The Hemobahn-Viabahn Stent-Grafts

19

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The Hemobahn stent-graft (W. L. Gore & Ass., Flagstaff, AZ, USA) was introduced in Europe in 1996. The stent consists of an exoskeleton made of a continuous filament of nitinol arranged in a helical manner to form a mesh and is covered internally with a thin layer of expanded PTFE. This self-expanding stent-graft presents flexibility and tolerance to torsion, longitudinal compression, and radial force.

When later introduced in the USA, the device was modified and appealed as Viabahn (Figs. 19.1 and 19.2). While the Hemobahn was deployed by unfolding and from proximal to distal, the Viabahn deployment is concentrical and from distal to proximal.

In September 2007, the heparinized Viabahn was introduced. Heparin molecules were bonded to the inner surface with end point covalent bonding: this would keep heparin anchored to the endoprosthesis surface, the bioactive site remaining free to interact with blood. Between 2007 and 2009, the Viabahn was furtherly improved, through reduction of the delivery profile and laser contouring of the proximal edge.

Fig. 19.1 The Viabahn stent-graft

19.1 A: Reports with at Least Ten Cases

Reviewing the available literature, we found several reports dealing with ten cases or more. It may be said that each study is different from the others and, owing to the lack of homogeneity in study plannings (most are retrospective studies) and protocols, it is really difficult to draw precise conclusions about the efficacy and durability of the method(s).

Albeit painstaking for us and maybe annoying for the reader, we tried to resume and tabulate

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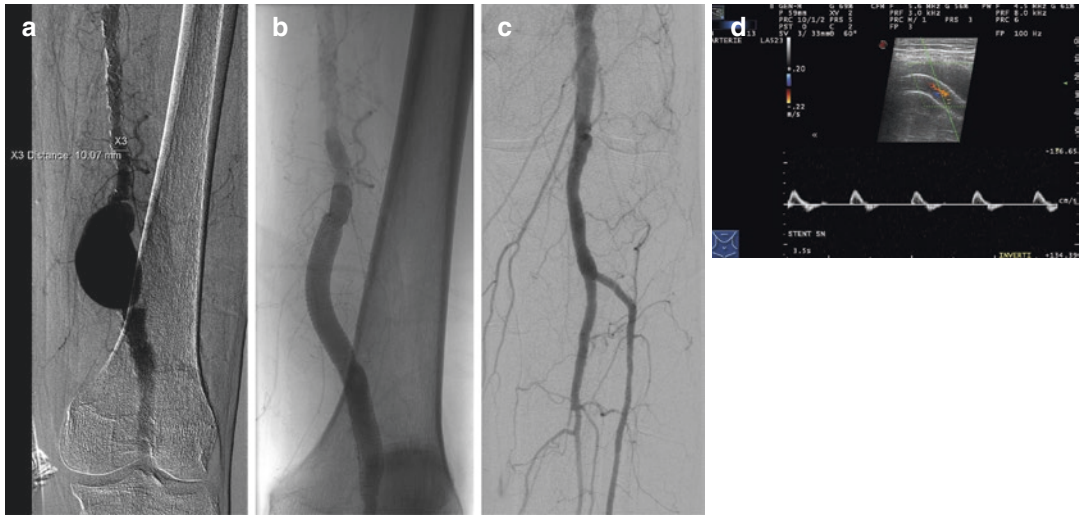

Fig. 19.2 Exclusion of a popliteal aneurysm with the Viabahn stent-graft. (**a**) Selective arteriography showing a large aneurysm of the popliteal artery with adequate landing zones. (**b**) After delivery of a Viabahn endoprosthesis, complete exclusion of the aneurysm. (**c**) Control arteriography after endografting: satisfactory runoff without signs of embolization. (**d**) Duplex control after 1 year: fair patency of the stent-graft and exclusion of the aneurysm

(Tables 19.1, 19.2, 19.3, 19.4, 19.5, 19.6, and 19.7) these reports, to allow, as far as possible, a correct judgment about the real impact of each experience on the current knowledge in the treatment of popliteal artery aneurysms (PAAs).

19.1.1 The Gröningen Experience

In 2003, Tielliu et al. [23] published the first large series of PAAs treated with the Hemobahn stent-graft: 22 atherosclerotic aneurysms. Five stent-grafts occluded within 6 months, but only in one case that the occlusion was closely related to the technique: incomplete proximal deployment caused a folding, which was corrected by thrombolysis and angioplasty. At a mean follow-up of 15 months (2–37), the cumulative patency rate was 74%. Interestingly, the two cases with only one runoff vessel were patent, respectively, at 2 and 26 months, and none of the three definitive occlusions required amputation.

The study was updated in 2005 [24], the Viabahn being used from June 2003, now relying on 57 PAAs in 48 patients, of which 12 were symptomatic (five with acute ischemia and successfully submitted to thrombolysis vs. only one in the earlier experience). With a mean follow-up of 24 months (1–72), primary and secondary patencies were, respectively, 80% and 90% at 1 year and 71% and 78% from the third year onward. Twelve stent-grafts occluded after 1–28 months, and eight of these were treated with thrombolysis. On a whole, complications occurred in 21/57 cases (37%); no amputation was performed. The authors considered important, for a positive outcome, the introduction of dual antiplatelet therapy (clopidogrel 75 mg added to aspirin (ASA) for 6 months); also, they observed that it was wise to avoid putting the overlapping at the hinge zone of the knee (to avoid the coincidence of marked compliance variation with the maximum of mechanical stress from movements, which was apparently responsible for stent fracture). They also strongly suggested patients to avoid prolonged flexion of the knee of >90°. On the basis of their rather gratifying results, they affirmed that, in their hospital, endografting of PAAs was now considered the therapeutic option of choice even in cases with available greater saphenous vein for classic bypass (the so-called gold standard). They also stressed the importance of endografting in limbs presenting with ischemia, as the technique avoids any incision on low perfused leg tissues.

Table 19.1 Synthesis of study characteristics (study design, material, methods, etc.) of series with ten or more cases of PAA endografting with Hemobahn/Viabahn stent-grafts

A: Inclusion criteria, type of patients, basic procedural premises	
B: Exclusion criteria[a]	
C: Protocol variations during the study period	
D: Anesthesia	
E: Type of access	
F: Stent-graft size	
G: Overlapping, if any	
H: Posttreatment therapy and suggestions[b]	
I: Type of follow-up	
Tielliu et al. 2007 [1]; single center; June 1998 to Feb. 2007; prospective; 72 cases	
A:	Symptomatic 6/72 (acute ischemia, pre-op. thrombolysis); asymptomatic, if diameter >20 mm; landing zones at least 30 mm; at least one runoff vessel patent
B:	Extensive aneurysmal or occlusive disease inflow tract
C:	From the 24th case, clopidogrel added to posttreatment therapy; avoidance of overlapping at the hinge zone of the knee
D:	Local; general in case of difficult access or planned concomitant procedure
E:	Open technique
F:	Oversize 1 mm
G:	Overlapping 20 mm
H:	Initially, ASA 80 mg; from the 24th case, clopidogrel 75 mg and ASA 100 mg for 2 months and then ASA indefinitely; advice against prolonged knee flexion >90°
I:	Duplex scan; lateral plain X-ray of the knee extended and flexed; mean follow-up 37 months (1–104)
Curi et al. 2007 [2]; single center; Jan. 2000 to March 2006; retrospective; 15 cases	
A:	Two symptomatic (none acute ischemia); landing zones at least 20 mm; at least one outflow vessel patent; stent-graft not extending below the popliteal artery
B:	Wide variation in the diameter between landing zones, particularly for short distance between the two
E:	Cut-down 11; percutaneous 4
F:	Oversize 10–15 mm
G:	Overlapping 20–30 mm
H:	Clopidogrel in 87%
I:	Follow-up 14 ± 3 months
Antonello et al. 2007 [3]; single center; Jan. 1999 to Dec. 2006; prospective, partly randomized; 21 cases	
A:	Asymptomatic, diameter >20 mm, aneurysm neck >10 mm
B:	Age <50; runoff score >8 [4]
C:	Only initially, embolization of significant branches arising from aneurysm
D:	Locoregional
E:	Prevalently percutaneous
F:	Suggested oversize 10–15% but used also greater
G:	At least 10 mm
H:	ASA 100 mg, ticlopidine 500 mg for 1 month, and then ASA indefinitely
I:	Duplex scan, plain x-ray of the knee bent at 120°; mean follow-up 47.8 months (11–97)
Rajasinghe et al. 2007 [5]; single center; June 2004 to March 2006; prospective; 23 cases	
A:	Diameter 150% adjacent vessel; landing zones at least 10–15 mm; at least one runoff vessel patent; 21 asymptomatic, two symptomatic
B:	Acute limb ischemia
D:	Local
G:	Overlapping 20 mm
H:	Clopidogrel 75 mg; avoid bending the knee >90°
I:	Duplex scan; mean follow-up 7 months; one lost to follow-up

(continued)

Table 19.1 (continued)

Thomazinho et al. 2008 [6]; single center; Jan. 2005 to Oct.2006; prospective; 11 cases	
A:	Eight asymptomatic, three symptomatic; landing zones at least 20 mm; at least one runoff vessel patent; avoiding the stent-graft end at the articular interline
B:	Age <50; acute ischemia; symptoms of compression
D:	Local
E:	Ten cut-down, one percutaneous
F:	Oversize about 20%
G:	Overlapping 20 mm
H:	Clopidogrel 75 mg, ASA 200 mg
I:	Color flow Doppler; ten followed up (8 for 20 months); one excluded (endoleak)
Etezady et al. 2010 [7]; single center; Aug. 2004 to Jan. 2009; retrospective; 18 cases	
A:	Acute ischemia 1, chronic ischemia 11, asymptomatic 6 (five with diameter >20 mm, one diam. 300% native popliteal art.), 13 partially thrombosed. Distal landing zone minimum 30 mm from origin of anterior tibial artery. Landing zones at least 20 mm
D:	Local
E:	Cut-down 6, percutaneous 12
F:	Oversize 1 mm
G:	Overlapping 20–30 mm; avoiding of overlapping at the kink zone (upper margin of patella)
H:	Clopidogrel 75 mg, ASA 325 mg for 3–6 months; lifelong regimen of ASA
I:	Duplex scan; mean follow-up, in 14/17 cases, 15 months
Ascher et al. 2010 [8]; single center; March 2005 to May 2009; prospective; 15 cases; studied only with ultrasound, without any diagnostic contrast arteriography	
A:	11 symptomatic (nine claudication, one rest pain, one acute ischemia pretreated with ultrasound-guided suction thrombectomy); four asymptomatic (minimum diameter 20 mm or mural thrombus). No patent outflow vessel in two cases. Landing zones at least 25 mm. End of the stent-graft: three above the knee, six behind the knee, six below the knee
D:	14 local, one regional (concomitant open repair of femoral aneurysm)
F:	Oversize 1 mm
I:	Mean follow-up 11 months
Midy et al. 2010 [9]; multicenter, Dec. 1999 to Dec. 2007; retrospective; 42 cases	
A:	Diameter >20 mm or 150% adjacent vessel; landing zones at least 15 mm; patients at high risk for conventional surgery or without available great saphenous vein
C:	Initially, postoperative ASA 75 mg; after 2004, added Clopidogrel 75 mg for 6 weeks in elderly patients, indefinitely in the others
D:	Mostly general
E:	Cut-down or percutaneous
F:	Oversize 1 mm
G:	Overlapping at least 20 mm
H:	See C
I:	Duplex scan, plain X-ray of the knee (extended and flexed); mean follow-up 36 ± 19.4 months (minimum 6 months)
Garg et al. 2012 [10]; single center; Sept. 2004 to Jan. 2011; retrospective; 26 cases	
A:	Landing zones at least 15 mm; avoiding the stent-graft ending at the bend of the popliteal artery; asymptomatic 16/26; 24/26 crossing the knee joint
B:	Patients who frequently flexed the knee >90° for extended periods
D:	10/26 local; seven regional; nine general
E:	23 cut-down, three percutaneous
F:	Oversize 10–15%
G:	Overlapping 20 mm
H:	ASA or clopidogrel
I:	Clinical; color DU imaging; mean follow-up 22 months (1–57); one lost to follow-up

(continued)

Table 19.1 (continued)

Pulli et al. 2013 [11]; multicenter; Jan. 2000 to Dec. 2011; retrospective; 134 cases	
A:	Symptomatic (ten ischemia, pretreated with thrombolysis; one rupture); asymptomatic if diameter >20 mm; landing zones at least 20 mm; at least one runoff vessel patent
C:	Initially, only focal lesions with two runoff vessel patent
E:	Surgical access 92 (69%), percutaneous 42 (31%)
F:	Oversize 10–15%[c]
G:	Overlapping at least 20 mm[c]
H:	Double antiplatelet therapy
I:	US examination; mean follow-up (128 cases) 35 months (1–124)
Note: The outflow vessel of the aneurysm was the proximal PA 78, the middle PA 54, and the distal PA or tibioperoneal trunk 2	
Stone et al. 2013 [12]; single center; 2001–2011; retrospective; 23 cases	
A:	Ten symptomatic (three acute ischemia, pretreatment thrombolysis; seven claudication); 13 asymptomatic (diameter >20 mm or mural thrombus); landing zones 10 mm
E:	Mostly percutaneous
G:	Overlapping 10 mm
I:	Mean follow-up 33.9 months (2–105)
Huang et al. 2014 [13]; single center; Jan. 2005 to June 2012; retrospective; 42 cases	
A:	Symptomatic 11 (26%) (ten acute ischemia with salvageable limb, all treated with thrombolysis; one chronic ischemia); asymptomatic if diameter > 20 mm or mural thrombus or evidence of previous thromboembolism; landing zones at least 15 mm; at least one runoff vessel patent (but no runoff in one case)
B:	Age < 50 years; symptoms of compression; mismatch >4 mm between proximal and distal landing zones; active subjects frequently bending the knee >90°
C:	Heparin-bonded stent-graft in 29 cases (69%)
D:	General 24 (57%); local 18 (43%)
E:	Cut-down 28 (66.6%); percutaneous 14 (33.3%)
F:	Oversize 1–2 mm
G:	Overlapping at least 40 mm
H:	Clopidogrel 300 mg/day and ASA 325 mg/day for 3 months or lifetime
I:	Duplex scan, CT angiography; mean follow-up 30 months (1–78)
Smialkowski and Huilgol 2014 [14]; multicenter; April 2009 to July 2012; retrospective; 20 cases	
A:	Mean diameter 20 mm; 1–3 runoff vessels patent
E:	Percutaneous
F:	No oversize
G:	Overlapping 20 mm
H:	Mostly dual antiplatelet therapy
I:	Duplex scan or CT angiography; mean follow-up 12 months (0–24)
Wissgott et al. 2014 [15]; single center; retrospective; ten cases	
A:	Asymptomatic 1; critical ischemia 1; claudication 8; landing zones at least 20 mm; at least one runoff vessel patent
D:	Presumably local
E:	Presumably percutaneous
G:	At least 20 mm
H:	ASA 100 mg long term; clopidogrel 75 mg for at least 6 weeks
I:	Standard treadmill ergometry, ultrasound; follow-up 24 months
Saunders et al. 2014 [16]; single center; April 2005 to June 2012; retrospective; 34 cases	
A:	Asymptomatic 23 (68%), thrombosed 3 (9%), embolized with acute ischemia 5(14%), local painful swelling 3 (9%). Landing zones 20 mm. Distal landing zone at least 20 mm from popliteal terminal branching. Two-vessel runoff (occasionally accepted one vessel runoff)

(continued)

Table 19.1 (continued)

D:	Local
E:	Percutaneous
F:	Oversize 10%
H:	Clopidogrel 75 mg and ASA 75 mg for 2 years. If patient already under warfarin, added clopidogrel 75 mg for 6 months
I:	Duplex ultrasound; mean follow-up 40 months (4–86)
Note: In case of acute ischemia, endograft deployment first and then PTA/thrombolysis	
Serrano Hernando et al. 2015 [17]; single center; Jan. 1993 to Dec. 2013; retrospective; 32 cases	
A:	High-risk patients or nonavailable autologous vein; asymptomatic 23 (71.9%); 0–1 runoff vessel 6 (19%). Landing zones >10 mm. Distal landing zone not beyond the infragenicular popliteal artery
B:	Mismatch >2 mm between proximal and distal landing zones; acute ischemia at presentation
C:	p.o. medication ASA 100 mg initially; after 2009, ASA 100 mg and clopidogrel 75 mg for 6 months and then clopidogrel 75 mg indefinitely
E:	Non-percutaneous
H:	See C
I:	Duplex ultrasound; median follow-up 22 months
Speziale et al. 2015 [18]; two centers; Jan. 2004 to Dec. 2013; retrospective; 53 cases	
A:	Symptomatic (12/53, 22,6%; pre-op. thrombolysis 8); asymptomatic if diam. > 20 mm or huge mural thrombus; landing zones at least 15 mm; at least one runoff vessel patent
B:	Age <65, good clinical status; mismatch >5 mm between proximal and distal landing zones
D:	General or local
E:	Percutaneous up to 9F diameter of the introducing sheath
F:	Oversize 10–15%
G:	At least 20 mm
H:	Clopidogrel 75 mg, ASA 100 mg
I:	Duplex scan; mean follow-up 37.4 ± 29.3 months
Note: distal landing zones: 50 below the knee level; three tibioperoneal trunk (ant. tib. artery occluded)	
Ronchey et al. 2015 [19]; single center; 2000–2013; retrospective; from Jan. 2004 included in Speziale et al. [18]; 25 cases	
A:	Symptomatic (pre-op. thrombolysis 4); asymptomatic if diameter > 20 mm; landing zones at least 15 mm
B:	No runoff vessel patent
C:	Up to 2010, only patients at high risk for conventional surgery; later on, all patients with unavailable greater saphenous vein
D:	General 20%; local 80%
E:	Cut-down 68%, percutaneous 32%
F:	Oversize 1 mm
K:	Dual antiplatelet regimen for at least 1 month
I:	Duplex scan; mean follow-up 49 months (1–145)
Leake et al. 2016 [20]; single center; Jan. 2006 to March 2014; retrospective; 76 cases	
A:	Seven acute ischemia (four pre-op. thrombolysis); five claud./rest pain; three rupture; 61 asymptomatic. Landing zone below the aneurysm of adequate diameter and at least 20 mm before any tibial takeoff; runoff score <7 [4]
B:	Inadequate access
C:	Probably a number of stent-grafts were of the heparinized type
E:	Cut-down 38.2%; percutaneous 61.8%
H:	Clopidogrel + ASA in most patients
I:	Duplex scan (available in 62 patients); mean follow-up 28.3 months

[a]Common exclusion criteria were the contraindication to antiplatelet or anticoagulant or thrombolytic therapy and severe disease of the inflow tract

[b]Oral anticoagulation when the patient was already following it

[c]Data from the leading center [21]

Table 19.2 Primary patency of Hemobahn/Viabahn stent-grafts in series of ten cases or more

Author	No. cases	Primary patency percentage (months)						
		6	12	24	36	48	60	72
Tielliu [1]	72				77		70	
Curi [2]	15			83				
Antonello [3]	21	80.9	80.9		71.4	71.4	71.4	71.4
Rajasinghe [5]	23		93					
Thomazinho [6]	11			90[a]				
Etezady [7]	18	86						
Ascher [8]	15	82	82		53[b]			
Midy [9]	42	92.8	90.3	90.3	86.4	86.4		
Garg [10]	26		91.2	85.5	78.4	78.4		
Pulli [11]	134		79.1	76.9		73.4		
Stone [12]	23		92.9		63.7			
Huang [13]	32[c]		87		75			
	10[d]		54		54			
Smialkowski [14]	20		85					
Wissgott [15]	10	80	80	80				
Saunders [16]	34		88		82		82	
Serrano-Hernando [17]	32	83.8	79.7	79.7				
Speziale [18]	53	100	100	98.1	92.4	81.1	77.3	73.6
Ronchey [19]	25						71	
Leake [20]	76		88.8		73.2			

[a]20-month patency (9/10 patients)
[b]30-month patency
[c]Elective
[d]Emergency

Table 19.3 Secondary patency of Hemobahn/Viabahn stent-grafts in series of ten cases or more

Author	No. cases	Secondary patency percentage (months)						
		6	12	24	36	48	60	72
Tielliu [1]	72				86		76	
Curi [2]	15			100				
Antonello [3]	21	90.5	90.5	90.5	85.7	85.7	85.7	85.7
Rajasinghe [5]	23		100					
Thomazinho [6]	11			90[a]				
Garg [10]	26		91.2	91.2	91.2	91.2		
Pulli [11]	134		90.8	85.5		85		
Huang [13]	32[b]		97		83			
	10[c]		79		79			
Smialkowski [14]	20		90					
Saunders [16]	34		90		86		86	
Serrano Hernando [17]	32	89.8	88.3	88.3				
Speziale [18]	53							92.4
Ronchey [19]	25						88.0	
Leake [20]	76		95.4		83.0			

[a]20-month patency (9/10 patients)
[b]Elective
[c]Emergency

Table 19.4 Series of Hemobahn/Viabahn stent-grafts with ten cases or more: adverse procedural and clinical events—I

Author	No. cases	Occlusion	Total endovascular reintervent.	Amputation	Conversion to open surgery
Tielliu [1]	72	18	14	0	2
Curi [2]	15				
Antonello [3]	21	4	5	0	3
Rajasinghe [5]	23	1	1	0	0
Thomazinho [6]	11	1			2
Etezadi [7]	18	2	5		2
Ascher [8]	15	3			
Midy [9]	42	5			
Garg [10]	26	3		0	2
Pulli [11]	134	27	25	4	1
Stone [12]	23	4	1	0	1
Huang [13]	42	12	19	2	5
Smialkowski [14]	20	3	1	1	2
Wissgott [15]	10	2			2
Speziale [18]	53	14	10	0	0
Ronchey [19]	25	5	4	0	0
Leake [20]	76	12	7	1	3

Table 19.5 Series of Hemobahn/Viabahn stent-grafts with ten cases or more: adverse procedural and clinical events—II

Author	No. cases	Problems at deploy.	Stenosis	Kinking	Migration	Endoleak	Fracture
Tielliu [1]	72	0	2		9	6	3
Curi [2]	15					3	
Antonello [3]	21	2	2	0		0	0
Rajasinghe [5]	23	0	1	0	0	0	0
Thomazinho [6]	11	0	0	0	1	1	0
Etezady [7]	18	3	0	0	0	2	0
Ascher [8]	15		0	0			
Midy [9]	42					3	
Garg [10]	26	1	0	0	0	0	0
Pulli [11]	134					1	
Stone [12]	23					0	
Huang [13]	42	1	1			3	
Wissgott [15]	10					0	0
Speziale [18]	53	0	2	0	0	0	3
Leake [20]	76	0				5	

The results of the Gröningen prospective study were really impressive. However, Diaz and Tamashiro [25], from Buenos Aires, warned that avoidance of knee flexion could represent an impairment of the quality of life in many persons, particularly those of Oriental culture, who exert extreme and prolonged knee flexion while eating or praying.

In a further update in 2007, Tielliu et al. [1] reported on 72 PAAs in 60 patients (June 1998 to Feb. 2007). They expressed a more cautious opinion about indication, particularly if younger

Table 19.6 Series with at least ten cases of PAA endografting with Hemobahn/Viabahn stent-grafts: analysis of stent-graft failures

Tielliu, 2007 [1]
18 occlusions: 5/23 at <1 month without clopidogrel; 13/49, if clopidogrel, from the eighth month onward
Of 18 occlusions, 2 from critical disease of the inflow tract, 1 from embolism, 2 from stent fracture, 1 from proximal fold, 1 from repeated sitting on the knees. One case converted to open surgery, 7 managed conservatively, 7 treated with thrombolysis (3 with stenting), 3 with thrombectomy: of the last ten, five reoccluded
Endoleaks: 2 type I, from stent migration, treated with additional stent-graft; 2 type II, persistent, treated with thrombin injection; 1 type III, from loss of overlapping, treated with bridging stent-graft; 1 type IV from stent fracture and graft tear, treated by ligation and bypass
Stenoses: 2, treated with PTA (repetitive in 1)
Curi, 2007 [2]
Endoleaks: 1 combined types I and III, treated with additional endografts: ok. 2 type II: surveillance
Antonello, 2007 [3]
1 early occlusion from difficult distal release: thrombolysis and dilatation: ok
1 early occlusion from excessive oversize producing folding; reocclusion after PTA and stenting: conversion to open surgery
2 asymptomatic stenoses at 6 and 24 months, treated with covered stent: 1 occluded and converted to open surgery; 1 occlusion in patient heterozygous for factor V Leiden: unsuccessful thrombolysis, conversion to open surgery
Rajasinghe, 2007 [5]
1 occlusion at 6 months from proximal stenosis due to incomplete unfolding: thrombectomy and uncovered nitinol stent: ok
Thomazinho, 2008 [6]
1 proximal migration of the distal end, with endoleak, sac refilling, and distal embolism: converted to open surgery
1 occlusion at 9 months: converted to open surgery
Etezady, 2010 [7]
3 technical problems at deployment: 1 stent folded within the popliteal artery: conversion to open surgery; 1 distal embolization: ok after suction thrombectomy; 1 non-deployment of the distal part: rescued
Endoleak type I: 2 cases, ok with additional stent-graft
2 occlusion at 6 months: 1 stent-graft explanted for suspected but non-confirmed infection, conversion to open surgery; 1 refused treatment
Ascher, 2010 [8]
3 occlusions, respectively, at 2, 5, and 30 months (of these, two in case of initially no runoff vessel patent)
Garg, 2012 [10]
1 problem (stent collapse) at deployment: conversion to open surgery
3 occlusions, respectively, at 4, 14, and 26 months: 2 open thrombectomy: ok 1 converted to open surgery
Pulli, 2013 [11]
27 occlusions
13 at <30 days: reintervention in all
In one case (concomitant EVAR), conversion to open surgery; graft thrombosis; major amputation; death
14 late, 12 reinterventions; 7 rethrombosis; 3 major amputations
Endoleak: 1 type II, from large genicular artery; slight sac enlargement; surveillance
Stone, 2013 [12]
4 late occlusions between 5 and 25 months: 2 conservative treatment; 1 conversion to open surgery;
1 thrombolysis + PTA + stent: ok
Huang, 2014 [13]
1 technical insuccess (problems at deployment): conversion to open surgery
12 occlusions: 3 early, of which 2 rethrombosis and major amputation in pts. >85 with 0/1 runoff vessels (one died); 9 late, of which 3 converted to open surgery
1 stenosis, from infolding
Endoleaks: 2 type I; 1 persistent type II, converted to open surgery
Smialkowski, 2014 [14]

(continued)

Table 19.6 (continued)

2 early occlusions: 1 in patient with undiagnosed prothrombotic condition: conversion to open surgery, graft thrombosis, amputation, death
1 in patient with bleeding diathesis: conversion to open surgery
1 occlusion at 2 months: thrombolysis: ok
Speziale, 2015 [18]
Occlusions 14, none early
3 from stent fracture: new Viabahn stent-graft: ok
2 distal folding: bare metal stent: ok
6 from interrupted antiplatelet therapy and 3 from repeated and prolonged knee bending: 4 no reinterventions, 5 thrombolysis: ok
Leake, 2016 [20]
1 amputation in patient presented with too advanced ischemia
12 late occlusions: 5 successful endovascular reintervention; 3 converted to open surgery; 4 treated conservatively
Endoleaks: 2 type I (1 early, 1 late) treated with extension stent-graft; 3 type II, surveillance

Table 19.7 Outcome of 72 endografting procedures with the heparinized Viabahn stent-graft, from Golchehr et al. [22]

	6 months	12 months	24 months	36 months
Primary patency	88.3%	82.8%	69%	69% (9[a])
Second. patency	95.7%	88.3%	80.9%	75.9% (9[a])

[a]Limbs at risk

and active subjects are concerned. Furthermore, they tried to define the importance of the learning curve: considering the first cases (before clopidogrel) vs. the cases with clopidogrel, they found a significant difference of adverse events: 61% vs. 32%. The authors concluded this report asserting that the technique was feasible and safe (no amputation) but that the incidence of complications was still too high.

19.1.2 The Italian Experience

Antonello et al. [26], from Padua, in 2005, tried to launch the first (and till now unique) randomized trial to compare endografting and surgical treatment of asymptomatic PAAs. However, they observed that, to achieve significant study power, 302 cases should be enrolled (probably during 50 years, for their center): consequently, in effect, the study, initially consisting of the comparison between 15 endograftings and 15 open repairs, became a careful prospective study on 21 cases, updated in 2007 [3], always maintaining the aim of comparison with open surgery (27 cases). In this series, primary and secondary patency rates were, respectively, 80.9% and 90.5% at 12 months and 71.4% and 85.7% from the third year onward; no amputation was required, and conversions to open surgery were three.

In 2013, the largest series of PAA endografting was reported in a multicenter (seven Italian centers) retrospective study relying on 134 cases, leaded by the Dept. of Vascular Surgery of the University of Florence [11]; 1 year before, the leading center had published the personal experience on 21 cases [21]. A small number of cases requiring urgent treatment were included (11 cases, of which ten acute ischemia, one rupture). Primary and secondary patencies were, respectively, 79.1% and 90.8% at 1 year and 73.4% and 85% at 4 years. Factors adversely affecting the outcome were identified in poor runoff and in the clinical presentation of limb-threatening ischemia; also, the need to land into the distal posteroanterior (PA)/tibioperoneal trunk resulted in a predictor of complications; these affected 21% of the cases, and while conversion to open surgery was required only once, four major amputations were performed.

In 2015, Speziale et al. [18], from Rome University, reported a series of 53 cases (2004–2013), partially including the experience of another center of vascular surgery in Rome [19]. Preoperative thrombolysis was performed in

eight cases. The estimated 72-month primary and secondary patency rates were, respectively, o73.6% and 92.4%. No limb was lost, and conversion to open surgery was never required.

19.1.3 The North American Experience

The device was introduced into the clinical practice in 2000.

In 2007, Curi et al. [2] reported 15 cases, with a mean follow-up of 14 months and an estimated 2-year secondary patency of 100%. The authors felt that the impressively good results were biased by the low number of cases and the short follow-up and consequently advised that the unrestricted use of endovascular popliteal aneurysm repair (EVPAR) was far from being recommended. The study was updated in 2010 [27], reporting the same rates of primary and secondary patencies at 5 years, again underlining that these very good results needed the support of larger and more complete experiences, as the number of patients was rather limited and, moreover, no case had required an urgent treatment.

Rajasinghe et al. [5] reported 23 cases, treated during a 22-month period, with exclusion of cases presenting with acute ischemia. Only one thrombosis occurred, and patency was reestablished through thrombolysis and stenting. However, in this series, the very short follow-up (mean 7 months) avoids to draw any consistent consideration.

In 2010, Etezadi et al. [7] reported 18 cases, of which 12 were symptomatic (only one with acute ischemia), and observed a 6-month primary patency of 86%; two cases needed conversion to open surgery. Also in this series, mid- and long-term follow-up is lacking. The authors put into evidence the importance of an optimal sizing of the stent-graft, to avoid heavy problems on deploying.

A very interesting report comes from the Maimonides Medical Center (New York), where Ascher et al. [8] demonstrate, in a series of 15 cases, the feasibility of PAA endografting without either pre- or intraoperative use of X-ray and contrast media, relying on accurate ultrasound techniques.

Garg et al. [10] reported 26 cases, of which 16 were asymptomatic, excluding patients whose lifestyle involved repeated >90° flexion of the knee for prolonged periods. In most cases (24/26), the stent-graft crossed the knee joint. Primary patency was 91.2% at 1 year and 78.4% at 4 years, with a 4-year secondary patency rate of 91.2%. No amputation was performed, and two cases were converted to open surgery, of which one following stent-graft infolding at deployment [28]. In spite of the good results, the authors stated that larger experience and longer follow-up were needed to define the exact role of PAA endografting and textually asserted that one should be cognizant that open repair remained the gold standard.

In 2013, Stone et al. [12] described the results in 23 cases (13 asymptomatic), with a primary patency of 92.9% at 1 year and 63.7% at 3 years, remarking that in their institution (the West Virginia University at Charlottesville), the general attitude was still rather conservative, supporting open surgery in younger individuals in good clinical conditions.

The Mayo Clinic experience is illustrated in two successive papers [13, 29]. The more recent paper deals with 42 cases. The exclusion criteria were rather rigid: age <50 years, active subjects, symptoms of compression, and heavy mismatch between the landing zones. In 29 cases, the heparinized stent-graft Viabahn was used. On a whole, four cases were converted to open surgery, and one early amputation was performed. The 36-month primary patency was 75% in elective and 54% in urgent cases, but secondary patencies reached, respectively, 83% and 79%.

A large series was published recently by Leake et al. [20], from Pittsburgh. Most patients (80%) were asymptomatic. One major amputation was necessary in a case presenting with too advanced ischemia; conversions to open surgery were three. After 3 years, primary and secondary patency rates were, respectively, 79.5% and 83%. Like the colleagues in Gröningen, also these authors underline the importance of the learning curve: in the earlier experience (24 cases, 2006–2008),

33% of the stent-graft occluded, while the rate of occlusion was only of 7.8% in the further series (51 cases, 2009–2013).

19.1.4 Reports from Other Countries

Australia, 2006, Mohan et al. [30]: in a series of 26 cases, five occlusions occurred within a follow-up of 1–95 months (mean 24 months); one was treated conservatively, one converted to open surgery, and three were treated with thrombolysis (successful in two) and no amputation. In the entire experience of 30 cases (four treated with other types of stent-graft), primary and secondary patencies, at 36 months, were, respectively, 74.5% and 83.2%; three endoleaks were observed, none requiring reintervention.

Australia, 2014, Smialkowski and Huilgol [14]: 20 cases, primary patency of 85% at 12 months and one amputation.

Brazil, 2008, Thomazinho et al. [6]: 11 cases, of which two converted to open surgery; primary and secondary patency rates were 90% at 20 months.

Brazil, 2015, Borges Domingues et al. [31]: 13 cases. Two early failures, of which one converted to open surgery and one successfully treated with thrombolysis. Four late failures (one attributed to discontinuation of antiplatelet therapy), all treated conservatively. Mean follow-up 14.8 months.

France, 2010, Midy et al. [9]: 42 cases, primary patency of 86.4% at 48 months and no amputation.

Germany, 2014, Wissgott et al. [15]: ten cases; one occlusion at 1 month, one at 3 months, and both converted to open surgery; primary patency at 24 months (8/10 cases), 80%.

Spain, 2015, Serrano Hernando et al. [17]: 32 cases; seven occlusions during follow-up; at 24 months, primary patency is 79.7%, and secondary patency is 88.3%.

United Kingdom, 2014, Saunders et al. [16]: 34 cases. Five-year primary and secondary patencies, respectively, were 82% and 86%. Five occlusions: one asymptomatic, one ok thrombolysis, one reoccluded after thrombolysis and managed conservatively, and two amputations.

19.2 B: Single-Case Reports, Short-Series Reports, and Reports on Mixed Stent-Grafts

Other reports on PAA endografting with Hemobahn-Viabahn are found in the literature, and some of them deal with the results of these stent-grafts mixed with the outcome of different devices. For the sake of completeness and because some interesting considerations may derive, they are synthetically outlined below, following a chronological order.

1998, Bürger et al. [32] (Magdeburg, Germany): one case, presenting with acute ischemia from 4 h; successful thrombolysis and deployment of Hemobahn stent-graft; ok at 6 months.

2003, Gerasimidis et al. [33] (Thessaloniki, Greece): six cases (two ruptured) with 1–3 vessel runoff (not clear if one case was due to Behçet's disease), treated with the Hemobahn stent-graft. One patient died p.o. with patent graft; primary patency in two cases, respectively, at 4 and 19 months. Three occlusions: one very early, successfully treated with thrombolysis and patent for 3 months (when the patient died); one at 30 days, rethrombosed after thrombolysis, with the limb saved at 11 months; and one at 5 months, apparently successful thrombolysis (but follow-up is lacking). In this small series, acenocoumarol was the principal discharge medication, successively coupled or changed with ASA.

2006, Nelson and Lee [34] (Gainesville, FL, USA): a case of open repair of a femoral aneurysm coupled with Viabahn endografting of a concurrent popliteal aneurysm; ok at 6 months.

2006, Angotti F. de Monteiros and Gaspar [35] (São Paulo, Brazil): two cases of bilateral PAA, both treated in the same session (one Hemobahn, one Viabahn): ok, respectively, at 30 days and 6 months.

2008, Sadat et al. [36] (Cambridge, UK): Hemobahn stent-grafting of a large PAA; ok at 12 months.

2009, Idelchik et al. [37] (Houston, TX, USA): 33 cases in 29 patients, symptomatic (claudication) or asymptomatic (diameter >20 mm or 150%

of the native artery or mural thrombus). It is not clear how many cases were treated with Wallgraft (15 stent-grafts used) or Viabahn (44 stent-grafts used). The study ended in 2007 and Viabahn was introduced in 2005 and exclusively used from 2006. On a whole, the follow-up was 35.4 months (6–120), and each patient was followed up for at least 6 months. The occlusions were four in three limbs: one stent-graft occluded at 24 h and reoccluded at 10 months (the only definitive occlusion). No amputation. Postoperative therapy: clopidogrel 75 mg, ASA 325 mg, and statins.

2010, Saratzis et al. [38] (Nuneaton, UK): one case of acutely thrombosed PAA at the level of the knee joint: stent-grafting with Viabahn, apparently without preliminary thrombolysis; ok at 22 months.

2016, Wooster et al. [39] (Tampa, FL, USA): 25 cases treated from 1999 to 2013 with Wallgraft (20%) or Viabahn (80%). In the entire group, the primary patency was slightly less than 70% from 12 to 48 months. Of six occlusions, five were converted to open surgery, and one successfully submitted to thrombolysis. Also, one reintervention for stenosis and one for extension of the disease.

19.3 C: The Heparinized Viabahn Stent-Graft

This improved form of Viabahn stent-graft was largely used in some series [13], but we found only two papers dealing exclusively with it.

In 2013, Guzzardi et al. [40] (from Novara, Italy) reported ten cases, treated from January 2009 to July 2010; eight aneurysms were supragenicular and two infragenicular; three limbs presented with claudication, one with critical ischemia and six asymptomatic. Dual antiplatelet therapy was followed in all cases. One stent-graft occluded at 3 months and was successfully rescued with thrombolysis and percutaneous transluminal angioplasty (PTA). Primary and secondary patencies, after 12 months, were, respectively, 90% and 100%.

A multinational study was published in 2015 by Golchehr et al. [22], consisting of 72 aneurysms in 70 patients, treated from April 2009 to March 2014. The contributing centers were four (Arnhem and Gröningen, the Netherlands; Nuremberg, Germany; Padua, Italy). The clinical presentation was asymptomatic 56 (78%) and symptomatic 16 of which seven with critical limb ischemia. On a whole, 169 PAAs were observed during the study period, and endografting was chosen when the lesion was anatomically suitable and at least one runoff vessel was patent. During the follow-up (0–63 months, mean 13 months), seven patients died from unrelated causes, and three patients were lost. Primary and secondary patencies are illustrated in Table 19.7. Occlusion was observed in 13 cases (18% of the entire cohort): seven were converted to open surgery, two were successfully treated with thrombolysis, and four were managed conservatively. The loss of patency was not significantly influenced by number of stent-grafts used, number of patent outflow vessels, postoperative use of clopidogrel, and type of clinical presentation.

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