THE INVESTIGATION OF VENOUS DISORDERS OF THE LOWER LIMB BY STRAIN-GAUGE PLETHYSMOGRAPHY

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1 ABSTRACT

These studies were undertaken to assess the value of strain-gauge plethysmography in the investigation of venous disorders of the lower limb. The equipment used recorded calf girth changes by means of a mercury-in-silastic strain-gauge placed around the calf. Experiments were performed in an attempt to measure venous distensibility in subjects with and without varicose veins. A further series of experiments was undertaken using an ambulatory test of venous function in normal subjects and subjects with a variety of venous disorders.

Venous distensibility was calculated, according to a method described by previous workers, from recordings of calf girth changes following inflation of a pneumatic thigh cuff. The maximum calf girth increase was recorded at different cuff inflation pressures, and a graph constructed of maximum calf girth increase versus cuff pressure. The slope of the line obtained from the graph was called the venous distensibility index. Although this method actually measured the distensibility of the whole limb, other workers had previously shown it to be a useful measurement in the investigation of varicose veins. A series of preliminary experiments in a total of 46 subjects on the measurement of venous distensibility examined the reproducibility of results, the effect of variations in strain-gauge and subject position and of changes in local temperature.

It was found that alterations in the experimental conditions produced changes in the venous distensibility index, and that it was important to maintain the same experimental conditions in order to achieve reproducibility of results.

A comparison was made of the venous distensibility indices obtained from 20 normal subjects and 47 patients with varicose veins recorded under standard conditions. It was found that patients with varicose veins tended to have lower values for venous distensibility than normal subjects. However, there was a

considerable overlap of results which, together with the lack of reproducibility, made the measurement of venous distensibility by this method of little value in the investigation of varicose veins.

Simultaneous calf girth and invasive venous pressure recordings were obtained, following thigh cuff inflation, from 10 normal subjects and 20 varicose vein patients. The direct measurement of venous pressure was intended to eliminate the variation resulting from the same pneumatic cuff pressures being applied to different thigh circumferences. The results obtained from this study demonstrated no constant relationship between thigh cuff pressure and venous pressure. Distensibility indices were calculated for these subjects by plotting calf girth increase against the directly measured venous pressure. Although this method of calculation of venous distensibility produced different results, it did not improve the separation of normal and varicose vein subjects according to their distensibilities.

The conclusion drawn from these results was that variations in venous tone were sufficient to obscure any differences in distensibility between normal and varicose vein subjects. Also, the results of this series of experiments question the validity of the work of other investigators who have found this method of venous distensibility measurement to be useful in the investigation of venous disorders.

The second part of this study consisted of a series of experiments, using an ambulatory test, to determine whether calf girth changes recorded during exercise could provide a satisfactory alternative to invasive venous pressure measurements in the investigation of venous disorders of the lower limb. Calf girth recordings were made during quiet standing and whilst performing 30-second periods of heel-raising exercise with and without inflation of a pneumatic thigh cuff to 100mmHg (in order to occlude the superficial veins).

The method of calculation of the ambulatory calf change was different from that used by other workers. The measurement of refilling time was found to be complicated by the fact that the calf girth rarely returned to the original base line after cessation of exercise. Also, the calf girth change at the end of calf contraction was found to reflect mainly the calf muscle bulk of the subject. Therefore, the change in calf girth at the end of calf relaxation was the measurement chosen, and this was found to be an indirect measurement of the venous refilling time.

Preliminary ambulatory test experiments were performed on 10 normal subjects to show the effect of variation in strain-gauge position and the reproducibility of the results. A comparison of the results of simultaneous calf girth and venous pressure change on exercise showed similar patterns of response with a strong positive correlation ($r = 0.88$) for the two sets of results. However, venous pressure measurements only reflect changes in one portion of the venous pool, whereas calf girth changes are the resultant of changes taking place throughout the venous system at that level and so may be more relevant in the investigation of venous disorders.

A range of normal values for the ambulatory calf girth change was established by comparing the results obtained from 20 normal with 40 varicose vein subjects with primary varicose veins, and the patterns of response in different venous disorders examined. The results of clinical examination, Doppler ultrasound testing and ambulatory strain-gauge plethysmography were compared in a further 50 varicose vein subjects. Strain-gauge plethysmography was found to compare favourably with the Doppler ultrasound results, although it was more time-consuming to perform. However, plethysmography is not so dependant on observer training for the production of satisfactory results, and also it provides a numerical result which may be used as an assessment of the severity of the venous disease, and the effect of treatment. Plethysmography was also found useful in the investigation of obese subjects and those with recurrent varicose veins.

15 subjects with symptoms of deep venous incompetence were investigated by strain-gauge plethysmography and by ascending and descending phlebography. Plethysmography was found to be a useful, non-invasive technique for confirmation of the diagnosis of deep venous incompetence, and, in those subjects in whom surgery is not contemplated, could be used instead of phlebography.

Ambulatory strain-gauge plethysmography was also used to study 20 varicose vein patients pre-operatively and one year post-operatively. The pre-operative plethysmographic results were compared with subjective and objective assessments of the results of surgery. It was found that plethysmography results were not able to predict the outcome of varicose vein surgery, but it was felt that a one year follow-up period was really too short to provide meaningful results. It is intended to review these patients annually for the next five years, by which time the discrepancies between the post-operative plethysmography results and the clinical assessments may have been resolved.

The results of a trial to compare the results of stripping or not stripping the long saphenous vein following sapheno - femoral disconnection in the treatment of 200 patients with varicose veins have also been included in this study. All these patients had pre-operative assessment by means of strain-gauge plethysmography. It was hoped that the plethysmographic results might correlate with the post-operative clinical assessment of these patients at their follow-up visits. Up to one year post-operatively, no difference has been found between the results obtained from the two groups of subjects. Again, however, a period of one year is probably too short to assess the results of any treatment for varicose veins, and these patients will continue to be reviewed annually for the next five years.

2 INTRODUCTION

Venous disease of the lower limb is one of the commonest conditions affecting the inhabitants of the United Kingdom, estimated to affect between 10 and 20% of the population (Weddell 1969; Piachaud and Weddell 1972). Despite this prevalence, the sphere of venous disorders is one in which there is a relative lack of experimental and objective evidence on which to base treatment regimens and to judge their effects. The result has been a confusing variety of treatments, justified by dogmatic statements, without the use of controlled trials to test their validity (Hobbs 1977). This state of affairs is surprising in view of the facts that veins are easily accessible and produce obvious effects when diseased. Indeed, many of the orginal physiological observations on the circulatory system were made upon veins (Brecher 1969).

However, the explanation of this paradox may be that, although common, venous disease is rarely fatal; it does not produce dramatic effects in its sufferers; and its treatment results are equally unspectacular. Also, until recently, the only investigative techniques available for venous disorders have been invasive which were uncomfortable for the subjects and also not without complications. Veins are also known to respond to a variety of local and generalised stimuli by changes in their tone, and this causes difficulties in the production of reproducible results (Webb-Peploe and Shepherd 1968 (a)). In contrast, arteries do produce dramatic, and often fatal, results when diseased and the results of treatment may be extremely impressive. Also, arteries behave in a more predictable manner, and for these foregoing reasons, have attracted far more attention by way of investigative techniques.

Measurement of the superficial venous pressure was the first technique used to investigate venous function, although the observations were mainly confined to the upper limb and neck, and these findings may not be applicable to the lower limb in which the veins have a different morphology. The modern pressure measurement devices now allow more sensitive recording of venous pressure changes, and these recordings remain the "gold standard" by which other investigative techniques must be judged (Strandness 1978). However, even these measurements produce different results depending on whether deep or superficial veins are being studied (Arnoldi 1965 (b)). Non-invasive investigations will produce a composite picture of the changes occuring throughout the venous pool and thus may more accurately reflect the haemodynamic changes which take place throughout the limb in various forms of venous disorder.

This study was therefore undertaken to evaluate the role of strain-gauge plethysmography, in the investigation of venous disorders.

It has been suggested that a possible basic defect in the aetiology of varicose veins is abnormal distensibility of the vein walls and there has been some experimental evidence in favour of this theory from in vivo and in vitro studies (Zsoter and Cronin 1966; Zsoter, Moore and Keon 1967). A method of measurement of venous distensibility of the lower limb veins by means of strain-gauge plethysmography has been described (d'Inverno 1980 and 1981), but without precise experimental details being quoted.

The first part of this study was concerned with a more accurate analysis of the use of strain-gauge plethysmography to measure venous distensibility. An experimental design was devised, and then used to compare distensibility measurements obtained from normal and varicose vein subjects; the eventual intention being to use distensibility measurements to study the aetiology of varicose veins.

In the second part of the study, the use of strain-gauge plethysmography in the investigation of venous disorders was examined. A modification of previously-described ambulatory tests was used and the results obtained compared with invasive and other non-invasive techniques in the investigation of lower limb venous disorders. This method of examination was also used in pre- and post-operative studies on patients to determine whether the results of strain-gauge plethysmography could have a predictive value on the out-come of varicose vein treatment.

3 HISTORICAL REVIEW

3.1 Venous Research In General

Since the earliest writings, veins have always been recognised as vessels filled with blood as opposed to arteries which were thought to be air-carrying ducts partially filled with blood, until this was disproved by Galen of Pergamon (130-200 AD). The correct description of the vein is probably due to their superficial position, and to the widespread practice of phlebotomy, a procedure well established from the earliest historical records.

Herophilus of Chalcedon (working in Alexandria in the third century BC) was the first person to differentiate veins from arteries, stating that arteries had vigorous pulsations whilst veins showed little, if any pulsation. Galen noted that the venous system communicated with the arterial system through terminal anastomoses via "capillary" or hair-like branches. The observation that the veins became more prominant if a ligature was applied to the arm was first recorded by Galen, who also made valuable observations on injured gladiators. He described the differences between arterial and venous haemorrhage and also noted the pulsations in the central veins in laid-open chests (Brecher 1969).

The presence of valves in veins was first demonstrated in 1536 by Giambattista Canano working at the University of Ferrara, Italy. Alberti was the first to publish drawings of the valves. Canano passed on his discovery of venous valves to the Dutch anatomist, Andreas Vesalius (1514 - 1564) who, after his appointment as Professor of Anatomy at the University of Padua, passed on the information to his pupil, Fallopius (1532 - 1562). Subsequently, Fallopius himself became Anatomy Professor at Padua and informed his favourite student, Hieronymus Fabricius of Aquapendente (1533 - 1619) of the discovery. Fabricius was the first person to publish a detailed account of venous valves but thought that their purpose was to prevent blood flooding into the hands and feet. Fabricius' pupil, William Harvey (1578 - 1657) deduced from the position of the venous valves that blood could not ebb and flow, as had been thought since Galen's time, and led to his discovery of the circulation (Franklin 1927).

The first measurements of venous pressure were made by Stephen Hales (1677 - 1761) who measured the pressure directly in several animals, by inserting glass tubes into their jugular veins. Hales noted the height of the column of blood in the glass tube, and its rise and fall on respiration and muscular effort. Hales also measured arterial pressures in the same way, using a longer tube. Jean Poiseuille (1799 - 1869) made the measurement of arterial pressure simpler by his invention of the mercury manometer (he called it the haemodynamometer), but this made the investigation of venous pressure more difficult. The mercury manometer is unsuitable for measuring the small changes in pressure that can accompany large volume changes in the veins. Poiseuille's other achievement was to establish the relationship between pressure and flow in rigid tubes, and its application to the moderately rigid arteries. However, these findings were not applicable to the thin-walled veins which collapse as the pressure decreases (Brecher 1969).

Thus, whilst investigation of the arterial circulation proceeded apace, original findings in venous haemodynamics, during the remainder of the 19th century, were confined to clinical observations on subjects with varicose veins.

Varicose veins had been known to exist from before the time of Hippocrates (460 - 377 BC) who associated leg ulcers with enlarged veins. In Roman times, ulcers were treated by bandaging and varicose veins were avulsed or cauterised. However, it was not until after Harvey's discovery of the circulation of blood that the modern theories of varicose vein causation superceded Galen's humoral theory. In 1676, Wiseman recorded that venous dilatation results in valvular incompetence and also coined the term "varicose ulcer" as he considered the ulcer to be a consequence of the venous disorder. Many writers in the 19th century stressed the importance of varicose veins in association with leg ulcers. Gay and Spender (1868) both pointed out the association of venous thrombosis with ulceration and Gay noted that severe varicosity may exist without ulceration (Anning 1976).

The tourniquet test for varicose veins was first described by Sir Benjamin Brodie (1783 - 1862) in 1846, but its significance in demonstrating valvular incompetence of the long saphenous system was established by Friedrich Trendelenburg (1844 - 1925) (Dodd and Cockett 1976). Georg Perthes first observed in 1895 that the pressure in the veins of the leg decreased on ambulation, and that this did not occur in extremities with incompetent veins unless these veins were occluded above the area observed. These observations were made by placing a rubber band around the calf which could be seen to contract as the pressure fell.

The earliest venous pressure recordings from the lower limb were non-invasive (von Recklinghausen 1906 and Hooker 1911). The apparatus used consisted of a plastic capsule placed over the long saphenous vein at the ankle. The air pressure within the capsule was increased until the vein collapsed, at which point the air pressure in the capsule equalled the venous pressure. The results of these investigations showed a very low pressure in the normal superficial veins in the motionless erect position. Beecher, Field and Krogh (1936 (a) & (b)), using similar equipment, confirmed these results and also demonstrated a fall in venous pressure on exercise in normal subjects. However, it was found that this device did not work if the vein was surrounded by oedema or fibrosis.

Invasive measurements of venous pressure, using needles in the long saphenous vein attached to saline manometers, showed that the venous pressure in the standing position corresponds approximately to the distance from the point of measurement to the heart in normal subjects (Smirk, 1935; Hojensgard and Sturup, 1949; Warren, White and Belcher, 1949; Pollack and Wood 1949) and varicose vein patients (Hojensgard and Sturup, 1949; Pollack et al, 1949).

The effect of exercise on the pressure in the superficial veins was first noted by Hooker (1911) and the first recording of pressure decrease during walking was made by Smirk (1935). Pollack and Wood (1949) investigated the pressure changes taking place in a single step, and found that there was an initial slight rise in pressure followed by a sharp fall and then a gradual rise back to the resting pressure at the end of the step. Henry and Gauer (1950) demonstrated that venous pressure recordings at rest and during exercise showed a wide variation if the local temperature of the foot was varied, either by immersion in a water bath or by room temperature changes.

Recordings from the popliteal vein were first made by Veal and Hussey (1940) who found that the resting pressure in the popliteal vein was 30 to 60mmHg (a mercury manometer was used for the recordings). Subsequent workers (Bauer 1948; Hojensgard and Sturup 1952; Arnoldi 1965 (b)) have shown that the popliteal vein pressure corresponds to the hydrostatic pressure. All these workers showed that, although the pressure fluctuated, the mean pressure in the popliteal vein did not change during exercise.

Superficial venous pressure changes on exercise were found to distinguish normal subjects from those with varicose veins or deep venous incompetence (Hickam, McCulloch and Reeves 1949; Hojensgard and Sturup 1949 and 1952; Warren, White and Belcher 1949; Sturup and Hojensgard 1950; Lofgren 1954; Schneewind 1954). Subjects with varicose veins were found to have a normal venous pressure fall on exercise if the exercise was performed with tourniquets on the leg or after varicose vein surgery (White and Warren 1949). Although, all these recordings were made from the long saphenous vein and thus provided no information on the status of perforating veins.

Patients with a history of deep venous thrombosis have little decrease in venous pressure on exercise with a faster return to the resting pressure (refilling time), and this abnormal response is not affected by tourniquets on the leg or by ligation of the superficial femoral vein (Pollack et al 1949; Warren, White and Belcher 1949; De Camp et al 1951). Walker and Longland (1950) found that, following popliteal vein ligation, subjects with deep venous incompetence had an almost normal reduction in superficial venous pressure on exercise. Popliteal vein division had been recommended by Bauer (1948) as treatment for the post-thrombotic syndrome which he had first described in 1942.

The mercury manometer was found to have too much inertia to accurately reflect venous pressure changes on exercise, but the saline manometer has been employed by many authors to further investigate venous physiology. Van der Hyde (1961) compared the results of superficial venous pressure measurement with the results of ascending and descending phlebograms and found that abnormalities in the venous system seen on the X-rays corresponded to ambulatory venous pressure patterns. In an elegant series of experiments, Arnoldi (1965 and 1966) compared venous pressure recordings from the long saphenous, posterior tibial and popliteal veins with the results of ascending and dynamic phlebography in normal subjects and patients with venous disease. The results of these studies showed that all subjects had resting venous pressures (in all of the veins) corresponding to the hydrostatic pressure. The popliteal vein pressure was found to vary little on exercise. Normal subjects showed an increase in venous pressure on calf contraction, followed by a fall in pressure on relaxation in the long saphenous and posterior tibial veins, resulting in a net fall in mean venous pressure. The subjects with venous disease showed a smaller net decrease in venous pressure on exercise and a shorter recovery time to the resting pressure, but retaining the normal pattern of response. Further investigations by Arnoldi, Greitz and Linderholm (1966) and Arnoldi and Linderholm (1966, 1968, 1969 and 1971) demonstrated the calf muscle pump; ambulatory venous pressure differences between normal subjects, varicose vein subjects and subjects with deep venous incompetence; and showed that intracalcaneal pressure recordings corresponded to the recordings from the posterior tibial vein.

Hjelmstedt (1968) recommended that ambulatory pressure fall be used for comparisons of venous pressure as the absolute venous pressure on exercise depends on the resting pressure, and there is a wide scatter of results for the return time to the resting pressure after exercise. Subsequent investigators have used an ambulatory test combined with venous pressure measurement, except for Martin and Odling-Smee (1976) who showed that straining had no effect on venous pressure.

Direct venous pressure studies have been used to measure the effect of pressure bandaging (Husni et al 1968 and 1970 and O'Donnell et al 1979), to differentiate between superficial and deep venous incompetence (Bjordal 1971; Lewis et al 1973) in the detection of deep venous thrombosis (Gerlock 1977; Ellwood and Lee 1979; Martin et al 1979) and to assess the effect of treatment of venous disease (Zelikovski et al 1979).

Ambulatory venous pressure measurements using a saline manometer, or the more sensitive pressure transducer, have now become well documented in subjects with venous disease (Nachbur 1977; Strandness 1978; Schanzer and Peirce 1982 (a) and (b)), and being direct measurements, are the standard by which other investigations have to be judged. Bjordal (1970 and 1972) used a combination of venous pressure measurements and electromagnetic flowmeter recordings to show the bidirectional flow of blood in the perforating veins on exercise. Two studies comparing venous pressure and blood flow (using Xe 133 clearance) showed that the venous pressure decreased as the blood flow increased on exercise, providing indirect evidence for a veno-arteriolar reflex (Henriksen and Sejrsen 1977; Nielsen 1982).

Superficial veins have been shown to have an active tone by experiments in vivo (Burch and Murtadha 1956; Sharpey-Schafer 1961) and in vitro (Sutter 1965; Alexander 1967) and this is affected by a variety of factors, including exercise, emotion, hyperventilation, environmental temperature and posture (Webb-Peploe and Shepherd 1968 (a) and (b); Seaman et al 1973). The superficial veins have adrenergic receptors linked to the thermoregulatory centre and responsive to local effects and also to neurohumoral substances and drugs, including acetyl choline, histamine, 5-hydroxytryptamine, prostaglandins, cardiac glycosides and halothane (Gero and Gerova 1968 (a); Vanhoutte and Janssens 1978; Shepherd and Vanhoutte 1979; Vanhoutte 1981). The veins within the calf muscles have no sympathetic fibres but do react to humoral and local factors (Altura 1977). Varicose veins have similar reactions to normal veins in their response to drugs, thus there is no primary deficiency of smooth muscle contractility in varicose veins (Thulesius and Gjores 1974; Barthel and Grossmann 1982). However, normal veins do show more response to veno-constrictive agents than varicose veins, and this may be due to the degeneration of muscular and elastic components in the varicose vein wall (Johnsson and Arenander 1963; Svejcar et al 1963; Grobety and Bouvier 1977; Niebes, Engels and Jegerlehner 1977; Shepherd 1978; Leu, Vogt and Pfrunder 1979; Jurukova and Milenkov 1982). Differences between vein walls in normal and varicose veins suggested a possible theory of varicose vein formation.

A number of studies have been done on the measurement of venous distensibility in vivo and in vitro. Ryder, Molle and Ferris showed in 1944 that excised human forearm veins responded to distension in a similar way to thin-walled rubber tubes. However, experiments on in situ forearm veins showed that their distensibility varied with mental state, exercise and local factors (Burch and Murtadha 1956; Greenfield and Patterson 1956; Watson 1962; Robinson 1981). Early studies of lower limb distensibility using water plethysmography in normal subjects showed good reproducibility (Coles, Kidd and Moffat 1957; Kidd and Lyons 1958). However, the inertia inherent in this equipment make it unsuitable for measuring small changes in venous distensibility. This fact was confirmed by Gauer and Thron in 1962 who found that distensibility measured in vivo by water plethysmography was not comparable with that measured in isolated vein segments. Later studies using water plethysmography have not demonstrated significant differences in distensibility between varicose veins and control subjects (Eiriksson 1968; Eiriksson and Dahn 1968; Gundersen, Haeger and Lindell 1971).

Zsoter and Cronin (1966) measured venous distensibility in the forearm veins of control subjects and patients with varicose veins by an invasive method. These workers found a significant difference between the distensibility of control and varicose vein subjects. However, the control subjects were not well matched for age and sex with the varicose vein subjects, neither were they truly normal subjects, as they were convalescent patients in hospital, and so may have been receiving drug treatment. Also, there were no reproducibility experiments in this study, the invasive nature of which would be certain to influence venous tone. Zsoter, Moore and Keon (1967) also measured the distensibility of surgically removed varicose veins, and found them to be more distensible than veins removed from a control group without varicose veins. However, again the two groups studied were not well matched for age and sex, and the veins used as controls were removed from cadavers and thus could not be regarded as normal. A similar study was performed by Bocking and Roach (1974) who also found that surgically removed varicose veins were more distensible than those removed at autopsy. An additional criticism of this study is that the varicose veins were removed using a vein stripper which may have damaged the veins. Thulesius and Gjores (1974) compared the contractility of veins removed during varicose vein and arterial operations and found no significant difference, indicating that there is no primary deficiency in smooth muscle contractility in varicose veins. The relationship between pressure and volume in excised veins is non-linear, not related to the modulus of elasticity alone, and compounded by the changes in cross-sectional shape as the venous pressure and volume increase (Moreno et al 1970; Azuma and Hasegawa 1973; Gero and Gerova 1968 (b)).

In vivo measurements of venous distensibility are also difficult to obtain as the effects of venous tone, stress relaxation and the creep phenomenon produce variations in the results, affecting the reproducibility of the experiments (Alexander 1963; Attinger 1969). Recent studies using strain-gauge plethysmography to measure venous distensibility have shown differences between the results obtained from normal and varicose veins subjects (Pupita, Rotatori and Frausini 1981; Franco, Langeron and Harle 1981). However, neither of these papers included details of reproducibility studies, neither group of workers used constant environmental conditions, and the study of Franco, Langeron and Harle did not include results from normal subjects. Thus, the validity of venous distensibility measurements remains uncertain and the question of whether differences in distensibility exist between normal and varicose veins remains unanswered. However, distensibility measurements can be used to study the effect of drugs in individual subjects (Robinson 1981).

As yet there is no proven theory as to aetiology of varicose veins. Heredity and race appear to be definite factors in varicose vein development (Gundersen and Hauge 1969; Reagan and Folse 1971; Da Silva et al 1974; Dodd and Cockett 1976); whilst evidence of physical or auto-immune causes have remained unconfirmed (Basmajian 1952; Ludbrook 1962; Ludbrook and Beale 1962; Pentecost 1964; Haimovici, Steinman and Caplan 1966; Weddell 1969; Fegan and Kline 1972; Gero et al 1973; Buchala and Laszt 1975; Zelikovski et al 1977; Makitie 1977). The morphological changes that have been found in the lower limbs of subjects with varicose veins may be secondary to the varicose veins, and not a primary defect (Fegan and Kline 1972; Makitie 1977). Also, the finding that venous valves do not decrease in number with increasing age (Kosinski 1926; Powell and Lynn 1951; Cotton 1961) would not support the theory that varicose veins result from degeneration of venous valves.

The treatment of varicose veins is also an area in which there are still unanswered questions. The earliest treatment (from Roman time onward) of varicose veins was by ligature and/or excision. This was gradually superceded by enthusiasm for sclerotherapy in the period 1930 to 1950. However, the numerous recurrent varicose veins after sclerotherapy resulted in a swing back towards surgery with stripping of the long saphenous vein (Linton and Hardy 1949; Myers 1957), and also ligation of incompetent perforators whose anatomy was described in 1953 (Cockett and Jones). The value of a careful technique of injection sclerotherapy with its good long term results was shown by Fegan (1963).

There have been a number of trials comparing the results of surgery and sclerotherapy for varicose veins (Hobbs 1968, 1974, 1980; Weddell 1970; Chant, Jones and Weddell 1972; Seddon 1973; Doran and White 1975; Beresford et al 1978; Jakobsen 1979). There are economic advantages to the sclerotherapy method of treatment (Piachaud and Weddell 1972) and the results of sclerotherapy appeared satisfactory (Fegan 1963; Dejode 1970; Stother, Bryson and Alexander 1974). It became clear that the results of surgery and sclerotherapy were equally good up to 3 years after treatment (Hobbs 1968; Weddell 1970; Chant, Jones and Weddell 1972; Seddon 1973; Doran and White 1975). However, when longer follow-up times were assessed (Hobbs 1974; Beresford et al 1978; Jakobsen 1979), injection sclerotherapy was found to give inferior results to surgery. However, the two forms of treatment have been found not to be mutually exclusive, but satisfactory results may be obtained by a combination of techniques, although it is generally accepted that sapheno-femoral or sapheno-popliteal incompetence require surgical treatment (Hobbs 1980).

Recurrences do occur after treatment of varicose veins (Lofgren and Lofgren 1971; Doran and Barkat 1981), and there has been an increasing use of pre-operative investigations in order to try and improve the results of treatment. The position of incompetent perforators has been investigated by Dopper ultrasound (Folse 1970; Folse & Alexander 1970; Miller and Foote 1974), fluorescein injection (Chilvers and Thomas 1970), thermography (Patil, Williams and Lloyd-Williams 1970), infra-red photography (Beesley and Fegan 1970) and phlebography (Chant et al 1972; Field et al 1972; Thomas et al 1972). However, the only investigation that was found to be a significant improvement over clinical examination was phlebography (Noble and Gunn 1972; Callum, Gray and Thomas 1973; O'Donnell et al 1977) which is a costly, invasive investigation with a recognised morbidity (Albrechtsson and Olsson 1976; Bettmann and Paulin 1977). Crane (1979) suggested that treatment for varicose veins should be based on the results of venous pressure measurements. But this method of investigation provides no more information than can be obtained by careful clinical examination, or by the non-invasive Doppler ultrasound investigation.

The prevalence of varicose veins makes their out-patient surgical treatment an attractive proposition. Although the long saphenous vein may be stripped under local anaesthetic (Arenander 1960; Richards 1973; Taylor et al 1981), this operation is usually performed under general anaesthetic and involves a recommended post-operative stay of between six hours and one week (Nabatoff and Stark 1972; Doran, White and Drury 1972; Rintoul and Macpherson 1975; Lumley 1977; Tanabe 1979). In the presence of sapheno-femoral incompetence, a high saphenous ligation is necessary for satisfactory results (Haeger 1975), although the necessity of stripping the long saphenous vein has been questioned (Salzmann 1972; Thomson 1979). Trials which have compared the results of stripping or not stripping the long saphenous vein have been retrospective (Larson et al 1974; Lofgren 1978) or non-randomised (Rintoul and Macpherson 1975). Thus, the value of stripping the long saphenous vein is still in question, requiring prospective trials, such as the one in this study, for its answer.

3.2 Non-Invasive Venous Investigations

The principle of measuring variations in body volume by volume displacement was originally described in the 17th century by Glisson and Swammerdam and re-introduced by Mosso in the 19th century (Ensink and Hellige 1981 (a)). Hewlett and van Zwaluwenberg (1909) were the first to use a venous occlusion cuff with a plethysmograph to measure blood flow in a limb. Since then, a variety of methods of volume measurement have been devised. Measurements of venous distensibility using a water plethysmograph were made by Litter and Wood (1954) and Kidd and Lyons (1958) and Eiriksson (1968). Wood and Eckstein (1958) demonstrated venoconstriction in the forearm secondary to local temperature changes using the same equipment. The water plethysmograph was found not to be of value in the diagnosis of deep venous thrombosis (Dahn and Eiriksson 1968) or deep venous insufficiency (Gundersen, Haeger and Lindell 1971).

An air-filled plethysmograph was used by Barcroft & Dornhorst

(1949 (a) & (b)) to demonstrate the effect of the "muscle pump" in reducing the calf volume on exercise. The air plethysmograph does not have the problem of the inertia of the water plethysmograph and has been used to study venous distensibility (Winsor and Hyman 1961; Sakaguchi et al 1968), deep venous thrombosis (Cranley, Grass and Simeone 1973; Zetterquist, Ericsson and Volpe 1975) and deep venous incompetence (Bygdeman, Aschberg and Hindmarsh 1971; Aschberg 1973). However, the apparatus is subject to movement artefact (making exercise effects impossible to measure), is very sensitive to temperature changes and there is a large overlap of results between normal subjects and patients with venous disease.

Impedance plethysmography may be used to measure limb volume changes by recording changes in electrical impedance to an alternating current passed through the limb. The measurement obtained is the resultant of a number of variables, is affected by the quality of contact between the electrode and the skin and the change in impedance measured is small compared with the total impedance. Therefore, complex equipment is required, which is easily affected by artefact (Cranley, Grass and Simeone 1973). Early studies found impedance plethysmography to be of no use in the detection of deep venous thrombosis (Johnson and Kakkar 1974; Liapis et al 1980) but, modifications in the methodology and equipment have made this investigation the most accurate non invasive method of deep venous thrombosis detection (Hull et al 1978; Hull et al 1981; Gray and Mackie 1982; Wheeler et al 1982; O'Donnell et al 1983), and it may also be of value in the detection of deep venous incompetence (Lee et al 1982).

The measurement of cutaneous colour changes by photoplethysmography, using the time to return to baseline after exercise, shows a good correlation with venous pressure changes (Abramowitz et al 1979). Although only a small area of the limb is studied by this method, and the point of return to the baseline may be hard to judge (Figar 1959).

Foot volumetry (Norgren and Gjores 1977; Gjores and Thulesius 1977) is also of value in the assessment of venous disorders of the lower limb by means of an exercise test. However, the equipment is cumbersome, it is important to maintain the foot baths at a constant temperature, and the exercise uses the thigh muscles rather than the calf contractions used in the other exercise tests.

The use of mercury-filled rubber tubes to measure changes in limb volume was first described by Whitney (1949 and 1953), and was found to compare well with other blood flow measurements (Burger, Horeman and Brakkee 1959; Dahn and Hallbook 1970; Hellige et al 1979). The original equipment has been improved by various workers (Brakkee and Vendrik 1966; Hallbook, Mansson and Nilsen 1970; Barendsen, Venema and Van den Berg 1971; Hokanson, Sumner and Strandness 1975; Brugmans et al 1977; Baten 1979; Ensink et al 1979) to produce lightweight mercury-in-silastic strain-gauges of high sensitivity and a constant current calibration circuit as opposed to the original Wheatstone bridge circuit.

There have been four published studies comparing simultaneous venous pressure and strain-gauge plethysmographic changes on exercise, but none demonstrated a satisfactory method of assessment of the results. Holm et al (1974) measured the time taken for the calf volume to return to the initial volume after exercise in 17 subjects. This study seemed to show a wide difference between normal and abnormal legs, however, the accuracy and reproducibility of the results was not quoted and the group with abnormal legs were not subdivided according to their venous disease, and even included some subjects with arterial disease.

Niederle and Prerovsky (1975), using a heel-raising exercise, compared the results from 15 normal subjects and 15 subjects with primary varicose veins or a history of deep venous thrombosis. It is not clear how the results were calculated in this study, although the measurement appeared to be the maximum calf volume decrease at the end of each calf contraction. The results obtained were quoted to 3 significant figures and were in the range of 1.8% to 0.5% volume change. Although there was a significant difference between the means of the results obtained from the two groups, there was a considerable overlap. Thus, no clearly defined normal range could be identified. This is not too surprising, as, in the absence of occlusive venous disease, the volume decrease on calf contraction would be similar in the two groups, as this depends mainly on the subject's calf muscle volume and its associated venous plexus. Venous disorders affect the refilling time, and this is reflected in the volume at the start of the calf contraction. The coefficients of variation for the results obtained varied between 14% and 27%, although only two recordings were made from each subject and no day-to-day reproducibility studies were performed. This degree of variation negates the extreme accuracy to which the results were quoted. The comparison of results from normal subjects with such a heterogenous group of subjects with venous disorders makes it impossible to separate different patterns of response from the various disorders. This study did, however, show a good correlation between ambulatory venous pressure and strain-gauge plethysmographic recordings.

The heel-raising exercise test of Fernandes et al (1979) also showed a good correlation between venous pressure and strain-gauge plethysmographic changes. The subjects studied were subdivided according to the type of venous disorder and compared with normal subjects. The measurements used were the maximum calf volume decrease at the end of the calf contraction and the time to return to the resting volume after cessation of exercise (refilling time). No reproducibility studies were quoted. A clear separation of the different groups with venous disorders and normal subjects was obtained with both of these measurements. This is surprising as volume changes at the end of calf contraction are mainly the result of muscle contraction, except in subjects with venous outflow occlusion. Also, the refilling time may be more difficult to measure than is shown, as changes in venous tone (known to occur in exercise) may prevent the calf volume from returning to the pre-exercise base line.

The same criticisms apply to the work of Mason and Giron (1982) who again used the maximum volume drop on calf contraction and the refilling time in their investigation of normal, varicose and post-phlebitic limbs. The coefficient of variation on recordings made one week apart from six subjects was 17%; and there was a considerable overlap of results from the different subject groups. Both Fernandes et al (1979) and Mason and Giron (1982) mentioned that some subjects with post-phlebitic limbs actually increased their calf volume on exercise, although no further comment was made on this observation by either author.

These studies all showed a good correlation between venous pressure and strain-gauge plethysmography measurements (the correlation coefficients varying between 0.6 and 0.9) but the methods of assessment of the non-invasive results were open to criticism, as was the work of Holm (1976).

Comparison with technecium scanning has shown that strain-gauge plethysmography reflects calf volume changes, although the strain-gauge measures changes in calf circumference (Partsch 1981). Doppler ultrasound and photoplethysmographic results in venous disease are similar to those obtained by strain-gauge plethysmography (Barnes, Ross and Strandness 1975; Linhardt, Queral and Dagher 1982).

The measurement of venous outflow, by calculating the rate of calf volume decrease after release of a thigh tourniquet, has been used to diagnose deep venous thrombosis. Results of these investigations in general show a large overlap of results between normal and abnormal legs which restrict its usefulness (Hallbook and Gothlin 1971; Barnes et al 1972 and 1977; d'Iverno 1980; Barnes 1982), although the presence of a biphasic venous emptying pattern is suggestive of the presence of venous thrombosis (Bergqvist and Hallbook 1979). Also, results are improved if only the latter part of the emptying curve is studied (Brakkee and Kuiper 1982).

Other investigators have used strain-gauge plethysmography to investigate venous disorders by measuring the calf volume secondary to inflation of a thigh pneumatic cuff, and the rate of volume decrease on deflation of the thigh cuff (Barnes et al 1973 and 1974; Forconi et al 1979; Tripolitis et al 1979; Rudofsky 1979). None of these studies gave any results of reproducibility, an important point in measurements which may be affected by changes in venous tone. The "venous volumes" quoted by these investigators are strictly percentage volume increases and not absolute venous volumes secondary to thigh cuff inflation. All of these studies showed significant differences between the means of the results obtained from normal, varicose and post-phlebitic limbs. However, the great overlap of results from the three groups means that individual recordings are of no value in differentiating the different types of venous disorder. Further studies have been performed under carefully controlled experimental conditions and using correction factors to allow for artefacts due to tissue movement and the fluid filtration effect (Brakkee 1979; Thirsk, Kamm, and Shapiro 1980; d'Iverno 1981; Rudofsky 1981). However, despite these corrections, there was still a scatter of results from the different groups of subjects studied.

The measurement of venous distensibility by recording the maximum calf volume increase following inflation of a pneumatic thigh cuff to different pressures has been found to be of value in the differentiation of normal from varicose limbs. All the investigators used the same method of calculation of venous distensibility. Brakkee (1981) was the only one to maintain a constant environmental temperature during recordings, but none of the investigators quoted results of reproducibility studies. Van der Heyning-Meier

(1979 and 1981) gave descriptions of the method of venous distensibility measurement but no indication of the ranges of results to be obtained from normal subjects or those with venous disorders. Pointel et al (1981) measured venous distensibility in a large number of normal subjects but did not use a constant-temperature room for their recordings, and gave no figures for the reproducibility of their results. Venous distensibility results were found to differentiate well between normal subjects and patients with primary varicose veins by Pupita, Rotatori and Frausini (1981). These recordings were not made in a temperature-controlled room and again no reproducibility figures were quoted. A small study from Franco, Langeron and Harle (1981) showed a difference between the venous distensibility of subjects with primary varicose veins and those with post-thrombotic syndrome. However, the numbers studied were small, no normal subjects were studied, recordings were not made in a temperature-controlled room and no reproducibility experiments were performed.

It is very important in all venous investigations that reproducibility studies are performed as variations in venous tone may negate apparent differences between groups of subjects.

3.3 Deep Venous Disease

Following Homans' differentiation of lower limb ulceration into those due to simple varicose veins and the postphlebitic type (1916), and Edwards and Edwards (1937) demonstration of venous valve incompetence after venous thrombosis, Bauer described the characteristics of the post-phlebitic syndrome (1942) and recommended popliteal vein division as treatment for the symptoms of bursting calf pain (1948). Subjects with these symptoms required investigation by ascending phlebography to demonstrate the patency of the veins, retrograde or descending phlebography to assess the competence of the venous valves, and possibly dynamic phlebography which may show pooling of contrast in the soleal veins when other X-rays are normal (Ferreira, Villamil and Ciruzzi 1951; Lockhart-Mummery and Smitham 1951; Cockett 1953; Gryspeerdt 1953; DeWeese and Rogoff 1959; Arnoldi 1961 (a) and (b); Gullmo 1963). It was noted that there was a number of patients with symptoms of deep venous incompetence but without a history of deep venous thrombosis. These patients were found to have absent or incompetent deep venous valves, presumably as a congenital lesion (Moore 1951; Lodin and Lindvall 1961; Arnoldi 1964 and 1965 (a)).

Left iliac vein compression was also demonstrated by ascending phlebography, suggested as a reason why deep venous thrombosis is commoner in the left leg (Cockett and Thomas 1965) and an operation devised to relieve the compression (Trimble et al 1972). Phlebography has now come to be regarded as the definitive investigation in deep venous thrombosis (Lewis and Dale 1971; Nicolaides et al 1971; Thomas 1982), although there is an appreciable incidence of side effects from phlebography (Albrechtsson and Olsson 1976; Bettmann and Paulin 1977).

The mechanism by which the venous disease results in ulceration of the leg is still unresolved. Homans (1917) thought that stagnant blood in tortuous and dilated veins close to the skin resulted in tissue anoxia and cell death. De Takats (1929) found a lower oxygen tension in varicose veins than in the ante-cubital vein. However, Blalock (1929) showed that the oxygen tension was higher in the venous blood of legs with venous ulcers than that in normal legs, and this work has been confirmed by others (Holling 1938; Fontaine 1957). Thus, the concept of stasis producing anoxia is probably wrong.

Pratt (1949) and Brewer (1950) advanced the theory that arterio-venous anastomoses under the skin produced cell death by anaemic anoxia in venous ulceration. Evidence in favour of this theory is not very strong (Brewer 1950; Guis 1960; Haimovici, Steinman and Caplan 1966), and more recent investigations using radio-labelled microaggregates (Lindemayr 1972) have failed to confirm the existence of these shunts.

Browse and Burnand (1982) have proposed that venous ulceration is due to the deposition of an insoluble fibrin layer around the capillaries which prevents oxygen diffusion and leads to tissue anoxia. The fibrin layer forms from the leak of fibrinogen molecules through the widened interendothelial pores which result from high venous pressure causing distension of the capillary bed. Elevation of venous pressure has been shown to increase pressure in the capillary bed (Landis 1930) and increase capillary filtration (Pappenheimer 1948). Also, raised venous pressure is associated with an increase in the capillary bed in patients (Dodd and Cockett 1976; Burnand et al 1981) and in animal models (Burnand et al 1982). Interendothelial pores have been shown to stretch and fibrinogen to escape when the intraluminal pressure rises (Pietra et al 1969); and animal studies have shown an increase in lymph fibrinogen following femoral vein ligation (Leach and Browse 1981). These findings, combined with the results of treatment with fibrinolytic enhancement in venous ulceration (Browse et al 1977; Burnand et al 1980), lend support to this theory of ulcer formation in venous disease.

The majority of patients with deep venous incompetence can be managed by conservative measures, using support bandaging or stockings, possibly combined with injection sclerotherapy of associated varicosities (Boyd et al 1952; Hobbs 1977; Owens 1978). However, there are a number of patients whose symptoms persist despite these measures, and a number of surgical procedures have been described in order to relieve these patients. The problem in assessing the results of these procedures is that, with the small numbers of patients having operations, controlled trials comparing the results are not possible. Thus, much of the evidence in favour of any operation is anecdotal, with few reports including objective evidence of the results of treatment.

After his description of the post thrombotic syndrome, Bauer recommended division of the popliteal vein as treatment (1948). The purpose of the operation was to direct the venous return into anastomotic channels around the knee, and the results appeared satisfactory (Bauer 1950, 1955 and 1965; Arnoldi 1965 (a)), although this has not been a universal finding (Boyd et al 1952). Superficial femoral vein ligation has also been proposed, with a similar rationale to popliteal vein ligation, and it may be performed together with excision of all superficial veins (Linton and Keeley 1939; Glasser 1949; Dohn 1952; Linton 1952, 1953, 1977). Extensive superficial vein surgery has been recommended (De Palma 1974), however, calf vein surgery alone has not been of benefit in this syndrome (Burnand et al 1976; Hyde, Litton and Hull 1981).

The use of a cross-over long saphenous vein graft to bypass an occluded iliac vein was described in 1958 and appeared to produce good initial results (Palma and Esperon 1960). Studies in humans and animal models followed (Bryant, Lazenby and Howard 1958; DeWeese and Niguidula 1960; Dale 1965; Harris 1965; Dale and Harris 1968; Husni 1971; Dale 1979) without such satisfactory results, but the addition of a distal arterio- venous shunt for a few weeks post-operatively may improve the results (Dumanian et al 1968; Frileux, Pillot-Bienayme and Gillot 1972; Hiratzka and Wright 1978; Dale 1982). Bypass of an occluded superficial femoral vein using the long saphenous vein has not been as successful (Kunlin 1953; Dale 1961; Hardin 1962; Dale and Scott 1963; Baird et al 1964; Cerimo, McGraw and Luke 1964; Husni 1970 and 1971) and again temporary arterio-venous fistulas have been suggested to improve patency of the grafts (Levin et al 1971). Other operative treatments that have been recommended include interposition of a vein segment with a competent valve

(McLachlin et al 1965; Waddell et al 1967; Taheri, Lazar and Elias 1982), transposition of veins with incompetent valves into veins with competent valves (Kistner and Sparkuh 1979; Queral et al 1980), the restoration of competence to venous valves by suture (Kistner 1975, 1976; Jones, Elliott and Kerstein 1982) or external wrapping (Hallberg 1972) and use of muscle transfers to produce a "substitute valve" (Haeger 1968; Psathakis 1975).

The main lessons to be derived from these reports are the value of full preoperative investigation by ascending and descending phlebography, and pre- and post-operative follow up using one of the methods of venous investigation to objectively assess the results of any treatment (Boyd at al 1953; Dohn 1952; Boijsen and Eiriksson 1968; Husni 1970; Burnand et al 1977; Kistner 1980; Bergan, Flinn and Yao 1982; Schanzer and Peirce 1982 (a) & (b)).

4 MATERIALS AND METHODS

4.1 Experimental Conditions

All experiments took place in a room whose temperature was maintained between 33 and 35 degrees Centigrade by means of a Qualitair split-system air conditioning unit (model QSS 120H) which has a nominal cooling capacity of 12,000 British Thermal Units per hour and is fitted with a background heater. The thermostat fitted to the unit has a tolerance of plus or minus 1 degree centigrade.

During experiments on venous distensibility, subjects under investigation lay quietly on the couch with their legs exposed and strain-gauge attached, for twenty minutes prior to the commencement of any experiment. This time period allowed equilibration of the subject's limb temperature with the environment and the strain-gauge. The limb temperature was monitored during the experiments by means of a thermistor taped to the dorsum of the foot at the base of the hallux and attached to a two-channel reflectance galvanometer temperature recorder (Ellab instruments model TE3). A second thermistor attached to the wall of the laboratory, and connected to the same recorder, monitored the environmental temperature. All subjects were checked to ensure that their limbs had reached a steady state temperature before any experiments were started.

In the experiments using the ambulatory test, subjects again had a twenty minute period of equilibration, sitting quietly with their legs exposed with strain-gauge attached, before testing began.

In all investigations testing the reproducibility of results, experiments were performed at the same time on consecutive days.

4.2 Selection of Subjects

Subjects studied were either volunteers drawn from the hospital staff or patients attending the vascular clinic. Normal controls were subjects with no history or family history of venous disorders, who were otherwise healthy and had no abnormalities of the lower limbs on clinical examination. Patients selected for the venous distensibility studies had had no previous treatment of their varicose veins, no history suggestive of deep venous insufficiency and Doppler ultrasound studies demonstrated their deep veins to be patent.

The initial studies using the ambulatory test were confined to normal controls and patients with untreated, primary varicose veins. Later experiments were performed on patients with recurrent varicose veins and also on patients with symptoms suggestive of deep venous insufficiency.

Patients with a history suggestive of deep venous insufficiency and no evidence of arterial disease on examination were further investigated by both ascending and descending phlebography in order to demonstrate both the patency of the deep veins and the competence of their valves.

Altogether, 83 healthy controls and 340 patients with venous disease (285 with primary varicose veins) were examined.

4.3 The Plethysmograph

The plethysmograph used was the Janssen "Periflow" which uses a two-strand mercury-filled silastic tube as the strain-gauge. The gauges are of light weight, small diameter and high sensitivity (requiring a force of 0.5 grammes for a 1% elongation) and are supplied in a series of lengths which plug into the terminal of the input cable. A gauge is selected for each subject such that the two strands of the strain-gauge when placed around the calf and looped over the gauge-lock fitting in the input cable are a close-fit to the skin with minimum extension of the gauge.

There are two reasons why it is important to select an appropriate gauge for each subject. Firstly, there must be the least possible compression of the tissues beneath the gauge so that changes in calf girth will not be affected by tension in the gauge. Also, there is a linear relationship between electrical resistance and strain-gauge length up to 100% elongation of the gauge (Ensink and Hellige 1981 (a)). Thus, in order that the gauge may operate within this range, there must not be over-extension of the gauge when applied to the calf.

One of the strain-gauges used is shown in Figure 1 and the manner in which the input cable is attached to the calf by means of adhesive tape is shown in Figure 2. This method of attachment prevents distortion of the gauge by traction from the input cable.

The principle of strain-gauge plethysmography is that changes in limb volume will produce changes in the electrical resistance of the strain-gauge secondary to changes in the length of the gauge (Whitney 1949).

The electrical resistance (R) of the strain-gauge is given by the following formula:

$$R = \frac{l}{a} \times r$$

where l = length of mercury thread
a = cross-sectional area of mercury thread
r = specific electrical resistance of mercury

At a constant temperature, the mercury in the silastic tube has a constant volume, V.

$$V = l \times a$$

Therefore, substituting for a:

$$R = l^2 \times \frac{r}{v}$$

$\frac{r}{v}$ is a constant and hence the resistance of the mercury thread is proportional to the square of its length. Thus, changes in length of the strain-gauge will result in proportional changes in electrical resistance. Thus, the ratio of lengths of a strain-gauge may be calculated from the ratio of its corresponding resistances:

$$\frac{R_1}{R_2} = \frac{(l_1)^2}{(l_2)^2}$$

R_1 = resistance of mercury before variation of gauge length

R_2 = resistance of mercury after variation of gauge length

l_1 = length of mercury thread before variation of gauge length

l_2 = length of mercury thread after variation of gauge length

The length of the mercury thread does not exactly correspond to the calf circumference at the measurement site, due to the inextensible gauge-lock fitting. Depending on the gauge length selected, this inextensible portion makes up between 18% and 6% of the total circumference (see Figure 3 and Table 1) as the gauge is passed around the limb twice at the measuring site.

Fig. 1

THE STRAIN-GAUGE

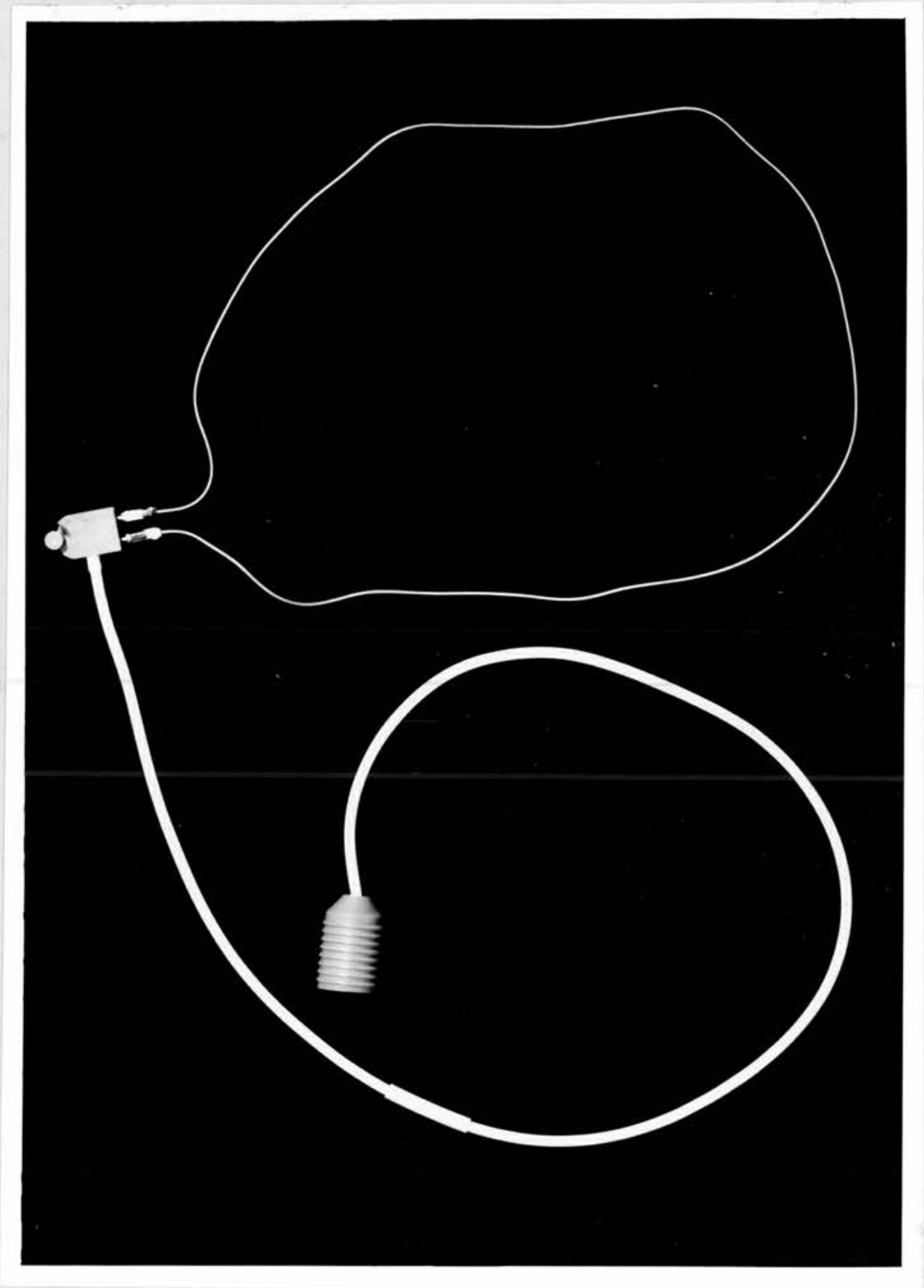


Fig.2

STRAIN-GAUGE ATTACHED TO CALF

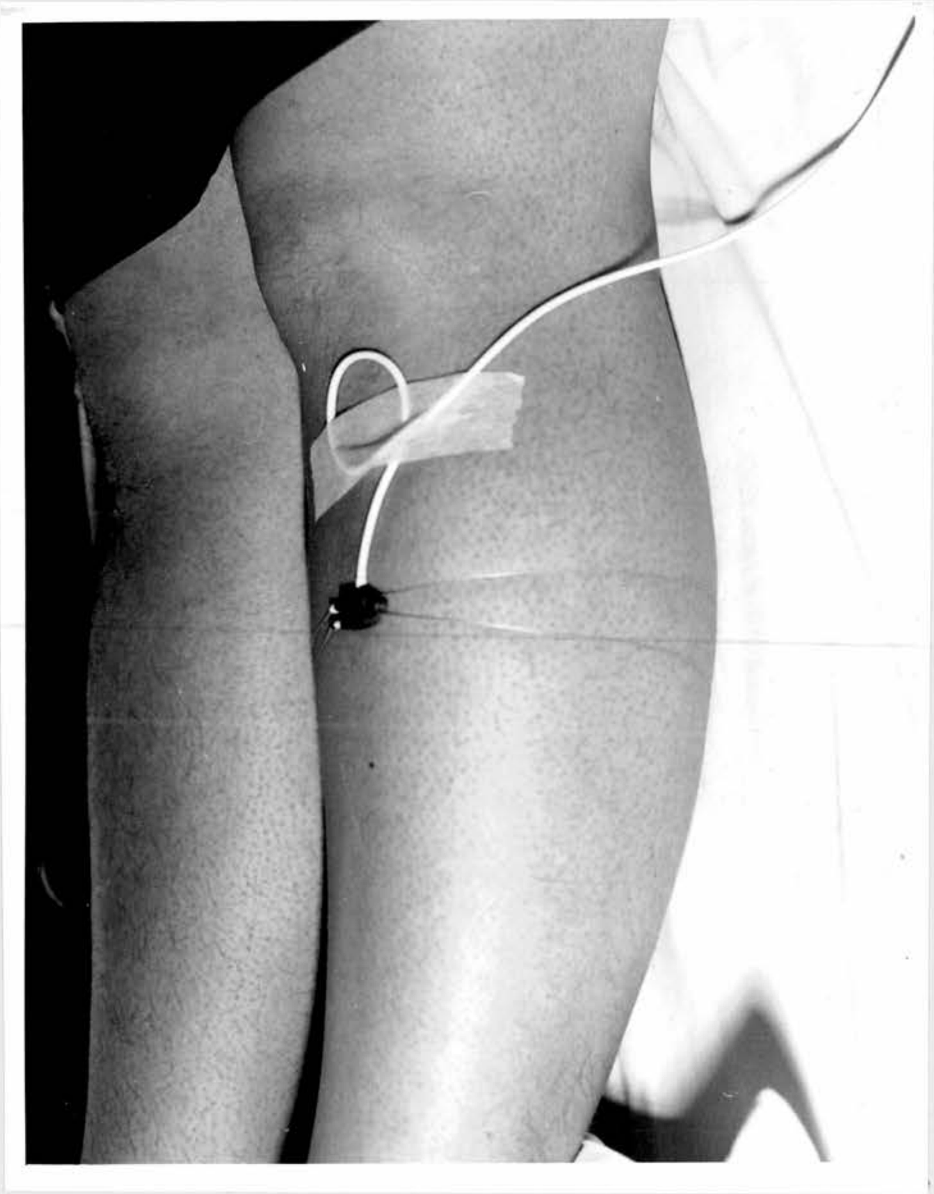


Fig. 3

Diagram to illustrate the inextensible portion of the strain-gauge.

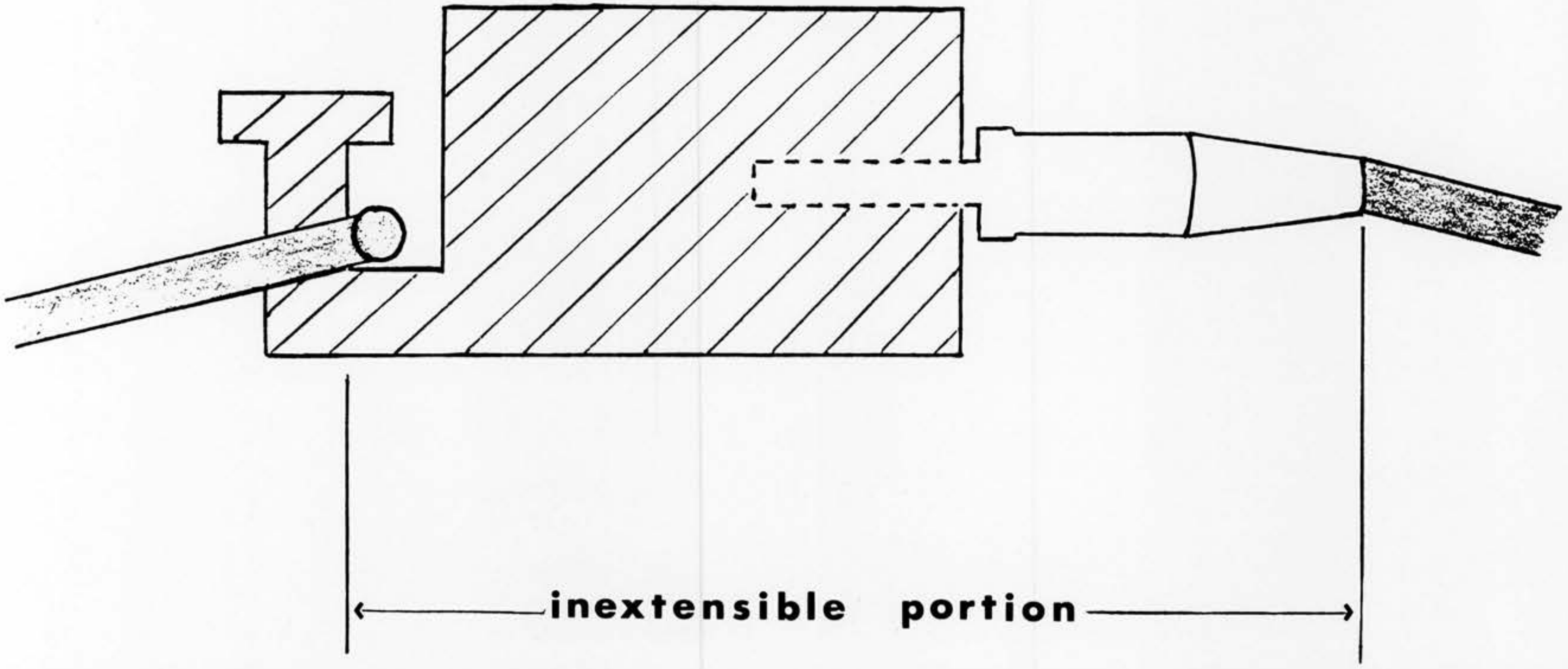
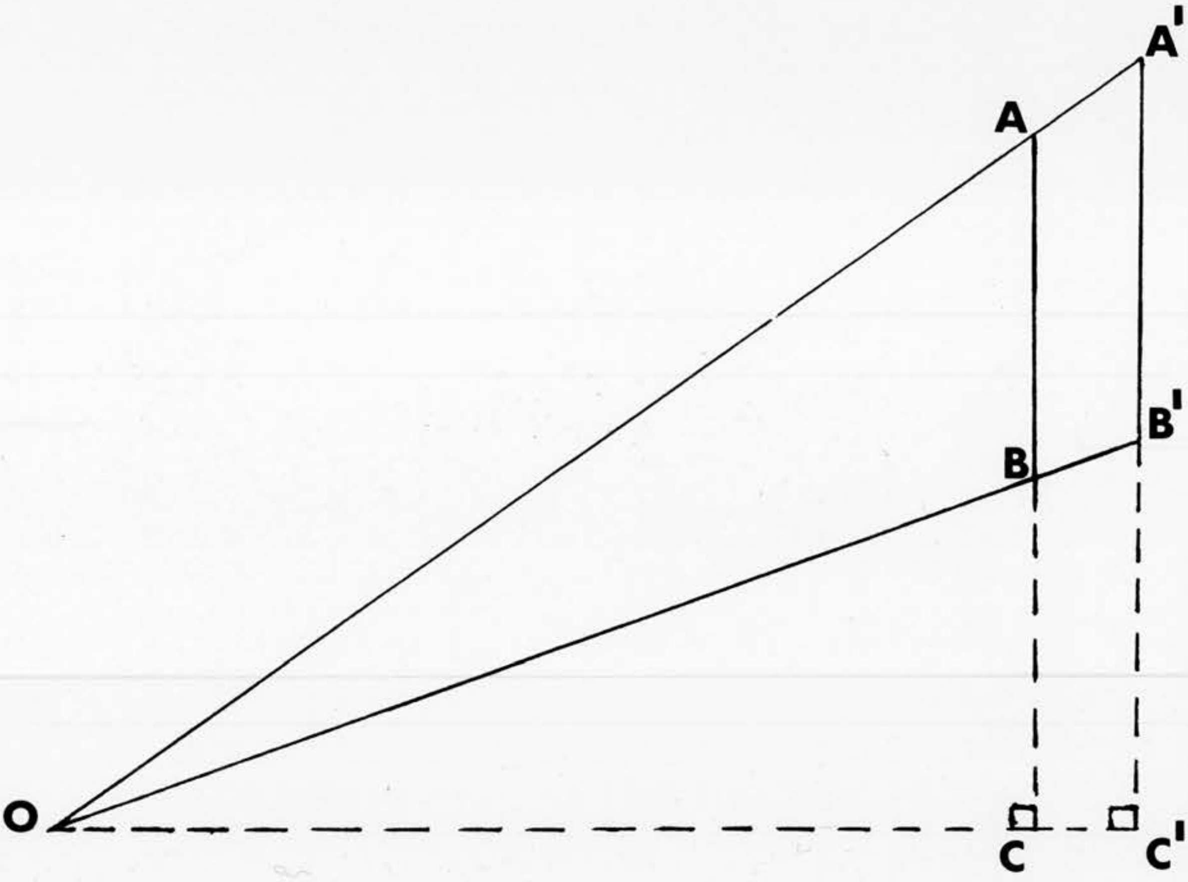


Fig. 4



The division of a transverse section of the limb into a large number of triangular segments (Whitney, 1953).

TABLE 1

strain-gauge length (cm)	length of extensible portion (cm)	minimum measurable circumference (cm)	percentage of inextensible part as % of minimum measurable circumference (%)
23	22	13.5	18.5
26	25	15.0	16.7
30	29	17.0	14.7
35	34	19.5	12.8
40	39	22.0	11.4
46	45	25.0	10.0
53	52	28.5	8.8
61	60	32.5	7.7
70	69	37.0	6.8
81	80	42.5	5.9

The circumference at any point on the limb has a definite mathematical relationship to the corresponding cross-sectional area. If the length of the limb remains constant, the change in volume will be directly proportional to the change in cross-sectional area. The cross-section is not circular, and so a specialised mathematical derivation is required to decribe the relationship between volume change and circumference change. Whitney (1953) considered the transverse section to be divided into a large number of triangular segments and that, with any increase in area, the shape of the segment remained the same.

Let the triangle OAB (Figure 4) be one such segment, and AB to be a small part of the circumference of the limb. An increase in area of the transverse section, without a change of shape, results in an increase of segment OAB to OA'B'. If the shape radii drawn from O must increase in the same proportion, ie.

$$\frac{AA'}{OA} = \frac{BB'}{OB} = k$$

From simple geometrical principles, A'B' is parallel to AB. Let AB and A'B' be produced to meet OCC' at right angles.

Geometrically: $\frac{A'B'}{AB} = \frac{OA'}{OA}$

$$\frac{OA'}{OA} = \frac{OA + AA'}{OA} = \frac{OA}{OA} + \frac{AA'}{OA} = 1 + k \qquad (1)$$

Thus, $A'B' = AB\ (1 + k)$ (2)

or $\frac{A'B' - AB}{AB} = k$

or $\frac{\text{increase in length of portion of circumference}}{\text{initial length of portion of circumference}} = k$ (3)

Similarly, $\frac{OC'}{OC} = \frac{OA'}{OA} = 1 + k$ - from (1)

Thus, $OC' = OC\ (1 + k)$ (4)

The formula for calculation of the area of a triangle = ½ base x height. The base of triangle OAB = OC and the base of triangle OA'B' = OC'.

The area of triangle $OA'B' = \frac{1}{2}OC'.\ A'B'$

From equations (2) and (4)

area of triangle $OA'B' = \frac{1}{2}OC(1 + k).AB(1 + k)$

or $\frac{1}{2}OC.AB\ (1 + k)^2$

$(1 + k)^2 = 1 + 2k + k^2$

If the increase in size of the section is small, then k^2 becomes very small.

Therefore $(1 + k)^2 \simeq 1 + 2k$

Thus, $\frac{1}{2}OC'.A'B' \simeq \frac{1}{2}OC.AB\ (1 + 2k)$

or $\frac{1}{2}OC'.A'B' \simeq \frac{1}{2}OC.AB + \frac{1}{2}OC.AB.\ 2k$

or $\frac{1}{2}OC'.A'B' - \frac{1}{2}OC.AB \simeq \frac{1}{2}OC.AB.2k$

or $\dfrac{\frac{1}{2}OC'.\ A'B' - \frac{1}{2}OC.AB}{\frac{1}{2}OC.AB} \simeq 2k$

Or $\dfrac{\text{The increase in area of the triangular segment}}{\text{The initial area of the triangular segment}} \simeq 2k$ - (5)

From equations (3) and (5) the proportionate increase in area of the segment is, to a close approximation for small proportionate area increases, equal to twice the proportionate increase of circumference of the segment.

If all the segments of the transverse section are summated, and an increase, dG, in the initial circumference, G, accompanies an increase, dH, in the initial area, H, then:

$$\frac{dH}{H} = 2 \qquad \frac{dG}{G}$$

to a close approximation for small values of dH.

Since, for uniform length of segment, $\frac{dH}{H} = \frac{dV}{V}$

if $\frac{dV}{V}$ is the proportionate increase in the volume of the segment.

Then $\frac{dV}{V} = \frac{2dG}{G}$ to a close approximation if dV is small compared with V.

Ensink and Hellige (1981) used a geometry constant which is different for the various cross-sectional shapes of the limb.

Thus, $C = g\sqrt{A}$

where C = circumference of extremity
A = cross-sectional area at point of measurement
g = geometry constant

Providing that the shape of the cross-sectional area remains the same during variation of the circumference and area, thus:

$$\frac{C'}{C} = \frac{\sqrt{A'}}{\sqrt{A}}$$

(the geometry coefficient being the same before and after variation of the area).

Where C = initial circumference of limb
C' = new circumference of limb
A = initial area at level of measurement
A' = new area at level of measurement

Assuming the limb to be of constant length, then,

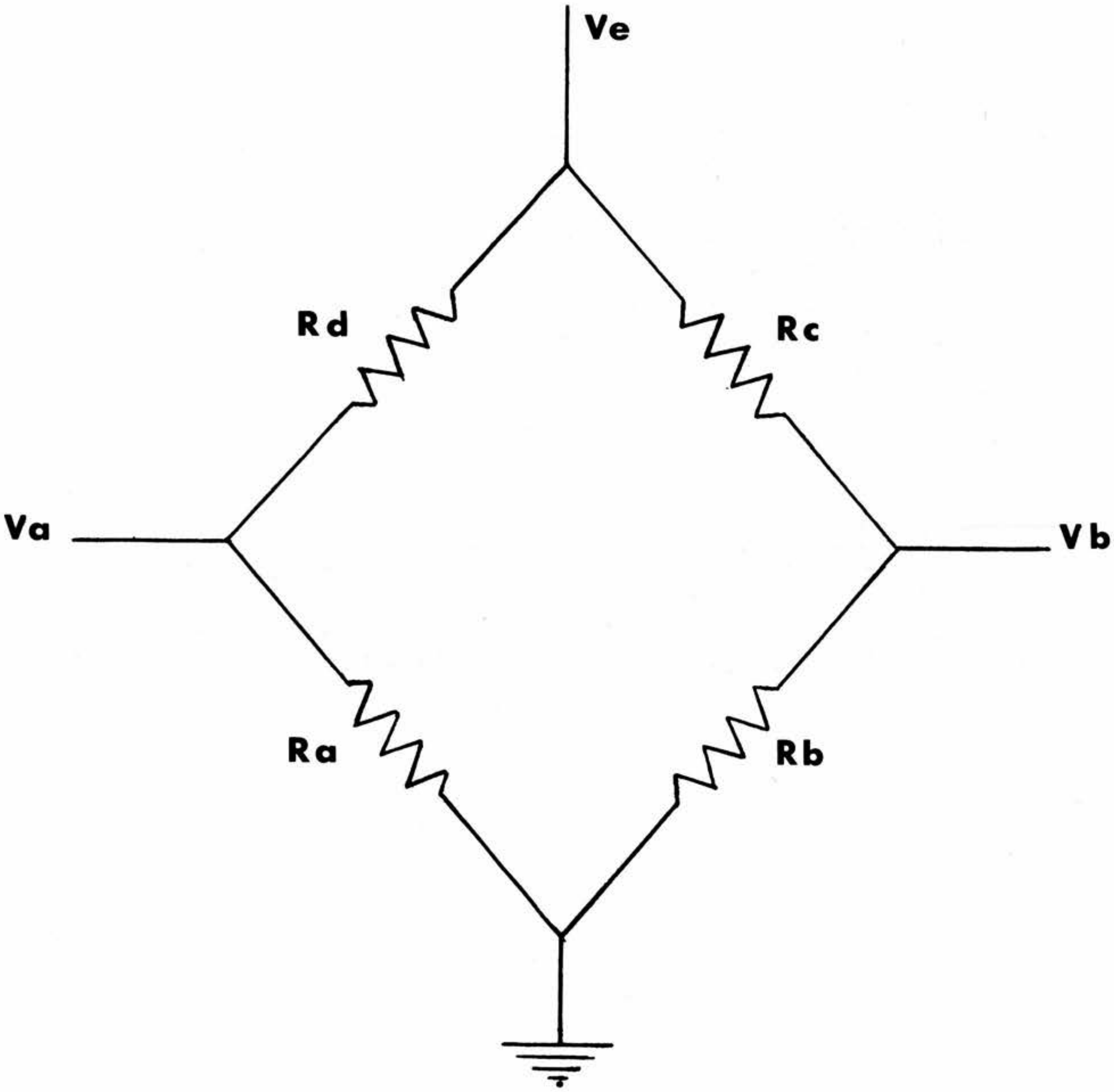
$$\frac{C'}{C} = \frac{V'}{V}$$

Where V = initial limb volume
V' = new limb volume

Hence, changes in limb volume will produce proportional changes in limb circumference which will result in resistance changes in the mercury strain-gauge. Whitney (1953) used a Wheatstone bridge circuit to measure the changes in resistance (Figure 5).

Fig. 5

The Wheatstone Bridge Circuit.



In figure 5, the three resistances, Ra and Rb are known and constant and Rc is a variable resistance. Electrical balance is achieved when

$$\frac{Rd}{Ra} = \frac{Rc}{Rb}$$

Thus, the unknown resistance, Rd, can be calculated by use of the variable resistance, Rc.

However, using this type of circuit, the equipment must be recalibrated whenever the length of the mercury strain-gauge is changed.

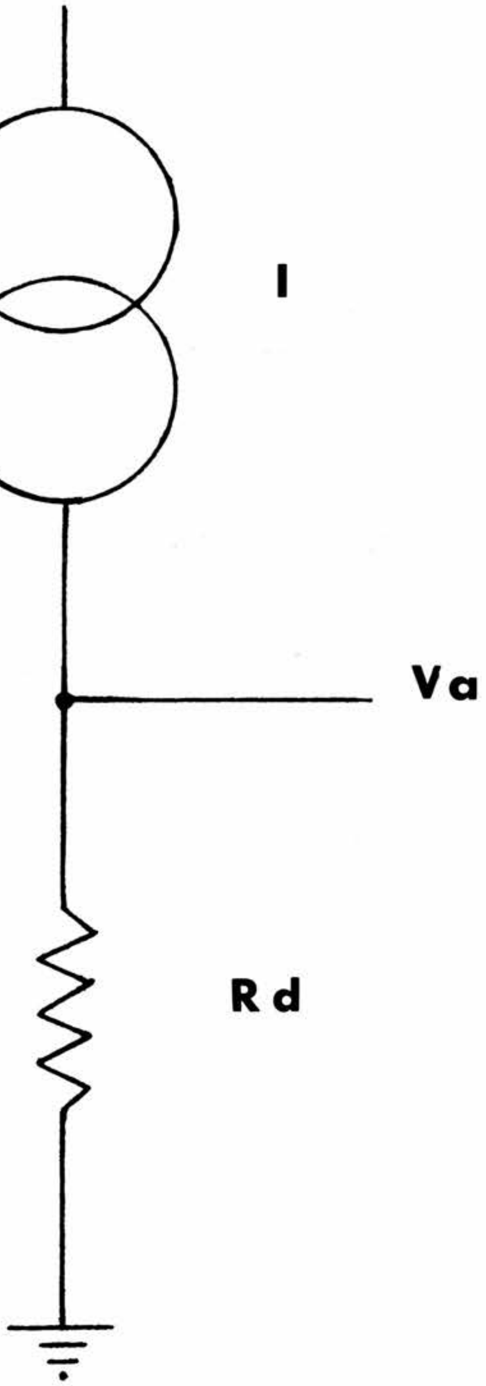
The circuit used in the "Periflow" is a modification of the constant current source method of measurement of a variable resistance (Figure 6).

This system gives a linear relationship between voltage and resistance, but different strain-gauge lengths give different voltage changes for the same percentage strain-gauge length change. Therefore, an automatic calibration circuit is added, which changes the current source for each strain-gauge to produce a voltage drop of 125 millivolts (mv) across the resistance of the initial strain-gauge length. Thereafter, the current source remains constant and so the same percentage strain-gauge length changes will produce the same voltage changes despite the differences in initial length of the strain-gauges (Baten 1979).

The mercury gauge amplifier input cable has independent current-carrying leads and voltage-sensing potential leads in order to eliminate errors in volume change due to the resistance of the lead wire.

Fig. 6

Constant Current Circuit with Variable Resistance.



$Va = I \times Rd$

Environmental temperature changes can cause errors in measurement, and Whitney (1953) incorporated compensating resistances into the measuring bridge in order to try to overcome this problem. However, this makes the circuitry considerably more complicated.

Temperature changes will change the cross-sectional area of the strain-gauge and also have an effect on the specific resistance of the mercury. If the temperature increases, the mercury will expand and so will increase the cross-sectional area of the gauge, as the length of the gauge remains constant. This may be expressed as follows:

$$\frac{dR}{R} = \frac{-\gamma \ dT}{1+\gamma \, dT}$$

Where dR = change in resistance
R = original resistance
dT = change in temperature
γ = coefficient of thermal expansion
(18.1×10^{-5} degree centigrade $^{-1}$)

Thus, temperature variation will imitate a limb volume variation of approximately 0.018 percent per degree Centigrade by its effect on the cross-sectional area of the gauge.

However, temperature change has the opposite effect on specific resistance to that on cross-sectional area.

Hence, $\frac{dR}{R} = \alpha \, dT$

Where α = temperature coefficient of specific resistance.
(0.99×10^{-3} degree Centigrade $^{-1}$)

This will cause a limb volume variation of approximately 0.1 percent per degree Centigrade in the opposite direction from the effect on cross-sectional area.

Thus, the two sources of error will tend to cancel each other out, and will be negligible as the temperature variation during the recordings is very small. As the mass and specific heat of the mercury in the strain-gauge are low, then the temperatures of the limb and strain-gauge quickly equilibrate. Once this equilibration has occurred then any errors induced by temperature change will be negligible (Ensink et al 1981). Therefore, as the temperature of the room was maintained at a constant level, no other specific precautions were taken to prevent errors due to temperature changes.

The chart recorder of the "Periflow" plots the changes in electrical resistance of the strain-gauge as volume change in ml/100ml. However, from the foregoing discussion, although limb volume changes will produce proportional changes in electrical resistance it is inaccurate to plot the resistance changes directly as ml/100ml. The reason for this is that different portions of the calf circumference contribute different amounts to the total calf circumference, with the area over the subcutaneous portion of the tibia changing least. This phenomenon was well demonstrated by Knox et al (1982) using three separate strain-gauges distributed around the calf circumference. Consequently, the results obtained are recorded as percentage change in limb girth (dL) whose unit is percent (%), after Zicot, Parker and Caro (1977).

The speed of the chart recorder was 2.5 centimetres per minute (cm/min).

4.4 The Measurement of Venous Pressure

Venous pressure recordings were obtained from a 19G "butterfly" needle (internal diameter 0.8 millimetres) inserted percutaneously into the long saphenous vein at the ankle. Prior to insertion of the needle, the proposed puncture site was infiltrated with 0.25 millilitres (ml) of 1% w/v lignocaine hydrochloride. Initial studies had shown that cannulation of the long saphenous vein without anaesthesia was associated with considerable discomfort to the subject. The needle was securely positioned, using adhesive tape, and connected via polythene tube (internal diameter 2mm) containing 0.9% saline solution with added heparin (1 International unit (I U) /100ml) to a pressure transducer (Bell and Howell model 4-3271) via a three- way tap. The third outlet of the tap was connected to a reservoir 500ml bag of 0.9% saline with heparin (1 I U /100ml) in order to allow flushing of the tubing between experiments.

Pressure changes were relayed from the transducer via an amplifier to a separate channel on the chart recorder of the plethysmograph. This allowed simultaneous recordings of pressure and limb girth changes to be displayed on the same chart.

Before each set of experiments, the transducer was calibrated against a mercury sphygmomanometer. The venous pressure was recorded in millimetres of mercury (mmHg) (1 Kilopascal (KPa) = 7.5mmHg).

The pressure transducer was positioned with its diaphragm level with the upper border of the medial malleolus during studies of venous distensibility, and level with the strain-gauge at mid calf height during studies involving the ambulatory test.

4.5 The Use of the Doppler Ultrasound Probe

The equipment used was a Sonicaid BV 380 which has a 5 Hertz probe (5mm diameter) and changes in blood velocity were demonstrated by audible changes in the sound from the loudspeaker in the equipment.

Subjects were examined whilst standing with their body weight supported by the non-examined limb and with the limb being examined slightly flexed at the knee, in order to relax the calf muscles.

The probe was positioned over the common femoral vein, the sapheno-femoral junction and varicosites elsewhere in the limb. The direction of blood flow was demonstrated during compression and release of the relaxed calf. The presence of retrograde flow on release of the calf demonstrated incompetence of the venous valve, and the site of maximum reflux sound was used to localise incompetent perforating veins. Also, the presence of normal antegrade flow in the common femoral vein after calf compression was suggestive of deep venous patency, but the ultrasound probe was not found to be of value in the detection of deep venous incompetence.

4.6 Phlebography

The contrast medium used for all the phlebograms was meglumine iothalamate (Conray 280) and a volume of 50 ml was used for each examination.

During ascending phlebography, the superficial veins were occluded by tourniquets at the ankle and above the knee, the patient lying supine on the X-ray couch which had a slight head-up tilt. Contrast was injected via a 19G or 21G butterfly needle inserted into a dorsal foot vein. The passage of the contrast up the leg was continuously monitored and films were taken of the soleal plexus, popliteal region, thigh and iliac veins. The two tourniquets were released and manual calf compression applied when the iliac veins were examined. The ascending phlebogram was used to demonstrate the anatomy and patency of the deep veins of the leg, attempts to demonstrate valvular function in the deep veins by this technique were unsuccessful.

Thus, subjects with patent but possibly incompetent deep veins had descending phlebography performed to demonstrate the competence of the valves in the deep veins. The technique used was to introduce a cannula via a Seldinger technique into the proximal external iliac vein after infiltration of the skin over the common femoral vein with 3-5ml 1% lignocaine hydrochloride. The patient was supported in the nearly-vertical position on the X-ray table whilst the contrast was injected and the patient performed a Valsalva manoeuvre. On screening, contrast could be seen passing distally through incompetent valves as a continuous column as distinct from the minor amount of reflux occasionally seen through normal valves. The descending phlebogram was deemed to show deep venous incompetence if the column of contrast passed into the popliteal vein without hold-up at a valve. Using this technique, there was no problem in differentiating patients with and without deep venous incompetence. Also, it was felt that the descending phlebogram was a more physiological test of deep venous function as the X-rays were performed with the subjects in the position in which they experienced their symptoms.

4.7 Statistics

Calculation of correlation coefficients, coefficients of variation and two sample t test all calculated according to the methods described by Armitage (1971). The value of p taken to indicate significance was .05

4.8 Measurement of Venous Distensibility

The subjects lay supine on a couch with a strain-gauge attached around the maximum calf circumference and a 10cm wide pneumatic cuff applied around the thigh with its lower border 15cm proximal to the upper border of the patella. The subjects' ankles were supported at a height sufficient to keep their calves clear of the couch. Following a period of 20 minutes rest for equilibration, measurements of percentage girth change were recorded during four successive inflations of the cuff to 30,50,70 and 90mmHg (4, 6.6, 9.3 and 12 KPa). The pneumatic cuff provided a very rapid cuff inflation (1 second) and the cuff was maintained at each pressure until there had been no girth change for 30 seconds. The cuff was then rapidly deflated to zero and the girth allowed to return to the resting level for 30 seconds before the cuff was inflated to the next pressure.

Toe temperature was monitored via a thermistor attached to the base of the hallux and this temperature remained constant during the readings.

The maximum girth increase (% x 50) at each cuff pressure was then plotted against the inflation pressure of the cuff and the slope of the line was called the venous distensibility index (V D I). Veins which are easily distensible will have larger percentage girth changes and a larger VDI.

This method of calculation of venous distensibility has been described by other workers (Pupita, Rotatori and Frausini 1981; Franco, Langeron and Harle 1981) who have found it to be useful in the investigation of venous disease. This is despite the fact that the calf girth changes recorded actually measure the distensibility of a cross-section of the whole limb.

Figure 7 is a photograph of the experimental set-up to show the placing of the strain-gauge, pneumatic cuff and thermistor.

An illustration of a tracing obtained in this manner from a normal subject is shown in Figure 8. The recording shows the thigh cuff pressures and corresponding calf girth changes, and the method of measurement of the maximal calf girth increases. The calf girth increase corresponding to a thigh cuff inflation pressure of 90mmHg has been superimposed on the recordings at the lower cuff pressures, after adjustment of the baseline. This procedure was necessary in all distensibility recordings in order to fit all the measurements for each subject on to one chart. Alteration of the baseline does not affect the calibration of the strain-gauge, nor the percentage calf girth change occuring secondary to the thigh cuff inflation. This illustration also shows the calibration used for all distensibility measurements in which a vertical deflection of 2.5cm in the calf girth recording is equivalent to a 1% change in strain-gauge length. In order to calculate the V D I, the maximal calf girth increase (% x 50) at each cuff pressure is measured from the recording and plotted against the thigh cuff pressure (Figure 9). The large numbers obtained may give a false impression of the size of the percentage calf girth increases. In fact, the actual percentage calf girth increases may be obtained by dividing the results for the maximal calf girth increases by 50 (as the strain-gauge is doubled around the calf) and lie within the range of 0.5% to 5.5%. Therefore, the percentage calf girth changes at each cuff pressure are relatively small, and there are only small differences between the results obtained at each cuff pressure. These differences are magnified by the use of the recorded calf girth increases and may be partly responsible for the production of the excellent straight lines obtained on the graphs for the calculation of the V D I's.

It is important to ensure that the girth increase has reached its maximum following each thigh cuff inflation before the cuff is deflated. The reason for this is that, after an initial rapid increase in calf girth, there is a period of slower girth increase before a plateau occurs. This phenomenon is more noticeable at higher cuff inflation pressures. Therefore, an interval of 30 seconds is allowed to elapse after the girth has ceased to increase after each cuff inflation before the cuff is deflated. This ensures that the maximum calf girth increase is measured at each cuff inflation pressure.

The purpose of this study was to compare the venous distensibility results obtained by this method from normal subjects and patients with varicose veins. A series of preliminary experiments was first performed to determine the most suitable conditions for distensibility recordings. These conditions were then used for further experiments to assess the reproducibility of the results.

Fig. 7

APPARATUS FOR VENOUS DISTENSIBILITY MEASUREMENTS

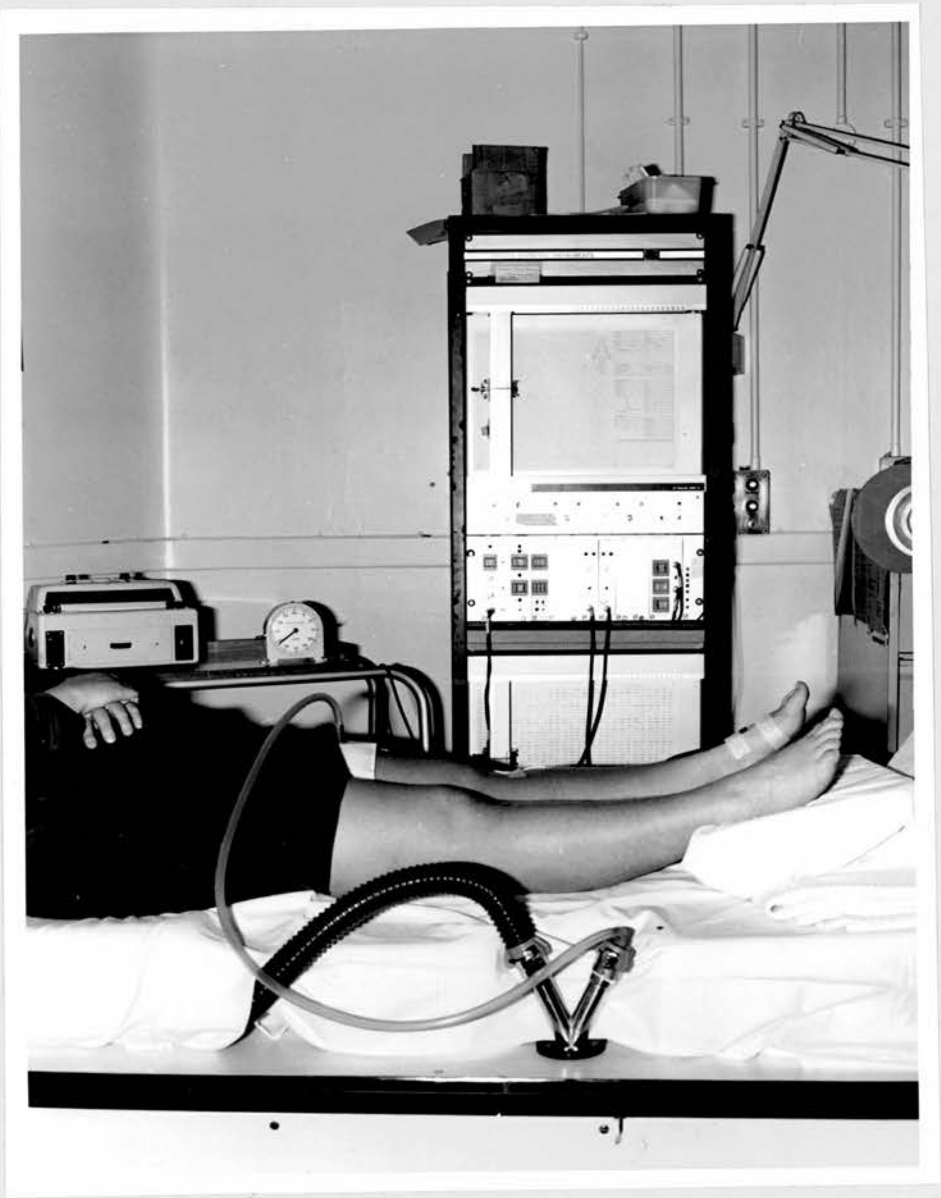
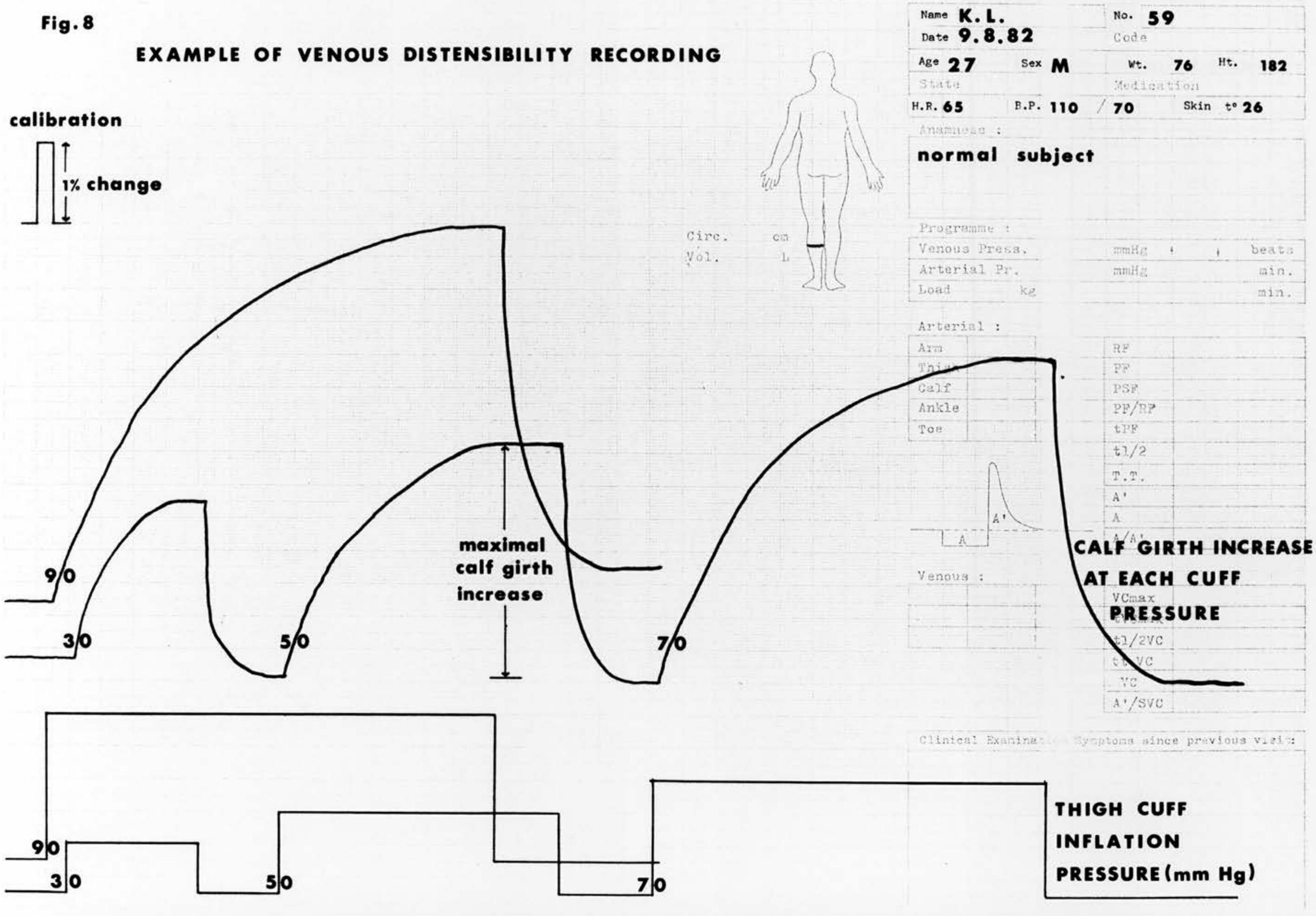


Fig. 8

EXAMPLE OF VENOUS DISTENSIBILITY RECORDING



Name **K. L.**
Date **9.8.82**
No. **59**
Code
Age **27** Sex **M** Wt. **76** Ht. **182**
State
Medication
H.R. **65** B.P. **110 / 70** Skin t° **26**
Anamnesis :
normal subject

Fig. 9

CALCULATION OF VENOUS DISTENSIBILITY INDEX

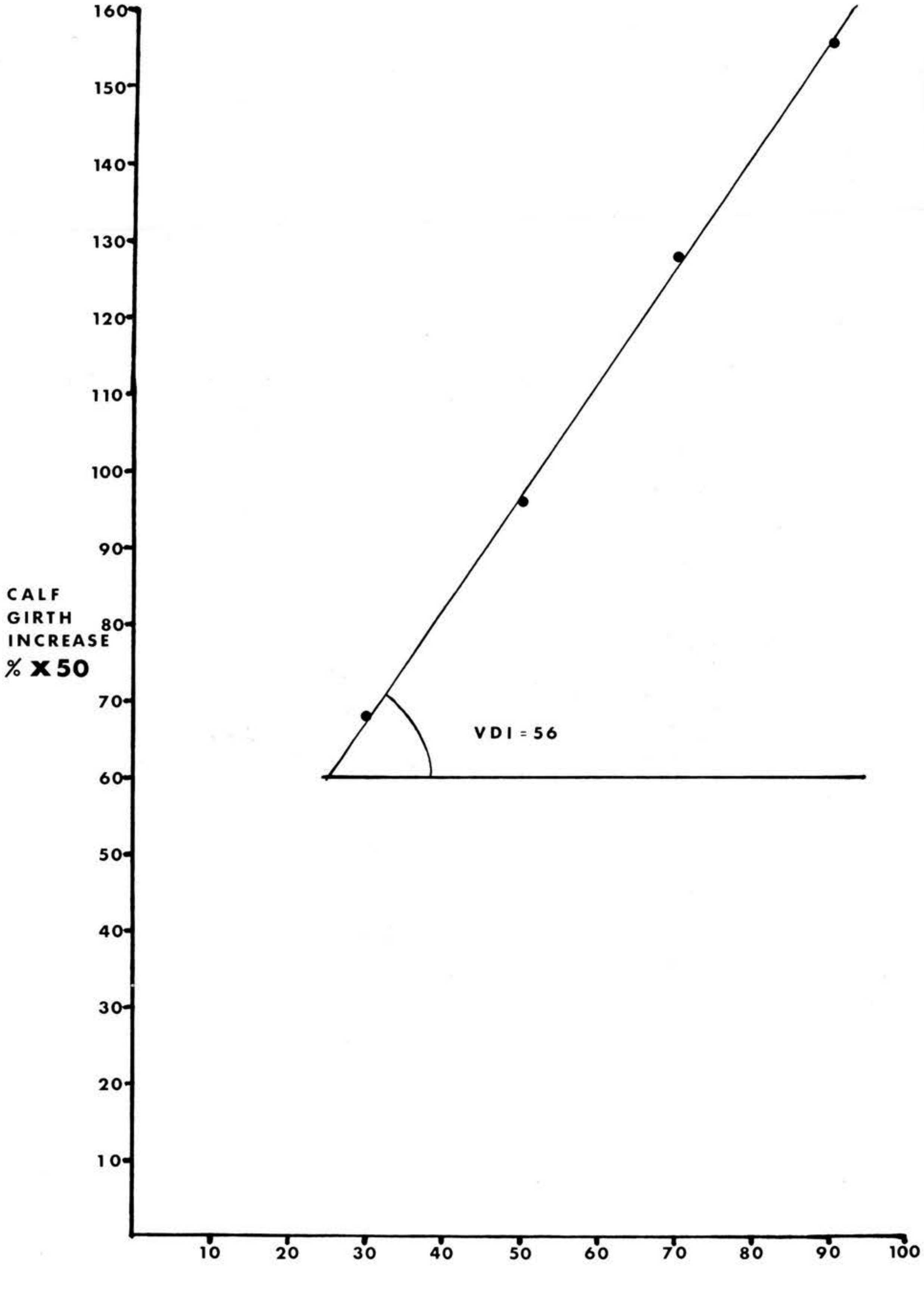
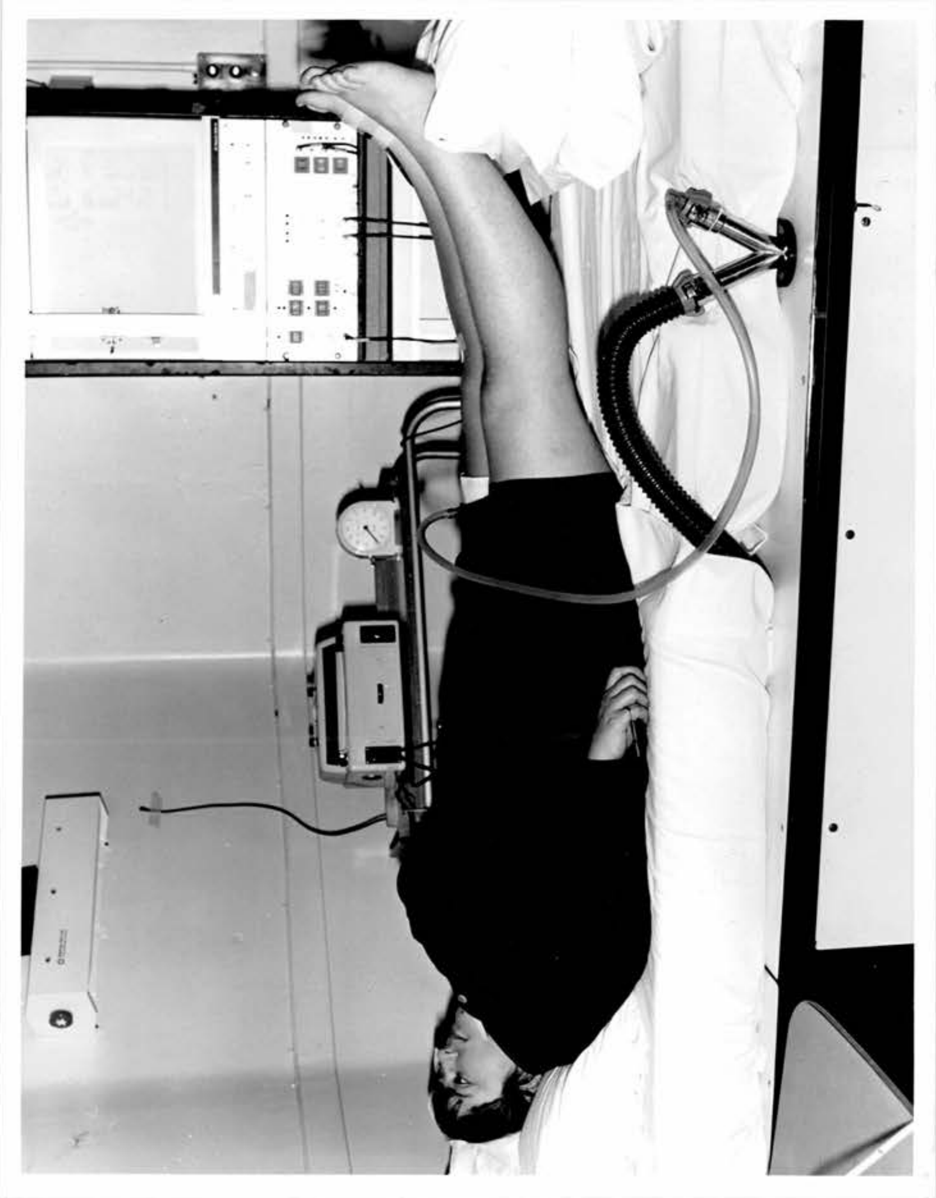


Fig. 10

RECORDING WITH LEGS ELEVATED



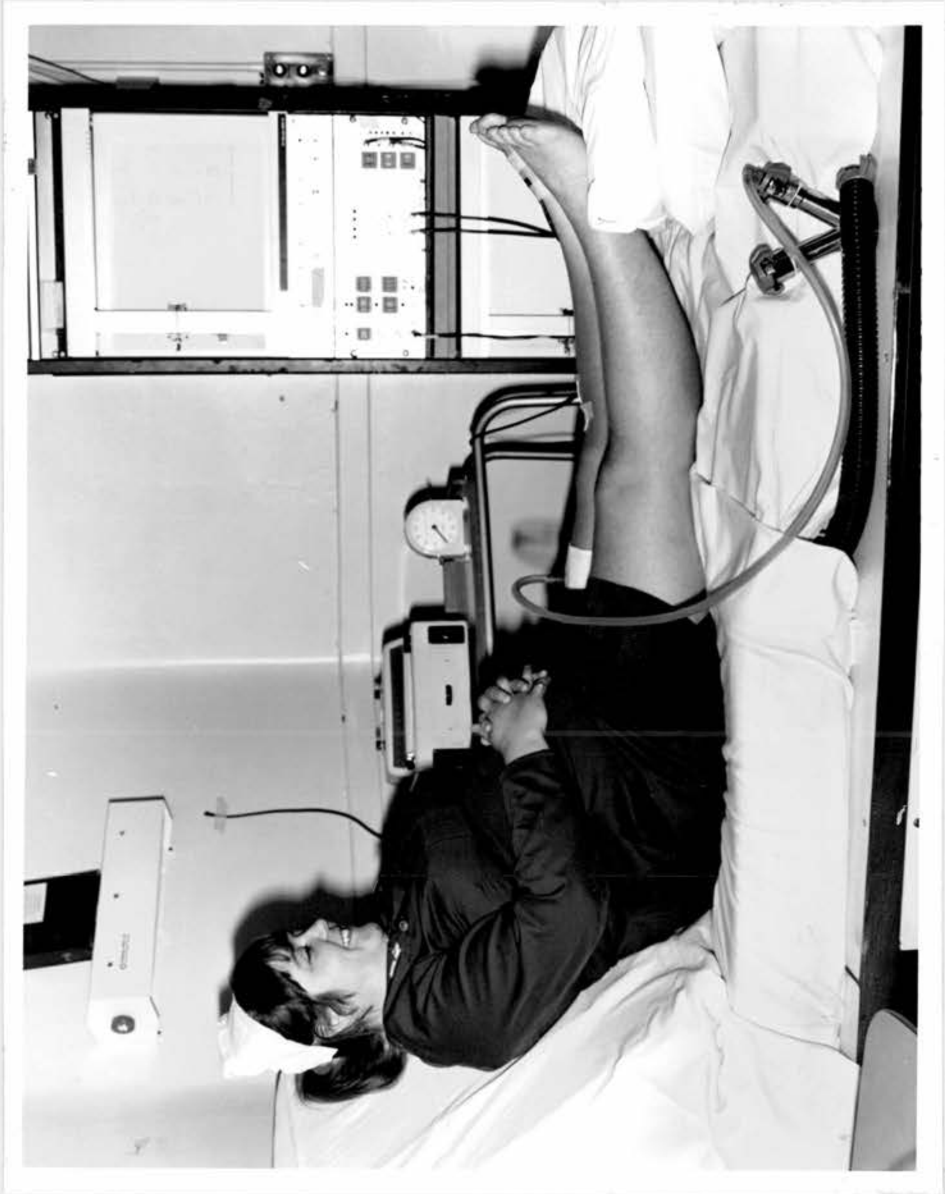


Fig. 11

RECORDING WITH SUBJECT SEATED

4.9 Preliminary Venous Distensibility Experiments

4.9.1 Effect of Variation in Strain-Gauge Position

5 normal subjects (1 male and 4 females, age range 23-30 years, mean 25.6 years) and 5 patients with varicose veins (2 males and 3 females age range 22-31 years, mean 26 years) had measurements of venous distensibility performed with the strain-gauge positioned at points 2.5, 5, 7.5 and 10cm distal to the lower border of the tibial tubercle and also around the ankle immediately proximal to the upper border of the medial malleolus.

4.9.2 Effect of Changes in Body Position

16 normal subjects (7 males and 9 females age range 22-43 years, mean 29.3 years) and 30 patients with varicose veins (11 males and 19 females age range 22-72 years, mean 46.4 years) had recordings made whilst the subjects lay supine with their calves supported clear of the couch and level with their hearts (Fig 7), and were repeated with the calves 15cm above this position (Fig 10). Further recordings were made with the subjects sitting upright, but with their calves supported horizontally (Fig 11).

4.9.3 Effect of Local Temperature Changes

Recordings were made from 6 normal subjects (3 males and 3 females age range 23-33 years mean- 28 years) in order to assess the effect of local changes in temperature on the V D I.

For this series of experiments, the subjects' ankles and lower calves were enclosed in a thermostatically-controlled electric blanket (Boots electric heating pad), but the toes and thermistor were left exposed (Fig 12). A period of 20 minutes equilibration was allowed at each temperature setting of the blanket before any recordings were made, to ensure that the temperature remained constant at each level during the measurement of changes in calf girth.

Recordings were made with the toe temperature constant at 28, 30, 32, 34 and 36°C and the V D I's calculated for each subject at each of the temperatures.

4.10 Venous Distensibility Recordings from Normal and Varicose Vein Subjects

The V D I's were calculated for 20 normal subjects (10 males and 10 females, age range 23-43 years, mean 29.1 years) and 20 subjects with varicose veins (10 males and 10 females, age range 22-45 years, mean 29.75 years). All recordings were made with the subjects supine with their calves supported clear of the couch and level with their hearts. The toe temperature of the subjects varied between 25.5°C and 26.8°C at the time of the recordings.

Apart from the presence of varicose veins, all subjects were healthy and none had a past history of venous thrombosis or arterial disease. In addition, none had skin ulceration or clinically detectable evidence of varicose eczema and their varicose veins were all associated with sapheno-femoral incompetence.

The results obtained from these subjects showed no significant difference between the mean V D I's of the two groups. Therefore, a further group of 47 patients with primary varicose veins (21 males and 26 females, age range 26-72 years, mean 48.2 years) were subdivided into 4 groups according to the severity of their varicose veins, and studied. The first group contained 10 patients (4 males and 6 females, age range 22-39 years, mean 30.3 years) with unilateral varicose veins affecting the long saphenous system, but without skin changes, and with no clinical or Doppler ultrasound evidence of varicose veins in the apparently normal leg. These subjects had recordings taken from both legs, and the results from the normal legs comprised one group for comparison with the control subjects. The results from the 10 legs with varicose veins were combined with results obtained from 10 subjects with bilateral varicose veins (5 males and 5 females, age range 24-56 years, mean 37.8 years) associated with sapheno-femoral incompetence, but without skin changes. This latter group of subjects had their recordings made from the clinically worse-affected leg.

A further 20 patients with varicose veins (8 males and 12 females, age range 33-72 years, mean 58.7 years) associated with skin changes and ulceration were similarly studied. These patients had sapheno-femoral incompetence and below-knee perforator incompetence, but no history of deep vein thrombosis.

Another 7 patients (3 males and 4 females, age range 26-71 years, mean 48.2 years) with varicose veins secondary to below-knee perforator incompetence but with no evidence of sapheno-femoral incompetence also had their V D I's calculated.

The results from each of the four groups of subjects were compared with those from the normal subjects, to see if measurement of venous distensibility could be used to differentiate between subjects with and without varicose veins, and whether differences in distensibility were related to the severity of the varicose veins.

Fig. 12

RECORDING WITH A VARIABLE TEMPERATURE

ELECTRIC BLANKET

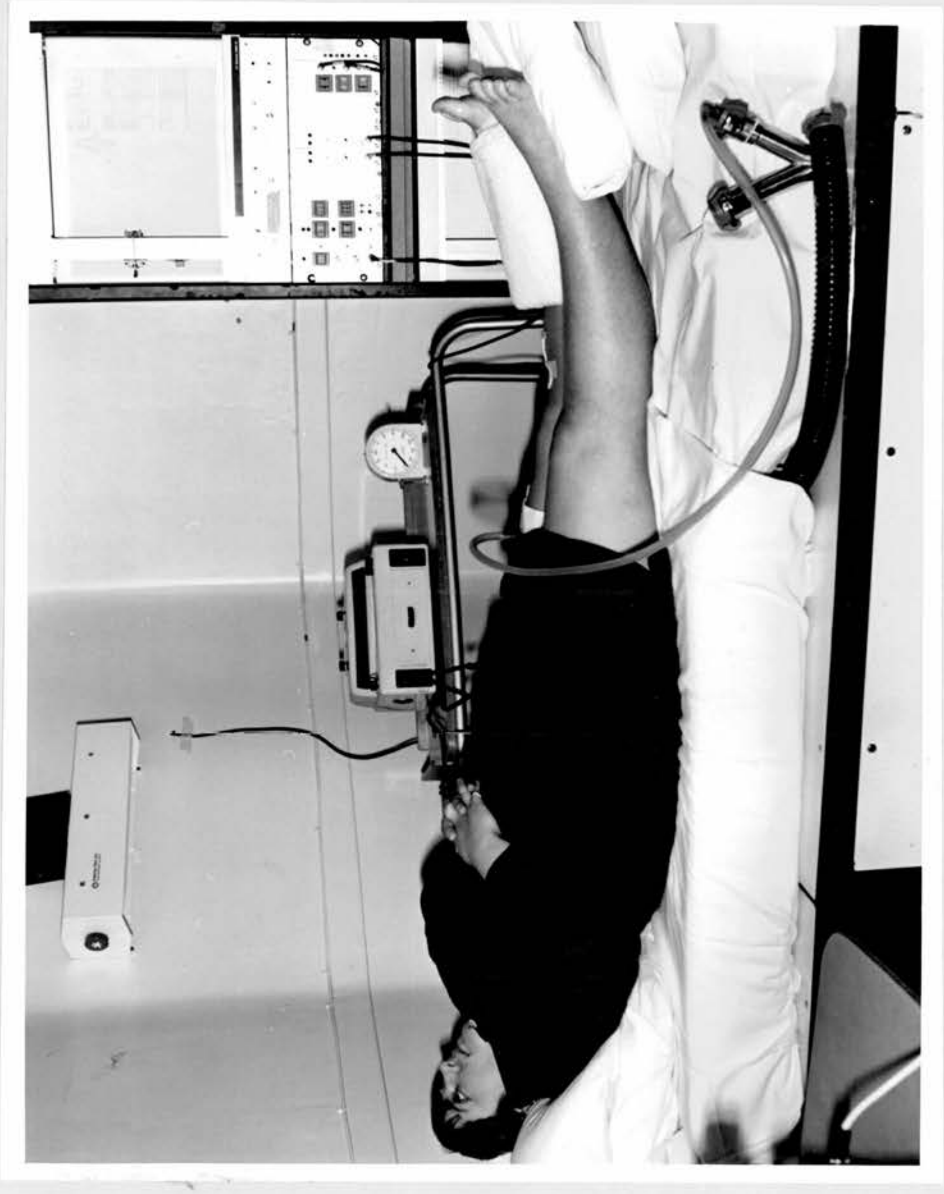


Fig. 13

SIMULTANEOUS VENOUS PRESSURE AND CALF GIRTH MEASUREMENT

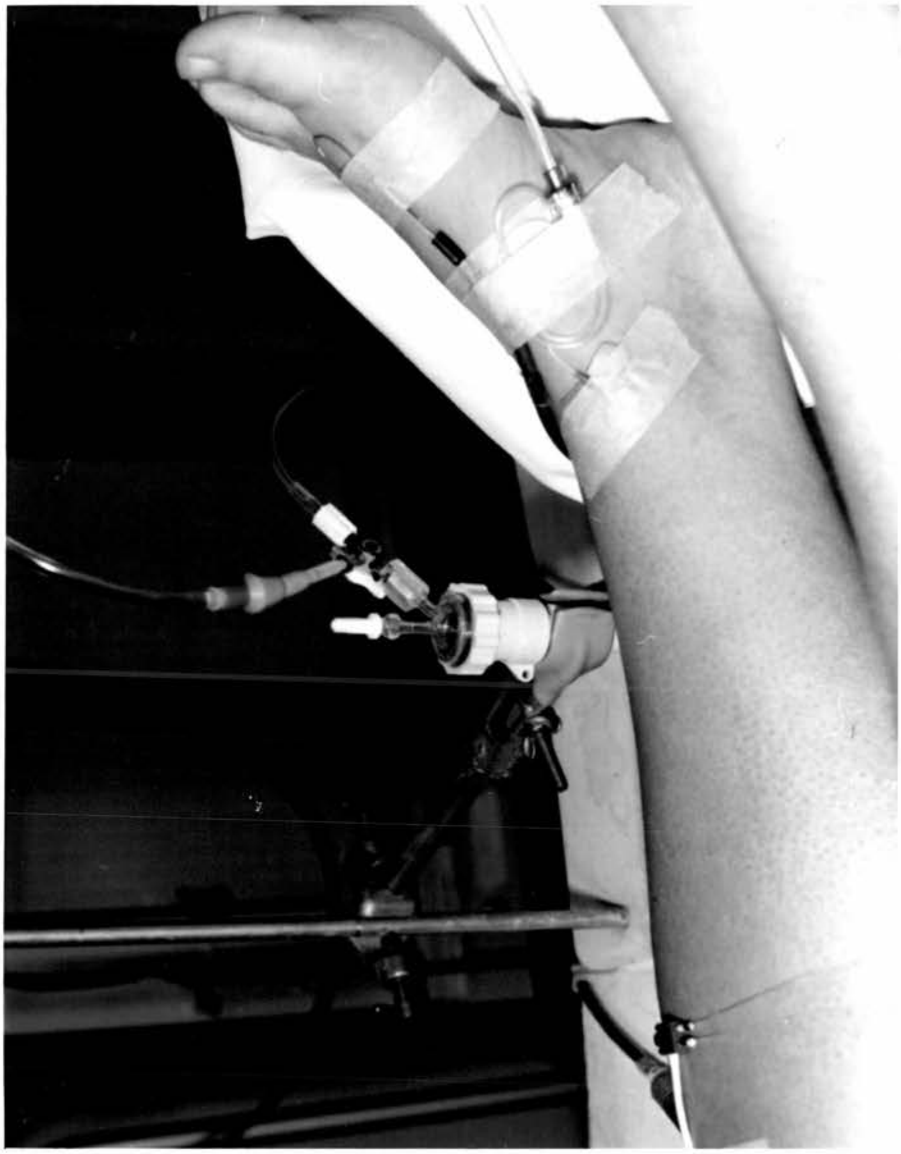
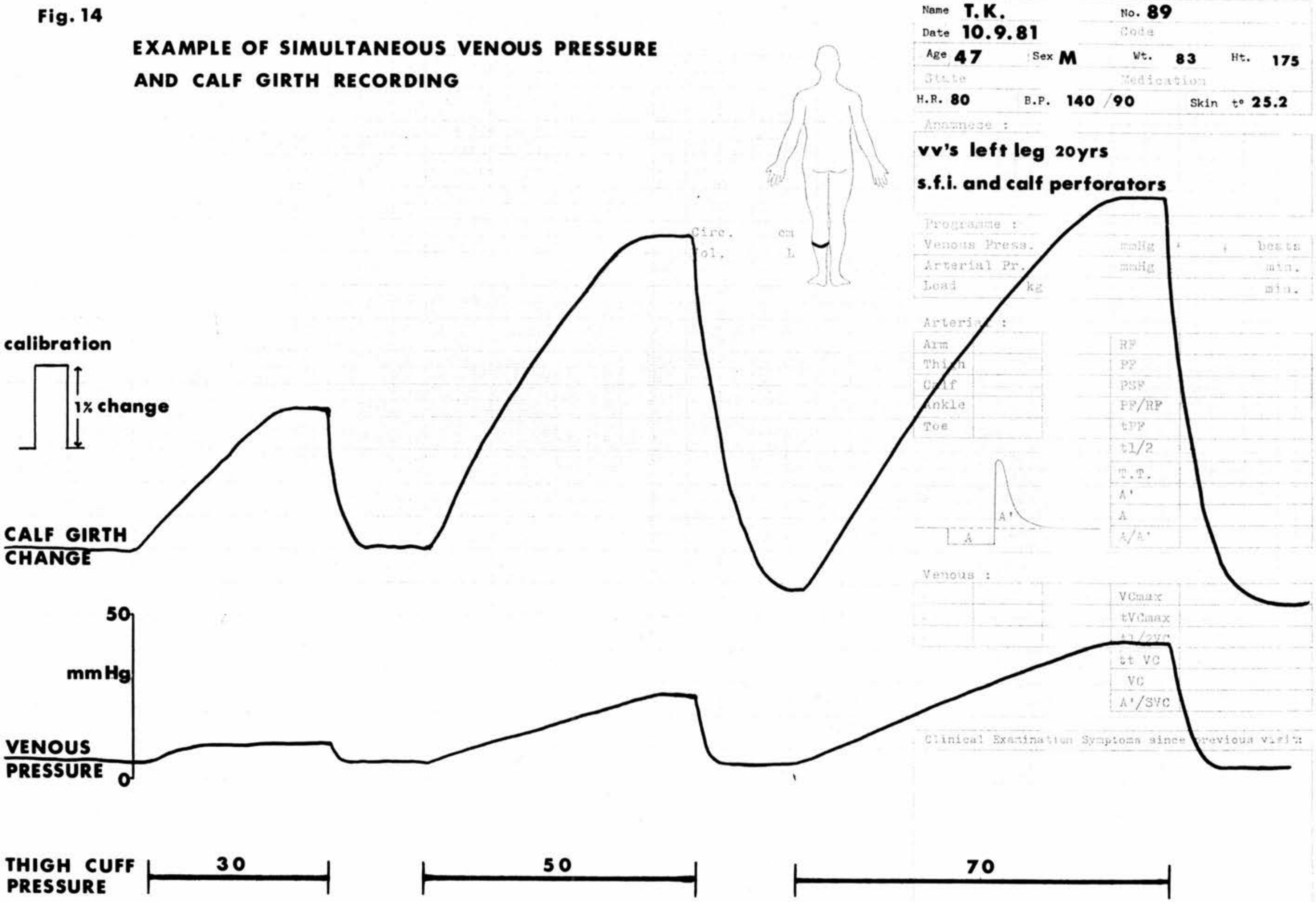


Fig. 14

EXAMPLE OF SIMULTANEOUS VENOUS PRESSURE AND CALF GIRTH RECORDING



4.11 Reproducibility of Distensibility Results

Recordings were obtained from 11 normal subjects (4 males and 7 females, age range 22-32 years, mean 27.5 years) on 5 consecutive days. All measurements were made with the subjects lying supine with their calves supported clear of the couch at heart level. The subjects were examined at the same time of day, and after a 20 minute period of equilibration with the environment. The toe temperature was the same for each subject on all five occasions. Also, the distance of the strain-gauge from the lower border of the tibial tubercle was measured on the first day of the recordings for each subject, and, on subsequent days, the same position for the strain-gauge was reproduced.

On each occasion, the percentage girth changes on cuff inflation were measured three times and the venous distensibility indices were calculated by plotting all the readings of girth change against the cuff pressure.

4.12 Simultaneous Venous Pressure and Calf Girth Measurement in Distensibility Recordings

10 normal subjects (4 males and 6 females, age range 22-36 years, mean 27.7 years) and 20 subjects with primary varicose veins without skin changes or ulceration (8 males and 12 females, age range 21-56 years, mean 39.7 years) had simultaneous recordings of venous pressure and calf girth changes whilst the thigh cuff was inflated to 30, 50 and 70 mmHg (4,6.6 and 9.3 KPa) successively.

The subjects all lay supine with their calves supported clear of the couch at heart level, and the diaphragm of the pressure transducer was adjusted to be level with the upper border of the medial malleolus. The strain-gauge was placed around the maximum calf circumference of each subject. Figure 13 illustrates the apparatus for this series of experiments, and

Figure 14 is an illustration of a tracing obtained in this way from a subject with varicose veins.

The maximal venous pressure and calf girth changes (% x 50) recorded following each inflation of the thigh cuff were plotted against one another. The slopes of the lines obtained were measured and designated the venous distensibility index (venous pressure) (V D I (p)). The VDI(p)s for all the subjects were compared with the VDIs as originally calculated for the same subjects.

The venous pressures recorded following each cuff inflation were compared with the inflation pressure of the cuff to see if they bore a constant relationship to one another, as it has been suggested that, for a given cuff width, the venous pressure is a constant fraction of the cuff pressure (Brakkee 1979).

The principle of this method of measurement of distensibility depends on the assumption that the thigh cuff pressure bears a constant relationship to the venous pressure.

4.13 Details of Experiments Employing an Ambulatory Test of Venous Function

4.13.1 Description of Performance of Ambulatory Test and Method of Calculation of Results

Subjects assessed by means of the ambulatory test stood upright holding onto a horizontal bar, with a strain-gauge attached around the maximum calf circumference, and performed a series of heel-raising exercises. Each period of exercise lasted for 30 seconds, and each cycle of calf contraction and relaxation lasted 2 seconds.

The subjects sat quietly in a chair for 20 minutes equilibration before performing the test and, during this time, the nature and purpose of the test was carefully explained. Before any recordings were made, each subject practised the heel-raising exercise at least once. During every period of exercise the subjects kept their calf contractions and relaxations in time with the second hand of a large face stop clock. Figures 15 and 16 illustrate the ambulatory test performance.

Recordings were made from each subject during two 30 second periods of exercise, followed by a third exercise period which was performed after the application of a pneumatic cuff around the thigh (15cm proximal to the upper border of the patella) and its inflation to 100mmHg (13.3 KPa).

The calf girth changes (% x 50) during exercise and recovery were recorded and the girth change (% x 50) measured from the resting value to the girth recorded at the start of calf contraction for the first 10 calf contractions. The average value for one calf contraction was calculated, and this was called the ambulatory calf girth change and was usually a reduction in calf girth. An example of a recording taken from a normal subject is shown in Figure 17 and Figure 18 shows the method of calculation of the ambulatory calf girth change.

The calibration of the percentage calf girth change obtained from the strain-gauge is shown in Figure 17. A vertical deflection of 2.5cm on the calf girth change recording is equivalent to a 1% change in length of the strain-gauge. The measurements taken for the calculation of the ambulatory calf girth change were the actual deflections recorded on the chart, and were not converted to percentages.

Studies were performed with normal subjects exercising whilst the recorder speed was increased to 5cm/min. (Figure 19) and the results obtained showed that the major component of the ambulatory calf girth change was the rate of return of calf girth towards the base line on calf relaxation. The girth decrease on calf contraction produced a vertical line on the chart, whereas the corresponding girth increase on calf relaxation produced a slope the angle of which was presumably related to the speed of refilling of the veins emptied during calf contraction. Thus, the ambulatory calf girth change that was measured was an indirect measurement of the refilling time of the calf veins.

Fig. 15

PERFORMANCE OF AMBULATORY TEST (calves relaxed)

Fig.16

PERFORMANCE OF AMBULATORY TEST (calves contracted)

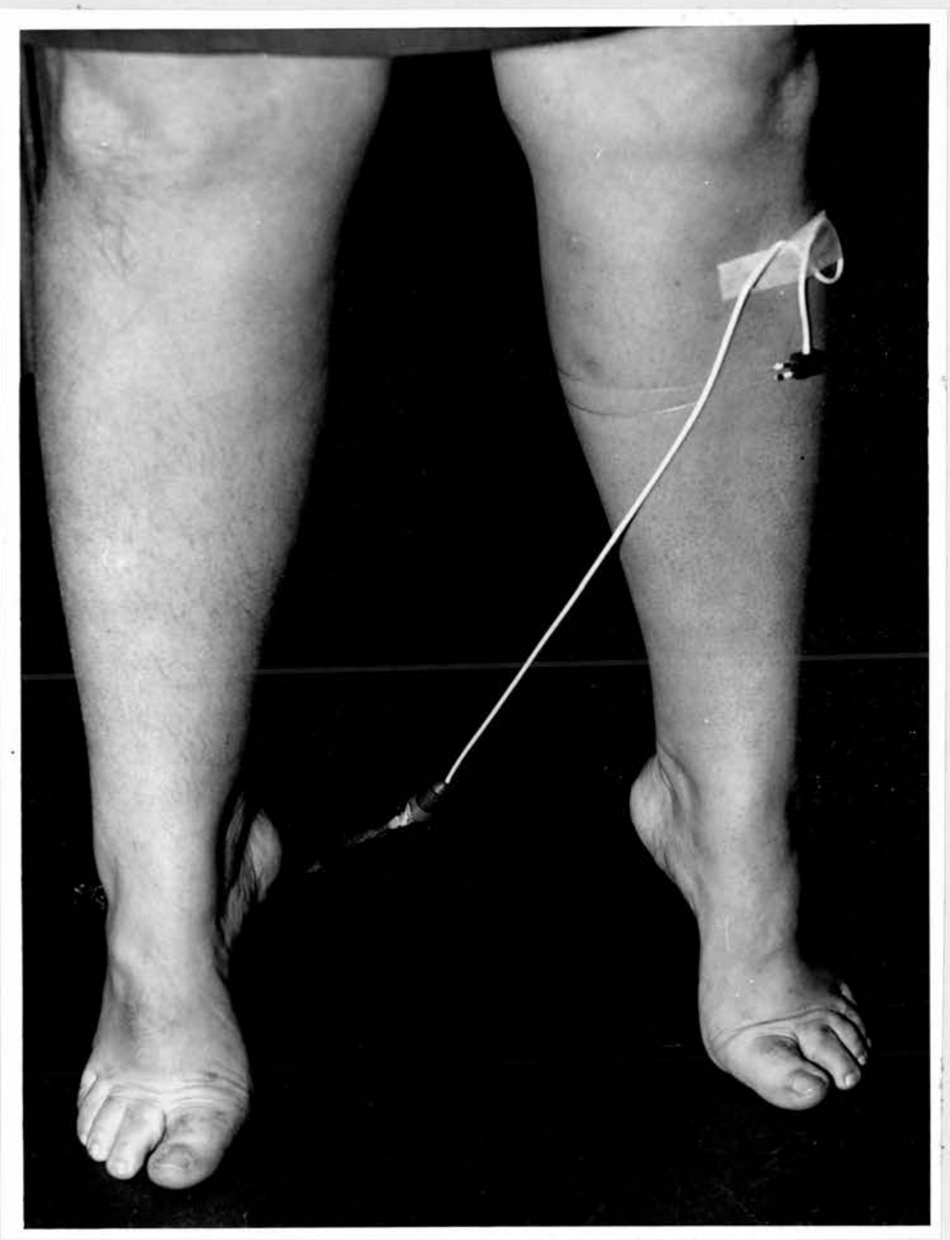
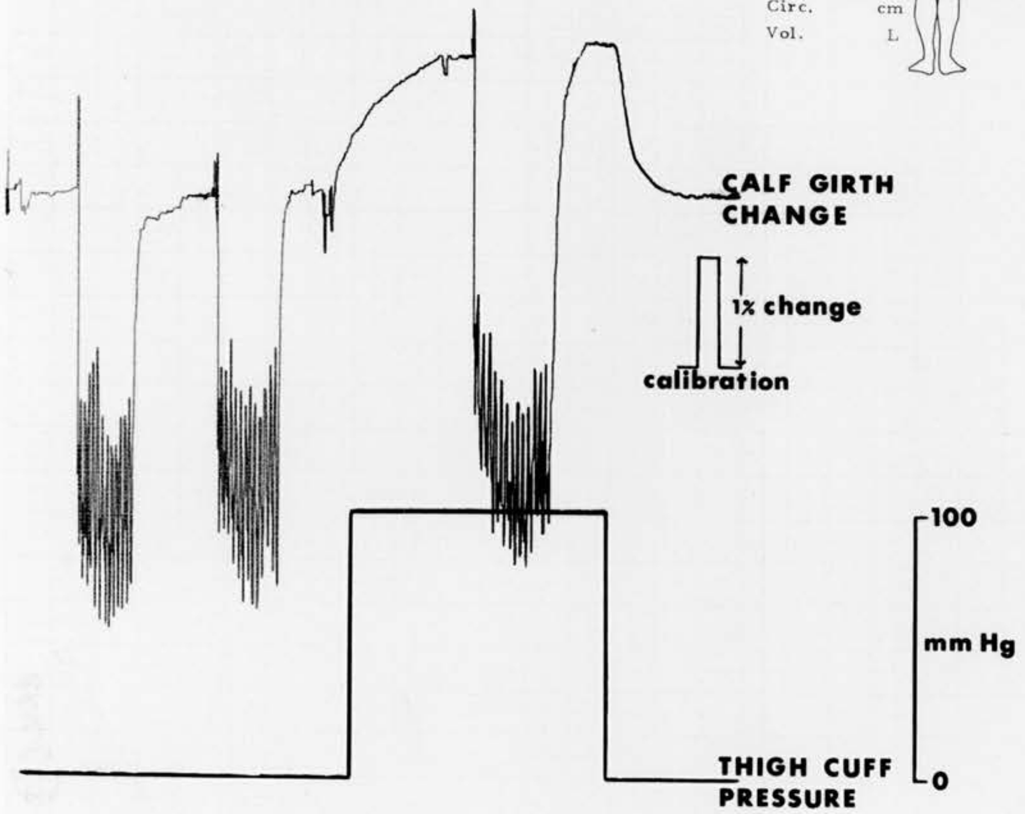
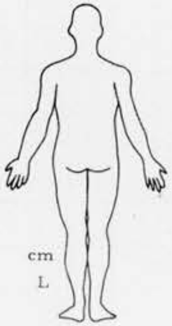


Fig. 17

EXAMPLE OF AMBULATORY TEST RECORDING





Circ. cm
Vol. L

Name **A.A.**		No **26**	
Date **14.8.81**		Code	
Age **37**	Sex **M**	Weight **85**	Height **170**
State		Medication	
HR **90**	BP **130**	**/ 70**	Skin t°

Anamnese:

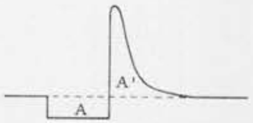
bilateral vv's for 3yrs
right leg - s.f.i. and calf vv's

Programme:

Venous Press.	mmHg ↑	↓	beats
Arterial Pr.	mmHg		min.
Load kg.			min.

Arterial:

Arm			RF	
Thigh			PF	
Calf			PSF	
Ankle			PF/RF	
Toe			tPF	
			t 1/2	
			T. T.	
			A'	
			A	
			A/A'	



Venous:

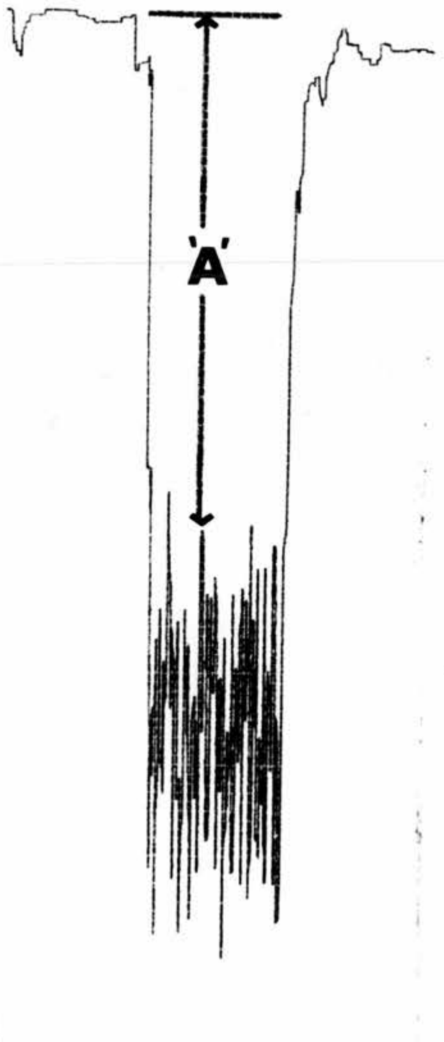
.			VCmax	
.			tVCmax	
.			t 1/2VC	
			tt VC	
			VC	
			A'/SVC	

Clinical Examination Symptoms since previous visit:

SU4-Periflow

Fig. 18

METHOD OF CALCULATION OF THE AMBULATORY TEST RESULT



measurement 'A' is taken for the first ten calf contractions, and the average value calculated.

note: girth rarely returns to original value after exercise.

This method of measurement was adopted as it was felt that abnormalities of venous function mainly affect the refilling time of the veins, unless there is an obstruction to venous outflow. The calf girth changes at the end of calf contraction would thus be similar in all subjects without venous obstruction. Early results showed that measurement of the time taken for the girth to return to the original base line after cessation of exercise was unreliable as the girth rarely returned to its original base line and so an "end-point" was hard to define. The measurement of the calf girth change at the end of calf relaxation was simple to measure and gave an indirect measurement of the venous refilling time.

4.13.2 Experiments to Show the Effect of Variation in Strain-Gauge Position

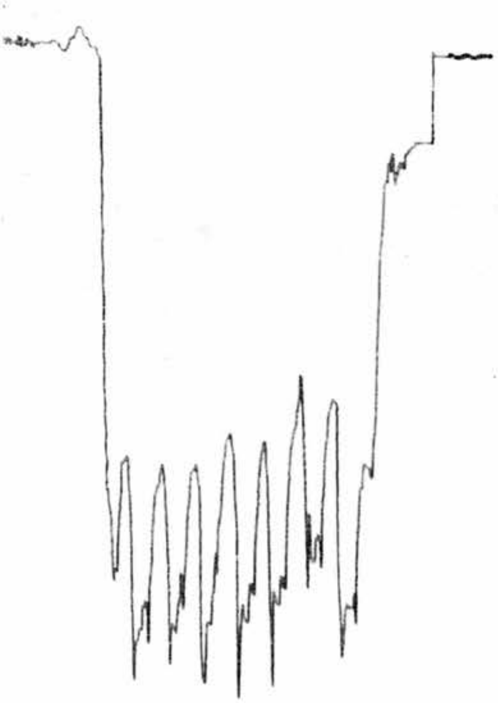
10 normal subjects (5 males and 5 females, age range 23-44 years, mean 31.5 years) were studied by means of the ambulatory test. Each subject performed two periods of exercise for each of 4 different positions of the strain-gauge on the calf. The strain-gauge was placed at distances of 2.5cm, 5cm, 7.5cm and 10cm from the lower border of the tibial tubercle.

4.13.3 Experiments to Demonstrate the Reproducibility of the Ambulatory Test Results

10 normal subjects (5 males and 5 females, age range 23-44 years, mean 31.5 years) were studied on 5 consecutive days. The strain-gauges were positioned around the maximum calf circumference and the subjects performed two periods of exercise.

Fig. 19

AMBULATORY TEST RECORDING USING A FASTER RECORDER SPEED



recording from a normal subject, using a recorder speed of 5cm./min.

calf contraction produces a downward deflection on the graph.

4.13.4 Simultaneous Venous Pressure and Calf Girth Recordings During the Ambulatory Test

Recordings of venous pressure and calf girth changes on exercise were made on 25 subjects (10 normal : 5 males and 5 females, age range 23-44 years, mean 31.5 years; and 15 varicose vein subjects: 6 males and 9 females, age range 24-56 years, mean 35.4 years).

A photograph of the apparatus is shown in Figure 20 and an example of the tracing obtained from a normal subject is shown in Figure 21.

The venous pressure change on exercise was calculated by measuring the pressure change from the resting value to the pressure at the start of each calf contraction for the first ten calf contractions. The average value for one calf contraction was calculated (this was called the ambulatory venous pressure change) and this value was compared with the ambulatory calf girth change. Figure 22 illustrates the method of calculation of the ambulatory venous pressure change.

4.14 Comparison of Ambulatory Test Results in Normal and Varicose Veins Subjects

The ambulatory test was performed on 20 normal subjects (10 males and 10 females, age range 22-44 years, mean 30.9 years) and 40 subjects with varicose veins (18 males and 22 females, age range 24-56 years, mean 37.8 years). 20 of the latter subjects had sapheno-femoral incompetence as judged by clinical examination and Doppler ultrasound testing, and the other 20 subjects had varicose veins confined to the calf without evidence of sapheno-femoral incompetence.

The range of results obtained from the normal subjects was compared with that from the varicose vein subjects.

4.15 Application of the Ambulatory Test to Subjects with Varicose Veins

50 patients (19 males and 31 females, age range 22-65 years, mean 41.9 years) attending the varicose vein clinic were assessed at their initial presentation by clinical examination (including tourniquet tests), Doppler ultrasound testing and strain-gauge plethysmography (using the ambulatory test).

The results of the three examinations were correlated for each patient, and the data obtained were used to compile a table of values to be found in subjects with varying patterns of varicose veins.

Fig. 20

SIMULTANEOUS AMBULATORY CALF GIRTH

& VENOUS PRESSURE RECORDING

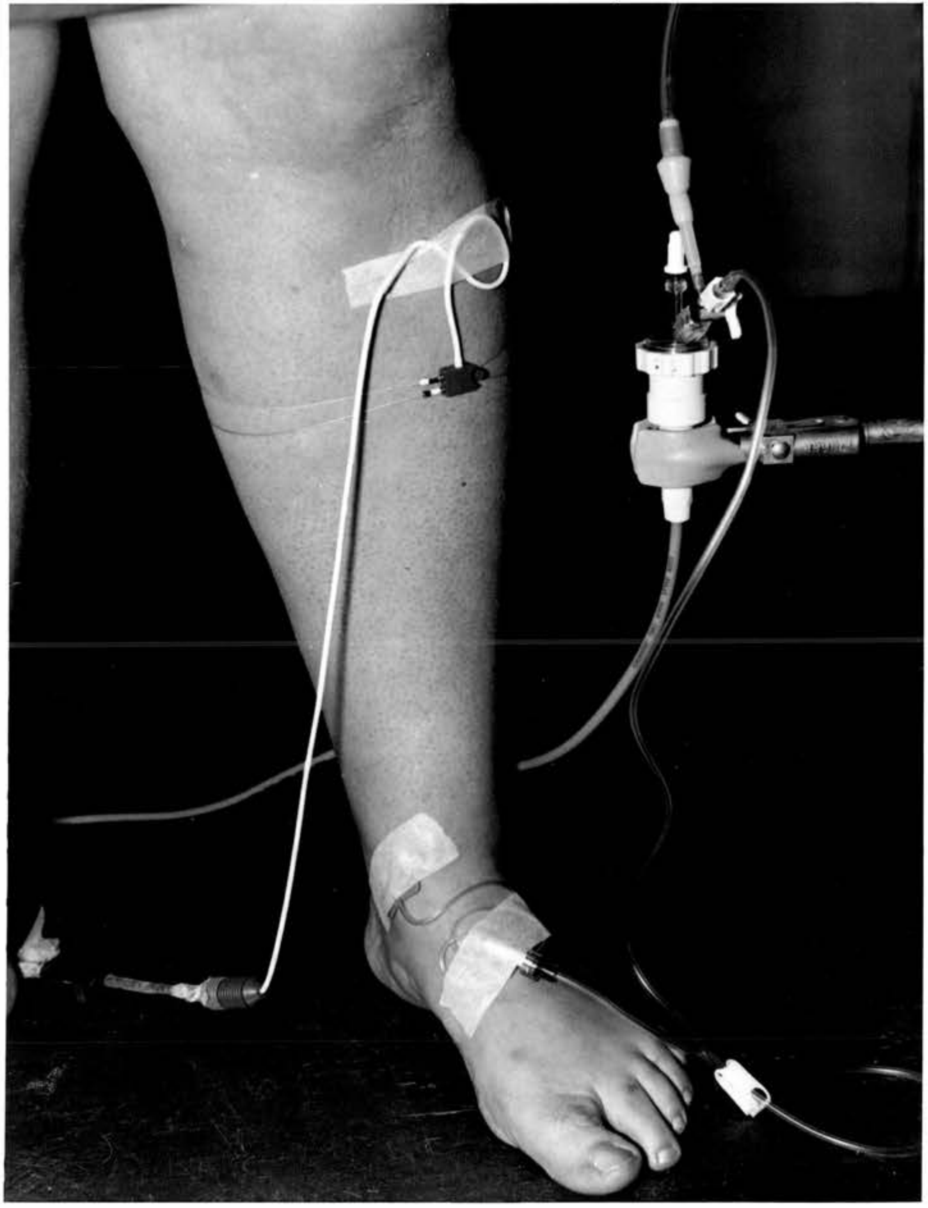
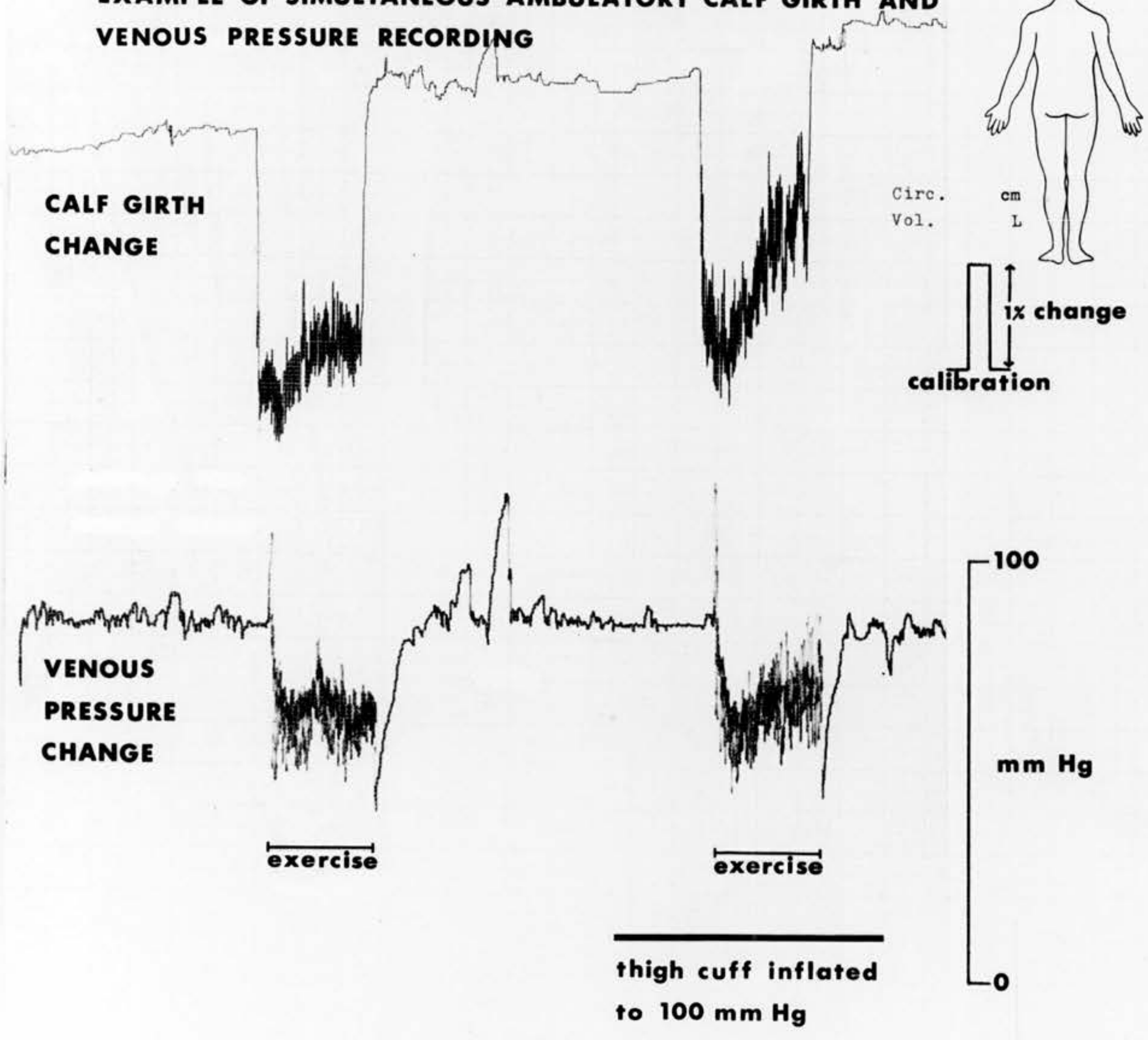


Fig. 21

EXAMPLE OF SIMULTANEOUS AMBULATORY CALF GIRTH AND VENOUS PRESSURE RECORDING



Name **A.B.**		No **5**
Date **19.3.81**		Code
Age **33**	Sex **M**	Weight **59** Height **183**
State		Medication
HR **90**	BP **120/80**	Skin t°

Anamnese :

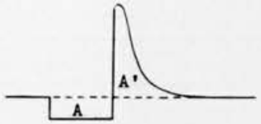
normal subject

Programme :

Venous Press.	mmHg	↓ ↓	beats
Arterial Pr.	mmHg		min.
Load kg			min.

Arterial :

Arm			RF	
Thigh			PF	
Calf			PSF	
Ankle			PF/RF	
Toe			tPF	
			t1/2	
			T.T.	
			A'	
			A	
			A/A'	



Venous :

			VCmax	
			tVCmax	
			t1/2VC	
			tt VC	
			VC	
			A'/SVC	

Clinical Examination Symptoms since previous visit:

Fig.22

METHOD OF CALCULATION OF THE AMBULATORY VENOUS PRESSURE RESULT

measurement 'B' is taken for the first ten calf contractions, and the average value calculated.

4.16 Findings in Subjects with Deep Venous Incompetence

15 patients (4 males and 11 females, age range 24-66 years, mean 44 years) presenting to the vascular clinic with symptoms of deep venous incompetence were investigated by ambulatory strain-gauge plethysmography, Doppler ultrasound testing and ascending and descending phlebography.

The variations in the anatomical abnormalities found on phlebography were compared with the plethysmographic results.

If surgical treatment was indicated, then pre-and post-operative plethysmography was performed, and the results compared with the patient's subjective assessment of the effectiveness of the surgery.

4.17 Pre- and Post-Operative Studies on Varicose Vein Patients

This study was undertaken to investigate whether the results of strain-gauge plethysmography had any predictive value on the outcome of varicose vein surgery.

20 patients (7 males and 13 females, age range 28-63 years, mean 42.5 years) who had had no previous treatment for their primary varicose veins were assessed by questionnaire, clinical examination and strain-gauge plethysmography on their initial presentation. Their legs were photographed in monochrome with infra-red lighting before any treatment was performed.

All patients received treatment based on the results of their investigations and this consisted of surgery with or without injection sclerotherapy. 15 patients had high saphenous ligations, stripping of their long saphenous veins and calf perforator ligation and the remaining 5 patients had multiple perforator ligations. All the operations were performed by the same surgeon (the author). Injection sclerotherapy, if indicated, was performed 1 week after surgery. All injections were performed by the same surgeon, using the same technique.

All the patients were assessed by questionnaire and clinical assessment by medical staff at 1 week, 3 weeks, 3 months, and 1 year post-operatively. The pre-treatment photographs were compared with the patients' legs at the follow-up examination to provide an objective assessment of the results of the treatment.

The answers to the questionnaire and the doctor's assessment result were recorded as numerical scores on special forms as illustrated in Figure 23. The range of score possible for the questionnaire was 3 to 12 and for the objective assessment, 4 to 12. A high score indicated a poor result.

All the patients had ambulatory strain-gauge plethysmography performed at their 1 year follow-up examination.

4.18 Study of the Effect of stripping the Long Saphenous Vein in the Treatment of Varicose Veins

In the light of the work of Cotton (1961) and Thomson (1979) and also as a result of observations made on the subjects studied pre- and post-operatively, it was decided to conduct a prospective trial on the effect of stripping the long saphenous vein. It was also intended to demonstrate whether strain-gauge plethysmography could be used to decide which type of treatment was most appropriate for each patient.

The subjects of the study were 200 consecutive patients referred to the varicose vein clinic with primary varicose veins requiring surgical treatment, none of whom had had previous treatment of their varicose veins. Surgical treatment of varicose veins was considered necessary if tourniquet testing suggested sapheno-femoral incompetence.

Subjects were randomly allocated to be treated by high saphenous ligation, stripping of the long saphenous vein and perforator ligation with avulsion of calf varices or to have high saphenous ligation and ligation of thigh perforators without stripping the long saphenous vein. All subjects had pre-operative investigation by ambulatory strain-gauge plethysmography and careful mapping of incompetent perforators by means of Doppler ultrasound. All investigations were performed by the same person, and all subjects had their legs photographed prior to treatment to compare with the surgical results.

Those subjects allocated to stripping of the long saphenous vein had their surgery performed under general anaesthetic, whilst those subjects not having their long saphenous veins stripped had the operation performed under local anaesthetic.

Those operations under general anaesthetic were performed by a consultant surgeon or by one of two post-fellowship registrars, according to a standard procedure. The long saphenous vein was identified in the groin, its tributaries ligated and divided and a flush ligation of the long saphenous vein performed at its junction with the common femoral vein. A stripper was passed down the long saphenous vein from the groin to a point approximately 5 cm distal to the line of the knee joint where it was located via an incision over the tip of the stripper. After division of the long saphenous vein it was stripped towards the groin, the medial thigh tributary being identified and separately ligated if possible. Small incisions were then made over the marked perforator sites, perforating veins identified, ligated, divided and associated varicosities avulsed. The wounds were closed with 4/0 monofilament nylon and the legs were firmly enclosed in crepe bandages. The patients were encouraged to be ambulant post-operatively and were discharged 48 hours after surgery.

All the operations under local anaesthetic were performed by the same surgeon. The positions of the sapheno-femoral junction and any incompetent thigh perforators were carefully marked, using Doppler ultrasound and these areas were infiltrated with a total of 10 to 15 ml of 0.25% bupivacaine hydrochloride (Marcain plain). The sapheno-femoral junction was identified, the tributaries of the long saphenous vein were ligated and divided and the long saphenous vein was divided and ligated flush with its junction with the common femoral vein. Any detected incompetent thigh perforators were located via small incisions and ligated. The wounds were closed with 4/0 monofilament nylon and Scholl elastic stockings fitted to the legs. These patients all left hospital on the same day as their surgery and were encouraged to remain ambulant at home.

All the patients had their sutures removed after one week and, at the same time, injection sclerotherapy was performed on any residual varicosities by the same person (a clinical assistant) who uses a standard technique.

All the patients were assessed at 1 week, 3 weeks, 3 months and 1 year after surgery by means of a questionnaire and objective assessment by doctors unaware of which type of surgery had been performed. The results of these assessments were scored numerically as before, and the results compared for the two groups of patients at each assessment time.

A follow-up period of only one year is, of course, too short to be able to draw any conclusions as to whether there is any advantage to stripping the long saphenous vein, It is, however, intended to continue to asess these patients at yearly intervals for the next five years.

Fig. 23

EXAMPLE OF POST-OPERATIVE ASSESSMENT QUESTIONNAIRE

FOLLOW-UP **3 MONTHLY** **V.V. No.**

Date: 31/11/80 **Assessor:** ABw Injection: [✓ Operation] 31/8/82

QUESTIONS TO PATIENTS
(Please encircle the appropriate numbers)

	Right	Left
Do you think the result is		
Excellent	[✓ 1]	1
Good	2	2
Unsatisfactory	3	3
Terrible	4	4
If you had further problems would you have the same treatment?		
Yes	[✓ 1]	1
No	2	2
Do your legs feel better?		
All symptoms gone	[✓ 1]	1
Symptoms improved	2	2
Symptoms unchanged	3	3
In your opinion, do your legs look better?		
Yes	[✓ 1]	1
No	2	2

	Right	Left
SCARS ON LEGS		
Not visible	1	1
Visible	[✓ 2]	2
Gross	3	3
PIGMENTATION		
Absent	[✓ 1]	1
Slight	2	2
Gross	3	3
VARICOSE VEINS		
Absent	[✓ 1]	1
Much improved	3	3
Slight	5	5
Virtually unchanged	7	7

COMMENTS:

FOLLOW-UP **YEARLY**

Date: 31/8/81 **Assessor:** H.D. Injection: [✓ Operation:] 31/8/82

QUESTIONS TO PATIENTS
(Please encircle the appropriate numbers)

	Right	Left
Do you think the result is		
Excellent	[✓ 1]	1
Good	2	2
Unsatisfactory	3	3
Terrible	4	4
If you had further problems would you have the same treatment?		
Yes	[✓ 1]	1
No	2	2
Do your legs feel better?		
All symptoms gone	[✓ 1]	1
Symptoms improved	2	2
Symptoms unchanged	3	3
In your opinion, do your legs look better?		
Yes	[✓ 1]	1
No	2	2

	Right	Left
SCARS ON LEGS		
Not visible	[✓ 1]	1
Visible	2	2
Gross	3	3
PIGMENTATION		
Absent	[✓ 1]	1
Slight	2	2
Gross	3	3
VARICOSE VEINS		
Absent	[✓ 1]	1
Much improved	3	3
Slight	5	5
Virtually unchanged	7	7

COMMENTS:

5 RESULTS

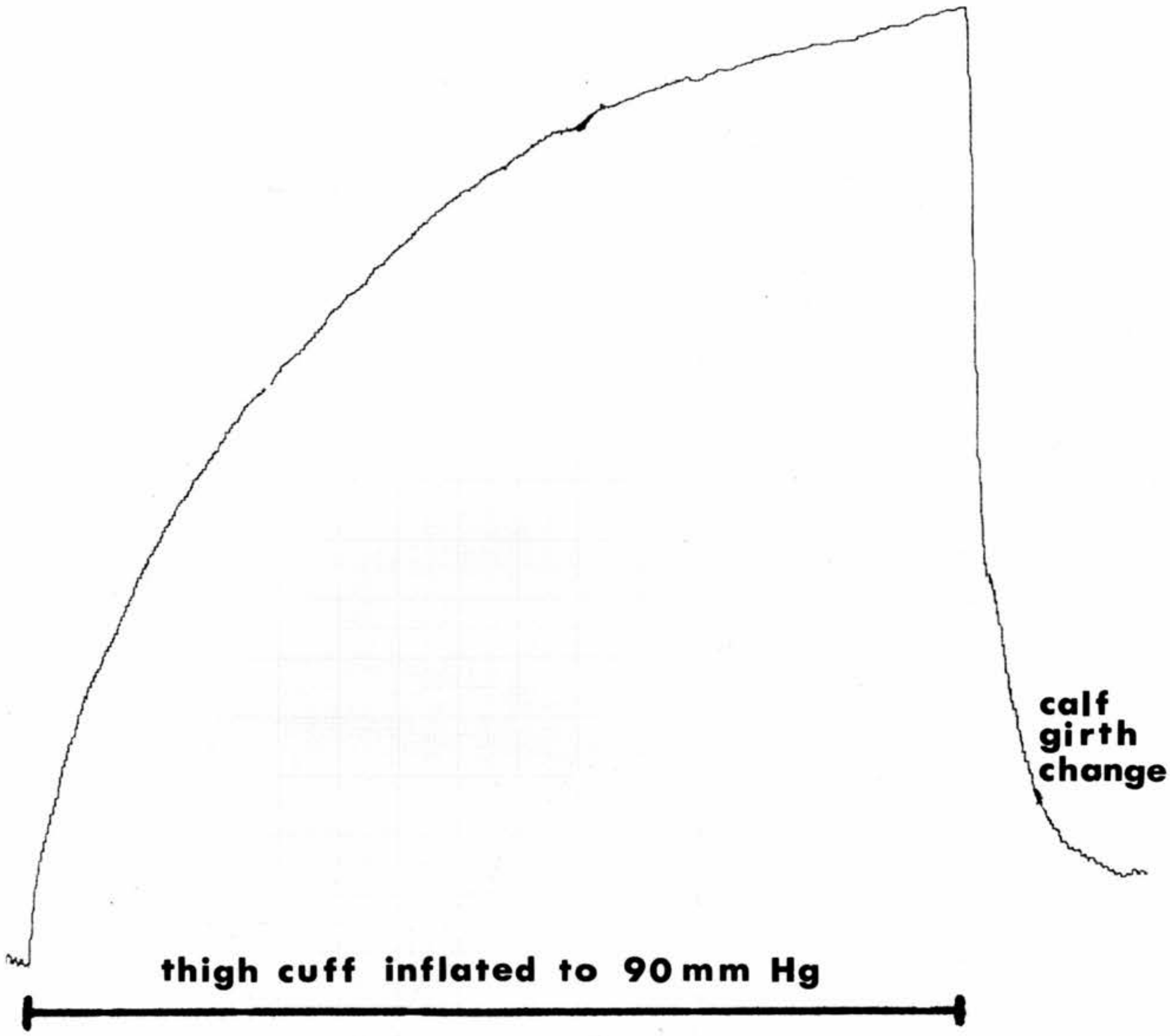
5.1 Venous Distensibility Measurement

The V D I's obtained as shown in Figures 8 and 9 were measured in degrees, but no units have been given to the V D I. One of the parameters from which the V D I is derived has no units itself (ie % calf girth change) and thus the V D I has a non-linear relationship to the thigh cuff pressure (VDI $\propto$ cotan mmHg). Any units given to the V D I would thus be extremely complex and so have been omitted for purposes of clarity.

It was noticed in some subjects that, following inflation of the thigh cuff to 90 mmHg, the calf girth increase failed to reach a plateau (Figure 24). This phenomenon was presumed to be due to the increased rate of fluid transudation at capillary level, secondary to the venous obstruction. The possible error introduced by the attempted measurement of the maximum girth increase following the 90 mmHg cuff inflation in these subjects would affect the calculation of the V D I. Therefore, when this problem occurred, the maximum calf girth increase at a cuff pressure of 90 mmHg was not included in the graph to determine the V D I which was then plotted from only three recordings.

Fig. 24

PORTION OF DISTENSIBILITY RECORDING FROM A VARICOSE VEIN SUBJECT SHOWING THE LACK OF A PLATEAU IN THE CALF GIRTH CHANGE



5.2 Preliminary Venous Distensibility Experiments

5.2.1 Effect of Variation in Strain-Gauge Position

Recordings were made from 5 normal subjects (numbered 1 to 5) and 5 patients with varicose veins (numbered 6 to 10) with the strain-gauge positioned at points 2.5, 5, 7.5 and 10 cm distal to the lower border of the tibial tubercle and also around the ankle immediately proximal to the upper border of the medial malleolus. Tables 2, 3 and 4 show the results obtained and the V D I's calculated for each strain-gauge position.

Table 2

Preliminary Venous Distensibility Experiments

Effect of Variation in Gauge Position (1) Normal Subjects

Subjects referred to as Nos 1-5

Position of gauge distal to tibial Tubercle (cm)	Cuff Pressure (mm Hg)																			
	30					50					70					90				
	subjects					subjects					subjects					subjects				
	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5
2.5	35	49	31	31	8	47	70	47	68	41	70	96	67	87	68	82	111	87	107	95
5	40	54	31	34	11	56	76	52	64	47	65	100	69	92	72	90	118	83	114	99
7.5	43	55	32	35	12	62	67	56	68	49	69	93	73	97	82	95	102	89	120	113
10	39	52	28	36	17	58	63	53	68	55	66	88	67	95	89	89	96	78	112	118
ankle	45	44	29	13	12	76	61	48	22	38	97	76	58	38	62	111	88	81	59	81

The above figures are the maximum percentage calf girth changes (% x 50) at each cuff pressure and are used to calculate the venous distensibility index for each subject at each gauge position as shown.

Table 3

Preliminary Venous Distensibility Experiments

Effect of Variation in Gauge Position (2) Varicose Vein Subjects

Subjects referred to as Nos 6-10

Position of gauge distal to tibial Tubercle (cm)	Cuff Pressure (mm Hg)																			
	30					50					70					90				
	subjects					subjects					subjects					subjects				
	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10	6	7	8	9	10
2.5	70	49	69	52	25	120	85	110	111	68	147	98	140	157	93	173	113	173	178	118
5	72	56	71	56	26	126	87	115	115	67	152	110	146	163	97	184	127	187	185	142
7.5	79	65	77	65	29	135	91	120	116	62	161	122	155	175	99	196	153	194	193	141
10	75	55	73	63	34	133	85	118	115	64	157	117	150	167	89	191	140	187	188	133
ankle	88	22	32	45	30	146	54	54	98	62	171	67	72	133	69	192	97	89	157	79

The above figures are the maximum percentage calf girth changes (% x 50) at each cuff pressure and are used to calculate the venous distensibility index for each subject at each gauge position as shown.

Table 4

Preliminary Venous Distensibility Experiments
Effect of Variation in Strain-Gauge Position
Venous Distensibility Indices Calculated from Tables 2 and 3

Position of gauge distal to tibial tubercle (cm)	Normal Subjects					Varicose Vein Subjects				
	1	2	3	4	5	6	7	8	9	10
2.5	41	41	44	51	55	60	47	59	75	56
5	41	46	41	53	56	61	52	61	64	61
7.5	41	42	43	54	58	62	55	65	65	62
10	40	42	41	52	58	62	55	61	64	60
ankle	48	36	39	38	49	59	52	43	60	37

Variation of Results - Excluding Ankle Results

Normal Subjects

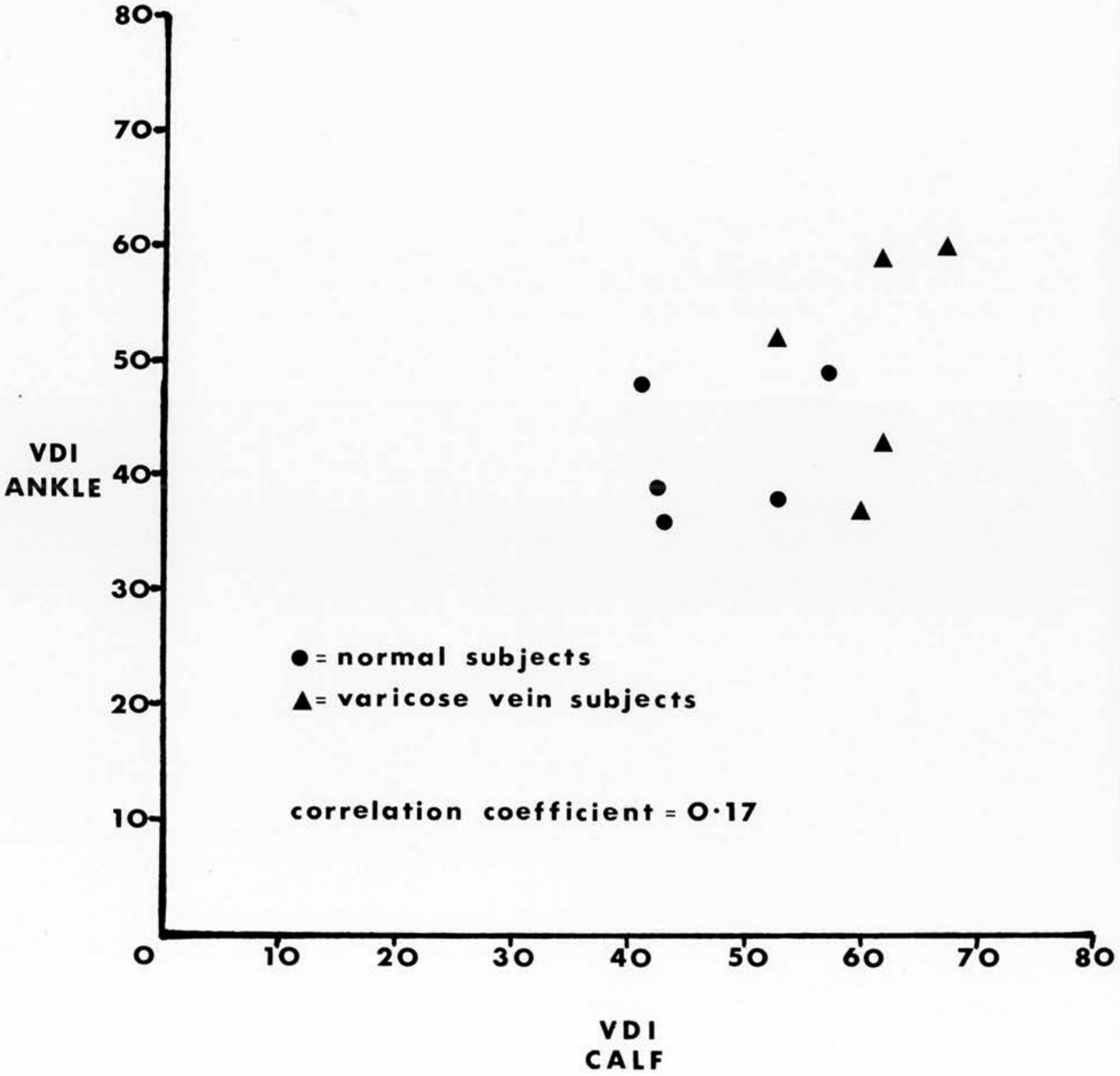
Subjects	1	2	3	4	5
mean VDI's	40.75	42.75	42.25	52.5	56.75
standard deviations	0.5	2.2	1.5	1.3	1.5
coefficients of variation	1.2%	5.2%	3.6%	2.5%	2.6%

Varicose Vein Subjects

Subjects	6	7	8	9	10
mean VDI's	61.25	52.25	61.5	67.0	59.75
standard deviations	1.0	3.7	2.5	5.4	2.6
coefficients of variation	1.6%	7.2%	4.1%	8.0%	4.4%

Fig. 25

COMPARISON OF VDI's OBTAINED FROM CALF AND ANKLE RECORDINGS



The recordings obtained when the strain-gauge was positioned around the calf showed some variation depending on where the strain-gauge was placed (coefficients of variation varying from 1.2% to 8.0%). However, the maximum calf girth changes (% x 50) were always recorded from strain-gauges placed around the maximum calf circumference (usually between 5 and 7.5 cm distal to the tibial tubercle). The actual site of maximum calf circumference is variable amongst subjects. Thus, using a constant measurement point (eg 5 cm distal to the tibial tubercle) would mean that comparison of results from different subjects would be affected by the dimensions of their lower limbs.

The positioning of the strain-gauge around the ankle was intended to examine an area of the limb where changes in circumference would be due to changes in superficial veins, as there was little muscle bulk in this area, and hence fewer deep veins. There was no significant difference between the mean V D I's derived from recordings obtained from the calf and the V D I's derived from the recordings at the ankle. However, the circumference of the lower limb at the ankle is of such an irregular shape that a large proportion of the strain-gauge is not in contact with the skin, and this introduces errors into the calculation of venous distensibility. Also, there was a poor correlation between the V D I's calculated from the calf and ankle recordings (r=0.17) and this may be due to the errors in recordings from the ankle (Figure 25).

It was therefore decided to use the maximum calf circumference as the measurement point for all future venous distensibility experiments.

5.2.2 Effect of Changes in Body Position

Recordings were taken from 16 normal subjects and 30 patients with varicose veins with the strain-gauges placed around the maximum calf circumference. In order to investigate the effect of body position on the V D I, the subjects were studied whilst lying supine with their calves at heart level, 15 cm above heart level and whilst sitting with the legs horizontal.

The V D I's were calculated from recordings obtained when the subjects were in each of the positions. The supine position with the calves at heart level was taken as the primary position, results from which were compared with those obtained when the subjects were positioned differently (Tables 5 and 6).

There was no significant difference between the mean V D I's calculated for subjects lying with their legs at heart level compared with the mean V D I's obtained from the same subjects with their legs 15 cm above heart level. However, for each subject, there was often a considerable difference between the results obtained from the two positions. There was no constant relationship between the sets of results, some V D I's were greater with the legs elevated and some greater with the legs lowered. There was a poor positive correlation between the two sets of figures ($r = 0.61$ Figure 26). Lying with the legs elevated results in the superficial veins being empty prior to the thigh cuff inflation. However, this effect should be the same at each cuff inflation and hence the proportional girth increase and V D I should be the same despite the position changes.

Table 5

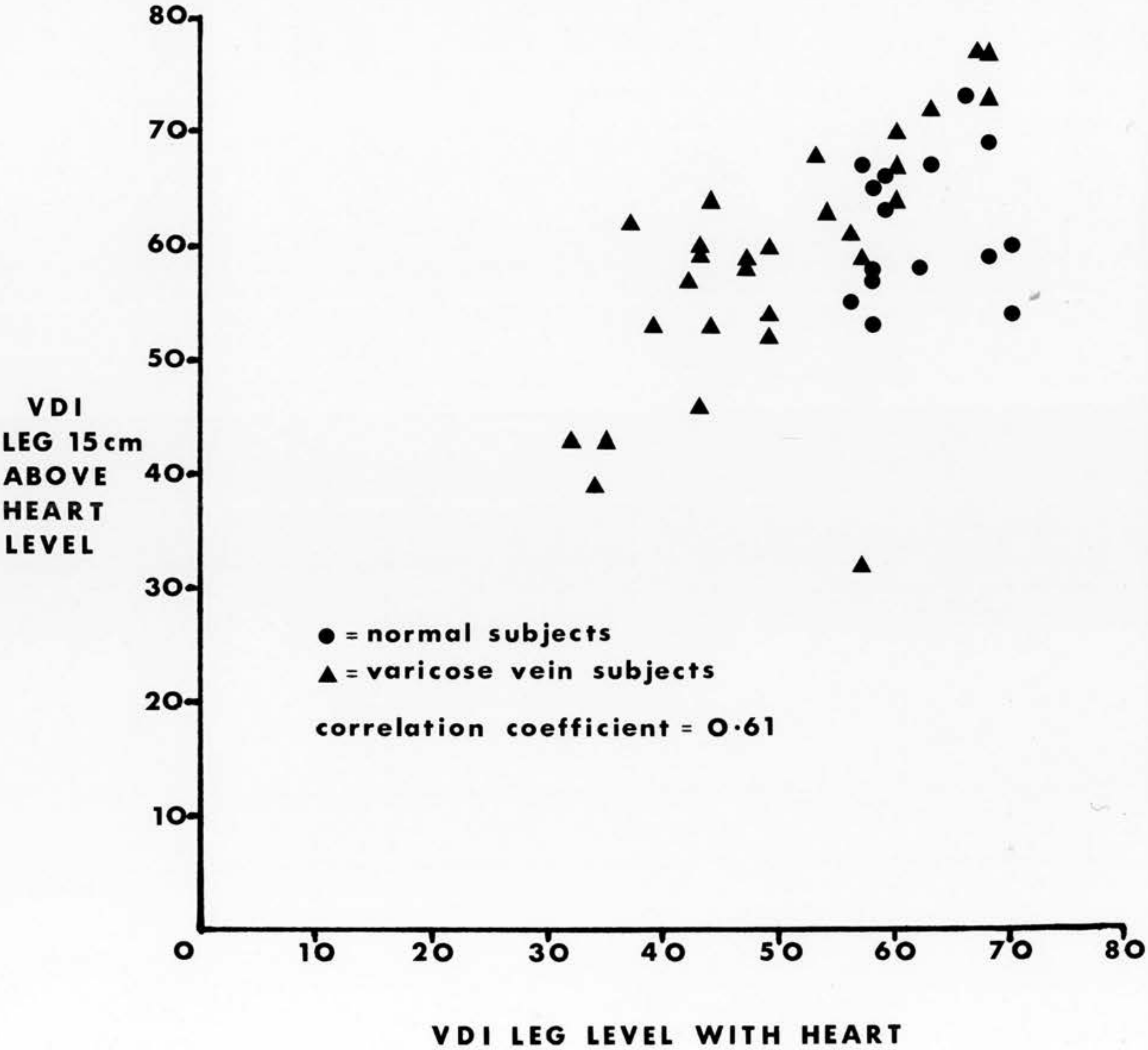
Venous Distensibility Index Related to Subject Position

	Normal Subjects		Subjects with Varicose Veins	
	Leg at heart level	Leg elevated to 15 cm above heart level	Leg at heart level	Leg elevated to 15cm above heart level
	58	65	44	64
	58	58	35	43
	57	67	60	67
	58	53	60	64
	58	58	54	63
	63	67	68	73
	66	73	68	77
	68	69	60	70
	56	55	53	68
	58	57	63	72
	62	58	49	60
	68	59	47	58
	70	60	42	57
	70	54	43	60
	59	66	49	52
	59	63	57	32
			44	53
			43	46
			32	43
			39	53
			47	59
			49	52
			57	59
			49	54
			56	61
			34	39
			43	59
			37	62
			68	73
			67	77
mean	61.8	61.4	50.6	59
standard deviation	5.0	5.9	10.7	11.1

There was no significant difference between the mean VDI's of the two groups of subjects recorded from two different subject positions (two sample t test).

Fig. 26

COMPARISON OF VDI's OBTAINED FROM RECORDINGS MADE USING TWO DIFFERENT LEG POSITIONS



The sitting position was intended to fill the superficial veins more than the supine position prior to the thigh cuff inflation. Again, the proportional girth increases and hence the V D I's should be similar in the two positions. There was again no significant difference between the means of the V D I's for the two positions. The results from the sitting and lying positions had a much better positive correlation (r = 0.82 Figure 27).

The results from this series of experiments show that variations in body position make no significant difference to the mean V D I's of a group of subjects with and without varicose veins. However, individual differences in the V D I's obtained from subjects in different positions make it important that comparisons of results are confined to results obtained from subjects in the same position during the experiments.

All future experiments on venous distensibility were conducted with the subjects lying supine on a couch with their calves supported clear of the couch at heart level.

Table 6

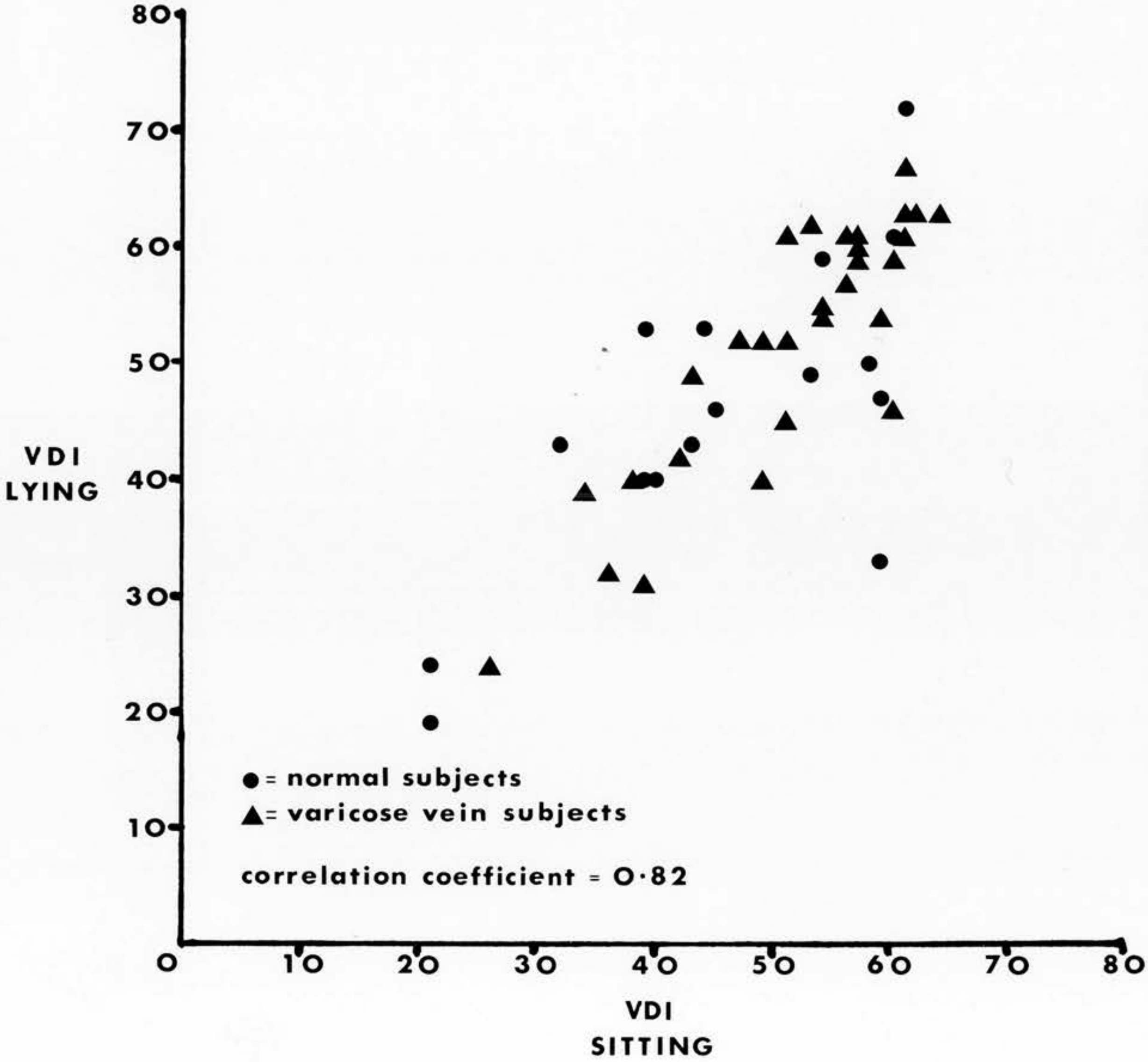
Venous Distensibility Index Related to Subject Position

	Normal Subjects		Subjects with Varicose Veins	
	Lying	Sitting	Lying	Sitting
	33	59	61	56
	49	53	63	62
	47	59	39	34
	40	39	32	36
	53	39	55	54
	46	45	49	43
	53	44	61	61
	43	32	59	57
	72	61	57	56
	50	58	54	54
	43	43	52	49
	40	40	42	42
	61	60	60	57
	59	54	46	60
	19	21	61	57
	24	21	63	64
			52	51
			24	26
			31	39
			40	38
			40	49
			45	51
			52	47
			55	54
			62	53
			63	61
			61	51
			59	60
			67	61
			54	59
mean	45.8	45.5	51.9	51.4
standard deviation	13.3	13.2	10.9	9.5

There was no significant difference between the mean VDI's of the two groups of subjects recorded from two different subject positions (two sample t test).

Fig.27

COMPARISON OF VDI's OBTAINED FROM RECORDINGS MADE USING TWO DIFFERENT SUBJECT POSITIONS



5.2.3 Effect of Local Temperature Changes

Six normal subjects had measurements of their venous distensibility performed whilst their feet were maintained at 5 different temperatures (28, 30, 32, 34 and 36 degrees Centigrade) by means of a thermostatically-controlled electric blanket.

The results of calf girth increase (% x 50) at each cuff pressure for the different temperatures are shown in Table 7, together with the calculated V D I's.

It can be seen that local temperature changes have an effect on the venous distensibility, with higher temperatures tending to increase the V D I (Figures 28 & 29). Four subjects (numbers 1, 4, 5 and 6) had an increase in the V D I at 36° compared with their mean V D I's. Subject 2 had no change from the mean V D I and subject 3 had a fall in the V D I at 36° with the mean.

However, the magnitude of the changes with temperature is small (coefficients of variation ranging between 2.64 and 5.17%) for each subject. It was found that, with the environmental temperature maintained between 33 and 35°, the toe temperatures of the subjects under investigation varied between 25 and 27°. It was therefore decided that, except for reproducibility experiments, the small variations in distensibility due to toe temperature differences could be ignored. This would allow comparison of distensibility results between groups of subjects, providing their toe temperatures were within the range of 25 to 27°.

All subsequent measurements of venous distensibility were preformed when the subjects' toe temperatures were in the range 25 to 27° after equilibration with the environment.

Table 7

Effect of Local Temperature Changes on 6 Normal Subjects

Maximum Percentage Calf Girth Changes (% x 50) at Each Cuff Inflation

Cuff Pressure in mm Hg		Temperature				
		28°C	30°C	32°C	34°C	36°C
30	1	53	79	74	81	88
	2	12	9	17	19	23
	3	66	73	75	83	77
	4	87	94	98	102	109
	5	23	26	37	44	47
	6	5	13	28	31	32
50	1	90	132	105	123	131
	2	39	48	46	50	47
	3	111	105	101	114	116
	4	113	108	120	119	129
	5	36	43	54	55	61
	6	52	49	68	69	82
70	1	144	186	153	178	193
	2	78	76	69	96	90
	3	142	144	138	156	142
	4	124	132	149	144	146
	5	59	56	75	81	88
	6	81	98	120	102	124
90	1	178	207	188	215	232
	2	105	122	106	127	114
	3	187	172	176	185	183
	4	158	146	176	170	175
	5	74	78	92	101	113
	6	121	132	158	141	181

Table 7

Effect of Local Temperature Changes on the VDIs of 6 Normal Subjects

	Temperature				
Subjects	28°C	30°C	32°C	34°C	36°C
1	65	65	63	67	68
2	58	60	56	62	59
3	62	60	58	61	59
4	43	45	49	46	48
5	42	41	45	42	46
6	61	64	66	63	68
mean	55.2	55.8	56.2	56.8	58

Analysis of variance

Source of variation	Sum of squares	Degrees of Freedom	Mean Square
between temperatures	4.8	4	1.2
within temperatures	2321.36	2.5	92.85

$$\text{variance ratio} = \frac{92.85}{1.2} = 77.37$$

Thus, the within temperature variance is many times larger than the between temperature variance.

Consequently, it is unlikely that the between temperature variation is caused by real differences in the between temperature means. Therefore, local temperature changes have little effect on the VDI.

Fig. 28

THE EFFECT OF LOCAL TEMPERATURE CHANGES ON THE VDI's OF SIX NORMAL SUBJECTS

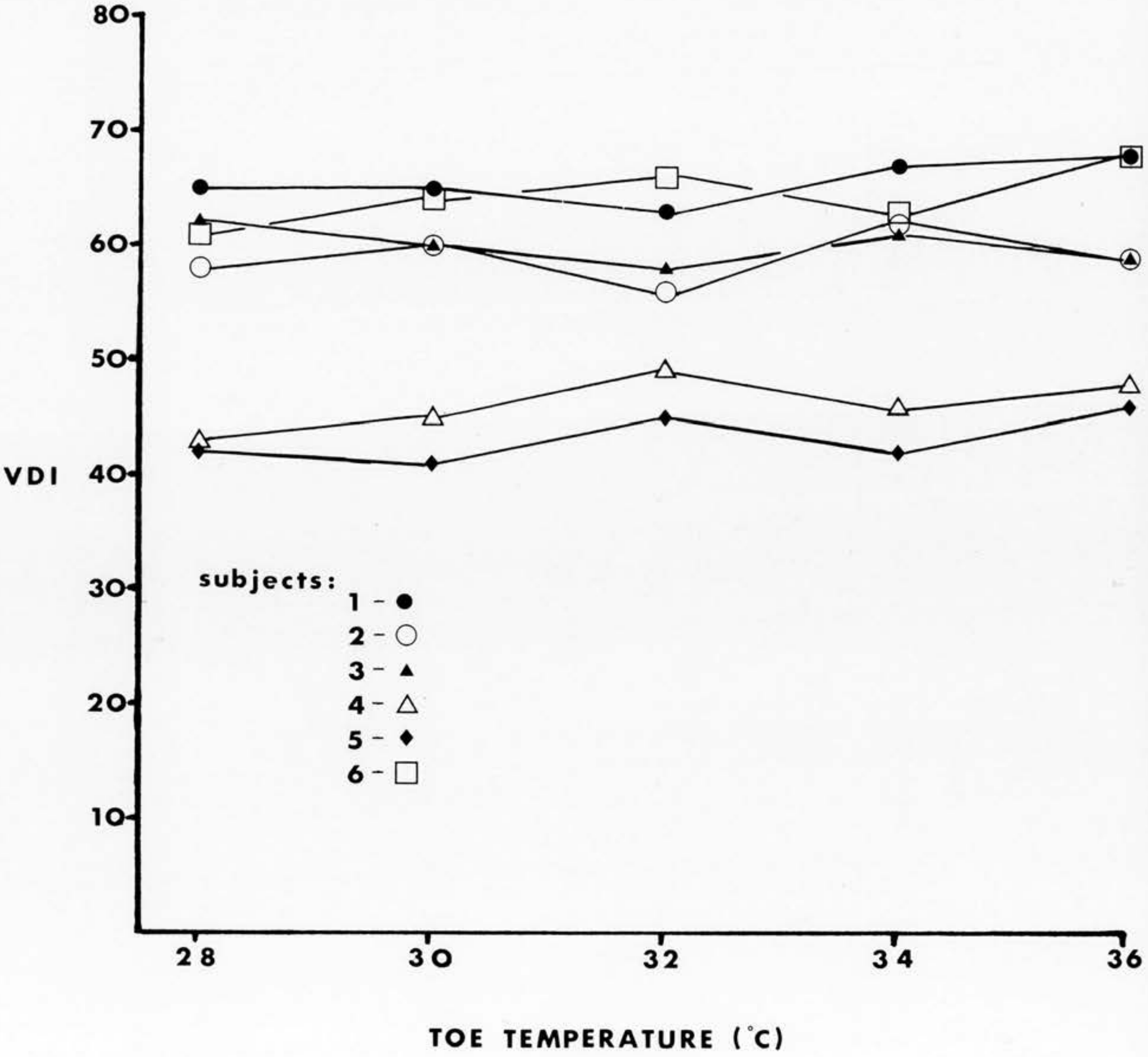
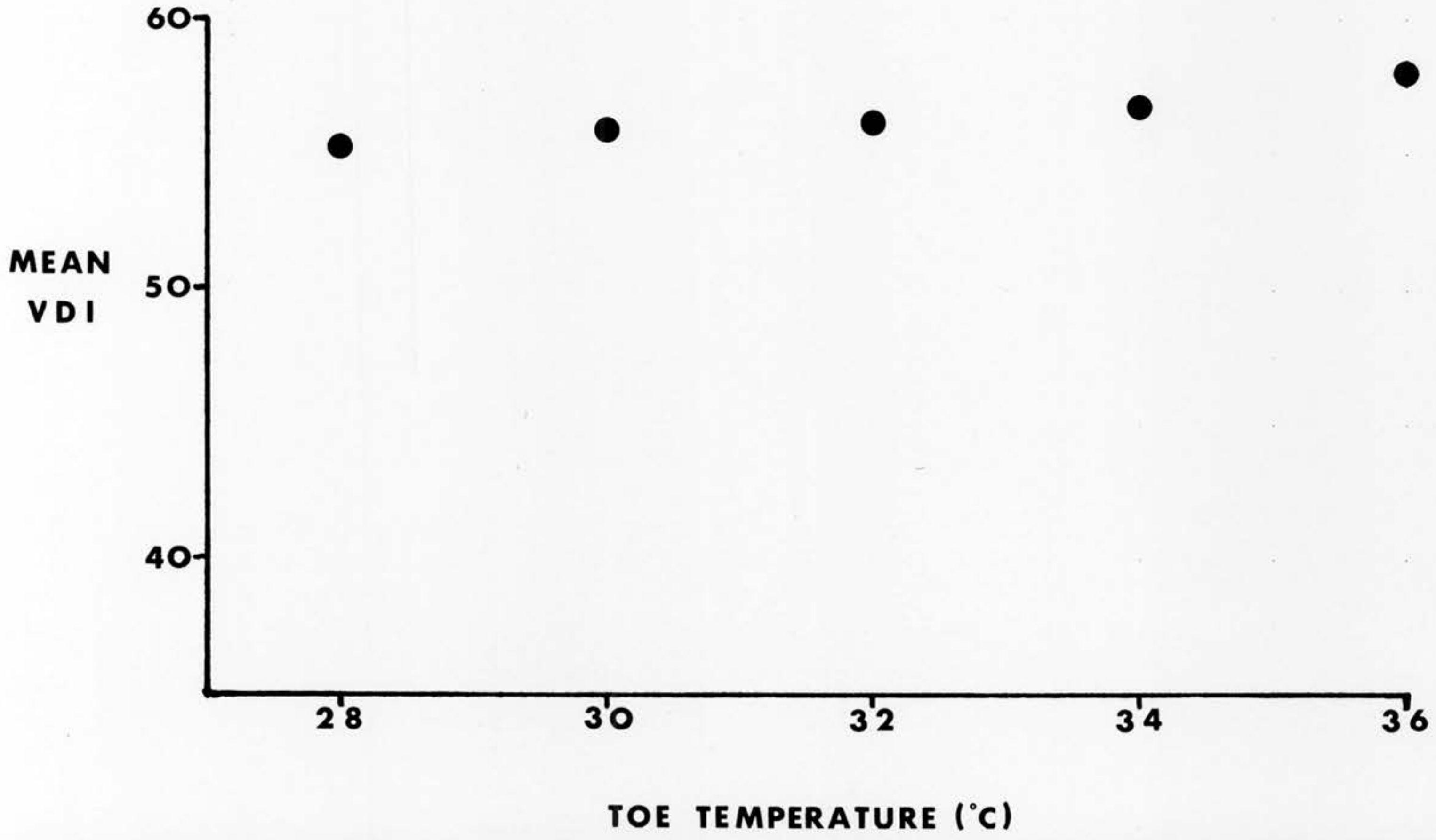


Fig. 29

THE MEAN VDI's OF SIX NORMAL SUBJECTS RECORDED AT FIVE DIFFERENT TOE TEMPERATURES



5.3 Venous Distensibility Indices of Subjects Subdivided According to Severity of Venous Disease

The initial comparison of the results obtained from 20 normal subjects and 20 subjects with varicose veins showed no differences between the mean V D Is of the two groups (Table 8 and Figure 30). The result was surprising in comparison with previously published work, and so a further series of 47 varicose vein subjects were studied, subdivided as follows:

(i) The normal legs of 10 subjects with unilateral varicose veins without skin changes.

(ii) 20 subjects with varicose veins affecting the long saphenous system but without skin changes. 10 sets of results were from the legs with varicose veins from group (i) and the remaining 10 were from the worse-affected leg of subjects with bilateral varicose veins.

(iii) 20 patients with varicose veins associated with skin changes and either ulceration or a healed ulcer above the medial malleolus. All these subjects had bilateral varicose veins, and the recordings were taken from the worse leg.

(iv) 7 patients with varicose veins secondary to below-knee perforator incompetence with no clinical, or ultrasonic, evidence of sapheno-femoral incompetence. None of these subjects had any skin changes associated with their varicose veins.

The mean V D I's obtained from each of these groups were compared with that of the normal subjects (Table 9 and Figure 31).

The only group of subjects studied that had a significantly different mean V D I from that of the normal subjects was that containing the patients with below-knee varicose veins without sapheno-femoral incompetence or skin changes (group (iv)). [redacted] Subjects with long-standing varicose veins and associated skin changes maintained a normal distensibility. [redacted]

Table 8

Comparison of Venous Distensibility Indices from Normal and Varicose Vein Subjects

The following venous distensibility indices were calculated for 20 normal and 20 varicose vein subjects. All subjects were studied whilst lying supine with the legs supported clear of the couch at heart level. The strain-gauge was positioned around the maximum calf circumference.

Venous Distensibility Index

	Normal Subjects	Varicose Vein Subjects
	71	68
	66	63
	63	55
	61	59
	63	52
	65	57
	62	63
	58	65
	41	66
	49	60
	40	66
	60	71
	59	63
	46	59
	53	37
	59	53
	63	46
	58	40
	62	57
	67	62
mean	58.3	58.1
standard deviation	8.4	8.9

No significant difference between two means using two sample t test.

Fig. 30

COMPARISON OF THE VDI's OF TWENTY NORMAL AND TWENTY VARICOSE VEIN SUBJECTS

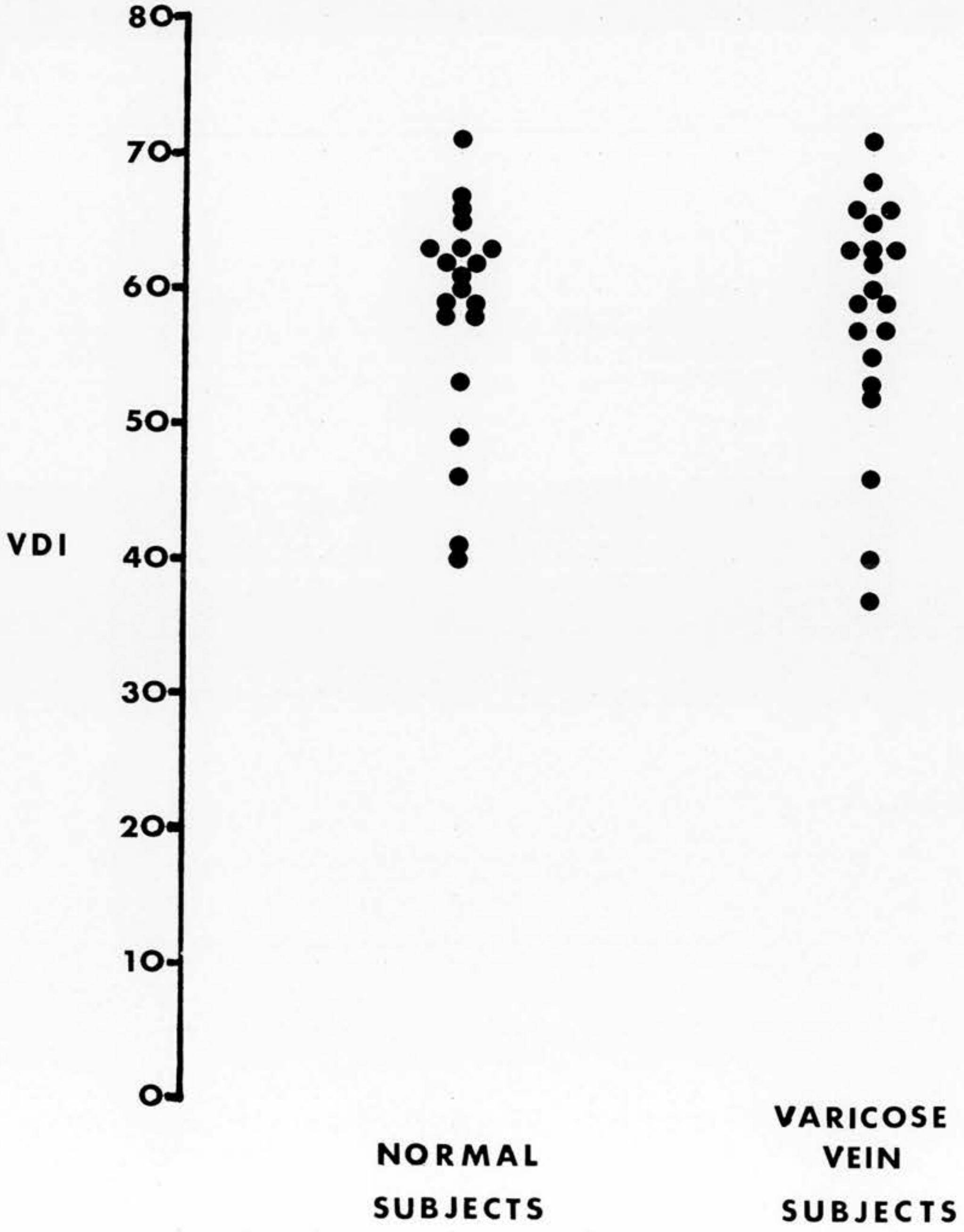


Table 9

Venous Distensibility Indices of Subjects Subdivided According to Severity of Venous Disease

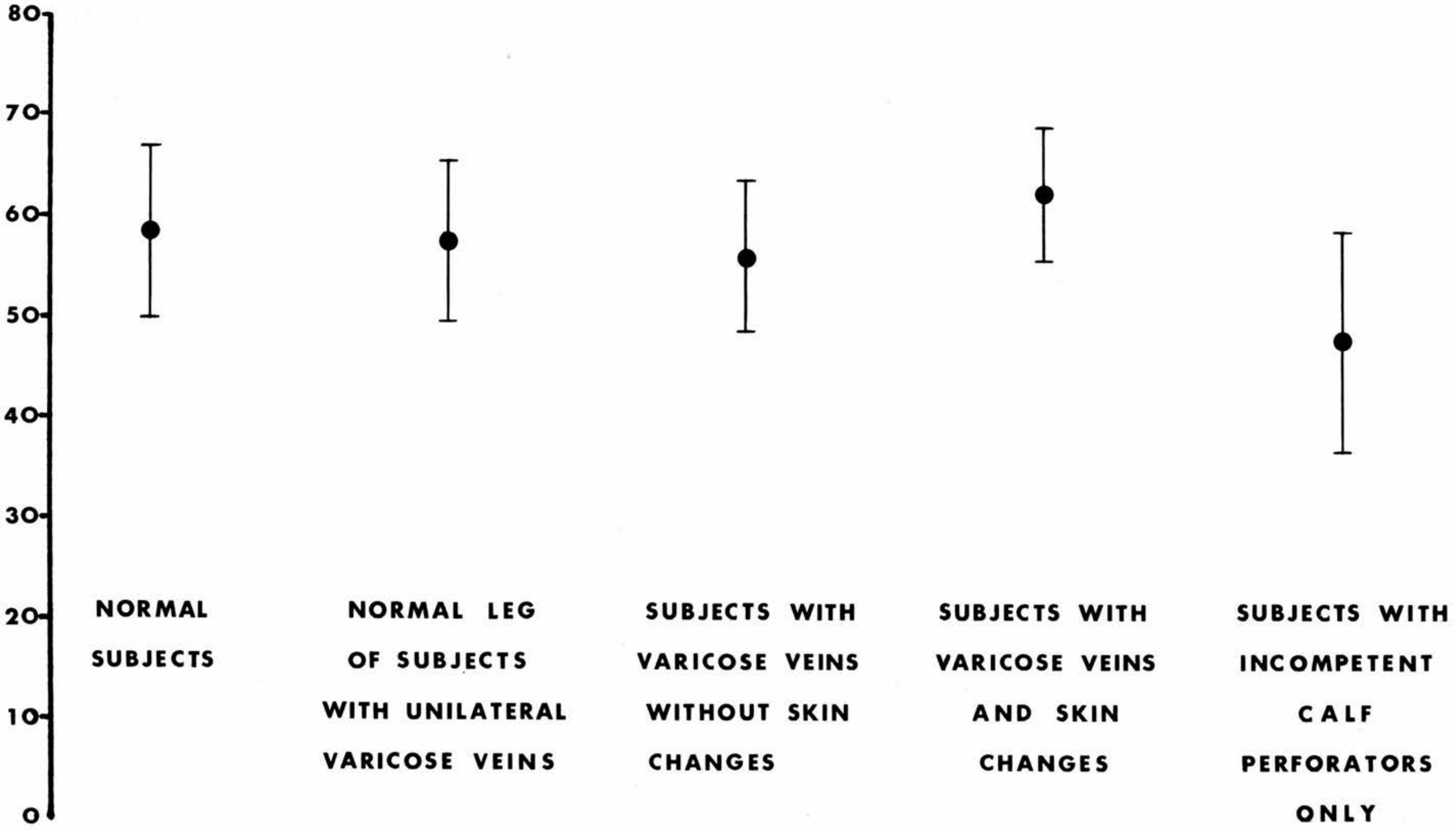
	Normal	(i) Normal Leg of Unilateral Varicose Veins	(ii) Varicose Veins Without Skin Changes	(iii) Varicose Veins With Skin Changes	(iv) Perforators Only Without Skin Changes
	71	56	68	63	36
	66	56	56	61	37
	63	54	59	59	46
	61	63	62	63	40
	63	63	67	66	63
	65	60	68	71	54
	62	52	48	53	58
	58	40	46	58	
	41	68	57	50	
	49	62	59	46	
	40		57	65	
	60		48	64	
	59		52	65	
	46		53	66	
	53		46	56	
	59		40	65	
	63		59	68	
	58		55	68	
	62		53	70	
	67		62	66	
mean	58.3	57.4	55.8	62.2	47.7
standard deviation	8.4	7.8	7.4	6.7	10.8

No significant difference between means (two sample t test)

Varicose vein subjects subdivided according to results obtained from clinical examination and Doppler ultrasound testing.

Fig. 31

COMPARISON OF THE VDI's OF NORMAL SUBJECTS AND THOSE OF SUBJECTS SUBDIVIDED ACCORDING TO THE SEVERITY OF THEIR VARICOSE VEINS (MEANS ± 1 STANDARD DEVIATION)



A comparison of the results of venous distensibility from the normal and the abnormal legs in subjects with unilateral varicose veins shows no significant difference between the V D I's obtained from the two groups of legs (Table 10 and Figure 32).

A number of possible conclusions may be drawn from these results. Firstly, the process that produces varicose veins affects both legs, despite the fact that varicosities may only be detectable in one leg. Alternatively, the method of examination may be too imprecise to detect minor differences in venous distensibility. However, it is possible that venous distensibility may not be related to the [illegible] of varicose veins, or that [illegible] method [illegible] examination [illegible] measuring venous distensibility, despite [illegible] claims that it does.

Table 10

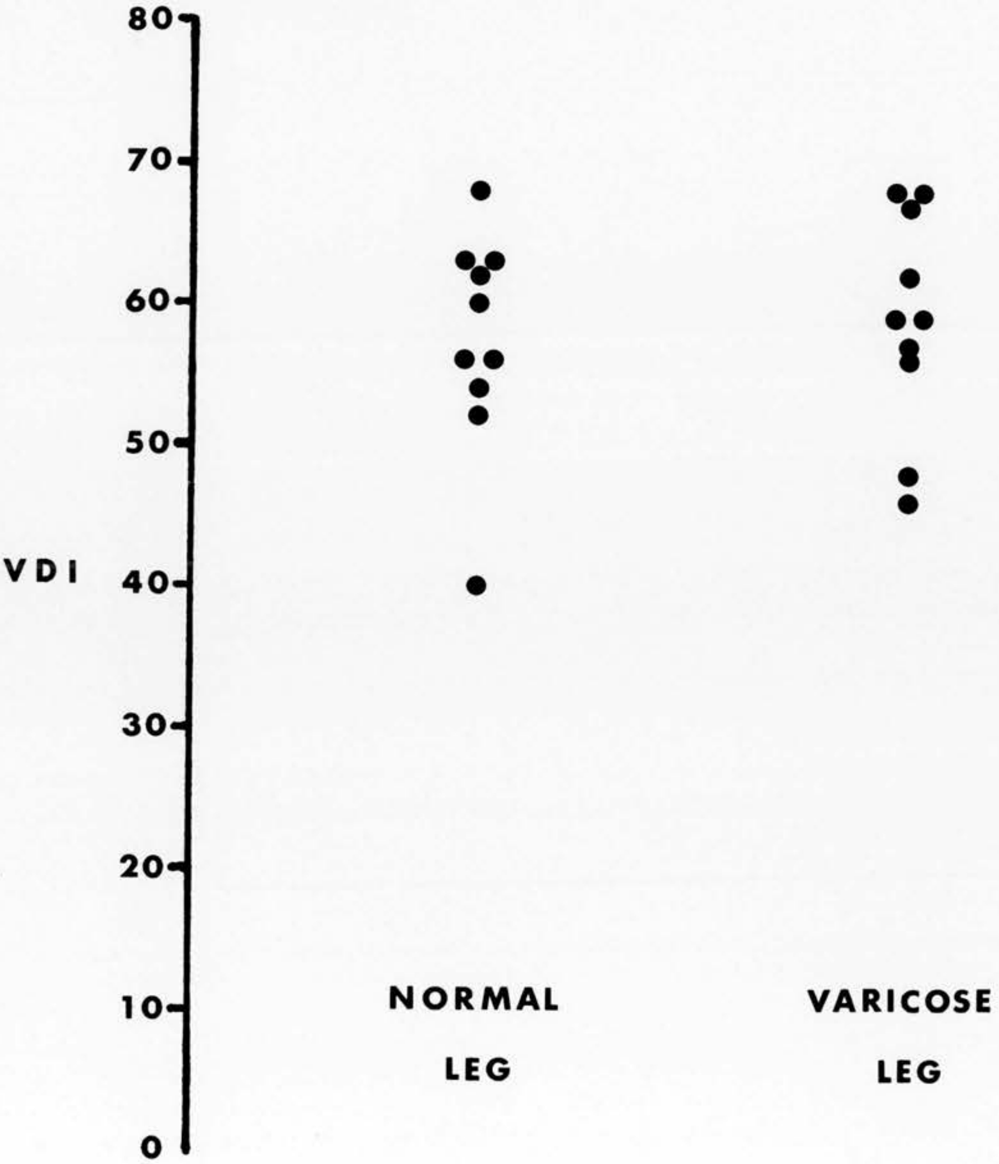
Comparison of the Venous Distensibility Indices of Both Legs in Subjects with Unilateral Varicose Veins

	Normal Leg	Varicose Vein Leg
	56	68
	56	56
	54	59
	63	62
	63	67
	60	68
	52	48
	40	46
	68	57
	62	59
mean	57.4	59
standard deviation	7.8	7.7

There is no significant difference between the means of the two groups of results (two sample t test).

Fig. 32

COMPARISON OF THE VDI's OF BOTH LEGS
IN SUBJECTS WITH UNILATERAL VARICOSE VEINS



5.4 Reproducibility of Venous Distensibility Measurements

A study of the reproducibility of the method was made using recordings obtained from 11 normal subjects assessed at the same time of day on 5 consecutive days. The toe temperature was the same for each subject on each occasion, and the strain-gauge was in the same position on the calf.

The results are shown in Table 11 and Figure 33 and show the considerable day to day variation obtained, despite the careful attempts to maintain the same experimental conditions. This variation combined with the overlap of results for normal and varicose vein subjects makes the differentiation of these two groups of subjects impossible by this method.

Table 11

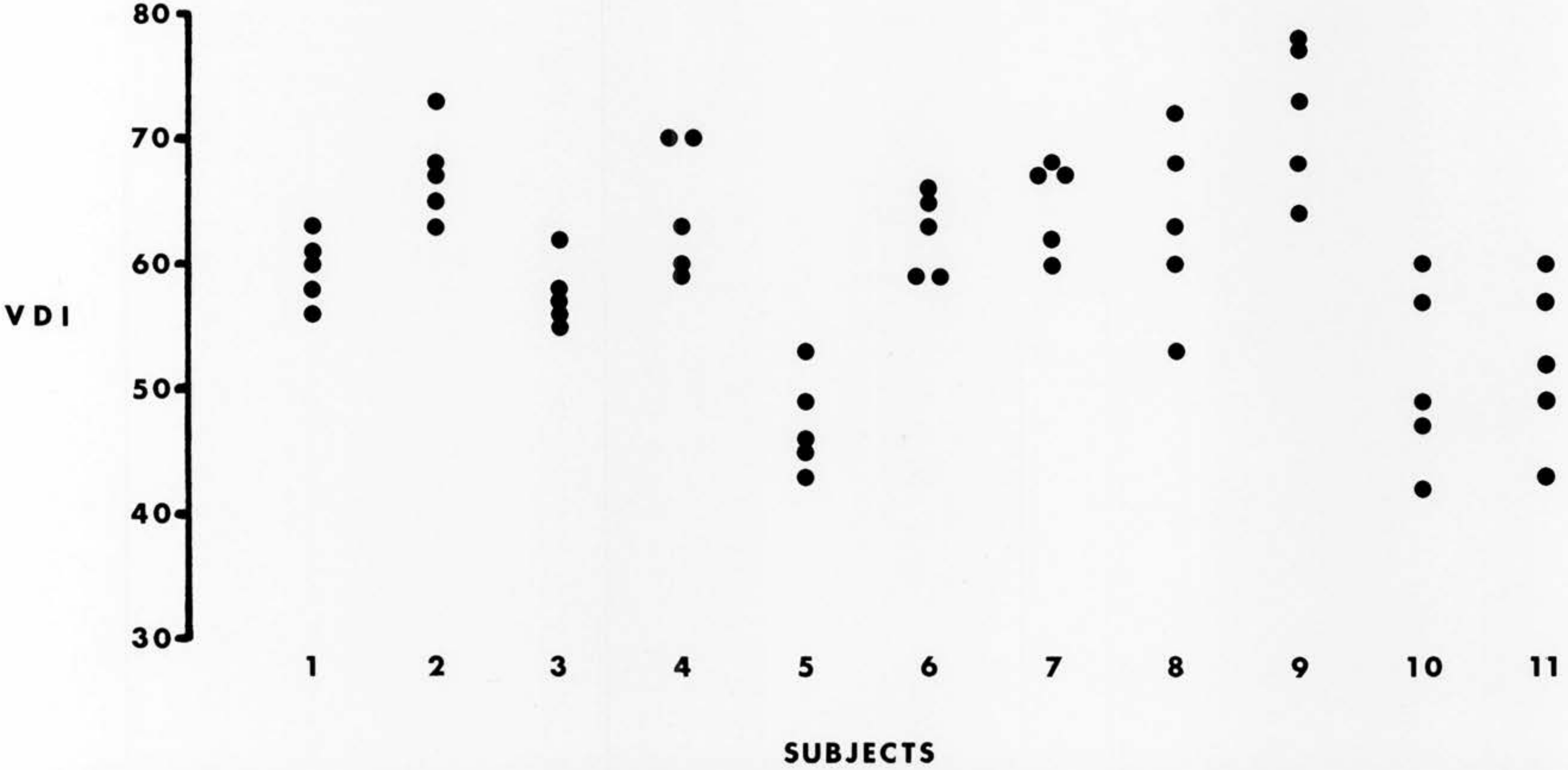
Reproducibility of Venous Distensibility Results

Subject	Day 1	Day 2	Day 3	Day 4	Day 5	Mean	Standard Deviation	Coefficient of Variation
1	63	61	58	60	56	59.6	2.7	4.5%
2	63	65	68	67	73	67.2	3.8	5.6%
3	56	58	55	62	57	57.6	2.7	4.7%
4	70	59	63	60	70	64.4	5.3	8.3%
5	46	53	43	45	49	47.2	3.9	8.3%
6	63	59	66	59	65	62.4	3.3	5.3%
7	67	68	62	60	67	64.8	3.6	5.5%
8	60	63	53	68	72	63.2	7.3	11.6%
9	77	68	73	78	64	72	6.0	8.3%
10	49	47	60	42	57	51	7.4	14.5%
11	43	49	57	60	52	52.2	6.7	12.8%

The table shows the venous distensibility indices calculated on 5 consecutive days from recordings from 11 normal subjects.

Fig. 33

DISTRIBUTION OF THE VDI's OF 11 NORMAL SUBJECTS OBTAINED FROM RECORDINGS MADE ON FIVE CONSECUTIVE DAYS



5.5 Simultaneous Venous Pressure and Calf Girth Change Measurement in Distensibility Recordings

Venous pressure and calf girth changes were recorded simultaneously in 10 normal subjects and 20 subjects with varicose veins whilst the thigh cuff was inflated to 30, 50, and 70mmHg.

The slopes of the graphs obtained by plotting calf girth change (% x 50) against cuff pressure (VDI) were compared with those obtained by plotting calf girth change (% x 50) against venous pressure (VDI (p)) and the results are shown in Tables 12 and 13 and Figures 34 and 35.

There is a good correlation between the VDI and the VDI (p) in both groups of subjects (r = 0.95 and 0.93 for normal and varicose vein subjects respectively). Thus, despite the fact that the same cuff width was used on subjects with a wide range of thigh circumferences, the venous distensibility is the same regardless of whether the applied pressure or the actual venous pressure is used to calculate the results.

If the VDI (p)s of the normal subjects and varicose vein subjects are compared, again there is a considerable overlap of results (Figure 36). Thus, even using the actual venous pressure to calculate the venous distensibility index does not provide sufficient separation of the results from normal and varicose vein subjects to make the investigation of value in the assessment of varicose veins.

Table 14 and Figures 37 and 38 demonstrate the lack of relationship between thigh cuff pressure and recorded venous pressure.

This finding is not in agreement with the work of Brakkee (1981) who suggested that there was a constant relationship between the width of the thigh cuff and the venous pressure recorded following inflation of the cuff. This suggestion had seemed unlikely in view of the wide variety of thigh circumference and adipose content encountered during the course of the experiments; an impression confirmed by the experimental findings.

The V D I (p)s were, with one exception, all greater than the V D I's, a reflection of the lower values recorded for venous pressure than the corresponding thigh cuff pressures. Also, there was a considerable variation in the differences between the V D I's and V D I (p)s in these two groups of subjects.

Thus, there was no constant relationship between the V D I's and the V D I (p)s, but there was a good correlation between the two sets of results. This implies that calf girth and venous pressure changes follow similar patterns in response to pneumatic thigh cuff inflation in individual subjects. Thus, the non-invasive measurement of calf girth change reflects changes in venous pressure, but, due to the lack of a constant relationship between the two recordings, calf girth recordings cannot be used as a non-invasive measurement of venous pressure, as has been suggested (Brakkee 1981).

Table 12

Simultaneous Venous Pressure and Calf Girth Measurement

Simultaneous calf girth (% x 50) and venous pressure recordings during inflation of the thigh cuff to 30, 50 and 70mmHg.

Normal Subjects

Cuff	30mmHg		50mmHg		70mmHg	
Pressure	Girth	Pressure	Girth	Pressure	Girth	Pressure
1	76	3	135	24	203	37
2	69	18	89	37	123	56
3	40	2	95	26	140	39
4	61	5	99	18	128	32
5	12	2	34	15	70	33
6	48	8	90	24	114	41
7	55	10	70	27	89	44
8	16	3	53	19	77	36
9	47	8	87	24	111	40
10	8	2	33	17	47	33

	VDI	VDI(p)
1	72	75
2	53	54
3	63	75
4	59	68
5	55	62
6	59	63
7	41	45
8	57	62
9	58	63
10	45	51
Mean	56.2	61.8
standard deviation	8.7	9.7

There was no significant difference between mean VDI and mean VDI (p) (two sample t test).

Table 13

Simultaneous Venous Pressure and Calf Girth Measurement (% x 50)

Varicose Vein Subjects

Cuff	30mmHg		50mmHg		70mmHg	
Pressure	Girth	Pressure	Girth	Pressure	Girth	Pressure
1	70	5	103	12	178	26
2	121	14	153	32	185	50
3	63	16	93	33	134	51
4	46	8	75	22	114	41
5	110	13	143	32	227	49
6	42	5	95	21	117	37
7	53	9	66	21	95	40
8	15	4	41	19	66	35
9	72	6	92	22	123	35
10	26	7	47	22	70	38
11	48	10	67	29	111	46
12	21	5	47	19	79	35
13	49	13	75	28	106	45
14	181	15	219	33	275	50
15	85	11	135	30	195	48
16	39	5	79	24	133	42
17	118	13	152	32	238	46
18	63	7	135	25	183	43
19	90	10	131	30	203	51
20	30	2	98	18	117	25

Table 13

Varicose Vein Subjects

	VDI	VDI(p)
1	70	79
2	58	60
3	61	64
4	60	64
5	70	73
6	63	67
7	47	54
8	53	58
9	51	60
10	48	55
11	58	59
12	56	62
13	55	61
14	67	70
15	70	71
16	67	68
17	72	75
18	72	73
19	70	69
20	65	75
Mean	61.7	65.9
standard deviation	8.1	7.2

There is no significant difference between mean VDI and mean VDI (p) (two sample t test).

Also there was no significant difference between means of VDI (p) for normal and varicose vein subjects (two sample t test).

Fig. 34

COMPARISON OF THE VDI's AND THE VDI(p)'s OBTAINED FROM TEN NORMAL SUBJECTS

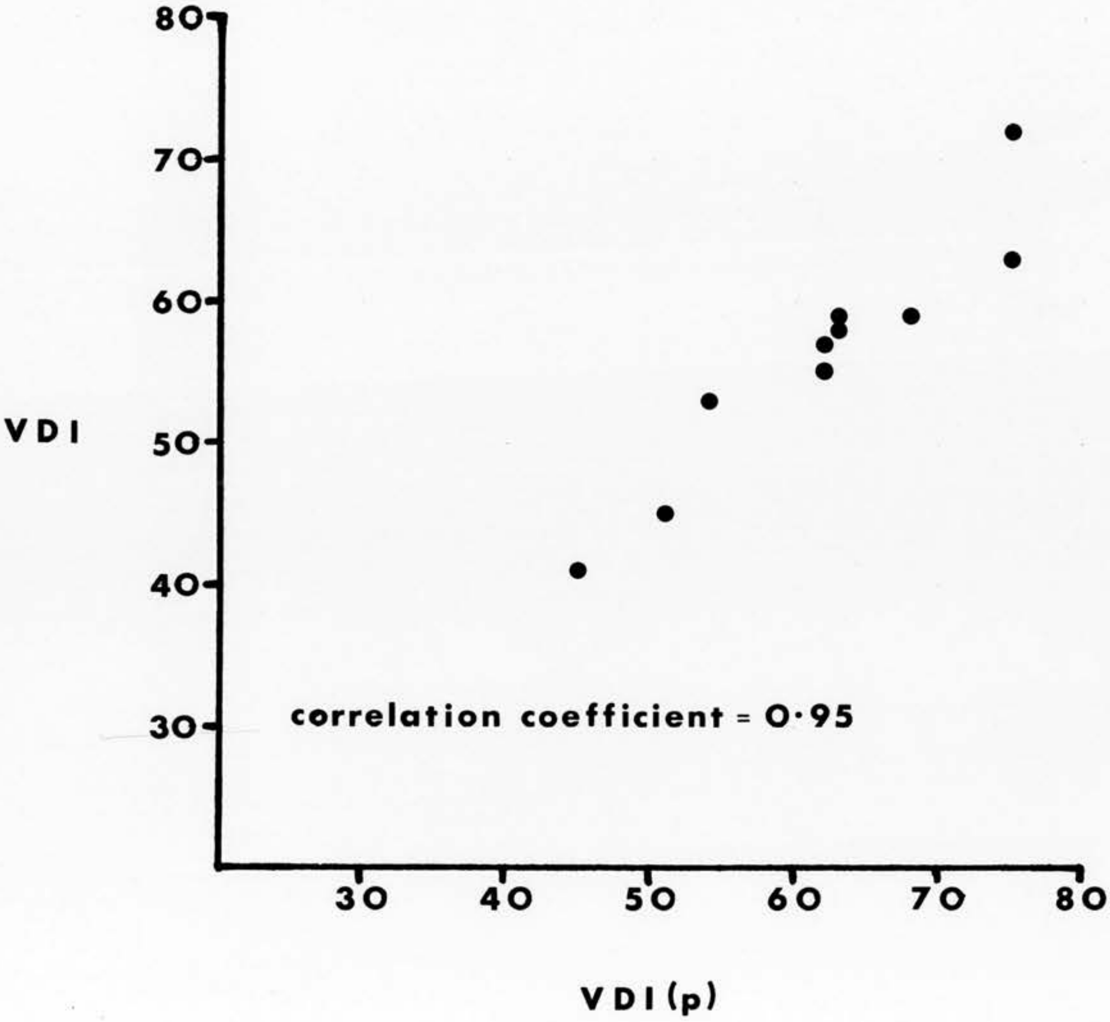


Fig. 35

COMPARISON OF THE VDI's AND THE VDI(p)'s OBTAINED FROM 20 VARICOSE VEIN SUBJECTS

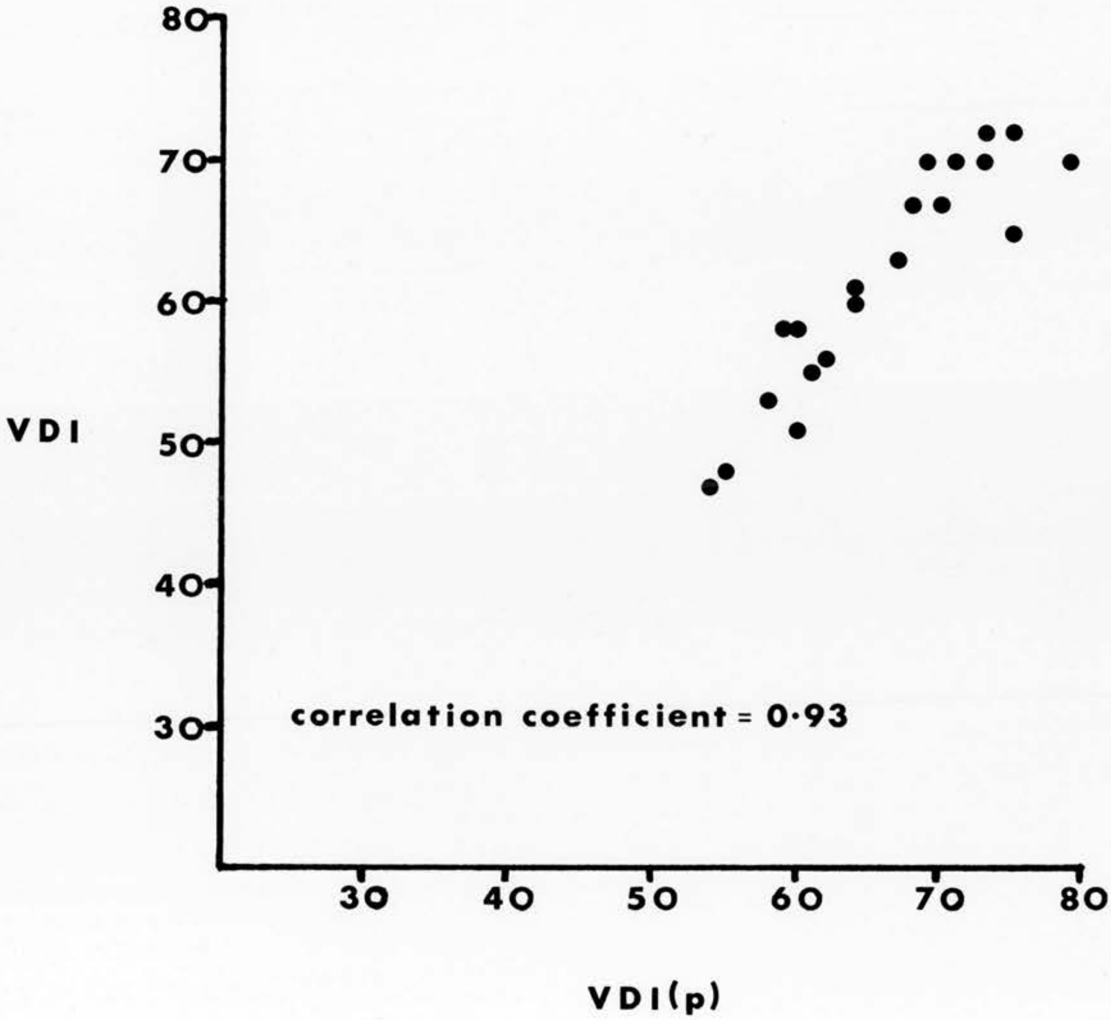


Fig. 36

COMPARISON OF THE VDI(p)'s OBTAINED FROM 10 NORMAL AND 20 VARICOSE VEIN SUBJECTS

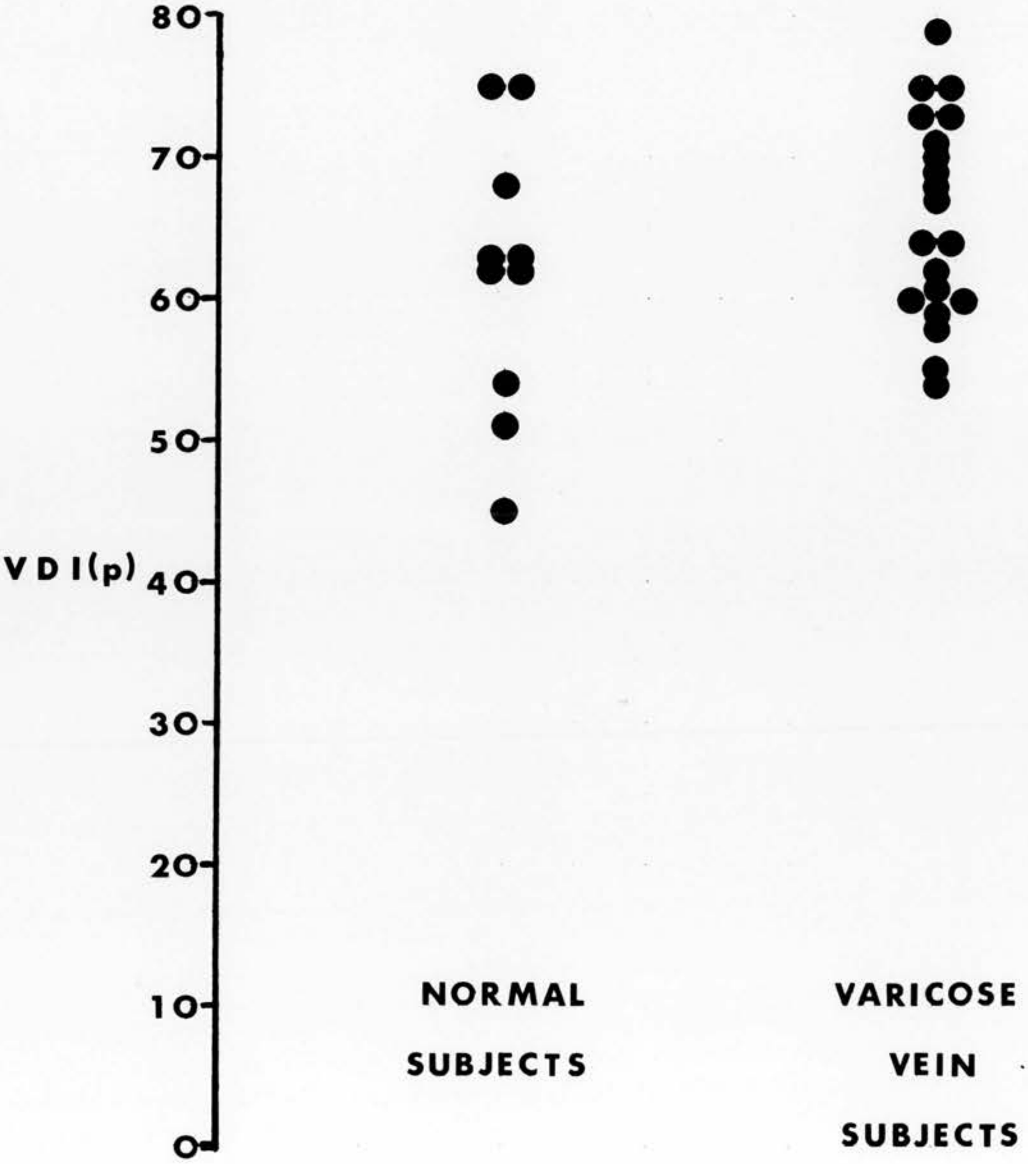


Table 14

Venous Pressure Differences Between Each Cuff Pressure to Demonstrate the Lack of a Constant Relationship Between Cuff Pressure and Venous Pressure Rise

Normal Subjects

	venous pressure rise between 30 & 50 mmHg cuff pressure	venous pressure rise between 50 & 70 mmHg cuff pressure
1	21	13
2	19	19
3	24	13
4	13	14
5	13	18
6	16	17
7	17	17
8	16	17
9	16	16
10	15	16

Table 14

Varicose Vein Subjects

	venous pressure rise between 30 & 50 mmHg cuff pressure	venous pressure rise between 50 & 70 mmHg cuff pressure
1	7	14
2	18	18
3	17	18
4	14	19
5	13	17
6	16	16
7	12	19
8	15	16
9	16	13
10	15	16
11	19	17
12	14	16
13	15	17
14	18	17
15	19	18
16	19	18
17	19	14
18	18	18
19	20	21
20	16	7

Fig. 37

THE VENOUS PRESSURES RECORDED AT 3 CUFF INFLATION PRESSURES FROM 10 NORMAL AND 20 VARICOSE VEIN SUBJECTS

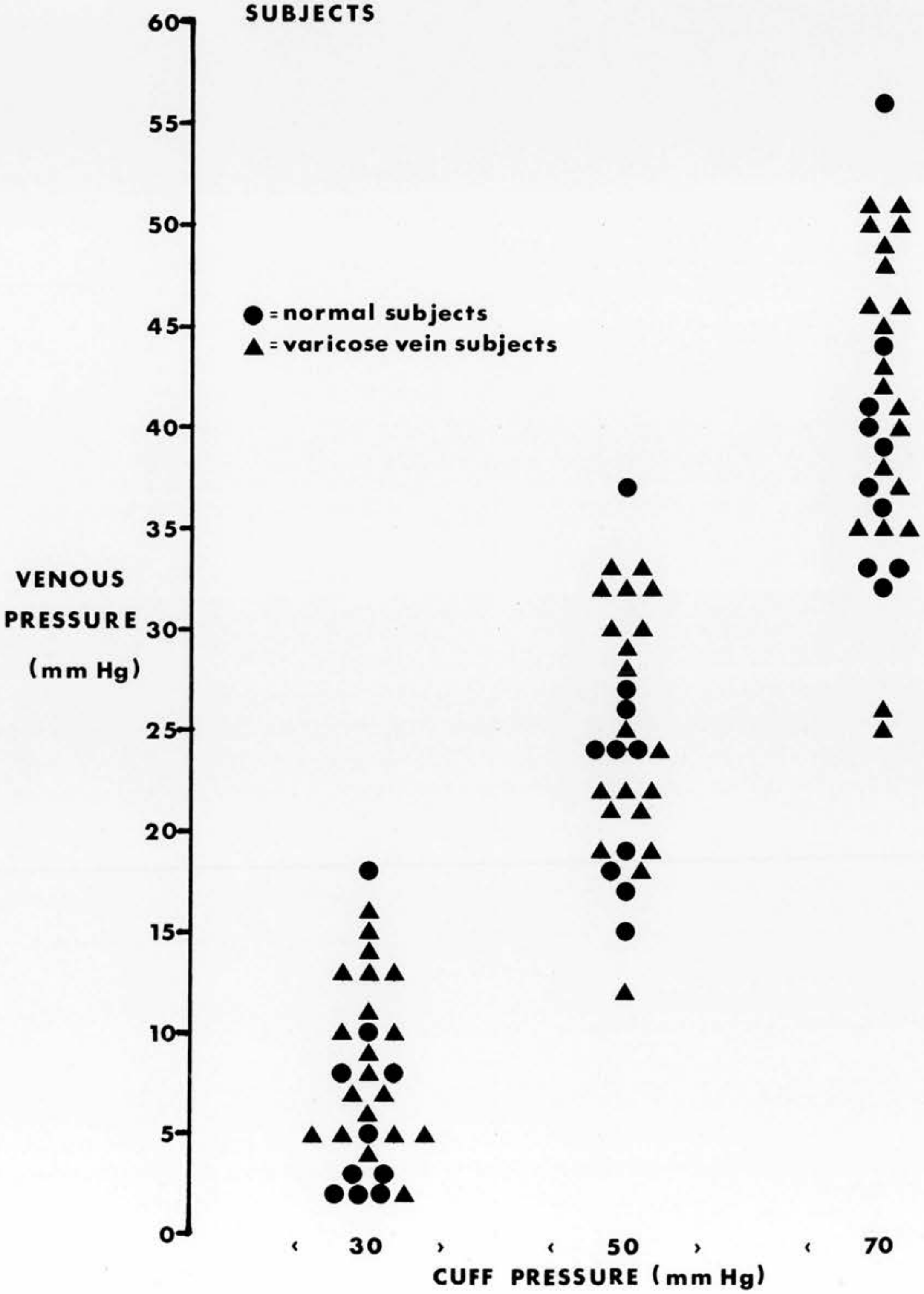
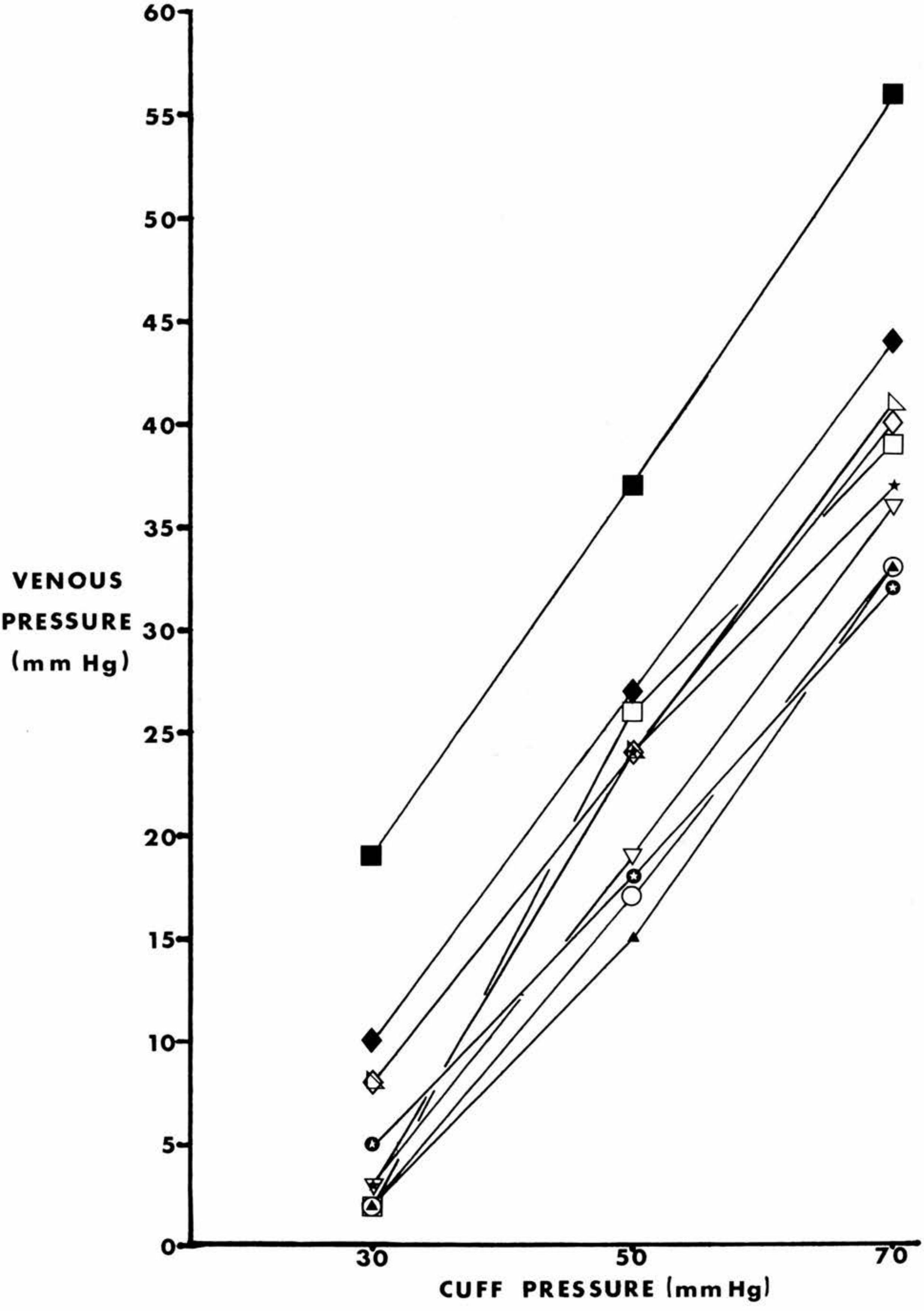


Fig. 38

THE DIFFERENT RATES OF VENOUS PRESSURE INCREASE IN 10 NORMAL SUBJECTS



These studies recording calf girth changes secondary to thigh cuff inflation as a measurement of venous distensibility have shown little difference between normal and varicose veins. Also, there are sufficient day to day variations in distensibility results to negate any apparent differences detected. The invasive venous pressure measurements show similar changes to those of calf girth secondary to thigh cuff inflation. Thus, it would appear that the calf girth recordings are measuring actual changes in the lower limb.

5.6 Ambulatory Test Preliminary Experiments

5.6.1. The Effect of Variation in Strain-Gauge Position

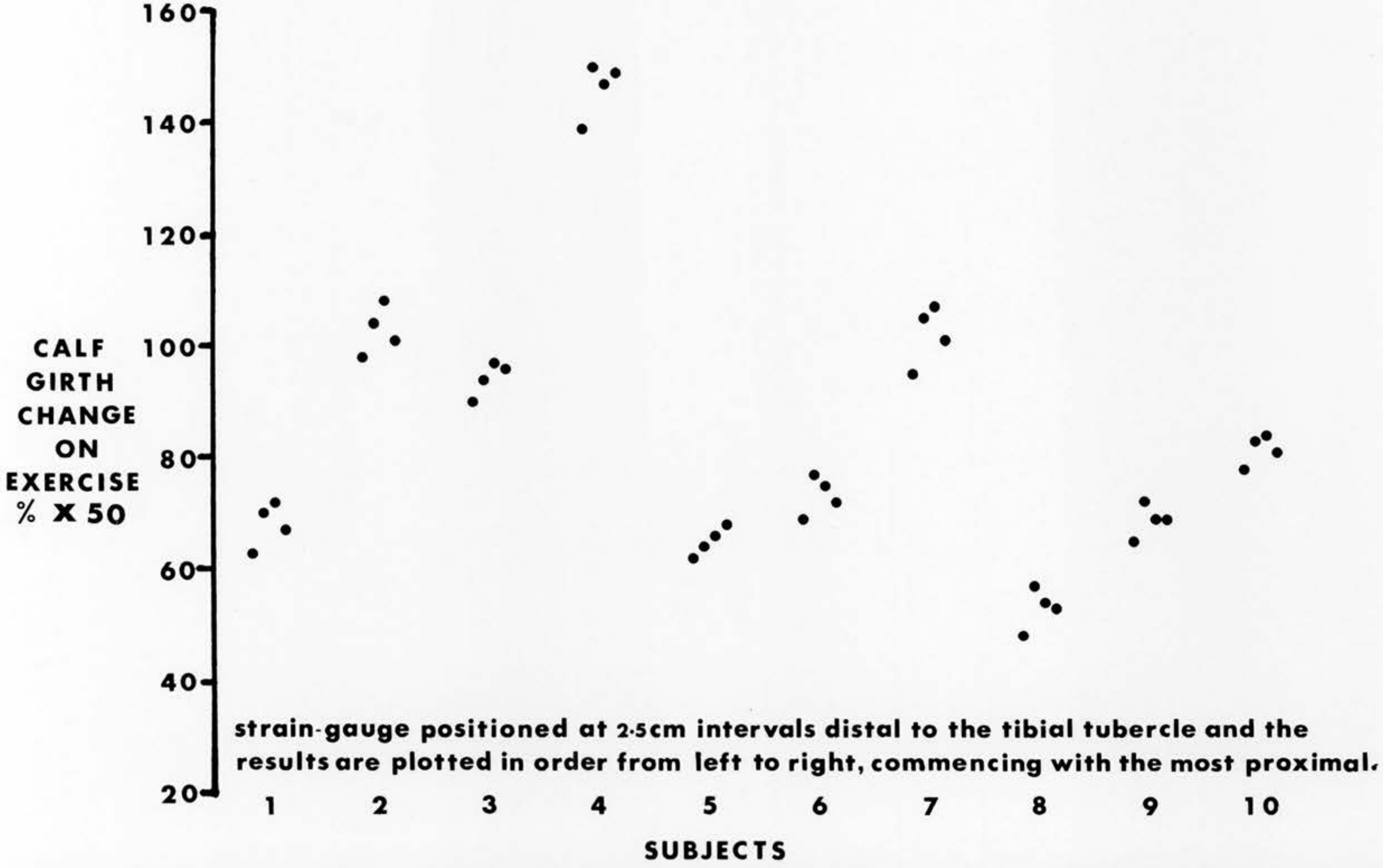
The heel-raising exercise was repeatedly performed by 10 normal subjects with the strain-gauge placed at distances of 2.5cm, 5cm, 7.5cm, and 10cm distal to the lower border of the tibial tubercle.

The results in Table 15 and Figure 39 show the range of variation of results to be 3.2% to 7.1%. The greatest girth changes occured around the maximum calf circumference (generally between 5cm and 7.5cm distal to the tibial tubercle), as shown by the mean percentage change at each measurement point.

Figure 39 shows that the subject to subject variation in results is far greater than any differences due to strain-gauge position. The results obtained from this group of subjects showed the normal range to be very large, and that the actual position of the strain-gauge matters little. All subsequent recordings were made with the strain-gauge attached around the subjects' maximum calf circumference.

Fig. 39

THE DISTRIBUTION OF THE AMBULATORY TEST RESULTS OBTAINED FROM 10 NORMAL SUBJECTS USING 4 DIFFERENT GAUGE POSITIONS



strain-gauge positioned at 2·5cm intervals distal to the tibial tubercle and the results are plotted in order from left to right, commencing with the most proximal.

Table 15

Ambulatory Test Results

Effect of variation in gauge position. Results from 10 normal subjects with strain gauge positioned 2.5cm, 5cm, 7.5cm, and 10cm distal to the tibial tubercle.

Subject	Percentage calf girth decrease on exercise (% x 50) gauge position distal to tibial tubercle				
	2.5cm	5cm	7.5cm	10cm	mean
1	63	70	72	67	68
2	98	104	108	101	102.75
3	90	94	97	96	94.25
4	139	150	147	149	146.25
5	62	64	66	68	65
6	69	77	75	72	73.25
7	95	105	107	101	102
8	48	57	54	53	53
9	65	72	69	69	68.75
10	78	83	84	81	81.5
mean	80.7	87.6	87.9	85.7	

Coefficients of Variation

Subject

1 = 5.8%
2 = 4.2%
3 = 3.3%
4 = 3.4%
5 = 4.0%
6 = 4.8%
7 = 5.2%
8 = 7.1%
9 = 4.2%
10 = 3.2%

Standard Deviations

Subject

1 = 3.9
2 = 4.3
3 = 3.1
4 = 5.0
5 = 2.6
6 = 3.5
7 = 5.3
8 = 3.8
9 = 2.9
10 = 2.6

5.6.2 The Reproducibility of Results

10 normal subjects were studied on 5 consecutive days performing two periods of heel-raising exercise with a strain-gauge positioned around their respective maximum calf circumferences. An average of the two recordings for each day was taken and the results obtained are shown in Table 16 and Figure 40.

The ambulatory calf girth changes were measured directly from the graphs obtained and these figures were used without conversion to true percentage strain-gauge length changes for ease of calculation. The calibration of the recording equipment (2.5cm vertical deflection = 1% strain-gauge length change) gave results in the range of 60 to 158 for the ambulatory calf girth change. These results may be converted to percentage strain-gauge change by dividing the results by 50 (as the gauge is doubled around the calf). Thus, the range of percentage calf girth change is 1.2% to 3.16%.

The greatest calf girth decrease on exercise was seen in subject 4, a 23 year old male, who was a regular sports player and cyclist. It was noted that subjects with greater calf muscle bulk (as judged by maximum calf circumference) produced greater percentage calf girth decreases on exercise.

The day to day variation in results from each subject was in the range of 3.2% to 5.7%.

Table 16

Reproducibility of Ambulatory Test Results

Results from 10 normal subjects on 5 consecutive days.

Ambulatory calf girth change on exercise (% x 50)

Subject	Day 1	Day 2	Day 3	Day 4	Day 5	Mean
1	65	70	74	69	72	70
2	100	104	106	98	110	103.6
3	99	103	91	95	90	95.6
4	158	142	155	147	153	151
5	63	60	67	65	61	63.2
6	77	77	72	79	69	74.8
7	97	98	102	97	105	99.8
8	58	57	52	53	55	55
9	68	69	73	67	71	69.6
10	78	81	83	77	82	80.2

Coefficients of Variation

Subject

1 = 4.8%
2 = 4.6%
3 = 5.7%
4 = 4.3%
5 = 4.5%
6 = 5.5%
7 = 3.6%
8 = 4.6%
9 = 3.5%
10 = 3.2%

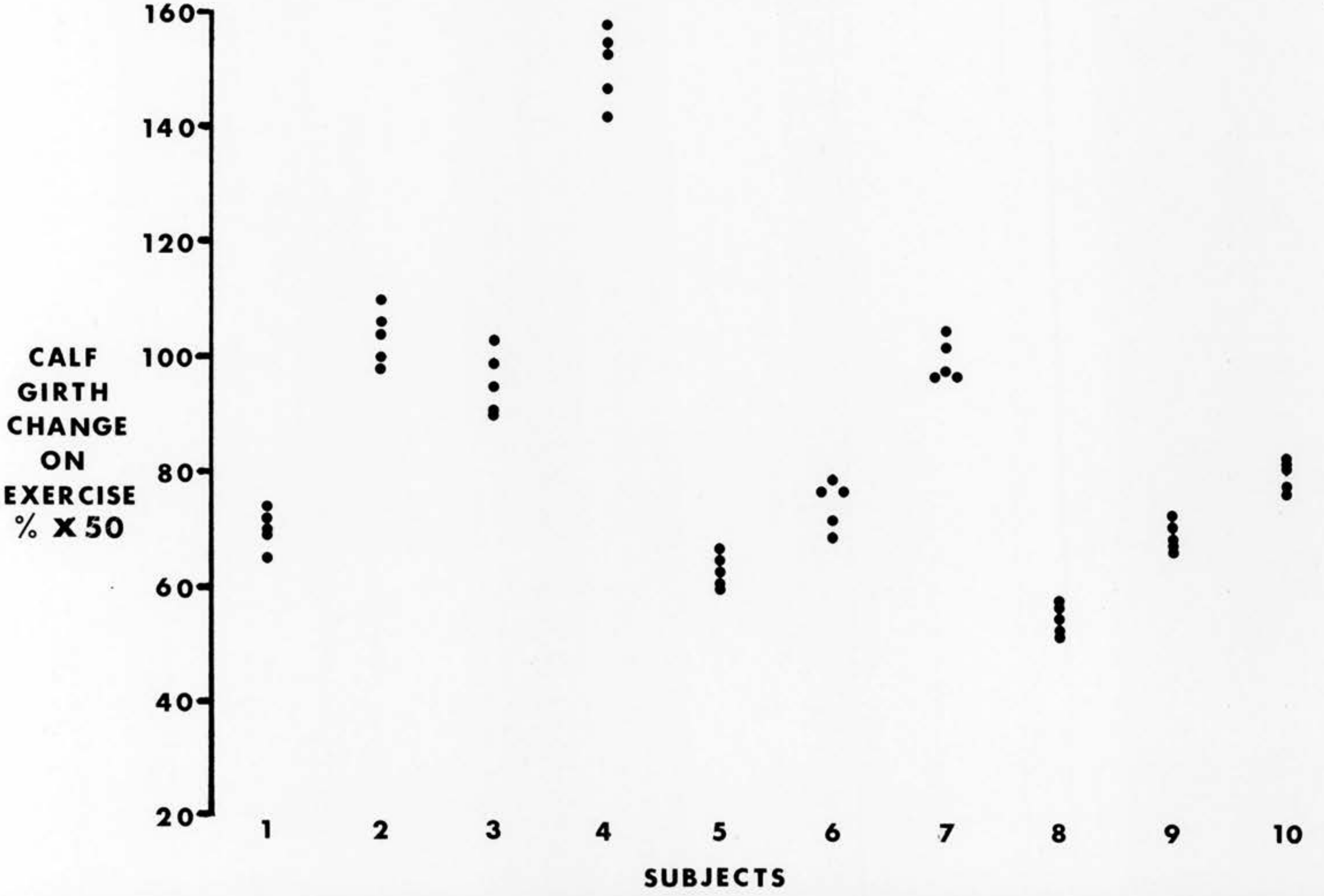
Standard Deviations

Subject

1 = 3.4
2 = 4.8
3 = 5.5
4 = 6.5
5 = 2.8
6 = 4.1
7 = 3.6
8 = 2.5
9 = 2.4
10 = 2.6

Fig. 40

THE DISTRIBUTION OF THE AMBULATORY TEST RESULTS OBTAINED FROM 10 NORMAL SUBJECTS RECORDED ON 5 CONSECUTIVE DAYS



5.7 Simultaneous Ambulatory Venous Pressure and Calf Girth Recordings

Venous pressure and calf girth recordings were simultaneously taken from 10 normal subjects and 15 patients with varicose veins during 30 second periods of heel-raising exercise. The venous pressure and calf girth changes were seen to follow similar patterns (Figure 21). The ambulatory venous pressure change was calculated by measuring the venous pressure fall for the first 10 calf contractions and taking the average value for one calf contraction (Figure 22). The ambulatory venous pressure change was compared with the ambulatory calf girth change (% x 50) for periods of exercise performed with and without inflation of the pneumatic thigh cuff to 100mmHg (13.3 KPa) (Tables 17 and 18).

There is a good correlation between the ambulatory pressure and girth changes (r = 0.84) (Figure 41), although varicose vein subject number 7 has an abnormally large pressure decrease on exercise, and normal subjects 1 and 9 have unusually small pressure decreases on exercise. However, if the recordings from these 3 subjects taken with the thigh cuff inflated are examined, it can be seen that varicose vein subject 7 had a larger pressure and girth decrease and that the two normal subjects had no change in their pressure but a small girth decrease. These results confirm the presence of sapheno-femoral incompetence in the varicose vein subject and the normality of the results from the other subjects. These results illustrate that there is a better separation of the normal from the abnormal results using calf girth changes than there is when venous pressure changes are used, and this is well demonstrated in Figure 41.

Venous pressure recordings only provide information from one part of the venous system whereas the girth measurements provide a composite picture of the results of the venous disorder on the haemodynamics of the calf.

Figure 42 shows a series of tracings of calf girth and venous pressure changes taken from a normal subject, a subject with long saphenous incompetence and a subject with perforator incompetence. The recordings were made during periods of heel-raising exercise performed with and without inflation of the thigh pneumatic cuff to 100mmHg. The illustration demonstrates the similar patterns of response in calf girth and venous pressure changes and also shows the different results obtained from subjects with venous disorders.

The ambulatory calf girth changes (% x 50) recorded from four different subjects are shown in Figures 43, 44, 45 and 46. The recording from the normal subject (Figure 43) shows that the calf girth decreases on calf contraction (downward deflection on the chart) and also that the calf girth increases on inflation of the thigh cuff whilst the subject is stationary. This girth increase is presumably due to venous obstruction, but the ambulatory calf girth change (% x 50) is still in the normal range when the exercise is performed with the thigh cuff inflated. The subject with long saphenous incompetence (Figure 44) also produced a calf girth decrease on calf contraction. However, the ambulatory calf girth change (% x 50) did not enter the normal range until the exercise was performed with the thigh cuff inflated preventing reflux down the long saphenous vein. Both of the subjects with calf perforator incompetence (Figures 45 and 46) increased their calf girth on calf contraction, but the subject with a combination of long saphenous and perforator incompetence showed an alteration in the ambulatory calf girth change (% x 50) towards the normal range when exercising with the thigh cuff inflated. It should be noted that a similar tracing to Figure 45 is obtained from subjects with deep venous incompetence. These illustrations also show that the calf girth does not usually return to the pre-exercise baseline after cessation of exercise.

Table 17

Comparison of Venous Pressure and Calf Girth Changes on Exercise

Results from 10 normal subjects.

Recordings of pressure and calf girth changes (% x 50) on exercise with thigh pneumatic cuff deflated and inflated to 100mmHg.

Subjects	Venous Pressure Drop		Calf Girth Drop	
	cuff deflated	cuff inflated	cuff deflated	cuff inflated
1	14	14	50	46
2	37	32	61	49
3	35	27	70	74
4	55	51	104	106
5	24	19	99	91
6	47	41	158	155
7	32	31	63	60
8	49	52	77	77
9	11	11	58	49
10	34	32	68	66

Table 18

Comparison of Venous Pressure and Calf Girth Changes on Exercise

Results from 15 subjects with varicose veins.
Subjects 1-8 inclusive had long saphenous incompetence.
Subjects 9-15 inclusive had a mixture of perforator incompetence and long saphenous incompetence.
Recordings of pressure and calf girth changes (% x 50) on exercise with thigh pneumatic cuff deflated and inflated to 100mmHg.

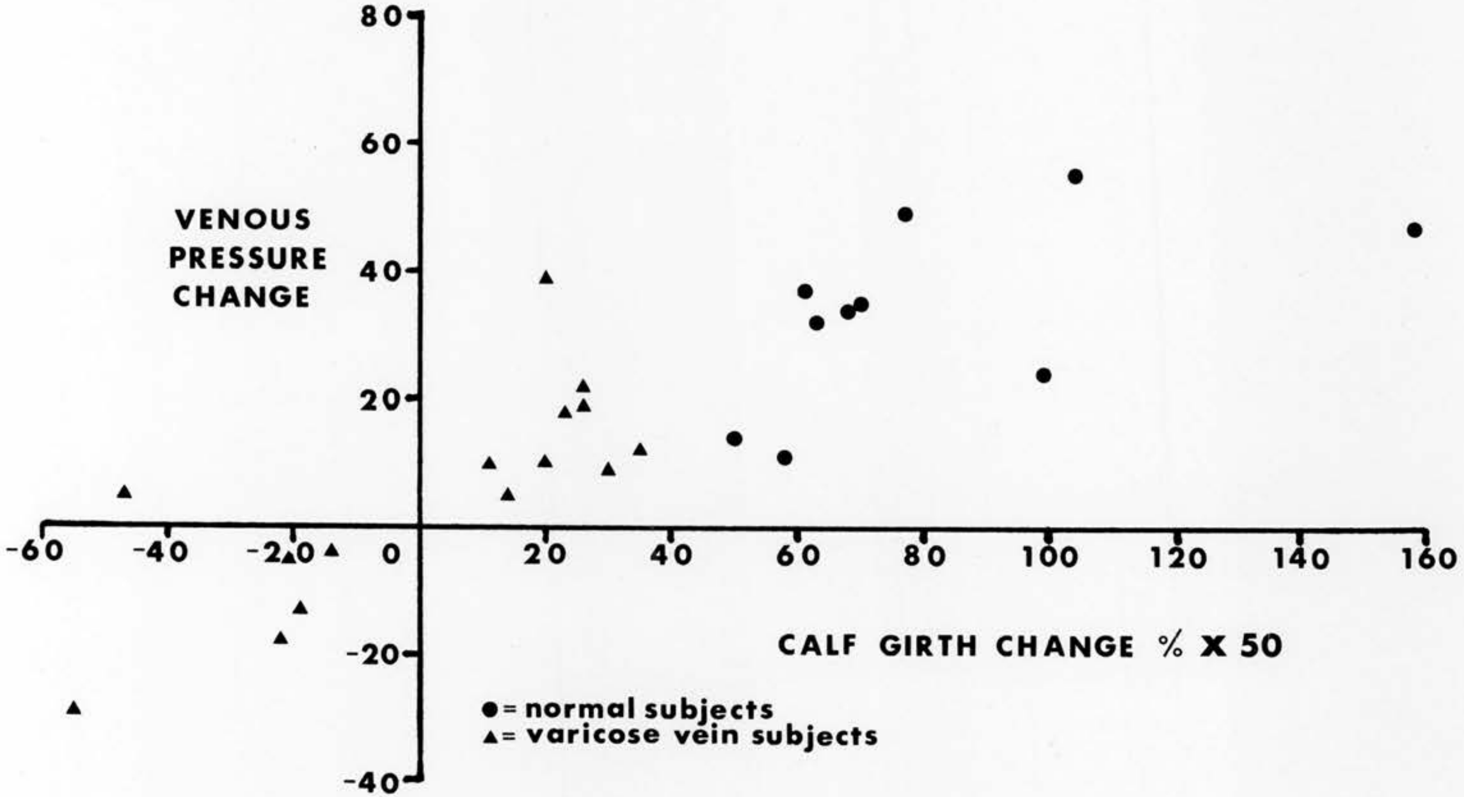
Subjects	Venous Pressure Drop		Calf Girth Drop	
	cuff deflated	cuff inflated	cuff deflated	cuff inflated
1	10	47	20	39
2	9	38	30	55
3	19	55	26	82
4	-5	15	-21	50
5	12	30	35	102
6	5	41	-47	15
7	39	69	20	80
8	5	41	14	59
9	-13	-26	-19	-43
10	22	6	26	18
11	-18	-50	-22	-59
12	18	11	23	25
13	10	9	11	7
14	-29	-17	-55	-37
15	-4	-12	-14	-31

Negative values indicate a venous pressure or calf girth rise on exercise.

Fig. 41

COMPARISON OF THE VENOUS PRESSURE AND CALF GIRTH CHANGES ON EXERCISE RECORDED FROM 10 NORMAL AND 15 VARICOSE VEIN SUBJECTS

(recordings made with thigh cuff deflated)



correlation coefficient = 0·84

Fig. 42

EXAMPLES OF THE SIMULTANEOUS AMBULATORY CALF GIRTH AND VENOUS PRESSURE RECORDINGS FROM THREE SUBJECTS

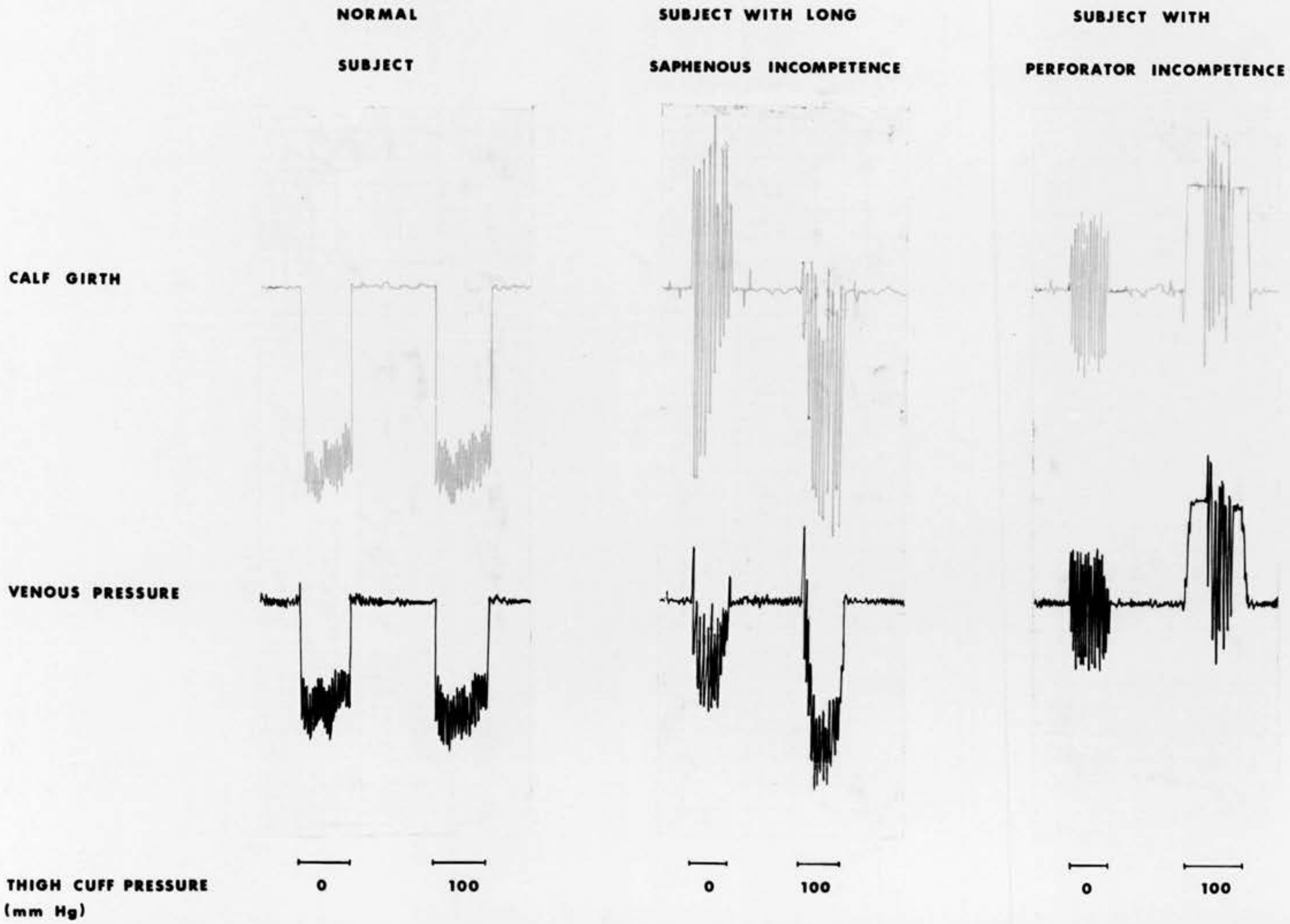


Fig. 43

AMBULATORY TEST RECORDING FROM A NORMAL SUBJECT

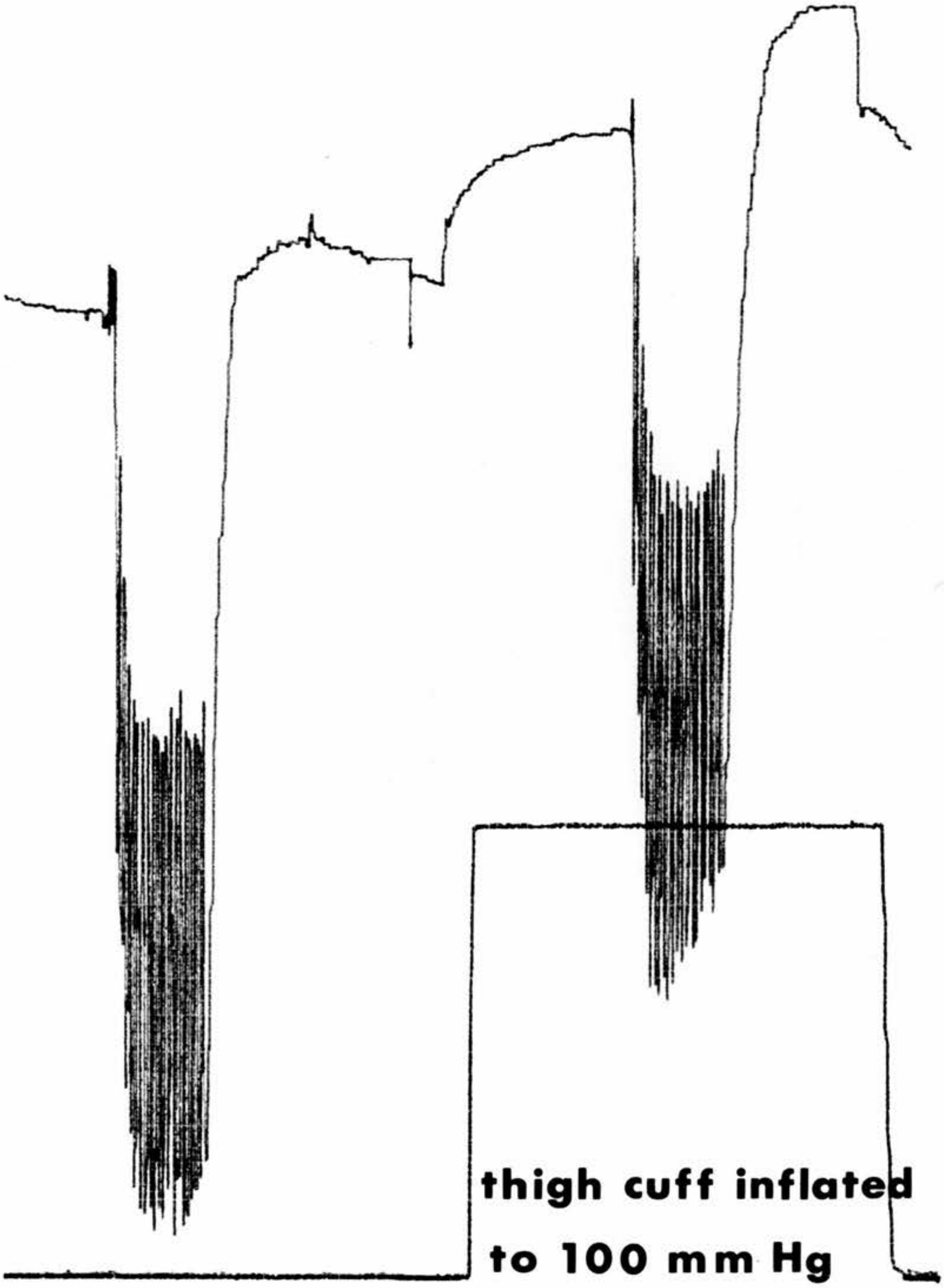


Fig.44

AMBULATORY TEST RECORDING FROM A SUBJECT WITH LONG SAPHENOUS INCOMPETENCE

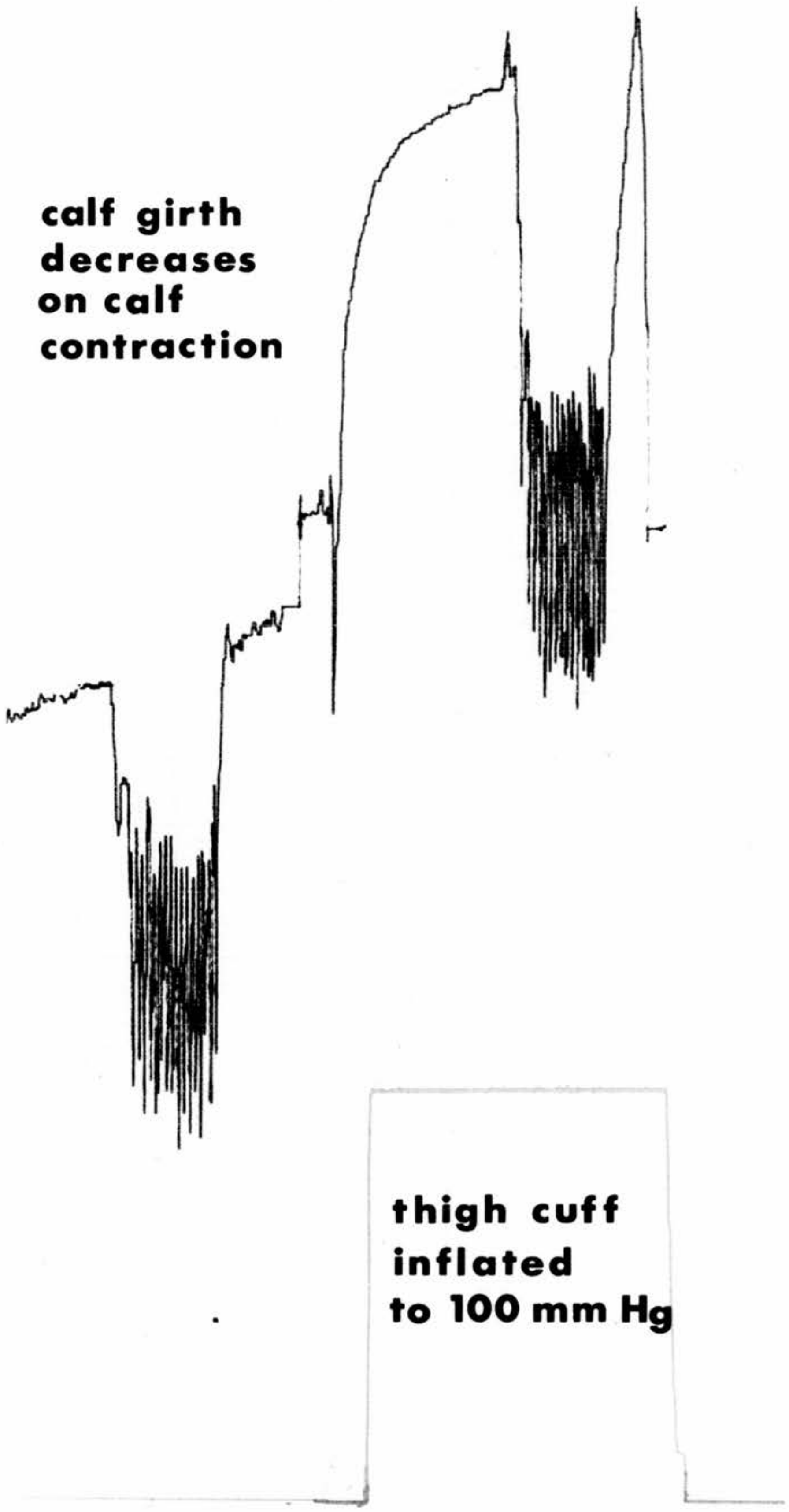


Fig. 45

AMBULATORY TEST RECORDING FROM A SUBJECT WITH PERFORATOR INCOMPETENCE

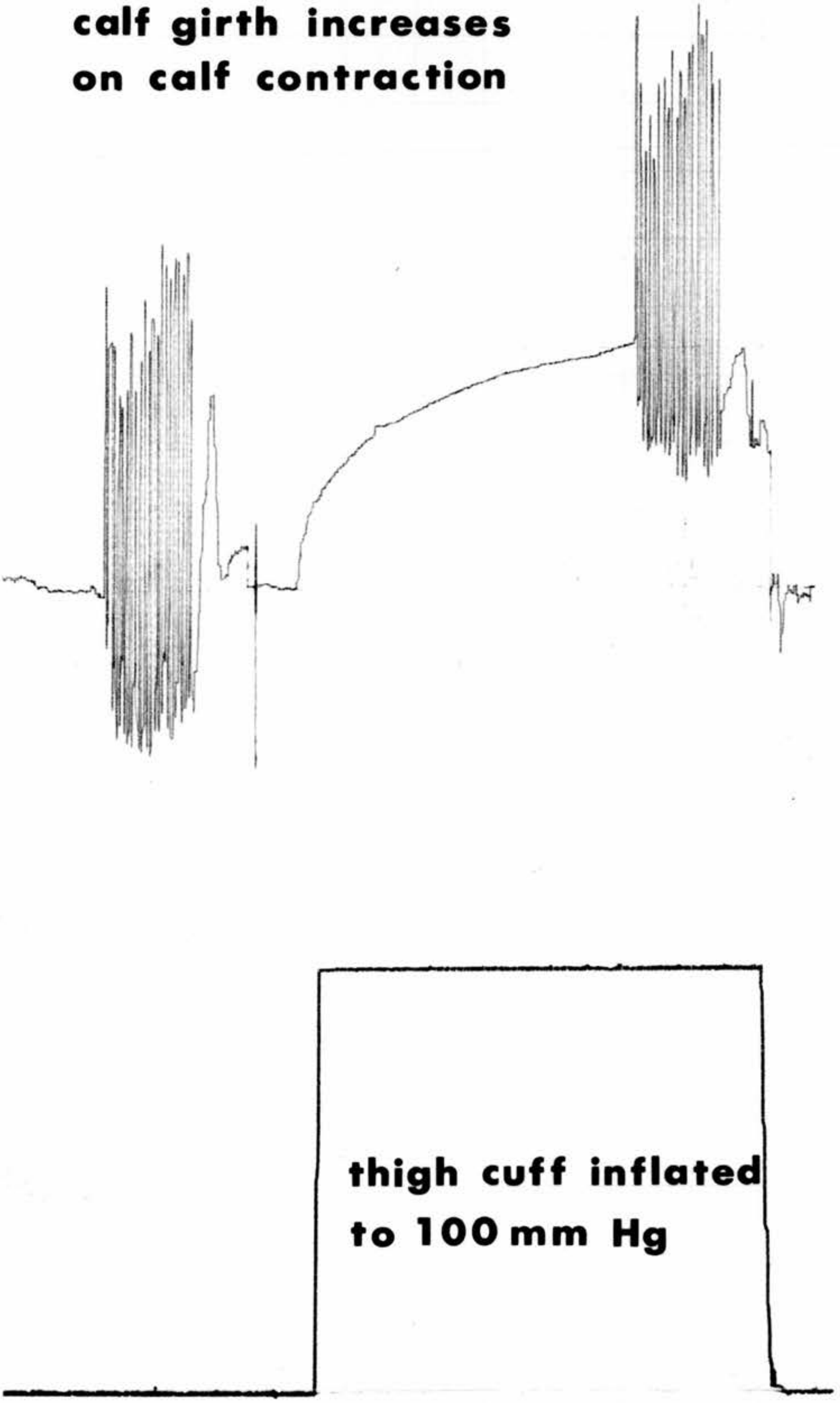
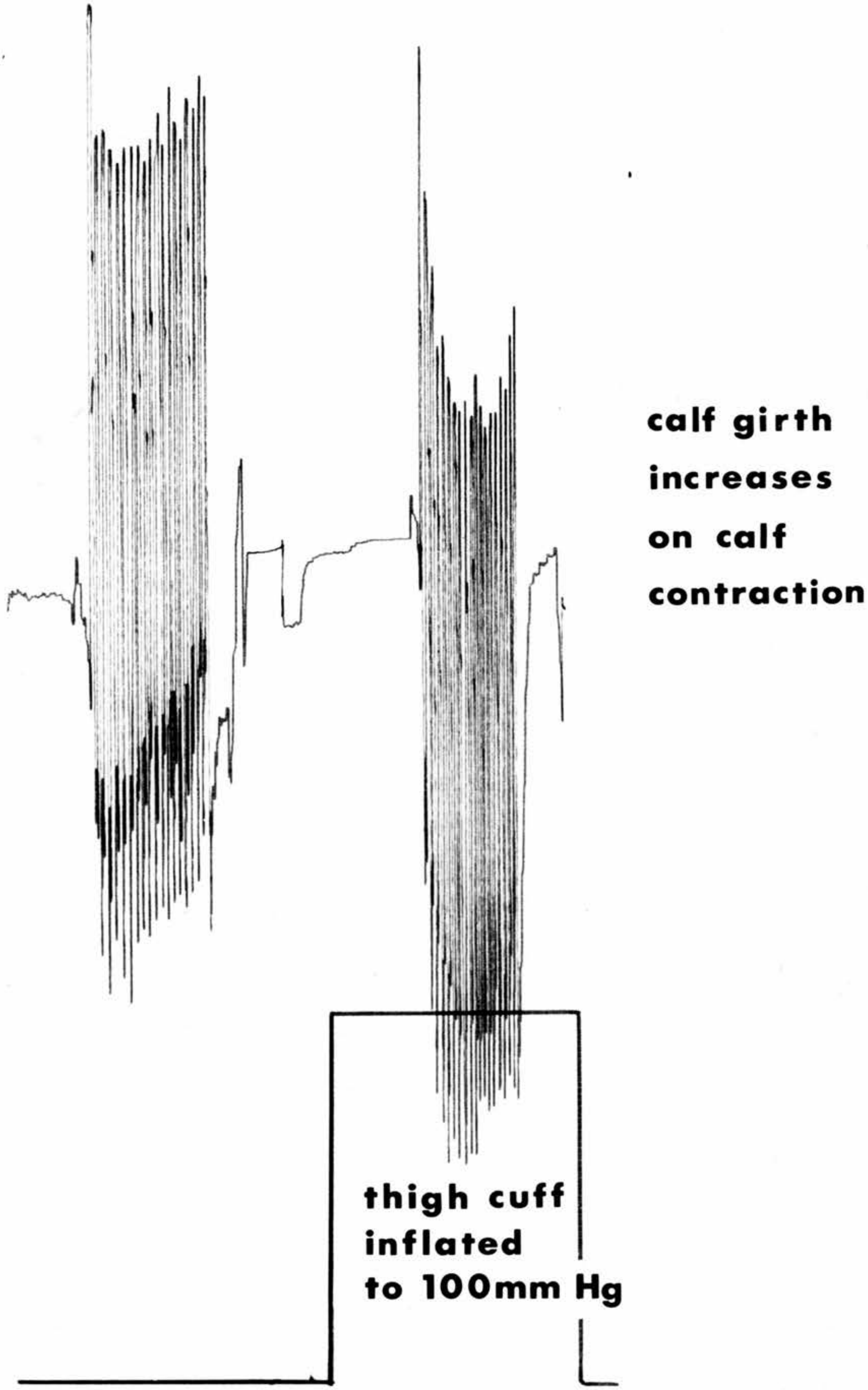


Fig.46

AMBULATORY TEST RECORDING FROM A SUBJECT WITH LONG SAPHENOUS & PERFORATOR INCOMPETENCE



5.8 Comparison of Results from Normal and Varicose Vein Subjects

The results from the ambulatory test in 20 normal subjects and 40 subjects with varicose veins were compared. 20 varicose vein subjects had evidence of sapheno-femoral incompetence on clinical examination and Doppler ultrasound testing. The remaining 20 varicose vein subjects had varicose veins confined to the calf without evidence of sapheno-femoral incompetence.

The periods of heel-raising exercise were performed without and with inflation of the pneumatic thigh cuff to 100mmHg. The purpose of the thigh cuff inflation was to occlude the long saphenous vein and thus the ambulatory test is a sophisticated form of Perthes' test.

The results are shown in Table 19 and Figures 47 and 48, some of the figures are shown as negative values, these latter values indicate that instead of a fall, these subjects have a rise in calf girth on exercise.

Normal subjects were seen to produce an ambulatory calf girth decrease (% x 50) of at least 46 on exercise without thigh cuff inflation (equivalent to a percentage calf girth decrease of 0.92%). Exercise with the thigh cuff inflated resulted in a smaller ambulatory calf girth decrease (% x 50) in most cases, due to the impairment of the normal venous return, although the smallest ambulatory girth decrease (% x 50) was still 38 (0.76% decrease in calf girth).

The ambulatory calf girth decrease (% x 50) on exercise without cuff inflation in both groups of varicose vein subjects was never greater than 35 (0.7% decrease in calf girth). The subjects with long saphenous incompetence, when exercising with the thigh cuff inflated, produced ambulatory calf girth (% x 50) results either within the normal range or which moved towards the normal range by at least 20 (0.4% calf girth decrease).

None of the varicose vein subjects without sapheno-femoral incompetence had an ambulatory test result within the normal range, regardless of whether or not the thigh cuff was inflated during the exercise period. In some of these subjects, exercise with the cuff inflated caused the ambulatory test result to move further away from the normal range, providing evidence for a normally functioning long saphenous vein.

Two of the subjects without evidence of sapheno-femoral incompetence on clinical examination or by Doppler ultrasound examination were found to have an ambulatory calf girth change (% x 50) which approached the normal range by more than 20 when the exercise was performed with the thigh cuff inflated. These two subjects were found on further Doppler ultrasound examination to have incompetent mid-thigh perforators. This illustrates a pitfall in the ambulatory test whereby occlusion of an incompetent thigh perforator by the pneumatic cuff will give an erroneous impression of sapheno-femoral incompetence. However, the test was not performed in isolation and the absence of sapheno-femoral incompetence on clinical and Doppler ultrasound examination suggested the presence of thigh perforators. In fact, the inconsistency of the plethysmographic result caused a search to be made for previously undiagnosed incompetent thigh perforators, and a change in the planned treatment of the varicose veins of these subjects.

This series of experiments established a normal range for the ambulatory test and also the results to be expected in subjects with varicose veins. There was a complete separation of the normal and abnormal results when the period of exercise was performed with the thigh cuff deflated, and subjects with an ambulatory calf girth decrease (% x 50) of greater than 40 (0.8% change) were deemed to be normal.

These results also showed that normal subjects and those with long saphenous incompetence produced a calf girth decrease (% x 50) on calf contraction. Whereas, subjects with perforator incompetence produced a calf girth increase on calf contraction. This is not surprising as subjects with perforator incompetence would produce a superficial venous engorgement as the blood refluxed through the perforating veins on calf contraction. Whilst subjects with competent valves in their perforating veins would reduce their calf girth on calf contraction and sapheno-femoral incompetence would be manifest by a more rapid refilling time.

A number of subjects were found to have negative value for their ambulatory calf change (% x 50), and this indicated an increase in calf girth on exercise. This phenomenon was seen in subjects with such rapid venous refilling that the calf girth at the end of calf relaxation was greater than that at rest, presumably due to the filling of veins dilated by the physiological effects of exercise. However, negative ambulatory calf girth values (% x 50) were also given to subjects whose calf girth increased on calf contraction and decreased on calf relaxation. This inversion of the normal pattern of response was clearly abnormal. however, measurement of the ambulatory calf girth change (% x 50) at the end of calf relaxation would have given a result in the normal range. Thus, for subjects whose calf girth increased on calf contraction, the measurement of ambulatory calf girth change (% x 50) was taken at the end of each calf contraction, instead of relaxation, producing a negative value for the ambulatory calf girth change (% x 50).

Table 19

Results from Normal and Varicose Vein Subjects

Comparison of exercise test result in 20 normal subjects and 40 subjects with long saphenous incompetence and 20 subjects with long saphenous incompetence and 20 subjects with perforator incompetence without sapheno-femoral incompetence.

The table of results shows the calf girth drop (% x 50) on exercise with and without inflation of the thigh pneumatic cuff.

Normal Subjects		Subjects with long saphenous incompetence		Subjects with perforator incompetence	
cuff deflated	cuff inflated	cuff deflated	cuff inflated	cuff deflated	cuff inflated
78	58	30	39	-55	-37
102	81	14	59	-19	-43
46	38	30	55	26	18
61	49	-21	50	-22	-59
70	74	35	102	23	25
104	106	-37	36	8	14
99	91	29	121	-14	-31
158	155	-79	56	3	22
97	58	1	91	11	7
142	98	21	53	-46	5
63	60	14	60	17	-7
77	77	-47	15	13	14
58	47	20	80	-5	11
68	68	16	30	-120	-87
97	62	-34	26	-12	-6
148	104	9	31	26	17
65	58	27	53	-16	-11
110	103	-17	20	-15	-22
56	59	1	17	-66	-59
85	76	-28	9	-10	-31

Negative values mean an increase in ambulatory calf girth (% x 50) on exercise. From these results, a normal result was concluded to be a girth drop (% x 50) of greater than 40 and sapheno-femoral incompetence to be present when the response moved towards the normal range by at least 20 (% x 50) on inflation of the thigh cuff.

Fig. 47

THE AMBULATORY TEST RESULTS OBTAINED FROM 20 NORMAL AND 40 VARICOSE VEIN SUBJECTS (THIGH CUFF DEFLATED)

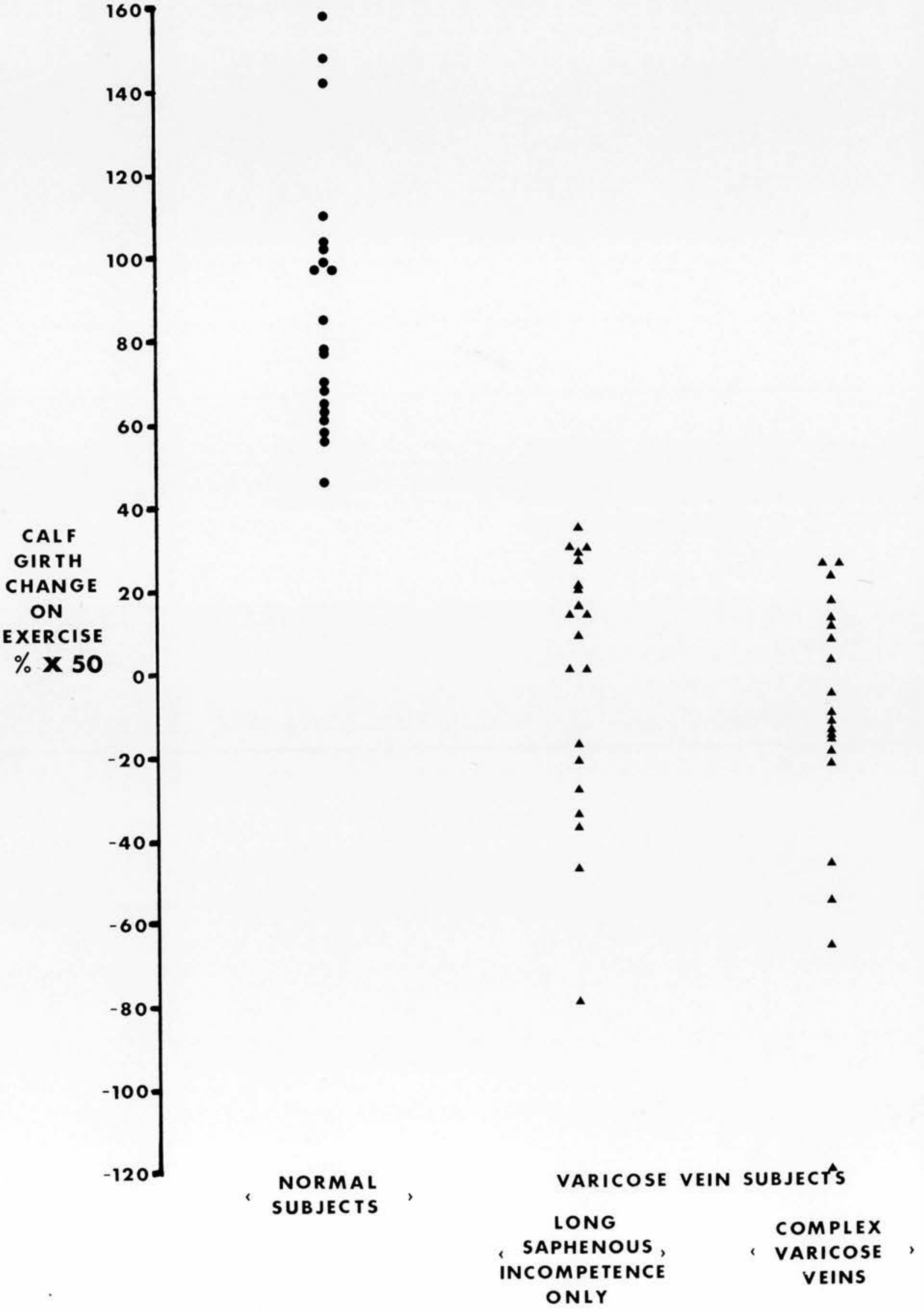
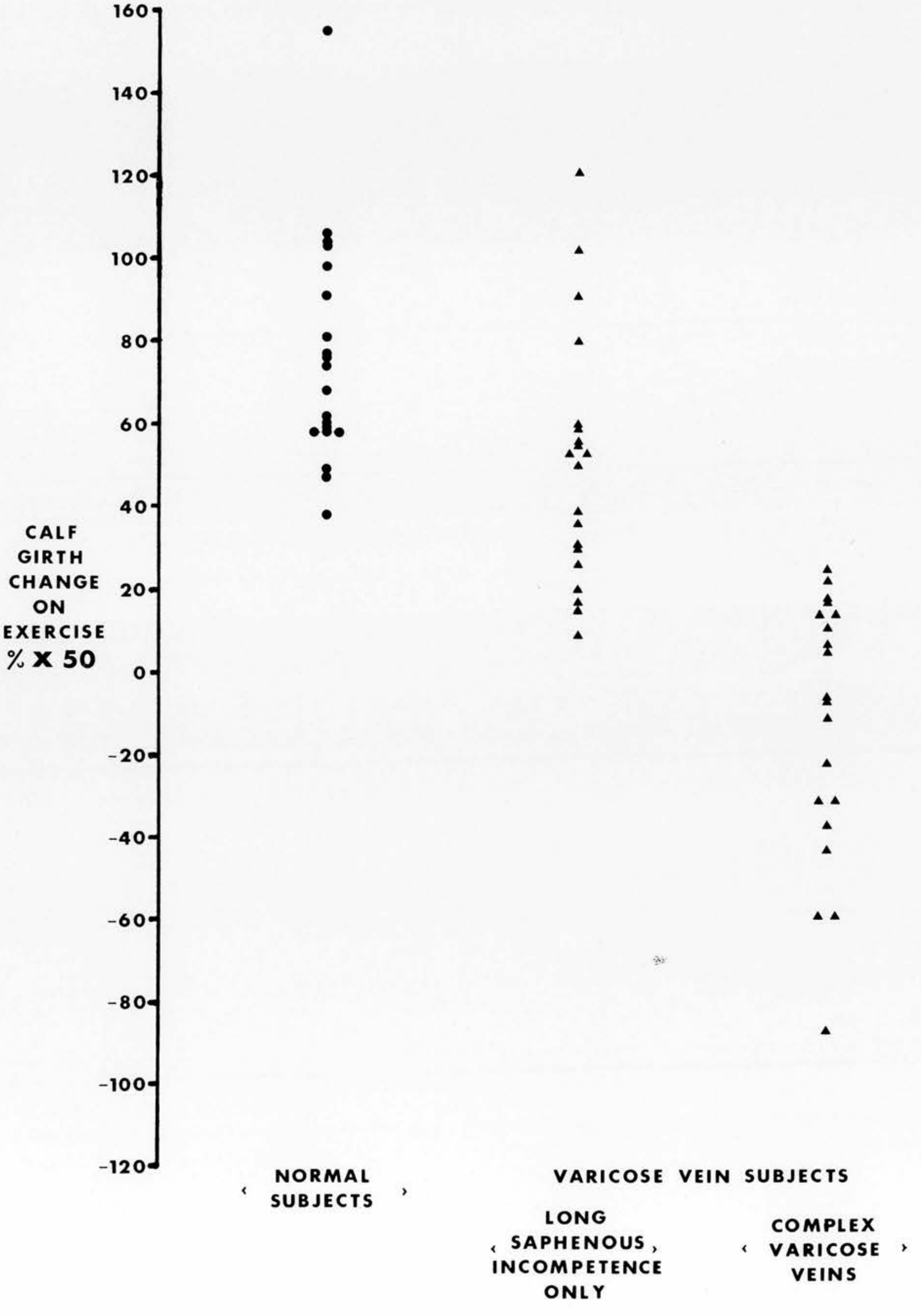


Fig. 48

THE AMBULATORY TEST RESULTS OBTAINED FROM 20 NORMAL AND 40 VARICOSE VEIN SUBJECTS (THIGH CUFF INFLATED)



5.9 Application of the Ambulatory Test to Subjects with Varicose Veins

A comparison of the results of clinical examination, Doppler ultrasound assessment and strain-gauge plethysmography in the assessment of the varicose veins of 50 patients on their initial attendance at the varicose vein clinic.

Table 20

	Clinical Examination	Doppler Result	(% x 50) Plethysmography	
			cuff deflated	cuff inflated
1	SFI calf vvs	SFI, 4 calf perfs	-46	5(SFI)
2	SFI calf vvs	SFI, 2 calf perfs	16	59(SFI)
3	SFI calf vvs	SFI	-17	20(SFI)
4	SFI calf vvs	No SFI 1 thigh perf	13	14
5	SFI lateral thigh vvs	No SFI 2 thigh perfs	-6	11
6	SFI calf vvs	SFI 1 calf perf	1	17
7	SFI lateral thigh vvs	No SFI 3 thigh perfs	-120	-87(SFI)
8	SFI lateral thigh vvs	No SFI 3 thigh perfs	-13	-6
9	SFI calf vvs	No SFI 1 thigh perf	26	17
10	SFI calf vvs	SFI 3 thigh perfs 4 calf perfs	-28	9(SFI)
11	calf vvs	SFI	-15	-3
12	SFI calf vvs	SFI	1	45(SFI)
13	thigh perfs	SFI + 2 thigh perfs	-66	-59
14	SFI calf vvs	SFI + 2 thigh perfs	-15	-22
15	SFI calf vvs	SFI	32	52(SFI)
16	SFI calf vvs	3 thigh perfs	9	104(SFI)

KEY:-SFI = sapheno-femoral incompetence
perf = perforator incompetence
vvs = varicose veins

Table 20

Clinical Examination	Doppler Result	(% x 50) Plethysmography	
		cuff deflated	cuff inflated
17 SFI lateral thigh vvs	4 thigh perfs	26	52(SFI)
18 SFI calf vvs	SFI 3 thigh perfs 4 calf perfs	-49	-37
19 SFI calf vvs	No SFI 1 thigh perf 3 calf perfs	-29	-30
20 SFI calf vvs	No SFI 3 thigh perfs	-58	-36(SFI)
21 Thigh + calf vvs	SFI 4 thigh perfs	-10	-23
22 SFI calf vvs	SFI 7 calf perfs	1	22(SFI)
23 SFI calf vvs	No SFI 1 thigh perf	-9	5
24 SFI calf vvs	SFI 2 thigh perfs	15	46(SFI)
25 SFI calf vvs	SFI	21	89(SFI)
26 SFI calf vvs	SFI 3 thigh perfs	-5	23(SFI)
27 SFI calf vvs	SFI 3 calf perfs	29	79(SFI)
28 SFI calf vvs	SFI	7	61(SFI)
29 SFI calf vvs	SFI 1 calf perf	27	57(SFI)
30 Lateral thigh vvs	SFI 2 thigh perfs	-16	7(SFI)
31 SFI calf vvs	SFI 4 calf perfs	-55	-35(SFI)
32 SFI calf vvs	No SFI 4 calf perfs	39	11
33 calf vvs	No SFI 3 calf perfs	-23	-19
34 SFI calf vvs	SFI	7	51(SFI)
35 calf vvs	Recurrent SFI	13	41(SFI)
36 SFI calf vvs	SFI 3 thigh perfs 6 calf perfs	-67	-68
37 SFI calf vvs	No SFI 3 calf perfs	-50	-44
38 SFI calf vvs	SFI 2 calf perfs	-49	-17(SFI)

KEY:- SFI = sapheno-femoral incompetence
perf = perforator incompetence
vvs = varicose veins

Table 20

Clinical Examination	Doppler Result	(% x 50) Plethysmography	
		cuff deflated	cuff inflated
39 SFI calf vvs	SFI 3 calf perfs	17	49(SFI)
40 SFI calf vvs	SFI	40	68(SFI)
41 SFI calf vvs	No SFI 1 thigh perf 3 calf perfs	-8	23(SFI)
42 SFI calf vvs	SFI 3 thigh perfs	30	50(SFI)
43 SFI calf vvs	SFI 2 calf perfs	14	38(SFI)
44 calf vvs	3 calf perfs	-36	-33
45 SFI calf vvs	SFI 1 thigh perf 3 calf perfs	-37	9(SFI)
46 SFI calf vvs	SFI 4 calf perfs	-40	16(SFI)
47 SFI calf vvs	SFI 3 calf perfs	-16	37(SFI)
48 SFI calf vvs	SFI	13	58(SFI)
49 SFI calf vvs	SFI 3 calf perfs	-18	40(SFI)
50 calf vvs	Recurrent SFI	20	68(SFI)

KEY:= SFI = sapheno-femoral incompetence
perf = perforator incompetence
vvs = varicose veins

5.9 Application of Ambulatory Test to Subjects with Varicose Veins

Table 21

Comparison of Clinical Examination, Doppler Ultrasound Testing and Strain-Gauge Plethysmography in the Diagnosis of Sapheno-Femoral Incompetence

		Investigation		
		Clinical Examination	Doppler Ultrasound	Strain-gauge Plethysmography
Sapheno-femoral	Present	42	35	33
Incompetence	Absent	8	15	17

Presence and absence of sapheno-femoral incompetence in the 50 patients, according to the three methods of examination.

Clinical Examination Versus Ultrasound Testing

Agreement

Sapheno-femoral incompetence present,
with both tests -29

62% agreement

Sapheno-femoral incompetence absent,
with both tests - 2

Disagreement

Sapheno-femoral incompetence present on clinical
examination but absent on ultrasound testing - 13

38% disagreement

Sapheno-femoral incompetence absent on clinical
examination but present on ultrasound testing -6

Ultrasound Testing versus Strain-Gauge Plethysmography

Agreement

Sapheno-femoral incompetence present
with both tests -29

78% agreement

Sapheno-femoral incompetence absent
with both tests - 10

Disagreement

Sapheno-femoral incompetence present on ultrasound testing but absent on strain-gauge plethysmography - 6

22% disagreement

Sapheno-femoral incompetence absent on ultrasound testing but present on strain gauge plethysmography - 5

Clinical Examination Versus Strain-Gauge Plethysmography

Agreement

Sapheno-femoral incompetence present
with both tests - 30

70% agreement

Sapheno-femoral incompetence absent
with both tests - 5

Disagreement

Sapheno-femoral incompetence present on clinical examination but absent on strain-gauge plethysmography - 12

30% disagreement

Sapheno-femoral incompetence absent on clinical examination but present on strain-gauge plethysmography - 3

5.9 The Application of the Ambulatory Test to Varicose Vein Subjects

The results of plethysmography showed a 78% agreement with those of Doppler ultrasound and 70% agreement with the findings on clinical examination, in the diagnosis of sapheno-femoral incompetence. No absolute test of the competence of the sapheno-femoral junction (eg phlebography) was used,

Strain-gauge plethysmography was particularly useful in obese patients, in whom tourniquet testing is often equivocal as it is difficult to occlude the long saphenous vein and in whom Doppler ultrasound testing may be difficult due to the thickness of the subcutaneous layer. In these subjects, the direction of calf girth change on calf contraction indicates whether or not incompetent calf perforators are present, and the pneumatic cuff provides a satisfactory long saphenous vein occlusion.

Subjects with recurrent varicose veins after previous surgery, in whom it is important to decide whether recurrent sapheno-femoral incompetence is present, were another group in whom strain-gauge plethysmography was helpful. Again, the direction of calf girth change suggested the presence or absence of calf perforators, and the exercise with the cuff inflated demonstrated whether or not there was sapheno-femoral incompetence.

However, plethysmography was a more time-consuming test to perform than tourniquet testing, and could not be used for the localisation of incompetent perforators. Also, despite positioning the pneumatic cuff as proximally as possible on the thigh, it is possible that cuff inflation could occlude a thigh perforator and thus erroneously suggest sapheno-femoral incompetence.

5.10 Findings in Subjects with Deep Venous Incompetence

15 out of the (approximately 200) new patients referred to an arterial clinic over a two-year period with symptoms of pain in the leg on exercise were subsequently found to have deep venous incompetence. These 15 patients had similar symptoms. The pain in their legs was characteristically aching or bursting in nature, worse towards the end of the day, was present when the patients stood still for any length of time, but was aggravated by exercise. 10 of these patients gave a history of previous deep venous thrombosis. None of the patients had any evidence of arterial disease on clinical examination, and all had normal Doppler pressures in their dorsalis pedis and posterior tibial arteries.

These 15 patients were referred to the arterial clinic as they were thought to have arterial disease because their pain was present on exercise. However, the symptom of deep venous incompetence (venous claudication) differs from arterial claudication in that it starts with the commencement of exercise and the pain at rest is relieved by sitting with the legs elevated.

The aching pain in the legs experienced by some patients with primary varicose veins differs from venous claudication in that it is present when the patients are standing still, but is eased by exercise. Nonetheless, two of this group of 15 patients had undergone recent varicose vein surgery in an unsuccessful attempt to relieve their symptoms.

These 15 patients were assessed by clinical examination, Doppler ultrasound examination, ambulatory strain-gauge plethysmography and ascending (and, where indicated, descending) phlebography.

The histories and findings on clinical and Doppler ultrasound examination from these 15 patients are described as follows:-

VC1 F 39 yrs - Right DVT 1966; right venous claudication, and ankle ulcer ever since. No other abnormality on physical examination. No abnormality detected with Dopper ultrasound. Left leg normal.

VC2 F 47 yrs - No history of DVT; right venous claudication for 5 years, 2 operations for varicose veins on the right leg. Now minimal varicose veins right calf. Doppler ultrasound examination revealed one above knee incompetent perforator. Left leg had calf varicose vein.

VC3 F 66 yrs - Right DVT 1964; right venous claudication for 9 years. No abnormality on clinical examination nor by Doppler ultrasound. Left leg normal.

VC4 F 53 yrs - Left DVT 1972; bilateral venous claudication 4 years (left more than right). No abnormality on clinical examination nor by Doppler ultrasound.

VC5 F 43 yrs - Left DVT 1972; bilateral venous claudication for 3 years (left more than right) bilateral varicose vein surgery 1980, symptoms persisted and varicose veins recurred within 6 months. On examination, multiple varicosities over both thighs and calves and 1 Doppler detectable perforator in left thigh and 2 Doppler detectable perforators in right thigh.

VC6 M 50 yrs - Left DVT 1975; recurrent left ankle ulceration and venous claudication since then. Healed ulcer proximal to left medial malleolus with surrounding varicose eczema, no visible varicose veins. No abnormality detectable by Doppler ultrasound. Right leg normal.

VC7 M 41 yrs - Left DVT 1975; left venous claudication ever since. No visible varicose veins, slight pitting oedema of left ankle. 2 Doppler-detectable incompetent perforators in left calf. Right leg asymptomatic but calf varicosities with multiple calf perforators.

VC8 F 54 yrs - Right DVT 1961; right varicose veins since then with intermittent ulceration right calf and right venous claudication for 10 years. Gross varicosities of long saphenous system with thigh varicosities, extensive varicose eczema and multiple superficial ulcers over lower calf. Doppler ultrasound demonstrated sapheno-femoral incompetence, 3 thigh perforators and multiple calf perforators. Left leg asymptomatic but calf varicosities with 4 perforators.

VC9 F 24 yrs - No history of DVT; bilateral venous claudication for 6 years. Injection of calf varicosities 1980, with no relief of symptoms. No abnormality on physical examination or by Doppler ultrasound.

VC10 M 63yrs - Left DVT 1977; left leg swollen ever since with increasingly severe venous claudication. Pitting oedema and varicose eczema from ankle to knee. No abnormality detectable on Doppler ultrasound examination. Right leg asymptomatic with pitting oedema around ankle, no Doppler abnormality.

VC11 F 25yrs - Left DVT 1981; left leg swollen ever since and with progressively severe venous claudication. Patient's mother and elder sister had similar histories. Pitting oedema of ankle on examination. No abnormality detectable on Doppler ultrasound examination. Right leg asymptomatic and no abnormality detected.

VC12 F 35yrs -Right DVT 1978; right venous claudication ever since. No abnormality on clinical examination nor by Doppler ultrasound examination. Left leg asymptomatic and no abnormality detectable.

VC13 F 38yrs -No history of DVT; left venous claudication for 4 years. No abnormality on clinical examination nor by Doppler ultrasound examination. Normal right leg.

VC14 M 39yrs -No history of DVT; bilateral varicose veins since 1953 and had undergone varicose vein surgery on 4 occasions. Left venous claudication for 10 years. Gross recurrent varicose veins both legs with Doppler detectable multiple perforators in thigh and calf.

VC15 F 43yrs -No history of DVT; bilateral venous claudication for 4 years. No abnormality on clinical examination nor by Doppler ultrasound examination.

Summary of Clinical Features

Out of the total of 15 patients there were 11 females and 4 males with an age range of 24 to 66 years (mean = 44years). The symptoms of venous claudication had been present for between 1 and 17 years (mean = 6.5 years) and affected the right leg in 5 patients, the left leg in 6 patients, and was bilateral in 4 patients. 10 patients gave a history of a previous deep venous thrombosis (4 in the right leg and 6 in the left leg) and all of these patients had received treatment with oral anticoagulants for at least 3 months following the thrombosis. Only three patients had visible varicose veins on examination, and these were the only patients to have had previous varicose vein surgery. Three patients had ulceration above the medial malleolus, and none of these had varicose veins.

Table 22

Results of investigations on 15 subjects with deep venous incompetence

Subject	(% x 50) Strain gauge plethysmogaphy cuff deflated	cuff inflated	Ascending phlebogram	Descending phlebogram
VC1 right	11	3	Patent veins	Non-functioning valves in SFV
	girth increased on calf contraction			
left	64	44	—	—
	girth decreased on calf contraction			
VC2 right	-110	-93	Patent veins	Non functioning valves in SFV
	girth increased on calf contraction			
left	-11	14	—	—
	girth decreased on calf contraction			
VC3 right	5	0	Patent veins	Valves competent in thigh
	girth increased on calf contraction			
left	41	38	—	—
	girth decreased on calf contraction			

KEY:- SFV = superficial femoral vein

Table 22

Subject	Strain gauge plethysmography (% x 50)		Ascending phlebogram	Descending phlebogram
	cuff deflated	cuff inflated		
VC4 right	13 girth increased on calf contraction	8	Patent veins	Incompetent valves in SFV
left	-1 girth increased on calf contraction	-3	Patent veins	Incompetent valves in SFV
VC5 right	-34 girth increased on calf contraction	-24	Patent veins	Incompetent valves in SFV
left	-22 girth increased on calf contraction	-22	Patent veins	Incompetent valves in SFV
VC6 right	43 girth decreased on calf contraction	48	——	——
left	-57 girth increased on calf contraction	-51	Patent veins	Incompetent valves in SFV
VC7 right	-2 girth increased on calf contraction	-9	Patent veins	Competent valves in SFV
left	-3 girth increased on calf contraction	-8	Patent veins	Incompetent valves in SFV

KEY:- SFV = superficial femoral vein

Table 22

Subject	(% x 50) Strain-gauge plethysmography cuff deflated	cuff inflated	Ascending phlebogram	Descending phlebogram
VC8 right	9 girth increased on calf contraction, slow response	-8	Occluded SFV	-
left	11 girth increased on calf contraction	3	-	-
VC9 right	4 girth increased on calf contraction	1	Duplex SFV	Incompetent valves in one of the SFV
left	16 girth increased on calf contraction	9	Duplex SFV	Incompetent valves in one of the SFV
VC10right	-14 girth increased on calf contraction	-36	Occluded femoral & iliac veins	-
left	1 girth increased on calf contraction	-26	Occluded femoral & iliac veins	-
VC11right	45 girth decreased on calf contraction	38	-	-
left	-28 girth increased on calf contraction	-30	Patent veins	Incompetent valves in SFV

KEY :- SFV = superficial femoral vein

Table 22

Subject	(% x 50) Strain-gauge plethysmography		Ascending phlebogram	Descending phlebogram
	cuff deflated	cuff inflated		
VC12right	-8	-5	patent veins	incompetent valves in SFV
	girth increased on calf contraction			
left	52	44	-	-
	girth decreased on calf contraction			
VC13right	48	45	-	-
	girth decreased on calf contraction			
left	3	-7	Patent veins	Incompetent valves in SFV
	girth increased on calf contraction			
VC14right	14	35	Patent veins	-
	girth decreased on calf contraction			
left	-92	-62	Patent veins	-
	girth increased on calf contraction			
VC15right	-76	-73	Patent veins	Incompetent valves in SFV
	girth increased on calf contraction			
left	-98	-95	Patent veins	Incompetent valves in SFV
	girth increased on calf contraction			

KEY :- SFV = superficial femoral vein

The results of ambulatory strain-gauge plethysmography obtained from the 15 patients with deep venous incompetence all showed a calf girth increase on calf contraction and were outside the normal range. The pattern of ambulatory calf girth change in all cases was similar to that obtained from subjects with calf perforator incompetence. However, the majority of the patients with deep venous incompetence did not have varicose veins, and subjects with perforator incompetence alone do not have symptoms of venous claudication. Thus, a history of venous claudication, combined with the above pattern of ambulatory calf girth change is indicative of a diagnosis of deep venous incompetence. Also, a normal ambulatory calf girth change result would exclude the diagnosis of deep venous incompetence. Therefore, ambulatory strain-gauge plethysmography is a useful screening test in the diagnosis of deep venous incompetence.

Subjects with deep venous incompetence may have occlusion of their deep veins or incompetence of their deep vein valves, and therefore require ascending and descending phlebography to demonstrate the anatomical or physiological basis for their symptoms. Some of the abnormalities found on phlebography are shown in Figures 49-59. These investigations are invasive and have recognised complications, and therefore a reliable non-invasive screening test is of great value in selecting patients for further investigation. This is especially true as it seems that deep venous incompetence may be considerably more common than generally assumed. For instance, during the period that the above 15 patients were being investigated, a further 10 patients presented to the vascular clinic with symptoms of venous claudication. These 10 patients had abnormal ambulatory calf girth changes, but declined further investigations, and so have not been included in this study.

There has as yet been no generally accepted operative treatment for deep venous incompetence, and the majority of patients are managed conservatively. Therefore, it is possible that patients with symptoms suggestive of deep venous incompetence could have a confirmation of their diagnosis made by strain-gauge plethysmography, and appropriate treatment instituted, without the need for phlebography.

Fig. 49

Subject V.C. 4 - Ascending Phlebogram

patent s.f.v. communicates with p.f.v.

Fig. 50

Subject V.C.4 – Descending Phlebogram

reflux of contrast in s.f.v.

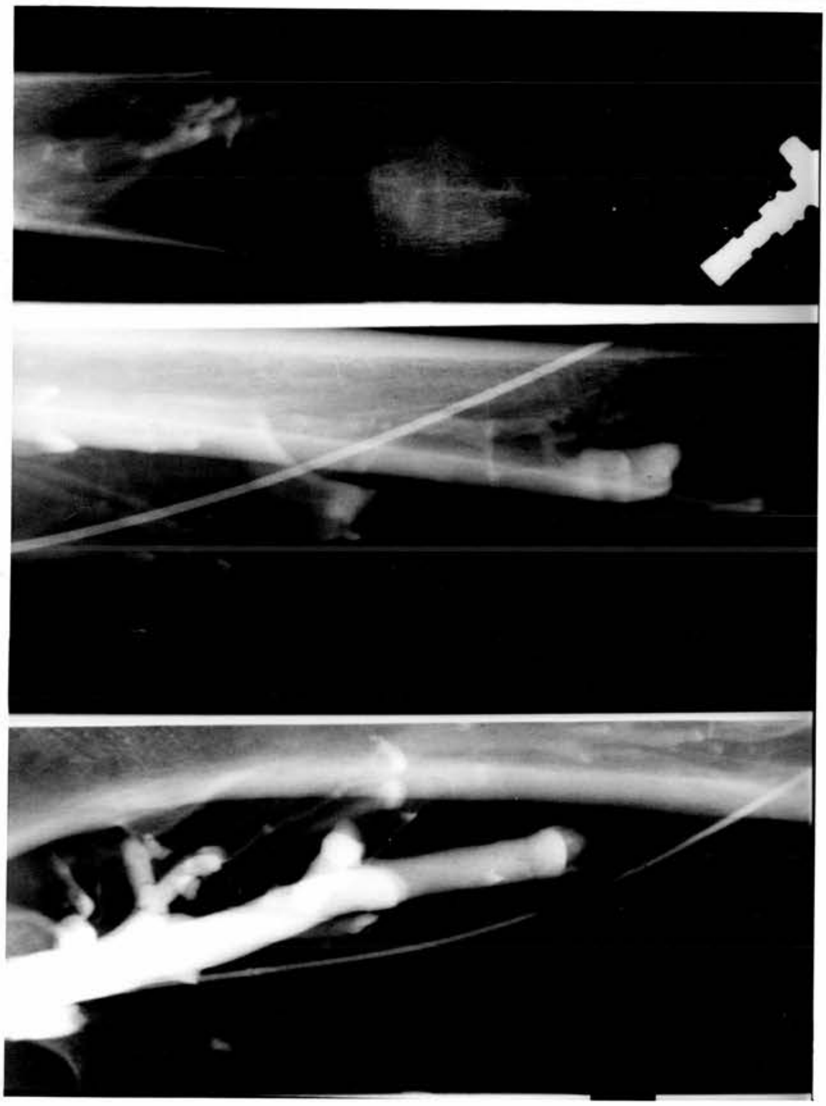


Fig. 51

Subject V.C. 5 - Descending Phlebogram

reflux of contrast in s.f.v.

Fig. 52

Subject V.C.6 - Ascending Phlebogram

patent s.f.v. communicates with p.f.v.

Fig. 53

Subject V.C. 6 - Descending Phlebogram

reflux of contrast in s.f.v.

Fig. 54

Subject V.C. 7 - Descending Phlebogram

competent valves in right s.f.v.

Fig. 55

Subject V.C. 7 - Descending Phlebogram

reflux of contrast in left s.f.v.

Fig. 56

Subject V.C. 8 - Ascending Phlebogram

occluded s.f.v.

Fig. 57

Subject V.C. 9 - Ascending Phlebogram

duplex s.f.v.

Fig. 58

Subject V.C.10 - Ascending Phlebogram

occluded iliac veins

5.11 Results of Treatment for Deep Venous Incompetence

5.11.1 Graduated compression stockings

All subjects found the stockings difficult to put on and very uncomfortable to wear.

Subject VC3 found all her symptoms relieved by wearing graduated compression stockings and continues to wear them.

Subject VC8 had satisfactory healing of the lower leg ulceration whilst wearing graduated compression stockings. However, she was unable to tolerate the long term use of the stockings, and the ulcers have since recurred.

None of the other subjects felt that the stockings relieved their symptoms. This is possibly because the subjects did not like wearing the stockings, or possibly because the stockings lose their effectiveness during the day, due to stretch, and hence the symptoms return.

5.11.2 Operative treatment

3 subjects underwent ligation of the superficial femoral vein (subjects VC4, VC6, and VC9). Subjects VC4 and VC6 were noted on the ascending phlebogram to have an anastomosis in the thigh between the superficial and profunda femoral veins (Figures 49, 50, 52, and 53) and underwent a double ligation of the superficial femoral vein immediately proximal to its junction with the profunda femoris vein. Subject VC9 had the duplex superficial femoral vein (Fig 57) and the vein with the incompetent valves was identified by operative phlebography and ligated.

None of these three subjects has been subjectively improved by these operative procedures.

5.11.3 Results of pre- and post-operative plethysmography following surgery for deep venous incompetence.

Table 23

	Plethysmography (cuff deflated) (% x 50)	
	Pre-operative	Post-operative
Subject VC 4 right	-1	7
Subject VC 6 left	-57	-26
Subject VC 9 right	4	9
Subject VC 9 left	16	21

During all recordings from the above subjects, the calf girth increased on calf contraction.

The results show that in all cases the ambulatory calf girth change moved towards the normal range, although none of the results became normal, after surgery.

5.12 Pre- and Post-Operative Studies of Varicose Vein Subjects

20 patients with varicose veins were assessed plethysmographically pre-operatively and 1 year post-operatively. At their post-operative attendance they were assessed by questionnaire and by medical staff unaware of the study, numerical scores being assigned to the results. (Fig 23 shows an example of the assessment sheet).

Table 24

Pre- and Post-Operative Studies of Varicose Vein Subjects

	Pre-operative Plethysomgraphy		Post-operative Plethysmography		Post-operative assessment	
Subjects	cuff deflated	cuff inflated	cuff deflated	cuff inflated	by patient	by doctor
	(% x 50)		(% x 50)			
1	-8	-6	53	57	9	7
2	1	5	32	23	5	3
3	29	53	42	49	9	7
4	16	59	33	35	9	7
5	19	50	48	54	6	5
6	15	39	50	46	7	4
7	-28	9	34	40	4	3
8	-16	-11	1	-1	8	6
9	-66	-59	-51	-47	5	4
10	-15	-22	-43	-45	6	6
11	9	104	-2	93	4	5
12	4	85	9	76	4	5
13	-58	-36	-12	-9	6	4
14	-59	-32	-16	-11	5	4
15	-5	23	15	27	6	5
16	22	31	24	28	5	5
17	-55	-35	-72	-77	5	5
18	12	17	3	5	7	4
19	9	31	37	43	4	4
20	-46	5	11	26	7	9

Scores for the post-operative assessment had a possible range of 3 to 12; the higher the score the worse the result.

5.12 Pre- and Post-Operative Studies of Varicose Vein Subjects

The possibility that strain-gauge plethysmography might be able to predict the outcome of varicose vein surgery was examined.

The pre-operative plethysmography results were divided into 3 groups as follows:

1 Subjects whose ambulatory calf girth decrease (% x 50) came into the normal range when the exercise was performed with the thigh cuff inflated.

2 Subjects whose ambulatory calf girth decrease (% x 50) moved towards the normal range by more than 20 when the exercise was performed with the thigh cuff inflated.

3 The remaining subjects studied.

The one year follow-up scores recorded from the patients' and doctors' assessments were compared for the 3 groups and are shown in Table 25.

Table 25

Pre-operative Plethysmography and Post-operative Assessment

1 Subjects with results in the normal range

Subject number	Patients' assessments	Doctors' assessments
3	9	7
4	9	7
5	6	5
11	4	5
12	4	5
	mean 6.4	mean 5.8

2 Subjects with results improved by more than 20

6	7	4
7	4	3
13	6	4
14	5	4
15	6	5
19	4	4
20	7	9
	mean 5.6	mean 4.7

3 Remaining Subjects

1	9	7
2	5	3
8	8	6
9	5	4
10	6	6
16	5	5
17	5	5
18	7	4
	mean 6.3	mean 5.0

5.12 Pre- and Post-Operative Studies of Varicose Vein Subjects

The mean scores for the patients' and doctors' assessments were compared for groups 1 and 3, groups 2 and 3 and a combination of groups 1 and 2 with group 3.

There were no significant differences between the means of any of the groups studied.

Thus, strain-gauge plethysmography would appear to be unable to predict the outcome of varicose vein surgery. However, it may be that follow-up at 1 year may be too soon to detect differences in post-operative results (Hobbs 1974). Further follow-up at 5 years may show a predictive role for strain-gauge plethysmography.

All of the subjects were studied by strain-gauge plethysmography at their 1 year follow-up appointment. The post-operative results were divided into 2 groups as follows:

1 Subjects whose calf girth decrease (% x 50) was greater than 30 on exercise with the cuff deflated ("normal range").

2 The remaining subjects

A comparison was made of the 1 year assessments by patients and doctors between these two groups (Table 26). Again there was no significant difference between the mean scores for patients' or doctors' assessments of the two groups. Surprisingly, subjects 11 and 12 who appear to have recurrent sapheno-femoral incompetence or thigh perforator incompetence, have good assessment scores from both the patients and the doctors. Again, it is possible that the post-operative follow-up period is too short to obtain meaningful results.

Table 26

Post-operative Plethysmography and Post-operative Assessment

1 Subjects with results in the normal range

Subject number	Patients' assessments	Doctors' assessments
1	9	7
2	9	7
3	6	5
4	7	4
5	5	3
6	9	7
7	4	3
19	4	4
	mean 6.6	mean 5

2 Remaining subjects

Subject number	Patients' assessments	Doctors' assessments
8	8	6
9	5	4
10	6	6
11	4	5
12	4	5
13	6	4
14	5	4
15	6	5
16	5	5
17	5	5
18	7	4
20	7	9
	mean 5.7	mean 5.2

5.13 Comparison of Two Treatment Regimens for Varicose Veins

Although this experiment was designed to compare the results of stripping versus non-stripping of the long saphenous vein in the treatment of varicose veins, all the subjects had pre-operative strain-gauge plethysmography.

In Table 27, the results of the one year follow up scores are shown divided into two groups according to the pre-operative plethysmographic result. Group 1 consisted of those subjects whose ambulatory test (% x 50), with the thigh cuff inflated, was in the normal range or moved towards the normal range by more than 20 when compared with the result with the cuff deflated. Group 2 was composed of the remaining subjects.

Table 27

The follow-up results at one year compared in subjects separated according to their pre-operative plethysmography result (n = 57)

	Patients' assessments (mean)	Doctors' assessments (mean)
1 Subjects with normal results or greater than 20 improvement (n = 37)	5.2	5.4
2 Remaining subjects (n = 20)	6.25	5.8

There is no significant difference between the mean scores of the patients' assessment for the two groups. However, the difference between the mean scores for the doctors' assessments reaches significance at the 10% level (two sample t test). This may be suggestive of a predictive value for strain-gauge plethysmography in the treatment of varicose veins. However, a longer follow-up period is required to see if a more significant difference appears between the two groups.

At present there is no significant difference between the results from subjects whose long saphenous veins were stripped compared with those who had high saphenous ligation only (Table 28). The same comment regarding length of follow-up is applicable here; but, if the results from the two groups remain similar after five years, then conclusions may be drawn as to the effectiveness of the two types of treatment, and the implications for out-patient treatment of varicose veins.

Table 28

Comparison of Two Treatment Regimens for Varicose Veins

		3/52 assessment	3/12 assessment	1 year assessment
		n=131	n=116	n=66
VEIN	patients' assessment	5.6	5.3	5.3
STRIPPED	doctor's assessment	8.8	5.4	5.6
		n=119	n=92	n=50
VEIN NOT	patient's assessment	5.4	5.5	5.6
STRIPPED	doctor's assessment	8.2	5.4	5.6

Numbers in each group refer to numbers of legs treated. There is no significant difference between the mean scores in each group.

6 DISCUSSION

6.1 Limitations of Equipment

The strain-gauges used for the experiments were light in weight and require little force for elongation. Therefore, there is little compression of the underlying tissues as the limb expands. The major inaccuracies in the measurement are due to the inextensible portion of the strain-gauge and the changes in the cross-sectional area as the volume of the limb changes (the temperature effects upon the cross-sectional area of the gauge and upon the specific resistance of the mercury are so small as to be negligible). Despite these problems, the calf girth changes recorded in the venous distensibility and ambulatory experiments correlated well with venous pressure recordings. Undoubtedly, the strain-gauge recordings reflect changes in limb volume, although it was felt that the assumptions necessary to translate the recordings obtained directly into volume changes introduced needless inaccuracies. Therefore, the results obtained were expressed as percentage calf girth changes (after Zicot, Parker and Caro 1977). The recordings obtained, were similar to those obtained by other workers (Forconi et al 1979; Van de Heyning-Meier 1981), but the units in which the results were expressed were different.

The equipment was simple to use, with a high degree of patient compliance, although the recording equipment was rather cumbersome. Thus, repeated measurements were obtained without difficulty, an important consideration when assessing the effects of treatment and a major disadvantage of invasive venous pressure measurement. Venous pressure recordings only show the changes in one part of the venous pool (although multiple recordings may be made, Arnoldi and Linderholm 1966), whereas strain-gauge plethysmography records the resultant of all the changes. This could be advantageous, for instance, a normal long saphenous vein may be present with gross incompetence of calf perforating veins. In practice, the results of the two investigations were found to parallel one another in almost all of the subjects studied.

Strain-gauge plethysmographic recordings provide a permanent record of the results, and are less liable to observer error than Doppler ultrasound scanning, which is very subjective.

There are drawbacks associated with each of the forms of non-invasive venous investigation. Foot volumetry requires cumbersome equipment, may be affected by changes in venous tone and the exercise involves the thigh as opposed to the calf muscles. Photoplethysmography only examines a very small portion of the limb and may only reflect changes in the superficial venous system. Lastly, impedance plethysmography measures very small changes in impedance compared with total impedance of a limb, and is thus subject to artefactual change.

6.2 Venous Distensibility Measurement

The technique of measurement of venous distensibility was the same as has been described by other workers, although there is a paucity of reported experimental details. The works of Brugmans et al (1977) and Forconi et al (1979) were mainly concerned with the use of strain-gauge plethysmography in the assessment of arterial disease, but mentioned the measurement of venous distensibility without any experimental details or results. Brakkee (1981) and Rudofsky (1981) measured calf girth changes secondary to inflation of a thigh cuff in a temperature-controlled room. Neither of these workers gave any other details of their experiments, nor did they include any results to show a normal range or the reproducibility of the method. Franco, Langeron and Harle (1981) studied 12 patients with post-thrombotic syndrome and 5 patients with primary varicose veins, using the same method of measurement of venous distensibility. This study included no details of the experimental method and included no results from normal subjects nor any reproducibility studies. 50 normal subjects had their venous distensibility measured by Pointel et al (1981) using the same method as in this study and included details of the method of measurement in their paper. The results obtained were similar to those obtained in this study, although a slightly different method of calculation of the VDI was used. However, none of the experiments performed by Pointel et al took place in a temperature-controlled room, and neither were any reproducibility results given. The work of Van de Heyning-Meier (1981) unfortunately contains no details of experimental design nor any data with which to compare results. A comparison of the venous distensibility of 20 normal subjects and 20 patients with varicose veins was made by Pupita, Rotatori and Frausini (1981). These workers used measurement of calf girth change secondary to thigh cuff inflation to calculate the VDIs of their subjects. Their results showed a significant difference between the results obtained from the two groups of subjects, but the experiments were not performed in a temperature-controlled environment and no reproducibility studies were reported. d'Inverno (1981) measured venous distensibility in 40 normal legs, 51 legs with varicose veins and 71 legs with recent or previous deep venous thrombosis. The experiments were not performed in a temperature-controlled room, nor were any reproducibility studies quoted. There was a considerable overlap of results from the three groups of subjects in this study, although it was claimed that they could be separated by the use of a special graph.

Many factors affect venous tone and have been shown to affect recordings of calf girth changes (Thirsk, Kamm and Shapiro 1980). Thus, it is very important to give full experimental details of venous distensibility studies, including any precautions taken to reduce the effect of environmental influences. It also is essential that results of reproducibility studies are included, as the wide range of results from individual subjects may obscure differences between groups of individuals. Therefore, in the absence of the results of reproducibility studies, the validity of the previously published studies on venous distensibility, using strain-gauge plethysmography, must be questioned.

The experiments performed in the present study initially examined the effects of variation in strain-gauge and body position. It was found that recordings taken from around the maximum calf circumference produced the maximum calf girth changes. However, in this area there is a large volume of calf muscle with its associated venous plexus. Although the pressures in the thigh cuff should have had little effect on the deep veins, it is possible that the deep veins could contribute to the volume changes in this area. It is for this reason that the ankle was chosen as a possible measurement point, as this area contains little muscle and hence it may more truly reflect changes in the superficial veins. Indeed, there was a difference between the venous distensibility indices calculated from recordings at the ankle and the mean calf recordings. However, the irregular cross-sectional shape at the ankle results in only a small percentage of the strain-gauge being in contact with the skin, making recordings from this area very inaccurate.

Further investigations of venous distensibility were performed with the strain-gauge around the maximum calf circumference and the subjects in various positions to assess the effect of varying degrees of venous filling on venous distensibility measurement. Variations in body position made no significant difference to the mean VDI of the group studied, but differences were found in individuals when recordings were made with the subjects in different positions. It is thus important in descriptions of experiments on venous distensibility to carefully define the positions of the subjects during recordings of venous distensibility.

Venous pressure has been shown to be affected by local temperature changes (Henry and Gauer 1950) and venous capacity is also altered by temperature variations (Rudofsky 1981). The influence of local temperature changes was found in this series of experiments to have little effect on venous distensibility measurements in relation to differences between subjects at the different temperatures.

There have been reports of differences in venous distensibility between normal subjects and patients with varicose veins (Zsoter and Cronin 1966; Pupita, Rotatori and Frausini 1981; Franco, Langeron and Harle 1981), and also subjects with deep venous thrombosis (d'Inverno 1981). Although these studies showed an overlap of results, it was suggested that venous distensibility could be used as an index of severity of varicose veins and also in the detection of deep venous thrombosis. The experiments in this study used a similar technique for the measurement of venous distensibility and showed a great overlap of results between normal subjects and patients with varicose veins. In fact, the only statistically significant difference between distensibilities was found in patients whose varicose veins were confined to below-knee incompetent perforators. However, the number of patients in this group was small and this throws doubt onto the significance of the difference. Thus, this study failed to show the value of venous distensibility measurements in the differentiation of normal from varicose veins.

Subject age also, does not appear to affect venous distensibility. The initial comparison of a group of normal subjects with a group of varicose vein subjects were well matched for age, and there was no significant difference between their venous distensibility indices. However, the later group of varicose vein subjects had a considerably older mean age, but still there was no significant difference between their distensibilities. This finding was a little surprising in view of the reported degenerative changes in varicose vein walls which might be expected to affect their distensibility (Svejcar et al 1963; Grobety and Bouvier 1977; Niebes, Engels and Jegerlehner 1977; Leu, Vogt and Frunder 1979; Jurukova and Milenkov 1982), and the in vitro demonstration of increased distensibility in varicose veins (Johnsson and Arenander 1963; Zsoter, Moore and Keon 1967; Bocking and Roach 1974). However, it has been pointed out that veins have an active tone which is altered by many factors (Gauer and Thron 1962; Alexander 1963; Attinger 1969) and also, the contractile ability of isolated segments of varicose veins is no different from that of normal veins (Thulesius and Gjores 1974).

It is the presence of venous tone, and the factors known to influence it such as mental activity, sleep, deep inspiration, exercise, local cutaneous stimulation, coughing, heart failure, anaemia and drugs (Burch and Murtadha 1956; Sharpey-Schafer 1961; Sutter 1965; Webb-Peploe and Shepherd 1968 (a) and (b); Seaman et al 1973; Vanhoute and Janssens 1978), which are felt to be responsible for the lack of reproducibility of the venous distensibility measurements, despite the precautions taken to keep the experimental conditions as constant as possible. Nevertheless, the venous pressure and calf girth changes do follow similar patterns in distensibility measurements, except that the calf girth may not reach a plateau at the higher thigh cuff inflation pressures, despite a venous pressure plateau being reached. This lack of a plateau in the calf girth change is probably due to increased capillary filtration, and has been noted by other workers (Alexander 1963; Pointel et al 1981) and a correction factor has been suggested (Brakkee 1981).

Another factor that could have caused inaccuracies in the measurement of venous distensibility was the relative width of the pneumatic thigh cuff in comparison to the subjects thigh circumference. Thus, at the same inflation pressure, there could be different effects on the underlying veins in different subjects due to the variation in thigh circumference. A correction factor has been derived to try and eliminate this effect (Brakkee 1981) but this does not take into account any factor other than thigh circumference, for instance, the thickness of the subcutaneous tissue. However, the use of venous pressure measurements for calculation of the venous distensibility eliminates this problem. There was a good correlation between the VDIs calculated using the thigh cuff pressure and those calculated using the venous pressure, and there was no significant difference between the means of the VDIs and the VDI(p)s. However, there was still no significant difference between the results obtained from normal subjects and those from subjects with varicose veins. Interestingly, it was found that there was no constant relationship between thigh cuff inflation pressure and venous pressure, making it impossible to confirm the value of a correction factor to relate cuff width to thigh circumference (Brakkee 1981). It is not surprising that the venous pressure should vary in this way, as it too must be affected by changes in venous tone (Alexander 1963; Attinger 1969). Although, it was shown that calf girth and venous pressure change in a similar manner when a pneumatic thigh cuff is inflated.

The studies of reproducibility showed that the venous volume change at one cuff pressure showed considerable variation. Thus it is shown to be an unreliable measurement in the assessment of venous disease, although it has been suggested to be of value in the diagnosis of deep venous thrombosis (Hallbook and Gothlin 1971; Tripolitis et al 1979). In view of the overlap of results presented by other workers in the use of venous outflow measurements in the assessment of deep venous thrombosis (Barnes et al 1972 and 1977; Bergqvist and Hallbook 1979; d'Inverno 1980, Brakkee and Kuiper 1982) and the postphlebitic syndrome (Barnes et al 1973, 1974 and 1975) no measurements of venous outflow were made.

Thus, the active venous tone in the lower limbs makes the measurement of venous distensibility by this method of no value in the differentiation of normal from varicose veins, although it may be used to assess the activity of drugs (Barthel and Grossmann 1982).

6.3 Ambulatory Test Experiments

The ambulatory test was devised to produce a simple method by which non-invasive strain-gauge plethysmography could be used to assess venous disease. Previous studies had used the time to return to the baseline after exercise as the measurement in ambulatory strain-gauge plethysmography (Holm et al 1974; Holm 1976; Fernandes et al 1979; Mason and Giron 1982; Linhardt, Queral and Dagher 1982). This measurement had not shown clear differences between normal subjects and those with venous disease, and it was found, early in the assessment of the ambulatory test, that the calf girth rarely returned to the pre-exercise resting value after cessation of exercise. This finding is not too surprising, in view of the fact that exercise is one of the factors known to alter venous tone (Webb-Peploe and Shepherd 1968 (a)).

The method of measurement of ambulatory calf girth change was chosen as it seemed to provide good separation of normal and abnormal results in preliminary studies. The calf girth change from the resting level was measured at the start of calf contraction, and not at the end of contraction as the latter measurement showed little difference between normal subjects and subjects with venous disease. However, it was noticed that some subjects with varicose veins and deep venous incompetence actually increased their calf girth on contraction. This phenomenon has been reported once before, in subjects with the postphlebitic syndrome (Mason and Giron 1982). In subjects whose calf girth increased on calf contraction, the measurement was taken at the end of calf contraction. The reason for this was that often the value at the start of calf contraction was in the normal range, although the pattern of response was obviously grossly abnormal.

This method of calculation of results provides statisfactory reproducibility (coefficient of variation less than 6%), which compares favourably with the only published reproducibility study (coefficient of variation of 17%; Mason and Giron 1982). Also, the results obtained with this method (which is in effect an indirect measure of the refilling time) show a clear separation of normal from abnormal results. Whereas studies using different methods of measurement have had the problem of overlapping results (Niederle and Prerovsky 1975; Mason and Giron 1982).

A possible criticism of this ambulatory test is that the subjects are all doing different amounts of work in the exercise depending upon their body weight. However, it was felt that this form of exercise was well accepted in other exercise tests of venous function (Nachbur 1977; O'Donnell et al 1979; Neilsen 1982), was simple to teach to the subjects under investigation, each subject did the same work each time he performed the test and the results correlated well with those obtained from subjects performing a standard exercise in the supine position (Rudofsky 1979). However, it is important to monitor the performance of the test to ensure that the exercise is performed in a standard manner.

The recordings obtained by simultaneous calf girth and venous pressure measurement on exercise show a similar pattern to other published results (Holm et al 1974; Niederle and Prerovsky 1975; Fernandes et al 1979; Mason and Giron 1982). However, different workers have used different methods for calculating their results. Holm et al (1974) studied 17 subjects (5 normal subjects, 8 patients with varicose veins and 4 patients with arterial disease) and measured the time to return to the resting venous pressure and calf girth. These workers did not quote a correlation coefficient for their figures nor did they report actual values for their results. Thus, comparison with the present study is not possible. All the illustrations of their recordings show the calf girth returning to the pre-exercise level after exercise, this occurence was unusual in the present study. Niederle and Prerovsky (1975) do not give precise details of the method of calculation of their results from 15 normal subjects, 5 patients with varicose veins and 10 patients with a history of deep venous thrombosis. These workers measured the fall in pressure and girth on exercise and found a correlation coefficient of 0.75 between the two sets of recordings with an overlap between the results obtained from the normal and abnormal limbs. However, the results from the number of varicose vein patients were not separately identified, thus producing a very heterogeneous group of abnormal legs. Indeed, some of the patients with a history of deep venous thrombosis could have had normal veins as no details were given as to when the thrombosis had occured.

Fernandes et al (1979) measured the refilling time and also the maximum pressure and calf girth decrease on calf contraction in 27 subjects, and found a correlation coefficient of 0.90 between the pressure and girth changes. Unfortunately, there were no normal controls in this study, the normal values being obtained from the apparently normal legs of subjects with unilateral venous disorders. Neither of their methods of calculation of results has been found satisfactory in the present study, although it is clear that there is a good correlation between calf girth and venous pressure changes. The work of Mason and Giron (1982) did not include calculation of a correlation coefficient for their venous pressure and calf girth measurements on exercise. These workers measured the maximum calf girth and venous pressure fall on calf contraction, and also the recovery time. The latter two papers also noted that some post-phlebitic subjects increased their calf girth on calf contraction, but offered no explanation. Because of the lack of a standard method of calculating results from ambulatory strain-gauge plethysmographic recordings, it is not possible to compare the ranges of values obtained from different groups of subjects. The method of recording results in this study is presented as being simple, reproducible and free from the problems associated with the methods used by previous workers.

Most importantly, the calf girth changes (measured by the described technique) produced a better separation of results between the normal subjects and those with venous disease than did the direct venous pressure changes.

The reason for this is probably that venous pressure recordings only register a portion of the large venous pool, in which many different changes may be occuring. For instance, changes in incompetent perforating veins will not be reflected in the long saphenous vein. The calf girth changes, however, provide a composite picture of the changes that occur, and reflect the resultant alterations. Thus, while calf girth changes may not be so accurate in the particular changes, the overall picture is of more value in the separation of normal from abnormal changes in the lower limb.

In the use of the ambulatory test for the assessment of varicose veins, there was good agreement between the results of clinical examination, Doppler ultrasound testing and strain-gauge plethysmography. However, in general, the information provided by strain-gauge plethysmography was little more than could be provided by careful clinical examination. The main value was found to be in the assessment of obese subjects, and those who had recurrent varicose veins (particularly in the diagnosis of recurrent sapheno-femoral incompetence). Even in these situations, Doppler ultrasound examination could provide equally good results with less cumbersome equipment and also could detect the positions of incompetent perforating veins. However, Doppler ultrasound does require experience in the use of the equipment to produce satisfactory results; and the mapping of incompetent perforators may not be as accurate as it is claimed to be (O'Donnell et al 1977).

Strain-gauge plethysmography does provide a written record of the results of varicose vein assessment. This means that results are available for comparison with any future recordings, providing an objective assessment of the results of treatment. This is also important in the assessment of deep venous incompetence, and particularly in the follow-up of any treatment.

In the diagnosis of deep venous incompetence, strain-gauge plethysmography has been found to be valuable in confirming the clinical diagnosis and selecting which patients should be further investigated by phlebography. A reliable non-invasive investigation is necessary in the management of deep venous incompetence, as follow-up studies are necessary and repeated phlebograms are undesirable (particularly as one complication of phlebography is venous thrombosis). Other workers have found strain-gauge plethysmography to be useful in the diagnosis of deep venous incompetence (Holm et al 1974; Fernandes et al 1979; Mason and Giron 1982). However, it is still necessary to use ascending and descending phlebography to define the anatomical lesions causing the symptoms of deep venous insufficiency.

There has only been one previously reported study of the results of the pre- and post-operative strain-gauge plethysmography in varicose veins (Holm 1976). In this study, all of the post-operative results moved into the normal range, however, there was no attempt to assess the results of surgery objectively. Unfortunately, the results of pre- and post-operative strain-gauge plethysmography in this present study failed to show a correlation between subjects whose plethysmographic result moved into the normal range and a satisfactory objective assessment of the results of surgery.

However, the same comment may be made on these results and also on the results from the study comparing two forms of treatment for varicose veins; that the follow-up time is too short to draw meaningful conclusions.

7 CONCLUSIONS

This series of experiments was devised to test the value of strain-gauge plethysmography in the assessment of venous disorders of the lower limb.

In both the measurement of venous distensibility and the ambulatory test of venous function, the strain-gauge plethysmographic results were found to correlate well with the invasive "gold standard" venous pressure results.

The results of venous distensibility measurement obtained from recordings of calf girth changes, secondary to inflation of a pneumatic thigh cuff, were found to vary with changes in subject and strain-gauge position. Local temperature changes were seen to have little effect on the results of venous distensibility recordings. Despite strenuous attempts to maintain the same experimental conditions, a considerable variation was found in the venous distensibility recordings obtained from the same subjects on different days. A considerable overlap was found between the distensibility results obtained from normal subjects and patients with varicose veins. This overlap, combined with the lack of reproducibility of the results, makes the measurement of venous distensibility by this method of little value in the investigation of venous disorders of the lower limb. In fact, it is probable that this and other studies using this method of venous distensibility recording are not actually measuring distensibility of veins. The recordings probably reflect changes in venous tone in the lower limbs, and thus may be more useful in studying the effect of drugs on the venous tone.

The results of ambulatory strain-gauge plethysmography showed a satisfactory degree of reproducibility and were able to detect and quantify abnormal venous haemodynamics. In the assessment of varicose veins, strain-gauge plethysmography was found to be superior to careful clinical examination or Doppler ultrasound examination in the investigation of subjects who were obese, or who had recurrent varicose veins. Strain-gauge plethysmography was found to be less liable to observer-error than Doppler ultrasound examination, and it also provided a numerical score result which could be used to quantify the severity of disease or to assess the results of treatment. However, the plethysmograph could not be used for the localisation of incompetent perforators but it was useful in identifying those subjects in whom a careful search for incompetent thigh perforators should be made.

Ambulatory venous pressure and calf girth changes follow similar patterns, and give similar information regarding the diagnosis of venous disorders. However, the non-invasive plethysmographic measurements do not have the discomfort or possible complications of venous pressure recordings, and so are more suitable for repeated measurements in assessing the results of treatment of venous disorders. Plethysmography also gave better separation of the normal and varicose vein subjects than venous pressure measurement.

The studies performed showed no predictive value for strain-gauge plethysmography in varicose vein surgery, but the follow-up time is probably too short for definite conclusions to be drawn from this study. Also, no advantage has been shown for stripping the long saphenous vein in the surgical treatment of varicose veins, although, here too, the shortness of the follow-up time precludes firm conclusions being drawn.

The ambulatory strain-gauge plethysmographic test was found to be particularly useful in the diagnosis of deep venous incompetence. The combination of symptoms of venous claudication and the appropriate pattern of ambulatory calf girth change was found to be sufficient for the diagnosis of deep venous incompetence. Subjects with deep venous incompetence in whom surgery is contemplated require further investigation with phlebography (both ascending and descending) to demonstrate the anatomical and physiological defect responsible for their symptoms. However, if surgery is not intended, and there are, as yet, no entirely satisfactory surgical procedures available for the treatment of deep venous incompetence, then plethysmography provides a non-invasive diagnostic test without the need for phlebography with its well-recognised complications.

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10 APPENDIX

The following article is the text of a paper presented at the Second Workshop on Peripheral Haemodynamics, October, 1980, held in Siena, Italy, and published in the proceedings of the conference - Noninvasive Methods on Cardiovascular Haemodynamics, Editor - A H M Jageneau.

The correlation of Periflow and direct manometric results in venous disorders

A.B. Woodyer, A.J.G. Batch, A. Berent and J.A. Dormandy

The noninvasive technique of strain gauge plethysmography has become well established in the assessment of peripheral arterial disease, and is frequently in use in our department.

Recently, however, we have become interested in the use of this technique for the investigation of venous pathophysiology, and also for the diagnosis of venous disorders of the lower limb.

The "gold standard" in the investigation of venous disease is venous pressure measurement, using an invasive technique, and so we have used venous pressure measurements as a comparison for our plethysmographic results.

It has been suggested that the vein walls in patients with varicose veins may be congenitally weaker than those in the normal population, and that this is a factor in the development of varicose veins.

If this is so then there ought to be a detectable difference in the distensibility of the veins of patients with varicosities from those of the normal population. This difference should be detectable using plethysmographic techniques.

To investigate this proposition, an experiment was devised to see if the Periflow strain gauge plethysmograph was capable of detecting differences in venous distensibility, and also to assess the accuracy of the results obtained.

Subjects for the experiments were placed supine on a couch with the calves supported clear of the couch and at heart level.

Changes in calf volume were measured using a mercury in silastic strain gauge placed around the maximum calf circumference during periods of inflation and deflation of a pneumatic cuff placed around the thigh.

Cuff pressures of 30, 50, 70 and 90 mmHg were used and the maximal percentage volume increase for each cuff pressure was recorded. The maximal percentage volume increase at each pressure was plotted against the cuff pressure to produce a graph of venous distensibility. Fig. 1 shows such a graph plotted for both legs of a patients with unilateral varicose veins. The slope of the line obtained is called the venous distensibility index (VDI). In Fig. 1 the slopes of the two graphs are the same, indicating that the veins are equally distensible in both legs.

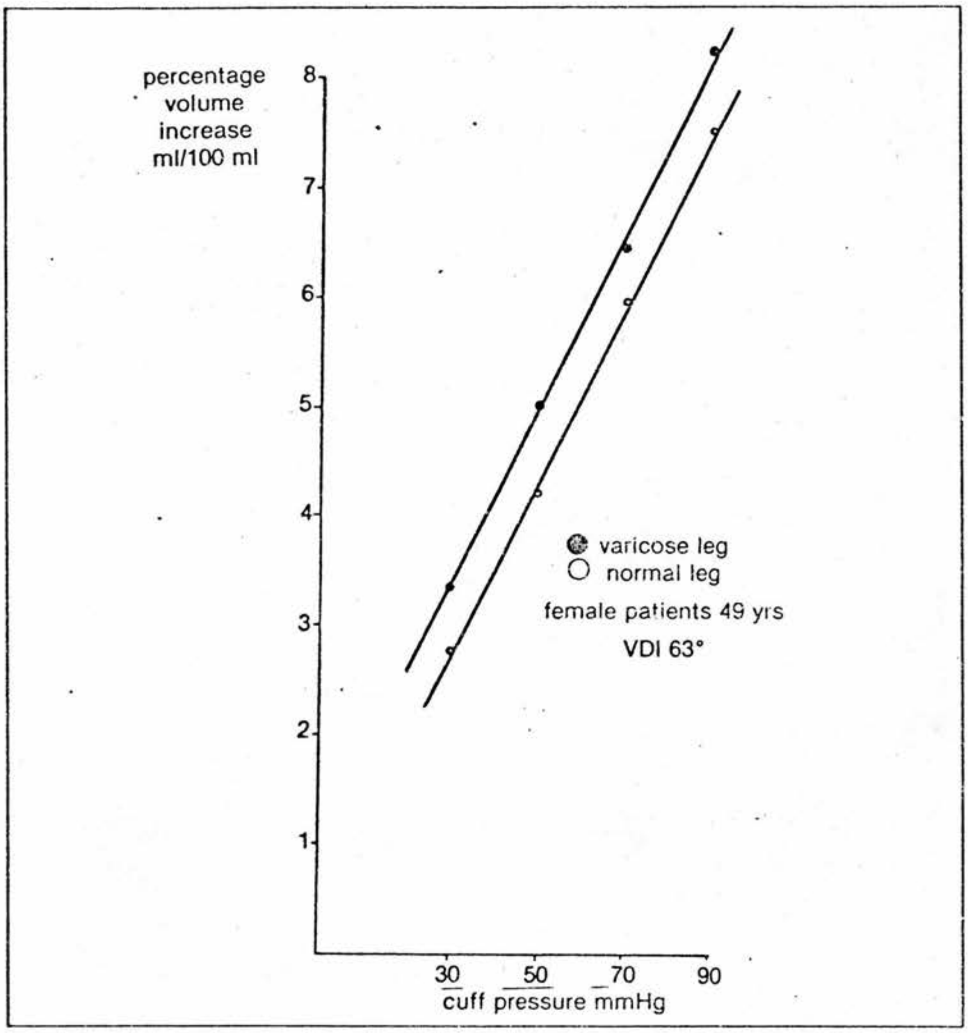

Fig. 1

It can be seen that the greater the distensibility of the veins, the higher will be the VDI, as, for each cuff pressure there will be a correspondingly greater volume change. Thus, varicose vein patients might be expected to have higher VDI's than normal subjects. The VDI's have been calculated for 30 varicose vein patients and 30 normal subjects, matched for age and sex, and the results are shown in Fig. 2. The results were divided into five groups as follows: - normal subjects (1); the normal legs in patients with unilateral varicose veins (2); patients with mild to moderate varicosities (3); patients with gross long saphenous incompetence (4); and patients with added perforator incompetence and eczema or ulceration (5). The arithmetic mean (with its interval estimate) of the VDI is shown for each group. There was a statistically significant difference between the patients with long saphenous incompetence and the normal subjects ($p = 0.001$) indicating that the varicose veins were more distensible. However, there was a considerable scatter in the results and it was decided to investigate some of the factors that could have been responsible.

The factors considered were : reproducibility of results, limb temperature and position, and variability in the cuff pressure.

To assess the reproducibility of our results, 11 normal subjects were repeatedly tested on different days and at different times during the day. The results of the VDI's for these subjects are shown in Fig. 3. It can be seen that for each subject there is a wide variation in the results obtained and we have no adequate explanation for this variation, possibily it may be due to differences in the active tone of the vein wall.

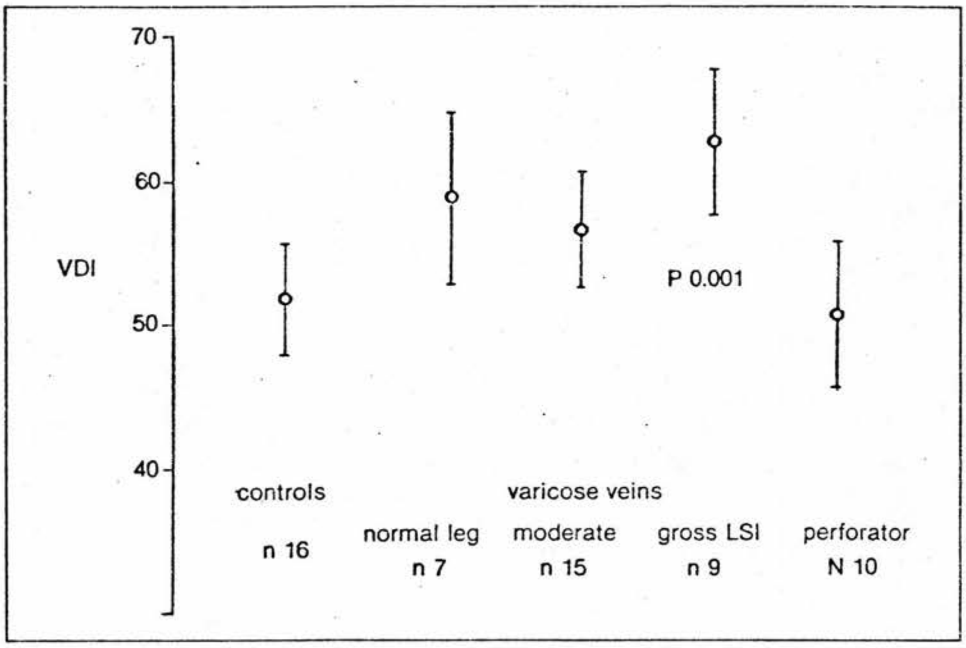

Fig. 2

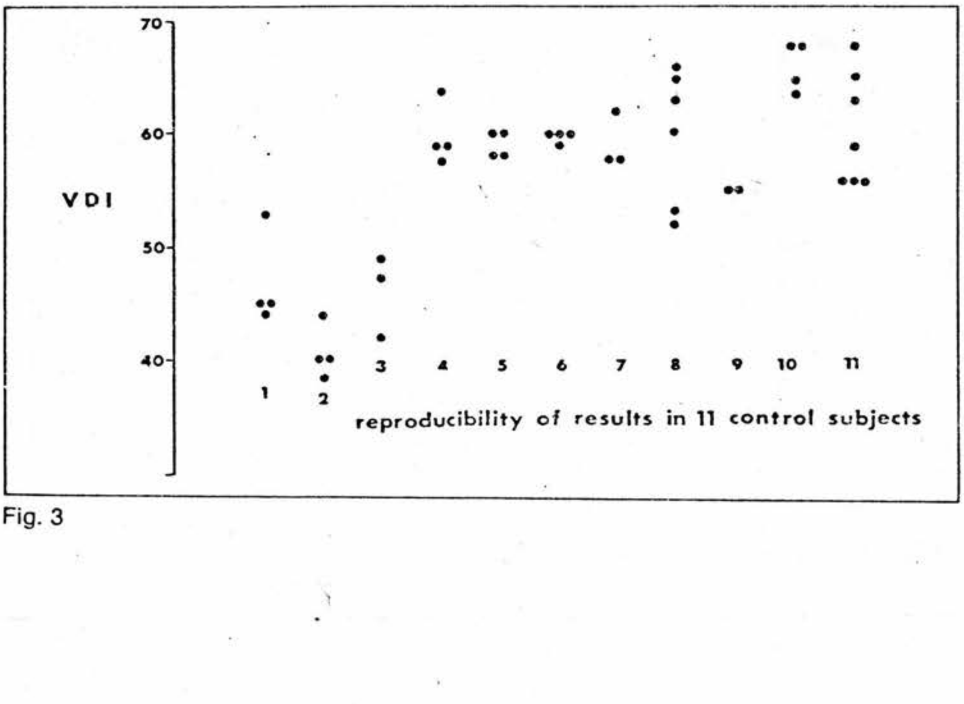

Fig. 3

Fig. 4 shows the VDI's of 6 normal subjects measured on several occasions when the recorded steady state temperatures was different. The lines tend to run horizontally, indicating that distensibility does not vary significantly with limb temperature within the physiological range.

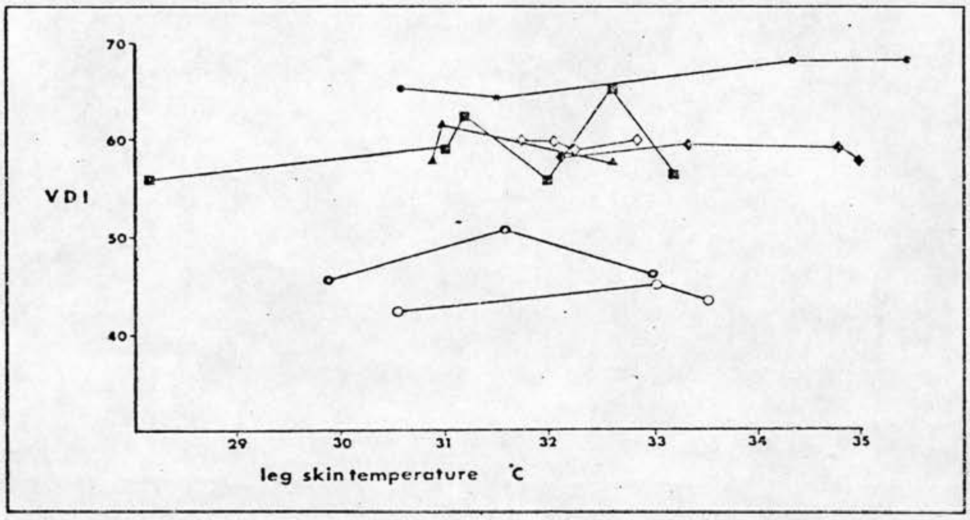

Fig. 4

The effects of variation in limb position were also studied. Recordings were made with the subjects lying supine with the calves at heart level and then at 15 cm above heart level and also sitting with the legs extended. The VDI's were calculated and the results from each position plotted against another (Fig. 5 & 6). If the position of the limb had no effect on the VDI then all the points would fall along the line of identity. However, measurements taken with the limb elevated produce higher values for the VDI, indicating more distensibility of the veins. This effect may be due to at least part of the volume change measurement being of venous filling rather than elasticity of the vein wall. Results from subjects lying and sitting tend to be along the line of identity, indicating that changing to a sitting position has no effect on the VDI (Fig. 6). We now take all recordings from subjects lying down with their calves at heart level.

In order to assess the accuracy of our recordings, the plethysmographic results were compared with simultaneous measurements of venous pressure taken from a cannula in the long saphenous vein at the ankle and attached to a pressure transducer. Both cuff volume and pressure changes were fed to a two channel recorder to give direct comparison of results. The recordings (from varicose vein patients and normal subjects) were obtained with the subjects in the supine position, with the cannula, pressure transducer and strain gauge all at the same height.

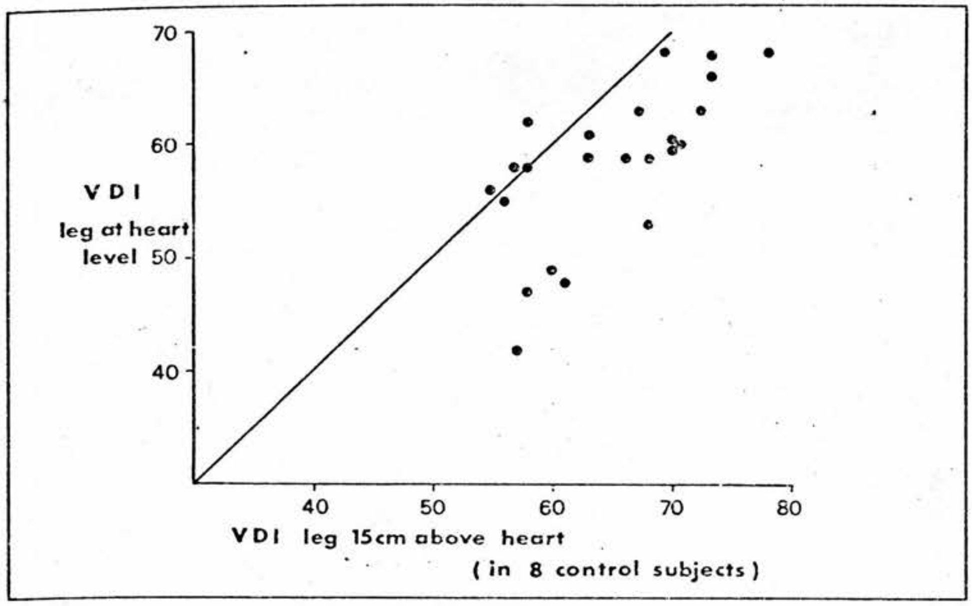
70
60
50
40
V D I
leg at heart level
40
50
60
70
80
V D I leg 15cm above heart
(in 8 control subjects)

Fig. 5

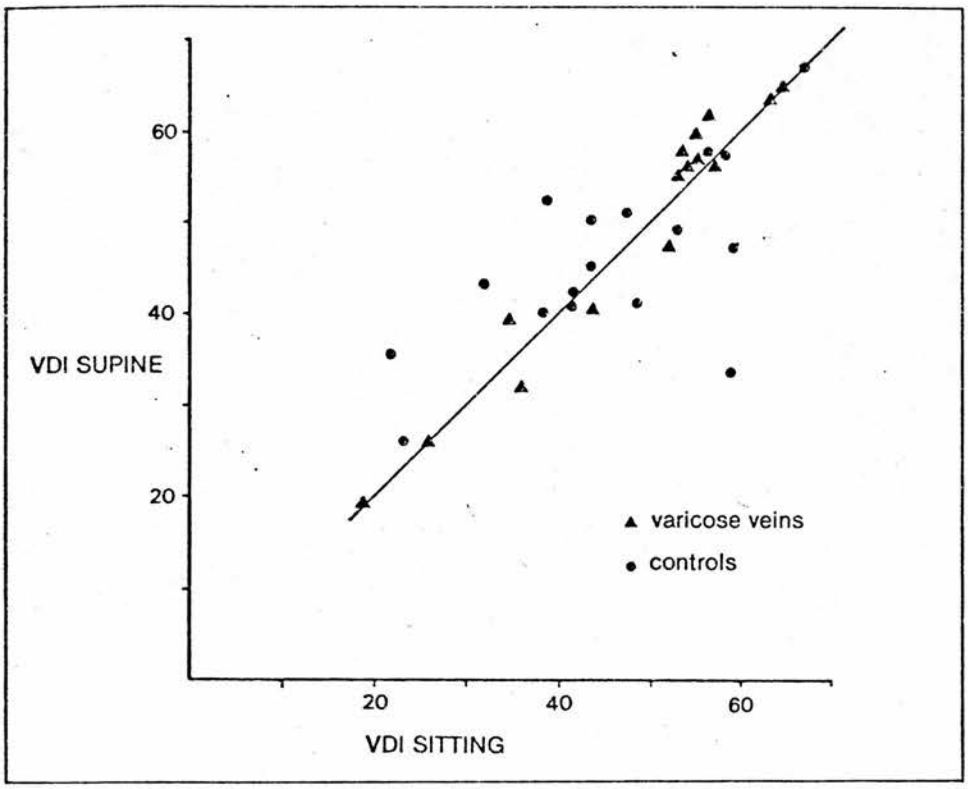
60
40
20
VDI SUPINE
20
40
60
VDI SITTING
▲ varicose veins
● controls

Fig. 6

Our first finding was that the recorded venous pressure was consistently lower than that applied by the thigh occlusion cuff (Fig. 7). There was no constant relationship for this difference, but for each patient the results were consistent. This difference in pressures is probably an effect of the ratio of cuff width to thigh circumference producing dissimilar pressures in different limbs. If the VDI is calculated using venous pressure rather than the cuff pressure, then the results show less scatter and a better separation of results (Fig. 8). However, this still does not explain the day to day variation of recorded distensibility in the same subject.

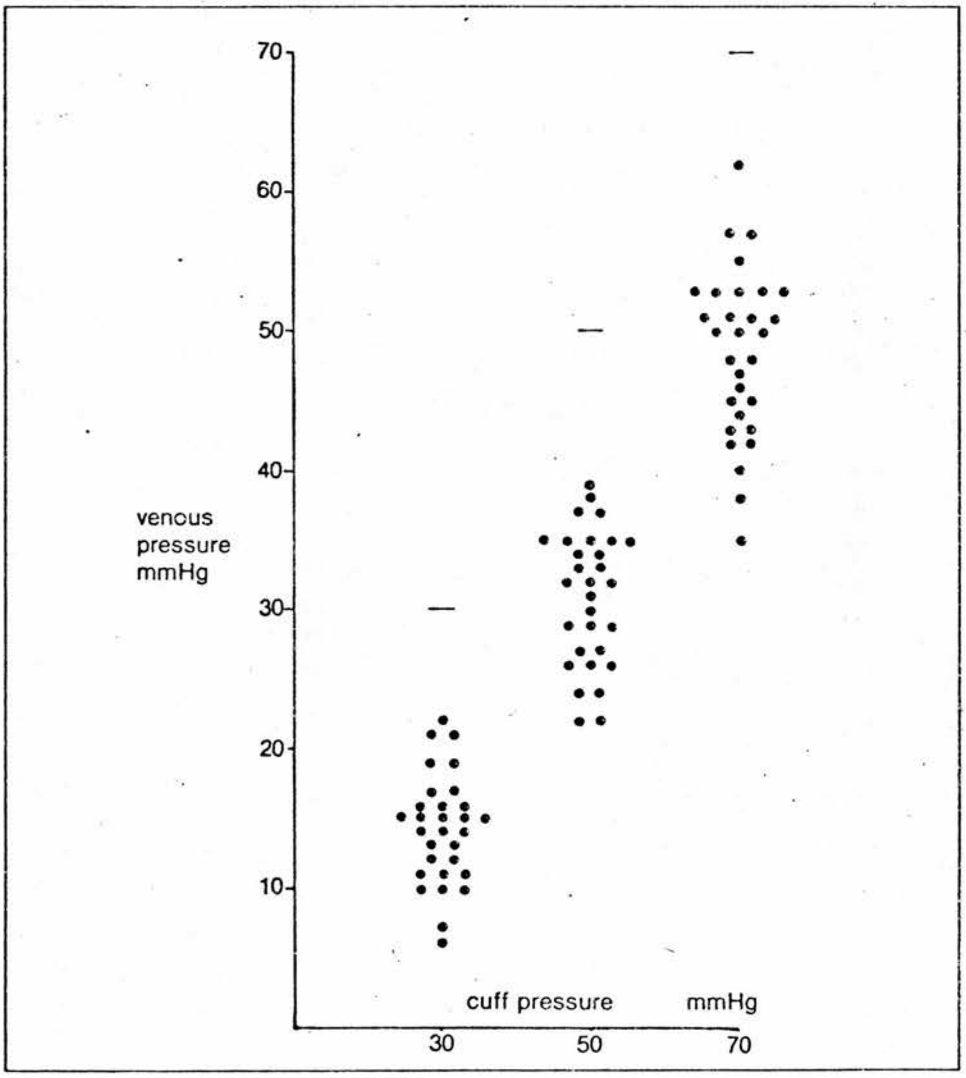

Fig. 7

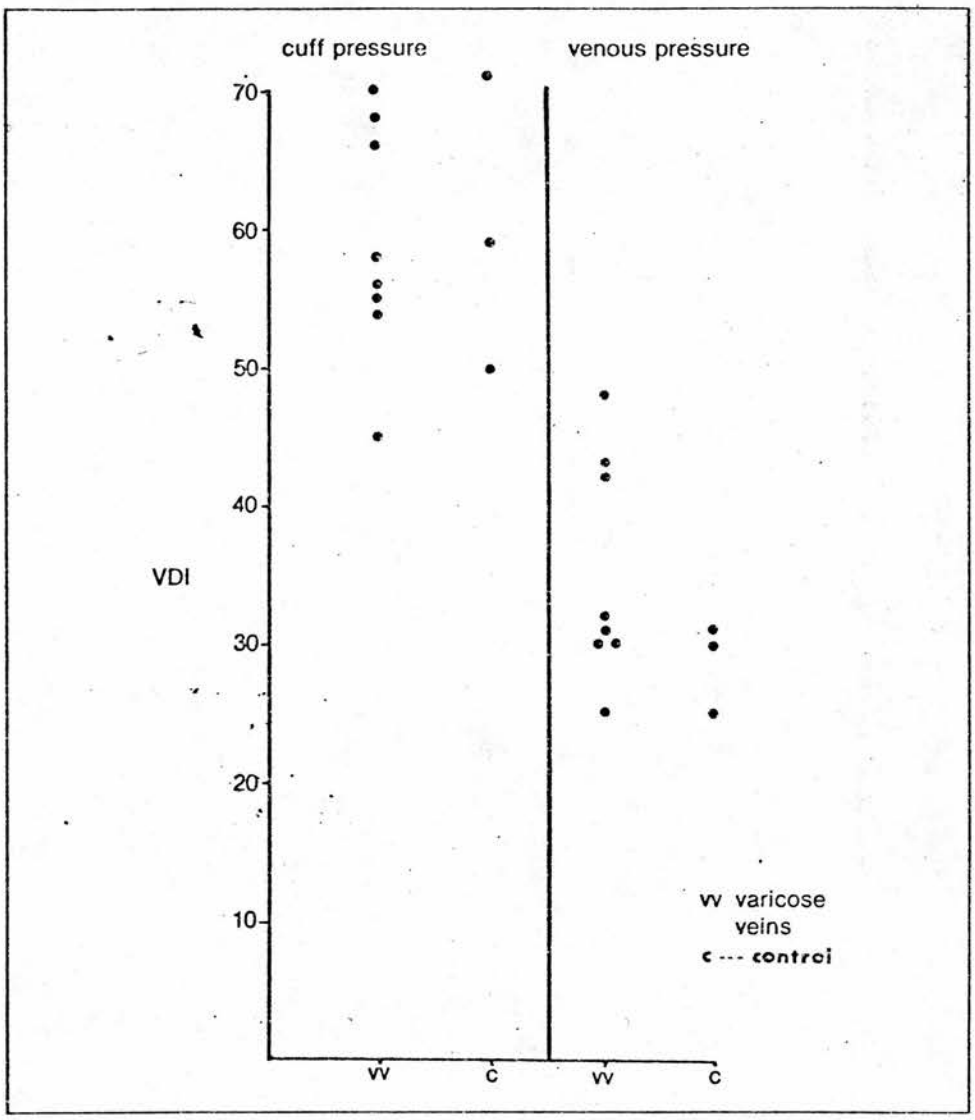

Fig. 8

It was also noted during these experiments that there were occasions when it was difficult to decide on the end point of the volume change. Fig. 9 shows an example of the calf volume and pressure changes during inflation of the thigh cuff to 70 mmHg. It can be seen that the calf volume continues to increase despite the plateau of the pressure, thus making it difficult to decide on the end point and hence producing another source of error.

Thus, from our experience, it would seem that strain gauge plethysmography when used in the standard way, is inaccurate and requires refinement before it can be of use in the investigation of venous disorders.

This being so, can the Periflow machine be used as a diagnostic instrument in venous disease? To try and answer this question we have again made use of simultaneous pressure and volume measurements, this time with the subject standing and also during 1 minute periods of heel raising exercise. This exercise was performed with and without inflation of the thigh occlusion cuff to 100 mmHg.

The patients with long saphenous incompetence has an abnormal response which is returned to normal by inflation of the thigh cuff, however, the patient with perforator incompetence has an abnormal response which is accentuated by cuff inflation. It is thus possible by the use of the exercise test to obtain useful diagnostic information.

In conclusion, we feel that our studies have shown that strain gauge plethysmography required refinements to improve its accuracy before it can be used as a research tool in the investigation of venous pathophysiology. However, it does represent a useful, non-invasive diagnostic aid in the assessment of venous disease.

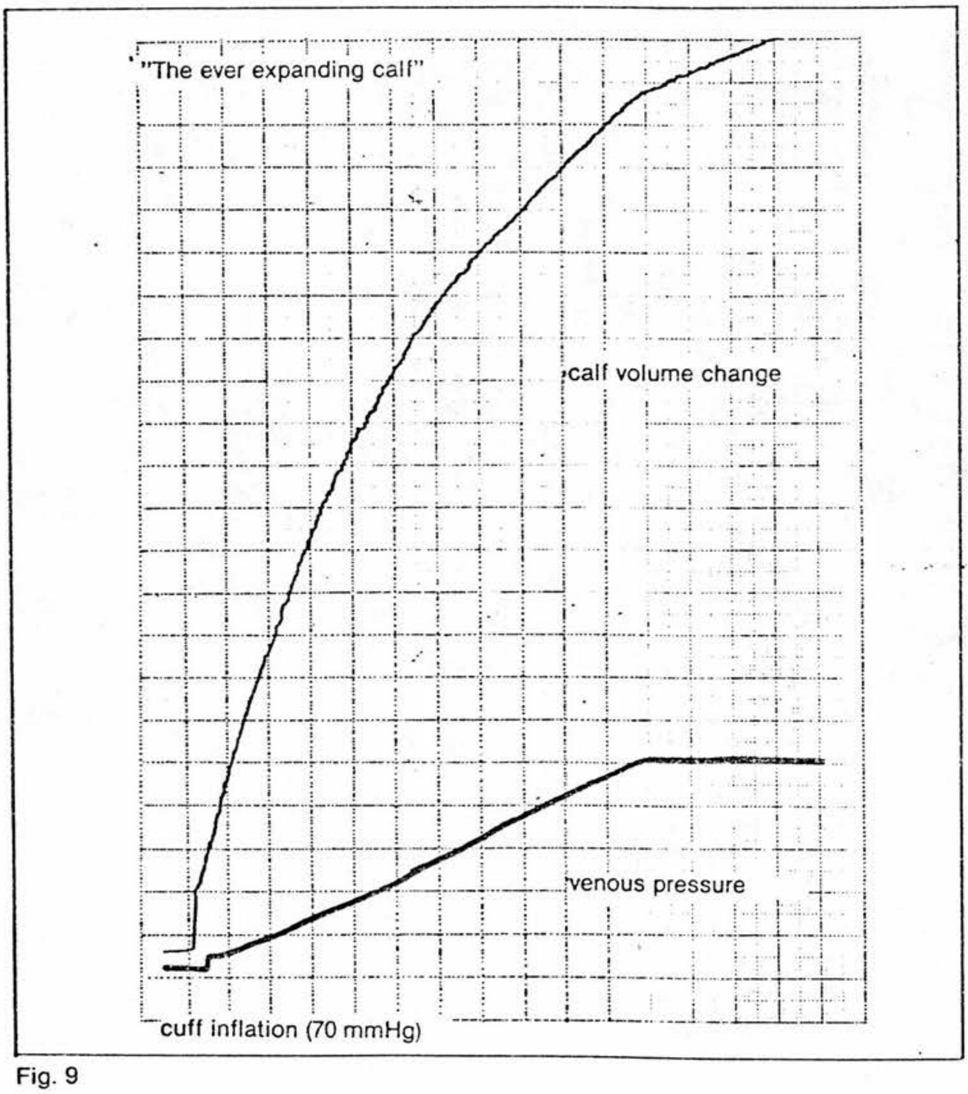

Fig. 9