Long-Term Behavior of a Dacron Arterial Substitute: *

Clinical, Roentgenologic and Histologic Correlations

D. Emerick Szilagyi, M.D., Roger F. Smith, M.D., Joseph P. Elliott, M.D., Hubert M. Allen, M.D.

From the Department of General Surgery of the Henry Ford Hospital, Detroit, Michigan

Although plastic arterial prostheses are in extensive use, a systematic evaluation of their clinical performance, at this writing, has not been reported, and the information relative to their behavior is largely limited to sporadic and usually censorious comments. To gain a better understanding of the long-term clinical behavior of these devices we surveyed the pre- and postoperative history of the operations we performed between January 1, 1957 and November 30, 1964, in which a Dacron prosthesis of special (and formerly described) construction was used. These cases had been followed according to a rigorous clinical and angiographic routine that permitted the correlation of the clinical events with the findings of serial pre- and postoperative arteriograms and with the tissue changes noted at secondary operations and in recovered prosthetic specimens studied grossly and microscopically. The purpose of this report is to describe our more important observations. Since by far the most extensive, best controlled and, therefore, most instructive part of our experience had to do with plastic implants in the aorto-iliac and femoro-popliteal areas, our presentation will be limited to findings in cases with operations in these anatomic regions.

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Case Material and Method of Study

The patient population from which the cases for detailed analysis were chosen comprised 1,277 arterioplasties utilizing grafts (Table 1). Among these, 916 represented operations with plastic arterial substitutes, of which 858 were Dacron prostheses. As already mentioned, because of the completeness of the follow-up information available for aorto-iliac and femoro-popliteal plastic implants, the aorto-iliac and femoro-popliteal operations were singled out for detailed study. Needless to say, there is no cogent reason to believe that the behavior after implantation of the same type of prosthesis would be fundamentally different in other anatomic locations. The elastic Dacron prosthesis used in these cases (to be henceforth designated as the D-S prosthesis) has been described in detail,[1] and its rather extensive laboratory investigation encompassing observation periods of up to seven years has likewise been published.[2] The Dacron fiber which forms the fundamental unit of the prosthesis is the same as that employed in other types of fabrication of Dacron arterial substitutes but the construction of the fabric has significant differences. The fabric is not crimped and it derives its elasticity from the incorporation of a specially treated fiber made into a yarn that constitutes the warp or longitudinal component of the tubular fabric. The construction pattern is that of taffeta weave. Eight hundred and

TABLE 1. *Clinical Material (1957–1964)*

All arterioplastics using grafts	1277
Plastic prostheses	916
D-S prostheses	858
AI and FP D-S prostheses	835
Aneurysms	369
Occlusive disease	428
Other	38

thirty-five such implants were investigated, of which 369 were used in operations for aneurysms, 428 in operations for occlusive disease, and 38 in operations of other types of arterial reconstruction.

The clinical observation of the cases followed a strict routine. The ideal plan for which we aimed comprised a clinical check-up examination of the patient every 6 to 12 months and an angiographic check-up two to six weeks postoperatively as well as every 6 to 24 months thereafter. The postoperative patency of the prosthesis was confirmed by an aortogram in over 95 per cent of the cases. Thereafter an implant was accepted as being patent if during subsequent examinations the clinical condition of the limb or limbs was unchanged and the previously existing pulses were still present. If an implant appeared to be normal in angiograms for one to two years following the patient's operation, the subsequent aortographic check-ups were placed further apart, usually every two to three years. However, implants showing changes in the first or second postoperative aortogram were followed at 6- to 12-month intervals. Because of practical exigencies the ideal schedule could not always be maintained. The completeness of the follow-up in accordance with this plan was 96.6 per cent for clinical, and 80.8 per cent for angiographic observations as of December 31, 1964, the closing date of the study. The distribution according to follow-up periods is given in Table 2; nearly half of the cases had been followed for four years or more.

TABLE 2. *Distribution According to Clinical Follow-Up Periods in 835 Cases of AI and FP D-S Prostheses*

	Follow Up (Yr.)	Total Cases	% of Total	
1964	<1	111	13.3	
1963	1	101	12.2	
1962	2	108	12.9	
1961	3	113	13.5	
1960	4	113	13.5	
1959	5	131	15.7	
1958	6	124	14.8	48.1
1957	7	33	4.0	
	>7	1	0.1	
		835	100.0	

The total assessment of an arterial substitute must be based on the following 4 criteria: (1) the late patency rates, (2) the morphologic changes in the implant as determined by roentgenologic examinations, (3) the histologic deportment of the implant whenever the needed investigative material is available, and (4) the rate of healing complications in the operative wound that can be related to the prosthesis. The relevance of these criteria of assessment is easy to see. (1) Late patency rates are the best measure of the practical usefulness of the prosthesis, since the purpose of the use of vascular grafts is to restore circulation and patency means restored function. It should be noted in this connection that from the point of view of the judgment of the performance qualities of a prosthesis, early patency rates have no meaning since the intrinsic characteristics of prosthetic implants of the type here discussed are not among the factors influencing early patency rates. Since in the assessment of the late functional performance of plastic prostheses the most stringent test is the maintenance rate of patency after operations for occlusive arterial disease, in this study the analysis of the clini-

cal results will be limited to surgical procedures for this type of lesion. (2) The continuous observation of the morphologic changes in the prosthesis is the only source of information capable of supplying a clue to the long-term behavior of the implant. Even though at a given time a prosthesis may be clinically functioning, if it shows alterations in its morphology that may lead to eventual failure, the determination of this fact is essential for the establishment of its ultimate value. The only practical way in which these changes can be detected and followed is roentgenologic examination by the appropriate technic. In the study of the cases here discussed routine arteriographic methods [3] were employed, a description of which would be superfluous. (3) The macroscopic and microscopic study of recovered implants complement the information yielded by the morphologic changes noted in roentgenograms and has the same fundamental value for the ultimate prognosis of graft function as x-ray examinations. The specimens described in this study were recovered after death from causes unrelated to the patient's original operation or were examined at times of reoperation. Routine histologic methods [2] were used for obtaining microscopic sections and in interpreting the sections reliance was placed on hematoxylin-eosin and Gomori trichrome stains. Tensile strength studies on the recovered specimens were not carried out since the amount of tissue required for such studies would have seriously interfered with adequate sampling for histologic studies. There is abundant evidence in animal studies that the tensile strength of implanted Dacron does not appreciably change in at least seven years of implantation.[2] (4) The evaluation of the rate of healing complications complete the strictly clincial assessment of the prosthesis. As will be seen, these complications have a particular significance in the assessment of plastic prostheses, which are essentially implanted foreign bodies.

TABLE 3. *Comparative Late Patency Rates of 165 Aorto-Iliac D-S Grafts and 82 Aorto-Iliac Endarteriectomies (1957–1964)*

	Grafting Operations		Endarteriectomy	
Follow Up (Yr.)	No. Cases	% Cases Open at Indicated Follow-Up Intervals	No. Cases	% Cases Open at Indicated Follow-Up Intervals
<1	16	93.8	7	85.7
1–2	26	100.0	3	91.7
2–3	34	97.1	10	90.0
3–4	19	94.7	9	100.0
4–5	28	89.3	13	84.6
5–6	17	82.4	14	92.9
6–7	25	84.0	26	96.2

Findings

1. Late Patency Rates of D-S Grafting for Occlusive Disease

The evaluation of the late results of grafting operations for occlusive arterial disease is made extremely difficult by the constantly shifting temporal frame of reference as the operations performed in different years pass through varying lengths of postoperative follow up. The method of presenting late results of arterioplasties shown in Tables 3 and 4, although not without shortcomings, is a reliable and informative one. All the operations of immediate success are grouped according to the length of time elapsed since the date of their performance, and for each group the per-

TABLE 4. *Late Patency Rates in 117 Femoro-Popliteal D-S Grafts (1957–1964)*

Follow Up (Yr.)	No. Cases	% Cases Open at Indicated Follow-Up Intervals
<1	12	83.3
1–2	10	80.0
2–3	8	75.0
3–4	10	50.0
4–5	16	37.5
5–6	33	15.2
6–7	28	17.8

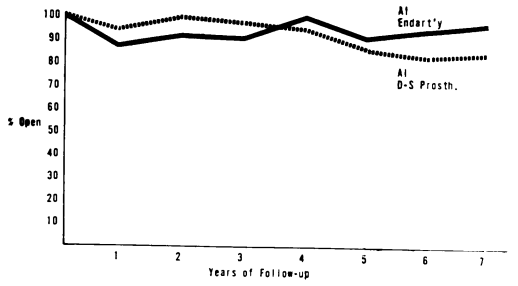

FIG. 1. Comparative late patency rates in 165 cases of D-S grafting and 82 cases of endarterectomy for *aorto-iliac* occlusive disease (1957–1964).

centage of patency at their respective intervals of follow up is calculated. The status of the patients who died at varying intervals after their operations (before, of course, the closing date of this survey) with their grafts open are placed in the follow-up column corresponding to the length of survival. The obvious shortcoming of this method of evaluation is the unavoidable disregard of the periods of patency preceding closure in cases found closed at the time of the survey. Moreover, it must be clearly kept in mind that in this type of tabulation the starting point is a patency of 100 per cent, that is, the patency of all cases with immediate success. In order to obtain the true over-all patency rate of each group arranged according to the length of follow up, the immediate failure rates would have to be deducted from the later patency rates of each follow-up group. This correction would not only call for the omission of all the patients that died with successful operative results but would also obscure the main purpose of the analysis, which is the evaluation of the trend of permanence in the cases with immediate success. For a clear representation of this trend the method is eminently suitable.

TABLE 5. *Angiographic Case Material*

	No.	%
Entire patient group	835	100.0
Cases unsuitable for angiographic analysis (early failure, amputations, early and late mortality, etc.)	274	32.7
Cases suitable for angiographic analysis	561	67.3
With angiographic changes	198	35.3
Without angiographic changes	363	64.7
Aorto-iliac operations	427	76.1
Femoro-popliteal operations	134	23.9

Table 3 lists the late patency rates for D-S grafts and for endarteriectomies performed during the same period of time (1957–64). Taken by themselves the patency rates of D-S grafting operations appear to be very satisfactory, showing only a slight deterioration from year to year and never falling below the patency rate of 82.4 per cent. As compared to the endarteriectomy patency rates, the rates of D-S grafts appear to be inferior by a margin of from 5 to 12 per cent. This difference must not, however, be interpreted as a proof of the inferiority of D-S grafting, since the degree of advancement of the occlusive disease in the endarteriectomy group was much lower than in the D-S grafting group. The interpretation of the significance of the observed difference will be given below.

Figure 1 represents a comparison of the late patency rates of aorto-iliac D-S grafts and aorto-iliac endarteriectomies in graphic form.

The late results of femoro-popliteal D-S grafts for occlusive lesions are listed in Table 4 in a manner similar to that employed in Table 3. The trend of permanence of the results in this group shows a markedly different course from that observed with aorto-iliac operations, the patency rates declining at a faster rate and by wider margins. After four years of follow up only 50 per cent and at the six- to seven-year interval only 17.8 per cent of the implants are patent. In Figure 2 the trends in patency rates for D-S grafts, arterial homografts and autogenous vein grafts are compared. The observations cover only the first four postoperative years (this being the maximum available follow-up period for autogenous vein grafts) and relate to op-

erations performed at different epochs. These circumstances weaken to some degree the statistical validity of the comparison, but the trends of behavior are so well marked and consistent that the differences shown are undoubtedly representative and true. The modest superiority of D-S prostheses over arterial homografts and their distinct inferiority to autogenous vein grafts are well demonstrated.

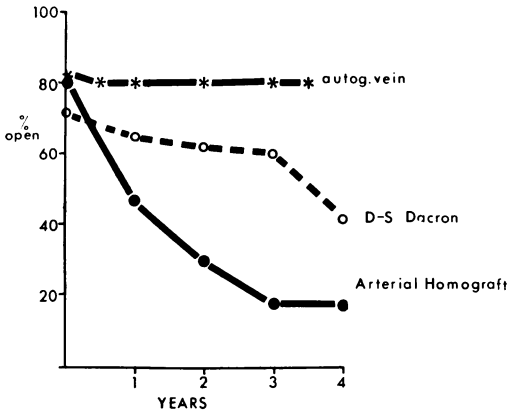

FIG. 2. Comparative patency rates in femoropopliteal occlusive disease treated by bypass grafting utilizing D-S prostheses (193 cases), arterial homografts (94 cases) and autogenous venous grafts (79 cases). (Noncontemporaneous observations.)

2. Angiographic Findings

Of the 835 cases comprising the total clinical group, 561 were found suitable for angiographic analysis (Table 5). In order to qualify for inclusion in the study group, a case must have had at least two postoperative angiograms 6 to 24 months apart. In 274 cases, because of clinical circumstances (such as early failure of the graft, amputation required by advance of the disease, and early and late mortality) as well as for individual reasons peculiar to each case, the required angiographic schedule could not be maintained. Among the 561 cases accepted for the study, 427 represented aorto-iliac and 134 femoro-popliteal operations. Of this group, 198 or 35.3 per cent showed angiographic changes of some degree; about half of these cases had been followed for four years or more (Table 6).

The types of abnormal appearance observed in the angiograms are schematically presented in Figure 3; examples of their variations are shown in Figures 4–8. The most common change was an alteration of the outline of the prosthesis which resulted in a wavy or coiled appearance. This finding occurred in two variants which were much alike morphologically but displayed some important differences in behavior. By far the greater number showed more widely spaced coils or pleats, was usually seen in the proximal part of the prosthesis and, as will be seen in more detail, ran a very benign course; this finding was designated *pleating*. The other, much rarer, finding of this type differed in having tighter wrinkles, in being located further distally in iliac prostheses, and in a tendency to progress; the name *wrinkling* was attached to this change. Although the morphologic differences appear trivial, making a distinction between the two changes is of considerable clinical importance, for whenever the opportunity arose to inspect the pros-

TABLE 6. *Distribution of Follow-up Periods in 234 Cases of AI-FP D-S Prostheses with Angiographic Changes*[1]

	Follow Up (Yr.)	No. Cases	% of Total	
1964	<1	27	11.5	
1963	1	36	15.4	
1962	2	34	14.6	
1961	3	33	14.1	
1960	4	38	16.2	
1959	5	23	9.8	
1958	6	34	14.6	44.4
1957	7	8	3.4	
	>7	1	0.4	
		234	100.0	

[1] Cases (36) in which the first *late* angiographic change was closure of the graft are included.

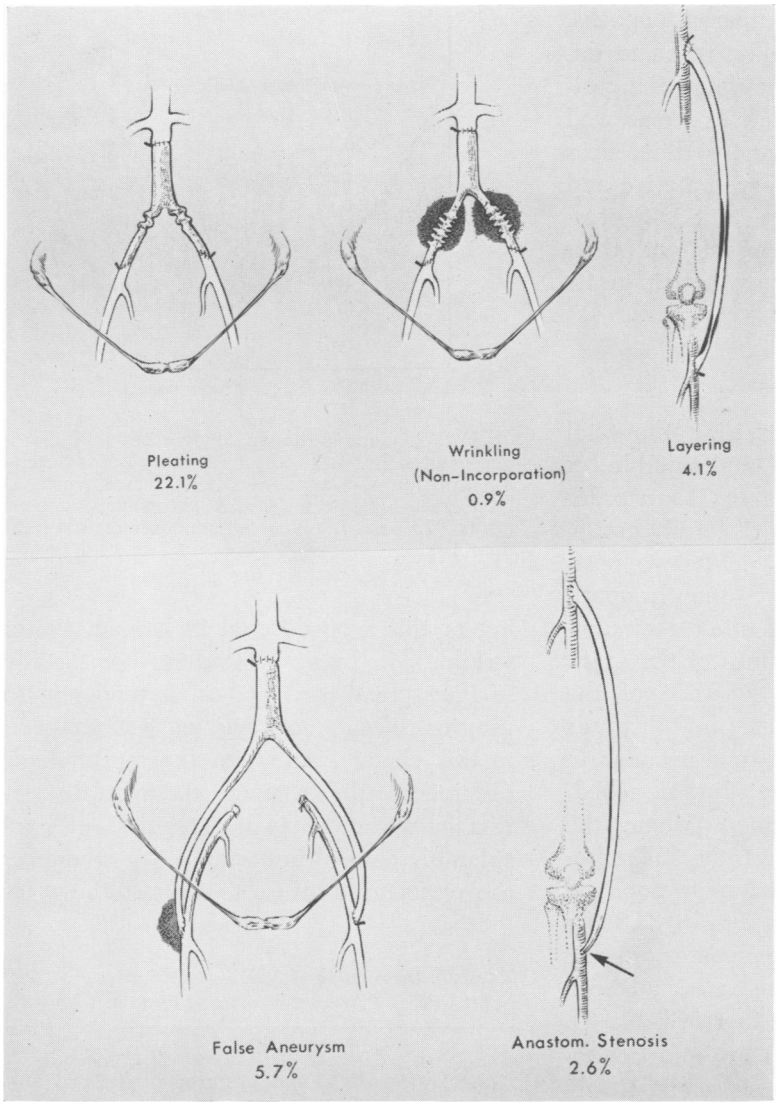

FIG. 3. (Top) Angiographic changes in 561 D-S prostheses directly attributable to the behavior of the prosthesis. (Bottom) Angiographic changes in 561 D-S prostheses due to technical factors.

theses showing the appearance of wrinkling at secondary operation (and rarely at necropsy), the segment with the abnormal roentgenologic finding disclosed a lack of incorporation by the surrounding tissues. (Indeed, this lack of incorporation was the circumstance that made reoperation necessary by causing graft malfunction.) Because of this, "wrinkling" has been alternately named "nonincorporation." The next most frequently encountered roentgenologic finding consisted of an irregularity of the luminal surface of the prosthesis, giving the impression of the deposition of a layer of clot resulting in some narrowing of the lumen; this change was named *layering*. Although the roentgenologic findings designated as *false aneurysm* and *stenosis of the anastomosis* are not strictly intrinsic graft changes (being caused by technical errors or healing complications), in some tabulations they were listed as such since angiographic evidence is often the first sign of their presence. The various changes often occurred in combination, and in order to avoid a cumbersome list of variations,

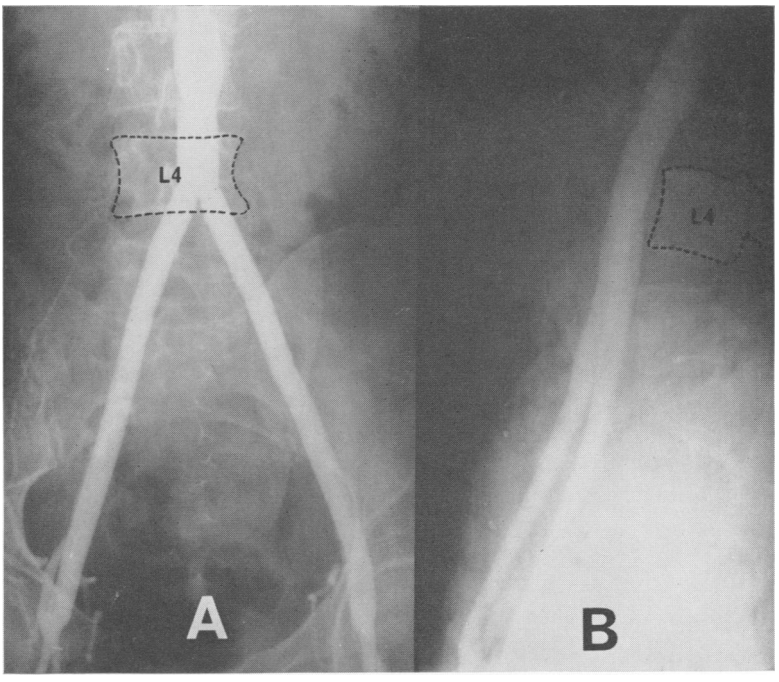

FIG. 4. Normal aortographic appearance of a bilateral aorto-femoral D-S bypass graft 33 months postoperatively. A) Postero-anterior, B) lateral view.

the most important or the most advanced change in these combinations was listed in a given case.

A scrutiny of Tables 7 and 8 discloses that in the aortic-iliac area the most common change was pleating, which occurred in 26.5 per cent of this group. After the femoro-popliteal operations, on the other hand, the most frequently seen angiographic change was false aneurysm. The overall incidence of angiographic changes was higher in the aorto-iliac operations, due mainly to the very high frequency of occurrence of pleating. Intimal layering occurred with approximately equal frequency in both regions. In general, although the

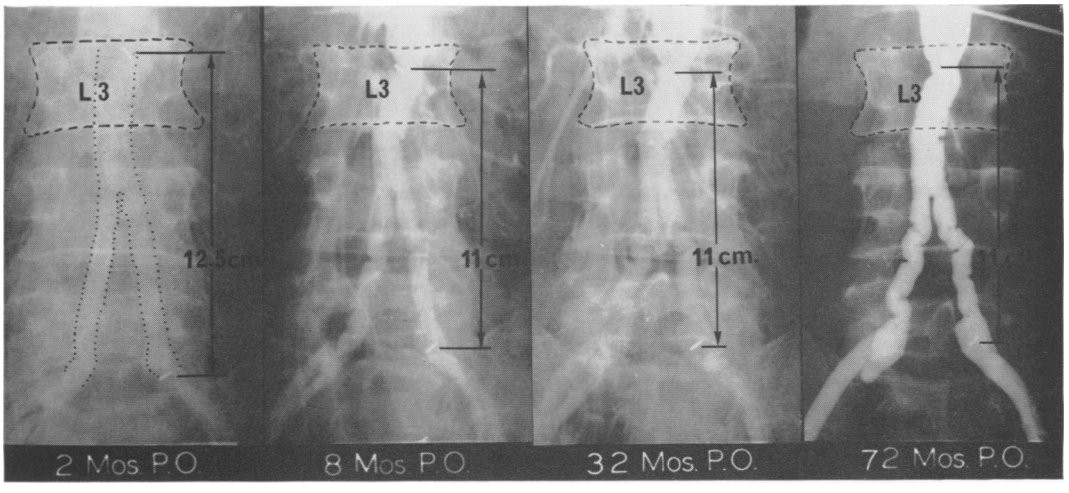

FIG. 5. Aortographic appearances of a bilateral aorto-femoral D-S bypass graft showing pleating. No progression during 64 months.

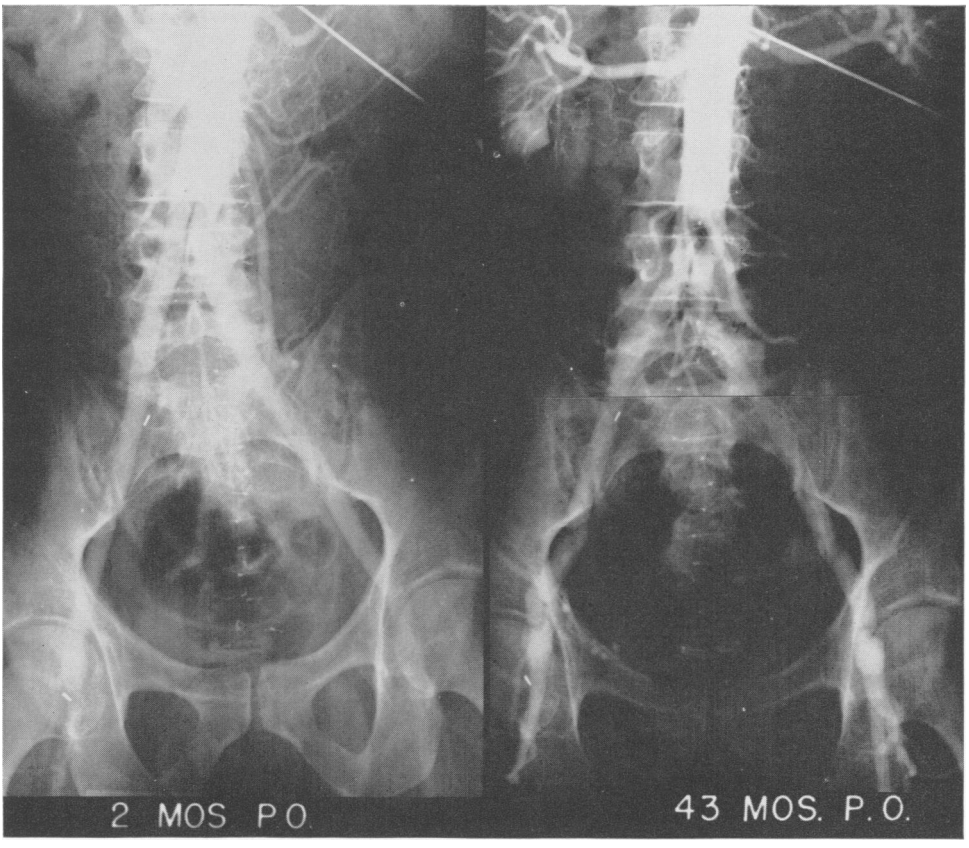

FIG. 6. Wrinkling of the proximal portions of the limbs of a bilateral aorto-femoral bypass. The segments of the implant showing the angiographic change were found at exploration to be sequestered.

incidence in both anatomic areas appears to be high (38.6 and 24.6%, respectively), if one analyzes the severity of the changes one finds that by far the largest percentage of the changes was of the mild variety. Only 4 per cent of the aorto-iliac and 9 per cent of the femoro-popliteal operations showed changes that were severe enough to be graded 3+. A special note should be made of the incidence of the slow flow of blood which quite frequently was observed in femoro-popliteal prostheses. Although this is not a direct manifestation of intrinsic graft change, it has great importance in the ultimate behavior of the prostheses, as will be discussed presently.

TABLE 7. *Type and Severity of Angiographic Changes in 427 AI Grafts*

Extent		Pleating	False Aneurysm	Intimal Layering	Stenosis of Anastomosis	Non-incorp.	Total No.	Total %
1+		92	4	14	10	3	123	28.8
2+		15	5	2	2	1	25	5.9
3+		6	8	1	1	1	17	4.0
Total	No.	113	17	17	13	5	165	
	%	26.5	4.0	4.0	3.0	1.2		38.7

Note: 2 AI D-S prostheses showed, in addition, *slow* blood *flow*.

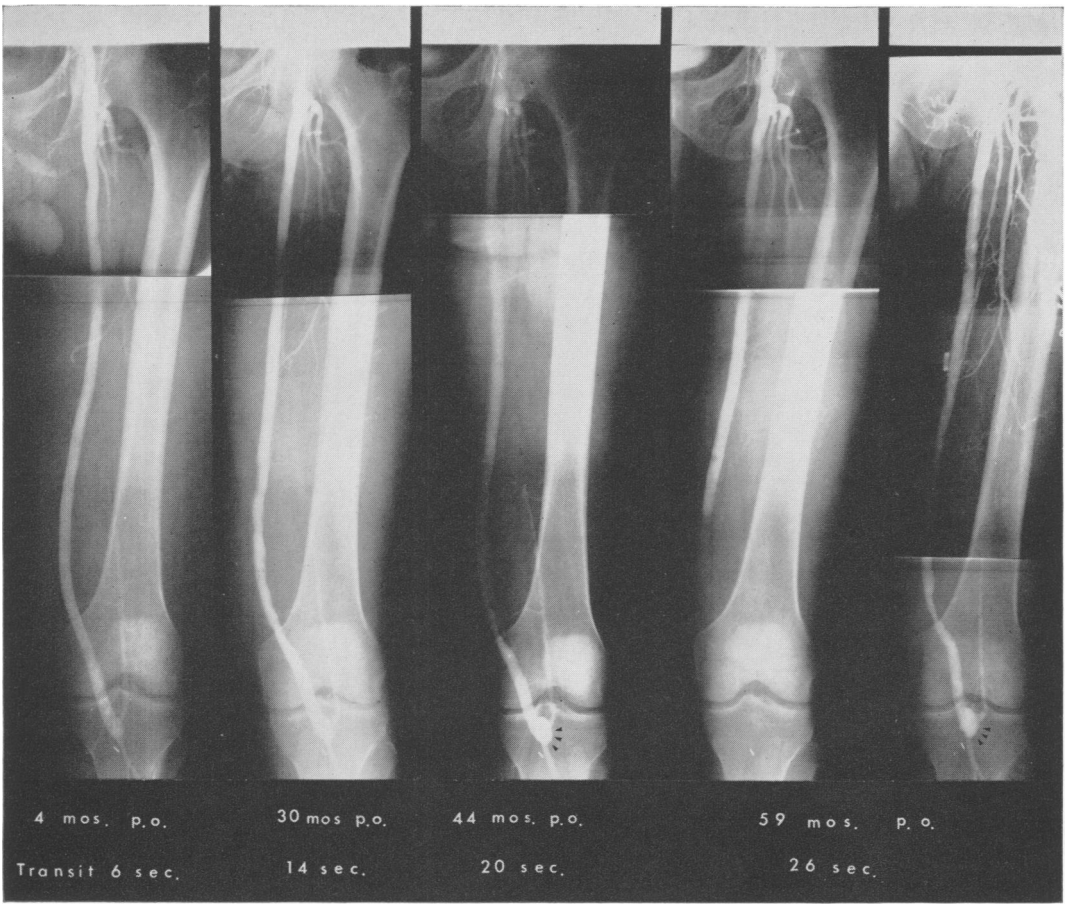

FIG. 7. Arteriographic evolution of layering. First appearance of luminal surface clotting at 30 months, with simultaneous appearance of a small aneurysm at distal suture line; transit time slightly prolonged. At 44 months: layering is more marked, increase in size of false aneurysm. At 59 months: marked prolongation of transit time, luminal surface thrombosis more severe. (3 months later graft occluded).

In Tables 9 and 10 the location of the changes along the course of the prosthesis is tabulated. The most common site in the aorto-iliac area was one iliac limb, while next in order, both iliac limbs were affected. In the femoro-popliteal prostheses the changes tended to be diffuse.

For finding an answer to the question of whether the morphologic changes noted in angiograms of prostheses are due to

TABLE 8. *Type and Severity of Angiographic Changes in 134 FP Grafts*

Extent		Pleating	False Aneurysm	Intimal Layering	Stenosis of Anastomosis	Non-incorp.	Total No.	Total %
1+		3	2	2	1	0	8	6.0
2+		7	4	2	0	0	13	9.7
3+		1	9	2	0	0	12	9.0
Total	No.	11	15	6	1	0	33	
	%	8.2	11.3	4.5	0.7	0		24.7

Note: 7 FP D-S prostheses showed, in addition, *slow* blood *flow*.

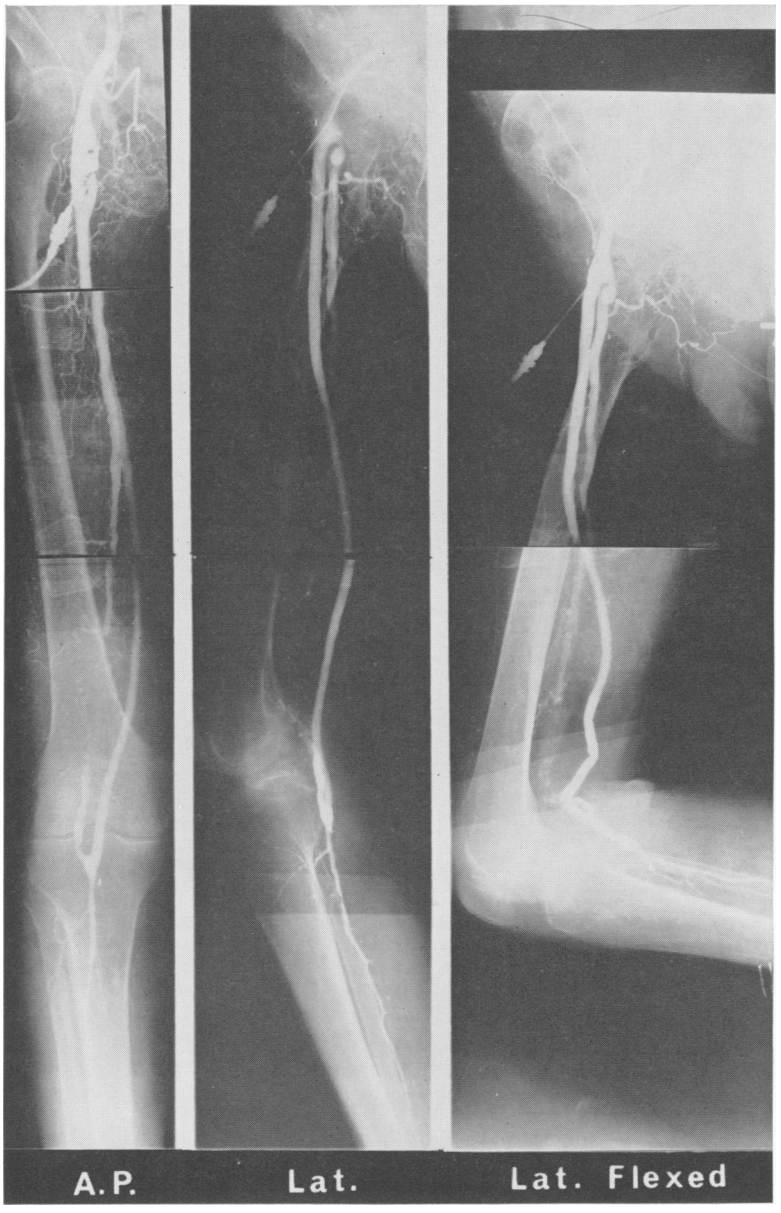

FIG. 8. Three views of a femoro-popliteal D-S bypass at 18 mo. postop. Buckling in the popliteal area is present only in a sharply flexed knee position. No evidence of change in the contour of the prosthesis in either anteroposterior or lateral views when the knee is extended or slightly flexed.

factors directly related to the structure of the prosthesis or whether they are due to factors essentially extraneous to the prosthesis, the tabulation of the time of the first appearance of these changes is of obvious importance. If one assumes that the

TABLE 9. *Location of Angiographic Changes in 427 AI D-S Prostheses*

	One Iliac Limb	Both Iliac Limbs	Aortic Shaft	Aortic Shaft Both Il. Limb	Aortic Shaft One Il. Limb
No. Cases	74	60	20	9	0
% of Total	17.3	14.1	4.7	2.1	0

changes noted are caused by some deterioration of the fabric of the prosthesis, these changes should occur after some lapse of time following operation and should be progressive. A tabular representation (Table 11) of the dates of the first appearance of the changes shows that all types but one occur in the very early postoperative period and that the incidence very seldom increases with time. The only change that has a sustained occurrence over a period of years is intraluminal layering. From this observation one would, therefore, implicate factors outside the prosthesis in the causation of most of the morphologic alterations and certainly in the causation of pleating. An inspection of Table 12 bears out this assumption—pleating is far more common, severe and progressive in aorto-iliac than in aorto-femoral grafts, a fact that suggests that anatomic factors must play a part. As regards the causative mechanism of pleating, instructive information can be obtained from the measurement of the clips that mark the anastomotic lines in aorto-iliac operations, as shown in Figure 5. These measurements show a postoperative shortening of the distance between the lines of anastomosis and indicate that the pleating of the prosthesis results principally from the necessity for accommodation to the shortened distance between the upper and lower anastomoses. This shortening of the interanastomotic line, on the other hand, is brought about by the movement of the arterial stumps which were dissected free and to which the prosthesis was affixed. The greater frequency and severity of pleating in aorto-iliac grafts is explained by the circumstance that this movement is much freer when the distal anastomosis is at the level of the common iliac or external iliac arteries than it is when the distal anastomosis is made between the prosthesis and the common femoral artery, the latter structure being essentially fixed even after the completion of the anastomosis.

From the fact that the most commonly seen angiographic morphologic change, pleating, was of mild degree and did not

TABLE 10. *Location of Angiographic Changes in 134 FP D-S Prostheses*

Type of Change	No. Showing Changes	% of Total Grafts
Diffuse	59	44.0
Proximal	12	9.0
Distal	7	5.2

TABLE 11. *Postoperative Interval Preceding Appearance of Angiographic Changes*

		Postoperative Year of First Appearance of Change													
		1		2		3		4		5		6		7	
Type of Change	Location	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%	No.	%
Pleating	AI	60	47.2	22	17.3	20	15.7	12	9.4	2	1.6	0	0	1	0.8
	FP	3	2.4	3	2.4	3	2.4	0	0	0	0	1	0.8	0	0
	Total	63	49.6	25	19.7	23	18.1	12	9.4	2	1.6	1	0.8	1	0.8
False aneurysm	AI	12	34.3	0	0	5	14.3	0	0	0	0	1	2.9	0	0
	FP	10	28.5	3	8.6	1	2.9	2	5.7	1	2.9	0	0	0	0
	Total	22	62.8	3	8.6	6	17.2	2	5.7	1	2.9	1	2.9	0	0
Intimal layering	AI	7	33.3	4	19.0	2	9.5	2	9.5	0	0	0	0	0	0
	FP	0	0	1	4.8	1	4.8	1	4.8	3	14.3	0	0	0	0
	Total	7	33.3	5	23.8	3	14.3	3	14.3	3	14.3	0	0	0	0
Stenosis of anastomosis	AI	10	76.9	0	0	1	7.7	1	7.7	0	0	0	0	0	0
	FP	0	0	0	0	1	7.7	0	0	0	0	0	0	0	0
	Total	10	76.9	0	0	2	15.4	1	77.7	0	0	0	0	0	0

Note: Wrinkling (nonincorporation) appeared in 5 cases: three cases in the first year, two cases in the second year.

TABLE 12. *Pleating: Comparative Frequency, Severity and Progression of Pleating According to Type of Surgical Technic in 407 Angiographically Studied Cases**

Technic	Total Oper. (with Angio.)	Pleating %	Extent (%) +1	+2	+3	Progression %
Aorto-iliac graft	265	34.0	25.3	6.8	1.9	10.2
Aorto-femoral graft	142	20.4	19.7	0	0.7	5.6

* Cases in which the first *late* angiographic change was closure of the graft are not included.

show a tendency for progression, one would conclude that the role of this change in causing ultimate failure of the prostheses must be a minor one. This conclusion is supported by several strong pieces of evidence. As is shown in Table 13, in 46 prostheses with angiographic changes that were followed serially for from two to six years only 3 or 6.5 per cent ended in occlusion. Moreover, a study of the causes of 47 late graft failures among 198 cases that had been followed by serial angiography demonstrated that in only 15 or 31.9 per cent could the graft be implicated in the chain of events leading to closure (Table 14). Significantly, two thirds of the cases in which graft change played a major role in the causation of failure occurred in the femoro-popliteal area. Finally, in the total group of cases in which serial angiographic examinations were carried out, there were 36 in which the first angiographic change was the evidence of closure, without a suggestion in the preceding angiographic delineation of the graft that any morphologic change was taking place.

In cataloguing the angiographic findings of plastic arterial prostheses one must consider a phenomenon that has been given a rather serious interpretation by others. This alteration is almost always present in the angiograms of plastic prostheses extending from the groin to the popliteal artery when the roentgenogram is obtained in a lateral view with the knee in a sharply flexed (90° or more) position, and consists of buckling of the retrogenicular portion of the implant. We have not discussed this finding earlier since it is never encountered in routine angiographic studies. Moreover, lateral angiographic studies of femoro-popliteal plastic prostheses obtained consecutively in the flexed and extended positions of the knee demonstrate that the phenomenon of buckling is transient; it is not present in the extended limb (Fig. 8). Since the sharply flexed knee position required to produce this distortion of the prosthesis is rarely assumed by patients for prolonged periods and since prostheses displaying this type of change have often been followed for long intervals of time without showing progression, it appears to play only a minor role in the causation of the failure of prostheses.

3. Histologic Findings

The task of an accurate presentation of the histologic observations gathered from

TABLE 13. *Clinical Fate 46 D-S Prostheses with Angiographic Changes Followed 2–6 Years by Serial Angiograms*

Type of Change	Total	Open s̄ Symptoms	Open c̄ Symptoms	Closed	Amputation
Pleating	37	32 (87%)	2 (5%)	2 (5%)	1 (3%)
Intimal layering	3	2	1	0	0
Stenosis of anastomosis	2	2	0	0	0
False aneurysm	4	3	0	1	0
Total	46	39 (85%)	3 (6.5%)	3 (6.5%)	1 (2%)

TABLE 14. *Causes of 47 Late Graft Failures in 198 Cases Followed by Serial Angiography*

	Cause of Failure				
	Progression of Disease	Graft Change	Healing Complications	Other	Total
Aorto-iliac operations	9 (52.9%)	5 (29.4%)	1	2	17
Femoropopl. operations	19 (63.4%)*	10 (33.3%)	1	0	30
Total	28 (59.5%)	15 (31.9%)	2	2	47

* In 7 cases: marked increase in transit time across prosthesis.

the study of the recovered specimens of D-S prostheses (Table 15) is fraught with difficulties. These difficulties are due both to the factors that are inherent in any objective presentation of descriptive data and to circumstances that are peculiar to the histologic behavior of plastic arterial prostheses. These special circumstances are the result of the variations in the behavior of the implants in accordance with their tissue surroundings. The same prosthesis may present excellent arteriogenesis in one segment—when the adjacent tissue possesses adequate vascularity, absence of exudative reaction and freedom from infection—and show lack of incorporation in another segment a relatively short distance away—when the surrounding tissue conditions are unfavorable. In assessing recovered specimens of this type, a balance of the favorable and unfavorable changes must be struck, and the clinical behavior of the implant must also be taken into consideration. For similar reasons, in evaluating an implant that has shown malfunction because of poor arteriogenesis in the presence of infection or excessive exudative tissue changes, the failure of the prosthesis cannot properly be ascribed to the intrinsic defect of the plastic prosthesis.

In this account of the histologic findings, implants showing improper acceptance because of infection or tissue reaction caused by excessive bleeding or collection of serum—and in which, therefore, the normal event of arteriogenesis cannot have been expected to take place—were excluded from the grading of the performance of the prostheses; they were, nevertheless, an important source of information for the understanding of the natural history of prosthetic arteriogenesis. In the assessment of the remainder, a framework of criteria was applied that took into consideration the gross appearance of the graft as a whole and the gross and histologic appearances of the connective tissue ingrowth into the fabric and of the pseudo-intima and that graded them on an arbitrary semiquantitative scale. This method of evaluation has been reported in detail in the description of our long-term experimental investigation of the D-S prosthesis.[2]

The *gross* findings (Fig. 9–13) in the prosthesis revealed a generally satisfactory connective tissue binding of the fabric to the surrounding tissue. The connective tissue reaction around the implant almost always allowed the sharp dissection of a well-defined tissue plane, the dissection

TABLE 15. *Summary of Findings in 28 Human D-S Prostheses Recovered After Death or at Reoperation*

Findings		No.	%
Duration of implantation (mo.)	6–12	10	36
	13–24	8	29
	25–36	7	25
	37–81	3	10
Region of implantation	AI	12	43
	FP	16	57
Extent of specimen	Whole	17	61
	Partial	11	39
Over-all grading of quality	Good	19	68
	Fair	6	22
	Poor	3	10

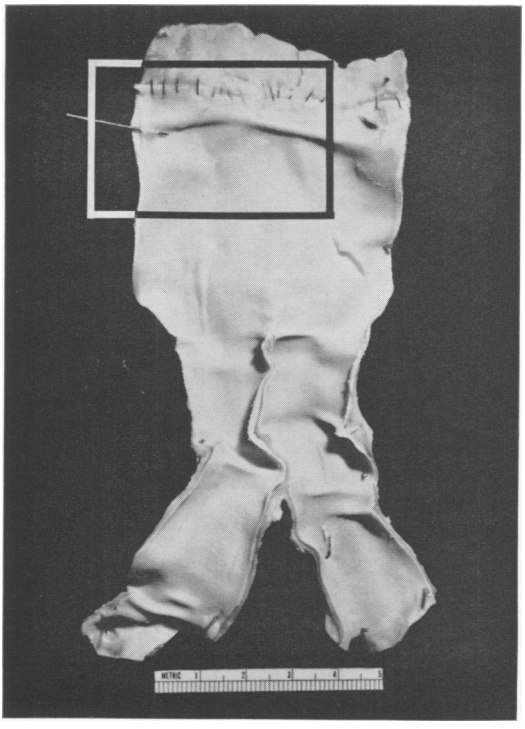

FIG. 9. Aorto-iliac D-S replacement graft recovered 22 months postoperatively. Good incorporation but thin intima.

thus leaving a brim of tissue 2–3 mm. in width adhering to the outside surface of the fabric. At times, especially in aorto-iliac specimens, the connective tissue reaction was excessive and the outer shell measured 4–5 mm. in thickness. In long femoro-popliteal implants short segments (measuring 3–4 cm. in length) which showed lack of incorporation were encountered at times; these segments were bathed in a glary, inspissated, nonpurulent exudate enclosed by a thick (2–3 mm.) connective tissue capsule that most likely represented a partially absorbed and perhaps subclinically infected seroma or hematoma. When feasible, this exudate was examined bacteriologically and usually rendered negative results after culture and smear studies. The internal surface of the prosthesis corresponding to these areas lack intimal covering, or its intimal covering consisted of a fresh thrombus. In every specimen examined the fabric was intact, even when the incorporation was defective (as in the instances just mentioned). The most common abnormal morphologic gross change in the fabric was the alteration of outline described before as pleating. This change in the profile of the implant was most frequently encountered in the iliac limbs of aorto-iliac grafts and, unless of a marked degree, did not interfere with orderly arteriogenesis; even in the most marked instances, the connective tissue ingrowth was adequate but the neo-intima was defective and ulceration was common. The development of the neointima showed markedly constant features. Whenever the incorporation of the prosthesis was normal, the intimal covering appeared intact. With few exceptions, to be mentioned presently, the intima was thin—1 mm. or even slightly less. In two femoro-popliteal implants in which slow blood flow had been described *in vivo*, the intima showed excessive thickness (2–3 mm.) with frequent superimposed unorganized thrombi of recent origin. Either on gross inspection or on scrutiny of roentgenograms of the prosthesis, calcification could not be detected. In two aorto-iliac prostheses and one femoro-popliteal implant recovered three to almost seven years after implantation, early atheromatous changes of the intima were noted in the

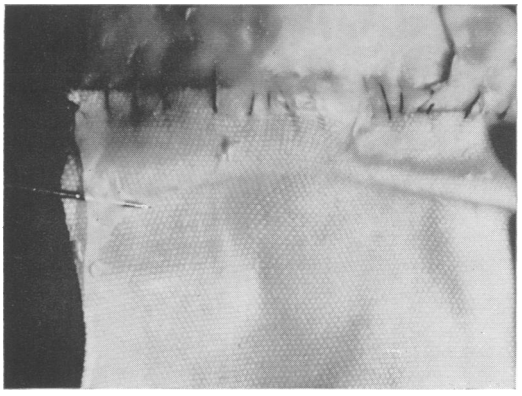

FIG. 10. Close-up view of bracketed area in Fig. 9.

form of small (4–8 mm.), slightly raised, soft, yellow-colored plaques.

On microscopic examination (Figs. 14–16), the adventitial connective tissue of the implant appeared to be composed of collagen fibers of very low cellularity. Inflammatory exudate was entirely absent unless the prosthesis showed gross lack of incorporation described above. The connective tissue extended into the fabric and invaded not only the interstices but also the spaces among individual fibers in the yarn. This connective tissue ingrowth reached the luminal surface of the prosthesis and seemed to support the pseudo-intima. Although much more cellular than the adventitial layer, the connective tissue within the fabric was markedly free from inflammatory cells or foreign body cellular reaction. The intimal layer was quite uniformly thin and showed an orderly arrangement; its most superficial layer consisted of hyalinized connective tissue that stained like collagen with the Gomori trichrome stain. The cellularity of the pseudo-intima increased as one proceeded outward (away from the lumen) and in its most external portion it contained connective-tissue-like

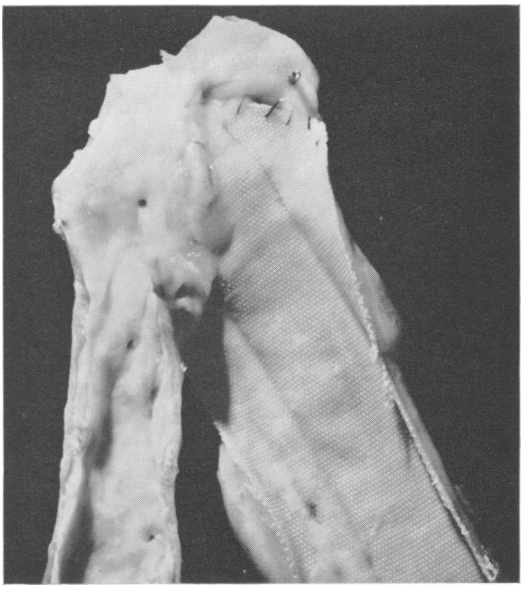

FIG. 12. Close-up view of the proximal luminal surface of the prosthesis shown in Fig. 11.

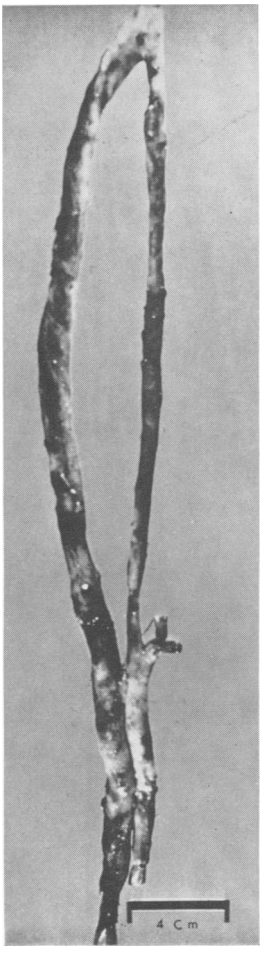

FIG. 11. Adventitial surface of a femoro-popliteal D-S bypass. Firm and uniform connective tissue binding.

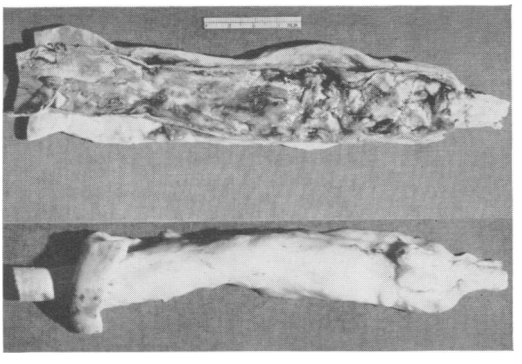

FIG. 13. (Top) The adventitial surface of a segment of a femoro-popliteal D-S bypass showing nonincorporation. Thick connective-tissue shell in which the implant lies loose. (Bottom) The inner surface of the same prosthesis. Complete lack of pseudo-intimal formation; extensive surface clotting.

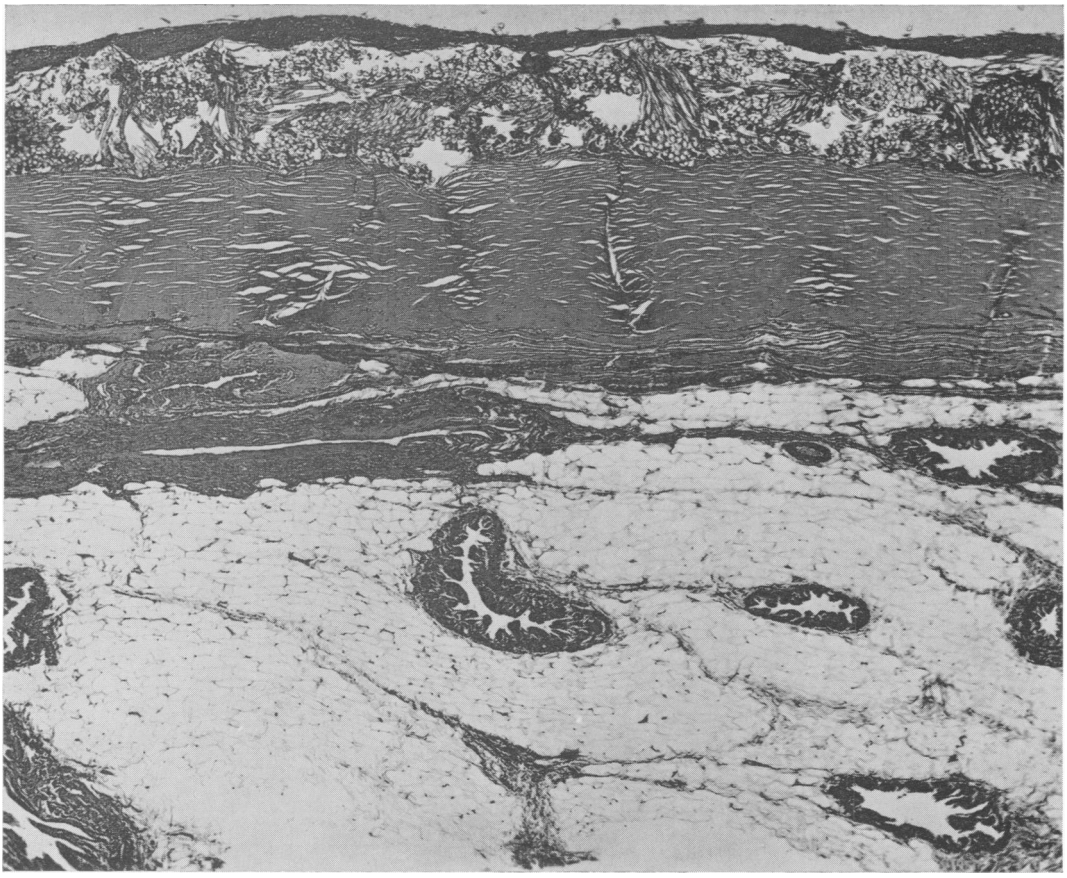

FIG. 14. Microscopic section of the wall of the aorto-iliac D-S prosthesis shown in Fig. 9. Good connective tissue ingrowth; intima well formed but thin. (H & E, ×75)

pegs that seemed to extend into the inner surface of the fabric. At times the collagen-appearing pseudo-intima was covered by a thin layer of substance staining like fibrin. The microscopic appearance of all these structural details appeared to be stabilized by the end of the first year of implanation. Thereafter, the only observed alteration was the appearance of small atheromata in the pseudo-intima. Calcification was absent even in the oldest specimens.

A synoptic assessment of these findings permits the grading of the prostheses examined as good in 19, fair in 6, and poor in 3 cases (Table 15). Both the implants graded as good and those graded as fair were fully compatible with satisfactory clinical function. It should be further noted that the prostheses graded as poor, on close analysis, appeared to owe their unsatisfactory arteriogenesis primarily not to their intrinsic qualities but to circumstances that were, fundamentally, technical errors or healing complications.

4. Healing Complications

It should be stressed, perhaps superfluously, that the healing complications listed in Tables 16 and 17 include only those cases in which the prosthesis was the starting point, or became a part, of the pathologic healing process. Complications confined to the healing of the surgical incision, usually superficial infection, without in-

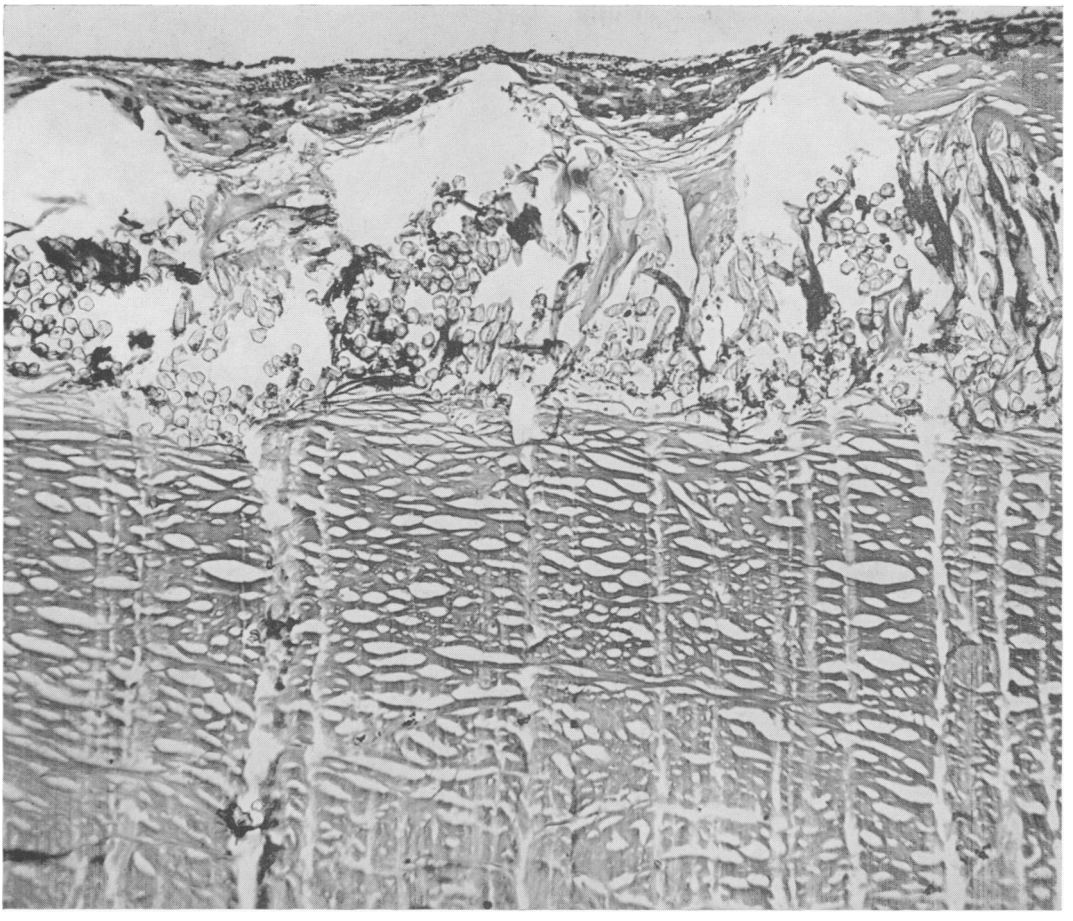

FIG. 15. Microscopic section of the wall of the femoropopliteal D-S prostheses shown in Fig. 11 and 12. Satisfactory invasion of the fabric by fibroblasts. Intima thin. (Gomori trichrome stain; ×105.)

volving the implant were not here taken into consideration.

The most common healing complication was false aneurysm of the suture line, and it occurred with much greater frequency in femoro-popliteal implants. Indeed, even in most of the cases of false aneurysms listed as having occurred in aorto-iliac prostheses the site of the false aneurysm was in the region of the femoral anastomosis. The next most common healing complication was infection, followed hy hemorrhage. The gravity of these complications is well illustrated by the associated loss of life and limb.

In order to determine the extent of the part that the prosthesis plays in the causation of these complications, it is desirable to compare their respective incidences in grafting operations using D-S prostheses and in endarteriectomies. Insofar as the present clinical material is concerned, this comparison must be limited to aorto-iliac operations since the number of endarteriectomies performed in the femoro-popliteal region was very small. As a matter of fact, there is a marked disparity even between the sizes of the aorto-iliac graft and endarteriectomy groups, but a comparison of trends seems to be valid. As shown in Table 16, the incidence of infection and false aneurysm was much higher in the

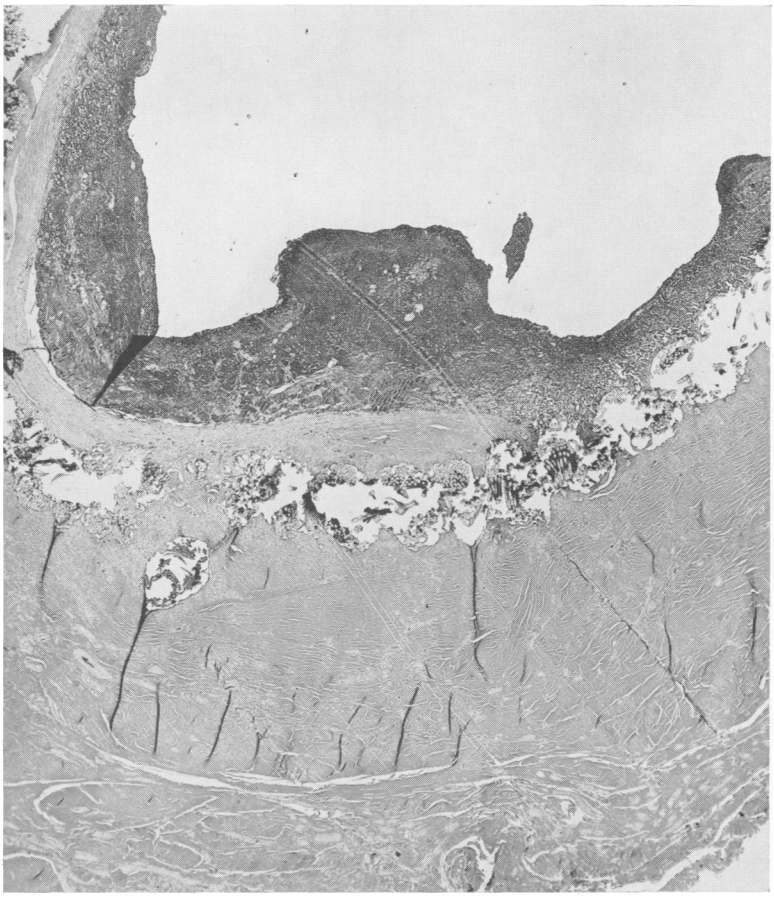

FIG. 16. Femoro-popliteal D-S prosthesis recovered 50 months postoperatively. Superimposition of layers of surface thrombi of various ages. Velocity of blood flow *in vivo* was markedly reduced. (Gomori trichrome stain; ×25.)

grafting operations, another indication of the hazard to healing that plastic prostheses, as implanted foreign bodies, represent. With the application of special care to technical details, this hazard can be reduced to an acceptable level, as has been done in this group of cases during the latter part of the clinical experience (Fig. 17).

Discussion

Comments of Case Material. For the assignment of proper weight to some of the statistical analyses, certain aspects of the selection of case material need clarification.

In evaluating the patency rates in cases with D-S grafts, the immediate postopera-

TABLE 16. *Healing Complications in 619 D-S Grafts and 87 Endarteriectomies (AI Operations)*

Type of Operation	Infection		False Aneurysm		Hemorrhage		Infection & Hemorrhage		Hematoma	
	No.	%	No.	%	No.	%	No.	%	No.	%
Endarteriectomy	0	0	0	0	2	2 3	1	1 2	0	0
D-S prosthesis	8	1.3	18	2.9	5	0.8	5	0.8	1	0.2

Endarteriectomy: 1 death, 1 amputation.
D-S prosthesis: 7 deaths, 5 amputations.

TABLE 17. *Healing Complications in 619 AI and 210 FP Dacron Prostheses*

Type of Operation	Infection		False Aneurysm		Hemorrhage		Infection c Hemorrhage		Hematoma	
	No.	%	No.	%	No.	%	No.	%	No.	%
AI D-S prostheses	6*	1.0	18	2.9	5	0.8	5*	0.8	1	0.2
FP D-S prostheses	2	1.0	23**	11.0	0	0	1**	0.5	1	0.5

* 7 deaths, 2 amputations.
** 3 amputations.

tive rates of patency were not considered for at least two reasons. First, assuming that the arterial substitute used is not grossly defective, its intrinsic qualities have only slight influence on the immediate success or failure of the reconstructive operation. The state of advancement of the disease and the technical factors have far more decisive roles in this respect. The inclusion of early patency rates in the assessment would, therefore, have introduced a serious source of error. Secondly, the consideration of early patency rates would not have contributed to the achievement of the main purpose of this study, that is, the estimation not only of the performance of the arterial substitutes over as wide a span of clinical observation as our experience can provide but also of the expectation of their future function.

The restriction of the survey of the patency rates to observations after operations for occlusive disease was based on the reasoning that the behavior of the prosthesis should be judged by the results in the cases in which it is put to the most severe test. In aneurysmal disease the problem of the loss of postoperative patency is not a serious one and the addition of the results of aneurysmectomies to the pool of clinical cases studied for the maintenance of late patency would have weakened this particular criterion of evaluation.

Thought must be given also to the adequacy of the samples used for the study of the morphologic changes seen in angiograms and for the histologic findings in recovered specimens. The group studied roentgenologically, encompassing 67.2 per cent of the total case material, seems amply sufficient to permit conclusions with reference to the entire patient population. On the other hand, the sample of 28 recovered specimens appears very small from the point of view both of the total clinical group and of the prostheses that ideally could have been obtained for examination. (The last named group, of course, is a theoretical one; it's size can be placed somewhere near the combined number of late postoperative deaths and of the amputations yielding usable specimens). Fortunately, however, the deficiency in the number of recovered specimens is importantly supplemented by the abundance of the morphologic data gained from angiograms. The correlation of histologic and angiographic data permits a combined interpretation of the information supplied by each and not only lends a material basis for the roentgenologic observations but permits a generalization of the histologic

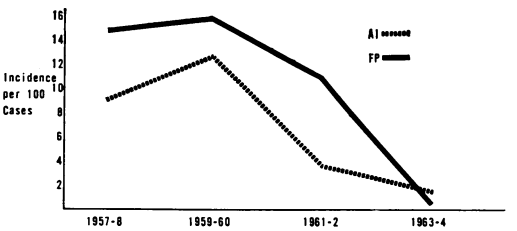

FIG. 17. Biennial incidence of healing complications in 835 operations with D-S prostheses.

findings. This is to say that a given roentgenographic finding, once its anatomic significance has been established with the help of the information obtained from the examination of histologic specimens, can be interpreted, when observed again, in anatomic terms without the actual histologic proof in every instance. It can be pointed out also that the histologic events observed in human plastic implants can reliably and profitably be amplified by the much more abundant knowledge of the events of experimental graft behavior.

Comparative Value of D-S Grafts and Endarteriectomy for Aorto-Iliac Lesions. Because of differences in the criteria of case selection, the case material of aorto-iliac endarteriectomies and that of aorto-iliac grafting procedures are not closely similar but, as will be seen from the considerations to follow, this circumstance does not invalidate the conclusions one may draw from a comparison of the results achieved with their use. We restrict the use of endarteriectomy to occlusive disease that does not significantly involve the arterial tree distal to the common iliac bifurcation, while we perform grafting operations in any technically suitable case presenting an acceptable risk regardless of the state of advancement of the occlusive process. Obviously, therefore, the cases with endarteriectomy represent a much more favorable clinical and technical group.* With these facts in mind, the difference in the success rates of the two procedures—ranging from 5 per cent to 12 per cent in favor of endarteriectomy—does not seem significant. One can justifiably assume that if endarteriectomies had been used more frequently in cases of more severe degree of involvement their success rate would have been lower or, conversely, that the results of the group with grafting operations would have been better if it had included a larger number of early cases. This assumption is supported by the statistical reports of others with the exclusive use of endarteriectomy in aorto-iliac occlusive disease, which supply patency data almost identical with our results with grafting.[4] One may well ask whether the application of the much more complex operation that endarteriectomy of the entire aorto-ilio-femoral arterial axis represents is warranted as a routine method to manage all aorto-iliac lesions when the reward in better results is either slight or nil.

Correlation of Histologic, Roentgenologic and Clinical Findings. The starting point of the correlation of the finding gained by the use of the three methods of observation is the normal histogenesis of the arterial substitute.

The available evidence, while not abundant, is sufficient to allow the conclusion that human arteriogenesis around the D-S implant is in all essential respects very similar to that observed in experimental (i.e., canine) implants of the same type.[2] The essential events are the sealing of the interstices of the fabric by fibrin plugs, the ingrowth of connective tissue through the interstices, and the formation of a pseudo-intima on the inner surface of the prosthesis. The pseudo-intima is fundamentally a thin layer of thrombus which by the end of 6 to 12 months of implantation becomes organized, most likely by the transformation of the multipotential cellular elements of the blood into a layer of modified connective tissue resembling, but by no means identical with, endothelium. The outstanding difference between canine and human arteriogenesis is the poor development of the pseudo-intima in the latter. The human pseudo-intima is always thin and is not as well bound to the parietal connective tissue as is the pseudo-intima of a canine implant. Both in the human and the canine implants, the pseudo-intima, although it may

* In actual numbers, the incidence of early and advanced occlusive disease in grafting operations was 67 and 33 per cent and in endarteriectomies 86 and 14 per cent, respectively.

be formed before the connective tissue ingrowth has taken place, requires connective tissue support to maintain itself. Healing at suture lines between implant and artery takes place through a process roughly similar to the sealing of the interstices of the fabric. The suture line is closed by a fibrin layer which soon is replaced by connective tissue. True intima does not extend from the arterial side into the prosthesis for a distance greater than a few millimeters. Since the tensile strength of the connective tissue bridge on the outside of the suture line is of a low order, the integrity of the anastomotic line will depend largely on the strength of the suture itself.

In spite of the poorly developed intima, the new artery around the D-S prosthesis under normal healing conditions has all the essential qualities to serve as an effective blood conduit, as proved by the very satisfactory clinical behavior of aorto-iliac prostheses. Even relatively coarse distortions of its contour, creating ridges in the way of the blood stream, has no serious effect on its capacity to function; the example of pleating in angiographic studies of implants clearly demonstrates this. Its pseudo-intima, however, is extremely vulnerable to clotting. Whenever the velocity of blood flow falls below a critical value, thrombi readily form over the pseudo-intimal lining. The thrombosis takes place over an extended surface in a thin layer, and such layers gradually become superimposed, one upon another. The ultimate result is occlusion of the prosthesis, usually because of the obliteration of the distal suture line, as a rule the narrowest segment of the implant. The hemodynamic conditions of the aorto-iliac arterial segment seldom allow the drastic fall of velocity needed for these changes. In the femoral artery, however, the conditions are often present; a restricted distal arterial bed, a distal anastomosis that is often inadequate owing to the poor state of the recipient artery, and the length of the nonpulsatile rigid prosthesis all contribute to a drop in flow velocity that may at times be one thirtieth of normal. As shown in the studies described, in 7 of the 19 femoro-popliteal prostheses that occluded, the flow velocity was markedly reduced and was the main contributory cause of the loss of function.

In order that the normal arteriogenesis around the prosthesis may proceed without interruption, there must be a free access of the surrounding tissues to the prosthesis for the ingrowth of connective tissue. Whenever this ingrowth is prevented, the development of the formation of a new artery cannot take place normally. A fact not generally recognized is that apparently trivial causes may prevent this connective tissue invasion.

The varieties of abnormal incorporation of the prostheses fall into two broad categories: (1) those caused by inhospitable but grossly uninfected tissue environment and (2) those caused by manifest infection in the adjacent tissues.

(1) The most common circumstance that renders the tissue bed of the graft unreceptive to the prosthesis is excessive exudation of serum, lymph or blood. Collections of exudate of this type may arise in certain anatomic areas in spite of the use of the requisite gentleness of dissection and tissue handling. The inguinal region is notoriously prone to become the site of this complication as also is the long submuscular tunnel in the thigh which must be prepared for the reception of the prosthesis. Unkind handling of tissues and brusque dissection will obviously increase the probability of unfavorable conditions of healing. It is very likely that many of these collections of exudate become secondarily infected but the infective process does not become clinically manifest. (Organisms can occasionally be cultured from accumulations of fluid of this type although suppurative changes are always absent). The seroma, lymphoma or hematoma act as a barrier between the prosthesis and the tissues in

the environment and prevent the access of connective tissue to the implant. The prosthesis will then lie bare in a connective tissue capsule filled wtih a thick inspissated exudate. If the area of nonincorporation involves only a short prosthetic segment, the graft may still function clinically for months or years. Inasmuch as the section of the implant without incorporation has no pseudo-intimal lining, the more extensive the area of sequestration the more likely that the prosthesis will thrombose. While, as seen in the serial angiographic studies, the distortion of the contour of the prosthesis caused by its accommodation to the changing anatomic demands of its environment (so-called pleating) is an essentially stationary change, the wrinkling brought about by nonincorporation usually shows progression. The reason for this behavior is easy to see. In pleating, arteriogenesis is normal and thus the prosthesis becomes fixed early by the connective tissue ingrowth, and by the time the pleating fully develops, further distortion of the implant is not likely; in wrinkling, on the other hand, owing to the lack of proper incorporation, the prosthesis, or a section of it, is virtually loose and is capable of altering its contour for a longer period of time.

The single most common healing complication of the prosthesis, false aneurysm, is in most instances a special case of nonincorporation or improper arteriogenesis. The essential condition for the occurrence of this complication is the presence of a collection of blood, serum or lymph in the vicinity of the suture line, with or without an accompanying low-grade infection. As a result, the suture line fails to be appropriately sealed by connective tissue and a small secondary hemorrhage ensues. This is temporarily tamponaded by the confining effect of the adjacent tissues, and a hematoma forms. The hematoma undergoes partial lysis, allowing more blood to escape. This event may repeat itself serially; the peripheral brim of the hematoma eventually becomes organized into a sac-like connective tissue shell that in the end ruptures. It is rare that the original escape of blood is made possible by the textile imperfection of the fabric of the prosthesis, in which case the resulting false aneurysm can be ascribed to graft failure. (Indeed, we have not seen this occurrence after the first year of the use of the D-S prosthesis, when its textile characteristics were changed.) Nor is the breakage of the thread forming the suture line an important cause of bleeding from the anastomosis. The usual cause is either a small leak from imperfectly placed suture lines or the exudative reaction in the adjacent tissues. As a consequence, false aneurysms make their appearance almost invariably soon after the operation, usually within a few weeks, although months or years may pass before they are clinically recognized. The angiographic studies described clearly demonstrate this fact.

(2) The second type of improper arteriogenesis, that caused by overt infection, hardly requires comment. The reasons for the lack of incorporation in an area where purulent infection is present are self evident. It is to be noted, however, that when the infection does not involve the suture line, even a grossly infected prosthesis may function for a considerable length of time (for several months). As has been proved by ample clinical evidence, however, these prostheses are, with very rare exceptions, ultimately unsalvageable.

Current Value and Possible Improvement. From what has been presented regarding the deportment of the D-S prosthesis, one can conclude that this arterial substitute (and undoubtedly other textile prostheses made of the same plastic) has qualities that render it a satisfactory blood conduit in most anatomic circumstances, provided certain conditions for arteriogene-

sis are present in the tissue environment. These essential conditions are the presence of healthy and well vascularized tissues and the absence of exudate, sterile or infected, in the bed of the implant. The provision of these conditions requires exceptional care in tissue dissection and in the avoidance of contamination. Since the prosthesis is essentially an implanted foreign body, the securing of the last-named condition is particularly important. Even in the most favorable circumstances of healing, however, the new artery built around the D-S prosthesis has the serious deficiency of an inadequate intimal lining. This deficiency, together with the likelihood of the occurrence of inhospitable tissue surrounding, reduces the quality of the performance of the D-S prosthesis in the femoro-popliteal region to an unsatisfactorily low degree. The imperfect intima also renders the prosthesis unsuited for arterial replacements when the new conduit has a diameter less than 6 to 8 mm.

It would be tempting but unprofitable to speculate on ways to improve the performance of this (and other similar) prostheses. The obvious need would be to achieve the formation of a neo-intima more closely approaching the qualities of the biologic arterial lining. At this time it seems highly questionable that this goal can be reached by changes in the technic of fabrication. Minor improvements in the gross features of arteriogenesis may be possible through technical modifications, but an approach to truly biologic qualities in a plastic arterial substitute is out of the reach of any but the boldest imagination.

Summary and Conclusions

In a study covering seven years of clinical experiences, the performance of a Dacron prosthesis as an arterial substitute was evaluated on grounds of late patency rates, morphologic changes in serial angiograms, histologic behavior in tissue specimens, and the incidence of healing complications.

The maintenance of late patency rates was found very satisfactory in aorto-iliac operations but disappointing in the reconstruction of the femoro-popliteal arterial stem. The late results in the aorto-iliac region were about the same as with endarteriectomy, but those in the femoro-popliteal region were much inferior to the four-year success rate of operations using autogenous vein grafts.

Morphologic alterations of the plastic implant could be demonstrated in over 30 per cent of the cases by means of postoperative serial angiograms, but with few exceptions these changes were of minor character and did not affect the functional capacity of the prostheses. The angiographic study suggested that over 80 per cent of the prostheses were faultlessly incorporated by the recipient tissues. The gross and histologic study of 28 recovered prosthetic specimens confirmed this impression. The histologic investigation further disclosed that improper incorporation of the prosthesis, or of parts of it, was the result of inhospitable tissue environment frequently associated with or created by infection. The only great deficiency of the well-incorporated prosthesis was its pseudo-intima that was poorly developed and vulnerable to thrombosis in the presence of stagnant blood flow. The latter defect, in association with hostile hemodynamic conditions, was the principal cause of the frequent late failure of the prosthesis in the femoro-popliteal region.

In the group as a whole, the incidence of healing complications directly involving the implant was high, a fact that underlines the hazards that an implanted foreign body (which an arterial prosthesis is) represents for the proper healing of tissues. The circumstances by which special attention to technical details reduced by a margin of 90 per cent the incidence of the

complications in the last years of the experience reported emphasize the need for and effectiveness of fastidious care in the use of these devices.

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Discussion

Dr. Robert Richie Linton (Brookline, Mass.): I rise primarily to give you a little different explanation for the high failure rate of bypass plastic grafts in the lower extremity from what Dr. Szilagyi has given us. I have implanted 35 such grafts and only 2 (6%) are patent after five years, a failure rate of 94 per cent, whereas in 150 saphenous vein bypass autografts for the same number of years approximately 85 per cent are patent, a failure rate of only 15 per cent.

It is my opinion that the chief cause of failure is the tremendous amount of scar tissue that forms around these plastic grafts, with the resulting loss of elasticity in them. It is not, I am sure, in the majority of patients an advance in their disease or my ineptness of implanting this type of graft or we should see it in our saphenous vein autografts as well, since many of them have much poorer outflow or run-off vessels than those I used the prosthesis on.

(Slide) This first slide is a Dacron prosthesis, or a portion of one, removed 3 months after it was implanted because of occlusion. It demonstrates, I believe, the adherent difficulty with these prostheses as we have them today since it shows a tremendous amount of scar tissue which has formed around the prosthesis within as short a time as 3 months. The pseudo-intima on the inside looks extraordinarily good.

(Slide) Dr. Szilagyi will recognize this as one of his combinations of Teflon and Dacron. It worked very well for 4 years and then one night while the patient was in bed it suddenly occluded. Like many of the occluded prostheses it resulted in such severe tachemia of the foot and lower leg that an amputation was necessary. Again notice the tremendous amount of scar tissue about the graft.

(Slide) This slide demonstrates an arteriogram performed on a patient who has had a successful prosthesis, now in for a period of approximately 5 years, but you will notice that when his knee is at a right-angle genuflexion there is a tremendous amount of kinking which I am sure interferes with blood flow through the graft. This also I think may result in dislodgement of the pseudo-intima if it is loosely attached and this is especially true of the pure Teflon grafts with resulting embolization of the distal arterial tree.

(Slide) In contradistinction to this marked kinking with prostheses please note this arteriogram demonstrating the gentle curving of a saphenous vein bypass autograft with the knee in right-angle genuflexion without any evidence whatever of kinking.

It seems to me that further research is indicated in trying to develop some new type of prosthesis because of the failure of so many of these that have been used and because there are certain cases that they would be most valuable in, in which we cannot do a saphenous vein bypass graft or a thrombo-endarterectomy.

Dr. Jere W. Lord, Jr. (New York): I take issue with one point Dr. Szilagyi has mentioned, namely, the question that all prostheses are essentially of equal value. This is suggested in the abstract, not so much in his presentation today.

Prostheses are like the Westerns on TV. There are the *good guys* and the *bad guys*. I think some Dacrons and Teflons are better than others, and we have had the best results with Dr. DeBakey's crimped, knitted Dacron over the past 7 years.

I would like to cite one case—a man of great stamina and faithfulness. I operated on him three times. In 1957 this man came to the hospital with an intermittent claudication of 6-month duration, early gangrene of the tips of the toes of both feet. Femoral pulses were absent. An aortogram showed a block of the common iliac arteries and terminal aorta.

An endarterectomy of the distal aorta and proximal common iliac arteries restored good pulses, and he did well for 6 months. His symptoms then then recurred, and he was re-admitted in October 1957 and another aortogram showed the same problem. This time we used an ethigraft manufactured by the Ethicon Compatny and anastomosed the aorta end-to-end to the prosthesis and end-to-end to each common iliac artery. This prosthesis functioned beautifully for 10 months and then