



Surgical Management of Aorto-Iliac Occlusive Vascular Disease

Edwin J. Whitman, M.D., and Dwight C. McGoon, M.D., Rochester, Minn.

RAPID STRIDES have occurred in the past 10 years in the development of surgical procedures for occlusive disease of the abdominal aorta and iliac vessels. Thrombo-endarterectomy was the first definitive surgical operation used in restoring circulation to the extremities. Homologous arterial grafting was next. Homografts were a great boon to the treatment of occlusive vascular disease of the aorta and the iliac vessels and were the first material that could actually replace diseased blood vessels with a fair degree of success. A better type of graft appeared desirable, and about 1957 the crimped nylon prosthesis became available. Teflon and Dacron prostheses followed. Credit for this rapid development must be extended to many persons working in the field.¹⁻⁵ Welch and associates⁶ reported 74 cases in which homografts were used prior to June, 1956, at the Mayo Clinic. Fifty-one of the 74 (68.9 per cent) patients had excellent results; 13 (17.6 per cent) had fair results; 7 (9.5 per cent) showed no improvement; and 3 (4.0 per cent) died. The follow-up period averaged only 7 months. Since late 1956 plastic prostheses have replaced homografts.

In this paper we will review the results of surgical management of aorto-iliac occlusive disease at the Mayo Clinic in the 3 years, January, 1957, through December, 1959.

Clinical Data

Eighty-seven procedures were performed on 80 patients for occlusive aorto-iliac disease. There

The authors have analyzed the results of direct surgical attack on aorto-iliac occlusive disease in 80 patients at a clinic in the 3 years from 1957 through 1959. Of the 87 procedures performed, 28 were thrombo-endarterectomies, and 59 consisted of insertion of plastic prostheses. Morbidity and mortality rates were considered reasonable when compared with those of other major procedures. The risk of operation was about 2 per cent. Study of the early and late results in these cases indicates that surgery has much to offer many patients with occlusive vascular disease of the aorta and iliac vessels.

were 64 men and 16 women in the group. Seventy-seven primary procedures were performed for atherosclerosis obliterans including bilateral procedures performed on 2 patients. Eight procedures were performed because of failure of previous procedures and 2 for embolic occlusion associated with mitral stenosis (Table 1). The average age of patients when the prosthesis was inserted was 51 years and the age when thrombo-endarterectomy was performed, 51.7 years. The majority of patients were in the fifth and sixth decades (Fig. 1). There were 3 postoperative deaths in the entire series.

Although 80 patients had operations for occlusive vascular disease of the aorta and iliac arteries, a far larger number of patients were seen but were not treated surgically. In other series the operabil-

Fellow in Surgery (Dr. Whitman) and from the Section of Surgery (Dr. McGoon), Mayo Clinic and Mayo Foundation.

ity rate varied from 25 to 60 per cent. Rigid criteria were used in determining the advisability of operation in each case. The mere presence of occlusive vascular disease was not considered an indication for operation. Some patients were considered

were obtained on 74 patients. All 28 patients who had undergone thrombo-endarterectomy and all except 3 who had been treated with prosthesis and survived responded with follow-up information.

Surgical Procedure Employed

The magnitude of the surgical procedure in each patient was determined by the extent of the pathologic process as indicated on angiographic study and as noted by the surgeon at the time of operation.

Thrombo-Endarterectomy.—This was the sole procedure in 28 patients. Five thrombo-endarterectomies were performed for segmental occlusion of the distal portion of the abdominal aorta; 8, for occlusion of the distal portion of the aorta and one or both common iliac arteries, and 15, for occlusion of the common and external iliac vessels (Table 2). In 11 patients in whom a prosthesis was inserted, endarterectomy of a major vessel was also

Table 1.—Pathologic Process in Surgical Cases

	Procedures	Patients
Atherosclerosis obliterans	77	75
Embolie occlusion due to mitral stenosis	2	2
Failure of previous surgical procedure		
Homograft failure	3	3
Nylon prosthesis failure	1*	
Teflon prosthesis failure	1*	
Thrombo-endarterectomy failure	3*	
Total	87	80

* Patients included with those undergoing operations for atherosclerosis obliterans.

poor candidates because of generalized atherosclerosis which made long-term survival improbable. Other patients elected to postpone operations. Thus, the present surgical series is weighted with

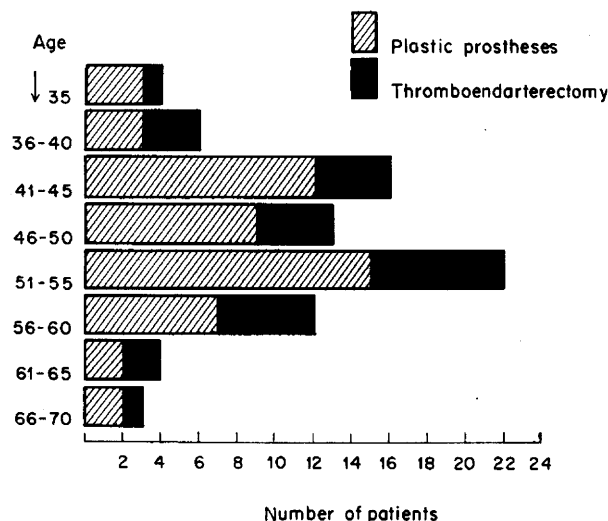


Fig. 1.—Age of patients at time of operation for aorto-iliac occlusive disease.

cases of more severe aorto-iliac occlusive disease, because in many cases of less severe disease medical management was employed.

The study included a thorough review of results including preoperative and postoperative pulsations, review of angiograms, and other pertinent factors. Data were obtained by return visits of the patients, by letters from the home physician, or by means of a detailed questionnaire sent to each patient. The patient was questioned in regard to ability to walk without claudication, further surgical procedures performed, use of anticoagulants, and ability to carry on his occupation. On physical examination, palpation of peripheral pulses was considered as the most reliable criterion of patency of the prosthesis. Angiograms were not routinely obtained in the follow-up period. Follow-up data

Table 2.—Surgical Procedures Employed

Procedure	No.
Thrombo-endarterectomy	
Aortic occlusion	5
Aorto-iliac occlusion	8
Iliac occlusion	15*
Total	28
Plastic prosthesis inserted	
Bypass only	
Bifurcation of aorta	21
Aorta to one iliac or femoral artery	13
Iliac to femoral artery	14
With resection	
End to end in aorta to end to side in iliac artery	9
Total	59
Grand total	87

* Four of these 15 procedures were bilateral.

necessary, either proximal to the prosthesis in the abdominal aorta to insure good run-in or distal to it in the iliac vessels to insure good runoff.

Plastic Prosthesis Inserted.—Fifty-nine plastic prostheses were inserted into the aorta or iliac vessels; 14 were Nylon, and 45 were Teflon. These will be discussed together because surgical results from the use of the 2 materials in these large vessels did not differ appreciably. This is in contrast to the situation in the femoral-popliteal region,⁷ where Teflon proved significantly superior.

Forty-eight of the 59 prostheses were inserted to bypass an occluded segment (Table 2). The ends of the prosthesis, cut obliquely, were sutured to openings created in the side of the proximal and the distal vessel. By this means the collateral circulation was not significantly disturbed as would occur with complete resection of the occluded vessel.

Twenty-one of the 48 prostheses inserted to bypass the occlusion were bifurcation prostheses: 13 extended from the aorta to the iliac or common femoral on one side, and 14 were inserted from the iliac to the femoral artery.

Table 3.—Site of Pathologic Process as Indicated by Angiograms Made Prior to 67 Operations

Angiographic Finding	Operative Procedures (Late Results)					
	Thrombo-Endarterectomy			Prosthesis		
	Total	Functioning	Failure	Total	Functioning	Failure
Aortic occlusion (segmental)	5	4	1	9	5	4
Iliac occlusion (segmental)						
Unilateral	8	7	1	7	6	1
Bilateral	1		1	2	1	1
Aorto-iliac occlusion (segmental)	9	8	1	10	6	4
Aorto-iliac occlusion (also distal atherosclerosis obliterans)				7	2	5
Iliac and femoral occlusion (segmental)	1	1		2	2	
Iliac, femoral, and distal atherosclerosis obliterans				6*	3	2
Total	24	21	3	43*	25	17

* One patient was lost to follow-up.

In nine of the 59 procedures the aorta was transected, and the proximal portion was anastomosed in an end-to-end fashion to the prosthesis. The distal end of the aorta was closed, and the distal end of the prosthesis was anastomosed in an end-to-side manner to the distal patent vessel or vessels. This technique seemed to allow more satisfactory proximal anastomosis in these patients.

Two patients had resections of the terminal aorta with insertion of a prosthesis at the bifurcation. In 12 patients lumbar sympathectomy was performed as a concomitant procedure to insertion of the prosthesis.

Extent and Severity of Lesion in Angiograms Correlated with Operative Procedure.—An attempt was made to discover whether there was a distinct difference in the severity and extent of the disease process among patients undergoing thrombo-endarterectomy as opposed to those having a prosthesis inserted. Four clinic surgeons performed the operations, and each used his own judgment in selecting the preferable procedure for each patient. A review of the angiographic studies was undertaken in the attempt to correlate the extent and nature of the pathologic process, the surgical procedure, and the result achieved.

Angiographic studies, consisting of aortograms and femoral arteriograms, or both, were available in 66 patients (67 operations). This included 24 patients on whom thrombo-endarterectomy was performed. For purposes of evaluation, the operative procedures were grouped according to anatomic location and extent of occlusion (Table 3). Both thrombo-endarterectomy and prostheses were used in segmental occlusion of the aorta and proximal iliac arteries, but prostheses only were employed in preference to thrombo-endarterectomy in all cases of associated involvement of the femoral arteries or the distal external iliac arteries. Thus, a definite tendency was noted to select patients with localized segmental disease having good distal runoff for thrombo-endarterectomy.

Results of Thrombo-Endarterectomy

Thrombo-endarterectomy continues to play a role in the treatment of aorto-iliac occlusive disease. In

fact, some surgeons⁸⁻¹⁰ continue to place more reliance on this procedure than on insertion of prostheses. In short segmental occlusions endarterectomy has proved of great value. At times when a prosthesis is inserted, it is a valuable adjuvant, for it improves the vessels proximally and distally.

Four of the 28 thrombo-endarterectomies performed as primary procedures were unsuccessful soon after the operation. These will be referred to as acute failures (Table 4). Thrombosis occurred in 3 of these patients and a false aneurysm, in the fourth. In 3 of these patients a Teflon prosthesis, inserted within several days of the failure, achieved a

Table 4.—Early Results of Thrombo-Endarterectomy

Result	Patients	%
Acute failure	4	15
Functioning vessels	24	85
Total	28	

Details of acute failures in 4 patients, morbidity (immediate postoperative period)

Pa- tient	Age, Yr.	Sex	Condition	Additional Operation	Outcome
1	41	M	Thrombosis	None	Failure
2	34	M	False aneurysm	Insertion of Teflon prosthesis	Functioning
3	40	M	Distal thrombosis	Insertion of Teflon prosthesis	Functioning
4	43	F	Thrombosis	Insertion of Teflon prosthesis	Functioning
5	57	M	Peroneal palsy	None	Resolved in 3 mo.

good result. The only additional complication was the development of peroneal palsy in one patient, which resolved in 3 months. There was no mortality in this group.

In 3 of the 24 patients in whom satisfactory restoration of circulation followed the early postoperative period, failures occurred in the period of follow-up (Table 5 and Fig. 2). These late failures occurred 11, 16, and 19 months after operation, and none of the patients underwent additional operations. All except 4 patients have been followed for more than 12 months. Seventeen patients had good results more than 12 months after operation and 7 for longer than 24 months.

Eleven of the 24 patients were receiving anticoagulants at the time of follow-up (Fig. 2). Nine of these had satisfactory circulation.

Table 5.—Late Results of Thrombo-Endarterectomy
(24 Patients)

Length of Follow-Up, or of Function, Mo.	Functioning at Follow-Up	Failure at Follow-Up (Functioned for Period Indicated)
0-6	1	
7-12	3	1
13-18	3	1
19-24	7	1
25 or more	7	0
Total	21	3
Per cent	88	12

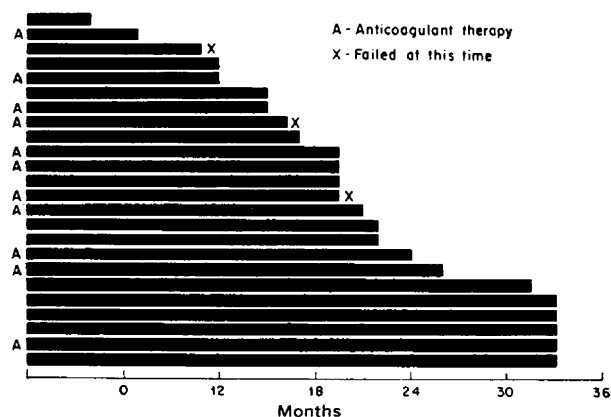


Fig. 2.—Status at follow-up of 24 patients treated by thrombo-endarterectomy for aorto-iliac occlusive disease. Numbers under abscissa represent months.

Results of Insertion of Plastic Prostheses

Ten acute failures followed insertion of a prosthesis (Table 6). Three of these failures resulted in death. Six other patients had significant morbidity but had a good result from the surgical procedure. Three deaths occurred in the early postoperative period.

CASE 6.—One patient (Table 6) was a 50-year-old woman. A thrombus developed in the prosthesis which was a bypass from the aorta to the left common femoral artery. Thrombo-endarterectomy was performed later the same day, but gangrene developed, and amputation of the left lower extremity was necessary. The patient died 2 days after returning home from what appeared to be a pulmonary embolus.

CASE 7.—A 54-year-old man died in the early postoperative period after insertion of a bypass prosthesis from the aorta to both iliac arteries and thrombo-endarterectomy of the upper part of the abdominal aorta for extensive atherosclerosis. Hypotension and anuria developed, and the patient succumbed from mesenteric thrombosis.

CASE 8.—A 67-year-old man had a secondary procedure after occlusion of a prosthesis which had been inserted 12 months previously. Bilateral thrombosis and gangrene developed, for which bilateral amputations high in the thighs were required. Infection involving the prosthesis ensued, and the patient died 6 weeks after the amputation.

Postoperative Morbidity.—Thrombosis of the graft, or the vessel proximal or distal to the graft, was the leading cause of morbidity in this series. This complication was encountered in 9 of the 10 patients in whom early failure of the operation occurred. The exception was 1 patient who died of anuria and mesenteric thrombosis. Thrombosis also occurred in 2 other patients. An attempt at thrombectomy in 4 patients resulted in restoration of circulation in 2. Thus of the 11 patients in whom thrombosis of the graft or adjacent vessel occurred, 2 were relieved by thrombectomy, 6 required amputation, and in 3 the limbs survived, but circulation to the extremities had not improved by the operation.

Amputation is the most serious morbidity encountered after insertion of prostheses into the aorta or iliac vessels. In 2 of the 6 patients requiring amputation, the vascular operation at the Mayo Clinic

Table 6.—Early Results of Plastic Prostheses

	Type of Prosthesis		Total	
	Nylon	Teflon	No.	%
Acute Failure	3	7	10	17
Functioning	11	38	49	83

Details of acute failures, morbidity, and mortality						
Case	Age, Yr.	Sex	Prosthesis	Morbidity	Surgical Procedure	Outcome
6.....	50	F	Teflon	Thrombosis	Thrombectomy; later amputation above knee	Died
7.....	51	M	Teflon	Anuria; mesenteric thrombosis	None	Died
8 [*]	67	M	Teflon	Thrombosis; gangrene	Bilateral amputations above knees	Died
9.....	56	M	Teflon	Thrombosis; gangrene	Amputation above knee	Amputation
10.....	55	M	Teflon	Thrombosis; false aneurysm	Amputation above knee	Amputation
11.....	54	M	Teflon	Thrombosis; gangrene	Amputation above knee	Amputation
12 [*]	43	M	Nylon	Thrombosis; gangrene	Amputation above knee	Amputation
13.....	43	M	Teflon	Thrombosis	None	Failure
14.....	58	F	Nylon	Thrombosis	None	Failure
15.....	49	M	Nylon	Thrombosis, in prosthesis	Thrombectomy	Failure
Other complications						
16.....	52	M	Teflon	Hemorrhage; suture line	Surgical control	Functioning
17.....	51	M	Teflon	Thrombosis, in prosthesis	Thrombectomy	Functioning
18.....	49	M	Nylon	Thrombosis, distal to prosthesis	Thrombectomy	Functioning
19.....	54	M	Teflon	Orchitis; phlebitis	Orchiectomy	Functioning
20.....	48	M	Nylon	Anuria; parotitis	Renal dialysis	Functioning
21.....	52	M	Nylon	Hypotension; hemorrhage (?)	Negative abdominal exploration	Functioning

^{*}Secondary procedure.

was a secondary procedure after failure of a prosthesis inserted earlier. Two patients having amputation died in the postoperative period.

Other causes of morbidity included hemorrhage from the suture line, anuria, parotitis, hypotension, orchitis, and phlebitis (Table 6). An orchiectomy was necessary in the case of orchitis. Renal dialysis was employed with a favorable result in the case of anuria.

Late Results.—Forty-nine prostheses functioned after the postoperative period, and follow-up data are available concerning 46 of these (44 patients). Twenty-eight prostheses were functioning at the time of the follow-up, and 18 failures of function occurred in the follow-up period (Table 7, Fig. 3 and 4). Sixteen of the late failures appeared due to

Table 7.—Late Results after Insertion of Plastic Prosthesis

Length of Follow-Up or of Function, Mo.	Functioning at Follow-Up	Failure at Follow-Up (Functioned for Period Indicated)
0-6	2	7
7-12	11	3
13-18	4	4
19-24	5	4
25 or more	6	0
Total	28	18
Per cent	61	39

thrombotic occlusion. Three of these patients had thrombosis limited to the prosthesis. Occlusion in many of the others appeared due to atherosclerosis of the distal vessels. The other 2 failures were due to false aneurysm. Two patients had amputations following late failure of the prosthesis. The other patients had return of claudication without severe ischemic symptoms. Seven of the late failures occurred within the first 6 months after operation.

Eleven patients with functioning prostheses at time of follow-up were receiving anticoagulant therapy. In 4 patients the prosthesis had failed to function while the patients were receiving anticoagu-

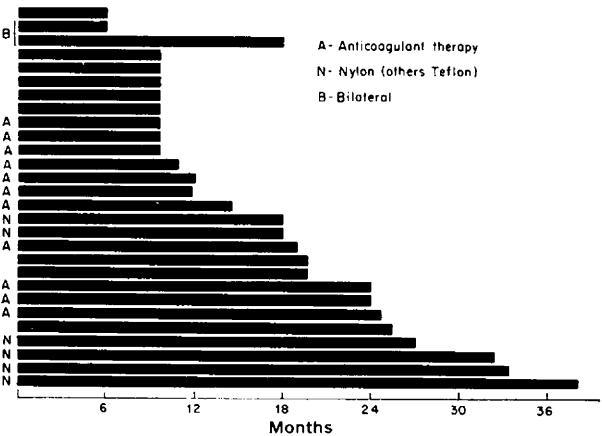


Fig. 3.—Duration of function of 28 prostheses, inserted because of aorto-iliac occlusive disease, that were functioning at time of follow-up. Numbers under abscissa represent months.

lants. Anticoagulant therapy may be of value in preventing recurrent occlusive disease or thrombosis in the prosthesis or distal vessels (Fig. 3).

The 27 patients (28 prostheses) considered as having good results had good peripheral pulses and were asymptomatic. Most of the patients who had late failures were bothered only by return of claudication. The relative absence of severe ischemic changes following late failure was probably due to the fact that the bypass method interferes little with collateral circulation, which thus is able to dilate again and support the circulation distal to the occlusion.

It is encouraging to note that 27 patients (28 prostheses) were asymptomatic and were able to carry on normal activities (Fig. 3). One patient stated he could now walk 10 miles, and another was able to play 18 holes of golf without difficulty; this is especially remarkable since it is to be recalled that only the patients with the most disabling symptoms underwent operations, and most of these patients could walk only one-half to one block without claudication before operation.

Results Correlated with Site of Lesion and Type of Operation.—An attempt was made to correlate the type of surgical procedure and late results with the extent and location of the occlusion as indicated in the preoperative angiograms. Forty-three plastic prostheses were inserted in cases in which angiograms were available (Table 3).

Twenty-six of these patients exhibited segmental occlusion of the aorta, one iliac artery, or aorto-iliac bifurcation. In 17 of these patients function was good at the time of follow-up.

In 16 patients (17 prostheses) more than one ves-

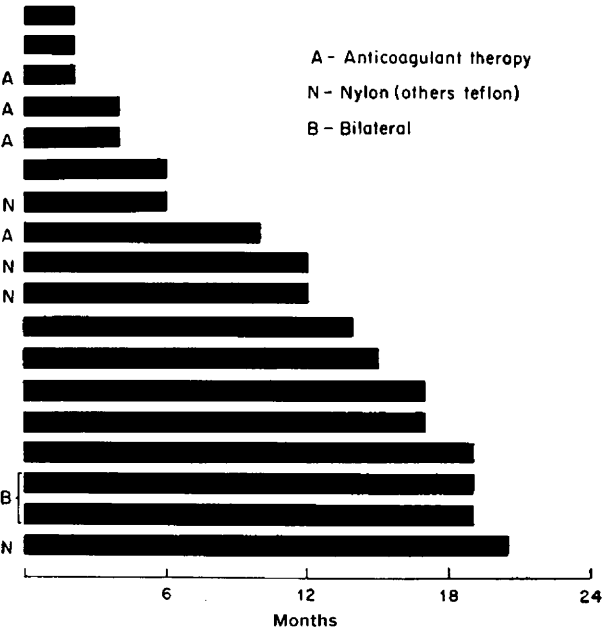


Fig. 4.—Duration of function of prostheses from time of insertion to time of failure.

sel was involved. There were only 8 functioning prostheses in this group at follow-up; 1 patient had 2 prostheses, only 1 of which was functioning. The highest failure rate was in the group with aortoiliac occlusion plus distal atherosclerosis obliterans. There were 5 failures in the 7 patients (Table 3). The most favorable result was in the cases of unilateral segmental iliac occlusion; there were 6 functioning prostheses at follow-up in 7 patients.

This correlates well with the expected. The best results occur in localized segmental occlusive disease, and the worst when multiple vessels are involved.

Type of Prosthesis.—Results from use of Nylon prostheses and those from Teflon prostheses in our series differed little at the time of follow-up. The early and late failure rates were almost identical. In the femoral-popliteal region, however, the failure rate when Nylon prostheses were used was extremely high. For technical reasons, Teflon has proved more satisfactory than Nylon. It is easier to suture, does not require coagulation of the ends with heat, and is less porous. Also, Teflon, in contrast to Nylon, retains its tensile strength following insertion.

Both knitted and woven Teflon have been utilized in prostheses. Loss of blood through the prostheses was minimal with the woven prostheses; however, on theoretical grounds a more porous prosthesis, now available in a finer knitted form, is desirable to enable the pseudo-intimal lining to become more firmly adherent.

Sympathectomy.—In the 12 patients on whom lumbar sympathectomy was performed at the time of insertion of a prosthesis, the early and late failure rates did not differ appreciably from those in the other patients.

Comment

Most reports of the surgical treatment of aortoiliac disease do not discuss the late results adequately. It appears logical to assume that the longer the interval following operation the less favorable will be the result. In order to justify a surgical procedure, a substantial number of patients should be relieved of symptoms for a prolonged period. In this type of operation we are only relieving one portion of a diseased vascular tree. True, an occlusion may be segmental, but a year or 2 later a distal vessel may occlude negating the early favorable surgical result.

Endarterectomy appears to be a suitable procedure for isolated segmental occlusion of the distal portion of aorta or the proximal portion of the iliac vessels or both. The results of endarterectomy in our series appear similar to those reported by others.^{7,8} Anticoagulant therapy, though theoretically attractive following endarterectomy, was not demonstrated to have a beneficial effect in this series. However, review of the cases suggests that anti-

coagulant therapy was employed in patients with more extensive disease.

Use of plastic prostheses in this series was followed by acute failures in 17 per cent of patients including the 3 in whom death occurred. Only one acute failure has followed the last 25 Teflon prostheses inserted. Szilagyi⁴ reported initial success with prostheses made from elastic Dacron in 88 per cent, and Crawford and associates^{1,2} reported as many as 98 per cent immediate successes with Dacron prostheses. In several series the highest rate of failure is present in the first 6 months after insertion of prostheses. This was suggested in our series in which there were 10 acute failures and 7 additional failures in the first 6 months.

Six prostheses were functioning more than 24 months after operation, and another 9 were functioning longer than 12 months. It is still early in the era of synthetic substitutes for blood vessels. Improvements will certainly be made in both technique and prosthetic material.

Anticoagulants appear to be of value in maintaining patency of the prostheses and preventing occlusion of distal vessels. Eleven of 15 patients maintained on anticoagulant therapy had functioning prostheses at the time of follow-up, whereas only 17 of 31 prostheses were functioning in patients not treated with anticoagulants.

The most favorable candidate for operation appears to be the patient with a short localized occlusion of the aorta and iliac arteries and good runoff. The worst results were in patients who had associated femoral occlusive disease. Many of the late failures were actually due to distal occlusion rather than to occlusion of the prosthesis.

Summary and Conclusions

A review of 87 surgical procedures on 80 patients for the treatment of aortoiliac occlusive vascular disease is presented. These procedures were performed in the period from January, 1957, to January, 1960. Twenty-eight thromboendarterectomies were performed. There were 4 acute failures and 3 additional failures at the time of follow-up. Fifty-nine plastic prostheses were inserted. Ten acute failures (17 per cent) occurred, including 3 deaths.

Follow-up data were available concerning 46 of the 49 prostheses that were successful initially. Twenty-eight prostheses (60 per cent of those functioning initially) had maintained satisfactory patency to the time of follow-up.

This study indicates that surgery has much to offer many patients with occlusive vascular disease of the aorta and iliac vessels, and many persons are restored to years of active productive life following surgical treatment. It is, however, only a palliative effort in the treatment of systemic disease and does nothing to retard or prevent progressive vascular disease. Both thromboendarterectomy and the bypass grafting are valuable techniques for the relief

of aorto-iliac occlusive disease and must be selected according to individual requirements. Morbidity and mortality rates are reasonable as compared with other major surgical procedures. The risk of operation in a primary uncomplicated case is in the neighborhood of 2 per cent.

The present series of cases is too small to demonstrate absolutely a beneficial effect of long-term postoperative anticoagulant therapy, but the evidence tends to support this view.

Surgical management has progressed far in the short time that direct surgical approach to occlusive vascular disease has been utilized. The search for better methods including ancillary medical means to ensure long-term relief from occlusive vascular disease following surgery must continue.

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ACHILLY RECEPTION.—Such was the band of supporters chosen by Lister to assist him in the eventful mission to London. They did not expect to be welcomed there, and indeed their reception was even colder than they anticipated. It was not that the surgical world of London was actively hostile; that would have indicated, at least, an interest in Lister's discovery. No such interest was shown, and the attitude was one of complete indifference, or, at best, of good-natured tolerance. As for the students, there was no need for them to hurry, as did the Edinburgh students, to secure a good seat in Lister's lecture theatre. Most of the benches were empty, and those who did come had merely strolled in out of curiosity. In Edinburgh, Lister's class frequently numbered 400 students; in London, some ten or twenty might turn up, but these gradually fell off. Ten years after his arrival Lister referred to his small classes at King's, after his crowded audiences in Edinburgh, as "a humiliating experience." The plain truth was that, as Lister's teaching was so far ahead of his time, few of his hearers realised its significance. Furthermore, however valuable the knowledge might be for the practice of surgery, it was of little service in examination, especially as the examiners were surgeons of the old school. His lectures provided no "tips" for examinations. Lister had a contempt for the methods of the "coach" or the "grinder." Cramming had no place in his scheme of teaching; he wished his students to think for themselves, and he disdained all learning which did not include the understanding of first principles.

It is easy to imagine the feelings of dismay and disappointment which must have been aroused in Lister and his little group of assistants as they looked at those empty seats. In the graphic words of John Stewart, "We four unhappy men wandered about, and wondered why men did not open their eyes. We thought of the crowded hours of glorious work in Edinburgh and . . . we remembered the enthusiasm of an introductory lecture there, when the theatre would be filled with four hundred eager listeners, and our hearts were chilled by the listless air of the twelve or twenty students who lounged in to the lecture at King's."

But if students and London surgeons were apathetic over the revolution in surgery being wrought in their very midst, it was not so with foreigners, who soon after Lister's arrival in London poured into King's College Hospital from the ends of the earth.—Guthrie, D.: *Lord Lister: His Life and Doctrine*, Baltimore: Williams & Wilkins Company, 1949.