

6-1958

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Szilagyi, D. Emerick and France, Lloyd (1958) "An Elastic Arterial Substitute Made Of Dacron Textile Fabric," *Henry Ford Hospital Medical Bulletin* : Vol. 6 : No. 2 , 203-212.

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AN ELASTIC ARTERIAL SUBSTITUTE MADE OF DACRON TEXTILE FABRIC

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The rapid development of vascular surgery during the past ten years was made possible by the revival and perfection of operative techniques that make use of homologous arterial grafts. The versatility and ease of technical handling of arterial homografts as well as the excellence of their early success rate still stand unchallenged. However, observations on the histologic changes in these implants uncovered a serious deficiency.^{1,2} Contrary to the expectations of many, homologous arterial grafts share the fate of all homologous tissue transplants, and, instead of being receptively incorporated by the host tissues and reinforced by ingrowth of connective tissue elements, they are as a rule only passively tolerated and occasionally even actively rejected. In either case they may fail. If they are rejected, they may fail early by thrombosis or disruption; if they are sequestered they gradually lose their structural strength, and often become dilated, tortuous or aneurysmal, in which case they either occlude or, rarely, rupture. In the instance of aortic grafts this process of wearing out may take many years; indeed, in most cases the graft outlives the patient. Femoral arterial grafts, however, show a relatively early as well as a much higher incidence of structural failure.

Ever since the important observation of Voorhees and his associates³ that the animal body builds a connective tissue channel around a porous textile fabric placed in the path of the flowing blood, the search for arterial substitutes made of plastic materials has been intensive mainly for the reason of the practical advantages that a man-made arterial prosthesis offers. The lack of permanence in the structural strength of arterial homografts just mentioned has lent further urgency to this search. A number of plastics have been investigated by many workers and have gained varying degrees of popularity.

In studying plastic arterial prostheses during the past four years in our laboratory,^{4,5} in order to reproduce the hemodynamic conditions of the human arterial system with the greatest practicable fidelity, a canine preparation was used that permits the implantation of arterial substitutes approaching the dimensions of the human femoral artery. In this manner woven seamless prostheses of nylon, dacron and teflon were implanted in groups of dogs. All these prostheses showed an excellent rate of early functional success; indeed, the only failures were those caused by technical errors, among which the commonest was inadvertent kinking of the implant. In non-yielding rigid tubes bending results in buckling which inevitably leads to thrombosis. This fault of plastic prostheses had been noted by others but it was particularly conspicuous in these experiments in which the great length of the implants provided frequent occasion for bending. It soon became evident that the ability to elongate and mold—or the quality of elasticity—was a necessary attribute of plastic prostheses if they were to serve in locations where they are apt to be flexed (as they are in almost all clinical situations).

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Since there is no plastic fiber with intrinsic elasticity that would otherwise fulfill the requirements essential for an arterial substitute, we thought of incorporating in the textile fabric a yarn that had been specially processed for resilience. Our first experiment two and a half years ago utilized an elastic prosthesis woven of "Helanca" nylon, which then was the only available plastic fiber so processed. The elastic and handling qualities of these prostheses were excellent but their durability was unsatisfactory for use in the replacement of arteries larger than the femoral.

Fourteen months ago a dacron fiber processed with the "Helanca" method came to our notice. Prostheses constructed in a manner similar to that used in making "Helanca" nylon prostheses were then subjected to laboratory investigation.*

The result of these studies will be summarized in the following paragraphs.

Experimental observations. The elastic dacron prosthesis is woven with a taffeta weave and is seamless. As disposed in the tubular fabric, the longitudinal threads forming the warp are made of fibers that have been specially processed; the transverse threads, or woof or filling, consist of untreated dacron fibers. The special process to which the fibers of the warp yarn have been subjected is the same as that used for the manufacture of "Helanca" nylon fiber. In this process the fibers are twisted into tight spirals and then heat-set at 270° F. Fibers of opposite directions of twist are combined into the yarn in about equal amounts in order to assure balance. The fibers are stretchable since on pull the spirals uncurl; when the pulling force is released the fibers shorten owing to a tendency to resume their heat-set spiral shape. When yarn composed of such fibers is woven into fabric this quality of elasticity is largely retained. It is necessary, however, to boil the fabric in liquid soap to restore complete resiliency. (The contact with soap leaves no deleterious effects provided the fabric is thoroughly rinsed.) The finished tube has an ability to elongate 15-20 percent without deformity (Fig. 1).

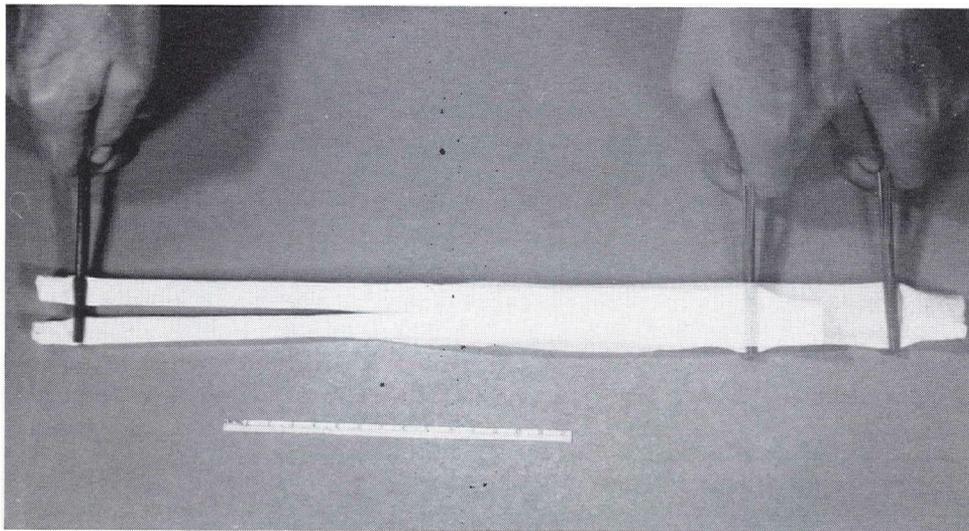


Figure 1

Double exposure of a bifurcation prosthesis showing the range of stretch of the fabric.

*The elastic dacron prosthesis came from the looms of John Sidebotham, Inc., Frankford-Philadelphia, Pennsylvania, whose technical help was essential in its development.

Table 1
Textile Characteristics of Elastic Dacron Prosthesis

Diameter	Ends/cm.	Elastic	Picks/cm.	Filling
mm.	(Warp)	Dacron	(Woof)	(Woof)
10	80 to 100	70/2	47	200
The yarn in the warp: 70 denier 2-ply 70-14 Bright type 51 dacron.				
The yarn in the woof: 220 denier 220-50 Bright type 51 dacron.				

The textile characteristics of the prostheses used experimentally are given in Table 1. The mesh-size and the weight of the yarn were arrived at after many experimental trials and appeared to fulfill optimally the basic criterion of minimum bulk with maximum strength. The porosity is such that pre-clotting is necessary (see below).

The experimental preparation employed was that first described by McCune and slightly modified by us. The details of the operative technique were given in full in earlier publications.^{4,5} Briefly, the procedure consists in implanting a bypass between the upper thoracic and lower abdominal canine aorta, the proximal anastomosis being an end-to-end one, thus assuring a complete shunting of the aortic blood into the prosthesis. The method permits the insertion of implants 18-26 cm. in length and 7-10 cm. in diameter (depending on the size of the animal). We believe that this preparation affords a much more realistic test of a prosthesis than the customary short-segment replacements in many of which the bridging effect of the healing process of the stumps of the host aorta is difficult or impossible to distinguish from the histologic changes peculiar to arteriogenesis. Twenty-one such preparations were made, in 10 of which the prosthesis was implanted with enough slack to allow a tortuous course, thus testing the ability of the prosthesis to mold.

The experimental animals were investigated by observation of their general condition and state of health; by periodic aortograms; and by scheduled sacrifice. The recovered grafts were inspected for gross appearance, tested for tensile strength and studied for histologic characteristics. All the implants remained patent until the death of the animals. In 8 animals that were sacrificed on schedule after periods of time up to 11 months after implantation, and in 5 animals that died of intercurrent causes not related to the function of the implants, the recovered prosthesis showed excellent arteriogenesis (Fig. 2) and a remarkably slight tendency to elicit inflammatory reaction in the host tissues (Fig. 3). During 11 months the tensile strength of the implants remained essentially unchanged in marked contrast to the findings with "Helanca" nylon prostheses in which the tensile strength rapidly declined after two month's implantation (Figs. 4 and 5).

Thus the tubular prosthesis woven with elastic "Helanca" dacron yarn displayed most of the advantageous qualities of the prosthesis made of elastic nylon and, in addition, it appeared to have marked superiority in its durability after implantation; this last property may be looked upon as the result of the marked non-reactivity of dacron yarn.

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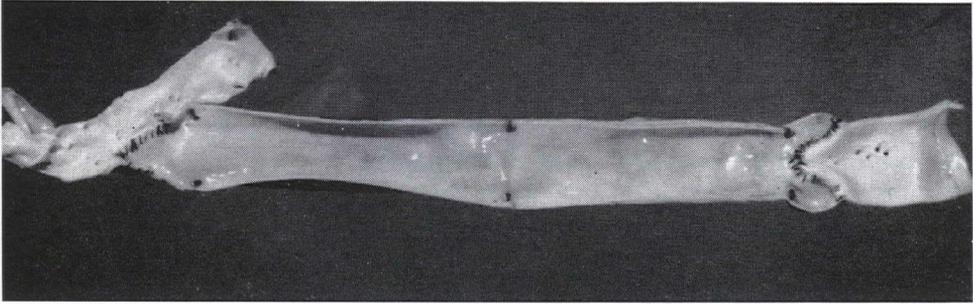


Figure 2

Gross appearance of a canine implant 6 months after insertion. The fabric is completely covered by a smooth flawless pseudo-intima about 1 mm. in thickness. The connective tissue shell and in-growth are firmly adherent to the fabric and thin but sturdy. The mean total thickness of the new artery is 1.0—1.5 mm.

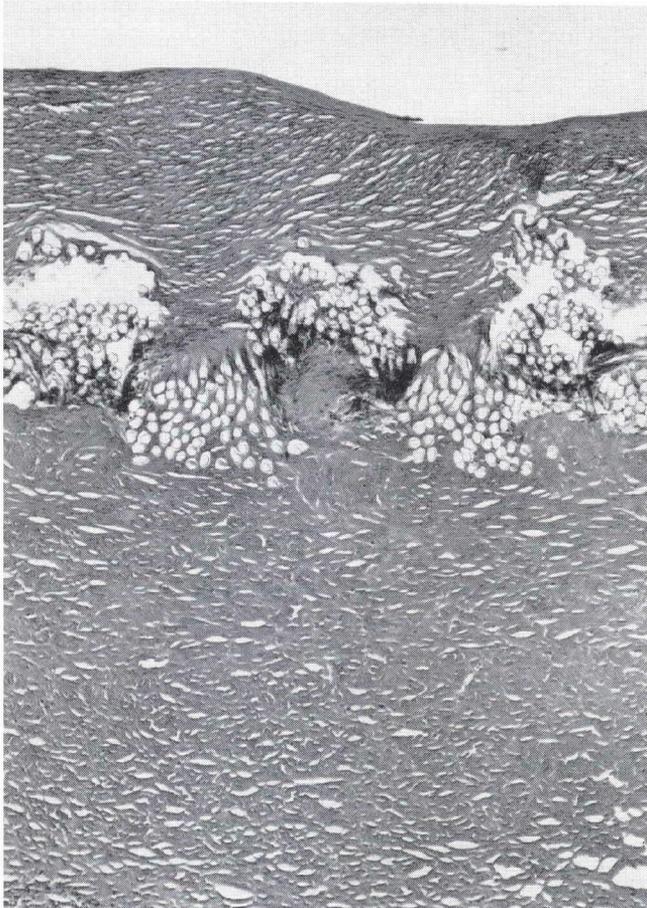


Figure 3

Microscopic section of the mid-portion of implant shown in Figure 2. This is as satisfactory a process of arteriogenesis as we have seen. Cellular exudative reaction is almost completely absent. The growth of connective tissue appears to serve only one purpose: the integration of the plastic fibers into a firm structure. (x70, H.E. Stain.)

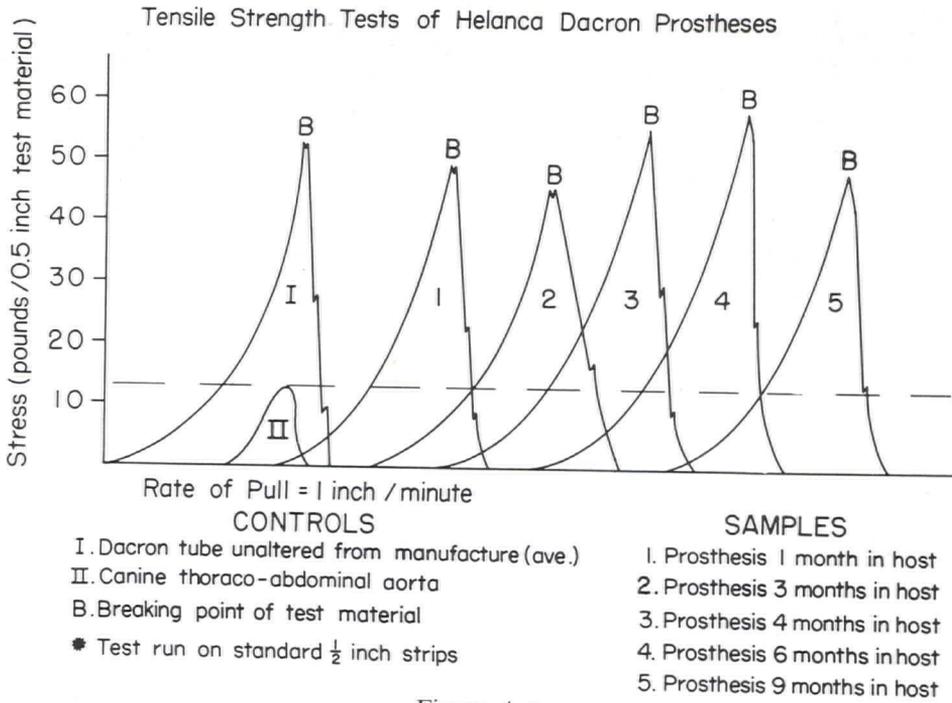


Figure 4 Legend on drawing.

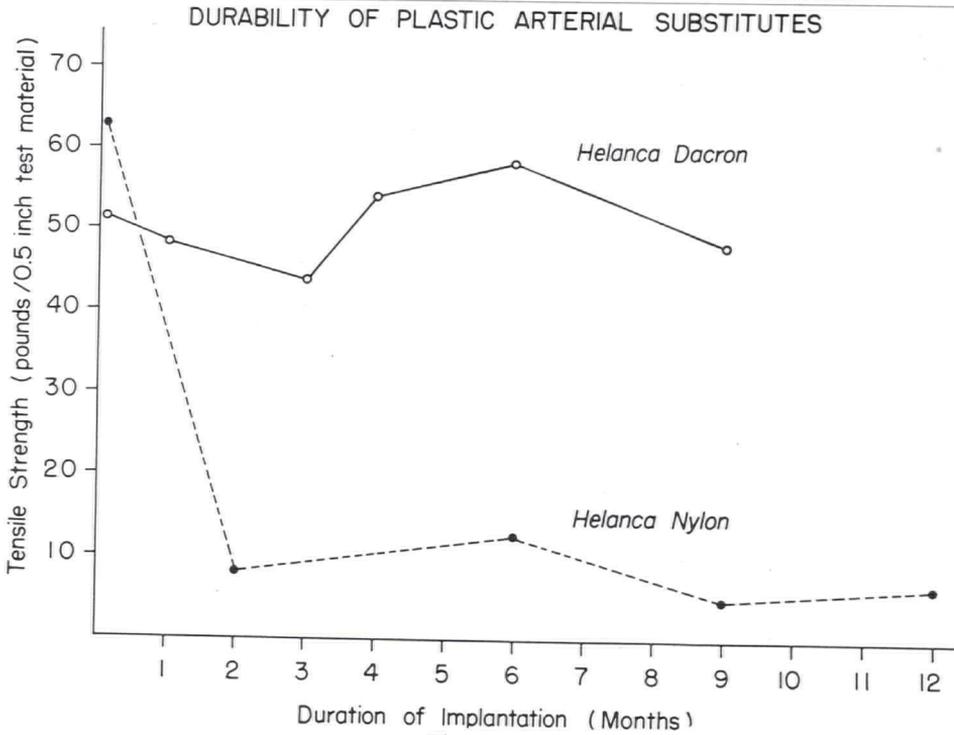


Figure 5 Legend on drawing.

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On grounds of these experimental results, in May 1957 we began the clinical use of the elastic dacron prosthesis.

Properties of the Elastic Dacron Prosthesis—The external appearance of the prosthetic tube of stretch dacron as used by us is very similar to that made of stretch nylon. It is white (or, rather, colorless) soft, pliable, smooth, light and moderately porous. On handling it, one is impressed by the lack of bulkiness that is peculiar to knitted or crimped tubes and the absence of stiffness that is characteristic of teflon textiles. The prosthesis does not require any special precautions for storage. It can be sterilized chemically or by boiling and autoclaving. As a sterilizing agent zephiran chloride in 1:1000 solution for 18 hours of contact has been effective. It should be noted that repeated autoclaving reduces elasticity.

Technical details in the clinical use of Elastic Dacron Prosthesis.—Without some appropriate pre-treatment, a fabric of the porosity of the elastic dacron prosthesis will leak blood rather vigorously. We have found that by rinsing the inner and outer surfaces of the prosthesis with 15 to 20 ml of blood obtained from an unheparinized segment of the exposed arterial tree, and by allowing the prosthesis to soak in this blood for 3-4 minutes one can bring about just enough clotting to seal off the meshes of the fabric. A moderate amount of oozing may still occur after the prosthesis has been inserted and blood allowed to flow through it but this can be readily controlled by short periods (20-30 seconds) of occlusion of the inflow while the blood is allowed to remain in the prosthesis. It is of the utmost importance to use great care in the process of clot-sealing. After the in-vitro clotting, the prosthesis must be checked for the presence of visible or palpable thrombi, and if any are found they must be removed by gentle milking or, if necessary, by rinsing with a heparin-saline solution (0.5 mg of heparin per 1.0 ml of saline). The same precaution must be observed during the performance of the insertion of the implant. Obviously, stagnant blood is never allowed to remain in the prosthesis once the clot-sealing has been accomplished. If owing to some technical mishap it becomes necessary to stop the flow of blood through a prosthesis already in place, before the distal clamp is applied the blood is milked out of the implant and the implant is filled with heparin-saline solution until the flow may be re-established. Leaving a layer of thrombus in the lumen of the prosthesis that is thicker than about 0.1-0.2 mm or allowing the presence of lumps of clot may have disastrous consequences. It may not only delay or prevent the orderly formation of the pseudointima, thus resulting in early occlusion, but it may lead to a rapid, almost immediate, progression of the clotting process to a point where the prosthesis cannot function at all.

The free cut end of a woven fabric tends to unravel, particularly if the component yarn contains smooth-surfaced fibers as is the case with the elastic dacron prosthesis. This tendency can be easily corrected, however, by melting and fusing the ends of the cut fibers through the application of heat. We have found it convenient to heat-seal the prosthesis *before* beginning the implantation. The length of the implant is judged by placing a heavy black thread in the exact position the prosthesis is to occupy and by using this measure as the base for the simple calculation. Ten to 15 percent of the length of the thread (depending on the slightly variable elasticity of the plastic tube) is subtracted to obtain the desired dimension. In case of doubt, care is exercised to

make the implant slightly longer rather than shorter than is ideal. The ends of the prosthesis of the desired length are cut with scissors at the angle needed for the proposed anastomosis. The cut ends are lightly touched with a flat-tipped electric cautery which has been heated just short of being red. The ideal heat-seal is a narrow (about 1.0 mm) even and smooth band of fused plastic which lies exactly in line with the scissors cut.

A light touch and attention to technique are necessary for the proficient use of any plastic prosthesis, and they are of special import when dealing with light woven fabrics. The manual handling and the suturing of the elastic dacron prosthesis demand great gentleness. The prosthesis must not be picked up with instruments having a rough surface, and clamps applied to it must be rubber-shod. If, nevertheless, separation of some of the threads occurs, the flaw can usually be corrected by gentle rubbing between fingers. In placing sutures, only the slightest strain is allowed on the fabric.

The optimal size of prosthesis to be used in a given case is a matter of some doubt. Theoretical arguments can be advanced in favor of the use of implants significantly larger in diameter than the host artery and also in favor of reducing the size of the prosthesis. As an empirical proposition, the use of prostheses of approximately the same size as the proximal host artery has appeared to us entirely satisfactory. In the femoral and popliteal areas an upward correction of about 2.0 mm in the inside diameter is made in order to allow for the thickness of the luminal component of the connective tissue conduit to be built by the host.

The technical details enumerated are valid for the straight tubular as well as for the bifurcated prostheses. Because of problems inherent in weaving techniques the undersurface of bifurcations (the so-called "crotch") is not truly seamless. Although we have found that the seal of the weave at the crotch has been consistently strong, it is advisable to inspect this part of the bifurcation prostheses with particular attention before use.

Clinical Material. During the period covered by this report (May 1957 to March 1958) as well as the 12 months immediately preceding it, the criteria governing our choice of direct surgical procedures for occlusive disease and our preference for arterial substitutes favored bypass operations over replacements and plastic substitutes over homografts. Thromboendarterectomy was used more frequently than before, but always for sharply localized lesions, particularly in the aortoiliac area. The more advanced and diffuse instances of occlusive disease were treated with bypass procedures, bilateral aorto-femoral and long common-femoral-popliteal bypasses having been particularly common. The implant material in the angioplastic procedures was, with very rare exceptions, plastic tubing.

The advanced state of the disease in the cases chosen for grafting, and the frequent use of bilateral aorto-femoral and of the long femoro-popliteal bypasses emphasize the severity of the test to which the elastic dacron prosthesis was put in this clinical series. Both these operations are rather complex, and they demand a tortuous placement of the implant; moreover, in the femoro-popliteal bypasses the length of the prosthesis is great (without exception in excess of 31.0 cm), a circumstance that—other factors being equal—is unfavorable to patency in an arterial replacement.

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The immediate and early results of the operations in which elastic dacron prosthesis was used are listed in Table 2. The postoperative periods of observation in these cases ranged from 1 to 12 months. Patency of the graft was always verified by angiography. The results tabulated are cumulative. "Immediate result" denotes the state of the implant at the time of discharge from the hospital; "early result" refers to the condition of the implant at the time of the last angiographic examination. Clinical examinations were made monthly. The results are slightly inferior to those we have generally observed with the use of homografts. This difference can be largely explained by the selectivity of the case material; as pointed out above, an unduly great proportion of the cases in which elastic dacron prostheses were used were examples of advanced disease. The initial lack of familiarity with the new fabric may also well have contributed to the lesser success. It seems probable, however, that the early results of operations using homografts cannot be matched, much less surpassed, by procedures with plastic prostheses. The superiority of plastic substitutes lies in the long-range outlook, that is, in the hope that the good early results will remain good late results in a significantly larger proportion of cases than after homografting.

Table 2
Results of Elastic Dacron Grafting Procedures — May 1957 — April 1958

	Immediate		Early	
	Open	Closed	Open	Closed
Aorto-iliac	30 91%	3 9%	30 91%	3 9%
Femoro-Popliteal	23 82%	5 18%	20 72%	8 28%
Total	53 87%	8 13%	50 82%	11 18%

The prosthetic qualities of elastic dacron tubes. It is our belief that a plastic prosthesis suitable for wide-range clinical use that will yield the best results must combine the following qualities: It must be seamless, smooth-walled, easy to handle, durable and relatively non-reactive; its porosity and bulk must meet certain critical requirements; and finally it must possess the ability to elongate and recoil. (Further important but not truly essential requirements for such a prosthesis would be economical cost, easy storage and simplicity of sterilization.)

The reasons for the significance of these attributes are cogent. The presence of a seam and of ridges on the luminal surface of the prosthesis is undesirable since surface irregularities would increase friction and, therefore, resistance to flow; moreover, and perhaps more importantly, they would promote excessive clotting along the areas of contact with the blood, a circumstance that, under many marginal conditions, may mean the difference between patency and thrombotic occlusion. The need for ease of handling (as well as for less essential factors of low cost and simplicity of storage and sterilization) is self-evident. Durability is also an obvious requirement. It is less obvious that durability is largely dependent on lack of tissue reactivity. Regardless of the magnitude

of tensile strength that the original fabric possesses, if after implantation the fabric provokes active cellular reaction in the host tissues it will be attacked by the exudative process, and in the end, partly or completely destroyed. The optimal degree of porosity in the fabric is the sum of two requirements: the mesh size must be large enough to allow ingress for the ingrowth of connective tissue but it must also be small enough not to interfere with hemostasis. The restrictions on the bulk (or wall thickness) of the prosthesis are less easy to justify. Undoubtedly thick-walled, heavy prostheses have served well in many situations during short-term observations. However, a plastic prosthesis is a foreign body, and sound surgical principles would suggest that its mass should be kept to a minimum as long as this restriction does not result in a disadvantage such as lessening its initial tensile strength or its durability. While conclusive evidence condemning thick-walled prostheses cannot at this time be quoted, it is an easily confirmed observation that the connective tissue reaction around bulky prostheses is excessive, and this is undesirable. The importance of the quality of elasticity has already been discussed. It may be mentioned, however, that the accomplishment of elasticity through specially treated fibers has distinct advantages over methods involving the treatment of the finished tube, namely, crimping, which increases bulk and luminal friction.

While far from ideal, the elastic dacron prosthesis comes reasonably close to meeting the requirements just enumerated. Its construction is light, seamless and smooth-walled, providing a porosity that is satisfactory both from the point of view of arteriogenesis and from that of hemostasis. Its tissue reactivity is of the order of that of teflon, and during the period of experimental observation its tensile strength has remained remarkably stable. It also meets the other prerequisites mentioned that have less fundamental importance but are significant in a practical way.

Some imperfections of the elastic dacron prosthesis should, however, be pointed out. There is some experimental and clinical evidence that the new-formed lining of the prosthesis is slow to develop, apparently slower than that seen in nylon implants. Since the formation of this pseudointima is greatly influenced by the technique of pre-clotting which is largely a matter of personal skill, the evidence in this regard is not entirely clear-cut or convincing. Moreover, it is reassuring that in older canine specimens the new intima was always found to be satisfactory and in most instances excellent. Because of the delay in the formation of the new lining, angiographic visualization of the prosthesis should be delayed until at least the sixth postoperative week.—The other shortcoming of the prosthesis is troublesome rather than grave, and it consists in the tendency of the component threads of the fabric to slip and separate. Measures—chief of which is gentleness in handling—have been mentioned to prevent this mishap or to correct its consequences. This imperfection is to large extent a manufacturing problem. Studies are now in progress to prevent its occurrence by using in the woof a dacron yarn of different finish and much greater cohesion.

*It should be borne in mind that elasticity has very little, if anything to do with the physiological function of the plastic prosthesis. The prosthesis must be able to elongate and recoil not because of the requirements of pulsatile flow but because of the need to accommodate itself to the anatomical features of its surrounding. Once the implant has become fixed in its optimal anatomical position this need ceases to exist. As a matter of fact, the ingrowth of connective tissue does dissipate the elastic quality, and after 2 to 3 months following implantation in the dog the prosthesis is found to be quite rigid.

SUMMARY

An account is given of the experimental and clinical findings in the use of an arterial substitute, woven of dacron yarn, which is seamless, smooth-walled, finely porous, light, and has elastic qualities.

In animal experiments, during 14 months of observation, the prosthesis showed low tissue reactivity, good arteriogenesis and excellent durability.

Used as direct replacement and as bypass graft in the aorto-iliac and femoro-popliteal areas, in 61 clinical cases (the earliest of which has been followed for 12 months) the prosthesis has yielded patency rates only slightly lower than those obtained by us with homografts. Further observation is needed to show whether the use of this prosthesis will reduce the rate of late failures due to degenerative changes noted in homologous arterial transplants.

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