

Do Endografts Have A Place In The SFA ?

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Infrainguinal Interventions Femoral PTA

- Review summarizing previous studies with High Quality of Evidence (QOE; efficacy,safety, cost effectiveness)
- Technical success- 89%
- Major complication rate- 8.1%
- 30 day mortality- 0.9%
- Patency rates based on meta-analysis

Kandarpa K. JVIR June 2001; 12:683-695

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Infrainguinal Interventions Femoral PTA

- Meta-analysis 1,003 pt.s
 - Original reports
 - Patency as per life table or K-M analysis
 - Patency defined as hemodynamic improvement
 - No duplicate material
- PTA Patency
 - 1 yr.- 59%
 - 2 yr.- 54%
 - 3 yr.- 52%
 - 4 yr.- 49%
 - 5 yr.- 45%

Hunink MG. Med Decis Making 1994 Jan-Mar; 14(1):71-81

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Infringuinal Interventions

Femoral PTA

- **SCVIR Transluminal Angioplasty and Revascularization (STAR) registry**
 - Prospective
 - Initial enrollment- 397 limbs in 383 patients
 - Final study cohort- 219 limbs in 205 patients
 - Attrition 2° concurrent tx (70) or lost to f/u (108)
 - Isolated fem/pop PTA procedures
 - Adherent to SVS/ISVCS/SCVIR reporting standards

Clark TW. J Vasc Interv Radiol 2001 Aug;12(8):923-33

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Infringuinal Interventions

Femoral PTA

- **Angiographic characteristics**
 - Stenosis- 78.5%
 - Occlusion- 11.0%
 - Mean lesion length- <5cm
 - \geq single vessel run-off- 62%
- **F/u of 5 years on all patients**

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Femoral PTA

- **Major complications- 1.8%**
- **Patencies**
 - 12 mo.- 87%
 - 24 mo.- 80%
 - 36 mo.- 69%
 - 5 yr.- 55%
- **Predictors of poor outcome (multivariate analysis)**
 - DM 36 mo. Patency- 56% vs 77%
 - < 1 vessel runoff 36 mo. Patency- 30% vs 87%

Clark TW. J Vasc Interv Radiol 2001 Aug;12(8):923-33

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Infringuinal Interventions Femoral PTA

Summary of studies evaluating patency of femoral PTA

Study	Year	Patients	Patency (%)	Follow-up (y)
Gallino*	1984	251	67	5
Krepel*	1985	164	70	5
Hewes*	1986	70	61	3
Cappek*	1991	217	58	5
Johnston	1992	254	38	5
Matsi	1994	140	42	3

* Excluded technical failures

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Infringuinal Interventions Femoral Stenting

- Meta analysis on high QOE reports
 - 600 patients
 - Technical success- 98%
 - Patencies
 - 1 year- 62%
 - 2 year- 52%
 - 3 year- 43%
 - Major complications- 5.9%

Kandarpa K. JVIR June 2001; 12:683-695

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Infringuinal Interventions Femoral PTA vs. Stenting

Randomized studies evaluating femoral PTA vs Stent (n > 50)

Study	Year	N	Patency (%)		F/U (y)	Stent
			PTA	Stent		
Vroegindewij	1997	51	85	74	1	Palmaz
Grimm	2001	53	67	73	3	Palmaz
Rosenfield	2001	266	34	41	.75	IntraCoil
Cejna	2001	141	65	65	2	Palmaz

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Infringuinal Interventions

Femoral PTA vs. Stenting

- FDA randomized multicenter trial comparing PTA vs IntraCoil stenting of fem/pop segment
- 266 patients;
 - PTA- 131
 - Stent- 135
- 368 lesions
- Angiographic f/u at 9 mo.s
- Lesions up to 12cm (occlusions) and 15 cm (stenosis)

Rosenfield K. ISET January 21-25, 2001
 IFU, IntraCoil® self-expanding stent, Sulzer IntraTherapeutics

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Infringuinal Interventions

Femoral PTA vs. Stenting

Results of IntraCoil SFA study

Procedure	Tech. Success (%)	Ang. restenosis [% (9mo.s)]	TLR (%)	TVR (%)	MACE (%)
PTA	95	34	84	83	81
Stent	98	41	86	83	81

Rosenfield K. ISET January 21-25, 2001
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Femoral PTA vs. Stenting

- **Approved indication;**
 - “...for improving peripheral luminal diameter in patients with symptomatic atherosclerotic disease due to stenotic lesions or occlusive lesions in femoropopliteal arteries...”
- **In other words- to tx failed angioplasty**

Rosenfield K. ISET January 21-25, 2001
 IFU, IntraCoil® self-expanding stent, Sulzer IntraTherapeutics

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Lower Extremity Interventions: Why Infra-inguinal Interest?

Segment	Clinical Indications	Vessel Length	Seg. Ext. of Disease	Procedure Frequency	Patency	Clinical interest for Improvement
Aortoiliac	Many Claud Limb salv. T/E, BT	Short	Limited	High	Good	Low
Femoral-popliteal	Many Claud Limb salv. T/E, BT	Long	Variable	Highest	Inter-mediate	High
Tibial	Few Limb salv. T/E	Inter-mediate	Extensive	Low	Poor	Intermediate

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Lower Extremity Interventions: Prevalence- OSF (Peoria) Experience

Number of Peripheral Interventions By Location (7/2000-6/2002)

Location	PTA/Stent	Thrombolysis	Total
Iliac	296	10	306
Fem/Pop	328	192	520
Tibial	37	9	46
Renal	245	2	247
Brach.	36	2	38
Total	942	215	1157

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Infrainguinal Interventions Femoral Stent-graft

- Early reports
 - "Homemade"- PTFE+Palmaz stents
(Cragg AH. Radiology 1993 Jun;187:643-8)
 - 8 patients, 6 month patency
 - Manufactured- Cragg Endopro (nitinol and Dacron)
(Henry M. J Endovasc Surg 1994 Sep;1:31-43)
 - 21 patients, 8 month angiographic f/u- 86% patency
 - 14% major complications

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Infrainguinal Interventions Femoral Stent-graft (Dacron-covered)

- Single center prospective study
- Evaluating Dacron-covered stent-graft (Cragg Endopro System 1)
- 30 patients
- Treatment of recurrent femoropopliteal Dz
- SVS/ISCVS/SCVIR criteria

Ahmadi R. Radiology 2002 May;223(2):345-50

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Infrainguinal Interventions Femoral Stent-graft (Dacron-covered)

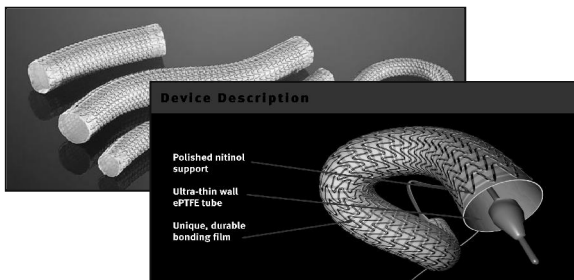
- Technical success- 100%
- Post implantation inflammatory (syndrome) response
 - Fever- 40%
 - Elevated C-reactive protein- 57%
- Early recurrent occlusions (24 hr.s)- 17%
- Patency

	6 mo.s	12 mo.s
primary	27%	23%
secondary	63%	60%

Ahmadi R. Radiology 2002 May;223(2):345-50

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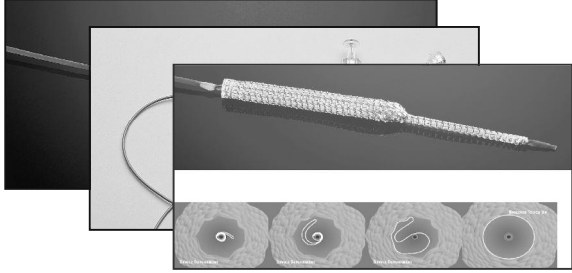
Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)



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Infrainguinal Interventions

Femoral Stent-graft? (Hemobahn/Viabahn)



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Femoral Stent-graft? (Hemobahn/Viabahn)

- Prospective, multicenter feasibility study
- Tx iliac and femoral dz
- 127 patients, 141 limbs
 - Iliac- 53 patients, 61 limbs
 - Femoral- 74 patients, 80 limbs
- SVS/ISCVS/SCVIR criteria

Lammer J. Radiology 2000 Oct; 217:95-104

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Femoral Stent-graft? (Hemobahn/Viabahn)

- 62% of lesions > 10 cm
- Mean length of device- 13.1 cm
- Technical success- 100%
- Major complications- 2.1%
- One year patency (color flow duplex)
 - 1°- 79%
 - 2°- 93%

Lammer J. Radiology 2000 Oct; 217:95-104

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Infringuinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- Preliminary report on USA HEMOBAHN multicenter phase II SFA trial
- Prospective randomized study of PTA vs PTA and Hemobahn, June '98 - December '99
- Looking for 15% superiority in patency of HEMOBAHN over PTA
- 244 patients treated (46 training cases, HEMOBAHN)
- 198 patients enrolled (randomized)
 - 98-HEMOBAHN
 - 100- PTA

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Infringuinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- Definitions/endpoints;
 - Technical success
 - Duplex patency; Patency of device + 1 cm
 - MACE; composite endpoint of 30 day MI, death, or target vessel revascularization (TVR)

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Infringuinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- Study halted because of;
 - Change in design of delivery catheter, distal olive
 - Leading to increase in required enrollment b/c of question of poolability of patients
 - Slow enrollment
 - Equivalent patency of PTA vs HEMOBAHN
 - Not because of inferior performance of device or safety issues

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Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- **Mean treatment length**
 - HEMOBAHN 7.5 cm (8.0-13.0cm)
 - PTA 6.8 cm (0.4-15.0cm)
- **Technical success**
 - HEMOBAHN 99% (97/98)
 - PTA 91%, (91/100)

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Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- **Patency (duplex)**

	<u>1 year</u>	<u>2 years</u>
• HEMOBAHN	81% (n=75/96)	62% (n=37/84)
• PTA	80% (n=67/91)	71% (n=32/82)
- **Freedom from MACE**

	<u>1 year</u>
• HEMOBAHN	82%
• PTA	82%

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Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- **Summary**
 - Hemobahn not superior to PTA
 - However, not inferior to PTA
 - No post implantation inflammatory response
 - Hemobahn not associated with increased adverse events when compared to PTA

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Infringuinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

Results using Hemobahn in SFA

Study	Year	N	Technical success(%)	Occlusion length(cm)	1°/2° patency(%)	F/u(y)
Railo(1)	2001	15	100	4-10	84/93	2
Deutschmann(2)	2001	18	94	8	49/61	.5
Bleyn(3)	2002	67	100	14	80/89	1
Bauermeister(4)	2001	35	100	22	73/83	1

1. Railo M. Annales Chirurgiae et Gynaecologiae 2001; 90: 15-18
2. Deutschmann H. J Vasc Interv Radiol 2001 Aug; 12:943-949
3. Bleyn J. (Abstract) Society of Endovascular Surgery, 15th Annual Congress 2002
4. Bauermeister G. J Endovasc Ther 2001;8:315-320

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Infringuinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

- OSF Saint Francis Medical Center
- 29 limbs treated in 28 patients
- Technical success 100%
- Mean f/u 9.0 months (range 0-50 mo.s)
- 4 limbs thrombosed in three patients
(2 mo.s, 3 mo.s, 4 mo.s, 22 mo.s)
- 1° Patency; 6 mo.s- 87% (13/15)
 1 yr- 80% (8/10)

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Infringuinal Interventions Femoral Stent-graft?

- Indications for endograft in femoropopliteal Dz?
 - Salvage of long segment failed angioplasty
 - Treatment of long segment occlusions
 - Treatment of wide spread tandem lesions

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Femoral Stent-graft? (Hemobahn/Viabahn)

- OSF; Incidence of tx with Endograft (2002)

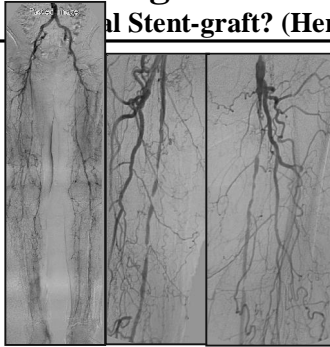
- Aortoiliac PTA/stent-	110 pt.s
- Fem/pop PTA/ stent-	165 pt.s
- Tibial PTA-	21 pt.s
- Visceral PTA/stent-	100 pt.s
- Brach/carotid PTA/stent-	37 pt.s
- SFA endograft-	18 pt.s
- Total	451 pt.s

- Incidence= 4% of treated patients, 10% of SFA interventions

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Femoral Stent-graft? (Hemobahn/Viabahn)



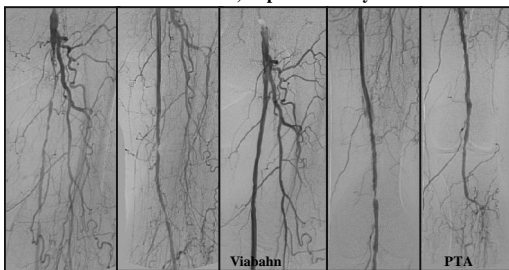
- 82 y/o female w/ BLE severe claudication
- No vessel runoff
- poor surgical candidate

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Femoral Stent-graft? (Hemobahn/Viabahn)

LLE- SFA tx'ed w/ Viabahn, Popliteal artery tx'ed w/ PTA



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Femoral Stent-graft? (Hemobahn/Viabahn)

RLE- SFA & Popliteal artery tx'ed w/ Viabahn

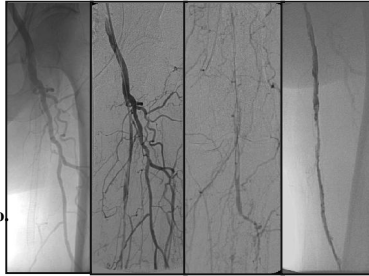


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Femoral Stent-graft? (Hemobahn/Viabahn)

- Following day- Left foot cold
- Weak doppler pulses
- Mild ↓ sensation
- Angiojet unsuccessful
- Lysis unsuccessful
- 2° bleeding
- Successfully Treated w/ heparin and GP IIb/IIIa
- Patent L Viabahn @ 6 mo. on duplex



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Infrainguinal Interventions

Femoral Stent-graft? (Hemobahn/Viabahn)

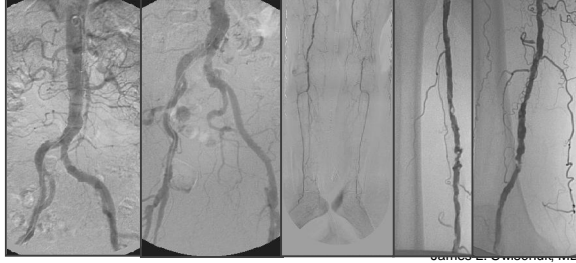
69 y/o male w/ mixed symptoms of neuropathy and 1 block claudication



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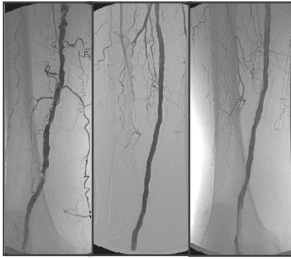
Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

82 y/o female w/ severe claudication



Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

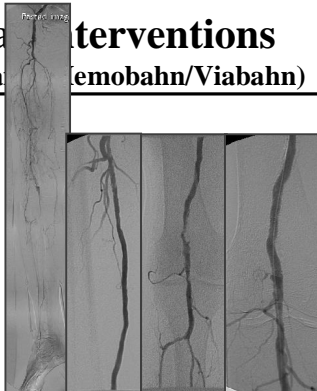
82 y/o female w/ severe claudication s/p placement of 15 cm Viabahn



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Infrainguinal Interventions Femoral Stent-graft? (Hemobahn/Viabahn)

82 y/o female now 3 months s/p Viabahn w/ recurrent claudication. Treated with overnight infusion of r-PA @ 0.25 units/hr. Popliteal artery treated w/ control stent.



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Femoral Stent-graft?

- **Conclusions**
 - PTA should be initial treatment for limited fem/pop disease in most clinical settings
 - Stents in fem/pop segment reserved for PTA salvage
 - Stent-grafts may further broaden indications for percutaneous approach to longer segment disease, especially occlusions
 - ? Intravascular brachytherapy, ? Drug-coated stent

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