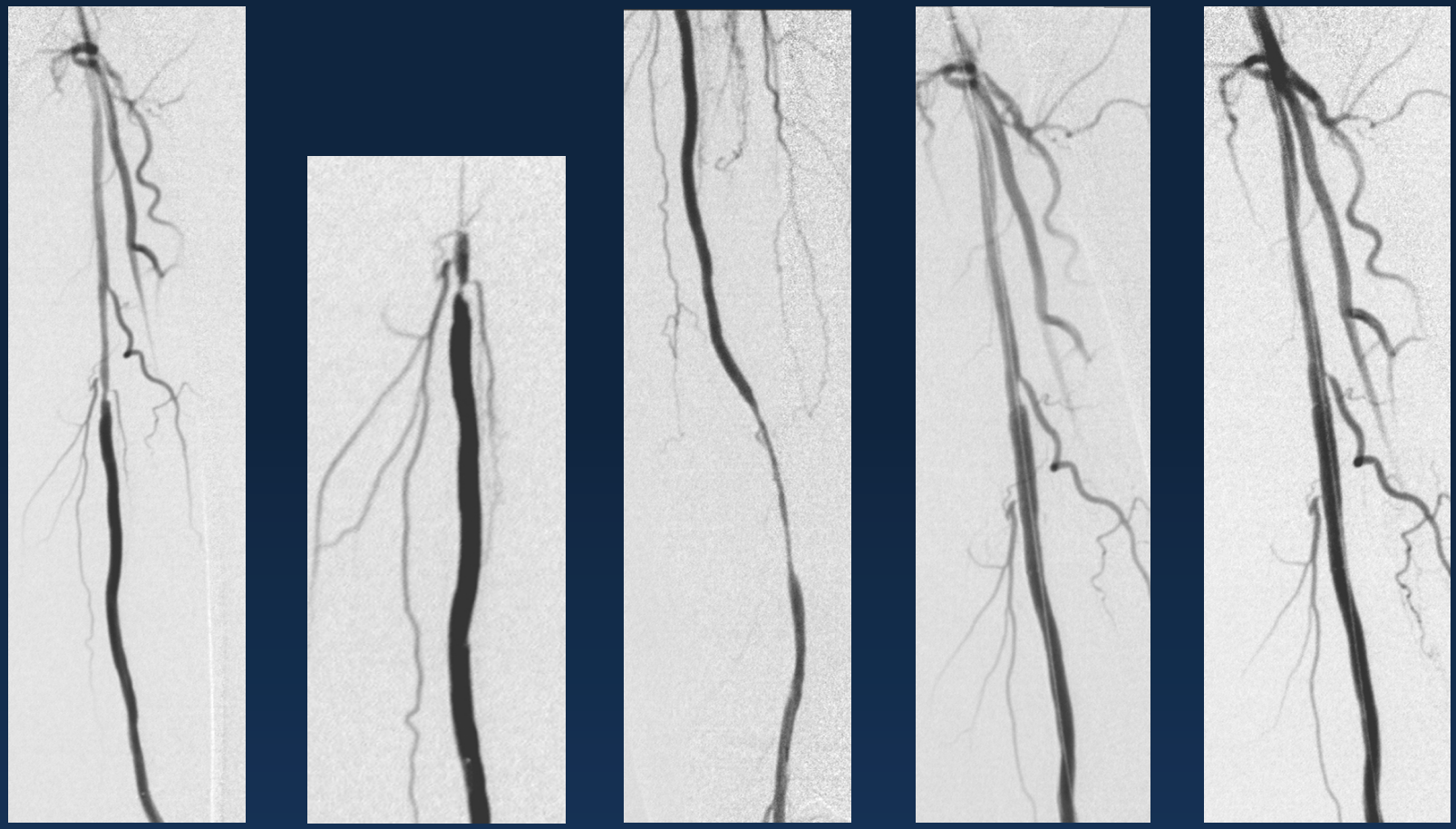
Gesamte Läsionslänge 11cm (TASC B)
Viabahn 5/150, Nachdilatation 4 mm

Stentgraftverschluss 4 Monate nach Eingriff
Absetzen von Plavix nach 3 Monaten

Fibrinolyse
über 24 Stunden

Verbleibende Dissektion nach Rekanalisation
BMS 5/60

Reverschluss nach weiteren 8 Monaten



Demaskierung nach Fibrinolyse

- Edge-Stenose proximal → PTA+Stent
- In-Stent Restenose distal →PTA

Technische Empfehlungen

- Gute Ein- und Ausstromgefäße; Mitbehandlung erforderlich
- Entsprechende Vordilatation; keinePrimärstentung
- Kein Oversizing > 20
- Proximale und distale Landezone 1 cm im gesunden Gefäß
- Überlappung von Endoprothesen zumindest 1,5 cm
- Abdecken der gesamten Läsionslänge; kein „Spot Stenting“
- Forcierte Nachdilatation und nur in der Endoprothese
- **Medikation: TASS und Clopidogrel (zumindest 6 Monate)**

Aneurysma A. poplitea

- Inzidenz 0,1-2,8%
- Beidseitig ~ 50%; AAA ~ 30%
- Symptomatisch bei Diagnose 30-50%
- Unbehandelt Auftreten von Komplikationen in 18-77%
  - lokale Thrombose
  - distale Thromboembolien
  - Neurovaskuläre Komplikationen
  - Extremitätenverlust bis zu 36%

- Behandlungsindikation Größe > 2 cm
  Wandständiger Thrombus

Endovascular Exclusion of Popliteal Artery Aneurysms With Stent-Grafts: A Prospective Single-Center Experience

Idelchik GM et al. J Endovasc Ther 2009;16:215-23

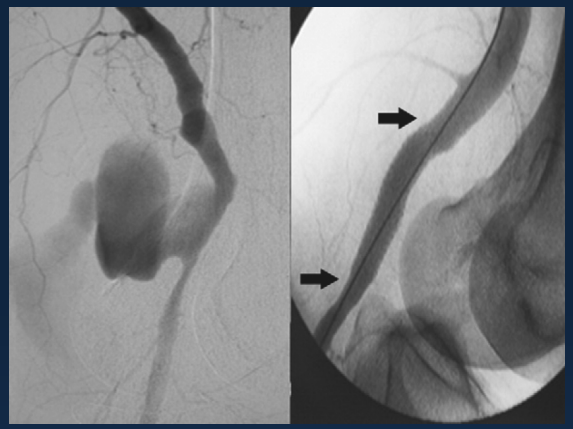
Procedural Results in 33 Popliteal Artery Aneurysms

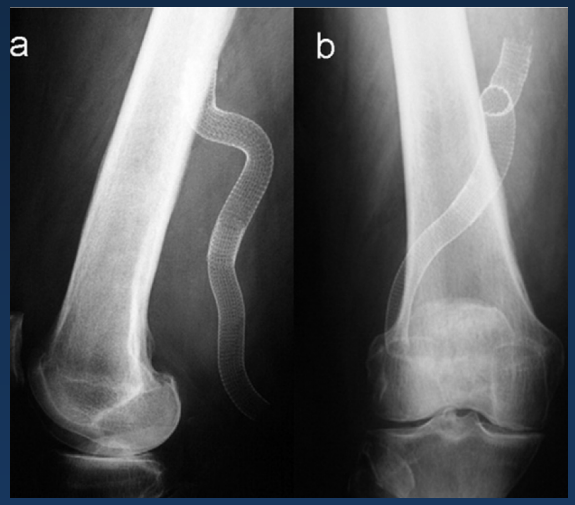
Stent-grafts implanted	59
Wallgraft	15
Viabahn	44
Stent-grafts implanted per lesion	1.9±0.4 (1–3)
Length of hospital stay, d	1.5±1.8 (1–11)
Acute thrombosis (within 24 hours)	2 (6%)
Subacute thrombosis	3 (9%)
Access site hematoma	3 (9%)

Primary and secondary patency rates	6 mo	93,9%	100%
	24 mo	87,5%	96,8%
	48 mo	84,8%	96,8%

A retrospective multicenter study of endovascular treatment of popliteal artery aneurysm

Midy D et al. J Vasc Surg 2010;51:850-6





57 PAA (50 pts)	Hemobahn/Viabahn	42
	Wallgraft	14
	Passager	1

Primary technical success	98,2%
Mean follow-up	36 months (range, 6-96)
Stent-graft occlusion	9 (16%)
Endoleak	1 primary, 5 late (10,5%)

	Primary	secondary patency
1 year	85,8%	87,5%
3 years	82,3%	87,5%

Significantelly higher occlusion- and EL-rate in Wallgrafts, but no significant difference in patency rates

Open repair versus endovascular treatment for asymptomatic popliteal artery aneurysm: Results of a prospective randomized study

Antonello M et al. J Vasc Surg 2005;42:185-93

Procedural early results

	Group A (OR)	*Group B (ET)*	*P*
Graft/endograft occlusion	0	1 (6.7%)	NS
Primary patency rate	100%	93.3%	NS
Assisted patency rate	—	100%	NS
Limb salvage rate	100%	100%	NS
Endoleaks	—	0	NS
Mean operative time (min)	75.4 (50-90)*	195.3 (120-255)*	<.01
Mean hospital stay (days)	7.7 (7-11)*	4.3 (2-9)*	<.01

		Bypass	**Stent-graft**	**p**
Primary patency	1 year	100%	86,7%	ns
Secondary patency	3 years	90,9%	100%	ns

Endovascular therapy preferntially used in patients with high surgical risk

Stent fractures in the Hemobahn/Viabahn stent graft after endovascular popliteal aneurysm repair

Tielliu IFJ et al. J Vasc Surg 2010;51:1413-8

78 PAAs in 64 patients; mean stented length 20cm

Mean follow-up 50 months (range, 1-127)

- 15 circumferential fractures 13/78 (16,7%) cases; (overlap zone 93%)
- Younger age was a significant predictive factor (mean age with fracture 60,6 ys and without 68,4 ys)
- Total occlusion rate was 26,9% (21/78)
- Primary patency rate was not different for the fracture group compared with the nonfracture group

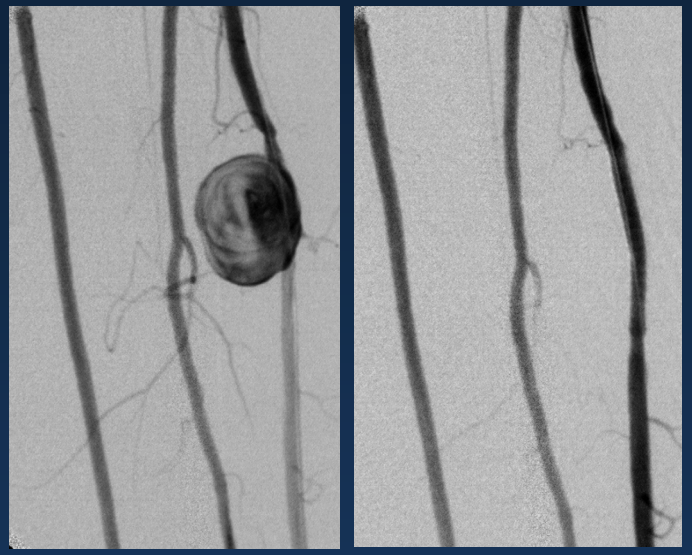
Nachteile und Bedenken

- Größeres Profil als BMS
- Kein „Spot Stenting“
- Edge Stenose
- Verschluss von Kollateralgefäßen
- Oberschenkelschmerzen in 6-20% (entzündliche Reaktion, Trauma)

Gesicherte Stentgraft-Indikation

- Aneurysmabehandlung in Nicht Bewegungssegmenten
- Traumatische und iatrogene Gefäßverletzungen

PA Bypass-Anastomose
Viabahn 6/50 und 7/50



Posttraumatisches PA
Jostent Graftmaster 3/26

Ballonexpandierbarer Stentgraft

Peripheral Jostentgraft

2 stainless steel Stents (Sandwich), ePTFE

DM 4-9 mm; large size 6-12 mm

Abbott Vascular

Jostent® Graftmaster Coronary Stentgraft

DM 3-5 mm, Länge 12-26 mm

7 Fr, 0,014¨

Mögliche Indikationen

Periphere arterielle Verschlusskrankheit femoropopliteal

Popliteaaneurysma

Vielversprechende Literaturergebnisse

Mangelnde randomisierte Ergebnisse

Aktuelle randomisierte Studien

Gore Viabahn Endoprosthesis vs Bare Nitinol Stent in the Treatment of
Long Lesions (>8 cm) SFA Occlusive Disease

Primärer Endpunkt: primäre Offenheit nach 3 Jahren, Safety
Rekrutierung abgeschlossen

The Gore Viabahn® Endoprosthesis with Propaten Bioactive Surface Versus Plain Old Balloon Angioplasty (POBA) for the Treatment of SFA In-Stent Restenosis

Primärer Endpunkt: primäre Offenheit nach 1 Jahr, Safety
Laufende Rekrutierung

GORE VIABAHN® Endoprosthesis with Bioactive Propaten Surface versus Bare Nitinol Stent in the Treatment of TASC B, C and D Lesions in SFA Occlusive Disease

Primärer Endpunkt: primäre Offenheit nach 1Jahr, Safety
Laufende Rekrutierung

clinicaltrials.gov

Selbstexpandierende Stentgrafts

Fluency® Plus Vascular Stentgraft

Bard Peripheral Vascular

Nitinol, beidseitig ePTFE gecovert

DM 5-13,5 mm, 8-10 Fr

Länge bis 12 cm

Führungsdraht 0.035“