An investigation into current and new technologies for best identifying those 'at risk' of developing diabetic foot problems.

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Summary:

Introduction:

As a complication of diabetes mellitus, diabetic foot disease is a well-established concept in which vascular, neurological, and biomechanical factors conspire to cause disorders that have a great impact on patient health, mobility, life-expectancy, and quality of life, and are a significant economic burden. This study aimed to explore the use of the currently used and the more advanced techniques available in the early identification of those 'at risk' of developing diabetes-related foot complications. This study also aimed to identify deficiencies in patient knowledge and awareness of such complications and deficiencies in current foot care being received.

Methods:

A volunteer sample group of the diabetic population in the Vale of Glamorgan (n=545) were asked to complete two questionnaires relating to their demographics, historical and current general and diabetic health and current foot health care provisions. They also underwent thorough foot and foot wear examinations, thorough vascular and neurological tests and thorough dynamic plantar pressure analysis. A smaller number of non-diabetic control subjects were later recruited from the general population (n=50) for comparative use in the neuropathy part of the study.

Results:

It was evident that although subjects were receiving their annual general diabetes check they were not always having their feet checked. Intense education on diabetes-related foot complications and self-care was required, as was the continuing need for advice on accommodative footwear. The neurological assessment showed high correlation between the 10g-monofilament and neurothesiometer. The accuracy of the neurothesiometer with 0.5v increments and vibration starting being much more easily detected, out weighed any benefits of the tuning fork. A single VPT cut off value for all subjects was shown to be inappropriate with age adjustments being essential for accurate diagnosis. The vascular study particularly highlighted the unreliability of using palpation of pulses as a single method of vascular assessment. ABPI's proved to provide greater information however, these can often be difficult to obtain in some patients, incredibly painful and produce falsely elevated results. The pulse volume recorder however, proved to be exceptionally accurate, pain free, easy to use and suitable for all patients. Plantar pressure analysis proved that time and pressure should be analysed together, before implementing a treatment plan.

Discussion:

From the results it is evident that the advanced methods of assessment can provide more reliable and more useful results than many of the currently used methods. Specifically, the use of age-adjusted centile charts to be used when assessing vibration perception thresholds using the neurothesiometer would prove invaluable in making the appropriate diagnosis. With vascular Consultants moving away from ABPI scores being useful in diagnosis, the pulse volume recorder provides an accurate, useful and easy vascular assessment alternative for use in the community prior to referral. Current cost implications of the Vascular Assist which houses the PVR would limit accessibility and therefore its use. The results of this study indicate the usefulness of a dedicated pulse volume recorder to be manufactured.

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Last but by no means least, to my husband Huw and son Iwan, a big thank you for putting up with me, and the untidiness over the past three years and to you both I dedicate this thesis.

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List of abbreviations

ABPI	Ankle Brachial Pressure Index
ASP	Ankle systolic pressure
AGEs	Advanced Glycation End-products
Ab	Abnormal
BSP	Brachial systolic pressure
CI	Confidence interval
COF	Centre of Force
CV	Coefficient of variation
DM	Diabetes mellitus
DN	Diabetic neuropathy
DRSSW	Diabetes Retinopathy Screening Service for Wales
DRU	Diabetes Research Unit
DNA	Did not attend
DPN	Diabetic peripheral neuropathy
DP	Dorsalis pedis
df	Degrees of freedom
ESRD	End stage renal disease
GP	General Practice/Practitioner
GDM	Gestation diabetes mellitus
HDL	High density lipoprotein
HV	Hallux valgus
IDDM	Insulin dependent diabetes mellitus
IGT	Impaired glucose tolerance
IWGDF	International Working Group on the Diabetic Foot
IDF	International Diabetes Federation
ID	Inter-digital
LDL	Low density lipoprotein
MRDM	Malnutrition-related diabetes mellitus
Min	minimum
Max	maximum
MPJ	metatarsophalangeal joint
NDS	Neurological disability score
NSS	Neurological symptom score
NIDDM	Non-insulin dependent diabetes mellitus
NHS	National Health Service
NICE	National Institute for Clinical Excellence
n	Number
PEDIS	Perfusion, Extent/size, Depth/tissue loss, Infection and Sensation
PPG	Photoplethysmography
PVR	Pulse Volume Record/Recorder
PVD	Peripheral vascular disease
PAD	Peripheral arterial disease
PAOD	Peripheral arterial occlusive disease
PT	Posterial tibial
PPP	Peak Plantar Pressure
RAGE	Receptor to Advnced Glycation End-products
SPSS	Statistical Package for the Social Sciences
SD	Standard Deviation

SBP	Systolic blood pressure
SDN	Specialised Diabetes Nurse
$TcPO_2$	Transcutaneous Peripheral Oxygen tension
TBPI	Toe brachial pressure index
TSP	Toe systolic pressure
UK	United Kingdom
VPT	Vibration perception threshold
WHO	World Health Organisation
WPCAG	Welsh Primary Care Audit Group
Yr	Years

List of International system of units (SI) abbreviations

Hz	hertz
Kg	kilogram
kPa	kilopascal
m	metre
MHz	megahertz
min	minute
g	gram
v	volt
cm	centimetre
mm	millimetre
mmHg	millimetres of mercury
ms	millisecond
%	percentage
°C	degrees centigrade

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CHAPTER ONE: INTRODUCTION

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1.1 Brief history of Diabetes Mellitus

A condition characterized by a polyuric state was described back in the 15th century BC with the sweetness of the urine in the disease first being recorded in Sanskrit literature of the 5th-6th centuries that could be describing diabetes. Some time in the 2nd century AD however, Aretaeus of Cappadoci, was the first to clinically describe diabetes and wrote that 'diabetes is a wonderful affection, not very frequent among men, being a melting down of the flesh and limbs into urine'. The great Arabian physician Avicenna further described clinical characteristics and noted complications such as gangrene and sexual dysfunction in the 10th century. However, it was not until the late 17th century, after Thomas Willis, Physician to Charles II, had repeated the observation of the polyuric state characterized by sweet urine, that the adjective 'mellitus' (Latin for honey) was applied to distinguish the disease from other polyuric states with insipidus urine.

In 1869, Paul Langerhans, then a medical student, discovered special groups of cells in the pancreas that make and secrete hormones that help to break down and use food. These cells sit in clusters in the pancreas and are known as the islets of Langerhans, named after the German scientist. There are five types of cells in the islet: beta cells, which make insulin, alpha cells, which make glucagons delta cells, which make somatostaton, and PP cells and D1 cells, about which little is known. It was not until later in the 19th century that the dysfunction of the pancreas was identified as the probable cause of diabetes. In 1889, two scientists working on fat metabolism noted that the removal of the pancreas from a dog caused it to develop diabetes and the link between diabetes and the pancreas was confirmed. However with effective treatment remaining elusive, patients with the now known Type 1 diabetes still faced a short life, with ketoacidosis usually causing death. A starvation diet was implemented to

try to normalise blood glucose levels however with malnutrition inevitable, life was often only prolonged for a few months.

The link between diabetes and the pancreas paved the way for Frederick Banting, a physician surgeon, and his student assistant Charles Best, working in the University of Toronto in Canada in 1921, to develop a technique for isolating pancreatic secretion. After a number of experiments, the pair found that, by injecting the serum they developed into the dogs with diabetes, it lowered blood glucose and kept them alive. In 1923 Banting and his Professor, MacLeod, were awarded the Nobel Prize for their work. This they shared with Best, Bantings' student assistant, and Collip a biochemist who had helped them. Now that insulin had been discovered, countless people afflicted with diabetes mellitus were rescued from an inevitable early and disgusting death.

1.2 **Prevalence of Diabetes Mellitus**

Diabetes mellitus is thought to be one of the main threats to human health in the 21st century and is considered to be the 4th or 5th leading cause of death in most developed countries and of epidemic proportions in developing and newly industrialised countries (International Diabetes Federation 2003, Zimmet et al. 2001). The prevalence of diabetes in adults was estimated to be 194 million worldwide and this is set to rise to 333 million by the year 2025. In the developed countries the majority of those with diabetes are aged 65 years and over whereas in the developing countries the majority of those with diabetes are in the age range of 45-64 years (King et al. 1998).

Approximately 1.8 million people in the UK are known to have diabetes and at least a million more –'the missing million'- are thought to have diabetes but do not know it

yet (Diabetes UK 2004). The number of people with diabetes in Wales, supplied by the Office of National Statistics for 1998, was 107,037 representing 3.7% of the population.

The populations of most countries are ageing. Diabetes mellitus (DM) is particularly common in the ageing population and is increasing in proportion to the number of people living longer. In 2003 it was reported that the World Health Organisation (WHO) estimated that 2.5-15% of annual health budgets were spent on diabetes-related illnesses (International Diabetes Federation 2003). With the increases in the ageing population and proportional increase in the numbers with DM, these costs are set to spiral.

1.3 Definition and classification

The term diabetes mellitus is described as a disease in which there is a defect in the transfer of glucose from the bloodstream into the cells, leading to abnormally high levels of sugar in the blood and urine. There are frequently other metabolic deviations, including abnormalities of carbohydrate, protein and lipid metabolism, and pathological changes in blood vessels and in nerves (West 1978). The metabolic abnormalities are due to the deficient action of insulin on target tissues resulting from either resistance to, or lack of insulin.

The lack of, or resistance to, insulin within the body leads to a reduction in the uptake of glucose, predominantly by the skeletal muscles and the uncontrolled output of glucose from the liver. This culminates in hyperglycaemia. When glucose levels are beyond the absorption levels for the kidneys, glucose will appear in the urine (glucosuria). This causes an osmotic differential and the volume of urine increases resulting in polyuria and can result in dehydration, hence the person will have an

excessive thirst and their fluid intake rises through excess drinking as they feel that their thirst cannot be quenched (polydipsia). While these symptoms may be a result of increased blood glucose levels, the cause of this increase may have different aetiopathologies, thus the different classifications of Diabetes Mellitus, the most significant being Type 1 and Type 2.

In its most severe form, ketoacidosis or a non-ketotic hyperosmolar state may develop and lead to stupor, coma and, in the absence of effective treatment, death. Often symptoms are not severe, or may even be absent. Hyperglycaemia of a sufficient degree to cause pathological and functional changes may be present for a long time before a diagnosis is made. The main controlling factor on the level of blood glucose is insulin, secreted by the pancreas, therefore, if there is inadequate insulin circulating in the blood, diabetes is the result and this lack of insulin can be either relative or absolute. Due to increasingly sedentary lifestyles and a rising prevalence of obesity, diabetes mellitus has emerged as reaching world wide epidemic proportions.

The first widely accepted classification of diabetes mellitus was published by the World Health Organisation (WHO) in 1980 and, in modified form, in 1985. The 1980 and 1985 classifications of diabetes mellitus and allied categories of glucose intolerance included clinical classes and two statistical risk classes (World Health Organisation 1985). The 1980 Expert Committee proposed two major classes of diabetes mellitus and named them IDDM or Type 1, and NIDDM or Type 2. In 1985, the terms Type 1 and Type 2 were omitted, but the classes IDDM and NIDDM were retained, and a new class of Malnutrition-related Diabetes Mellitus (MRDM) was introduced. In both the 1980 and 1985 reports other classes of diabetes were included as 'Other Types' and 'Impaired Glucose Tolerance' (IGT) as well as 'Gestational Diabetes Mellitus' (GDM). In 1998 a report from the WHO in Diabetic Medicine

reported that the terms insulin-dependent diabetes mellitus (IDDM) and non-insulin-dependent diabetes mellitus (NIDDM) were to be eliminated due to confusion resulting in patients being classified based on treatment rather than on pathogenesis. The terms Type 1 and Type 2 were reinstated and their aetiological classifications are explained below:

Table 1.1 - Aetiological classification of disorders of glycaemia

Classification	Description
Type 1	**Beta-cell destruction, usually leading to absolute insulin deficiency, can be autoimmune or idiopathic**
Type 2	**May range from predominantly insulin resistance with relative insulin deficiency to a predominantly secretory defect with or without insulin resistance**
Other specific types	**Genetic defects of beta-cell function** **Genetic defects in insulin action** **Diseases of the exocrine pancreas** **Endocrinopathies** **Drug or chemical induced** **Infections** **Uncommon forms of immune-mediated Diabetes** **Other genetic syndromes sometimes associated with diabetes**

1.3.1 Type 1 Diabetes Mellitus

Type 1 diabetes mellitus affects mainly people under the age of 40 with rapid onset, which can present as a diabetic coma. Type 1 diabetes mellitus can be best thought of as a chronic autoimmune disease, which involves a highly selective destruction of the

β-cells of the islets of Langerhans leaving the pancreas of a patient with Type 1 diabetes almost completely devoid of β-cells. There is a strong genetic pre-disposition to the development of Type 1 diabetes mellitus however the auto-immune response is believed to be triggered by environmental factors. The presence of a virus such as Mumps or Rubella appears to be the most significant, although viruses may also cause β-cell damage by direct invasion. As a result of these genetic, immunological and environmental factors, absolute insulin deficiency occurs, often rapidly. The subsequent onset of diabetes is fast and aggressive and insulin treatment is necessary for survival.

1.3.2 Type 2 diabetes mellitus

Type 2 diabetes mellitus, often previously referred to as 'late onset', affects mainly the more mature person. However, the number of younger people being diagnosed with Type 2 diabetes is on the rise due to the nation's increased sedentary lifestyle reflecting its strong correlation with obesity. Type 2 diabetes accounts for approximately 75% of all those with diabetes mellitus. Onset is not sudden but rather a more gradual progression and patients do not automatically require insulin. Type 2 diabetes mellitus, is a result of either insulin deficiency, insulin resistance or most often a combination of the two.

Insulin resistance involves the removal of the inhibitory effect of insulin on hepatic glucose output, and peripheral glucose uptake. This invariably results in an increase in blood glucose levels resulting in hyperglycaemia. The situation is self-perpetuating with hyperglycaemia itself causing increased insulin resistance and impaired insulin secretion, known as glucose toxicity. Other contributory factors towards insulin resistance include obesity, age, and lack of exercise, diet and genetic components. Type 2 diabetes mellitus is associated with an increased level of Low Density

Lipoprotein (LDL). There are two main forms of cholesterol, Low Density Lipoprotein (LDL) and High Density Lipoprotein (HDL). Low Density Lipoprotein (LDL) is associated with atherosclerosis and is toxic to endothelial cells. High Density Lipoprotein (HDL) has a protective influence removing cholesterol from peripheral tissues and protecting endothelial cells from damage by LDL.

1.4 **Complications of diabetes mellitus**

Diabetes cannot be considered a single disease. It is a compilation of systemic malfunctions causing long-term damage, dysfunction and failure of various organs. These complications include hypoglycaemia and hyperglycaemia, increased risk of infections, microvascular complications (i.e. retinopathy, nephropathy, peripheral and autonomic neuropathies), and macrovascular complications (i.e., hypertension, coronary artery disease, peripheral vascular disease, cerebro-vascular disease, hyperlipidaemia).

1.4.1 Diabetic retinopathy

Patients with diabetes are more likely to develop eye problems such as cataracts and glaucoma, but the disease's affect on the retina is the main threat to vision, making diabetes the major cause of blindness in adults aged 20-74 years. Most patients develop diabetic changes in the retina after approximately 20 years with the main effect of diabetes on the eye being called diabetic retinopathy.

Over time, diabetes affects the circulatory system of the retina, the earliest phase of the disease being known as background diabetic retinopathy. In this phase, the arteries in the retina become weakened and leak, forming small, dot or blot-like haemorrhages. These leaking vessels often lead to swelling or oedema in the retina and decreased vision.

Proliferative diabetic retinopathy follows where circulation problems cause areas of the retina to become oxygen-deprived or ischaemic. New, fragile vessels develop as the circulatory system attempts to maintain adequate oxygen levels within the retina. This is called neovascularisation. Unfortunately, these delicate vessels haemorrhage easily, blood may leak into or on the retina and vitreous causing decreased vision. In the later stages of the disease, abnormal vessel growth and scar tissue may cause serious problems such as retinal detachment and glaucoma. The affect of diabetic retinopathy on vision varies widely, depending on the stage of the disease.

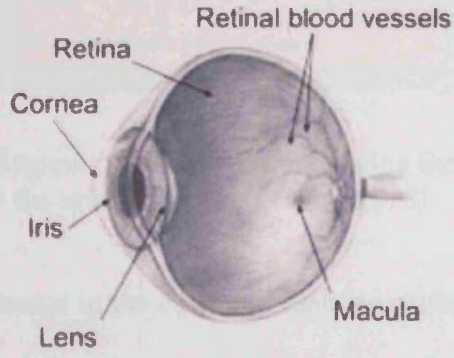


Figure 1.1 Labelled diagram of the human eye (National Eye Institute 2005).

1.4.2 Diabetic nephropathy

Diabetic nephropathy is a complication of diabetes where the kidney looses its ability to function properly. The condition is characterised by high protein levels in the urine.

Each kidney is made of more than a million units called nephrons. Each nephron has a tuft of blood vessels called a glomerulus. The glomerulus filters blood and forms urine, which drains down into collecting ducts to the ureter.

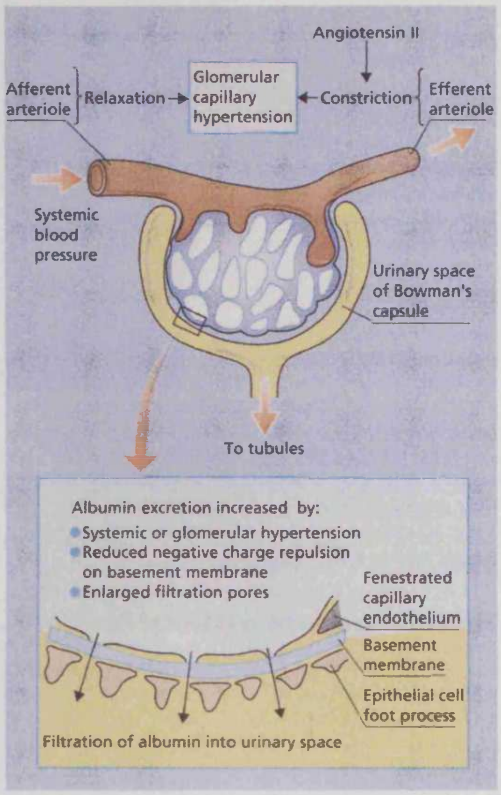


Figure 1.2 – Schematic diagram of glomerulus, indicating the main factors influencing excretion of albumin into the urine (Ward & Tesfaye 1998).

The earliest detectable change in the course of diabetic nephropathy is a thickening in the basement membrane of the glomerulus. At this stage, the kidney may start to leak albumin (protein) into the urine and this can be detected by sensitive tests for albumin. This early stage is called "microalbuminuria". As diabetic nephropathy progresses, increasing numbers of glomeruli are destroyed and the amounts of albumin being excreted in the urine increases. Over time, the kidney's ability to remove poisons from the blood deteriorates such that 2-6 years later the kidneys are almost completely unable to remove these poisons from the blood. This is called 'end stage renal disease' (ESRD), and unless treated, the poisons can build up to fatal levels. In this situation dialysis would be required. 50% of those patients requiring dialysis are diabetic of which 50% have type 2 diabetes.

Diabetic nephropathy is generally accompanied by other diabetes complications including hypertension, retinopathy, and vascular changes, although these may not be obvious during the early stages of nephropathy.

Diabetic nephropathy is the most common cause of chronic kidney failure and end-stage kidney disease in the United States and Europe. This disorder continues to progress toward end-stage kidney disease, usually within 2 to 6 years after the appearance of high protein in the urine (proteinuria) and is a significant cause of death in diabetes. People with both type 1 and type 2 diabetes are at risk and the risk is higher if blood-glucose levels are poorly controlled. However, once nephropathy develops, the greatest rate of progression is seen in patients with poor control of their blood pressure.

1.4.3 Diabetic neuropathy

Diabetic neuropathy is thought to result from nerve ischaemia or the accumulation of fructose and sorbitol, metabolized from glucose in peripheral nerves, which disrupts the structure and function of the nerve.

Diabetic neuropathy can be classified as either reversible (e.g. reduced nerve conduction velocity) or established (focal, multifocal, symmetrical and mixed neuropathies) as the table below describes:

Table 1.2 Classification of diabetic neuropathy

Rapidly reversible phenomena:	Distal sensory symptoms Reduced nerve conduction velocity Resistance to ischaemic conduction failure
Established neuropathy:	Focal and multifocal neuropathies - • Cranial mononeuropathies

Symmetrical neuropathies: Mixed syndromes	• Thoracoabdominal neuropathy • Focal limb neuropathies • Symmetrical/asymmetric proximal lower limb motor neuropathy (diabetic amyotrophy) • Sensory autonomic polyneuropathy • Proximal lower limb motor neuropathy

Symmetrical sensory neuropathy is the most common form of neuropathy and first affects the most distal parts of the largest nerves, i.e. the toes and the plantar surfaces of the feet. Symptoms consist of numbness, tingling and pain, which is typically worse at night. Involvement of the hands is less common and results in a 'stocking and glove' sensory loss. Complications include unrecognized trauma, such as blistering caused by an ill-fitting shoe or a hot-water bottle, leading to ulceration. Abnormal mechanical stress and repeated minor trauma, usually prevented by pain, may lead to the development of a neuropathic arthropathy (Charcot's joint) in the ankle and knee, where the joint is grossly deformed and swollen.

Autonomic neuropathy may present with impotence, postural hypotension, diarrhoea, and nausea and vomiting as a consequence of gastroporesis. In addition, bladder involvement may result in a neuropathic bladder with painless urinary retention.

In acute painful neuropathy, the patient describes burning or crawling pains in the lower limbs. These symptoms are typically worse at night, and pressure from bed clothes may be intolerable. There is usually a good response to improved glycaemic control.

In diabetic mononeuropathy, individual nerves are affected. In some instances this relates to local pressure, e.g. carpal tunnel syndrome. In others it results from a localized nerve infarction, commonly the 3rd or 6th cranial nerves are affected, resulting in diplopia. More than one nerve may be affected which is known as mononeuritis multiplex.

Diabetic amyotrophy or proximal motor neuropathy presents with painful wasting, usually asymmetrical, of the quadriceps muscles. The wasting may be very marked and knee reflexes are diminished or absent. Diabetes related peripheral neuropathy will be considered in more detail later in this chapter.

1.4.4 Diabetic vascular disease

Cardiovascular disease (CVD) is a major cause of morbidity and mortality among subjects who have diabetes. It is estimated that cardiovascular complications are responsible for up to 75% of deaths among people who have type 2 diabetes and constitute a two to four times increased risk of coronary heart disease (CHD), stroke, and peripheral vascular disease events compared with non-diabetic individuals. CVD is also the leading cause of death in subjects with type 1 diabetes (Del Pilar Solano & Goldberg 2005). Poor glycaemic control, obesity, smoking, lack of exercise and insulin resistance are all risk factors. Vascular disease can be sub-divided into macro- and micro- vascular problems.

Macrovascular impairment in diabetes results in cardiac problems and a subsequent increase in blood pressure. Problems within the heart seem to stem from neuropathy. The heart muscles are also susceptible to wasting in diabetes leading to diabetic cardiomyopathy. Nervous reflexes that control the heart pulses are also within the confines of autonomic neuropathy and prone to its effects. These factors, combined

with the metabolic effects of increased fatty acids within the blood, will cause acute myocardial infarction to be responsible for twice as many deaths in the presence of diabetes compared to the normal population.

Hypertension in diabetes is a substantial contributor to increased mortality, levels being four to five times those of the normal population (Klein & Klein 2002). This is due to coronary heart disease and strokes, but also it augments other peripheral pathologies such as retinopathy and peripheral vascular related foot problems. Hypertension may also be linked with the high levels of lipids that may be circulating in the patient with poorly controlled diabetes. The lipids can adhere to the artery walls and cause them to be narrowed and further increase blood pressure levels.

Microvascular dysfunction results in neuropathy and nephropathy as previously mentioned, and also is paramount in the development and progression of diabetic retinopathy and diabetic foot disease. The endothelium of the blood vessels is vital in the control of vascular tone and communication. It senses haemodynamic changes and converts signals received by surrounding tissues. Dysfunction of the endothelium could be of great importance in the aetiology of diabetic microvascular disease. The various biological toxins that are circulating in diabetes have been implicated in this breakdown, including oxygen free radicals, and non-enzymatic products of glucose and albumin.

1.4.5 Diabetic foot problems

Diabetic foot disease represents a spectrum of complex pathological interactions, a consequence of multi-system dysfunction, however, the chief factors responsible for foot problems in diabetes are neuropathy and ischaemia or a combination of the two.

Diabetic foot complications are common and have potentially devastating consequences with the two major problems being foot ulceration and amputation.

Figure 1.3-Ramses II

Foot ulceration is both a common and devastating complication of diabetes with at least 15% of patients developing an ulcer during their lifetime and in the UK 1.4% of patients with type 2 diabetes having an active ulcer at any one time. Diabetic foot ulcers precede amputation in about 85% of cases and it has been estimated that people with DM are 15-40 times more likely to require a lower-limb amputation compared to the general population (Dinh & Veves 2004; International Diabetes Federation 2003; Most & Sinnock 1983). Diabetic foot ulceration and related amputation is therefore associated with increased morbidity and mortality (Pecoraro et al. 1990).

Diabetic foot disease is one of the most common and troublesome complications of diabetes mellitus, and the number of people afflicted is likely to increase steadily as

the incidence of diabetes in the developed world rises. Despite advances in our understanding and treatment of diabetes mellitus, diabetic foot disease remains a formidable problem, a result of both its complexity and the growing diabetic population. In the UK more than 50% of the bed occupancy, attributable to diabetes, is due to foot problems (Kumar et al. 1994c). Patients admitted with diabetic foot disease or complications of neuropathy tend to have a longer than average hospital stay, with the associated human and medical costs being enormous (Coles & Coppini 2004), and it has been estimated that per capita costs are about 3 to 4 times those of the non-diabetic population (West 1978).

Diabetes has been recognised as the commonest cause of non-traumatic lower limb amputation in the western world, and people with diabetes being 15-40 times more likely to undergo an amputation compared to the rest of the population, approximately 45-70% of all non-traumatic amputations are performed on diabetic patients (Boulton 2001; West 1978). Foot problems continue to exact a heavy toll on the quality of life of the diabetic patient with the prognosis of those patients having already undergone an amputation being poor, the contralateral limb becomes at risk and only 50% of these patients survive the first 3 years. These problems appear to be compounded in type 2 diabetic patients with at least half being over 65 years of age, having poorer eye sight reducing their ability of thorough foot checks, living in isolated social conditions as well as the associated major risk factors of neuropathy and peripheral vascular disease.

Dinh and Veves (Dinh & Veves 2004), separate the risk factors for diabetic foot ulceration into three distinct groups: pathophysiologic, anatomic deformities, and environmental influences. The pathophysiologic processes of peripheral sensory neuropathy, macrovascular and microvascular problems causing peripheral vascular

disease and a compromised immune system reduce wound healing ability. Motor neuropathy and Charcot neuro Arthropathy are the main causes of foot deformity and external factors such as minor or major traumas. These problems may occur exclusively but more frequently they occur together in varying degrees, placing patients at risk for morbidities, such as ulceration, gangrene, and infection.

A relatively rare but important cause of foot deformity that can lead to pressure ulceration is the Charcot Arthropathy. This is the result of increased blood flow to bone in the foot in cases of severe autonomic neuropathy. The foot will become inflamed and oedematous with an increase in temperature, at least 2°C warmer than the contralateral foot. The bony architecture of the foot is destroyed creating deformities including the rocker-bottom deformity. X-ray reveals fragmentation, fracture, new bone formation, subluxation and dislocation. These physiological and structural changes will often develop very rapidly especially with an insensate foot, where a patient may continue to be mobile and is unaware of any pain causing greater deformity in the already unstable foot. Only a slight pressure over a fixed bony deformity, such as a prominent metatarsal head or a hammer toe, can lead to ischaemic necrosis and ulceration of the skin.

The causal pathway to diabetic foot ulceration can consist of a combination of factors that may trigger the ulceration such as lower limb ischaemia, peripheral neuropathy, foot deformity, foot trauma, foot oedema and callus formation (Dinh & Veves 2004). Reiber et al in 1999, (Reiber et al. 1999) identified a critical triad of neuropathy, minor foot trauma, and foot deformity in 63% of foot ulcers in his causal pathway study.

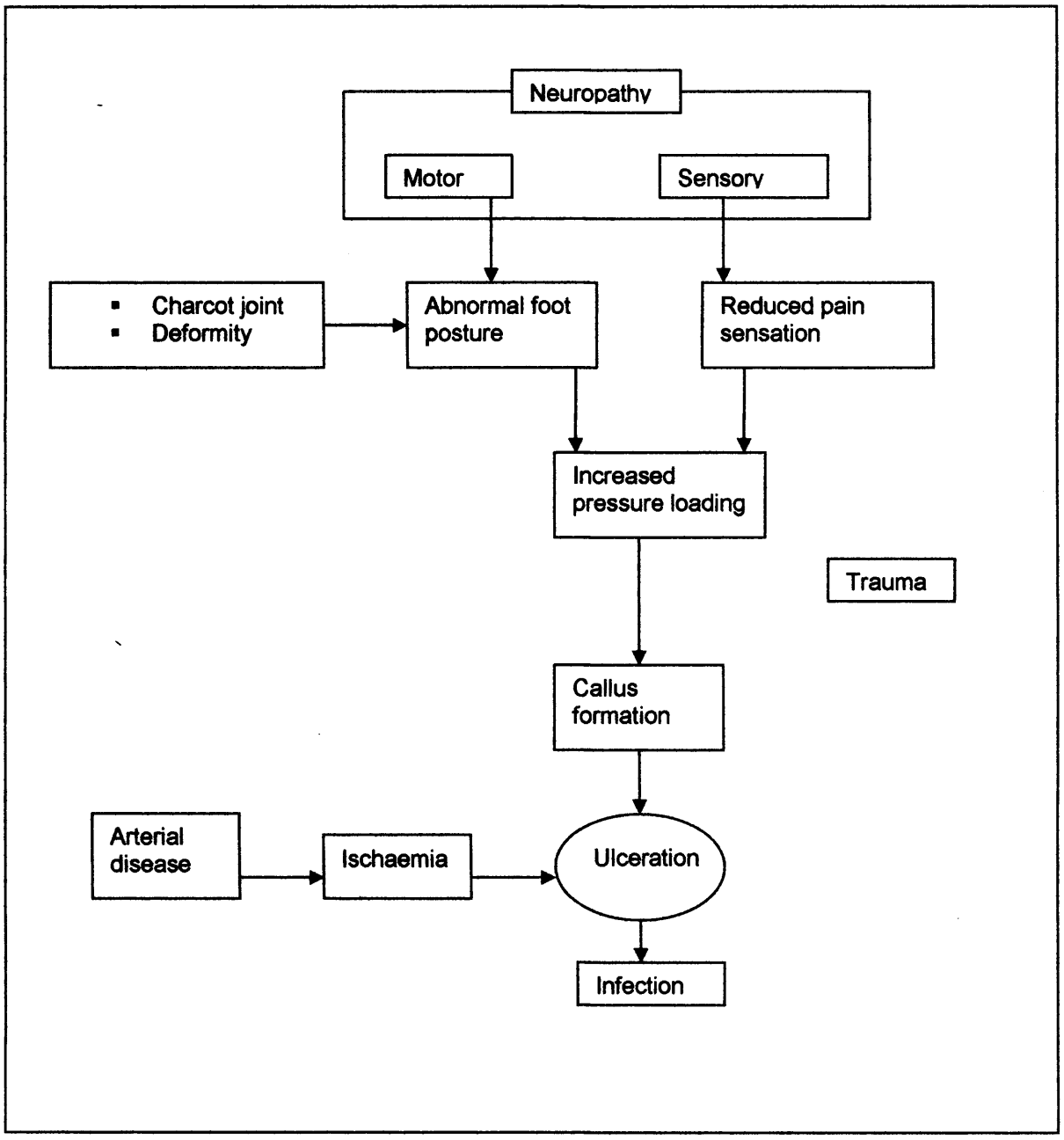


Figure 1.4 - Aetiology of foot ulceration in diabetic patients adapted from The Textbook of Diabetes (Boulton 1998)

Up to 40% of all patients with diabetes have significant peripheral neuropathy and/or peripheral vascular disease, two of the main risk factors for foot ulceration. Peripheral neuropathy is the first component to develop within the vast majority of foot ulcers rendering the foot insensate. This is usually followed by the development of trauma related to high foot pressures under the foot. The third component is impaired healing ability due to the development of peripheral vascular problems

reducing the blood supply to the wound area. As previously mentioned, it is usually a combination of these factors that leads to the development of chronic ulceration and in a substantial number of cases, leading to lower extremity amputation. These complications become more common with increasing age, with the average age of patients suffering diabetic foot problems thought to be over 60 years (Young M.J. 2003).

In common with non-diabetic patients, patients with diabetes develop acute ulceration. The difference is that in diabetes, ulceration frequently becomes chronic and complicated. This is generally due to a patients predisposition such as neuropathy or deformity, the late presentation of the foot problem (due to neuropathy or ignorance), and poor healing due to a compromised vascular supply resulting in poor tissue perfusion.

It is peripheral sensory neuropathy that is thought to be the main factor in more than 50% of ulcers, but it is vascular disease that can profoundly affect healing. Loss of pain can damage the foot indirectly through tightly fitting shoes, a foreign body in the shoe or walking on a hot surface. The sheer forces generated whilst walking stimulate skin thickening creating callus on high pressure areas that have been developed through the decreased action of the intrinsic muscles of the foot due to the motor component of neuropathy. This often causes the arch of the foot to rise and toes to claw making the dorsum of the digits and prominent metatarsal heads vulnerable. Haemorrhage or necrosis that often develops in such callus can break through to the surface to form an ulcer making callus an important predictor of ulceration (Young M.J. 2003).

Ischaemia results from atherosclerosis of the leg vessels, which in a person with diabetes is often bilateral and distal, usually involving arteries below the knee and is

often more aggressive and extensive in patients with diabetes than non-diabetic subjects. This compromises the oxygen and nutrient supply to the tissues of the foot, which can cause delayed healing of foot ulcers. Various vascular procedures can be carried out to address this problem and improve tissue perfusion and therefore facilitate healing. However, ulcers have been known to remain static or even rapidly deteriorate where there is no significant large vessel disease present. Thus attention is turned to the blood flow through the microcirculation which may also be impaired in patients with diabetes, affecting the nutritive blood supply to the tissue bed (Young M.J. 2003). Those ulcers attributable to purely ischaemia are relatively rare (<10% of all cases), neuropathy is usually present with a vascular component.

Table 1.3 - Causes of foot ulceration.

Cause	**Mechanism**
Neuropathy Affects up to 40% of older Diabetic patients and is present in 80% of patients with foot ulcers	Loss of pain sensation, allowing damage to occur, e.g. from foreign bodies in shoes, or even the repetitive trauma of walking. Impaired proprioception and power in the small muscles of the feet, leading to abnormal foot posture and thus abnormal pressure loading. Autonomic neuropathy, causing decreased sweating and cracked dry skin. Sympathetic denervation opens arteriovenous anastomoses and may shunt oxygen and nutrients past the tissue capillary bed.
Vascular	Ulceration ultimately represents microcirculatory failure. Large vessel disease exacerbates pre-existing microvascular abnormalities.

Mixed origin A combination of neuropathy and vascular disease	Combination of the mechanisms above
Abnormal pressure loading resulting from neuropathy or anatomical deformity	Increased pressure on certain areas and an increased susceptibility to ulceration. The formation of callus through pressure trauma at localized sites (typically the metatarsal heads) accentuates abnormal pressure loading and shear stresses, further increasing risk of ulceration.

Classification of the diabetic foot was best described by Edmonds and Foster, (Edmonds & Foster 2000). They initially suggest that the diabetic foot can be divided into two entities, the neuropathic foot and the ischaemic foot. However, as other authors point out, a purely ischaemic foot with no concomitant neuropathy is rarely seen, it is usually associated with neuropathy so is called the neuro-ischaemic, neuro-vascular foot or of mixed origin. Classification can be summarised as follows:

The neuropathic foot

- Warm, well perfused foot with bounding pulses due to arteriovenous shunting and distended dorsal veins.
- Diminished sweating causing the skin to become dry and prone to cracking, and any callus present tends to be dry and hard.
- Raised arch of the foot and toes may be clawed increasing the prominence of the metatarsal heads.
- Ulceration commonly develops on the plantar surface of the foot, and is associated with neglected callus and high plantar pressure.

- Necrosis can develop secondary to severe infection, despite good circulation.
- The foot is prone to bone and joint problems (the Charcot foot).

Neuro-ischaemic foot

- It is a cool, pulseless foot with poor perfusion and is associated with peripheral neuropathy.
- The colour of the severely ischaemic foot can be a deceptively healthy pink or red, caused by dilatation of capillaries in an attempt to improve perfusion. If severely infected, the ischaemic foot may feel deceptively warm.
- It may be complicated with swelling, often secondary to cardiac failure.
- Intermittent claudication and rest pain may be absent because of neuropathy and the distal distribution of the arterial disease to the leg.
- Even in the presence of neuropathy and high plantar pressures, plantar ulceration is rare, probably because the foot does not develop heavy callus, which requires good blood flow.
- Neuro-ischaemic ulcers are commonly seen on the margins of the foot, including the tips of toes and the areas around the back of the heel, and are usually caused by trauma or wearing unsuitable shoes, which do not accommodate foot deformities.
- The foot develops necrosis in the presence of infection or if tissue perfusion is critically diminished. (Edmonds & Foster 2000)

Edmonds and Foster have gone as far as staging the diabetic foot into six stages which does help to identify the severity of diabetic foot problems and in prescribing the appropriate care pathway. These stages were briefly described as follows:

Stage 1- Normal – The foot is not at risk and does not have the risk factors of neuropathy, ischaemia, deformity, callus and oedema, Stage 2 – High risk – The patient has developed one or more of the risk factors for foot ulceration and may be divided into neuropathic or neuro-ischaemic, Stage 3 – Ulcerated – There is skin breakdown on the foot, usually an ulcer that has been present for more than a week. The ulcer will be on the plantar surface in a neuropathic foot and on the margins in a neuro-ischaemic foot, Stage 4 – Cellulitic – The ulcer has developed infection with cellulitis present causing complications for both the neuropathic and the neuro-ischaemic foot Stage 5 – Necrotic – Infection is normally the cause of necrosis, and Stage 6 – Major amputation – The foot cannot be saved and will need a major amputation (Edmonds & Foster 2000).

At Stages 3, 4 and 5 where ulceration, infection and necrosis are described, further classifications are required. There are a number of classification methods that are currently used that try to categorise ulcers, these include such well known methods as the University of Texas Diabetic Wound Classification which gives an evaluation of the diabetic foot ulcer and the Wagner Ulcer Classification which is the most commonly used classification system but does not distinguish lesions with ischemia or infection:

University of Texas Diabetic Wound Classification

A) Stages

Stage A: No infection or ischemia

Stage B: Infection present

Stage C: Ischemia present

Stage D: Infection and ischemia present

B) Grading

Grade 0: Epithelialized wound

Grade 1: Superficial wound

Grade 2: Wound penetrates to tendon or capsule

Grade 3: Wound penetrates to bone or joint

Wagner Grading System

Grade 1: Superficial diabetic ulcer

Grade 2: Ulcer extension

1. Involves ligament, tendon, joint capsule or fascia
2. No abscess or Osteomyelitis

Grade 3: Deep ulcer with abscess or Osteomyelitis

Grade 4: Gangrene to portion of forefoot

Grade 5: Extensive gangrene of foot

Despite these attempts at classification, it is felt that there is not one widely accepted method for classifying or even describing foot ulcers (Jeffcoate & Harding 2003). The International Working Group on the Diabetic Foot (IWDF) is defining a diabetic foot ulcer classification system for improved international communication and research purposes. The IWGDF agreed that the classification system should include the five items of the PEDIS system. In this PEDIS system Perfusion, Extent/size,

Depth/tissue loss, Infection and Sensation should be categorized in each patient and a strict grading system developed for each patient. The last version was discussed in depth during a Consensus/Implementation meeting in May 2003. This system, together with The Practical Guidelines on the Management and Prevention of the Diabetic Foot and the original International Consensus document of 1999, were published by the IWGDF in May 2003 (Bakker 2003; Edmonds & Foster 2000).

It was the aim of the St. Vincent Declaration in 1990 that over a period of 5 years there should be a significant reduction in the number of lower extremity amputations. In fact it was hoped that the number would be reduced by 50%, this however has not universally been achieved (Boulton 2001). To be able to achieve this reduction, preventative measures need to be met, thus reducing the numbers that are actually reaching the amputation stage.

The screening of patients with diabetes mellitus for diabetic foot problems, or to identify those at risk of developing diabetic foot problems with appropriate treatment care pathways and/or appropriate referral pathways, would seem the most likely way to reduce the numbers of those reaching even the ulcer stage of foot problems. This however is still not routinely carried out. Cavanagh (Cavanagh 2004) writes of the need for good screening of all patients with diabetes as a means of prevention, together with well-established and validated interventions. The question of what should be the minimum tests carried out during a screening session is still being asked and until this question is answered, too many or more worryingly, too few tests will be performed giving an inadequate or incomplete neuropathic and vascular patient profile.

There is no question that the associated morbidity of diabetic foot disease is considerable and the associated costs of diabetic foot disease are enormous. It

therefore follows that continued efforts to identify high-risk patients, ensure adequate availability of preventative care, and prompt treatment remain the best means of reducing the destructive consequences of foot ulceration, amputation and death (Dinh & Veves 2004).

CHAPTER TWO: SCREENING FOR DIABETIC FOOT PROBLEMS

2.1 Review of previous screening studies

2.2 Study Aims

2.1 **Review of previous screening studies**

Foot ulceration is one of the major chronic complications of diabetes mellitus and poses a great burden on both the patient and the health care system. Diabetes related foot ulcers have a tendency to be poor at healing and can result in infection and gangrene, leading to long-term in-patient and outpatient treatment, and often to amputation.

The foot in a diabetic patient is at the crossroads of several pathological processes, in which almost all components of the lower extremity are involved: skin, subcutaneous tissue, muscle, bone, joints, nerves and blood vessels. The foot ulcer therefore, is seen as a result of a complex interplay of several aetiological factors.

Foot ulcers in a person with diabetes has a major negative effect on the quality of life due to chronic morbidity, loss of work, loss of mobility and reduction of social activities. In addition, these ulcers and their consequences are associated with high health care costs.

Although there are national guidelines (NHS National Institute for Clinical Excellence 2004) published for screening the 'at risk' diabetic foot, there is no single unified scoring system that would allow frequency and consistency in assessment. Several attempts have been made to address this issue.

A number of studies have been conducted concentrating on individual 'risk factors' that lead to foot ulceration, for example peripheral neuropathy. This element has probably resulted in the majority of research studies to date, many focusing on individual components of neuropathic assessment. Guidelines have been developed from an international consensus meeting for the diagnosis and outpatient management of diabetic peripheral neuropathy (Boulton et al. 1998). This obviously tackles the

peripheral neuropathy status in great depth and is being regularly updated. Young (Young et al. 1993) and his team carried out a 'multi-centre study of the prevalence of diabetic peripheral neuropathy in the UK hospital clinic population'. This study looked at the neuropathic problem independently of the vascular status in a secondary care clinic population thus missing the entire primary care patient population. A few studies have looked at the integrity of the peripheral vascular system and again a few at plantar pressures. Only a limited number have considered the complete picture and taken all elements into account within their study. Some have attempted diabetic foot screening in population or cohort studies to a limited extent, but have not gone further than merely scratching the surface.

The aim of the diabetic foot study conducted in the North West of England was to determine the incidence of, and clinically relevant risk factors for, new foot ulceration in a large cohort of diabetic patients in the community health care setting (Abbott et al. 2002). Their study group covered a large area of the North West of England, screening over 6,000 patients in six different localities over two years. Patients' neurological assessment appeared to be fairly thorough using a modified version of both the Neurological Symptom Score (NSS) and the Neurological Disability Score (NDS), pain sensation with the Neurotip, vibration sensation using a 128Hz tuning fork and dorsal temperature with cold and warm rods, Achilles reflex using a tendon hammer, and 10g monofilament for cutaneous pressure perception. However, when it came to the vascular assessment, palpation of pulses alone was used, with no ability to assess efficiency and adequacy of circulation and no indication of further assessments should there be <2 pulses present per foot.

Although other studies have used modified versions of the Neuropathic Symptom Score and Neuropathic Disability Score systems in the past, it is becoming evident

that, due to researchers using their own very different modified versions, these scoring systems are no longer standardised and therefore hold limited value. In addition, patients' perception of pain and feelings are very different and cannot be easily compared between individuals. However, a local study currently being carried out in Cardiff by Cardiff and Vale NHS Trust recognises that a combination of clinical tests, questionnaires and symptom scoring will most successfully identify those with peripheral neuropathy. Unpublished preliminary results show that the symptom scoring should include such symptoms as numbness, allodynia, and prickling, aching, burning and lancinating pain being experienced by the patient.

Klenerman (Abbott et al. 2002; Klenerman et al. 1996) and his team under took a study to screen for patients at risk of diabetic foot ulceration in a general hospital outpatient clinic. Their aim was also to examine the reproducibility of three tests for identifying patients at risk of diabetic foot complications using the 10g monofilament, the biothesiometer and palpation of pedal pulses. A physical examination for deformity, presence of callosities and foot hygiene were also included. The study encompassed persons with both Type 1 and Type 2 diabetes, which is positive as many restrict their studies to Type 2 only. Large nerve fibres were assessed by light touch and vibration perception, however the vascular assessment was again restricted to palpation of pedal pulses and no indication of further assessment should these be abnormal. Patients showing abnormal neurological or vascular results were called back for a second assessment two weeks later where the three tests were repeated. Out of the three screening tools used in this study, only the 10g monofilament was found to be consistently reproducible. Palpation of pedal pulses was not particularly reproducible as it relies heavily on the assessor's ability to locate the pulses. The mean biothesiometer scores were compared giving a range in variation of 5 volts

which shows a clinically significant level of variation which can lead to a change in diagnosis/severity between one measurement and the next. No indication is made as to whether the same assessor carried out the tests on each occasion or indication of assessors receiving any training in carrying out the three tests. Inter observer error could have some part to play in the inconsistent reproducibility.

Pham (Pham et al. 2000) carried out a prospective multicentre trial for identifying people at high risk for diabetic foot ulceration. Patients were recruited from foot clinics in Boston, Massachusetts, San Antonio, Texas and San Francisco, California. This study used a modified and simplified version of the neuropathy symptom score and neuropathy disability score as previous studies have done. Although this study aimed to explore both neuropathy and vasculopathy, it again appears very thorough in its assessment of neuropathy but not so when assessing vasculopathy. Large nerve fibres were assessed using the 10g monofilament and small nerve fibres were assessed using the pinprick, and a test tube of cold water for temperature perception. Medium and large nerve fibres were examined with a plain tuning fork and biothesiometer for vibration perception. Peripheral vascular disease was assessed by palpation of pedal pulses and as in the previous study, no indication of further investigations in cases of one or more pulses being absent.

This study did however include an additional assessment for identifying people at high risk of foot ulceration. Measurements of dynamic plantar foot pressures were taken using the F-Scan mat system. The mean reading of three, mid gait footsteps were used. Those with foot pressures $\geq 6 kg/cm^2$ were considered as being indicative of patients at a greater risk for foot ulceration (Frykberg et al. 1998). Unfortunately this study showed weak vascular assessment.

Kumar (Kumar et al. 1994) and colleagues from Manchester, Sheffield and Salford conducted a prevalence study using similar techniques to that of Klenerman (Klenerman et al. 1996). This study looked at a community population cohort recruited from general practices in the cities named above. They restricted their study to known Type 2 patients over the age of 40 years and being treated with diet alone or with oral hypoglycaemic agents. They, too, used a modified neuropathy symptom score and neuropathy disability score, as previous studies have done. Pain perception was assessed using pinprick, vibration perception using both the tuning fork and biothesiometer and temperature perception using a cold tuning fork. When it came to vascular assessment, pedal pulses alone were assessed and again no indication of any further investigations being carried out of those with one or more pulses absent per foot.

A similar trend seemed to be appearing with the majority of screening studies carried out prior to 2000, with just two exceptions. In 1995 McNeely (McNeely et al. 1995) conducted a study looking at the independent contributions of diabetic neuropathy and vasculopathy in persons with foot ulceration. This study used the 10g monofilament and a basic tuning fork for nerve conduction studies. This time they looked more closely at the peripheral vascular status by calculating ankle brachial pressure indices and cutaneous perfusion by measurement of transcutaneous oxygen tension (TcPO2) on the dorsum of the foot. This study could not rule out a neurological mechanism for abnormal cutaneous vasculature, which is largely independent of traditional clinic markers for neuropathy, such as loss of monofilament or vibratory sensation. One of the limitations of this study is the author's inability to establish with certainty that the Neurovascular abnormalities identified as risk factors preceded the foot ulcer event.

The second study was carried out by Boyko (Boyko et al. 1999), which conducted the same tests for neuropathy and peripheral vascular status as McNeely, in 1995 (McNeely et al. 1995). However, this time measures of both large vessel perfusion and skin oxygenation, were identified as being related to a higher risk of foot ulcers. This study demonstrates that skin oxygen plays an important role not only in the prediction of healing diabetic foot ulcers, but also in the development of these lesions. This study considers the possibility of the higher risk being due to lower skin oxygenation, leading to chronic non-healing ulcers. It did highlight previous studies' inability to identify cutaneous perfusion as an independent risk factor. As previously mentioned, these measurements were taken on those already with ulceration.

Sampson (Sampson et al. 2002) explored the idea of combining a mobile foot screening service with a retinal screening for those with Type 2 diabetes managed in primary care. Their aim was to undertake a vascular and neurological assessment on the feet of all patients with Type 2 diabetes managed solely in primary care. The theory behind this study illustrated an ideal situation by combining two screening processes with just one appointment. This helped to reduce non-attendance rates with just one appointment rather than two separate ones. The screening process itself encompassed both neurological examinations with the use of the 10g monofilament and vibration perception threshold assessment with a biothesiometer. Vascular assessment was not just palpation of pedal pulses as seen in previously studies, ankle brachial pressure indices were also recorded.

The down side of this study was the subject exclusions. Patients with retinopathy under consultant opthalmological follow-up were ineligible for retinal screening and therefore did not have foot screening. Also nearly all patients with Type 1 diabetes, or with insulin treated Type 2 diabetes, attend a secondary care diabetes centre, and

did not have retinal screening, and therefore did not have foot screening. Those patients under primary care alone but attending a specialist diabetes foot clinic, were not included. However they would be receiving ongoing assessment during their regular foot clinic appointments.

It would be a large task to undertake a screening study to encompass assessments designed for early detection of potential complications for the development of diabetic foot ulcers. Some authors have concentrated their research to include neurological and vascular elements. However, very few have successfully addressed all pathological processes involved in the development of the diabetic foot ulcer and its prevention.

An article was written in the Diabetic Foot Journal addressing missing elements from evidence-based diabetic foot care. The first part tackles screening and prevention and how the evidence shows that the use of the 10g monofilament and palpation of pedal pulses is wholly inadequate for identifying those with 'at risk' feet, yet the 10g monofilament is still treated as being as "reliable as the caesium clock" and pulses being palpated as "some sacred rite." (Cavanagh 2004)

Table 2.1 Summary of previous related screening studies

Lead author (date)	NSS	NDS	10g	Pinprick	Tuning Fork	Bio/Neuro	Shape	Reflexes	Thermal	Plantar Pressure	Pulses	ABPI	TcP02	Outcome/ recommendations
Young (1993)	X	X		X		X (Bio)		X	X					NSS and neurothesiometer
Kumar (1994)	X	X		X	X	X (Bio)		X	X		X			History of amputation, absent pulses, NDS
McNeely (1995)			X		X			X				X	X	TcPO2 and 10g monofilament
Klenerman (1996)			X			X (Bio)					X			10g monofilament
Frykberg (1998)			X			X (Bio)				X				Foot pressures, neurothesiometer, 10g monofilament
Boyko (1999)			X		X		X	X				X	X	Deformities & mobility, TcPO2, 10g monofilament
Pham (2000)	X	X	X			X (Neuro)				X	X			Clinical examination & 10g mono together, foot pressures
Abbott (2002)	X	X	X				X				X			NDS, 10g mono, foot pulse palpation
Johansson (2002)			X								X	(+TBPI) X		Toe pressures
Sampson (2002)			X			X (Bio)		X			X	X		Pulses, ABPI <1.0, VPT >25v at hallux, with absent Achilles reflex or absent 10g mono at hallux

NSS - Neuropathic Symptom Score
NDS - Neuropathic Disability Score
Bio/Neuro - Biothesiometer/Neurothesiometer
ABPI - Ankle Brachial Pressure Index
TBPI - Toe Brachial Pressure Index
TcP02 - Transcutaneous oxygen tension

2.2 **Study Aims**

Loss of a limb, part of a foot or even to suffer an ulcer through diabetes can devastate a person's life and make them feel socially unacceptable. Therefore effective screening for early detection of those 'at risk' of developing these diabetes-related foot problems would help reduce the number of those developing foot ulcers and thus reduce those requiring digital or foot amputations.

As previously mentioned, many studies have focused on one area such as peripheral neuropathy, which is known to increase the risk of foot ulceration, in some detail but few have tackled the many areas known to cause an 'at risk' foot in one study. Those that have been carried out appear to skim rather than have depth. This study aims to tackle all the known diabetic foot 'risk' areas in a single study population in detail. It aims to discover whether using the current minimum assessment techniques for the diabetic foot truly reflects the size of the problem and should remain as the minimum data set or whether introducing more advanced techniques of screening and the building of patient profiles will assist in identifying those 'at risk' of developing foot problems at a much earlier stage and therefore allow for earlier appropriate referral and intervention.

The study also aims to identify the deficiencies in patient knowledge and understanding of diabetes-related foot complications, and the deficiencies in foot care received by themselves or delivered by Health Professionals.

It is certainly intended to disseminate appropriately, all that has been learned from this study and its recommendations.

CHAPTER THREE: STUDY DESIGN AND STUDY POPULATION

3.1 **Subject recruitment**

3.2 **Inclusion criteria**

3.3 **Suggested Care Pathway**

3.4 **Study duration and location**

3.5 **Characteristics and distribution of study population**

3.1 **Subject recruitment**

Due to data protection and patient confidentiality, it was not possible to utilise the Diabetic Retinopathy Screening Service for Wales (DRSSW) patient register, diabetic subject recruitment, therefore had to be conducted through GP Practices instead. All 19 GP practices within the study area were initially contacted via mail to ascertain the interest in their patients being included in the study. The Research Podiatrist (JL) visited the practices in person to explain the practice involvement in patient recruitment, the purpose of the study and what was to be achieved by the study outcomes. There was 100% initial interest from the GP practices following the visit.

Most GP practices agreed to send their registered diabetic patients a joint letter from themselves and the Diabetes Research Unit (DRU), offering them the opportunity to be involved in the study. The patients were asked to return a tear-off slip with their name and contact details to the DRU for further information. Other practices agreed to inform their patients of the study when attending for their annual diabetic review, giving them the DRU contact details or agreed to display information regarding the study in their waiting areas.

For those practices sending letters, the GPs were asked to exclude, as far as possible, those not fitting the inclusion criteria (see section 3.2) before sending the letters out.

Once the tear-off slips were returned, the patients were contacted by telephone, where possible, to further explain the details of the study. The same details were given to those phoning in. If the subjects were happy with the study details and met the inclusion criteria, a patient questionnaire (Appendix 2), written details of the study in the form of a patient information sheet (Appendix 1) and a screening appointment was sent to them. The patients were asked to bring their completed questionnaire with

them to their screening appointment. This recruitment continued throughout the screening period.

Out of the 19 practices initially agreeing to invite their patients to take part in the study, patients from 10 practices took up this invitation giving a 52% practice participation rate. The total number of known letters sent to patients was 1,048, three practices used alternative methods and therefore were unable to provide patient figures. Out of the 1,048 patients contacted by letter, 40 declined the invitation for reasons varying from being housebound to diabetes denial and 298 failed to respond, a total of 710 patients responded positively giving a 72% response rate. After commencement of the study, a number of patients passed away, had moved or were unable to attend due to health problems before their screening had taken place.

A total of 41 patients did not attend (DNA) their given appointments which resulted in a <6% DNA rate. Of the 710 (100%) patients that originally agreed to take part in the screening study, minus those no longer able to take part, those that did not attend, and those unable to be seen due to study time constraints, 545 (77%) had their screening completed. Fifty non-diabetic control subjects, representative of the case/study population age groups, were recruited from the general population. The inclusion criteria for the case and control subjects are shown below.

3.2 **Inclusion criteria**

The basic inclusion criteria for the **study case subjects** were as follows:

- Patients should be over 18yrs
- Have Type 1 or Type 2 diabetes mellitus according to WHO criteria for diagnosis
- Must not have a current foot ulcer

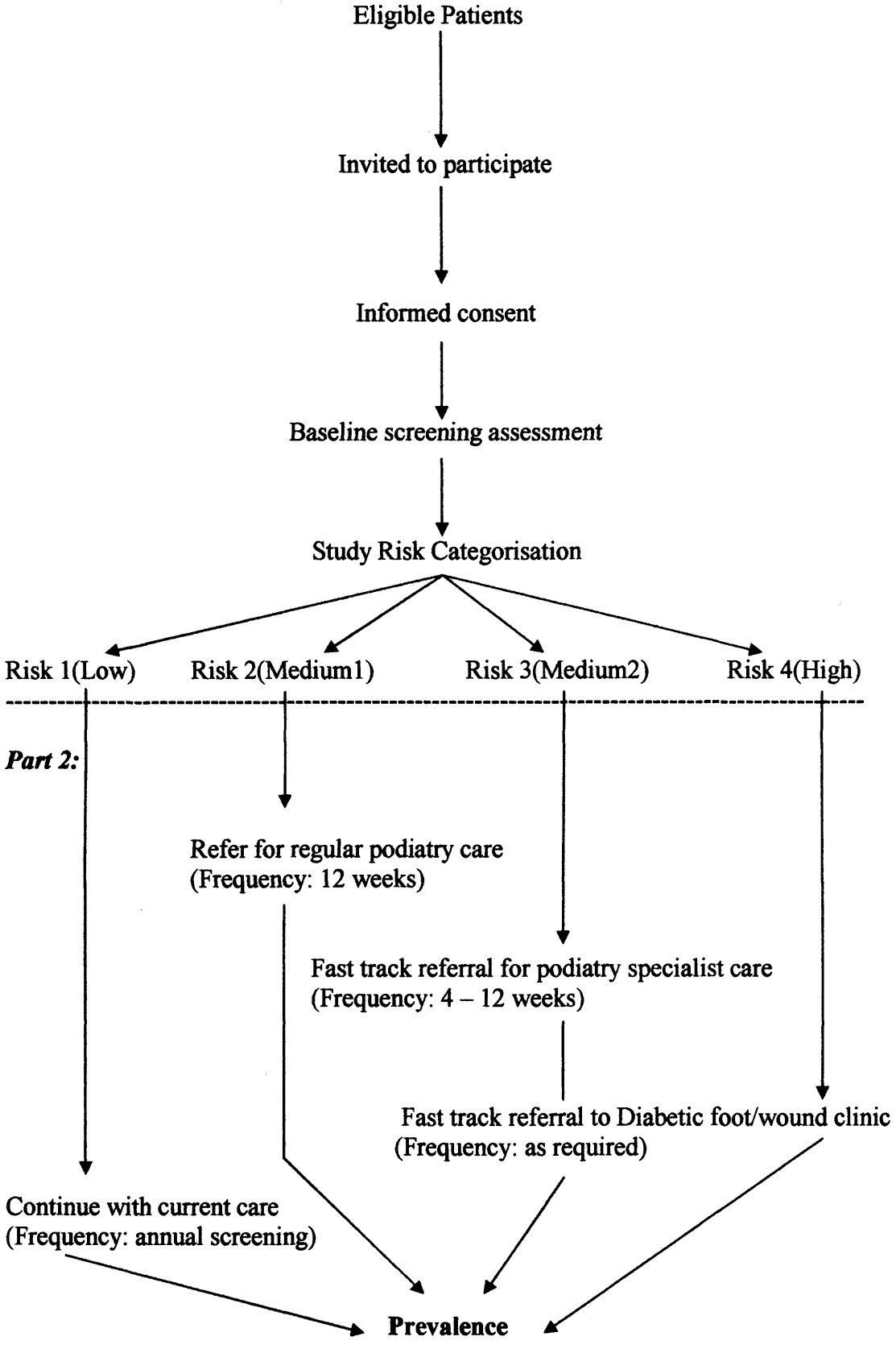
- Must have both limbs, digital amputations would be acceptable
- Ability to give informed consent
- Ability to attend one of two assessment locations

The basic inclusion criteria for the **control subjects** were as follows:

- Not be a known diabetic
- Not have any history of vascular problems
- Not have any history of neurological problems
- Not have any current or previous foot ulcers
- Not have any whole foot, partial foot or digital amputations
- Not be under 18 years of age
- Ability to give informed consent.

3:3 **Suggested Care Pathways**
Part 1 only to be addressed within this study. (Risk Categories explained in detail later in thesis)

Part 1:



3.4 **Study duration and location**

The screening began in November 2002 with a single full-time Research Podiatrist (JL) screening 3 days per week in two locations within the study area and continued for 1 year, excluding holidays. The Research Podiatrist (JL) was also responsible for all administrative work associated with the study, patient recruitment, patient appointments, cancellations and re-bookings, appropriate patient referral according to assignment of **study** risk category and dissemination of results to community Podiatry departments and GP practices.

3.5 **Characteristics and distribution of study population**

There were a total 545 volunteer subjects and a total of 1090 limbs studied. The volunteer group was represented by 56.3% (n=307) males and 43.7% (n=238) females. Although there was representation of ages from 22years (minimum) to 93years (maximum), the average age was 66years (SD=11.407), with the largest proportions falling between the 60-69yr and 70-79yr groups. The age distribution can be seen in the bar chart below.

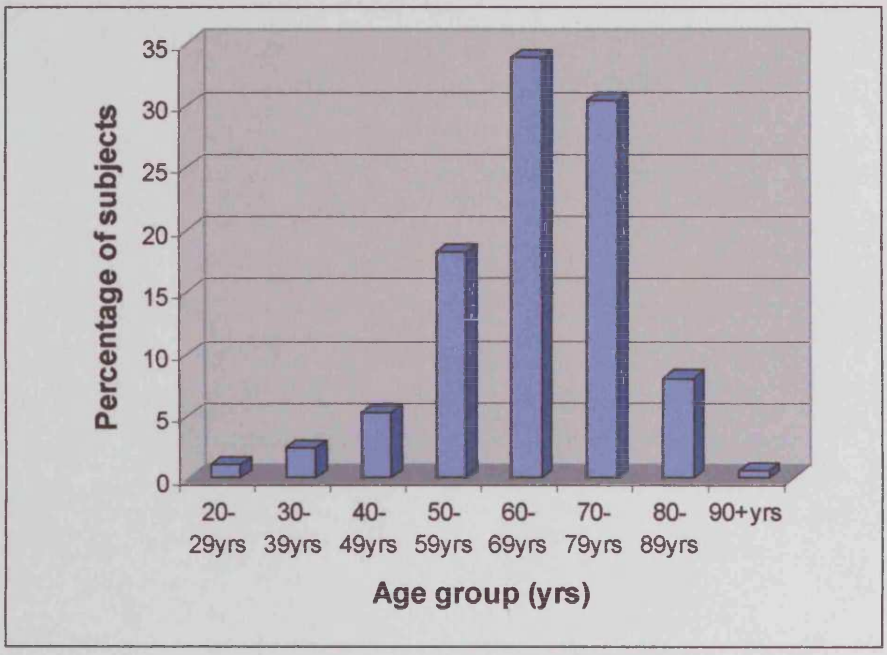


Figure 3.1 Distribution of age within study group (10yr bands)

80.9% (n=441) of the subject group were Type 2 and 19.1% (n=104) Type 1. Of those with Type 2 diabetes, 59% (n=259) were males and 41% (n=182) were females, and of those with Type 1 diabetes, 46% (n=48) were male and 54% (n=56) were female. 23.1% (n=126) of the subjects were current members of Diabetes UK, 76.9% (n=419) were not members of Diabetes UK or any other diabetes related patient awareness group.

41.5% of the subjects (n=226) had a known duration of diabetes mellitus of less than 5yrs, which represented the largest group. Of these 93.4% (n=211) had Type 2 diabetes mellitus and only 6.6% (15) had Type 1. This trend was similar in each duration group except the 20yrs+ group where only 39.4% (n=26) had Type 2, compared to 60.6% (n=40) of the subjects having Type 1 diabetes mellitus.

Table 3.1-Distribution of type and know duration of diabetes mellitus within case study population.

		Diabetes Type		Total
		Type 1	Type 2	
Known duration of diabetes mellitus	<5yrs (41.5%)	6.6%(15)	93.4%(211)	226
	5-9yrs (24.4%)	12.8%(17)	87.2%(116)	133
	10-19yrs (22%)	26.7%(32)	73.3%(88)	120
	20yrs+(12.1%)	60.6%(40)	39.4%(26)	66

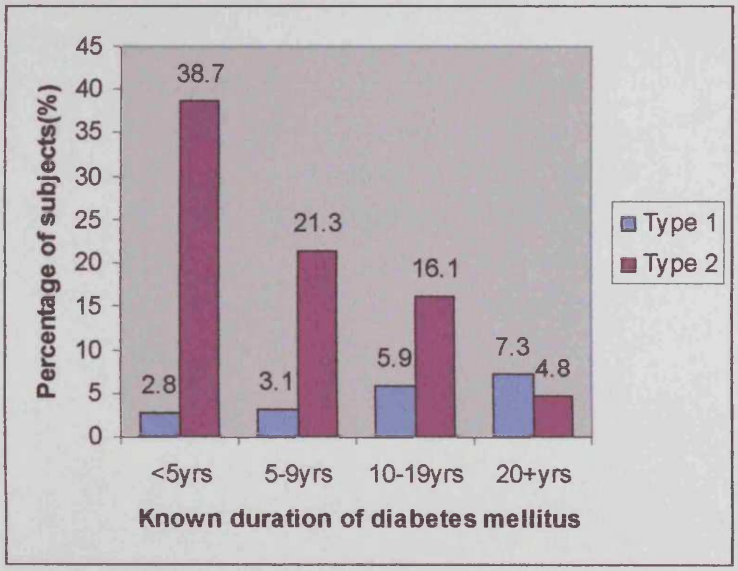


Figure 3.2 Distribution of type and known duration of DM within case study population

92.3% (n=503) of the case subjects had their eyes screened by the DRSSW (Diabetic Retinopathy Screening Service for Wales) at least once with 73.6% (n=402) being screened within the last 12 months indicating no sight threatening eye disease.

When looking at lifestyle issues of the case subjects it was found that 13% (n=40) of the males and 30% (n=72) of the females lived alone. Over half (53.8%, n=293) did not smoke (had not smoked for at least 5 years), a little over one third (34.1%, n=186) were ex-smokers having given up at least six months prior to the study, and 12.1% (n=66) were current smokers.

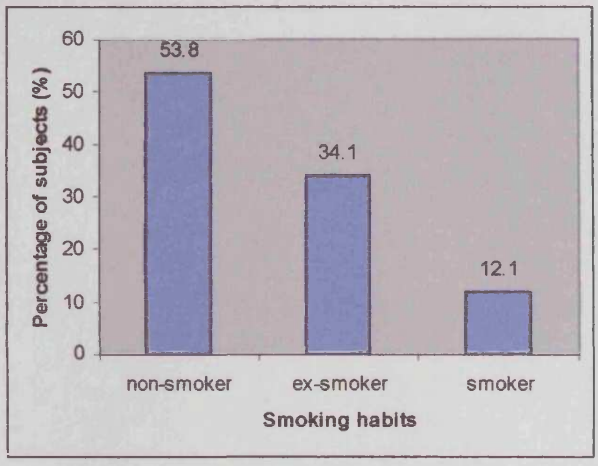


Figure 3.3 Smoking habits within the case population

The distribution of alcohol consumption within the case subjects showed that the vast majority (81%) admitted consuming less than 10 units per week, with half of these admitting to abstaining completely. The distribution of results can be seen in the figure below.

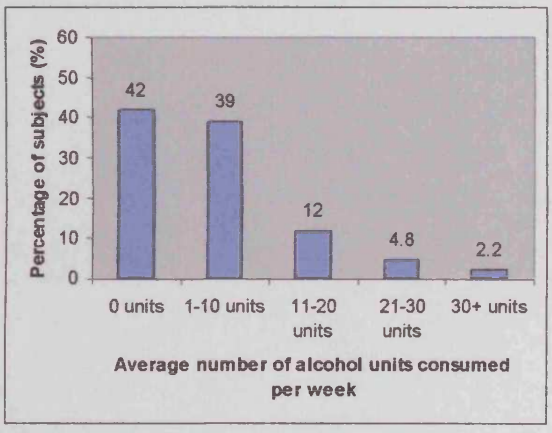


Figure 3.4 Distribution of alcohol consumption for case population

When asking about such topics as smoking status and alcohol consumption, inaccurate responses are often received due to the sensitivity of the subject.

CHAPTER FOUR: METHODOLOGY

4.1 **Questionnaires**

4.2 **Foot examination**

4.2:1 Foot temperature

4.2:2 Foot appearance - colour, shape, lesions

4.3 **Neurological assessment**

4.3.1 10g-monofilament

4.3.2 Neurotip

4.3.3 Rydel-Seiffer graduated tuning fork

4.3.4 Neurothesiometer

4.3.5 Cold tuning fork

4.3.6 Reproducibility Study – Neurological parameters

4.4 **Vascular assessment**

4.4.1 Brachial Systolic Pressure

4.4.2 Ankle Systolic Pressure

4.4.3 Toe Systolic Pressure

4.4.4 Waveform analysis

4.4.5 Pulse Volume Records

4.4.6 Reproducibility Study – Vascular parameters

4.5 **Digital images**

4.6 **Plantar Pressure analysis**

4.7 **Summary of methods used**

4.8 **Summary of statistical methods used**

4.1 **Questionnaires**

Prior to attending the full vascular and neurological assessment, all the subjects were sent a Patient Questionnaire (Appendix 2.1) to be completed at home requesting information on their lifestyle, past and present medical history and current foot health care status. The subjects were requested to bring the completed Patient Questionnaire with them on attending their first assessment appointment at either the Diabetes Resource Unit at Llandough Hospital or the Podiatry Department at Barry Hospital.

The Patient Questionnaire was checked by the Research Podiatrist ensuring all questions had been understood and answered. Before proceeding with the first assessment a second questionnaire (Appendix 2.2) was administered by the Research Podiatrist. The purpose of this was to assess consistency in response to previously asked questions and to further establish the subject's knowledge and understanding of the implications of diabetes on their foot health and record current levels of Health Professional foot care being received.

4.2 **Foot examination**

4.2.1 Foot temperature

The foot examination began with foot (dorsal aspect) temperatures being taken with a handheld, digital, infrared thermometer (Dermatemp, Smith and Nephew) (Fig 4.1). The patient was asked to remove all footwear and sit with legs outstretched on the examination couch. To eliminate problems with raised temperature from walking or other external temperature variation, the subject's full history was completed, allowing the foot temperature to normalise within the constant room temperature environment.

The Dermatemp was held approximately 5mm above the skin surface on the dorsum of the foot, above the mid tarsal joint. The scan button was held depressed for approximately five seconds, which directed an infrared beam onto the skin enabling the Dermatemp to take and display the temperature at that site. This was carried out bilaterally and both temperatures recorded.

4.2.2 Foot appearance - colour, shape, lesions.

Foot colour assessment followed, with healthy pink being described as normal and any other described as abnormal. Details of the abnormal colour such as red, pale or cyanotic were noted. Oedema was described as either present or absent and if present whether it was bilateral or unilateral. Digital photography was employed, to record the presence of oedema, severe colour abnormalities, along with foot shape and lesion patterns.

Lesions were identified as being present or absent for each foot. These were specifically noted for corns, callus, ulcers, and fissures, nail pathologies and inter digital maceration. History of past lesions and their location were also noted.

The main deformities for identification were hammer toe (figure 4.2b, 4.2c), claw or retracted toe (figures 4.2a, 4.2f), any bony prominences such as hallux valgus (HV) (figure 4.2e), Charcot's arthropathy or prominent metatarsal heads (figure 4.2a). These were noted as either present or absent for each foot. Amputations were identified with the level of amputation for each foot being recorded as digital, partial foot, ankle or below knee (figure 4.2d).

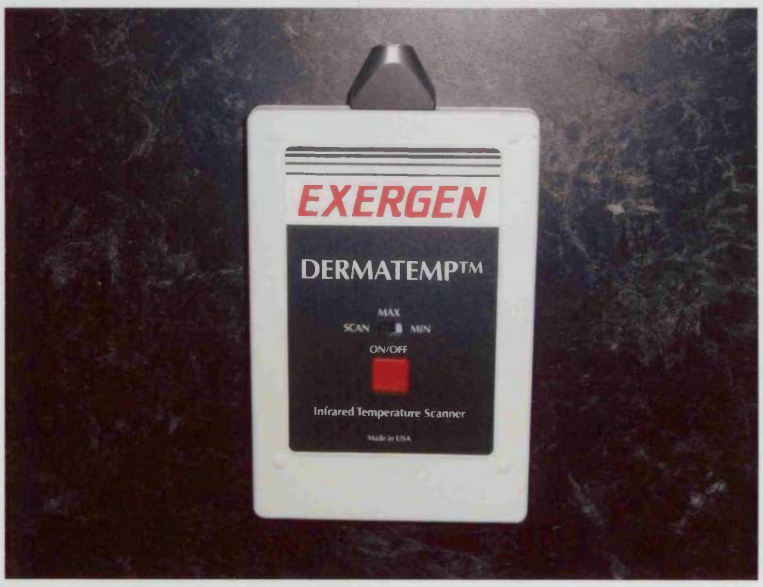


Figure 4.1a Dermatemp thermometer

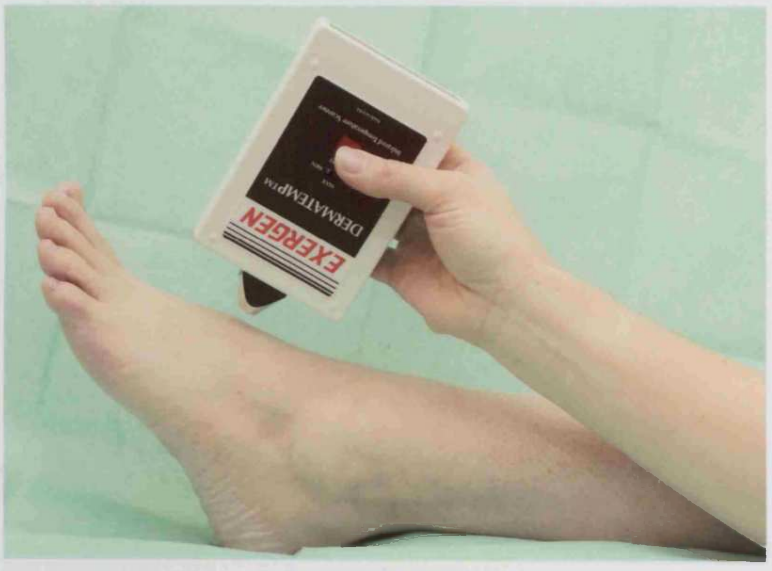


Figure 4.1b – Dermatemp test site

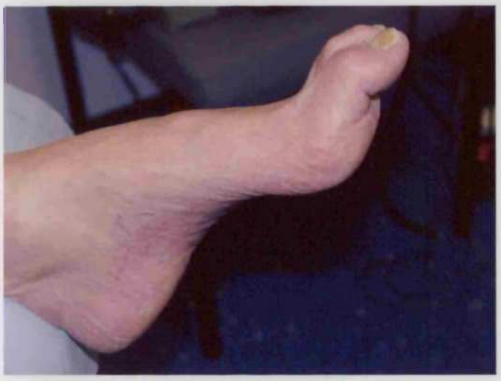


Figure 4.2a - Retracted digits with prominent metatarsal heads and highly arched mid foot.

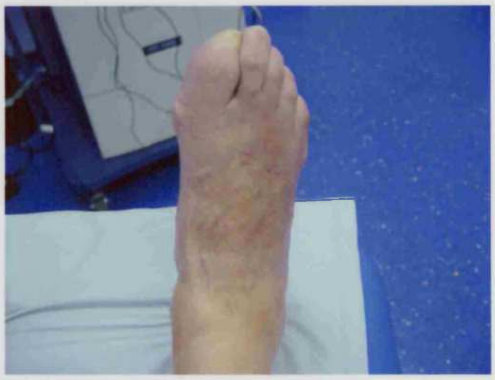


Figure 4.2b - Hammered hallux and lesser digits

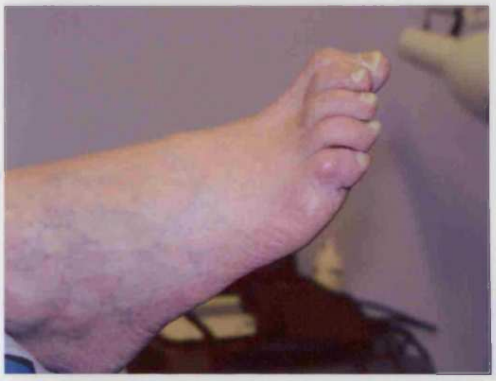


Figure 4.2c - Retracted toes with hammered hallux

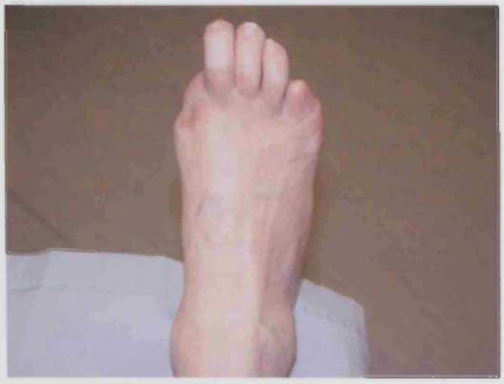


Figure 4.2d - Amputated hallux and apex of 5th toe

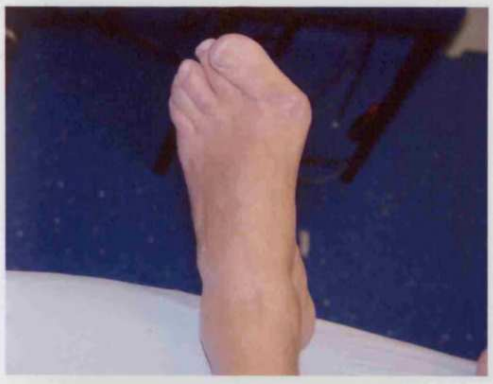


Figure 4.2e - Hallux valgus

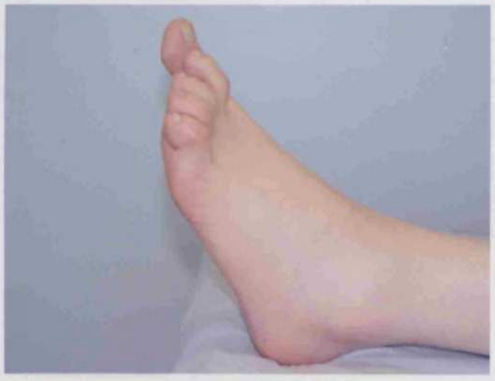


Figure 4.2f - Retracted lesser digits

Figure 4.2 Clinical presentations of deformities

4.3 **Neurological assessment**

Before beginning the neurological assessments, it was ensured that the subjects were adjusted to room temperature, comfortable and feeling relaxed. Each test was explained (why and what), before being performed and was also demonstrated on another area of the body where there was not likely to be any sensory loss, thus ensuring that the subject felt and could describe the sensation they perceived for each test. If there was any doubt in the subject's response, the test was repeated several more times without any leading or prompting (Baker et al. 2005).

4.3.1 10g-monofilament

Although there are various weights of monofilament (1g, 10g, and 75g), NICE Guidelines recommend the use of the propriety 10g-monofilament for the testing of foot sensation (NICE 2004), and there are a number of 10g-monofilaments available for assessing large nerve fibre function and light cutaneous pressure. A study carried out by Young (Young et al. 2002) compared the readily available 10g-monofilaments and found the Neuropen and one other (Bailey 10g-monofilament) to perform to a higher standard than the others regarding reproducibility and length of life through repetitive use. There is debate in the literature regarding the number of sites to be tested and the definition of what is considered an 'insensate foot'. After a thorough search and careful consideration of the available literature, it was decided by the Study's Steering Committee that the Neuropen 10g-monofilament (Owen Mumford, Oxford) would be the instrument of choice for this study and to test five plantar sites and one dorsal site on each foot (Birke & Rolfsen 1998; Perkins et al. 2001; Rith-Najarian et al. 1992).

Figure 4.3 – Illustration of 10g-monofilament and pinprick test sites.

The foot was classified as insensate if one or more sites were unable to be detected by the subject. The Neuropen had the added advantage of combining an interchangeable 10g monofilament for light cutaneous pressure assessment (large nerve fibre function), with a calibrated sterile Neurotip delivering a force of 40g (small nerve fibre function) to assess pain (sharp) sensation. These were both contained within one plastic, 'pen-like', hand-held device (figure 4.4). Callous formation under any of the test sites was removed prior to the testing but would be a consideration when analyzing the results (a limitation).

To assess light pressure perception, the Neuropen 10g-monofilament was placed against the skin surface until it buckled and held in place for 2 seconds before removal, as demonstrated in figures 4.5a and 4.5b. The patient was requested to affirm when a stimulus was felt. This was performed on the plantar surface of each hallux, the 1st, 3rd and 5th metatarsal heads and the plantar mid heal, in random order. These sites were chosen, as they are areas that most frequently ulcerate in diabetic patients as a result of high pressure loading, and these sites have previously been shown to be most accurate in identifying patients at risk of foot ulceration.

The number of sites at which the monofilament was felt was recorded. Patients were categorized as having normal pressure perception being able to feel all 5 sites. Inability to feel one or more sites would indicate an insensate foot. This

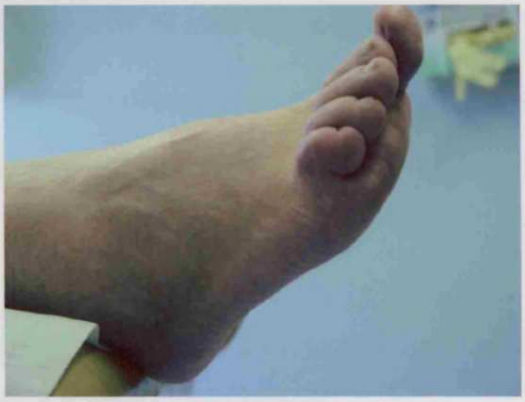


Figure 6.1a Retracted toes

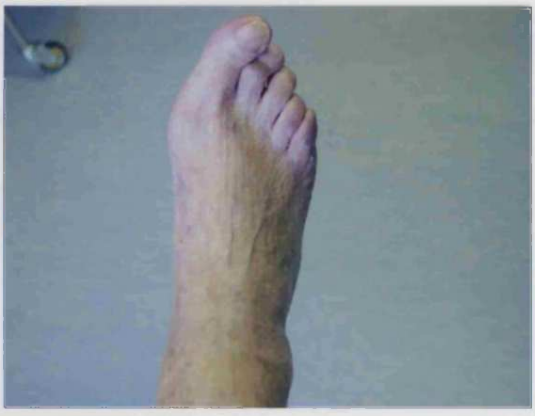


Figure 6.1b Hallux valgus / retracted and hammered lesser toes

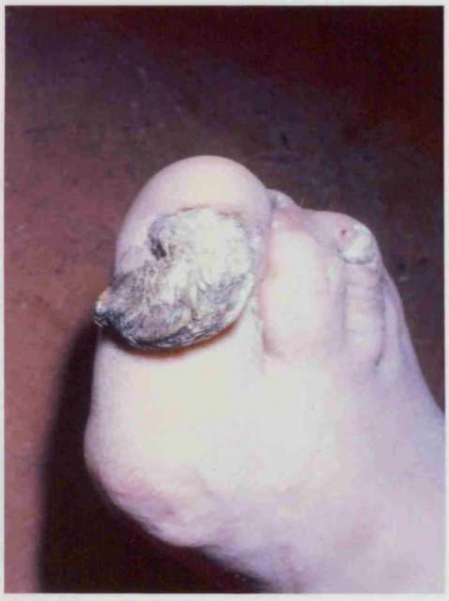


Figure 6.2 Rams horn nail

categorization must be made with caution where test areas have had over lying plantar callous removed and the monofilament is not felt. The callus should always be removed prior to testing or the closest area without callous tested.

4.3.2 Neurotip

The Neuropen pinprick application was used to assess pain (sharp) sensation (small nerve fibre function). In random order the sharp end of the Neurotip was pressed against the plantar surface of the hallux, the 1^{st}, 3^{rd} and 5^{th} metatarsal heads together with the plantar mid heal on both feet, until the guiding markers on the Neuropen were aligned. As with the monofilament, the patients were asked to affirm when the stimulus was felt with the number of sites at which the Neurotip could be felt being recorded out of 5 for each foot. Patients were again categorized as having normal pain perception if 5/5 sites were felt and abnormal if <5/5 sites were felt for each foot.

The monofilament and pinprick tests were performed on the right and the left feet. Inability to feel sensation on either or both feet indicated an overall abnormal result.

Figure 4.4 - Neuropen (encompasses 10g-monofilament and Neurotip)

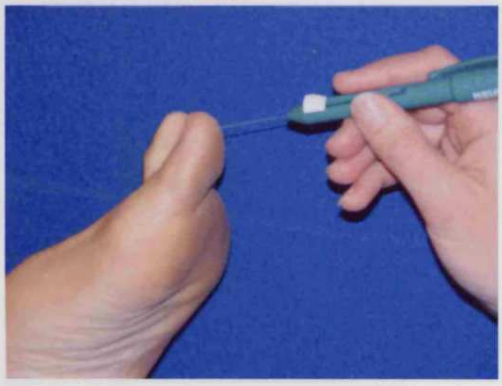


Figure 4.5a – Correct use of 10g-monofilament

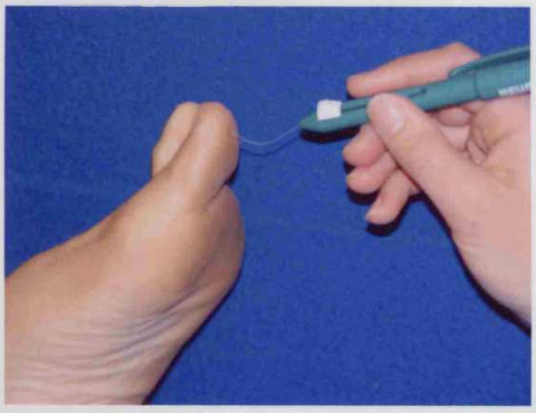


Figure 4.5b – Correct use of 10g-monofilament

4.3.3 Rydel-Seiffer graduated tuning fork

Both arms of the tuning fork bore calibrated weights at their extremities imprinted with a nine-point arbitrary scale from 0 to 8 and the shape of an elongated triangle beside this scale which forms a cone as the magnitude of vibration decreases (figure 4.7). The two prongs of the tuning fork were squeezed together then released to initiate the vibration, the tuning fork vibrates at 64 Hz and the triangle on each arm appears as two virtual, intersecting triangles. The intersection moves exponentially up the scale with decreasing vibration amplitude of the arms. When the point of the triangle met at the 0 mark, the tuning fork was placed on the tip of the hallux and the patient asked if the vibration was felt (figure 4.6). As the vibration decreased so the cone progressed up the scale towards the number 8 mark (figure 4.7).

When the subject could no longer sense vibration, the nearest value (to the closest half-point, in this study) to the point of intersection of the triangles is recorded as the vibration threshold on the assessment form. This technique was carried out on both great toes and both medial malleoli, repeated three times at each site. All three readings, along with the calculated mean, were noted.

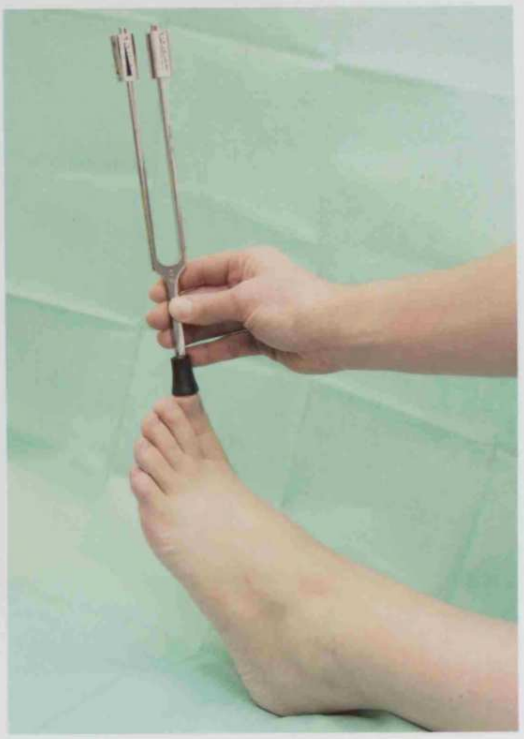


Figure 4.6 – VPT testing of the hallux with the Rydel-Seiffer tuning fork

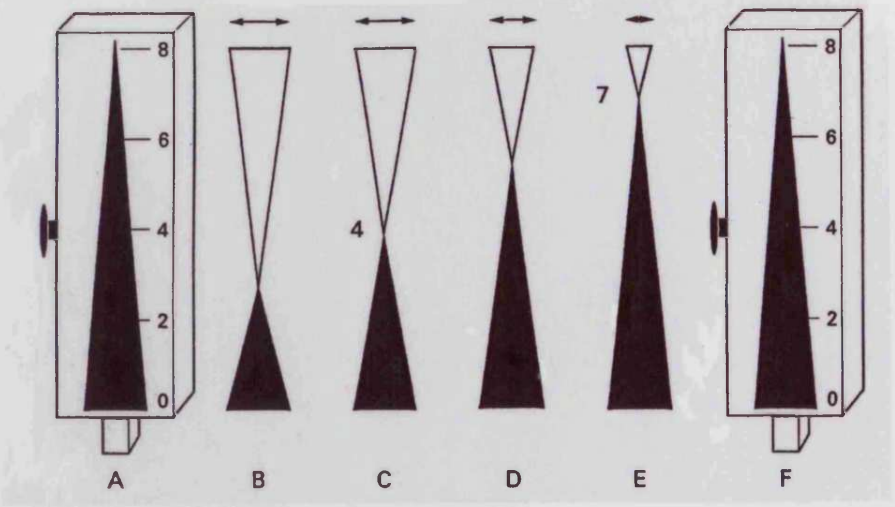


Figure 4.7 - Illustration of increasing graduated tuning fork scale adapted from Martina et al.

4.3.4 Neurothesiometer

The Neurothesiometer (S.L.S. Ltd, Nottingham) is battery driven from a rechargeable power pack and has no direct mains power (fig 4.8a). It vibrates at 56Hz. The voltage supplied to the vibrating head is displayed on a digital display in 0.5volt steps and has an expanded mode where the voltage increment, up to 25 volts, is lower for a given angle of turn of the dial. This allows a greater precision in the reading of the scale.

The probe of the Neurothesiometer was balanced in a light grip, resting vertically under its own weight on the pulp of the great toe. The dial was set at 0.0 volts and was advanced gradually increasing the vibration at 0.5 volt increments until the patient was able to perceive the vibration sensation at that site. The patient indicated verbally that they felt the sensation at which time the voltage reached, shown on the Neurothesiometer, was noted.

This technique was carried out on the tips of both great toes and both medial malleoli and repeated three times (4.8b). All three readings together with the calculated mean were recorded.

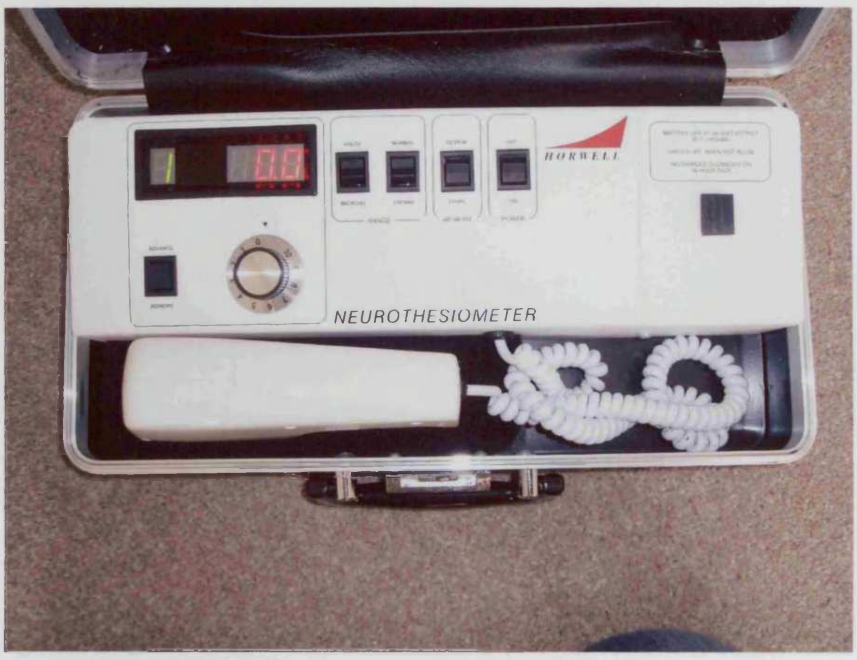


Figure 4.8a – Neurothesiometer

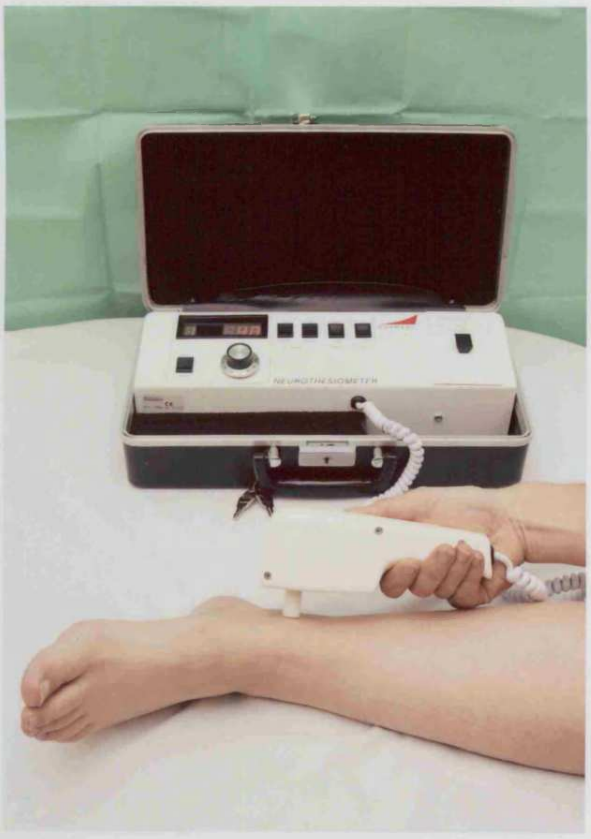


Figure 4.8b – VPT testing on the medial malleolus with the neurothesiometer

4.3.5 Cold tuning fork

Small nerve fibre function of temperature appreciation was assessed by placing a cold tuning fork on the dorsum of the mid tarsal joint of each foot (Carrington et al. 2002). The patient was asked to identify whether the tuning fork felt cold, warm or no change in temperature. An affirmation of cold sensation by the patient gave a normal thermal perception result and a feeling of warmth or no difference gave an abnormal thermal perception test result. This simple procedure was performed on both left and right feet with the results being recorded on the patient assessment form.

A paper published after the data had been collected for this study (Baker et al. 2005), suggested that the dorsal surface of the hallux, proximal to the toe nail should be the area for assessment of temperature appreciation. Although this location was not referenced it could possibly be considered for future studies of temperature appreciation.

4.3.6 Reproducibility study – Neurological parameters.

A small sample of subjects underwent a full assessment of their neurological status which was re-assessed within three weeks to assess the reproducibility of the measurements of light cutaneous touch, sharp sensation and vibration perception. The second set of data was collected blindly without reference to the initial findings. The non-parametric Mann-Whitney U test for comparing two independent-samples was run on each variable for significance of differences between means.

The sample of subjects was selected to encompass a range of age, sex, treatment type and duration of diabetes without taking into account any previous assessment results.

Table 4.1 - Neurological data for 1st assessment of sample group.

	Subjects									
	1	2	3	4	5	6	7	8	9	10
Age (yrs)	30	77	83	58	87	65	76	56	63	72
Gender	F	F	M	M	F	F	F	M	F	M
**Duration group	2	3	1	3	2	3	4	2	1	2
Treatment	Insulin	Insulin	Diet	Tablets	Diet	Tablets	Combo	Combo	Diet	Diet
Previous ulcer	No	No	Yes	No	No	No	Yes	No	No	No
10g Monofilament	5	5	3	3	1	5	1	5	1	5
Pinprick-Neurotip	5	5	4	3	2	5	2	5	2	5
Tuning fork*	4	8	4.5	3	0	7	7	2.5	0	6
Hallux - score	(0)	(0)	(0.5)	(0)	(0)	(0)	(0)	(0.5)	(0)	(0)
Medial malleolus*	4	7	5	2.5	1	7	8	3	0	7
- score	(0)	(0)	(0)	(0.5)	(0)	(0)	(0)	(0)	(0)	(0)
Neurothesiometer*	26.5	11	23.5	23	34.5	10	13	28.5	39	8
Hallux - volts	(0.5)	(2.5)	(1.8)	(7.8)	(6.9)	(1.7)	(1.0)	(0.5)	(6.2)	(1.0)
Medial malleolus*	20	10.5	37	24	45.5	11.5	14	37	38	7.5
- volts	(0.5)	(0.5)	(1.0)	(7.8)	(5.8)	(0.5)	(1.0)	(4.9)	(1.7)	(0.5)

* Mean. **Duration groups – 1= <5yrs; 2= 5-9yrs; 3= 10-19yrs; 4= 20/+yrs.

Combo=Combined oral agents and insulin.

Figures in brackets represent intra-subject coefficient of variation.

Table 4.2 - Neurological data for 2nd assessment of sample group.

	Subjects									
	1	2	3	4	5	6	7	8	9	10
10g Monofilament	5	5	3	3	1	5	1	5	1	5
Pinprick-neurotip	5	5	4	3	2	5	2	5	2	5
Tuning fork*	5	8	6	4	1	7	7.5	3	0	7
Hallux – score	(0)	(0)	(0)	(0.5)	(0)	(0)	(0.5)	(0)	(0)	(0.5)
Medial malleolus*	4	7	4	4	2	7	7.5	3	0	7.5
- score	(0)	(0)	(0.5)	(0)	(0)	(0)	(0.5)	(0)	(0)	(0.5)
Neurothesiometer*	25	12.5	21	23.5	35.5	12	13.5	29	37	8.5
Hallux – volts	(1)	(0.7)	(1.0)	(3.0)	(6.3)	(0.5)	(1.0)	(1.0)	(4.9)	(0.5)
Medial malleolus*	20	10	35.5	24.5	45	10	14	36.5	36.5	7
- volts	(0.5)	(1.0)	(3.0)	(1.5)	(5.8)	(0.5)	(1.0)	(2.5)	(0.5)	(0.5)

*Mean.

Figures in brackets represent intra-subject coefficient of variation.

When the results of each table are considered in more detail, the following patient profiles can be identified. In the table 4.1, subjects 1 and 2 are both Type 1 subjects, are both female and treated with insulin but have differing duration of diabetes and a great difference in age. They both have intact light touch and sharp sensation when tested with the 10g-monofilament and Neurotip. Vibration perception was also intact when tested with the tuning fork. When tested with the Neurothesiometer, subject 1 had an abnormal response at the hallux but a normal response at the medial malleolus, and subject two had a normal response at both test sites. These results remained the same in table 4.2.

The remaining subjects (3-10) were all Type 2 subjects, four males and 4 females. Their diabetes treatments varied between diet controlled, tablet controlled or a combination of insulin and tablets. Their known duration of diabetes varied considerably from less than 5 years (subjects 3 and 9 both diet controlled) to 20+ years (subject 7 – combination therapy). Three of the eight subjects had intact light touch and sharp sensation when tested with the 10g-monoflament and neurotip. However only two of these three subjects had intact vibration sensation when tested with the tuning fork and neurothesiometer, subject 8 having normal 10g-monofilament and neurotip response but abnormal VPT. Those with an abnormal response at the hallux for the tuning fork also had an abnormal response at the medial malleolus. This proved to be the same with the normal responses. This pattern followed for the neurothesiometer in all but subject 3 where there was a normal response at the hallux but an abnormal response at the medial malleolus. The scores in table 4.2, although varied slightly from table 4.1, produced similar results in all but subject 4 where table 4.1 shows an abnormal response for the tuning fork at both sites and table 4.2 shows a normal response at both sites.

The reproducibility study showed that although slight variations in scores occurred when collecting the data, comparison of data showed high consistencies in scores and outcomes. These all resulted in $p>0.05$, showing no significant difference between the two sets of scores.

4.4 **Vascular assessment**

The patients remained in a supine position on a couch. Adjustments were made for individual comfort where necessary. Brachial, ankle and toe (hallux) systolic blood pressure (SBP) measurements were obtained for calculation of ankle-brachial pressure indices (ABPI) and toe-brachial pressure indices (TBPI). Both arms were used in the assessment of the brachial pressures, as there is frequently a difference in upper limb blood pressures, particularly in those with arterial disease. The higher brachial pressure value was used in all calculations. The Vascular Assist (Huntleigh Healthcare) was used for taking and assessing brachial, ankle and toe systolic blood pressures, and for the calculation of ABPI and TBPI values (figure 4.9).

This machine employs several modalities in a mobile unit that has a detachable interface/porting dock. Infrared Photoplethysmography (PPG) is one modality – which consists of an infrared photo sensor (APPG1 Transducer), housed in a small clip, which is attached to the end of a digit. This picks up distal reperfusion when performing blood pressure measurements using a standard, well fitting pneumatic cuff. All tests were performed on both lower limbs of each individual.

4.4.1 Brachial systolic pressure (BSBP).

An appropriately sized cuff was wrapped around the upper arm with the artery pointer on the cuff placed over the brachial artery and the infrared finger sensor placed over the index finger of the hand (figure 4.10).

The Vascular Assist requires the entry of patient details to enable the collected data to be stored. Having entered the required patient information, the main menu displays a list of modalities from which the infrared PPG for the appropriate digits, in this case the 'fingers', was selected on a touch screen.

Once selected the display demonstrated the waveform trace and allowed for any adjustments to be made to obtain the optimal waveform amplitude. Once a full cycle on the screen had been completed, the blood pressure could be measured. The pneumatic cuff was inflated via the Vascular Assist. The waveform was continually displayed during this time so that disappearance of the signal could be seen. The pressure exerted by the cuff was displayed in mmHg in the top right corner of the screen.

The cuff deflation button, when pressed, deflated the cuff allowing 3mmHg pressure to be released every second. The SBP was detected by a return of the waveform and the cuff pressure at that point. The pressure recorded was stored to the Vascular Assists' memory.

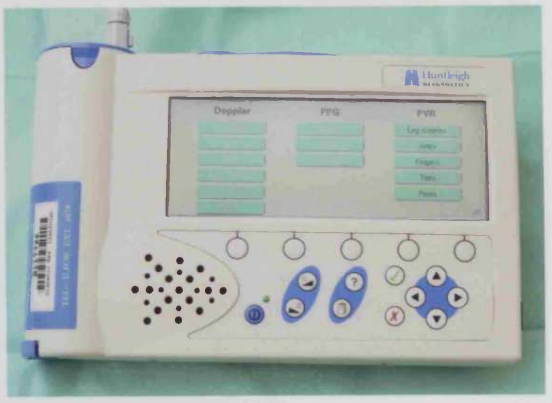


Figure 4.9 - Vascular Assist

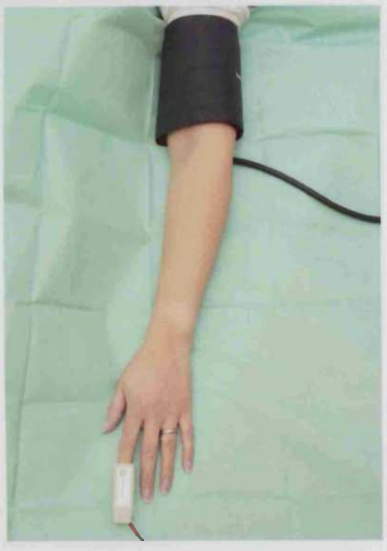


Figure 4.10 - Brachial systolic pressure being taken.

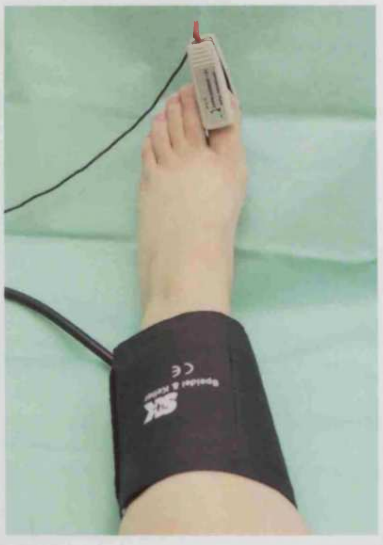


Figure 4.11 - Obtaining the ankle systolic pressure.

4.4.2 Ankle pressure

The pressure cuff was applied between the ankle and the calf. Again, care to fit an appropriate size cuff was taken. The PPG was placed over the tip of the hallux (fig 4.11). The procedure was then the same as for the brachial measurement, but selecting 'toes' on the touch screen. The pressure recorded for the ankle was saved to the Vascular Assist's memory and together with the higher brachial pressure was then used to calculate the Ankle-Brachial Pressure Index (ABPI).

$$\textbf{ABPI} = \frac{\textbf{Ankle systolic pressure}}{\textbf{Highest Brachial systolic pressure}}$$

4.4.3 Toe pressures

Toe pressures were performed using the PPG and specially adapted cuffs made for digital pressure measurements. Two sizes of cuff, the DC1.9 and PC 2.5 were used with most measurements being performed using the smaller 1.9 cuff. Toe pressure cuffs were placed on each hallux and where this was not possible, on the second toe. A dual cuff adaptor was attached to the toe cuffs to enable both toe pressures to be measured simultaneously. The dual cuff adaptor was attached to the Vascular Assist machine, the digital Photoplethysmography (PPG) clips were placed over the tip of each toe and the pressures were obtained in the same way as the brachial and ankle pressures although far less inflation was required (figure 4.12). The systolic pressure recorded was saved to memory and used to calculate the Toe-Brachial Pressure Index.

$$\textbf{TBPI} = \frac{\textbf{Toe systolic pressure}}{\textbf{Highest Brachial systolic pressure}}$$

The brachial, ankle and toe systolic pressures together with the ABPI and TBPI calculations were noted on the patient assessment form.

4.4.4 Waveform analysis

The continuous Doppler waveform analysis function on the Vascular Assist used an 8MHz Doppler probe. On the main menu, selection of the Doppler mode and then the appropriate region, 'feet', would allow analysis to be performed. The arteries for study on each limb were preset by selecting the appropriate artery and side, and placed to memory by confirming the sequence of the examination.

Contact gel was applied to the skin behind the medial malleolus. The 8MHz probe was placed in the area at an angle of between 45^0 and 60^0 to the skin surface in line with the artery and with the tip in tact with the gel pointing proximally towards flow. The probe was held gently and without excessive movement against the skin with gel between it and the skin to facilitate best sound conduction (fig 4.13).

Once the probe detected the flow, the Vascular Assist displayed the waveform and produced an audible signal similar to that produced by a hand held Doppler device. Generally the probe can detect venous as well as arterial flow, arterial flow is pulsatile and high pitched in contrast to venous flow which is non pulsatile and low pitched. On the screen waveform presentation, arterial flow towards the probe generates a waveform above the axis. Through gently altering the angle of the probe, the operator can judge the optimal waveform demonstrated on screen. The optimal waveform had to be maintained for at least 5 seconds to facilitate waveform analysis. At this point the stop button on either the probe or the Vascular Assist was depressed to stop recording. The waveform image was then stored on the Vascular Assists memory.

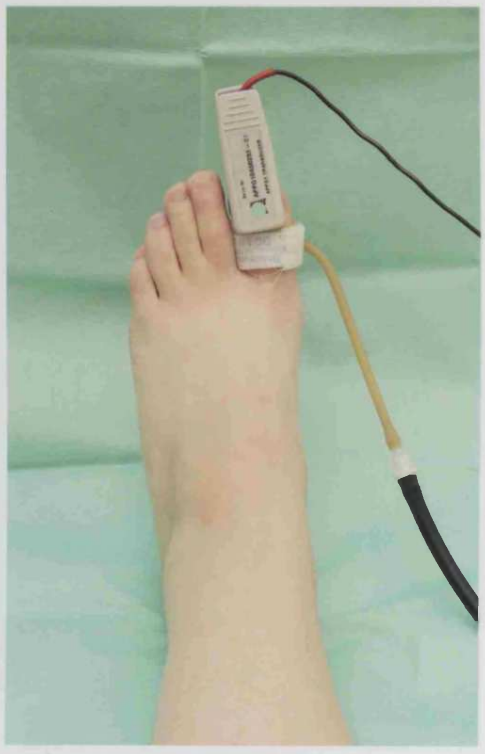


Figure 4.12 – Obtaining the toe systolic pressure.

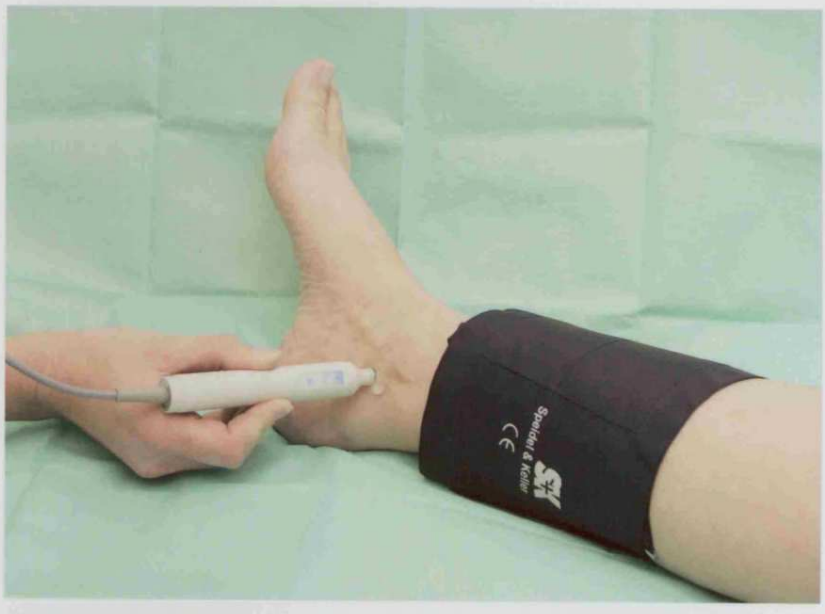
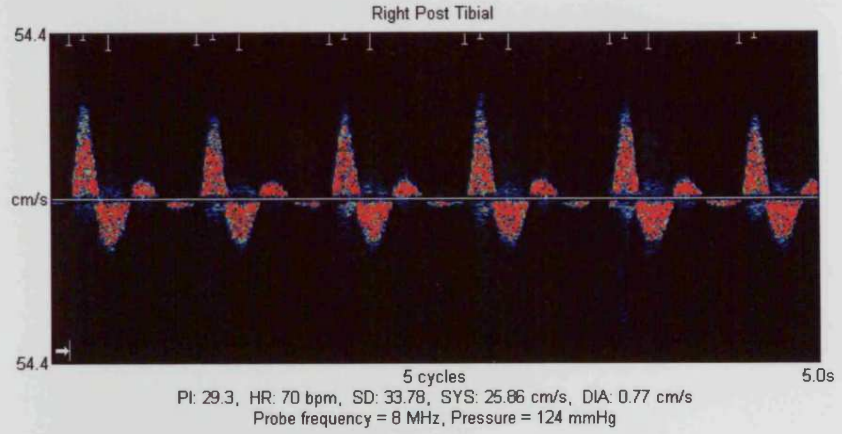
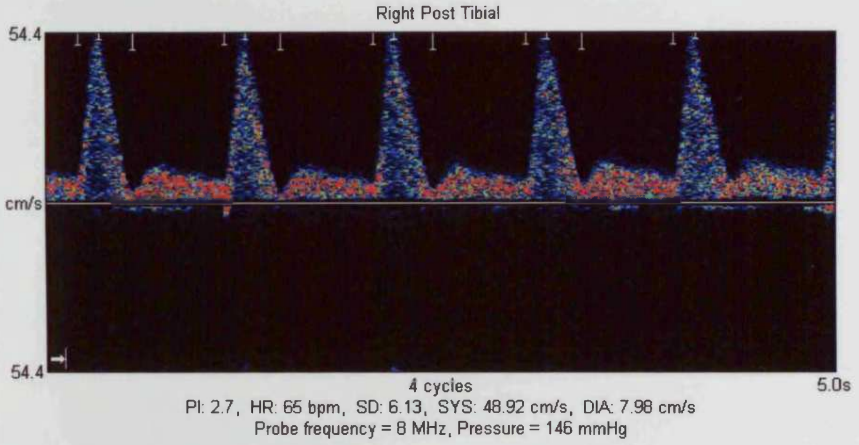


Fig 4.13 - Obtaining the Posterior tibial waveform.

A) Example of Triphasic waveform



B) Example of Biphasic waveform



C) Example of Monophasic waveform

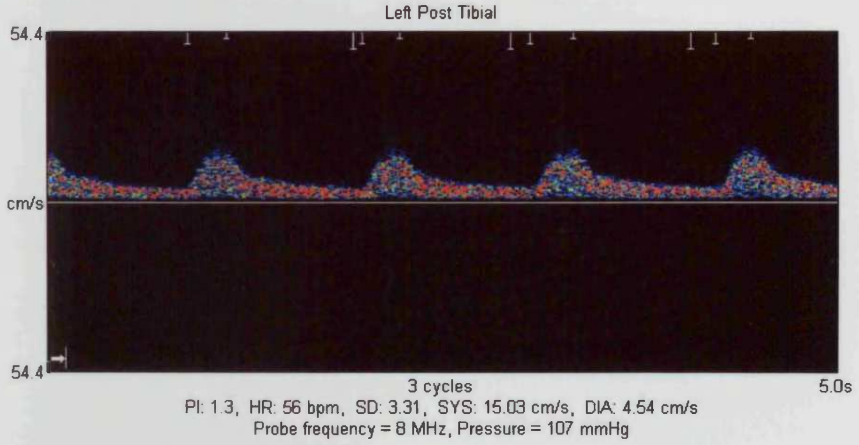


Figure 4.14 Examples of monophasic, biphasic and triphasic waveforms from subjects.

4.4.5 - Pulse Volume Records

To obtain pulse volume records (PVR), the appropriately sized pneumatic cuff was placed on the leg between the calf and the ankle. The cuff pressure must be sufficiently high to allow adequate contact between the cuff bladder and the limb segment. Since the cuff pressure will by necessity reduce the transmural pressure in the underlying arteries, distortion of the recorded pulse contour would result at higher cuff pressures.

In line with the manufacturers recommendations the cuff pressure of 65mmHg was employed as this is reported to give excellent pneumatic gain and surface contact and maintains the important contour characteristics. Following this procedure ensured that at a given pressure the cuff volume surrounding the limb was constant from reading to reading. When 65mmHg was reached, inflation was stopped. After approximately 5 seconds an image appeared on the monitor showing a single line pulse volume wave profile. After a further 5 seconds, the screen demonstrated a complete cycle, which was stored to the memory of the Vascular Assist. Once the image was stored the cuff fully deflated. This allowed for identification of possible stenosis in the lower limb. These images were then graded manually according to a previously established grading system (Rumwell & McPharlin 1998).

A: Normal: - Sharp systolic peak with prominent dicrotic wave.

B: Mildly abnormal: - Sharp peak, absent dicrotic wave, down-slope is bowed away from baseline.

C: Moderately abnormal: - Flattened systolic peak, up-slope and down-slope time decreased and nearly equal, absent dicrotic wave.

D: Severely abnormal: - Absent or low-amplitude pulse wave with equal up-slope and down-slope time.

Figure 4.15 A-D – Illustration of PVR grading

C and D always reflect haemodynamically significant disease proximal to the level of the tracing. If the amplitude of the tracing was reduced but there were no changes in the contour of the wave profile (i.e. dicrotic wave was present), the findings were likely to be insignificant, unless it was unilateral.

The cuff can be moved from the ankle to below the knee, above the knee or to the femoral area as is required until a normal image appears. The images recorded for both ankles were saved to the Vascular Assist's memory before being transferred to a mass storage device.

a) b)

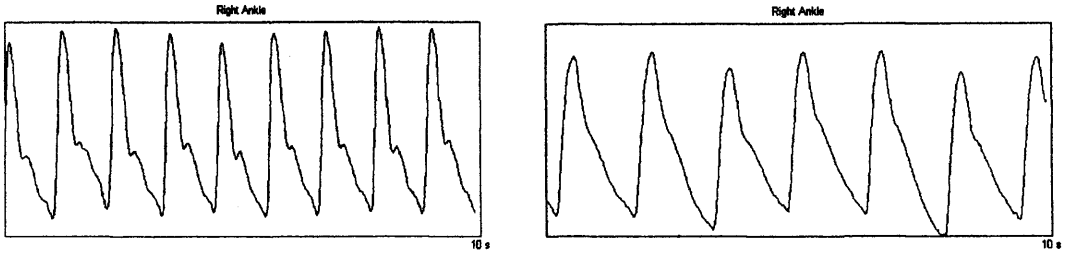


Figure 4.16 – Illustrations of a) normal and b) mildly abnormal PVR profiles.

4.4.6 Reproducibility Study – Vascular parameters.

As described for the neurological assessment, at the early stages of data collection, the 10 sample patients underwent a full vascular assessment and then re-assessed within three weeks. The 2nd assessment was performed blindly without reference to the earlier findings. Later data comparisons showed high consistencies in scores and outcomes. Mann-Whitney U tests were run on each variable to find *p*-values which resulted in $p>0.05$, showing no significant difference between the two sets of data. The following tables show both sets of vascular data for the selected sample.

Table 4.3 - Vascular data for 1st assessment of sample group.

	1	2	3	4	5	6	7	8	9	10
Pulses	4	4	0	4	2	4	4	4	0	4
ABPI	1.32	.95	.72	1.26	.82	1.21	.95	1.4	.82	1.30
TBPI	1.25	.59	.63	.83	.79	1.41	.94	1.28	.74	.95
*Waveform	T/T	M/M	T/T	T/T	T/B	T/T	T/B	T/T	B/B	T/T

*T-Triphasic; B-Biphasic; M-Monophasic

Normal ABPI >0.9

Normal TBPI >0.5

Table 4.4 - Vascular data for 2nd assessment of sample group.

	1	2	3	4	5	6	7	8	9	10
Pulses	4	4	0	4	2	4	4	4	0	4
**ABPI	1.32(0)	.95(0)	.71(.98)	1.26(0)	.80(1.23)	1.19(.83)	.94(.74)	1.39(.50)	.83(.84)	1.30(0)
TBPI	1.25	.59	.63	.83	.79	1.41	.94	1.28	.74	.95
Waveform	T/T	M/M	T/T	T/T	T/B	T/T	T/B	T/T	B/B	T/T

(** Figures in brackets represent intra-subject coefficient of variation.)

Although slight variations in scores can be seen, the patterns of results are very consistent. The ankle/brachial (ABPI) and toe/brachial (TBPI) figures were calculated from the actual brachial, ankle and toe systolic pressures. The low intra-subject CV figures show no significant difference between the two sets of scores.

4.5 **Digital images**

The choice of digital camera for skin lesion detection and use in Telemedicine was made relatively arbitrarily due to the limited literature available for review of similar studies, therefore, verbal recommendations were also sought. The members of the Steering Committee followed these recommendations in their final choice of the Sony Cyber-shot DSC-F707 digital still camera (fig 4.17). The specifications of this camera enabled clear images to be taken allowing for general foot shape to be recorded along with any foot deformities or lesions to be identified.

With the subject in a supine position and legs stretched out on the leg rests of the patient chair, four images of each foot were taken. The images were taken from the dorsal and plantar views together with the lateral and medial views. The patients were asked to relax their feet to limit ligament or muscle involvement in the foot shape. It was decided that the foot images would be taken non-weight bearing to allow for four angles of each foot to be taken. As images were not being taken for the purpose of monitoring ulcer size, a graded measurement scale was not required.

The images were initially stored on the camera's memory card before being transferred to compact disc for analysis and archive storage. The images, with the subjects study identification number but no other identification details, were stored in a locked room for data protection purposes.

Figure 4.17 – Sony Cyber-shot camera used

4.6 **Plantar pressure**

The 1 meter square MatScan dynamic plantar pressure capture system is made up of over 2,000 individual pressure sensing locations arranged in rows and columns covered by a protective surface. The pressure mat is connected by a sensor tab to the sensor handle which in turn connects to the parallel interface module. From this module the system can be linked to mains power, needed for operation, a printer, which is optional, and a computer which is also needed for operation. For practicality and mobility purposes a laptop computer was used but not a printer while collecting data in the community.

When all the equipment had been connected together, the pressure mat was placed on the floor with adequate room for the subjects to walk across it.

Having removed footwear and having had any plantar callus removed, subjects were asked to stand with both feet flat on the pressure mat, arms hanging loosely by their side and head up looking straight ahead. The subject's body weight was entered onto the computer, allowing the pressure mat to be calibrated for each individual (figure 4.18).

Each subject was allowed to familiarize himself/herself with the testing procedure by walking over the pressure mat at their own self-selected comfortable pace several times. Subjects were instructed not to look down at the platform to prevent targeting but to look ahead at a fixed position distant to the pressure mat.

Each subject had data collected using the two step method (Bryant et al. 1999), rather than the similarly acceptable mid-gait methods due to restrictive space available in community settings. Each subject's starting position was determined such that the subject commenced walking with the opposite foot to that being tested, with the test foot making contact with the pressure mat on the second step from the starting position (figure 4.19).

Figure 4.18 – Calibrating the MatScan

Fig 4.19 - Plantar pressure data collection

Several trials of each foot were then collected for each subject. Trials were rejected if they were considered under strided, over strided, hesitant, or targeted. Trials that partly missed the platform, or were too close to the edge of the data sensing area were also discarded. At least three from each foot were selected for analysis. Although the foot strikes collected were dynamic foot strikes, static images in various dimensions were also viewed, examples of which can be seen below.

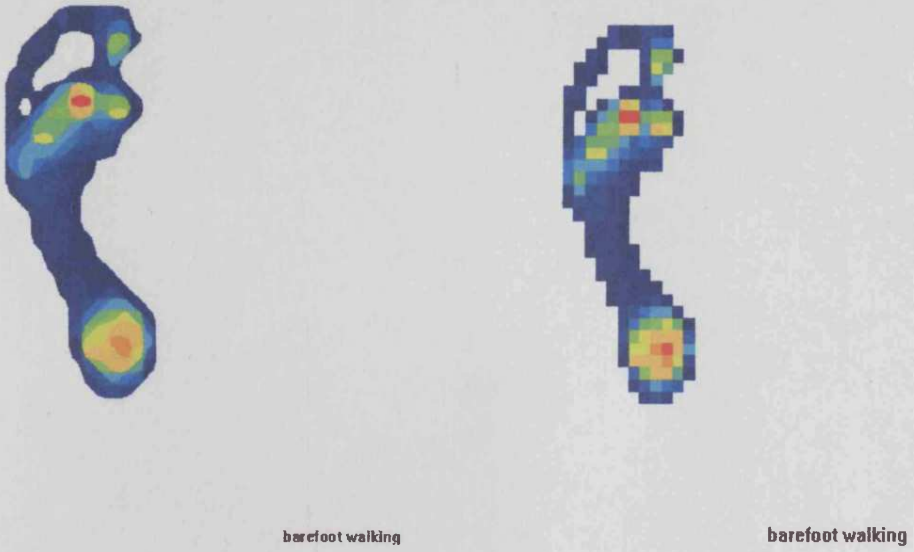


Figure 4.20 - Two dimensional images

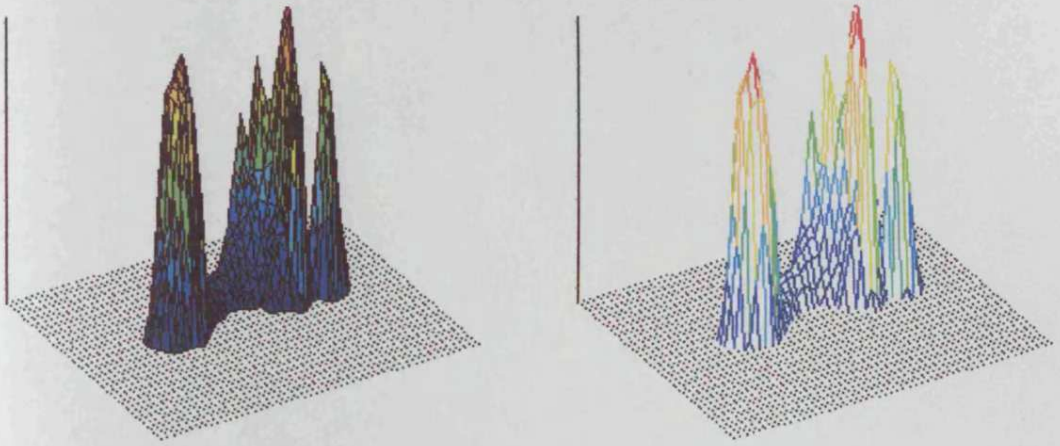


Figure 4.21 – Three dimensional images

When the testing was complete, the results were shared with the subjects and individual verbal and/or written advice given for continuing foot care. A copy of the subject's results was also sent to their GP.

4.7 **Summary of methods used**.

1. Patient Questionnaire – Administered for collection of demographic information, medical history and current general health status, obtain the level of the subjects understanding regarding the impact of diabetes mellitus on their foot health and to identify current levels of foot care administered by subjects, careers and health professionals.

2. Foot/footwear examination – Identify presenting foot lesions, deformities and amputations, identify, illustrate and educate on the impact of incorrect/correct footwear on foot health.

3. Neurological assessment – Light touch assessed using Neuropen 10g-monofilament (large nerve fibre function), Sharp sensation using the Neuropen neurotip (small nerve fibre function), Vibration sensation using the Rydel Seiffer graduated tuning fork (semi-quantitative) and Neurothesiometer (quantitative)(large nerve fibre function), temperature appreciation using a cold tuning fork (small nerve fibre function).

4. Vascular assessment – Palpation of dorsalis pedis and posterior tibial pulses, brachial systolic pressure and ankle systolic pressure for calculation of ABPI, brachial and toe systolic pressures for calculation of TBPI, analysis of posterior tibial waveforms, analysis of pulse volume records (PVRs) at ankle level.

5. Digital images – Recording of lesions, deformities and amputations from medial, lateral, plantar and dorsal views for future comparison and explore usefulness of identifying the 'at risk' foot through remote diagnosis.

6. Plantar pressure – Explore usefulness in analysing areas of high pressure loading patterns and increased time integrals through dynamic plantar pressure analysis for identifying areas of potential high risk.

4.8 **Statistical methods used**.

All statistical analysis was completed using the Statistical Package for the Social Sciences (SPSS) version 11.

Subject characteristics and distribution were described using descriptive statistics and graphical representation throughout. The results were summarised using means, standard deviations and frequencies to describe the central tendency and variability of the data. Non-parametric Mann-Whitney U test for comparing the means of 2-

independent samples, were used on the neuropathic and vascular reproducibility study data, resulting in an intra-subject coefficients of variation being obtained, ensuring accurate use of equipment and collection of data within subjects (Bland 2000).

Boxplots were used to visually inspect the data, to help indicate whether the distribution of the data was skewed and whether there were any unusual outliers in the data. Box plots show extreme values (minimum and maximum values), the lower and upper quartiles and the median value. Scatterplots were used to give a visual picture of the relationship between sets of bivariate data, assisting in the interpretation of the statistical findings (Bland 2000). To measure the strength of linear association or correlation coefficient between the visual foot inspection and digital imagery data, the Pearson correlation statistical test was performed.

Chi-square tests were used to determine whether an association between 2 variables was likely to reflect a real association between the variables in the study population (Bland 2000). The probability value (p) calculated, reflected the probability of the observed association having occurred by chance (Bland 2000). The alpha level (α) was set at 0.05.

The student's t-test was used where the data was independent and normally distributed (Bland 2000). The assumption of homogeneity was assessed using the Levene's test for homogeneity.

Altman's method (Altman 1993), was used for the determination of age related reference ranges when looking at the vibration perception data. Regression was used to find the straight line of best fit, where the variation of the real data above and below the line is minimised. The line fitted produced an equation which represented the model used (Chapter 7). Tolerance limits were employed to estimate the 95%

limits of the population since the population standard deviation was unknown, as only a sample of the overall diabetic population was studied (Diem & Lentner 1975).

CHAPTER FIVE: QUESTIONNAIRES – DEMOGRAPHICS, GENERAL HEALTH, FOOT HEALTH AND FOOT HEALTH NEEDS

5.1 **Introduction**

It was felt by the Steering Committee that due to the large number of subjects being targeted and time constraints of the study period, the most effective method for collection of demographic information, general health and foot health information, would be through the administration of a questionnaire. This method would also collect additional information such as whether the subject's foot care needs were being met by current levels of personal and/or professional foot care. The questionnaire would allow for uniformity of approach, processing and analysis, ease of administration and would avoid bias. It would not however, allow for depth of questioning and would limit the range of responses. The Steering Committee considered the advantages to outweigh the disadvantages in the type of information that was required.

5.2 **Results**

The Patient Questionnaire (Appendix 2.1), completed by the subject at home, was divided into three sections. The first related to general demographic details, the second to general and diabetic health and the third to foot health.

5.2.1 Demographic information

Q1. How would you describe your ethnic origin? (You do not have to answer this question.)

African	☐ 1	Chinese	☐ 4	White/Caucasian	7	☐	
Afro Caribbean	☐ 2	Indian	☐ 5	Other	8	☐	
Bangladeshi	☐ 3	Pakistani	☐				

Q2. Please list **all** treatments and medication that you are currently taking.

Q3. Are you a member of Diabetes UK, or any diabetic patients support group in your area?

Yes	1	☐
No	2	☐

Q4. Are you?

Male	1 ☐
Female	2 ☐

Q5. How old are you?

0-19 years	1 ☐
20-29 years	2 ☐
30-39 years	3 ☐
40-49 years	4 ☐
50-59 years	5 ☐
60-69 years	6 ☐
70 years and over	7 ☐

Q6. Do you live alone?

Yes	1 ☐
No	2 ☐

The ethnic origin question was answered by all subjects and revealed that 95.2% (n=519) described themselves as 'White/Caucasian', 0.4% (n=2) as 'Afro-Caribbean', 0.4% (n=2) as 'Indian' and 4% (n=22) as 'Other'. The gender split for the study group was relatively even with 56.3% (n=307) males and 43.7% (n=238) females. 79.1% (n=431) of all subjects cohabited, with 20.9% (n=114) living alone and only 23.1% (n=126) were members of Diabetes UK.

The mean age was 66 years (SD = 11.4) with the largest proportion falling into the 60-69 year and 70-79 year age groups.

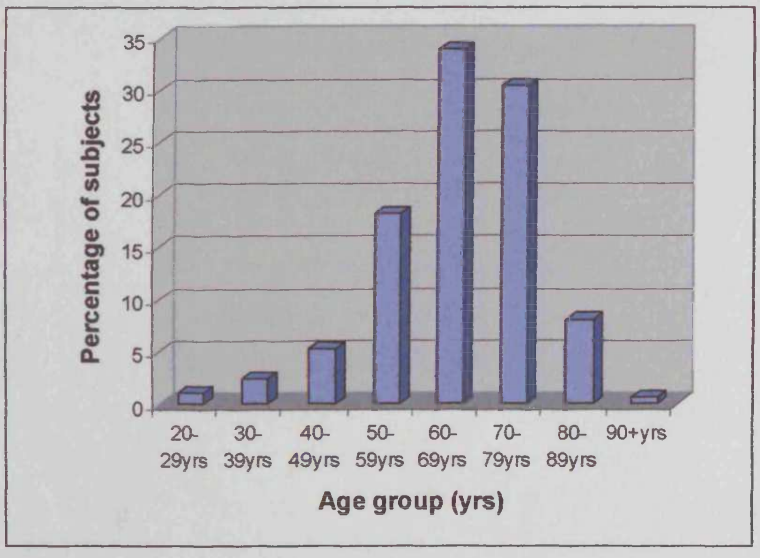


Figure 5.1 – Age group distribution for study group (10yr bands).

In respect to lifestyle questions, smoking habits and alcohol consumption were addressed.

Q7. Do you smoke?

Yes	1	☐
No (more than 5 years)	2	☐
Ex smoker (longer than 6 months)	3	☐

Q8. How much alcohol do you drink in a week?
1 unit = ½ pt beer/larger = small glass wine = single pub measure spirit

0 units per week	1	☐
1-10 units per week	2	☐
11-20 units per week	3	☐
21-30 units per week	4	☐
30+ units per week	5	☐

The patients were categorised as 'smoker', 'non-smoker' (having not smoked for 5+ years) or 'ex-smoker' (having not smoked for 6 months or more). 12.1% (n=66) admitted they were smokers, 34.1% (n=186) revealed they were ex-smokers and 53.8% (n=293) stated they were non-smokers. The results for the average number of alcohol units consumed in a week can be seen in the table and figure below.

Table 5.1 Distribution of alcohol consumption

Alcohol consumption (units)	% (n)
0	42.0 (229)
1-10	39.1 (213)
11-20	11.9 (65)
21-30	4.8 (26)
30+	2.2 (12)

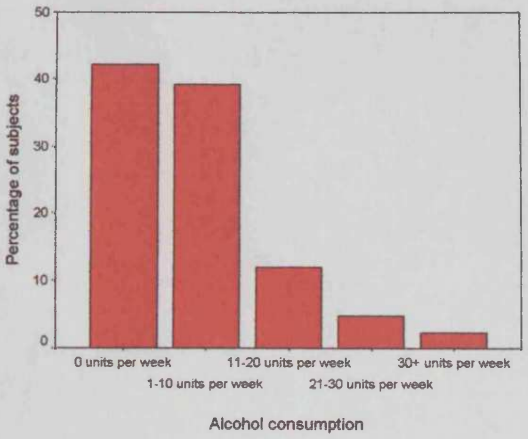


Figure 5.2 – Distribution of alcohol consumption.

5.2.2 General and diabetes health

Section 2 was concerned with the subject's general and diabetes health.

Q9. When were you first diagnosed with diabetes?

Less than 5 years ago	1	☐
Between 5-9 years ago	2	☐
Between 10-19 years ago	3	☐
More than 20 years ago	4	☐

Q10. How is your diabetes treated?

Diet alone	1	☐
Tablets alone	2	☐
Insulin alone	3	☐
Insulin with tablets	4	☐

80.9% (441) had type 2 diabetes mellitus and 19.1% (n=104), type 1 diabetes mellitus. Known duration of diabetes was split into duration bands due to subjects not recalling exactly how many years they had been diagnosed (see table 5.2). 41.5% (n=226) were known to have had diabetes for less than 5 years which represented the largest group, and of these 93.4% (n=211) were type 2 and 6.6% (n=15) were type 1.

Table 5.2 Distribution of known duration and type of Diabetes Mellitus within study group

Known duration of DM			Diabetes Type	
	%	(n)	Type 2 % (n)	Type 1 % (n)
<5yrs	41.5%	(226)	93.4 (211)	6.6 (15)
5-9yrs	24.4%	(133)	87.2 (116)	12.8 (17)
10-19yrs	22.0%	(120)	73.3 (88)	26.7 (32)
20yrs+	12.1%	(66)	39.4 (26)	60.6 (40)

Treatment regimes were split into those that control their diabetes with diet alone, those that are prescribed oral hypoglycaemic agents, those on insulin therapy and those that are on a combination of oral agents and insulin therapy. The distribution of treatments can be seen in the figure below.

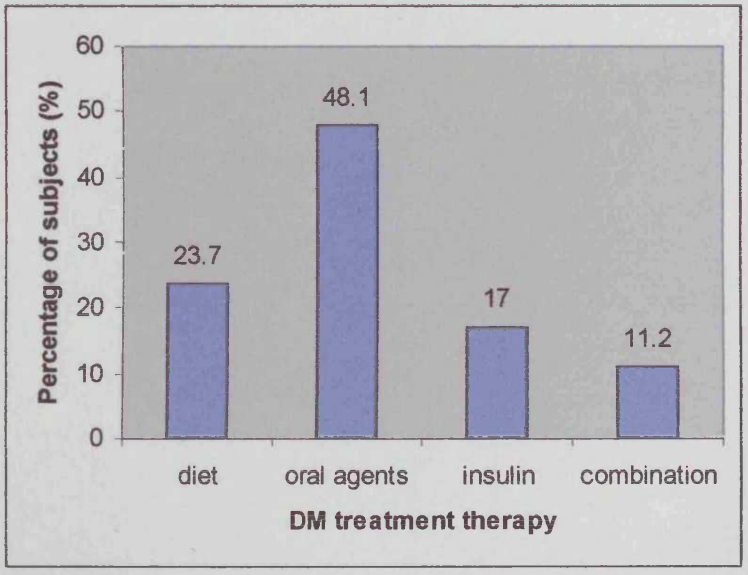


Figure 5.3 – Distribution of treatment regime.

23.7% (n=129) treated their diabetes through adjusting their diet alone. 48.1% (n=262), the largest percentage treated their diabetes with oral hypoglycaemic agents,

17.0% (n=93) treated their diabetes with insulin therapy and 11.2% (n=61) used a combination of oral hypoglycaemic agents and insulin.

The next three questions all related to the eyes.

Q11. Have you had your eyes photographed by the Diabetic Retinopathy Screening Service?

Yes	1	☐
No	2	☐

Q12. If yes, how long ago?

Less than 6 months ago	1	☐
6 – 12 months ago	2	☐
More than 12 months ago	3	☐

Q13. Does your eyesight allow you to see your feet in detail/clearly? (Using your glasses if you normally wear them)

Yes	1	☐
No	2	☐

It was important to identify those subjects that had problems checking their own feet due to eye sight problems rather than due to perhaps body shape (obesity). It also provided a way of identifying those that were not receiving regular diabetic eye screening.

There was a total of 90.8% (n=495) who felt they could see their feet clearly enough to check for abnormalities. 92.5% (n=504) said that they attended regular appointments for Diabetic Retinopathy Screening and therefore did not have any sight threatening problems, (those with sight threatening problems would have been referred for further treatment and would no longer be attending screening appointments). This attendance rate illustrated good compliance by this patient group.

It was important to establish if any of the subjects had experienced previous peripheral vascular or neurological problems that might affect the assessment results.

Q14. Have you had any operations involving the blood vessels in your legs? (Not surgery for varicose veins)

Yes	1	☐
No	2	☐

Q15. Have you ever had a stroke?

Yes	1	☐
No	2	☐

Q16. Have you had any operations or accidents involving your?

Back	1	☐
Hips	2	☐
Knees	3	☐
Ankles	4	☐
Feet	5	☐

Table 5.3 Incidence if previous vascular or neuropathic problems

Peripheral vascular problem		% (n)
Have had a previous stroke?	No	90.8 (495)
	Yes	9.2 (50)
Have had previous vascular surgery?	No	92.5 (504)
	Yes	7.5 (41)
Peripheral nerve damage		
Have had previous orthopaedic trauma?	No	68.8 (375)
	Back	7.1 (39)
	Knee	7.0 (38)
	Ankle	5.9 (32)
	Foot	11.2 (61)

5.2.3 Foot health

Section three of the questionnaire related to the subject's foot health. The questions were designed to enquire about their knowledge of the impact diabetes can have on foot health, and also to enquire about the foot health care the subjects were receiving.

Q17. Since you have had diabetes, have you had an ulcer, an open wound or even a sore on either of your feet?

Yes	1	☐
No	2	☐

Q18. Similarly, have you ever had an infection involving either of your feet?

Yes	1	☐
No	2	☐

12.8% (n=70) of subjects had previous problems with open wounds and 23.3% (n=127) experienced previous foot infections. It was only a very small number however that had previously had an infected wound/ulcer (7%, n=38). The remaining infections were due to nail fungal or tinea pedis infections.

Q19. Are you aware of the foot problems that relate to diabetes?

Yes	1	☐
No	2	☐

Q20. Would you like to know more about foot problems related to diabetes?

Yes	1	☐
No	2	☐

Q21. Have your feet been checked by any of the following during the last year? (Tick more than 1 box if necessary)

Nobody	1	☐
GP/Practice Nurse	2	☐
Diabetic Specialist Nurse	3	☐
District Nurse	4	☐
Podiatrist (Chiropodist)	5	☐
Hospital Doctor	6	☐

Q22. How often do you, or a family member, or carer look at your feet?

Never	1	☐
Daily	2	☐
Weekly	3	☐
Monthly	4	☐
Yearly	5	☐
Other	6	☐

Q23. Has anyone explained to you why you should inspect your feet regularly?

Yes	1	☐
No	2	☐

Q24. Has anyone explained to you, or a family member or your carer, how to inspect your feet properly?

Yes	1	☐
No	2	☐

Q25. Have you been told what to look for?

Yes	1	☐
No	2	☐

Q26. Has anyone explained the need for you to have your feet inspected regularly by a Health Professional (e.g. Nurse, GP, Podiatrist / Chiropodist)?

Yes	1	☐
No	2	☐

When asked if they knew about the effects that diabetes can have on the foot, three quarters of the subjects felt they were aware of at least some of the problems but a quarter (25.9%, n=141), did not have any idea at all of what damage diabetes can do to the feet. It was refreshing that when asked if they would like to know more about diabetes related foot problems, that 92.1% (n=502) responded positively, 1.1% (n=6) did not want to know. As a quarter of the subjects had no idea of the possible problems that could arise through diabetes, the questions relating to 'why' they should examine their feet, 'what' they should look for and 'how' they should examine their feet, became even more important.

Table 5.4 Patients knowledge of foot inspection

		% (n)
Know why you should examine feet?	Yes	61.7 (336)
Know what to look for?	Yes	35.6 (194)
Know how to examine feet?	Yes	38.7 (211)

Although three quarters of the subjects were able to suggest at least one diabetes related foot problem, from the table above it can be seen that just over half of these subjects knew why they should examine or have their feet examined and much less than half actually knew what it was they were looking for or how their feet should be examined.

57.2% (n=312) said they checked their feet on a daily basis and although a quarter of the subjects were not aware of diabetic related foot problems, only 11.9% (n=65) admitted never checking their own feet which meant that the remaining 88.1% (n=480) checked their own feet at least annually. When related to the information above, it suggests that although the subjects were looking at their feet, they are not sure what it was they were looking for.

Table 5.5 Regularity of self foot check

	% (n)
Never	11.9 (65)
Daily	57.2 (312)
Weekly	21.5 (117)
Monthly	6.1 (33)
Other (rarely checked)	3.3 (18)

All of these results indicate that there is a very low level of knowledge.

The subjects were also asked which, if any, health professionals had checked their feet in the preceding year. The results can be seen in the table below.

Table 5.6 Health professional foot check in last 12mths

	% (n)
No Health Professional	10.3 (56)
GP/Practice Nurse	20.4 (111)
Diabetes Specialist Nurse	12.5 (68)
District Nurse	0.3 (2)
Podiatrist	49.2 (268)
Hospital Doctor	7.3 (40)

It was calculated that just 2% (n=13) of the whole study group (n=545) were not having their feet checked by themselves, relatives or a Health Professional. It was disappointing however that a number of subjects having annual foot checks from a health professional, felt it unnecessary to check their own feet between annual health professional checks.

The remainder of the questionnaire related to footwear.

Q27. Has anyone explained to you the importance of wearing suitable shoes for your feet?

Yes 1 ☐
No 2 ☐

Q28. Have you had shoes made for you?

Yes 1 ☐
No 2 ☐

Q29. If you have, how often do you wear them?

Never 1 ☐
Sometimes 2 ☐
Most times 3 ☐

More than half (64.4%, n=351) said that the importance of well fitting shoes had been explained to them, however 35.6% (n=194) said they had not had this emphasized. 3.9% (n=21) had required tailor made shoes to accommodate foot deformities, of

these patients, 57.1% (n=12) said they wore them 'most of the time' with the remainder saying they 'never' wore them.

As explained in the methods chapter, the purpose of the supplementary questionnaire was to confirm responses to the 1st questionnaire and to obtain further information.

When asked about the connection between diabetes mellitus and foot health, 63% were consistently aware and 16% were consistently unaware of the connection. 21% showed inconsistency in their response. In the 2nd questionnaire, the subjects were asked how often they **should** check their own feet. These results were then compared with how often they **actually** checked their feet from the 1st questionnaire. 53% (n=289) consistently responded 'daily' in both instances (table 5.7 illustrates other responses).

Table 5.7 Comparison of foot check results from 1st and 2nd questionnaires

		Regularity of own foot check % (n) *(1st Questionnaire)*					
		Never	Daily	Weekly	Monthly	Yearly	Other
How often should feet be checked % (n) *(2nd Questionnaire)*	Never	5.3(29)	0.7(4)	1.5(8)	0.7(4)	0.2(1)	0.7(4)
	Daily	4.5(25)	53.0(289)	11.2(61)	2.8(15)	0.9(5)	0.4(2)
	Weekly	1.5(8)	3.1(17)	7.4(41)	1.3(7)	0.2(1)	0.4(2)
	Monthly	0.6(3)	0.4(2)	1.3(7)	1.3(7)	0.4(2)	0.2(1)

In the 2nd questionnaire the subjects were asked what changes they would look out for with the option to answer 'don't know' if necessary. The results indicated that although a number of subjects were unaware of any changes in the 1st questionnaire, when questioned slightly differently in the 2nd questionnaire, they were able to suggest at least one related change (table 5.8).

Table 5.8 Foot changes suggested by patient.

	% (n)
Don't know	26.0 (142)
Nail changes	3.1 (17)
Skin breaks	53.6 (292)
Colour changes	4.6 (25)
Sensation changes	7.5 (41)
Callous/corns	4.6 (25)
Hair on feet	0.2 (1)
Swelling	0.4 (2)

The subjects were asked if they were aware that they should have a foot check at their annual general diabetes review from their Diabetologist or GP. There was a very encouraging response by 86.2% (n=470) being aware and just 13.8% (n=75) unaware. When asked if they received an annual general diabetes review from one of the above, 97.4% (n=531) were and only 2.6% (n=14) were not. Of those receiving an annual general diabetes review, 50.1% (n=273) were also seen by either an NHS Podiatrist (41.3%, n=225) or Private Practice Podiatrist (8.8%, n=48). The regularity of treatment received by the subject's varied and can be seen in the table below.

Table 5.9 Podiatry treatment intervals

	% (n)
N/A	49.9 (272)
1-2 months	23.7 (129)
2-3 months	19.8 (108)
3-4 months	4.6 (25)
4+ months	2.0 (11)

The frequency of podiatry visits were compared to the pathologies presented by the subjects, the results of which can be seen in table 5.10.

Table 5.10 Frequency of Podiatry visits within pathology groups

Duration (months)	Mixed % (n) (n=123)	PVD only % (n) (n=47)	Neuropathy only % (n) (n=174)	*No complications % (n) (n=201)*
N/A	33.3 (41)	40.4 (19)	44.3 (77)	*67.2 (135)*
1-2	27.6 (34)	31.9 (15)	29.3 (51)	*14.4 (29)*
2-3	32.5 (40)	21.3 (10)	16.7 (29)	*14.4 (29)*
3-4	5.0 (6)	2.1 (1)	6.3 (11)	*3.5 (7)*
4+	1.6 (2)	4.3 (2)	3.4 (6)	*0.5 (1)*

5. 3 - **Summary**

The ethnic origin categories used were the same as those used by the Welsh Primary Audit Group. The majority (95.2%) of subjects screened for this study were white with an even split between males and females and an average age of 66yrs (SD=11.4), with most falling within the 60-80yrs age bands.

Over 50% of the subjects considered themselves as non-smokers (ceased smoking for >5yrs), 34.1% as ex-smokers (ceased smoking for >6mths) and 12.1% as smokers. 81% of subjects estimated their alcohol consumption as less than 10 units of alcohol per week. However, these are areas that often get an inaccurate response from individuals, often yielding under estimated values. A little over 20% of the subjects lived alone and only 23% were members of Diabetes UK.

More than 90% of the subjects attended the eye screening service regularly, indicating that they were currently free from sight threatening complications, therefore allowing them to see/examine their own feet (body shape permitting). This supported good patient compliance.

More than 80% were diagnosed with Type 2 diabetes mellitus, at least half of these having been diagnosed within the previous five years. A little fewer than 20% were diagnosed with Type 1 diabetes mellitus, with the majority of these having been diagnosed for 20+years.

Approximately 75% were attempting to control their blood glucose levels through diet alone or a combination of diet and oral agents, the remainder controlling their blood glucose levels with either insulin or a combination of oral agents and insulin.

The vast majority of subjects reported no previous peripheral vascular problems or peripheral nerve damage through trauma to the lower body that might influence assessment results.

When questioned about their knowledge of diabetic foot problems, 74.1% were aware of some of the problems but this left a quarter having no idea of any connection between diabetes and foot health. The comforting response was that 92.1% were keen to learn and understand more, a little worrying was that 7.9% did not want to know more and 1.1% did not know anything and did not want to know anything about the relationship between diabetes and foot health. These results showed a low level of knowledge leading to a low level of awareness.

Table 5.5 illustrates the regularity of subjects own foot care which highlights that 88.1% of subjects did check their feet a minimum of annually. Foot care by health professionals revealed that 49.2% had their feet checked by a podiatrist, 20.4% by their GP or Practice Nurse and 10.3% said that no health professional checked their feet. Some of these subjects were checking their own feet and in fact it was just 2% that were not having their feet checked by anyone.

64.4% had been informed of the importance of wearing correctly fitting footwear and due to foot shape, 3.9% had bespoke footwear issued to them. However, approximately half of these admitted to never actually wearing the bespoke footwear, usually because they were uncomfortable or ugly.

The answers obtained from the two questionnaires showed no significant difference ($p<0.05$) in responses. The results from both questionnaires revealed that subjects are getting a general diabetes review but not necessarily including foot checks by health professionals. A large proportion of subjects with vascular, neuropathic or mixed pathology did not require podiatry treatment. Those receiving podiatry intervention were doing so at between 1 and 3 month intervals.

5.4 **Executive Summary**

- The most frequently occurring patient profile from the results of the questionnaires for this subject group would be a white male or female in their 60's who did not smoke and did not consume more than 10 units of alcohol per week. They did not live alone and had adequate eye sight for self examination of their feet. They had type 2 diabetes that had been diagnosed less than 5yrs prior to this study and taking oral hypoglycaemic agents to control their blood glucose levels and did not have any prior vascular or neurological complications.
- These subjects were found to be receiving their annual general diabetes checks but not always receiving foot checks if they were not being seen regularly by a podiatrist.
- The final message that came across from these results was the lack of knowledge and understanding the subjects had regarding the possible foot

problems related to diabetes mellitus and the very important, simple methods that can be adopted for self care.

CHAPTER SIX: ASSESSMENT OF VISUAL APPEARANCE OF THE FOOT/FOOTWEAR

6.1 **Introduction**

6.2 **Results**

6.3 **Summary**

6.4 **Executive Summary**

6.1 **Introduction**

The diabetic foot is more likely to develop complications therefore, a systematic assessment is vital to identify 'high-risk' patients, with the aim of preventing or limiting the subsequent risk of complications. Part of this assessment will include a physical examination consisting of an evaluation of the foot for deformity, the presence of callosities, foot hygiene and also footwear (Klenerman et al. 1996).

Details of any previous ulceration, clinic attendance for foot related problems, surgical intervention (e.g. vascular reconstruction or amputation), are essential. Patients with a history of foot ulcers are more likely to develop subsequent ulcers more commonly at the same location. History of any presenting foot condition, type and changes of footwear and any precipitating events need to be recorded.

Footwear must be closely examined since it may contribute to the development and/or enhance lesions or deformities. Tight shoes worn by patients with peripheral neuropathy, especially new shoes, may lead to pressure necrosis or to unnoticed blisters that may progress to ulceration (Santos & Carline 2000). Often the upper side of an ill-fitting shoe will change its shape when worn for some time. Those patients who develop neuropathies may not feel pain and may therefore fail to report foot problems at an early stage. Footwear should also be assessed for the presence of foreign objects, especially for patients with peripheral sensory neuropathy, as they may lead to tissue breakdown and ulceration.

The skin should be visually examined for signs of autonomic neuropathy such as dry, anhydrotic skin, fissuring especially around the heels and dilated superficial veins. In some cases, the skin may appear dusky red or cyanotic blue where impaired perfusion has resulted in blood stagnation within dilated arterioles. Absence of hairs on the

dorsum of the digits, poor nail plate growth, and atrophy of the skin may be observed in cases of chronic ischaemia. However, hair absence alone appears to be a poor indicator of the severity of ischaemia (Santos & Carline 2000).

Variations in temperature between feet should also be checked. This can be done by either feeling both feet simultaneously then each foot with the same hand to find a warm area or 'hot spot', or by using an infrared handheld digital thermometer. When a significant temperature variation is detected between feet it could be an indication that a significant problem has developed such as infection, neuropathic Charcot's joint, or could be due to impaired circulation (a cold foot). A temperature variation of more than 2°C between the right and left feet is deemed clinically significant (Dorgan et al. 1995).

Peripheral oedema in the lower limb, especially bilaterally, could indicate heart or kidney failure, or venous stasis problems. Unilateral localized swelling of the foot area can indicate infection or an acute Charcot's arthropathy with dilated superficial veins.

Deformity can be associated with peripheral neuropathy and foot ulceration. However, foot deformity without peripheral neuropathy seems not to be associated with foot ulceration since patients with rheumatoid arthritis and abnormally high plantar foot pressures without neuropathy seem not to be affected (Fernando et al. 1991). Deformities to be looked for should include retracted or clawed toes - characterized by hyperextension at the metatarsophalangeal joints and flexion at the proximal interphalangeal joints (figure 6.1a), hammer toes - characterized by plantar flexion at the distal interphalangeal joint causing the tip of the distal phalanx to press down on the ground, and hallux valgus - characterized by medial deviation of the first

metatarsal with lateral deviation of the proximal phalanx at the first metatarsophalangeal joint (figure 6.1b) (Boyko et al. 1999a; Dorgan et al. 1995).

On occasions clawed toes will actually become dorsally dislocated. In persons with diabetes, these deformities can be a sign of distal motor neuropathy and muscle atrophy. Along with claw toes, dorsal humping of the foot, distal displacement of the fat pad under the ball of the foot, high pressures over the prominent metatarsal heads, all characteristics of pes cavus, and evidence of pressure from tight-fitting shoes on the dorsal aspects of the toes may occur. Such deformities or functional abnormalities may cause high plantar foot pressures, which will be considered in greater detail in Chapter 11.

Both feet should be examined not only for abnormal shape, but for lack of symmetry. Note should be made of abnormalities such as mid foot collapse, indicating arthropathy, as well as flat or high arches (pes planas and pes cavus respectively), and signs of past surgical procedures.

Hypertrophic (thick) toenails are often caused by fungal infections and may injure the toe with the deformed infected nail as well as adjacent toes, especially if the toes are squeezed together in tight shoes. Toenails that are in grown or too long can cause ulceration subungually or at the nail margins (figure 6.2).

Even though the aetiology of callus is not always clear, the presence of callus contributes to high plantar pressure (Cavanagh & Ulbrecht 1993), and possibly signifying the presence of a previous problem. Callus commonly forms on the dorsum or apices of toes or plantar surface of the foot in response to high stress resulting from bony prominences, foot deformities or tight shoes. As callus continues to build up, it can create increasing pressure, analogous to the presence of a foreign body (Cavanagh & Ulbrecht 1993; Dorgan et al. 1995).

In a patient with neuropathy (insensitive feet), haemorrhage beneath untreated callosities can develop without awareness. Although this may be quite subtle at times, it implies that enough traumas have occurred to cause tissue damage. As this can further develop into an ulcer on eruption of the skin, haematoma within callus must be taken as seriously as an ulcer (Cavanagh & Ulbrecht 1993).

High pressure on both the dorsal and plantar surfaces is a cause of skin injury. On the dorsal aspect of the foot, the problems encountered are usually the result of poorly fitting shoes or deformity, the most common from clawing of the toes. On occasion the toes will actually become dorsally dislocated. Although uncommon, bony prominences on the dorsal aspect of the mid-foot are very troublesome because this region of the foot is likely to be particularly involved in the transfer of propulsive forces from the foot through the footwear to the floor during gait. Such dorsal prominences are sometimes seen in patients with Charcot's arthropathy.

A thorough examination of the foot, including foot temperature, lesions and deformities as detailed in the methodologies chapter, was carried out on every subject. A thorough inspection of the footwear was also carried out enabling patient education and advice on suitable footwear to be given.

6.2 Results

As previously mentioned, a contralateral difference in foot temperature of 2^0C or more, was regarded as significant. In this study group 5% (n=27) of subjects had a 2^0C or more contralateral difference in temperature with the remainder 95% (n=518) having less than 2^0C or no difference in temperature between limbs.

Table 6.1 - Distribution of temperatures recorded within study group.

	Left foot(°C)	Right foot (°C)
Mean	29.73	29.65
Median	29.86	29.83
SD	2.07	2.04
Range	22.39 – 34.22	21.33 – 33.89

The following table describes the difference between contralateral limbs as a complete group and also those with a temperature difference equal to or greater than 2^0C and those with a lesser or no difference.

Table 6.2 Intra-subject foot temperature differences in degrees

	Mean	Median	SD	Min	Max	% of total
Complete group	0.69	0.50	0.65	0.00	5.39	100
=/>2°C	2.63	2.28	0.82	2.00	5.39	5
< 2°C	0.59	0.44	0.45	0.00	1.94	95

The number of subjects showing a difference in contralateral foot temperature =/> 2^0C was low at 5% showing no significance.

97.8% of subjects had a normal healthy pink colour for both left and right feet, 1.6% presented with both left and right feet being abnormal in colour and the remaining 0.6% showing unilateral abnormality.

The presence of oedema was found in 26.8% of subjects which was predominantly bilateral with only 1.8% presenting with oedema unilaterally. 25.5% presented with oedema of the right foot and 26.3% of the left foot. The following cross tabulation table illustrates the findings within subjects. As with foot temperature, there was not a sufficient number of subjects presenting with oedema bilaterally or unilaterally to show significance in isolation and any association with other diabetic related foot complications will be considered in a later chapter.

Table 6.3 Presence of oedema

		Right foot	
		Ab	N
Left foot	Ab	25%	1.3%
	N	0.5%	73.2%

Lesions and deformities have long been considered as complications that perhaps do not cause foot ulceration in isolation but can contribute to the development of foot ulceration. The presence of these lesions and deformities were noted for each subject, the results of which can be seen below (Table 6.4).

Table 6.4 Distribution of foot lesions and deformities within study group

Lesions identified	**%**	**(number)**
Callus	55.2	(301)
Corns	20.4	(111)
Fissures	2.6	(14)
Nail pathologies	10.5	(57)
Inter-digital maceration	4.0	(22)
Deformity identified	**%**	**(number)**
Hammer toes	12.3	(67)
Retracted/clawed toes	27.3	(149)
Hallux valgus (HV)	13.4	(73)
Prominent metatarsal heads	15.8	(86)
Charcot arthropathy	1.5	(8)
Amputation at any level	1.1	(6)

The most frequently occurring lesion was callus formation in 55.2% (n=301) of subjects, recorded as having one or more areas of plantar or dorsal callus present. The most frequently occurring deformity was that of retracted or clawed toes in 27.3% (n=149) subjects. Of those presenting with callus, 32.9% (n=99) also presented with retracted or clawed toes, 20.3% (n=61) with prominent metatarsal heads, 18.3% (n=55) with Hallux valgus, 17.6% (n=53) with hammer toes and 2.7% (n=7) with Charcot arthropathy.

20.4% (n=111) of subjects were recorded as having corns, and of these 81% (n=90) had accompanying callus, 36% (n=40) had retracted or clawed toes, 31.5% (n=35) had prominent metatarsal heads, 26% (n= 29) presented with hallux valgus, 19%

(n=21) with hammer toes and 3.6% (n=4) with Charcot arthropathy. Those identified has having an amputation all presented with digital amputations.

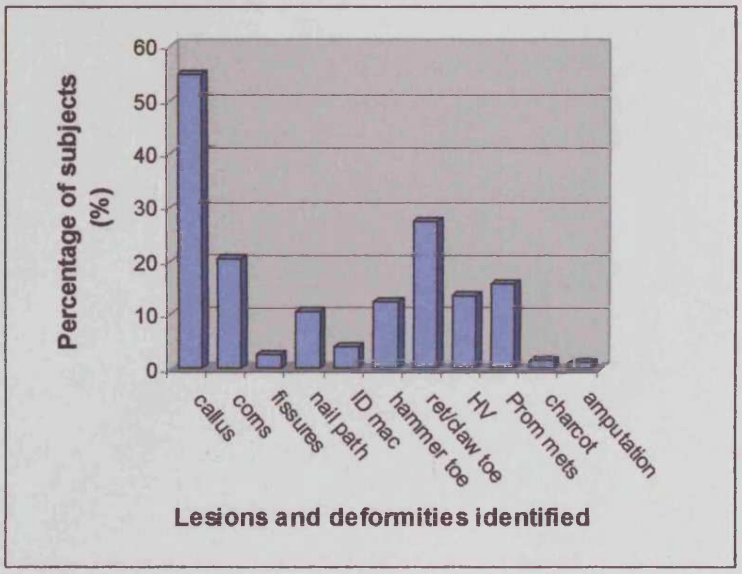


Figure 6.3 Distribution of lesions and deformities identified within the study group.

Those subjects who had suffered previous foot ulceration were also identified and represented almost 3% of the total study group (2.9%, n=16). The lesion and deformity characteristics of those with a history of foot ulceration are described below.

Previous foot ulceration

Callus	=	81%
Corns	=	31.2%
Fissures	=	6.3%
Nail pathologies	=	12.5%
ID maceration	=	6.3%
Hammer toes	=	37.5%
Retracted/clawed toes	=	43.8%
Hallux valgus	=	25%

Prominent metatarsal heads	=	43.8%
Charcot arthropathy	=	25%

6.3 **Summary**

The presence of callus appears to be a significant factor within this patient group, as does foot shape with 30-50% presenting with deformity. Lesions and deformities like these are identified as important complications especially in the presence of neuropathic and vascular deficits.

The careful and thorough inspection of each foot allowed for the identification of all presenting lesions and deformities. The thorough inspection of footwear, inside and out, allowed for the causative factors of the lesions to be identified, thus allowing for identification, illustration and education of the impact of ill fitting footwear on foot health. 3% of the total study group were recorded as having had a previous ulcer, with more than 80% of these identified as having callus present and 25-45% identified as having hammer, retracted or clawed toes, prominent metatarsal heads, corns or combinations of these lesions and deformities.

Although approximately 50% presented with deformity, it was evident that very few patients wore appropriately accommodating footwear and even those issued with bespoke footwear rarely wore them, if at all.

Exploration of foot temperature data revealed little benefit for identifying the 'at risk' foot however it was considered useful in the identification of hot spots (under lying infection) of the foot.

6.4 **Executive Summary**

- The presence of callus and deformity of the foot had a high presence in this subject group. Those having previous foot ulceration showed this to be highly significant.
- The message of the importance of correctly fitting footwear appears to be acknowledged by the subjects but is not being addressed by >50% of those subjects with foot deformity.

CHAPTER SEVEN: ASSESSMENT OF THE NEUROPATHIC STATUS OF THE FOOT

7.1 Introduction

Diabetic peripheral neuropathy is one of the most prevalent of the complications of diabetes, affecting approximately 30%-50% of the diabetic population (Kumar et al. 1994; Young et al. 1994; Young et al. 1995). 15% of persons with diabetic neuropathy develop ulcers in their life time (Bild et al. 1989). Diffuse symmetrical distal sensory motor neuropathy is the commonest form of peripheral neuropathy (Young et al. 1995) and can generally be divided into painful and painless varieties. There are two extremes of the scale in which some patients have very painful symptoms with very few signs of neuropathy, whilst many more may be insensate with few, if any, symptoms. Painful neuropathies are difficult to treat and can be distressing for the patient but are fortunately in the minority. These patients are generally less likely to develop significant morbidity of neuropathy, namely foot ulcers where as the asymptomatic patient with an insensate foot is at greater risk. Unfortunately, these latter patients do not have the painful warning signs that there might be something wrong, they fail to seek any foot care for ulcer prevention and may not be aware of the presence of an ulcer until it has been present for some time. For this reason, unless regular screening of all patients' with diabetes and more frequent assessment for asymptomatic patients is performed it will continue to be common for an ulcer to be the first presenting sign of neuropathy.

The detection and assessment of peripheral neuropathy is varied, ranging from simple single sensory tests, to highly quantitative multiple testing. The quantitative sensory tests assess the cutaneous sensation using methods that give actual numerical values reflecting the degree of sensory function. These quantitative tests are however, psychophysical tests so tend to have higher coefficients of variation than other electrophysiological tests, but do have the advantage of being able to test different

nerve fibre types and with the results combined, can provide a more complete picture of the level of damage to the nerve fibres in individual patients.

The measurements of light pressure and vibration perception threshold reflect large nerve fibre function, and are essential elements of any neurological examination, providing routine methods of screening for peripheral neuropathy. The current and most frequently used methods (by Podiatrists, GP's and Practice Nurses in the Primary Care setting) for sensory testing are those of the Semmes-Weinstein 10g-monofilament for light pressure and/or the non-graduated 128Hz tuning fork for vibration. Each was felt to offer a quick and simple method of assessing the presence or absence of diabetic neuropathy. The traditionally used non-graduated tuning fork, which was invented in 1711 and introduced by Bonnafont as a diagnostic test in general medicine (Martina et al. 1998), only measures the presence or absence of the vibration sense with no quantification of the degree of dysfunction. It is of clinical importance that the vibration sense should be measured quantitatively and consistently, as this allows for the progression of dysfunction to be monitored. Restricting the tests for presence or absence of neuropathy to only these two methods provides only a limited ability to obtain a comprehensive neurological status of that foot. By introducing additional and/or alternative quantitative methods of assessment (Goldberg & Lindblom 1979), a fuller picture of an individual's neuropathic status can be determined. This will allow earlier detection, and where necessary earlier and more appropriate referral and treatment, it also allows for documentation of the progress of an individuals' neuropathy status over time.

In this study, assessment of the medium and large nerve fibres was carried out using 1) the Rydel-Seiffer graduated tuning fork (Granton Ragg Ltd, England), representing the currently most often used semi-quantitative method of assessment of vibration

perception, 2) the Neurothesiometer (SLS, Nottingham), as the less used technology in the community for quantitative assessment of vibration perception thresholds, 3) for light pressure assessment, the10g-monofilament end of the Neuropen was used (Owen Mumford, Oxford).

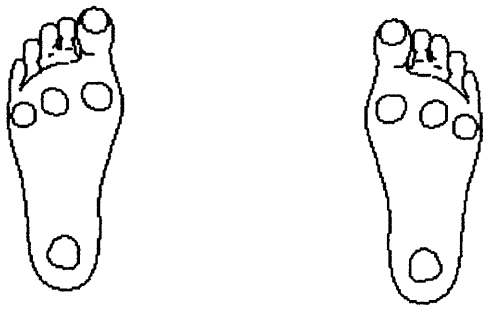
Small nerve fibre function was assessed using 1) the Neurotip end of the Neuropen for sharp sensation and 2) a cold tuning fork for temperature appreciation. Details of the methodologies used for all of these tests can be seen in Chapter 4.

7.2 **Results**

The neurological tests used have generally accepted values for what is considered normal or abnormal, some of which are stated within nationally published guidelines. An abnormality in one or more of these neurological tests would be considered sufficient to identify peripheral neuropathy.

7.2.1 10g-monofilament

As previously mentioned the 10g-monofilament was used to test the ability to feel light sensation at the five sites on each foot illustrated in figure 7.1. If a subject was unable to feel the monofilament at any one or more of the five sites tested on either foot, they were considered as having neuropathy.



Plantar right foot Plantar left foot

Figure 7.1 – 10g-monofilament test sites as found on the Patient assessment Form.

Out of the 1,090 limbs that were tested (545 subjects), 27% (n=295) of the limbs were recorded as having an abnormal response to the 10g-monofilament and 73% (n=795) a normal response. When the left and right limbs were analysed independently it showed that 26.8% (n=146) had an abnormal response on the left foot and 26.1% (n=142) had an abnormal response on the right foot. The tables below show the distribution of monofilament results for the right and left limbs and the total numbers/percentages for abnormal and normal limbs within the study group (tables 7.1 & 7.2).

Table 7.1 - Distribution of responses to the 10g- monofilament.

Foot	<5 sites (insensate) % (n)	=5 sites (normal) % (n)	Total
Right	26.1% (142)	73.9% (403)	100% (545)
Left	26.8% (146)	73.2% (399)	100% (545)

Table 7.2 - The following table shows a more detailed break down of the monofilament scores for left and right limbs thus indicating the degree of insensitivity.

Number of sites Identified	Right foot % (n)	Left foot % (n)
0	4.2% (23)	5.2% (28)
<3	7.9% (43)	7.5% (41)
3-4	14.0% (76)	14.1% (77)
5	73.9% (403)	73.2% (399)
Total	100% (545)	100% (545)

Concordance between limbs was also considered. From the cross-tabulations below (table 7.3) it can be seen that those with a symmetrically normal response to the 10-g monofilament (68%, n=371) represent the largest group, followed by those that are considered bilaterally insensitive to the 10g-monofilament (22.2%, n=121). This leaves 9.8% (n=53) showing asymmetry in their response.

Table 7.3 – Cross tabulation between limbs for the 10g-monofilament.

		Left limb	
		<5 (ab)	=5 (n)
Right limb	<5 (ab)	22.2% (121)	4.8% (26)
	=5 (n)	5.0% (27)	68.0% (371)

The Chi-Square test for association was performed which gave a p-value <0.0001. From the smallness of the p-value, it can be concluded that there is a high association between left and right limbs, however it must be noted that 9.8% (n=53) of the subjects do have a unilateral abnormal response indicating the necessity for bilateral inspection.

When categorising the subject's neurological status it was the foot with the lower score for the monofilament that was considered for diagnosis. The subject did not have to have bilateral insensitivity to be considered as having peripheral neuropathy. With this in mind it was found that within this study group 68.1% (n=371) had a normal response in both feet, 9.7% (n=53) an abnormal response in one foot and 22.2% (n=121) an abnormal response to the 10g-monofilament in both feet (fig 7.2).

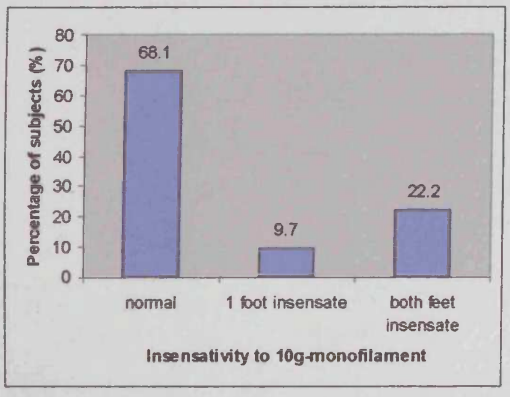


Figure 7.2-Distribution of insensitivity within case subjects when considering the lowest scoring foot for the 10g-monofilament.

7.2.2 Neurotip and temperature appreciation (small nerve fibre function)

Having both the monofilament and the Neurotip contained within the same Neuropen, enables both large and small nerve fibre tests to be carried out easily, however the test for 'sharp', (Neurotip) is not routinely performed. The subjects' response to the Neurotip was included in this study as an assessment of small nerve fibre function and was performed on the same test sites as the 10g-monofilament described previously. Those able to detect all 5 sites were considered as having normal perception of pain and those unable to detect one or more sites on either foot, considered insensate. The same considerations for callus over lying test areas were made.

Table 7.4 Distribution of neurotip results for the study group.

Foot	<5 sites (insensate) % (n)	=5 Sites (sensate) % (n)	Total
Right	17.6 (96)	82.4 (449)	100 (545)
Left	17.2 (94)	82.8 (451)	100 (545)

The table above shows the percentage (and numbers) of those found to be insensate and those found to have full sensation for both right and left limbs.

The table below (table 7.5), indicates the degree of insensitivity of the subject's feet by identifying the number of sensate sites for each foot.

Table 7.5 Shows the number of sensate sites for each foot and cross-tabulation showing concordance between limbs.

Number of sites Identified	Right foot % (n)	Left foot % (n)
0	1.8%(10)	1.8%(10)
<3	6.4%(35)	6.0%(33)
3-4	9.4%(51)	9.4%(51)
5	82.4%(449)	82.8%(451)
Total	100%(545)	100%(545)

		Left limb	
		<5 (ab)	=5 (n)
Right limb	<5 (ab)	13.6% (74)	4.0% (22)
	=5 (n)	3.7% (20)	78.7% (429)

It was found that 78.7% (n=429) of subjects had a normal response to the Neurotip on both feet and 21.3% (n=116) had an abnormal response at either one or both feet. It should be noted that although the concordance between limbs was highly significant with $p<0.001$, 7.7% (n=42) of feet tested had a unilateral abnormal response to the neurotip sharp sensation.

Temperature appreciation was also carried out to assess small nerve fibre sensitivity. The results were compared to those of the neurotip and were found to be highly concordant ($p<0.001$). The cross-tabulation below illustrates the findings which can be compared with those of the neurotip in the table above.

Table 7.6 Cross-tabulation of thermal appreciation results for right and left limbs.

		Left limb	
		ab	n
Right limb	ab	11.7% (64)	4.4% (24)
	N	3.9% (21)	80% (436)

As previously mentioned, these small nerve fibre function tests were not used for diagnostic purposes within this study.

7.2.3 Vibration Perception Thresholds (VPT)

The measurement of vibration perception threshold is a routine method of screening for peripheral neuropathy in diabetes, and impaired vibration perception is associated with an increased risk of foot ulceration (Young et al. 1993). The 128-Hz plain or Rydel Seiffer graduated tuning fork are the most frequently used method for

perception thresholds in the community, as previously mentioned, due to the benefits of being reasonably priced and very portable. Clinicians in hospital outpatient departments more frequently use the Neurothesiometer although it is larger and has higher cost implications. The difference between the graduated tuning fork and Neurothesiometer, other than size and cost, is that the Neurothesiometer gives a quantitative value for vibration perception with 0.5 volt increments up to 50 volts, and the tuning fork will give a semi-quantitative value with an arbitrary scale of zero to eight.

Vibration perception thresholds are probably the most widely used of the quantitative sensory tests. Although neuropathy is thought to follow a stocking distribution from the digits back proximally across the foot and up the lower limb, both the pulp of the hallux (great toe) and medial malleolus (inside ankle bone) are routinely assessed for vibration perception. The results have therefore been analysed for left and right limbs at both the hallux and medial malleolus sites.

Rydel-Seiffer graduated tuning fork

The graduated tuning fork's scale appears on the weights fixed at the tip of each prong of the fork and represents the level of vibration perceived by the subject being tested. The actual level reached by each subject was noted although it is routinely accepted that the level of vibration perception scored between four and eight is considered normal, and a score below four is deemed abnormal or impaired (Martina et al. 1998). Table 7.7 illustrates the results for both left and right limbs and at both the hallux and medial malleolus. The score bands indicate the level of insensitivity felt by the subjects.

Table 7.7 – Distribution of insensitivity with Rydel-Seiffer tuning fork.

R/S tuning fork score	Right limb		Left limb	
	Hallux	Med. malleolus	Hallux	Med. malleolus
0	6.4%(35)	5.1%(28)	6.2%(34)	6.1%(33)
0.5-3.5	27.3%(149)	21.7%(118)	26.1%(142)	19.6%(107)
----------	----------	----------	----------	----------
=/>4	66.3%(361)	73.2%(399)	67.7%(369)	74.3%(405)
Total	100% (545)	100% (545)	100% (545)	100% (545)

Table 7.7 shows that on the right foot 66.3% (n=361) have a normal response to the tuning fork at the hallux and 33.7% (n=184) an abnormal response. On the left foot 67.7% (n=369) have a normal response at the hallux and 32.3% (n=176) an abnormal response. At the medial malleolus 73.2% (n=399) have a normal response and 26.8% (n=146) an abnormal response on the right limb, and on the left foot 74.3% (n=405) have a normal response and 25.7% (n=140) have an abnormal response.

It can be noted from the figures in the table above that there are a greater number of subjects with diminished vibration perception at the hallux than the medial malleolus (6.6% (n=36) greater on the left limb and 7% (n=38) on the right limb).

When concordance between limbs was considered it was found to be highly significant ($p<0.0001$, $df=1$) at both the hallux and the medial malleoli. It was noted however, that at the hallux 12.5% (n=68) and at the medial malleoli 13.6% (n=74) showed unilateral abnormality in response to the tuning fork.

Concordance was also considered between sites on each limb. Both right and left limbs showed 84.6% concordance between sites and 15.4% asymmetry and therefore highly significant with $p<0.0001$ ($df=1$). It is important to note the 15.4% (n=84) that

showed unilateral abnormality to the tuning fork, highlighting the need for bilateral examination.

Those subjects with an abnormal response to the tuning fork at either the hallux or the medial malleolus on either limb were considered as having diminished vibration perception or as having peripheral neuropathy. The responses of this subject group resulted in 52.5% (n=286) having a normal response and 47.5% (n=259) having an abnormal response to the tuning fork.

Neurothesiometer

The Neurothesiometer was also used to test vibration perception at the hallux and medial malleoli of both left and right limbs to give a quantitative value of the vibration perception threshold. The vibrating stimulus was set at zero and then gradually increased until the patient first reported that they could feel the stimulus at which point the actual voltage was noted. The process was repeated three times, as mentioned previously, using the calculated mean of the three tests thus reducing the coefficient of variation. The value for 'normal' vibration perception threshold of <25volts, as recommended by National Guidelines (NICE 2004), was used in this study with those scoring =/>25 volts considered as having an abnormal vibration perception threshold. Those unable to feel vibration at 50v (the top of the scale) were scored at 51v.

Table 7.8 - Summary of Neurothesiometer vibration perception thresholds (volts)

	Left hallux	Right hallux	Left med. mall	Right med. Mall
Mean	17.46	17.03	19.47	18.61
Median	15.50	15.00	18.00	17.00
(SD)	(9.11)	(9.07)	(9.03)	(8.70)
Min.	5.00	3.00	4.50	4.50
Max.	51.00	51.00	51.00	51.00

The bar graphs below represent the distribution of Neurothesiometer results for both right and left limbs at both test sites.

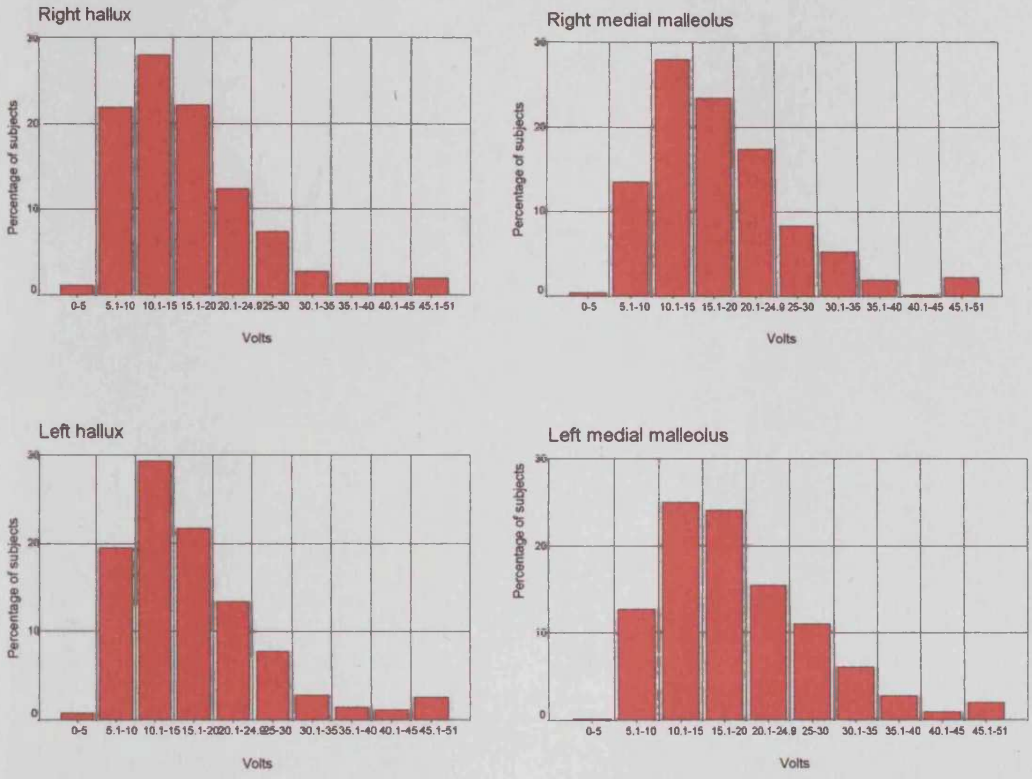


Figure 7.3 Neurothesiometer results for hallux and medial malleolus on both limbs

All of the bars in the above graphs are seen to be skewed to the left indicating that a larger proportion of subjects fall within the NICE guidelines cut off level for 'normal' of <25 volts. According to these guideline values, there was an abnormal response at the right hallux of 16.1% (n=88) and 16.7% (n=91) at the left hallux. These figures were slightly higher at the medial malleoli with 19.1% (n=104) on the right and 24.2% (n=132) on the left being recorded as having an abnormal response. When considering concordance between limbs 12.1% (n=66) were found to have a bilateral abnormal response at the hallux and 14.9% (n=81) to have a bilateral abnormal response at the medial malleoli.

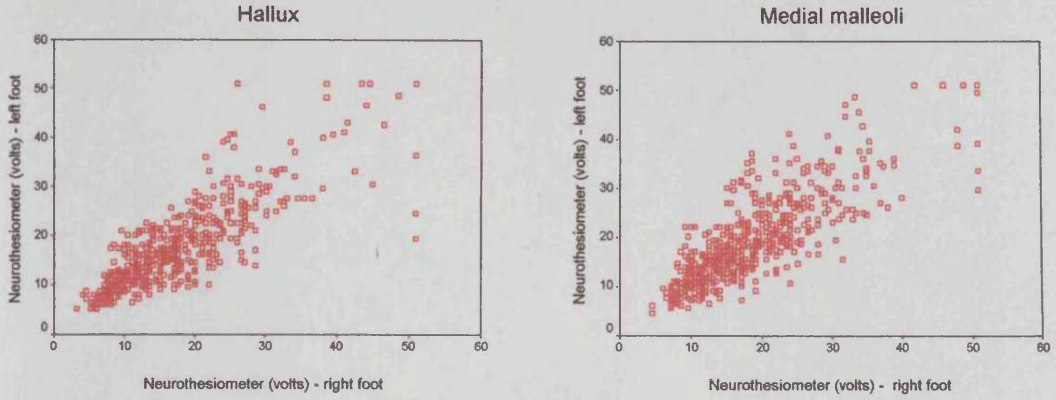


Figure 7.4 - The scatter plots above illustrate the distribution of vibration thresholds at each site bilaterally.

8.6% (n=47) were found to have a unilateral abnormality, 12.1% (n=66) a bilateral abnormality and 79.3% (n=432) having a bilateral normal response at the hallux. 13% (n=74) were found to have a unilateral abnormality at the medial malleoli, 15.5% (n=81) a bilateral abnormality and 71.5% (n=390) having a bilateral normal response at the medial malleoli.

When considering left and right limbs independently 77.3% (n=421) were found to have a normal response at the right hallux and right medial malleolus, 12.5% (n=66) having an abnormal response at both sites and 10.3% (n=56) having an abnormal response at just one site. On the left limb, 71.7% (n=391) had a normal response at both sites, 12.7% (n=69) an abnormal response at both sites and 15.6% (n=85) an abnormal response at just one site. It should be remembered that one or more abnormal sites on either limb would identify a subject as being neuropathic, 30.3% (n=165) of the total study group were therefore identified as neuropathic in this manner.

The results of the tuning fork and neurothesiometer tests were compared for concordance, the results of which can be seen below.

Table 7.9 – Distribution of results from the R/S tuning fork and neurothesiometer for the (a) hallux and (b) medial malleolus.

a) Hallux

	Hallux	
Right limb	***Abnormal***	***Normal***
Tuning fork	33.8%	66.2%
Neurothesiometer	16.1%	83.9%
Left limb	***Abnormal***	***Normal***
Tuning fork	32.3%	67.7%
Neurothesiometer	16.7%	83.3%

b) Medial malleolus

	Medial malleolus	
Right limb	***Abnormal***	***Normal***
Tuning fork	26.8%	73.2%
Neurothesiometer	19.1%	80.9%
Left limb	***Abnormal***	***Normal***
Tuning fork	25.7%	74.3%
Neurothesiometer	24.2%	75.8%

From the results above it can be seen that at the hallux, the tuning fork consistently identified twice as many subjects with neuropathy than the Neurothesiometer. At the medial malleolus the difference between the two modalities was much smaller especially on the left limb where there is only a 1.5% difference in the number of subjects identified. Having at least one abnormal site on either foot identifies the subject as neuropathic, therefore concordance between modalities with this in mind was analysed. The cross tabulation box below illustrates the findings.

Table 7.10 Comparison of tuning fork and neurothesiometer results

	Tuning fork		
	<4 (Ab)	=/>4 (N)	Total
Neurothesiometer			
=/>25v (Ab)	21.6% (118)	8.6% (47)	30.3% (165)
<25v (N)	25.9% (141)	43.9% (239)	69.7% (380)
Total	47.5% (259)	52.5% (286)	100% (545)

The above shows that 21.6% of subjects were identified as neuropathic using both modalities and 43.9% of subjects being identified as normal using both modalities. It also highlights however, that 25.9% of subjects were identified as neuropathic with just the tuning fork and a much smaller number (8.6%) identified as neuropathic with just the neurothesiometer.

The table below shows the results of the t-test carried out for the tuning fork and the neurothesiometer on both the case and control subjects for comparison.

Table 7.11 – Results of t-test for VPT in non-diabetic controls and diabetic case subjects using the neurothesiometer and R/S tuning fork.

	Normal controls (n=50) Mean (SD)	Patients (n=545) Mean (SD)	Significance t Value	p Value
Neurothesiometer (V):				
Right hallux	11.9 (7.5)	17.0 (9.1)	3.3	<0.001
Left hallux	10.6 (5.4)	17.5 (9.1)	8.1	<0.001
Right medial malleolus	12.8 (8.9)	18.6 (8.7)	3.4	<0.001
Left medial malleolus	12.0 (8.0)	19.5 (9.0)	6.2	<0.001
Tuning fork (arbitrary units)				
Right hallux	5.9 (1.7)	4.5 (2.0)	5.3	<0.001
Left hallux	6.2 (1.5)	4.6 (2.0)	6.8	<0.001
Right medial malleolus	6.0 (1.8)	4.8 (1.9)	4.8	<0.001
Left medial malleolus	6.5 (1.5)	4.8 (2.0)	7.4	<0.001

It can be seen that the diabetic case subjects had significantly higher thresholds for vibration perception than the non-diabetic controls for the neurothesiometer. The

tuning fork results showed a similar trend with significantly lower scores for the diabetic subjects on the arbitrary scale than those of the non-diabetic controls.

Without carrying out costly, time consuming nerve conduction studies on the subjects, we do not have a 'Gold Standard' for the identification of peripheral neuropathy through vibration perception thresholds. It is therefore hard to answer the question of which modality is more reliable at identifying those subjects with peripheral neuropathy. The one thing that did become clear while conducting the vibration perception tests was that most subjects felt it easier to detect vibration starting than to detect when vibration had stopped. The other question to be asked is whether the routinely used threshold cut off values are appropriate.

There have been a number of papers indicating that the magnitude of vibration felt by an individual may be influenced by certain factors, such as temperature, height, sex, smoking, alcohol consumption and age. The influence of age on vibration perception threshold results, although not routinely considered when assessing for neuropathy, has been repeatedly addressed in papers as an area of great importance (Armstrong et al. 1991; Meh & Denislic 2004; Verrillo et al. 2002; Wiles et al. 1991), and that such considerations should be taken into account when defining normal values. Age-related centile charts would allow use of vibration perception thresholds as a simple screening test for the presence of neuropathy and for long-term follow-up of such groups of patients.

It seems appropriate at this point to comment on the effect of age on vibration perception threshold levels of the diabetic study subjects and those of non-diabetic control subjects to allow interpretation of the results. Due to limitations of this study it was not possible to collate large numbers of non-diabetic control subject data therefore previously published study data for 'normal' vibration perception thresholds

were consulted (Armstrong et al. 1991; Wiles et al. 1991). Both the Armstrong study and Wiles study were considering vibration perception thresholds within non-diabetic subjects. They looked at both upper and lower limb extremities although it was the lower limb extremity results that were of most interest for this study. Although both studies reported their results graphically, they were unfortunately either presented without axis titles or in log data format. The Armstrong study actually stated that centile charts had been created from the results but after much searching and contact with the researchers it was not possible to obtain any raw data or the centile charts that had been referred to. However, the models fitted were decoded from the limited data presented which showed both papers reporting an increase of vibration perception with increased age as can be seen in the graph below.

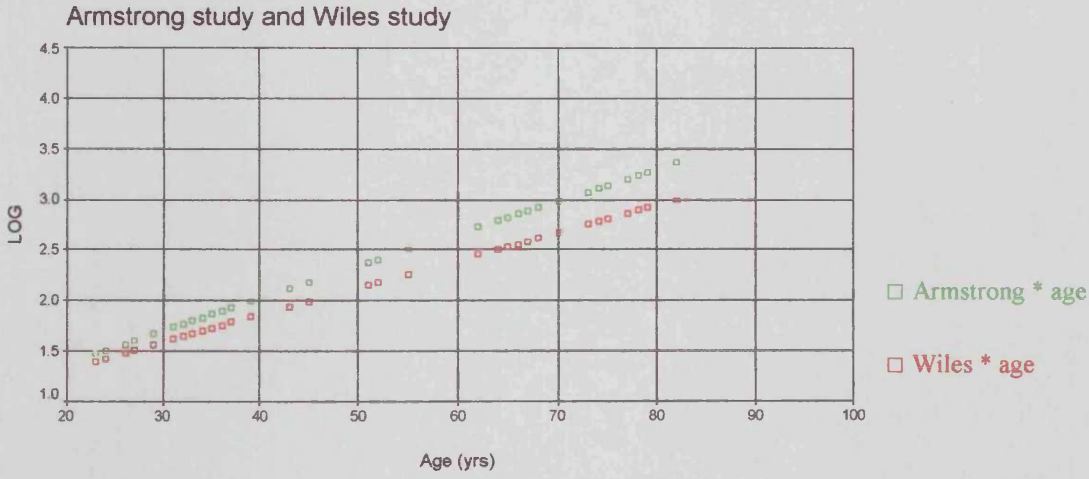


Figure 7.5 Armstrong control study and Wiles control study log VPT data plotted against age (yrs).

Both sets of results start at similar points but departed from each other for older ages with Armstrong's results increasing at a slightly steeper angle than that of Wiles. It was then necessary to establish if these models were valid for this study's data. The model was fitted to the smaller number of non-diabetic control log data (Figure 7.6) and the diabetic case log data (Figure 7.7) for the right hallux. After calculating the

estimate of standard deviation for the reference limits, the equations for the upper and lower limits were calculated.

Figure 7.6 Control subject log VPT data – (right hallux) plotted against age (yrs).

Figure 7.7 Case subject log VPT data – (right hallux) plotted against age (yrs).

The graphs above suggest that the angle of the linear regression line for both sets of data is very similar and is less steep than those of Armstrong or Wiles. The graph below (fig 7.8) illustrates Wiles, Armstrong, diabetic case, and non-diabetic control linear regression lines for comparison. It can clearly be seen that both the case and control lines have a higher starting point than Armstrong and Wiles yet their angles

are less steep with the case data finishing at a slightly higher level than the control data.

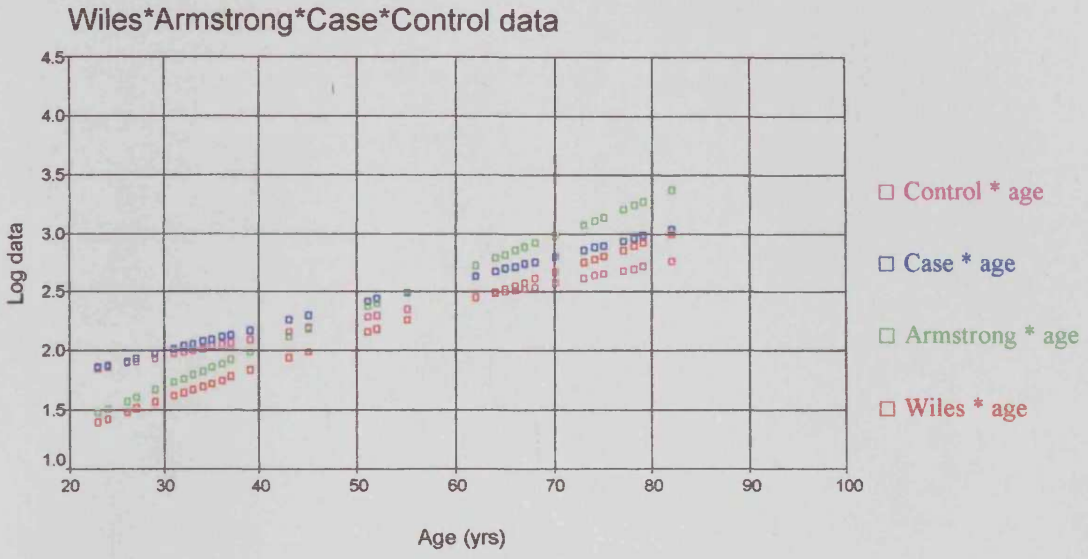


Figure 7.8 Linear regression lines for Wiles, Armstrong, study case, and study control log VPT data (right hallux).

From these results, it was considered more appropriate to use the control data from this study rather than the control data from either the Armstrong or Wiles studies for comparison, keeping in mind of course the lower subject numbers.

In order to establish risk factors for vibration perception in diabetic subjects the determination of normal reference limits for VPT using non-diabetic control data had to be carried out. Relationship between VPT and age was assessed graphically and analytically. As previously considered, graphical analysis suggested that both VPT and age were normally distributed in both the non-diabetic and diabetic subjects. The scatter plots above (figures 7.6 and 7.7) of logVPT against age suggested linear relationship although the data were very scattered.

Altman's method (Altman 1993) was used to determine VPT age adjusted 95% reference ranges which were then applied to the diabetic case data to enable classification of VPT status. 95% constant reference ranges were calculated as mean

non-diabetic log VPT ± 1.96 (2.0018) standard deviation (sample tolerance limits without confidence probability) (Diem & Lentner 1975). Tolerance limits were used to estimate 95% limits of the population since the population standard deviation is unknown, this being only a sample of the overall diabetic population.

Altman's method is a simple parametric approach for the determination of age related reference ranges which avoids the creation of arbitrary age groups. This method is based on the assumption that the variable has a normal distribution at all ages (as addressed above), therefore the un-standardised residuals from the regression of log VPT with age were checked for normality (residuals being the difference between the estimated log VPT value and actual log VPT value for the subjects age).

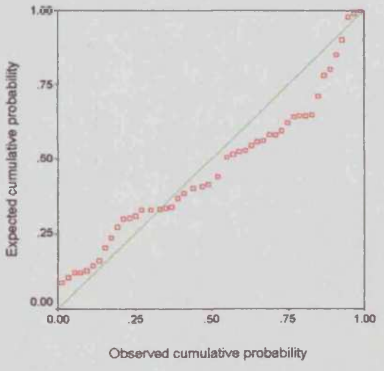
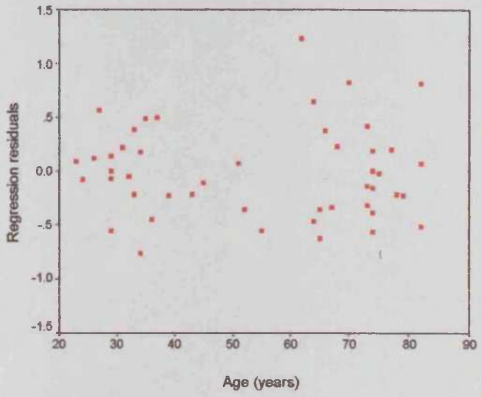


Figure 7.9 Normality plot of residuals

If the standard deviation is not reasonably constant over age then age-specific estimates of *s* (SD) need to be obtained. Therefore regression analysis was carried out to confirm that there was no dependence of the residuals on age. Regression analysis on non-diabetic data revealed no dependence of the absolute value of the residuals on age. Figures 7.10 and 7.11 shows the residuals and absolute residuals plotted against age for non-diabetic data. No significant trend with age was observed.



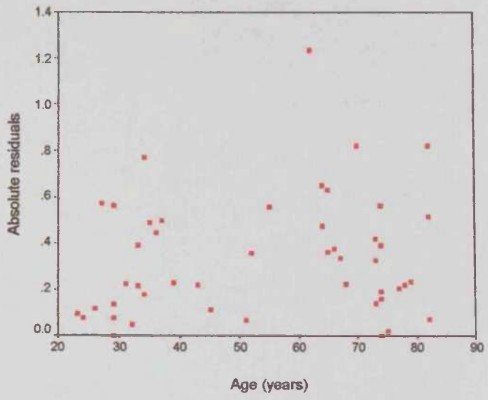


Figure 7.10 Regression residuals vs. age

Figure 7.11 Absolute residuals vs. age

Since the assumption is upheld, the absolute values of the residuals follow an approximate normal distribution and the standard deviation of the residuals (s) can be estimated by $\sqrt{(\pi/2)}$x(mean absolute residual). Upper and lower age adjusted reference limits can then be calculated for the non-diabetic subjects from mean logVPT $\pm$ k x s where s= 0.4024 and k=2.0296 for n=50 (sample tolerance limits without confidence probability) (Diem K and Lentner C 1975).

$$\text{logvpt} \pm 2.0296 \times 0.4024 \quad \text{i.e. logvpt} \pm 0.8188$$

Again tolerance limits were used since it is the estimated population 95% limits that are required, (upper and lower limits = 1.497 + 0.0155 x age $\pm$ 0.8188). These are then anti-logged to get the reference limits in the original units (volts).

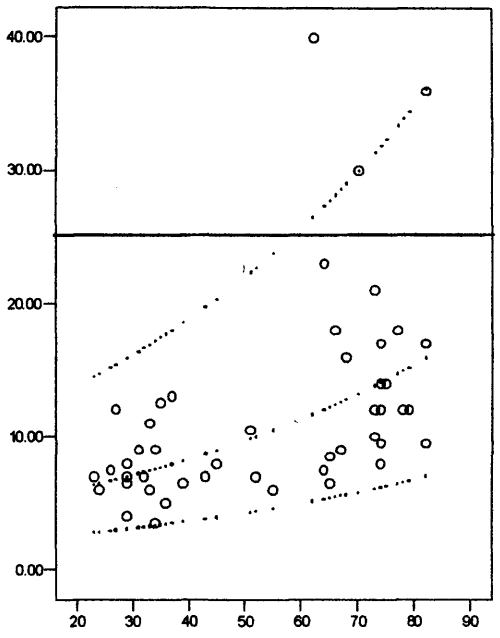


Figure 7.12 95% age adjusted reference limits for non-diabetic subjects (n=50) (anti-logged)

The normal non-diabetic maximum VPT value per decade can therefore be seen as:

20yr old = 14volts; 30yr old = 16volts;

40yr old = 19volts; 50yr old = 22volts;

60yr old = 25volts; 70yr old = 30volts and

80yr old = 34volts.

The same model was then applied to the diabetic case data to allow for valuable age-adjusted vibration perception threshold values to be obtained (Figure 7.13).

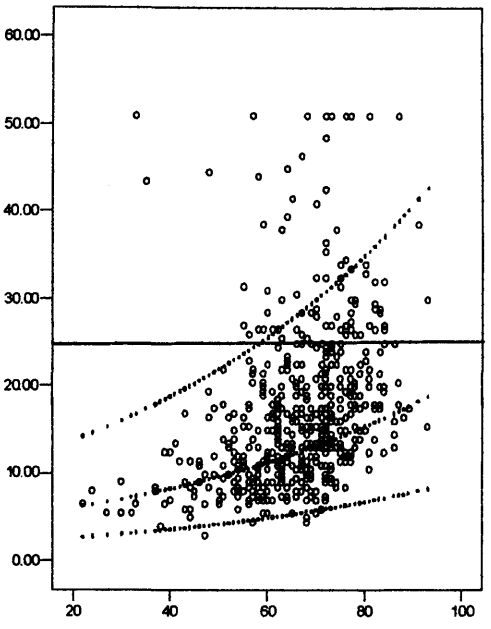


Figure 7.13 Age-adjusted reference ranges applied to diabetic case subject data (anti-logged).

The percentage of diabetic subjects with an abnormal VPT using the single cut off value of 25volts was 14.7% (n=80) for the right hallux. Using the calculated age adjusted upper limits, this is reduced to 6.6% (n=36). It should be noted that this example is for the right hallux only. However, if the above maximum age adjusted limits for the right hallux were applied to the case subjects worst VPT score, 15% (n=82) would be diagnosed as neuropathic rather than 30.3% (n=165) with the single cut off value of 25volts. As a patient is diagnosed on their worst scoring limb and site, centile charts for each limb and for both the hallux and medial malleoli should be referred to and indicates the need for further exploration of age adjustments.

7.3 **Summary – Neuropathy study.**

A total of 31.7% (n=173) of subjects were identified as having neuropathy using the 10g-monofilament and although there was a high association between left and right limbs, it is important to note that 9.8% (n=53) showed unilateral abnormality highlighting the need for careful assessment of both limbs when making a diagnosis.

The neurotip identified a total of 21.3% (n=116) subjects as neuropathic, again showing high association between limbs but again with approximately 10% having unilateral abnormality. 17.1% (n=93) of subjects were therefore found to be neuropathic by both the 10g-monofilament and the neurotip, leaving 73% (n=398) to be normal by both tests. 9.2% (n=50) were found to be abnormal using the 10g-monofilament but normal using the neurotip and just 0.7% (n=4) were found to be normal using the 10g-monofilament and abnormal using the neurotip. Tests between sites on each limb and between limbs were found to be highly concordant ($p<0.01$).

The Rydel Seiffer tuning fork identified a total of 47.5% (n=259) of subjects as neuropathic. High concordance between test sites on each limb and between limbs were found ($p<0.001$) however approximately 13% showed unilateral abnormality therefore highlighting again the importance of assessing both limbs when making a diagnosis.

The quantitative neurothesiometer identified a total of 30.3% (n=165) of subjects as having peripheral neuropathy (VPT $\geq$25volts). Concordance was seen between test sites and limbs however a slightly higher number were recorded has having an abnormal response at the medial malleolus than the hallux which might not be expected. Approximately 10% showed unilateral abnormality as did previous neurological tests, again highlighting the need for careful assessment of both limbs.

Reducing the VPT value to ≥21volts, increased the number of subjects identified as neuropathic to 48% (n=262) which is much closer to that identified by the tuning fork (47.5%, n=259), however the issue of adjustments for age was also explored.

The importance of adjusting vibration perception values for the subject's age became most apparent from the results. Figure 7.12 shows the great variation in normal reference ranges and illustrates the importance and usefulness of age adjusted centile charts during diabetic foot assessments. It should also be considered that if age adjustments are made to the scores of the neurothesiometer, age adjustments should also be made for the tuning fork and the 10g-monofilament. It was also recognised that there could be other potential confounders when considering normal VPT such as height, sex, smoking and alcohol effects. It was not the intention to consider these issues within this study however it was felt that a future study should be considered to explore these additional issues.

7.4 **Executive Summary**

- It is important to assess both limbs when checking for signs of neuropathy due to the degree of asymmetry shown between limbs within this study group.
- When assessing VPT, adjustments for age should be considered using centile charts giving normal values.
- Age adjustments for all neuropathic assessments should be considered.

CHAPTER EIGHT: ASSESSMENT OF THE VASCULAR STATUS OF THE FOOT

8.1 Introduction

As previously mentioned, amongst the major risk factors associated with diabetic foot disease is peripheral neuropathy (easier to manage, possibly easier to assess and was addressed in Chapter 7) and peripheral vascular disease, which will be addressed in this chapter.

There is growing evidence that the vascular contribution to diabetic foot disease is greater than has previously been realised (Diabetes Association 2003; Edmonds 1999; Jeffcoate & Harding 2003). Peripheral vascular disease, (PVD) also called peripheral arterial disease (PAD) or peripheral arterial occlusive disease (PAOD), is thought to be common in diabetic foot ulceration (Dinh & Veves 2004). In fact it has been demonstrated to be a greater 'risk-factor' than neuropathy in both foot ulceration and lower limb amputation in patients with diabetes (Alder et al. 1999; McNeely et al. 1995), and can be present in 30% of this diabetic population (Dinh & Veves 2004).

Ischemia in itself is not only a 'risk-factor' for development of a foot ulcer, but it also complicates and delays wound healing. Peripheral vascular disease in diabetes is characterized by impairment of both the micro- and macro-vasculature. The macrocirculatory disease in diabetic patients is essentially similar to the atherosclerotic changes found in non-diabetic patients (Dinh & Veves 2004), where as the microcirculatory disease is unique to the patient with diabetes.

Although it is generally recognised that small vessel disease exists in lower limb cutaneous tissue, its exact nature is unclear. It is likely that the micro-vascular changes seen in Type 1 and Type 2 diabetes have both common and separate causal pathways (Tooke 2000). Type 2 patients may well have been exposed to high levels

of glucose and insulin for many years prior to diagnosis. This is in contrast to Type 1 diabetes who generally would have presented relatively acutely and not been exposed to metabolic disturbances for a long period.

Basement membrane biochemical and physical changes have been identified in all types of diabetes and generally affects all tissues. While there are no occlusive lesions in the diabetic micro-circulation, structural changes do exist, most notably, thickening of the capillary basement membrane. These changes decrease the vessel wall elasticity, limiting vasodilation and can also act as a barrier to the normal exchange of nutrients and cellular migration, decreasing the ability of the diabetic foot to fight infection and thus contributing significantly to impaired wound healing, (Dinh & Veves 2004) particularly in the presence of significant macro-vascular disease.

Before macrovascular disease is established, diabetes, especially Type 2 diabetes, is associated with structural and functional changes in large arteries that lead to abnormal pulse wave motion (endothelial dysfunction), increased stiffness (atherosclerosis), and systolic hypertension. Structural changes result mainly from glycation of vessel wall components and lipid deposition. Functional changes originate in endothelial dysfunction with impaired vasodilation. Increased arterial stiffness and/or decreased distensibility due to sheer stress on endothelial cells, increases pulse wave velocity and the amplitude of reflected waves, so that reflected waves arrive early and increase the central systolic pressure (Nicolaides & Jones 2002). The non-atherosclerotic structural and functional changes seen in large vessels are the result of modification of elastin and collagen by cross-linking due to non-enzymatic glycation, so-called advanced glycation end-products (AGEs) via its receptor (RAGE). AGEs are found in many tissues of diabetic patients and are responsible for many identified structural and functional changes. It has been

hypothesised that increased numbers of these end-products interact in the arterial wall and act as a focus for chronic inflammatory vasculitis and thereby predispose to atherosclerosis (Colwell 1999).

In individuals with diabetes and autonomic neuropathy, scleroses of arterial and venous vessel walls are common findings and are associated with calcium deposition (Monckeberg's medial calcification) in lower limb arteries. Associated changes in endothelial function and intima-medial thickness play an important role in large vessel disease and the subsequent development of hypertension and cardiac disease. Early functional changes in large vessels have been identified in first-degree relatives of Type 2 diabetic patients (Nicolaides & Jones 2002).

The atherosclerosis seen in Type 2 diabetes, which is often advanced when diabetes is first diagnosed, have given rise to the hypothesis that atherosclerosis may precede diabetes and progress in parallel. Chronically elevated plasma insulin levels in Type 2 diabetes have been cited as a possible cause and insulin resistance has been associated with decreased toe-brachial pressure indices (Wollesen et al. 2002). Increased arterial stiffness, (as measured by increased pulsewave velocity), a potential early marker of arterial disease, has been demonstrated to be elevated in patients with diabetes. Diabetic lower limb atherosclerosis is frequently associated with heavy calcification, which further complicates assessment imaging (Laser Doppler, Colour duplex imaging) and treatments.

The autonomic nervous system is closely related to the lower limb circulation. Its disruption therefore has significant affects on both the macro- and micro-circulation. Disruption of vascular sympathetic innervation causes vasodilation and decreased peripheral resistance. This results in lower limb venous pooling and oedema formation.

As peripheral neuropathy is a frequent dominant feature when assessing the diabetic foot, it often leads to the failure in recognition of less obvious ischaemic clinical presentation. Neuropathy may mask the typical symptoms and signs of lower limb ischaemia where they occur together in the lower limb, confusing diagnosis.

The presence of an impaired vascular system due to macro-vascular disease and a dysfunctional micro-circulation, could impair the local hyperaemic response to infection, making diagnosis more difficult (Williams et al. 2003).

There are a growing number of tests that reflect the vascular status of the lower limb, its perfusion and/or oxygenation. The detection of peripheral vascular disease is paramount in treating diabetic foot disease, as vascular insufficiency is potentially reversible. Therefore the aim of this part of the study is to determine the single or combination of tests to best describe the status of the peripheral vasculature of the foot.

As signs and symptoms of lower limb arterial insufficiency in diabetes can often be unreliable, additional information via non-invasive tests are of great importance and are an integral part of the vascular element of the diabetic foot assessment. All tests are limited however and testing in the community setting puts limitations on the use of more specialist vascular tests such as those that provide information on perfusion at tissue level or those that reflect tissue oxygenation (Transcutaneous oxygen tension - TcPO2). There are a number of procedures that can be carried out in the community that can provide valuable insight into the vascular status allowing for appropriate referral for more complex vascular assessment if and when necessary.

In previous studies the extent of the vascular assessment commonly amounts to whether foot pulses are present or absent on palpation. The two main arteries

palpated at the foot and ankle, are the dorsalis pedis, palpated between the first and second metatarsals on the dorsum of the foot and the tibialis posterior, palpated just posterior to the medial malleolus at the ankle. In 10% of the non-diabetic population and in a greater proportion of people with diabetes, one of these pulses can be absent. In addition, patients with diabetes are more prone to peripheral oedema which makes palpation of pulses more difficult. Therefore, detecting and characterising foot pulses are often difficult in patients with diabetes. In a previous study four experts testing pulse presence in the foot had a 53% agreement for the Posterior tibial pulse and 67% for the Dorsalis pedis pulse (Cavanagh 2004). It is also recognised that the absence of pulses, due to the difficulties in assessment, is not a true indicator of vascular insufficiency (Williams D.T. et al. 2003). Therefore evidence shows that palpation of pulses as a single vascular screening method has limitations and that additional vascular investigations are required when assessing the foot for vascular disease.

In cases of diabetic patients with foot ulceration, the Second European Consensus Document recommends additional, non-invasive vascular assessments (The International Working Group on the Diabetic Foot 2003), to include the Ankle-Brachial Pressure Index (ABPI) and Toe-Brachial Pressure Index(TBPI). Presence or absence of palpable pulses gives little insight into the efficiency of the circulation and its ability to heal wounds. There is therefore a need to determine the single or combination of tests to best describe the status of the peripheral vasculature in the foot.

In this study, assessment of the vascular status was carried out by 1) the palpation of foot pulses, namely the dorsalis pedis and posterior tibial pulses of both limbs, which represents the current, most frequently used method of vascular assessment, and 2) by using the Vascular Assist (Huntleigh Healthcare) allowing for Ankle-Brachial

Pressure Index (ABPI's) and Toe-Brachial Pressure Index (TBPI's) to be calculated, audible and visual identification of waveforms and pulse volume records (PVR's) to be made within one easy to use piece of equipment, this being the lesser used technology.

The handheld Doppler and ABPI/TBPI (Ankle-brachial/Toe-brachial Pressure Index) technique allows comparative measurement of upper and lower limb systolic blood pressures (SBP). The blood pressure cuff is applied to the upper arms and proximal to the ankle with the return of blood flow during the graduated release of the cuff being detected audibly by a Doppler probe placed over the artery representing the SBP. This technique is more sensitive than finger palpation, often detecting blood flow in 'pulseless' vessels and relaying basic blood flow characteristics on screen. The posterior tibial artery is the vessel of choice for hand held Doppler assessment, however if it is difficult to assess due to ulceration or oedema, the dorsalis pedis should be used. The Doppler probe should be held at between 45^0 and 60^0 in the line of the artery and requires the application of a water-based coupling gel to the skin (figure 4.14).

TBPI is an additional investigation. The arterial calcification seen frequently in the lower limb arteries of patients with diabetes often spares the digital arteries. Thus the potential for artificially raised systolic pressures generated by calcified, poorly compliant arteries at the ankle is avoided. This test may then reveal arterial insufficiency, otherwise hidden by a normal or elevated ABPI (Johansson et al. 2002).

The Photoplethysmography (PPG), using an infrared sensor, is probably the most commonly used method but can be hampered by oedematous or short toes unable to accommodate both tourniquet and sensor. It has been commented that an ABPI of >1.30 suggests that the index is unreliable and TBPI should then be calculated

(Brooks et al. 2001). More recent studies have suggested ABPI arbitrary values of 1.15 or 1.40 to be the upper limit. However, in the presence of diabetic peripheral neuropathy, arterial calcification is far more likely and the accuracy of ABPI's must then be in doubt (Edmonds et al. 1982).

Previous studies have demonstrated reduced toe pressures in patients with recurrent ulceration, or with a history of foot infection, but no significant reduction of toe pressure in the absence of foot disease (Edmonds et al. 1982). A patient with foot disease and a falsely elevated ABPI is therefore potentially at a greater risk than a patient with low ABPI subsequently identified on duplex scanning as having no significant arterial disease. It could be argued that in the presence of peripheral neuropathy, a TBPI should be performed. In the absence of peripheral neuropathy an ABPI would be sufficient and an ABPI <0.9 generally would require colour duplex assessment for further definition of Peripheral Vascular Disease.

The Doppler waveform analysis technique relies on the interpretation of a continuous Doppler waveform usually by a single ultrasonic transducer, which emits and then receives a reflected ultrasonic beam from blood flowing through a vessel in its field. The technique can be used to assess flow in any vessel, but its use in assessing the waveforms of the lower limb arteries has generated much interest. Higher ultrasonic frequencies are utilised where possible, typically 5 to 8MHz, as this gives better waveform definition. The Doppler waveform is displayed on screen with qualitative analysis being based on the shape of the wave profile. The waveform profile in the lower limb arteries are normally triphasic throughout their length with preservation of reverse flow. The waveform is influenced by cardiac function, vessel disease and altered peripheral resistance. The presence of significant arterial stenosis causes a loss of reverse flow distal to the obstruction demonstrating both a reduction of the

signal amplitude and loss of reverse flow, thus changing the waveform to a biphasic or monophasic profile. In the presence of diabetic foot disease, a reduced signal, particularly a monophasic signal, even in the presence of foot pulses, would warrant further investigation. In the absence of foot disease, a reduced monophasic signal with absent foot pulses warrants further attention.

The pulse volume recorder, records instantaneous pressure changes in the segmental monitoring cuff that is placed around the extremity. Cuff pressure change reflects alteration in cuff volume, which in turn reflects momentary changes in limb volume. The PVR unit is calibrated so that 1 mmHg pressure change in the cuff provides a 20 mm chart deflection. Simultaneous PVR traces have been compared with direct intra arterial pressure recordings taken at the same location to determine the optimal cuff pressure required. In clinical practice it was reported that a cuff pressure of 65 mmHg gives excellent pneumatic gain and surface contact and maintains the important contour characteristics (Raines 1993).

8.2 **Results**

Vascular data was collected from all subjects using the methods detailed in the earlier methodology chapter (Chapter 4.4). The recording of basic pulse palpation through to collection of ankle/brachial pressures, toe/brachial pressures, waveform analysis and pulse volume record data allowed for the comparison of procedures and more importantly, analysis and comparison of the results obtained.

The results in this chapter will be concentrating on those presenting with one or more vascular deficits. There is much debate in the literature with respect to the identification of peripheral vascular disease in patients with diabetes. Therefore for the purpose of this study, the criteria for identifying peripheral vascular disease was

less than 2 pulses present per foot and/or an ABPI arbitrary value of <0.9 or >1.30 on either limb and/or a TBPI arbitrary value of <0.5 on either limb.

Those with 2 pulses per foot present, a normal ABPI (0.9 - 1.30) and a normal TBPI (>0.5) were considered as not having vascular complications; those with less than 2 pulses per foot, and/or an ABPI <0.9 or >1.30 but with a TBPI >0.5 would be considered as having vascular complications and impaired healing ability; and those with less than 2 pulses present per foot; and/or an abnormal ABPI and a TBPI <0.5 would be considered as high risk with compromised healing ability. Posterior tibial waveforms and pulse volume records were also determined and will also be considered.

The number of patients with peripheral vascular disease only, as defined by the above criteria represented 8.8% (n=48) of the total number of subjects assessed (n=545). Those with mixed origin represented a further 22.6% (123) making the total number of subjects displaying a vascular dysfunction as 31.4% (n=171) of the whole study group (n=545) and it will be this group (n=171) that will be considered within this chapter.

The gender split was fairly even with males representing 53.2% (n=91) and females representing 46.8% (n=80). Subjects with Type 2 diabetes represented a much larger proportion of those with vascular complications (81.3% n=139 (25.5% of the total group and 31.5% of all Type 2 subjects)) than Type 1 subjects (18.7%, n=32 (5.9% of the total group and 30.8% of all Type 1 subjects)). The majority of those with vascular complications fell within the 50-90 year age groups.

The mean age = 70.5yrs, median age = 72yrs, SD = 9.8yrs (range = 37-93years).

56.1% (n=96) of the subjects were non-smokers, 32.2% (n=55) were ex-smokers and 11.7% (n=20) were smokers. The profile of the case subject at this stage would be a 70-79 year old male with Type 2 DM with a history of smoking.

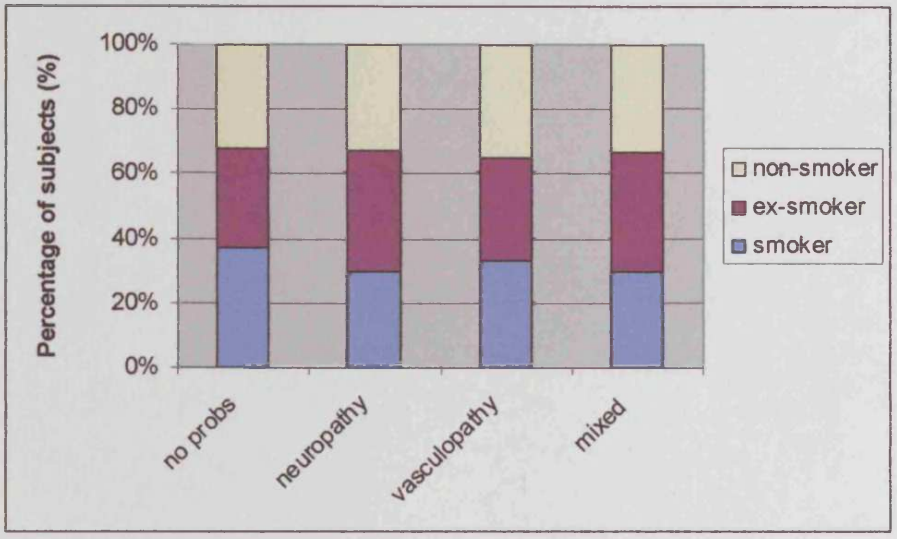
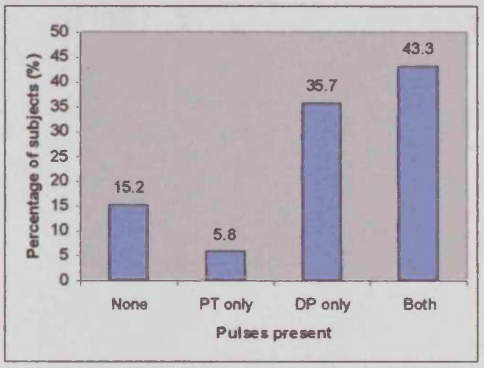


Figure 8.1 - Distribution of smoking habits within pathology groups.

As can be seen from the graph above, there is little difference in the smoking habits of subjects between the pathological groups. Although it was perhaps surprising to see the largest group of smokers did not have neuropathic or vascular complications.

The following figure illustrates the distribution of palpable pulses within the group categorised as having vascular complications (vasculopathy only and mixed groups n=171).

Right foot



Left foot

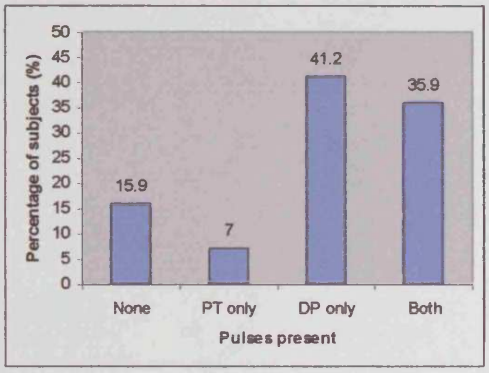
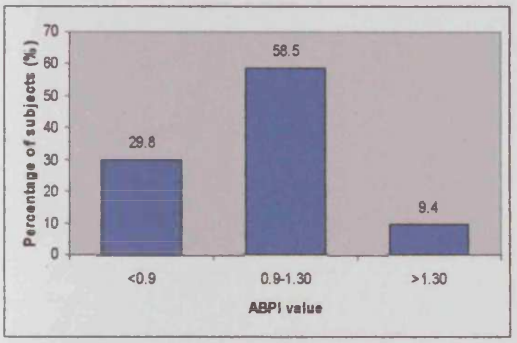


Figure 8.2 – Distribution of pulses present in right and left feet.

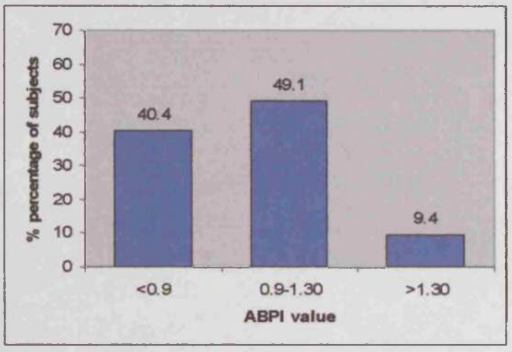
In the graphs above, a similar number of subjects have both pulses absent in each foot. The graphs also illustrate that a larger proportion of subjects have just the dorsalis pedis present (right foot 35.7%, left foot = 41.2%) than those that have just the posterior tibial pulse present (right foot = 5.8%, left foot = 7%). A difference also exists in those with both pulses present, in the right foot these represent 43.3% of subjects and in the left foot 35.9% of subjects which results in 56.7% (n=97) having one or more pulses absent in the right foot and 64.1% (n=110) having one or more pulses absent in the left foot.

An additional test for assessing vascular status is the calculation of the ankle/brachial pressure index (ABPI). This is calculated by dividing the ankle systolic pressure by the higher of the two brachial systolic pressures, as previously mentioned. The graphs and scatter plot below show the distribution of ABPI values for both left and right limbs. It was not possible to obtain an ABPI for 4 subjects on the right foot and 2 subjects on the left foot within this group.

A) Right limb



B) Left limb



C) Right and left limbs

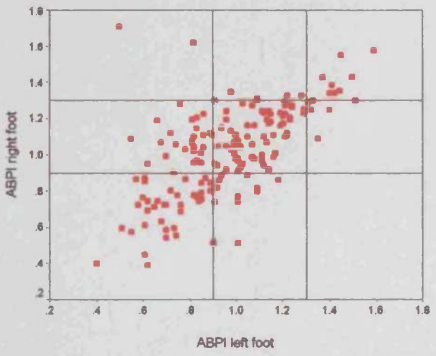


Figure 8.3 Distribution of ABPI values for A) right and B) left foot and C) compared with each other.

The reference lines plotted on the scatter graph represent the current cut off levels for normal and abnormal values. A person does not need to have a bilateral abnormal score to be categorised as having vascular complications, unilateral abnormality is sufficient. With this in mind, 46.8% (n=80) of subjects had at least one limb scoring <0.9 and 11.7% (n=20) scoring >1.30. This left 40.9% (n=70) of subjects with a normal ABPI (0.9 -1.30).

When the ABPI results are compared to the number of pulses found, little or no correlation was seen. It was discovered that just 31.6% (n=54) were found to have an abnormal vascular status with both modalities.

Table 8.1 – Shows no correlation between pulses present and ABPI values.

	4 pulses present (n)	<4 pulses present (ab)	Total
ABPI <0.9 (ab)	27.0% (46)	20.0% (34)	80
ABPI 0.9-1.30 (n)	2.6% (4)	38.8% (66)	70
ABPI >1.30 (ab)	0% (0)	11.6% (20)	20
Total	50	120	100% (170)

The remaining 66% (n=112) were diagnosed with a vascular deficit using just one of the modalities. 39% (N=66) were diagnosed with a vascular deficit on palpation of pulses yet a normal ABPI was calculated, and 27% (n=46) with an ABPI calculated as being <0.9 had all four pulses present. This produced a number of false positive and false negative diagnoses. It was not possible to obtain an ABPI on either limb of 1 subject within this group.

When analysing the ABPI results, those diagnosed with an ABPI >1.30 are done so with caution as raised ABPI could be due to calcification of the blood vessel rather than arterial occlusion.

Normally, toe pressures would not be considered necessary unless the subject had an ABPI of <0.9. However, in this study all subjects underwent an assessment of their toe/brachial pressure index (TBPI). The following scatter plot illustrates the distribution of scores for both right and left limbs of those categorised as having vascular complications. The reference lines on the x and y axes representing the 0.5 normal cut-off levels.

(A) (B)

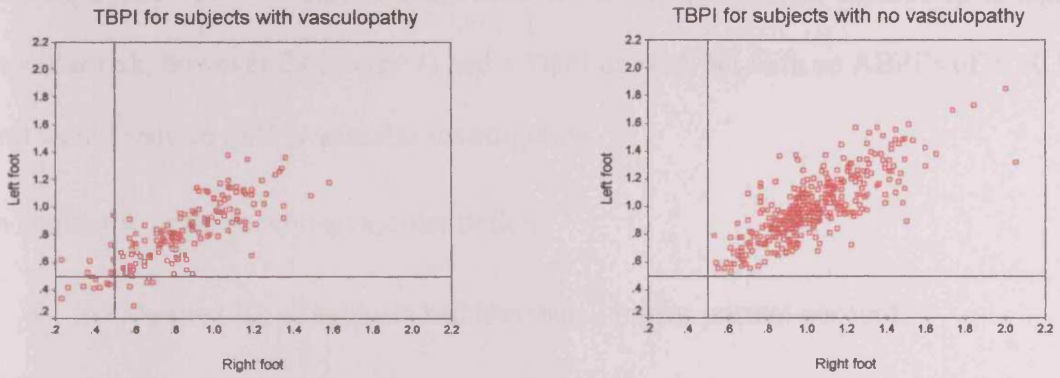


Figure 8.4 – Distribution of TBPI scores with and without vasculopathy.

From scatter plot (A) it can be seen that the vast majority of subjects had a TBPI above 0.5 with 14% (n=24) (4.4% of the total group n=545) having a TBPI of <0.5. Scatter plot (B) illustrates those without vasculopathy in contrast, all having TBPI values >0.5. As previously mentioned, TBPI's are usually only considered if the ABPI value is <0.9, a cross tabulation was carried out for the vasculopathy group, to establish the ABPI values for those scoring a TBPI value of <0.5.

Table 8.2 ABPI and TBPI value comparison

	ABPI value			
TBPI value	<0.9	0.9-1.30	>1.30	% (n)
<0.5	70.8% (17)	25% (6)	4.2% (1)	100 (24)
=/>0.5	43.2% (63)	43.8% (64)	13% (19)	100 (146)
N	80	70	20	170

In table 8.2 it can be seen that there are a number of subjects exhibiting an abnormal ABPI yet a normal TBPI. This was felt to reflect arterial calcification in the posterior tibial artery but that the pathology does not extend further into other blood vessels supplying the foot indicating the disease to be patchy. These subjects would therefore be diagnosed as having vasculopathy from their ABPI result but considered not to be

vascularly compromised when considering the TBPI result. 70.8% (n=17) of those scoring a TBPI of <0.5 also had an ABPI of <0.9 and would be considered at high vascular risk, however 29.2% (n=7) had a TBPI of <0.5 but with an ABPI's of =/>0.9 and would require further vascular investigation.

In summary, of those with a vascular deficit:

- 70.2% (n=120) of subjects had less than 2 pulses present per foot.
- 31.6% (n=54) had an abnormal ABPI (i.e. <0.9 or >1.30) and
- 5.3% (n=9) had an abnormal TBPI (i.e. <0.5).
- 10.6% (n=18) had an abnormal ABPI and abnormal TBPI, however only
- 1.2% (n=2) had less than 2 pulses present per foot, an abnormal ABPI and an abnormal TBPI putting them at a high vascular risk.

Posterior tibial waveforms and pulse volume records (PVR's) were also completed during the vascular assessment, neither of which were considered as criteria for diagnosing vasculopathy but considered for their usefulness in identifying presence of vasculopathy.

Arterial waveforms

The arterial waveform is primarily performed on the posterior tibial artery for assessing the lower limb, the methods of which have been described in the methodology chapter (Chapter 4.4.4). The findings are clearly set out in the table below. It was not possible to obtain two left and one right waveforms, therefore the total number of waveforms collected for the left limb was 169 and for the right limb 170, for the total vasculopathy group (n=171).

Table 8.3 Distribution of Posterior tibial waveforms.

Left limb	%	N
Monophasic	12.9	22
Biphasic	33.3	57
Triphasic	52.6	90
Right limb	%	N
Monophasic	15.8	27
Biphasic	28.1	48
Triphasic	55.0	95

From the data it can seen that bilateral concordance does not always occur. The following cross tabulation highlights this.

Table 8.4 Concordance of waveforms between right and left limbs

		Right limb		
		Monophasic	Biphasic	Triphasic
Left limb	Monophasic	8.9%(15)	1.8%(3)	2.4%(4)
	Biphasic	5.4%(9)	21.4%(36)	7.1%(12)
	Triphasic	1.2%(2)	5.4%(9)	46.4%(78)

It can be seen that

- Approximately 50% (46.4%,n=78) of subjects have 'normal' waveforms (triphasic) on both limbs,
- A little over 20% (21.4%,n=36) have normal biphasic waveforms on both limbs and
- A little under 10% (8.9%,n=15) have abnormal monophasic waveforms on both limbs,
- The remaining 23.3% (n=39) having unilateral differences.

This highlights the importance of bilateral assessment when considering a subjects 'at risk' status. The individual foot is of great importance, as one 'at risk' foot represents one 'at risk' person.

The waveforms for each limb were considered against the number pulses present within each limb. It was found that for the right limb, 77.4% (n=422) had both pulses present and had a normal biphasic or triphasic waveform, 16.7% (n=91) had <2 pulses present but had a normal bi/triphasic waveform, 4.2% (n=23) had both pulses present but only a monophasic waveform and 1.3% had <2 pulses present and a monophasic waveform. The results for both limbs can be seen in the tabulation below.

Table 8.5-Comparison of pulses present with waveform profile for each limb

Right foot	Monophasic % (n)	Biphasic % (n)	Triphasic % (n)
0 pulses present	2.3 (4)	5.8 (10)	6.4 (11)
1 pulse present	1.8 (3)	9.4 (16)	30.4 (52)
2 pulses present	11.7 (20)	12.9 (22)	18.7 (32)
Left foot	Monophasic	Biphasic	Triphasic
0 pulses present	2.3 (4)	4.7 (8)	8.2 (14)
1 pulse present	3.5 (6)	13.5 (23)	31.0 (53)
2 pulses present	7.0 (12)	15.2 (26)	13.5 (23)

When the waveform results were considered along side those for ABPI and TBPI results, the waveforms were found to correlate much better with the TBPI results than with the ABPI. This would indicate that a waveform would give a clearer picture of vascular status than an ABPI as does a TBPI.

Table 8.6a - Waveforms compared with ankle/brachial pressures

	Right foot Waveform			Left foot Waveform	
	N(Tri/Bi)	Ab(Mon)		N(Tri/Bi)	Ab(Mon)
N ABPI	58%(97)	1.8%(3)	N ABPI	48.8%(82)	1.2 %(2)
Ab	25.8%(43)	14.4%(24)	Ab	38%(64)	12%(20)

Table 8.6b - Waveforms compared with toe/brachial pressures

	Right foot Waveform			Left foot Waveform	
	N(Tri/Bi)	Ab(Mon)		N(Tri/Bi)	Ab(Mon)
N TBPI	78.2%(133)	11.8%(20)	N TBPI	84%(142)	8.3 %(14)
Ab	5.9%(10)	4.1%(7)	Ab	3%(5)	4.7%(8)

The following two figures (figure 8.5a/b) demonstrate histograms of those with monophasic wave forms compared with their ABPI results and those with biphasic and triphasic waveforms again with their ABPI results. The figures displayed are for the left limb as an example. When these two histograms are superimposed a line can be drawn through the cross over point of the normality curves, an ABPI value of between 0.9 and 0.95 can be found. This would indicate that this study's value for normal/abnormal ABPI scores of 0.9 would be appropriate.

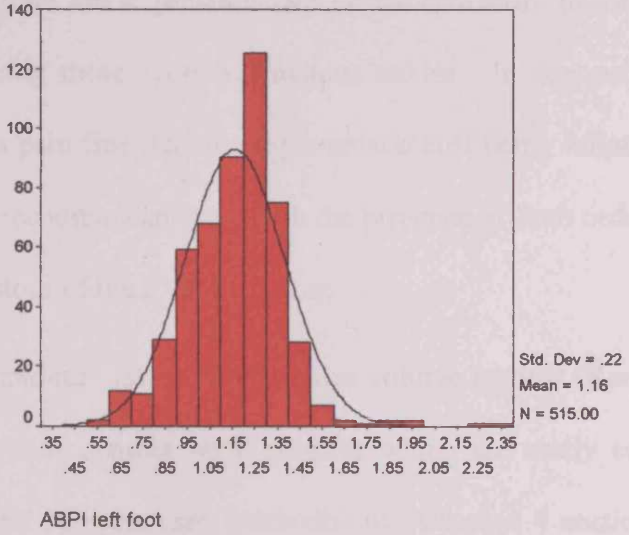


Figure 8.5a Histogram illustrating the distribution of ABPI scores for those subjects with biphasic and triphasic waveform for the left limb.

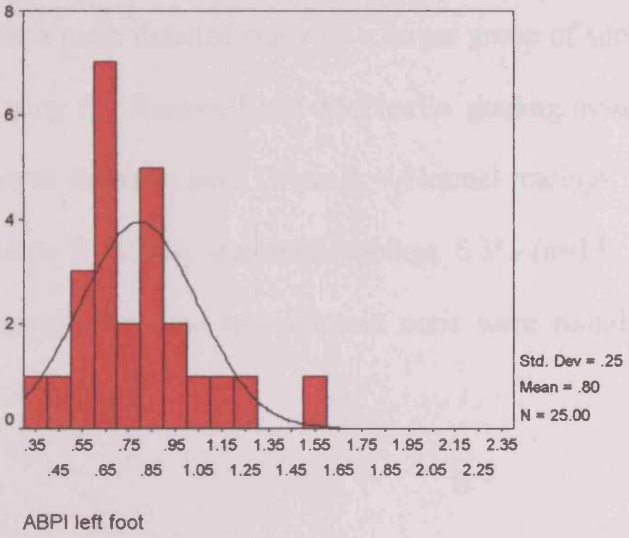


Figure 8.5b Histogram illustrating the distribution of ABPI scores for those subjects with monophasic waveform for the left limb.

Pulse volume records (PVR)

Pulse volume records are not routinely used when assessing the vascular status of an individual. However, it was decided to include this method of vascular assessment due to the ease of use, ease of interpretation and to assess its potential value.

Obtaining a systolic ankle pressure can be exceptionally uncomfortable for many patients particularly those with oedematous ankles. In contrast, obtaining a pulse volume record is pain free due to the pneumatic cuff being inflated to just 65mmHg (manufacturers' recommendations), with the presence of limb oedema not influencing the height or contour of the PVR recording.

An established grading system for the pulse volume records (Rumwell & McPharlin 1998) describes four distinct wave profiles which are easily comparable to those obtained from the subjects (see Methodology, Chapter 4 section 4.5). The PVR assessment was carried out on a smaller sample of subjects (n=205). It had been previously decided that the assessment outcomes of this sample group would help to determine whether a more detailed study on a larger group of subjects was warranted in the future. Using the Rumwell and McPharlin grading system (Chapter 4.4.5), 78.5% (n=161) were found to have Grade A – Normal tracings, 15.2% (n=31) were found to have Grade B- Mildly abnormal tracings, 6.3% (n=13) were found to have Grade C- Moderately abnormal tracings and none were found to have Grade D- Severely abnormal tracings.

A

B

C D

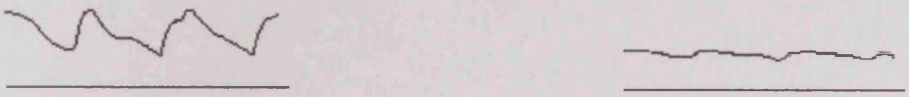


Figure 8.6 Illustrations of the Rumwell & McPharlin PVR grading system as described in Chapter 4, section 4.4.5

These results described above can be seen in the bar graph below.

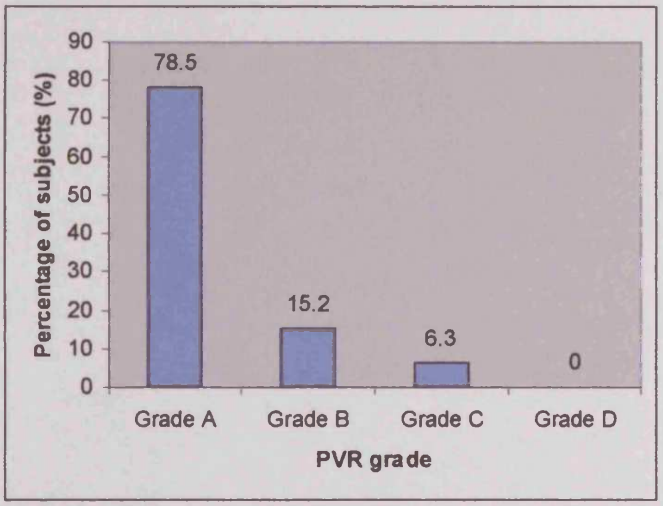


Figure 8.7 – Distribution of PVR grades found within sub-group.

The pulse volume records (n=205) were considered with their ABPI values of which the results can be found in table 8.7.

Table 8.7 – Distribution of all findings for those with completed PVR's (n=205).

PVR Grade

ABPI	A-normal % (n)	B-Mildly abnormal % (n)	C-Moderately abnormal % (n)	% (n)
<0.9	36.4 (8)	31.8 (7)	31.8 (7)	100% (22)
0.9 – 1.30	72 (77)	22.4 (24)	5.6 (6)	100% (107)
>1.30	100 (76)	0 (0)	0 (0)	100% (76)

Those with an ABPI >1.30 may be falsely elevated due to calcification within the blood vessel rather than due to arterial occlusion in the leg. It can therefore be seen that 74.6% (n=153) with an ABPI =/>0.9, had a Grade A-normal PVR profile, 11.7% (n=24) had a Grade B-mildly abnormal PVR profile and 5.6% (n=6) had a Grade C-moderately abnormal PVR profile. Of those subjects with an ABPI <0.9 (n=22), 31.8% (n=7) showed Grade B-mildly abnormal and 31.8% (n=7) a Grade C-moderately abnormal PVR wave profiles, compared to 36.4% (n=8) showing a Grade A-normal PVR profile. These results are shown to be significant ($p<0.001$) however the numbers within these groups are relatively small and would therefore suggest that larger numbers of subjects with ABPI values <0.9 be assessed to establish true significance.

Table 8.8 Cross-tabulation of PVR and ABPI values

		PVR	
		N	Ab
ABPI	N	37.6%(77)	***14.6%(30)***
	Ab	***41%(84)***	6.8%(14)

The consensus appears to be moving towards the PVR as a more reliable indicator of vascular efficiency. With this in mind the table above shows 41% (n=84) of subjects possibly inaccurately identified as having vascular insufficiency which would result in inappropriate referrals. In the same way, 14.6% (n=30) of subjects would not have been identified as having a vascular deficit.

8.3 **Summary – Vascular study.**

31.4% (n=171) of subjects were identified as having one or more vascular deficit. Of these, 70.2% (n=120) were identified as having less than 2 pulses present per foot, which is a very high proportion of subjects when considering its validity; 58.5% (n=100) were identified as having an abnormal ABPI (<0.9 or >1.30) and 14% (n=24) an abnormal TBPI.

When comparison between these results was made, it was found that 31.6% (n=54) had <2 pulses present per foot and an abnormal ABPI, 37.4% (n=64) had an abnormal ABPI and abnormal TBPI and 1.2% (n=2) had <2 pulses present per foot, an abnormal ABPI and an abnormal TBPI making them at high vascular risk.

The results of the waveform analysis, within the group showing one or more vascular deficits, for the right foot produced 85.9% (n=147) with normal triphasic or biphasic waveforms and 12.9% (n=22) abnormal monophasic waveforms. For the left foot 83.7% (n=143) had normal triphasic or biphasic waveforms and 15.8% (n=27) had abnormal monophasic waveforms.

Comparison between pulses present and waveform profiles showed similar results for each limb however a large number of subjects were identified as having <2 pulses present yet normal biphasic or triphasic waveforms (53% right limb, 64% left limb). A very much smaller number (11.8% on the right foot and 7.1% on the left foot) was

recorded as having both pulses present yet an abnormal monophasic waveform. This resulted in a high proportion of subjects being incorrectly diagnosed. When the waveform profile results were compared with the results for the ABPI's, the right foot produced 58% (n=97) normal ABPI's and normal waveforms and 14% (n=24) abnormal ABPI's and abnormal waveforms. The left foot produced 48.8% (n=82) normal ABPI's with normal waveforms and 11.9% (n=20) abnormal ABPI's with abnormal waveforms, these results showing good concordance between methods.

The waveform results were also compared with the TBPI's, the right foot produced 78.2% (n=133) normal TBPI's with normal waveforms and 4.1% (n=7) abnormal TBPI's with abnormal waveforms. The left foot produced 84% (n=142) normal TBPI's with normal waveforms and 4.7% (n=8) abnormal TBPI's with abnormal waveforms. A number of subjects showed asymmetry indicating the need for thorough investigation of both limbs.

When the PVR results were compared with the waveform results, 89% (n=132) of those with a triphasic waveform also had a Grade-A PVR, 76.7% (n=33) of those with a biphasic waveform had a Grade-B PVR and 61.9% (n=13) of those with a monophasic waveform also had a Grade-C PVR. The most noticeable outcome however was for those with an ABPI of >1.30. Table 7.6 shows this group to all have Grade-A normal PVR results indicating that the elevated ABPI is probably due to calcification within the blood vessel rather than arterial occlusion.

Table 8.7 illustrates the lack of concordance in results between the PVR's and ABPI's and with the consensus moving towards PVR's for their reliability in identifying those with vascular complications, this part of the study would justify further research.

These results highlight the need for reliable and accurate vascular assessment and that there are inconsistencies in the numbers being identified using the different modalities. The most reliable and accurate test would be the one that correlated closely to the gold standard of duplex imaging.

8.4 **Executive Summary**

- When carrying out a vascular assessment it is important to examine both limbs due to the degree of asymmetry present within this study group.
- Assessment of foot pulses alone showed to be unreliable within this subject group.
- ABPI values are not always easy to obtain particularly in subjects with oedema or those with calcified arteries (often producing falsely elevated scores), and can be very painful for the subject.
- Pulse volume recording proved to be the most successful of the vascular assessments. It was quick and easy to perform, produced easy to analyse results that were highly concordant with those obtained from waveform analysis and proved to be completely pain free for patients. It can be used in all types of patients including those with oedema, with the results not being affected by calcified arteries.

  These results indicated that further research with comparisons to gold standard vascular assessments such as colour duplex imaging would be of great benefit with the possible out come of a dedicated PVR instrument being produced.

CHAPTER NINE: COMPARISON OF NEUROPATHY ONLY, VASCULAR ONLY AND MIXED COMPLICATIONS

9.1 Introduction

This chapter aims to explore the results of those subjects with 1) no discernable neurological or vascular complications, 2) neuropathic complications only, 3) vascular complications only, and 4) mixed/neurovascular complications (individuals with both neurological and vascular pathologies).

This chapter will utilise the diagnostic criteria for neuropathy and vasculopathy as set out by the national guidelines (NICE 2004), although chapters 7 and 8 did highlight limitations relating to particular methods of assessment and thresholds for diagnosing the presence or absence of a complication.

The diagnosis of **neuropathy** was based on one or more of the following tests being abnormal:

Neuropathy normal ranges:

- 10g-monofilament: 5 plantar test sites identifiable on both feet.
- Neurothesiometer: Vibration perception threshold <25 volts at 2 sites on each foot.
- Rydel Seiffer tuning fork: Vibration perception threshold >4 on the tuning fork arbitrary scale at 2 sites on each foot.

The diagnosis of **vasculopathy** was based on one or more of the following tests being abnormal:

Vasculopathy normal ranges:

- Pulses: 2 pulses present on each foot.
- ABPI: ABPI value between 0.9-1.30 on each limb.

Using the above criteria the subjects were allocated into the 4 sub-groups.

The distribution of subjects within the four sub-groups can be seen in table 9.1 and figure 9.1.

Table 9.1 Distribution of subjects within sub-groups

Group	Number	% of total study group
1 – Normal	202	37.0
2 – Neuropathy only	174	31.9
3 – Vasculopathy only	47	8.6
4 – Mixed/Neurovascular	123	22.5

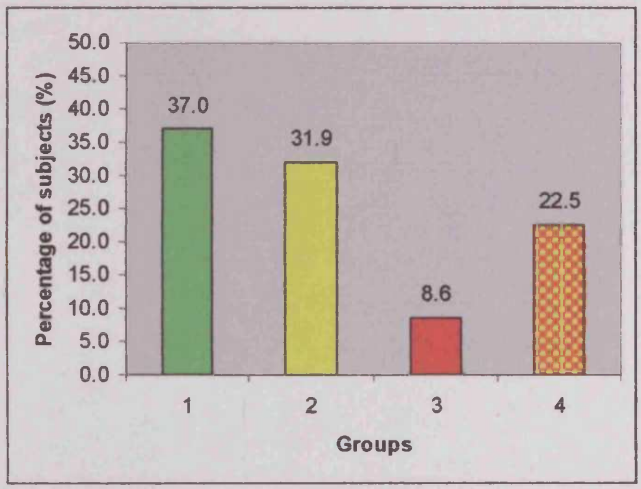


Figure 9.1: Distribution of subjects: group 1-normal, 2-neuropathy only, 3-vasculopathy only and 4-mixed/neuropathic.

9.2 **Results**

An individual is ultimately diagnosed as having neuropathic, vascular or mixed/neurovascular complications based on the result of their worst scoring limb, therefore the following analysis will be reported as such.

The mean age for each of the abnormal patient groups was higher than that of the normal group with no discernable pathologies. Those with mixed/neurovascular

pathologies (group 4) however, appeared to be older for both the mean age and age range (table 9.2).

Table 9.2 Distribution of age within the 4 sub-groups

Sub-group	**Mean age (yrs) (SD)**	**Range (yrs)**
1	60 (11.3)	22-81
2	68 (9.8)	33-86
3	67 (10.8)	37-86
4	72 (9.1)	40-93

The distribution of gender, diabetes type, known duration of diabetes, according to the four sub-groups is included in table 9.3.

Table 9.3 Distribution of gender, diabetes type and known duration of diabetes within all sub-groups

Diabetes duration	Group	No. of subjects	% of group	Male	Female	Type 1	Type 2
<5yrs	**1**	**93**	**46**	**54.8% (51)**	**45.2%(42)**	**9.7%(9)**	**90.3%(84)**
	2	72	41.4	65.3% (47)	34.7% (25)	4.2%(3)	95.8%(69)
	3	23	48.9	26.1% (6)	73.9% (17)	4.4% (1)	95.6% (22)
	4	***38***	***30.9***	***63.2% (24)***	***36.8%(14)***	***5.3%(2)***	***94.7%(36)***
5-9yrs	**1**	**48**	**23.8**	**52.0% (25)**	**48.0%(23)**	**12.5% (6)**	**87.5%(42)**
	2	47	27.0	74.5% (35)	25.5% (12)	10.6% (5)	89.4% (42)
	3	8	17.0	22.5% (1)	87.5% (7)	0% (0)	100% (8)
	4	***31***	***25.2***	***67.7% (21)***	***32.3% (10)***	***19.4% (6)***	***80.6% (25)***
10-19yrs	**1**	**37**	**18.3**	**35.1% (13)**	**64.9%(24)**	**27.0% (10)**	**73.0% (27)**
	2	39	22.4	74.4% (29)	25.6% (10)	23.1% (9)	76.9% (30)
	3	12	25.5	33.3% (4)	66.7% (8)	25.0% (3)	75.0% (9)
	4	***32***	***26.0***	***59.4% (19)***	***40.6% (13)***	***31.2% (10)***	***68.8% (22)***
20+yrs	**1**	**24**	**11.9**	**45.8% (11)**	**54.2%(13)**	**70.8%(17)**	**29.2% (7)**
	2	16	9.2	37.5% (6)	62.5% (10)	81.2% (13)	18.8% (3)
	3	4	8.5	50.0% (2)	50.0% (2)	25.0% (1)	75.0% (3)
	4	***22***	***17.9***	***59.1% (13)***	***40.9% (9)***	***40.9% (9)***	***59.1% (13)***

Bold type – Group 1 normal

Bold italics – Group 4 mixed/neurovascular

With respect to gender, it is interesting to note that males appear to dominate the neuropathy only group in up to 20yrs duration sub-groups. However, this pattern changes in the 20+yrs duration sub-group where females dominate the neuropathy only group. It is also interesting to note that females appear to dominate the

vasculopathy only group, again changing in the 20+yrs duration sub-group where the number of males and females become equal.

Type 2 diabetes dominates up to 20yrs duration sub-groups and pathology sub-groups. However, this changes in the 20+yr sub-group where type 1 diabetes appears to be more frequent.

9.2.1 Comparison of neuropathy only and mixed/neurovascular results.

The following comparison of neuropathy between group 2 and group 4 will look at the findings when using the 10g-monofilament, neurothesiometer and tuning fork separately. Table 9.4 and figure 9.2 give the 10g-monofilament results for Group 2 (neuropathy only) and Group 4 (mixed/neurovascular).

Table 9.4 -10g-monofilament results for Groups 2 and 4

Group	Number of sites identified	% of subjects (n)
Group 2	Normal (all 5 sites identified)	46.6 (81)
	Abnormal (<5 sites identified)	53.4 (93)
Group 4	Normal (all 5 sites identified)	34.1 (42)
	Abnormal (<5 sites identified)	65.9 (81)

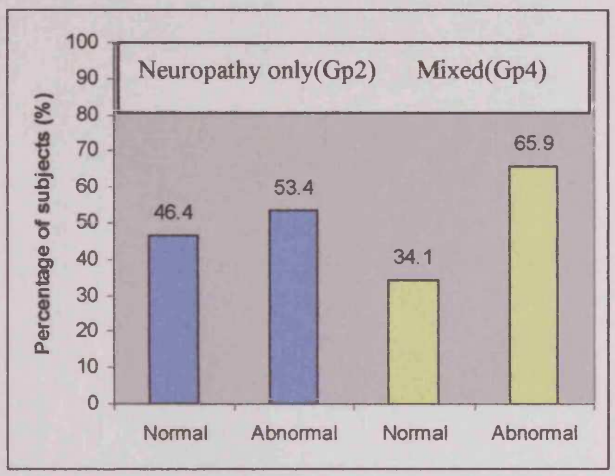


Figure 9.2 - Percentage of subjects identified with/without neuropathy using 10g-monofilament within groups 2 and 4.

From table 9.4 and figure 9.2 it can be seen that in group 2 there is little difference between the number of normal and abnormal responses to the 10g-monofilament. In group 4 however, there are fewer normal responses than abnormal responses to the 10g-monofilament. The graph in figure 9.3 indicates that there are a larger number of patients with more severe neuropathy in group 4 (mixed/neurovascular) than in group 2 (neuropathy only).

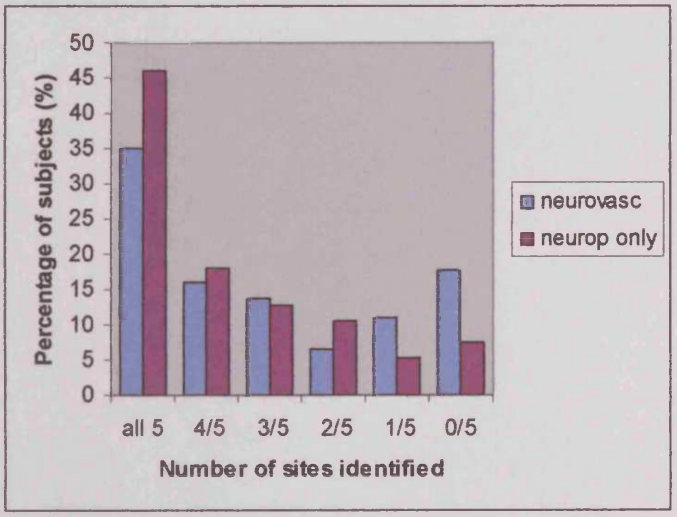


Figure 9.3 Severity of neuropathy in groups 3 (vasculopathy only) and 4 (mixed/neurovascular) using the 10g-monofilament.

The same pattern as for the 10g-monolfilament was seen using the neurothesiometer. In group 2 (neuropathy only) there were equal numbers of patients with or without abnormal vibration perception thresholds. In group 4 (mixed/neurovascular) however, there were fewer normal vibration perception thresholds than abnormal (table 9.5 and figure 9.4).

Table 9.5 –Neurothesiometer results for groups 2 and 4

Group	**Number of sites identified**	**% of subjects (n)**
Group 2	Normal (vibration identified at <25volts)	51.1 (89)
	Abnormal (vibration identified at ≥25 volts)	48.9 (85)
Group 4	Normal (vibration identified at <25 volts)	35.8 (44)
	Abnormal (vibration identified at ≥25 volts)	64.2 (79)

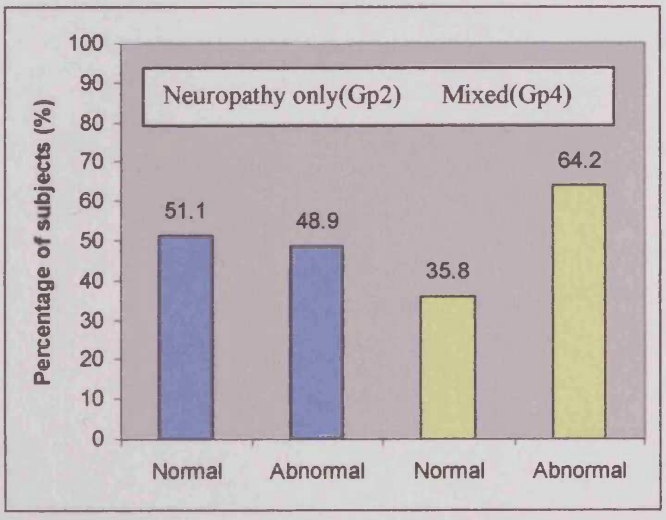


Figure 9.4 - Percentage of subjects identified with/without neuropathy using the neurothesiometer within groups 2 and 4.

The Boxplots in figure 9.5 illustrate that the mixed/neurovascular group appear to have more severe neuropathy than the neuropathy only group. This can be seen by the minimum, maximum and median values being higher in group 4 (mixed/neurovascular) than in group 2 (neuropathy only)

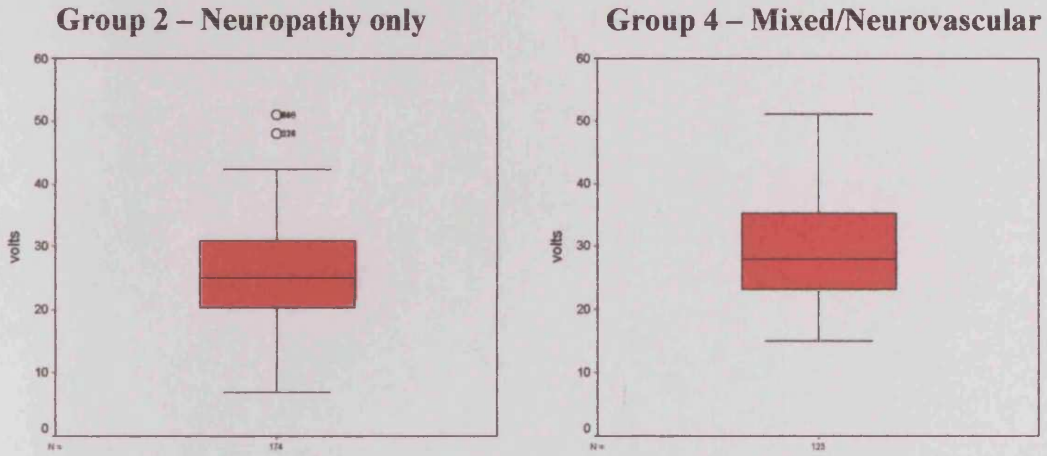


Figure 9.5 Boxplots illustrating the median, minimum and maximum neurothesiometer scores with outliers for Groups 2 and 4.

The tuning fork results in table 9.5 and figure 9.6 showed a higher number of patients with abnormal vibration perception in **both** groups 2 and 4 than normal. Analysis showed no significant difference ($p>0.05$) in the degree of neuropathy between groups 2 and 4. The findings previously reported, using the 10g-monofilament and neurothesiometer however, showed the level of neuropathy in group 2 to be different to that in group 4.

Table 9.6 – Tuning fork results for groups 2 and 4

Group	Number of sites identified	% of subjects (n)
Group 2	Normal (vibration identified at ≥ 4 on arbitrary scale)	28.7 (50)
	Abnormal (vibration identified at < 4 on arbitrary scale)	71.3 (124)
Group 4	Normal (vibration identified at ≥ 4 on arbitrary scale)	25.2 (31)
	Abnormal (vibration identified at < 4 on arbitrary scale)	74.8 (92)

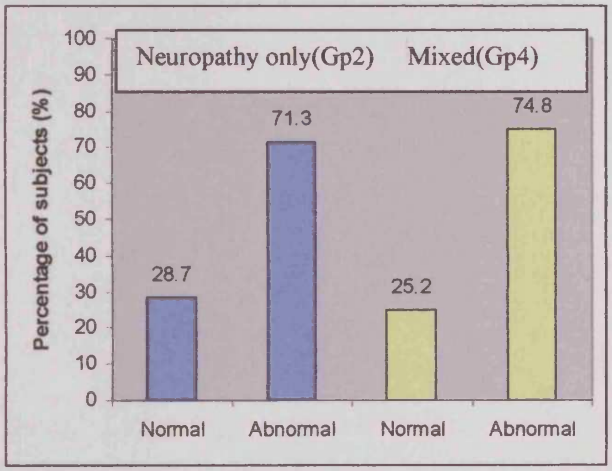


Figure 9.6 - Percentage of subjects identified with/without neuropathy using the tuning fork within groups 2 and 4.

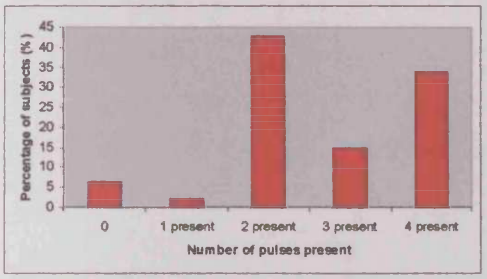
9.2.2 Comparison of the group with vasculopathy only (group 3) with those with mixed/neurovascular deficit (group 4).

The following comparison of vasculopathy between group 3 and group 4 will look at the presence or absence of pulses and ABPI results separately.

The presence or absence of pedal pulses has long since been the primary method for identifying those with possible peripheral vascular disease, particularly in a community setting. Those identified as not having 2 pulses per foot totalled 66%

(n=31) in group 3 and 72.4% (n=89) in group 4. The distribution of palpable pulses can be seen in figure 9.7.

Group 3 – Vasculopathy only



Group 4 – Mixed/neurovascular

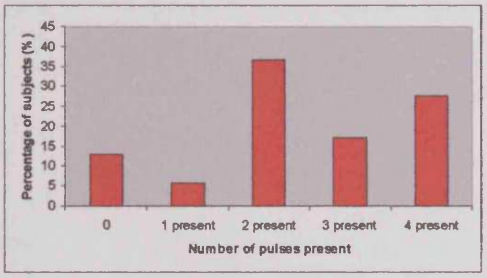


Figure 9.7 – Total number of pulses present for both feet in Groups 3 and 4.

It is generally regarded that the palpation of pulses has limited value in relation to other vascular assessment modalities such as ankle brachial pressure indices which have been shown to give more detail when considering a subjects' vascular status. Table 9.7 and figure 9.8 illustrate the findings for ABPI scores for groups 3 and 4.

Table 9.7 – ABPI scores for groups 3 and 4

Group	ABPI score	% of subjects (n)
Group 3	Normal	53.2 (25)
	Abnormal	44.7 (21)
Group 4	Normal	36.6 (45)
	Abnormal	63.4 (78)

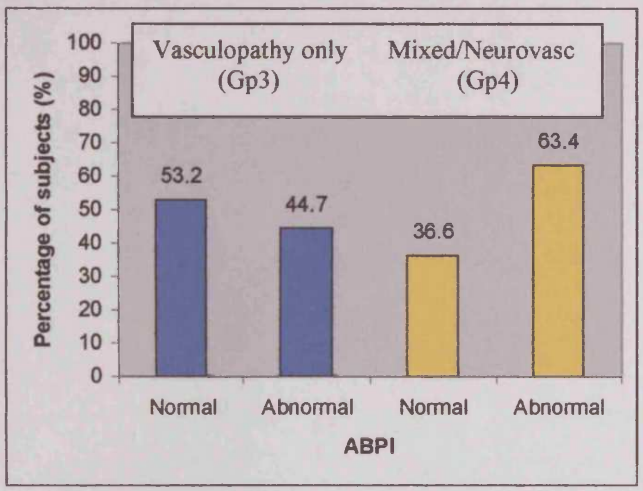


Figure 9.8 Percentage of subjects identified with/without vasculopathy using ABPI's in groups 3 and 4.

The results in table 9.7 and figure 9.8 show that in the vasculopathy only group, the numbers of patients with or without abnormal ABPI scores are not very different. In the mixed group however, there is a greater number of patients with abnormal ABPI scores than normal.

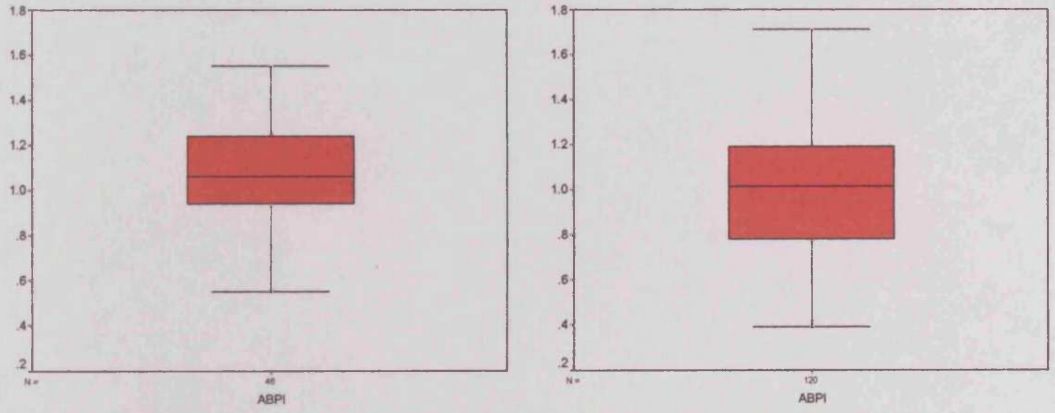


Figure 9.9 Boxplots illustrating the minimum, maximum and median ABPI scores for groups 3 and 4.

The Boxplots in figure 9.9 indicate that the number of patients with abnormal ABPI scores are greater in those within mixed/neurovascular sub-group than those within

the vasculopathy only sub-group, suggesting that the vascular complications in group 4 (mixed/neurovascular) are more severe than in group 3 (vasculopathy only).

The relationship between the two methods of vascular assessment were then considered, the results of which can be seen below.

Table 9.8a-Group 3 vasculopathy only

	ABPI			
Pulses	<0.9	0.9-1	>1.30	% (n)
<4	6.7%(2)	73.3% (22)	20% (6)	100 (30)
=4	81.3%(13)	18.8% (3)	0% (0)	100 (16)
Total	(15)	(25)	(6)	(46)

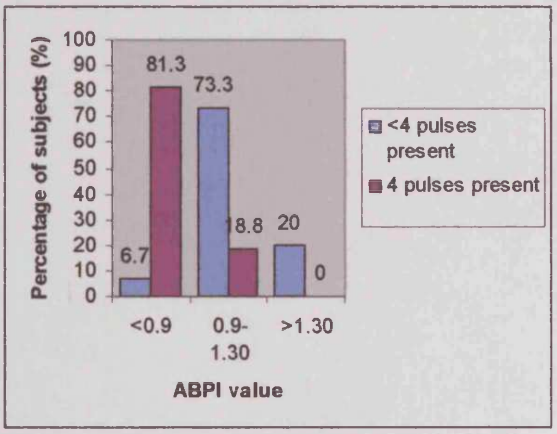


Figure 9.10a – Group 3 vasculopathy only

Table 9.8b-Group 4 mixed/neurovascular

	ABPI			
Pulses	<0.9	0.9-1.30	>1.30	% (n)
<4	36%(32	49.4%(44)	14.6%(13)	100 (89)
=4	97.1% (33)	2.9% (1)	0% (0)	100 (34)
Total	(65)	(45)	(13)	(123)

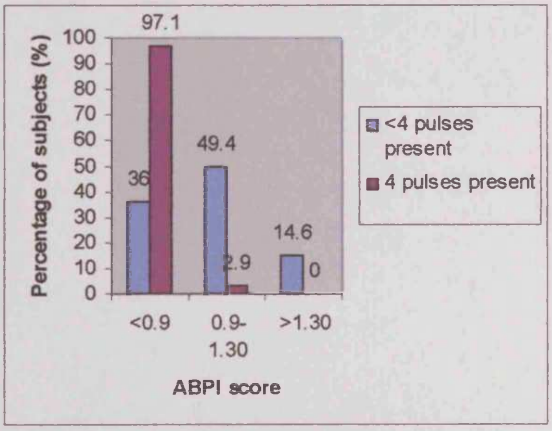


Figure 9.10b – Group 4 mixed/neurovascular

Interestingly both groups show similar differences in the results with no relationship between the number of pulses present and ABPI scores based on the criteria used.

9.3 **Summary**

From the results it can be seen that group 4 (mixed/neurovascular) are older than all the other sub-groups.

When known duration of diabetes was considered, males dominate the neuropathy only sub-group in all known duration groups up to 20yrs, and females dominate the vasculopathy only sub-group in all duration groups up to 20yrs. This changes in the 20+yr known duration group, where females dominate the neuropathy only group, and the gender is evenly distributed in the vasculopathy only group. Previous studies have also found similar gender pattern, however, no further work has been done to try to explain the gender effect (Kodali et al, 1990; Sorensen et al, 2002).

The neuropathy tests within groups 2 and 4, showed a difference in the number being normal to be lower in the mixed group (group 4). It was evident that a greater number of patients were identified as neuropathic in group 4 than group 2, using the 10-g monofilament and neurothesiometer. The tuning fork however, discovered no apparent difference between the two groups.

Palpation of pedal pulses showed little agreement when compared to the results of the ABPI. ABPI results appeared to give more detail of the subject's vascular status which again proved to be more severe in the mixed/neurovascular group (group 4) than the vasculopathy only group (group 3). It was interesting then to see in tables 9.8a/b and figures 9.10a/b that a statistically significantly number of patients with an abnormally low ABPI had all 4 pulses present.

Waveform analysis identified 10.6% of subjects having abnormal monophasic waveforms in group 3 and 35.5% of subjects in group 4, again indicating that those

with mixed pathologies have more severe vascular complications than those with vascular complications alone.

9.4 **Executive Summary**

It was intended to discover if there were any differences between those patients with both neuropathic **and** vascular deficits (group 4) compared to those patients with neuropathy alone (group 2) or those patients with vasculopathy alone (group 3).

- Males appeared to dominate in the neuropathy only group and females in the vasculopathy only group, no explanation for this gender difference has been found as yet.
- The neuropathic test and vascular test results indicate that patients in group 4 (mixed /neurovascular) have more severe neuropathy and vasculopathy than patients in the neuropathy only or vasculopathy only groups.
- The patients in group 4 (mixed/neurovascular) are older than in the other pathological groups (groups 2 and 3), as well as those with no discernable pathology (group 1).
- These results indicate that to assess a single pathology within a group of patients with diabetes would not give a true representation of the degree of risk due to the increased severity of both neuropathy and vasculopathy within those exhibiting mixed/neurovascular complications.

CHAPTER TEN: STUDY TO ASSESS THE USEFULNESS OF DIGITAL IMAGERY OF THE DIABETIC FOOT

10.1 **Introduction**

Many diabetic foot clinics employ photography when recording sizes of ulcers. By taking regular photographs and keeping them in the patient file, it allows comparison over time of the increase or reduction in size of ulcerations. Although a thorough search of literature was under taken, it was not possible to find details of any studies carried out to identify the diabetic foot in a neuropathic, vascular or mixed pathological state prior to ulceration or amputation using digital images.

It was considered that paper photographs kept in patient files could easily fade over time resulting in poor quality images if indeed they had not been lost during repeated patient note transfers. The use of digital photography would allow for images to be stored on disc or computerised patient notes without the worry of being lost or of a reduction in quality over time. It was also considered that perhaps through telemedicine procedures, these digital images would be very useful in remote diagnosis. A digital image of an unusual foot shape or lesion pattern, not easily identifiable by the Podiatrist or other Health Professional, could be sent via telemedicine communication allowing immediate specialist review and diagnosis.

In addition, these digital images, if archived, would allow for comparison of future digital images taken of the same foot to track any colour changes, foot shape changes or lesion patterns that may occur. This would allow for early treatment plans to be set up to minimise future changes in shape or the re-occurrence of lesions.

Finally, digital diabetic foot images could be sent to and stored at a central base that could be accessed by other Health Professionals allowing information to be gathered and disseminated.

Four non-weight bearing images were taken of each foot one each from dorsal, plantar, lateral and medial views. Details of the methods used can be found in the methodology chapter (chapter 4).

10.2 **Results**

To analyse the usefulness of digital imagery in identification of the diabetic neuropathic, vascular or mixed pathology foot the images were studied and scored according to signs of neuropathy and vascular complications identifiable from the images of each of the four angles taken of each foot. The patient study ID and results were then used to compare concordance with those identified through visual inspection of the foot.

The following table shows those lesions and deformities found through visual inspection of the foot, together with those identified through studying the digital images.

Table 10.1 – Indication of neurological/vascular complications identified through visual and digital image inspection.

Lesion/deformity	**Visual inspection % (n)**	**Digital image inspection % (n)**
Callus	55.0 (301)	35.0 (191)
Corns	20.4 (111)	8.3 (45)
Fissures	2.6 (14)	0.0 (0)
Nail pathology	10.5 (57)	17.6 (96)
ID maceration	4.0 (22)	0.0 (0)
Hammer toe	12.3 (67)	9.0 (49)
Retracted/claw toe	27.3 (149)	29.0 (162)
Hallux valgus	13.4 (73)	13.0 (72)

Prominent met heads	15.8 (86)	14.0 (77)
Charcot arthropathy	1.5 (8)	1.1 (6)
Amputation	1.1 (6)	1.1 (6)
Abnormal colour	1.7 (9)	(not clear)
Absence of hair	17.0 (93)	(not clear)

As can be seen from the table above, no fissures or inter-digital maceration were identified on the digital images due to each foot being photographed in four planes which did not include an inter-digital angle, therefore not allowing for any ID lesions to be visible or recorded. The digital images did not easily identify loss of hair or abnormal colour enough to be a reliable record. This may have been clearer had any of the subjects had severe colour abnormalities.

The identification of more retracted/claw toe deformities from the digital images than from visual inspection may be due to the subjects feet not being completely relaxed when the images were being taken. The contraction of the dorsal interossei muscles can give the appearance of retracted toes when the foot muscles are not relaxed.

To measure the strength of linear association or correlation coefficient between the 11 deformities and lesions found through visual inspection and the same 11 found through digital imagery, the Pearson correlation statistical test was performed on the data above.

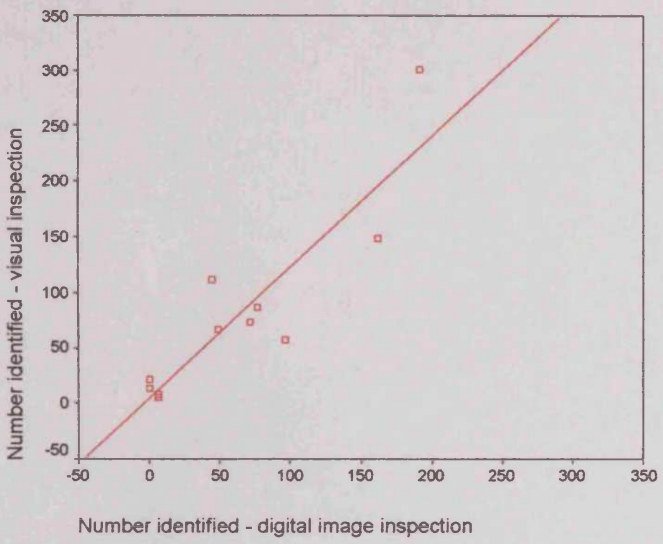


Figure 10.1 – Pearson correlation scatter plot and correlations table.

Correlations

		Number identified	Number identified
Number identified	Pearson Correlation	1	.896(**)
	Sig. (2-tailed)	.	.000
	N	11	11
Number identified	Pearson Correlation	.896(**)	1
	Sig. (2-tailed)	.000	.
	N	11	11

** Correlation is significant at the 0.01 level (2-tailed).

With an r value of 0.896 and p-value <0.0001, it can be concluded that the correlation between the two sets of results is significant beyond the 1 per cent level.

$$r=0.896;\ n=11;\ p<0.0001.$$

The scatter plot reinforces the results table by illustrating the linear relationship between the variables.

The results of any changes in lesion patterns or deformities could not be analysed within this study due to time constraints but would be more suited to a future longitudinal study.

10.3 **Summary**

Although digital imagery for diagnosis could not totally replace detailed visual inspection, this study does show high correlation between deformity and lesion identification through both methods. Through this it can be seen that digital images for remote diagnosis of unusual deformities or lesions would be invaluable. However, the identification of signs of vascular complications such as colour changes, dilation of veins on the dorsum of the foot, temperature, loss of hair and night cramps proved unsuccessful. Sensitivity of digital images for signs of neuropathy were therefore high but sensitivity for signs of vascular complications were low. This could be improved by including a colour scale next to the foot when taking the image however, the use of thermal imaging for assessing tissue perfusion would be more effective and reliable. Thermal imaging would also prove useful for identifying such neuropathic complications as Charcot arthropathy.

Further longitudinal investigations are required to analyse the benefits of documenting changes in lesion patterns and foot shape over time through comparisons and storage of digital images.

10.4 **Executive Summary**

- Digital images would be useful for remote diagnosis.
- Digital imagery showed high sensitivity for the identification of signs of neuropathic complications but low sensitivity for signs of vascular complications.

CHAPTER ELEVEN: STUDY TO ASSESS PLANTAR PRESSURE OF THE DIABETIC FOOT

11.1 **Introduction**

Included is a brief description of basic foot anatomy and normal gait before describing the effects of diabetes mellitus on foot function, gait and the associated foot complications related to diabetes mellitus.

The foot is divided into two anatomical regions: the forefoot and the rearfoot. The forefoot is composed of the bones and joints located anterior to the midtarsal joint. These include the cuneiforms, navicular, and metatarsals (bones that help to form the arch of the foot) and the phalanges (the bones of the toes). The forefoot may be further divided into three columns: the medial column, consisting of the hallux, first metatarsal and medial cuneiform; the central column, which is made up of the second, third and fourth phalanges, their metatarsals, and the corresponding cuneiforms; and the lateral column, which includes the fifth phalange and metatarsal, together with the cuboid.

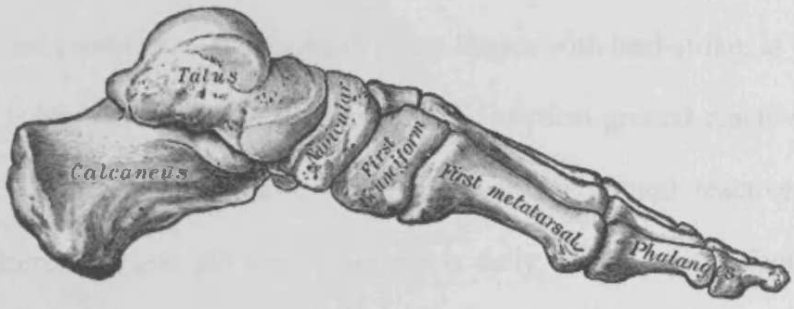


Figure 11.1 – Medial aspect of the normal skeletal foot.

The medial and lateral columns have independent ranges of motion and are slightly more flexible than the more rigid and fixed central column. The rearfoot, which is located underneath and posterior to the midtarsal joint, is composed of the calcaneus and talus.

The most important joints in the normal functioning of the foot during movement are the metatarsophalangeal joints (MPJ's) of the forefoot and the subtalar joint of the rearfoot, which functions differently during certain stages of the gait cycle. At one stage the medial column works as a rigid lever and at another stage as a mobile adapter to the terrain. The soft tissue components of the foot include muscles, tendons, ligaments, fascia, and fat pads, all of which have specific functions during standing and walking. The pull of the muscles and tendons produce joint movement, and the ligaments help to provide stability between the bones. The plantar fat pad has two components; the heel or calcaneal fat pad and the fat pad under the ball of the foot or metatarsal heads. Both of these areas act as cushions that distribute the pressure of the underlying bony structures to the weight-bearing surface.

The gait cycle can be divided into two phases: the swing phase and the stance phase. During the swing phase, the foot is completely off the ground and is preparing for heel-strike, which is the initiation of the stance phase. The stance phase, which represents the weight-bearing phase, is divided into three further phases: contact, midstance, and propulsion. The contact phase begins with heel-strike, at which point the weight is transferred to the rearfoot, and the vertical ground reactive forces are increased. During the midstance phase, the vertical ground reactive forces are markedly decreased, and the body's weight is fully loaded on the foot in a static distribution, converting it from a mobile adapter to a rigid lever necessary to produce forward propulsion. The propulsive phase begins with the heel lifting off the ground and continues with the weight being transferred across the hip and knee joints and developing into plantar flexion of the foot, which transforms the medial column into a rigid lever as the hallux lifts off the ground.

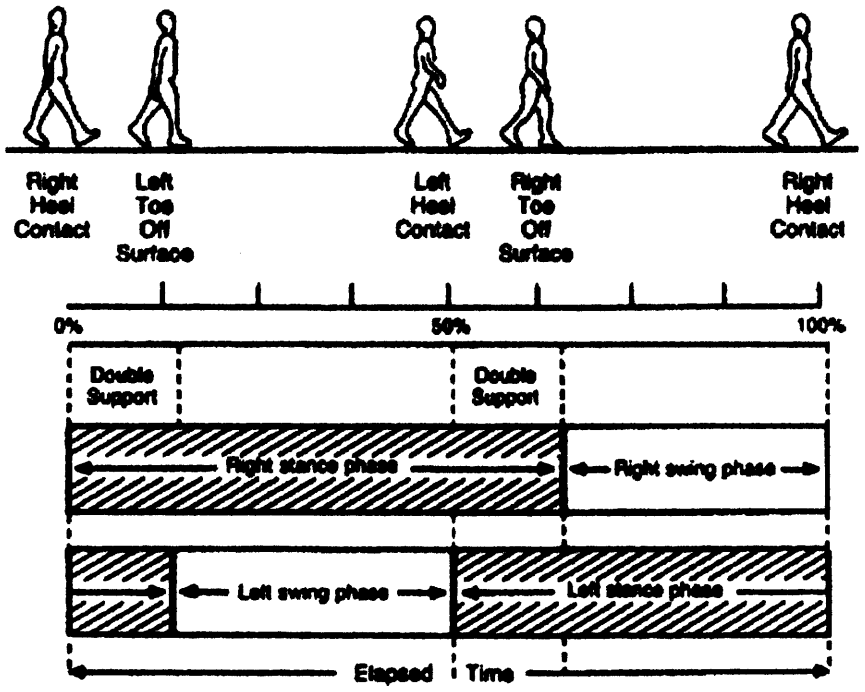


Figure 11.2 - Normal gait cycle

The highest plantar forces develop at the beginning of stance phase, when the heel strikes the ground, and at the end of the same period, when there is propulsion of the foot from the ground. An inability of the subtalar joint to absorb the shock produced by the heel-strike or of the forefoot to distribute the high forces required for propulsion can result in the development of high foot pressures.

Diabetes can affect the foot in several ways that can lead to the development of high foot pressures. The main contributing factors include neuropathy, both chronic sensorimotor and autonomic, limited joint mobility, and callus formation. The most important factor for the development of high foot pressures is the motor neuropathy, which accompanies the existence of sensory neuropathy. Also, motor nerve fibre loss leads to small muscle atrophy in the foot, imbalance between flexor and extensor muscle function, which causes clawing of the toes, high arching of the foot, prominent metatarsal heads and anterior migration of the metatarsal fat pads increasing

metatarsal head pressure (Boulton et al. 1993). This simultaneous action of the toes clawing increases the depth of the foot and the risk of shoe-induced ulceration.

Changes such as clawed or hammered toes, pes cavus, pes planas and hallux valgus can greatly impair the ability of the foot to distribute high forces during walking or standing and result in abnormally high pressures that can subsequently lead to callus formation and foot ulceration in the insensate foot. This foot shape, and the consequent changes in foot pressures, is typical of peripheral neuropathy so it has been suggested that measuring plantar pressures might be used in conjunction with sensory testing for detecting the early stages of neuropathy (Boulton et al., 1987).

Autonomic neuropathy can cause denervation of the sweat glands, leading to dry atrophic skin, callus formation, and severe cracking of the skin, which facilitates microbial infections. Although callus is a normal reaction to shear forces acting upon the skin, in the neuropathic patient the callus acts as a foreign body, making it an important sign of, and a major contributor to, high plantar foot pressures (Young et al. 1992), and can accelerate the development of an ulcer.

A highly significant association has been demonstrated between the presence of areas of plantar callus and the subsequent formation of neuropathic ulceration which is known to occur at sites of elevated and abnormal plantar pressures (Boulton et al. 1983; Boulton et al. 1987; Masson et al. 1989). Elevated plantar foot pressure has therefore been identified as an important factor for foot ulceration in people with diabetes (Boulton et al. 1983). Such ulceration is considered to be a late complication of nerve damage and generally does not develop without the loss of protective sensation (Boulton et al. 1983; Boulton et al. 1987; Masson et al. 1989). According to Edmonds et al (Cavanagh et al. 2000), most neuropathic ulcers occur on the toes

(39%), the hallux (30%), and the metatarsal heads (24%). A summary of factors that may increase plantar pressure is shown in the table below.

Table 11.1: Factors that can lead to elevated plantar pressure under the foot during walking.

Intrinsic	Extrinsic	Behavioural
Foot architecture		Walking without shoes
Long second toe		
High arch		
Soft tissue alterations	Poor footwear	Poor choice of shoes
Callus	Tight or loose shoes	
Glycosylation (presumed)	Shoes with hard soles	
Migration of tissue		
Thin tissue		
Limited joint mobility	Accidents and incidents	Inadequate callus care
Foot deformity	Prior Surgery	Walking patterns
Claw toes		
Hallux valgus		
Charcot fracture		

(Cavanagh et al. 2000)

The distribution of pressure at vulnerable regions of the foot may provide important information in patients at increased risk of foot ulceration. Identification and reduction of this high pressure is essential to prevent foot ulceration.

There have been attempts at measuring foot pressures for more than 50 years. The first techniques were simple, innovative methods that provided the investigator with crude, semi-quantitative measurements. The introduction of the optical pedobarograph greatly improved the accuracy (Donaghue & Veves 1997), but the computer era has allowed the development of new techniques that provide accurate and reliable measurements and can be used not only for research purposes, but also for assessing and treating individual patients.

As there is not one perfect plantar pressure measurement system, consideration was taken of the type of subjects, location of assessments and portability before the Steering Group selected a platform system rather than an in-shoe system to full fill the specific requirements of the study. Platforms enable collection of data in a barefoot

state, removing the influence of footwear, which can mask high pressures. The entire foot/ground contact is captured and the subject does not have wires and a data box attached to them, which could influence their gait. The Diabetic Foot Interest Group (Young 2002) recommend that any plantar pressure measurement equipment be built into a walkway. However, due to the need for portability, it was necessary to have a platform slim enough to simply be placed on the floor.

Having explored the equipment available within the financial constraints, and literature relating to use of plantar pressure systems, the Steering Committee agreed that the TekScan MatScan system would be the most appropriate for the requirements of the study.

11.2 **Results**

There is some debate about the critical magnitude of plantar pressure that is required for tissue damage. A number of papers aim their analysis of plantar pressure at a specific figure relating to kg/cm2 (Pham et al. 2000) this being a cut off value for defining those that exhibit normal pressure loading and those exhibiting abnormally high pressure loading. Veves (Veves et al. 1992) believed that a value of over 1000kPa during barefoot walking is required while other studies report ulceration at values below 500kPa. Armstrong (Armstrong et al. 2003) suggested that a threshold of 700kPa is the best compromise between sensitivity and specificity.

This however does not take into consideration the great variation in subject height, subject weight or size of foot. Peak pressures alone, however, do not give sufficient information. Temporal parameters such as pressure/time integrals and contact time should also be taken into consideration.

Therefore the aim of this plantar pressure study was to randomly select a sub group from the main study group and look at four particular parameters.

1) Peak Plantar Pressure (kPa);

2) The centre of pressure line.

3) Time to reach peak plantar pressure (ms), and

4) contact time (ms) at the site of highest pressure;

Due to the intra-subject asymmetry shown between left and right foot strikes, it was agreed that analysis in this study would be carried out on each foot individually. To assess the peak plantar pressure the foot strike was first divided into forefoot and rearfoot, this gave peak plantar pressure values for these two areas. These areas encompassed part of the mid-foot and toe area in the forefoot section and part of the mid-foot and heel in the rearfoot section. These two areas are seen highlighted in red for the forefoot and green for the rearfoot.

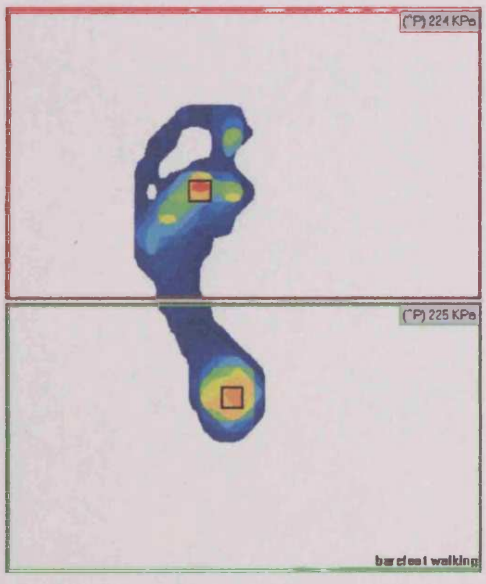


Figure 11.3 – Forefoot and rear foot divisions.

Having considered the literature it was also decided that within each limb, three sites would be considered, the heel, the hallux and the metatarsal head area, these being identified as most likely places of ulceration on the plantar surface of the foot (Cavanagh et al. 2000). This second method placed assessment boxes over each area in question giving the peak plantar pressure for that specific area only i.e. the heel, the hallux and the metatarsal area, independently to the rest of the foot.

For the second method, consideration for the size of the areas to be assessed then had to be addressed. It was considered that although shoe size was not a variable that had been collected, the total surface area of the foot strike could be used to calculate a mean surface area for males and females enabling a common assessment box size for male subjects and a separate box size for female subjects reflecting the average foot size for males and females. However, the variation within the male subjects and within the female subjects made this impractical. It was then agreed that the assessment boxes would be adjusted manually for each subject to encompass the appropriate area under investigation. An example of this can be seen in figure 11.4.

barefoot walking

Figure 11.4 – Plantar pressure assessment boxes.

In 1979, Hutton and Dhanendran carried out a study of the distribution of load in normal subjects during walking which set similar parameters allowing normal values and gait patterns to be considered when looking at differences in patients with diabetes (Hutton & Dhanendran 1979). Their results looked at variations in loading with age, sex and body weight and are summarised below.

Age: 1) The age range of the subjects was 6yrs-65yrs

2) The load carried by the hallux was more than twice that for the other toes combined

3) In younger subjects the load carried by the hallux was approximately three times that carried by the midfoot, whereas by 60yrs the load carried by the midfoot was the greater

4) The 1st and 2nd metatarsal heads each carried about the same load which was less than that carried by the lateral three metatarsal heads

5) The load carried by the heel decreased with age

6) Variations in the contact times were greatest at the hallux and the midfoot, the hallux decreasing with age and the midfoot increasing.

7) The metatarsal heads at all ages showed a high contact time as compared to the rest of the foot.

Sex: At all ages males carried higher loads under the hallux and the heel than females but lower loads under the midfoot.

Body weight:

1) Midfoot loading increased with body weight while the lateral three metatarsal heads showed a decrease in loading with increasing body weight.

2) The contact time for all areas of the foot increased with increasing body weight.

The total number of subjects involved in this part of the study was 141 of which 57.4% were males and 42.6% were females. Their ages ranged from 33 to 88yrs with a mean age of 66.0yrs (SD=10.4yrs).

11.2.1 Peak Plantar Pressure (PPP)

The peak plantar pressure was analysed for each subject and these ranged from a minimum of 26kPa (at the hallux) to a maximum of 328kPa (at the metatarsal heads) which shows a great degree of variation. The mean values for the three main areas defined as the hallux, the heel and the metatarsal head area were calculated as 147.05kPa (SD=56.33kPa) for the hallux; 192.16kPa (SD=50.48kPa) for the heel and

205.99kPa (SD=49.11kPa) for the metatarsal head area. The peak plantar pressures for individual subjects varied in location.

Table 11.2 – Description of findings at the three main sites.

	Hallux peak pressure (kPa)	Heel peak pressure (kPa)	Metatarsal head area peak pressure (kPa)
Mean	147.05	192.16	205.99
Std. Deviation	56.33	50.48	49.12
Median	157.00	211.00	219.00
Range	26.00 - 255.00	65.00 – 257.00	86.00 – 328.00

There was considerable variation between minimum and maximum values for the three areas. The standard deviation within the different sites was similar (Table 11.2), however, by looking at the results in this manner it shows the high variation that occurs between subjects. There have been studies that highlight those with diabetes mellitus and accompanying related neuropathy as a particularly vulnerable group. It was therefore felt appropriate to consider the group with neuropathy separately with the study results. Neuropathy presence was defined previously in Chapter 7 as VPT >25volts (or <4 with the tuning fork) and/or insensitivity to the 10g monofilament at one or more sites.

A little over half (57%, n=81) were found to have neuropathic complications and of these 63% (n=51) were males and 37% (n=30) were females. The age range for this group was 33 to 88yrs with a mean age of 68.5yrs (SD=10.3yrs). Of the remaining non-neuropathic subjects (43%, n=60), 50% were male and 50% female. The age ranged from 37 to 83yrs with a mean age of 62.5yrs (SD=9.4yrs). The mean peak plantar pressure (composite of hallux, heel and metatarsophalangeal joint sites) was

higher in the non-neuropathic group than the neuropathic group (212.33kPa vs. 204.36kPa).

The figures in Table 11.3, illustrate that the mean, minimum and maximum values for the hallux are higher in the non-neuropathic group than the neuropathic group however, the SD value is higher in the neuropathic group showing a wider range of pressures. At the metatarsal head site all values are higher in the non-neuropathic group. At the heel the mean and minimum values are higher in the neuropathic group however the maximum and SD values are higher in the non-neuropathic group.

The peak pressures for the hallux, metatarsal head area and heel for both groups can be seen in the table below. These figures illustrate that the maximum kPa value at the heel and hallux areas show little or no difference between the two groups, however a greater difference is seen at the metatarsal head area. When the mean kPa values are considered, the greatest difference between the two groups is seen at the hallux (23.42kPa greater in the non-neuropathic group).

Table 11.3 – Summary of pressure found at sites analysed.

	Hallux peak pressure kPa		Metatarsal head peak pressure kPa		Heel peak pressure kPa	
	Neuro	Non-neuro	Neuro	Non-neuro	Neuro	Non-neuro
Mean	137.08	160.50	204.36	208.20	194.75	188.66
Minimum	26.00	45.00	86.00	95.00	78.00	65.00
Maximum	255.00	255.00	256.00	328.00	255.00	257.00
Std. Deviation	59.07	49.77	48.15	50.73	49.59	51.87

11.2.2 Centre-of-Force trajectory line (COF)

In normal foot function, the centre-of-force (COF) trajectory line commences in the proximal part of the heel, passes over the medial side of the midfoot into the second metatarsal head and terminates at the lateral border of the great toe (hallux). In normal subjects these COF lines can vary considerably as illustrated in figure 11.5 where a) represents the average COF line; b) demonstrates a lateral shift in forefoot loading with the lateral three rays carrying more load than normal; c) illustrates excessive midfoot loading due to a collapse of the longitudinal arch and d) shows that the toes play no part at kick-off.

The following images demonstrate the variation of centre-of-pressure lines found within our subject group. These lines do not only show the centre line but also the time spent during the foot strike. The line is split into boxes with the longer boxes representing shorter periods of time and the smaller boxes the longer periods of time.

Figure 11.5a)	Figure 11.5b)

Figure 11.5 a) Illustrates a considerable medial shift over the midfoot and then considerable lateral shift over the forefoot before propulsion which has little toe involvement. It also shows how the heels contact with the ground is very short when compared to that of the forefoot.

Figure 11.5 b) Shows relatively equal amounts of time spent during the cycle until the forefoot where more time is spent. Here the COF line again shifts medially before moving laterally over the 2nd digit.

Figure 11.5c)

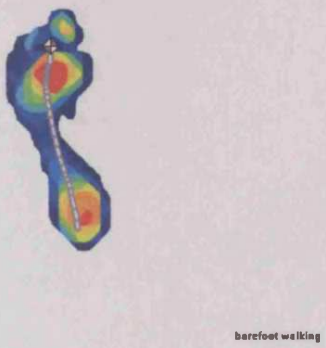


Figure 11.5d)

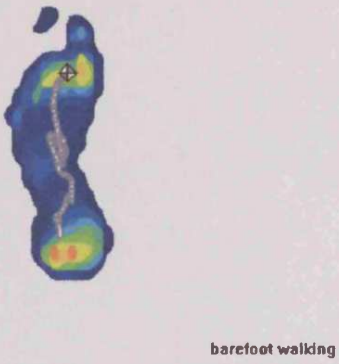


Figure 11.5 c) Illustrates a relatively normal COF line.

Figure 11.5 d) illustrates an incredible variation in weight and direction transfer during the strike with no toe involvement in the propulsive phase.

Figure 11.5 e) Again illustrates variation in weight and direction transfer but this time has more toe ground contact allowing the hallux to assist in propulsion.

Figure 11.5e)

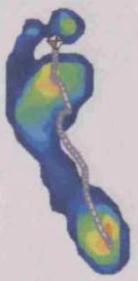
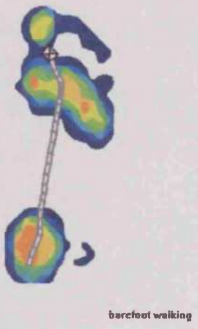


Figure 11.5 f) and g) both represent images showing no medial or lateral arch contact with the ground. Figure 11.5 f) illustrates a variation in direction and weight transfer with no hallux involvement during the propulsive phase, and g) demonstrates a relatively normal COF line with some medial hallux involvement.

Figure 11.5f)	Figure 11.5g)



In most of the images recorded it was found that more time was spent over the metatarsal head area than at any other part of the foot strike and will be considered in greater detail later.

11.2.3 Time to, and Contact Time of, Peak Plantar Pressure

The length of time the subject took to reach the peak plantar pressure for each foot strike varied considerably between subjects. This was due to the variation in total time of stance phase and the location of peak plantar pressure for each subject. The mean duration of stance phase for the group was 0.96 seconds (SD=0.25 secs).

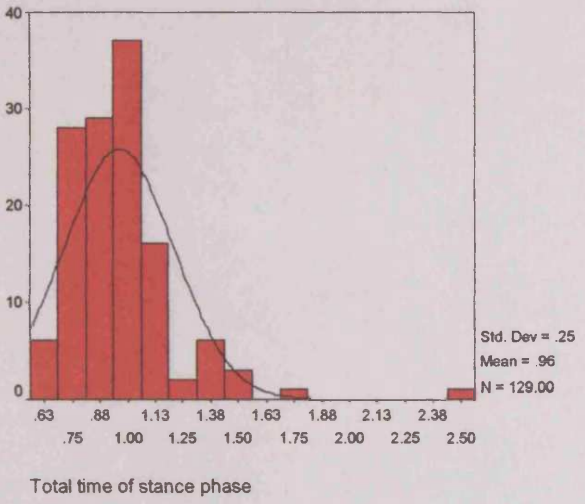


Figure 11.6 – Time to peak pressure.

A large proportion of subjects scored their peak plantar pressure over the metatarsal head, however some recorded their peak plantar pressure at heel strike which in most cases would occur earlier than the metatarsal head ground contact. Examples of the variations found between subjects follows with Subject 1 representing peak plantar pressure over the metatarsal head region; Subject 2 representing peak plantar pressure over the heel region; and Subject 3 illustrating equal peak plantar pressures over both the heel and metatarsal head regions.

Subject 1

Area	=	metatarsal heads
Peak plantar pressure (PPP)	=	236KPa
Duration of foot strike	=	0.83 seconds
Time to PPP	=	0.52 seconds
Duration at PPP site	=	0.67 seconds
% of total strike time	=	80%

Subject 1 – barefoot walking

The graphical representation (Appendix 4) shows the force and contact time that the metatarsal head area has with the ground. It also shows the force and contact time that the heel has with the ground. From this graph it can be seen that the heel has ground contact for a relatively short amount of time and that the metatarsal heads also have very early contact with the ground and therefore remain in contact for 80% of the complete ground contact time.

Subject 2

Area	=	heel
Peak plantar pressure (PPP)	=	217KPa
Duration of foot strike	=	1.06 seconds
Time to PPP	=	0.26 seconds
Duration at PPP site	=	0.89 seconds
% of total strike time	=	84%

Although the metatarsal head area showed less plantar pressure than the heel area (223KPa at heel area compared to 178KPa at metatarsal head area), the duration of time spent at this area was 0.88 seconds which represented 83% of the total strike time, only 1% less time than that spent on the heel area. In this case the metatarsal head area may pose an equal threat to developing complications as the heel area.

Subject 2 – barefoot walking

barefoot walking

Subject 3

Area	=	heel and metatarsal head areas
Peak plantar pressure (PPP)		
Heel	=	102Kpa
Metatarsal heads	=	102KPa
Duration of foot strike	=	0.83 seconds

Time to PPP

Heel	=	0.16 seconds
Metatarsal heads	=	0.50 seconds

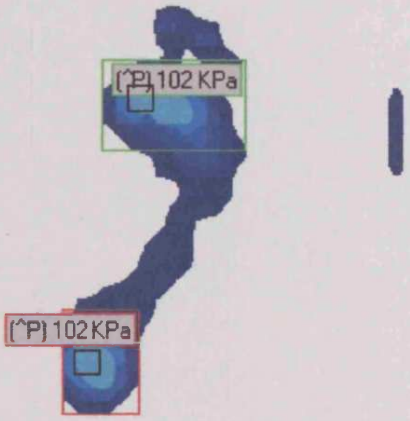
Duration at PPP site

Heel	=	0.47 seconds
Metatarsal heads	=	0.76 seconds

% of total strike time

Heel	=	56.6%
Metatarsal heads	=	91.6%

Subject 3 – barefoot walking



When analysing subject 3's foot strike, the heel is highlighted as receiving the greatest plantar peak pressure. On further investigation it appears that the metatarsal head region is experiencing exactly the same amount of pressure which when compared to other subjects is relatively low and may be felt to be too low to warrant any preventative measures to be taken. When the force and its duration at the two sites are

considered together however, a completely different analysis is found. The Force vs. Time graphs (Appendix 4) illustrate that only 0.47 seconds was being spent on the heel compared to 0.76 seconds on the metatarsal heads these representing 56.6% and 91.6% respectively of the total strike time. The metatarsal head area may now represent more of a potential problem than had previously been considered.

The 'Integral/Impulse' display option gives a similar display to that shown with the 'Peak/Phase' display option.

'Peak/Phase' display

'Integral/Impulse' display

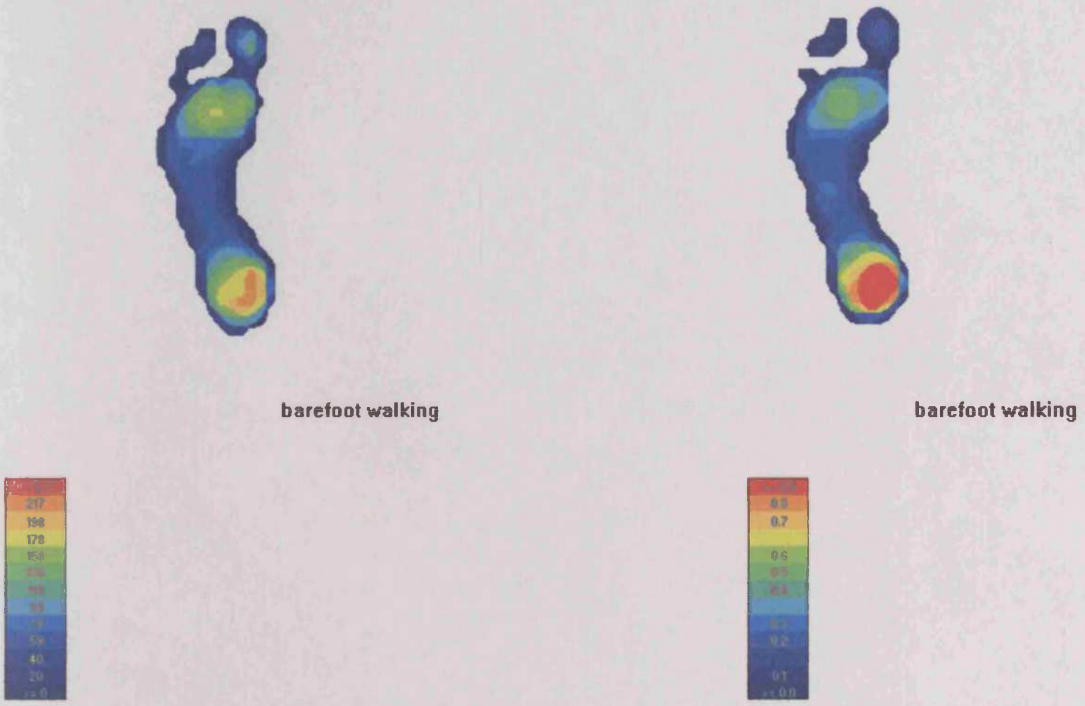


Figure 11.7 – Illustrations of Peak/Phase and Integral/Impulse

The two foot images above represent the two types of display with their appropriate colour scales below for the same foot strike. The 'Peak/Phase' display on the left illustrates the area of different pressure in KPa and is colour coded according to the varying degrees of pressure. The 'Integral/Impulse display on the right takes into

account time and force in Kg*sec, also colour coded according to the various force*time figures.

The above foot images are that of Subject 2 where the heel was initially identified as having the greatest PPP. When duration of load was considered, the metatarsal head area spent almost the same percentage of time loaded as the heel increasing its potential for risk. Looking at the 'Integral/Impulse' display option, taking into consideration both pressure and duration of load, the heel is identified as the main area of concern once again.

Subject 1 highlighted the metatarsal head area as the main area of concern with the heel following. The following images show the heel to no longer be of such concern and goes further to identify the 1st metatarsal head as taking the greatest load for the longest duration.

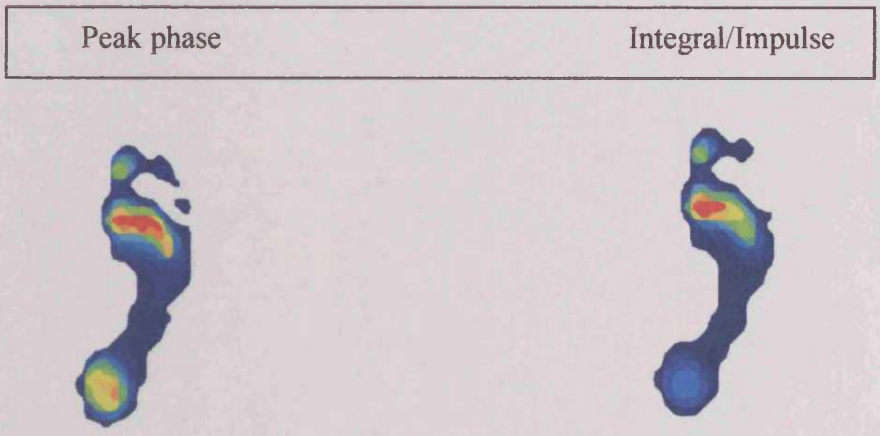


Figure 11.8 – Peak/Phase and Integral/Impulse images for Subject 1

Subject 3 illustrated equal pressure at both the heel and the metatarsal head areas. When time was considered, the metatarsal head area was found to experience the pressure for the longer duration increasing its potential risk for future complications.

When both force and time are considered, and the images are compared, the following can be seen:

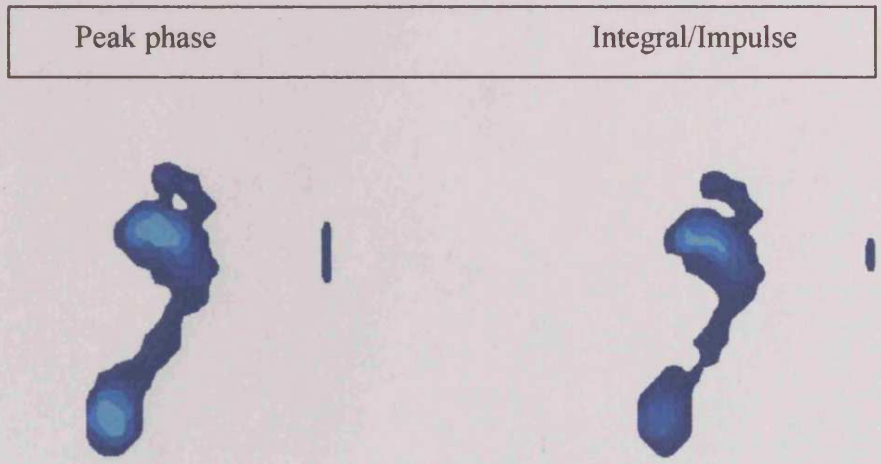


Figure 11.9 – Peak/Phase and Integral/Impulse images for Subject 3.

Although the over all pressure is less than previous images shown, it can be seen that there is a reduction in the pressure over the heel and that the pressure over the metatarsal head area remains. In this example it is also possible to see that at no time does the hallux make ground contact. It might be thought that the hallux had been amputated however this was not the case.

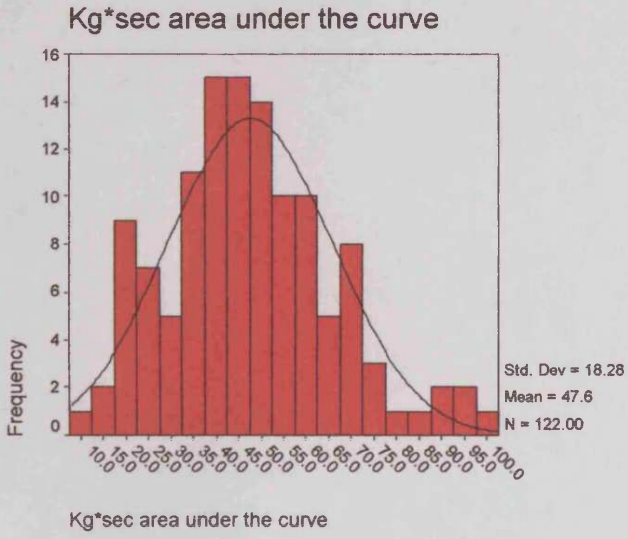


Figure 11.10 - The distribution of the Force*Time (Integral/Impulse) value for the sub group can be seen in the histogram.

11.3 **Summary – Plantar Pressure Study**

The theory from literature suggests that a specific peak plantar pressure cut off value could be used for all individuals when identifying the foot as being 'at risk'. This was proved to be inconsistent with the results obtained from this plantar pressure study. The vast range of plantar pressure values recorded between subjects and sites shows this theory not to be possible especially as size and weight of the subjects is not considered.

The theory that the plantar pressures exerted by those with diabetic neuropathy are greater than non-neuropathic subjects was also inconsistent with the findings of this study. 57% of the sub-group studied were found to be neuropathic and when compared to the non-neuropathic group (43%) it was found that the mean PPP (peak plantar pressure) was greater in the non-neuropathic group (212.33kPa) than the neuropathic group (204.36kPa).

Although PPP would highlight a particular area of the plantar foot to be at greater risk, it was considered that perhaps time spent on any particular area of the foot during foot strike should also be considered. In normal gait, the heel would find ground contact first and may be considered the area of greatest impact and greatest risk however, when time was considered it was found that most subjects spent more time on the metatarsal head area than other areas of the foot during ground contact which may suggest greater risk potential. It was also found that a greater percentage of subjects obtained their PPP over the metatarsal head area.

When considering force and time together (Kg*sec) it was found that the initial diagnosis from PPP changed. These are illustrated by the results of the individual subjects highlighted earlier. Subject 1 initially showed the metatarsal head area as a whole being of concern however, the force*time analysis highlighted the 1st metatarsal head area at greatest risk than any other plantar aspect of the foot. Subject 3 identified equal pressure at the metatarsal head and heel areas, when time was considered the longest duration was spent over the metatarsal head area, this was confirmed with the force*time analysis.

The main point highlighted by this study is that it is important to consider both force and time when identifying a particularly area of the plantar aspect of the foot that shows potential for future problems. This method of identifying potential 'at risk' areas of the foot should be considered when formulating individual treatment plans thus pre-empting future plantar lesions and ulcers.

11.4 **Executive Summary**

- The three main areas for analysis are the plantar hallux, plantar metatarsal head area and plantar heel, these being the most frequent sites for plantar foot ulceration.
- The analysis of plantar force and time together appeared to enhance identification of the 'at risk' foot allowing for the formulation and implementation of individual treatment plans therefore pre-empting plantar pressure lesions that often lead to plantar ulceration.

CHAPTER TWELVE: FINAL SUMMARY

12.1 **Summary and discussions of study findings**

12.2 **Suggestions for further research**

12.1 **Summary and discussion of study findings.**

Diabetic foot disease is a major complication of diabetes mellitus. It is a well-established concept in which vascular, neurological, and biomechanical factors, often with the added complication of infection, conspire to negatively impact on patient health, mobility, quality of life and life-expectancy. As a consequence, diabetic foot disease results in a significant personal and social burden. In the last few decades, problems relating to the diabetic foot have received an increased amount of attention from both clinicians and basic researchers. However, while the majority of studies involving the diabetic foot have focused on treatment of foot ulceration, many aspects of its pathogenesis are still far from clear. A review of the literature demonstrates that previous screening studies have utilised either non-quantitative or semi-quantitative testing methodologies on large cohorts of subjects. Other studies have involved small subject numbers when focusing on specific areas of concern such as peripheral neuropathy alone or peripheral vascular disease alone. Many of the screening studies have been conducted within a secondary care hospital setting without having to take into consideration the logistics and practicalities of screening in the primary care community setting, and often using equipment not suitable for large scale community based studies.

This thesis consists of a series of studies aimed to explore less costly, more mobile assessment methods, whilst trying to be as comprehensible and relevant to screening as possible in a community based setting.

The independent, yet related investigations aimed at evaluating a number of currently adopted methods and also less commonly used techniques which are available for use in screening for the presence of diabetic foot problems. Thus assessing and

identifying the level of risk for the possible development of diabetic foot disease in the form of ulcerations.

Knowledge of the level of risk of diabetic foot disease through regular screening can highlight possible future problems allowing treatment plans to be devised for the individual person. Current screening procedures for detecting the 'at risk' diabetic foot are often found to be both inconsistent in frequency and in the methods used.

A Patient Questionnaire and a Supplementary Questionnaire were developed, which yielded important information regarding the study population's demographics, past and present general health and foot health status. The subjects appeared to be receiving an annual diabetes review which did not always include foot examination, unless they were receiving separate, regular podiatric assessments. The main finding highlighted by the questionnaires, was the lack of knowledge that the patients had about the potential effects of diabetes mellitus on their feet. Unfortunately they appeared unaware that simple routines, such as foot examinations and wearing appropriate footwear, can be adopted to lessen these complications. By having identified these areas of deficiencies, plans to deliver effective patient education need to be put in place.

Examination of the feet and footwear of the participants indicate that callus was present in 81% of subjects, and abnormal foot shape, in 50%. These are significant risk factors for this patient group regardless of the presence of any other pathology. It is well recognised that the combination of increased pressure, increased sheer stress and an abnormal foot shape places the foot at great risk of ulceration. Ill-fitting footwear, which proved to be evident in up to 50% of patients, can only further compound the problem for such 'high risk' feet. Patients who understand the importance of suitable footwear would reduce many of the lesions involving the

dorsal and lateral margins of the foot, therefore reducing the risk of foot ulceration especially in the presence of peripheral neuropathy and/or peripheral vascular disease.

Exploration of the neuropathy status in this study looked at those patients with one or more neuropathic deficit, such as reduced light touch sensation and reduced vibration sensation, identifying the patient as having neuropathy. The results from this study emphasized the need for careful bilateral foot examination before making a diagnosis due to the degree of asymmetry found within this study group. Up to 14% of those identified with neuropathy, presented with unilateral deficits. The results from using the 10g-monofilament (based on <5 sites identified) and neurothesiometer (abnormal threshold of ≥25volts), identified a similar number of patients with neuropathy (31.7% and 30.3% respectively). The tuning fork however, identified many more subjects with neuropathy (<4 on the arbitrary scale being abnormal), than either the 10g-monofilament or the neurothesiometer. This could be due to the high threshold adopted for normal vibration perception using the neurothesiometer. An analysis of the vibration perception threshold for non-diabetic subjects, showed an increase in vibration perception threshold with age, as found previously. These findings therefore emphasis the need for age adjusted centile charts for vibration perception threshold measurements, rather than having a single value for all subjects irrespective of age.

Similarly, consideration for age adjustments when using the tuning fork and 10g-monofilament should also be explored. It is recognised that there could be other potential confounders when assessing VPT such as height, sex, smoking and alcohol intake, suggesting the need for better standardisation.

The small nerve fibre neurotip test results (<5 sites identified regarded as being abnormal), were considered along side those of the large nerve fibre tests. The neurotip identified 4% (n=23) more subjects with a neurological deficit than the 10g-

than the 10g-monofilament, 5.7% (n=31) more subjects than with the tuning fork and 6.4% (n=35) more subjects than with the neurothesiometer.

The presence of vasculopathy in this study was defined as those patients with one or more vascular deficit such as <2 pulses present per foot, an abnormal ankle brachial pressure index (ABPI) or abnormal toe brachial pressure index (TBPI). Within the study group, 31.4% (n=171) were identified as having one or more vascular deficit. 70.2% (n=120) of these were identified as having absent foot pulses, 58.5% (n=100) an abnormal ABPI and 14% (n=24) an abnormal TBPI. Interestingly, little or no agreement was found between the presence or absence of pedal pulses and the ABPI's with a large number of patients having all 4 pulses present but with abnormal ABPI. This questions the reliability of both vascular assessments. The posterior tibial colour waveform analysis and pulse volume record (PVR) image analysis were also determined. Colour waveform analysis identified 67.8% (n=114) of the patients with vasculopathy as having normal triphasic or biphasic waveforms, 8.9% (n=15), with abnormal monophasic waveforms and the remaining 23.3% (n=39) showing asymmetry. Abnormal pulse volume record analysis (PVRs) identified 21.5% (n=44) with a mild or moderately abnormal PVR (grade B or C), the remainder (88.5%, n=206), had normal PVR grades (grade A). Agreement was found between ABPI results and PVR results. The most noticeable outcome however was the disagreement of those with an ABPI of >1.30, where all subjects had normal grade-A PVR's.

Of all the vascular assessments conducted in this study, the PVR proved to be, from a clinical point of view, a quick and easy method, and able to yield results from all patients including those with peripheral oedema. From the patients' point of view, this was the preferred method being quick and comfortable.

It was also considered important to establish whether the severity of either neuropathy or vasculopathy when present alone differed to the neuropathy **and** vasculopathy when appearing together. Patients with neuropathy only and vasculopathy only where compared with those subjects having both neuropathic **and** vascular complications (mixed/neurovascular). It was found that males dominated in the neuropathy only group and females dominated in those with vasculopathy only when the duration of diabetes was below 20 years. In those diagnosed diabetic for 20+yrs however, this pattern was reversed with females dominating the neuropathy only group but there was no gender difference in the vasculopathy only group. Although previous studies have found similar gender patterns, no explanation has yet been established for this gender effect. Those patients with mixed/neurovascular pathologies appeared to be older than the single pathology groups, and older still than those with no discernable pathologies. The results from the neuropathy tests showed that the mixed/neurovascular group had more severe neuropathy than the neuropathy only group. Similarly, the results from the vascular tests showed the mixed/neurovascular group also had more severe vascular complications than those with vasculopathy only. These results indicate that an assessment of risk based on a single pathology is limited, in that the severity of both neuropathy and vasculopathy was seen to be greater in the mixed/neurovascular group so would therefore under estimate the risk of this mixed/neurovascular group.

Plantar pressures and duration of plantar pressures were also considered due to their involvement in increasing the risk of diabetes related foot complications. The results suggested that using one specific force threshold for identification of an 'at risk' foot is inappropriate due to the vast range of plantar pressure values recorded between subjects and sites, in addition to variation in size and weight of the subjects. It

became evident that there was a need to consider both force and time together when identifying the potential 'at risk' areas of the plantar surface of the foot. For example, the high pressure of a heel strike may last for less than half a second and therefore might not pose as much of a threat as perhaps the same pressure but of longer duration experienced over the plantar metatarsal head area. Plantar pressure analysis, along with duration of plantar pressure, to identify potential 'at risk' areas of the foot should therefore be considered when formulating individual treatment plans thus pre-empting and minimizing future plantar lesions and ulcerations.

The usefulness of digital images of the feet for identifying subjects with neurological or vascular complications was also explored. Although limitations were apparent due to the inability to identify inter-digital lesions from the four views used, this study showed high sensitivity for the identification of subjects with neuropathy, but low sensitivity for the identification of subjects with vascular complications. Patients with more severe peripheral vascular disease with skin colour changes, significant hair loss or arteriovenous shunting on the dorsum of the foot should be more easily identified with the digital camera than less advanced disease.

Digital images is an advance to printed Polaroid images kept in patient files, and for the purpose of remote consultation – 'Telemedicine' - of unusual foot deformities and lesions. Digital foot images can also be of use in documenting progression of foot deformities and lesions over time. It was evident that digital images would not replace a thorough visual inspection but could be used to enhance it by the images being kept as a record of foot health progression.

The Study Steering Committee also defined 'Study Risk Categories' (categories 1-4), prior to commencement of data collection (see Appendix 3). After a full and thorough assessment of each patient a risk category was assigned.

The distribution of subjects assigned to each category

	%		N
Category 1	15.2		83
Category 2	25	low risk	136
Category 3	59.4	medium risk	324
Category 4	0.4	high risk	2

In the light of the findings in chapters 7-9, however, the criteria for risk stratification could be improved. For example, vibration perception threshold using <25v as the normal threshold for the neurothesiometer, identified 30.3% of subjects with neuropathy whereas if the normal threshold were to be changed to <21v, 48% of subjects would be identified as neuropathic. Age adjustments to vibration perception thresholds for all patients would also alter these results considerably.

As stated above, the main aim of this study was to examine and evaluate, current and newer methods for assessing the neuropathic, vascular and biomechanical status of the diabetic foot with respect to their use in a community setting.

On consideration of the results, the researcher recommends that the following be used as a minimum when performing an initial and subsequent examination of the diabetic foot:

- Questionnaire to obtain information regarding general and foot health status, symptoms relevant to foot and lower limb problems and to establish each patient's knowledge regarding affects of diabetes on their foot health.
- Thorough visual examination of the foot and foot wear for lesions, foot shape, and the suitability of foot wear and wear patterns.
- Peripheral neuropathy assessment:

For large nerve fibre function, the 10g-monofilament for light touch at 5 plantar sites as described in the methods chapter, and neurothesiometer for determining the vibration perception threshold using age adjusted centile charts. For small nerve fibre function, the neurotip test. The Owen Mumford Neuropen would be the instrument of choice as this has proven to have good repeatability, is durable and encompasses both the neurotip and 10g-monofilament within one device.

- The pulse volume recorder for vascular assessment.
- Assessment of the plantar force and time integral using the TekScan MatScan portable force plate, which proved ideal for this purpose.

Limitations of study

- The study would have benefited from a larger number of non-diabetic control subject data for both neuropathy and vascular analysis.
- The questionnaire could be re-designed to include symptom scoring.
- Photography of inter-digital spaces would provide additional information.

12.2 Suggestions for further research

- Longitudinal study – re-assess all subjects in 5yrs to observe any changes in foot health status and behaviour/knowledge level of patients.
- Consider other possible confounders, such as height, weight and sex, when identifying diabetes related peripheral neuropathy and further explore age adjustments in diagnosis of diabetes related neuropathy.

- Further small nerve fibre function research is required to clarify the accuracy of the neurotip for detection of peripheral neuropathy and perhaps identify any trends or patterns in damage to different sized nerve fibres.
- Further explore the pulse volume recorder against duplex scanning regarded as the 'Gold Standard' to identify its accuracy and usefulness as a single vascular screening method, leading to the possible production of a realistically priced, dedicated PVR device that can be routinely used for screening in the community.
- Consider a longitudinal study of plantar force and time analysis of diabetic subjects prior to ulceration.

This study emphasises the continued need for further research in view of the magnitude of the problem with the diabetic foot.

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Appendix 1

Documentation relating to patient information and consent

Patient Enquires to:

Jane Lewis BSc (Hons), Diabetes Research Podiatrist
Diabetes Research Unit, 1st Floor Academic Centre
Llandough Hospital, Penarth. CF64 2XX
Tel: (029) 20716911

DIABETIC FOOT RISK ASSESSMENT AND REDUCTION STUDY

PATIENT INFORMATION

The Diabetes Research Unit at Llandough Hospital is carrying out a community-based study of patients with diabetes to establish those with an increased risk of developing foot complications. To be able to do this, we require a large number of patient volunteers, we would therefore be very grateful for your participation.

The purpose of this information sheet is to describe the process of the foot screening appointment. If you have any questions about the procedure, please do not hesitate to ask.

BEFORE SCREENING

You will be sent an appointment to attend either the Podiatry (Chiropody) Department at Barry Neighbourhood Hospital, Barry or the Diabetes Resource Centre at Llandough Hospital. The location will be to your convenience where possible. With this letter you will receive a questionnaire which you should complete and bring with you to your appointment.

YOUR SCREENING APPOINTMENT

A Diabetes Specialist Podiatrist (Chiropodist) will be carrying out the tests so please feel free to ask any questions. The Podiatrist (Chiropodist) will run through your answered questionnaire with you, then complete a couple of further questions before starting the tests, most of which you will be familiar with as they will have been carried out with you before. You will be asked to remove your shoes and socks.

The Podiatrist (Chiropodist) will firstly check your circulation. This will involve

- Noting the temperature of your feet using an infrared thermometer.
- Feeling for the blood pulses in your feet, both on the top of your feet and by your anklebone.
- Some clear gel will be put on your skin and a probe placed on the gel to enable the flow of your blood to be heard and measured.
- Your blood pressure will also be taken.

The Podiatrist (Chiropodist) will check your sensation next. Your feet will be tests to see if you can feel touch, cold temperature and vibration.

- Firstly a small blunt instrument, secondly a sharper instrument will be placed on 5 different areas on the soles of your feet and thirdly a cold instrument on the tops of your feet. These will assess your ability to feel touch, pain and cold temperature.
- To check if you can feel vibration, a probe will be placed on the end of your big toe and your anklebone. The probe's vibration will be increased until you are able to feel it, and then decreased until you are no longer able to feel it.

Foot photographs: Approximately 4 photographs of each foot will be taken from different positions. These will be kept with your records to monitor any changes in your foot shape over time.

Finally: You will be asked to replace your socks and walk (assisted if necessary) across a flat mat. This mat contains sensors, which will show how much pressure, and how much time you spend on different parts of your feet while you are walking. This information will be stored on a computer.
You may now put your shoes back on and you are free to go!

There is no requirement for you to take part in this study. Should you choose not to take part it will not affect any current or future foot care you receive.

***IMPORTANT*: THIS APPOINTMENT IS IN ADDITION TO ANY OTHER FOOTCARE APPOINTMENT YOU HAVE BEEN GIVEN. HOWEVER, SHOULD ANY PROBLEMS BE IDENTIFIED, ONGOING CARE WILL BE PROVIDED.**

Should you require any further information, please contact:
Jane Lewis BSc (Hons), Diabetes Research Podiatrist
Diabetes Research Unit, 1st Floor Academic Centre
Llandough Hospital, Penarth. CF64 2XX Tel: (029) 20716911

LLANDOUGH DIABETIC FOOT RISK ASSESSMENT AND REDUCTION STUDY

CONSENT FORM

The Diabetic Research Unit at Llandough Hospital is carrying out a community based study to assess patients with diabetes for foot related problems.

As we require a large number of patients, we are looking for volunteers to be involved in this study.
You would be required to attend an appointment at either Llandough Hospital or Broad Street Clinic, Barry to undergo a thorough foot assessment session lasting between ½ and ¾ of an hour. The results will be used for our research and in your future Diabetic foot care. The assessment procedure will be fully explained to you before commencement and you may withdraw from the study at any time.

.....

Patient ID .....

NAME: .....

ADDRESS: .....

.....

POSTCODE: ..... TEL NO: .....

I would be happy to be part of this study ☐

Llandough Hospital ☐ Barry Hospital ☐

I would be happy to be part of a Diabetic Foot Patient Interest Group ☐

VOLUNTEER (Signature) .....

(Print name) .....

RESEARCHER (Signature) .....

(Print name) .....

WITNESS (Signature) .....

(Print name) .....

Appendix 2

Questionnaire for completion at home by subject and Supplementary Questionnaire

Llandough
Diabetic
Foot
Risk
Assessment &
Reduction
Study

LLANDOUGH DIABETIC FOOT RISK ASSESSMENT AND REDUCTION STUDY

PATIENT QUESTIONNAIRE

The Diabetic Research Unit at Llandough Hospital are carrying out a community based study of patients with diabetes to establish who may be "at risk" or have developed diabetes related foot complications.

We would be very grateful if you would take the time to complete this questionnaire and bring it with you for your foot examination appointment.

Please try to answer all the questions by placing a tick (✓) in the box opposite your answer.

Patient ID: ☐

Title: Mr/Mrs/Miss/Dr/Prof./Rev/Other **Date of Birth:**

Surname: _____

Forename(s): _____

Address:

_____

Postcode: _____

Telephone Number: _____

05/08/02-Version 3

Section 1 – About yourself

1. How would you describe your ethnic origin? (You do not have to answer this question.)

African	☐ 1	Chinese	☐ 4	White/Caucasian	☐ 7
Afro Caribbean	☐ 2	Indian	☐ 5	Other	☐ 8
Bangladeshi	☐ 3	Pakistani	☐ 6		

2. Please list **all** treatments and medication that you are currently taking.

3. Are you a member of Diabetes UK, or any diabetic patients support group in your area?

Yes	☐ 1
No	☐ 2

4. Are you?

Male	☐ 1
Female	☐ 2

5. How old are you?

0-19 years	☐ 1
20-29 years	☐ 2
30-39 years	☐ 3
40-49 years	☐ 4
50-59 years	☐ 5
60-69 years	☐ 6
70 years and over	☐ 7

6. Do you live alone?

Yes	☐ 1
No	☐ 2

7. Do you smoke?

Yes	☐ 1
No	☐ 2
Ex smoker (longer than 6 months)	☐ 3

8. How much alcohol do you drink in a week?
1 unit = ½ pt beer/larger = small glass wine = single pub measure spirit

0 units per week	☐ 1
1-10 units per week	☐ 2
11-20 units per week	☐ 3
21-30 units per week	☐ 4
30+ units per week	☐ 5

Section 2 – About your diabetes and health

9. When were you first diagnosed with diabetes?

Less than 5 years ago	☐ 1
Between 5-9 years ago	☐ 2
Between 10-19 years ago	☐ 3
More than 20 years ago	☐ 4

10. How is your diabetes treated?

Diet alone	☐ 1
Tablets alone	☐ 2
Insulin alone	☐ 3
Insulin with tablets	☐ 4

11. Have you had your eyes photographed by the Diabetic Retinopathy Screening Service?

Yes	☐ 1
No	☐ 2

12. If yes, how long ago?

Less than 6 months ago	☐ 1
6 – 12 months ago	☐ 2
More than 12 months ago	☐ 3

13. Does your eyesight allow you to see your feet in detail/clearly? (Using your glasses if you normally wear them)

Yes	☐ 1
No	☐ 2

14. Have you had any operations involving the blood vessels in your legs? (Not surgery for varicose veins)

Yes	☐ 1
No	☐ 2

15. Have you ever had a stroke?

Yes	☐ 1
No	☐ 2

16. Have you had any operations or accidents involving your?

Back	☐ 1
Hips	☐ 2
Knees	☐ 3
Ankles	☐ 4
Feet	☐ 5

Section 3 – About your feet

17. Since you have had diabetes, have you had an ulcer, an open wound or even a sore on either of your feet?

Yes	☐ 1
No	☐ 2

18. Similarly, have you ever had an infection involving either of your feet?

Yes	☐ 1
No	☐ 2

19. Are you aware of the foot problems that relate to diabetes?

Yes	☐ 1
No	☐ 2

20. Would you like to know more about foot problems related to diabetes?

Yes	☐ 1
No	☐ 2

21. Have your feet been checked by any of the following during the last year? (Tick more than 1 box if necessary)

Nobody	☐ 1
GP/Practice Nurse	☐ 2
Diabetic Specialist Nurse	☐ 3
District Nurse	☐ 4
Podiatrist (Chiropodist)	☐ 5
Hospital Doctor	☐ 6

22. How often do you, or a family member, or carer look at your feet?

Never	☐ 1
Daily	☐ 2
Weekly	☐ 3
Monthly	☐ 4
Yearly	☐ 5
Other	☐ 6

23. Has anyone explained to you why you should inspect your feet regularly?

Yes	☐ 1
No	☐ 2

24. Has anyone explained to you, or a family member or your carer, how to inspect your feet properly?

Yes	☐ 1
No	☐ 2

25. Have you been told what to look for?

Yes	☐ 1
No	☐ 2

26. Has anyone explained the need for you to have your feet inspected regularly by a Health Professional (e.g. Nurse, GP, Podiatrist / Chiropodist)?

Yes	☐ 1
No	☐ 2

27. Has anyone explained to you the importance of wearing suitable shoes for your feet?

Yes	☐ 1
No	☐ 2

28. Have you had shoes specially made for you?

Yes	☐ 1
No	☐ 2

29. If you have, how often do you wear them?

Never	☐ 1
Sometimes	☐ 2
Most times	☐ 3

THANK YOU FOR TAKING TIME TO COMPLETE THIS QUESTIONNAIRE

SUPPLEMENTARY QUESTIONS

NOTES TO PODIATRIST:
These questions are to be asked at the Clinical Appointment having received the fully completed Patient Home Questionnaire. The 'Yes' responses to Q17 and Q18 of the Patient Home Questionnaire should be further investigated and the information reported on the reverse of this sheet.

1. Is there a connection between Diabetes Mellitus and your foot health?
   Y / N

2. Is it important for you, a family member or your carer to look at your feet regularly?
   Y / N

3. How often do you think that you, or a family member or carer should look at your feet?

4. Do you know what changes are you looking for with your feet?
   Y / N
   If yes, detail.

5. Who should you contact if you experience any changes in the feeling and/or appearance of your feet?

6. Do you know that you should have a regular review of your feet? Y / N

7. How often should this be done?

8. Do you receive an annual review? Y / N

9. If not, what is the reason?

10. Do you currently visit a Podiatrist? Y / N

11. If yes is this an NHS or private Podiatrist?

12. Do you visit on a regular basis? Y / N

PLEASE ENTER DETAILS TO Q17 AND Q18 OF PATIENT HOME QUESTIONNAIRE ON THE REVERSE OF THIS SHEET

Appendix 3

Clinical assessment form – (data collection)
Patient Risk Assessment Form – (patient categorisation)

CLINICAL ASSESSMENT FORM

Assessment Date: _____ **Clinician:** _____

PATIENT DETAILS

Title: Mr/Mrs/Miss/Ms/Prof./Rev/Other **Date of Birth:**

Surname: **LDFRARS No:**

Forename(s): **Hospital No:**

Address:

Postcode: **Tel No:**

FOOT TEMPERATURE - (Infrared Thermometer)

Right Foot	Description	Left Foot
Actual temperature ^{0}C	**Dorsum of foot**	Actual temperature ^{0}C

VISUAL ASSESSMENT

Right Foot	Description	Left Foot
Y/N	Normal foot colour	Y/N
	< If 'No' describe > < abnormality >	
Y/N	Oedema	Y/N
Y/N Y/N Y/N Y/N Y/N Y/N	**Current Lesions** Corns Callus Ulcer Fissure Nail Pathology ID Maceration	Y/N Y/N Y/N Y/N Y/N Y/N

Right Foot	Description	Left Foot
Y/N Y/N At/Above At/Above	**Amputations** Digit/s Partial foot Ankle Knee	Y/N Y/N At/Above At/Above

Right Foot	Description	Left Foot
Y/N Y/N Y/N Y/N 1 / 2 / 3 Y / N	**Deformities** Hammer toe Claw/Retracted toe Bony prominence including HAV Charcot arthropathy Stage 1, 2 or 3 (*see end for stage explanation) Prominent metatarsal heads	Y/N Y/N Y/N Y/N 1 / 2 / 3 Y/N

Right Foot	Description	Left Foot
Y/N Y/N Y/N Y/N Y/N Y/N	**Previously resolved lesions** Corns Callus Ulcer Fissure Nail Pathology ID Maceration	Y/N Y/N Y/N Y/N Y/N Y/N

NEUROPATHIC ASSESSMENT

Right Foot	Description	Left Foot
	10g Monofilament	
	Pin-prick Test	

Enter '+' or '-' for every site
'+' = positive, '-' = negative
(no feelings)

Enter '+' or '-' for every site
'+' = positive, '-'= negative
(no feelings)

05/08/02 - Version

VPT - TUNING FORK (RYDEL SEIFFER)

Right Foot	Description	Left Foot
	Distal tip of hallux (Mean of 3 recordings)	
	Medial Malleolus (Mean of 3 recordings)	

VPT - NEUROTHESIOMETER

Right Foot	Description	Left Foot
Volts	**Distal tip of hallux** (Mean of 3 recordings)	volts
Volts	**Medial Malleolus** (Mean of 3 recordings)	volts

THERMAL PERCEPTION - (Cold Tuning Fork)

Right Foot	Description	Left Foot
Y/N	**Cold perception** (dorsum of foot)	Y/N

VASCULAR ASSESSMENT

Right Foot	Description	Left Foot
Y/N Y/N	**Palpable foot pulses Dorsalis Pedis Posterior Tibial**	Y/N Y/N
Mono/Bi/Tri	**Waveforms (P.T.)**	Mono/Bi/Tri
mmHG	**Systolic Blood Pressure**	mmHG
mmHG Actual index =	**Ankle systolic pressure ABPI**	mmHG Actual index =
mmHG Actual index =	**Toe systolic pressure TBPI**	mmHG Actual index =

OTHERS

Right Foot	Description	Left Foot
Y/N Y/N Y/N Y/N	**Digital Images** Plantar Dorsal Medial Lateral	Y/N Y/N Y/N Y/N
Y/N	**Plantar Pressures Assessed**	Y/N

Right Foot	Description	Left Foot
Y/N	**Footwear** Specialised footwear required?	Y/N
Y/N	Specialised footwear previously issued?	Y/N
Y/N	Evidence of specialised footwear being worn?	Y/N

***Chatcot Arthropathy Stages**

Stage 1- Hyperemic fragmentation of joint - warm, swollen, looks like infection - patients can't feel but joint is painful.

Stage 2- Coalescence - bones become denser and start to re-ossify

Stage 3- Consolidation

ADDITIONAL COMMENTS

General foot hygiene:

Condition of nails (require cutting/monitor infection etc):

Evidence of harmful self-operating:

Details of previous lesions:

Infection

Ulcers

Trauma - heat, accident, foreign body in shoe etc.

PATIENT RISK ASSESSMENT FORM

Title: Mr/Mrs/Miss/Ms/Dr/Prof/Rev/Other **Date of Birth:**

Surname: **LDFRARS No:**

Forename(s): **Hospital No:**

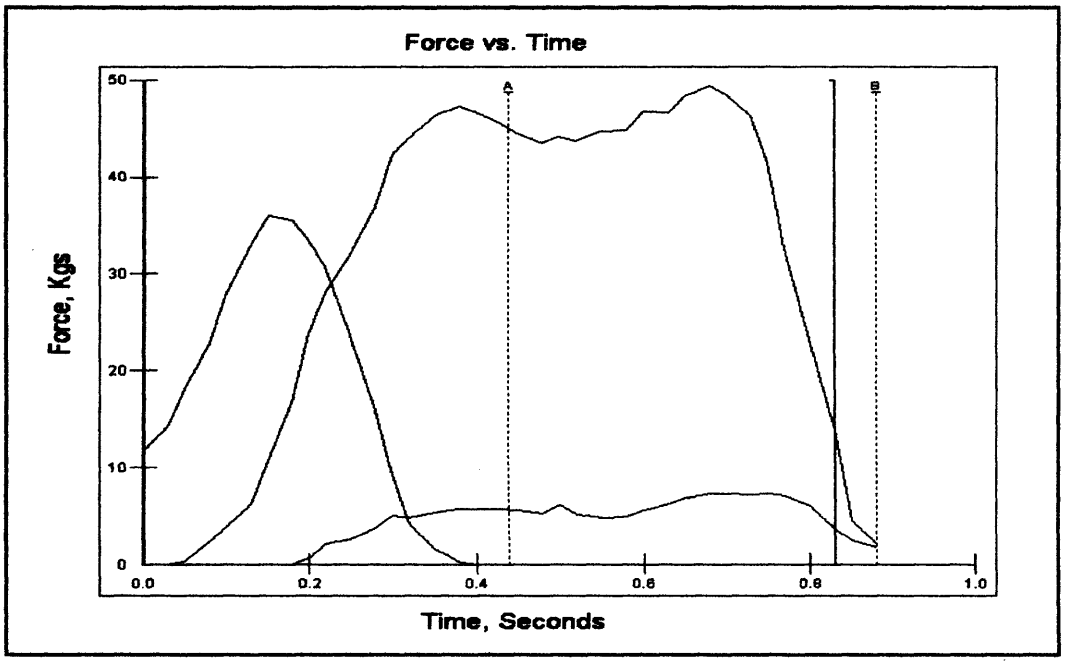
Assessment Date: **Clinician:**

	Risk Right Foot	***Description***	***Risk Left Foot***	
Grade				**Grade**
		No previous ulcer		
1(a)		No significant deformity		1(a)
☐		VPT <25 volts		☐
		ABPI ≥ 0.9		
		TBPI ≥ 0.5		
		+ve 10g monofilament at all 5 sites		
1(b)		Palpable foot pulses (D.P. &/or P.T.)		1(b)
☐		No evidence of callus/corns		☐
		Features of 1a plus one or more of:-		
2		-ve 10g monofilament at 1 or more sites		2
☐		1 or less foot pulses per foot		☐
		Evidence of callus/corns present		
		Features of 2 plus 1 or more of:-		
		Previous ulcer		
3		Foot deformity present		3
☐		VPT ≥ 25volts		☐
		ABPI < 0.9		
		TBPI < 0.5		
4 ☐		**New ulceration, cellulitis, discolouration**		4 ☐

1a, 1b = Low Risk 2 = Medium Risk 3 = High Risk 4 = Foot care emergency

Appendix 4
MatScan Force*Time graphical output

Subject 1



Subject 3