THE EFFECT OF A MECHANICAL VENOUS PUMP ON THE CIRCULATION IN THE FEET IN THE PRESENCE OF ARTERIAL OBSTRUCTION

BY

JAMES. C.W. PARROTT, B.Sc., B.Sc. (MED), M.D.

DEPARTMENT OF PHYSIOLOGY

UNIVERSITY OF MANITOBA

SUBMITTED IN PARTIAL FULFILLMENT OF THE

REQUIREMENTS FOR THE M.Sc. DEGREE

OCTOBER, 1972

ACKNOWLEDGEMENTS

The author is most obliged to Dr. Peter Gaskell for his encouragement and supervision, and providing, for me, this valuable learning experience.

The author is also indebted to: Dr. Allan Downs for his help in the development of the study and for providing access to his patients for investigation.

Drs. John Farr, Harvey Chochinov and Jack McDougall for the provision of patients for study.

Mr. Rodger Paulsen and Mrs. Karen Gordon, Department of Nuclear Medicine, Winnipeg General Hospital, for provision of Xe^{133}, and equipment for this study.

The Nursing Staff of the surgery wards of Winnipeg General Hospital for care of the patients and equipment during clinical studies.

Mrs. Margaret Potts for being a superb typist.

A special thanks to Mrs. Carol Munson for technical help and encouragement through all phases of the study without whose help this project could not have been completed.

ABSTRACT

It is frequently observed that patients with occlusion of the main arteries of their lower limbs severe enough to cause rest pain, obtain relief by placing the foot in a dependent position. However, some patients with very severe ischemic rest pain do not obtain relief by this postural maneouver. For various reasons these patients are often not amenable to immediate surgical correction. Therefore, some other form of immediate therapy is desirable. It is proposed that a mechanical, pneumatic, venous pump which lowers venous pressure in the foot in the erect subject, thereby increasing the perfusion pressure and blood flow in the capillaries of the foot, can give relief of ischemic rest pain in these circumstances.

The mechanical venous pump consisted of a clear, single-layer, vinyl plastic boot which compressed the foot by separate, but essentially simultaneous, inflations, of the boot and an occluding cuff which sealed the top of the boot at ankle level.

The effectiveness of the mechanical venous pump in lowering venous pressure in the foot was determined by direct measurement of venous pressure. These studies indicated that a foot compression pressure of sitting venous pressure plus 10mm Hg., a compression period of 2 seconds, a compression interval (interval between the beginning of one compression to the beginning of the next) of 15 seconds and a delay period between cuff and boot inflation of 0.5 seconds were effective and practical in lowering foot venous pressure. It was found, using these parameters, that foot venous pressure could be lowered to approximately 10mm Hg.

in the sitting subject.

The standard compression boot, described above, was found to be more effective in lowering foot venous pressure than was a long-legged boot which compressed the foot and calf as a unit, or a 15cm. wide pneumatic cuff placed at ankle level used as a venous pump.

The effectiveness of the mechanical venous pump in increasing foot blood flow was also studied. Rate of blood flow in the skin of the forefoot was estimated by the rate of clearance of Xe^{133} from a subdermal injection. Thirty-four patients with arterial occlusion in the lower limbs were studied in this manner, however, 13 were deleted from the final analysis for various technical and clinical reasons. In 19 of the 21 patients, on whom complete experiments were performed, the overall effect of the mechanical venous pump was to increase the rate of blood flow in the subdermal tissues of the forefoot by an average of 90.9% $\pm$ 32.5 S.E. ($p < 0.02$) over sitting blood flow.

The direct local effect on blood flow of pumping the foot, corrected for the generalized effect of pumping, was to increase blood flow in the foot on the average by 77.4% $\pm$ 26.3 S.E. ($p < 0.01$)

In addition to studying the effect of the mechanical venous pump on blood flow, the effect of posture alone on flow in the foot was also estimated. It was found that in patients with arterial occlusive disease in the lower limbs, blood flow was an average of 40.6% $\pm$ 14.0 S.E. greater when sitting than when supine ($p < 0.01$)

The effect of the erect posture and the mechanical venous pump on blood flow were summed and the combined effect was an average increase in rate of blood flow of 135.2% $\pm$ 34.1 S.E. over the supine rate of blood flow ($p < 0.001$)

From these results, it is proposed that a mechanical venous pump, as an aid to circulation may have a place in the management of patients with severe arterial occlusions in the foot and who are not immediately amenable to surgical correction.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

INTRODUCTION

INTRODUCTION

The treatment of severe occlusive vascular disease, for the most part, is surgical. In recent years surgical techniques have been developed to render prompt and long lasting relief to the patient with severe or incapacitating vascular occlusions. Prior to this, surgery was not used in the management of occlusive disease nearly as often as it is today. More frequently, in the past, was the disease allowed to run its natural course with often only minor and discouraging medical intervention. Mechanical methods for improving blood flow in an ischemic extremity were employed frequently without success. These modes of therapy appear to have been used, for the most part, on a subjective, imperical basis with usually limited physiological grounding. Some procedures such as intermittent arterial occlusion, using a tourniquet applied to the limb, in an effort to produce a reactive hyperemia, and intermittent venous occlusion, using a tourniquet also, in order to expand the vascular bed, can be considered on physiological grounds to actually be harmful to the patient with an acute or chronic occlusive vascular lesion. On the other hand, limb dependency, either active or passive - for example the Sander's oscillating bed, is still employed today in the patient with ischemic rest pain.

Recently, renewed, but modest, attention has been given to the concept of mechanical intermittent compression or pumping of the ischemic limb to improve blood flow. Intermittently pumping the ischemic limb in the dependent position with the patient in the upright posture, lowers venous pressure, thereby increasing the arterial-venous pressure difference across the capillary bed. It has frequently been observed clinically that patients who have ischemic rest pain in the foot when supine, obtain relief on putting the foot in a dependent position. The relief is the result of the increase in blood flow in the foot on assuming the upright position. (Gaskell and Becker - 1967). In a normal subject this increase in blood flow does not occur. When a normal subject stands, the pressure in the arteries of the foot rises and may be considered as made up of two components: the driving pressure produced by the contracting heart, and the hydrostatic pressure produced by the column of blood created. The high intra-arterial pressure tends to distend the arteries in the foot. The arterial distention, in turn, produces a local myogenic vasoconstrictor response. In addition, a centrally mediated vasoconstriction occurs in the foot vessels. These two factors tend to reduce the foot blood flow. If this were the situation in patients with main artery occlusions, one would expect that, on lowering the foot, the blood flow would decrease causing accentuation of ischemic rest pain rather than relief which is commonly observed. When a patient, with an occluded main artery in the leg with rest pain in the foot, is supine, the pressure in the foot is lower than central arterial pressure. Blood flow through the foot is abnormally low. When the patient sits or stands, the columns of blood created, in both arteries and veins, exert high hydrostatic pressure in the foot vessels. In the arteries, the increased pressure distends the collateral vessels around the blocked arterial segment, thereby lowering the resistance to flow in these vessels. Consequently, a greater than expected rise in arterial pressure occurs in the foot vessels. This increase in available pressure may be sufficient, in some patients, to increase foot perfusion and relieve ischemic rest pain. However, the increased venous pressure and capillary pressure during prolonged dependency will produce tissue edema.

Consider now if in the upright patient, the venous pressure in the foot could be artificially lowered for a prolonged period of time. This would effectively increase arterial venous pressure difference across the capillary bed and thereby increase capillary perfusion. Also, keeping the veins empty and moving blood toward the heart would prevent vascular congestion and its resulting edema.

Lowering of venous pressure by emptying the veins can be accomplished by various methods. Muscular contraction actively empties the veins and reduces venous pressure. This is, however, inefficient in that contracting muscle demands a greater blood flow which may, in some cases, be more than the increased blood flow produced by the contraction. Passive and active postural exercise will effectively empty the veins and produce similar effects. These methods, however become impractical, if not impossible in severely ill patients. Intermittent, mechanical, pneumatic compression of the lower limb will effectively lower venous pressure provided that reflux of blood back into the foot is prevented by competent venous valves. (Allwood 1957: Henry and Winsor 1965: Loane 1959).

It is the purpose of this investigation to study the effect on venous pressure in the dependent foot of mechanical, pneumatic, intermittent compression of the lower limb. Of further, and more important interest, is the effect of prolonged lowering of venous pressure on the blood flow through the skin of the foot in patients with occlusive vascular disease. A further purpose is to establish this as an effective mode of therapy in patients with ischemic rest pain and/or ischemic skin lesions who are not subject to immediate surgical intervention.

A review of the literature pertaining to earlier mechanical (non-drug, non-surgical) methods of treating more severe degrees of arterial obstruction in the lower limbs will be presented followed by a report of the investigation and use of a combination of posture and a mechanical venous pump to improve blood flow in the ischemic foot.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

A) Introduction

Before the advent of modern surgical techniques for the treatment of occlusive vascular disease, little in the way of definitive treatment could be offered to patients with ischemic rest pain in the lower limbs. Because of this, several modes of treatment were described in the preventive and active aspects of therapy. A few of these are retained today while others have, for various reasons, been abandoned. A brief historical and critical review of some of these methods will be presented here.

B) Body Heating

Heating a limb directly, or remote parts of the body, will produce a vasodilatation in the extremities. Because of this, these principles have been employed in the treatment of occlusive arterial disease.

Freeman (1940) evaluated the effect of locally applied heat on the circulation in the heated part. Using venous occlusion pletheymography, he showed, in normal subjects and patients with occlusive lesions, that blood flow in an extremity varied directly with the temperature of the limb. The author, however, recognized that heat also raises the metabolism of the part, and "the increase in tissue needs occasioned by the elevation in temperature may be greater than any possible improvement in circulation". Furthermore, Freeman recognized that the impaired blood supply, in a patient with an occlusive lesion, may not be sufficient to carry away or dissipate the applied heat, so that the temperature of the extremity may rise to levels which may produce tissue injury. The author cites several patients where uncontrolled heat had produced gangrene in feet where poor circulation had existed. The author concludes that vasoconstriction associated with cold should be avoided in patients with compromised limb circulation. He proposed that the temperature of the air surrounding the affected limb should be between 30° and 34° C and that this is best accomplished by the use of a thermo regulated cradle placed over the affected limb. Bennett, Hines and Krusen (1941) studied the use of short-wave diathermy, applied to remote areas of the body, to produce an indirect vasodilation in the affected extremity. The authors found that remote heating could raise the skin temperature in the feet of normal subjects and patients with occlusive vascular disease. They concluded that this form of treatment tended to produce generalized hyperpyrexia in patients and cause discomfort. Despite this, the authors feel that indirect body heating, "under careful medical supervision" has a place in the management of patients with peripheral arterial occlusive disease.

Because of its potential dangers, the use of body heating today is discouraged and patients are usually councelled to avoid extremes of temperature.

C) Intermittent Venous Occlusion

It became popular in the 1940's and early 1950's to use intermittent venous occlusion of an affected limb to increase blood flow. It was thought that occluding the veins of a limb, with a blocked arterial segment would produce generalized vascular congestion in the limb which in turn produced a generalized vasodilatation of the arteries and veins. This generalized vasodilatation produced a fall in resistance to blood flow, and consequently blood flow would increase through the limb during the period of occlusion.

Also, upon release of the occluding cuff, after several minutes of inflation, a mild reactive hyperemia of the limb would occur.

Linton, Morrison, Ulfelder and Libby (1941) studied the effect of venous occlusion on the hind limb of dogs. Using a thermostromuhr flow meter on the femoral and iliac arteries, the authors found that blood flow to the limb could be increased several fold during venous occlusion periods of 3 minutes to 34 minutes. They also noted that the increased flow gradually decreased the longer the veins were occluded. From this experiments they concluded that intermittent venous occlusion for periods of 3 to 5 minutes could be beneficial in patients with arterial occlusions.

Veal and McCord (1941), however noted, using arterial-venous oxygen saturation difference as an indication of blood flow in the arms of normal subjects, that blood flow decreased through the limb during total venous occlusion for periods of 15 to 60 minutes. From this they concluded that: "any favourable effects claimed for this type of therapy must therefore result not so much from an increase in the rate or the volume of the blood flow as from some chemical changes produced in the tissues incident to the venous congestion and the changes produced by the increased venous pressure."

This form of therapy has been largely abandoned because occluding the veins lead to edema formation with its resulting complications. Furthermore, using occlusive pressures of 60-80mm. Hg. could also occlude arteries in limbs with low perfusing pressures which would interrupt or decrease blood flow into the limb and possibly aggravate any existing ischemia.

D) Intermittent Arterial Occlusion

Related to intermittent venous occlusion is the concept which advocated intermittent arterial occlusion using a cuff placed at the groin, to produce reactive hypermia in an ischemic limb. It is well known that reactive hyperemia following a brief period of arterial occlusion will increase blood flow in a normal limb several fold. Thiele (1930) proposed this as a therapeutic measure to enhance blood flow in the extremities of patients with occlusive arterial disease. From clinical observation only, he concluded that reactive hyperemia was useful in the treatment of a wide variety of vascular diseases. Little increase in blood flow through the ischemic portion of the limb can be expected since the blood vessels in the ischemic area are already dilated due to the ischemia, and the resistance to flow is high in the collateral vessels. The small increase in blood flow to the area would do little more than repay the oxygen debt incurred during the period of occlusion.

This form of therapy has also been abandoned since its use could possibly damage an already ischemic limb and, furthermore, no good objective evidence has appeared in the literature which supports its usefulness.

E) Alternate Suction and Pressue - Passive Vascular Exercise (Pavaex Boot)

This form of treatment consisted of placing the affected limb, of a recumbent person, in an enclosed chamber and applying suction (80-120 mmHg.) for a period of time (usually 25 seconds) alternating with a period of positive pressure (20-80mmHg.) for 5 seconds. Patients were treated usually 2-4 hours per day until lasting clinical improvement was obtained, and it was not unusual for patients to be treated in this manner for several weeks. The rationale for this form of treatment was that circulation could be increased by "sucking" blood into the lower leg and foot during the period of negative pressure and then forcing blood out through the veins during the brief period of positive pressure.

Landis and Gibbon in 1933 studied the effect of the use of the pavaex boot on the circulation of the lower legs and feet of normal subjects and patients with occlusive arterial disease. They first studied its effects on the flow through a mechanical "schema" consisting of various lengths of capillary glass tubes simulating an arterial obstruction while a rubber bag simulated the distensible capillary and venous beds. A valve was inserted in the outflow tube, leading from the bag, which acted like the venous valves. They found that: "Flow was uniformly greater during suction and pressure. Suction for 25 seconds and pressure for 5 seconds increased the outflow by 45 to 63 per cent". Following this the authors, using skin temperatures as an indication of blood flow, studied its use in normal subjects and patients. They found that in normal subjects, the skin temperature of an extremity rose invariably when subjected to alternate suction and pressure. The rise of skin temperature was interpreted as indicative of an increase in blood flow. Five patients with "varying grades of peripheral vascular disease" were studied. "In each patient alternate suction and pressure produced a conspicuous rise of surface temperature in the affected extremity, even in the presence of advanced organic vascular disease."

In 1933, Hermann and Reid reported the results of treatment, with the pavaex boot, on 51 patients with "organic obliterative arterial disease." All patients were treated with 80mm Hg. negative pressure and 20mm Hg. positive pressure with an average length of each cycle of about 15 seconds. In all cases the foot and leg was elevated several inches above the level of the heart. Also, all patients were treated with bed rest, meticulous foot care, and warm environmental temperature. The authors stated that: "calormetric evidence of an increase in the circulation in the distal parts of the extremities occurred in all 51 patients of the series , yet 13.73 percent received little or no relief from their symptoms. Forty-four patients (86.27 percent) were greatly benefitted by this form of therapy".

This mode of therapy rapidly became popular and other reports appeared in the literature. Shipley and Yeager (1934) reported excellent clinical improvement in patients with various clinical entities. They proposed that: "such a method has great possibilities as a therapeutic measure, not only in thrombo-angiitis, arteriosclerosis, and the various occlusive disease, but also in ununited fractures, arthritis (atrophic and hypertrophic), frost-bite gangrene, and the various circulatory disturbances that result from trauma".

Conway (1936) reported that 80.5 percent of 36 cases of arteriosclerosis showed clinical improvement following treatment with alternate suction and pressure. He further reported that "Passive vascular exercise seemed to have a distinctly favourable effect on the healing of grafts," but that "vascular exercise is not beneficial in cases of advanced diffuse arteriosclerosis of the extremity".

In 1935 Allen and Brown reviewed the literature to that date concerning the use of the pavaex boot and also reported their own experience with it. They noted that in most reports in the literature other forms of supportive therapy were used in conjunction with the pavaex therapy. They pointed out that such things as bed rest, proper foot care and application of judicious heat are effective in promoting clinical improvement. From their review they concluded: "One thing appears quite certain: the alternate suction and pressure method of treatment has not produced any results that have not been observed repeatedly as a result of simpler methods" and "Good results ordinarily follow changing environmental pressure treatment in cases in which good results could be expected from other measures, and that when good results do not follow other measures, passive vascular exercise is usually valueless."

There are several criticisms of this form of therapy. Using the apparatus for only a few hours each day would produce hemodynamic changes for that period of time only and not during the time that the foot was not being treated. Furthermore, all patients were treated in a recumbent position with the foot elevated. This in itself is disadvantageous to the patient in that the elevated position tends to retard arterial blood flow. As pointed out by Allen and Brown (1935), the pavaex treatment was used in conjunction with other forms of therapy and therefore it is difficult to evaluate its own merits. The results presented in most papers are of a clinical nature with no control data and with little in the way of physiological, objective results. The use of changes in superficial skin temperature as an indication of blood flow may be unreliable. Simple vascular engorgement without an increase in blood flow can cause the skin temperature to rise and, furthermore, merely confining the foot and leg in the treatment chamber would reduce heat loss and a rise in skin temperature would be expected on this basis alone.

The use of the pavaex treatment has been abandoned mainly due to the development of definitive surgical procedures. The pavaex treatment was a cumbersome and occasionally uncomfortable method of treatment and it afforded little advantage over more simple methods of treatment.

F) Posture

It has been frequently observed that a patient, with occlusive arterial disease and rest pain, will obtain relief by dangling the foot. When normal people, assume the erect position, blood flow in the feet usually decreases (Becker and Gaskell 1967, and Folkow 1962), while in patients with occlusive arterial disease it will usually increase (Becker and Gaskell 1967). The absolute increase in blood flow may be small, but it is often sufficient to relieve rest pain. Even though prolonged dependency of an ischemic foot will produce tissue edema, patients today are encouraged to use posture in their relief of symptoms.

In 1924, Buerger introduced a series of postural exercises for the treatment of occlusive arterial disease. Buerger suggested that:

"certain passive exercise may be of value in inducing hyperemia or rubor in the affected limb, and therefore, therapeutically beneficial in increasing the blood supply". The procedure was as follows: "The affected limb is elevated with the patient lying in bed, to from 60^o or 90^o above the horizontal, being allowed to rest upon a support for from 30 seconds to 3 minutes, the period of time being the minimum amount of time necessary to produce blanching or ischemia. As soon as blanching is established, the patient allows the foot to hang down over the edge of the bed for from 2-5 minutes, until reactionary hyperemia or rubor sets in, the total period of time being about one minute longer than that necessary to establish a good red color. The limb is then placed in a horizontal position for about 3 to 5 minutes, during which time an electric heating pad or a hot water bag is applied, care being taken to prevent the occurrence of a burn. The placing of the limb in these three successive positions constitutes a cycle, the duration of which is usually from 6 to 10 minutes. These cycles are repeated over a period of about one hour, some 6 to 7 cycles constituting a seance." These exercises gained wide acceptance for a time even though no direct physiological evidence was ever presented as to their effect on blood flow. Elevating an ischemic foot for 30 seconds to 3 minutes would have a definite adverse effect on arterial blood flow. Elevating the foot did, however, empty the veins and this may be beneficial to the patient in that when the foot is lowered over the edge of the bed, blood flow may increase during the time that the veins are filling.

Once the veins are filled, the greater arterial-venous pressure difference across the veins no longer exists and blood flow will decrease.

Buerger's exercise are no longer used to any extent in the management of patients. It was generally found that patients received very little relief for the time spent, and they usually discontinued the exercises on their own.

Sanders, (1936) introduced the motorized oscillating bed for the treatment of patients with vascular disease in the lower limb. The bed was first introduced as a treatment for peripheral edema, but the author recognized that patients with occlusive arterial disease obtained relief from ischemic rest pain when treated on the bed. Sanders explained this as follows: "Physiologically, the improvement is due to two factors: a) relief of venous stasis and back pressure, and b) intravessel aspiration, promoting better arterial supply." The bed alternated the patient between a head-up and head-down position. In the head-down position the veins would empty, and in the head-up position the hydrostatic pressure in the arteries of the foot was increased. The valves in the veins prevented blood from refluxing back into the foot so that, for a short period to time, very little hydrostatic pressure existed in the veins. Therefore, the hydrostatic pressure in the arteries produced an increased perfusion pressure across the capillary bed which tended to increase blood flow through the capillaries. This increased perfusion pressure would slowly diminish as the veins filled with blood and, therefore, the increased blood flow occurred only while the veins were empty or nearly so.

Barker and Roth (1939) reported very good clinical results in patients, with "pretrophic pain, pain of ischemic neuritis and pain of ulceration and gangrene," using the oscillating bed. They also pointed out that the bed produced little change in symptoms in patients with claudication only.

The oscillating bed is still used in the present day management of patients with severe rest pain awaiting surgical correction or amputation.

In 1948 Scheinberg, Dennis, Robertson and Stead, studied the effect of posture on the blood flow in the feet of normal subjects and one patient with arterial occlusive disease of the lower limb. Blood flow determinations, using venous occlusion plethysmography, were made on the foot in the supine and erect posture after the veins in the foot had been emptied by a momentary compression of the foot within the plethysmograph. A compression pressure of 8 to 15 mmHg. above standing venous pressure at the foot, as calculated from the fourth interspace, was sufficient to fully empty the foot veins. The authors found that in all subjects, including the one patient, blood flow was increased by an average of 2.5 times in the erect position as compared with the original resting blood flow obtained in the supine position. The duration of the rapid flow produced by emptying the foot of blood while standing erect depends upon the time that it takes to fill the veins of the foot. Once the veins are full, the increase in venous hydrostatic pressure balances the increase in arterial hydrostatic pressure and the flow through the capillaries decreases.

These experiments show the combined effect of erect posture and venous emptying on the blood flow in the foot. It is impossible to show, by this method, the individual contribution of either erect posture or venous emptying alone. It was proposed by the authors that a "peripheral venous pump", designed to rhythmically empty the veins of the foot, might increase the blood flow in the feet of patients in the erect posture.

Similar work was published by Allwood in 1957. Using venous occlusion plethysmography he studied the blood flow in the feet of normal subjects, patients with occlusive arterial disease, and patients with occlusive arterial disease who had had recent sympathectomies. In each sitting subject "resting blood flow" was measured as the flow in the foot when a collecting cuff pressure of 110-120 mm Hg. for normal subjects and 80-90 mm Hg. for patients was used at the ankle. If the hydrostatic venous pressure was more than 50 mm Hg., the subject was excluded from the study on the grounds that a pressure greater than 50 mm Hg. in the veins filled the veins to an extent such that the use of venous occlusion plethysmography became invalid. Following the measurement of "resting blood flow" in each individual, the veins of the foot were partially emptied to about a venous pressure of 26 mm Hg. by rapid, intermittent inflations of the collecting cuff. The collecting cuff was then inflated to the appropriate collecting pressure and blood flow measured. In all individuals tested, there was an increase in foot blood flow after "milking" relative to "resting blood flow".

The author concluded that: "These experiments have shown that blood flow may be increased in normal and pathological limbs by increasing the effective pressure gradient locally by lowering the local venous pressure with a pneumatic cuff used as a muscle-pump".

Allwood (1955), in another paper, states that venous pressure - volume curves obtained, using venous occlusion plethysmography, show that veins of the foot are maximally distended at 80-90 mm Hg. hydrostatic pressure. From this he concludes that at venous pressures of 50mm Hg. there is sufficient further distensibility of the venous bed available to make accurate flow measurements. However, at a starting venous hydrostatic pressure of 50mm Hg. blood flow in the foot, with the venous collecting cuff inflated, would be expected to raise venous pressure above 50mm Hg. rapidly as flow continued thereby, decreasing the arterial-venous pressure differential across the capillaries. If this were the case, one would not be measuring true "resting blood flow". Also, the pressure in the occluding cuff during flow measurements (110-120mm Hg. in normal subjects and 80-90mm Hg. in patients) may be high enough to retard the blood flow in the arteries. Furthermore, with this technique, the author is measuring a combined effect of sitting plus venous pumping on the blood flow in the foot, and cannot distinguish the effect of either component alone. Allwood, however, has indeed shown that, in all subjects, sitting, plus pumping, increases the absolute blood flow in the dependent foot.

Loane (1959), also measured the blood flow in the dependent foot of normal subjects in the sitting position after "milking" of the veins by intermittent inflations of a cuff placed at the ankle. Blood flow, as measured by venous occlusion plethysmography, heat flow discs of Hatfield, and heat elimination using the calorimetric method. Control measurements were made simultaneously on the opposite foot by each of the three methods. To empty the veins the collecting cuff was inflated to a pressure of 110mm Hg. at a frequency of 50 times per minute for 10 minutes. In other experiments, the subjects lay horizontally and a cuff pressure of 70mm Hg. was used for both venous collection and "milking".

Loane reported that: "an increase in blood flow in the foot, produced by "milking" has been confirmed by the three methods." He could, however, show no evidence that "milking" increased flow in the foot in the lying subject.

Loane thought that because the veins are full and distended in the control limb, blood flow as measured by venous occlusion plethysmography is probably an underestimation. "Too low an estimate of flow in the "unmilked" limb and a correct estimate in the "milked" limb would lead to too high a value for the percentage increase in flow on "milking"." The author further concluded: "that the true increase in blood flow is more accurately reflected by the calorimetric and heat flow estimations and that it is probably about proportional to, and not greatly in excess of, the increase in perfusion pressure."

Henry and Winsor (1965), were the first to measure the effect of mechanically lowering venous pressure on blood flow in the dependent foot of the sitting subject using clearance of a locally injected radioactive material (I^{131}) as an indicator of blood flow. An inflatable cuff placed around the calf was used to intermittently compress the veins. Venous pressure was measured in normal subjects by direct venous cannulation of a foot vein below the cuff. In patients with arterial occlusive disease the venous pressure in the foot was measured indirectly using a capsule applied to the skin overlying a small foot vein in which the air pressure could be adjusted to collapse the vein. The air pressure, which would just collapse the vein under observation, was taken as the hydrostatic pressure in the foot veins. In the majority of normal subjects the period of inflation of the cuff was 3 to 5 seconds with an off period of 15 to 20 seconds. A peak inflation pressure of 60-100mm Hg. was applied. However, in patients with occlusive disease, inflation periods of up to 15 seconds were used at pressures of 60-100mm Hg. with an off period of 30 to 45 seconds. It was found that using these regimes the venous pressure in the feet of normal subjects and patients, could be lowered to less than 50mm Hg.

In the I^{131} studies, each normal subject had the test leg massaged for 3 hours. The opposite leg served as a control and was not massaged. At the end of 2 hours massage, a small dose of I^{131} was injected into the skin of the test foot. The clearance of I^{131} was measured for 30 minutes. Following this an equally small dose of I^{131} was injected into the control foot and its clearance measured for the remaining 30 minutes while massaging of the test limb continued. In alternate experiments, the control foot was injected first. In these experiments with normal subjects, they found that blood flow, as related to I^{131} clearance, was greater in the foot of the massaged limb. It seemed apparent then that reducing venous pressure in the foot of sitting normal subjects may increase blood flow in that foot.

In the patients with occlusive disease, the I^{131} clearance studies were conducted in a similar manner as for normal subjects except the massage parameters were changed, as noted previously, and the massage time, prior to the I^{131} injection and clearance measurements, was reduced to one hour. The authors found that clearance of I^{131} was greater in the massaged limb of patients with occlusive arterial disease indicating an increase in blood flow through the foot.

A second group of patients were studied in the following manner. The test limb was massaged for one hour, allowed to rest for 30 minutes, after which I^{131} was injected into the skin of the test foot and clearance measures for another 30 minutes. In alternate experiments the control foot was injected first. The results of these experiments indicated that flow continued at a higher rate in the test foot during the time following massage. The authors felt that: "The continued improvement in the removal of fluid from the tissues of the leg that had been massaged, despite the absence of pumping action in the calf for half an hour prior to and during the I^{131} clearance run, indicates that the effect(s) of the massage continue for some time after its cessation."

This apparent lasting effect could not be explained by the authors.

Several criticisms of this paper can be made with regards to their methods, and interpretation of the results. In the studies on normal subjects, the inflation period of the cuff was 3 to 5 seconds, however, in patients with occlusive disease inflation periods of up to 15 seconds were employed. It may be considered that this prolonged compression of the calf, at pressures of 60-100mm Hg. would tend to retard blood flow into the foot, especially in patients with low perfusing pressures. The fact that the venous pressure in normal subjects and patients could be lowered only to approximately 40mm Hg. indicates that massaging the calf alone is an inefficient method of lowering venous pressure in the foot. It would be of much greater advantage to massage the foot rather than the calf, since this would tend to lower venous pressure in the foot to well below 40mm Hg.

The experiments could have been much better controlled if clearance of I^{131} in the test foot and the control foot were measured simultaneously using two counters, or better still, if the test foot served as its own control by measuring clearance for a time prior to massage and/or immediately after massage. Furthermore, it is difficult to compare the clearance rates of two separate injections in different limbs since the injections cannot be made in exactly the same manner and therefore, tissue distribution of the I^{131} would tend to vary. Also, it is impossible to accurately compare the clearances in the feet, of a patient with occlusive arterial disease, since the circulation in the two limbs cannot possibly be the same. The test foot must, therefore, serve as its own control.

The authors noted that: "The effects of the massage continue for some time after its cessation." They could not explain this apparent lasting effect. On close analysis we can see that this apparent lasting effect may not result from the massage at all, but could be adequately explained by the fact that merely sitting a patient, with occlusive arterial disease, will increase blood flow through the dependent foot, (Gaskell and Becker 1967), and it is conceivable that compressing the calf of a patient with low perfusing pressures, for as long as 15 seconds and at pressures of 60-100mm Hg. would actually cause an overall decrease in blood flow through the foot relative to the flow that would occur by merely having the foot in a dependent position.

From this review we can see that many modes of therapy have been proposed for the treatment of peripheral arterial occlusive disease. Many of these have been abandoned for various reasons, while others have been retained for certain situations. The concept of a venous pump for improving blood flow is not new, however, no good studies in the literature have provided good physiological grounding for its use in patients with occlusive disease. We will, in this present study, provide this evidence and on that basis propose the use of a venous pump in the management of selected patients with peripheral arterial disease.

THE PROBLEM

THE PROBLEM

It has frequently been observed that patients with occlusive arterial disease of the lower limb, severe enough to cause ischemic rest pain, often obtain relief on placing the foot in a dependent position. The relief of rest pain results from the added hydrostatic pressure in the arteries and collateral vessels in the leg distending the collaterals so that more pressure energy is available in the foot to increase blood flow. This increase in pressure in the foot may be small in magnitude and the resultant increase in flow may be correspondingly small in terms of absolute flow, but it is often enough to increase tissue perfusion to the extent of relieving ischemic pain.

However, on assuming the upright position a hydrostatic head of pressure is also created in the veins equal to the hydrostatic pressure on the arterial side of the circulation. This venous hydrostatic pressure, if maintained for long periods of time, will produce tissue edema. Occasionally, the amount of arterial obstruction is severe enough to cause rest pain even when the foot is lowered. If one could effectively lower the venous pressure in the foot of a standing or sitting patient and keep it lowered, while maintaining the increased arterial pressure, one could avoid edema and increase the pressure difference across the capillary bed, and thereby further increase tissue perfusion, affording relief of rest pain and promoting healing of ischemic changes in the tissues.

Venous pressure may be lowered in a number of ways. Active muscle exercise will compress the veins and drive blood toward the heart. This, however, has the disadvantage that exercising muscle requires an increase in blood flow and the added flow required may be more than the resulting increase in perfusion pressure can provide. Postural manoeuvers, whether performed by the patient, or on the Sanders' oscillating bed, will lower venous pressure, but the patient receives the beneficial effect only while the foot is dependent, and the effect lasts only until the veins fill. Here also, the pressure difference across the capillary bed slowly decreases as the veins fill causing blood flow to slowly decrease. An effective method of lowering venous pressure, provided the valves in the veins are competent, is by mechanical, pneumatic, intermittent compression of the foot veins using a pressure high enough to completely collapse the veins, without interfering to any extent with arterial inflow. Several reports in the literature (Allwood 1957: Henry and Winsor 1965; Loane 1959) show that venous pressure can be effectively lowered and maintained at a low pressure using this technique. These authors, however, do not supply sufficient evidence to show that this technique produces any beneficial effect on blood flow and tissue perfusion in patients with occlusive arterial disease.

Maximum increase in blood flow in the dependent foot would be obtained if the foot were briefly compressed (2-3 seconds) at appropriate intervals to maintain the venous pressure at a minimum. A compression pressure should ideally be high enough to fully collapse the veins and yet interfere with arterial flow as little as possible. Data concerning these factors is unavailable in the literature.

It is our objective to provide the above mentioned data and to study the effectiveness of a pneumatic venous pump in increasing blood flow in the foot as indicated by the clearance from the tissues of a radioactive tracer. Further, we would like to propose mechanical, intermittent venous compression, using a pneumatic venous pump, as a rational mode of therapy for patients, with severe ischemic occlusive arterial disease, who for various reasons are not immediately amenable to surgical correction.

MATERIALS AND METHODS

MATERIALS AND METHODS

The effectiveness of an inflatable plastic boot, employed as a venous pump, in lowering venous pressure was studied in normal subjects and patients with occlusive arterial disease of their lower limbs. All subjects considered "normal" were Winnipeg General Hospital employees, of both sexes, who had no symptoms or signs of peripheral vascular disease. All patients were evaluated clinically and with measurement of local systolic blood pressure at ankle level. Arteriograms were available for most patients and careful note was made of the site of occlusion as well as collateral vessel developement.

The inflatable boot was made of a single layer of clear, flexible, vinyl plasticand fitted over the entire foot. The top of the boot was adjusted to fit snuggly, but not tightly around the ankle. The toe end of the boot was open and fitted with a broad brass ring held firmly in place with elastic bands. A large, removeable rubber stopper fit tightly into the brass ring and carried: an air line from an air reservoir to inflate the boot, a pressure transducer to measure pressure changes within the boot, and a connector tube (4' high pressure luer lock injection and monitoring line with male and female luer locks, Code Laboratories, Inc. Denver, Colorado) joining the cannula in a foot vein to a second external pressure transducer. A 15 cms. wide cuff shaped to fit snuggly on a cone was connected to a separate air pressure reservoir. Inflation of cuff (hereafter referred to as the "occluding cuff") served to seal the top of the boot around the ankle, and to govern the maximal attainable air pressure in the boot. Inflation and deflation of the occluding cuff and of the boot was controlled by their separate, but linked, timing switches * which could be regulated to give the desired inflation periods. The pressure in the boot was regulated by setting the inflation pressure for the occluding cuff to the desired boot pressure and providing a reservoir air pressure for the boot inflation well above this. The reasons for such a system will be dealt with in the discussion. Prior to the insertion of the foot into the boot, a thermistor probe (Yellow Springs Instrument Co., Inc. probe no. 421 used with Tele-Thermometer Model No. 43TA), for recording skin temperature, was taped to the dorsum of the forefoot and its lead brought out of the boot along the ankle. The foot, within the boot, was also enclosed in orthopaedic stockinette and cotton dressings to prevent heat loss.

The inflation apparatus consisted of two, five gallon reservoir tanks, one each for the boot and cuff, connected to a high pressure air source through their separate reducing valves. Delivery of the air pressure, to the boot and the cuff, was controlled by two separate solenoid air valves operated by the electronic timing device. The inflation apparatus and the plastic boot will from now on be called the "mechanical venous pump" (figure 1).

* (The special electronic timing switches were designed and manufactured by Mr. M. Raber, Department of Bioengineering Winnipeg General Hospital)

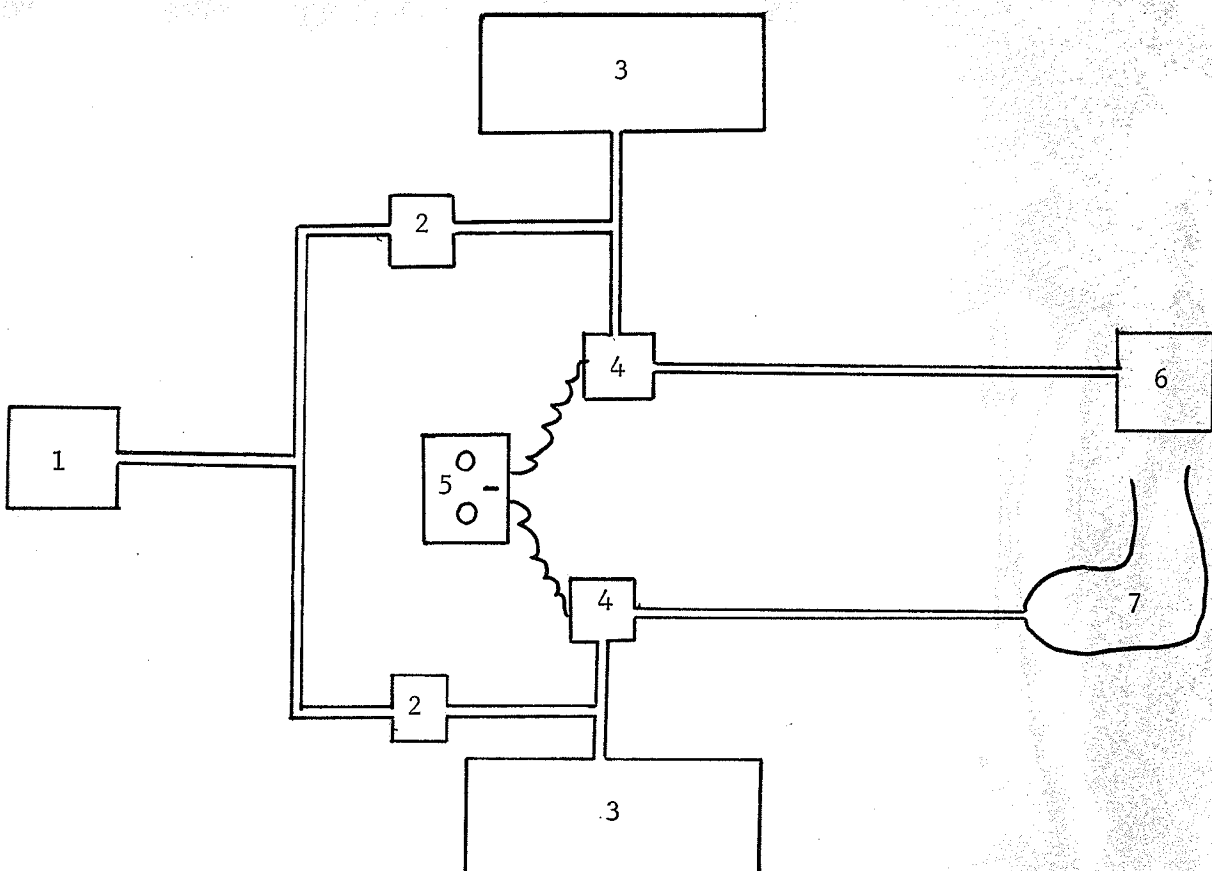


Figure 1 - Mechanical Venous Pump

1. Air pressure valve
2. Reducing valve
3. Air pressure reservoir
4. Solenoid air valve
5. Timing switch
6. Occluding cuff
7. Compression boot

For measuring venous pressure in the foot, a vein with several tributaries was selected and cannulated with a number 18 ôr 20 Jelco intravenous catheter. The venous catheter was connected to a pressure transducer through the section of high pressure tubing, noted above, and a 3-way stopcock. Patency of the cannula was maintained by a continuous very slow flow or normal saline, through the side-arm of the stopcock from a reservoir under high pressure, forcing the saline through a high resistance connected to the stopcock. (Gaskell 1953). A second 3-way stopcock connected to the transducer dome allowed rapid flushing of the system when desired. The transducer was supported at the level of the cannula in the foot vein.

The pressure measurements were recorded by a Beckman Offner Type R dynograph at a paper speed of 100mm/minute.

VENOUS PRESSURE STUDIES

The objectives of the venous pressure studies were to determine the ability of the venous pump to reduce the venous pressure in the foot and how this is affected by various compression pressures, compression periods, compression intervals (time interval from the beginning of one compression to the next), and delay periods. (time interval between inflation of cuff and boot). Preliminary experiments revealed that a compression pressure equal to sitting venous pressure plus 10mm Hg., a compression period of 2 seconds, a compression interval of 15 seconds was effective and practical. Using these as standard settings, the effect of varying each parameter was determined individually. The compression pressure, increasing by 10mm Hg. increments, ranged from 20mm. Hg. below to 40mm Hg. above sitting venous pressure. Compression periods ranged from 0.5 to 4 seconds with 0.5 second increments. Compression intervals of 5, 10, 15, 20 and 30 seconds, and delay periods of 0, 0.5, 1 and 2 seconds were tested.

Venous pressure measurements were made on 8 normal subjects and 3 patients under controlled room temperature of 20^{o}C. Each subject, covered with an electric heating blanket, was seated on a Circolectric bed, (Stryker Circolectric Universal Hospital Bed Model 460, Stryker Corporation, Kalamazoo, Michagan). The subjects were kept comfortably warm so that the skin temperature of the forefoot, within the boot and cotton padding, was maintained between 32-34^{o}C unless otherwise stated. Sitting brachial blood pressure was measured by auscultation. Hydrostatic venous pressure, at the foot while sitting, was calculated using 1.06 and 13.56 as the specific gravities of blood and mercury respectively.

Two normal subjects and 1 patient were also studied in the leaning-standing position on the tilted Circolectric bed.

The effect of intermittenly inflating the occluding cuff only, as a venous pump was studied in 3 patients, using compression pressures of 50-160mm Hg. and compression periods of 1 to 3 seconds.

The effect of a combined calf and foot boot, employed as a unit, was studied in 1 normal subject.

BLOOD FLOW STUDIES

Kety in 1949 showed that blood flow from a vascular bed could be accurately estimated by measuring the clearance of a radioactive substance from the vascular bed. In this study Xenon ^{133} was used as the radioactive material to estimate the blood flow.

The objective of the Xenon ^{133} clearance studies was to determine the effect of the mechanical venous pump on blood flow through the skin of the foot in sitting patients with arterial occlusive disease of the lower limb. The change in blood flow that occurred when the subjects were changed from a supine to sitting position was determined as well so that the combined effect on blood flow of the erect posture and the venous pump could be estimated. To accomplish this, Xe^{133} clearance, from a subdermal injection just proximal to the toes, on the dorsum of the test foot, was monitored in 4 normal subjects and 21 patients in the following positions and circumstances:

A	Supine	-	no pumping
B	Sitting	-	no pumping
C	Sitting	-	pumping test foot
D	Sitting	-	no pumping
E	Sitting	-	pumping opposite foot
F	Sitting	-	no pumping
G	Supine	-	no pumping

In 5 patients the order of C & E were reversed.

On the assumption that the rate of blood flow in the tissue being cleared is proportional to the clearance rate of Xe^{133} and therefore, inversely proportional to the half-time of Xe^{133} clearance in minutes, the half-times for the clearances were obtained graphically from the semi-log plots of radioactivity remaining in the tissues, measured over each succeeding 30 second period. The clearances over the first 5 to 10 minutes immediately following a change of posture or circumstance was ignored when drawing, by inspection, the best fit lines of the plot. Thus approximately 20 minutes of continuous recording was available to indicate the proper slope of the line. The injection of Xe^{133} was made at least 20 minutes before any test monitoring was begun so that the gas would have come into good equilibrium in the tissue.

The relative changes in blood flow resulting from changes in posture or circumstance as listed above were calculated from the half-times of the clearances and expressed as a percentage increase or decrease in rate of blood flow in the test foot according to the following formulae:

1. Percentage change in blood flow in the test foot as a result of sitting relative to lying

$$\left(\frac{\frac{A \& G}{2}}{\frac{B \& F}{2}} - 1\right) \times 100\%$$

where the letters refer to the half-times in minutes for the corresponding designated positions and circumstances listed above and the result represents the average effect of the two changes in posture at the beginning and end of the protocol.

2. Percentage change in blood flow in the test foot caused by pumping the test foot while sitting:

$$\left(\frac{\frac{B \& D}{2}}{C} - 1\right) \times 100\%$$

where the average of the blood flow during the periods before and after the pumping is taken as representing the initial or control blood flow.

3. Percentage change in blood flow in the test foot caused by pumping the opposite foot while sitting:

$$\left(\frac{\frac{D \& F}{2}}{E} - 1\right) \times 100\%$$

Formula (2) will give the change in blood flow caused by both local and direct effects of venous pumping in the test foot and any general vasomotor reflex alterations resulting from the pumping.

Formula (3) will allow estimation of the effects of general vasomotor reflex alterations during pumping.

Subtracting the result obtained by formula (3) from that obtained by formula (2) will give an estimation of the percentage increase in blood flow in the test foot resulting from the local direct effects of venous pumping. It is realized, of course, that alterations in the general vasomotor state, and that of the test foot, may occur independently of the use of the mechanical venous pump or change in posture.

The sum of the results of application of formulae (1) and (2) will give an estimate of the combined effect of the erect posture and use of the mechanical venous pump, both of which are expected to increase blood flow in the foot supplied by markedly obstructed main arteries.

The significance of the changes in rate of blood flow resulting from changes in posture or circumstance were tested by "students" T test for paired date.

In carrying out the experiments, each subject was made comfortable on the levelled Circolectric bed in the controlled temperature room (20^{o}C). Prior to the insertion of the test foot into the boot, 30 to 50 microcuries of Xe^{133} in saline (not more than 0.1ml.) was injected just below the skin 3 cms. proximal to the cleft between the first and second toes. Compression boots were applied to each foot and general arrangements were completed in the same manner as in the venous pressure studies but omitting the venous cannula. After at least 20 minutes, to allow tissue distribution of the Xe^{133}, the scintillation probe, with a sodium iodide crystal, was moved over the injection site and maintained at 6 cms. above the site for the duration of the study. Radio-activity remaining in the tissue was recorded in counts per minute at intervals of 30 seconds by a Radiation Counter Laboratories Incorp. Four Hundred Channel Analyzer. At the end of the experiment, the analyzer typed out the counts per minute for each 30 second interval of the experiment and these were in turn plotted by hand on semi-log paper for analysis as previously noted. Care was taken to keep the foot as still as possible, and brachial blood pressure and foot skin temperature, with the temperature probe at the level of the injection site, were monitored periodically.

CLINICAL TRIAL

One patient, Mr. E. C. with severe rest pain in his left foot and superficial interdigital ischemic ulcers, was treated with intermittent venous compression. The patient, aged 74, had been at home suffering from his rest pain for approximately 10 days with little relief of the pain on dangling the foot. The mechanical venous pump was applied to the foot of the sitting patient and set to compress the foot for 2 seconds every 15 seconds at a compression pressure of 55mm Hg. This regime was maintained continuously for 100 hours, while the patient awaited surgical correction, stopping only to give foot care twice a day. The patient was encouraged to move his feet during the treatment. The venous pump was removed 18 hours prior to surgery to allow preparation of the foot and leg for surgery. After removal of pump rest pain returned and strong analgesics were administered in an attempt to alleviate the pain.

RESULTS

RESULTS

Clinical data on 23 patients on whom successful experiments were carried out is presented in Tables IA, B and C. Appendix A includes diagrams of the arterial lesions and collateral vessels in the lower limbs of most of these patients as seen in arteriograms. Among these patients, 16 had supine local systolic blood pressure at ankle level of 65mm Hg. or less in the test limb and of these, 7 suffered from rest pain.

In the Xe^{133} clearance experiments, the radioactivity counts of the Xe^{133} remaining in the test foot obtained every 30 seconds for approximately 20 minutes, were plotted on semilog paper and best fit lines were drawn by inspection. Thirty-four patients were studied in this manner, but 13 patients were deleted from the study for various reasons. Some were unable to complete all phases of the experiment because of prolonged immobility during the testing while others with severe rest pain could not tolerate the supine positions nor the nonpumping periods. Several patients were omitted because their plots from the radioactivity counts were so erratic, due to changes in vasomotor tone and foot position, that meaningful curves could not be drawn. The following data on blood flow studies concerns the 21 patients who had successful experiments.

Figure 2 shows the plots obtained from a patient in an unsuccessful experiment. The plots are too erratic to draw radioactivity clearance curves. Figure 3 exhibits the curves drawn from the plots of a successful experiment.

T A B L E IA - PATIENT CLINICAL DATA

PATIENT	SEX	AGE	DIAGNOSIS	COMPLAINT	DURATION
A.D.	M	53	Atherosclerosis Diabetic 2 years Bilateral external iliac occlusion	None	
P. Mc	M	58	Bilateral superficial femoral occlusion Atherosclerosis	Bilateral claudication 1 block Rest pain left foot	4 years 2 weeks
W.A.	M	63	Atherosclerosis Right external iliac stenosis Right superficial femoral occlusion Left superficial femoral occlusion Left external iliac stenosis	Right claudication 1 block	9 years
C.P.	F	41	Left external iliac stenosis Diabetes 15 years Atherosclerosis	Claudication left 3 blocks	2 years
J.C.	M	64	Atherosclerosis Right superficial femoral occlusions Left superficial femoral occlusions	Right claudication 1 block	2 weeks
W.F.	M	73	Atherosclerosis Left superficial femoral and popliteal occlusions Right superficial femoral occlusions Diabetes 7 years	Left claudication ½ block Left rest pain	2 weeks 2 weeks
T.G.	M	40	Atherosclerosis Right common iliac occlusion Left external iliac stenosis	Right claud- ication 1 block	4 years
L.S.	F	46	Atherosclerosis Bilateral Super- ficial femoral occlusions Secondary to infection	Claudication ¼ block	5 years

TABLE IA (continued)

PATIENT	SEX	AGE	DIAGNOSIS	COMPLAINT	DURATION
D.E.	M	71	Atherosclerosis Bilateral superficial femoral occlusion Left common femoral occlusion	Left rest pain	1 day
N.H.	M	58	Atherosclerosis Right superficial femoral occlusion Left superficial femoral stenosis	Right claudication ½ block rest pain	1 year 2 weeks
J.P.	M	54	Atherosclerosis Bilateral superficial femoral occlusion Frost bite right foot	None	
F.H.	M	65	Atherosclerosis Bilateral superficial femoral occlusion	Right claudication 1 block Left claudication ½ block	1 year
H.H.	M	77	Atherosclerosis Right superficial femoral occlusion	Right claudication 1 block Right superficial femoral occlusion	1 year
S.T.	M	68	Atherosclerosis Left superficial femoral occlusions	Claudication 1 block	1 year
P.T.	M	49	Atherosclerosis Right common femoral occlusions Left superficial femoral occlusions	Left claudication 1 block	1 year
H.S.	M	67	Atherosclerosis Bilateral superficial femoral occlusions	Right claudication 1 block	1 year

T A B L E IA (continued)

PATIENT	SEX	AGE	D I A G N O S I S	COMPLAINT	DURATION
L.B.	M	66	Atherosclerosis Bilateral common iliac stenosis Bilateral superficial femoral occlusions	Left claudication 1 block	2 years
E.C.	M	75	Atherosclerosis Left superficial femoral occlusion	Claudication ½ block Rest pain	6 months 2 weeks
R.W.	M	69	Atherosclerosis Right common iliac occlusion Left common iliac stenosis Abdominal aneurysm	Claudication ½ block	2-3 years
D.T.	M	63	Atherosclerosis Right superficial femoral occlusions Left occlusions of aorto-femoral graft	Claudication ½ block	3 months
H.G.	M	64	Atherosclerosis Bilateral superficial femoral occlusions Diabetes	Left claudication ½ block Left rest pain	2 years 6 months
L.F.	F	64	Atherosclerosis Right superficial femoral occlusion	Right claudication ¼ block	1 year
J.R.	M	82	Atherosclerosis Right superficial femoral occlusion	Right claudication ¼ block Rest pain	1 year 3 months

T A B L E IB - PATIENT CLINICAL DATA

PATIENT	PREVIOUS SURGERY		PULSES F	P	P.T.	D.P.
A.D.	1969 ilio-femoral bypass 1971 aorto-bifemoral graft	R. L.	4 4	3 1	2 2	2 2
P.M.	Left aorto-femoral bypass -1968 Right iliac endarterectomy-1968 Left sympathectomy	R. L.	3 3	0 0	0 0	0 0
W.A.	N O N E	R. L.	1 3	0 0	0 0	0 0
C.P.	N O N E	R. L.	4 2	4 2	4 1	4 2
J.C.	N O N E	R. L.	1 4	0 3	0 3	0 3
W.F.	Right femoral popliteal vein graft - 1968	R. L.	3 3	3 0	0 0	0 0
T.G.	N O N E	R. L.	0 4	0 4	0 4	0 4
L.S.	Right femoral-popliteal bypass(infected)	R. L.	2 3	0 0	0 0	0 0
D.E.	N O N E	R. L.	4 4	0 0	0 0	0 0
N.H.	N O N E	R. L.	3 4	0 0	0 0	0 0
J.P.	N O N E	R. L.	4 4	0 0	0 0	1 1
F.H.	N O N E	R. L.	4 4	0 0	0 0	0 0
H.H.	N O N E	R. L.	4 4	0 3	0 3	0 3
S.T.	N O N E	R. L.	4 4	4 0	3 0	3 0
P.T.	N O N E	R. L.	1 3	0 0	2 0	2 0
H.S.	N O N E	R. L.	4 4	0 0	0 0	0 0

T A B L E IB - PATIENT CLINICAL DATA - (continued)

PATIENT	PREVIOUS SURGERY	PULSES	F	P	P.T.	D.P.
L.B.	N O N E	R.	3	0	0	0
		L.	3	0	0	0
E.C.	N O N E	R.	4	4	3	3
		L.	4	0	0	0
R.W.	N O N E	R.	0	0	0	0
		L.	2	0	0	0
D.T.	Aorto-bifemoral graft-1971	R.	3	0	0	0
		L.	0	0	0	0
H.G.	Bilateral sympathectomy -1972	R.	4	0	0	0
		L.	4	0	0	0
L.F.	N O N E	R.	3	0	0	0
		L.	4	4	4	4
J.R.	N O N E	R.	3	4	4	0
		L.	3	0	0	0

T A B L E IC - PATIENT CLINICAL DATA

PATIENT	BRACHIAL B.P.	ANKLE BLOOD PRESSURE RIGHT	LEFT	FOOT BLOOD PRESSURE RIGHT	LEFT
A.D.	127/75	123-128	* 82-87	--	--
P.Mc	115/75	73-78	* 60-65	60-65	38-43
W.A.	110/66	* 60-65	83-88	--	--
C.P.	138/78	120-125	* 80-85	--	--
J.C.	128/76	* 45-50	85-90	--	--
W.F.	140/78	128-133	* 27-32	70-75	--
T.G.	130/85	* 65-70	115-120	--	--
L.S.	150/90	* 50-55	93-98	43-48	68-73
D.E.	138/68	53-58	* 50-55	45-50	43-48
N.H.	119/66	* 28-33	73-78	--	--
J.P.	140/68	* 78-83	90-95	73-78	70-75
F.H.	113/68	* 48-53	57-62	--	--
H.H.	160/77	143-148	* 80-85	145-150	50-55
S.T.	140/89	122-127	* 58-63	115-120	60-65
P.T.	119/78	73-78	* 60-65	--	--
H.S.	127/75	* 60-65	70-75	50-55	60-65
L.B.	155/81	90-95	* 88-93	78-83	70-75
E.C.	130/82	125-130	* 33-38	--	--
R.W.	160/87	* 62-67	108-113	--	--
D.T.	114/70	70-75	* 30-35	--	--
H.G.	115/71	76	* Unable		
L.F.	130/70	* 65-70	135-140	40-45	143-148
J.R.	140/89	147-152	* 38-43	--	--

* Test Foot

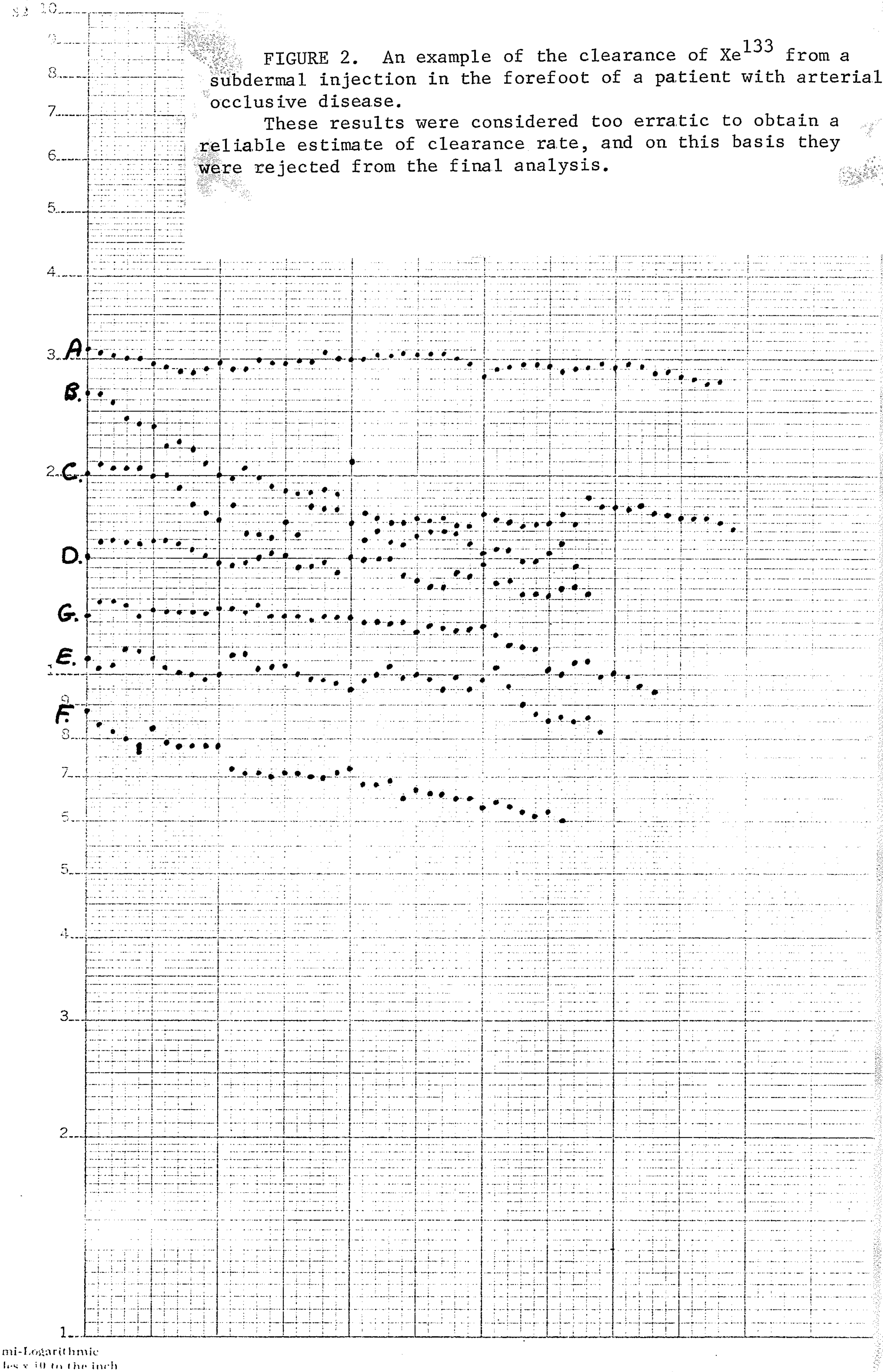


FIGURE 2. An example of the clearance of Xe^{133} from a subdermal injection in the forefoot of a patient with arterial occlusive disease.

These results were considered too erratic to obtain a reliable estimate of clearance rate, and on this basis they were rejected from the final analysis.

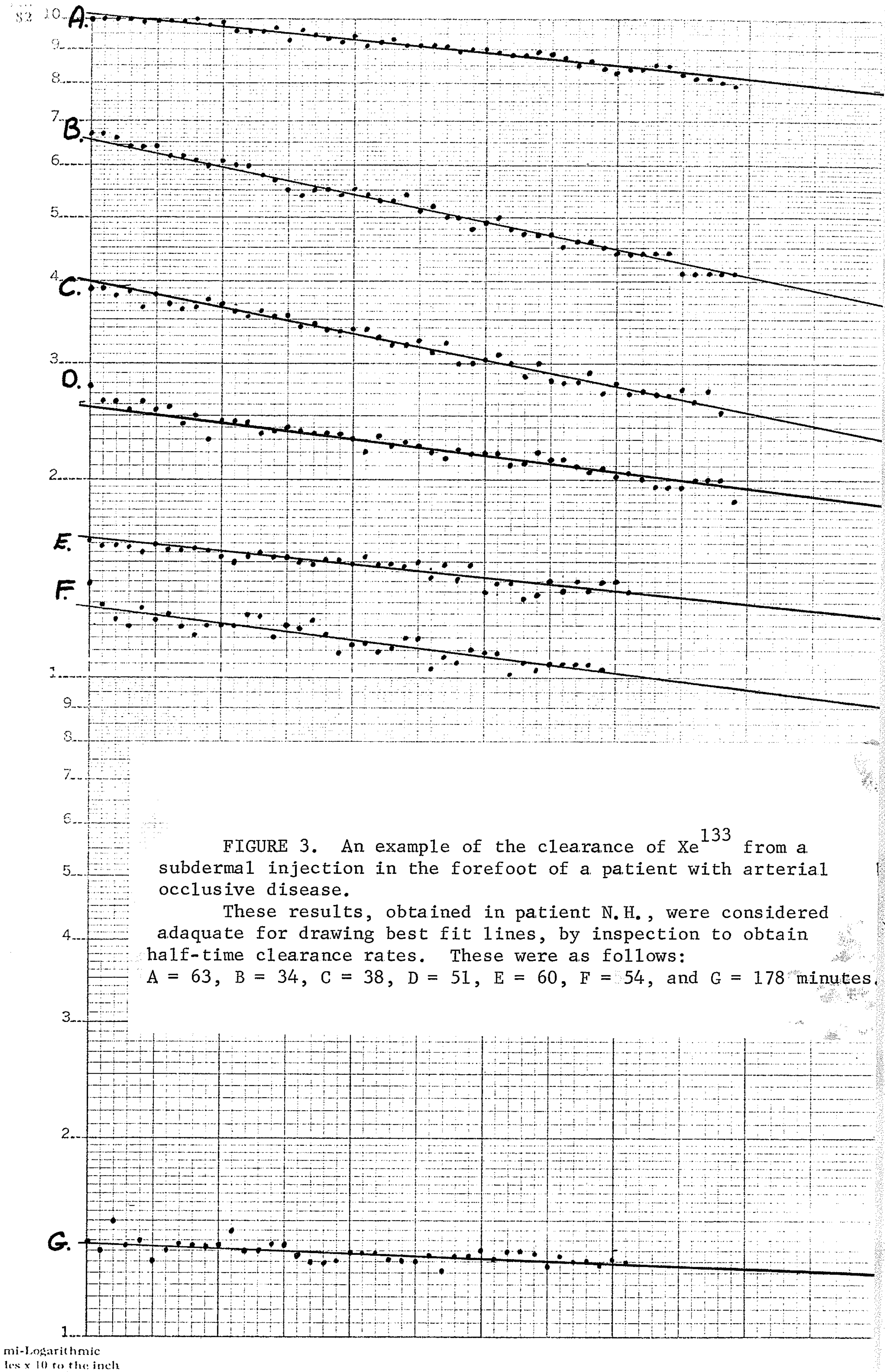


FIGURE 3. An example of the clearance of Xe^{133} from a subdermal injection in the forefoot of a patient with arterial occlusive disease.

These results, obtained in patient N.H., were considered adaquate for drawing best fit lines, by inspection to obtain half-time clearance rates. These were as follows: A = 63, B = 34, C = 38, D = 51, E = 60, F = 54, and G = 178 minutes.

VENOUS PRESSURE STUDIES

The standard venous pump consisted essentially of the plastic boot covering the foot and sealed at the ankle by separate inflations of an occluding cuff. Results indicating the effectiveness of this arrangement in lowering venous pressure at the foot are presented here.

The effectiveness of various compression pressures in the foot of the erect subject was studied in 8 normal subjects and 4 patients. Compression pressure was varied while the other parameters for the mechanical venous pump were kept constant. In all subjects the minimum venous pressure obtained fell as compression pressure was increased towards sitting venous pressure in the foot. (figure 4)

Maximum lowering of venous pressure occurred when the compression pressure reached approximately each subjects' sitting venous pressure (figure 5 and 6). It should be noted that compression pressures well below sitting venous pressure are capable of partially emptying the veins and lowering venous pressure.

A single compression, at least equal to sitting venous pressure also lowered venous pressure to within a few mm. Hg. of the minimum venous pressure obtained following a series of compressions, however, the veins were not emptied quite as much, as indicated by a more rapid venous filling (figure 7).

It is important not only to reduce venous pressure, but to maintain it at a low level. The ability of the venous pump to empty the veins and maintain a low venous pressure may be indicated by the venous filling time. This is the time required

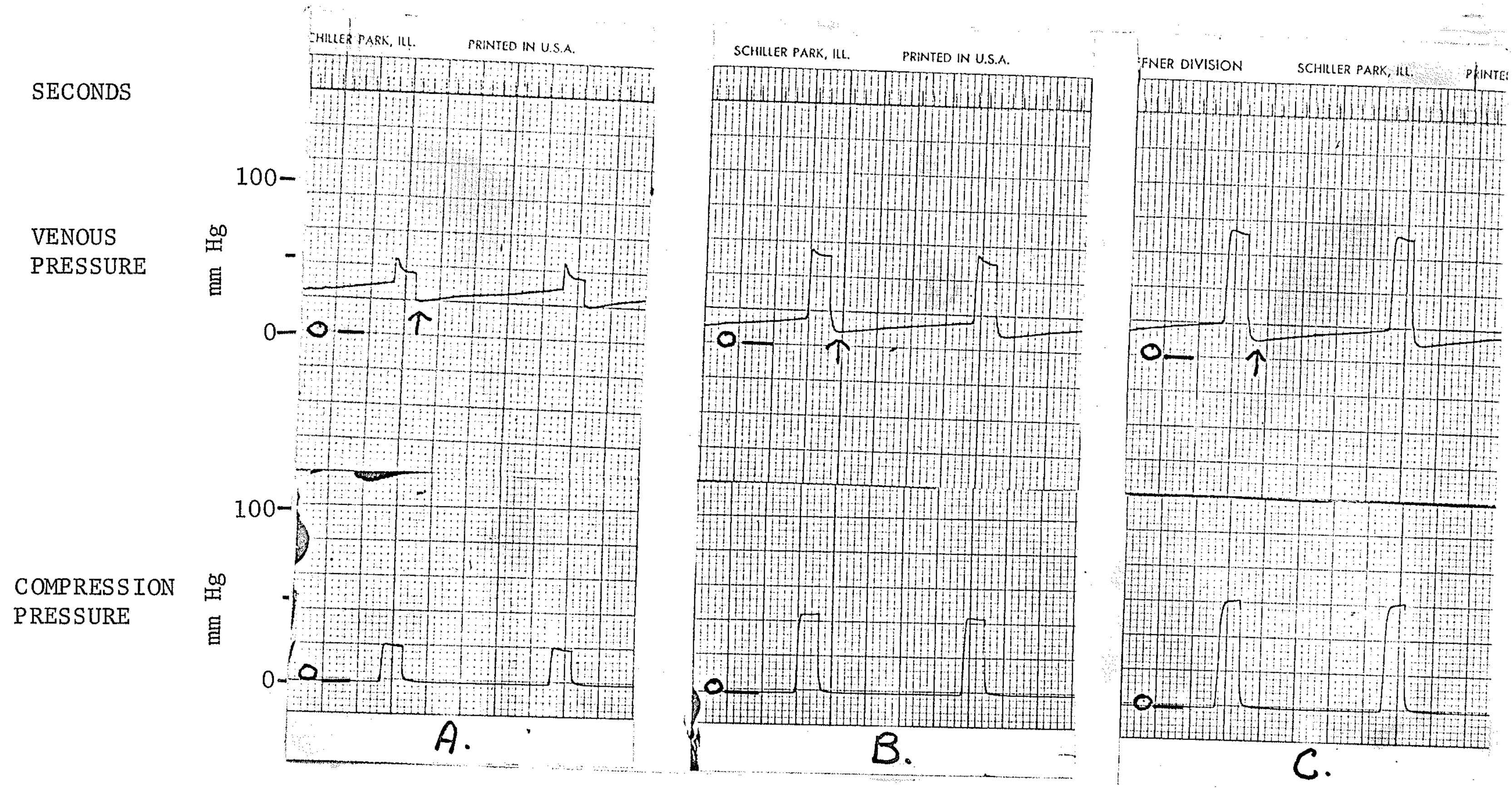


FIGURE 4. The relationship between the compression pressure used in the mechanical venous pump and the minimum venous pressure obtained in the foot in the patient L.F. while sitting.

In panels A, B, and C the compression pressures are 21, 45, and 62 mm Hg respectively while the corresponding minimum venous pressures are 23, 9, and 12 mm Hg.

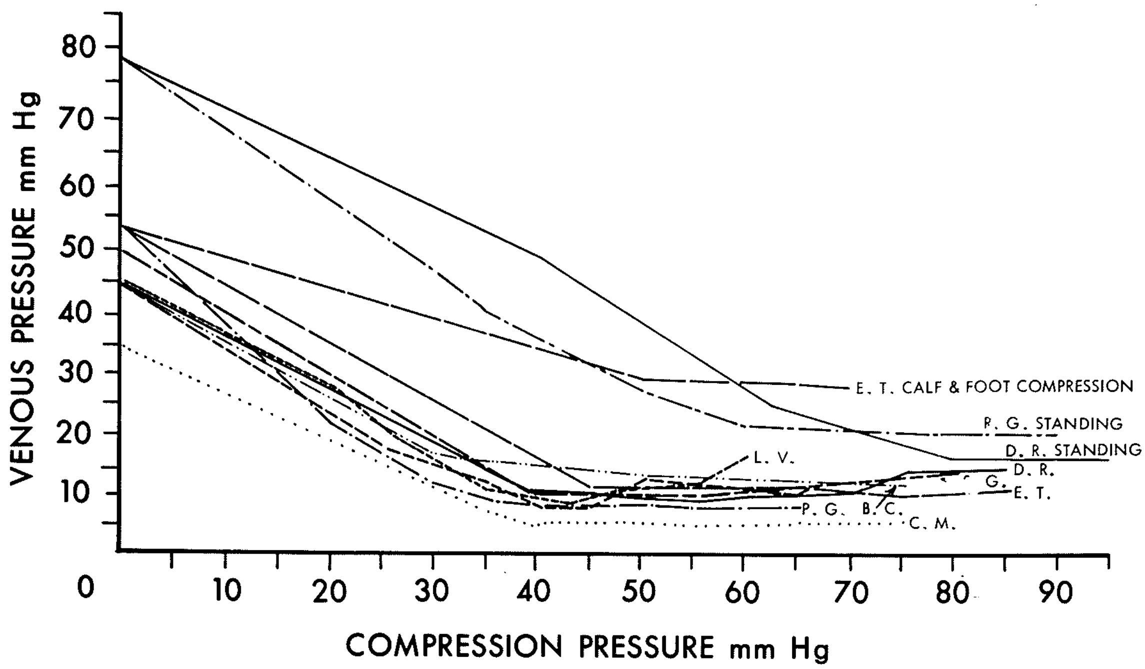


FIGURE 5. The relationship between the compression pressure used in the mechanical venous pump and the minimum venous pressure obtained in the foot in normal subjects.

Lowest minimum venous pressures were obtained when the compression pressure was approximately equal to sitting venous pressure. Note that in subject E.T. simultaneous compression of the leg and foot contained within a single long-legged boot was not as effective in lowering venous pressure in the foot as the standard boot. The latter was capable of reducing venous pressure effectively in the standing (P.G., D.R.) as well as the sitting subject.

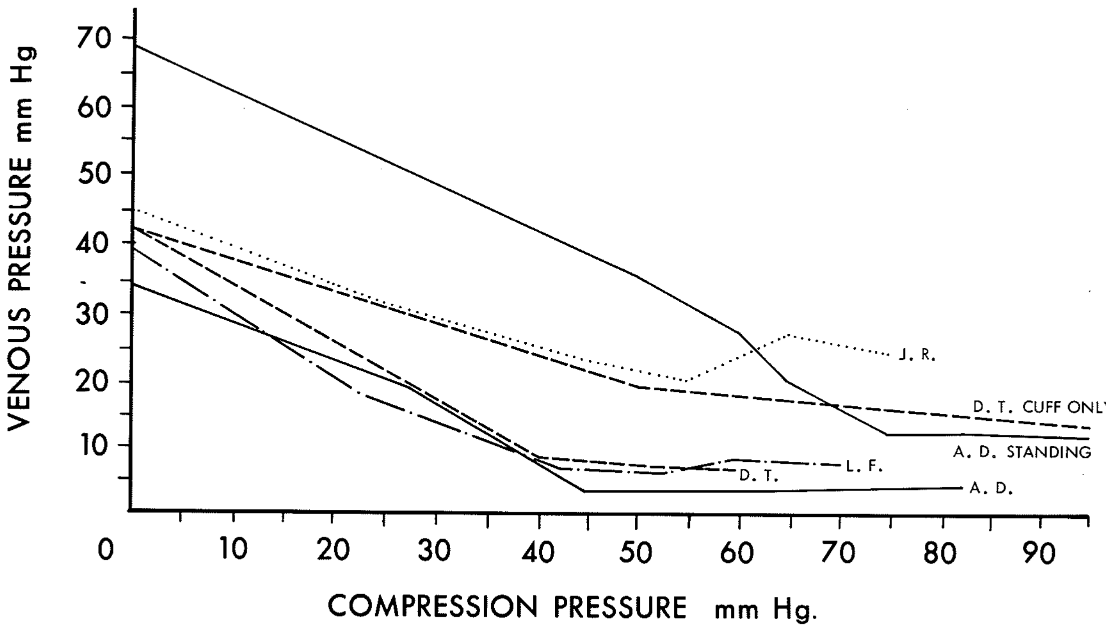


FIGURE 6. The relationship between the compression pressure used in the mechanical venous pump and the minimum venous pressure obtained in the foot in patients with arterial occlusive disease in the lower limb.

Lowest minimum pressure was obtained when compression pressure was approximately equal to sitting venous pressure. Note that in patient D.T., use of the ankle occluding cuff only as the venous pump did not reduce venous pressure as well as inflation of boot and cuff.

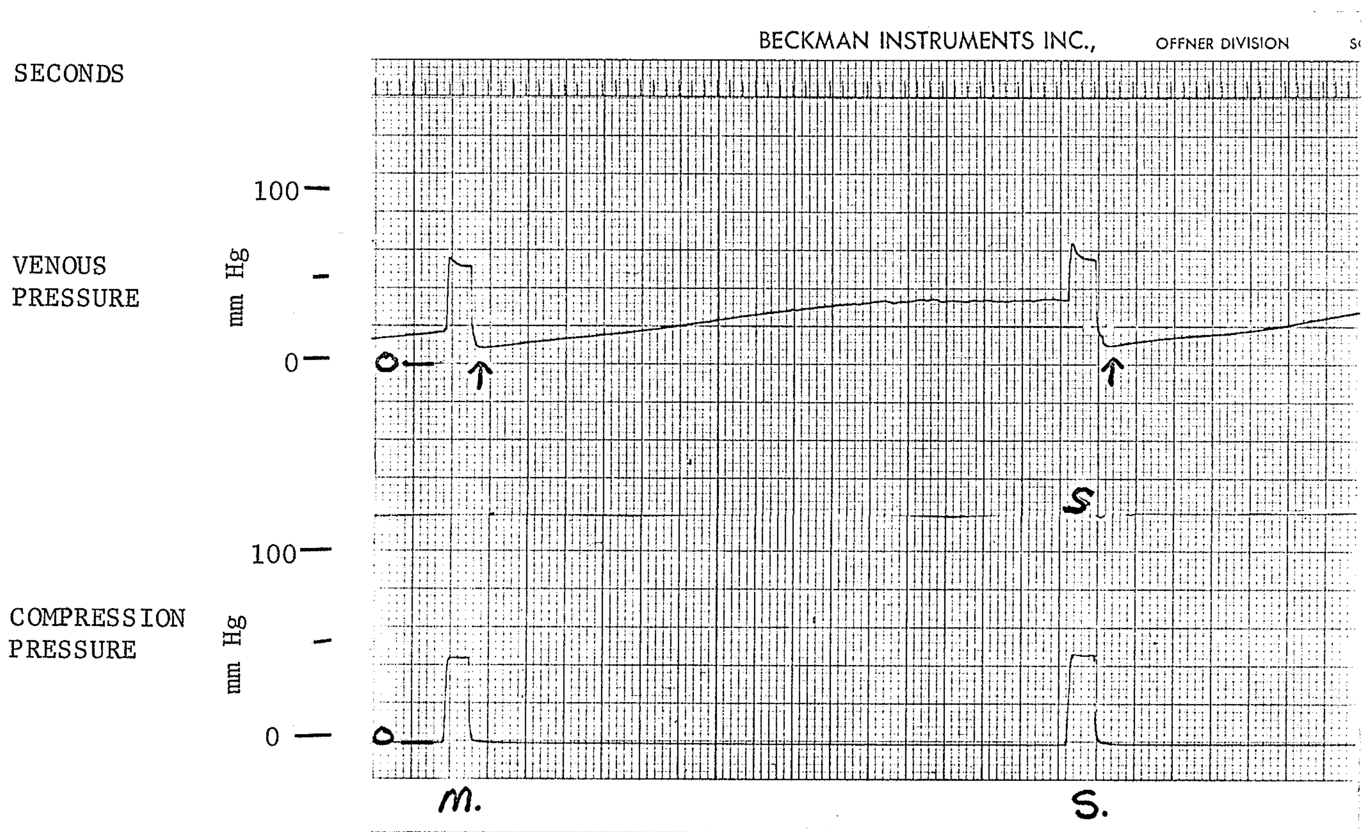


FIGURE 7. The effect on venous pressure in the foot of a single compression of the foot with the standard venous pump in patient L.F.

"S" indicates the single compression while "M" is the last of a series of compressions at compression intervals of 15 seconds. A single compression lowers venous pressure to almost the same level, and venous filling is slightly more rapid following a single compression.

for the venous pressure to regain the maximum value following the last compression period. Figure 8 illustrate some venous filling times, observed in 6 normal subjects, plotted against the compression pressure in the venous pump. It is of note that the venous filling times plotted for normal subjects and for patients are single values observed following a series of compressions at each compression period.

It is evident that venous filling time varies among the normal subjects even though skin temperatures for each are comparable. It is also apparent, e.g. D.R., that venous filling time in any individual, as might be expected can vary independent of compression pressure and this variability in normals makes it difficult to discern a regular pattern in the relationship between venous filling time and compression pressure. However, the overall picture does suggest that venous filling time increases with increasing compression pressure until it is above sitting venous pressure. Note the example of the effect of temperature on venous filling time in the results obtained for subject B.S. (figure 8). The venous filling times observed in D.R. illustrate how this parameter is influenced by compression pressure, but in addition the prolonged venous filling time observed when standing may be the result of increased vasoconstrictor tone in the foot vessels as a result of the postural change from standing as opposed to sitting.

In the 4 patients for whom this information is available (figure 9), the relationship between venous filling time and

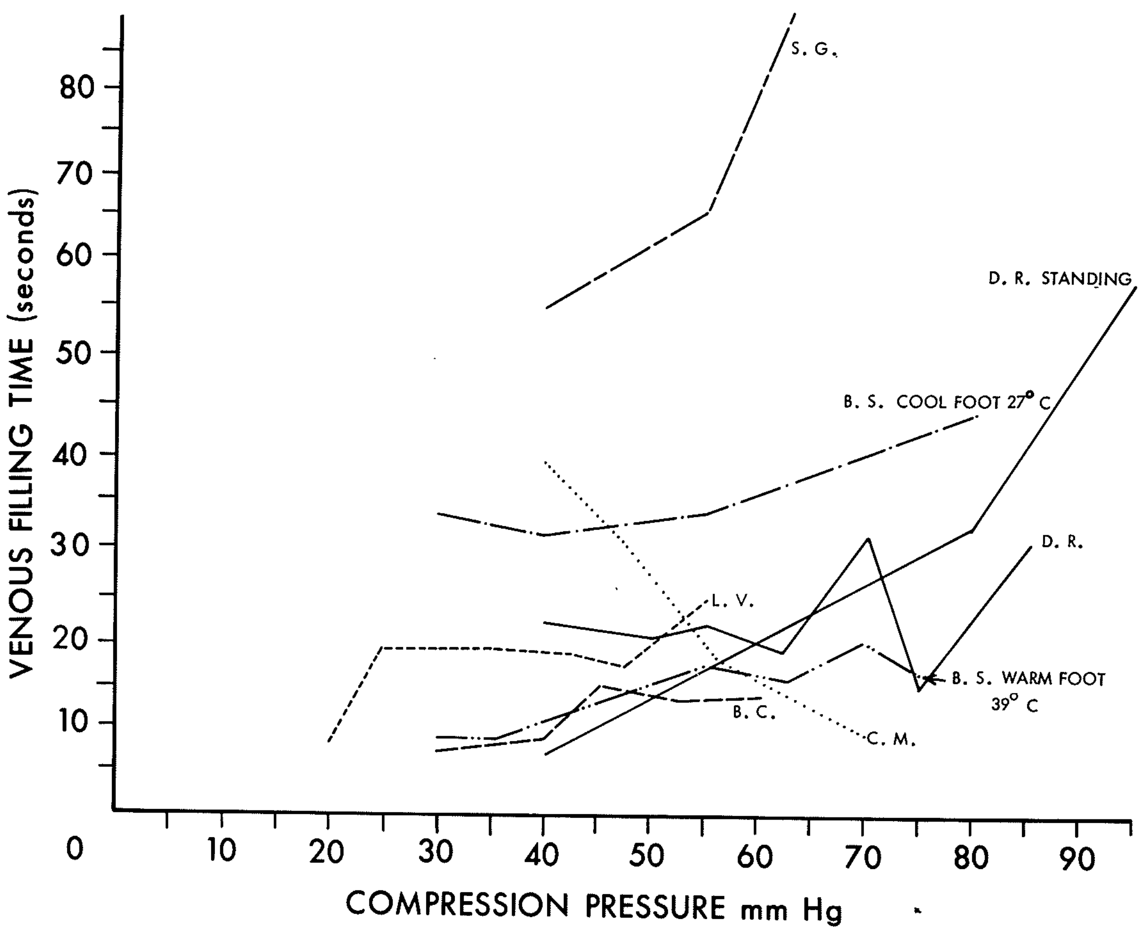


FIGURE 8. The relationship between the compression pressure used in the mechanical venous pump and the venous filling time in normal subjects.

In most subjects the venous filling time was longer with compression pressures equal to or higher than the sitting venous pressure in the foot. The sitting venous pressures in these subjects were: C.M. = 34, B.S. = 44, L.V. = 42, B.C. =49, D.R. = 45, and S.G. = 45 mm Hg. The standing venous pressure for D.R. was 87 mm Hg.

Note the effect of a lower local temperature in subject B.S.

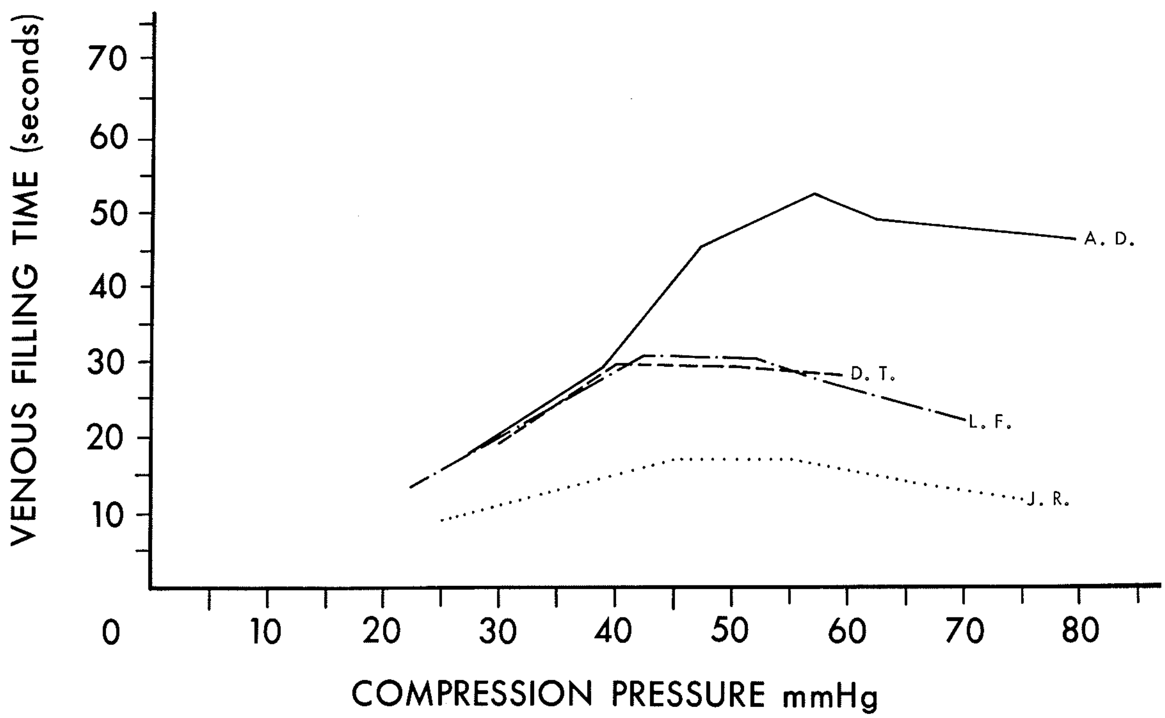


FIGURE 9. The relationship between the compression pressure and venous filling time in patients with arterial obstructive disease in the lower limb.

The sitting venous pressures in the feet of these patients were: A.D.=34, D.T.=42, L.F.=39, and J.R.=45. There is a more regular pattern discernible in these results than in those obtained in the normal subjects.

compression pressure is more regular; the venous filling time increasing to a maximum when compression is about equal to sitting venous pressure. The venous filling time, with compression pressure above venous pressure,was usually well above 15 seconds even in the warm foot, though in J.E., it is close to 15 seconds in spite of a supine ankle pressure of 38-43 mm Hg.

It is apparent that the duration of the compression period will influence the minimum venous pressure obtained by the pump. Too short a period will not allow time for development of the desired pressure (panel A, figure 10). It was found that compression periods of 1.5 to 2.0 seconds produced maximum lowering of venous pressure, and longer compression periods of 3-4 seconds produced little added effect (figures 11 and 12)

It seems apparent from the results in normal subjects (figure 13) and patients (figure 14) that there is little advantage to be gained in emptying the veins, as judged by venous filling time, by increasing the compression period more than 2 seconds under the circumstances of our experiment.

In normal subjects, except for D.R., venous filling time increased slowly as compression period increased. (figure 13). In patients, maximum venous filling time was reached at 1.5 to 2.0 seconds, thereafter longer compression periods produced no further increases in venous filling time (figure 14).

It will be obvious that as compression interval is lengthened, the venous pressure just prior to the next compression will be higher. Prolonged compression intervals will allow the venous

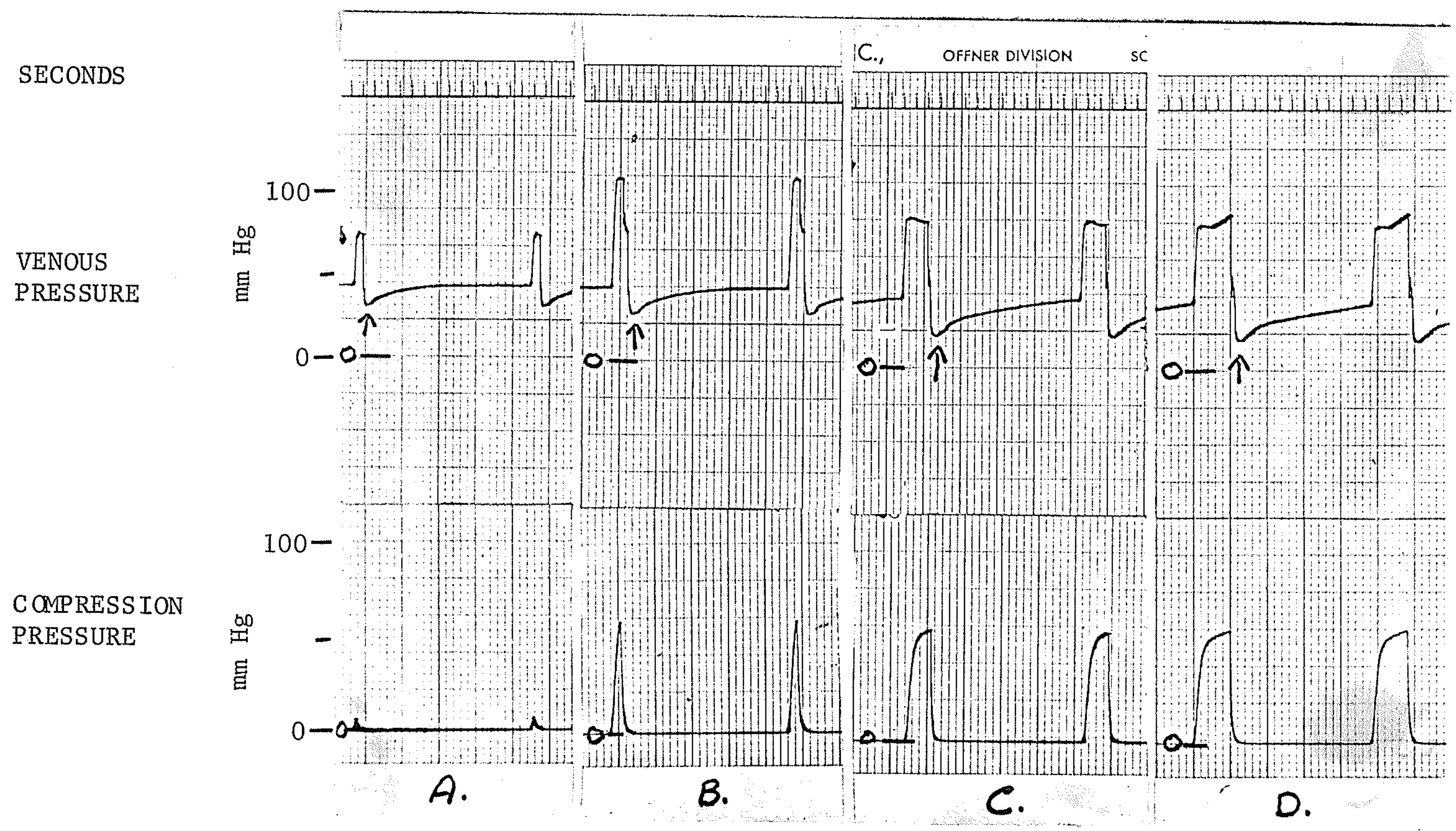


FIGURE 10. The relationship between the compression period and the minimum venous pressure obtained in the foot using the mechanical venous pump.

In panels A, B, C, and D, the compression periods were 0.5, 1.0, 2.0, and 3.0 seconds respectively while the corresponding minimum venous pressures were 32, 29, 19 and 18mm Hg. The compression pressure was intended to be 60 mm Hg.

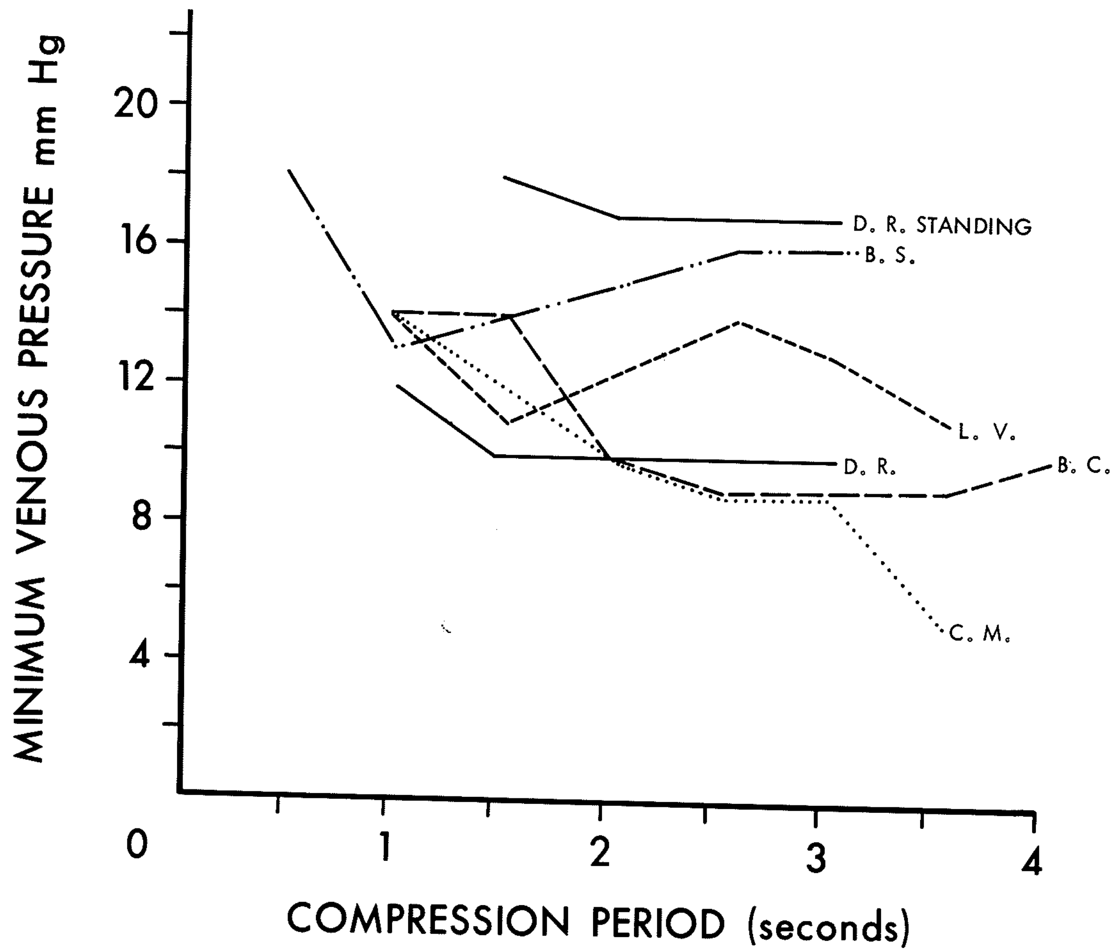


FIGURE 11. The relationship between the compression period and the minimum venous pressure obtained in the foot using the mechanical venous pump in normal subjects.

Shorter periods than 1.5 seconds were inadaquate for obtaining the minimum venous pressure while 2.0 seconds appeared to be satisfactory.

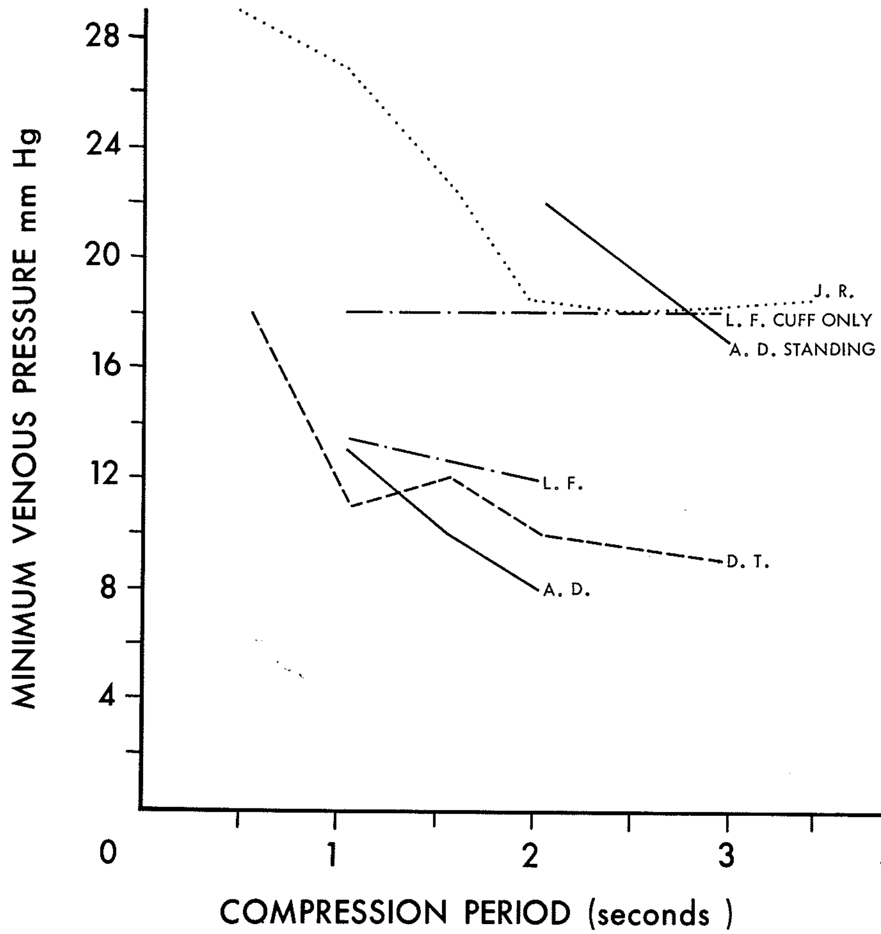


FIGURE 12. The relationship between the compression period and the minimum venous pressure obtained in the foot using the mechanical venous pump in patients with occlusive arterial disease in the lower limb.

Note that when the ankle occluding cuff only was used as the venous pump on patient L.F., compression periods even as long as 3 seconds did not lower venous pressure to the same extent as the standard boot.

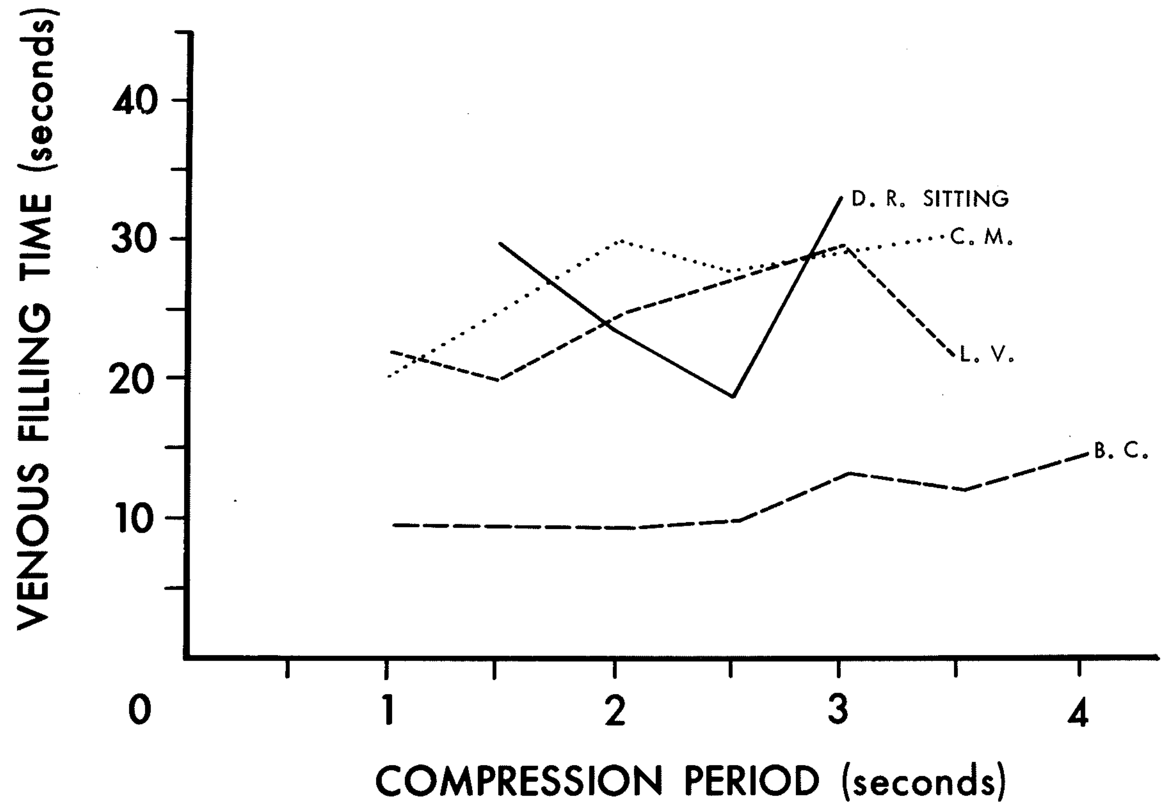


FIGURE 13. The relationship between the compression period and the venous filling time in the foot during use of the mechanical venous pump in normal subjects.

A longer venous filling indicates better emptying of the veins if vascular resistence remains constant.

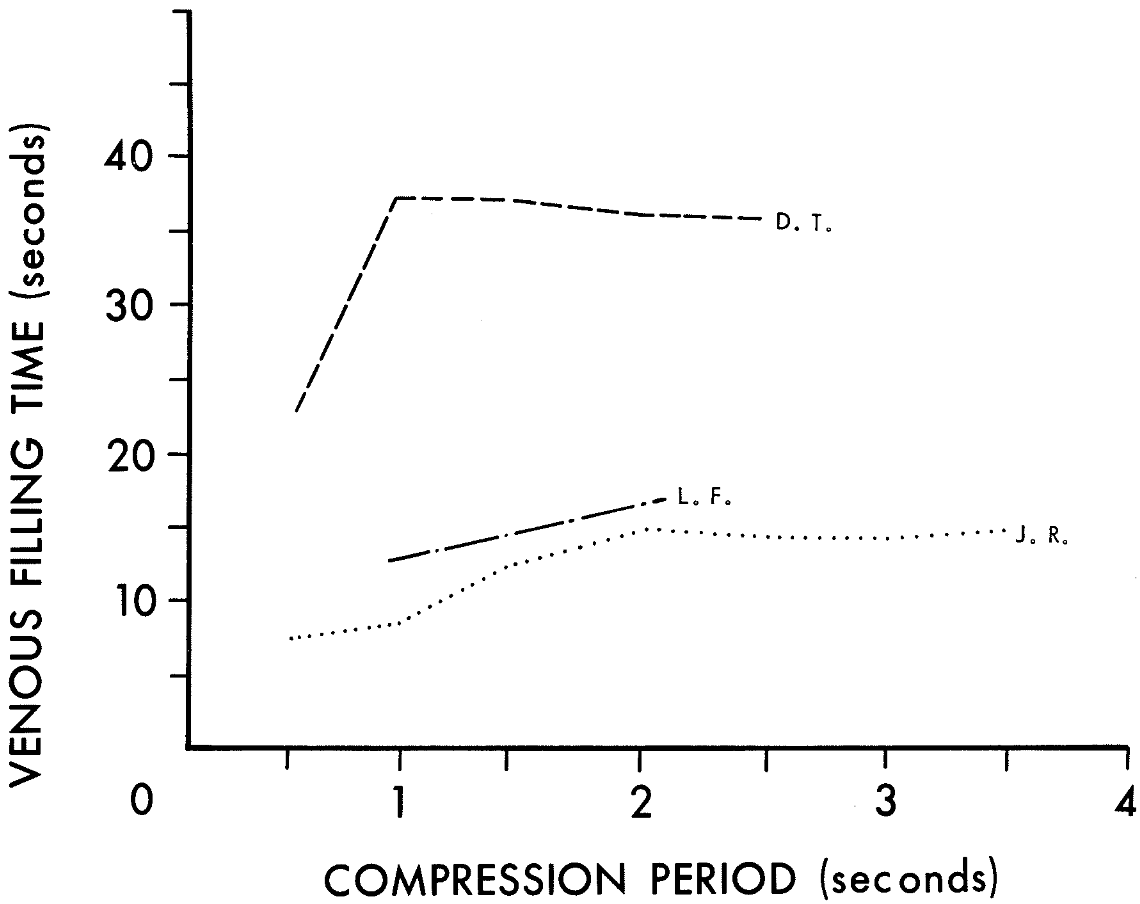


FIGURE 14. The relationship between the compression period and the venous filling time in the foot during use of the mechanical venous pump in patients with arterial occlusive disease of the lower limbs.

pressure to rise to sitting venous pressure and the advantage of an increased arterio-venous pressure difference is lost. It appears from figures 15 and 16 that an interval of about 15 seconds is short enough to maintain a reduced venous pressure in essentially all patients yet long enough to be practical- the compression period of 2 seconds being only a small portion of it.

The effect of varying the delay period between cuff and boot inflation was studied in 2 normal subjects and 2 patients. In all subjects, delays of 0 to 2 seconds were equally good and none adversely affected the extent to which venous pressure could be lowered by the pump (figure 17).

The mechanical venous pump was capable of adequately reducing venous pressure in the foot when the subject was in the leaning-standing posture. As in the sitting subject, lower minimum venous pressures were attained as compression pressure increased until compression pressures equalling standing venous pressures were reached, thereafter, no further fall in venous pressure occurred (figure 5 and 6).

Similarly, as the compression period was prolonged up to 2.5 to 3.0 seconds, minimum venous pressure attainable become lower. Thus, generally longer compression periods were required to attain minimum venous pressures than when the subject was sitting (figure 11 and 12). This is understandable since the pressure within the boot must be raised to a higher level and

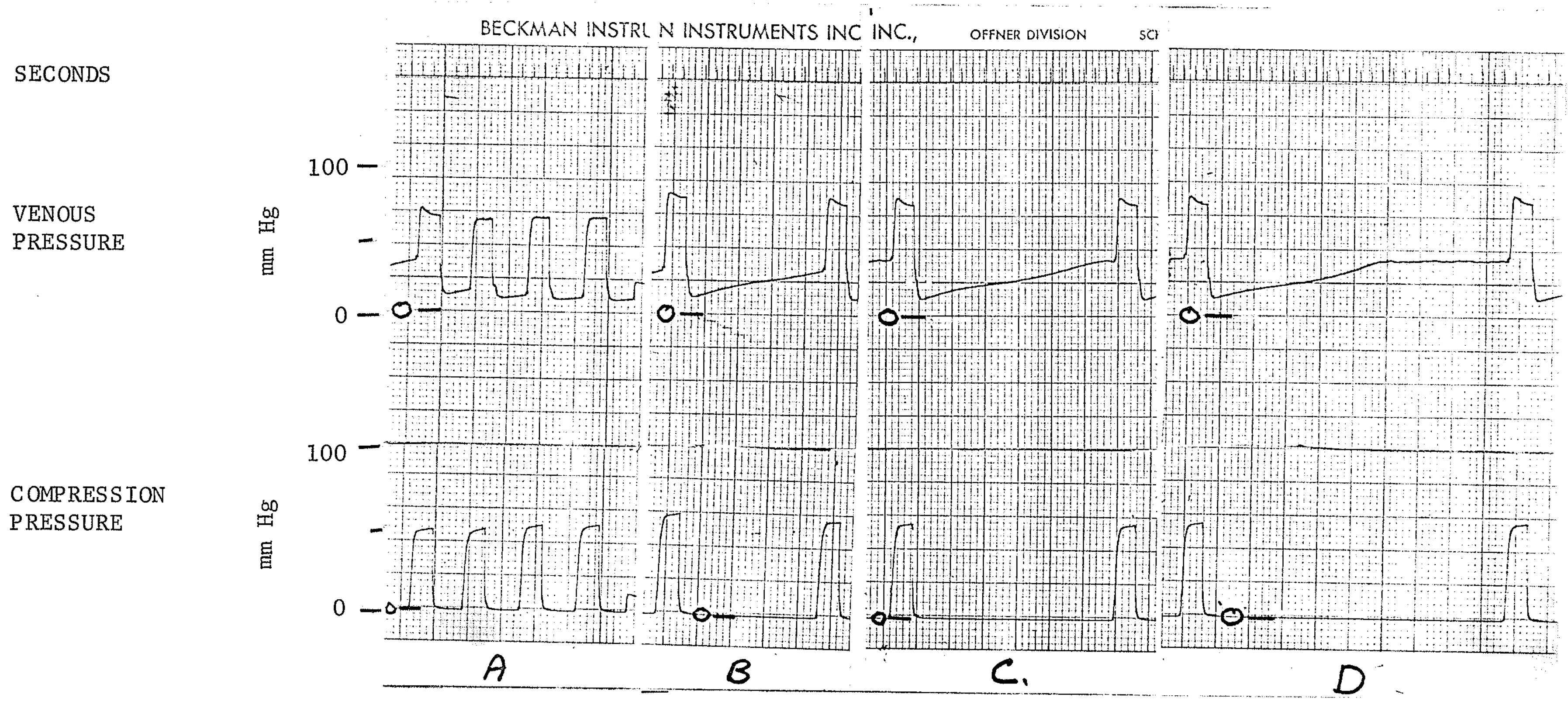


FIGURE 15. The relationship between the compression interval and the venous pressure in the foot during the use of the mechanical venous pump. Results obtained in patient L.F. In panel A, B, C, and D the compression intervals were 5, 15, 20, and 30 seconds respectively. Maximum sitting venous pressure was 36 mm Hg and compression pressure was 60 mm Hg.

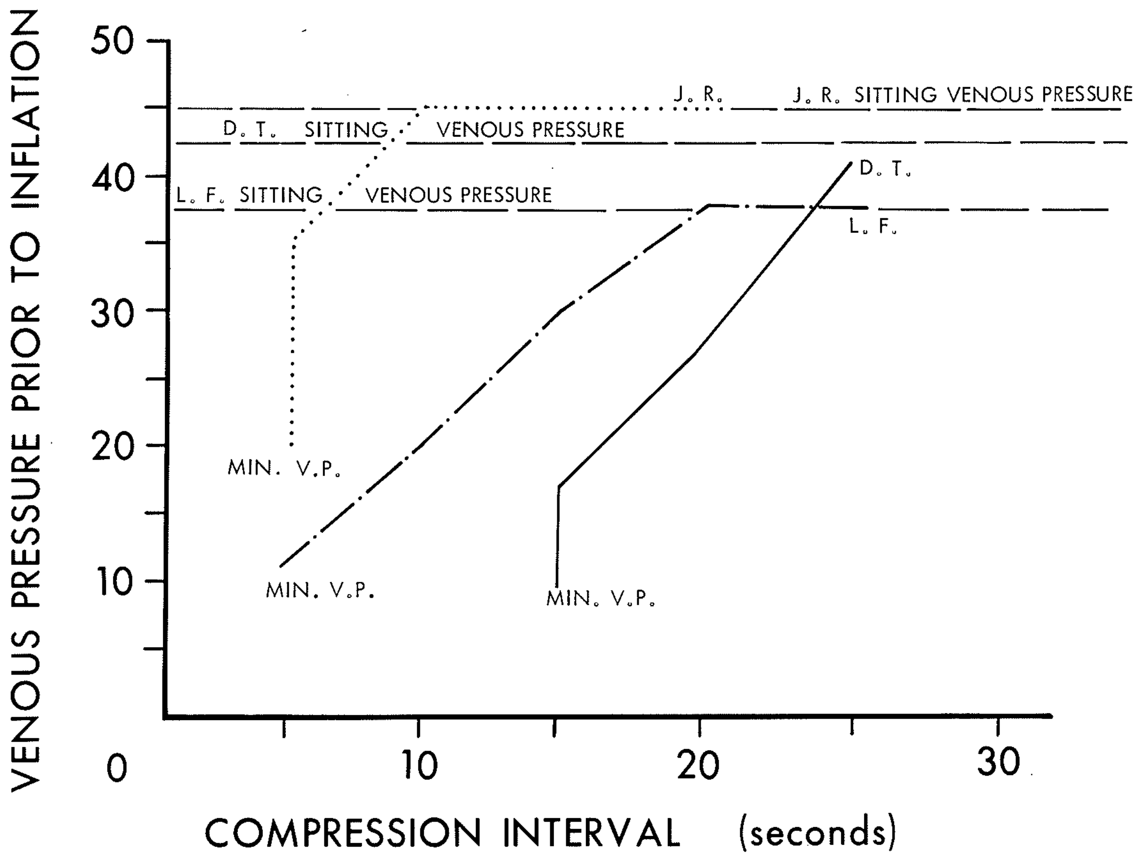


FIGURE 16. The relationship between the compression interval and the venous pressure in the foot during use of the mechanical venous pump in patients with arterial occlusive disease in the lower limbs.

The supine local systolic blood pressure at ankle level in these patients was: J.R. = 38 - 43, L.F. = 65 - 70, and D.T. = 30 - 35 mm Hg. Skin temperature of the forefoot at the time of the venous pressure studies was 32 - 34°C.

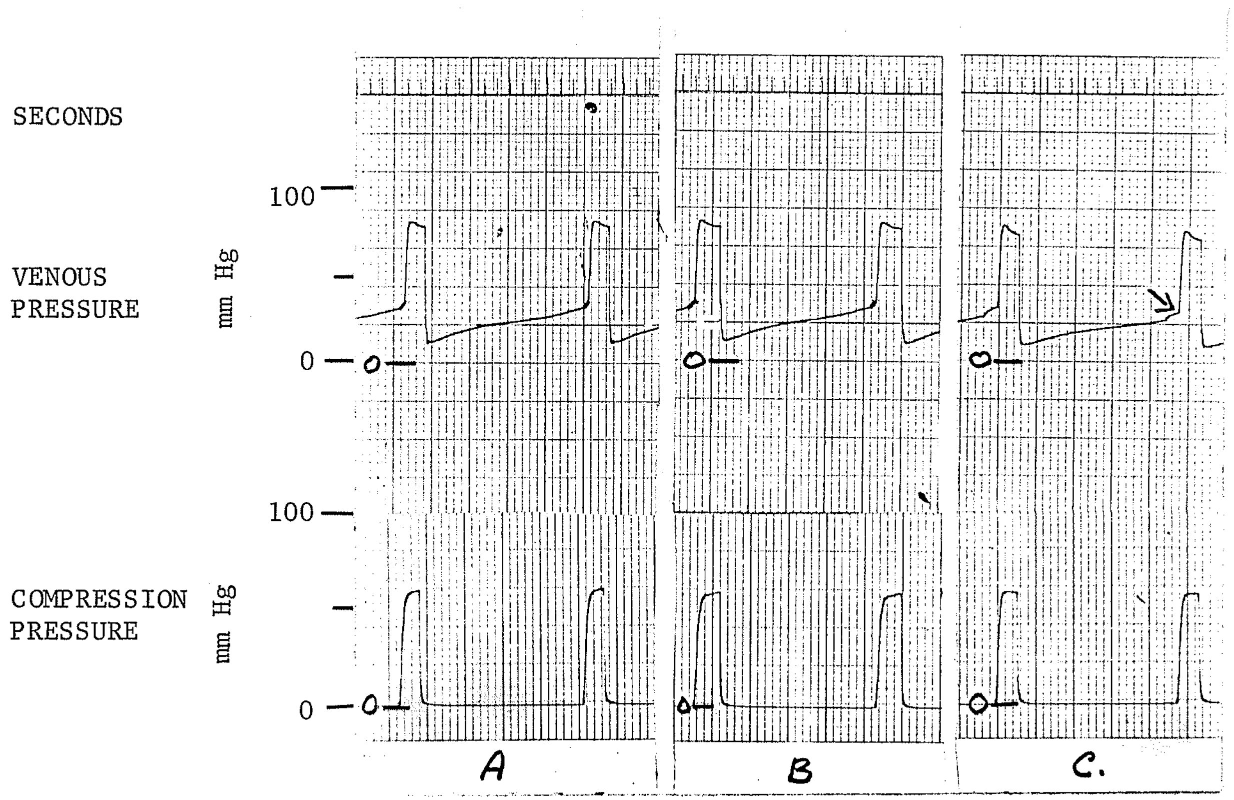


FIGURE 17. The relationship between the delay period and the venous pressure measured in the foot during the use of the mechanical venous pump in patient L.F.

In panels A, B, and C, the occluding cuff was inflated 0.0, 0.5, and 1.0 seconds respectively, before the boot. The small rise in venous pressure produced by cuff inflation is indicated by an arrow.

the blood in the veins displaced against a higher pressure.

The effectiveness of a large boot, which compressed the calf and foot as a unit, in lowering venous pressure, was compared to the standard boot. Subject E.T., in figure 3, had the calf and foot compressed in the large boot during the same experiment as for the standard boot. The large boot lowered venous pressure to only 30mm Hg. while a minimum venous pressure of 10mm Hg. was attained with the standard boot.

The effectiveness in lowering venous pressure of a 15 cm. wide occluding cuff, used as a venous pump by intermittently inflating it but not the boot was studied. Venous pressure could not be lowered to the same extent as when the boot was also inflated, even when high compression pressures and prolonged compression periods were used for the cuff. (figure 6 & 18)

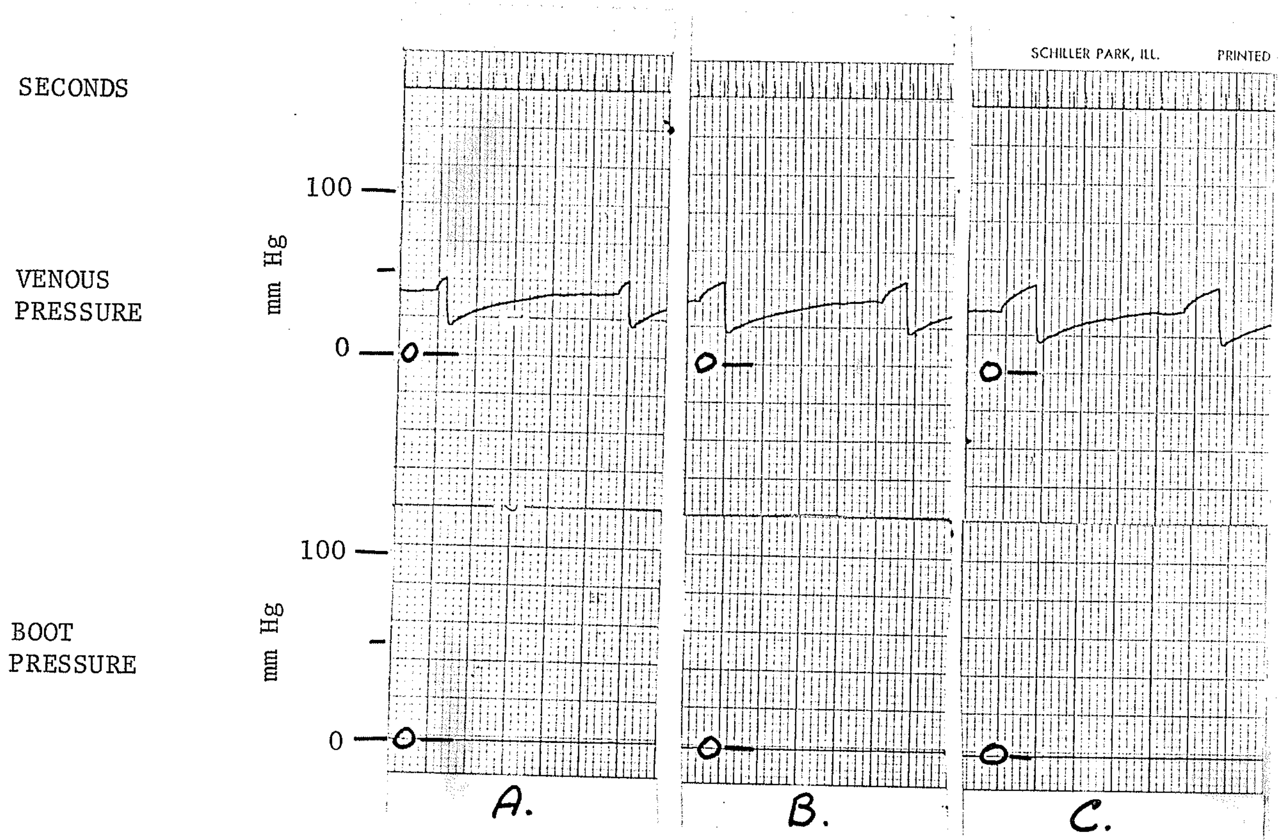


FIGURE 18. The relationship between the compression period and minimum venous pressure obtained in the foot during inflation of the occluding cuff only (no inflation of the boot) as a venous pump.

In A, B, and C, compression periods were 1, 2, and 3 seconds respectively, with a compression pressure of 55 mm Hg in the cuff.

BLOOD FLOW STUDIES

In these studies the clearance of Xe^{133}, from subdermal depot in the foot, was used to assess blood flow through the skin. Four normal subjects and 34 patients with varying degrees of occlusive arterial disease were studied. Data from 13 of these was not included in the subsequent analysis for various reasons. The results obtained in the remaining 21 patients are shown in Tables II and III.

Effect of Posture on Blood Flow in the Foot

In 3 of the 4 normal subjects rate of blood flow in the skin of the forefoot was less during sitting than when lying and in the fourth subject, there was no difference. However, of the 21 patients only 5 had a lower rate of flow when sitting; in 14, the rate of flow was greater when sitting than when lying, and 2 were unchanged (column I Table III). The average reduction in rate of flow in normal subjects was - 35.5% $\pm$ -18.3 S.E. This result is not significant ($p < 0.1$). In the patients there was a mean increase of 40.6% $\pm$ 14.0 S.E. These results are highly significant ($p < 0.01$). It is noteworthy that in 5 of the patients whose blood flow in the foot was less when sitting than when lying, 4 had relatively high supine systolic pressure at the ankle (83, 85, 91 and 93mm Hg. respectively). On examining appendix A all 4 patients had single vessel occlusion with excellent collateral vessels and peripheral run off.

T A B E II - EFFECT OF POSTURE AND OF MECHANICAL VENOUS PUMP ON THE CLEARANCE OF Xe-133 FROM THE SKIN OF THE FOREFOOT

Xe^{133} CLEARANCE HALF-TIMES IN MINUTES

PATIENT	SUPINE (A)	SITTING (B)	SITTING&PUMP TEST FOOT (C)	SITTING (D)	SITTING&PUMP OPPOSITE FOOT (E)	SITTING (F)	SUPINE (G)
C.M.*	41	60	49	78	71	272	106
E.T.*	36	66	92	107	91	146	60
L.V.*	31	52	31	91	87	92	115
B.S.*	36	43	44	47	40	62	60
A.D.	31	45	48	71	75	104	88
P.M.	39	22	8	91	42	49	62
W.A.	60	74	67	75	77	83	206
C.P.	58	57	49	79	83	71	53
J.C.	139	111	119	186	136	147	134
W.F.	144	78	62	153	290	60	31
T.G.	32	42	48	62	61	62	97
L.S.	47	52	51	94	77	89	118
D.E.	120	126	136	147	88	74	255
N.H.	63	34	38	51	60	54	178
J.P.	25	32	32	52	68	51	---
F.H.	48	51	49	60	65	65	67
H.H.	110	59	61	57	58	49	108
S.T.	139	81	51	134	164	89	170
P.T.+	44	71	75	139	154	98	190
H.S.+	33	69	52	76	93	81	157
L.B.	78	77	84	157	119	137	101
E.C.+	268	83	53	65	158	90	270
R.W.+	140	96	56	140	173	115	143
D.T.+	82	60	73	410	107	258	---
H.G.+	307	114	32	170	60	155	184

* NORMAL SUBJECT + PATIENT HAD OPPOSITE FOOT PUMPED BEFORE TEST FOOT

TABLE III

EFFECT OF POSTURE AND A MECHANICAL VENOUS PUMP ON THE RATE OF BLOOD FLOW IN THE SKIN OF THE FOREFOOT

% CHANGE IN RATE OF BLOOD FLOW IN TEST FOOT

SUBJECT	1 SUPINE VS. SITTING	2 SITTING VS. PUMPING TEST FOOT	3 SITTING VS. PUMPING OPPOSITE FOOT	4 DIRECT LOCAL EFFECT OF PUMPING TEST FOOT COLUMN 2-3	5 TOTAL EFFECT OF POSTURE PLUS VENOUS PUMP COLUMN 1-2
NORMAL SUBJECTS					
C.M.	-55%	41%	146%	-105%	- 14%
E.T.	-77	- 5	27	- 32	- 82
L.V.	0	132	0	132	132
B.S.	-10	0	38	- 38	- 10
	-35.5% ±	18.3*			
PATIENTS					
A.D.	-20	21	17	4	1
P.Mc	42	610	68	542	652
W.A.	68	12	0	12	80
C.P.	-11	35	-10	45	24
J.C.	5	25	23	2	30
W.F.	25	87	-65	152	112
T.G.	25	8	0	8	33
L.S.	25	43	19	24	68
D.E.	88	0	26	-26	88
N.H.	173	13	-12	25	186
J.P.	-40	32	-23	55	72
F.H.	0	15	- 3	18	15
H.H.	70	- 5	-10	5	65
S.T.	82	112	-32	144	194

\+ - HAD OPPOSITE FOOT PUMPED BEFORE TEST FOOT

* - MEAN ± STANDARD ERROR.

NOTE - + SIGN INDICATES AN INCREASE IN BLOOD FLOW,-SIGN INDICATES A DECREASE

T A B L E III (continued)

SUBJECT	1 SUPINE VS. SITTING	2 SITTING VS. PUMPING TEST FOOT	3 SITTING VS. PUMPING OPPOSITE FOOT	4 DIRECT LOCAL EFFECT OF PUMPING TEST FOOT COLUMN 2-3	5 TOTAL EFFECT OF POSTURE PLUS VENOUS PUMP COLUMN 1-2
P.T.+	31	40	- 19	59	71
H.S.+	27	40	- 15	55	67
L.B.	-18	40	25	15	22
E.C.+	212	40	- 51	91	252
R.W.+	34	110	- 29	139	144
D.T.+	-48	290	212	78	242
H.G.	82	340	162	178	422
	40.6%± 14.0*	90.9%± 32.5*	13.5%± 14.2*	77.4%± 26.3*	135.2%±34.1*

+ - HAD OPPOSITE FOOT PUMPED BEFORE TEST FOOT.

* - MEAN ± STANDARD ERROR.

NOTE - + SIGN INDICATES AN INCREASE IN BLOOD FLOW, - SIGN INDICATES A DECREASE

<u>The Effect of the Mechanical Venous Pump on Blood Flow in the Foot of the Sitting Subject</u>

The response to venous pumping in the test foot in the 4 normal subjects tested was variable with little change in blood flow in 2 and an increased flow in 2. However, this is only a small sample of normal subjects.

Among the 21 patients with arterial obstruction 19 showed a marked increased in clearance rate while 1 showed no change, and 1 a small decrease in clearance rate (column 2, Table III). The average change in blood flow rate in the patients was an increase of 90.9% $\pm$ 32.5 S.E. These results are highly significant ($p < 0.02$).

When the opposite foot was pumped, 3 of the 4 normal subjects and 8 of the 21 patients had an increase in clearance rate from the test foot, while 11 of the 21 patients had a decrease, and 2 had no change. (column 3, Table III). The mean change in the blood flow rate in 21 patients was 13.5% $\pm$ 14.2 S.E. These results are not significant ($p > 0.3$) since the effect of pumping the foot on the general circulation can be quite variable.

The estimated direct local effect of pumping of the test foot on blood flow, obtained by subtracting the value in column in 3 from column 2 of Table III, is given in column 4 of the same table. The direct effect seems to have been a reduction of blood flow in 3 of the 4 normal subjects, but among the patients 20 of the 21 had an increase in rate of blood flow. In the 21 patients the mean change in rate of blood flow was an increase of

77.4% $\pm$ 26.3 S.E. These results are highly significant ($p < 0.01$).

The combined effect of posture and the mechanical venous pump on the rate of blood flow in the test foot is shown in column 5 of Table III as the sum of the values in columns 1 & 2. Again, in 3 of the 4 normal subjects the overall effect seems to have been a reduction in flow but among the patients 20 of the 21 showed an increase while only 1 showed little change. The mean increase in flow rate in the patients was 135.2% $\pm$ 34.1 S.E. Again, this is highly significant ($p < 0.001$)

CLINICAL TRAILS

One patient, Mr. E. C., who had previously shown an overall increase in blood flow for the combined effect of posture plus venous pumping of 252% in his ischemic foot during venous pumping, had complete relief of rest pain during continuous treatment for 100 hours with the mechanical venous pump, but had prompt return of pain after the pump was discontinued.

Of the 7 patients studied, with rest pain in their ischemic foot, 4 obtained relief on sitting which was maintained during the pumping periods. Three patients had rest pain during the supine and sitting phases of the experiment, but had complete relief during pumping of the test foot with increase in blood flow of 87%, 13% and 340% in the acute experiments. In addition 4 patients were unable to complete all phases of the experiment because of severe rest pain on lying and sitting. However, all 4 patients had relief of rest pain during pumping of the test foot in the acute experiments.

DISCUSSION

DISCUSSION

Frequently, patients, with occlusive arterial disease in the lower limb severe enough to cause rest pain in the foot obtain relief by putting the foot in a dependent position. This is primarily due to the increase in blood flow that occurs through the foot secondary to the increased hydrostatic pressure in the arteries and collaterals around the blocked segment. (Gaskell and Becker 1971). All too often the block is so severe and collaterals so poorly developed that only a small change in blood flow occurs on dependency and rest pain may be only partially relieved, if at all. It may be considered that by adding to the flow advantage produced by the erect posture the principle of a mechanical venous pump applied to the foot, the blood flow through the foot may be further enhanced.

Schienberg et al (1948) first proposed the concept of a mechanical venous pump and demonstrated, using venous occlusion plethysmography that blood flow through the foot could be enhanced over supine flow using the erect posture and a mechanical venous pump applied to the foot. They were, however, unable to distinguish the effect of either posture or pumping alone using this technique.

Allwood (1957), who used venous occlusion plethysmograph stated that blood flow could be increased using a venous pump consisting of the foot plethysmograph inflated around the foot, at rather high frequency,in the sitting subject. He failed to recognize the unsuitability of a partially distended venous system for accurate blood flow determinations by venous occlusion plethysmography and consequently was unable to determine a true resting blood flow in the sitting subject. Furthermore, he did not produce any data concerning supine flow, and therefore his results cannot show the effects of posture or his venous pump on the rate of blood flow in the foot.

In 1959, Loane, recognizing the limitations of venous occlusion plethysmography, showed that blood flow in the foot, as determined by heat flow and heat elimination techniques, was increased by using a cuff at the ankle as a mechanical venous pump in the erect subject.

More recent work by Henry and Winsor (1965) deals with the effect of a calf pump on foot venous pressure and foot blood flow. Rate of blood flow was assessed by monitoring, from the skin and muscle of the foot, the clearance of I^{131}. A series of rapid inflations of a large cuff which completely enclosed the calf, but not the foot, was effective in lowering the foot venous pressure to 40mm Hg. in normal subjects, and patients with occlusive vascular lesions. This is to be compared with the present study where minimum venous pressures of about 10mm Hg. were obtained in the sitting subject using foot compression. In their studies on normal subjects, compression pressure of 60-120mm Hg., compression periods of 3-5 seconds and compression intervals of 15-20 seconds were employed. The I^{131} clearance studies indicated that blood flow was increased in the foot of the sitting subject using this procedure. However, in patients, they used prolonged compression periods of 15 seconds with compression intervals of 30-45 seconds. They interpreted their results to mean that blood flow was greater through the pumped foot than the nonpumped foot. It is difficult to understand why the authors would compress on atherosclerotic limb for 15 seconds, since this prolonged compression would tend to retard blood flow. The authors also employed a longer compression interval for patients, assuming that venous filling time would be much slower. It was shown in the present study that despite poor circulation, venous filling time can be fairly rapid especially in a warm foot.

In the I^{131} clearance studies of Henry and Winsor, the clearance from the dependent nonpumped foot served as the control value with which clearance from the test foot was compared to ascertain the effect of the venous pump. However, they did not indicate, whether vessels supplying both lower limbs were obstructed, and if they were, the relative degree of obstruction, the distribution of obstruction, or how the test foot was chosen. It would be difficult to use the clearance rate from one foot to represent the initial, or control, value for the other foot of atherosclerotic patients whose circulation in the two feet may be quite different even before one limb is subjected to venous pumping. Furthermore, significant comparision between these two clearances may be difficult to make since tissue distribution, and therefore clearance rate, of the separate injections may not be the same in the two feet. Changes in the clearance rate from a single injection in the test foot, as employed in the present study, would be expected to indicate better the effect of venous pumping on rate of blood flow.

In other experiments, Henry and Winsor pumped the calf of the test limb for 1 hour, allowed it to rest for 30 minutes and then measured the clearance rate from the test foot for 30 minutes, comparing this with the clearance rate in the opposite, nonpumped, control foot measured subsequently. They noted that the clearance rate in the pumped foot was enhanced for at least 1 hour even after the pumping had been discontinued. They interpreted this as a "lasting effect" of the pumping and were unable to give an explanation for this. However, the explanation may be that the difference in clearance rate between the pumped and the nonpumped foot was the same as the difference between the clearance rate which might have been measured in the two feet prior to any pumping. If this were so, one could suggest that the prolonged compression periods and high compression pressures, as used in their patients, had mitigated against any increased in blood flow being produced by the pumping.

In this present study the effectiveness of a mechanical venous pump applied to the foot in lowering foot venous pressure and increasing blood flow was evaluated. The mechanical venous pump was made from a single layer of flexible, vinyl plastic which was inflated directly with air to avoid having the plastic in contact with the skin. This ensured that the tissues of the foot were not distorted during compression, and that masceration of the skin was avoided. Having the top of the boot open, without adhering to the skin in any way, and closed by an essentially simultaneous inflation of the occluding cuff at the ankle, should avoid the above mentioned as well as effectively controlling boot pressure.

It was found that venous pressure could be lowered to about 10mm Hg. in sitting subjects, and neither a large boot, which included the foot and the calf, nor a 15cm. wide cuff around the ankle only, both employed as venous pumps, were as efficient in reducing venous pressure as was the standard boot.

It is to be expected that the effectiveness of a venous pump in increasing blood flow should parallel its effectiveness in lowering venous pressure. This expectation was realized to be so, in that blood flow was increased in 20 of 21 patients using the venous pump.

Since the effectiveness of the pump depends upon the degree to which venous pressure can be lowered and the maintanance of a low pressure, care was taken to select the most appropriate compression pressures, compression periods, compression intervals and delay period that would meet these requirements. Prolonged compression periods,high compression pressures,and too short compression intervals were avoided as not to interfere with blood inflow. An unduly long compression interval was also avoided because it was shown, even in patients with severe occlusions that venous filling time may be quite rapid,especially in the warm foot. A short delay between cuff inflation and boot inflation ensured a good air seal around the top of the boot during inflation.

The standard boot was also capable of effectively lowering venous pressure in the leaning-standing subject. Understandably, higher compression pressures were required to maximumly lower venous pressure, and furthermore, longer compression periods were necessary to produce the desired high compression pressures and to empty the veins against a higher pressure. The leaning-standing subject offers the advantage that greater arterial-venous pressure differences can be achieved with venous pumping, thereby producing even greater flow through the capillaries than in the sitting subject.

From the venous pressure studies, it was found that the most effective and practical pressure and time settings for lowering venous pressure and maintaining a low pressure were: a compression pressure of sitting venous pressure plus 10mm Hg., a compression period of 2 seconds, a compression interval of 15 seconds, and a delay period of 0.5 seconds. These settings were, therefore, used in the $Xenon^{133}$ clearance studies for all noraml subjects and patients.

It must be pointed out that, even though venous pressure may be adequately lowered by pumping it does not necessarily follow that blood flow will be increased, because the actual pumping, the noise of the pump, and apprehension of the patient may initiate local responses and centrally mediated reflexes that may override the effects of pumping and produce an actual decrease in blood flow. These factors may have been responsible where an actual decrease in blood flow occurred during pumping. However, it is felt that as the patients become accustomed to the mechanical pump, over prolonged periods of treatment, these effects should dissipate and the full potential of the pump realized.

Because an effective decrease in venous pressure is not necessarily equated with an increase in blood flow, the actual effect of the pump on blood flow must be evaluated. In the present study, the clearance rate of Xe^{133} from the skin of the forefoot was used as an indication of the rate of blood flow. Care was taken to provide adequate controls in that the test foot served as its own control rather than the opposite foot. This eliminated the error that would be produced by separate injections in feet with dissimilar circulation. Furthermore, the counting was not started until at least 20 minutes had elapsed after the injection of the Xe^{133}. This allowed for proper tissue distribution of the Xe^{133}. The clearance rates, measured during each of the phases of the blood flow studies, enabled us to assess the effects of posture, and venous pumping on the blood flow in the foot. Going from a supine to a sitting position in normal subjects produced a decrease in blood flow in the foot. Likewise for patients with less severe obstructions, as evidenced by relatively higher supine ankle pressures, blood decreased on sitting. However, in patients with more severe obstruction, blood flow was usually increased. This is due to the greater than expected increase in local arterial pressure at the ankle, in patients with severe obstruction, as a result of distention and reduction in resistance to flow in the collateral vessels. It might be expected that the effect of this phenomenon would be greater in those with the most marked obstruction and lowest supine ankle pressure since the extra gain in pressure forms a higher proportion of the local blood pressure. Furthermore, collateral vessel development may be greater in patients with more marked obstruction of main arteries.

The generalized and local effect of pumping the test foot was to produce an increase in flow over the effect of sitting alone in all but two patients. The generalized effect of pumping was assessed by pumping the opposite foot while measuring clearance from the test foot. From these results we can assess the local effects of pumping by subtracting the per cent change in blood flow due to the generalized effects from the per cent change in blood flow of the generalized plus the local effects. In some cases the generalized effect was to produce a vasoconstriction thereby detracting from the local direct effect of pumping while in others a vasodilatation occurred thereby enhancing the local direct effect of pumping. When the above calculation was made the results indicated that the direct local effect of the venous pumping was to increase the rates of blood flow in all but one patient.

The overall combined effect of pumping plus posture can be assessed by adding the per cent change that occurs with sitting only to the per cent change that occurs on the addition of pumping. As expected, the increase in flow was greater than with either one alone, and it was noted in some patients, in whom a reduction of flow had occurred on sitting, that this reduction was partially, or completely, reversed by pumping.

It is interesting to reassess Sander's experience (Sanders 1936) with the oscillating bed, and Buerger's exercises (Buerger 1924) in view of our findings. The oscillating bed is presumed capable of lowering venous pressure in the foot by tilting thereby increasing the arterial-venous pressure difference across the foot capillaries. During the time that the patient is being tilted to the head-up position, the veins will tend to fill quite rapidly and therefore this advantage of low venous pressure on blood flow may be rapidly reduced, so that only a small arterial-venous pressure difference existed for the remainder of the head-up position. While the patient is in the head-up position a small increase in blood flow may be expected to occur. The oscillating bed does not appear to offer nearly the increase in blood flow that is produced by the mechanical venous pump.

Buerger's exercises lower venous pressure when the foot is elevated, and for a time when the foot is dependent, an increased arterial-venous pressure difference will exist across the foot capillaries. Elevation periods were so prolonged that in a foot with low perfusion pressure, the arteries as well as the veins will be emptied causing a greater degree of ischemia. Therefore, part of the advantage of lowering venous pressure is lost. Buerger also employed long dependency periods of 2-5 minutes and during most of that period both arteries and veins would be full with essentially no added increase in arterial-venous pressure difference. These exercises succeed in producing a reactive hyperemia in the foot, and provided little in the way of overall increased tissue perfusion.

Both the Sander's bed and Buerger's exercise have essentially been abandoned because they were often uncomfortable to the patient and difficult to maintain.

The long term use of the venous pump in one patient with good results indicates that the mechanical venous pump can be useful and practical in the temporary management of severe rest pain. If this, through further studies, proves to be the case, then modifications to the pump will be made to make it more compact,more portable, easy to manage, and quieter running.

CONCLUSIONS

CONCLUSIONS

1. A mechanical venous pump, which intermittently compresses the veins of the foot, is effective in producing and maintaining a low venous pressure in the foot of erect normal subjects and patients with atherosclerotic arterial occlusion in the vessels of the lower limb.

2. Blood flow, in the subdermal tissues of the foot, increases as a result of a mechanical venous pump which intermittently reduces the venous pressure in the foot in the sitting position.

3. Blood flow, in the subdermal tissues of the foot, tends to decrease in the normal subject and patients with mild to moderate arterial obstruction, and increase in the patient with severe arterial obstructions when the posture is changed from supine to sitting.

4. The combined effect of posture plus the mechanical venous pump is to increase blood flow more than either one alone.

5. It is proposed that a mechanical venous pump has a place in the managements of patients, with severe ischemic rest pain and/or ischemic skin changes in the foot, awaiting surgical correction or amputation.

BIBLIOGRAPHY

BIBLIOGRAPHY

Allen E.V. and Brown G.E. 1935. Intermittent pressure and suction in the treatment of chronic occlusive arterial disease. J.A.M.A. 105, 2029-2034.

Allwood M.J. 1955. Distensibility of the venous bed of the foot in vivo. J. Physiol. 129, 74P-75P.

Allwood M.J. 1957. The effect of an increased local pressure gradient on blood flow in the foot. Clin. Sci. 16, 231-239.

Barker N.W. and Roth G.H. 1939. Treatment of occlusive arterial disease of the legs by means of the Sander's vasocillator. Amer. Heart J. 18, 312-317.

Bennet R.L., Hines E.A. Jr. and Krusen F.H. 1941. Effect of short-wave diathermy on cutaneous temperatures of the feet. Amer. Heart J. 21: 490-503.

Buerger L. 1924. The circulatory disturbances of the extremities. Philadelphia W.B. Saunders Co. Page 380.

Conway J.H. 1936. Obliterative vascular disease. A report of fifty-one cases treated with passive vascular exercise. J.A.M.A. 106: 1153-1156.

Folkow B. 1962, Transmural pressure and vascular tone - Some aspects of an old controversy. Arch. Int. Pharmacodyn 139: 455-491.

Freeman N.E. 1940. Influence of temperature on the developement of gangrene in peripheral vascular disease. Arch. Surg. 40: 326-333.

Gaskell P. 1953. A constant pressure perfusing system for the use with small-bore catheters in monometry. Journ. of Appl. Physiol. 6, 199-200.

Gaskell P. and Becker W.J. 1971. The erect posture as an aid to the circulation in the feet in the presence of arterial obstruction. C.M.A. Journal 105, 930-934.

Henry J.P. and Winsor T. 1965. Compensation of arterial insufficiency by augmenting the circulation with intermittent compression of the limbs. Amer. Heart J. 70, 79-88.

Hermann L.G. and Reid M.R. 1939. Passive vascular exercises: Treatment of peripheral obliterative arterial disease by rhythmic alteration of environmental pressure. Arch. Surg. 29, 697-704

Kety S. 1949. Measurement of regional circulation by the local clearance of radioactive sodium. Amer. Heart J. 70, 79-90.

Landis E.M. and Gibbon J.H. Jr. 1933. The effects of alternate suction and pressure on blood flow to the lower extremities. J. Clin. Invest. 12, 925-961.

Linton A.R., Morrison P.J., Ulfelder H. and Libby A.L. 1941. Therapuetic venous occlusion. Amer. Heart J. 21; 721-742.

Loane A.R. 1959. Effect of rhythmically inflating a pneumatic cuff at the ankle on blood flow in the foot. Jour. Appl. Physiol. 14, 411-413.

Sanders C.E. 1936. Cardiovascular and peripheral disease: Treatment by a motorized bed. J.A.M.A. 106; 916-918

Scheinberg P, Dennis E.W., Robertson R.L., and Stead E.A. 1948. The relationship between arterial pressure and blood flow in the foot. Amer. Heart Journ. 35, 409-420.

Shipley A.M. and Yeager G.H. 1934. Passive vascular exercise in the treatment of peripheral circulatory disease. Surg. Gynec. and Obst. 59, 480-485.

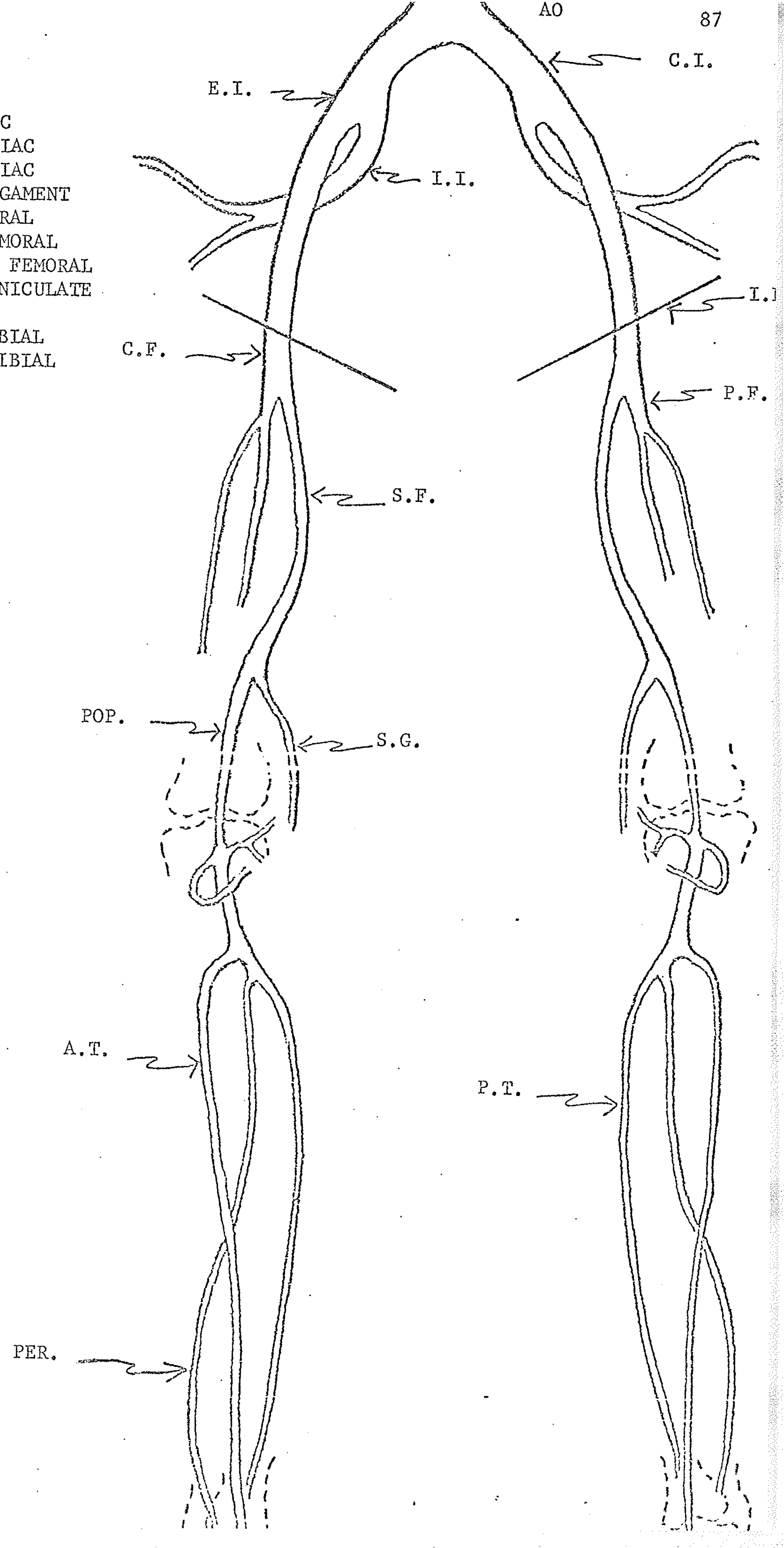
Thiele Wolfgang 1938. Ueder die behandlung mit aktiver hyperamic nach Ganter. Munchen Med. Wchnschr 85, 988-990.

Veal J.R. and McCord W.M. 1939. Blood oxygen changes following intermittent venous occlusion. Amer. Heart J. 17, 401-405.

APPENDIX A

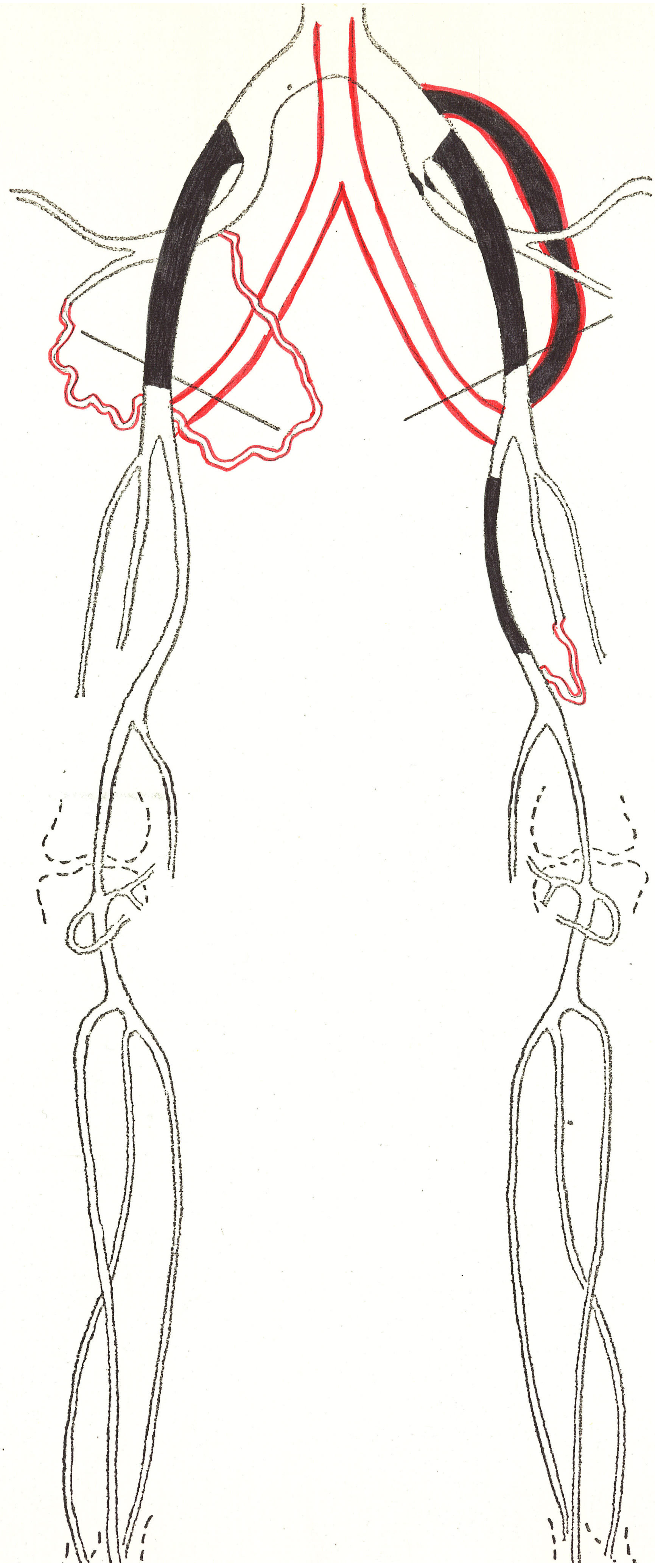
LEGEND

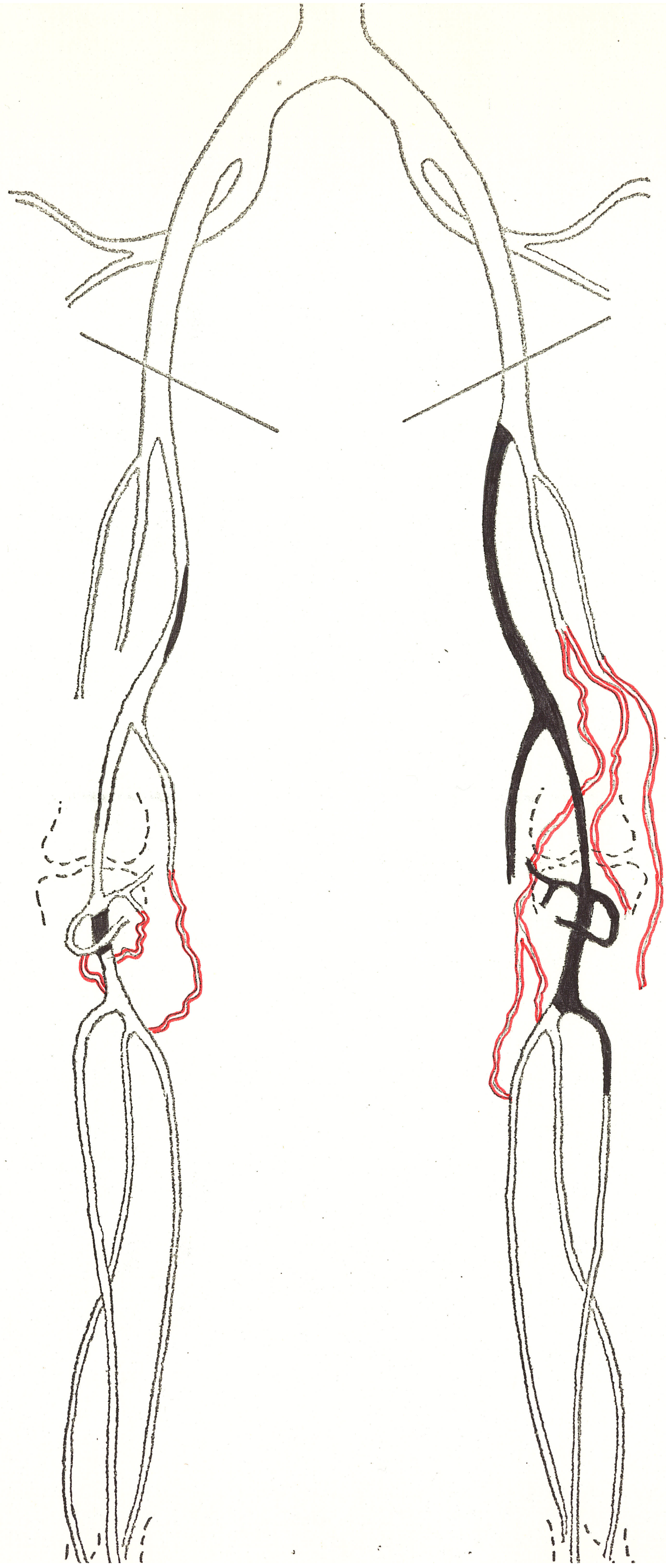
AO - AORTA
C.I.- COMMON ILIAC
E.I.- EXTERNAL ILIAC
I.I.- INTERNAL ILIAC
I.L.- INGUINAL LIGAMENT
C.F.- COMMON FEMORAL
P.F.- PROFUNDA FEMORAL
S.F.- SUPERFICIAL FEMORAL
S.G.- SUPERIOR GENICULATE
POP.- POPLITEAL
A.T.- ANTERIOR TIBIAL
P.T.- POSTERIOR TIBIAL
PER.- PERONEAL

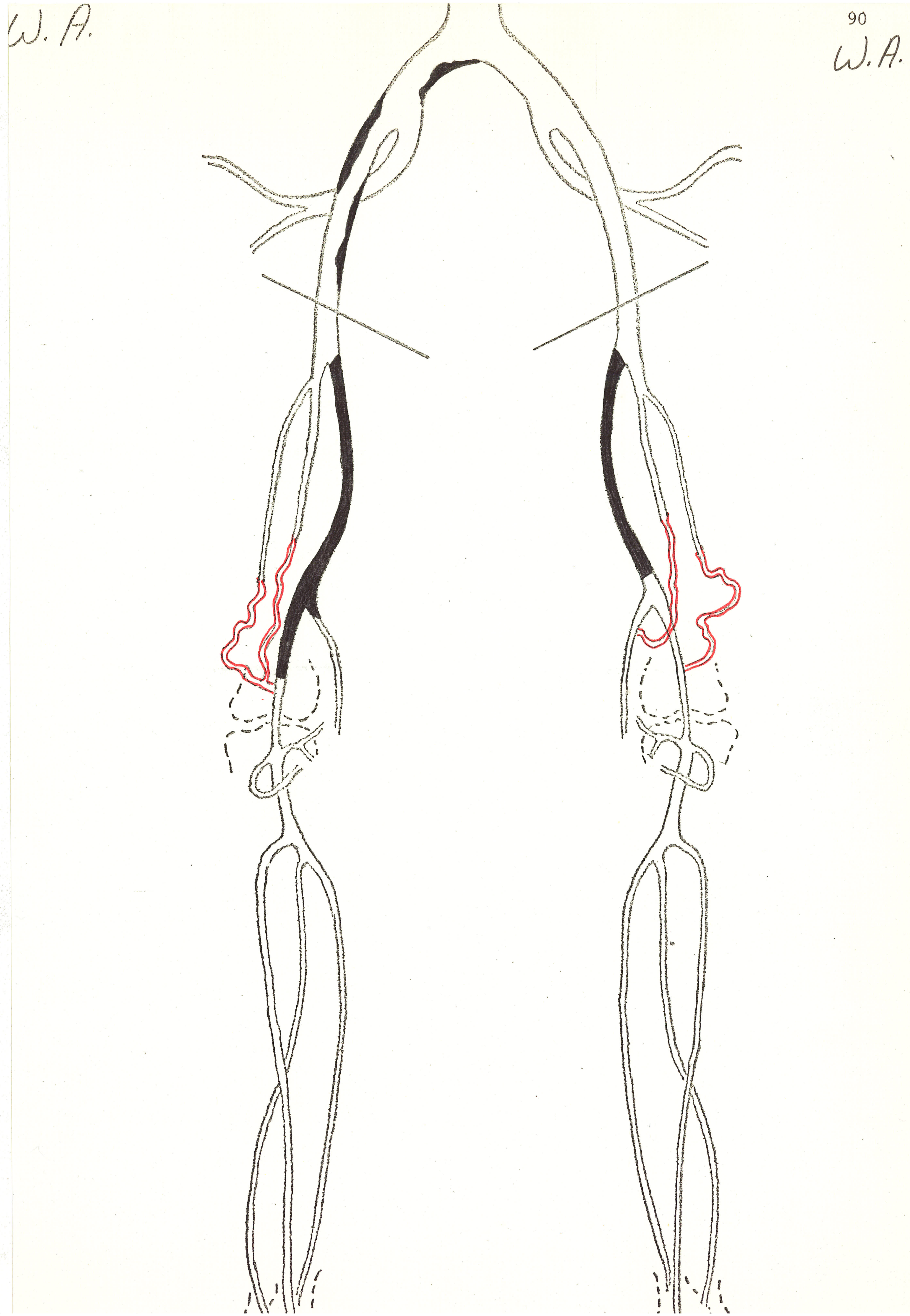


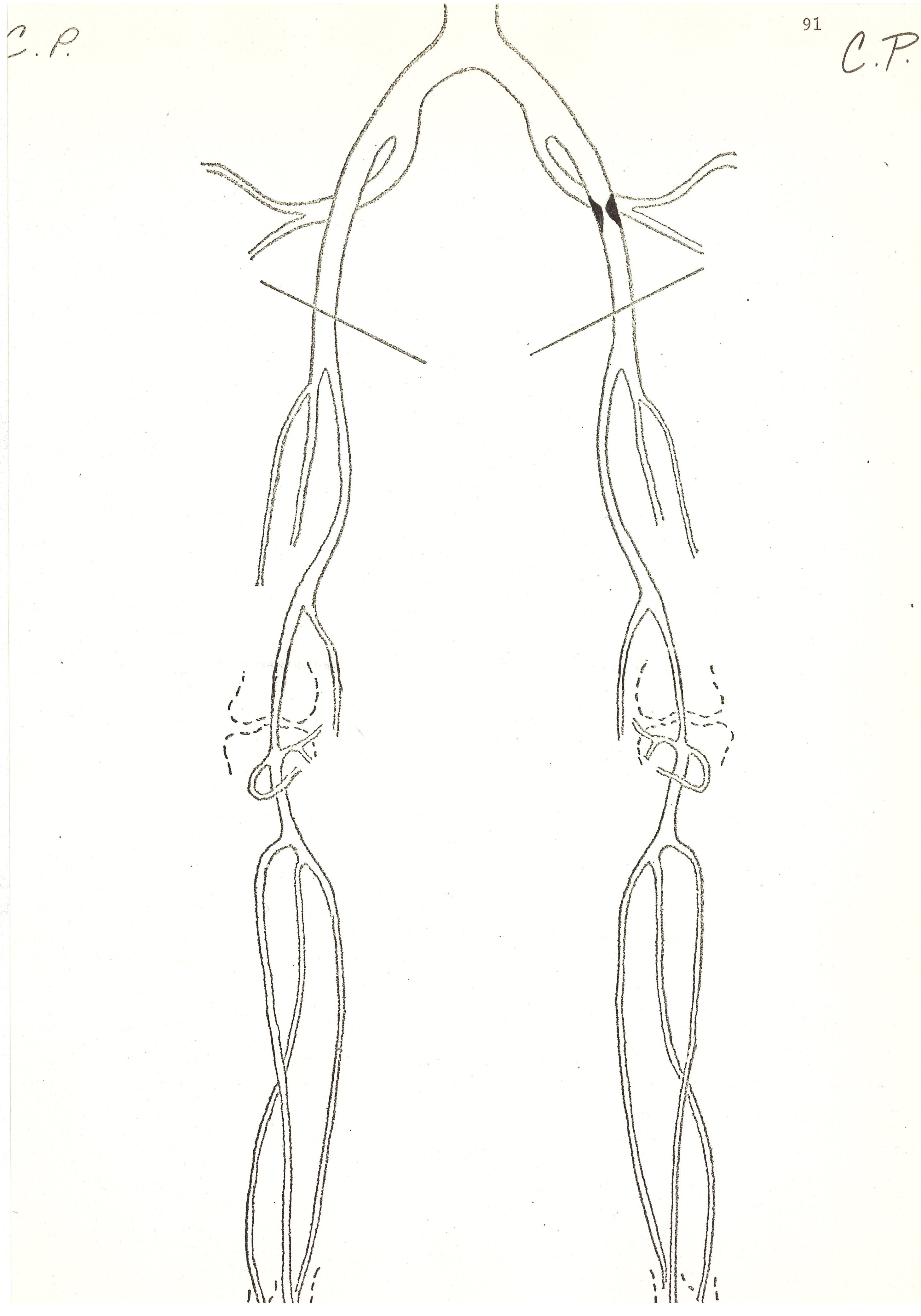
A. D.

A. D.

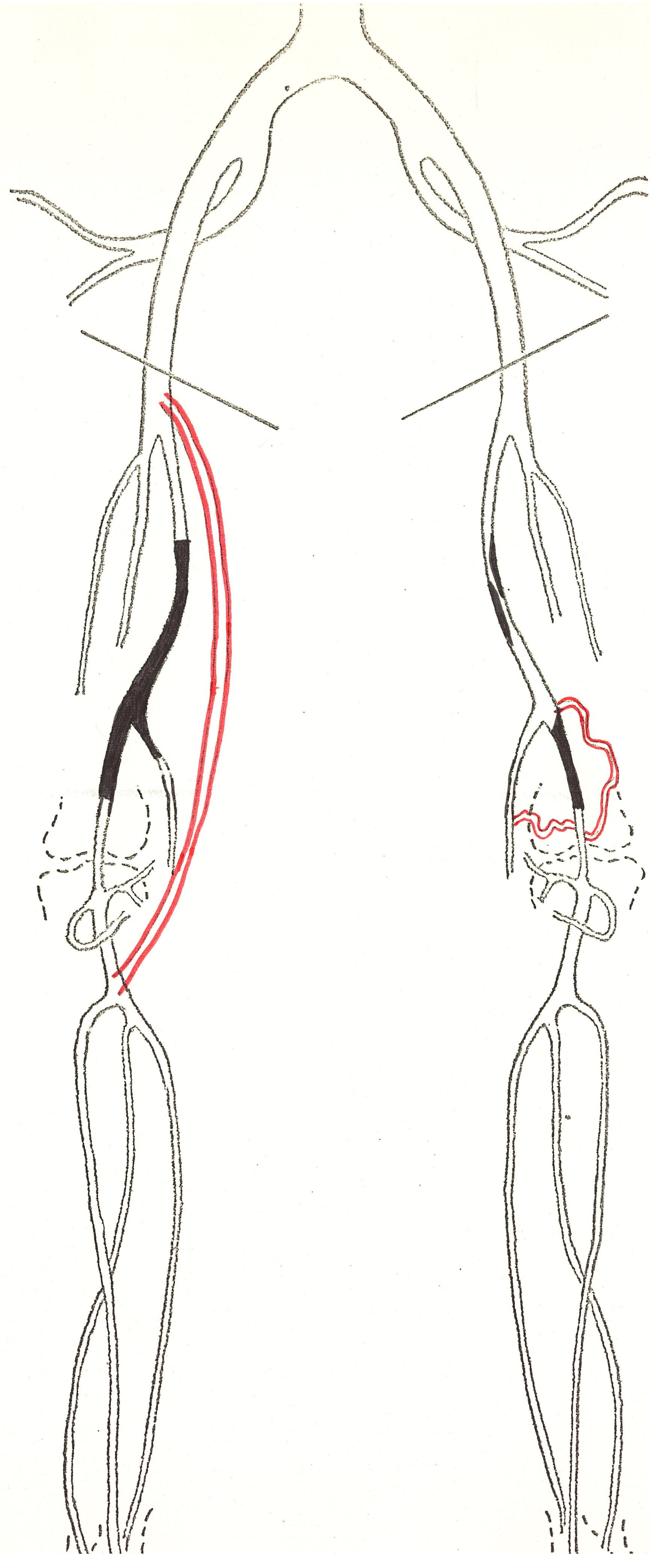





W. A.
W. A.

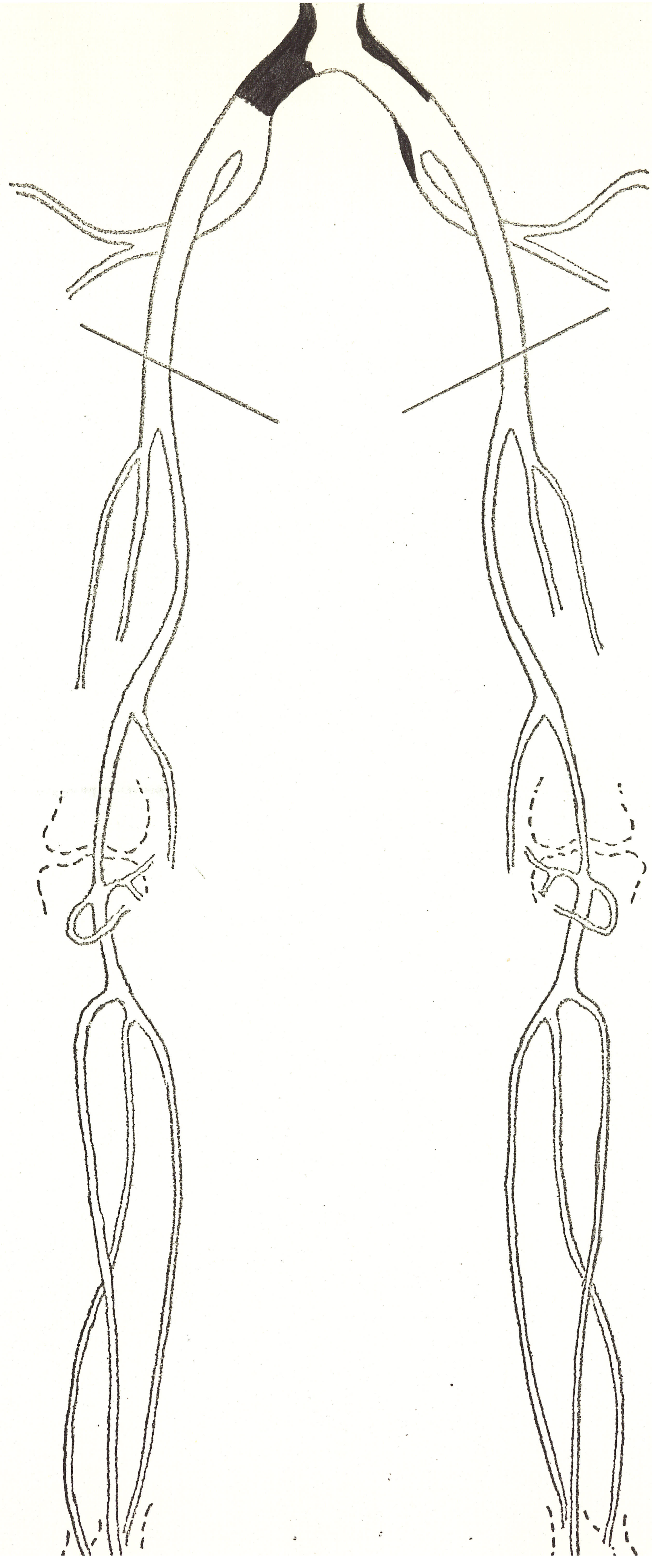


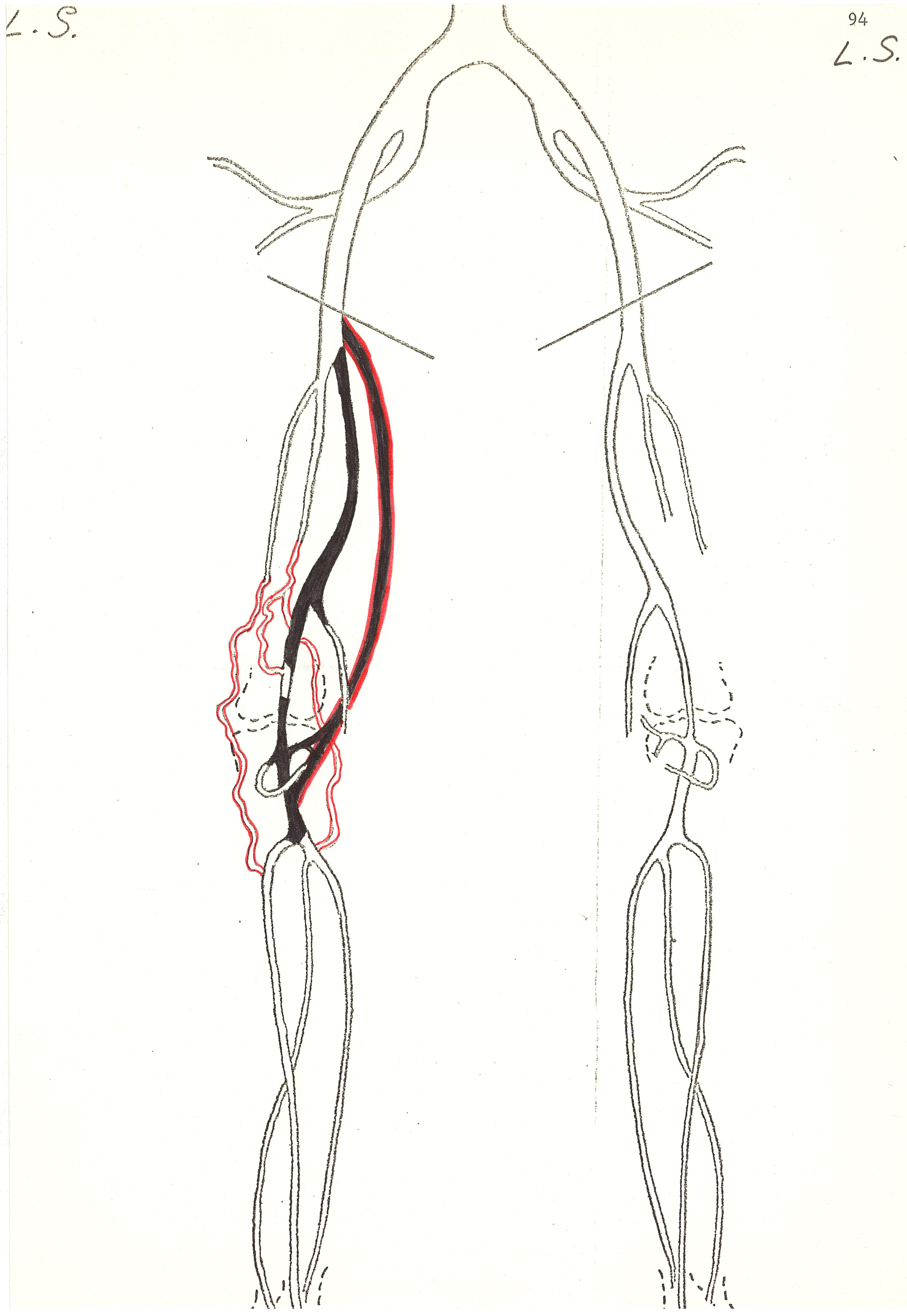
W. F. W. F.

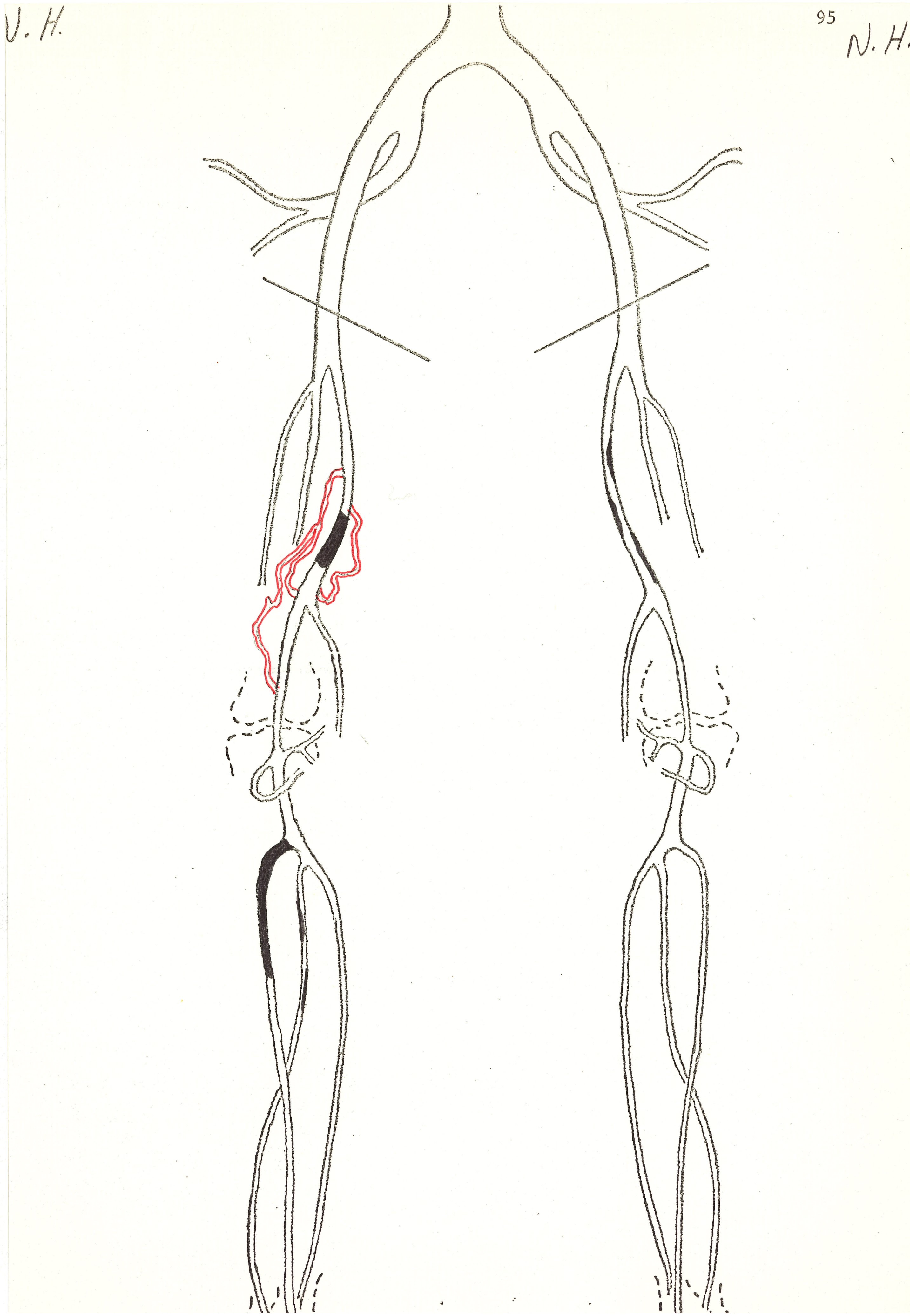


T. G.

T. G.

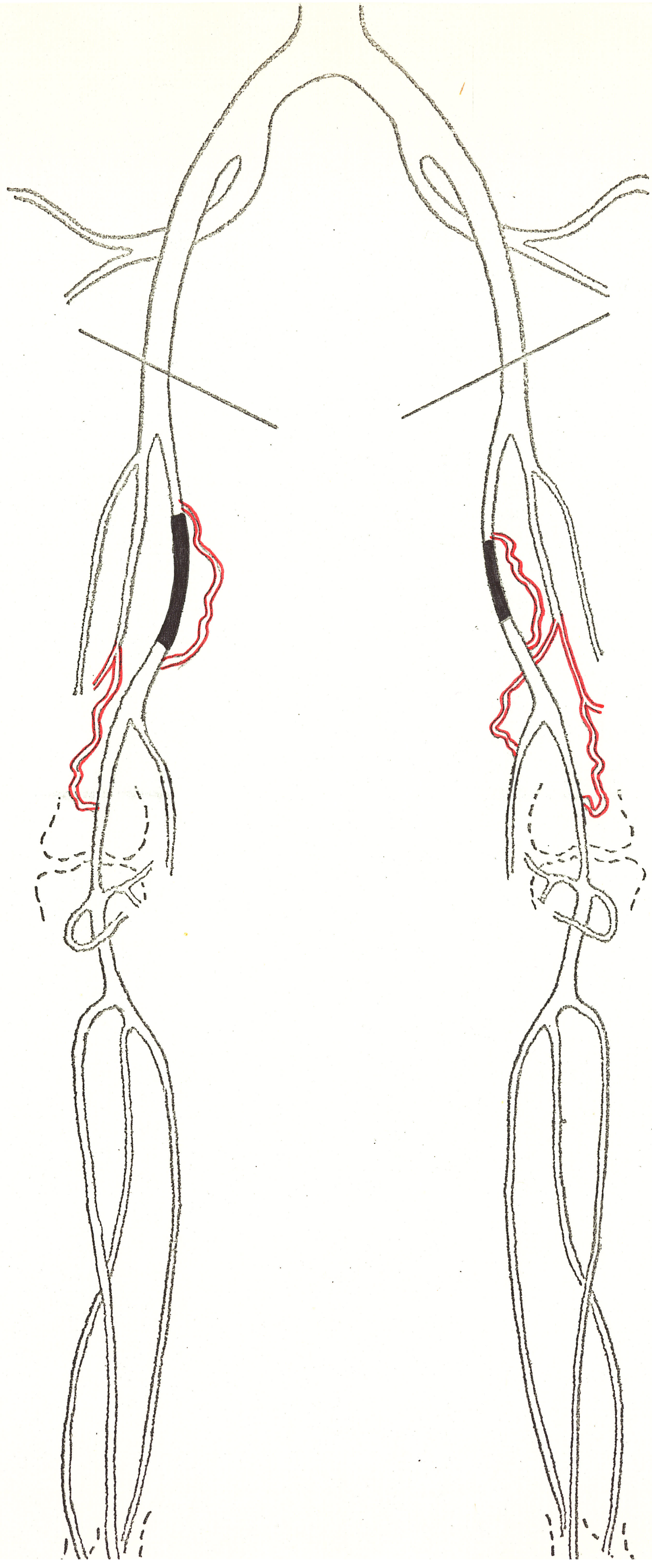



L. S.
L. S.


N. H.
N. H.

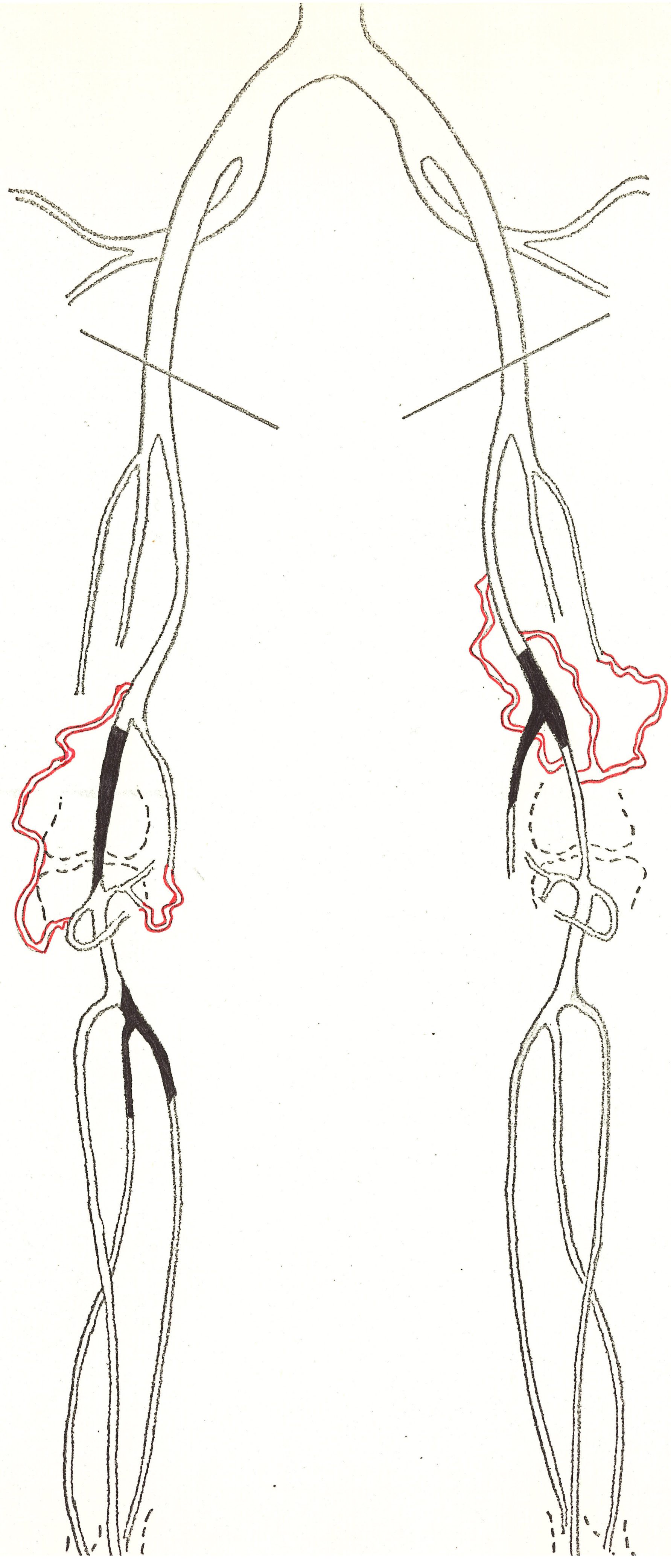
F.

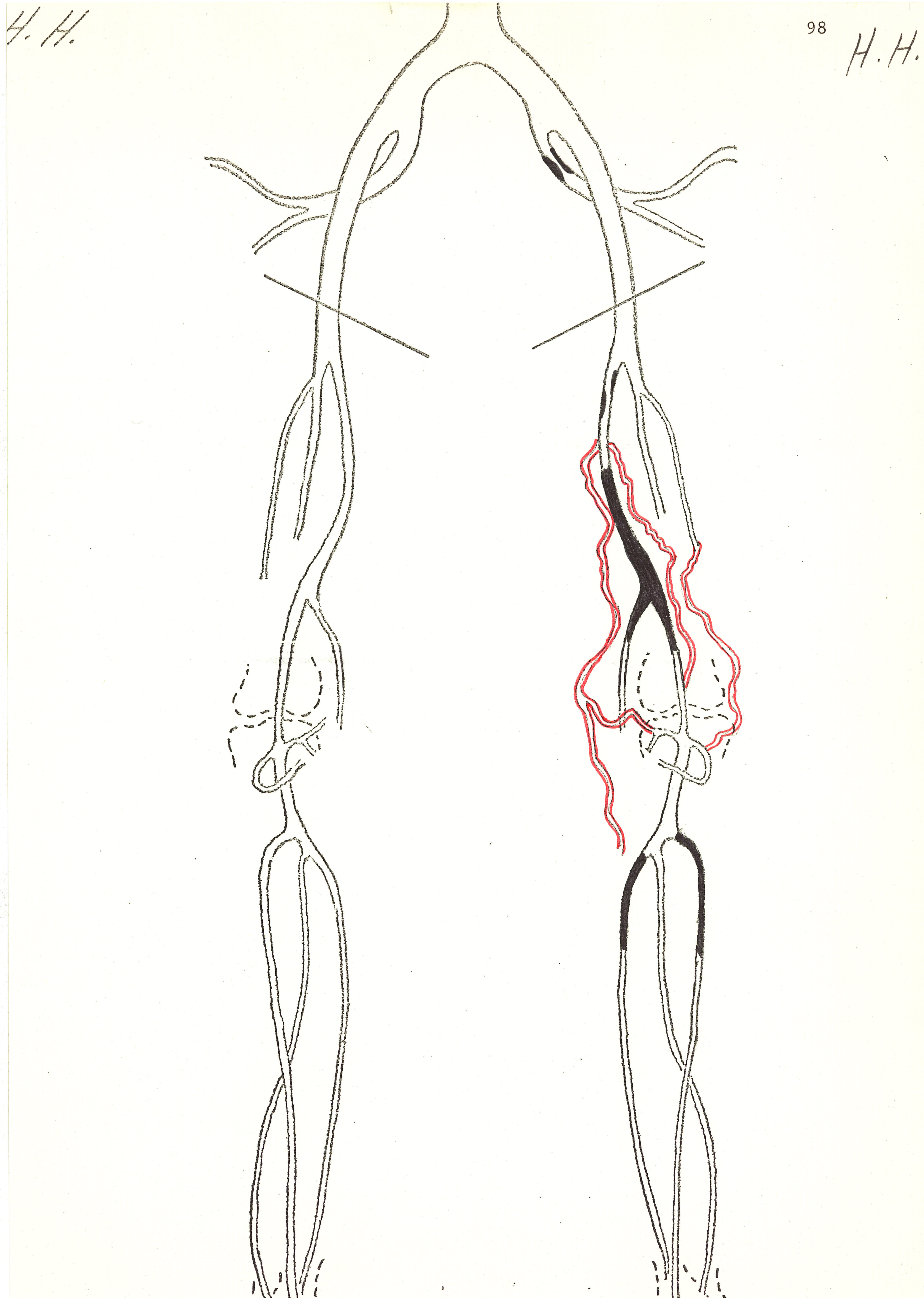
J. P.



F.H.

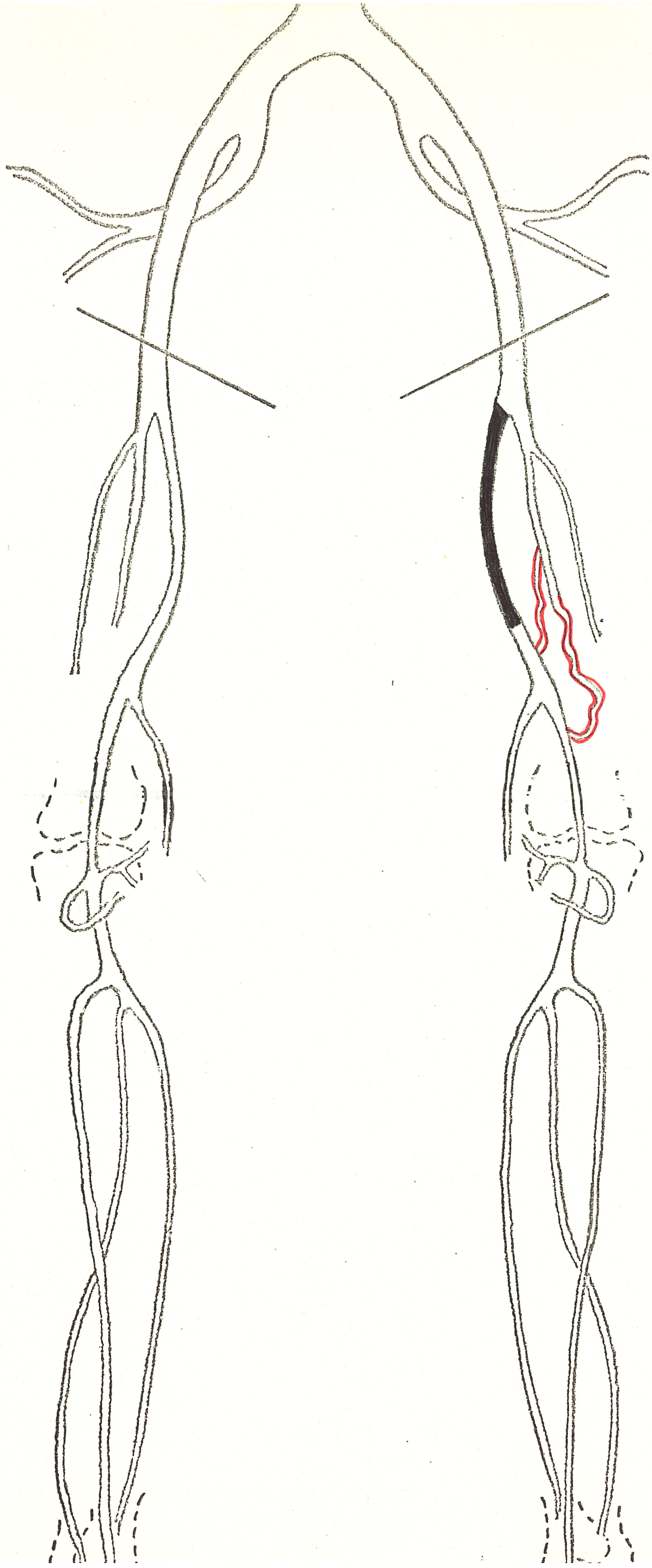
F.H.



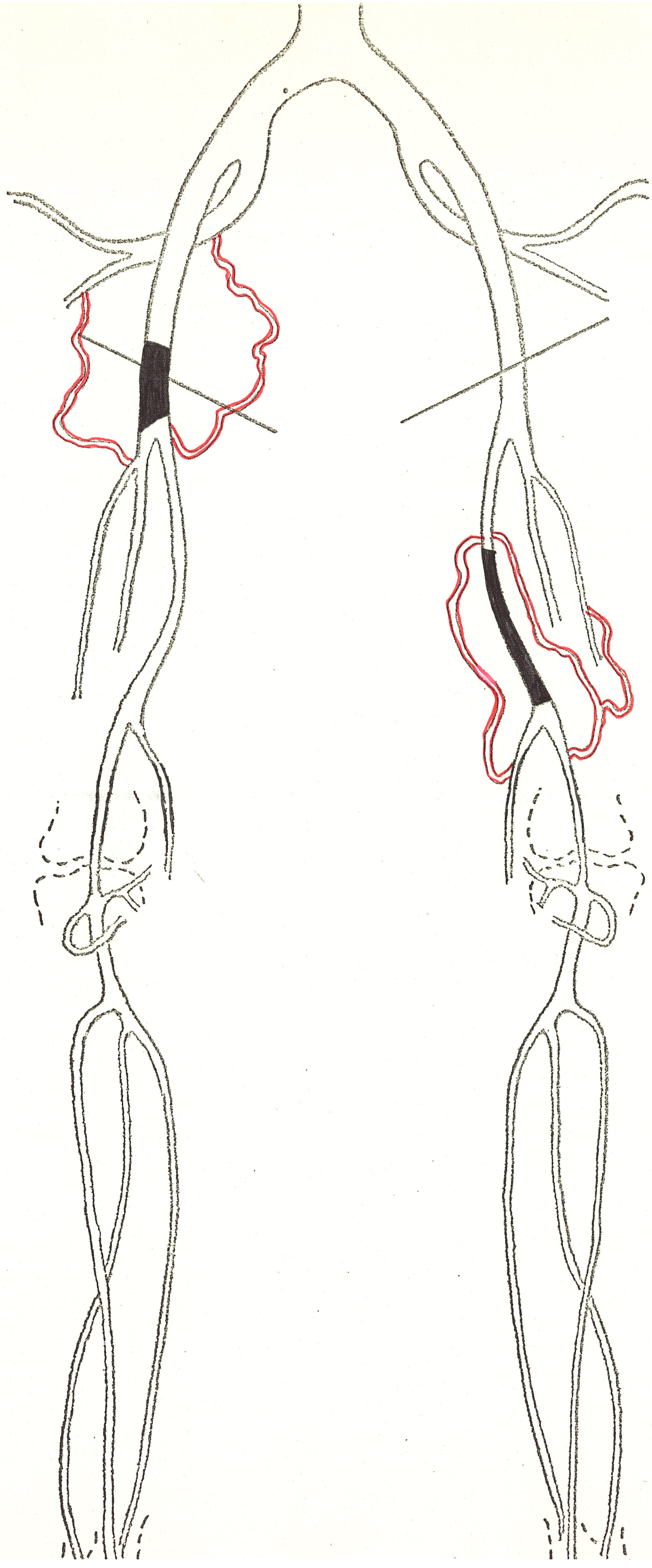

H. H.
H. H.

1.

S. T.

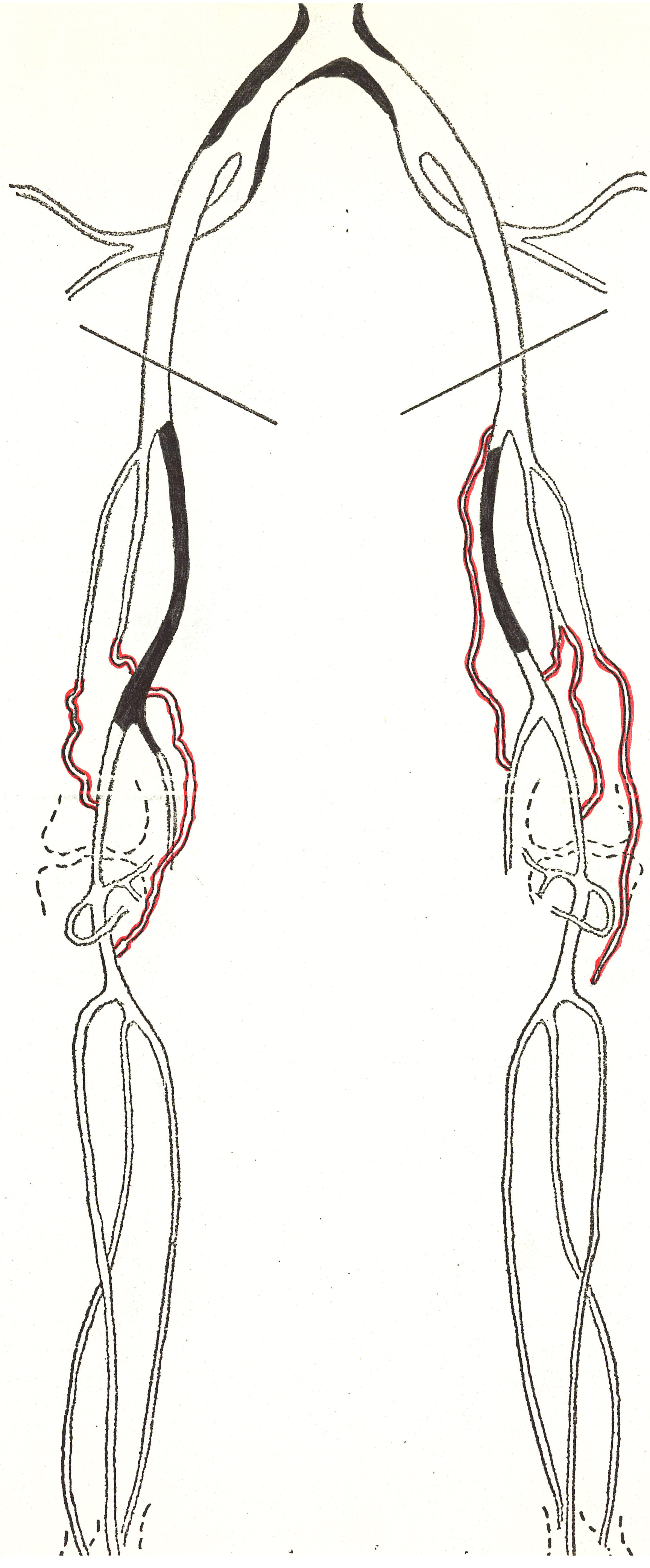


P.T.



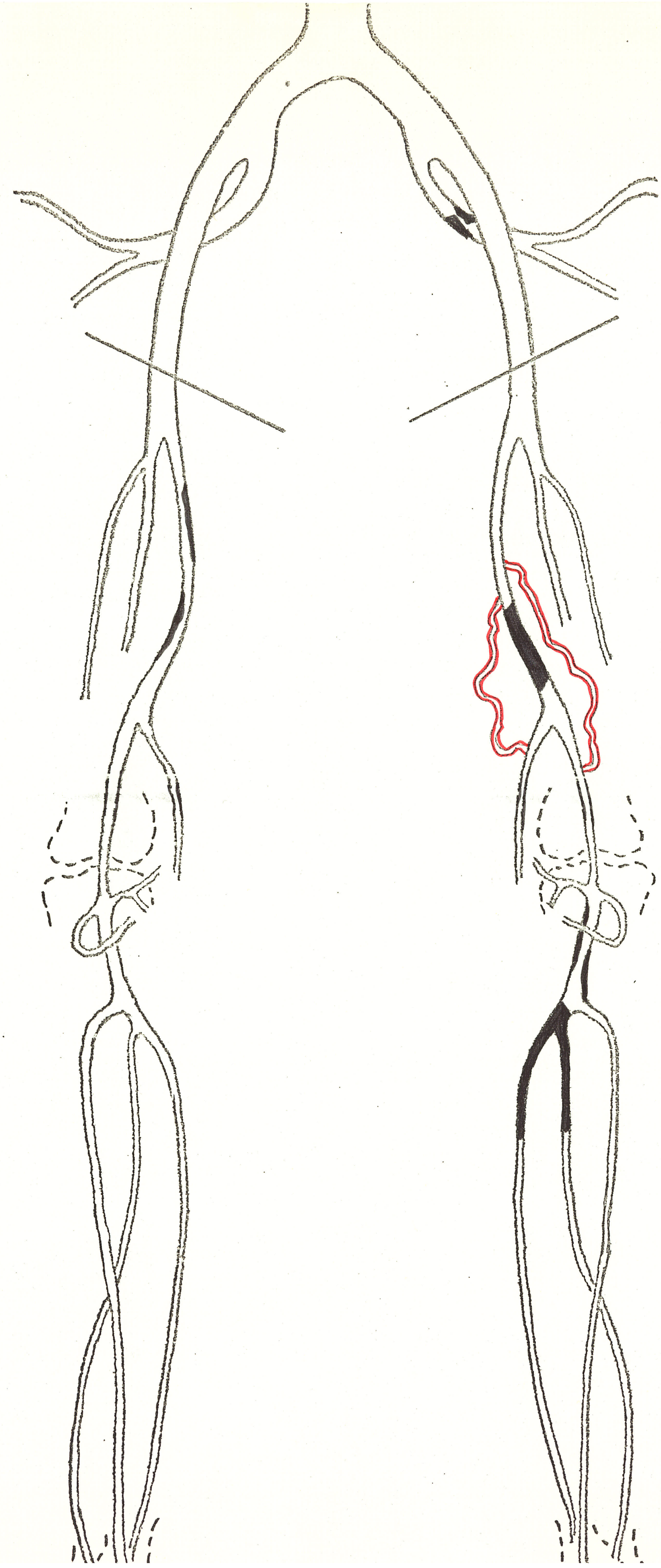
L.B.

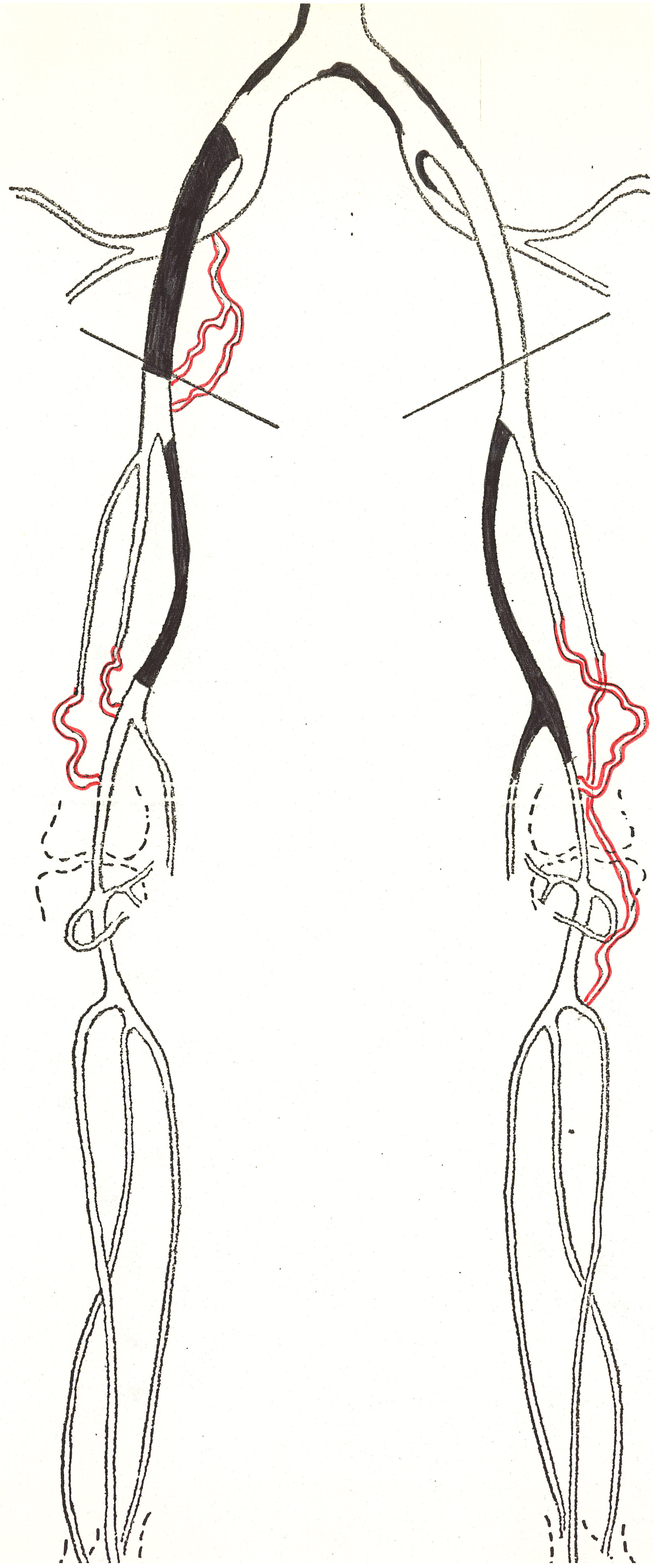
L.B.

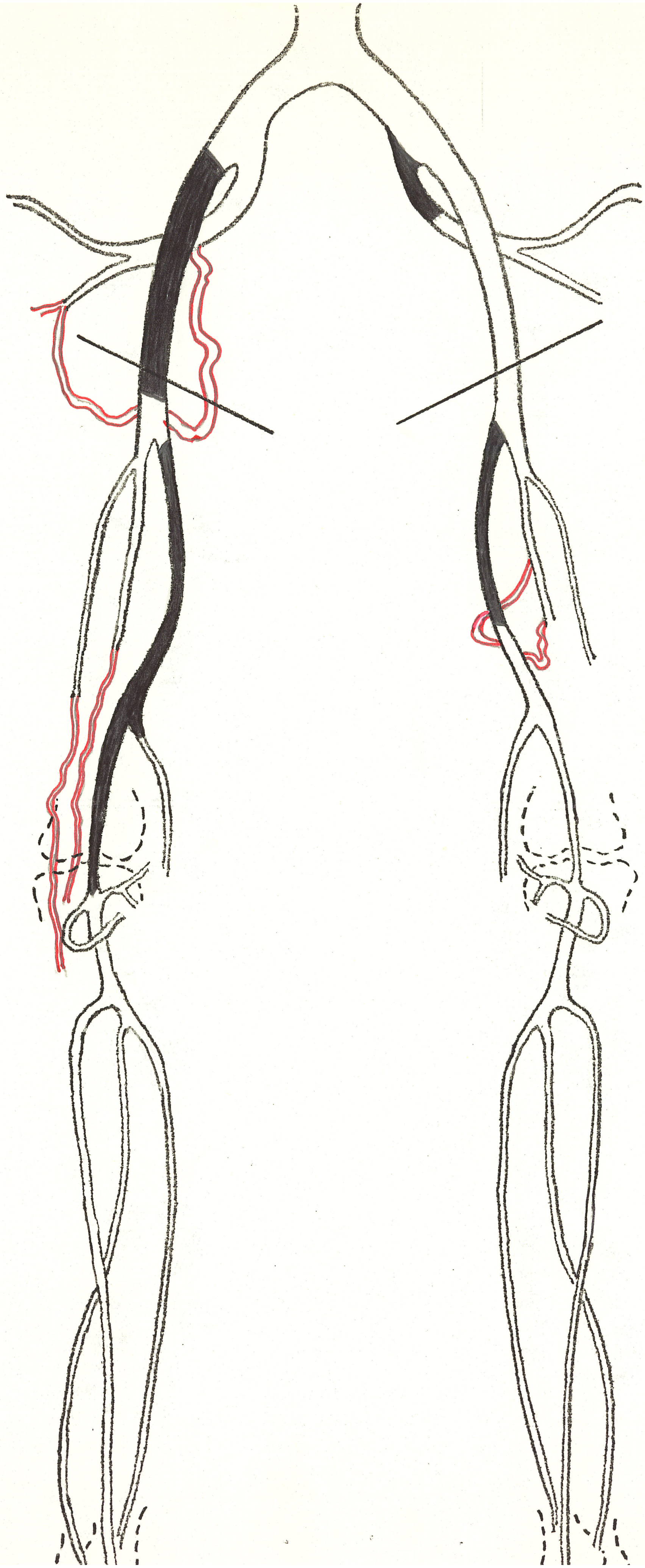


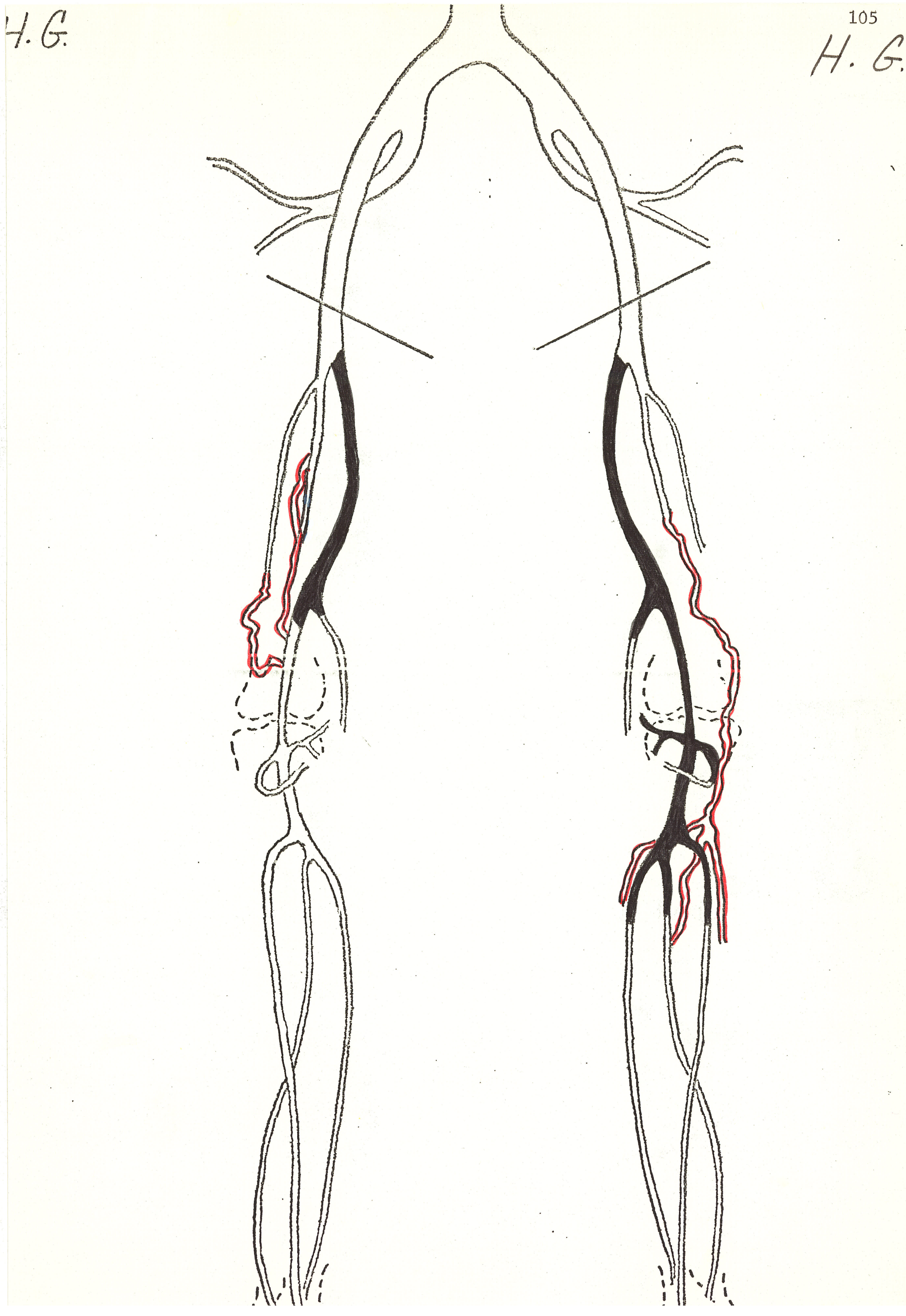
E.C.

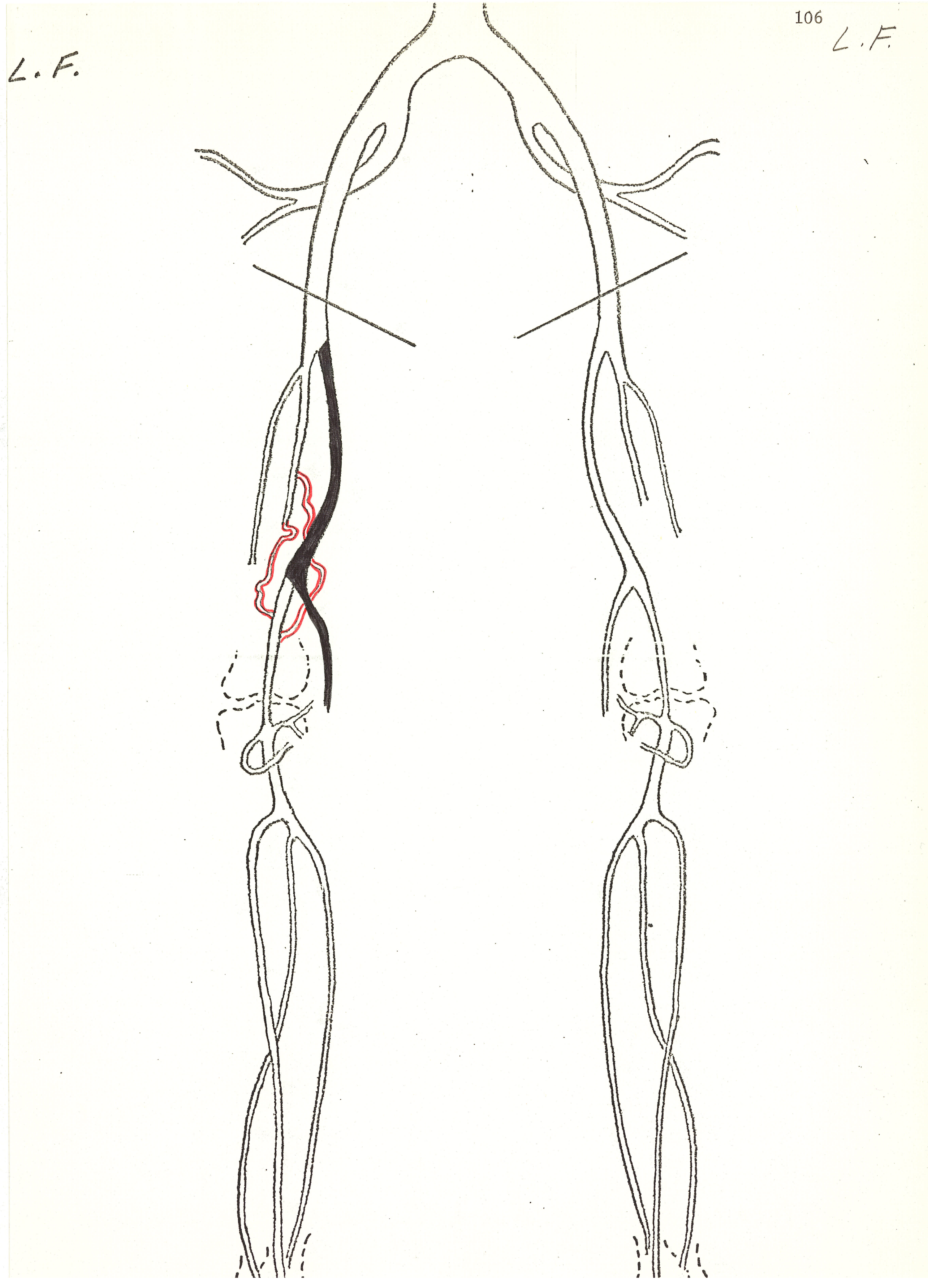
E.C.




R.W.
R.W.




H. G.
H. G.


L.F.
L.F.