Experimental Evaluation of a Marlex Vascular Prosthesis.* (26580)

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A variety of vascular prostheses are available, yet search for the ideal graft continues as indications and demands for grafts increase (1). The use of synthetic materials as vessel replacement is progressing and work along these lines must continue as new materials and methods of production are developed. Recently a high density polyethylene called Marlex has been shown to possess ideal physical and biologic properties as a surgical prosthesis and clinical observations proved its usefulness in replacement of tissue defects (2). The present study was undertaken to test the suitability of this plastic as a vascular prosthesis.

Methods. The Marlex used has a tensile strength of 50,000-150,000 lb/sq inch, is nonwettable and is resistant to acids, alkalies and to most organic solvents. It is thermostable at temperatures up to 250°F and sterilization may be accomplished either by boiling or with chemical agents. The tubular prosthesis used was knitted from 2 strands of 70 denier multi-filament yarn to a diameter of 10 mm. The individual prostheses were crimped and cut at lengths from 15 to 25 cm.

The prosthesis was implanted as a long bypass graft between the mid-thoracic and lower abdominal aorta in 22 dogs. The method of bypass was essentially the same as described by McCune and Blades(3). Through a thoraco-abdominal or separate flank and thoracic incisions, the side of the abdominal aorta immediately proximal to the trifurcation was anastomosed to the distal end of the graft. The graft was then tunnelled retro-peritoneally and retro-pleurally through a hiatus made in the posterior attachment of the left leaf of the diaphragm, and an end-to-end anastomosis was performed between the graft and proximal end of the divided thoracic aorta. The distal stump was sutured. This method of vascular bypass insured reliance on a patent prosthesis for survival of the animal.

The quality of the femoral pulses and general condition of the animals were recorded bi-monthly, and the state of the grafts was noted by interval percutaneous transventricular aortography. The animals were sacrificed at 1, 3, 6 and 12 months after operation. An aortogram was made at time of sacrifice and the graft and adjacent aorta were removed and the specimen placed in formalin (10%). After fixation selected specimens were washed and placed in alcohol 80% to regain color and then photographed. Representative portions were embedded in paraffin and consecutive microscopic preparations were stained with hematoxylin and eosin, Masson's trichrome, and Weigert's elastic tissue stains.

Results. Since the graft is of a porous knit, blood loss is considerable at the initial restoration of blood flow; however, the loss is not excessive if care is taken to pre-clot the graft and allow coagulation to occur in the crevices of the fabric by intermittent interruption of flow through the graft. Of the 22 animals in which the prosthesis was inserted as a long aortic bypass 18 survived for 48 hours or longer. Four animals died in the first 48 hours; however, in none was the cause of death related to the prosthesis *per se.* One dog died 3 weeks following operation because of disruption of the proximal anastomosis in an infected wound. Another dog died 3 months after implantation of the graft as the result of malabsorption and it is assumed that there was impairment in the retrograde flow by which the blood from the bypass reaches the abdominal viscera. The remaining 16 animals were sacrificed at various periods. Each maintained normal femoral pulses up to day of death. Interval aortograms demonstrated patency of all

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FIG. 1. Angiogram of dog illustrating a Marlex vascular prosthesis in place for 6 mo.

grafts without dilatation or constriction along the bypass or at either anastomosis (Fig. 1). None of the implanted prostheses exhibited stenosis, aneurysm or plaque formation. Four prostheses, however, contained small deposits of fibrin on the luminal surface in areas of kinking. In the rest of the prostheses as well as in those without kinks, there was a smooth glistening lining. The entire intimal surface of the prosthesis had this smooth lining 3 months after implantation. A moderately thick layer of fibrous tissue surrounded the implants and the peri-prosthetic tissue was firmly attached to the interstices of the fabric. Tensile strength of the prosthesis appeared unchanged after one year of implantation.

In Fig. 2 is shown a Marlex prosthesis in place for 9 months. The proximal segment of the aorta is continuous with a Marlex bypass prosthesis 18 cm long anastomosed to distal abdominal aorta. The prosthesis is encased in fibrous connective tissue. The inner surface is smooth and glistening with the pattern of fabric shining through. In cross sections the Marlex fibers appeared in columns of about 40 fibers regularly separated by septa that penetrated the width of the prosthesis. The encasing fibrous connective tissue on the inside equalled the width of the fabric while that on the outside was 3 times as wide as the fabric.

In Fig. 3 is shown a Marlex prothesis in place for 12 months. A segment of the aorta is continuous with the bypass prosthesis 10 cm long that is anastomosed to the distal abdominal aorta. The prosthesis is encased in a film of tissue with the structure of the fabric shining through (a). In microscopic preparations the pattern was somewhat different in sections cut longitudinally

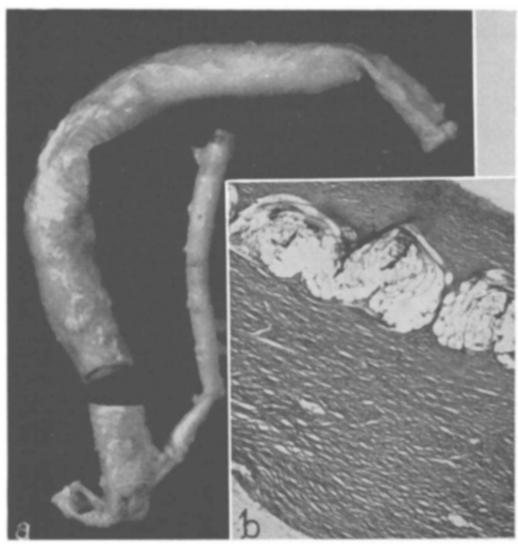

FIG. 2. Marlex prosthesis in place for 9 mo. Prosthesis is encased in fibrous connective tissue. Inner surface is smooth and glistening with pattern of the fabric shining through (a). In microscopic preparations, on cross section, the Marlex fibers appear to be in columns of about 40 fibers regularly separated by septa that penetrate the width of the prosthesis. The encasing fibrous connective tissue on the outside is about 3 times the width of the fabric; that on the inner surface equals width of fabric (b). (Weigert's elastic tissue stain × 50.)

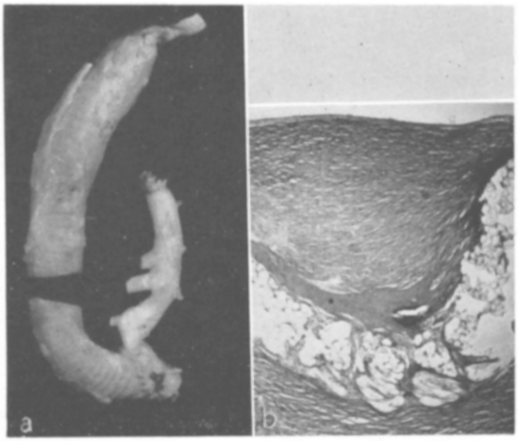

FIG. 3. Marlex prosthesis in place for 12 mo. Prosthesis is encased in a film of tissue through which structure of the fabric shines through (a). In a microscopic preparation cut longitudinally (b), the encasing fibrous connective tissue dips between the crests of the weave. At bottom of wedge between the crests there is osteoid and osseous tissue. (Weigert's elastic tissue stain × 50.)

and transversely. When cut longitudinally, the anisotropic, round or oval Marlex fibers, 6 to 10 rows deep, formed a wavy pattern with convex and concave areas alternating. The weave was of even width with the fibers close and with almost no space between them. A pink coagulum or ground substance and some elongated cell nuclei appeared here and there between the fibers. At intervals, complete or incomplete septa containing blood vessels or endothelium lined spaces extended between the outer and inner surfaces of the prosthesis. Both the outer and inner surfaces of the fabric were covered by a band of hyalinizing fibrous connective tissue composed of coarse collagenous bundles containing few elongated cell nuclei and no elastic fibers. This encasing fibrous connective tissue dipped between the crests of the weave filling the space and was thinner over the crests. At the bottom of the wedge between crests of the weave osteoid or osseous tissue formation was noted (b). The plaques of osteoid were more numerous on the intimal surface of the prosthesis than on the adventitial surface. The width of the encasing connective tissue was about that of the prosthesis except at the crests on either surface where it was thinner. In places a coagulum of varying widths was attached to the intimal surfaces and contained some cell nuclei.

Comment. For evaluation of a vascular prosthesis the experiment should be designed to simulate the planned clinical use of the graft. The method of bypass in this experiment seemed acceptable since the size of the vessel and length of the graft closely approximate those used in femoral-popliteal bypass in the human. Experimentally the prosthesis has proved suitable; however, there are adverse properties of the material which preclude its clinical use. The physical properties of the multi-filament yarn resisted close knit. Also the usability of the prosthesis is somewhat limited because the low melting point of the plastic prevents autoclaving. The physical properties of this material also present technical problems of handling at operation. Because this material lacks resiliency, the crimp in the prosthesis and thereby the protection against kinking is lost with stretching. Furthermore, the cohesiveness of the material impedes anastomotic suturing.

Summary. A vascular prosthesis of Marlex was implanted as a long aortic bypass graft in dogs and left in place up to 12 months. After 3 months of implantation, the inner surface of the prosthesis had a smooth lining and was firmly attached through the interstices to the periprosthetic tissue. None of the implanted prostheses exhibited stenosis, aneurysm or plaque formation. The inner and outer surfaces of the fabric were covered by a band of hyalinizing fibrous connective tissue. Plaques of osteoid were numerous on the intimal surface. Although the Marlex prosthesis functions adequately as a vascular substitute, unsatisfactory physical properties of this material limit its clinical use.

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