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Current Status of Synthetic and Biological Grafts for Hemodialysis

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1. Introduction

Patients with chronic kidney disease (CKD) stage 4 or 5 have the option of kidney transplantation, hemodialysis (HD), peritoneal dialysis (PD), or conservative management.[1] National Kidney and Urologic Disease Information Clearinghouse reported that in 2007, there were 368, 544 U.S. residents with ESRD who were receiving dialysis, of whom 341, 264 were undergoing HD.[2] Quality of life and long-term survival of patients with CKD who are on HD depends on the successful placement of vascular access, as autogenous arteriovenous access, prosthetic arteriovenous access, or tunneled central venous catheter. DOQI guidelines are emphatic that autogenous arteriovenous access placement should be considered first, as it provides the optimal vascular access, followed by prosthetic grafts if autogenous arteriovenous access placement is not possible. There is a great deal of controversy regarding the choice of synthetic or biological material, as the guidelines suggest that it should be based on surgeon's experience and preference. The evidence to support the superiority of tapered versus uniform tubes, thick- versus thin- walled characteristics, elastic versus non-elastic arterial, stretch vs. standard PTFE, externally supported vs. unsupported grafts, is still evolving.

An ideal vascular graft would have the following characteristics: 1) appropriate size to match host vessels, 2) mechanical strength, 3) low thrombogenicity/ complete endothelialization, 4) rapid/ complete healing, 5) ease of handling, 6) resistance to infection, 7) structural durability in face of repeated needle puncture, 8) low incidence of hyperplastic intimal changes and 9) low cost.[3]

In this chapter, we will review the development of vascular grafts over the years and discuss the advantages of one over the other.

2. Prosthetic grafts for hemodialysis

Although the first synthetic graft used for HD access in the United States was made of Dacron dating back to the early 1970s, unfavorable results and the availability of better prosthetic materials like expanded PTFE (ePTFE) forced its abandonment. In 1976, Dr. Baker presented the first results of ePTFE grafts in 72 HD patients. Since then ePTFE remains the graft of choice for vascular access.[4] ePTFE is considered the material of choice due to the fact that it is readily accessible, ease of implantation, good medium term patency, and relatively low complication rates compared to other synthetic and biological materials.[5] The medical community has made strenuous efforts to increase the use of autogenous arteriovenous access, prevalence has increased from 22% in 1995 to 57.7% in 2011. However, the use of synthetic grafts still remains significant (18.4% prevalence in 2011).[6,7]

2.1 Indications for use of prosthetic grafts

Autogenous arteriovenous access are clearly superior in terms of long term patency to grafts, but not feasible in many patients undergoing HD[8]. The indications for prosthetic grafts include: lack of suitable vessels particularly in elderly and diabetic patients, need for immediate cannulation and in children who cannot tolerate multiple painful venipunctures.[5]

2.2 Complications associated with prosthetic grafts

Graft failures are typically caused by stenosis (leading cause of graft failure) due to thrombosis and neointimal hyperplasia at site of anastamosis, as well as graft infection (contributes to 10-15% of graft failure).[9,10] Other less common complications of prosthetic accesses include; steal syndrome, seromas, aneurysm formation, central vein stenosis and bleeding.[11] Thrombosis seems to occur soon after implantation due to technical problem, with a clot typically forming at the surface of the graft when it is first exposed to blood. The clot is formed initially of platelet aggregates, and then fibrin and thrombin is laid down via activation of the coagulation cascade. Platelet activity is generally most intense during the first 24 hours and subsides to a very low level after 1 week.[9] Neointimal hyperplasia in prosthetic conduits can be attributed to upstream and downstream events. The upstream factors include; hemodynamic stress at the graft-vein anastamosis, compliance mismatch between the graft material and vein (more studies required to establish this factor), arterial injury at the time of graft placement, intrinsic properties of the synthetic graft itself (shown to attract macrophages which then secrete specific cytokines bFGF, PDGF, and VEGF), graft injury from dialysis needles, as well as the presence of uremia (causing endothelial dysfunction even prior to synthetic graft implant).[12-14] The downhill events are essentially a consequence of the upstream events. Pro-inflammatory cells release cytokines promoting the migration of smooth muscle cells and myofibroblasts from the adventitia media into the intimal layer, where they proliferate and cause lesions of neointimal hyperplasia.[13] These stenotic lesions are usually treated by percutaneous angioplasty (PTA) or open patch angioplasty, which unfortunately, predisposes the patient to restenotic lesions due to endothelial and smooth muscle cell injury.[15]

Infection is the second most common complication of synthetic grafts and can lead to further complications such subacute bacterial endocarditis, epidural or brain abscess.[11] These complications can lead to graft failure in up to 35% of patients.[16] Graft infections have an incidence rate as high as 2%, and are 4 times as prevalent in synthetic grafts when compared to autogenous veins.[9] Common causative organisms are Staphylococcus aureus (26.32% of

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Johnson et al.[47]	USA	1983	548 Impra® grafts	N/A	N/A	N/A	Early thrombosis (<6 weeks) 9.58%; Late thrombosis (>6 weeks) 17.52%; Infection 7.12%; Perigraft hematoma 2.01%; Steal syndrome 15	7- yr cumulative patency 55%
Munda et al.[48]	USA	1983	67 (55 Gore-Tex®, 12 Impra® grafts)	N/A	N/A	N/A	Graft thrombosis (21%), infection (25%), or stenosis by neointimal hyperplasia (34%), pseudoaneurysm formation (8%), steal syndrome (3%)	Cumulative patency of 67% ± 6% (12 mo), 50% ± 7% (24 mo), 43% ± 9% (48 mo).
Schanzer et al.[49,50]	USA	1989	65 (30 Vasutek vs. 35 control PTFE grafts)	63% vs. 66% at 1 yr	N/A	75% vs. 67% at 1 yr	Thrombosis 36.6% vs. 28.5%; Infection 13.3% vs. 11.4% Seroma 3% vs. 0% Steal 3% vs. 0% Pseudoaneurysm 0% vs. 17.1	In PTFE-silicone group, mean time to first use was 1.3 days vs. 2 to 4 weeks for conventional PTFE grafts. Bleeding after needle removal was significantly decreased after early and late punctures of PTFE-silicone grafts vs. conventional PTFE grafts ($p < 0.001$).
Tsuchida et al.[29]	Japan	1992	Experiment 1: 20 carbon lined (CL) vs. 20 control PTFE grafts Experiment 2: 12 high porous grafts vs. 12 control PTFE grafts	N/A	N/A	N/A	N/A	Graft platelet accumulation index (GPAI) of CL graft was significantly reduced.

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Tordoir et al.[20]	Netherlands	1995	37 (17 stretch ePTFE vs. 20 standard ePTFE grafts)	59% vs. 29% (1 yr)	N/A	N/A	Thrombotic events: 40% (standard) vs. 12% (stretch)	Stretch ePTFE has better primary patency rates and less stenosis due to intimal hyperplasia vs. standard ePTFE grafts.
Dawidson et al[22].	USA	1996	270 Gore-Tex® stretch graft (96 cannulated within 14 days, 174 cannulated after 14 days)	N/A	N/A	N/A	Thrombosis: 14% of early cannulation group vs. 7% in late cannulation group. Infection: 7% early cannulation group vs. 1% late cannulation group.	Graft survival in late cannulation group (beyond 14 days) was 93, 92, and 91% vs. 80, 78 and 73% for the early cannulation group (earlier than 14 days) at 1, 2, and 3 yr. respectively (p=0.0008).
Taylor et al.[51]	USA	1996	45 lower extremity access grafts (39 ePTFE, 6 modified bovine heterographs)	59% (12 mo) 47% (24 mo)	N/A	N/A	Thrombosis (33%) graft infection (18%), distal limb ischemia (16%), aneurysmal dilatation of the graft requiring revision (7%), and fistula-induced congestive heart failure symptoms (4%)	Lower extremity AV dialysis accesses are associated with multiple complications and should be placed only if significant patient morbidity can be accepted and justified.
Hakaim et al.[21]	USA	1997	79 stretch ePTFE grafts (48 underwent early cannulation and 31 late cannulation)	N/A	N/A	N/A	Thrombosis occurred before cannulation in 2.0% of early cannulation and 3.2% of late cannulation group.	Cumulative primary patency estimates for early cannulation were 89%, 82%, and 70% vs. 86%, 78% and 74% for the late cannulation group at 3, 6, and 12 mo. respectively. Early cannulation of prosthetic dialysis grafts did not increase perioperative morbidity rates or decrease 12-month cumulative primary patency rates.

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Ritter et al.[52]	USA	1997	6 male rats per test group (control, Heparin irrigated and TDMAC heparin irrigated)	N/A	N/A	N/A	Mean number of emboli during a 20-minute period was 91 for the control group, 84 for the heparin-irrigated group, and 22 for the TDMAC-heparin group.	TDMAC-heparin coating of ePTFE microvascular prostheses reduces downstream microemboli.
Kaufman et al.[18]	USA	1997	129 (65 Impra® and 64 Gore-Tex® grafts	1 yr (Impra® 43%, Gore-Tex® 47%) and at 2 yr (Impra® 30%, Gore-Tex® 26%) (p = 0.78)	N/A	1 yr (Impra® 49%, Gore-Tex® 69%) and at 2 yr (Impra® 33%, Gore-Tex® 41%) (p = 0.15)	Thrombosis Infection: 11% Impra® and 14% Gore-Tex® Steal Syndrome: 6% in each group	No difference in the performance of 6-mm standard ePTFE grafts on the basis of manufacturer, whether Gore-Tex® or Impra®.
Khadra et al.[53]	Australia	1997	74 thigh PTFE grafts	N/A	N/A	N/A	Infection: 16%	Mean survival time for thigh PTFE grafts was 84.6 weeks (SD 76.1). Infection rate (16%) vs. forearm infection rates (20%).
Schuman et al[23]	USA	1997	632 grafts (438 reinforced Gore-Tex® vs. 194 nonreinforced Impra® grafts	Greater primary patency for nonreinforced Impra® grafts at 1 yr. (p=0.02)	N/A	80% nonreinforced vs. 77% reinforced at 1 year	Reinforced Gore-Tex® had a mean of 2.75 thrombosis/graft and required 1.20 revisions/graft, while non-reinforced Impra® only had a mean of 2.45 thrombosis/graft with 1.09 revisions/graft	Non-reinforced PTFE performed better than reinforced PTFE
Hurlbert et al.[19]	USA	1998	190 (100 Gore-Tex® vs. 90 Impra® grafts)	No difference between Gore-Tex® and Impra® grafts at 2 yr (P > 0.53)	N/A	No difference between Gore-Tex® and Impra® grafts at 2 yr (P > 0.13)	Ccomplications was similar between the two grafts.	No difference between Gore-Tex® and Impra® in the number of days before the first thrombectomy or in the number of thrombectomies or revisions per graft (P > 0.50).

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Jeschke et al[54]	USA	1999	69 [37 polycarbonate polyurethane (PU) vs. 32 ePTFE] grafts into abdominal aortas of male Sprague-Dawley rats	N/A	N/A	N/A	Neointimal cell proliferation lower in PU grafts compared with ePTFE at 56 days (1.4 +/- 0.1µ versus 8.6 +/- 1.5µ, P <.001) and at 6 mo (0.15 +/- 0.002µ versus 3.4 +/- 0.5µ, P <.001). Neointimal thickness at 6 mo after implantation was 3.2 +/- 0.8µ for PU compared with 10.3 +/- 3.1µ for ePTFE (P <.05).	Luminal surface of PU grafts took 4 weeks to completely endothelialize, whereas ePTFE grafts took 24 weeks (P <.05).
Longest et al.[25]	USA	2000	Computer Hemodynamic Analysis of Venaflo® II	N/A	N/A	N/A	N/A	Geometric design of the new graft-end was based on the reduction of three time- and area-averaged hemodynamic parameters (including the wall shear stress angle gradient, wall shear stress angle gradient, and radial pressure gradient).
Lemson et al.[24]	Netherlands	2000	120 (59 cuffed PTFE vs. 61 standard PTFE grafts)	Control: 69%, 56% , 42%, 34% vs. cuff group: 62%, 43%, 30%, and 19% at 6 mo, 18 mo, 2 yr respectively (P = .097)	Control: 76% , 62% , 52%, 43% vs. cuff group: 71%, 60%, 53%, and 41% at 6 mo, 18 mo, 2 yr respectively (p=0.53)	Control: 86%, 84%, 79% vs. cuff group: 89%, 81%, 76%, and 65% at 6 mo, 18 mo, 2 yr respectively (p=0.42)	Thrombotic occlusion lower in cuff group (0.68 ppy) than in control (0.88 ppy) (p=0.0007) Stenosis- CG: 0.22 ppy vs. control: 0.14 ppy; Infection- CG: 0.06 ppy vs. control: 0.01 ppy; Hemorrhage- CG: 0.10 ppy vs. control: 0.01 ppy; Pseudoaneurysm- CG: 0.04 ppy vs. control: 0.02 ppy; Ischemia- CG: 0.04 ppy vs. control: 0.00 ppy; Venous hypertension- CG: 0.00 ppy vs. control: 0.01 ppy; Seroma- CG: 0.04 ppy vs. control: 0.04 ppy	Cuffed PTFE did not result in a better patency rate. Initial vein diameter and local problems (edema, obesity, or skin atrophy) appear to be the most important risk factors for graft failure.

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Glickman et al. [35]	USA	2001	142 (71 Vectra® vs. 71 Gore-Tex® or Impra® grafts)	55% vs. 47% (6 mo) and 44% vs. 36% (12 mo) (P >.05).	N/A	87% vs. 90% (6 mo) and 78% vs. 80% (12 mo). (P >.05).	Higher incidence of graft kinking in PUU group (p<0.001) Infection, anastomotic obstruction or thrombosis, pseudoaneurysm, kinking, stenosis, wound healing	At ≥5 minutes, more PUU cannulation sites achieved hemostasis compared with ePTFE sites (P <.0001). 53.9% of all PUU grafts were cannulated before 9 days versus none with the ePTFE grafts (P <.001).
Nyberg et al.[27]	USA	2001	12 Venaflo® II grafts	N/A	N/A	Graft patency rates were 90.9% at 1 yr and 68.2% at 2 yr	No early postoperative complications. One graft was lost to thrombosis in the first yr; two grafts were lost to thrombosis in the second yr.	Cuffed ePTFE graft provided stable blood flow and satisfactory graft patency during 2 yr of follow-up, even in high risk patients with a prior history of vascular access thrombosis.
Sorom et al.[26]	USA	2002	48 (24 Venaflo® II vs. 24 Gore-Tex® grafts)	A significant advantage in primary graft patency was observed with the Venaflo® II at 12 months after placement (*P* <.01).	N/A	Significant improvement observed in the Venaflo® II group compared with the Gore-Tex® group at both 12 months (+32%, *P* = .037) and 24 months +37%, *P* = .021).	Graft-vein anastamosis stenosis: 15% Venaflo® II vs. 41% Gore-Tex®	Graft patency at 12 mo. was 64% vs. 32% (P =.037) and 58% vs. 21% at 24 mo. (P =.0213) for Venaflo® II and Gore-Tex® respectively. Incidence of graft failure was lower in the cuffed ePTFE graft group (P =.039).

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Huber et al.[55]	USA	2003	34 study meta-analysis (autogenous vs. various PTFE access)	72% vs. 58% (6 mo) 51% vs. 33% (18 mo)	N/A	86% vs. 76% (6 mo) 77% vs. 55% (18 mo)	N/A	Patency rate for upper extremity AVF in adults is superior to that for PTFE counterparts, although the overall quality of the studies in the meta-analysis was less than ideal.
Kiyama et al.[56]	Japan	2003	58 (30 Thoratec® PVG vs. 28 Gore-Tex® stretch grafts)	60.7% vs. 56.5% (1 yr); 54.7% vs. 51.8% (2 yr) PVG and Gore-Tex® stretch graft respectively	N/A	78.7% vs. 79.9% (1 yr); 78.7% vs. 69.3% (2 yr) PVG and Gore-Tex® stretch graft respectively	Thrombosis: 26.7% vs. 35.7%; Stenosis: 23.3% vs. 28.6%; Infection: 6.7% vs. 14.3%; Seroma: 0% vs. 3.6%; False aneurysm: 0% vs. 3.6%; Kinking: 3.3% vs. 3.6%; Arterial Steal: 0% vs. 3.6% PVG and Gore-Tex® stretch graft respectively	PVG is an acceptable alternative to the stretch ePTFE.
Peng et al.[57]	Singapore	2003	163 PVG	73% at 1 yr	N/A	86% at 1 yr; 64% at 3 yr	32.7% graft infection rate; 30% graft thrombosis rate. Infection caused 61.5% of graft loss	PVG were first cannulated at a median time of 19 days after implantation, with 12% used within 3 days.
Laredo et al.[28]	USA	2003	10 bilateral aortoiliac grafting in dogs (5 heparin adsorbed Carboflo® vs. 5 control Carboflo® grafts)	87.5% heparin coated vs. 50% control (7 days) P=0.28	N/A	N/A	N/A	8% of preimplantation heparin activity remained on heparin grafts after 2 hours and only 2% after 7 days.
Hazinedaroglu et al. [58]	Turkey	2004	5 PU grafts	N/A	N/A	N/A	N/A	Patients implanted with a PU graft were dialyzed within hours after surgery.

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Jefic et al.[34]	USA	2005	133 PUU grafts	51% and 33% at 6 mo and 1 yr respectively.	N/A	78% and 61% at 6 mo and 1 yr respectively	24% patients died (unrelated to graft placement), 49% (n=50) had graft thrombosis (94% or 47/50 underwent successful percutaneous thrombectomy)	Within the first 4 days after graft placement, 108 of 133 grafts (81%) were cannulated.
Liu et al. [59]	Taiwan	2006	39 (17 Venoflo II vs. 19 Gore-Tex® grafts)	N/A	N/A	N/A	Mean degree of stenosis in non-cuffed graft group (44.95%) was greater than that of the cuffed graft group (22.76%)	Degree of venous stenosis was significantly reduced.
Schild et al.[36]	USA	2007	30 Vectra® grafts in HIV + patients	42% at 12 mo	N/A	N/A	10% (n=3) developed infection	Infection was less (10% vs. 45%)
Tsoulfas et al.[60]	USA	2008	67 (41 Venaflo® II vs. 26 control ePTFE grafts)	37.7% vs. 25.7% at 1 yr, 35% vs. 10.3% at 2 yr, 28% vs. 5.1% at 3 yr (p = 0.086)	N/A	81.8% vs. 56.1% at 1 yr, 61.8% vs. 46.3% at 2 yr, 51.5% vs. 33.1% at 3 yr (p=0.047)	Thrombosis as a cause of complete graft failure was higher (34%) in the standard group than in the cuffed group (9%) (p = 0.0125). Infection of the graft was observed in 12% of the cuffed group and in 6% of the standard group (p = 0.55)	Cuffed ePTFE graft provided better long-term outcome.
Kakkos et al.[33]	USA	2008	117 (76 Vectra® grafts vs. 41 TBB)	92% vs. 100% (1 mo); 50% vs. 46% (12 mo); 26% vs. 31% (18 mo) P=0.62	93% vs. 100% (1 mo); 70% vs. 82% (12 mo); 58% vs. 78% (18 mo) P=0.033	97% vs. 100% (1 mo); 81% vs. 88% (12 mo); 87% vs. 84% (18 mo) P=0.91	6.6% graft infection rate Postoperative complications more frequent in TBB fistulas and late complications in Vectra® grafts.	Use of Vectra® grafts and TBB fistulas started after a median of 14 (7-30) and 70 (52-102) days, respectively (P < .001)

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Davidson et al.[30]	USA	2009	150 (83 Propaten® vs. 67 control ePTFE grafts)	CFS for all grafts was 69% at 12 mo. CFS for heparin bonded group was 88% and 78%, vs. 69% and 58% for the control group at 6 mo and 1 yr, respectively (p=0.007).	N/A	N/A	N/A	Heparin binding technology resulted in a 20% improved primary graft patency of about 80% at one yr.
Schild et al. [61]	USA	2010	31 Flixene grafts	78% at 6 mo	86% at 6 mo	N/A	N/A	94% of the patients were cannulated within 24 hours. 3% were cannulated within 24-48 hours 3% were cannulated within 48-72 hours.
Lioupis et al. [62]	United Kingdom	2010	108 (48 BBAVF, 15 ABBA, and 48 Flixene graft)	27%, 51%, and 55% for ABBAs, BBAVFs, and grafts respectively at 18 mo	N/A	N/A	Complications were not more frequent in AVGs than ABBAs and BBAVFs (p=0.127)	Median time to first use for AVGs was shorter (p<0.0001). Complications were not more frequent in AVGs than ABBAs and BBAVFs (p=0.127).

Abbreviations: polytetrafluoroethylene (PTFE), expanded polytetrafluoroethylene (ePTFE), carbon lined (CL), graft platelet accumulation index (GPAI), high porous (HP), tridodecylmethylammonium chloride (TDMAC), polycarbonate polyurethane (PU), per patient year (PPY), polyurethaneurea (PUU), polyurethane vascular graft (PVG), transposed brachio-basilic fistula (TBB), clot free survival (CFS), autogenous brachial vein-brachial artery access (ABBA), brachio-basilic arteriovenous fistula (BBAVF), Not available (N/ A)

Table 1. Clinical trials of prosthetic grafts for hemodialysis.

infections cultured), methacillin resistant Staphylococcus aureus (21.05%), followed by Pseudomonas aeruginosa (5.26%).[11] The largest number of infections occur when patients are going under routine dialysis (more than 50% of patients) and as a complication of chronic cannulation, rather than postoperative complications.[11] Reducing *Staphylococcus aureus* carrier state in patients undergoing HD and improving antiseptic technique may reduce the rate of infections in grafts.

2.3 Characteristics of PTFE grafts

While PTFE is available in various configurations and is produced by various manufacturers, very few have proven to be more beneficial in improving patency in randomized clinical trials for long-term.[1]

2.3.1 Effect of wall thickness

In order to examine the effect of wall thickness on patency, Lenz et al.[17] investigated both standard wall and thin wall configuration of PTFE. Although the incidence of complications and mortality did not statistically differ amongst the 2 groups, standard ePTFE had better patency rates. Studies comparing 2 manufacturers of ePTFE grafts: Gore-Tex® (W.L. Gore and Associates, Flagstaff, AZ) and Impra® (C. R. Bard Inc., Murray Hill, NJ) did not find any difference in the performance of 6-mm standard ePTFE grafts.[18 19]

2.3.2 Effect of stretch characteristics

In an attempt to reduce kinking of the graft in areas of angulation and to improve intraoperative handling, the graft was modified to stretch (Gore- Tex® Stretch). Tordoir et al. reported a cumulative primary patency rate of 59% in the stretch ePTFE group compared to 29% in standard ePTFE group at 1 year ($p < 0.01$). In addition, there were significantly fewer thrombotic events for the stretch ePTFE grafts as opposed to the standard ePTFE grafts (40%vs. 12%, $p<0.001$).[20] Early cannulation of stretch ePTFE grafts was not found to increase peri-operative morbidity rates or decrease 12-month cumulative primary patency rates.[21] In contrast, another study comparing the patency of early cannulation with late cannulation in Gore-Tex® stretch grafts showed that graft patency after thrombosis formation was significantly higher in the late cannulation group ($p=0.0002$).[22]

2.3.3 Effect of ringed reinforcement

Ring reinforced grafts were created to reduce kinking at the apex of loop grafts and decrease incidence of thrombosis associated with external compression. In a retrospective study in which 632 reinforced and non-reinforced PTFE grafts were compared for patency and complications, it was found that non-reinforced grafts had higher primary and secondary patency rates.[23]

2.3.4 Effect of cuff or hood on venous ourflow

One of the few modifications that improved patency rates in PTFE vascular grafts was placing a cuff or hood on the venous outflow. The main objective of placing a cuffed PTFE graft is to enlarge the outflow, and reduce mechanical sheer stress in order to reduce thrombotic occlusion caused by neointimal hyperplasia.[1] In a computer simulated model, Venaflo® II (C. R. Bard Inc., Murray Hill, NJ), a flared-end ePTFE graft to simulate a vein

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Wellington [63]	Canada	1981	23 Dardik Biograft™	N/A	N/A	N/A	Thrombosis: 26.1%; Infection: 13.0%	Overall patency rate at 1 yr was 60% (no obvious superiority of umbilical vein over expanded Teflon grafts)
Hurt el al.[64]	USA	1983	140 (62 Artegraft® vs. 78 PTFE [Gore-Tex® or Impra®] grafts)	N/A	N/A	N/A	No difference between BCAH and PTFE	Survival rate: 3 mo. (93% vs. 84%); 1 yr. (84% vs. 65%); 2 yr (72% vs. 63%); 3 yr (54% vs. 56%) for BCAH and PTFE respectively.
Enzler et al.[65]	Switzerland	1996	720 (429 AVF and 291 grafts [150 bovine xenografts, 69 PTFE grafts, 59 sheep collagen grafts, 10 autologous and 1 homologous vein grafts])	AVF: 70%, 64%, 59%, 51%, 32% at 1, 2, 3, 5, and 10 yr. respectively. Grafts: Bovine Xenografts: 51%, 21%, 13%; PTFE: 41%, 24%, 24%; Sheep Collagen: 54%, 48%, 39% at 1, 2, and 3 yr. respectively.	N/A	AVF: 74%. 67%. 64%, 56%, 36% at 1, 2, 3, 5, and 10 yr. respective-ly. Grafts: Bovine Xenografts: 56%, 29%, 24%; PTFE: 58%, 47%, 40%; Sheep Collagen: 71%, 58%, 45% at 1, 2, 3 yr. respectively	Overall Complication rate: 20.71% AVF, 66.6% PTFE, 55.93% sheep collagen, 37.33 bovine xenograft Infection: 0% AVF, 10% PTFE, 2% sheep col1agen, 1% bovine xenograft Thrombosis: 12% AVF, 45% PTFE, 44% Sheep collagen, 27% bovine xenograft..	AVF remains the procedure of choice. PTFE appears to be a reasonable second choice.
Bacchini et al. [42]	Italy	2001	53 PTFE, 10 reinforced PTFE, and 22 ProCol® grafts 404 native AVF	17.4 % (PTFE) vs. 23.9% (BMVG) at 12 mo AVF: 43% at 12 mo	N/A	50% at 12 mo and 6.6% at 50 mo for PTFE; 81.9% at 19 mo for BMVG; AVF: 52.4% at 50 mo and 46.5% at 90 mo	N/A	22 patients with a 20 mo follow-up confirms better survival of BVMG than PTFE ($p < 0.04$).

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Glickman et al. [43]	USA	2003	74 (59 ProCol® vs. 15 ePTFE grafts [Impra®, Gore-Tex® or Boston Scientific])	33% in BMVG vs. 18% in ePTFE group at 1 yr (p=0.120)	45% BMVG vs. 18% ePTFE at 1 yr (p=0.011)	67%/59% for BMVG group vs. 45%/15% for ePTFE group at 1 yr and 2 yr respectively (p=0.006)	Infection and thrombosis in the BMVG group were lower than the ePTFE group.	80% of the ePTFE grafts were abandoned vs. 34% of the BMVG group.
Matsuura et al.[39]	USA	2004	19 SynerGraft® in 12 canines (11 between carotid artery and jugular vein and 8 between femoral artery and vein)	72.6% and 58.6% for SG vs. 57.4% and 54.7% for the ePTFE grafts at 6 mo and 12 mo respectively.	N/A	N/A	None of the SG grafts became infected, but ePTFE graft group became infected within 54 days of implantation.	At 10 weeks, SG showed fibroblast cell migration and proliferation with incorporation into the surrounding subcutaneous tissue, and elongated cells expressing the contractile protein smooth muscle actin were also observed. After 24 weeks, procollagen synthesis was demonstrated in the fully colonized graft matrix.
Katzman et al.[44]	USA	2005	276 (183 ProCol® and 93 synthetic grafts [90 ePTFE, 1 silicone, 2 PUU])	35.6% ProCol® vs. 28.4% synthetic grafts at 12 mo (p=0.524)	N/A	65.6% ProCol® vs. 55.5% synthetic at 12 mo. 60.3% ProCol® vs. 42.9% synthetic at 24 mo (p =0.036).	Complication rates, including dilation, seroma, infection, and thrombosis, were lower for the ProCol® vs. synthetic grafts (p < 0.001).	Intervention rate was lower in the ProCol® group (0.97 versus 1.37) vs. synthetic grafts (p = 0.003).

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Madden et al.[66]	USA	2005	54 (27 SynerGraft® vs. 27 PTFE grafts)	No significant differences	No significant differences	No significant differences	No infections were seen in either group, but 2 aneurysms occurred in the SG group. No significant difference in the number of thrombectomies between the SG and PTFE groups (1.2 vs. 2.0, p = 0.3) Significantly more fistulagrams were performed in the SG group (p <0.05). Mild Steal syndrome: 1 SG vs. 4 PTFE recipient	Study interrupted by FDA. Considering the total number of interventions required by each group to maintain patency, patients with SG had a higher total cost than those with PTFE grafts. In patients without sufficient vasculature for native AVF, results do not support the routine use of SG in the general dialysis population.
Emrecan et al.[67]	Turkey	2006	4 total SynerGraft®	Patient 1 and 2: Radial artery-brachial vein implantation, and had a patency of 5 mo and 6 mo respectively. Patient 3 and 4: Brachial arteryaxillary vein implantation and had patency of 8 mo and 7 mo respectively.	N/A	N/A	Patient 4: True and pseudoaneurysm	N/A

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Darby et al.[40]	United Kingdom	2006	25 SynerGraft®	29% at 1 yr	45% at 1 yr	81% at 1 yr	5% infection rate at 1 yr	SG is an alternative when autologous vein is not available.
Tahami et al.[68]	Switzerland	2007	46 (23 ProCol® vs. 23 ePTFE grafts)	Patency rates did not differ	N/A	Patency rates did not differ	Less severe complications in the BMVG group	The BMVG is a viable alternative for HD access in patients where autologous construction is not possible, and should be given priority in patients with a failed ePTFE graft or high risk for infection.
Chemla et al.[41]	United Kingdom	2009	56 (29 SynerGraft® vs. 27 ePTFE grafts)	28% for SG vs. 48 % for ePTFE at 1 yr P = 0.290	52% vs. 64% at 1 yr P = 0.430	57% vs. 68% at 1 yr P = 0.370	4% vs. 9% infection rate for SG and ePTFE at 1 yr respectively (p=0.410)	Both grafts were adequate conduits for HD and amenable to repair. Anticipated advantages for SG were not seen in either patency or stability.

Abbreviations: bovine carotid artery heterograph (BCAH), polytetrafluoroethylene (PTFE), arteriovenous fistula (AVG), bovine mesenteric vein graft (BMVG), preserved saphenous vein (PSV), Endoscopic Vessel Harvesting System (EVHS), hemodialysis (HD), SynerGraft® (SG), polyurethaneurea (PUU), Not available (N/ A).

Table 2. Clinical trials of biological conduits for hemodialysis

cuff, showed measurable improvements in reducing wall shear stress gradient, wall shear stress angle gradient, and radial pressure gradient.[25] Sorom et al.[26]found that Venaflo® II was associated with increased blood flow rates during HD and improved graft patency compared with ePTFE graft. Similarly, in a smaller study it was found that a flared-end ePTFE graft provided stable blood flow and satisfactory graft patency during 2 years of follow-up, even in high risk patients with a prior history of vascular access thrombosis.[27] However, a European study did not show improvement in patency rate despite a reduction in thrombotic occlusion and stenosis.[24]

2.3.5 Effect of coating PTFE

Another technique meant to improve PTFE graft has been coating the PTFE vascular grafts with carbon or heparin to prevent early graft failure and improve overall patency rates.[28] In a canine model, Tsuchida et al. showed that the graft platelet accumulation index (GPAI) was significantly ($p<0.05$) lower in the carbon lined PTFE group when compared to the control PTFE group.[29] They concluded that carbon lining decreases platelet accumulation on PTFE grafts. Propaten®, ePTFE with bioactive heparin covalently bound to it (W.L. Gore and Associates) has also been shown to be effective in improving graft patency. It is the only vascular graft of its kind approved for HD access on the market. Davidson et al. [30] found 20% improved primary graft patency of about 80% at one year when comparing Propaten® to standard ePTFE. In order to diminish the risk of neointimal hyperplasia. Cagiannos et al.[31] studied the effects of coating an ePTFE graft with rapamycin in a porcine model. They showed that the rapamycin coated grafts significantly ($P <0.0001$) lowered cross sectional narrowing in the outflow graft when compared to non-coated grafts; as well as no evidence of medial necrosis or aneurysmal degeneration. After a four week observation period, coated grafts showed features of diminished neointimal hyperplasia compared to untreated ePTFE grafts. Researchers have also analyzed the effect of a bioabsorbable vascular wrap mesh containing paclitaxel on neointimal hyperplasia in a sheep model. Paclitaxel coated mesh significantly reduced neointimal hyperplasia and neointimal capillary density without toxicity to adjacent vessels.[32]

2.3.6 Self-sealing grafts

K/ DOQI recommends that PTFE grafts should not be routinely used until at least 2 weeks after placement and not until swelling has subsided so that palpation of the course of the graft can be performed. This time is needed for tissue-to-graft incorporation, reducing peri graft hematoma.[1] Due to this complication, newer "self-sealing" grafts have been designed that can be cannulated sooner.[11] Vectra® vascular grafts (C. R. Bard Inc., Murray Hill, NJ) made of a proprietary blend of segmented polyetherurethaneurea and a siloxane containing a surface-modifying additive (SMA), were designed to provide early cannulation, reducing the need for temporary central venous catheters to provide access until the graft matures. In a study of 76 patients, in which Vectra® grafts were compared to transposed brachio-basilic vein (TBB) autogenous access, Kakkos et al.[33] found that aggressive graft surveillance and endovascular treatment methods resulted in equivalent long-term secondary patency rates. The advantage of earlier use of Vectra® graft must be balanced against the need for more frequent secondary interventions and the risk of graft infection. In a single center study, Jefic

et al. obtained 81% (108 of 133 grafts) cannulation rate within 4 days of Polyurethane (PU) [Thoratec® Vascular Access Graft] graft placement in which none of the recipients required a temporary catheter. A shorter mean bleeding time after withdrawal of dialysis needle was also acquired in the PU graft group (4.0 minutes vs. 9.2 minutes in ePTFE group).[34] Similarly, Glickman et al. showed that PU grafts had achieved better hemostasis at cannulation sites compared to ePTFE sites when the two were compared at 5 minutes or less after dialysis ($P<0.0001$). Also, they showed that 53.9% of all PU grafts were cannulated before 9 days vs. none of the ePTFE grafts ($P<0.001$).[35] In the HIV- positive ESRD patient population, reduction of temporary catheter use and prevention of infection is critical. A study of 30 consecutive HIV positive patients receiving Vectra® graft implantation showed a lower infection rate (10% vs. 45%) than published reports of infection in PTFE grafts. It was concluded that the unique self-sealing property of the Vectra® grafts reduced the development of perigraft hematoma and may have accounted for decreased infection.[36]

3. Biological conduits for hemodialysis

Biological graft materials tend to have less intimal hyperplasia at the venous anastamosis, reduced tendency to thrombose, and a lower risk of infection when compared to PTFE.[11] Butler et al. compared bovine heterographs to PTFE and found that the synthetic graft had significantly fewer late thromboses, increased resistance to infection, easier to repair and had comparable longevity.[37] Anderson et al. found that bovine heterographs required twice as many revisions per dialysis month to maintain patency.[38]

SynerGraft® 100 (SG100 [CryoLife Inc., Atlanta, GA]) is a modified bovine ureter graft with some similarities to synthetic graft (similar internal diameter and strong tissue matrix). This graft has been processed to remove xenograft cells while maintaining a collagen matrix that is not chemically cross-linked by aldehydes allowing re-population by autologous cells. Matsuura et al. reported a primary patency rate of 72.6% and 58.6% for SG 100 vs. 57.4% and 54.7% for the ePTFE grafts at 6 months and 12 months, respectively. SG 100 graft showed fibroblast cell migration and proliferation with incorporation into the surrounding subcutaneous tissue after 10 weeks, and procollagen synthesis demonstrated at 24 weeks; while the ePTFE graft had no evidence of cellular ingrowth.[39] In a study of 23 patients receiving SG 100 grafts, Darby et al. found that the bovine ureter graft was a stable vascular access conduit, providing a suitable graft alternative when autologous vein was not available. Their study showed 29% primary, 45% primary assisted, and 81% secondary patency rates at 1 year, with only a 5% infection rate.[40] On the other hand, Chemla et al. found that both grafts were adequate conduits for HD, the anticipated advantages for SG 100 were not seen in either patency or stability.[41]

4. Future developments in prosthetic and biological conduits for hemodialysis

The use of pharmacological agents may hold the promise of long-term graft patency. Treatment with 200 mg of dipyridamole and 25 mg of aspirin twice daily resulted in significant improvement of patency rates while adverse effects in both the treatment and placebo groups remained the same.[45] Other agents, such as fish oil and anticoagulants have also been tried with limited success (table 4).

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Cagiannos et al[31]	USA	2005	22 Mongrel pigs into 3 groups: untreated ePTFE (n=6), adhesive-only coated ePTFE (n = 6), or adhesive- and Rapamycin-coated ePTFE (n = 10)	N/A	N/A	N/A	N/A	Rapamycin-eluting ePTFE grafts decrease neointimal hyperplasia in a porcine model.
Kohler et al[32]	USA	2007	40 male sheep into 5 groups: no mesh; or a 3-cm x 6-cm mesh with 0.0, 0.3, 0.7, or 1.2 μg/mm² of paclitaxel for a total dose of 0.0, 0.6, 1.3, or 2.2 mg, respectively.	N/A	N/A	N/A	N/A	Paclitaxel-eluting mesh significantly reduced neointimal hyperplasia and neointimal capillary density without toxicity to the adjacent vein.
Heise et al[46]	Germany	2010	In-vitro study of double outflow (bi-flow) grafts	N/A	N/A	N/A	N/A	New graft design addresses two major problems responsible for the development of venous stenosis of prosthetic grafts.

Abbreviations: expanded polytetrafluoroethylene (ePTFE), Not available (N/ A)

Table 3. Clinical trials of experimental conduits for hemodialysis

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Sreedhara et al.[69]	USA	1994	Dipyridamole, Aspirin, Dipyridamole + Aspirin, or placebo in: 84 Type I (new ePTFE graft) patients 23 Type II (previously revised ePTFE graft) patients	N/A	N/A	N/A	Angina pectoris, GI bleeding, headache, nausea, and vomiting reported	Type I patients: At the end of the 18 mo follow-up, cumulative rates of thrombosis were: 21± 9% on dipyridamole, alone, 25±11% on dipyridamole and aspirin combination, 42±13% on placebo, and 80±12% on aspirin alone. RR of thrombosis with dipyridamole was 0.35 (P = 0.02) with 95% CI of 0.15 and 0.80. The RR with aspirin was 1.99 with 95% CI of 0.88 and 4.48 (not significant, P=0.18). Type II patients: high thrombosis rates regardless of treatment group. Overall, 78% thrombosis in Type II patients and no statistical differences between study groups.
Zibari et al.[70]	USA	1997	408 various vascular access procedures (206 pre-operation treatment with vancomycin vs. 202 non-medicated control group)	N/A	N/A	N/A	Access infection developed in 1% of vancomycin group and in 6% of control group (P = 0.006). All 14 infections occurred in upper extremity PTFE grafts.	Use of preoperative single-dose IV vancomycin prophylaxis for hemodialysis vascular graft procedures reduces the risk of postoperative access infection

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AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Schmitz et al.[71]	USA	2002	24 total new Gore-Tex® graft patients (12 fish oil vs. 12 control oil group)	75.6% fish oil-treated group vs 14.9% control group at 1 yr	N/A	N/A	Gas, bloating most common complaints	Survival analysis revealed a significant difference between fish oil-treated and untreated patients ($P < 0.03$), with a power of 90%. Fish oil treatment also decreased venous outflow resistance and systemic BP, compared with control values.
Lok et al.[72]	USA	2007	232 new grafts for access (116 fish oil treatment vs. 116 control group)	N/A	N/A	N/A	N/A	Results of study not yet published
Dixon et al.[45]	USA	2009	649 total patients: 321 in dipyrida-mole and aspirin group vs. 328 in placebo group.	23% placebo vs. 28% dipyridamole/ aspirin group at 1 yr	N/A	N/A	Graft failure, death, and serious adverse events (including bleeding) did not differ significantly between study groups	Treatment with dipyridamole plus aspirin had a significant but modest effect in reducing the risk of stenosis and improving the duration of primary unassisted patency of newly created grafts
Chan et al.[73]	USA	2009	Anticoagulant and antiplatelet medications on 41,425 dialysis patients (8.3% on warfarin 8.3%, 10.0% on clopidogrel, 30.4% on aspirin, 8.1% patients on at least two of these drugs, and 59.7% not medicated)	N/A	N/A	N/A	N/A	Warfarin associated with a 27% ($P < 0.001$) increase in mortality, clopidogrel with a 24%($P = 0.0002$) increase in mortality, and aspirin with a 6% ($P = 0.02$) increase in mortality when compared with patients receiving none of these medications. Prescription of multiple drugs was associated with a 22% ($P < 0.0001$) increase in mortality. No statistically significant interaction was found among warfarin, clopidogrel, and aspirin on survival.

AUTHOR	COUNTRY	YEAR	NO. AND GRAFT TYPE	Primary Patency	ASSISTED PRIMARY PATENCY	Secondary patency	Complications	Comments
Dixon et al.[74]	USA	2011	649 patients with new AV grafts (272 on aspirin at baseline vs. 377 not on aspirin at baseline)	30% (aspirin group) vs. 23% (control) at 12 mo.	N/A	N/A	Serious adverse events in 56% of aspirin group vs. 53% of control group. Risk of bleeding, death, hospitalization, or vascular access events was not increased among participants on aspirin at baseline.	Use of aspirin at baseline associated with a dose-dependent prolongation of primary unassisted graft patency that approached statistical significance (p=0.06). Use of aspirin at baseline did not associate with prolongation of cumulative graft patency or participant survival.

Abbreviations: expanded polytetrafluoroethylene (ePTFE), polytetrafluoroethylene (PTFE), Not available (N/ A).

Table 4. Effects of various medications on vascular access grafts

In an approach of reducing neointimal hyperplasia by decreasing mechanical sheer stress, a new double channel (Bi-Flow) graft was designed. These grafts showed laminar flow and lower levels of turbulence, leading to lower risk of stenosis.[46]

5. Conclusions

Prosthetic grafts should be reserved for situations where autogenous vein is not available to perform an access. The most commonly used prosthetic graft is e-PTFE based. Newer advances in medication bonding to decrease thrombosis and formation of intimal hyperplasia may be promising. In addition, various graft characteristics such as flared-end and stretch may provide better patency. Biologic grafts are being tested; however, at this point data are lacking to show superiority over prosthetic grafts. This area is a fertile ground for randomized clinical trials in the search for a man made or biologic graft that would equal autogenous vein in patency and complication rates.

6. Abbreviations

Chronic kidney disease (CKD), hemodialysis (HD), peritoneal dialysis (PD), arteriovenous fistula (AVF), polytetrafluoroethylene (PTFE), expanded PTFE (ePTFE), transposed brachialbasilic vein (TBB), percutaneous angioplasty (PTA)

7. Definitions

Primary Patency: Interval of time from access placement to any intervention necessary tomaintain patency of access. Assisted Primary Patency: Interval of time from access placement to time of intervention necessary to maintain the functionality of the access. Secondary Patency: Interval of time from access placement to access abandonment including intervening surgical or endovascular manipulations

8. Manufacturer and graft

Graft	Graft Material	Manufacturer
Artegraft®	Bovine Carotid Artery Heterograft	Artegraft Inc., New Brunswick, NJ
Atrium Adventa™ VXT	Reinforced ePTFE	Atrium Medical Corp., Hudson, NH
Boston Scientific	ePTFE	Boston Scientific Corp., Natick, MA
Carboflo®	Carbon impregnated ePTFE	C.R. Bard Inc., Murry Hill, NJ
CryoVein®	Cryopreserved femoral vein	CryoLife Inc., Atlanta, GA
Flixene™	Trilaminate membrane	Atrium Medical Corp., Hudson, NH

Graft	Graft Material	Manufacturer
Gore-Tex®	ePTFE	W.L. Gore and Associates, Flagstaff, AZ
Gore-Tex® Intering® graft	reinforced ePTFE with radial support	W.L. Gore and Associates, Flagstaff, AZ
Gore-Tex® stretch graft	Stretch ePTFE	W.L. Gore and Associates, Flagstaff, AZ
Gore-Tex® stretch graft with removable rings	Stretch ePTFE with removable rings	W.L. Gore and Associates, Flagstaff, AZ
Impra®	ePTFE	C.R. Bard Inc., Murry Hill, NJ
Dardik Biograft™	Modified human umbilical vein	Meadox Medicals Inc., Oakland, NJ
ProCol®	Bovine mesenteric vein heterograph	Hancock Jaffe Laboratories Inc., Irvine, CA
Propaten®	Bioactive heparin convalently bound to ePTFE	W.L. Gore and Associates, Flagstaff, AZ.
SynerGraft® 100	Bovine Ureter Graft	CryoLife Inc., Atlanta, GA
Thoratec® Vascular Access Graft	Polyurethane	Thoratec Corp., Pleasanton, CA
VascuLink™	Self-sealing polycarbonate urethane graft	Lemaitre Vascular Inc., Burlington, MA
Vascutek®	Self-sealing ePTFE	Tarumo Interventional Systems, Somerset, NJ
Vectra®	Proprietary blend of segmented polyetherurethaneurea and a siloxane	C.R. Bard Inc., Murry Hill, NJ
Venaflo® II	Cuffed ePTFE	C.R. Bard Inc., Murry Hill, NJ

9. Disclaimer

The views expressed in this article are those of the authors and do not necessarily reflect the official policy of the Department of Army, the Department of Defense, or the US government.

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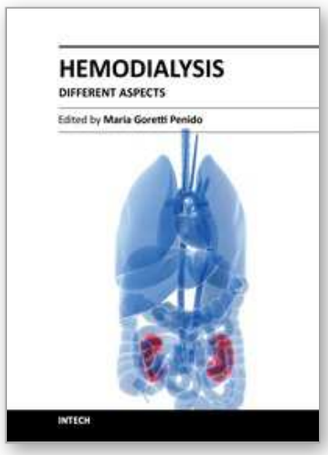
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The book provides practical and accessible information on all aspects of hemodialysis, with emphasis on day-to-day management of patients. It is quite comprehensive as it covers almost all the aspects of hemodialysis. In short it is a valuable book and an essential aid in the dialysis room.

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