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Selecting graft material for optimizing AV access for hemodialysis

HENRY C. VELDENZ

Department of Surgery, Division of Vascular Surgery, University of Florida Health Science Center, Jacksonville - USA

A native arteriovenous fistula (AVF) is the best option for patients requiring maintenance hemodialysis, but when this is not possible an arteriovenous bridge graft (AVG) is usually the next best alternative (1).

Many AVG options are currently available, but not all are well understood, and there is a paucity of solid data to help decide which graft material to choose. This is especially so for the newer innovations in AVG prosthetic grafts. The information, typically derived from industry sources, often lacks independent confirmation, both for expanded polytetrafluoroethylene (ePTFE) and for its modifications.

Since their introduction in 1975, expanded polytetrafluoroethylene grafts (ePTFE) have become the prosthetic graft of choice for hemodialysis access.(2,3,4) The original construction resulted in a thick non-compliant product that was difficult to handle and required careful tensioning and measurement for proper implantation. A thin version later became available, followed in 1991 by 'Stretch' versions that allowed for more technical leeway in measurement and tension (5). The wall thickness of stretch ePTFE from most manufacturers was around 0.6-0.65mm; and a thin walled stretch product (averaging 0.35 to 0.45mm) became available soon thereafter. As these materials were used at first for bypass conduits in peripheral vascular reconstructions, many centers performing vascular access predictably based their AVG material choice on habits derived from their peripheral vascular experience. Standard thickness ePTFE was initially used, but when thin wall ePTFE became available many centers began using them because of increased flexibility and ease of handling, despite a lack of scientific data showing the two wall configurations to be comparable in durability and patency rates. Other ePTFE modifications attempted to improve patency, durability, or hasten cannulation time by using coatings, hoods, layers, and actual ePTFE material changes - again without prospectively evaluating the claims of competing manufacturers.

Although most arteriovenous graft ultimately fail because of venous outflow tract stenosis (6) other causes of failure include pseudoaneurysms, patient hypotension, hypercoagulable states, disadvantaged inflow and outflow vessels, and graft infection. All these issues make the selection of grafts difficult and led to many attempts to overcome some of their disadvantages. The prosthetic material itself was modified by changing the wall structure, adding luminal or extramural coatings, or incorporating layers. Dacron as a graft material suffered from patency, bleeding, and wall integrity loss, but adding intra-luminal teflon did not improve the results (7, 8) nor did adding a silicone coating decrease bleeding or contribute to durable access when applied to ePTFE (7). Newer modifications have consisted of adding a carbon coating to the luminal surface (9-12) but have not been evaluated in rigorous studies, and indeed the data were derived from infrainguinal reconstructions free from cannulation trauma.

The impact of early cannulation of ePTFE AVGs has been reviewed (14). Material configurations and thickness probably have an impact on results, but the benefit of early access has been cancelled out by an increased early loss of patency (15, 16). Cannulation of ePTFE AVGs suffer from the need to stop bleeding that differs from the healing of AVF punctures. One attempt to reduce the effects of needle punctures on graft function was the Hemasite prosthesis, in which the PTFE graft incorporated a cannulation area that protected the rest of the conduit from punctures: but high rates of thrombosis and infection precluded its acceptance as a dialysis alternative (17) Another graft used a corethane/polyester composite construction, with the corethane fibers in a spun 30-60 micron pore layer

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in the lumen while the polyester reinforced the outer layer; this has had less bleeding and equal patency in animal models, but has not yet been applied to patients (18) There have been conflicting reports on the results of early cannulation of conventional ePTFE (14, 15). Hakim felt that this could be accomplished with no increased morbidity or worse patency outcomes. Coyne et al studied the stretch ePTFE versus a new multi-layered product (the Diastat) and found that the graft was plagued by higher early failure rates, a finding confirmed by other investigators (16).

When ePTFE material is looked at in isolation as a variable separate from configurations, anatomic beds, prior access history, and other patient factors in access graft outcomes, there is again little in the literature. In a prospective study Tordior et al found that the evolution of ePTFE to a "stretch" configuration was superior to the older, non-stretch configurations (19). Veldenz and Lenz et al demonstrated superior short term durability of standard thickness (0.64 mm) ePTFE compared to thin wall (0.37 mm) ePTFE20, but longer follow-up of the prospectively randomized grafts is needed. No other published study has compared the performance of differing wall thickness on AVG outcomes. Kaufman et al looked at similar thickness ePTFE from different manufacturers (6) (but introduced as a variable in that study the presence or absence of an outer wrap layer of PTFE to the conduit) and found no significant difference. Katzman (21) reported on the CHAPS study, a longitudinal review of two brands (with differences in the micro-nodal pattern of construction and the presence of on outer ePTFE wrapping layer) of ePTFE in a variety of configurations, anatomic sites, and from multiple centers. With over 678 patients and 18 months minimum follow-up, there was no real difference between group demographics and the numbers allowed comparison across differing configurations. The CHAPS study design and randomization was fair, but there was also no difference in primary patency, secondary patency, infections, and pseudoaneurysm formation (22). The material thickness of the products was not specifically mentioned.

The later study by Lenz et al tried to control for as many variables as possible in their angioaccess protocol, prospectively randomizing 108 patients so that differences in graft failure over a longer period of follow-up could be attributed to the material wall thickness itself. The forearm loop configuration was adhered to as much as possible so as to avoid the influence of configuration effects on graft outcome that others have noted (23). At an average follow-up of 36 months overall for the grafts, mean primary patency (as well as secondary patency) was 15-20% greater in the 56 patients with the standard wall ePTFE grafts as opposed to the 52 thin wall grafts. This difference was noted in early (6 month) and in later (27-36 month) patency outcomes (24).

The Lenz study could not account for the differences in the patency of the grafts except for the difference in material thickness, as other variables were controlled to a significant degree. No differences in pseudoaneurysm formation or infection was seen in either group. The Lenz study's patency rates are less than those described by most groups, the expected secondary patency rates of stretch ePTFE grafts ranging from 87-96% at six months to 86-93% at twelve months of those reported in the literature (2, 21, 24, 25, 26). Patency rates were at best 70-80% at six months and 55-75% at twelve months. In a prospective, non randomized study by Hodges et al comparing all types of dialysis access, secondary patency at one year for 215 ePTFE grafts was 59%(19) - not significantly different from the 64% one year secondary patency rate from Lenz's study.

Although most arteriovenous graft ultimately fail because of venous outflow tract stenosis (6) there are other causes of failure such as pseudoaneurysms, patient hypotension, hypercoagulable states, disadvantaged inflow and outflow vessels, and graft infection. Studies must attempt to control for as many variables as possible and randomize the patients prospectively, so that differences in graft failure can be distinguished. Issues of patient demographics, history and number of prior AVGs and AVFs, access cannulation data, adjunctive therapies, access anatomic sites, AVG configurations, and ideally target outflow quality must be addressed in any evaluation of new prosthetic material, configuration or modification. The data available today only highlights the frustrations of AVG use in hemodialysis: prosthetic access if far from ideal. For now, except for using a thick enough graft wall, the available information suggests that all ePTFE materials, modifications, and structural configurations are equivalent. Until new controlled data shows a real clinical benefit for a new ePTFE product, there is no guidance available for ePTFE AVG prosthetic material selection beyond that of using a thick enough conduit.

Reprint requests to:
Henry C. Veldenz, M.D.
Division of Vascular Surgery
Department of Surgery
University of Florida Health Science Center
Jacksonville, USA

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