CHAPTER 21

STRESS-STRAIN CHARACTERISTICS OF VASCULAR PROSTHESES: IS THERE A RELATIONSHIP TO HEALING AND GRAFT PATENCY?

Axel D. Haubold and Harvey S. Borovetz*

CarboMedics, Inc.
Austin, TX
USA
*University of Pittsburgh
Pittsburgh, PA
USA

Introduction

Considerable interest has been generated by the so-called compliance hypothesis. This hypothesis was formally introduced by Abbott et al. (1987) and by Clark et al. (1976) based on the observation that the patency of a series of vascular grafts correlated with the elasticity of these grafts. The hypothesis states that patency of a vascular prosthesis will be optimal if its mechanical properties match those of the anastomosed natural vessel. Intuitively, this premise appears obvious and seems to be supported by their data and that of others (Christenson et al., 1987; Kinley and Marble, 1980; Edwards and Mulherin, 1980; Walden et al., 1980; Seifert et al., 1979; White et al., 1987). Seifert et al. (1979), for example, indicated that the patency of polyurethane prostheses, whose elasticity closely approximated that of the native artery, was superior to prosthesis which were either more or less elastic than the native vessel. Consequently, prostheses have been developed to "match" and maintain the compliance of the native vessels (White et al., 1982; Hess et al., 1984; van der Lei et al., 1986; Taylor, 1982; Annis et al., 1978; Fisher et al., 1984; Gogolewski and Galleti, 1984). Herein lies the dilemma for the developer of a small diameter prosthesis - "what is meant by the term vessel wall compliance of an artery".

Compliance

Compliance is defined as the incremental change in the diameter of a vessel (ΔD), resulting from an incremental change in pressure (ΔP). In specifying values for compliance, investigators report the range in pressure over which ΔD is measured. Compliance can also be thought of as the inverse of "stiffness" and these parameters are often used interchangably in the literature.

The mechanics and properties (compliance) of blood vessels have been and continue to be a research topic of interest (Bergel, 1961; Brant et al., 1980; Carew et al., 1968; Caro et al., 1978; Gow et al., 1974; Gow, 1970; Patel and Fry, 1969; Nicolaides, 1987; Shiwazu et al., 1986). In the earliest studies on excised systemic vessels from swine
(Hardung, 1953), dog (Bergel, 1961; Shiwazu et al.,1986) and man (Learoyd and Taylor, 1966) vessel wall biomechanics was approximated by a simple viscoelastic model (parallel spring and dashpot). The vasculature however does not exhibit pure viscoelastic behavior. The dynamic elastic modulus is a function of the degree of distention and the frequency. The viscous modulus is relatively independent of frequency. These well established facts are ignored by many and account, in part, for the difficulties in comparing compliance values reported in the literature. As the incremental pressure increases, the native vessel's compliance becomes less, i.e., it becomes incrementally stiffer. In arterial hypertension the extensibility of the arterial wall is reduced below that measured for vessels exposed to normotensive hemodynamics (Brant et al.,1980; Gow,1974). Age (Kinley and Marble, 1980) and health (or diseased) state (Shimazu et al.,1986; Learoyd and Taylor, 1966) of the vessel further affect measured compliance. For example, Kinley and Marble (1980) showed that the compliance of human arteries excised from juveniles was on the average 3.5-4 times greater than that measured in vessels of 70 year olds. Shimazu and co-workers documented similar age dependencies and correlated vascular stiffness with the severity of the atherosclerosis of the arterial wall. These results are consistent with the early data of Peterson, Jensen and Parnell (1960) who reported that the wall stiffness was greater in the mature dog than in the puppy.

In Table I, compliance values from the literature for vascular prostheses of different composition and structure, as well as for native vessels and glutaraldehyde treated vessels are assembled. Clearly, the target compliance for a prosthesis is difficult to define. Ascer, et al. (1986) reported on the clinical difficulties associated with attaching replacement vessel prostheses to "rock-like" calcified arteries. Included in this study as replacements were the autogenous saphenous vein, ePTFE, and composite (ePTFE + vein) grafts. The results of graft patency were statistically compared and found to be independent of graft type and anatomic position. This even though three types of grafts were used with at least four different inflow sites. The three types of grafts were of differing compliance as were the vessels to which they were anastomosed. It is data such as this that further indicates more than just compliance is of importance as regards graft patency.

To additionally complicate the issue of compliance, Hasson et al. (1985) observed the development of a hypercompliant zone in the native vessel, adjacent to the suture line where the native vessel was attached to a prosthetic graft. Thus the pliability of the native vessel was found to change as a result of interposition of a prosthesis. Interestingly, in completely unrelated experiments, extensive platelet accumulation has been observed in the same region that was found to be hyper-compliant.

These observations need further study, and lead to the question of healing. "Healing" is defined as the formation, at the anastomotic sites, of an endothelial cell covered neointima which is resistant to platelet aggregation and thrombosis. It is widely held that anastomotic neointimal formation is essential for long-term graft patency. Interestingly, while this type of vascular healing is documented in prostheses implanted in dogs, the formation of a passivating neointima generally does not occur in man.

The data presented in Table I also indicate that compliance changes as a function of time following implantation. An extreme case of such compliance change was reported by Eggleton et al. (1986). They retrieved a 6mm ePTFE graft after eight years that was described as "rigid and bony hard". A histological examination of the graft showed it to be ensheathed with a layer of vascularized connective tissue containing both osteoblasts and osteocytes. True lamellar bone had formed in some areas on the outer surface of the graft as confirmed by scanning electron microscopy. The explanted graft was not compliant, nor even pliable. While this is quite an extreme example, it demonstrates convincingly that compliance changes do occur following implantation.