INDICATIONS FOR ARTERIAL RECONSTRUCTIVE SURGERY AND PRIMARY MAJOR AMPUTATION IN THE MANAGEMENT OF CHRONIC CRITICAL LOWER LIMB ISCHAEMIA

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Dedicated to Alastair, Nicola and my parents

DECLARATION

I hereby declare and affirm that this thesis is entirely my own work and composition.

Signature

Date ......2/8/99......

LIST OF ABBREVIATIONS

AKA	above-knee amputation
BKA	below-knee amputation
CI	confidence interval
CRAG	Clinical Resource and Audit Group
DHSS	Department of Health and Social Security
DSA	digital subtraction angiography
DSC	Disablement Services Centre
IPOP	immediate postoperative prosthesis
ISD	Information and Statistics Division
ISIS	International Study of Infarct Survival
NHS	National Health Service
OPCS	Office of Population Censuses and Surveys
PTA	percutaneous transluminal angioplasty
PTFE	polytetrafluoroethylene
QALY	quality-adjusted life year
SD	standard deviation
SMR	Scottish morbidity record
UK	United Kingdom
USA	United States of America

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ABSTRACT

Up to one person in one thousand develops critical lower limb ischaemia each year. In Scotland, this equates to around 5,000 new cases per annum. Arterial reconstructive surgery is attempted in only one-half of patients. Most of the remainder undergo either primary major amputation or conservative treatment. However, published case-series suggest that the proportion of patients undergoing limb-salvage procedures varies between units. An analysis of Scottish discharge data for 1989-1990 confirmed wide geographical variations in procedure rates. There was a five-fold variation in arterial reconstruction rates, and a four-fold variation in major amputation rates. Variations may be due to differences in case-mix. However, differences in clinical decision-making and practice were considered likely. Therefore a study was undertaken to derive specific indications for surgery in patients with chronic critical lower limb ischaemia, and to determine the extent to which practice throughout Scotland conformed with these indications.

Consensus methods provide an explicit and systematic method of deriving indications from published evidence and clinical experience. A review was undertaken of the published literature on outcomes following arterial reconstruction and primary major amputation, in terms of life-expectancy, limb-salvage, healing, reoperation, social and physical functioning, quality of life and cost-effectiveness. Thereafter, consensus indications were agreed using a modified Delphi method in which a postal questionnaire was completed by 29 vascular surgeons on two occasions, with feedback

between the rounds. This method has been used previously to develop indications for coronary artery bypass grafting and carotid endarterectomy. Use of a postal questionnaire avoided physical constraints on the selection of panellists, whilst also ensuring that undue weight was not given to the most dominant or vocal participants. Respondents indicated the appropriateness of arterial reconstruction and primary major amputation for 218 case-scenarios comprising all possible combinations of clinical and angiographic findings. Agreement was reached on 31 appropriate indications for major amputation and 65 for arterial reconstruction. The consensus indications were then compared with actual clinical practice in a stratified random sample of ten Scottish hospitals. Four hundred primary major amputations and arterial reconstruction operations were reviewed retrospectively. The clinical findings for 7 (4%) arterial reconstruction operations and 48 (24%) major amputations did not conform to the indications agreed by the Delphi method. The proportion of operations conforming to the agreed indications differed significantly by size of unit ($p<0.05$).

The study demonstrated that consensus could be reached on indications for surgery in patients with chronic critical lower limb ischaemia. The proportion of procedures conforming to the indications varied between units, suggesting that differences in clinical decision-making were apparent. Consensus guidelines have been disseminated to all vascular surgeons in Scotland.

CHAPTER 1

Introduction and outline of thesis

Peripheral arterial disease is a common condition. Therefore a substantial proportion of the population is potentially at risk of developing chronic critical lower limb ischaemia. The incidence of both peripheral arterial disease generally, and critical ischaemia specifically, increases with age. As life expectancy rises and birth rates fall, the elderly form an increasing proportion of the population. The incidence of diabetes mellitus, another risk factor for critical lower limb ischaemia, is also rising. Both of these factors will tend to increase the incidence of critical ischaemia over time. An overall decline in cigarette smoking may act to offset this effect. However, the increase in smoking among younger people, particularly young girls, may have a delayed adverse effect.

Critical ischaemia is a serious condition. Case-fatality rates are high, and one-quarter of those affected will lose at least one limb. Major amputation is associated with many adverse sequelae; functional impairment, physical dependency, loss of employment, social isolation and psychological trauma. Even in those patients who avoid amputation, quality of life is nonetheless impaired.

The costs of the disease and its treatment are high, both to the individual, and to society as a whole. Prolonged periods of in-patient treatment and intensive rehabilitation programmes are common, and failed operations or progression of disease often necessitate further surgery. Loss of independence following major amputation places a significant and prolonged burden on both professional support agencies and lay carers.

A number of treatment options are available for the management of chronic critical lower limb ischaemia, including conservative measures, major amputation and attempts at revascularisation. Anecdotal evidence and comparisons of case series suggest that clinical management varies considerably between areas. Therefore it is possible that the treatment offered to some patients is at best less than ideal, and possibly inappropriate. Because of the importance of this condition and the apparent variations in practice, the management of chronic critical lower limb ischaemia requires further assessment.

The objectives of this thesis are:

- to determine whether comparisons of operation rates support anecdotal evidence of geographical variations in the management of chronic critical lower limb ischaemia,

- to derive, through consensus methods, indications for the use of arterial reconstructive surgery and primary major amputation in the management of chronic critical limb ischaemia, and

- to compare current clinical practice with these agreed indications, thereby determining whether observed variations in operation rates reflect real differences in clinical practice or merely differences in case-mix.

Chapter 2 defines chronic critical lower limb ischaemia and illustrates its importance in terms of its burden on society. Evidence is presented of the frequency, distribution and determinants of this condition. Trends in operation rates are reviewed as evidence of changes in the underlying incidence of critical ischaemia. The natural history of peripheral arterial disease is described to determine the impact of critical lower limb ischaemia in terms of mortality, cost and surgical intervention.

Chapter 3 compares the outcomes following the two principal treatment modalities for chronic critical lower limb ischaemia; major amputation and arterial reconstructive surgery. The case for arterial reconstruction is assessed in terms of limb salvage rates, the impact of graft failure on amputation level and the need for secondary procedures. The operations are compared in terms of case-fatality, rehabilitation, quality of life and cost.

Chapter 4 highlights the increasing emphasis which has been placed on clinical effectiveness over the last few years and describes the tools which can be used to address it including clinical audit, benchmarking and clinical guidelines.

Chapter 5 reviews the evidence for widespread variations in clinical practice. It outlines the implications of such variations, the possible reasons underlying them, and the methods by which they may be reduced. Evidence is then presented of wide variations in the operation rates for critical limb ischaemia, both in Scotland and elsewhere.

Chapter 6 outlines the methods available to achieve consensus on the most appropriate management of patients. A description is given of the Delphi consensus method which is then used to achieve consensus on appropriate indications for the use of arterial reconstructive surgery and major amputation in the management of chronic critical lower limb ischaemia.

In Chapter 7, a retrospective sample of primary major amputations and arterial reconstruction operations performed for chronic critical lower limb ischaemia is compared with the consensus indications to determine the extent to which actual practice conformed with agreed practice, and whether this varied between hospitals.

Chapters 2 and 3 contain literature reviews which were used to provide the evidence-base to which the Delphi consensus method was applied. Chapter 4 puts the research contained in the subsequent chapters into context by discussing the methods used to investigate and improve clinical effectiveness, their general applications and limitations. Chapters 5, 6 and 7 describe original research undertaken by me. Chapter 8 includes a general discussion of the research undertaken and methods used including their limitations and Chapter 9 concludes by summarising the results obtained and the actions taken as a result.

CHAPTER 2

Epidemiology of chronic critical lower limb ischaemia

"Over the years man's ingenuity in developing the means of self-destruction has been equalled only by his resourcefulness in his efforts at reconstruction. The evolution of ever more destructive weaponry and the introduction of tobacco have necessitated refinement of surgical techniques, and the development of sophisticated prosthetic devices"

(Campbell and Thornberry 1988).

2.1. Introduction

Because peripheral arterial disease is a common condition, many people are at risk of developing chronic critical lower limb ischaemia. The prevalence of both peripheral arterial disease and critical ischaemia increase with age. With increasing life-expectancy and declining birth rates, the elderly account for an increasing proportion of the population. The incidence of diabetes mellitus, another risk factor for critical lower limb ischaemia, is also rising. Both of these factors will tend to increase the incidence of critical ischaemia over time. An overall decline in cigarette smoking may act to offset this effect. However, the increase in smoking among younger people, particularly young girls, may have a delayed adverse effect. Comorbidity is common among those with critical ischaemia, and case-fatality rates are high. Many patients require at least one amputation, and secondary procedures are common. This chapter reviews the epidemiology of chronic critical lower limb ischaemia, in terms of the frequency and determinants of the disease, and its natural history.

2.2. Definition of chronic critical lower limb ischaemia

From an epidemiological perspective, the definition of critical limb ischaemia is important, particularly if comparisons are to be made geographically or over time. The Fontaine classification (Table 2.1.) has been adopted widely in Europe as a means of grading the severity of ischaemia.

Table 2.1. The Fontaine classification of severity of limb ischaemia

Grade	Clinical presentation
I	No clinical symptoms
II	Intermittent claudication
III	Ischaemic rest pain
IV	Ischaemic ulceration or gangrene

However, its usefulness is limited by the fact that stage III (rest pain) is too broad a category to distinguish between claudicants suffering from nocturnal pain and patients with critical ischaemia but no tissue loss.

In 1981, a working party was established at the International Vascular Symposium in London to produce a more precise definition of critical limb ischaemia (Bell et al. 1982). This working party defined critical limb ischaemia in non-diabetics as either:

- Rest pain requiring repeated analgesia for at least four weeks, associated with an ankle Doppler pressure below 40 mmHg, or
- Superficial tissue necrosis or digital gangrene, associated with an ankle Doppler pressure below 60 mmHg.

A second working party was subsequently formed in the United States and generally supported this definition (Ad Hoc Committee 1986). However, a major criticism of these criteria was that diabetics were excluded. In spite of their large number, it was thought that diabetics should not be included because both the clinical presentation and outcome of critical ischaemia is different in diabetics and non-diabetics.

In 1986, the Joint Vascular Research Group in Britain (Wolfe 1986) undertook a prospective study to test the above criteria, and concluded that inclusion of Doppler ankle pressures was only of value in patients who had rest pain in the absence of ulceration and gangrene. Diabetics were found to have a similar range of ankle pressures to non-diabetics and were included. Their suggested criteria for critical limb ischaemia in both diabetics and non-diabetics were:

- Rest pain associated with an ankle Doppler pressure below 40 mmHg, or
- Rest pain with ulceration and/or gangrene.

In 1988, the European Working Group on critical limb ischaemia (European Working Group 1989) concluded that ankle pressure measurements were invalid in the large number of patients, particularly diabetics, who had arterial calcification. In view of this, an alternative criterion of absent peripheral pulses was included for these patients. The European Consensus Working Group's definition was employed in this thesis.

2.3. Impact of chronic critical lower limb ischaemia on society

2.3.1. Incidence and prevalence

There have been no population studies of the incidence of critical limb ischaemia. Therefore estimates of incidence have largely been deduced through indirect methods. Approximate numbers can be calculated using our knowledge of other stages in the natural history of peripheral arterial disease. Inferences can be drawn from the frequency of asymptomatic peripheral arterial disease and intermittent claudication, and their patterns of progression. Alternatively, data on amputation rates can be used, as in the estimated incidence of critical limb ischaemia quoted in the European Consensus Documents (European Working Group 1989, 1991).

<u>Asymptomatic peripheral arterial disease and intermittent claudication</u>

Peripheral arterial disease is a common condition which is greatly under-diagnosed. This is partly due to the fact that many patients with evidence of peripheral arterial disease from examination or non-invasive investigations are nonetheless asymptomatic. In the Basle study only one-third of those with detectable disease reported claudication

(Dormandy et al. 1989, Widmer et al. 1964). In the Edinburgh Artery Study, 5% of people aged 55-74 years reported intermittent claudication, but a further 8% had evidence of significant asymptomatic peripheral arterial disease (Fowkes et al. 1991). Other population studies have calculated the true prevalence of peripheral arterial disease to be five times greater than that reported for intermittent claudication (Criqui et al. 1985a). Conversely, a history of claudication can be present in the absence of significant peripheral arterial disease (Criqui et al. 1985a). In addition to unrecognised cases of asymptomatic disease, ascertainment of symptomatic cases can also be incomplete. Only 10%-50% of individuals with intermittent claudication present to the medical profession (Davey-Smith et al. 1990, Hughson et al. 1978, Reid et al. 1974). Population estimates of the prevalence of intermittent claudication range from 0.3% to 7.7% (Fowkes 1988).

In order to include asymptomatic disease in assessments of peripheral arterial disease prevalence, some surveys have used clinical evaluation of pulse abnormalities. In a British study of subjects over 60 years of age, an absent dorsalis pedis pulse was present in 22.7% of men and 9.8% of women (Ludbrook et al. 1962). An American study reported similarly high prevalence rates of 31.6% and 19.5% respectively (Sackett and Winkelstein 1965). However, there is marked inter-observer variation in the assessment of pulse abnormalities, regardless of clinical expertise (Ludbrook et al. 1962, Myers 1987), and it is of doubtful value in epidemiological surveys.

Non-invasive tests of the haemodynamic effects of arterial obstruction are recognised to be more valid and reliable than palpation of distal pulses. In one American study a number of non-invasive investigations were performed on 613 people with an average age of 66 years (Criqui et al. 1985a). Evidence of large vessel peripheral arterial disease was reported in 11.7%. A Danish survey of 666 people over 60 years of age demonstrated an ankle-brachial pressure ratio below 0.9 in 16% of men and 13% of women (Schroll and Munck 1981).

Major amputation rates

More than 60,000 amputations are performed in the USA each year (Berardi and Keonin 1978). In 1986, nearly 5000 new patients were referred to limb fitting centres in England, Wales and Northern Ireland following lower limb amputations for vascular insufficiency (DHSS 1989, Dormandy and Thomas 1988). This represented about half the total number of such amputations performed in these countries. An average district general hospital serving a population of 250,000, can expect to perform between 20 and 40 major amputations for limb ischaemia each year (Dormandy and Thomas 1988).

In 1990, 722 major amputations performed in Scotland had a principal disease code of peripheral vascular disease, diabetes or gangrene, equivalent to an annual amputation incidence of 142 per million population (Pell et al. 1994b). In Scotland, the annual rate of referral to limb-fitting centres is 132 per million population (Knight and Urquhart

1989). Therefore it appears that a higher proportion of Scottish amputees are referred for prostheses.

A UK multicentre study of 409 patients with critical limb ischaemia demonstrated that, one year following presentation, 25% had undergone major amputation, 55% had retained both legs and 20% were dead (Wolfe 1986). Approximately 90% of amputations are attributed to vascular insufficiency (DHSS 1989, Dormandy and Thomas 1988, Knight and Urquhart 1989, Renstrom 1981). The European Consensus Working Group utilised these pieces of information to estimate the population incidence of critical ischaemia from amputation rates (European Working Group 1989, 1991) (Table 2.2.). They assumed that the annual incidence of critical ischaemia would be approximately four times the incidence of major amputation. As shown in Table 2.2., this produced an estimated population incidence of critical lower limb ischaemia of around 600-1200 per million population per annum.

Table 2.2. Annual incidence of major amputation and estimated incidence of critical lower limb ischaemia from population surveys in UK, USA and Denmark

Study population	Reference	Annual incidence of amputation	Estimated annual incidence of critical ischaemia
Referrals to limb-fitting centres in England, Wales & N Ireland	DHSS 1989	$200/10^6$/year	$800/10^6$/year
Scottish routine discharge data	Pell et al. 1994b	$142/10^6$/year	$568/10^6$/year
Veterans Administration in USA	Kacy et al. 1982	$280/10^6$/year	$1120/10^6$/year
Danish hospital survey (non-diabetic)	Danish Amputation Register 1989	$280/10^6$/year	$1120/10^6$/year
Danish hospital survey (diabetic)	Danish Amputation Register 1989	$3000/10^6$/year	$12000/10^6$/year
Patients in USA (non-diabetic)	Hughson et al. 1978	$200/10^6$/year	$800/10^6$/year
Patients in USA (diabetic)	Hughson et al. 1978	$3900/10^6$/year	$15600/10^6$/year
Maryland USA	Tunis et al. 1991	$300/10^6$/year	$1200/10^6$/year

(Adapted from European Working Group on Critical Leg Ischaemia (1991). Second European Consensus Document on Chronic Critical Leg Ischaemia. *Circulation* (Suppl) **84**:IVI-IV26.)

Some authors believe the European Working Groups figures to be an overestimate. Data from West Berkshire and Oxfordshire suggested that the true incidence in these areas may lie between 250 and 300 per million population per year (Collin 1992, Gutteridge 1993).

2.3.2. Time-trends

In 1986, a prospective study by Wolfe demonstrated that 90% of patients with critical lower limb ischaemia undergo major amputation, arterial reconstruction or percutaneous transluminal angioplasty over the twelve months following presentation. More recent figures are not available. It is likely that the overall percentage of patients operated on has remained relatively constant, although the relative contributions made by individual procedures may have changed. Therefore time trends in amputation and limb salvage procedures provide some indication of changes in both the incidence and management of critical lower limb ischaemia.

Hippocrates of Cos (46-380BC) is attributed with the earliest descriptive account of amputation (Phillips 1973) although this was essentially a debridement procedure (Vitali et al. 1978). "De Medicus" written by Celsus in 50AD provides the earliest account of amputation through healthy tissue proximal to the diseased portion, and therefore provides the foundation of modern amputation (Celsus 1938). Below-knee amputations were introduced in the 1940's, but only adopted widely into practice in the 1970's.

Arterial reconstructive surgery is a much more recent innovation and came into general use in the early 1950's (Andros et al. 1988). During the late 1960's and 1970's, distal reconstructions were added to the surgical repertoire, following a growing number of reports of successful grafts to the peroneal and tibial arteries (Auer and Hershey 1973, Baird et al. 1970, Foster and Yonke 1971, Garrett et al. 1968, McCaughan 1966, Royster and Reiss 1968, Sheiber and Parks 1974, Tyson and DeLaurentis 1966, Tyson and Reichle 1969). There has been an increase in the percentage of grafts terminating at infrapopliteal arteries (Andros et al. 1988, Auer et al. 1983, Bandyk et al. 1989, Bernhard et al. 1972, Dale 1965, Fogle et al. 1987, Levine et al. 1985, O'Mara et al .1981, Tyson and Reichle 1969, Veith et al. 1981c&1985). Some surgeons now report more infrapopliteal than popliteal bypasses (Bandyk et al. 1989, Leather and Karmody 1986, Levine et al. 1985). Infrapopliteal bypasses have, in turn, led to bypasses to the crural vessels. Increasing numbers of distal reconstructions have been encouraged by a changing patient population as well as developments in surgical philosophy and technique. Of particular influence has been the general resurgence of the in-situ vein technique (Andros et al. 1988, Corson et al. 1984).

Percutaneous transluminal angioplasty (PTA) was first described thirty years ago (Dotter and Judkins 1964) and introduced more widely following development of a flexible catheter in 1974 (Gruntzig and Hopff 1974). PTA can be used as both an alternative and adjunct to arterial reconstruction and major amputation (Creasy et al. 1990, Jeans et al. 1986, Johnston et al. 1987).

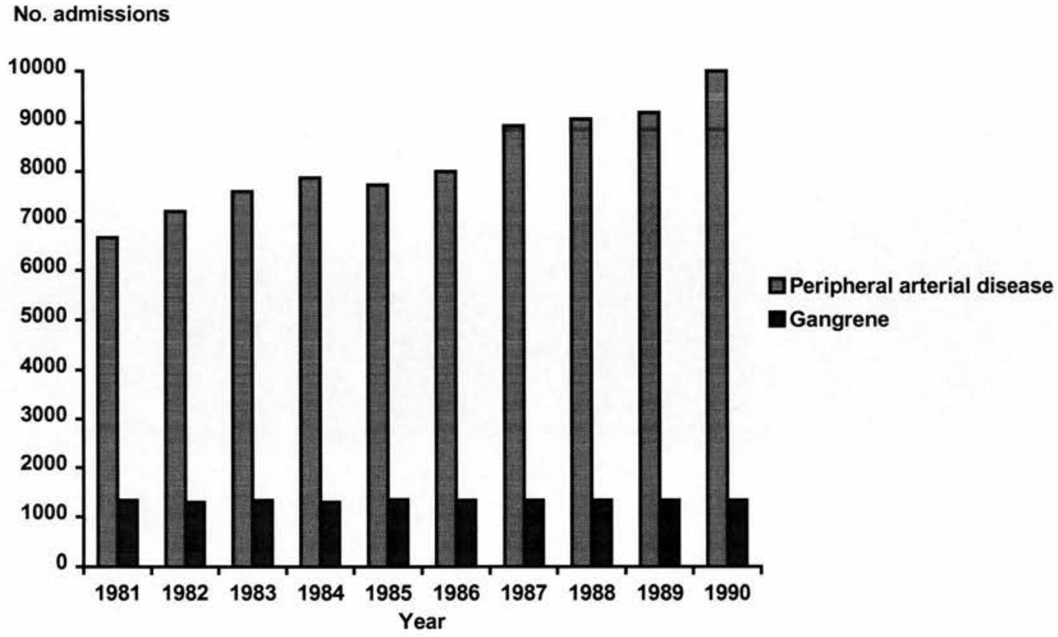
Amputation rates might have been expected to decrease following the development of "limb salvage" procedures such as arterial reconstructive surgery and PTA. Certainly a number of published case series from highly specialised tertiary centres did report a reduction in amputation rates (Coddington 1988, Imray et al. 1994, Jeans et al. 1986, Pedersen et al. 1994, Sernbo et al. 1991, Stern 1988, Vallance 1991, Veith et al 1990). However, the results of single institutions are affected by referral patterns and case-mix and may therefore be subject to selection bias (Luther et al. 1996). Early population studies failed to corroborate a decline in amputation rates. There was no decrease in lower limb amputations in the Danish county of Aalborg between 1961 and 1971 (Christensen 1976), and Liedberg and Persson (1983a) reported a four-fold increase in the age-standardised rate of amputations in Malmöhus county in Sweden between 1910 and 1980. Liedberg and Persson (1983a) speculated that one contributing factor may have been an increased life-expectancy among diabetics following the introduction of insulin. However, the proportion of diabetics remained constant, and their exclusion from the analysis left a residual three-fold increase in the age-standardised incidence of amputations. Sethia et al. (1986) also reported a one-third increase in amputation rates between 1974 and 1984.

A number of population-based studies have compared trends in amputation rates and limb salvage procedures over the same period. Earlier studies failed to demonstrate a beneficial effect from increased use of limb-salvage procedures. USA national discharge data indicated that a 56% increase in arterial reconstructive surgery from 1979 to 1985 was associated with a paradoxical 45% increase in lower limb amputations (Ernst et al. 1987). A more recent study from Maryland reported no decline in amputation rates between 1979 and 1989, despite a dramatic increase in PTA and a doubling in bypass surgery (Tunis et al. 1991).

Within Western countries, there has been a large increase in the total number of operations performed for critical limb ischaemia up to 1990. Although the incidence of peripheral arterial disease may have increased slightly over this period, there is no evidence of a rise sufficient in magnitude to account for the increase observed in operation rates (D'Agostino et al. 1989, Kannel et al. 1970, Kannel and McGee 1985, Sytkowski et al 1990). A number of alternative explanations have been suggested. With increasing pressure on surgeons to be conservative wherever possible, some patients who previously would have undergone primary major amputation may now be undergoing initial attempts at either arterial reconstruction or more distal amputation which may, in some cases, be unsuccessful requiring subsequent proximal amputation. Therefore the increased number of operations performed may not reflect a similar increase in the number of individuals treated. In a study from the Montiefiore Centre, in the USA, the average number of procedures performed for peripheral arterial disease rose from 1.2 per patient in 1974 to 1.8 in 1989 (Veith et al. 1990). In Leicester, the proportion of amputees who underwent prior attempts at revascularisation increased from 6% to 40% between 1974 and 1990 (Sayers et al. 1993). However, in Scotland between 1981 and 1990, the ratio of numbers of arterial reconstruction operations to numbers of individuals undergoing such operations remained fairly constant at between 1.1:1 and 1.2:1 (Pell et al. 1994a). Furthermore, the percentage of arterial reconstruction operations followed within one year by amputation fell steadily from 16% to 11%. These facts suggest that, within Scotland, increased numbers of operations are unlikely to be simply the result of increased numbers of procedures per patient.

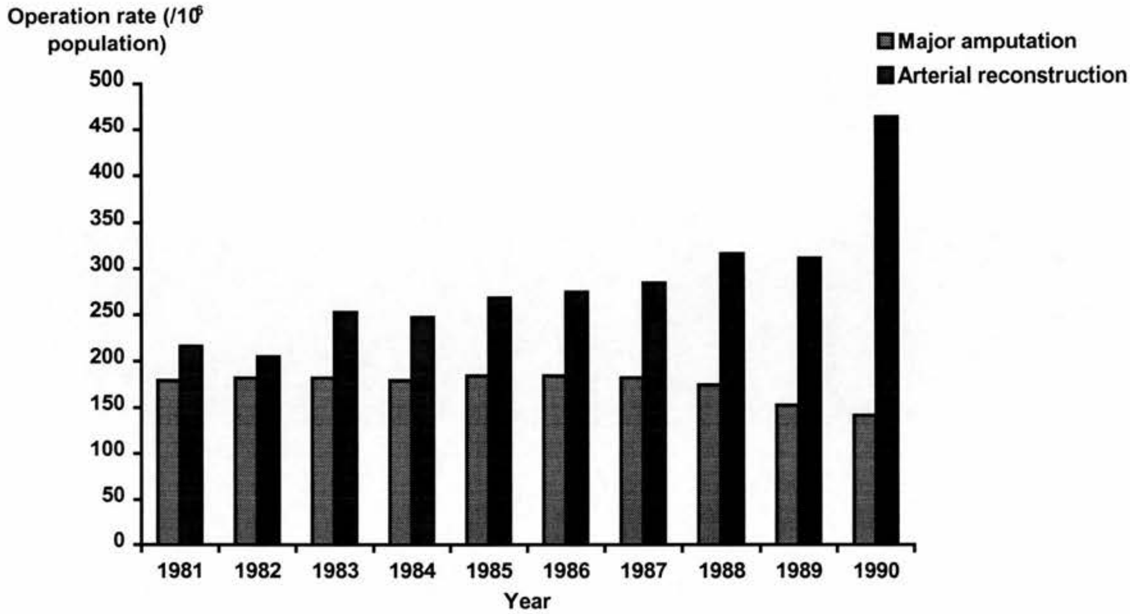
Another possible explanation for the increase in operations is that with advances in early non-invasive detection of disease and improved surgical technique, reconstructive surgery may now be performed on patients with earlier stages of disease for whom consideration of amputation would not have been appropriate. Within Scotland, hospital admissions attributed to "peripheral vascular disease" increased by 50% between 1981 and 1990. However, those coded as resulting from "gangrene" did not increase (Figure 2.1.).

Figure 2.1. Time trends in admissions to Scottish hospitals attributed to peripheral vascular disease and gangrene between 1981 and 1990



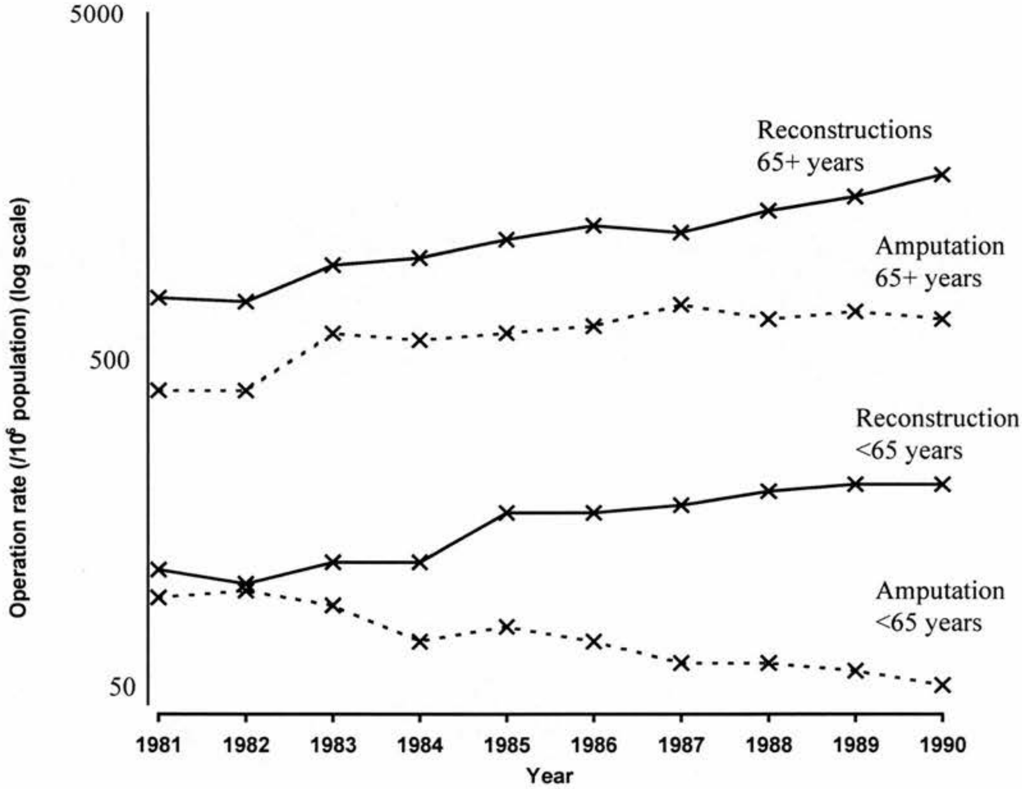
Although the introduction of limb salvage procedures failed to reduce amputation rates prior to the 1980's, evidence is now accumulating that they may since have had an impact. Prior to the widespread use of arterial reconstruction, around 10% of patients presenting to hospital with ischaemia underwent amputation (Dormandy and Thomas 1988). This figure has fallen since to nearer 3%. In one hospital in Edinburgh, amputation rates rose steadily up to 1990, but plateaued thereafter (Pell et al. 1994a). In Scotland as a whole, rates of arterial reconstruction doubled between 1981 and 1990. During this period, the age-sex standardised rate of major amputation for peripheral arterial disease fell by 22%, with most of this decline occurring after 1987 (Pell et al. 1994b) (Figure 2.2.).

Figure 2.2. Time trends in the age-sex standardised incidence of major amputation in Scotland between 1981 and 1990



This decline was not consistent in all age-groups. Amputation rates fell significantly in those under 65 years of age, but not in older age-groups (Fig 2.3.). This difference is likely to reflect a generally less aggressive approach to treatment of the elderly, since primary amputations and emergency procedures were significantly more common in this group.

Figure 2.3. Time trends in the age-specific rates of major amputation and arterial reconstruction for peripheral arterial disease in Scotland, 1981-1990.



Scottish evidence of a recent decline in amputations is corroborated by research from Denmark where amputation rates fell by 25% between 1986 and 1990 (Lindholt et al. 1994) and from West Berkshire where, between 1983 and 1991, an eleven-fold increase in rates of arterial reconstruction was associated with a one-third reduction in major amputation rates (Gutteridge 1993). In Western Australia, major amputation rates fell between 1980 and 1992 due to a decline in primary amputation which was only partially offset by an increase in the rate of amputations following failed attempts at reconstruction (Mattes et al. 1997).

2.4. Risk factors for chronic critical lower limb ischaemia

The majority of peripheral arterial disease can be attributed to advanced age, cigarette smoking and diabetes mellitus. In one study, only 12% of claudicants possessed none of these risk factors (Liedberg and Persson 1983b).

2.4.1. Age

The incidence of peripheral arterial disease increases with age (Auerbach et al 1968, Peabody et al. 1974, Widmer et al. 1964). In the Basle study, the annual incidence rose from 0.8% in those aged 35-44 years, to 3.6% in those over 65 years (Dormandy et al. 1989, Widmer et al. 1964). In a USA study, there was evidence of large vessel disease on non-invasive haemodynamic testing in only 3% of people under 60 years of age, compared with 20% of those over 75 years (Criqui et al. 1985a).

As with asymptomatic disease, intermittent claudication also increases with age, both in terms of incidence and admission rates (Tibell 1971). In the Basle study, the five year cumulative incidence of intermittent claudication was 1% in men aged 35-44 years, compared to 6% in those over 65 years (Widmer et al. 1985). Intermittent claudication was reported by 1.0%-1.5% of men under 50 years of age, compared to 2.2%-5.0% of those over 55 years (Criqui et al. 1985a, Dormandy et al. 1989, Dormandy and Murray 1991, Fowkes 1988, Fowkes 1990, Fowkes et al. 1991, Kannel and McGee 1985, Reid et al 1974, Smith et al. 1991).

Amputations are also much more common among the elderly. In Sweden, 45% of amputees were 80 years or older, and the annual incidence of amputation rose from 40 per 100,000 in those aged 60-69 years, to 540 per 100,000 in those aged 80-89 years (Kald et al. 1989, Liedberg and Persson 1983a). Similarly, in Denmark, the amputation rate increased from 0.3 per 100,000 population under 40 years of age, to 226 per 100,000 over 80 years (Eickhoff et al. 1980), and, in Oxford, from 32 per 100,000 in the 65-69 year age group, to 94 per 100,000 in those over 80 years of age (Sethia et al. 1986). Within Scotland, amputation rates currently range from 6 per 100,000 in those under 65 years, to 63 per 100,000 in those over 65 years (Pell et al. 1994b). In patients over 80 years of age, the rate is 146 per 100,000. In Edinburgh, 86% of amputees are over 60 years of age (Jamieson and Ruckley 1983). The age-distribution of amputees differs between men and women. Eighty five percent of female amputees are over 70 years of age, compared to only 50% of men (Harris et al. 1974). Of new referrals to limb-fitting centres in the United Kingdom, two-thirds are over 65 years of age and one-third over 75 years (DHSS 1989, Gregory-Dean 1991, Knight and Urquhart 1989). The median ages for men and women are 68 and 73 years respectively.

More than 5,000 patients over the age of 80 years present with critical limb ischaemia annually in the UK and Ireland (da Silva et al. 1994). Age at presentation affects both the management and outcome of critical ischaemia. Among those over 84 years, amputations are more likely to be performed as emergency procedures and less likely to be preceded by attempts at limb-salvage (Pell et al. 1994b). Da Silva et al. (1994) reported limb-salvage rates of 71.5% in younger patients, compared to only 59.7% in the elderly. Case-fatality rates were also significantly higher in older patients. However, although the overall fatality rate in critically ischaemic patients was 24%, one-third of these deaths occurred in patients treated conservatively. Case-fatality rates in elderly patients offered amputation or revascularisaton were only 5% and 9% respectively (da Silva et al. 1994). Although the length of stay was not related to age, only 40% of elderly patients were discharged home, compared to 67% of younger patients (da Silva et al. 1994).

2.4.2. Sex

Compared with women, men have a higher prevalence of both asymptomatic peripheral arterial disease and intermittent claudication (Gregory-Dean 1991, Hertzer 1991, Higgins and Kjelsberg 1967, Hughson et al. 1978, Peabody et al. 1974, Reunanen et al. 1982). A Danish survey of 666 people over 60 years of age, reported intermittent claudication in 5.8% of men, compared to only 1.3% of women (Schroll and Munck 1981). In general, population studies have reported a prevalence in men 1.3-4.5 times higher than that in women (Criqui et al. 1985a, Fowkes et al. 1991).

In the Framingham study, the annual age-adjusted incidence of intermittent claudication was 0.3% in men and 0.1% in women (Kannel et al. 1970, Kannel and McGee 1985). The incidence of intermittent claudication was comparable between the sexes when women were 10 years older than men (Kannel and Shurleff 1973). Although men had a higher incidence than women at all ages, the magnitude of this sex-difference decreased with age. Between 50 and 70 years of age, the annual incidence in men increased three-fold from 0.2% to 0.6%, whereas in women it rose seven-fold from 0.07% to 0.5% (Kannel et al. 1970, Sytkowski et al. 1990)

In addition to having a higher incidence of peripheral arterial disease, men also have a poorer prognosis following diagnosis. Men suffering from claudication are 1.7 times more likely to have local disease progression than women (PACK 1989). Therefore the male:female ratio for the incidence of intermittent claudication (1.3:1-4.5:1) is much lower than that for severe peripheral ischaemia (3:1-13:1) (Dormandy and Murray 1991).

A review of Danish national discharge data revealed a male:female ratio of 1.5:1 for the incidence of both lower limb amputation and vascular reconstruction (Eickhoff et al. 1980). In the United Kingdom the ratio for amputation is nearer 3:1 (Little et al. 1974, Weaver and Marshall 1973). Sixty three percent of new referrals to Scottish limb-fitting centres, and 71% of those to English centres are male (Davies et al. 1989, Gregory-Dean 1991, Knight and Urquhart 1989). Women have the same amputation incidence as men when 3.3 years older (Liedberg and Persson 1983b). However, as with intermittent claudication, the male-female ratio of amputees approaches parity with increasing age (Gregory-Dean 1991). An excess of male amputees is present up to 75 years of age, when numbers become equal. Beyond 84 years of age, amputees are predominantly female (Knight and Urquhart 1989).

2.4.3. Cigarettes

Cigarette smoking is a more important risk factor in the aetiology of peripheral arterial disease than that of coronary arterial disease (Fowkes et al. 1992). In the Framingham study, 78% of cases of intermittent claudication were attributed to cigarette smoking (Kannel and Shurleff 1973). Multivariate analyses suggest that the risk of peripheral arterial disease associated with smoking is greater than that associated with other risk factors and is independent of their effect (da Silva et al. 1979, Fowkes et al. 1991, Kannel and Shurleff 1973, Liedberg and Persson 1983b). The risk from smoking applies to all ages and increases with the number of cigarettes smoked (Cronenwett et al. 1984).

In addition to increasing the risk of developing peripheral arterial disease, smoking also worsens its prognosis (Kannel and Shurleff 1973). It increases case-fatality rates among claudicants by 1.5%-3.0% (Gyntelberg 1973, Reunanen et al. 1982). It also makes local progression of disease more likely (Cronenwett et al. 1984, PACK 1989). Amputation is more common among claudicants who smoke, particularly if they smoke heavily (Jelnes et al. 1986, Juergens et al. 1960). Sixty four percent of male vascular amputees smoke compared to only 43% of the male general population (Knight and Urquhart 1989). The corresponding figures for women are 38% and 35% respectively. Vascular amputees report smoking an average 12 cigarettes per day over a median of 50 years (Knight and Urquhart 1989). Claudicants who continue to smoke the same number of cigarettes are twice as likely to undergo amputation as those who stop or reduce their smoking habit (Hughson et al. 1978). Cessation of smoking can halt or delay vascular changes (Janzon 1974), but does not reduce the overall risk of amputation over the following 2-3 years (Jelnes et al. 1986). Only 1 in 7 amputees who smoke at the time of operation subsequently stop smoking (Knight and Urquhart 1989).

Since 1920, amputations have increased at a similar rate to cigarette smoking in Malmöhus county in Sweden (Liedberg and Persson 1983b). There were significantly more current smokers among amputees than among age-sex-matched controls, and smoking more than 10 cigarettes a day reduced the mean age at amputation by 13 years in men and 26 years in women (Kald et al. 1989, Liedberg and Persson 1983b).

The higher incidence of peripheral arterial disease and amputations in men has been attributed to the differences in smoking habits between the sexes. Indeed, an increasing number of female smokers may explain why the male:female ratio for claudication has gradually fallen from 10:1 in the 1960's (Mathieson et al. 1970, Reunanen et al. 1982, Taylor and Calo 1962) to nearer parity in the late 1980's (Fowkes et al. 1991). As yet, the sex-difference for amputation has not reduced significantly. However, a time lag would be anticipated between changes in the population experience of claudication and changes in amputation rates. Therefore an increase in the proportion of female amputees may yet occur.

2.4.4. Diabetes mellitus

Diabetes mellitus affects 1%-5% of people in Western countries, and 10%-20% of those affected are insulin-dependent (Bingley and Gale 1989, Krolewski and Warram 1985). Over the past three decades, there has been a 2-3 fold increase in the incidence of both insulin-dependent and non-insulin dependent diabetes mellitus (Orchard. 1998).

Diabetes mellitus has long been recognised as a risk factor for peripheral arterial disease (Fowkes 1988, Fowkes et al. 1991). The cumulative incidence of peripheral arterial disease in diabetics is 15% by 2 years, and 45% by 20 years (Beach et al. 1988, Melton et al. 1980). In the Framingham study intermittent claudication was approximately five times more prevalent among diabetics than non-diabetics (Kannel and McGee 1985).

In addition to being a risk factor for the development of claudication, diabetes mellitus also has an adverse effect on prognosis (Hughson et al. 1978, PACK 1989). Over a six-year period 40% of diabetic claudicants develop rest pain or gangrene, compared to only 18% of non-diabetic claudicants (Jonason and Ringqvist 1985). After eight years, the amputation rates are 56% and 20% respectively (Hughson et al. 1978). Only 50% of diabetic claudicants survive six years, compared with 74% of non-diabetic claudicants (Jonason and Ringqvist 1985).

Diabetes is more common among amputees than the general population (Gutman et al. 1987, Mazze et al. 1985, Most and Sinnock 1983). Diabetics consitute only 1%-5% of the general population, but form more than half the amputees in many series (Burgess et al. 1971, Moore et al. 1972, Warren et al. 1973). The association between diabetes and amputation is independent of other risk factors, including age and smoking (Liedberg and Persson 1983b). In a Swedish study, 37% of lower limb amputees were diabetic, compared with 4% of age-matched controls (Liedberg and Persson 1983b). In a Danish study, 45% of amputees were diabetic, and 56% of these were insulin-dependent (Kald et al. 1989). In England and Wales, 20% of amputees referred for limb-fitting had their amputation attributed to diabetes (DHSS 1989).

In the USA, the annual amputation rate among non-diabetics is only 200 per million population, compared with 3,900 per million in diabetics (Hughson et al. 1978, Most and Sinnock 1983). After age-adjustment, amputation rates are still 15 times higher in diabetics. Amputations were performed in 6.8% of diabetics in the Basle study, compared with only 0.6% of non-diabetics (Widmer et al. 1985). In a 12-year prospective study of Pima Indians, the annual incidence of primary amputations was 0.1 per 1000 in non-diabetics, compared with 10.4 per 1000 in diabetics (Jarrett et al. 1982)

The increased risk of critical ischaemia in diabetics is attributed not only to the development of large vessel disease, but also to the microangiopathy, neuropathy and infections that are classically associated with diabetes. Lower limb ulceration and gangrene occurs in 10% of all elderly diabetics (Jonason and Ringqvist 1985).

Diabetics generally undergo amputation at an earlier age than non-diabetics (Christensen 1976, Hansson 1964, Hierton and James 1973). In a Danish study, diabetic amputees were, on average, three years younger than non-diabetics (Christensen 1976). In a Swedish study, diabetic men and women were nine and five years younger respectively (Liedberg and Persson 1983b). Non-insulin dependent diabetics fall between insulin-dependent diabetics and non-diabetics with regard to their average age at amputation. The mean time from diagnosis of insulin dependence to amputation is 13 years (Liedberg and Persson 1983b). However, diabetes alone rarely causes symptomatic peripheral arterial disease before 60 years of age (Oakley et al. 1956), and amputations among non-smoking diabetics are very uncommon in this age group (Goldner 1960). In one Swedish study, only 5% of diabetic amputees were less than 60 years of age, and all were smokers (Liedberg and Persson 1983b).

Survival rates for diabetic amputees are poor. Operative mortality is up to 25% (Gutman et al. 1987), and only 50% survive three years (Bild et al. 1989). Within four years of amputation, 53% of diabetic amputees have undergone contralateral operations (Silbert 1952).

2.4.5. Other risk factors

Local progression of peripheral arterial disease has been shown to be associated with a low ankle-brachial pressure index (Jelnes et al. 1986, PACK 1989). Population studies suggest that a number of other factors, such as blood pressure, lipid levels and haemostatic factors, may be associated with the development of intermittent claudication, although their role in progression to critical ischaemia is not yet fully established.

A possible association between hypertension and intermittent claudication was suggested by a number of cross-sectional studies (Hughson et al. 1978, Isacsson 1972, Kannel and McGee 1985, Melton et al. 1980, Schroll and Munck 1981), and further supported by two longitudinal studies. In the Framingham study, hypertension was associated with a three-fold increase in the risk of intermittent claudication over 26 years (Kannel and McGee 1985). In a Danish longitudinal study of 50 year-old men, their initial blood pressure correlated significantly with their ankle-brachial pressure indices ten years subsequently (Schroll and Munck 1981). However, the Basle study demonstrated no association with hypertension (da Silva et al. 1979).

Hypercholesterolaemia has been reported in some studies to be an independent risk factor for peripheral arterial disease (Christensen 1976, Fowkes 1988, Hale et al. 1988, Leng and Fowkes 1991, Reunanen et al. 1982, Taylor and Calo 1962), although these findings are not corroborated by other studies (Hughson et al. 1978, Isacsson 1972). In the Framingham and Danish longitudinal studies, high initial serum cholesterol levels were associated with subsequent development of intermittent claudication (Kannel and McGee 1985, Schroll and Munck 1981), and in the Edinburgh Artery Study cholesterol levels were independently associated with both symptomatic and asymptomatic peripheral arterial disease (Fowkes et al. 1992). Serum cholesterol was shown to have a significant association with smoking, with the relationship between cholesterol and ankle-brachial pressure index being stronger in current smokers than ex- or non-smokers (Fowkes et al. 1992).

Although an association has been reported between raised triglyceride levels and peripheral arterial disease, it is not independent of other risk factors (da Silva et al. 1979, Fowkes et al. 1992, Pomrehn et al. 1986, Schroll and Munck 1981). HDL-cholesterol has been shown to possess a negative correlation with peripheral arterial disease, but again was not demonstrated to be an independent factor in most studies (Beach 1979, Fowkes et al. 1992, Jacobson et al. 1984, Leng and Fowkes 1991).

Some studies have suggested an association between haemostatic factors and peripheral arterial disease. Fibrinogen levels, haematocrit and plasma viscosity have all been found to be higher in cases of peripheral arterial disease than controls (Fowkes 1988, Hamer et al. 1974, Harris et al. 1978, Lowe 1987). However, all these factors are affected by smoking and therefore could be disease markers rather than causal factors. In the Framingham study, an elevated haematocrit was not associated with a greater risk of intermittent claudication (Kannel and McGee 1985).

Hyperuricaemia is known to have an effect on platelet aggregation (Leng and Fowkes 1991), and higher levels have been reported in cases of peripheral arterial disease than controls (Greenhalgh et al. 1971, Hughson et al. 1978, Sitori et al. 1974). However an association was not confirmed in the Danish Longitudinal Study (Schroll and Munck 1981).

2.5. Natural history of chronic critical lower limb ischaemia

2.5.1. Local disease progression

In the Basle study, as many as one-third of people with asymptomatic peripheral arterial disease ultimately developed intermittent claudication (Widmer et al. 1985). Most of our information on symptom progression and intervention rates after the onset of intermittent claudication is derived from studies restricted to those individuals referred to hospital. Untreated, the symptoms of three-quarter of claudicants will at least stabilise, and may improve, due to the development of collateral vessels (Cotton 1984, Dormandy and Mahir 1986, Dormandy and Thomas 1988, Dormandy et al. 1989, Hertzer 1991, Imparato et al. 1975, Jelnes et al. 1986, Juergens et al. 1960, McAllister 1976, MacPherson et al. 1970, Taylor and Calo 1962). In one-quarter of cases local disease progression does occur to some extent (Dormandy et al 1989, Dormandy and Murray 1991). However, only a minority develop critical ischaemia (Bloor 1961). This number is curtailed, in part, by the high number of premature deaths from other causes. Deterioration is most likely to occur during the first year after referral, during which time 7.5% of claudicants develop rest pain, ulceration or gangrene (Jelnes et al. 1986). This figure falls to 2.2% in subsequent years. Over five years, less than 5% of claudicants develop gangrene (Imparato and Riles 1984). In the HAWAII study, 55% of people undergoing below-knee amputations for critical ischaemia had no symptoms of ischaemia six months previously (Dormandy et al. 1994).

Before widespread use of arterial reconstruction, 3%-12% of claudicants underwent amputation over a 2-15 year follow-up period (Begg and Richards 1962, Biland et al. 1985, Bloor 1961, Bothig et al. 1976, Dormandy and Thomas 1988, Gyntelberg 1973, Hertzer 1991, Schadt et al. 1961, Silbert and Zazeela 1958, Singer and Rob 1960, Taylor and Calo 1962). In more recent studies, the amputation rate has fallen only slightly, with most studies reporting rates of 2%-7% over 2-8 years of follow-up (Criqui et al. 1985b, Cronenwett et al. 1984, Dormandy and Thomas 1988, Isacsson 1972, Jelnes et al. 1986, Kallero 1981, Taylor and Calo 1962). However, these studies are based on only those claudicants presenting to doctors. As mentioned previously, this is likely to represent only 10%-50% of claudicants present within the general population (Davey-Smith et al. 1990, Hughson et al. 1978, Reid et al. 1974, Reunanen et al. 1982). Therefore the true incidence of amputation among claudicants is probably nearer 1% (Dormandy and Thomas 1988, Reunanen et al. 1982). This figure is supported by community-based epidemiological studies in which only 1.2%-1.8% of those with intermittent claudication progressed to amputation (Dormandy et al. 1989, Dormandy and Murray 1991, Kannel et al. 1970, Kannel and McGhee 1985, PACK 1989, Widmer et al. 1964, Widmer et al. 1985).

Although few claudicants develop critical ischaemia, between 5.5% and 8% undergo arterial reconstructive surgery or PTA each year (MacPherson et al. 1970, PACK 1989). These procedures are aimed primarily at palliating symptoms. They are not intended to be curative since they are unlikely to alter the natural history of the underlying disease.

Between 75% and 90% of patients with critical ischaemia undergo some form of surgical intervention within twelve months of presentation (European Working Group 1991, Wolfe 1986). One-quarter have major amputation and one-half arterial reconstruction. Most of the remainder have PTA or conservative treatment. Amputation is more likely among those with more severe ischaemia, although not inevitable. Studies pre-dating arterial reconstruction, and other "limb-salvage" procedures, reported amputation rates of between 38% and 55% in those with critical ischaemia over 1-12 years of follow-up (Bloor 1961, Cranley et al. 1959, Hines and Barker 1940, Juergens et al. 1960, Schadt et al. 1961, Taylor and Calo 1962). In patients suffering from only rest pain with no tissue loss, the amputation rate was comparable to that in claudicants.

2.5.2. Mortality

Mortality among claudicants is 2-4 fold that in an age-sex matched normal population (Davey-Smith et al. 1990, Dormandy 1991, Fowkes et al. 1991, Gutman et al. 1987, Kannel et al. 1970, Reunanen et al. 1982, Rose et al. 1977, Widmer et al. 1964), and life expectancy is approximately ten years lower (Bloor 1961, Dormandy et al. 1989, Ernst et al. 1987). In a prospective study of 1969 claudicants, Dormandy and Murray (1991) reported an annual mortality of 4.3%. All-cause mortality rates at five and ten years were 30% and 50% respectively (Dormandy 1991).

The poor prognosis associated with claudication is related primarily to the presence of atherosclerosis at other sites. Fifty four percent of people with asymptomatic peripheral arterial disease, and up to 71% with intermittent claudication, have some evidence of ischaemic heart disease (Dormandy et al. 1989, Fowkes et al. 1991, Ruckley 1991), and 27%-29% have angiographic evidence of severe coronary artery disease (Hertzer 1991). The long-term incidence of serious coronary events among claudicants is twice the expected figure for men, and five times that for women (Kannel et al. 1970). Premature death occurs more commonly from co-existing cardiac and cerebrovascular ischaemia than local progression of peripheral arterial disease (Dormandy et al. 1989, Dormandy and Murray 1991, Gilliland et al. 1986). Myocardial ischaemia accounts for up to 63% of deaths in claudicants, and 40%-57% of deaths in those with asymptomatic peripheral arterial disease (Christensen 1976, Dormandy and Thomas 1988, Dormandy et al. 1989, Dormandy 1991, Kallero 1981, Widmer et al. 1985). A further 7%-28% die from cerebrovascular accidents, and 10% of deaths are due to other vascular events, such as ruptured aortic aneurysms (Dormandy et al. 1989, Dormandy 1991, PACK 1989). The most sensitive predictors of death among claudicants are advanced age, a history of ischaemic heart disease and a low ankle-brachial pressure index (Dormandy and Murray 1991, Jelnes et al. 1986, PACK 1989).

A UK multicentre study of 409 patients suffering from critical lower limb ischaemia, reported a 20% mortality rate one year following presentation (Wolfe 1986). In a Swedish study of 167 patients with rest pain who did not undergo operations following presentation, 50% of non-diabetics and 60% of diabetics died over five years (Hughson et al. 1978). As described in the next chapter, major amputation and arterial reconstruction have little effect on the high mortality in those suffering from critical ischaemia. As with intermittent claudication, myocardial infarction and stroke account for most deaths following major amputation. Ninety seven percent of amputees suffer from other diseases in addition to peripheral arterial disease and diabetes (Berardi and Keonin 1978). Up to three-quarters of those with critical lower limb ischaemia have evidence of heart disease or a history of a previous myocardial infarction, and up to one-quarter have a history of a previous stroke (Berardi and Keonin 1978, Jamieson and Ruckley 1983, Reichle et al. 1979).

As with claudication, deaths due directly to critical ischaemia are rare. Over half of those with critical ischaemia die from a cardiovascular event (Myers et al. 1978a, Reunanen et al. 1982). A further 10% die from strokes, and 8% from aneuryms and other manifestations of vascular disease (Reunanen et al. 1982). Only a minority of patients die in the peri-operative period from direct complications of the amputation.

The risk factors for death in those with critical ischaemia are similar to those in claudicants (Kihn et al. 1972, Myers et al. 1978a). The best predictor of death within three months of major amputation for vascular insuffiency is clinically detectable myocardial disease (Dormandy 1991). Diabetes is also an important factor. Fifty percent of non-diabetics presenting with critical ischaemia are alive at five years, compared to only 30% of diabetics (Myers et al. 1978a).

2.6. Conclusions

Studies of the incidence and prevalence of chronic critical lower limb ischaemia are lacking. Therefore these figures have had to be calculated indirectly from our knowledge of the prevalence of asymptomatic peripheral arterial disease and intermittent claudication and their natural history, and from major amputation rates.

One in twenty middle-aged people in Scotland have intermittent claudication (Fowkes et al. 1991), but asymptomatic disease is common and the true prevalence of peripheral arterial disease is 3-5 times higher (Criqui et al. 1985a, Dormandy et al 1989, Fowkes et al. 1991, Widmer et al. 1964). Of those patients with intermittent claudication who present to the medical profession, one-quarter experience some degree of local progression of disease (Dormandy et al. 1989, Dormandy and Murray 1991) but a much smaller proportion progress to critical ischaemia (Bloor 1961). Deterioriation is most likely to occur over the first year during which time 7.5% develop rest pain or tissue loss (Jelnes et al. 1986). In subsequent years this figure falls to 2.2% (Jelnes et al. 1986). Five percent of claudicants develop critical ischaemia within five years of presentation (Imparato and Riles 1984). However, only 10%-50% of claudicants present to doctors (Davey-Smith et al. 1990, Hughson et al. 1978, Reid et al. 1974). Therefore only 1%-2% of all claudicants in the community progress to critical ischaemia (Dormandy et al. 1989, Dormandy and Murray 1991, Kannel et al. 1970, Kannel and McGhee 1985, PACK 1989, Widmer et al. 1964, Widmer et al. 1985). This would equate to an incidence in the general population of between 500 and 1000 per million population.

The Eupean Consensus Group (1989, 1991) utilised the results of the study by Wolfe (1986) in which one-quarter of patients with chronic critical lower limb ischaemia underwent major amputation within one year of presentation. They concluded that the incidence of critical ischaemia can be estimated by multiplying the major amputation rate by four. This equates to an United Kingdom annual incidence of critical ischaemia of around 600-800 per million (DHSS 1989, Pell et al. 1994b) which is of a comparable magnitude to the figures derived from the studies of intermittent claudication. In Scotland, this would equate to around 3,000-4,000 new cases of chronic critical lower limb ischaemia each year. Since Wolfe's study was published the proportion of patients with critical ischaemia treated by major amputation may have fallen. Therefore, multiplying by a factor of four may now produce an under-estimate of the true incidence. In this case, the number of new cases of critical ischaemia per annum in Scotland may exceed the estimated figure of 4,000.

The results reported by Wolfe (1986) may no longer apply. However, we do not have access to more recent figures on the proportion of patients with critical limb ischaemia who proceed to major amputation and arterial reconstruction within one year of presentation. Within Scotland, the ratio of arterial reconstruction rate to major amputation rate has increased over the last decade (Pell et al. 1994b). At first glance, this would appear to suggest that the proportion of patients with critical ischaemia who undergo major amputation has fallen due to increased use of limb-salvage. However, the rate of arterial reconstruction includes patients with pre-critical disease. Also, the use of sequential operations on individual patients makes it difficult to draw conclusions about individual patients from population rates. Therefore, in the absence of more recent figures, the results reported by Wolfe (1986) continue to be applied.

Advanced age, cigarette smoking and diabetes mellitus are all independently associated with the development of peripheral arterial disease and its progression to critical ischaemia. The vast majority of disease can be attributed to these three factors with only 12% of claudicants possessing none of these risk factors (Liedberg and Persson 1983b).

In addition to being associated with an increased risk of developing critical lower limb ischaemia, age at presentation also affects both management and outcome. Elderly patients are more likely to have major amputations performed as an emergency and are less likely to have prior attempts at limb-salvage (da Silva et al. 1994, Pell et al. 1994b). Elderly patients have higher case-fatality rates, and are less likely to be discharged home (da Silva et al. 1994). With increasing life-expectancy and declining birth rates, the elderly account for an increasing proportion of the population. Therefore the burden of chronic critical lower limb ischaemia is likely to increase.

In addition to having a higher incidence of claudication, men also have a poorer prognosis. Men suffering from intermittent claudication are almost twice as likely to have local disease progression as women (PACK 1989). Therefore the sex difference in incidence is even greater for critical ischaemia than intermittent claudication. The incidence of intermittent claudication is comparable between the sexes when women are ten years older than men (Kannel and Shurleff 1973), and women have the same amputation incidence as men when three years older (Liedberg and Persson 1983a). The magnitude of both sex differences decrease with age.

Cigarette smoking is the most important risk factor in developing peripheral arterial disease. Seventy eight percent of intermittent claudication cases can be attributed to smoking (Kannel and Shurleff 1973). Smoking is associated with a poorer prognosis, both in terms of local disease progression and case-fatality rates. The higher incidence of peripheral arterial disease in men has been attributed to sex differences in smoking. Similarly, the declining sex-difference over recent years has been attributed to differing trends in smoking habits between the sexes. Whilst cigarette smoking has declined overall the incidence among young women has increased markedly. A reduction in the sex difference in criticial ischaemia has yet to be documented but may yet occur as a greater time-lag would be anticipated.

As with smoking, diabetes mellitus is a risk factor for developing both peripheral arterial disease and critical ischaemia. Over eight years, 40% of diabetic claudicants develop rest pain or gangrene, compared to only 18% of non-diabetic claudicants (Jonason and Ringqvist 1985). Major amputation rates are 20 times higher in diabetics than non-diabetics (Hughson et al. 1978, Most and Sinnock 1983), and insulin-dependent diabetics undergo amputation between three and nine years earlier than non-diabetics (Christensen 1976, Liedberg and Persson 1983b). Survival is also poorer among diabetics, with an operative mortality of up to 25% (Gutman et al. 1987), and 50% three-year survival rate (Bild et al. 1989).

The introduction of "limb-salvage" procedures such as arterial reconstructive surgery and PTA in the 1950's and 1970's respectively, did not initially result in a decline in major amputations. In fact, some studies continued to report an increase in amputation rates (Ernst et al. 1987). This has been attributed, in part, to both an increase in multiple procedures on individual patients (Veith et al. 1990) and a reduction in the threshold for surgical intervention. If these procedures are being performed on patients with earlier stages of disease a time-lag might be anticipated before any beneficial effect, and more recent studies have demonstrated a decline in amputation rates since the mid-1980's (Pell et al. 1994a&b, personal communication Eickhoff JH).

Mortality rates are several times higher in patients with intermittent claudication and critical lower limb ischaemia than in the general population (Davey-Smith et al. 1990, Dormandy 1991, Kannel et al. 1970, Reunanen et al. 1982, Rose et al. 1977, Widmer et al. 1964). However, deaths are rarely a direct result of peripheral arterial disease, being more commonly due to coexisting coronary and cerebrovascular disease. Three-quarters of patients with severe or critical ischaemia have evidence of coronary heart disease (Berardi and Keonin 1978, Dormandy et al. 1989, Fowkes et al. 1991, Jamieson and Ruckley 1983, Reichle et al. 1979, Ruckley 1991) and more than half of the deaths occurring in this group can be attributed to heart disease (Myers et al. 1978a, Reunanen et al. 1982). As a result lower limb surgery, such as major amputation and arterial reconstruction, have little effect on mortality and must be judged primarily in terms of symptom relief. The outcomes associated with these procedures are discussed in further detail in Chapter 3.

CHAPTER 3

Outcome following major amputation and arterial reconstructive surgery

"It cannot be too often repeated that when an operation is once performed, nobody can ever prove that it was unnecessary. If I refuse to allow my leg to be amputated, its mortification and my death may prove that I was wrong; but if I let the leg go, nobody can ever prove that it would not have mortified had I been obstinate. Operation is therefore the safe side for the surgeon."

(Preface to"The Doctor's Dilemma" Bernard Shaw)

3.1. Introduction

To date, there have been no randomised trials comparing primary major amputation, revascularisation procedures and conservative treatment in the management of chronic critical lower limb ischaemia. Because arterial reconstruction is now accepted as part of routine clinical practice such trials are unlikely to be undertaken. However, published observational studies and case-series provide some evidence of the relative effectiveness of primary major amputation and arterial reconstruction, and the complication rates following these procedures.

In reviewing non-randomised studies, it has to be borne in mind that case-selection often differs between the two procedures, with patients undergoing primary amputation tending to be older, with more widespread disease, and higher rates of comorbidity (Dormandy and Thomas 1988). Therefore some of the differences observed in outcomes may be due to differences in case-mix. Also, results are most likely to be published by centres with a special interest in these procedures where the results achieved are likely to be better than those achieved in non-specialist centres. Interpretation of results is further complicated by the lack of standardisation in the definitions applied to disease severity, type of procedure and outcomes, and the period of follow-up over which results are reported.

This chapter reviews the available evidence on outcomes following arterial reconstruction and major amputation. The risks and benefits of major amputation and arterial reconstruction are compared to each other. Because the majority of patients with chronic critical ischaemia undergo some form of surgery, comparisons with conservative treatment are generally lacking, and must be restricted to an historical control group.

3.2. Mortality

3.2.1. Perioperative mortality

The perioperative mortality associated with major amputation has improved considerably over the past few decades, In the 1940's mortality rates were commonly around 42% overall (Silbert 1948), and up to 75% in diabetics. Rates were higher still in those who presented with cellulitis or rapidly spreading gangrene (Herrmann and Gibbs 1945, Mandelberg and Sheinfeld 1946, Perlow and Roth 1949). Following the introduction of antibiotics mortality rates fell to below 30% (Dale and Jacobs 1962, Otteman and Stahlgren 1965, Thompson et al. 1965)

In the last twenty years, perioperative mortality for below-knee amputation has been reported to lie between 3% and 10% in most centres (Table 3.1). Mortality rates for above-knee amputation are generally higher, and in several series exceeded 20% (Table 3.1.). This reflects the fact that these patients tend to be older, in poorer general health, and have more widespread atherosclerotic disease. Primary above-knee amputation is sometimes preferred in these patients because post-operative mobilisation is less likely to be successful, and therefore less important than optimising the likelihood of primary healing.

Table 3.1. Perioperative mortality rates associated with below- and above-knee amputation

Source	Nº patients	BKA* mortality % (95% CI)	AKA** mortality % (95% CI)
Ecker and Jacobs 1970	178	8.7 (4.6, 2.8)	12.4 (7.6,17.2)
Kihn et al. 1972	427	8.5 (5.9,11.2)	13.0 (9.8,16.2)
Berardi and Keonin 1978	100	13.9 (7.1,20.7)	4.5 (0.4,8.6)
Potts et al. 1979	90	15.6 (8.1,23.1)	6.5 (1.4,11.6)
Finch et al. 1980	145	3.2 (0.3,6.1)	26.0 (18.9,33.1)
Rush et al. 1981	256	6.4 (3.4,9.4)	11.0 (7.2,1.8)
Haynes and Middleton 1981	286	6.9 (4.0,9.8)	29.0 (23.7,34.3)
Porter et al. 1981	312	16.4 (12.3,20.5)	1.1 (-0.1,2.3)
Jamieson and Ruckley 1983	64	17.0 (7.8,26.2)	28.0 (17.0,39.0)
Bunt et al. 1984	253	0.9 (-0.3,2.1)	2.8 (0.8,4.8)
Ratcliffe et al. 1984	62	10.8 (3.1,18.5)	9.5 (2.2,16.8)
Gregg 1985	183	8.0 (4.1,11.9)	23.0 (16.9,29.1)

* BKA Below-knee amputation
** AKA Above-knee amputation

(Adapted from Dormandy JA and Thomas PRS. (1988) What is the natural history of a critically iscahemic patient with and without his leg? In: Greenhalgh RM et al. (ed) Limb salvage and amputation for vascular disease. WB Saunders, Philadelphia p19.)

Some specialist centres with an interest in amputation for severe ischaemia have reported extremely low mortality rates of around 1% for below-knee amputation and 3% for above-knee amputation (Bunt et al. 1984). This has been attributed by some to aggressive medical management, including admission to an intensive care environment prior to elective surgery, meticulous surgical and nursing care, multidisciplinary team-work and the use of a "dry ice boot" to obtain a physiological amputation thereby preventing the release of toxic metabolites from gangrenous tissues (Bunt et al. 1984, Rosenberg et al 1970).

Published case-series report a perioperative mortality rate for arterial reconstruction of between 1.3% and 5.6% (Crawford et al. 1981, DeWeese and Rob 1977, Dormandy and Thomas 1988, Hobson et al. 1985, Kram et al. 1991, LoGerfo et al. 1977, Maini and Mannick 1978, Myers et al. 1978a, Ramsburgh et al. 1977, Reichle and Tyson 1972&1975, Reichle et al. 1979, Szilagyi et al. 1979, Taylor et al. 1990, Towne et al. 1981, Veith et al. 1981a). However, some of these series included patients with intermittent claudication. Compared to those with critical ischaemia, claudicants are younger and have less advanced and widespread atherosclerosis. Therefore mortality among claudicants is likely to be lower. Hence, some figures quoted may be an under-estimate of the true mortality associated with arterial reconstruction for critical ischaemia. However, those studies in which recruitment was restricted to patients with critical ischaemia nonetheless reported rates of under 6%.

In addition to the difficulties of taking account of differences in case-mix, many published series report "hospital" mortality rates rather than those at a fixed period of follow-up, such as 30 days. Since amputees tend to remain in hospital for longer periods than those undergoing arterial reconstruction, comparisons may again be biased in favour of the latter.

Perioperative mortality for secondary attempts at revascularisation has been reported to lie between 1% and 7.5% (Bartlett et al. 1987, Tyson et al. 1978, Veith et al. 1981a). This compares favourably with that reported for primary reconstructions. It does not increase significantly with the number of repeat revascularisation procedures (Bartlett et al 1987), and is still considerably less than that often reported for primary amputation (Finch et al 1980, Maini and Mannick 1978, Malone et al. 1979, Porter et al. 1981).

3.2.2. Late mortality

Long-term mortality rates following major amputation are high. Up to one-third of patients die within two years (Knight and Urquhart 1989, Lack et al. 1987, Stern 1988, Weiss et al. 1990) and between 50% and 75% die within five (Dormandy and Thomas 1988, Finch et al. 1980, Little et al. 1974, Myers et al. 1978a, Rush et al. 1981). As with perioperative mortality, long-term survival is poorer for above- than below-knee amputees. It has improved little over the past thirty years, despite improvements in surgical technique, patient selection and pre- and post-operative care. This may be due, in part, to changes in operative thresholds. Patients selected now for "limb-salvage" procedures are likely to be those who would have had the best prognosis following major amputation. Primary amputation may now be restricted to older patients, with significant comorbidity and widespread disease. However, the failure to reduce long-term mortality may also reflect our inability to influence the underlying disease and its progression, as well as the coexistence of coronary and cerebrovascular disease on which lower limb surgery has no effect.

The long-term mortality following arterial reconstruction is disputed. Myers et al. (1978a) reported a ten-year mortality rate of only 46%. This is superior to that following amputation. Even higher survival rates have been reported by some authors (Bartlett et al. 1987, Hertzer 1981). However, patients selected for arterial reconstruction may not be comparable to those undergoing amputation. Also, these favourable findings are not unanimous. Many authors have reported five-year mortality rates following arterial reconstruction which are more comparable with those following major amputation (DeWeese and Rob 1977, Dormandy and Thomas 1988, Towne et al. 1981, Veith et al. 1981a).

Comparable long-term survival following amputation and arterial reconstruction has been used as both an argument for revascularisation and an argument against it. Proponents of reconstruction argue that it can achieve improved quality of life without deteriment to survival (Kihn et al. 1972, Maini and Mannick 1978, Otteman and Stahlgren 1965, Perlow 1962, Scher et al. 1986, Veith et al 1981a) whilst antagonists argue that the extra cost of complex reconstruction operations, and the need for secondary procedures in a significant proportion of patients, cannot be justified if reconstruction fails to improve survival (Stoney et al 1971).

Mortality following distal reconstruction is higher than that following more proximal grafts. Maini and Mannick (1978) reported 36% five-year survival following femorotibial reconstructions, compared to 54% following femoropopliteal grafts. However, this is again likely to reflect selection bias, since distal reconstructions tend to be performed on patients with more widespread disease.

3.2.3. Factors affecting mortality

Age

Mortality following amputation increases with age (Harris et al. 1974, Potts et al. 1979), although this is a less important factor than disease status (Jamieson and Ruckley 1983). Age also affects mortality following arterial reconstruction. In a review of 20,000 infra-inguinal bypass operations, Plecah et al. (1985) reported an in-hospital mortality of 7% in those over 75 years of age, compared to only 2% in younger patients.

Comorbidity

Perioperative mortality following major amputation is most commonly due to sepsis or cardiovascular disease (Berardi and Keonin 1978, Huston et al. 1980, Potts et al. 1979, Rosenberg et al. 1970, Tripses and Pollak 1981). Above-knee amputees are at greater risk of dying from sepsis than below-knee amputees, who are more likely to die from myocardial infarction (Rush et al. 1981). The presence of co-existing medical conditions is not a significant factor in predicting perioperative mortality (Harrison et al. 1987, Kihn et al. 1972). However, the presence of diabetes, ischaemic heart disease or cerebrovascular disease does significantly reduce longer-term survival (Dormandy 1991, Finch et al 1980, Rosenberg et al. 1970, Weiss et al. 1990).

<u>Number of procedures</u>

In a study by Kihn et al. (1972), perioperative mortality following amputation was doubled if the operation occurred within three weeks of a failed attempt at reconstruction. However, other studies have reported no adverse effect from prior arterial reconstruction on perioperative mortality (Ellitsgaard et al 1990, Veith et al. 1981a).

3.3. Local outcomes and complications

3.3.1. Delayed healing or non-healing following primary amputation

Stump complications, such as wound infection, oedema and dehiscence, occur in 16%-37% of below-knee amputations (Berardi and Keonin 1978, Rosenberg et al. 1970, Tripses and Pollak 1981, Weiss et al 1990). These can result in delayed healing or non-healing of the stump (Potts et al. 1979, Stern 1988). Most studies have reported primary healing rates of around 70%, with a further 13%-22% of stumps undergoing delayed healing (Dormandy and Thomas 1988). However, the more recent HAWAII study, which recruited 713 patients from nine European countries, reported primary healing rates of only 42% (Dormandy et al. 1994). A number of factors influence stump healing:

Preoperative infection and tissue loss

Limbs which are infected preoperatively have a four-fold higher risk of postoperative wound infection (Berardi and Keonin 1978, Tripses and Pollak 1981, Weiss et al. 1990). Open drains also increase the likelihood of infection, even if used in conjunction with antibiotics (Tripses and Pollak 1981). Some studies have reported that the presence of gangrene does not adversely affect healing (Chilvers et al. 1971, Warren and Kihn 1968). However, others have shown that gangrene is significantly associated with a higher revision rate, even after adjusting for age, comorbidity, prior vascular surgery, amputation level and the presence of preoperative infection (Weiss et al 1990).

Diabetes mellitus

The effect of diabetes on stump healing is disputed. Some authors have reported that diabetics have a higher incidence of wound infections (Cruse and Foord 1973) and therefore heal more slowly (Kritter 1973, Sizer and Wheelock 1972). Some have attributed this to microvascular obstructive changes (Siperstein et al. 1968), and others to a direct effect of insulin on the wound healing process (Goodson and Hunt 1977).

Conversely, some authors have described higher healing rates among diabetics (Cranley et al. 1969, Dormandy 1991, Kacy et al. 1982, Moore et al. 1972), provided that the disease affects only small and not large vessels. Silbert and Haimovici (1950) reported that better healing in diabetics resulted in a larger proportion of them retaining the knee. Other studies have found no difference in stump complications and healing rates in diabetics and non-diabetics (Berridge et al. 1989, Eneroth and Persson 1992, Moller et al. 1985, Squires et al. 1982, Tripses and Pollak 1981).

Age

A number of studies have reported that younger patients are at a significantly greater risk of developing stump infections and necrosis (Couch et al. 1977, Roon et al. 1977, Tripses and Pollak 1981, Warren and Kihn 1968). They are more likely to require reamputation at a higher level because of failure of the stump to heal. These adverse results may simply reflect selection bias, whereby the amputation level is likely to be more distal in younger patients (Warren and Kihn 1968). This hypothesis is supported by studies, such as that published by Potts et al. (1979), in which healing is as good in younger patients. Sex and race have no significant effect on healing (Tripses and Pollak 1981).

Previous surgery

Sequential operations are common. Up to 30% of below-knee amputations are followed by reamputation at a higher level (Dormandy and Thomas 1988), and up to half of amputees have prior attempts at arterial reconstruction (Dormandy 1991). The effect of previous surgery on amputation healing and level are discussed in sections 3.3.2. and 3.3.4.2.

Amputation level

Above-knee amputees are twice as likely to suffer systemic complications (Potts et al. 1979) because they have more widespread disease and comorbidity. However, they are less likely to suffer wound complications (Potts et al. 1979). Healing rates for above-knee amputation are far higher than for below-knee amputation (Cohen et al. 1974). However, Kihn et al. (1972) showed that above-knee amputations which were undertaken following failed below-knee amputation had healing rates (74%) which were much lower than those of primary above-knee amputations (95%).

As mentioned previously the effect of previous surgery on amputation healing is discussed in more detail in section 3.3.2.

Selection of amputation level used to be based solely on pre-operative angiography, and the amount of bleeding in theatre. However, angiography reveals little about capillary blood flow and neither method was an accurate predictor of healing. A number of methods of assessing skin perfusion have since been developed, including Doppler systolic pressure measurements, transcutaneous oxygen and carbon dioxide measurements, fluorescein angiography, skin thermometry and intradermal xenon-133 measurement (Barnes et al. 1976, Burgess et al. 1982, Dowd 1986, Malone et al. 1987, Oishi et al. 1988, Ratcliff et al. 1984, Wagner et al. 1988). Some studies have reported that use of these methods can improve healing rates without adversely affecting the proportion of amputations performed below the knee (Dowd 1986, Malone et al. 1979&1981). These results would suggest more appropriate selection of amputation level. However, the advantages of skin perfusion measurement are not universally accepted, and these methods have not, as yet, been accepted into routine clinical practice in most centres.

Temporary prostheses

Some centres apply temporary prostheses at the time of operation to permit limited weight-bearing ambulation by the first or second postoperative day. This process is intended to accelerate rehabilitation and reduce lengths of stay in hospital. It may also decrease mortality by reducing the risk of complications associated with immobility, such as pneumonia and thromboembolism. Some critics have published evidence that immediate postoperative prostheses (IPOP) may be deleterious to healing (Cohen et al. 1974). However, others studies found no evidence that the application of IPOPs compromised healing (Moore et al. 1972), and others reported improved healing rates (Malone et al. 1981).

3.3.2. Reoperation following primary major amputation

Amputation does not prevent progression of the underlying disease. Therefore serial and bilateral amputations are common (Weiss et al. 1990). Ipsilateral reamputation is more common following below-knee than above-knee amputation. Up to 30% of below-knee amputations are followed by reamputation at a higher level (Dormandy and Thomas 1988, Dowd 1986, Holstein 1985, Kazmers et al. 1980, O'Dwyer and Edwards 1985). In a correlational study of a number of different centres, Dormandy and Thomas (1988) reported a positive correlation between the proportion of major amputations performed at the below-knee level and the percentage of below-knee amputations requiring reamputation at a higher level. The majority of ipsilateral operations are performed because of failure of the initial amputation stump to heal. Once a stump has healed, the likelihood of an ipsilateral re-amputation is less than that of a contralateral amputation (Dormandy and Thomas 1988). Only four percent of all major amputations, and 15% of below-knee amputations, are converted to a higher level after the stump has successfully healed (Dormandy and Thomas 1988, Kihn et al. 1972). This suggests that less blood flow is required to maintain healed tissues than to achieve healing of an ischaemic amputation stump.

Up to 50% of amputees require a contralateral amputation (Dormandy and Thomas 1988, Kihn et al. 1972). Hoar and Torres (1962) reported that diabetic amputees more commonly develop ischaemic lesions of the contralateral leg. However, Kihn et al. (1972) found that neither diabetes, age nor general mobility predicted the development of contralateral disease.

3.3.3. Graft failure following arterial reconstructive surgery

Whittemore et al. (1981) reviewed 109 failed femoropopliteal vein grafts and described three types of graft failure: early failure, failure during the first year following reconstructive surgery and failure after the first year.

Early graft failure occurs within 30 days of the operation and can, in some cases, be attributed to inappropriate patient selection or technical errors (Darling et al. 1967, Szilagyi et al. 1979, Tyson et al. 1978). With improvements in surgical technique, poor outflow has become the predominant cause of early graft failure, especially in the case of distal and polytetrafluoroethylene (PTFE) grafts (Ascer et al. 1984a&b&1985, Bell and Parvin 1988, Yeager et al. 1982). The use of preoperative and completion angiography to assess "run-off" has significantly reduced the risk of early graft failure (Ascer et al 1987). However, angiography used in isolation is not always an accurate measure of the quality or diameter of recipient vessels, particularly where these are distal vessels and flow is poor (Ascer et al. 1988a). The severity of disease can be overestimated due to faint or incomplete visualisation of arteries. Therefore supplementary methods such as Doppler pressure measurements, digital subtraction angiography (DSA) and biplanar films, are often required to assess the number or location of patent vessels to the ankle and the adequacy of the pedal arch (Ascer et al. 1984a&b, Roedersheimer et al. 1981).

Other factors shown to be associated with early patency include inflow (Charlesworth et al. 1975, Madiba et al. 1997), the presence of diabetes and heart disease, the angle of insertion of the distal end of the graft (Klimach et al. 1984), the type of graft (Bergan et al 1982, Charlesworth et al. 1985), the experience of the surgeon (Davies et al. 1989), the general condition of the patient, perioperative hypotension and blood loss (Bell and Parvin 1988).

Vein graft failure during the first year following reconstructive surgery is due to the development of stenotic lesions within the graft itself. Arterialised vein grafts may develop several different types of lesions: limited fibrotic stenoses, diffuse intimal thickening or fibrous intimal hyperplasia, vein valve fibrosis, suture line stenoses, diffuse atherosclerosis and aneurysmal dilatation (Imparato et al. 1972, Szilagyi et al. 1973). Vein grafts which develop diffuse intimal thickening, atherosclerosis or aneurysmal dilatation tend to remain patent. By contrast graft failure occurs in 67% of vein grafts with fibrotic valve lesions, 89% of those with fibrotic stenoses and 63% of those with suture line stenoses (Imparato et al. 1972, Szilagyi et al. 1973, Whittemore et al 1981).

Graft failure more than one year following reconstructive surgery is due to progression of the atherosclerosis in the vessels proximal or distal to the graft, rather than failure of the graft itself (Tyson et al. 1978, Whittemore et al. 1981). Factors affecting disease progression, and therefore long-term patency rates, include continued smoking (Myers et al. 1978c), diabetes mellitus, pseudointimal hyperplasia (Beard and Fairgrieve 1986), the use of antiplatelet drugs (Goldman et al. 1983) or warfarin (Kretschmer et al. 1986), and the level of graft insertion (Bell and Parvin 1988). Compared with men, women have lower five-year primary patency rates especially following grafts to the tibial artery (Belkin et al. 1995).

As mentioned above, the choice of conduit material, its length and location can affect both early and late patency rates.

<u>Conduit material</u>

Arterial reconstruction operations can be performed using autologous vein grafts or prosthetic conduits. Early results from experimental (Hastings et al. 1978) and clinical (Hobson et al. 1980) studies suggested that autologous saphenous vein and PTFE grafts produced comparable results. However, mid-term evaluations revealed higher failure rates for femoro-infrapopliteal bypasses performed using synthetic prostheses (Yeager et al. 1982). These results were confirmed by subsequent long-term results (Hobson et al. 1985). Over long periods of follow-up, failure rates of up to 78% have been reported for distal prosthetic grafts (Veith et al. 1986a).

Some doubt has also been raised regarding the performance of PTFE femoropopliteal grafts in the management of critical lower limb ischaemia (Hobson et al. 1985). Some investigators have reported superior patency rates for autologous vein grafts and have suggested that PTFE grafts may accelerate distal atherosclerosis (O'Donnell et al. 1984). Hobson et al. (1985) concluded that, for femoropopliteal grafts, PTFE should only be favoured over autologous vein when life-expectancy is low or the ipsilateral saphenous vein is unavailable or unsuitable for use. PTFE was not considered a suitable conduit for distal reconstruction. They advised that if an autologous vein graft was not feasible, primary amputation should be considered. However, this was an observational study which included patients who had previously undergone failed ipsilateral autologous vein grafts. Attempted autologous vein grafts have been demonstrated to have an adverse effect on the performance of subsequent PTFE grafts (Yeager et al 1982). Therefore the study design may have been biased against PTFE grafts.

Bergan et al. (1982) carried out a prospective trial in which patients with suitable saphenous veins were randomised to receive autologous vein or PTFE grafts. Three-year patency rates were comparable for the two materials following femoropopliteal reconstructions. However, following distal reconstruction, the cumulative patency rates were 37% and 20% respectively. Veith et al (1986a) reported five year primary patency rates of 12% following infrapopliteal PTFE grafts, compared to 49% with saphenous vein grafts. However when reoperations were taken into account, they reported no significant difference in overall patency rates.

Length of conduit

The relationship between vein graft length and patency has yet to be fully established (Ascer et al. 1988b). Veith et al. (1981b&1985) postulated that, in the presence of poor "run-off," short vein grafts may be more successful than long ones. Andros et al. (1988) compared two-year patency rates in 243 paramalleolar grafts of different lengths. One hundred and eleven were long grafts originating in arteries proximal to the adductor tendon, 88 were short grafts originating at or below the popliteal artery, and 44 were jump grafts originating near the distal end of a previous femorodistal bypass. The overall three year secondary patency rate for long autologous vein grafts was 72%. In-situ vein grafts possessed the highest patency rate of 92%. The figures for short and jump grafts were 81% and 53% respectively. The limb-salvage rates for long in-situ vein grafts, short and jump grafts were 90%, 80% and 89% respectively. Long grafts using prosthetic conduits produced graft patency and limb-salvage rates of under 35%. Andros et al. (1988) concluded that bypass grafts to the ankle and foot could be both effective and durable. However, if long conduits were necessary, autologous vein must be used. Shah et al. (1995) reported a 70% secondary patency rate and 90% limb-salvage rate ten years following 2,058 in-situ saphenous vein bypasses with no association demonstrable between graft length and outcome.

Distal level of graft

There has been some controversy over whether the level of distal anastomosis of PTFE femoropopliteal grafts is an important factor in determining primary patency rates (Brewster et al. 1981, Szilagyi et al. 1979, Veith et al. 1986a). Ascer et al (1987) reported 3-year patency rates for above-knee femoropopliteal grafts of 64%, compared to only 16% for below-knee femoropopliteal grafts. A further advantage of terminating grafts above-the-knee is the option of extending failed grafts to the below-knee popliteal segment. Ascer et al. (1987) demonstrated that this was possible in 28% of failed above-knee femoropopliteal grafts. However, this is not the only reason for the superior prognosis following above-knee grafts. Simple thrombectomy of occluded grafts is also more effective in above-knee bypasses (Ascer et al. 1987). Graft salvage operations on above-knee grafts produce 52% patency rates at 3 years, compared to only 13% following below-knee salvage procedures.

Views on grafts to isolated popliteal segments are mixed. Some authors report good long-term patency rates following such operations and therefore advocate femoropopliteal bypass to an isolated popliteal artery segment in preference to distal reconstruction (Davis et al. 1975, Imparato et al. 1974, Mannick et al. 1967, Veith et al. 1981b). Primary femoropopliteal PTFE bypasses have been shown to function well despite the presence of an isolated popliteal artery on pre-operative angiography (Veith et al. 1981b). However, this may be due, in part, to the limitations of pre-operative angiography, since demonstration of an isolated popliteal segment at the time of reoperation is a reliable predictor of femoropopliteal graft failure (Ascer et al. 1987). One year patency rates of only 8% are achieved in such patients (Veith et al. 1981b). Even if grafts to isolated segments remain patent, limb-salvage may nonetheless remain threatened, especially in the presence of extensive gangrene or infection in the foot (Veith et al. 1981b). Hence, some authorities advocate the use of a more distal reconstruction to a normal tibial vessel with good run-off, in favour of a more proximal reconstruction to an isolated patent popliteal segment with impaired run-off (Perdue et al. 1980, Reichle et al 1979).

A third option is the use of a multi-sequential bypass (DeLaurentis and Friedman 1971, Edwards et al. 1976, Flinn et al. 1980). However, these require further evaluation (Maini and Mannick 1978).

Location of graft

Outcome, in terms of both patency and limb-salvage, varies with the location of the graft. From a review of the data held by the National Center for Health Statistics, Stern (1988) observed that the time from failed reconstruction to amputation was 2-8 times longer for aorto-iliac reconstructions than femoropopliteal reconstructions, suggesting that aorto-iliac grafts remain patent for longer.

In a study of 359 patients with critical ischaemia, Perdue et al. (1980) reported five-year cumulative patency rates of 90% for aortofemoral grafts, 70% for femoropopliteal grafts and 49% for femorotibial grafts. The corresponding limb-salvage rates were 93%, 81% and 67% respectively. Similarly, Dardik et al. (1982) reported cumulative graft patency rates three years following femoropopliteal, femorotibial and femoroperoneal bypass of 58%, 48% and 25% respectively. The corresponding limb salvage rates were 64%, 55% and 49%. Maini and Mannick (1978) reported five-year patency rates for femoropopliteal and femorotibial grafts of 78% and 55% respectively, and limb-salvage rates of 89% and 73% respectively. Reichle and Tyson (1975) compared the results of femoropopliteal and femorotibial reconstructions performed for severe ischaemia in 364 patients. Eight weeks after the initial operation, 81% of femoropopliteal and 73% of femorotibial grafts were functional, resulting in respective limb-salvage rates of 81% and 69%. After four years, the graft occlusion rates were 32% and 25% respectively among survivors with intact limbs. Hobson et al. (1985) reviewed 155 femoropopliteal operations and 91 femorotibial operations. The two-year limb-salvage rates were 83% and 53% respectively for autologous saphenous vein grafts and 52% and 20% respectively for PTFE grafts. The five-year rates were 81% and 47% for autologous vein grafts, and 35% and 15% respectively for PTFE.

Distal reconstructions to the tibial, peroneal or crural vessels attract the greatest debate as to their merit. Antagonists have observed that they are technically more difficult, require lengthy and costly operations, and are far less likely to be successful than more proximal bypasses (Davies et al. 1989, Horrocks 1994). The presence of widespread atherosclerosis means that repeated attempts at revascularisation are less likely to be feasible and successful (Myers et al. 1978b, Veith et al. 1980&1981a). Therefore failure of a distal graft usually results in a return to severe limb-threatening ischaemia (Bartlett et al. 1987). However, it has also been claimed that recent improvements in limb-salvage rates can be attributed entirely to greater use of distal reconstructions (O'Donohoe et al. 1994). Also, an aggressive approach to revascularisation may be warranted because of the higher perioperative mortality and poorer rehabilitation associated with primary amputation (Hobson et al. 1985, Veith et al. 1986a).

In terms of patency and limb-salvage rates, distal grafts have been reported to result in poorer outcomes than more proximal grafts (Maini and Mannick (1978). Thirty day patency rates are between 64% and 81% for distal grafts (Imparato et al 1974, Maini and Mannick 1978, Reichle and Tyson 1975), compared to 76%-90% for femoropopliteal grafts (Cutler et al. 1976, DeWeese and Rob 1977, LoGerfo et al. 1977, O'Donnell et al. 1977, Ramsburgh et al 1977, Reichle and Tyson 1975). At five years, only about half of distal grafts are patent (Imparato et al. 1974, Maini and Mannick 1978, Reichle and Tyson 1975, Veith et al. 1981a). This compares to 60%-80% five-year patency rates following femoropopliteal reconstruction (Buda et al. 1976, DeWeese and Rob 1977, Maini and Mannick 1978). However, these results are obtained through observational studies in which the treatment groups are not truly comparable. Distal grafts tend to be performed in older patients with more severe generalised disease (Maini and Mannick 1978). Therefore graft failure cannot wholly be attributed to the technical problems associated with small vessel reconstruction. The presence of more extensive disease is undoubtedly a factor. Nonetheless, it has been argued that 50% patency at five years still represents a favourable outcome, since failure to perform distal reconstruction in patients with widespread disease would result in up to 76% requiring amputation within one year (Nicholas et al. 1973).

O'Donohoe et al. (1994) reviewed a series of 25 consecutive autologous vein grafts to inframalleolar vessels in 23 patients with critical ischaemia. In seven limbs, Duplex scanning or on-the-table exploration revealed patent vessels not demonstrated by pre-operative angiography. The cumulative patency rates at 30 days, 6 months, 1 year and 2 years were 84%, 79%, 79% and 59% respectively. The corresponding limb salvage rates were 91%, 82%, 82% and 73%. The authors concluded that autologous vein grafts to inframalleolar vessels were worthwhile procedures in the management of critical ischaemia.

Horrocks (1994) undertook a prospective study of 517 patients with severe ischaemia who underwent femorotibial or femoroperoneal bypass surgery at 21 specialist centres in England, Ireland, the Netherlands and Scandanavia. At twelve months, 42% of patients were asymptomatic or had claudication, 15% still had rest pain or trophic lesions, 6% were unclassified and 37% had died or undergone major amputation. Of the 517 distal reconstructions, 92 were performed using prosthetic grafts. At twelve months, the primary patency rate for vein grafts was 52%, compared to only 45% for prosthetic grafts. The secondary patency rates were 60% and 48% respectively. The outcome was particularly good for reversed vein grafts which had a primary patency rate of 61%.

Bypasses to branches in the foot produce better results than those to distal vessels in the leg (Ascer et al. 1988b). It has been suggested that this may be due to the greater degree of collateralisation in the run-off bed. The arterial branches in the foot have tributaries interconnecting with other major branches, whereas the muscular branches in the leg have a more restricted outflow. This hypothesis is supported by the appearance of completion angiograms (Ascer et al. 1988b). Since run-off is an important predictor of patency, distal grafts are often attached only to named arteries in the leg or foot which have angiographic evidence of good "run-off" (Imparato et al. 1973). However, some studies have shown that short (<40cm) vein grafts to named infrapopliteal arteries can produce acceptable patency and limb salvage rates even when the angiogram suggests poor "run-off" as demonstrated by lack of an intact pedal arch or high outflow resistance (Ascer et al. 1988b).

Ascer et al. (1988b) reviewed 24 cases of critical ischaemia in which preoperative angiography suggested occlusion of all the major infrapopliteal arteries, but at least one large branch of one of the tibial arteries was visualised. Reversed saphenous vein grafts were performed in all cases. Over 52 months of follow-up, 8 (33%) grafts thrombosed and 5 patients (21%) required amputation. Bypasses to unnamed branches of proximal tibial arteries did not fare well, but those to the plantar and lateral tarsal branches resulted in good graft patency and limb salvage rates. On the basis of these results, the authors advocated extending the indications for attempting limb-salvage.

Axillobifemoral grafts are both effective and safe in revascularising the limbs of elderly patients in whom major aortic procedures would carry a high risk (Maini and Mannick 1978). Early patency rates lie between 90% and 94% (Johnson et al 1977, LoGerfo et al. 1977). At five years 74%-77% of grafts are patent, and 78%-86% of limbs are intact (Johnson et al. 1977, LoGerfo et al. 1977, Maini and Mannick 1978).

Femorofemoral cross-over grafts can be used to treat patients with unilateral iliac occlusive disease. They are relatively simple operations, with minimal complications and good long-term results. Reports suggest long-term graft patency and limb-salvage rates of 89%-91% (Ascer et al. 1987, Maini and Mannick 1978).

3.3.4. Reoperation following arterial reconstructive surgery

Graft failure does not make limb loss inevitable. Some limbs remain intact despite graft occlusion, and others can be saved by further attempts at revascularisation.

Limb-salvage rates are 3%-18% higher than graft patency rates for all types of graft other than femorofemoral cross-over grafts where the rates are comparable (Maini and Mannick 1978, Perdue et al. 1980). The difference in patency and limb-salvage rates is particularly high for more distal reconstructions such as femorotibial and femoroperoneal grafts (Perdue et al. 1980). Dardik et al (1982) reported a limb-salvage rate for femoroperoneal grafts twice the patency rate.

The difference in patency and limb-salvage rates is thought to result from ischaemic tissues requiring a higher blood flow to initially heal, than is thereafter required to maintain the healed tissues (Myers et al. 1978b). Early graft occlusions are likely to precede healing. Therefore limb-salvage rates following early graft occlusion are poorer than those following later graft occlusion. In a study by Dormandy and Mahir (1986), 85% of early graft failures required amputation compared to only 55% of late graft failures.

Conversely, major amputation can nonetheless become necessary despite a graft remaining patent. One-third of major amputations follow failed attempts at reconstruction (Stern 1988), and one-third of these secondary amputations are required despite patent grafts (Couch et al. 1967, Martin and Foster 1975, Myers et al. 1978b, Naji et al. 1978, O'Donnell et al. 1977, Reichle and Tyson 1972, Reifsnyder et al. 1997, Stoney et al. 1971).

3.3.4.1. Serial attempts at revascularisation

Sequential attempts at reconstruction are not uncommon, and several reports suggest that they can produce prolonged patency and limb-salvage (Bell 1985, Dalsing et al. 1985, Raithel 1980). Repeated revascularisations are associated with overall patency and limb-salvage rates of 80% and 87% respectively at one-year, and 31%-37% and 50%-59% at five years (Bartlett et al. 1987, Brewster et al. 1983, Maini and Mannick 1978, Veith et al. 1986a&b, Whittemore et al. 1981). Whittemore et al. (1981)

demonstrated no correlation between the cause of graft failure and secondary salvage rates. They also found no deterioration in outcome with the number of secondary procedures required. However, as with primary reconstructive surgery, patency following repeat attempts at revascularisation varies with the location of the graft and the material used. Results also depend on whether revascularisation is attempted using graft salvage or reoperation.

Ascer et al. (1987) studied 724 PTFE grafts used to treat critical ischaemia. Twenty three percent of these grafts failed requiring secondary attempts at revascularisation. Attempts at graft salvage, such as thrombectomy or revision, resulted in three-year patency rates of 71% for axillofemoral grafts and 52% for femoropopliteal above-knee grafts. Graft salvage produced disappointing results for femoropopliteal below-knee grafts and femorodistal grafts, with patency rates of only 13% and 15% respectively. Use of a new graft to a different outflow artery resulted in far superior patency rates for these operations: 48% for femoropopliteal below-knee grafts and 39% for femorodistal grafts. Ascer et al. (1987) concluded that graft salvage procedures were justified following occlusion of PTFE axillofemoral or femoropopliteal above-knee grafts. However, failure of PTFE femoropopliteal below-knee or femorodistal grafts required bypass to a new site, preferably using autologous vein. Similarly, Veith et al. (1980) reported sustained improvements in patency after reoperation of failed femoropopliteal grafts. However, reoperation on more distal grafts was unrewarding (Veith et al. 1981c).

Whittemore et al (1981) demonstrated that regular graft surveillance enabled early identification of stenoses prior to complete occlusion. Under such circumstances, a simple vein patch could be performed, yielding an improved overall patency rate of 85% at five years. Once complete thrombosis had occurred, new vein grafts achieved the highest five-year patency rate. No prosthetic secondary grafts remained patent beyond three years.

Mortality rates following reoperation are comparable to those associated with the primary procedure (Ascer et al. 1987, Whittemore et al. 1981). However, infection rates are higher following revascularisation procedures, particularly following thrombectomy. Ascer et al. (1987) reported infection rates of 1.3% following primary arterial reconstruction, compared to 6% following thrombectomy. Also, the presence of local scar tissue can make secondary procedures technically difficult, and the associated neovascularisation results in an increased risk of post-operative haemorrhage, especially if the patient is on systemic anticoagulants. Wound haematomas are a frequent complication of reoperation, and require surgical drainage (Bartlett et al. 1987).

3.3.4.2. Limb-salvage following arterial reconstructive surgery

Although arterial reconstructive surgery is used as a "limb-salvage" procedure in patients with critical lower limb ischaemia, its effectiveness as such has not been properly assessed using randomised controlled trials. Therefore this has largely been inferred from observational studies, comparisons with an historical control group and correlational studies.

Currently half of patients presenting with chronic critical lower limb ischaemia undergo arterial reconstructive surgery (European Working Group 1991, Wolfe 1986). In those undergoing reconstructive surgery, early "limb-salvage" rates of 84% can be achieved (Veith et al. 1981a). By five years 48% of patients are alive, and two-thirds of these patients have retained their limb (Eckstein et al.. 1996, Veith et al. 1981a). Of the 52% who die, 88% do so with their limb intact. Therefore over five years limb-salvage is achieved in 78% of patients. Other studies have demonstrated limb-salvage rates of betwen 56% and 76% at five years follow-up (DeWeese and Rob 1977, Myers et al. 1978b, Reichle et al. 1979, Yogasundaram 1976). Since only one-half of critically ischaemic patients undergo reconstruction, limb-salvage rates in these patients are around 28%-39%. However, Veith et al. (1981a) claimed that 90% of patients with critical ischaemia could appropriately undergo arterial reconstructive surgery. If this were done without adverse effect on outcomes, up to 70% of limbs could be saved.

Comparisons can be made between the incidence of amputation in people presenting with ischaemia in the 1950's and the incidence in the 1970's and 1980's following more widespread use of arterial reconstruction. The amputation incidence has fallen from 10% to 3% (Dormandy and Thomas 1988) suggesting that approximately two-thirds of critically ischaemic limbs are saved by arterial reconstruction.

Other investigators have used cross-sectional or correlational studies to compare rates of major amputation and arterial reconstruction in different areas. If arterial reconstruction avoids the need for amputation in some patients, a negative correlation should exist. However, correlational studies in Denmark and the United States have demonstrated a positive correlation between amputation and reconstruction rates. Therefore contrary to expectations, residents living in areas with high reconstruction rates also experience high amputation rates (Chassin et al. 1986a, Eickhoff et al. 1980).

3.3.4.3. Amputation healing following arterial reconstructive surgery

Unsuccessful attempts at arterial reconstruction may result in amputation. Views differ on whether prior attempts at reconstruction adversely effect the healing of subsequent amputations, with reported healing rates ranging from 19% to 77% (Couch et al. 1967, Dardik et al. 1982, Evans et al. 1990, Kazmers et al. 1980, LoGerfo et al. 1977, Naji et al. 1978, Ramsburgh et al. 1977, Schlenker and Wolkoff 1975, Stoney 1978, Whittemore et al. 1981).

A number of studies have suggested lower healing rates when amputation is preceded by arterial reconstruction. Evans et al. (1990) compared healing rates in 551 primary below-knee amputations and 210 below-knee amputations following failed femoropopliteal or distal reconstructions. Within these groups, the healing rates were 89% and 77% respectively ($p<0.05$). Secondary amputations were associated with poorer healing regardless of the time delay between reconstructive surgery and amputation. The HAWAII study assessed the factors affecting healing in 713 below-knee amputations performed for critical ischaemia in nine European countries (Dormandy et al. 1994). Forty nine percent of the amputations were preceded by attempts at arterial reconstruction. Primary healing occurred in only 42% of all amputations, and the only factor shown to adversely affect healing was a prior attempt at revascularisation.

Popliteal pressure is a better predictor of stump healing in primary amputation than in amputation following arterial reconstruction. Evans et al. (1990) reported that pressures of over 60 mmHg predicted healing in 92% of primary below-knee amputations, but only 76% of secondary procedures. Kazmers et al. (1980) reported figures of 87% and 52% respectively.

A number of theories have been postulated as to how graft occlusion may adversely affect stump healing. The blood supply at the level of the stump may be adversely affected by a number of mechanisms. The surgical procedure itself may directly disrupt collateral vessels at or above the amputation level (Evans et al. 1990). Alternatively, the thrombus within the occluded graft may propogate to affect the inflow, outflow or collaterals vessels. Supporting evidence for this theory comes from the change in popliteal arterial pressure that follows some distal bypasses (Dean et al. 1975, Evans et al. 1990, Kazmers et al. 1980). Also, arterial reconstructive surgery may result in the creation of complex, intersecting incisions or fasciotomy sites which result in post-revascularisation oedema (Evans et al. 1990). Finally, healing may be impaired by surgical complications following arterial reconstruction such as wound infection or skin necrosis around knee incisions (Schlenker and Wolkoff 1975).

If prior attempts at arterial reconstruction do jeopardise stump healing, the final level of amputation might be expected to be more proximal in some cases than could have been achieved with primary amputation. A number of studies have reported an adverse effect on amputation level (Dardik et al. 1982, Kazmers et al. 1980, Ramsburgh et al. 1977, Stoney 1978, Szilagyi et al. 1979). Szilagyi et al. (1979) demonstrated that 68% of amputations following failed reconstructions were performed at the above-knee level. Couch et al. (1967) suggested that half of the above-knee amputations performed following failed reconstructions could have been performed below the knee as primary procedures. In a study by Hobson et al. (1985), 23% of below-knee amputations performed after arterial reconstruction required conversion to above-the-knee level. This compared with a revision rate of only 19% for primary amputation, although this difference was not statistically significant. Ellitsgaard et al. (1990) reported a reamputation rate of only 6% following primary amputation, compared to 14% when amputation was preceded by an unsuccessful attempt at reconstruction.

Contrary results have been reported in some studies which have demonstrated that, although arterial reconstruction may increase the likelihood of wound complications, delay stump healing and prolong convalescence, the final amputation level is not significantly affected (Burgess and Marsden 1974, Dean et al. 1975, Kihn et al. 1972, Murdoch 1967, Romano and Burgess 1971, Samson et al. 1982, Veith et al. 1981a).

In a much quoted study by Burgess and Marsden (1974), 83% of 140 primary below-knee amputations eventually healed, compared to 75% of 142 post-reconstruction below-knee amputations. Because the difference was not statistically significant, the authors concluded that prior arterial reconstruction did not adversely affect stump healing. However, under secondary amputations, they included 36 patients who had only had lumbar sympathectomies prior to amputation. Exclusion of these patients reduced the healing rate in this group to only 67%

In a study of 14 patients who had undergone unsuccessful attempts at arterial reconstruction, Dean et al. (1975) found a fall in popliteal pressure in five. However, only one of these five patients required above-knee amputation. They concluded that although prior arterial reconstruction appeared to have a deterimental effect on popliteal artery pressure, final amputation level was not affected. However, the number of patients recruited to this study was clearly very small.

Bartlett et al. (1987) reported that above-knee amputations were required in only 28% of patients undergoing multiple attempts at limb-salvage. They concluded that amputation level was not adversely affected by revascularisation in more than 90% of cases. In a study by Ellitsgaard et al. (1990) the BKA:AKA ratio following primary amputation was 1.2:1, which was not significantly different from the 1.1:1 ratio obtained for amputation following failed arterial reconstruction.

A number of studies suggest that the effect of failed reconstruction on subsequent stump healing varies with the location of the graft. In a study by Veith et al. (1981a), healing at the below-knee level was achieved in 90% of amputations following failed femoropopliteal reconstruction and 69% following failed distal reconstruction. The worst prognosis was associated with axillopopliteal reconstruction, following which only 30% of below-knee stumps healed. The authors argued that the adverse effect of prior axillopopliteal reconstruction merely reflected selection bias, since patients undergoing such procedures have advanced disease.

Samson et al. (1982) compared 161 primary amputations, 58 amputations performed within 3 months of a failed arterial reconstruction, and 23 amputations performed more than 3 months following arterial reconstruction. Healing at the below-knee level was obtained in 50% of the primary amputations, 79% of the early secondary procedures, and 56% of delayed amputations. Of the secondary amputations, healing rates were lowest in those amputations which followed more distal reconstructions. Ninety percent of amputations occurring more than 3 months after failed femoropopliteal reconstructions healed at the below-knee level, compared to only 40% of those performed more than 3 months after femorotibial or peroneal reconstruction. Ascer et al (1987) reported BKA:AKA ratios of 1:1 following failed femoropopliteal grafts compared to 1:4 following failed femorodistal grafts.

Conversely, some studies have suggested superior results following failed distal reconstructions. Dardik et al. (1982) reviewed 79 major amputations which followed arterial reconstruction performed for critical ischaemia. The poorest prognosis followed failed bypasses to the popliteal artery. Only 44% of amputations following popliteal bypasses healed at the below-knee level, compared to 54% of those to peroneal arteries, and 71% of failed tibial bypasses. The corresponding re-amputation rates were 33%, 22% and 17% respectively. The authors pointed out that these results compared favourably with the 10%-20% of primary below-knee amputations which required conversion to the above-knee level, and that the results were particularly favourable for peroneal grafts which have attracted the greatest criticism.

It seems counter-intuitive that the prognosis following peroneal grafts should be superior to that following popliteal grafts. However, two possible explanations have been proffered. Firstly, dissection of the popliteal artery for more proximal reconstruction may interrupt collateral vessels around the knee and, thereby, have a direct adverse effect on healing. Secondly, the planes of dissection for popliteal bypass surgery may become contiguous with those of a subsequent amputation leading to inflammation and possibly even infection. Conversely, the distal incisions used for tibial and peroneal bypass are remote from the below-knee amputation site and are therefore included in the amputated limb segment.

The lack of agreement between study findings is reflected in a range of views on the management of critical ischaemia. Some authorities advocate aggressive attempts at revascularisation to salvage limbs that would otherwise be amputated, reserving primary amputation for only a very small minority of patients (Bergan et al. 1982, Burnham et al 1978, Maini and Mannick 1978, Perdue et al. 1980, Reichle and Tyson 1975, Veith et al. 1981a). However, others advocate wider use of primary below-knee amputation to avoid secondary procedures, an increased risk of surgical complications and a more proximal final amputation level for those in whom reconstruction is unsuccessful (Stoney 1978, Yeager et al. 1982).

3.4. Rehabilitation

As discussed previously, surgery for critical ischaemia, whether arterial reconstructive surgery or major amputation, has little effect on long-term survival. Therefore the main aim of such procedures must be to alleviate symptoms, improve well-being and maximise function (Jamieson and Ruckley 1983).

Rehabilitation programmes are aimed primarily at enabling amputees to perform the basic activities of daily living. One of the main functions of such programmes is to achieve acceptable levels of mobility. Where possible, this should be achieved by helping amputees to become ambulant using a prosthesis. The earliest verifiable account of prosthetic use relates to Hegistratus of Elis, a seer who was condemned to death by the Spartans in 424BC (Campbell and Thornberry 1988). Tethered by his leg to await execution he escaped by amputating his own foot. When he was later captured (and put to death) it was noted that he was wearing a wooden foot. Prostheses have improved considerably since then with the development of lighter and more flexible materials, prosthetic joints and improved cosmesis.

3.4.1. Factors affecting rehabilitation

A number of factors influence the success of rehabilitation. Two of the most important are whether the amputation is unilateral or bilateral, and the level at which amputation is performed. The likelihood of successful rehabilitation is significantly reduced if bilateral amputations are performed. Preservation of the knee joint greatly decreases energy expenditure and improves mobility (Waters et al. 1976). Unilateral below-knee amputees walking with a prosthesis expend 10%-40% more energy than normal , and bilateral below-knee amputees exert 41% more energy (Corcoran et al. 1971, Erdman et al. 1960, Gonzalez et al. 1974, Traugh et al. 1975, Waters et al. 1976). For above-knee amputees, the corresponding figures are 65% and 75%-110% respectively. Hoffman et al. (1997) demonstrated that, although bilateral above-knee amputees walk 21% more slowly than normal, this is insufficient to offset their 49% higher metabolic demands.

Mobility rates following below-knee amputation are more than twice those following above-knee amputation (Houghton et al. 1992). Up to 80% of elderly patients regain independent bipedal gait after unilateral below-knee amputation (Samson et al. 1982). However, when the knee is sacrificed only 40% are able to walk unaided, and the rehabilitation time is doubled (Samson et al. 1982). In addition to impairing walking, loss of the knee affects basic activities of daily living, such as turning in bed and transferring from bed to a chair. These poor outcomes are disputed by some authors who claim a success rate of over 70% in mobilising elderly bilateral amputees (McCollough et al. 1972, Thornhill et al. 1986).

In a study by Knight and Urquhart (1989), four-fifths of unilateral below-knee amputees were able to walk indoors, compared with two-thirds of above-knee amputees and only one-fifth of double amputees. Only one-tenth of unilateral below-knee amputees required assistance with stairs, compared to one-quarter of above-knee amputees. More than three-fifths of below-knee amputees usually walked outdoors compared to only two-fifths of above-knee amputees.

The benefits of below-knee amputation in terms of improved mobility have to be weighed against the reduced healing rates compared with above-knee amputation (Baddeley and Fulford 1965, Silbert and Haimovici 1954, Warren and Kihn 1968). In patients in whom ambulation is potentially achievable, amputation should be performed at the most distal level at which healing and good function can be reasonably anticipated. In older patients who already have poor mobility, primary above-knee amputation is often advocated to ensure healing in a patient in whom ambulation is considered an unrealistic goal (Houghton et al. 1992). However, some authors oppose such decision-making. Previous mobility is not necessarily a predictor of the ability to walk with a prosthesis, amputation healing is unrelated to age, and older patients are less well able to mobilise following an above-knee amputation than younger amputees (Gregg 1985, Kihn et al. 1972, Knight and Urquhart 1989, Veith et al. 1981a). Stoney (1978) argued that the case for below-knee amputation was, in fact, strongest in older patients with poor mobility, since they were the people most at risk of further procedures and loss of independence.

Collin et al. (1992) reported that age was not an indicator of successful prosthetic training, but they studied a highly selected group of patients who had already been referred for prosthetic fitting. Mobility using a prosthesis is adversely affected by a number of factors, including degenerative joint disease, particularly if present on the amputation side, decreased vision due to diabetic retinopathy or cataracts, dementia, reactive depression and concomitant ischaemic heart disease (Stern 1988). All of these conditions are more prevalent in older patients. Also, women are more likely to require assistance with walking than men (Cameron et al. 1964, Knight and Urquhart 1989). Mobility is more likely to be preserved if a higher grade surgeon performs the amputation (White et al. 1997).

A below-knee:above-knee amputation ratio of 2.5:1 has been suggested as the mimimum acceptable figure within units offering an amputation service (Dormandy and Thomas 1988). However, in many reported series, the ratio remains well below 2.5:1 (Dormandy and Thomas 1988) and, within the United Kingdom as a whole, approximately equal numbers of above- and below-knee amputations are performed (DHSS 1986).

Although individual series have reported improvements in knee-salvage rates (Berardi and Keonin 1978, Jamieson and Ruckley 1983), there has been little improvement overall in the last twenty years. It has been suggested that this may be due, in part, to the increasing numbers of arterial reconstruction operations performed over this period. Arterial reconstruction may be more effective at avoiding below- than above-knee amputations (Gregg 1985, Kazmers et al. 1980, Szilagyi et al. 1979). Also, as discussed in section 3.3.4.2, prior arterial reconstruction may jeopardise the healing of subsequent amputations, thereby leading to an increase in the number of above the knee amputations ultimately performed.

3.4.2. Mobility and activities of daily living

Mobility following major amputation is poor. Between 30% and 85% of below-knee amputees and 11%-36% of above-knee amputees achieve full mobility by the end of their rehabilitation programme (Dormandy and Thomas 1988). Furthermore, the level of mobility may decline after completion of the rehabilitation programme. Although some studies have claimed much higher success rates, with only 5% of patients dependent on wheelchairs (Houghton et al. 1989, Narang et al. 1984), these studies included only amputees who were referred to "disablement services centres" (DSCs) and did not exclude non-vascular amputees. Although non-vascular amputees represent only about 7% of all amputees (DHSS 1989), they represent more than 50% of amputees who survive and attend DSCs (Houghton et al. 1989).

Less than half of vascular amputees are able to walk outdoors without assistance (Finch et al. 1980, Knight and Urquhart 1989, Pell et al. 1993). Most amputees leave the house less frequently than they were able to 4-5 months prior to surgery (Knight and Urquhart 1989). The proportion of below-knee amputees able to regain full mobility has increased over the years (Dormandy and Thomas 1988). This has been attributed, in part, to the introduction of early mobilisation programmes and an integrated "team approach" (Dormandy and Thomas 1988, Ham et al. 1985, Malone et al. 1981). The development of a multidisciplinary team with a special interest in amputation has been shown to be of benefit in terms of early mobility, length of hospital stay and cost effectiveness (Aristides 1989, Ham et al. 1985, Malone et al. 1979, Malone et al. 1981). As mentioned in section 3.3.1., some studies have reported improved mobility and reduced lengths of rehabilitation following the use of IPOPs (Malone et al. 1981, Moore et al. 1972). However, other studies have failed to corroborate this benefit (Cohen et al. 1974).

Rehabilitation is a lengthy process. It may take up to nine months to achieve maximum mobility (Dormandy and Thomas 1988). Further improvements thereafter are unlikely (Thompson and Haran 1983). More importantly, mobility and independence levels may decline following discharge from rehabilitation programmes (Collin et al. 1992, Froggatt and Mawby 1981, Houghton et al. 1992, Kald et al. 1989, Otteman and Stahlgren 1965). Patients often discontinue use of their prostheses, or may use them only when attending the limb fitting centre. Kihn et al. (1972) found that 30% of amputees who initially attained mobility were no longer using prostheses at two years follow-up. Similarly, Stephen et al. (1987) reported that 90% of amputees were fitted with a prosthesis and returned to the community. However, one year later, only 73%

were independently mobile indoors, and only 50% were totally independent in the activities of daily living. In a Scottish review, 13% of amputees fitted with a prosthesis wore it on less than four days a week or never wore it (Knight and Urquhart 1989). At six years follow-up, more than one-quarter of amputees have discontinued use of their prostheses and converted to a wheelchair (Collin et al. 1992, Weaver and Marshall 1973). The failure to maintain mobility is not simply due to cessation of the rehabilitation programme. Progression of the underlying disease, secondary operations, and occurrence of cardiovascular and cerebrovascular events all play a role. Disease progression is more important in predicting continued use of prostheses than amputation level (Finch et al. 1980).

The proportion of amputees who continue to use a prosthesis varies with the level of amputation. In the study by Knight and Urquhart (1989), 87% of unilateral below-knee amputees continued to wear their prosthesis for at least half the day each day, compared with 70% of unilateral above-knee amputees, and 59% of bilateral amputees. This is likely to reflect both the greater difficulty of walking with proximal and bilateral amputations, and the fact that these patients tend to have the more severe and widespread disease.

Compared with amputation, there is relatively sparse information on mobility following arterial reconstruction. It is often mistakenly assumed that mobility is achieved post-operatively by all those undergoing arterial reconstruction (Dormandy and Thomas 1988). In a study by Gupta and Veith (1988), one year following arterial reconstruction, only 79% of the 289 patients had salvaged limbs and full function. This was not significantly different from the 71% of amputees who were able to be successfully rehabilitated. By three years follow-up, only 60% of those undergoing reconstruction had maintained full function. However, most studies have demonstrated better rehabilitation following reconstruction than amputation. In a study by Holdsworth et al. (1993), 72% of patients undergoing arterial reconstruction for critical ischaemia were able to be discharged home, and only 7% were discharged to a nursing home. The corresponding figures for amputation were 60% and 15% respectively. Patients may remain mobile following reconstruction even if graft occlusion occurs or rest pain recurs (Bartlett et al. 1987).

Smith et al. (1993) compared 48 amputees with 116 patients undergoing arterial reconstruction for critical limb ischaemia. Three years after the intial operation, 57% of amputees could walk unaided or with a stick or frame, compared to 95% of those who had undergone reconstruction. Thirty eight percent of amputees could bathe themselves, 48% could cook for themselves and 24% could clean the house. The corresponding figures for arterial reconstruction were significantly higher at 79%, 77% and 60% respectively. Significantly more patients return home following arterial reconstructive surgery than major amputation (Humphreys et al. 1995).

3.5. Quality of life

Peripheral arterial disease has a deleterious effect on all aspects of quality of life: physical mobility, energy, pain and sleep (Hunt et al. 1982). More than half of claudicants are required to curtail their hobbies and interests, and one-third encounter problems with their social lives, holidays, sex lives and household chores (Hunt et al. 1982). Quality of life falls still further as the severity of disease increases (Crosby et al. 1993, Pell et al. 1994a), and attending physicians are poor at judging the impact of the disease on their patients' quality of life and tailoring their management accordingly (Pell 1995).

Arterial reconstruction can improve the quality of life of both claudicants and those with severe ischaemia (Albers et al 1992, Pell and Lee 1997). However, major amputation can produce deleterious effects (Froggatt and Mawby 1981, Parkes 1975, Pell et al. 1993, Thompson and Haran 1983). Relatively few studies have compared quality of life in amputees with those undergoing arterial reconstruction. Smith et al. (1993) compared 48 amputees with 116 patients undergoing arterial reconstruction for critical limb ischaemia. Sixty nine percent of those undergoing arterial reconstruction reported a subjective improvement in their quality of life, compared to only 19% of amputees ($p<0.001$). In a study by Weiss et al. (1990), 29% of patients felt that their subjective health status improved following amputation as a result of pain relief. However, one-quarter thought it became worse.

Sixty seven percent of amputees rate their health as poor or only fair, compared to 39% of the general population (Stockford 1985). Ratings are lowest for elderly, dependent patients with proximal amputations. On the Affect Balance Scale amputees attain significantly lower scores than elderly members of the general population (Moriwaki 1974, Weiss et al. 1990). On some single quality of life measures amputees attain scores comparable to those of cancer patients (Gough et al. 1983). Amputation is often associated with adverse psychological sequelae, causing feelings of helplessness and pessimism, emotional disturbance, autonomic reaction and social withdrawal (Froggatt and Mawby 1981, Parkes 1975, Stern 1988, Thompson and Haran 1983). These feelings can be as severe as those following bereavement and can persist longer (Parkes 1975). However, compared to non-vascular amputees, patients with chronic critical ischaemia have more time to adjust pre-operatively and are therefore less subject to acute post-operative depression (Parkes 1976).

In comparison to the general population, vascular amputees have significant impairment of all aspects of their quality of life (Pell et al. 1993). As well as having reduced mobility and greater pain, they are also more socially isolated and lethargic, and have greater sleep and emotional disturbance. Although no more likely to live alone, amputees feel more isolated. Between one-quarter and one-half of vascular amputees are unable to leave home even with assistance (Finch et al. 1980, Pell et al 1993), and amputees report significantly more problems with hobbies, holidays and their social lives. Despite faring badly in all aspects of their quality of life, mobility is the only independent predictor of amputees' overall quality of life (Pell et al. 1993).

Therefore it is plausible that much of the social isolation and psychological disturbance felt by amputees is secondary to their restricted mobility (Froggatt and Mawby 1981, Pell et al. 1993). This highlights the need for intensive rehabilitation and social support in this group. In those amputees who cannot regain ambulation, wheelchair rehabilitation provides an alternative means of enhancing their ability to perform the activities of daily living and therefore integrate them back into society (Davis et al. 1967, Katrak and Baggott 1980, Pell et al. 1993, Steinberg et al. 1985, Weiss et al. 1990).

One result of the social isolation felt by amputees is that they are inhibited in declaring their needs (Thompson and Haran 1983). Even where the needs of amputees do not differ from other groups, they feel less able to seek help. In particular amputees suffer considerable financial burden but lack knowledge of possible sources of advice and assistance (Thompson and Haran 1983).

Amputation has significant implications for employment (Stephen et al. 1987, Thompson and Haran 1983). In a study by Stephen et al. (1987), only 17% of amputees who had previously been employed were able to return to work. Being forced to remain at home alone during the day can cause boredom, frustration and loneliness (Parkes 1976).

3.6. Economic evaluation

Gupta and Veith (1988) reviewed 313 patients treated for chronic critical lower limb ischaemia over a three year period. Tweny four underwent major amputation and 289 arterial reconstruction. Those undergoing major amputation had arterial reconstruction precluded on the basis of their angiogram findings or degree of gangrene. The authors excluded patients for whom amputation was elected because of advanced age or organic mental syndrome. Thirteen amputations which followed failed attempts at reconstruction were included. Apart from angiogram findings and tissue loss, the two treatment groups were otherwise comparable, with no differences in age, sex and other risk factors. Costs were calculated over three years of follow-up. In addition to the initial treatments costs, the authors calculated the costs of hotel services, rehabilitation and rehospitalisation for complications.

Amputation resulted in an average length of stay of 60 days, compared to only 50 days for reconstruction ($p<0.05$). The overall costs for major amputation and reconstruction were $27,225 and $26,194 respectively. These were not significantly different. However, there was considerable variation within these broad groups. Femoropopliteal reconstruction required an average of only 43 days admission and cost $23,026, whereas infrapopliteal reconstruction required 58 days and cost $30,380. Amputation for necrosis required longer periods of hospitalisation and was often preceded by minor procedures and non-surgical treatment. Therefore it cost almost twice as much as amputation for rest pain alone: $32,653 compared to $19,189. Amputation costs were much higher for patients over 70 years of age. Postoperative wound infections and the presence of diabetes had no significant effect on cost. Overall costs were highest in those patients undergoing arterial reconstruction who subsequently required amputation. Rehabilitation was unsuccessful in 27% of these patients, and they cost an average of $42,107.

The authors concluded that amputations require longer admissions but incur similar overall costs. The additional costs incurred by an extended stay in hospital for rehabilitation was offset by reconstruction patients requiring angiography, lengthy operations and intensive care treatment. The highest cost procedures were infrapopliteal reconstructions which were prone to both early and late failure necessitating secondary procedures, including amputation. Similar results were obtained by Mackey et al. (1986) who reported no difference in the overall costs incurred by arterial reconstruction ($40,769) and primary amputation ($40,563), despite lengths of stay of 85 and 67 days respectively. Panayiotopoulos et al. (1997) calculated the cost of a successful femorocrural or femoropopliteal bypass for critical ischaemia to be £4,320, compared to £17,066 for a failed revascularisation attempt necessitating major amputation, and £12,730 for a primary amputation.

The main shortcoming of these economic analyses was the failure to include the costs of continued support for those patients requiring institutional care or care in the community. These costs are more likely to be incurred by amputees and, since they are likely to continue for a number of years, may represent a significant financial burden.

The costs of social support were included in a subsequent economic analysis by Davies et al. (1989), in which they reviewed 337 patients undergoing arterial reconstruction or major amputation over a four year period in a London hospital. There was a minimum follow-up period of one-year during which data were collected on the indications for surgery, graft success, level of mobility, level of independence, reoperation, complications, inpatient resource utilisation, rehabilitation, social support and survival.

The average ages of patients undergoing reconstruction and amputation were 60 years and 63 years respectively. One-quarter of amputees were diabetic, compared to only 12% of those undergoing reconstruction. The average length of operation was one hour for amputation, three hours for proximal reconstruction, and four hours for distal reconstruction. Graft patency rates differed considerably between distal and proximal reconstructions. Early failure rates were 72% and 43% respectively. Two-thirds of grafts required revision. Although patency rates differed between distal and proximal reconstructions, the revision rates were comparable. Overall failure rates following revision, were 54% for distal reconstructions and 19% for proximal reconstructions. Amputation was required following 31% of failed distal reconstructions, but only 23% of failed proximal reconstructions. The average inpatient length of stay was 16 days for proximal reconstruction, 21 days for distal reconstruction and 42 days for amputation. Twenty four percent of amputees were discharged to a rehabilitation ward where they remained for an average of 130 days.

All amputees received occupational therapy and home aids equipment, and 83% were supplied with a prosthesis. Only 5% of those undergoing reconstruction required social services support, compared to nearly half the amputees. Full mobility and independence was achieved following 65% of proximal reconstructions, 79% of distal reconstructions, 9% of below-knee amputations and 5% of above-knee amputations. Limited mobility or confinement to a wheelchair occurred following a further 0%, 4%, 27% and 33% respectively.

The average cost of a proximal reconstruction was £2,830 for the intial procedure plus £3,540 per revision if required. For distal reconstructions the corresponding figures were £3,450 and £4,630 respectively. Amputations cost an average of £7,430 for the intial procedure. Long-term support required a further £81-£1,195 depending on mobility levels.

Taking account of secondary procedure rates and long-term costs, the average costs were £6,590 for proximal reconstruction, £11,000 for distal reconstruction and between £10,400 and £10,850 for major amputation. Using the Rosser Kind distress-disability matrix, the authors calculated quality-adjusted life-years (QALYs) gained for the three procedures of 2.96, 2.92 and 2.82 respectively.

Overall, arterial reconstructions cost £2,730 less than major amputations. However, this could largely be attributed to proximal reconstructions which cost on average £3,810-£4,260 less than amputations, in addition to producing a net gain of 0.14 QALY per patient. Distal reconstructions were associated with a similar QALY gain, but at a small net cost of £150-£600 compared to amputation.

On sensitivity analysis, it was found that graft patency rates were an important determinant of expected costs and outcomes following reconstruction, particularly in the case of distal reconstruction. However, the benefit shown for proximal reconstructions was robust on sensitivity analysis.

As with Davies et al. (1989), Humphreys et al. (1995) calculated that the lower in-hospital costs of major amputation were more than offset by the community costs incurred following discharge. The authors calculated operative costs of £10,222 for arterial reconstruction and £6,475 for major amputation, and total costs of £13,546 and £33,095 respectively. The higher absolute costs derived by Humphrey et al. (1995), in part, reflect the effect of inflation during the six year interval between the two studies and, in part, reflect the fact that this study was restricted to an older cohort of amputees in whom longer lengths of stay and greater need for medical and social support are to be expected.

Critical limb ischaemia is an expensive condition to treat, regardless of the operation undertaken. In addition to the financial cost to the health service, there are social and health costs to the patient in the form of loss of mobility and independence, psychological morbidity and reduced life expectancy. Costs could also have to be met by lay carers who may have to sacrifice their own work and leisure time to provide practical assistance and psychological support.

3.7. Conclusions

Most of the available evidence on the effectiveness of major amputation and arterial reconstructive surgery for chronic critical lower limb ischaemia is restricted to observational studies and case-series. Interpretation of these studies is limited by selection and publication bias, and a lack of standardised definitions.

Perioperative mortality following arterial reconstructive surgery is between 2% and 6% for both primary and secondary operations (Ascer et al. 1987, Dormandy and Thomas 1988, Whittemore et al. 1981). Most series report a slightly higher perioperative mortality, of between 3% and 10%, following below-knee amputation. Gregg (1985) attributed the higher mortality to patient selection and demonstrated comparable figures following adjustment for age. Also, mortality rates as low as 1%-3% have been reported by some specialist centres (Bunt et al. 1984, Dormandy and Thomas 1988). Above-knee amputation is associated with much higher perioperative mortalty, with some centres reporting rates in excess 20% (Dormandy and Thomas 1988). Between 50% and 75% of patients undergoing major amputation or arterial reconstructive surgery for chronic critical lower limb ischaemia die within five years (Dormandy and Thomas 1988). In a Swedish study of 167 patients with rest pain who did not undergo surgery, 50% of non-diabetics and 60% of diabetics died over five-years (Hughson et al. 1978). Therefore survival is unaffected by both major amputation and reconstruction. This reflects the inability of lower limb surgery to influence either the local progression of disease or events due to atherosclerosis at other sites. Long-term mortality rates are highest in older patients and those with coexisting coronary and cerebrovascular disease. They are also higher following above-knee amputation and distal reconstruction because the patients selected to undergo such procedures tend to have more widespread disease.

Primary healing occurs in 70% of below-knee stumps, and a further 13%-22% undergo delayed healing (Dormandy and Thomas 1988). Delayed or non-healing can occur because of wound infection, oedema and dehisence. Such stump complications are more likely to occur in the presence of preoperative infection (Berardi and Keonin 1978, Tripses and Pollak 1981, Weiss et al. 1990). The effect of age, diabetes and gangrene, and the use of immediate postoperative prostheses is disputed. Healing rates are higher with above- than below-knee amputation. However, the benefits of improved healing associated with above-knee amputation must be weighed against the increased likelihood of successful rehabiliation following below-knee amputation. (Houghton et al. 1992, Samson et al. 1982). Between 30% and 85% of below-knee amputees regain their mobility, compared to only 11%-36% of above-knee amputees (Dormandy and Thomas 1988). A BKA:AKA ratio of 2.5:1 has been recommended as an appropriate target (Dormandy and Thomas 1988). However, this ratio remains nearer 1:1 in the United Kingdom. Other factors which adversely affect rehabilitation include bilateral amputation and the coexistence of degenerative joint disease, cerebrovascular disease, poor visual acuity or dementia. In some patients, the level of mobility achieved following a rehabilitation programme may decline thereafter due to disease progression, secondary operations or cardio- or cerebrovascular events (Kihn et al. 1972).

Compared to amputees, patients undergoing arterial reconstructive surgery are more likely to be discharged home (Holdsworth et al. 1993). However, the limited data comparing long-term levels of mobility are conflicting, with some studies supporting the common assumption that mobility levels are superior following arterial reconstruction (Smith et al. 1993), while others suggest comparable results at one year (Gupta and Veith 1988).

Peripheral arterial disease has an adverse effect on all aspects of quality of life, which increases with disease severity (Crosby et al. 1993, Hunt et al. 1982, Pell 1995). Arterial reconstructive surgery is associated with improvements in quality of life (Albers et al. 1992). However, amputation has been demonstrated to either produce lesser improvements (Smith et al. 1993), or to have an adverse effect (Weiss et al. 1990). Following major amputation, some aspects of quality of life can be as poor as in cancer patients (Gough et al. 1983). Also amputees can feel socially isolated (Pell et al. 1993) and unable to seek help (Thompson and Haran 1983).

Since neither amputation nor arterial reconstruction prevent progression of the underlying disease, sequential procedures are common. Thirty percent of below-knee amputations are followed by ipsilateral reamputation at a higher level, and 50% by contralateral amputation (Dormandy and Thomas 1988, Ecker and Jacobs 1970, Kihn et al. 1972). Ipsilateral reamputation most usually occurs as a result of non-healing of a more distal stump. Less blood flow is required to maintain the viability of tissues once healing has occurred. Therefore once healing has occurred, secondary amputations are more commonly contralateral.

From clinical follow-up studies and comparisons with historical controls, use of arterial reconstructive surgery appears to save between one- and two-thirds of critically ischaemic limbs. Failure to save limbs may result from graft failure or disease progression. Graft failure can occur because of inappropriate patient selection, technical errors, graft stenosis or thrombus propogation (Whittemore et al. 1981). Graft failure rates vary with the conduit material, length and location. Failure rates are higher for prosthetic conduits than autologous vein grafts (Hobson et al. 1985, Yeager et al. 1982), particularly in distal grafts with "poor outflow." However, graft failure is not necessarily associated with limb loss, since limb-salvage rates are up to 18% higher than graft patency rates (Maini and Mannick 1978, Perdue et al. 1980). Graft failure rates are higher for distal grafts. However, the difference between graft-patency and limb-salvage rates is also higher (Dardik et al. 1982, Perdue et al. 1980). Reoperations involving grafts to new sites have comparable limb-salvage rates to primary procedures (Whitemore et al. 1981). However, patency rates are low for salvage procedures on distal grafts (Ascer et al. 1987).

Most authors agree that prior attempts at arterial reconstruction can have an adverse effect on stump healing through a direct effect on blood flow due to disruption of collateral vessels and propogation of thrombus, or through indirect effects via post-revascularisation oedema, wound infection or skin necrosis (Dormandy 1991, Evans et al. 1990, Schlenker and Wolkoff 1975). However, there is a lack of agreement on whether lower healing rates result in a higher proportion of above-knee amputations. Opinions also diverge on the effect of graft location. Some authorities have suggested that distal grafts are followed by poorer stump healing because patients have more widespread disease (Samson et al. 1982, Veith et al. 1981a), whilst others claim improved healing rates because the incisision site is contained in the amputated segment (Dardik et al. 1982).

In terms of hospital costs, major amputations are comparable to arterial reconstructive surgery, with the cost of longer lengths of stay associated with amputation being offset by the higher angiography, operating theatre and intensive care costs of arterial reconstruction (Gupta and Veith 1988). Costs are higher in older patients and those with gangrene. If the costs of secondary procedures and long-term care are included, major amputation and distal reconstruction incur comparable costs, while proximal reconstruction is cheaper and is associated with a gain in QALYs (Davies et al. 1989). Assuming an average total cost of £10,000 per amputation (Cheshire et al. 1992, Davies et al. 1989) and £9,000 per arterial reconstruction, the annual cost of surgery and social care for patients with critical limb ischaemia in Scotland is almost £20 million.

CHAPTER 4

Clinical audit and guidelines

"the most important of my discoveries have been suggested to me by my failures"

(Sir Humphrey Davy, Strauss 1968)

The need to cater for escalating demands within limited resources has resulted in an increasing emphasis on clinical effectiveness. Attempts must be made to maximise quality of care and health gain whilst minimising cost. The tools available to assist this process include clinical and health services research, clinical audit, benchmarking and clinical guidelines. Research provides new knowledge of the potential benefits of interventions. Individual clinicians could not be expected to be fully conversant with the rapidly expanding literature. Therefore guidelines utilise both published research and group experience to produce a concise and consistent interpretation of the available evidence and practical guidance for clinicians. Clinicial audit assesses the extent to which research findings are converted into practice and to which published guidelines are adhered. These methodologies must therefore be viewed as complementary.

4.1. Clinical audit

Clinical audit has been defined as the "systematic peer evaluation of the quality of patient care, based on explicit and measurable indicators of quality, for the purpose of demonstrating and improving the quality of patient care" (Dixon 1991). Fowkes (1982) described the audit cycle in which observing practice and comparing it with agreed standards of care should be followed by the implementation of changes and then further examination of practice.

The success of audit is dependent on the selection of an appropriate topic, early involvement of key stakeholders and adoption of realistic expectations. An audit is appropriate if:

- the topic is clinically important because the intervention under scrutiny has the potential to achieve substantial health gain in a condition which is common or associated with a high level of morbidity or mortality,
- the topic is financially important because the procedure has a high cost or volume,
- deficiencies are likely to be found as suggested by variations in practice or anecdotal evidence,
- agreement is able to be reached on audit standards which are clinically relevant, clearly defined and realistically attainable,
- clinical practice is amenable to measurement and change,
- there is wide acceptance of the suitability and feasibility of the audit, and
- the cost of the audit itself is justified by the savings likely to be made by changes in practice.

Williamson (1978) summarised these factors into "achievable health benefit not achieved." Seedhouse (1990) suggested the use of four parameters to rank projects: clinical concern, cost, group support and feasibility.

Traditionally, audits were aimed at either the structure, process or outcome of healthcare. More recently attention has also been directed at assessments of patient satisfaction. Measuring outcomes has intuitive appeal since good outcomes should reflect high quality care and poor outcomes should reflect deficiencies in care, missed opportunities and wasted resources. Therefore audits of outcomes are often considered to be superior to those of process (Lawrence et al. 1994). However, a number of factors suggest that, in some instances, process indicators may be a more appropriate measure (Davies and Crombie 1995, Hicks 1994).

Selection of outcomes

The outcomes used are often those which are readily available, such as death, rather than those which are most appropriate (Wilson and Cleary 1995). In practice, many interventions are undertaken to improve disease status, quality of life or functional state. However, these may be difficult to measure. Also, the time interval between some interventions and their desired outcome may be too long to provide data within a useful time-scale. This is particularly pertinent for health educational interventions.

Statistical power

Some outcomes may be too infrequent to provide meaningful comparisons of centres or clinicians. Large variations in the use of proven therapies may result in relatively small differences in outcomes such as death. Mant and Hicks (1995) compared the relative sensitivities of process and outcome measures in relation to the management of acute myocardial infarction. They used the results of large randomised controlled trials and meta-analyses to determine the impact of interventions of proven efficacy on mortality in two hypothetical district general hospitals. Hospital-specific mortality was demonstrated to be a relatively insensitive measure. To demonstrate as statistically significant, differences of the magnitudes demonstrated in the large randomised trials would require collection of death data over 73 years. By contrast, process data would only need to be collected over a period of four months.

Case-mix adjustment

Crude outcomes are only of use in comparing identical groups of patients, such as occur within randomised trials. In clinical practice the patients treated by different hospitals are unlikely to be identical and case-mix adjustment becomes imperative. However, many attempts to adjust for case-mix are restricted to those parameters readily available such as age and sex which may be insufficient to allow correct interpretation of results. Complex risk scores which permit better adjustment for case-mix have been devised (Copeland GP et al. 1991, Hannan et al. 1990, Parsonnet et al.

1989, Peduzzi et al. 1982) but require the collection of large amounts of data which may not be feasible in routine practice. Furthermore, their use may provide false reassurance of the extent to which case-mix has been taken into account, since rankings change as increasingly detailed information is included (Green et al. 1990, Orchard 1994, Rockall et al. 1995).

Interpretation of outcomes

Variations in outcomes can be due to both under-usage and over-usage. Identification of the desirable figure may be difficult. Even if a deficiency can be easily identified the method of rectifying it may be less clear. For example, death following myocardial infarction is reduced by many factors including administration of aspirin, beta blockers and thrombolysis (Antiplatelet Trialists' Collaboration 1994, Fibrinolytic Therapy Trialists' Collaborative Group 1994, ISIS-1 1986). Therefore if a hospital has an unacceptably high case-fatality rate it may be unclear which of these factors needs to be addressed without undertaking a further audit of the process of care. By contrast, an initial audit of these process measures would provide both an overall assessment of quality of care and specific pointers as to those aspects of management which require attention. Audit of outcomes is therefore best restricted to outcomes with can be attributed to a single intervention.

4.2. Benchmarking

Benchmarking uses routinely collected data to compare individual units or doctors, resulting in what are commonly termed "league tables". Within Scotland, the Clinical Resource and Audit Group (CRAG) has published a number of outcome indicators based on routine discharge data, including thirty-day mortality following acute myocardial infarction. However, simple publication of outcomes in the USA has been shown to be of little merit in changing practice. In both Pennsylvania and New York case-mix adjusted case-fatality rates following coronary artery bypass grafting are published by individual surgeon. However, nearly nine out of ten cardiologists report no or negligible effect on their referral decisions and very few discussed the published outcomes with their patients (Schneider and Epstein 1996). Although the outcomes in New York and Pennsylvania improved following publication, comparable improvements were demonstrated in states in which outcomes were not published (Ghali et al. 1997, Hannan et al. 1994). Fears about data manipulation were vindicated by dramatic increases in the reported prevalence of comorbid conditions used in the weighting of outcomes. The reported prevalence of chronic obstructive pulmonary disease, congestive cardiac failure and renal failure increased three-, four- and seven-fold over two years (Green and Wintfeld 1995). Where changes in practice were confirmed these were generally undesirable. Cardiologists reported difficulties in finding surgeons who were prepared to operate on complex cases and surgeons acknowledged this (Schneider and Epstein 1996). A further problem with published "league tables" is the interpretation of rankings since changes in rankings due to changes in clinical practice cannot be distinguished from those simply due to regression to the mean.

4.3. Clinical guidelines

Clinical guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field and Lohr 1990, Nuffield Institute for Health et al. 1994). There has been an increasing interest in the development of clinical guidelines among managers, clinicians, politicians and medical educators (Conroy and Shannon 1995, Jenkins 1991, Lomas et al. 1989, NHS Management Executive 1993, NHS Executive 1994, Selker 1993). It has been suggested that clinical guidelines should at the very least inform commissioning and should, ideally, be the subject of clinical contracts rather than procedure volumes and costs (NHS Management 1993, NHS Executive 1994, Sheldon and Borowitz 1993).

Clinical guidelines have been developed for a number of reasons (Armstrong and Haines 1992, Consumers' Association 1990, Crombie and Fleming 1988, Fearon 1992, Fitzpatrick 1965, Haines and Hurwitz 1992, Hurwitz 1994, Launer 1988, Lomas 1993, Royal College of Radiologists 1993, Young 1965):

- to reduce inappropriate variations in clinical practice
- to improve health outcomes, health gain and clinical effectiveness

- to improve the overall quality of health care
- to decrease or avoid unnecessary referrals, investigations or interventions thereby avoiding wasted resources and unnecessary risk
- to improve health service efficiency and decrease health care costs
- to promote the appropriate use of medical technology
- to encourage the incorporation of research findings into medical practice
- to reduce the risk of legal liability in health care delivery
- to improve patients' awareness of health care needs and
- to provide the basis for continuing medical education

A reluctance to accept or implement clinical guidelines stems from a number of sources:

- a fear that adherence to guidelines conflicts with clinical freedom and autonomy, thereby reducing job satisfaction and the scope for innovation (Mittman et al. 1992, Tunis et al. 1994, Woolf 1993)
- a fear of the medico-legal consequences of non-compliance (Clark and Kinney 1994, Grimshaw and Russell 1993a, Lomas et al. 1989)
- a belief that the effort is not justified since they will not change anything and
- a belief that they are imposed by others rather than clinically driven

If the scope for healthy innovation is to be maintained, guidelines must be constructed in such a way as to honestly reflect areas of uncertainty. Guidelines can be developed by internal groups which are composed entirely of clinicians who will use them, intermedidate groups which contain some people who will use them and external groups which contain no-one who will use them (Grimshaw and Russell 1994). Development of internal guidelines can lead to a greater feeling of local relevance and ownership whereas those devised by others may be perceived as imposed (North of England Study of Standards and Performance in General Practice 1992, Putnam and Currey 1985). Internal guidelines require fewer resources for dissemination and implementation (Brook 1989) but can nonetheless be expensive to develop if many groups are working separately to develop similar guidelines. Also, they are less likely to be perceived as scientifically valid, credible and authorative (Brook 1989, Grimshaw and Russell 1993a, Sommers et al. 1984) because local groups tend to lack the skills, resources and time possessed by national expert panels (Grol 1990b, Haines and Jones 1994, Hayward and Laupacis 1993, North of England Study of Standards and Performance in General Practice 1991, Newton et al. 1992, Russell et al. 1993). In order to solve the conflicting needs to develop guidelines which are both scientifically valid and likely to be accepted and change practice CRAG advocated the development of national, scientifically valid guidelines which could then be modified locally to reflect context and resources (CRAG 1993, Grimshaw and Russell 1993b).

The guidelines produced by CRAG were based on consensus. Since 1994 the role of producing national guidelines in Scotland has been taken over by the Scottish Intercollegiate Guidelines Network (SIGN). SIGN was established as a joint initiative of the Royal Colleges to address a wide range of acute and mental health issues within both secondary and primary care.

4.3.1. Legal status

Clinical concerns about the legal status of guidelines and potential litigation resulting from non-compliance can be a barrier to guideline implementation. However, fears that guidelines encourage litigation are ill-founded. In the USA, a survey of medical malpractice actions demonstrated that guidelines played a pivotal role in only 7% of cases (Hymans et al. 1995).

In the UK, the legal standard of medical treatment that a doctor owes to a patient was established in the case of Bolam v Friern Hospital Management Committee (1957) where it was pronounced that "the test is the standard of the ordinary skilled man exercising and professing to have that special skill……..A doctor will not be guilty of negligence if he has acted in accordance with a practice accepted as proper by a responsible body of medical men skilled in that particular art" Therefore the standard of care is imposed by law but set by the medical profession (Hurwitz 1994).

The standard set by the medical profession is usually ascertained from expert testimony (Bolam v Friern Hospital 1957). Written guidelines may, nonetheless, be introduced by an expert witness as evidence of accepted and customary standards of care. In some cases adherence to guidelines has helped to demonstrate "acting with the benefit of guidance from a responsible and competent body of professional opinion as required by the Bolam test" (Airedale NHS Trust v Bland 1993, Clarke v Adams 1950). If guidelines are submitted as evidence by a witness, the witness may be questioned on their scope (W v Egdell 1989), their method of development and adoption (Early v Newham Health Authority 1994, Loveday v Renton and Wellcome Foundation 1990), the mandatory force of their recommendations (Ratty v Haringey Health Authority 1993, Wilsher v Essex Area Health Authority 1986), known exceptions to their application (Loveday v Renton and Wellcome Foundation 1990) and the existence of contrary views (Cranley v Medical Board of Western Australia 1992). Although guidelines can be cited by an expert witness, they cannot be introduced as a substitute for expert testimony because, without the possibility of challenging them, they could only be treated as hearsay (Howard and Crane 1982, Hurwitz 1994&1995, Ratty v Haringey Health Authority 1993).

However impressive the organisation that sponsored a guideline, or its process for developing it, the fact that a guideline exists for a particular conditon does not mean that what it proposes is necessarily true nor, more importantly in legal terms, that it accurately represents customary practice. The Bolam test would require a guideline to have achieved professional acceptance and use by a responsible body of doctors before it could be accepted as evidence of the standard of care required in a court of law. Compliance or lack thereof with clinical guidelines is unlikely to prove decisive in a medical negligence action, unless the intervention concerned is so well established that no responsible doctor acting with ordinary skill and care would fail to comply with it (Hunter v Hanley 1955, NIH et al. 1994).

Currently guidelines which do not reflect customary practice are likely to fail the Bolam test. There have been several examples of British judges who did not automatically equate established guidelines with common medical practice (Early v Newham Health Authority 1994, Loveday v Renton and Wellcome Foundation 1990). Similarly, in some cases, non-compliance has been accepted because it represented a reputable minority opinion (Cranley v Medical Board of Western Australia 1992, Hunter v Hanley 1995, Loveday v Renton and Wellcome Foundation 1990).

There have been suggestions that the Bolam test may, in the future, be challenged by evidence-based practice (Chalmers 1993&1994). However, at present, the criterion of professional adoption, rather than evidence-based health care, remains the basis for negligence (Bolam v Friern Hospital Management Committee 1957, Hurwitz 1994). It has been argued that, under the Bolam test, consensus guidelines may carry greater legal standing than evidence-based guidelines (Field and Lohr 1990).

Remaining well-informed of published guidelines is made problematic by their rapid proliferation. Lord Denning accepted that it would be "putting too high a burden on a medical man to say that he has to read every article appearing in the current medical press" (Crawford v Board of Governors of Charing Cross Hospital 1953) and suggested that guidelines would have to be proven, widely disseminated, generally accepted and generally adopted to be admissable as evidence.

Just as non-compliance with guidelines does not necessarily imply medical negligence, so adherence to them cannot be assumed to imply correct practice. In the USA, compliance with clinical guidelines cannot generally be used as a defence against liability if a physician's conduct is held to have been negligent, since "a physician who complies without protest when his medical judgement dictates otherwise cannot avoid responsibility for his patients' care" (Wickline v California 1986). However, a five-year experimental scheme is nearing completion in Maine in the USA. This was introduced to protect recruitment to specialties such as obstetrics where the risk of malpractice actions is high and therefore malpractice premiums are costly (Edwards 1992). Statewide, legally-validated guidelines were devised which could be admitted in court as evidence of the legally required standard of care in lieu of expert witnesses. Doctors who comply with these are shielded against liability in negligence cases (Smith 1993). Conversely, since guidelines devised outwith Maine are not also admissable in court, failure to comply with Maine guidelines does not constitute presumptive evidence of negligence (Smith 1993). It has been argued that this inconsistency results in an unfair bias in favour of the doctor (Hurwitz 1994).

In the USA, unlike the UK, third party organisations can be held liable if adherence to their guidelines contributes to patient harm (Wilson v Blue Cross of Southern California 1990).

4.3.2. Implementation

The development of guidelines does not, in itself, ensure adherence to them (Lomas et al. 1989) even if doctors are aware of what constitutes good practice (Grol 1990a). There are two phases involved in the successful implementation of guidelines. Firstly an "educational strategy" is required to target professionals and influence their attitudes to, awareness of and understanding of the guidelines (Grimshaw and Russell 1994). Thereafter, an "implementation strategy" is required to translate their knowledge into changes in practice (Buekens et al. 1993, Cohen et al. 1985, Conroy and Shannon 1995, Epstein 1991, Grol 1990a, Haines and Jones 1994, Mittman et al. 1992, Mugford et al. 1992, Woolf 1993, Yoong et al. 1992).

Educational strategies can be passive or active. The passive transfer of information through postal distribution or publication can improve awareness and knowledge of guidelines (Kosecoff et al. 1987, Lomas et al. 1991) and has occasionally been demonstrated to change practice (Bearcroft et al. 1994, De Vos Meiring and Wells 1990, Oakeshott et al. 1994). However, this is atypical. Educational interventions requiring more active participation from professionals include targeted seminars, educational outreach visits by trained personnel to practice sites (Avorn et al. 1988&1992, Soumerai et al. 1993) and the use of opinion leaders (Lomas et al. 1991).

Implementation strategies may be directly targeted at the doctor-patient consultation or take place outwith this setting. Examples of the former include the restructuring of medical records (Cheney and Ramsdell 1987, Cowan et al. 1992, Emslie et al. 1993), computer-based clinical decision support systems (Johnston et al. 1994), patient-specific reminders used during the consultation (McDonald et al. 1984, McDonald et al. 1992), and patient-mediated interventions (McPhee et al. 1989). Such strategies can be integrated into the process of health care delivery. Implementation strategies which take place outwith the consultation include patient-specific feedback (Tierney et al. 1986), aggregated feedback on compliance (Durand-Zaleski et al. 1992), financial incentives (Brook and Williams 1976, Lohr and Brook 1980), explicit marketing (Landgren et al. 1988) and professional peer review (Fowkes et al. 1986).

Comparisons of different strategies suggest that educational interventions requiring active professional participation and implementation strategies which operate directly on the doctor-patient consultation are more likely to lead to successful guidelines implemenation (Grimshaw et al. 1993b&1994, Grimshaw and Russell 1994, Grol 1992, Lomas et al. 1991, McMillan et al. 1991, Oakeshott et al. 1994, Royal College of Radiolgoists working party 1992, Weingarten et al. 1993). Combinations of methods may be required (Anderson 1993).

4.4. Conclusions

Interest in the effectiveness of clinical practice has increased greatly over the past decade. Clinical practice encompasses the structure and process of health care and its outcomes. Outcomes are, in part, a function of structure and process. Therefore if good outcomes are to be achieved and adverse outcomes avoided stringent attempts are required to ensure that the process of care achieves acceptable standards. Outcomes are also influenced by factors such as case-mix which are only partially within the control of clinicians. The selection of patients for procedures impacts on both process and case-mix and, therefore, influences outcome. Patient selection requires both that those patients who undergo interventions do so appropriately and that those patients who are denied access to interventions would not have been appropriate candidates. This thesis addresses the first of these issues. Chapter 5 compares operation rates throughout Scotland. Although geographical variations in operation rates can be an appropriate reflection of factors such as disease frequency, they are also often a reflection of differences in patient selection. Chapters 6 and 7 address this issue in more detail by deriving specific indications for both arterial reconstruction and major amputation in patients with chronic critical lower limb ischaemia and then determining whether clinical practice concorded with these consensus indications. This thesis does not attempt to determine whether the minority of patients with critical ischaemia who do not undergo any form of surgery were managed appropriately.

CHAPTER 5

Variations in the rates of arterial reconstructive surgery and major amputation

5.1. Introduction

Variations have been demonstrated in the management of many conditions (McPherson 1990, Wilkin 1992). The existence of variations in practice raises questions regarding the quality of clinical care, and whether resources are being used efficiently and effectively. Some patients may be denied access to beneficial treatments, whilst others may undergo unnecessary interventions, with their associated risks and costs.

5.2. Variations in procedure rates between countries

Clinical practice can vary considerably between countries. Admission rates for many diseases are significantly lower in the United Kingdom than in economically comparable countries, such as the USA and Canada (Pearson et al. 1968, Sanders et al. 1989). Similarly, many common procedures, such as tonsillectomy, adenoidectomy, cholecystectomy and Caesarian section are performed 2-5 times more frequently in the USA and Canada (Andersen and Kamper-Jorgensen 1984, Bunker 1970, Chalmers 1985, Notzon et al 1987, Pearson et al. 1968, Sheehan 1987, Vayda 1973, Vayda et al. 1982). Although the magnitude of the difference varies between treatment modalities, the direction of the difference between countries is often constant. These international variations may be due to differences in the historical and cultural settings within which health-care takes place, as well as differences in the availability of resources, and the presence of financial incentives and discincentives. Clearly, the fixed budget available for health-care spending in the United Kingdom limits the extent to which services can expand in response to increasing demands, whereas greater financial flexibility exists within the United States.

The method of reimbursement may also influence clinical practice, with fee for service systems, which are more commonly employed in the USA, tending to produce higher levels of utilisation than pre-payment systems. Health-care systems may also vary in the balance of power within the doctor-patient relationship. The greater the shift to patient autonomy, the greater the likelihood that intervention rates will reflect “demand” rather than “need.”

Within a supply-led environment, doctors themselves can "induce" demand (Evans 1974, Williams 1978), leading to “Roemer’s law” that “a built bed is a filled bed” (Roemer and Shain 1959). Kohn and White (1976) demonstrated that most of the 2-fold variation in hospital utilisation rates in 12 areas in the United Kingdom could be accounted for by variations in the availability of short-term beds. A similar argument could be made for the availability of other resources, such as health-care workers. Bunker (1970) equated the 2-fold higher overall operation rate in the USA compared to England, with the 2-fold higher rate of surgeons per capita, and Vayda (1973) also attributed the differences demonstrated between Canada and England to the relative numbers of surgeons.

5.3. Variations in procedure rates within countries

Comparisons of procedure rates between countries can conceal variations within the countries which are as wide if not wider (Andersen et al. 1987 Noone et al. 1989, Wennberg and Gittelsohn 1973, Wilkin and Smith 1986).

Some procedures are more prone to variations in usage than others. Small area variation analysis of seven surgical procedures in areas within the USA, United Kingdom and Norway revealed consistency between the countries in the rank order of variability for most procedures (McPherson et al. 1982). In all countries, high levels of variability were observed for rates of tonsillectomy, haemorrhoidectomy, hysterectomy and prostatectomy, whereas less variation was observed for appendectomy, hernia repair and cholecystectomy. A number of other authors have reported similar consistencies in the relative amounts of variability, both in cross-sectional comparisons of geographical areas and over time (Paul-Shaheen et al. 1987, Wennberg and Gittelsohn 1973, Wennberg et al. 1984).

McPherson et al. (1982) concluded that the degree of variation was more a characteristic of the procedure than of the country in which it was performed, and that the level of agreement between professionals on indications for procedures had a greater influence on the consistency of practice than resource levels. Most studies have concentrated on surgical procedures because the data are more readily available. However, variations in medical practice are even higher. Vayda et al. (1984) also found that the variations in eight common elective procedures in Canada reflected a lack of agreement on indications for surgery rather than varying access to resources.

However, as with international variations, some of the variation within countries has been attributed to a number of supply factors, such as the availability of doctors and beds (Cullis et al. 1981, Logan et al. 1972, London Health Planning Consortium 1979, Wennberg and Gittelsohn 1973). Lewis (1969) reported that 50%-60% of variations in operation rates could be attributed to differences in the numbers of beds and surgeons per capita, and the availability of other resources such as operating suites.

If variations in practice were simply due to chance, differences in individual decision-making should cancel out over an aggregated area. However, Wennberg and Gittelsohn (1982) described the phenomenon of a "surgical signature" whereby the overall approach of doctors within a given area is characteristically aggressive or conservative despite some variation between individuals. Black (1978) attributed this "group clinical judgement" to the communication which resulted from meetings, training and movement of staff within an area. Pasley et al. (1987) also reported "surgical practice styles" as a contributory factor. Variations in practice are apparent between teaching and non-teaching hospitals (Andersen and Lomas 1985).

5.4. Reasons for variations in procedure rates

Some degree of variation can occur simply by chance. This can be taken into account by testing the statistical significance of differences or determining whether confidence intervals overlap. Differences which are shown to be statistically significant are likely to reflect real differences in clinical practice due to variations in need, demand or supply.

Real variations in practice exist for a number of reasons. They can be explained, in part, by differences in a number of measures of need. Treatment rates have been shown to be associated with demographic factors (Cummins et al. 1981, Morrell et al. 1971, Sanders et al. 1989, Wilkin and Smith 1987), disease prevalence, (McPherson 1990, Wilkin 1992, Wilkin and Smith 1986), levels of socioeconomic deprivation (Bridgman 1979, Cummins et al. 1981, McCormick and Rosenbaum 1991, Morrel et al. 1971, Roos and Roos 1982) and case-mix. (McPherson 1990, Wilkin 1992, Wilkin and Smith 1986).

However, need accounts for relatively little of the variations observed (Blumberg 1982, Cullis et al. 1981, Joensson and Silverberg 1982, Mitchell and Cromwell 1982, Roos 1984a, Roos et al. 1977a&b, Roos and Roos 1981&1982, Winyard 1982). Hospitalisation rates bear a close relation to disease incidence only for the relatively few conditions in which diagnosis is relatively accurate and agreement on treatment is high, such as hip fractures (Wennberg 1986). However, this applies to well under 20%

of conditions, with the remainder demonstrating poor association between disease incidence and admission rates (California Health Facilities Commission 1985, Iowa Foundation 1985, Sanders et al. 1989, Wennberg et al. 1984).

There are a number of other factors which also produce variations, including differences in the knowledge and skills of health-care workers (Forsyth and Logan 1968, Wright 1968), patients' wishes (McPherson 1990), and previous personal experience and prevailing treatment customs (McPherson 1990).

Doctors and patients alike may vary in their perception of risk and attitude towards it, which may result in different decisions being made in the light of similar levels of information. Presented with the same clinical situation, equally well qualified surgeons will offer different opinons on the need for surgery (Rutkow 1982). Several studies have demonstrated no adverse effects on outcomes in the large number of patients who declined planned operations following a "second opinion" (Gertman et al. 1980, Graboys et al. 1987, McCarthy and Widmer 1974).

Intervention rates are also influenced by historical levels of intervention. In general historical levels tend to persist. However, they can also have the reverse effect on interventions and diseases which can only occur once. For example, in some parts of the USA, 18% of women have a hysterectomy performed between 45 and 65 years of age (Gittelsohn and Wennberg 1976). Because of this high intervention rate, only 4 out of 5 women over 65 years of age are at risk of hysterectomy. Hence, areas with high hysterectomy rates in younger women may have paradoxically low rates in older women. Therefore any consideration of current intervention rates must take account of the effect of previous practice on the proportion of the population at-risk.

Variations also result from differences in access to services, particularly between rural and urban areas (McCormick and Rosenbaum 1991), and from differences in the availability of resources (Forsyth and Logan 1968, McPherson 1990, Pell and Elton 1995, Wilkin and Smith 1987). The availability of resources may have either a direct effect, through the total lack of a service, or an indirect effect through rationing, long waiting lists, and low levels of manpower and beds.

Inaccuracies or differences in data collection and coding have been reported to account for relatively little of the observed variations (McPherson et al. 1982, Sanders et al. 1989). Within the United Kingdom problems may also be encountered with missing data on patients treated in the private sector. Although only one in ten of the population holds some form of private medical insurance (Office for National Statistics 1988), there is a four-fold variation throughout the country in the proportion of elective procedures undertaken in the private sector (Nicholl et al. 1984, OPCS 1983). Also, the proportion of procedures undertaken privately will vary with the type of procedure.

After attempting to adjust for these factors, residual variations in practice persist. These have been attributed to a lack of consensus on the most appropriate form of treatment. However, this collective uncertainty may not necessarily reflect uncertainty among individual clinicians regarding the treatment of individual patients, since "deep and intense disagreement on the basis of strongly held views will also yield a diversity of behaviour" (Evans 1990). Some of the lack of consensus can be attributed to a lack of available data on the efficacy of interventions (Cochrane 1973, Wennberg et al. 1982). New technologies are commonly adopted into routine practice before being evaluated thoroughly, and rapid technical and scientific advances render information obsolete (McPherson 1982, Wennberg et al. 1980). More than 80% of medical conditions are characterised by a lack of agreement on indications for admission and appropriate management (Morgan et al. 1987). This applies to even the most common interventions (Wennberg et al 1980). However, disagreement may also exist in the presence of high quality contemporary data, due to incorrect interpretation, greater emphasis being placed on personal experience than research findings, or problems encountered relating collective evidence to an individual patient's experience of illness, expectations and preferences (Sanders et al. 1989).

5.5. Consequences of variations in procedure rates

A number of authors have calculated the financial and health consequences of reducing variations in practice. Wennberg et al. (1980) estimated that $1.1 billion could be saved annually if UK rates for nine common surgical procedures were adopted in the USA. They also reported a potential saving of 16,000 surgery-associated deaths. This equated to a 5-fold reduction in surgery-associated deaths and a 0.21% reduction in total deaths.

Conversely, if USA Caesarian section rates were adopted in England and Wales, an additional 115,000 operations would be undertaken annually at an additional cost of £88M (Chalmers 1985). Ham (1988) calculated that the NHS spent £176 million annually on eight common surgical operations in 1986. If the Norwegian, Canadian and USA rates had applied, the corresponding figures would have been £160 million, £455 million and £447 million respectively. Crombie and Fleming (1988) demonstrated 2-fold variations in the costs of GP-initiated referrals to hospital and 12-fold variations in hospital expenditure.

Where variations in procedure rates are demonstrated, it may nonetheless be difficult to determine which is the correct rate (Bunker and Wennberg 1973) particularly if study data on effectiveness are lacking. Also, some degree of variation may be acceptable if comparable alternative therapies exist, or higher rates reflect the development and evaluation of innovations.

Increases in hospital admissions and procedures are generally perceived to reflect improvements in efficiency and productivity (Bevan and Ingram 1987). The risks associated with common procedures such as cholecystectomy, prostatectomy and appendectomy are often underestimated (Lembecke 1952, Lichtner and Pflanz 1971, Roos 1984b, Wennberg 1987, Wennberg et al. 1987&1988), and there is evidence that higher rates may simply result in excess morbidity and mortality (Bunker and Wennberg 1973, Vayda et al. 1977). Compared to Canada, England and Wales have a 5-fold higher rate of cholecystectomy and a 2-fold higher rate of deaths from diseases of the gallbladder (Vayda 1973). Although differences in disease frequency may account, in part, for some of this variation, some of the excess deaths may be due directly to the increased rate of surgery (Vayda 1973). Similarly, Lichtner and Pflanz (1971) reported appendectomy rates in the Federal Republic of Germany which were double those in neighbouring countries, together with case-fatality rates which were three times higher. Three-quarters of the appendices removed were normal, and the authors attributed the excess deaths to inappropriate and unnecessary surgery. Also, no association has been demonstrated between increased rates of Caesarian section for shoulder dystocia, and perinatal mortality (Sheehan 1987).

Evidence has been presented that some operations "are performed with a frequency in excess of documentable cost-benefit usefulness" (Bunker and Wennberg 1973). As rates increase a point will inevitably be reached when the operative risk exceeds the disease risk. However, care should be taken not to measure outcome purely in terms of death, since many operations are performed to relieve disability or discomfort (Bunker and Wennberg 1973).

5.6. Methods of reducing variations in procedure rates

Despite the influence of all of these factors, both demand and supply can be influenced. Medical audit followed by feedback of results can change clinical practice. Feedback to doctors on variations in practice has been shown to alter rates for a number of surgical procedures including hysterectomy and tonsillectomy (Dyke et al. 1977, Gruer et al.

1986, Lembecke 1956, Wennberg et al. 1977). However audit can only be of use if the correct rate can be defined so that the results can be interpreted appropriately. Also, feedback of results may be insufficient to change practice if used in isolation. A number of mechanisms exist for facilitating change including educational programmes, continuous monitoring, ownership of results, the use of representatives and advocates, and the use of incentives or disincentives (Jennett 1988a&b, Mitchell and Fowkes 1985, Mugford 1987, Shaw 1980a-e).

A number of authors have advocated increased consumer participation in clinical decision making as a means of increasing the appropriateness of patient selection for elective procedures such as hysterectomy and prostatectomy (Anon 1977, Barry et al. 1988, Coulter et al. 1988). Domenighetti et al. (1986) demonstrated a significant reduction in hysterectomy rates following a general media campaign which highlighted the undesirable increasing trend in hysterectomies. Targeted education of patients with urinary symptoms through the use of interactive videos and written material has also been shown to influence their views on the appropriateness of prostatectomy (Hunter et al. 1995, Shepperd et al. 1995)

5.7. Variations in procedure rates for chronic critical lower limb ischaemia

Within Scotland, variations have been demonstrated in the management of intermittent claudication (Pell and Elton 1995). Only some of this difference can be accounted for by case-mix, with the remainder being attributed to varying resources and a lack of agreement on the most appropriate management (Pell and Elton 1995).

Greater uniformity might be expected in the management of critical limb ischaemia because relatively few patients are managed conservatively, and primary major amputation should only be considered in those unsuitable for "limb-salvage" procedures.

In a cross-sectional study of 16 Danish counties, Eickhoff et al. (1980) demonstrated a 2-fold varation in the age-sex standardised amputation rato and a 2.5-fold variation in the age-sex standardised arterial reconstruction ratio. Furthermore, they demonstrated a non-significant positive correlation (r=0.4) between the two, suggesting that areas with high rates of arterial reconstruction tend to have higher rates of major amputation. Converse results were reported by Michaels et al. (1994), who demonstrated that the three Oxford districts with above average rates for arterial reconstruction had a lower than average amputation rate than the five districts with below average rates for arterial reconstruction. However, they did not report whether this inverse association applied to only grouped data, or held when all eight districts were considered separately.

This thesis describes the first attempt to examine geographical variations in operation rates for chronic critical lower limb ischaemia in Scotland, and to determine the extent to which observed differences reflect variations in clinical practice.

5.7.1. Methods

Discharge data on all patients in Scotland are collated by the Information and Statistics Division (ISD) of the Scottish Office Common Services Agency through the Scottish Morbidity Record (SMR) system. These include age and sex, disease, type of operation and health board of treatment and residence. The type of operation is coded using the OPCS system. 1989-1990 SMR data on all patients undergoing major lower limb amputation or arterial reconstruction for peripheral arterial disease were analysed, to give age-sex standardised annual operation rates for individual health boards of residence and treatment. In order to validate the accuracy of these data, a list of patients undergoing major amputation or arterial reconstruction in eight Scottish hospitals over a three month period was obtained from the SMR database and compared with the data held in the operating theatre registers and audit databases of these hospitals.

5.7.2. Results

Using the SMR database a list was produced of 3,190 major amputation or arterial reconstruction operations which had been performed in the eight hospitals over the three months. The hospital operating theatre registers and audit databases recorded 85% of these procedures correctly at the four digit OPCS3 level and 90% at the three digit level. These figures varied from 80% to 92% and 88% to 98% respectively betweeen hospitals. Operations which appeared in the local databases but had no corresponding SMR return were not sought.

The number of operations performed by health boards varied considerably. By health board of treatment, the rates of arterial reconstruction varied from 0 per million population to 520 per million (χ^2 $p<0.001$, SD 148, variance 21897, coefficient of variation 88%) (Figure 5.1). By health board of treatment, major amputation rates varied from 0 per million to 151 per million (χ^2 $p<0.001$, SD 48, variance 2349, coefficient of variation 66%) (Figure 5.2). The total rates for major amputation plus arterial reconstruction ranged from 0 to 670 per million population (χ^2 $p<0.001$, SD 183, variance 33556, coefficient of variation 76%). Amputation rates by health board of treatment showed a positive correlation with arterial reconstruction rates (Spearman rank correlation $r=0.8$, $p<0.01$) (Figure 5.3). However, there was a non-significant negative association between operation rates and the number of vascular surgeons per capita.

Figure 5.1. Age-sex standardised rates of arterial reconstruction for peripheral arterial disease by health board of treatment

Arterial reconstruction rate (/10^6)
(95% confidence intervals)

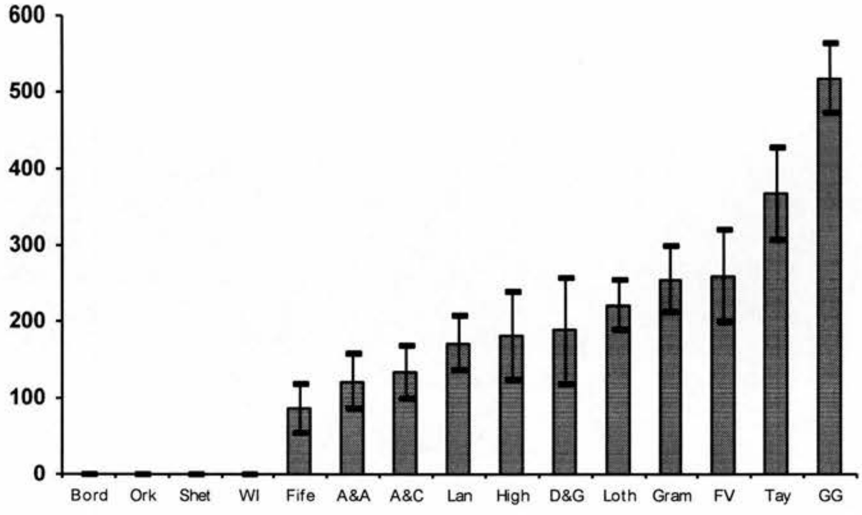


Figure 5.2. Age-sex standardised rates of major amputation for peripheral arterial disease by health board of treatment

Major amputation rate (/10^6)
(95% confidence intervals)

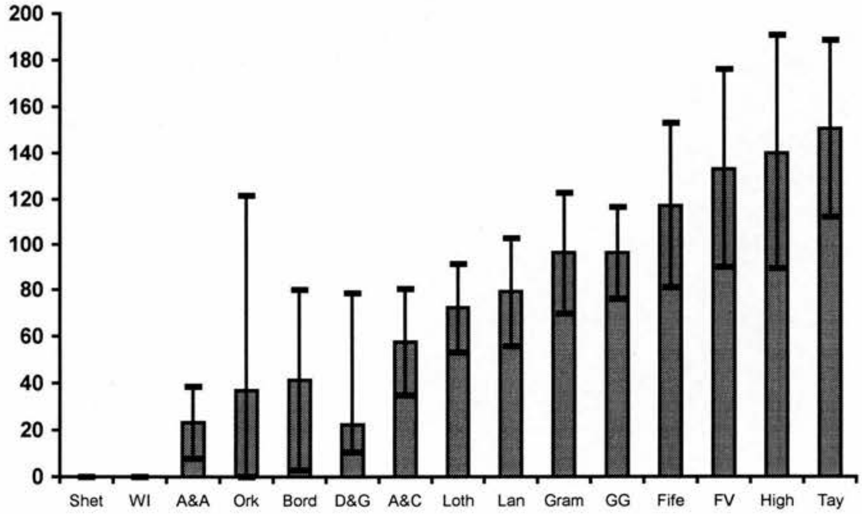
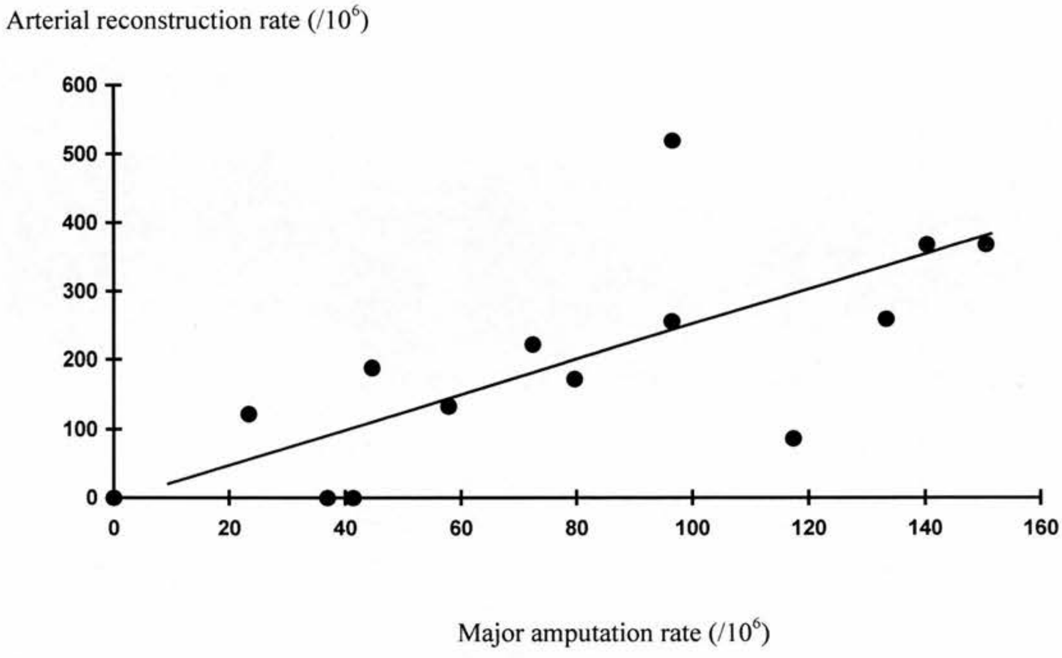


Figure 5.3. Association between rates of arterial reconstruction and major amputation for peripheral arterial disease by health board of treatment



By health board of residence rates of arterial reconstruction varied from 121 per million to 623 per million (χ^2 $p<0.001$, SD 123, variance 15181, coefficient of variation 50%) (Figure 5.4). Major amputation rates ranged from 36 per million to 147 per million (χ^2 $p<0.001$, SD 37, variance 1380, coefficient of variation 47%) (Figure 5.5). There was also a wide range in the total rates of arterial reconstruction plus major amputation by health board of residence, from 157 to 770 per million population (χ^2 $p<0.001$, SD 149, variance 22243, coefficient of variation 45%). Analysis by health board of residence, also demonstrated a positive correlation between major amputation rates and arterial reconstruction rates (Spearman rank correlation $r=0.6$, $p<0.05$) (Figure 5.6).

Figure 5.4. Age-sex standardised rates of arterial reconstruction for peripheral arterial disease by health board of residence

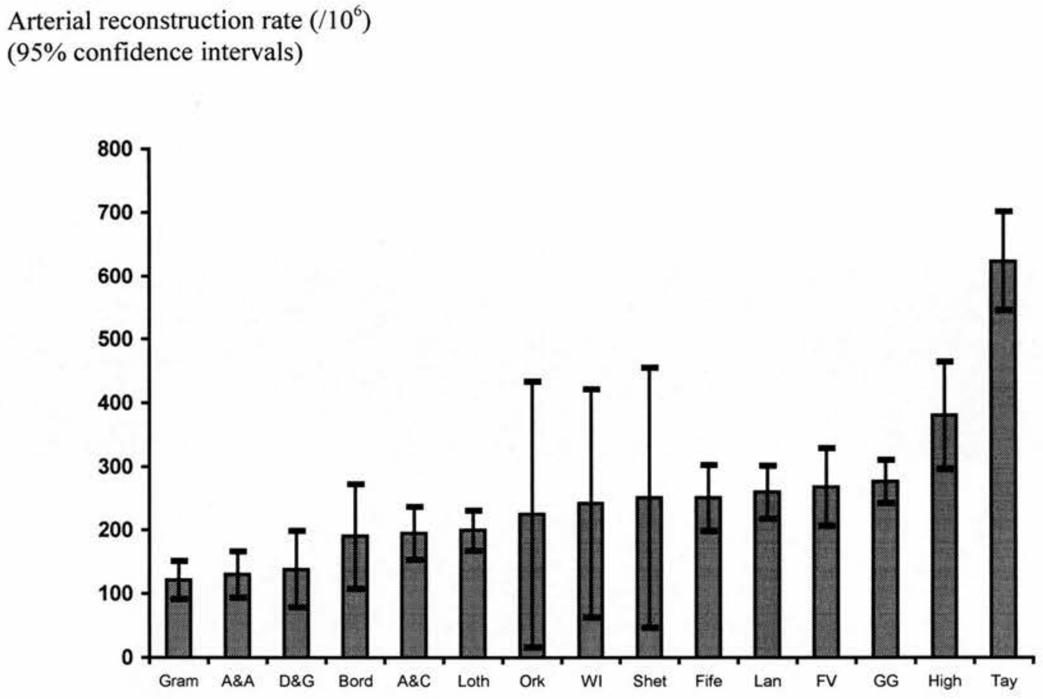


Figure 5.5. Age-sex standardised rates of major amputation for peripheral arterial disease by health board of residence

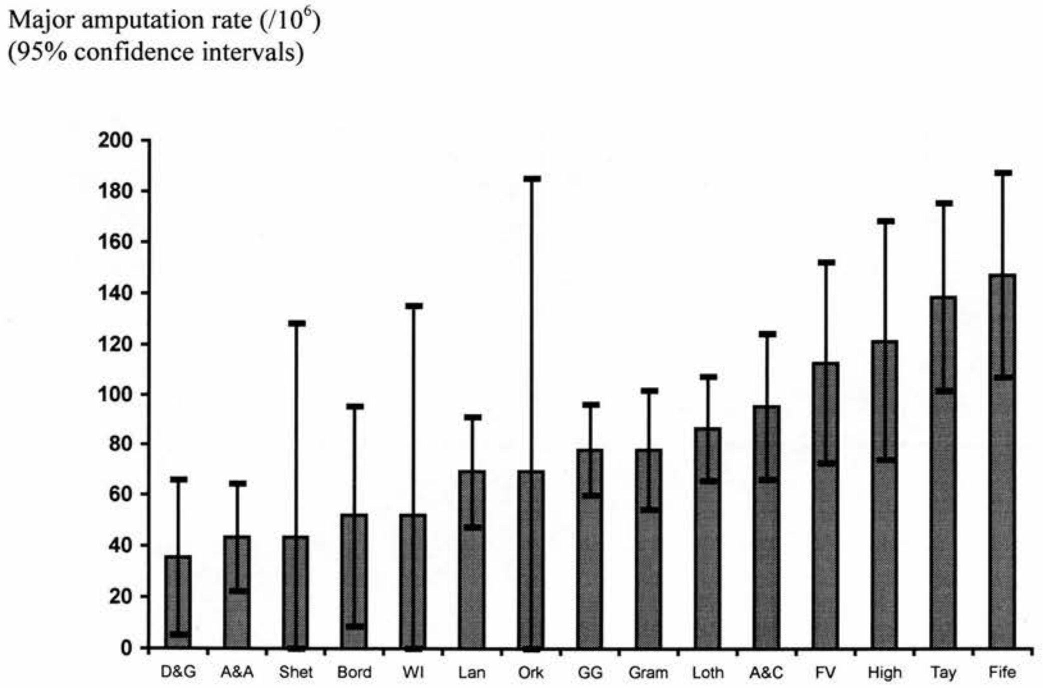
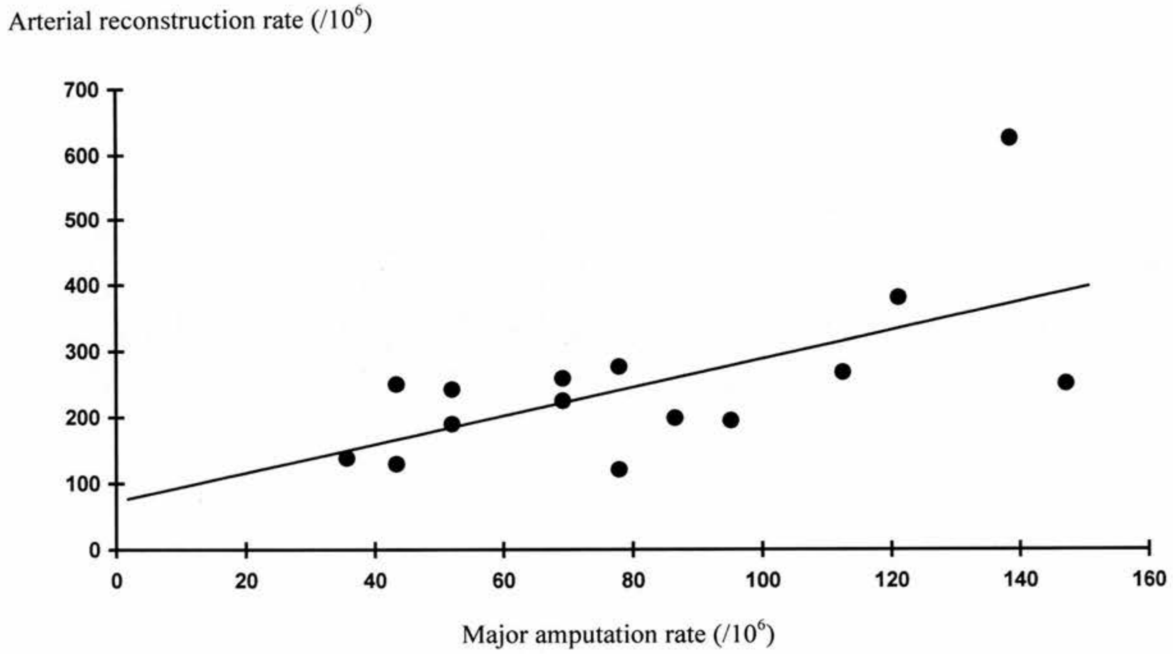


Figure 5.6. Association between rates of arterial reconstruction and major amputation for peripheral arterial disease by health board of residence



5.8. Conclusions

Wide geographical variations exist in the management of many conditions. These variations occur both between and within countries, and are consistently greater for some interventions than others. Although some of this variation can be accounted for by differing levels of need, much cannot. This suggests that some patients may be denied beneficial interventions, or that others may undergo unnecessary interventions and therefore be exposed to unnecessary risks. It also suggests inefficient use of limited health-care resources.

A number of factors have been demonstrated to contribute to varying procedure rates. These include supply factors, such as the availability of doctors and beds, financial

Erratum

Insert at the end of the second paragraph on page 135:

"However, as demonstrated by the wide and overlapping confidence intervals in figures 5.4 and 5.5., a large proportion of the variation demonstrated, particularly in major amputation rates, is consistent with the natural Poisson variation associated with infrequent events over the study period and, therefore, may be due simply to chance."

published by Eickhoff et al. (1980). However, care has to be taken in interpreting these data. Use of routine discharge data does not permit discrimination between arterial reconstructions performed for critical ischaemia and those performed for less severe disease. Furthermore, although standardisation for age and sex permitted adjustment for demographic differences, it is not possible to take account of differences in disease incidence, referral patterns and case-mix. Also, caution has to be taken in drawing conclusions about the experience of individual patients based on unlinked data collected at the population level. Higher total rates of procedures can result from more patients undergoing one operation or the same number of patients undergoing a greater number of procedures because of reoperations to the same leg or subsequent procedures to the other leg. Geographical variations in disease incidence may exist, but they are unlikely to be of sufficient magnitude to offer a complete explanation.

The range in rates of arterial reconstruction was exaggerated by very high rates in one health board area, Tayside, where the local vascular surgeons were known to be advocates of distal reconstruction. However, this area also had a relatively high amputation rate. This suggests that the very high reconstruction rate in Tayside can be explained only in part by a preference for distal reconstruction rather than amputation in patients with critical ischaemia, and is likely to also reflect other factors such as a lower threshold for intervention in patients with claudication.

Variations can be reduced through audit of clinical practice, feedback of the results and education on why and how practice should be changed. However, before audit can be undertaken appropriate practice must be defined. This can be done through a number of mechanisms (Roland 1992). Utilisation rates are often used as an index of appropriateness but may often be misleading as such (Goldacre and Griffin 1983). As mentioned previously confounding factors often cannot be taken into account and information is often lacking on what constitutes the correct rate. High rates may be interpreted erroneously to reflect productivity and good practice (Goldacre and Griffin 1983). Also, it is commonly assumed that outliers must represent inappropriate practice and that average practice is appropriate (Roland 1992). However, this may not be true. The appropriateness of practice can, in theory, be judged by the outcomes obtained (Ellwood 1988, Tarlov et al. 1989). However, the intervention under consideration is often not the only factor influencing outcomes. Case-mix, socio-economic factors and contemporaneous interventions may all affect outcome but may be difficult to define and measure. Furthermore, the most readily available outcome measures may not be the most appropriate. Because of these problems, practice is often most readily assessed in comparison with standards which define the process of care. Where possible, these are defined by the results of randomised trials. However, most interventions in common usage have not been subjected to such rigorous evaluation. More commonly evidence of effectiveness is predominantly derived from observational studies, case-series and personal experience. The following chapter describes how consensus methods can be used to synthesise the available evidence into a single set of indications or standards. Comparing areas by the extent to which they meet such indications, rather than by utilisation rates, overcomes many of the problems described, such as the need to take account of confounding factors and define appropriate practice.

CHAPTER 6

Development of indications for arterial reconstructive surgery and primary major amputation

6.1. Introduction

Ideally, appropriate indications for surgical procedures should be derived from the results of large randomised controlled trials. However, many procedures become accepted into routine clinical practice without rigorous evaluation.

Both arterial reconstructive surgery and primary major amputation are routinely used to treat patients with chronic critical lower limb ischaemia. However, evaluation of these methods has largely been limited to small-scale observational studies which are unable to define precise and comprehensive indications for either procedure. The future conduct of randomised trials is prohibited by the fact that arterial reconstruction has been adopted into routine clinical practice, thereby making randomisation to major amputation unacceptable in patients in whom limb salvage might be possible.

Where empirically-derived data are lacking, appropriate clinical practice can be defined by consensus methods (Fink et al. 1984). Consensus methods help to create a structured environment within which expert judgement and clinical data can be sensibly combined. They help to overcome the lack of conclusive comprehensive study data by utilising the knowledge and experience of practitioners in the field. Before seeking personal opinions and judgements, it is important to cull from existing sources all of the appropriate information, and synthesise this into a form which can be used to inform the panel. If the panel is not provided with the available study evidence, restricted though it may be, the consensus opinion will be based only on the limited experience and reading of the panel members.

The main purpose of consensus methods is to define areas and levels of agreement on controversial subjects. However, consensus methods can also be of use in identifying areas of divergent opinion, where future research could be most usefully directed (Fink et al. 1984, Rennie 1981).

Consensus methods have been used extensively in the United States, where the National Institutes of Health have organised more than 40 consensus development conferences since 1977. Consensus methods have also been used by many other United States organisations, including the Centre for Disease Control, American College of Physicians, University of California (UCLA) and the Rand Corporation. Within Europe, interest in consensus methods has grown over the last decade. In 1989 a European Working Group published a Consensus Document on Chronic Critical Leg Ischaemia (European Working Group 1989/1991). This document included some general recommendations on indications for arterial reconstruction and major amputation, but did not contain sufficient detail to define the most appropriate intervention for all clinical presentations of chronic critical lower limb ischaemia.

6.2. Consensus methods

A number of methods have been developed for deriving consensus in a systematic and explicit manner. Two of the first methods developed were the nominal group and Delphi methods. Both methods possess formal rules regarding the collection and analysis of information, and both require that the definition of consensus is agreed in advance of data collection. The nominal group method has a number of disadvantages. It requires a structured meeting of ten or less individuals, which is led by a nominated individual who must be trained in the methodology and possess no views or vested interest in the topic under discussion. The success of the methodology is highly dependent on the skills of the leader and the group dynamics (Van de Ven and Delbecq 1972). With the Delphi method, the "leader" is removed from participants, and has a primary responsibility to coordinate the survey and interpret and feed back results. Because the nominal group method requires consensus to be reached, in part, through direct discussions between group members, the results are subject to bias towards the views of the most dominant and vocal members. Thornell (1981) demonstrated that a nominal group process produced less frequent and stable consensus when applied to medical management than did the Delphi method. A number of more recent alternative methods have been developed which also provide participants with a structured environment for problem-solving. However, their methodologies have yet to be standardised and their most appropriate uses defined.

The consensus statements coordinated by the National Institutes of Health require a less explicit methodology than the Delphi method. As a result, they have been criticised as being "bland generalities that represent the lowest common denominator of a debate .... the only points on which the experts can wholeheartedly agree ... these points must be so mild, so far from the cutting edge of progress, and so well established that surely everyone must already know them" (Rennie 1981).

6.3. The Delphi method

The Delphi consensus method was developed in 1948 by Brook and colleagues at the Rand Corporation (Brook et al. 1988, Chassin et al. 1986a-c, Dalkey 1967 and 1969, Fink et al. 1984, Helmer 1966, Kahn et al. 1988, Park et al. 1986, Sackman 1975). Given that the method was intended to elicit expert opinion in an explicit and systematic manner, the decision to name the process after the Oracle at Delphi is somewhat ironic. Although an important source of wisdom in the ancient world, the Oracle at Delphi was criticised by Socrates for the ambiguity of the advice given: "What does the God mean? Why does he not use plain language?" (Trendennick 1969).

The Delphi method was originally applied to a variety of non-medical topics, including social, industrial and defence projects. Within medicine it has been used, on a number of occasions, to prioritise needs and services (Charlton et al. 1981, Clark and Friedman 1982, Goodale and Gander 1976, Gustafson et al. 1975, Hill and Goodale 1981, Koplon and Farer 1980, Kumaran et al. 1976, Loughlin and Moore 1979, Milholland et al. 1973, Moscovice et al. 1977, Thomson and Ponder 1979). It has also been used to determine appropriate indications for a variety of procedures, including carotid endarterectomy, coronary angiography and coronary artery bypass grafting (Brook et al. 1988, Chassin et al. 1986a-c, Gray et al. 1990, Merrick et al. 1987, Park et al. 1986).

The method is defined by a number of characteristics (Brown 1968, Milholland et al. 1973, Roland 1992, Sackman 1975, Starkweather et al. 1975):

<u>Consensus is derived by a panel of "experts."</u>

The results of the process must be acceptable to the wider group of individuals who may ultimately be charged with implementing changes in practice. If panel members are to be acceptable advocates for this wider group, they must represent the range of views and experience within it, and must have sufficient expertise and knowledge to proffer authoritative opinons. In medical projects consideration should be given to drawing panellists from a range of professions, and from different health-care settings located in a variety of geographical areas. However flexibility is essential, since the ideal panel size and composition will depend on the topic addressed.

Participants are polled individually and anonymously, usually using self-administered questionnaires.

Many alternative consensus methods have been criticised for tending to give undue weight to the views of the most dominant and vocal members of the group. The Delphi method gives equal weight to the opinion of all panellists, and anonymous completion of the questionnaire prevents one individual influencing the opinion of others. Thus each participant is able to express his or her views impersonally while ultimately contributing to the information generated by the entire group. Conducting rounds by post also overcomes the physical constraints on selection of panellists encountered in some alternative consensus methods. Although the views of panellists could be weighted as part of the Delphi methodology, this would be at variance to the underlying concept of allowing individuals to contribute equally to the consensus view formed.

The survey of opinion is conducted over more than one round.

After each round the results are collated and fed back to the panellists, before inviting them to complete a duplicate questionnaire amending previous responses if they so wish. The feedback informs individual participants how their responses relate to those of the group as a whole. The process is considered complete when it reaches the point of convergence of opinion or diminishing returns. The final appropriateness rating of each indication is determined by both the direction and dispersion of responses. The reliability of the method increases with the size of the group and the number of rounds, but panellists can become fatigued over more than two rounds and coordinating large groups and several rounds can be complicated and costly.

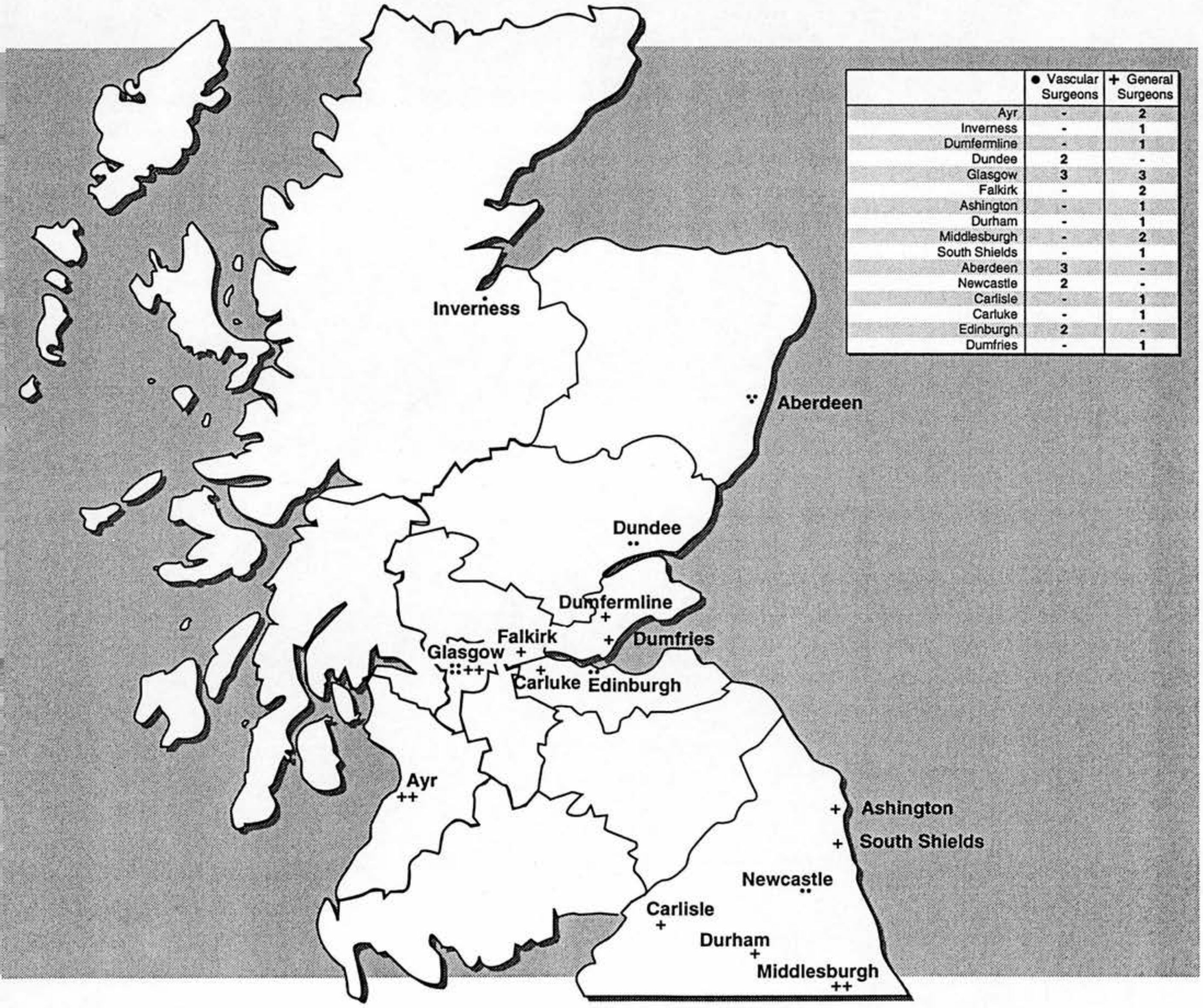
Research has shown that panels from different countries derive different indications for surgery (Brook et al. 1988). This, in part, reflects cultural differences in the way in which published literature is interpreted. Therefore the results of consensus panels should not be generalised to other countries.

6.4. Study methods

6.4.1. Panellists

The panel consisted of 29 vascular surgeons from Scotland and the north-east of England. The panellists equated to 64% of the vascular surgeons working in these areas and were chosen to reflect a range of perspectives. Twelve (41%) members of the panel were full-time vascular surgeons and 17 (59%) were general surgeons with a vascular interest. The panellists came from a spectrum of geographical locations (Figure 6.1.) and represented both teaching and district general hospitals. All of the 29 surgeons invited to participate agreed to do so and all completed both rounds of the questionnaire.

Figure 6.1. Map of locations from which panellists were drawn



	● Vascular Surgeons	+ General Surgeons
Ayr	-	2
Inverness	-	1
Dumfermline	-	1
Dundee	2	-
Glasgow	3	3
Falkirk	-	2
Ashington	-	1
Durham	-	1
Middlesburgh	-	2
South Shields	-	1
Aberdeen	3	-
Newcastle	2	-
Carlisle	-	1
Carluke	-	1
Edinburgh	2	-
Dumfries	-	1

6.4.2. Questionnaire

The questionnaire consisted of a series of hypothetical case scenarios describing different clinical presentations of chronic critical lower limb ischaemia (Appendix 1). Following the detailed review of the relevant literature contained in Chapters 2 and 3, and discussions with vascular surgeons, 218 case scenarios were selected for inclusion in the questionnaire. The number and types of scenarios included were intended to ensure that the scenarios were mutually exclusive, that they represented all possible presentations of critical limb ischaemia, and that surgery would be equally appropriate for all patients represented by one scenario.

The scenarios were described in terms of the key clinical parameters which determine decisions on whether to undertake major amputation or arterial reconstructive surgery:

- the presence or absence of rest pain,
- the presence or absence of tissue loss,
- if present, the site of tissue loss (none, digital, forefoot and heel)
- if present, the severity of tissue loss (deep or superficial),
- the availability of a vein for autologous grafting, and
- the angiographic findings (13 options presented pictorially).

For the purposes of the questionnaire, chronic critical limb ischaemia was defined in accordance with the Second European Consensus Document (European Working

Group 1989&1991). The patients described by the case-scenarios were deemed to have already received the following pre-operative medical management:

- control of diabetes mellitus, hypertension and hyperlipidaemia,
- adequate attempts at pain relief,
- use of sub-cutaneous heparin, prostanoids, vasodilator and antiplatelet drugs where indicated,
- antibiotic therapy for systemic infections,
- debridement of necrotic tissue, and
- advice on smoking cessation.

The patients described by the case-scenarios were also deemed to lack the following contra-indications to major surgery:

- dementia,
- severely restricted functional capacity, due to respiratory, cardiovascular or cerebrovascular disease,
- markedly reduced life-expectancy, due to concomitant life-threatening conditions or markedly advanced age,
- patient opposition to surgery, or
- lack of fitness for general anaesthesia.

The questionnaire was piloted by six vascular surgeons or general surgeons with a vascular interest. The aim of the pilot was to test how comprehensible the questions were and how easy they were to answer. As a result of their verbal and written feedback, the presentation of the questionnaire was revised to include pictorial presentations of the degree of gangrene to supplement the written descriptions. No changes to the content of the questionnaire nor order of the questions were felt to be needed.

6.4.3. Scoring and feedback

For each of the 218 case-scenarios, panellists were asked to rate the appropriateness of arterial reconstruction and primary major amputation separately using two multi-level scales ranging from 1 (extremely inappropriate) to 9 (extremely appropriate) (Figure 6.2.).

Figure 6.2. Rating scale of appropriateness used in questionnaire

extremely inappropriate $\Rightarrow$ $\underline{1}$ 2 3 4 $\underline{5}$ 6 7 8 $\underline{9}$ $\Leftarrow$ extremely appropriate

$\Uparrow$

equivocal

(neither clearly appropriate nor clearly inappropriate)

For the purpose of the sliding scales, "appropriate" was defined as meaning that the expected health benefit, in terms of increased life-expectancy, symptom relief or improved function, exceeded the expected adverse consequences by a sufficiently wide margin that the procedure was worth undertaking. "Inappropriate" was defined as the converse. In line with the Delphi methodology, panellists were asked to ignore the financial cost of procedures, and the availability of resources.

In analysing the results of the first round, the highest three ratings and lowest three ratings for each case-scenario were discarded. The remaining 23 scores were defined as showing "agreement" if they fell within a three-point range, and "disagreement" if they did not.

The indications were then classified on the basis of the median score and the level of agreement. Indications were classified as "appropriate" if the median score for the case-scenario was 7-9 and the range of scores suggested agreement, "inappropriate" if the median was 1-3 with agreement, and "equivocal" if the median was 4-6, or agreement was lacking (Table 6.1.).

Table 6.1. Classification of indications based on the median score and range of scores.

Median score	Level of agreement	Classification of indications
1-3	Agreement*	Inappropriate
1-3	No agreement**	Equivocal
4-6	Agreement*	Equivocal
4-6	No agreement**	Equivocal
7-9	Agreement*	Appropriate
7-9	No agreement**	Equivocal

* Scores within a three-point range after discarding three highest and three lowest scores.

** Scores outwith a three-point range after discarding three highest and three lowest scores.

The literature review contained in Chapter 3 was circulated to panellists with the initial questionnaire to ensure that all of the panellists were conversant with the published evidence available at that time. After completion and analysis of the first round, feedback was posted to panellists in the form of histograms of the group's scores for each question (Appendix 2). The panellist's personal score and the group median were marked on each histogram. Analysis of the second round was conducted in the same way as the first. A χ^2 test was applied to determine if convergence of opinion between the two rounds was statistically significant. The scores ascribed by the panellists to each of the 218 scenarios in both the first and second rounds are contained in Appendix 3.

6.4.4. Factors affecting ratings

In considering the factors affecting panel scores, the responses for major amputation and arterial reconstructive surgery were considered separately. The categories of rest pain, tissue loss, vein availability and angiography were ranked according to clinical severity. The mean panel score was calculated for each of these categories in turn. This enabled the face validity of the panel scores to be assessed, by determining whether a trend existed in the mean scores across the ranked categories.

Multiple linear regression analysis was undertaken using, as outcome variables, the 6,322 scores provided by the 29 surgeons to the 218 questions. The factors and their ranked categories contained in Table 5.4. were entered as the predictor variables and their levels. This enabled the statistical significance of the factors to be determined after adjustment for the other predictor variables.

Also, the variance provided information on the extent to which the variation observed in scores could be attributed to the four clinical factors described. This was important in assessing the reliability of the responses given to a lengthy questionnaire in which respondents may have become fatigued.

A Wilcoxon signed rank test was used to determine if the scores provided by specialist vascular surgeons differed significantly from those of general surgeons with a vascular interest. The multiple linear regression analysis was also repeated, assessing specialists and generalists separately, to determine if the different clinical factors exerted the same degree of influence on the decision-making of these two groups.

6.5. Study results

Between the first and second rounds opinion converged significantly on the appropriateness of indications for both primary major amputation (χ^2 test, $p<0.01$) and arterial reconstructive surgery (χ^2 test, $p<0.0001$) (Table 6.2.). In the second round, agreement was reached on 31 appropriate indications for major amputation and 66 for arterial reconstructive surgery.

Table 6.2. Ratings of appropriateness of case scenarios following first and second rounds of questionnaire.

		Number (%) case scenarios		
		Round I	Round II	Difference between I and II*
Major amputation	Appropriate	16 (7%)	31 (14%)	
	Inappropriate	53 (24%)	65 (30%)	p<0.01
	Equivocal	149 (68%)	122 (56%)	
Arterial reconstruction	Appropriate	45 (21%)	66 (30%)	
	Inappropriate	36 (17%)	61 (28%)	p<0.0001
	Equivocal	137 (63%)	91 (42%)	

* χ^2 test

No case scenarios were considered to represent appropriate indications for both procedures and none were inappropriate for both (Table 6.3.). In theory, indications could be classified as equivocal either because opinion was divergent or because there was a good consensus that the benefits and risks of the procedure were balanced. However, in practice the latter did not apply to any indications. All indications classified as equivocal were due to a divergence of opinion on the merits of the procedure in that sub-group of patients.

Table 6.3. Classification of indications according to appropriateness for arterial reconstruction and major amputation following second round of questionnaire.

Arterial reconstructive surgery	Primary major amputation	Number (%) indications
Appropriate	Appropriate	0 (0%)
Appropriate	Inappropriate	61 (28%)
Appropriate	Equivocal	5 (2%)
Inappropriate	Appropriate	31 (14%)
Inappropriate	Inappropriate	0 (0%)
Inappropriate	Equivocal	30 (14%)
Equivocal	Appropriate	0 (0%)
Equivocal	Inappropriate	4 (0%)
Equivocal	Equivocal	87 (40%)

The face validity of the responses was demonstrated to be good (Table 6.4). The questions were classified by rest pain, gangrene, vein availability and angiography in turn, and the categories for each clinical parameter then ranked according to severity of disease. For all clinical parameters, as disease severity increased, the mean panel score for primary amputation rose indicating its increasing appropriateness. Conversely, arterial reconstruction scores fell indicating decreasing appropriateness. For tissue loss and angiography which possessed more than two categories, a consistent trend in scores was observed across all the categories (Table 6.4).

Table 6.4. Mean panel score by categories of rest pain, tissue loss, vein availability and angiogram findings.

			Mean panel score	
		Number (%) of questions	Major amputation	Arterial reconstruction
Rest pain	Absent	66 (40%)	2.7	5.6
	Present	100 (60%)	4.6	5.3
Tissue loss	None	22 (10%)	2.9	5.8
	Digital	48 (22%)	2.9	5.6
	Superficial forefoot	48 (22%)	3.5	5.6
	Superficial midfoot/heel	48 (22%)	4.2	5.4
	Deep forefoot	26 (12%)	4.4	5.4
	Deep midfoot/heel	26 (12%)	6.6	4.0
Vein availability	Vein available	109 (50%)	3.9	5.7
	No vein available	109 (50%)	4.3	5.1
Angiogram findings	Inflow and/or SFA* occlusion	72 (33%)	1.5	8.5
	Inflow and outflow obstruction	38 (17%)	2.4	7.3
	Outflow occlusion but vessels patent at ankle	36 (17%)	4.5	5.1
	Outflow occlusion	18 (8%)	7.1	1.9
	Outflow and SFA* occlusion	54 (25%)	7.6	1.0

*SFA Superficial femoral artery

On multiple linear regression analysis, rest pain, gangrene, vein availability and angiogram findings explained 74% of the observed variation in amputation scores, and 75% of that in arterial reconstruction scores. Angiogram findings were the most significant determinant of the appropriateness of both major amputation and arterial reconstruction (overall $p<0.0005$) (Tables 6.5.&6.6.). Tissue loss was also independently associated with both scores. The availability of a vein was only significant in determining the appropriateness of arterial reconstruction and rest pain was only significant for major amputation.

Table 6.5. Multiple linear regression analysis of the association between major amputation appropriateness scores and clinical parameters for all panellists.

		Major amputation $\Delta\mu$ (95% CI)
Rest pain	absent'	0.00
	present	1.64 (1.33,1.95)***
Tissue loss'	none'	0.00
	digital	0.08 (-0.53,0.69)
	superficial forefoot	0.69 (0.08,1.30)*
	superficial midfoot / heel	1.34 (0.73,1.95)**
Vein availability	vein available'	0.00
	no vein available	0.42 (-0.16,1.00)
Angiogram findings	inflow and / or SFA occlusion'	0.00
	inflow and outflow occlusion	2.22 (1.32,3.12)***
	outflow occlusion but ankle patent	2.80 (1.94,3.66)***
	outflow occlusion	5.84 (4.73,6.95)***
	outflow and SFA occlusion	4.04 (3.28,4.80)***

$\Delta\mu$ difference in adjusted mean, CI confidence interval, SFA superficial femoral artery
' deep tissue loss missing because unable to classify by presence of rest pain
*p<0.05, **p<0.01, ***p<0.001

Table 6.6. Multiple linear regression analysis of the association between arterial reconstruction appropriateness scores and clinical parameters for all panellists.

		Arterial reconstruction
		Δμ (95% CI)
Rest pain	absent[†]	0.00
	present	-0.22 (-0.90,0.47)
Tissue loss[‡]	none[†]	0.00
	digital	-0.18 (-0.64,0.28)
	superficial forefoot	-0.24 (-0.70,0.22)
	superficial midfoot / heel	-0.46 (-0.92, 0.00)*
Vein availability	vein available[†]	0.00
	no vein available	-0.61 (-1.17,-0.05)*
Angiogram findings	inflow and / or SFA occlusion[†]	0.00
	inflow and outflow occlusion	-2.09 (-3.06,-1.12)***
	outflow occlusion but ankle patent	-3.21 (-4.14,-2.28)***
	outflow occlusion	-7.54 (-1.74,-6.34)***
	outflow and SFA occlusion	-5.57 (-6.39,-4.75)***

Δμ difference in adjusted mean, CI confidence interval, SFA superficial femoral artery
[‡] deep tissue loss missing because unable to classify by presence of rest pain
*p<0.05, **p<0.01, ***p<0.001, ****p<0.0005

Overall, vascular surgery specialists rated arterial reconstruction as more appropriate and major amputation as less appropriate than general surgeons with a vascular interest. However, the differences were not statistically significant (Table 6.7).

Table 6.7. Median appropriateness scores for major amputation and arterial reconstruction by type of surgeon

	Major amputation median (IQR)	Arterial reconstructive surgery median (IQR)
General surgeon	6.06 (1.82-7.97)	3.59 (1.82-6.76)
Vascular surgeon	6.33 (1.42-8.42)	3.50 (1.54-7.02)

IQR interquartile range

Applying multiple linear regression analysis to vascular and general surgeons separately, vein availability was a significant determinant of arterial reconstruction and major amputation score for vascular surgeons only (Tables 6.8&6.9). The significant associations demonstrated for angiography were common to both groups of surgeons, as was the significant association between major amputation score and both rest pain and tissue loss. Tissue loss was a significant predictor of arterial reconstruction score for vascular surgeons only.

Table 6.8. Multiple linear regression analyses of the association between major amputation appropriateness scores and clinical parameters for general and vascular surgeons.

		General surgeons	Vascular surgeons
		Δμ (95% CI)	Δμ (95% CI)
Rest pain	absent'	0.00	0.00
	present	1.40 (0.88,1.92)***	1.41 (0.82,2.01)***
Tissue loss‡	none'	0.00	0.00
	digital	0.15 (-0.68,0.98)	0.06 (-0.89,1.01)
	superficial forefoot	0.44 (-0.39,1.27)	0.82 (-0.13,1.77)
	superficial midfoot / heel	1.30 (0.47,2.13)**	1.35 (0.40, 2.30)**
Vein availability	vein available'	0.00	0.00
	no vein available	0.25 (-0.22,0.73)	0.56 (0.02,1.10)*
Angiogram findings	inflow and / or SFA occlusion'	0.00	0.00
	inflow and outflow occlusion	2.16 (1.43,2.90)***	1.89 (1.05,2.74)***
	outflow occlusion but ankle patent	2.66 (1.95,3.37)***	2.88 (2.07,3.70)***
	outflow occlusion	5.10 (4.19,6.02)***	5.26 (4.21,6.31)***
	outflow and SFA occlusion	3.70 (3.08,4.32)***	3.92 (3.21,4.64)***

Δμ difference in adjusted mean, CI confidence interval, SFA superficial femoral artery
‡ deep tissue loss missing because unable to classify by presence of rest pain
*p<0.05, **p<0.01, ***p<0.001

Table 6.9. Multiple linear regression analyses of the association between arterial reconstruction appropriateness scores and clinical parameters for general and vascular surgeons.

		General surgeons	Vascular surgeons
		Δμ (95% CI)	Δμ (95% CI)
Rest pain	absent'	0.00	0.00
	present	-0.20 (-0.78,0.37)	-0.31 (-0.99,0.38)
Tissue loss'	none'	0.00	0.00
	digital	-0.22 (-0.13,0.69)	-0.28 (-1.38,0.81)
	superficial forefoot	-0.26 (-1.17,0.65)	-0.40 (-1.50,0.69)
	superficial midfoot / heel	-0.35 (-0.82,0.12)	-0.58 (-1.14,-0.02)*
Vein availability	vein available'	0.00	0.00
	no vein available	-0.35 (-0.88,0.18)	-0.77 (-1.40,-0.14)*
Angiogram findings	inflow and / or SFA occlusion'	0.00	0.00
	inflow and outflow occlusion	-2.35 (-3.18,-1.52)***	-1.78 (-2.76,-0.80)***
	outflow occlusion but ankle patent	-3.13 (-3.91,-2.35)***	-3.34 (-4.28,-2.40)***
	outflow occlusion	-6.72 (-3.91,-2.35)***	-6.98 (-8.19,-5.77)***
	outflow and SFA occlusion	-4.98 (-5.67,-4.29)***	-5.04 (-5.87,-4.21)***

Δμ difference in adjusted mean, CI confidence interval, SFA superficial femoral artery
' deep tissue loss missing because unable to classify by presence of rest pain
*p<0.05, **p<0.01, ***p<0.001, ****p<0.0005

6.6. Conclusions

Because of the lack of randomised trials of the surgical management of chronic critical lower limb ischaemia, evidence of the appropriate indications for arterial reconstructive surgery and major amputation is limited to observational studies and clinical experience. Consensus methods provide a structured and explicit mechanism whereby the available evidence can be collated and translated into agreed indications for surgery. Consensus standards are not a substitute for experimentally derived standards, but can provide useful guidance in their absence and are preferable to arbitration by a single opinon.

The Delphi method has been used to derive indications for a number of other surgical procedures (Brook et al. 1988, Chassin et al. 1986a-c, Gray et al. 1990, Merrick et al. 1987, Park et al. 1986) and has advantages over other consensus methods. The method has been demonstrated to be both valid and reliable (Merrick et al. 1987). Equal weight is given to the opinion of all participants, and anonymous polling of views prevents one individual influencing the views of another. Some consensus methods require complete agreement and have therefore been criticised for producing "bland" recommendations which have already been implemented (Fink et al. 1984, Rennie 1981). By contrast the Delphi method allows for minor degrees of dissension by omitting the most atypical responses before assessing consensus. The reliability of the Delphi method increases with the size of the panel (Dalkey 1969) and, since questionnaires can be posted, there are no geographical constraints on the selection of participants. Because of cultural influences, panels from different countries may classify different proportions of hypothetical scenarios appropriate or inappropriate (Brook et al. 1988). However, they tend to rank scenarios in the same order (Brook et al. 1988). The panel should be composed of members from the country in which practice is to be assessed as this is likely to produce greater concordance between actual and ideal practice (Leape et al. 1993).

As in previous studies using this method, the large number of indications classified as inappropriate reflects the aim of making the questionnaire as inclusive as possible of all potential presentations.

Application of this method identified those clinical presentations where there was good agreement on how patients should be managed. These indications can be used as the basis of clinical guidelines. Of equal importance is the identification of those clinical situations where consensus is lacking. In this study, opinion was divided on the most appropriate managment of patients with occluded femoral, popliteal and proximal tibial arteries, but patent arteries at the ankle or foot level. In such situations, some surgeons would advocate femorocrural reconstruction, especially if a suitable vein is available for autologous grafting. However, this is a time-consuming procedure requiring high levels of surgical expertise and vascular laboratory and radiological support, and it does not find unanimous support (Anon 1992, Skillman 1993). Highlighting areas of divergent opinion helps to target future studies at those areas where they are most needed.

Indications derived by consensus must reflect all perspectives. In this study, the large number of panellists and their representation of all localities and types of unit reduced the risk of bias. Also, the fact that two-thirds of surgeons performing vascular surgery in Scotland participated directly in the rating of indications greatly increases the likelihood that they provided a good reflection of overall opinion. The good validation of the results and the ability of clinical parameters to explain most of the variability in scores further enhanced the credibility of the results. The high variance figures of 74% and 75% suggest that the scores obtained were largely explained by the clinical details contained in clinical scenarios. This is reassuring in light of the length of the questionnaire and the likely fatigue caused. By ensuring good representation of all interested parties ownership of results can be encouraged, thereby increasing the chance of addressing any deficiencies identified in the study.

CHAPTER 7

Comparison of clinical practice and consensus indications

7.1. Introduction

Comparisons of crude operation rates are an insufficient measure of variations in practice. Geographical areas may vary in terms of demography, disease incidence, disease natural history and referral patterns. Therefore variations in operation rates may reflect differences in volume and case-mix as well as differences in clinical management. Because of these reasons, it is more justified to compare clinical management in different areas by means of the percentage of operations conforming with agreed patient selection criteria. In this chapter the operations performed in a sample of hospitals throughout Scotland are compared with the appropriate and inappropriate indications agreed by the method outlined in the previous chapter.

7.2. Methods

Samples of primary major amputation and arterial reconstruction operations were selected using a two-stage sampling method. The 20 Scottish hospitals which perform vascular surgery were stratified into three groups according to the annual numbers of vascular operations performed. These figures were obtained from routine discharge data collated by ISD. "Low volume" hospitals were defined as those performing less than 100 major amputations plus arterial reconstructions per annum. "Medium volume" hospitals performed between 100 and 400 operations per annum, and "high volume" more than 400. The numbers of hospitals falling within these three categories were four, ten and six respectively. Stratified random sampling, using random number tables, was then used to select a total of ten hospitals which reflected the relative numbers of different types of hospitals present throughout Scotland as a whole. Thus, two hospitals were selected randomly from the "low volume" hospitals, five from the "medium volume" and three from the "high volume."

Within each of these hospitals, a list was compiled from the computer database or operating theatre registers of the most recent 20 consecutive arterial reconstruction operations and the most recent 20 primary major amputations which satisfied the study inclusion and exclusion criteria outlined in section 5.4.2. The case-notes and angiograms of each of these patients were reviewed and information collected on a standardised recording sheet (Appendix 4) on the type of operation, presence or absence of rest pain and tissue loss, site and severity of tissue loss and angiogram findings. This information was used to categorise patients into one of the 218 clinical presentations contained within the original Delphi questionnaire (Appendix 5). The appropriateness of these operations was then assessed in comparison to the indications previously defined (Appendix 5). χ^2 tests were used to determine whether the proportion of operations which conformed to the agreed indications differed significantly between individual units and by size of unit.

7.3. Results

Overall, 48% of arterial reconstruction operations conformed with the agreed indications (Table 6.1.). The 49% classified as equivocal were predominantly femorodistal reconstructions. Only 7 (4%) did not conform with the indications.

Only 31% of primary major amputations conformed with the agreed indications (Table 7.1.). Twenty four percent did not conform. These were predominantly patients with minor degrees of tissue loss and predominantly proximal disease.

Table 7.1. Numbers of arterial reconstruction operations and primary major amputations which conformed with the consensus indications.

Consensus category	Arterial reconstruction n (%) (95% CI)	Major amputation n (%) (95% CI)
Appropriate	95 (48%) (41,55)	62 (31%) (25,37)
Equivocal	98 (49%) (42,56)	90 (45%) (38,52)
Inappropriate	7 (4%) (1,7)	48 (24%) (18,30)

There were significant differences in the degree of conformity for arterial reconstruction operations both between individual hospitals (χ^2 test, $p<0.05$) and by size of unit (χ^2 test, $p<0.05$) (Table 7.2.). The percentage of arterial reconstructions which conformed with the indications was 65% in "low volume" hospitals compared to only 48% in "high volume" hospitals.

Table 7.2. Numbers of arterial reconstruction operations which conformed with the consensus indications by hospital volume of throughput.

Hospital category	Consensus category		
	Appropriate n (%) (95% CI)	Equivocal n (%) (95% CI)	Inappropriate n (%) (95% CI)
Low volume	26 (65%) (63,67)	13 (33%) (30,36)	1 (3%) (0,6)
Medium volume	41 (41%) (39,43)	54 (54%) (53,55)	5 (5%) (3,7)
High volume	29 (48%) (46,50)	30 (50%) (48,52)	1 (2%) (-1,5)
Overall	96 (48%) (47,49)	97 (49%) (48,50)	7 (4%) (3,5)

The percentage of amputations which did not conform with the indications also differed significantly by size of unit (χ^2 test, $p<0.05$), although there were no clear trends apparent (Table 7.3.). The difference between individual units was not statistically significant.

Table 7.3. Numbers of primary major amputations which conformed with the consensus indications by hospital volume of throughput.

Hospital category	Consensus category		
	Appropriate n (%) (95% CI)	Equivocal n (%) (95% CI)	Inappropriate n (%) (95% CI)
Low volume	15 (38%) (36,40)	18 (45%) (43,47)	7 (18%) (15,21)
Medium volume	21 (21%) (19,23)	54 (54%) (53,55)	25 (25%) (23,27)
High volume	26 (43%) (41,45)	18 (30%) (28,32)	16 (27%) (25,29)
Overall	62 (31%) (30,32)	90 (45%) (4,46)	48 (24%) (23,25)

7.4. Conclusions

Operation rates reflect disease frequency and case-mix as well as clinical management. Therefore comparisons of operation rates may give a misleading impression of the extent to which clinical management varies. This problem can be overcome by comparing the extent to which practice conforms to agreed criteria in different areas.

Overall, fifty five (14%) of the operations assessed did not conform to the agreed indications for surgery. This suggests that the actual practice of vascular surgeons in Scotland differed from their own ratings of appropriate practice. The discrepancies found may reflect inappropriate practice. If this is the case, and the results are generalised to all units in Scotland, over 170 patients in Scotland could be undergoing major amputation each year when arterial reconstruction may be more appropriate. Similarly, inappropriate attempts at limb-salvage may be undertaken in around 60 patients each year. In a similar study by Gray et al. (1990) in Trent, 21% of coronary angiograms and 16% of coronary artery bypass graft operations were classified as inappropriate despite more than half of these procedures being undertaken by members of the Delphi panel. The authors suggested that consensus panels inevitably formulate indications which are more conservative than actual practice since some panellists treat individual patients more aggressively than they are willing to admit openly (Gray et al. 1990). A legitimate reason for divergence from consensus indications is the inability to take account of all the factors relevant in individual cases in formulating consensus criteria or, indeed, evidence-based guidelines. Factors less likely to be considered include patients' wishes, available resources and surgical expertise. Therefore lack of adherence to consensus criteria does not necessarily infer poor management. In the study by Gray et al. (1990), 30% of patients who underwent apparently "inappropriate" angiograms subsequently underwent coronary artery bypass graft operations. The authors concluded that, given the limited resources and waiting lists which characterise the National Health Service, choices must be made and Delphi appropriateness ratings are helpful in devising guidelines to assist these choices.

There were significant variations between units in the proportion of arterial reconstruction operations which conformed with the criteria. The proportion was highest in "low volume" units which is likely to reflect a generally less aggressive aproach to limb-salvage in such units. This differed from the findings reported by Leape et al. (1993) who demonstrated no significant differences by hospital, region, procedure volume or teaching status in the percentages of coronary artery bypass operations which were performed inappropriately. However, this may reflect their generally low rates of inappropriateness.

The surgeons who participated directly in this study all received copies of the results in which their own hospital was identified. In addition, anonymised results were published in a peer-reviewed vascular surgery journal (Appendix 6), and were presented and discussed at the Annual Meeting of the Scottish Vascular Audit Group. Following feedback of the results, written guidelines were compiled which summarised the criteria on which agreement was reached (Appendix 7). These were discussed, revised and endorsed by the members of the Scottish Vascular Audit Group and, thereafter, circulated to all participating surgeons and agreed to by them. Their format was chosen to provide a quick reference document for use in clinical practice. As with all guidelines, they were intended to guide practice in general rather than prescribe it for individual patients.

CHAPTER 8

Discussion

Chronic critical lower limb ischaemia was chosen as the topic of this thesis because it is a relatively common condition, has a poor prognosis, is expensive to treat and may be managed in a number of ways. Also anecdotal evidence suggested a lack of consensus on its management. There was wide acceptance among the vascular surgical community that this was a subject worthy of study and a general willingness to participate.

Peripheral arterial disease is common and therefore a large number of individuals are potentially at risk of developing critical limb ischaemia. Around 5,000 new cases of chronic critical lower limb ischaemia present each year. It is a serious condition. Case-fatality rates are high, in both the short- and long-term, and one-quarter of those affected will lose at least one limb. Quality of life is adversely affected even in those in whom limb-salvage is successful. The costs of the disease and its treatment are high for the individual, the health service and society as a whole. It is characterised by prolonged in-patient treatment, intensive rehabilitation and serial procedures.

Patients and surgeons are faced with a choice of management options including attempted revascularisation, major amputation and conservative management. These treatment options have never been compared in a randomised controlled trial. They are unlikely to be subjected to such rigorous evaluation now in light of the adoption of arterial reconstructive surgery into routine clinical practice and the view that major amputation, being a relatively mutilating procedure, should only be undertaken in patients in whom arterial reconstruction is not appropriate. Despite the lack of trial evidence these treatment options are clearly very different in terms of their potential impact on mobility, physical and social functioning, self-image and quality of life.

Anecdotal evidence suggested that wide variations may exist in the management of patients with chronic critical lower limb ischaemia. Published case-series demonstrated variations in procedure rates by place of residence and place of treatment. Our results confirmed that wide variations also exist within Scotland in the rates of both major amputation and arterial reconstructive surgery.

Variations in the rates of a procedure may reflect real differences or may be due to random effect or statistical chance. A number of statistical methods can be used to help differentiate between the two. Two summary statistics commonly quoted to measure variation in a sample are variance and standard deviation. Both of these figures measure absolute variation. As such they are influenced by the scale of measurement. If the average rate of surgery in an area is high then the absolute variation will be correspondingly large. Comparisons of rates by area are influenced by both the average rates and the internal variability of these rates. Both of these factors are taken into account in the calculation of the coefficient of variation which is the standard deviation of the sample divided by the mean. If the sampling error is large, due perhaps to a small population, then the coefficient of variation will be large even though the variance and absolute variation may be small. Because of the differing bases and interpretations of these statistics all three are quoted in the thesis for comparison.

In determining whether the difference between rates in individual areas is statistically significant a number of methods can again be employed. In this thesis consideration of such aspects is limited to the inclusion of 95% confidence intervals for the age-sex standardised rates. To evaluate this properly would require the use of Poisson regression analysis to determine the statistical significance of the association between area of residence and the number of procedures performed on that population after taking account of covariates such as age and sex. However, this level of statistical complexity was felt to be inappropriate in this instance. Many pertinent covariates which impact on procedure rates such as disease incidence and natural history, comorbidity and referral patterns are not available. Therefore, undertaking more complex statistical analyses might have appeared to lend greater legitimacy to the misconception that variations in procedure rates are necessarily indicative of variations in hospital practice. For similar reasons, other methods such as that described by McPherson et al. (1982) were not employed.

Since geographical variations in rates may be appropriate where differences exist in factors such as disease incidence, natural history and comorbidity the variation demonstrated in this thesis can only be interpreted as a possible indication of differences in clinical practice which merit the more detailed study contained in Chapters 6 and 7.

The positive correlation between major amputation and arterial reconstructive surgery was greater for the analysis by health board area of treatment than that by health board area of residence. There are clearly a lot of factors influencing both of these. However the strong positive association by health board of treatment is be expected. The main factors contributing to the positive correlation by health board area of treatment are referral patterns and supply factors. Patients with both chronic critical ischaemia and intermittent claudication are more likely to be treated in health board areas which contain vascular surgeons and are least likely to be treated in health board areas in which there is no surgeon with a specific vascular interest. Health board areas containing specialist vascular surgeons in tertiary centres have a generally high throughput of patients. Therefore they may undertake relatively high numbers of major amputations even if they have a higher threshold for undertaking major amputation in individual patients. These centres will also perform large numbers of arterial reconstructive operations because of a relative preference for limb-salvage procedures in patients with critical ischaemia as well as cross-boundary referrals of intermittent claudication patients in whom they will also have a lower threshold for treatment.

The positive association by health board area of residence is more interesting and also more complex to understand. The lower positive correlation than for health board of treatment is to be expected due to supply factors. Patients who live near tertiary centres are more likely to undergo arterial reconstruction for both critical limb ischaemia and intermittent claudication because of easier access and a lower threshold for referral and operation. They are also less likely to undergo major amputation because of a relative preference for limb-salvage in tertiary centres. The fact that there is nonetheless a residual positive correlation is noteworthy. This may, in part, reflect sequential procedures since patients with critical limb ischaemia who live near tertiary centres are more likely to undergo arterial reconstruction than major amputation and those who undergo major amputation are more likely to undergo it at the below-knee level. Therefore, sequential operations and revisions are more likely to occur.

Because of the difficulty of measuring all covariates using routine data sources, it was decided to develop specific indications for both major amputation and arterial reconstructive surgery and to compare these with the information contained in the case-notes and angiograms of a retrospective sample of patients. Over the last few years there has been increasing emphasis placed on the need for the indications contained within guidelines and protocols to be "evidence-based." However in practice most aspects of medicine are characterised by a complete paucity of evidence. Even where evidence is available studies tend to recruit very small samples of highly selected patients and focus on a limited number of easily measurable outcomes. The results available are further limited by the effect of publication bias. Where only observational studies are available additional problems are encountered in the extent to which case-mix can be taken into account. Therefore developing comprehensive indications based on published evidence is rarely possible. As a result those evidence-based guidelines which have been published, such as those produced by SIGN, tend to include a relatively small number of highly focussed recommendations many of which carry a low grading.

Contrary to a common misconception, consensus indications and guidelines do take account of published evidence. One characteristic of the Delphi methodology employed in this thesis is that a comprehensive literature review is undertaken and circulated to all panellists prior to eliciting their views. However the method allows consideration also to be given to clinical experience and does not specify the relative weights which should be given to the various types of evidence considered. It is open to speculation as to whether the latter is disadvantageous in that it lacks scientific rigour and standardisation or is advantageous in that it provides greater flexibility and a greater ability to take account of the limitations of available evidence. As mentioned in Chapter 4 a further feature of consensus indications is that they may carry greater legal weight since professional acceptance is effectively a prerequisite of their development.

A number of methods have been developed for deriving consensus. The Delphi method was chosen because if confers a number of recognised advantages. Because it can be undertaken by post, physical constraints on the selection of panellists are avoided. Because meetings are not required panellists are not required to find time to travel to and attend meetings and there is no limitation on the number of panellists who can participate. The time required from support personnel is also kept to a minimum. The Delphi method is particularly well suited to topics where data are lacking or difficult to obtain and where experts represent diverse backgrounds and experience (Leape et al. 1992). Its essential characteristics are anonymity, controlled feedback and the statistical representation of results (Leape et al. 1992). These features minimise some undersirable aspects of face to face interactions. Anonymity eliminates the effect of socially dominant and vocal individuals and facilities free expression of divergent views. Because participants are nonetheless exposed to the divergent ratings of others, albeit in a less-challenging way, they are still stimulated to reconsider their own views. Controlled feedback encourages the panellists to remain focussed. However this might be viewed as a disadvantage since the component scenarios are fixed at the outset giving panellists no opportunity to revise them during rounds even if this is desirable. Statistical representation of the results, usually through use of the median, further minimises group pressures because there is no attempt to reach unanimity. This makes the method particularly useful for topics in which complete consensus is unlikely to be obtained.

It has been suggested that one disadvantage of the Delphi method is that it does not provide an opportunity of finding out why others have divergent views (Leape et al. 1992). Without an opportunity for clarification or comment the opportunity to achieve even greater consensus may be missed. Alternatively feedback without discussion may result in consensus on the wrong answer.

Another problem associated with the Delphi method is the fatigue caused by completing a long and monotonous questionnaire on more than one occasion. In this thesis the variance was relatively high at 74% and 75% for major amputation and arterial reconstructive surgery respectively suggesting that most of the variation observed in the appropriateness scores could be explained by the clinical parameters contained in the clinical scenarios. However 25%-26% could not be accounted for suggesting that some of the variation was spurious and therefore likely to be due, in part, to fatigue. Increasing the number of rounds provides greater opportunity to feed back results and influence panellists thereby facilitating consensus. However fatigue is also likely to increase with a greater number of rounds making non-response and erroneous entries more likely. In the context of this thesis, in which full-time clinicians were being asked to complete the questionnaires without reimbursement, two rounds were felt to be appropriate.

The ability to allow some degree of dissension is generally cited as an advantage of the Delphi method. However, the degree of dissension permitted, although agreed in advance, is arbitrary. Most studies using nine panellists allow one outlier at each extreme. It was decided that in this study in which 29 panellists were used a pro-rata figure of three omissions at each extreme should be employed. However this figure is no more justifiable than any other. Quoting inter-quartile ranges is an alternative option. However this is no more justifiable than using the range after omitting three outliers at each extreme since the latter effectively equates to using the 79th centile range. A sensitivity analysis was not undertaken as our participants felt that it was imperative that the figure should be fixed in advance to avoid any temptation to select the most desirable set of results. Altering the definition of agreement would undoubtedly have altered the results as was found by Park et al. (1986).

The Delphi methodology permits the number and composition of panels to be varied according to the topic being addressed. However it should be borne in mind that this may impact on the results obtained. It has been shown that surgeons who perform procedures are more likely to rate them as appropriate than physicians in related specialties who in turn rate them as more appropriate than primary care physicians (Kahan et al. 1996, Park et al. 1986). On average, those who undertake procedures rate the appropriateness of that procedure one point higher than those who do not (Kahan et al. 1996). Possible reasons include self-interest, economic gain, superior knowledge and bias. Although feedback from those performing the procedure does influence the ratings of those who do not, this does not invariably favour greater concordance since opinions change relatively equally in both directions (Kahan al. 1996). As a result, multi-specialty panels provide more divergent viewpoints than uni-specialty panels and rate fewer procedures as appropriate (Kahan et al. 1996). Similarly panels composed of a random sample of general surgeons produce greater divergence than those composed of nominated specialists (Leape et al. 1992). In this thesis the panel was composed of a mixture of general and vascular surgeons selected from district general and teaching hospitals and a spectrum of geographical areas. As might be predicted vascular surgeons tended to rate arterial reconstruction as more appropriate than general surgeons and major amputation as less appropriate.

Vein availability was a significant predictor of appropriateness score for vascular surgeons only. Arterial reconstruction can be performed using both prosthetic grafts and autologous vein grafts. Autologous vein grafts produce superior results in patients undergoing distal reconstruction which would be required in only a proportion of the case scenarios contained in the questionnaire. Distal reconstruction is more likely to be undertaken by vascular than general surgeons. They are therefore more supportive of the procedure and are possibly more aware of the literature regarding the relative effectiveness of the two types of graft. General surgeons are more likely to rate patients requiring distal reconstruction as inappropriate for arterial reconstruction and appropriate for major amputation. By contrast vascular surgeons are more likely to support major amputation only in those in whom veins are not available for grafting.

In designing the questionnaire for the development of indications it is important to ensure that scenarios are defined in such a way that all patients described by one scenario would be equally appropriate or inappropriate for the procedure. This was done at the development and pilot stages at which discussions took place as to whether further sub-division of the clinical parameters were pertinent in terms of their impact on clinical decision-making. Failure to ensure the homogeneity of scenarios has been cited as a possible explanation for divergence of opinion (Park et al. 1986). However unnecessary detail has to be avoided if the number of scenarios is to be kept to a minimum and co-operation encouraged.

On completing the questionnaire panellists were asked to consider only effectiveness and adverse outcomes not absolute cost or cost-effectiveness. This is in line with similar projects using the Delphi methodology and many of the evidence-based guideline methodologies such as that used by SIGN. Guidelines can be based on ideal, acceptable or minimum acceptable standards of practice. Consensus guidelines such as those developed in this thesis do take account of practical limitations and the difficulties of replicating trial results in practice. However our panellists did not explicitly take account of resource issues and rationing. As such, the indications developed fall somewhere between ideal and acceptable standards of practice. The inclusion of considerations of cost could be supported on the grounds that its sub-conscious influence cannot be avoided and therefore it should be considered in a more explicit and systematic way. Also, its inclusion would ensure that the indications developed were clearly based on acceptable rather than ideal standards and are therefore realistically attainable in actual practice. As mentioned in Chapter 5 some of the variation in the management of intermittent claudication in Scotland has been attributed to varying access to resources (Pell and Elton 1995). Resources might be expected to impact less on the management of critical limb ischaemia since relatively few patients are managed conservatively and primary major amputation should generally only be considered in patients unsuitable for arterial reconstruction. It could be argued that since neither operation has a waiting list for this sub-group of patients issues of absolute cost and cost-effectiveness make little impact on the daily decision-making of those who perform the procedure and who constituted the panel. Although not included in the literature review circulated to panellists, a review of the literature on cost-effectiveness is included in the thesis since it is pertinent to others such as managers and public health physicians who need to consider treatment options for critical limb ischaemia within the wider context of overall costs and opportunity costs.

The literature review contained information on the relative benefits of below- compared to above-knee amputation although these were not considered separately in the questionnaire. Their inclusion in the review relates to the fact that the two procedures have markedly different outcomes in terms of case-fatality rates, serial procedures and mobility. Therefore to discuss outcomes following major amputation without explicitly recognising these two distinct groups might be misleading. Their exclusion from the questionnaire relates to the fact that in clinical practice the parameters used to define the case scenarios enable a decision to be made as to whether arterial reconstruction or major amputation should be performed. It is only following a decision to undertake major amputation that a second decision is then made as to the appropriate level at which to perform it.

In order to compare the consensus indications with actual clinical practice, information was obtained retrospectively from case-notes and angiograms on a sample of major amputations and arterial reconstructions. The sample was identified using a stratified random sample of hospitals with equal numbers of patients then selected from each of the hospitals chosen. Stratified random sampling can be done using either the same sample size from each stratum or different sample sizes from each. Each method has its own advantages. The advantage of the former over a simple randomised sample is that it ensures that all strata form the same proportion of the sample as they do the population from which the sample is drawn. The latter method has the advantage that if some strata are small a sufficient number of representatives from this group can be included with a smaller overall sample size than would be required to achieve the same effect using a simple randomised sample. In this thesis we needed to compare practice between hospitals of varying sizes. Therefore the unit for the first stage of the sampling was the hospital rather than the patient. This sampling method ensured that the sample contained both 50% of all hospitals and 50% of each of the component strata, namely low, medium and high volume units. This ensured an adequate sample from each of the groups to be compared. However, when aggregating data to provide an overall figure for the appropriateness of a procedure, the sample selected inevitably over-represented patients operated on in smaller units.

The patients included in the sample were selected on the basis that they were a consecutive series which satisfied the inclusion criteria, did not possess the exclusion criteria and had complete information on the clinical parameters used to define the clinical scenarios. Because there were only four clinical parameters all of which are pertinent to the clinical management of patients, less than 5% of potentially eligible patients had to be excluded because of incomplete data.

As mentioned clinical practice was compared by the size of unit using three categories to define size. Clinical practice was not compared by health board area of residence for a number of reasons. The sample size would have been too small to support comparison between 15 different groups. Also the information required to define health board area of residence was not available in many sets of case-notes. Any differences demonstrated would have been difficult to interpret since they could be attributed to a multitude of factors including access, supply factors, referral patterns and operation thresholds. Finally, the sampling methodology was directed at the principal aim of comparing practice by hospital. If comparison by health board area of residence had been intended a different sampling methodology would have been used.

A significantly lower percentage of arterial reconstruction operations performed in high and medium volume units were in concordance with the consensus indications than in low volume units. This is not surprising since specialist vascular surgeons are more likely to attempt more distal reconstruction operations about which panellists' views were divergent. As mentioned previously the panel consisted of both general surgeons and vascular surgeons and vascular surgeons tended to give higher appropriateness scores than general surgeons.

There has been a gradual trend away from assessing clinical performance on the basis of process measures to assessing it using outcome measures, the general assumption being that the latter are superior. However comparing practice in terms of outcome may require larger sample sizes to demonstrate differences as statistically significant and the result may not be able to be interpreted without the subsequent examination of process (Mant and Hicks 1995). Most patients with chronic critical limb ischaemia die from other causes, such as coronary arterial disease or cerebrovascular disease. Neither arterial reconstructive surgery nor major amputation have been demonstrated to improve survival. Therefore surgery in such patients is aimed at relieving pain and improving mobility, physical and social functioning and overall quality of life, rather than increasing longevity. Such outcomes are more difficult to measure and interpret than survival. Also outcomes are dependent on process and case-mix both of which are affected by patient selection which was the topic of this thesis. In selecting patients for surgery the aim is to ensure that those who undergo surgery do so appropriately and those who are denied surgery are denied it appropriately. This thesis addressed only the former group. In 1986, 90% of patients with critical ischaemia underwent some form of surgery within one year of presentation (Wolfe 1986). Although a more recent figure is not available it is unlikely to have fallen and may have increased. Therefore although the management of patients who did not undergo surgery was not considered in this thesis they represent a minority of all patients with chronic critical lower limb ischaemia.

Following the results of this work a simple set of guidelines was produced and endorsed by the participants and disseminated to surgeons undertaking the relevant procedures in Scotland. The most recently available routine data suggest that the numbers of distal reconstruction operations performed in Scotland has fallen dramatically since their publication (personal communication Holdsworth R and Bain M). However the extent to which the decline can be attributed to this thesis can only be speculated.

CHAPTER 9

Conclusions and recommendations

Chronic critical lower limb ischaemia is an important condition in terms of the numbers of patients affected, the impact of the disease in terms of both survival and quality of life, and the cost of treatment. Whether estimated from studies of the incidence and natural history of intermittent claudication, or from the incidence of major amputation, around 5,000 people develop chronic critical lower limb ischaemia in Scotland each year. Almost £20 million pounds is spend each year on their health-care. However, most have concomitant cardio- or cerebrovascular disease, and less than half survive five years irrespective of the operations undertaken (Dormandy and Thomas 1988, Hughson et al. 1978). Severe ischaemia is associated with poor quality of life (Albers et al. 1992, Hunt et al. 1982, Pell 1995). Although arterial reconstruction can improve this, major amputation may itself have a deleterious effect on quality of life (Albers et al. 1992, Gough et al. 1983, Pell et al. 1993, Thompson and Haran 1983, Weiss et al. 1990). A BKA:AKA ratio of 2.5:1 has been recommended as an appropriate target (Dormandy and Thomas 1988). However, this ratio remains nearer 1:1 in the United Kingdom.

The introduction of "limb-salvage" procedures, such as arterial reconstructive surgery and percutaneous transluminal angioplasty initially failed to reduce rates of major amputation. However, more recent studies suggest that amputation rates are now starting to decline (Pell et al. 1994a&b, personal communication Eickhoff JH). From clinical follow-up studies and comparisons with historical controls, use of arterial reconstructive surgery appears to save between one- and two-thirds of critically ischaemic limbs. Failure to save limbs may result from graft failure or disease progression.

Since neither amputation nor arterial reconstruction prevent progression of the underlying disease, sequential procedures are common. Thirty percent of below-knee amputations are followed by ipsilateral reamputation at a higher level, and 50% by contralateral amputation (Dormandy and Thomas 1988, Ecker and Jacobs 1970, Kihn et al. 1972), and one-third of major amputations follow failed attempts at arterial reconstruction (Stern 1988). Sequential procedures place patients at an increased risk of surgical complications. Also, prior attempts at arterial reconstruction have an adverse effect on stump healing which, in turn, may result in more below-knee amputations requiring conversion to above-knee (Dormandy 1991, Evans et al. 1990, Schlenker and Wolkoff 1975).

Wide variations exist in the management of many conditions. Greater uniformity might be expected in the management of chronic critical lower limb ischaemia since relatively few patients are managed conservatively, and primary major amputation is generally undertaken in only those patients unsuitable for limb-salvage procedures. Nonetheless, wide variations do exist in the rates of both major amputation and arterial reconstruction (Eickhoff et al. 1980, Michaels et al. 1994). Within Scotland, patients resident in the 15 Health Board areas experienced a 5-fold variation in the age-sex

Erratum

Delete from the end of the first paragraph on page 188:

"This paradoxical result corroborates the results previously published by Eickhoff et al. (1980)."

Insert at the end of the first paragraph on page 188:

"This paradoxical result appears to corroborate the results previously published by Eickhoff et al. (1980). However, as mentioned in section 5.8, much of the variation may be accounted for by chance. Therefore caution needs to be exercised in interpreting the variation demonstrated as differences in practice."

adjusted rate of arterial reconstruction, and a 4-fold variation in age-sex adjusted amputation rate. Furthermore, a positive correlation was demonstrated between the two rates, indicating that patients living in areas with high rates of arterial reconstruction were also more likely to undergo major amputation. This paradoxical result corroborates the results previously published by Eickhoff et al. (1980).

However, comparison of operation rates is of limited use as a measure of the appropriateness of clinical practice, since they are influenced by differences in disease incidence, referral patterns and case-mix, and agreement on the correct rate may be lacking (Andersen and Lomas 1985, Goldacre and Griffin 1983, Roland 1992).

To overcome these limitations and determine whether variations exist in clinical decision-making, standards must be set against which to compare clinical practice. Where possible, these should be defined by the results of randomised trials. However, most interventions in common usage have not been subjected to such rigorous evaluation. More commonly effectiveness is judged by observational studies, case-series and personal experience. Consensus methods can be used to synthesise all of the available evidence into a single set of indications against which to compare clinical practice.

The Delphi consensus method has been used to derive indications for a number of surgical procedures (Brook et al. 1988, Gray et al. 1990, Merrick et al. 1987). It has been demonstrated to be a valid and reliable method (Merrick et al. 1987), and has advantages over other consensus methods. Equal weight is given to the opinion of all participants, and anonymous polling of views prevents one individual influencing the views of another. Some consensus methods require complete agreement and have therefore been criticised for producing "bland" recommendations which have already been implemented (Fink et al. 1984, Rennie 1981). By contrast, the Delphi method allows for minor degrees of dissension by omitting the most atypical responses before assessing consensus. The reliability of the Delphi method increases with the size of the panel (Dalkey 1969) and, since questionnaires can be posted, there are no geographical constraints on the selection of participants.

Application of this method to chronic critical lower limb ischaemia identified those clinical scenarios for which there was good agreement on how patients should be managed. These can be used as the basis of clinical guidelines. Of equal importance was the identification of those clinical situations where consensus was lacking. Opinion was divided on the most appropriate management of patients with occluded femoral, popliteal and proximal tibial arteries, but patent arteries at the ankle or foot level. In such situations, some surgeons would advocate femorocrural reconstruction, especially if a suitable vein is available for autologous grafting. However this is a time-consuming procedure requiring high levels of surgical expertise and vascular laboratory and radiological input, and it does not find unanimous support (Anon 1992, Skillman 1993). Highlighting such areas of divergent opinion helps to target future studies at those areas where they are most needed.

On comparing actual clinical practice with the consensus indications, 55 (14%) of the operations reviewed did not conform to the agreed indications for surgery. The discrepancies demonstrated may reflect inappropriate practice, with some patients being denied beneficial interventions or undergoing unnecessary interventions, thereby exposing themselves to unnecessary risks. If the results are generalised to all units in Scotland, over 170 patients each year may be undergoing major amputation despite arterial reconstruction being more appropriate. Similarly, inappropriate attempts at limb-salvage may be undertaken in around 60 patients each year.

The results of these studies were used to develop guidelines for Scottish vascular surgeons on the appropriate selection of patients for major amputation and arterial reconstruction (Appendix 7). These guidelines have been widely disseminated and discussed at local meetings and have been endorsed by the Scottish Vascular Audit Group who wish to repeat the study at a later date to determine whether variations in practice have since diminished.

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APPENDIX 1

Questionnaire circulated to panellists

QUESTIONNAIRE

INDICATIONS FOR ARTERIAL RECONSTRUCTIVE SURGERY AND PRIMARY MAJOR AMPUTATION IN PATIENTS WITH CHRONIC CRITICAL LIMB ISCHAEMIA

The intention of this questionnaire is to produce, by consensus, a list of indications for performing amputation and arterial reconstruction in patients with chronic critical lower limb ischaemia.

DEFINITION OF PATIENTS

In this questionnaire, the questions refer only to patients with chronic critical lower limb ischaemia who have received maximum conservative treatment and who possess no strong contra-indications to major surgery as defined below:

Chronic critical limb ischaemia

a. recurring ischaemic rest pain requiring regular analgesia for more than two weeks with an ankle systolic pressure at or below 50 mmHg (excluding diabetics), or
b. tissue loss (ulceration or gangrene) of the foot or toes, with an ankle systolic pressure at or below 50 mmHg (excluding diabetics).

(Second European Consensus Document)

Strong contra-indications to major surgery

a. dementia.
b. severely restricted functional capacity due to co-existing conditions such as respiratory, cardiovascular or cerebrovascular disease.
c. markedly reduced life-expectancy (less than twelve months) due to factors such as very advanced age, inoperable cancer or life-threatening conditions.
d. strong opposition from the patient to any intervention or a particular procedure.
e. judged by the anaesthetist to be unsuitable for major reconstruction.

Maximum conservative treatment

a. adequate attempts at pain relief comprising: keeping the leg dependent plus regular analgesics including opiates, nerve blocks or epidural if indicated.
b. trial of prostanoids in patients in whom PTA and arterial reconstruction are contraindicated, technically impossible or have failed.
c. adequate treatment of co-existing conditions such as hyperlipidaemia, diabetes and hypertension.
d. cessation of beta-blocker treatment in hypertensives and replacement with vasodilating drugs.
e. antibiotic therapy for systemic infections.
f. sub-cutaneous heparin in patients confined to bed, and antiplatelet drugs in ambulatory patients.
g. debridement of necrotic tissue, drainage of pus and topical anti-infective treatment in patients with tissue loss and superficial infections
h. patient strongly advised to stop smoking.

SCORING OF INDICATIONS FOR AMPUTATION AND ARTERIAL RECONSTRUCTION

In each question you are presented with the following information on the patient: the presence or absence of rest pain; extent of tissue loss; angiogram findings; and whether or not a suitable vein is available for reconstruction. Given this information you are then requested to score the appropriateness of carrying out both a primary major amputation (above, below or through knee) and arterial reconstruction on this patient using the following scale.

Appropriateness Scale

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

You circle on separate scales one number to signify the appropriateness of primary major amputation and one number for arterial reconstruction. The amputation and reconstruction scales do not have to mirror each other but are scored separately.

EXAMPLE

Suppose that a patient has rest pain plus deep heel or mid foot tissue loss, and angiogram suggestive of complete occlusion of the arterial tree (see angiogram I on the sheet attached to the questionnaire) and no vein is available for reconstruction. The question is structured as follows:

	Primary major amputation (circle one number)	Arterial reconstruction (circle one number)	
4. Tissue loss with/without rest pain			
ii. deep, heel or mid-foot tissue loss			
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(218)

By circling the numbers shown you would be indicating that, in such a patient, amputation would be extremely appropriate and arterial reconstruction extremely inappropriate.

Please indicate the appropriateness of primary major amputation (above, below or through knee) and arterial reconstruction for the following clinical situations. You can detach the angiogram sheet from the main questionnaire for ease of reference. Please skim through the questionnaire before beginning so that you can see how it is structured.

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

1. Rest pain with no tissue loss

+ rest pain

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(1)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(2)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(3)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(4)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(5)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(6)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(7)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(8)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(9)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(10)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(11)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(12)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(13)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(14)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(15)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(16)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(17)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(18)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(19)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(20)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(21)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(22)

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

2. Tissue loss only. No rest pain.

i. digital tissue loss only

	Primary major amputation (circle one number)	Arterial reconstruction (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(23)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(24)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(25)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(26)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(27)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(28)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(29)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(30)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(31)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(32)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(33)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(34)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(35)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(36)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(37)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(38)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(39)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(40)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(41)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(42)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(43)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(44)

no rest pain

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

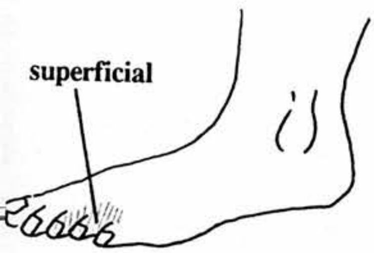
⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

2. Tissue loss only. No rest pain.

ii. superficial, forefoot tissue loss (extending no more than 3cm proximally to interdigital cleft on dorsum of foot and not proximal to base of toes on plantar surface ie. transmetatarsal amputation is possible)



no rest pain

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(45)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(46)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(47)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(48)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(49)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(50)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(51)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(52)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(53)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(54)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(55)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(56)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(57)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(58)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(59)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(60)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(61)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(62)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(63)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(64)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(65)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(66)

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

⇑

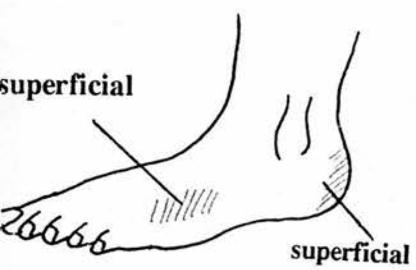
equivocal

(neither clearly appropriate nor clearly inappropriate)

2. Tissue loss only. No rest pain.

iii. superficial, heel or mid-foot tissue loss

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(67)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(68)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(69)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(70)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(71)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(72)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(73)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(74)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(75)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(76)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(77)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(78)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(79)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(80)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(81)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(82)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(83)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(84)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(85)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(86)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(87)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(88)



no rest pain

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

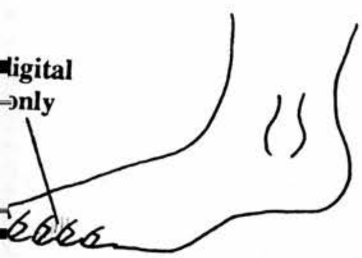
⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

3. Tissue loss plus rest pain

i. digital tissue loss only



+ rest pain

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(89)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(90)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(91)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(92)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(93)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(94)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(95)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(96)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(97)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(98)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(99)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(100)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(101)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(102)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(103)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(104)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(105)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(106)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(107)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(108)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(109)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(110)
L vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(111)
L no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(112)
M vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(113)
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(114)

extremely inappropriate ⇒ <u>1</u> 2 3 4 <u>5</u> 6 7 8 <u>9</u> ⇐ extremely appropriate

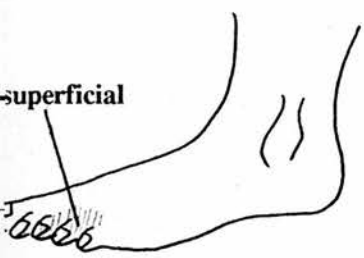
⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

3. Tissue loss plus rest pain

ii. superficial, forefoot tissue loss (extending no more than 3cm proximally to interdigital cleft on dorsum of foot and not proximal to base of toes on plantar surface ie. transmetatarsal amputation is possible)



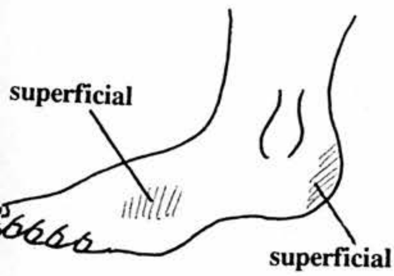
+ rest pain

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(115)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(116)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(1[illegible])
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(118)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(119)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(120)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(121)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(122)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(123)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(124)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(125)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(126)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(127)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(128)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(129)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(130)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(131)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(132)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(133)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(134)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(135)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(136)
L vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(137)
L no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(138)
M vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(139)
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(140)

extremely inappropriate ⇒ <u>1</u> 2 3 4 <u>5</u> 6 7 8 <u>9</u> ⇐ extremely appropriate
⇑
equivocal
(neither clearly appropriate nor clearly inappropriate)

3. Tissue loss plus rest pain

iii. superficial, heel and/or mid-foot tissue loss



+ rest pain

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(141)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(142)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(143)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(144)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(145)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(146)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(147)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(148)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(149)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(150)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(151)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(152)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(153)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(154)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(155)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(156)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(157)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(158)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(159)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(160)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(161)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(162)
L vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(163)
L no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(164)
M vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(165)
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(166)

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

⇑

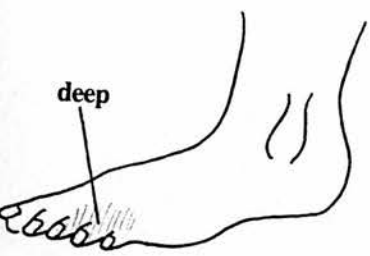
equivocal

(neither clearly appropriate nor clearly inappropriate)

4. Tissue loss with or without rest pain

i. deep, forefoot tissue loss (extending no more than 3cm proximally to interdigital cleft on dorsum of foot and not proximal to base of toes on plantar surface ie. transmetatarsal amputation is possible)

	Primary major amputation (circle one number)	**Arterial reconstruction** (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(167)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(168)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(169)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(170)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(171)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(172)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(173)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(174)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(175)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(176)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(177)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(178)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(179)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(180)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(181)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(182)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(183)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(184)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(185)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(186)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(187)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(188)
L vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(189)
L no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(190)
M vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(191)
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(192)



+/- rest pain

extremely inappropriate ⇒ 1 2 3 4 5 6 7 8 9 ⇐ extremely appropriate

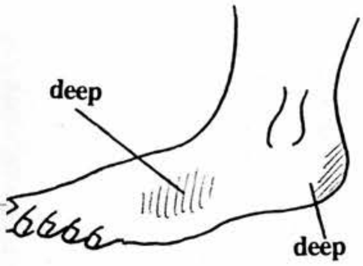
⇑

equivocal

(neither clearly appropriate nor clearly inappropriate)

4. Tissue loss with or without rest pain

ii. deep, heel or mid-foot tissue loss



+/- rest pain

	Primary major amputation (circle one number)	Arterial reconstruction (circle one number)	
A vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(193)
A no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(194)
B vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(195)
B no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(196)
C vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(197)
C no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(198)
D vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(199)
D no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(200)
E vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(201)
E no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(202)
F vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(203)
F no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(204)
G vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(205)
G no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(206)
H vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(207)
H no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(208)
I vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(209)
I no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(210)
J vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(211)
J no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(212)
K vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(213)
K no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(214)
L vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(215)
L no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(216)
M vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(217)
M no vein	1 2 3 4 5 6 7 8 9	1 2 3 4 5 6 7 8 9	(218)

ANGIOGRAM SCORES

Definitions

Severe inflow obstruction is defined as angiographic evidence of advanced disease of the aorto-iliac vessels, comprising majoi stenoses (>10cm long or >70% reduction in lumen) or complete occlusion.

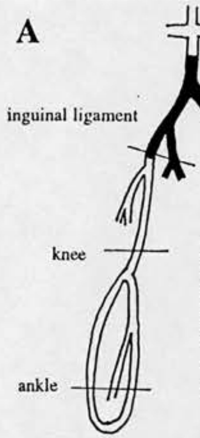
Severe outflow obstruction is defined as angiographic evidence of:

a. severe disease of the distal popliteal artery, due to either complete occlusion or long (>10cm) stenoses resulting in >70% narrowing of the lumen, as well as;

b. occlusion of the tibial arteries, resulting in no vessel flowing into the plantar arch which is both visibly patent on agiogram and suitable for distal anastomosis, or;

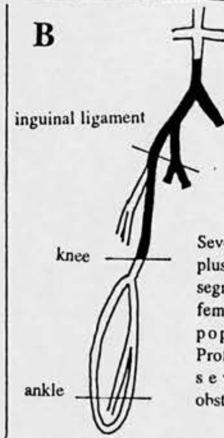
c. no other evidence of a vessel suitable for distal anastomosis by any criterion including exploration on the operating table or vascular laboratory tests.

A



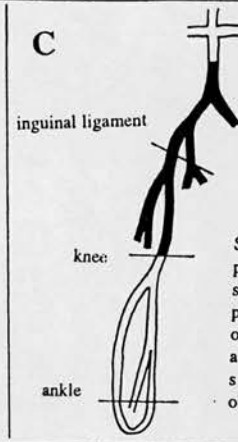
Severe inflow obstruction. Superficial and/or profunda femoral plus popliteal and tibial arteries free from complete occlusions or long stenoses.

B



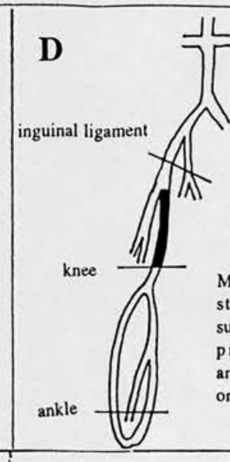
Severe inflow obstruction plus no visibly patent segment in superficial femoral or proximal popliteal arteries. Profunda patent and no severe outflow obstruction.

C



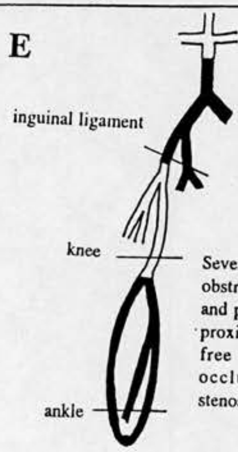
Severe inflow obstruction plus no visibly patent segment in superficial or profunda femoral arteries or proximal popliteal artery. No evidence of severe outflow obstruction.

D



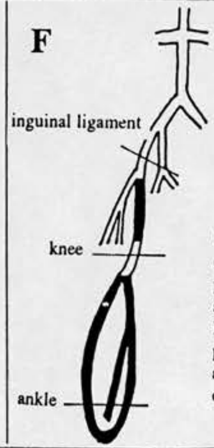
Major occlusions or long stenoses within the superficial femoral and proximal popliteal arteries. No severe inflow or outflow obstruction.

E



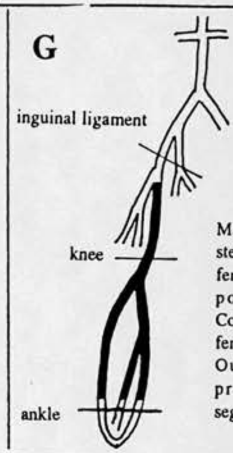
Severe inflow and outflow obstruction. Superficial and profunda femoral and proximal popliteal arteries free from complete occlusions or long stenoses.

F



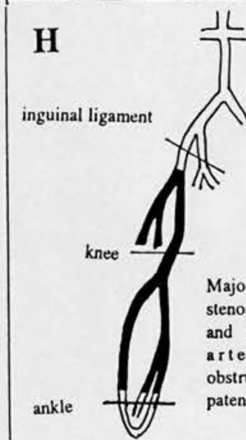
Severe outflow obstruction plus no visibly patent segment in superficial femoral artery. Profunda femoral and popliteal arteries patent and no severe inflow obstruction.

G



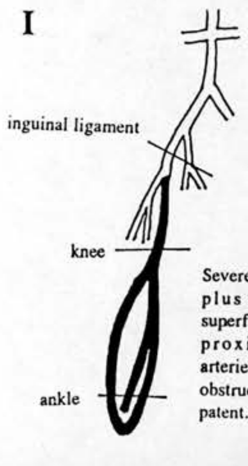
Major occlusions and long stenoses within superficial femoral and proximal popliteal arteries. Common and profunda femoral arteries patent. Outflow obstruction present but patent segments at ankle/foot.

H



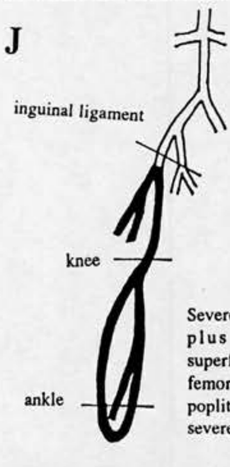
Major occlusions and long stenoses within femoral and proximal popliteal arteries. Outflow obstruction present but patent segments at ankle/fo

I



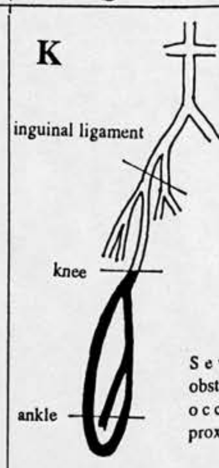
Severe outflow obstruction plus occlusion of superficial femoral and proximal popliteal arteries. No severe inflow obstruction and profunda patent.

J



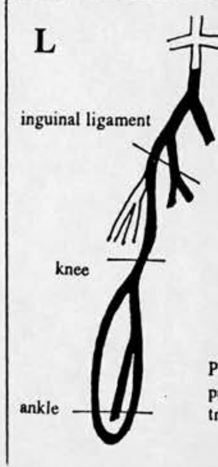
Severe outflow obstruction plus occlusion of superficial and profunda femoral and proximal popliteal arteries. No severe inflow obstruction.

K



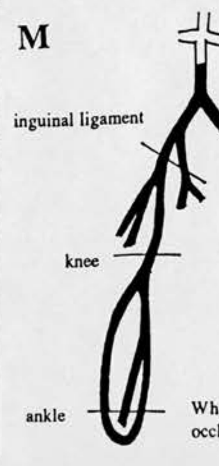
Severe outflow obstruction. No major occlusions more proximally.

L



Profunda femoral artery patent. Rest of arterial tree occluded.

M



Whole arterial tree occluded.

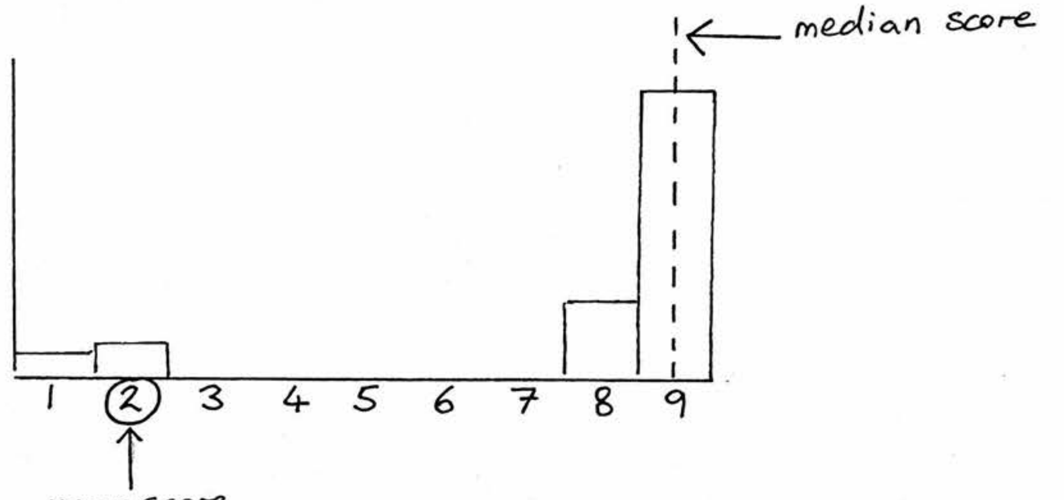
APPENDIX 2

Feedback circulated to panellists

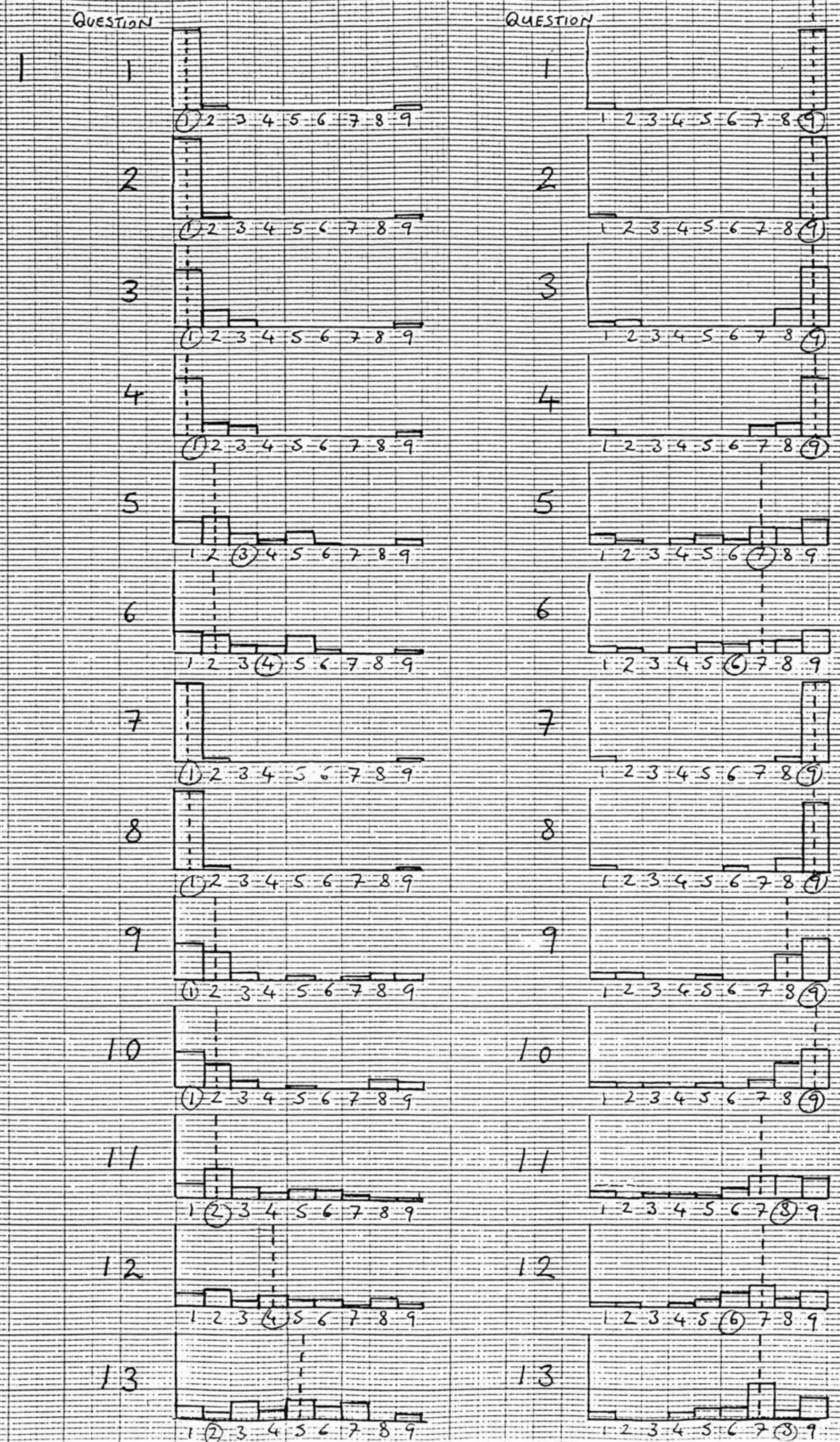
ROUND ONE RESULTS

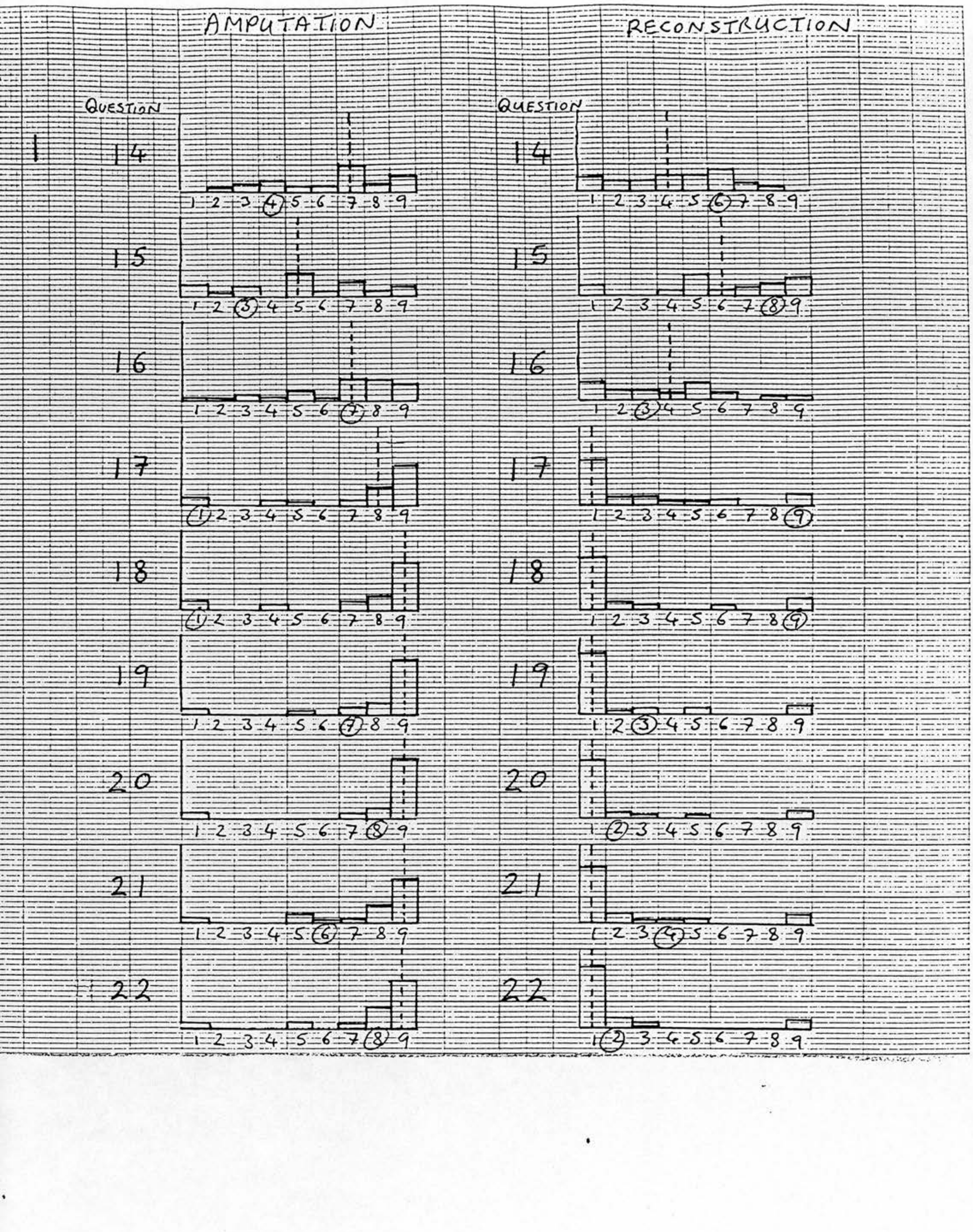
Enclosed, for your information, are the results of the first round of this questionnaire.

For each question, the group scores are presented in the form of a histogram.
In addition, the median score and your own score are indicated as shown below:

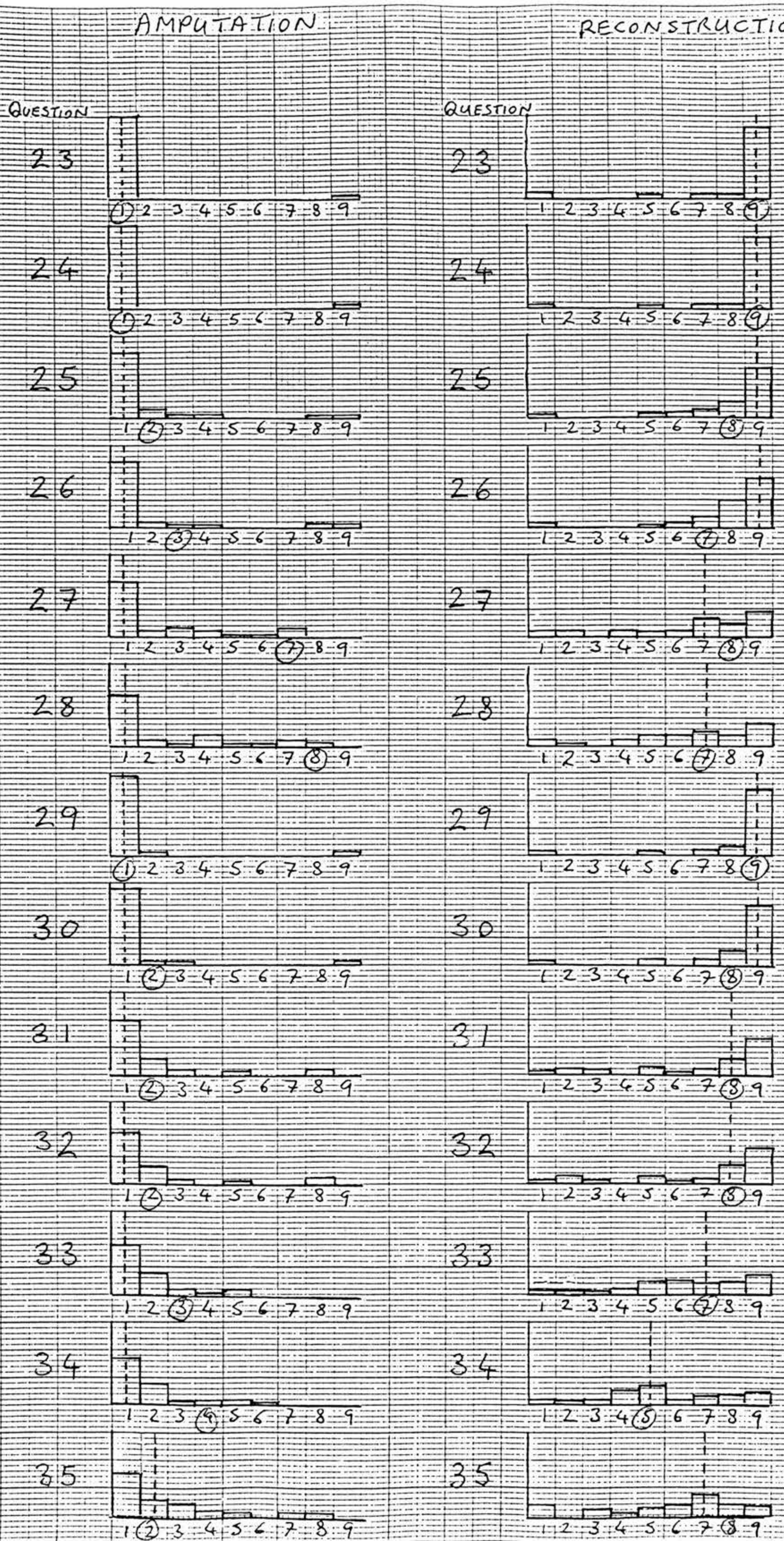


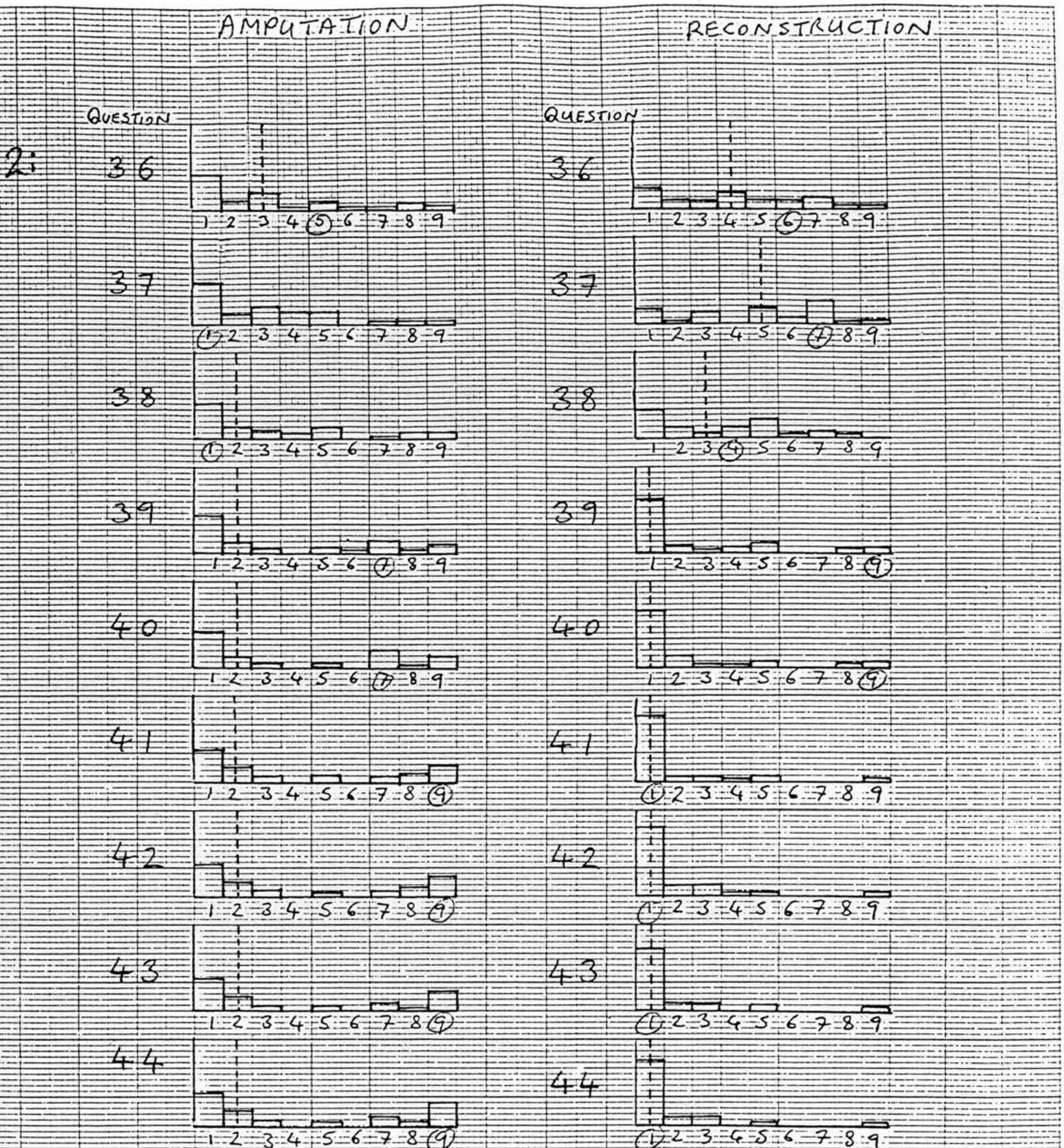
AMPUTATION RECONSTRUCTION



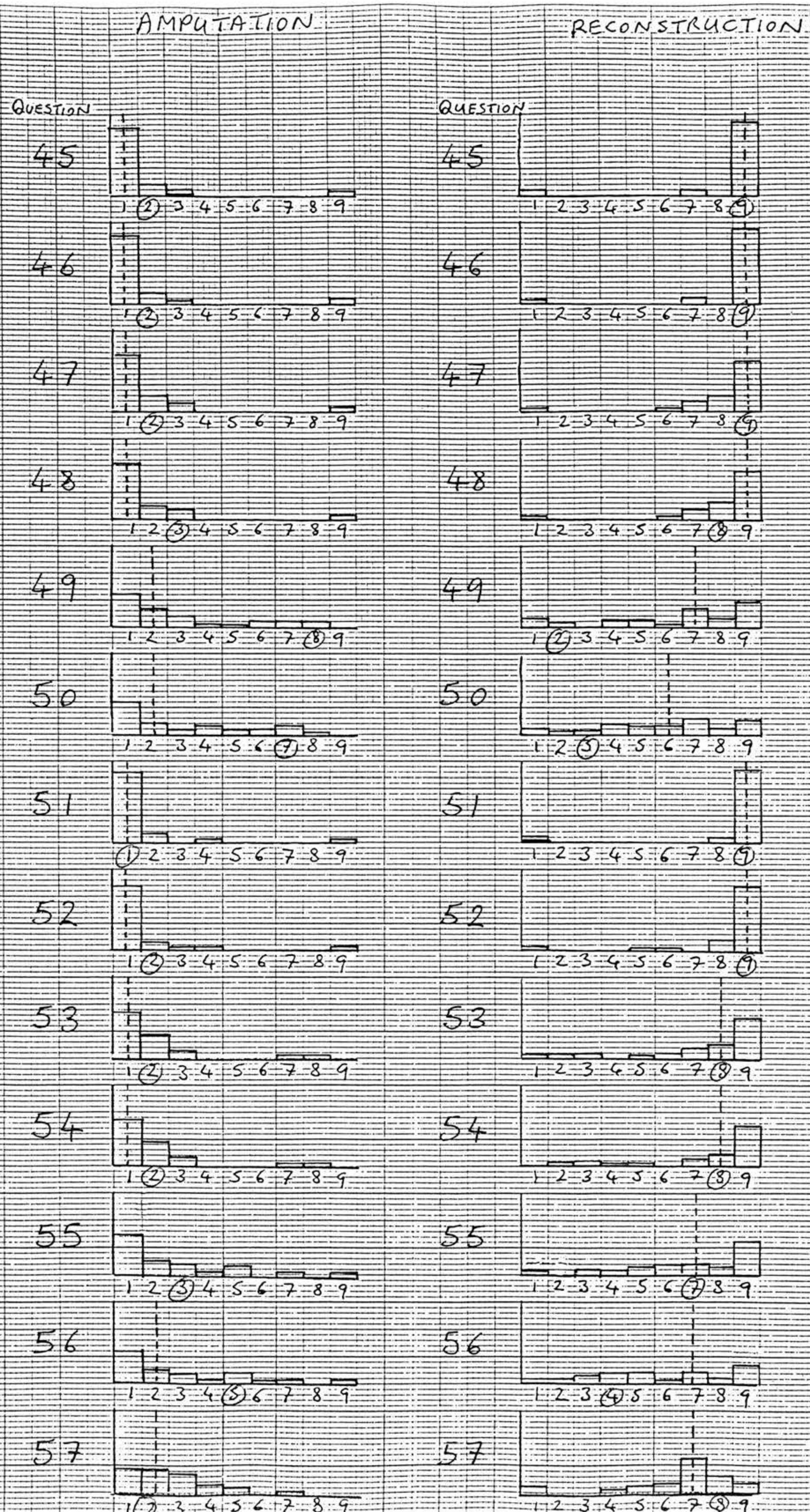

AMPUTATION
RECONSTRUCTION
QUESTION
1
14
15
16
17
18
19
20
21
22
1 2 3 4 5 6 7 8 9

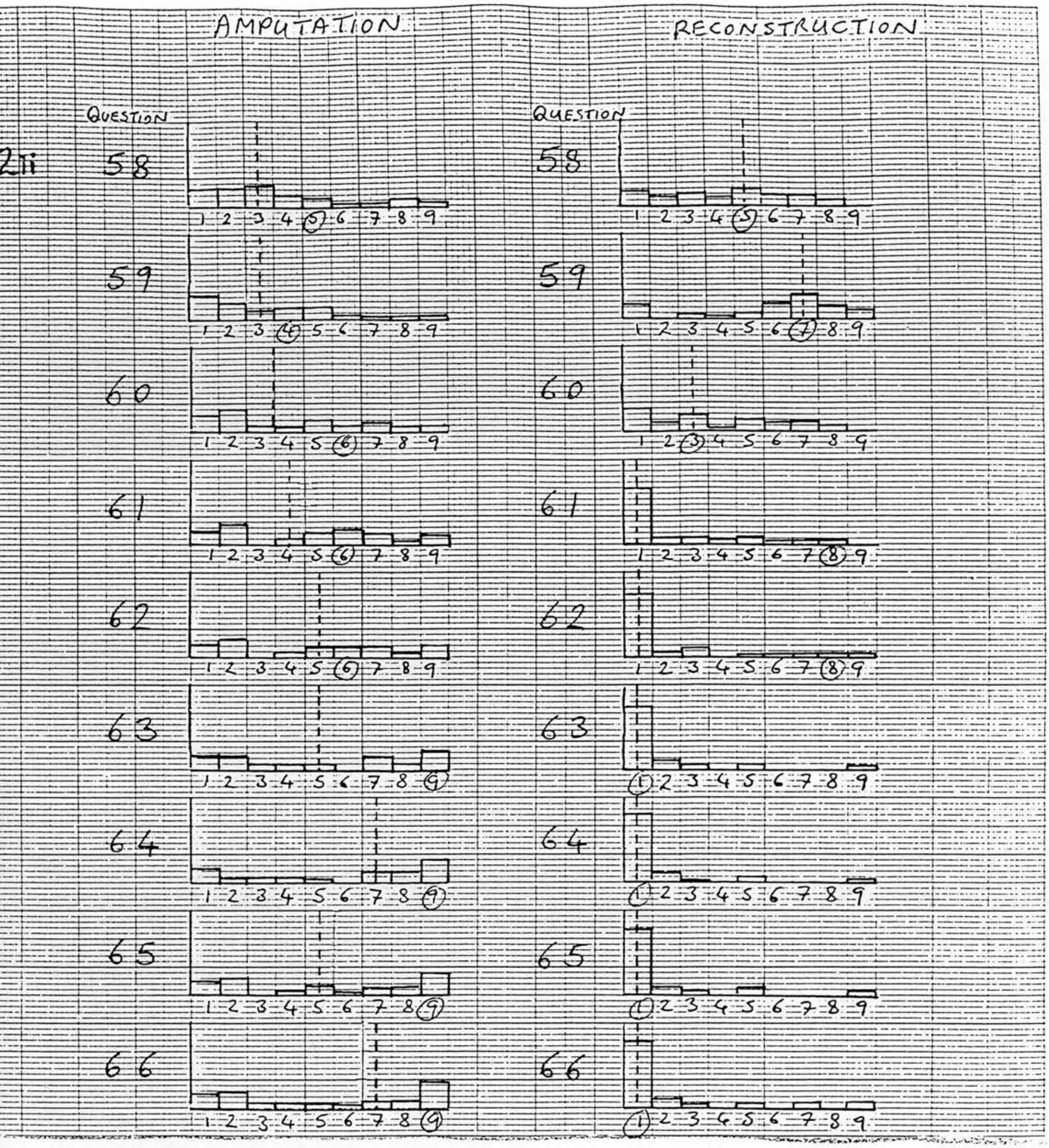
2i


AMPUTATION
RECONSTRUCTION
QUESTION
23
24
25
26
27
28
29
30
31
32
33
34
35
1 2 3 4 5 6 7 8 9


AMPUTATION
RECONSTRUCTION
2:
QUESTION
36
37
38
39
40
41
42
43
44
QUESTION
36
37
38
39
40
41
42
43
44
1 2 3 4 5 6 7 8 9

2ii


AMPUTATION
RECONSTRUCTION
QUESTION
45
46
47
48
49
50
51
52
53
54
55
56
57
1 2 3 4 5 6 7 8 9


2ii
AMPUTATION
RECONSTRUCTION
QUESTION
58
59
60
61
62
63
64
65
66
QUESTION
58
59
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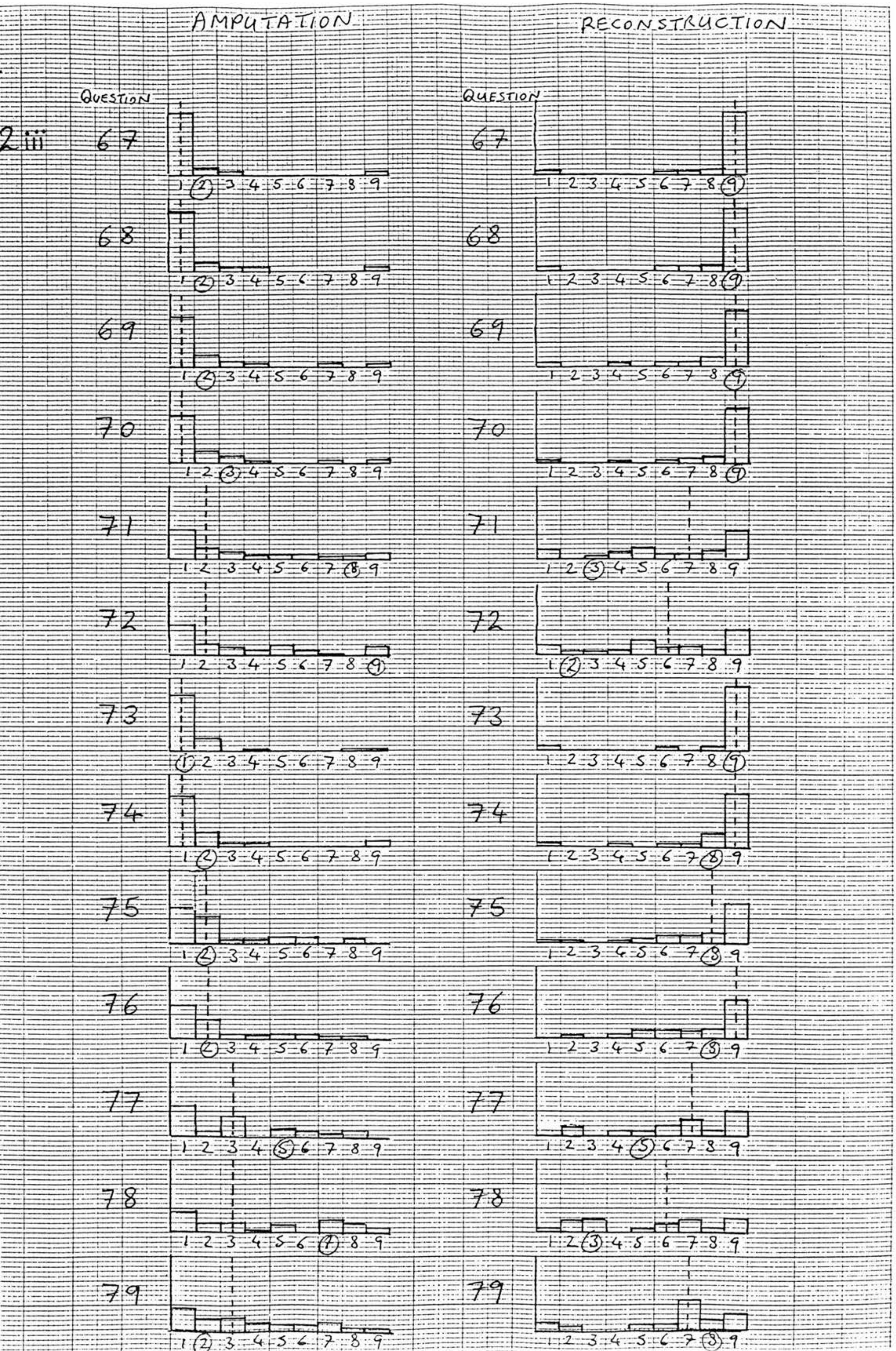
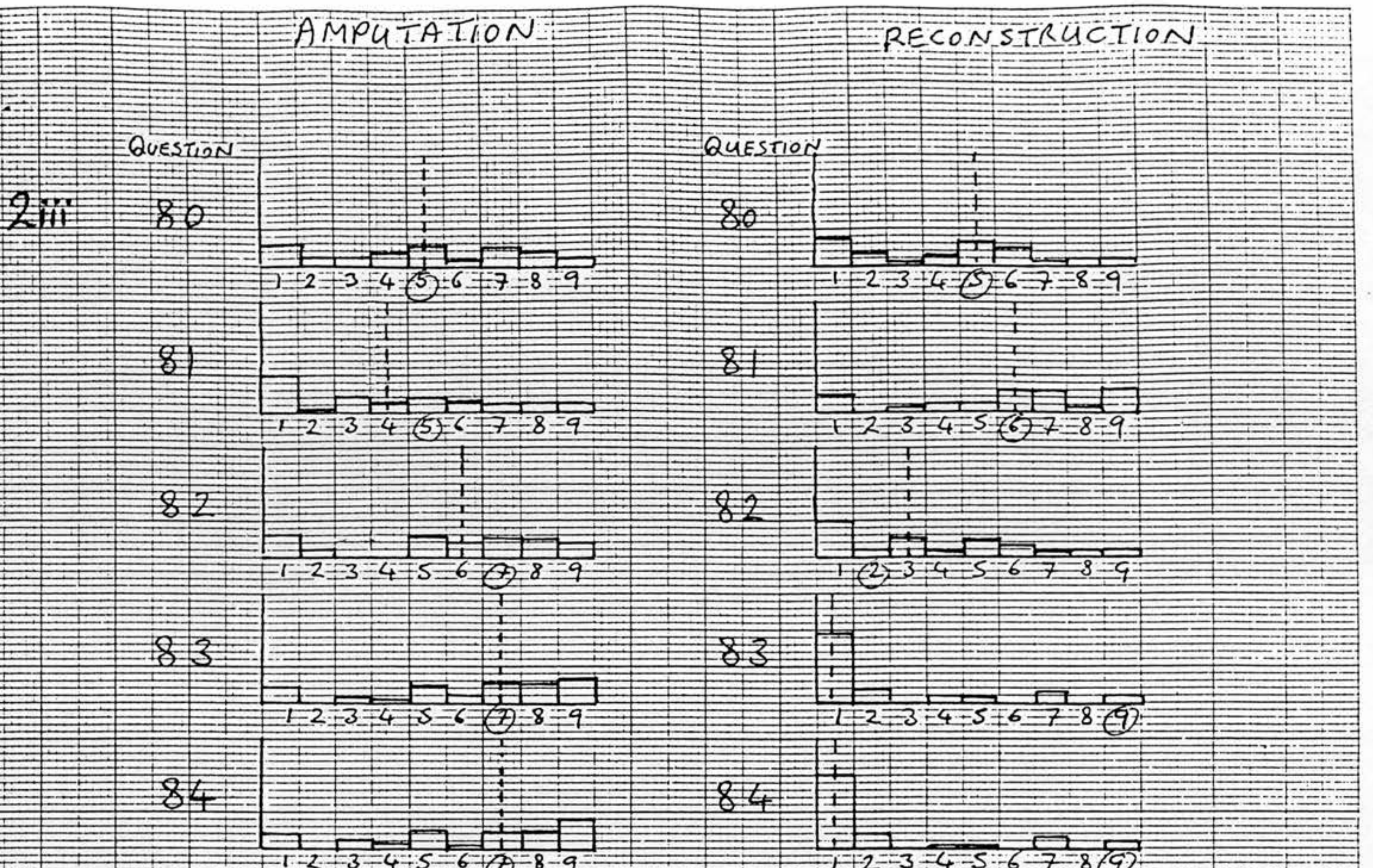
61
62
63
64
65
66
1 2 3 4 5 6 7 8 9



AMPUTATION
RECONSTRUCTION
2 iii
QUESTION
QUESTION
67
68
69
70
71
72
73
74
75
76
77
78
79
1 2 3 4 5 6 7 8 9


AMPUTATION
RECONSTRUCTION
QUESTION
QUESTION
2iii
80
81
82
83
84
86
86
87
88
80
81
82
83
84
85
86
87
88
1 2 3 4 5 6 7 8 9

AMPUTATION

QUESTION

3i

89

90

91

92

93

94

95

96

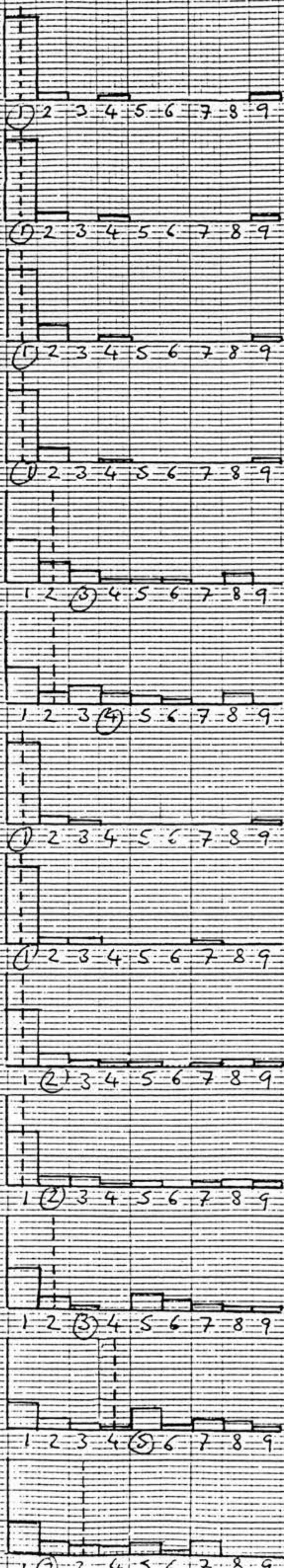
97

98

99

100

101



RECONSTRUCTION

QUESTION

89

90

91

92

93

94

95

96

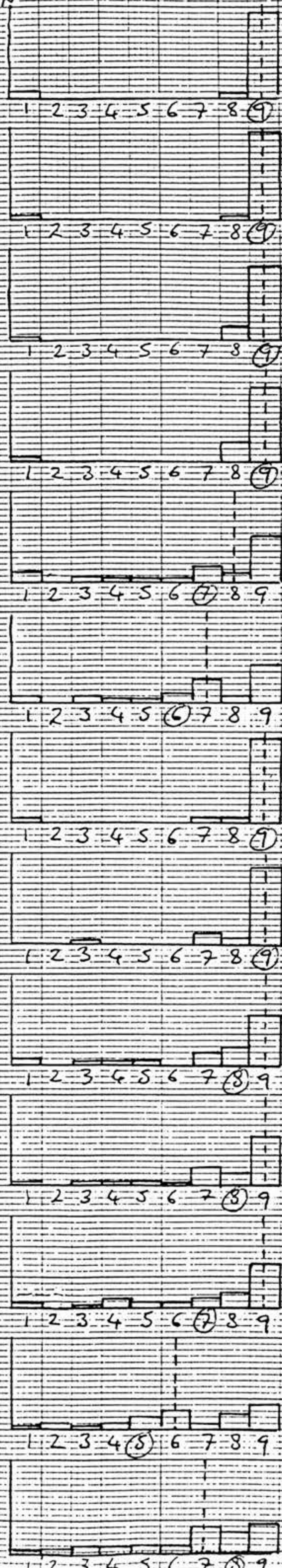
97

98

99

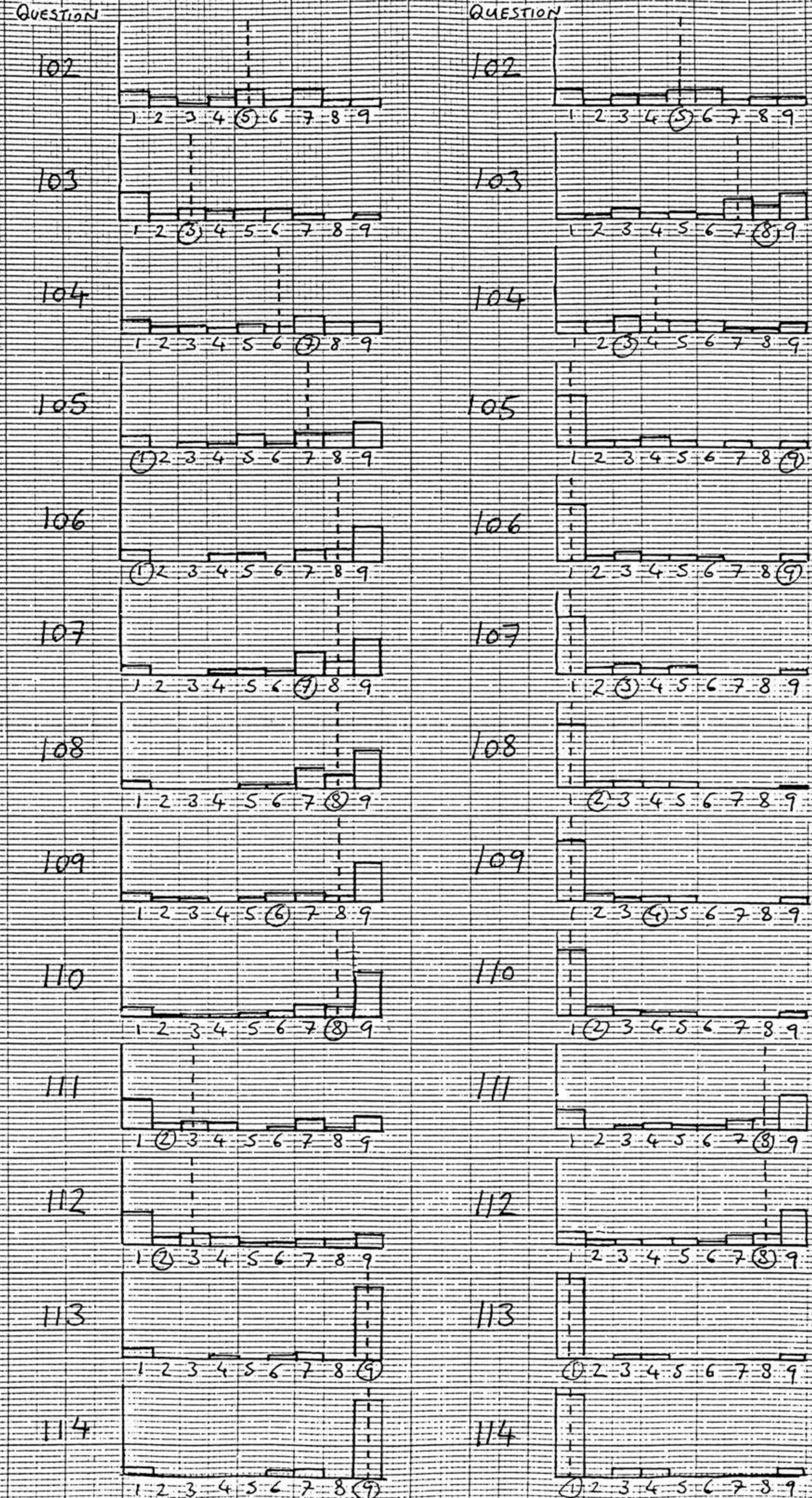
100

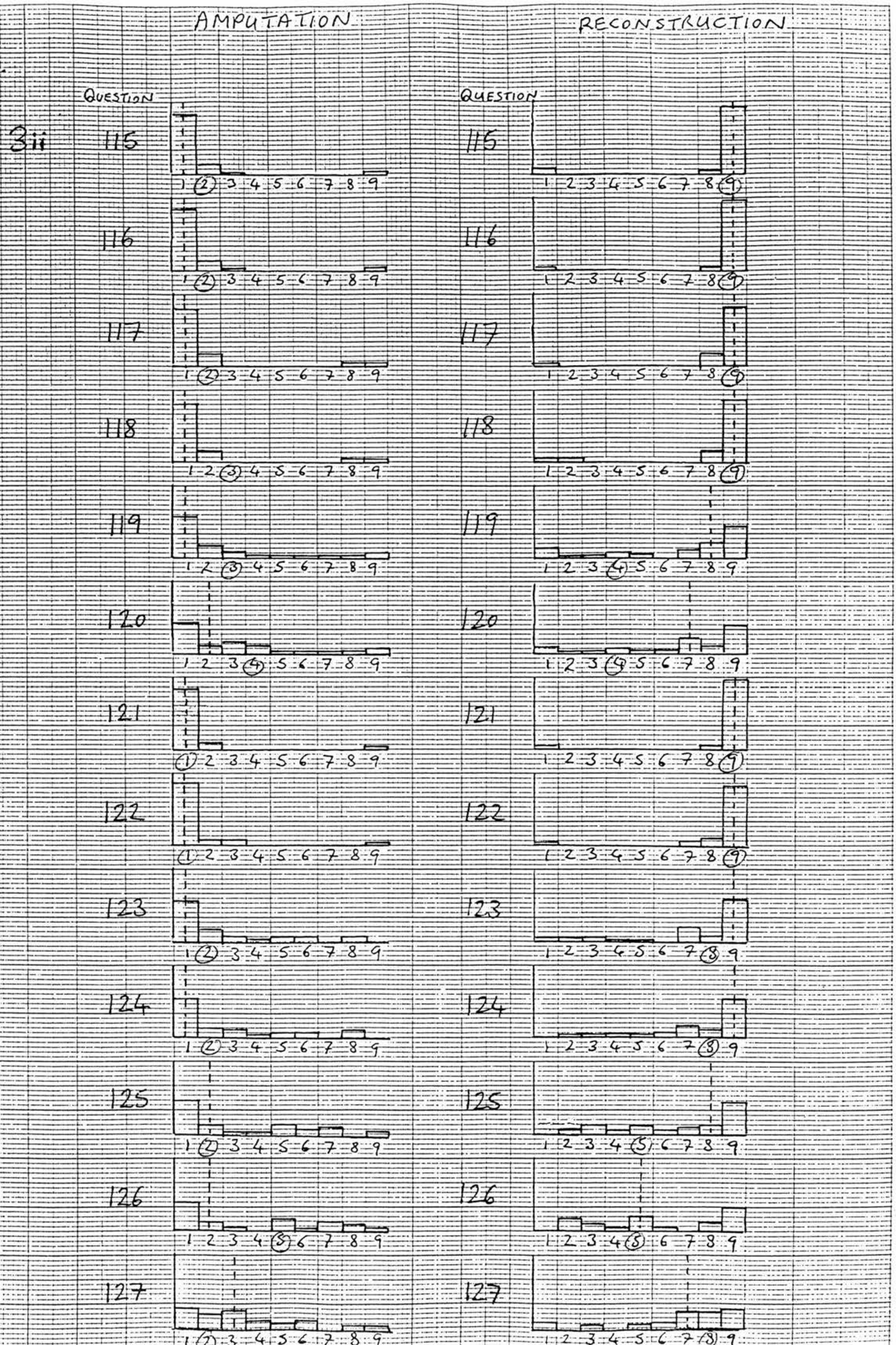
101



AMPUTATION RECONSTRUCTION

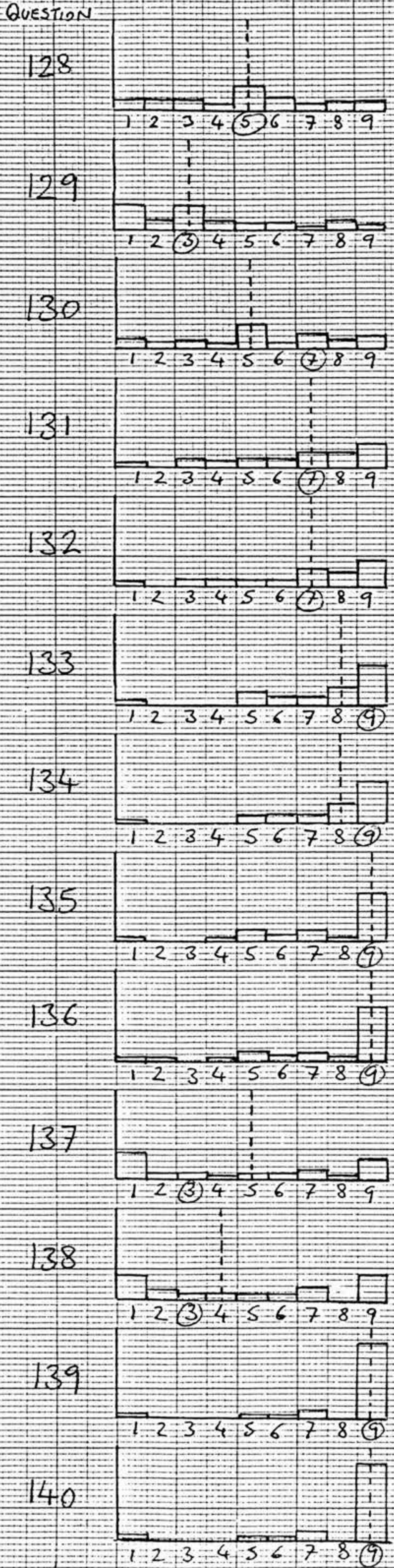
3i



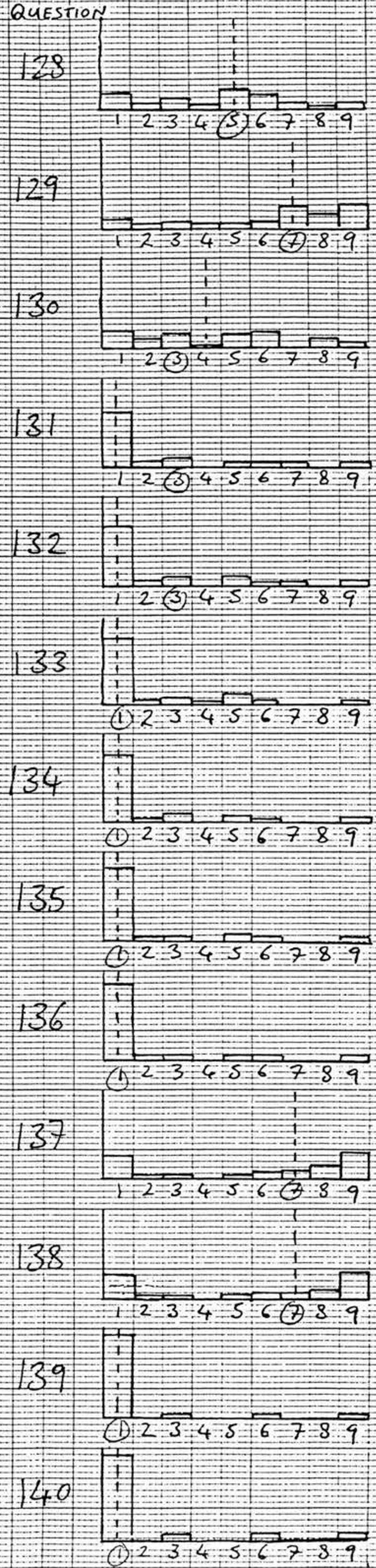

AMPUTATION
RECONSTRUCTION
3ii
QUESTION
115
116
117
118
119
120
121
122
123
124
125
126
127
QUESTION
115
116
117
118
119
120
121
122
123
124
125
126
127
1 2 3 4 5 6 7 8 9

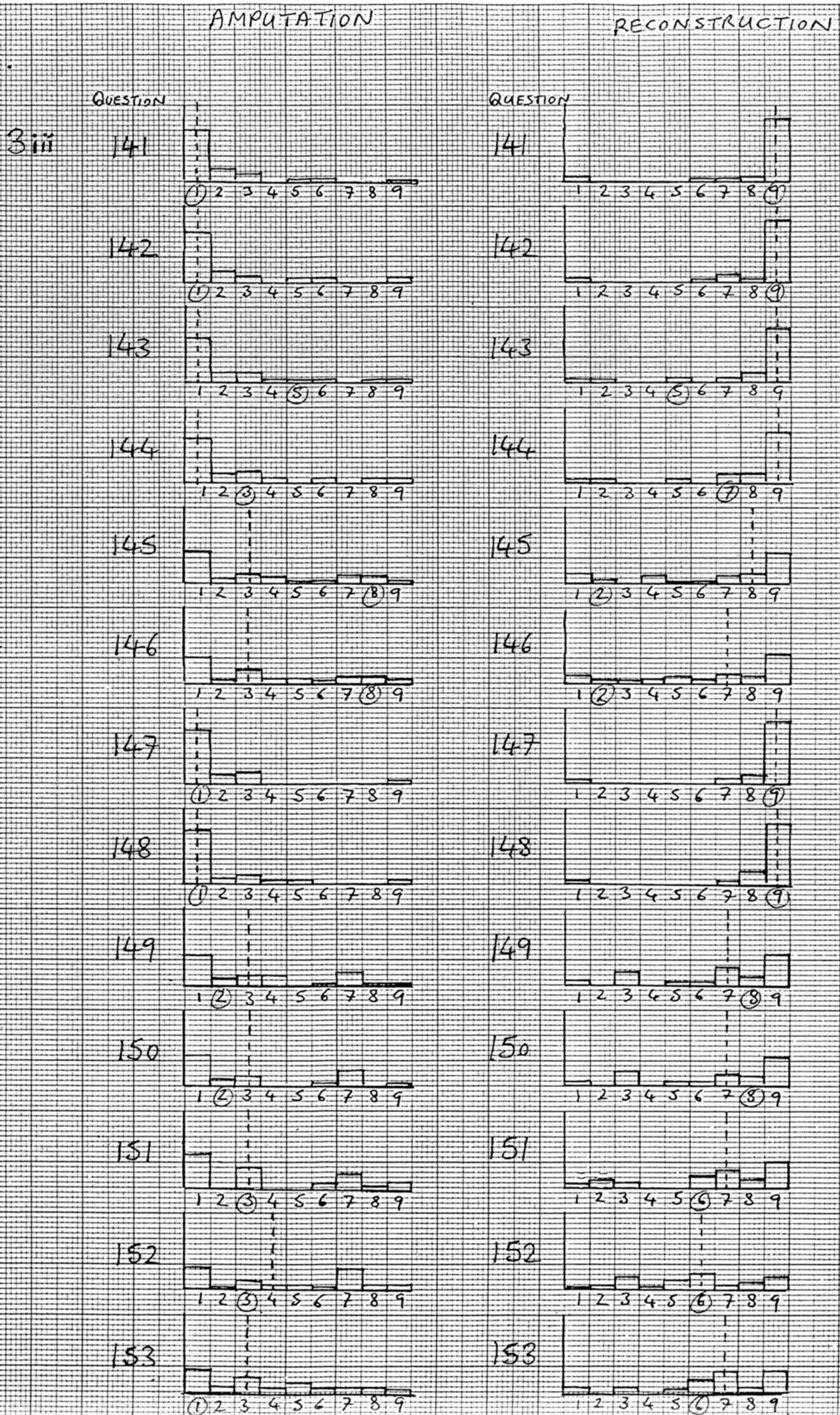
3ii

AMPUTATION



RECONSTRUCTION




AMPUTATION
RECONSTRUCTION
3iii
QUESTION
141
142
143
144
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146
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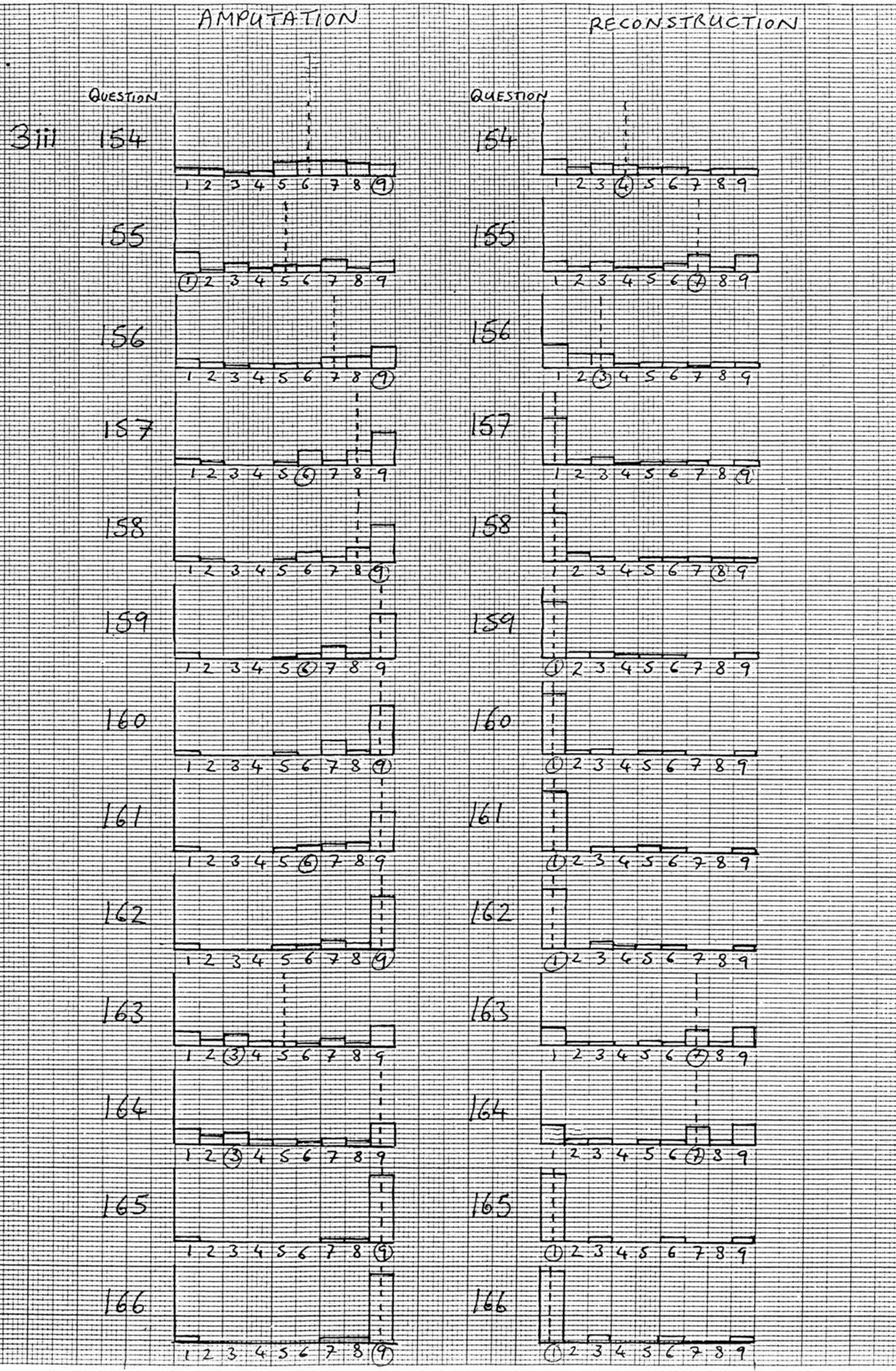
150
151
152
153
1 2 3 4 5 6 7 8 9


3iii
AMPUTATION
RECONSTRUCTION
QUESTION
QUESTION
154
155
156
157
158
159
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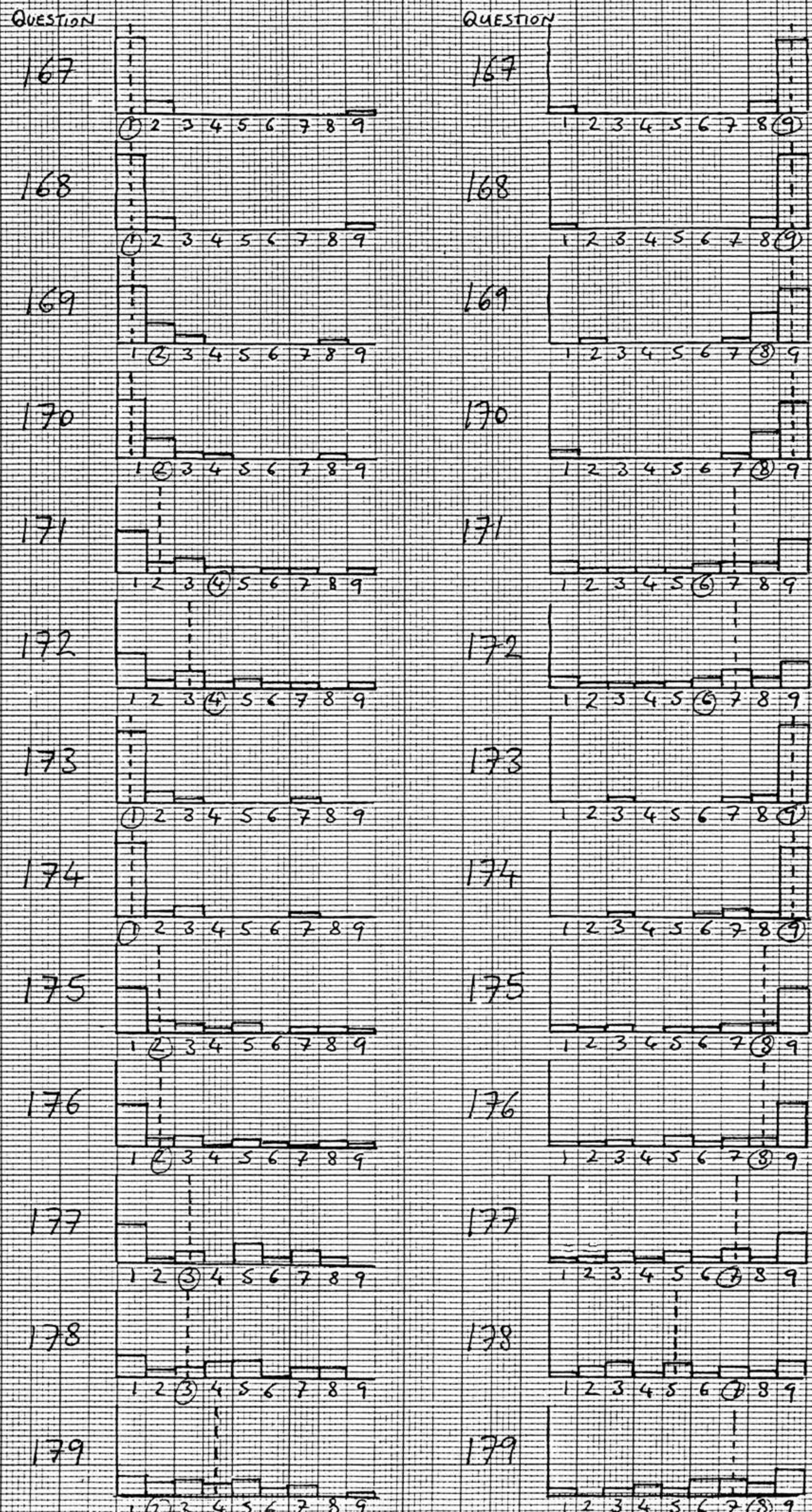
161
162
163
164
165
166
1 2 3 4 5 6 7 8 9

4i

AMPUTATION

RECONSTRUCTION



4i

AMPUTATION

QUESTION

180
181
182
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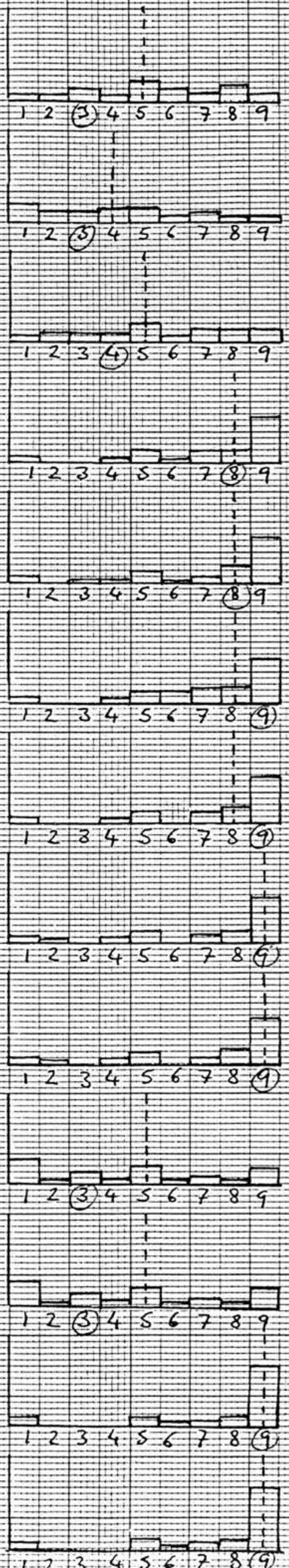
192



RECONSTRUCTION

QUESTION

180
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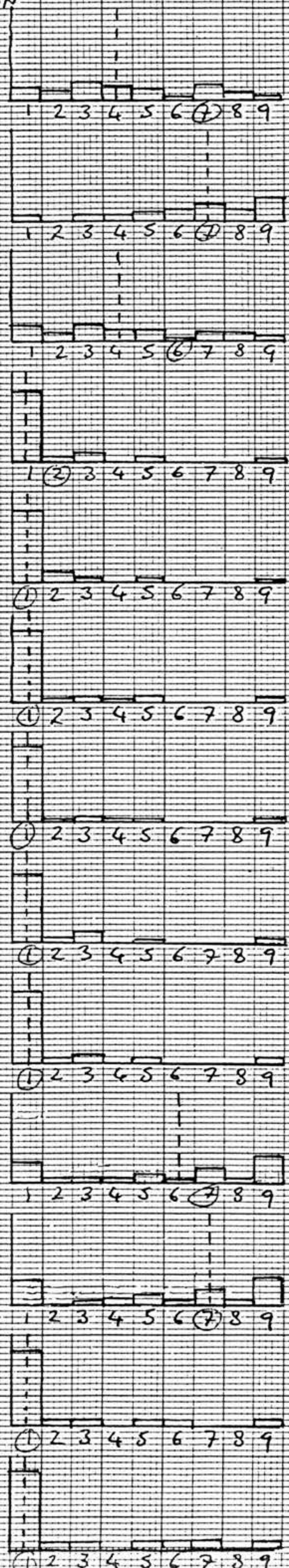
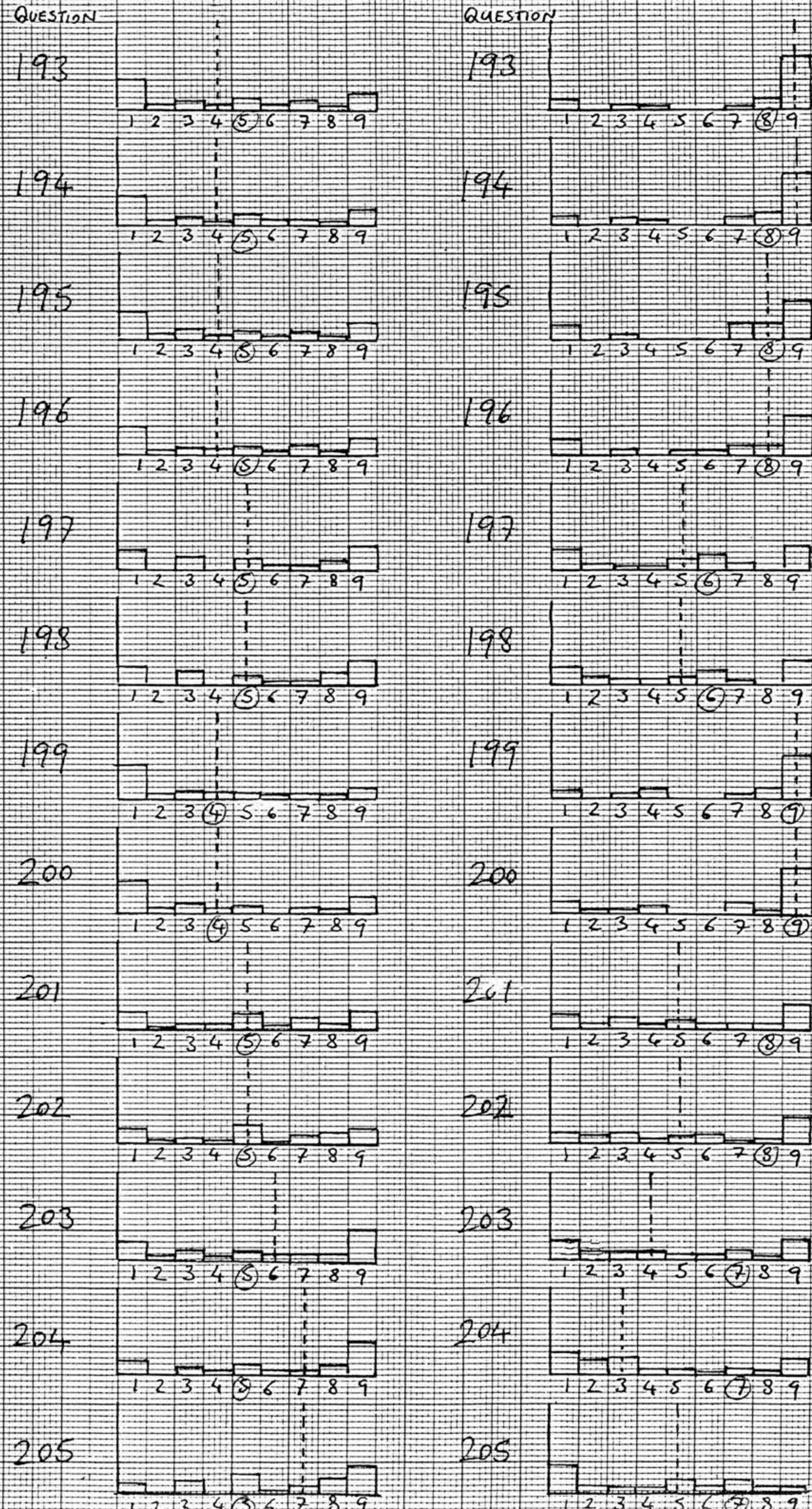
191
192



AMPUTATION RECONSTRUCTION

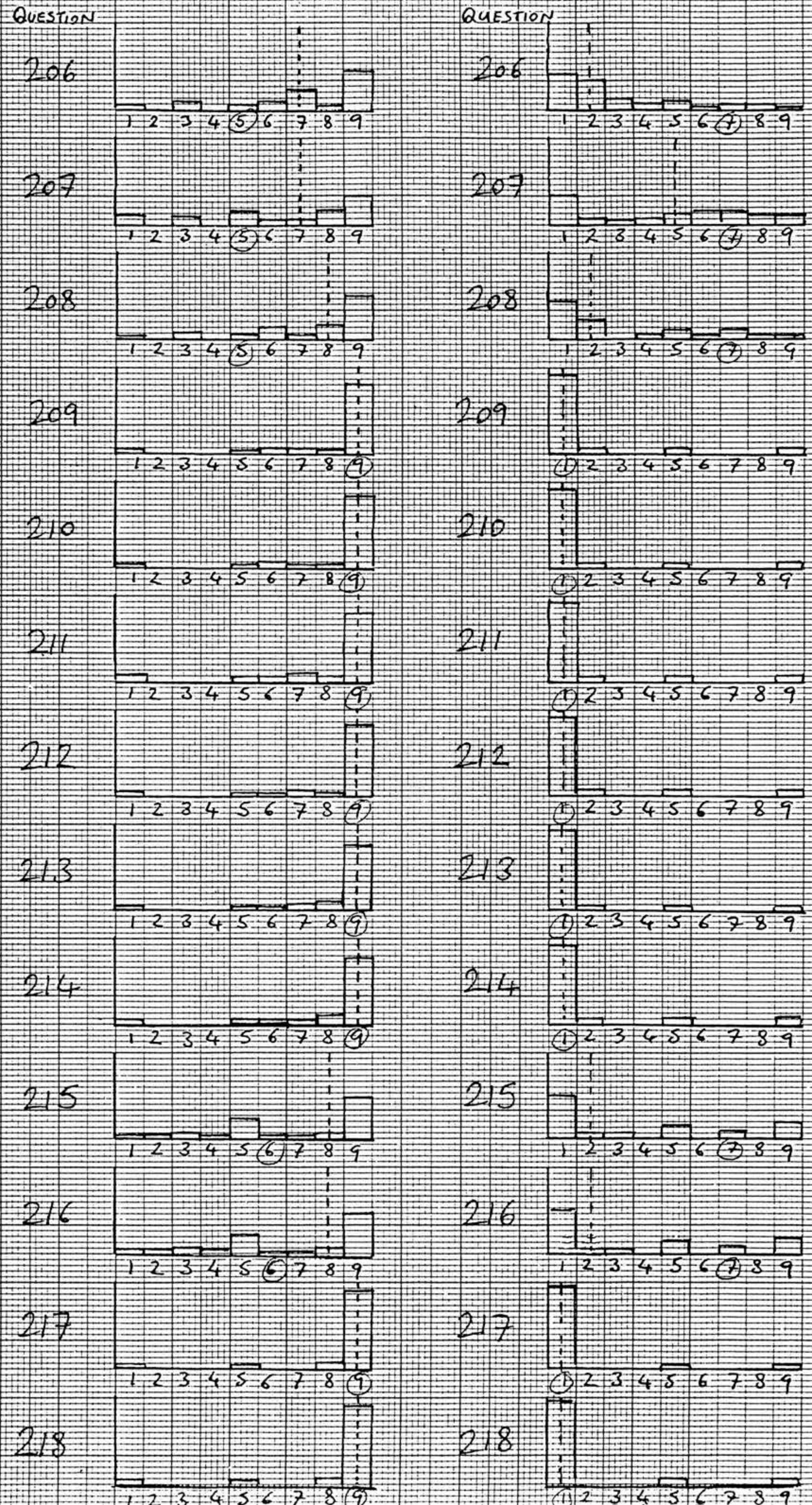
4ii



AMPUTATION

RECONSTRUCTION

4ii



APPENDIX 3

Scores ascribed to clinical scenarios by panellists

round	question	operation	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T	U	V	W	X	Y	Z	AA	AB	AC	median	agreement	appropriateness
1	1	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	Y	A
1	2	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
1	3	ARC	9	9	9	9	8	8	9	9	9	9	7	1	9	9	9	9	9	9	9	9	8	7	9	8	9	8	9	9	8	9	Y	A
1	4	ARC	9	8	9	9	8	8	9	9	9	9	7	1	9	9	9	9	9	9	9	9	8	7	9	7	9	8	9	9	7	9	Y	A
1	5	ARC	7	6	5	1	8	7	9	4	9	9	7	9	8	9	9	5	9	1	2	9	8	7	4	5	8	7	1	9	8	7	N	E
1	6	ARC	6	5	5	1	8	7	9	4	9	9	7	9	8	9	9	5	9	1	2	9	6	7	4	5	8	7	8	6	7	7	N	E
1	7	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	Y	A
1	8	ARC	9	9	9	9	9	8	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	6	9	8	8	9	9	8	9	Y	A
1	9	ARC	9	8	9	9	8	2	9	8	8	8	1	9	8	9	9	5	9	9	1	9	3	8	9	8	8	7	2	9	9	8	N	E
1	10	ARC	9	8	9	9	8	2	7	8	8	8	1	9	8	9	9	5	9	9	1	9	3	8	9	8	8	7	7	9	9	8	N	E
1	11	ARC	8	6	8	9	3	7	9	7	6	8	1	7	7	7	8	8	8	7	1	9	4	9	8	7	8	5	6	9	7	7	N	E
1	12	ARC	6	5	8	9	2	4	7	7	6	8	1	7	7	7	7	5	8	7	1	9	4	9	6	6	7	5	2	9	6	7	N	E
1	13	ARC	8	7	9	1	4	9	7	6	6	7	1	5	7	7	9	9	9	7	7	7	6	7	5	5	9	7	7	9	7	7	N	E
1	14	ARC	6	6	2	1	1	6	5	6	6	7	1	5	3	5	6	5	8	1	7	3	2	7	2	3	6	3	2	5	6	5	N	E
1	15	ARC	8	5	9	1	4	8	8	5	8	5	1	9	7	5	9	9	9	5	1	7	5	6	1	5	9	5	6	9	7	6	N	E
1	16	ARC	3	2	2	1	2	6	4	5	7	5	1	9	3	5	6	5	8	1	1	3	2	4	1	3	6	4	1	5	5	4	N	E
1	17	ARC	9	6	5	1	6	1	2	2	3	3	1	9	1	1	1	1	9	1	9	1	1	2	1	1	1	1	3	1	4	1	N	E
1	18	ARC	9	6	1	1	6	1	2	2	3	3	1	9	1	1	1	1	9	1	9	1	1	1	1	1	1	1	1	1	2	1	N	E
1	19	ARC	3	1	5	1	1	1	1	2	1	3	1	9	1	1	1	1	9	1	9	1	1	1	1	1	1	1	1	1	1	1	N	E
1	20	ARC	2	1	1	1	1	1	1	2	1	3	1	9	1	1	1	1	9	1	9	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	21	ARC	4	1	5	1	1	2	2	1	1	3	1	9	1	1	1	1	9	1	9	1	1	1	1	1	1	1	2	1	2	1	N	E
1	22	ARC	2	1	1	1	1	2	2	1	1	3	1	9	1	1	1	1	9	1	9	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	23	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	8	7	1	9	9	9	Y	A
1	24	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	9	9	Y	A
1	25	ARC	8	9	9	9	6	8	9	8	9	9	7	1	9	9	9	9	9	7	8	9	8	9	9	9	7	6	9	9	8	9	Y	A
1	26	ARC	2	9	9	9	6	8	9	8	9	9	7	1	9	9	9	9	9	7	8	9	8	9	9	9	7	6	9	9	8	9	Y	A
1	27	ARC	8	7	4	1	6	7	7	8	9	9	7	9	9	8	8	5	9	1	7	9	8	9	7	9	6	2	2	5	7	7	N	E
1	28	ARC	7	5	4	1	6	7	5	8	9	9	7	9	9	8	6	5	9	1	7	9	6	8	7	9	6	2	8	5	6	7	N	E
1	29	ARC	9	9	9	9	9	9	9	8	9	9	9	1	9	9	9	9	9	8	9	9	9	9	9	7	8	7	9	9	9	9	Y	A
1	30	ARC	8	9	9	9	9	8	9	8	9	9	9	1	9	9	9	9	9	8	9	9	9	9	9	7	7	5	9	9	8	9	Y	A
1	31	ARC	8	7	8	9	7	2	9	8	9	8	5	9	9	9	8	5	9	1	2	9	3	9	9	9	6	9	3	8	8	8	N	E
1	32	ARC	8	7	8	9	7	2	9	8	9	8	5	9	9	9	8	5	9	1	2	9	3	9	9	9	6	9	2	8	8	8	N	E
1	33	ARC	7	6	8	9	6	4	9	7	6	8	5	9	5	9	7	8	9	2	3	9	4	8	9	5	6	1	6	5	7	7	N	E
1	34	ARC	5	4	8	9	4	4	8	7	6	8	5	9	5	7	5	5	9	2	3	9	4	8	9	3	5	1	2	5	6	5	N	E
1	35	ARC	8	7	9	1	6	8	3	3	8	7	5	7	7	9	3	9	1	1	9	7	6	8	4	5	6	6	7	5	7	7	N	E
1	36	ARC	6	3	1	1	4	7	1	4	4	7	5	7	3	5	1	5	1	1	9	6	2	7	3	4	4	4	2	2	6	4	N	E
1	37	ARC	7	3	9	1	7	8	3	3	7	5	5	7	7	9	3	9	1	1	1	7	5	5	2	6	6	5	6	5	7	5	N	E
1	38	ARC	4	1	1	1	1	7	2	4	5	5	5	7	3	5	1	5	1	1	1	6	2	5	2	4	4	3	1	2	5	3	N	E
1	39	ARC	9	8	5	1	4	1	2	1	1	3	5	9	1	1	1	1	1	1	1	1	1	5	1	1	1	2	2	1	4	1	N	E
1	40	ARC	9	8	1	1	4	1	2	1	1	3	5	9	1	1	1	1	1	1	1	1	1	5	1	1	1	2	2	1	2	1	N	E
1	41	ARC	1	1	5	1	1	1	1	1	1	3	5	9	1	1	1	1	1	1	1	1	1	4	1	1	1	2	2	1	3	1	Y	I
1	42	ARC	1	1	1	1	1	1	1	1	1	3	5	9	1	1	1	1	1	1	1	1	1	4	1	1	1	2	2	1	3	1	Y	I
1	43	ARC	1	1	5	1	1	2	1	1	1	3	5	9	1	1	1	1	1	1	2	1	1	3	1	1	1	2	1	1	3	1	Y	I
1	44	ARC	1	1	1	1	1	2	1	1	1	3	5	9	1	1	1	1	1	1	2	1	1	3	1	1	1	2	1	1	3	1	Y	I
1	45	ARC	9	9	9	9	7	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	7	1	9	9	9	Y	A
1	46	ARC	9	9	9	9	7	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	Y	A
1	47	ARC	9	9	9	9	7	8	9	8	9	9	7	1	9	9	9	9	9	9	7	9	8	8	9	7	8	6	9	9	8	9	Y	A
1	48	ARC	8	9	9	9	7	8	8	8	9	9	7	1	9	9	9	9	9	9	7	9	8	8	9	7	8	6	9	9	8	9	Y	A
1	49	ARC	2	7	4	1	4	7	9	8	9	9	7	4	9	8	6	5	9	1	2	9	8	7	7	9	7	5	1	5	7	7	N	E
1	50	ARC	3	6	4	1	4	7	7	8	9	9	7	4	9	8	4	5	9	1	2	9	6	7	6	9	7	5	7	5	6	6	N	E
1	51	ARC	9	9	9	9	8	9	9	9	9	8	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
1	52	ARC	9	9	9	9	5	8	9	9	9	8	9	1	9	9	9	9	9	9	9	9	9	9	9	9	8	6	9	9	8	9	Y	A
1	53	ARC	8	7	8	9	7	2	9	8	6	7	5	3	9	9	9	9	9	9	9	9	3	8	9	9	6	7	1	9	8	8	N	E
1	54	ARC	8	7	8	9	7	2	9	8	4	7	5	3	9	9	9	9	9	9	9	9	3	8	9	9	6	7	5	9	8	8	N	E
1	55	ARC	7	6	8	9	6	3	9	7	5	7	5	9	5	8	6	3	9	8	1	9	4	9	9	9	6	3	9	9	7	7	N	E
1	56	ARC	4	4	8	9	4	3	7	7	5	7	5	9	3	5	4	3	9	8	1	9	4	9	9	7	5	2	9	7	6	6	N	E
1	57	ARC	8	7	9	1	6	8	5	7	7	5	5	5	7	8	7	8	1	8	7	8	6	7	4	9	7	7	7	9	7	7	N	E
1	58	ARC	5	3	1	1	4	7	3	6	6	5	5	5	1	3	2	8	1	1	7	7	2	6	4	7	5	3	2	5	6	5	N	E
1	59	ARC	7	6	9	1	1	8	6	7	6	3	5	6	7	8	7	8	1	8	1	8	5	4	1	9	7	7	7	9	7	7	N	E
1	60	ARC	3	6	1	1	1	7	3	6	3	3	5	6	1	3	2	8	1	1	1	7	2	3	1	7	5	3	2	5	5	3	N	E
1	61	ARC	8	7	5	1	6	1	3	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	2	1	4	1	N	E
1	62	ARC	8	7	1	1	6	1	3	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	3	1	N	E
1	63	ARC	1	1	5	1	1	1	3	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	2	1	2	1	Y	I
1	64	ARC	1	1	1	1	1	1	2	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	Y	I
1	65	ARC	1	1	5	1	1	2	5	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	N	E
1	66	ARC	1	1	1	1	1	2	7	1	1	2	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	Y	I

1	67	ARC	9	9	9	9	7	8	9	6	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	1	9	9	9	Y	A
1	68	ARC	9	9	9	9	7	8	9	6	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
1	69	ARC	9	9	9	9	8	7	9	6	9	9	9	1	9	9	9	9	9	9	4	9	8	8	9	9	9	8	9	9	9	9	Y	A
1	70	ARC	9	9	9	9	7	7	9	6	9	9	9	1	9	9	9	9	9	9	4	9	8	8	9	9	9	8	9	9	9	9	Y	A
1	71	ARC	3	7	4	1	5	6	9	5	9	9	9	9	9	5	8	5	9	1	1	9	4	8	5	9	8	4	1	6	7	6	N	E
1	72	ARC	2	6	4	1	5	6	7	5	9	9	9	9	9	5	3	5	9	1	1	9	5	8	5	9	8	4	7	6	7	6	N	E
1	73	ARC	9	9	9	9	9	9	9	6	9	9	9	1	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	8	9	Y	A
1	74	ARC	8	9	9	9	7	9	8	6	9	9	9	4	9	9	9	9	9	9	1	9	9	9	9	9	8	8	9	9	8	9	Y	A
1	75	ARC	8	7	6	9	6	2	9	6	9	7	5	9	9	9	9	9	9	8	9	9	5	8	9	9	7	4	1	9	8	8	N	E
1	76	ARC	8	7	6	9	6	2	9	6	9	7	5	9	9	9	9	9	9	8	9	9	5	8	9	9	7	4	5	9	8	8	N	E
1	77	ARC	5	7	7	9	4	2	9	6	9	7	5	9	7	7	6	8	9	2	2	9	6	8	9	9	7	4	6	9	7	7	N	E
1	78	ARC	3	3	7	9	3	2	9	6	9	7	5	9	1	2	3	2	9	2	2	9	3	7	9	7	6	3	3	6	7	6	N	E
1	79	ARC	8	7	9	1	1	7	7	7	8	5	5	9	7	7	6	9	1	9	8	9	7	7	2	9	8	6	7	9	7	7	N	E
1	80	ARC	5	4	1	1	1	3	4	6	6	5	5	9	1	5	1	5	1	1	8	9	2	6	2	7	6	4	2	5	6	5	N	E
1	81	ARC	6	6	9	1	1	4	6	7	6	3	5	9	5	7	6	9	1	9	1	9	7	4	1	9	8	6	6	9	7	6	N	E
1	82	ARC	2	6	1	1	1	3	3	6	4	3	5	9	1	5	1	5	1	1	1	9	2	3	1	7	6	3	1	4	5	3	N	E
1	83	ARC	9	7	4	1	7	2	2	1	7	1	5	9	1	1	1	1	1	1	1	1	1	4	1	1	1	2	1	1	2	1	N	E
1	84	ARC	9	7	1	1	7	2	2	1	7	1	5	9	1	1	1	1	1	1	1	1	1	4	1	1	1	2	1	1	2	1	N	E
1	85	ARC	1	1	4	1	1	1	1	1	7	1	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	N	E
1	86	ARC	1	1	1	1	1	1	1	1	7	1	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	Y	I
1	87	ARC	1	1	4	1	1	1	2	1	7	1	5	9	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	N	E
1	88	ARC	1	1	1	1	1	1	2	1	7	1	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	2	1	Y	I
1	89	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	1	9	9	9	Y	A
1	90	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
1	91	ARC	9	9	9	9	9	8	9	9	9	8	9	1	9	9	9	9	9	9	8	9	8	9	9	9	9	8	9	9	8	9	Y	A
1	92	ARC	9	9	9	9	9	8	9	9	9	8	9	1	9	9	9	9	9	9	8	9	8	9	9	9	9	8	9	9	8	9	Y	A
1	93	ARC	7	8	4	1	9	7	9	9	9	7	9	7	9	9	9	9	9	1	3	9	8	9	3	9	8	6	1	5	7	8	N	E
1	94	ARC	6	7	4	1	9	7	9	9	9	7	9	7	9	9	7	9	9	1	3	9	6	8	3	9	8	6	7	5	7	7	N	E
1	95	ARC	9	9	9	9	9	9	7	9	9	7	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
1	96	ARC	9	9	9	9	7	8	9	9	9	7	9	3	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	9	9	Y	A
1	97	ARC	8	7	8	9	8	8	9	9	9	5	4	9	9	9	9	7	9	9	1	9	3	8	9	9	7	3	1	9	8	8	N	E
1	98	ARC	8	7	8	9	8	7	9	9	9	5	4	9	9	9	9	7	9	9	1	9	3	7	9	9	7	9	6	9	8	9	N	E
1	99	ARC	7	7	8	9	8	4	9	8	9	5	4	9	5	9	8	9	9	6	1	9	4	9	9	9	7	9	6	9	8	8	N	E
1	100	ARC	5	5	8	9	8	3	9	8	9	5	4	9	5	6	6	9	9	6	1	9	4	8	9	7	6	2	2	6	7	6	N	E
1	101	ARC	8	7	9	1	4	7	7	7	3	3	4	9	7	8	8	9	9	9	8	9	6	5	2	9	9	8	7	9	8	8	N	E
1	102	ARC	5	6	1	1	1	6	7	6	3	3	4	9	1	5	3	5	9	1	8	9	2	4	2	5	6	8	7	5	6	5	N	E
1	103	ARC	8	7	9	1	4	8	7	7	3	3	4	9	7	8	8	9	9	9	3	9	5	5	2	9	9	6	7	9	8	7	N	E
1	104	ARC	3	2	1	1	2	6	5	6	3	3	4	9	1	5	3	5	9	1	3	9	2	4	2	7	6	4	6	5	6	4	N	E
1	105	ARC	9	7	5	1	7	1	2	1	3	3	4	9	1	1	1	1	5	1	1	1	1	4	1	1	1	2	1	1	4	1	N	E
1	106	ARC	9	6	1	1	5	1	2	1	3	3	4	9	1	1	1	1	5	1	1	1	1	3	1	1	1	1	1	1	4	1	N	E
1	107	ARC	3	1	5	1	1	1	1	1	3	2	4	9	1	1	1	1	5	1	1	1	1	3	1	1	1	2	1	1	4	1	N	E
1	108	ARC	2	1	1	1	1	1	1	1	3	2	4	9	1	1	1	1	5	1	1	1	1	3	1	1	1	1	1	1	4	1	N	E
1	109	ARC	4	1	5	1	1	1	1	1	3	2	4	9	1	1	1	1	5	1	1	1	1	2	1	1	1	2	1	1	3	1	N	E
1	110	ARC	2	1	1	1	1	1	1	1	3	2	1	9	1	1	1	1	5	1	1	1	1	2	1	1	1	1	1	1	3	1	Y	I
1	111	ARC	8	7	1	9	6	1	9	8	3	1	4	9	9	9	9	1	9	9	1	9	5	4	9	7	8	1	1	9	7	7	N	E
1	112	ARC	8	7	1	9	6	1	9	8	3	1	4	9	9	9	9	1	9	9	1	9	5	4	9	7	8	1	5	9	7	7	N	E
1	113	ARC	1	1	1	1	1	1	1	1	3	1	4	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	114	ARC	1	1	1	1	1	1	1	1	3	1	4	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	115	ARC	9	9	9	9	8	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	Y	A
1	116	ARC	9	9	9	9	8	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
1	117	ARC	9	9	9	9	9	8	9	9	9	9	9	1	9	9	9	9	9	9	2	9	8	8	9	9	9	8	9	9	8	9	Y	A
1	118	ARC	9	9	9	9	9	8	9	9	9	9	9	1	9	9	9	9	9	9	2	9	8	8	9	9	9	8	9	9	8	9	Y	A
1	119	ARC	4	8	4	1	9	7	9	8	9	9	9	3	9	8	9	9	9	1	1	9	8	8	2	9	8	7	1	9	7	8	N	E
1	120	ARC	4	7	4	1	9	7	9	8	9	9	9	3	9	8	7	9	9	1	1	9	6	7	2	9	8	7	7	5	7	7	N	E
1	121	ARC	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	5	8	9	N	E
1	122	ARC	9	9	9	9	7	8	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	8	8	9	9	7	9	N	E
1	123	ARC	8	7	8	9	4	7	9	9	9	5	3	9	9	9	9	7	9	9	2	9	3	9	9	9	7	7	1	9	7	9	N	E
1	124	ARC	8	7	8	9	4	6	9	9	9	5	3	9	9	9	9	7	9	9	2	9	3	8	9	9	7	7	6	9	7	8	N	E
1	125	ARC	5	7	8	9	2	3	9	8	9	5	3	9	5	9	7	9	9	3	2	9	4	9	9	9	7	3	6	9	8	8	N	E
1	126	ARC	5	5	8	9	2	2	9	8	9	5	3	9	3	5	5	9	9	3	2	9	4	9	9	9	6	2	2	5	8	5	N	E
1	127	ARC	8	7	9	1	1	6	8	8	7	5	3	9	7	8	8	9	9	8	7	9	6	6	1	9	9	7	6	9	8	8	N	E
1	128	ARC	5	6	1	1	1	5	5	7	6	5	3	9	1	6	3	5	9	2	7	8	2	5	1	5	6	4	3	3	6	5	N	E
1	129	ARC	7	3	9	1	1	8	7	7	7	5	3	9	7	8	8	9	9	8	2	9	7	4	1	9	9	6	6	9	8	7	N	E
1	130	ARC	3	2	1	1	1	8	6	6	6	5	3	9	1	6	3	5	9	2	2	8	5	3	1	5	6	3	1	3	5	3	N	E
1	131	ARC	3	7	5	1	7	1	2	1	6	2	3	9	1	1	1	1	5	1	1	1	1	6	1	1	1	1	1	1	3	1	N	E
1	132	ARC	3	7	1	1	5	1	2	1	6	2	3	9	1	1	1	1	5	1	1	1	1	5	1	1	1	1	1	1	3	1	N	E
1	133	ARC	1	1	5	1	1	1	1	1	6	2	3	9	1	1	1	1	5	1	1	1	1	4	1	1	1	1	1	1	3	1	N	E
1	134	ARC	1	1	1	1	1	1	1	1	6	2	3	9	1	1	1	1	5	1	1	1	1	3	1	1	1	1	1	1	3	1	Y	I
1	135	ARC	1	1	5	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	2	1	1	1	1	1	1	1	1	N	E
1	136	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	2	1	1	1	1	1	1	1	1	Y	I
1	137	ARC	7	7	1	9	6	1	9	8	6	1	3	9	9	9	8	1	9	8	1	9	6	2	1	5	8	1	1	9	7	7	N	E
1	138	ARC	7	7	1	9	6	1	9	8	6	1	3	9	9	9	8	1	9	8	1	9	6	2	1	5	8	1	1	9	7	7	N	E

1	139	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	140	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	141	ARC	9	9	8	7	9	8	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	6	1	9	9	9	Y	A
1	142	ARC	9	9	8	7	9	7	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	6	7	9	9	9	Y	A
1	143	ARC	5	9	8	7	9	8	9	9	9	9	9	1	9	9	9	9	9	9	2	9	8	9	9	9	9	5	7	9	8	9	N	E
1	144	ARC	7	9	8	7	9	7	9	9	9	9	9	1	9	9	9	9	9	9	2	9	8	8	9	9	9	5	7	9	8	9	Y	A
1	145	ARC	2	8	4	1	8	7	9	7	9	7	9	4	9	9	9	9	9	1	1	9	4	8	3	9	8	3	1	5	6	7	N	E
1	146	ARC	2	8	4	1	8	6	9	7	9	7	9	4	9	9	5	9	9	1	1	9	5	7	3	9	8	3	7	5	6	7	N	E
1	147	ARC	9	9	9	9	9	9	9	9	9	7	9	1	9	9	9	9	9	9	8	9	9	9	9	9	9	7	8	9	8	9	Y	A
1	148	ARC	9	9	9	9	8	8	9	9	9	7	9	1	9	9	9	9	9	9	8	9	9	9	9	9	8	5	8	9	7	9	Y	A
1	149	ARC	8	7	6	7	3	7	9	8	7	3	3	3	9	9	9	7	9	7	1	9	5	9	9	9	7	3	1	9	8	7	N	E
1	150	ARC	8	7	6	7	3	7	9	8	7	3	3	3	9	9	9	7	9	7	1	9	5	8	9	9	7	3	3	9	8	7	N	E
1	151	ARC	6	7	7	8	1	6	9	7	6	3	3	9	7	8	7	9	9	2	1	9	6	9	9	9	7	2	6	9	7	7	N	E
1	152	ARC	6	5	7	8	1	6	9	7	6	3	3	9	3	5	4	5	9	2	1	9	3	8	9	7	6	2	3	5	6	6	N	E
1	153	ARC	6	7	9	1	1	6	7	7	6	3	3	9	7	8	6	9	9	8	7	9	7	7	4	9	9	6	5	9	7	7	N	E
1	154	ARC	4	5	1	1	1	4	5	6	6	3	3	9	1	1	1	5	9	2	7	8	2	4	2	5	7	4	2	3	6	4	N	E
1	155	ARC	7	3	9	1	1	3	7	7	6	3	3	9	7	8	6	1	9	8	1	9	7	2	2	9	9	4	5	9	7	7	N	E
1	156	ARC	3	2	1	1	1	2	4	6	6	3	3	9	1	1	1	1	9	2	1	8	2	1	2	5	7	3	2	3	5	2	N	E
1	157	ARC	9	7	4	1	7	2	1	1	6	1	3	9	1	1	1	1	5	1	2	1	1	3	1	1	1	1	1	1	3	1	N	E
1	158	ARC	8	7	1	1	7	2	1	1	6	1	3	9	1	1	1	1	5	1	2	1	1	2	1	1	1	1	1	1	3	1	N	E
1	159	ARC	1	1	4	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	2	1	1	1	1	1	1	2	1	N	E
1	160	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	161	ARC	1	1	4	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	5	1	1	1	1	1	1	1	1	N	E
1	162	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	5	1	1	1	1	3	1	1	1	1	1	1	1	1	Y	I
1	163	ARC	7	7	1	2	2	1	9	8	6	1	3	9	9	9	8	1	9	7	9	9	5	1	1	5	9	1	1	9	7	7	N	E
1	164	ARC	7	7	1	2	2	1	9	8	6	1	3	9	9	9	8	1	9	7	9	9	5	1	1	5	9	1	1	9	7	7	N	E
1	165	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	166	ARC	1	1	1	1	1	1	1	1	6	1	3	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	167	ARC	9	9	9	9	9	9	9	9	9	8	9	1	9	9	9	9	9	9	8	9	9	8	9	9	9	8	1	9	9	9	Y	A
1	168	ARC	9	9	9	9	9	9	9	9	9	8	9	1	9	9	9	9	9	9	8	9	9	8	9	9	9	8	9	9	9	9	Y	A
1	169	ARC	8	8	9	9	8	8	9	9	9	8	9	2	9	9	9	9	9	9	8	9	8	7	9	9	9	8	8	9	8	9	Y	A
1	170	ARC	8	7	9	9	8	8	9	9	9	8	9	2	9	9	9	9	9	9	8	9	8	6	9	9	9	8	8	9	8	9	Y	A
1	171	ARC	6	6	7	1	7	7	9	8	9	7	9	4	9	8	9	9	9	1	2	9	8	6	1	9	8	3	1	5	7	7	N	E
1	172	ARC	6	5	7	1	7	7	7	8	9	7	9	4	9	8	7	9	9	1	2	9	6	6	1	9	8	3	6	5	7	7	N	E
1	173	ARC	9	9	9	9	9	9	9	9	9	7	9	3	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	8	9	Y	A
1	174	ARC	9	6	9	9	9	8	9	9	9	7	9	3	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	7	9	Y	A
1	175	ARC	8	6	9	7	2	7	9	8	9	3	5	9	9	9	9	5	9	9	1	9	3	8	9	9	7	6	1	9	7	8	N	E
1	176	ARC	8	5	9	7	2	6	9	8	9	3	5	9	9	9	9	5	9	9	1	9	3	8	9	9	7	6	5	9	7	8	N	E
1	177	ARC	7	6	7	7	2	3	9	7	3	3	5	9	5	9	5	3	9	2	1	9	4	9	9	9	7	4	5	9	8	7	N	E
1	178	ARC	7	5	5	7	2	2	9	7	3	3	5	9	3	6	5	3	9	2	1	9	4	9	9	7	6	3	2	5	8	5	N	E
1	179	ARC	8	6	7	1	4	6	9	8	3	3	5	4	7	9	5	9	9	8	4	9	6	6	1	9	9	7	6	9	8	7	N	E
1	180	ARC	7	3	2	1	2	5	7	7	3	3	5	4	1	3	1	5	9	2	4	8	4	5	1	7	7	4	3	3	6	4	N	E
1	181	ARC	7	6	7	1	4	8	7	8	3	3	5	9	7	9	5	9	9	8	4	9	6	5	1	9	9	6	6	9	8	7	N	E
1	182	ARC	6	3	2	1	1	8	5	7	3	3	5	9	1	3	1	5	9	2	4	8	4	4	1	7	7	3	2	3	5	4	N	E
1	183	ARC	2	1	5	1	1	1	2	1	3	1	5	9	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	1	3	1	Y	I
1	184	ARC	2	1	4	1	1	1	2	1	3	1	5	9	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	3	1	Y	I
1	185	ARC	1	1	5	1	1	1	1	1	3	1	5	9	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	3	1	Y	I
1	186	ARC	1	1	1	1	1	1	1	1	3	1	5	9	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	3	1	Y	I
1	187	ARC	1	1	2	1	1	1	3	1	3	1	5	9	1	1	1	1	1	1	3	3	1	2	1	1	1	1	1	1	1	1	Y	I
1	188	ARC	7	1	2	1	1	1	2	1	3	1	5	9	1	1	1	1	1	1	3	3	1	1	1	1	1	1	1	1	1	1	Y	I
1	189	ARC	7	5	8	4	7	1	9	8	3	1	5	9	9	9	4	1	9	9	1	9	6	2	1	5	7	1	1	9	7	6	N	E
1	190	ARC	1	5	8	4	7	1	9	8	3	1	5	9	9	9	4	1	9	9	1	9	6	1	1	5	7	1	1	9	7	5	N	E
1	191	ARC	1	1	2	1	1	1	9	1	3	1	5	9	1	1	1	1	1	1	1	1	1	1	1	6	1	1	1	1	1	1	N	E
1	192	ARC	1	1	2	1	1	1	9	1	3	1	5	9	1	1	1	1	1	1	1	1	1	1	1	6	1	1	1	1	1	1	N	E
1	193	ARC	8	7	7	1	4	9	9	3	9	9	9	1	9	9	9	9	9	9	9	9	8	9	9	9	8	3	1	8	9	9	N	E
1	194	ARC	8	7	7	1	4	9	9	3	9	9	9	1	9	9	9	9	9	9	9	9	8	9	9	9	8	3	7	8	9	9	N	E
1	195	ARC	8	7	7	1	1	9	9	3	9	9	9	1	9	9	9	1	9	9	7	9	8	7	9	9	8	2	7	8	8	8	N	E
1	196	ARC	8	6	7	1	1	9	9	3	9	9	9	1	9	9	9	1	9	9	7	9	5	6	9	9	7	2	7	8	8	8	N	E
1	197	ARC	6	5	2	1	1	6	9	2	9	7	9	6	9	9	6	1	9	1	4	9	4	5	5	9	7	1	1	5	6	6	N	E
1	198	ARC	6	3	2	1	1	6	9	2	9	7	9	6	9	9	2	1	9	1	4	9	4	5	5	9	7	1	6	5	6	6	N	E
1	199	ARC	9	8	4	1	3	9	9	4	9	7	9	1	9	9	9	9	9	9	9	9	8	9	9	9	8	3	8	4	7	9	N	E
1	200	ARC	9	7	4	1	1	9	9	4	9	7	9	1	9	9	9	9	9	9	9	9	7	9	9	9	7	2	8	4	6	9	N	E
1	201	ARC	8	7	2	1	3	6	9	3	3	4	5	9	9	9	2	9	1	9	4	9	5	7	9	9	6	1	1	8	5	6	N	E
1	202	ARC	8	6	2	1	3	6	9	3	3	4	5	9	9	9	2	9	1	9	4	9	5	7	9	9	6	1	2	8	5	6	N	E
1	203	ARC	7	4	2	1	1	4	9	2	3	4	5	9	7	8	3	1	9	2	1	9	6	9	9	9	6	1	5	1	7	5	N	E
1	204	ARC	7	3	1	1	1	4	9	2	3	4	5	9	3	5	2	1	9	2	1	9	3	9	8	7	5	1	2	1	6	3	N	E
1	205	ARC	7	4	2	1	1	6	9	1	2	4	5	9	7	7	3	1	1	8	8	9	5	5	1	9	8	1	6	1	7	5	N	E
1	206	ARC	7	1	1	1	1	3	5	1	2	4	5	9	1	4	2	1	1	2	8	8	3	3	1	7	5	1	2	1	6	2	N	E
1	207	ARC	7	5	1	1	1	4	8	1	2	4	5	9	7	7	3	1	1	8	7	9	5	2	1	9	8	1	5	1	7	5	N	E
1	208	ARC	7	2	1	1	1	2	5	1	2	4	5	9	1	4	1	1	1	2	7	8	2	2	1	7	5	1	1	1	6	2	N	E
1	209	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	210	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I

1	211	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	212	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	213	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	214	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	215	ARC	7	1	1	1	1	1	9	1	1	1	5	9	9	9	3	1	5	9	1	9	5	1	1	5	5	1	1	7	7	3	N	E
1	216	ARC	7	1	1	1	1	1	9	1	1	1	5	9	9	9	3	1	5	9	1	9	5	1	1	5	5	1	1	7	7	3	N	E
1	217	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	218	ARC	1	1	1	1	1	1	1	1	1	1	5	9	1	1	1	1	1	1	1	1	1		1	1	1	1	1	1	1	1	Y	I
1	1	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	2	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	3	MA	1	1	1	1	3	1	1	1	1	1	3	9	1	1	1	1	1	1	2	1	2	2	1	2	1	2	1	1	2	1	Y	I
1	4	MA	1	2	1	1	3	1	1	1	1	1	3	9	1	1	1	1	1	1	2	1	2	2	1	3	1	2	1	1	3	1	Y	I
1	5	MA	3	4	5	5	3	2	1	6	1	1	3	1	2	2	1	5	1	9	9	1	2	2	5	5	2	2	2	3	2	2	N	E
1	6	MA	4	5	5	5	3	2	1	6	1	1	3	1	2	2	1	5	1	9	9	1	4	2	5	5	2	2	2	3	4	3	N	E
1	7	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	8	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	9	MA	1	2	2	1	3	8	2	3	1	2	9	1	2	1	1	5	1	1	9	1	8	2	1	2	2	2	7	1	2	2	N	E
1	10	MA	1	2	2	1	3	8	3	3	1	2	9	1	2	1	1	5	1	1	9	1	8	2	1	2	2	2	8	1	2	2	N	E
1	11	MA	2	5	2	1	7	6	2	6	4	2	9	3	2	2	2	2	2	6	8	1	5	1	3	3	2	5	4	2	3	3	N	E
1	12	MA	4	6	2	1	8	8	3	6	4	6	9	3	2	4	3	2	2	6	8	1	5	1	5	4	2	5	7	2	4	4	N	E
1	13	MA	2	5	1	7	7	6	5	6	4	3	9	6	3	4	1	1	3	5	2	5	4	6	7	5	1	3	7	3	3	4	N	E
1	14	MA	4	7	8	7	9	7	7	6	4	3	9	6	7	5	4	5	3	9	2	7	8	7	8	7	3	7	9	7	4	7	N	E
1	15	MA	3	5	1	8	6	7	5	7	3	5	9	1	5	5	1	1	3	8	9	5	5	7	9	5	1	6	7	2	3	5	N	E
1	16	MA	7	8	8	8	8	8	8	7	2	5	9	1	7	6	4	5	3	9	9	7	8	7	9	7	3	8	9	7	5	7	N	E
1	17	MA	1	4	5	8	4	9	9	8	8	7	9	1	7	8	8	9	9	9	1	9	9	8	9	9	9	9	8	9	6	8	N	E
1	18	MA	1	4	9	8	4	9	9	8	8	7	9	1	7	8	8	9	9	9	1	9	9	9	9	9	9	9	9	9	7	9	N	E
1	19	MA	7	9	5	9	9	9	9	8	9	7	9	1	9	8	9	9	9	9	1	9	9	8	9	9	9	9	9	9	7	9	Y	A
1	20	MA	8	9	9	9	9	9	9	8	9	7	9	1	9	8	9	9	9	9	1	9	9	9	9	9	9	9	9	9	7	9	Y	A
1	21	MA	6	9	5	8	9	8	5	8	8	7	9	1	5	8	9	9	9	9	1	9	9	8	9	9	9	9	9	9	8	9	Y	A
1	22	MA	8	9	9	8	9	8	5	8	8	7	9	1	5	8	9	9	9	9	1	9	9	8	9	9	9	9	9	9	8	9	N	E
1	23	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	24	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
1	25	MA	2	1	1	1	4	1	1	1	1	1	3	9	1	1	1	1	1	1	8	1	2	1	1	1	1	1	1	1	2	1	Y	I
1	26	MA	3	1	1	1	4	1	1	1	1	1	3	9	1	1	1	1	1	1	8	1	2	1	1	1	1	1	1	1	2	1	Y	I
1	27	MA	7	1	6	7	4	4	1	1	1	1	3	1	1	2	1	5	1	1	7	1	3	1	1	1	1	1	2	1	3	1	N	E
1	28	MA	8	1	6	7	4	4	1	1	1	1	3	1	1	2	1	5	1	1	7	1	4	1	1	1	1	1	2	1	4	1	N	E
1	29	MA	1	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	30	MA	2	1	1	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
1	31	MA	2	2	2	1	3	3	1	1	1	2	1	1	1	1	1	5	1	1	8	1	8	1	1	1	1	1	2	1	2	1	Y	I
1	32	MA	2	2	2	1	3	3	1	1	1	2	1	1	1	1	1	5	1	1	8	1	8	2	1	1	1	1	2	1	2	1	Y	I
1	33	MA	3	2	2	1	4	2	1	1	2	2	1	1	5	1	1	2	1	1	2	1	5	1	1	1	1	1	2	1	3	1	Y	I
1	34	MA	4	2	2	1	6	2	1	1	2	2	1	1	5	1	1	2	1	1	2	1	5	1	1	1	1	1	2	1	4	1	N	E
1	35	MA	2	2	1	7	4	2	1	1	3	3	1	3	5	1	1	1	1	1	8	2	4	1	1	1	1	1	2	2	3	2	N	E
1	36	MA	5	3	9	7	6	3	1	1	3	3	1	3	7	5	1	5	1	1	8	3	8	1	1	1	1	1	2	2	4	3	N	E
1	37	MA	1	3	1	8	3	3	1	1	7	5	1	3	5	1	1	1	1	1	9	2	5	5	1	1	1	1	2	2	3	2	N	E
1	38	MA	1	4	9	8	3	3	1	1	4	5	1	3	7	5	1	5	1	1	9	3	8	5	1	1	1	1	2	2	5	3	N	E
1	39	MA	7	1	5	8	7	2	1	1	9	7	1	1	7	2	1	1	1	1	9	3	7	5	1	1	2	1	3	2	6	2	N	E
1	40	MA	7	1	9	8	7	2	1	1	9	7	1	1	7	2	1	1	1	1	9	3	7	5	1	1	2	1	3	2	7	2	N	E
1	41	MA	9	9	5	8	5	3	1	1	9	7	1	1	9	2	1	1	1	1	9	3	8	8	1	1	2	2	2	2	7	2	N	E
1	42	MA	9	9	9	8	5	3	1	1	9	7	1	1	9	2	1	1	1	1	9	3	8	8	1	1	2	2	2	2	7	2	N	E
1	43	MA	9	9	5	7	5	2	1	1	9	7	1	1	9	2	1	1	1	1	9	3	9	8	1	1	2	3	2	2	7	2	N	E
1	44	MA	9	9	9	7	5	2	1	1	9	7	1	1	9	2	1	1	1	1	9	3	9	8	1	1	2	3	2	2	7	2	N	E
1	45	MA	2	1	1	1	3	1	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1	Y	I
1	46	MA	2	1	1	1	3	1	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1	Y	I
1	47	MA	2	1	1	1	3	1	1	2	1	1	3	9	1	1	1	1	1	1	3	1	2	2	1	1	1	2	1	1	2	1	Y	I
1	48	MA	3	1	1	1	3	1	1	2	1	1	3	9	1	1	1	1	1	1	3	1	2	2	1	1	1	2	1	1	2	1	Y	I
1	49	MA	8	3	6	7	6	4	1	2	1	1	3	7	1	2	1	5	1	1	8	1	2	2	2	1	1	2	2	3	3	2	N	E
1	50	MA	7	5	6	7	6	4	1	2	1	1	3	7	1	2	1	5	1	1	8	1	4	2	2	1	1	2	2	3	4	2	N	E
1	51	MA	1	1	1	1	4	1	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	2	1	Y	I
1	52	MA	2	1	1	1	4	1	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	3	1	Y	I
1	53	MA	2	2	2	1	3	3	1	2	2	2	1	7	1	1	1	1	1	1	1	1	8	2	1	1	1	2	3	1	2	1	Y	I
1	54	MA	2	2	2	1	3	3	1	2	2	2	1	7	1	1	1	1	1	1	1	1	8	2	1	1	1	2	3	1	2	1	Y	I
1	55	MA	3	2	2	1	4	3	1	2	5	2	1	1	5	3	1	7	1	1	9	1	5	2	1	1	1	3	1	1	3	2	N	E
1	56	MA	5	2	2	1	6	3	1	2	5	2	1	1	7	5	1	7	1	1	9	1	5	2	1	1	1	3	1	3	4	2	N	E
1	57	MA	2	2	1	7	4	2	1	2	4	3	1	5	5	2	1	2	1	1	3	2	4	3	3	1	1	3	2	1	3	2	N	E
1	58	MA	5	3	9	7	6	3	1	2	5	3	1	5	8	2	2	2	1	1	3	3	8	4	3	1	1	4	2	3	4	3	N	E
1	59	MA	4	6	1	8	7	3	1	2	4	5	1	4	5	2	1	2	1	1	9	2	5	2	5	1	1	4	2	1	3	2	N	E
1	60	MA	6	6	9	8	7	3	1	2	7	5	1	4	7	2	2	2	1	1	9	3	8	2	5	1	1	5	2	2	5	3	N	E
1	61	MA	6	4	5	8	6	2	7	4	9	7	1	1	7	2	2	5	1	1	9	2	7	2	6	1	2	6	2	5	6	5	N	E
1	62	MA	6	4	9	8	6	2	7	4	9	7	1	1	7	2	2	5	1	1	9	2	7	2	6	1	2	6	2	5	7	5	N	E
1	63	MA	9	9	5	8	9	3	7	4	9	7	1	1	9	2	2	5	1	1	9	2	8	3	7	1	2	7	2	7	7	5	Y	E
1	64	MA	9	9	9	8	9	3	8	4	9	7	1	1	9	2	2	5	1	1	9	2	8	3	7	1	2	7	2	7	8	7	N	E

1	65	MA	9	9	5	8	9	2	5	4	9	8	1	1	9	2	2	5	1	1	9	2	9	3	7	1	2	8	2	7	7	5	N	E
1	66	MA	9	9	9	8	9	2	3	4	9	8	1	1	9	2	2	5	1	1	9	2	9	3	7	1	2	8	2	7	7	5	N	E
1	67	MA	2	1	1	1	1	2	1	4	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	2	3	1	1	1	1	Y	I
1	68	MA	2	1	1	1	1	2	1	4	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	2	3	1	1	1	1	Y	I
1	69	MA	2	1	1	1	2	3	1	4	1	1	1	9	1	1	1	1	1	1	7	1	2	1	1	1	2	3	1	1	2	1	Y	I
1	70	MA	3	1	1	1	2	3	1	4	1	1	1	9	1	1	1	1	1	1	7	1	2	2	1	1	2	3	1	1	2	1	Y	I
1	71	MA	8	3	6	7	2	3	1	4	1	1	1	1	1	5	3	5	1	9	9	1	4	2	1	1	2	6	2	3	2	2	N	E
1	72	MA	9	4	6	7	2	3	1	4	1	1	1	1	1	5	5	5	1	9	9	1	5	2	1	1	2	6	2	3	3	3	N	E
1	73	MA	1	1	1	1	1	2	1	4	1	1	1	8	1	1	1	1	1	1	9	1	1	2	1	1	2	2	1	1	2	1	Y	I
1	74	MA	2	1	1	1	1	2	2	4	1	1	1	9	1	1	1	1	1	1	9	1	1	2	1	1	2	2	1	1	3	1	Y	I
1	75	MA	2	2	4	1	5	8	1	5	1	2	1	1	7	1	2	1	1	2	1	1	6	2	1	1	2	6	3	1	2	2	N	E
1	76	MA	2	2	4	1	5	8	1	5	1	2	1	1	7	1	2	1	1	2	1	1	6	3	1	1	2	6	3	2	2	2	N	E
1	77	MA	5	3	3	1	6	8	1	5	1	2	1	1	5	3	3	2	1	8	7	1	3	3	1	1	2	6	3	1	3	3	N	E
1	78	MA	7	4	3	1	8	8	1	5	1	2	1	1	7	9	5	8	1	8	7	1	7	3	1	1	2	7	2	5	3	3	N	E
1	79	MA	2	2	1	7	9	8	5	6	2	4	1	1	5	4	3	1	1	2	7	1	3	3	1	1	2	4	7	1	3	3	N	E
1	80	MA	5	3	9	7	9	8	5	6	4	4	1	1	7	7	5	5	1	7	7	1	8	3	1	1	2	6	8	5	4	5	N	E
1	81	MA	5	6	1	8	9	8	4	6	4	7	1	1	5	4	3	1	1	1	9	1	3	5	1	1	2	5	7	1	3	4	N	E
1	82	MA	7	6	9	8	9	8	7	6	6	7	1	1	9	7	5	5	1	7	9	1	8	5	1	1	2	6	8	5	5	6	N	E
1	83	MA	7	4	6	7	3	9	7	7	7	8	1	1	9	3	5	5	1	8	9	8	9	5	1	5	6	8	9	9	5	7	N	E
1	84	MA	7	4	9	7	3	9	7	7	7	8	1	1	9	3	5	5	1	8	9	8	9	5	1	5	6	8	9	9	5	7	N	E
1	85	MA	9	9	6	8	2	9	8	7	7	8	1	1	9	3	5	5	1	8	9	9	9	6	1	5	7	9	9	9	6	7	N	E
1	86	MA	9	9	9	8	2	9	8	7	7	8	1	1	9	3	5	5	1	8	9	9	9	6	1	5	7	9	9	9	6	8	N	E
1	87	MA	9	9	6	7	2	8	3	7	7	9	1	1	9	3	5	5	1	8	9	9	9	5	1	5	3	9	7	9	6	7	N	E
1	88	MA	9	9	9	7	2	8	3	7	7	9	1	1	9	3	5	5	1	8	9	9	9	5	1	5	3	9	7	9	6	7	N	E
1	89	MA	1	1	1	1	1	1	1	2	1	1	1	9	1	1	1	1	1	1	4	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	90	MA	1	1	1	1	1	1	1	2	1	1	1	9	1	1	1	1	1	1	4	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	91	MA	1	1	1	1	1	1	1	2	1	2	1	9	1	1	1	1	1	1	4	1	2	1	1	1	1	2	1	1	2	1	Y	I
1	92	MA	1	1	1	1	1	1	1	2	1	2	1	9	1	1	1	1	1	1	4	1	2	1	1	1	1	2	1	1	2	1	Y	I
1	93	MA	3	2	6	8	1	2	1	2	1	3	1	3	1	1	1	1	1	8	8	1	2	2	1	1	1	4	2	3	2	2	N	E
1	94	MA	4	3	6	8	1	2	5	2	1	3	1	3	1	1	3	1	1	8	8	1	4	2	5	1	1	4	2	3	3	3	N	E
1	95	MA	1	1	1	1	1	2	1	1	1	3	1	9	1	1	1	1	1	1	1	1	1	1	5	1	1	2	1	1	1	1	Y	I
1	96	MA	1	1	1	1	3	2	1	1	1	3	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1	Y	I
1	97	MA	2	4	2	1	3	2	1	1	1	5	7	1	1	1	1	5	1	1	9	1	8	1	1	1	1	3	8	1	2	1	N	E
1	98	MA	2	4	2	1	3	3	1	1	1	5	7	1	1	1	1	5	1	1	9	1	8	1	1	1	1	3	8	1	2	1	N	E
1	99	MA	3	6	2	1	7	6	1	2	1	5	7	1	5	1	2	5	1	6	9	1	5	5	1	1	1	7	8	1	2	2	N	E
1	100	MA	5	7	2	1	8	7	3	2	1	5	7	1	5	1	5	5	1	6	9	1	5	5	1	1	1	8	8	2	3	5	N	E
1	101	MA	2	3	1	7	7	3	5	4	1	6	7	1	5	1	2	1	1	2	7	1	4	5	5	1	1	5	4	1	2	3	N	E
1	102	MA	5	6	9	7	9	4	8	4	1	6	7	1	9	2	7	5	1	7	7	1	8	5	5	1	2	5	7	3	4	5	N	E
1	103	MA	3	7	1	7	6	3	5	4	1	6	7	1	5	1	2	1	1	3	9	1	5	5	6	1	1	6	4	1	2	3	N	E
1	104	MA	7	8	9	7	9	4	8	4	1	6	7	1	9	2	7	5	1	8	9	1	8	5	6	1	2	7	7	5	4	6	N	E
1	105	MA	1	3	5	8	3	7	7	8	1	7	7	1	9	1	9	9	5	9	9	9	8	5	7	4	6	8	8	9	5	7	N	E
1	106	MA	1	4	9	8	4	7	9	8	1	7	7	1	9	1	9	9	5	9	9	9	8	5	7	4	6	8	9	9	5	7	N	E
1	107	MA	7	9	5	8	9	7	9	8	1	7	7	1	9	1	9	9	5	9	9	9	8	7	7	4	7	8	9	9	6	8	N	E
1	108	MA	8	9	9	8	9	7	9	8	1	7	7	1	9	1	9	9	5	9	9	9	8	7	7	4	7	8	9	9	6	8	N	E
1	109	MA	6	9	5	7	9	3	8	9	1	7	7	1	9	1	9	9	5	9	9	9	9	6	3	4	2	8	9	9	6	7	N	E
1	110	MA	8	9	9	7	9	3	8	9	1	7	7	1	9	1	9	9	5	9	9	9	9	6	7	4	2	8	9	9	6	8	N	E
1	111	MA	2	3	9	1	7	4	1	4	1	9	7	1	1	1	3	9	1	2	9	1	6	7	7	4	2	8	9	1	3	3	N	E
1	112	MA	2	3	9	1	7	4	1	4	1	9	7	1	1	1	3	9	1	2	9	1	6	5	3	4	2	8	5	1	3	3	N	E
1	113	MA	9	9	9	9	9	9	9	9	1	9	7	1	9	9	9	9	9	9	9	9	9	9	9	4	7	9	9	9	6	9	N	E
1	114	MA	9	9	9	9	9	9	9	9	1	9	7	1	9	9	9	9	9	9	9	9	9	9	9	4	7	9	9	9	6	9	N	E
1	115	MA	2	1	1	1	3	1	1	2	1	1	1	9	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	116	MA	2	1	1	1	3	1	1	2	1	1	1	9	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	1	1	Y	I
1	117	MA	2	1	1	1	1	1	1	2	1	1	1	9	1	1	1	1	1	1	8	1	2	1	1	1	1	2	1	1	2	1	Y	I
1	118	MA	3	1	1	1	1	1	1	2	1	1	1	9	1	1	1	1	1	1	8	1	2	1	1	1	1	2	1	1	2	1	Y	I
1	119	MA	3	3	6	8	1	2	1	3	1	1	1	7	1	1	1	1	1	9	9	1	2	2	4	1	1	3	2	5	2	2	N	E
1	120	MA	4	4	6	8	1	2	3	3	1	1	1	7	1	1	3	1	1	9	9	1	4	2	4	1	1	3	2	5	3	3	N	E
1	121	MA	1	1	1	1	1	2	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
1	122	MA	1	1	1	1	3	2	1	2	1	1	1	9	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
1	123	MA	2	4	2	1	6	2	1	2	1	5	6	1	1	1	1	5	1	2	8	1	8	1	1	1	1	3	5	1	3	2	N	E
1	124	MA	2	4	2	1	6	3	1	2	1	5	6	1	1	1	1	5	1	2	8	1	8	1	1	1	1	3	8	1	3	2	N	E
1	125	MA	2	6	2	1	7	7	1	3	1	5	6	1	5	1	2	5	1	7	9	1	5	1	1	1	1	7	4	1	2	2	N	E
1	126	MA	5	7	2	1	7	8	1	3	1	5	6	1	7	1	5	5	1	7	9	1	5	1	1	1	1	8	8	1	2	3	N	E
1	127	MA	2	3	1	8	9	4	2	3	2	5	6	1	5	1	3	1	1	3	3	2	4	2	6	1	1	3	6	1	2	3	N	E
1	128	MA	5	6	9	8	9	4	5	3	5	5	6	1	8	1	7	5	1	7	3	3	8	2	6	5	2	6	9	5	4	5	N	E
1	129	MA	3	8	1	8	9	3	3	3	2	5	6	1	5	1	3	1	1	3	8	2	3	4	7	1	1	4	6	1	2	3	N	E
1	130	MA	7	9	9	8	9	3	5	3	5	5	6	1	8	1	7	5	1	7	8	3	6	5	7	5	2	7	9	5	4	5	N	E
1	131	MA	7	4	5	8	3	6	3	8	4	8	6	1	9	3	9	9	5	9	8	7	9	6	7	5	7	8	9	9	7	7	N	E
1	132	MA	7	4	9	8	4	6	3	8	5	8	6	1	9	3	9	9	5	9	8	7	9	7	7	5	7	8	9	9	7	7	N	E
1	133	MA	9	9	5	8	9	7	5	8	5	8	6	1	9	8	9	9	5	9	9	7	9	6	8	6	8	9	9	9	7	8	N	E
1	134	MA	9	9	9	8	9	7	5	8	5	8	6	1	9	8	9	9	5	9	9	7	9	6	8	6	8	9	9	9	7	8	N	E
1	135	MA	9	9	5	8	9	4	7	9	5	9	6	1	9	9	9	9	5	9	9	7	9	6	7	5	2	9	9	9	7	9	N	E
1	136	MA	9	9	9	8	9	4	7	9	5	9	6	1	9	9	9	9	5	9	9	7	9	6	7	5	2	9	9	9	7	9	N	E

1	137	MA	3	4	9	1	7	9	1	7	5	9	6	1	1	1	2	9	1	5	9	1	4	8	7	6	2	9	9	1	3	5	N	E
1	138	MA	3	4	9	1	7	9	1	7	5	9	6	1	1	1	2	9	1	5	9	1	4	9	7	6	2	9	9	1	3	5	N	E
1	139	MA	9	9	9	9	9	9	9	2	5	9	6	1	9	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	7	9	Y	A
1	140	MA	9	9	9	9	9	9	9	2	5	9	6	1	9	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	7	9	Y	A
1	141	MA	1	1	2	3	6	2	1	2	1	2	1	9	3	1	1	1	1	1	3	1	1	1	1	1	1	5	2	1	1	1	Y	I
1	142	MA	1	1	2	3	6	2	1	2	1	2	1	9	3	1	1	1	1	1	3	1	1	1	1	1	1	5	2	1	1	1	Y	I
1	143	MA	5	1	2	3	4	3	1	2	1	2	1	9	3	1	1	1	1	1	8	1	2	1	1	1	1	6	3	1	2	1	Y	I
1	144	MA	3	1	2	3	7	3	1	2	1	2	1	9	3	1	1	1	1	1	8	1	2	1	1	1	1	6	3	1	2	1	Y	I
1	145	MA	8	2	6	8	7	4	1	3	1	3	1	2	3	1	1	1	1	8	9	1	4	2	1	1	1	7	3	5	4	3	N	E
1	146	MA	8	3	6	8	7	4	3	3	1	3	1	7	3	1	5	1	1	8	9	1	5	2	1	1	1	7	3	5	4	3	N	E
1	147	MA	1	1	1	2	3	1	1	2	1	3	1	9	3	1	1	1	1	1	3	1	1	1	1	1	1	3	2	1	2	1	Y	I
1	148	MA	1	1	1	2	4	2	1	2	1	3	1	9	3	1	1	1	1	1	3	1	1	1	1	1	1	5	2	1	3	1	Y	I
1	149	MA	2	4	4	4	7	3	2	3	1	7	7	7	3	1	1	3	1	4	9	1	6	1	1	1	1	7	8	1	2	3	N	E
1	150	MA	2	4	4	4	7	3	2	3	1	7	7	7	3	1	1	3	1	4	9	1	6	1	1	1	1	7	7	1	2	3	N	E
1	151	MA	3	6	3	3	9	6	1	3	1	7	7	1	7	1	3	1	1	7	9	1	3	1	1	1	1	8	7	1	3	3	N	E
1	152	MA	3	7	3	3	9	7	1	3	1	7	7	1	7	7	6	5	1	7	9	1	7	1	1	1	1	8	8	5	4	5	N	E
1	153	MA	1	3	1	8	9	6	3	4	1	7	7	1	5	6	4	1	1	3	8	2	3	2	5	1	1	4	5	1	3	3	N	E
1	154	MA	9	7	9	8	9	7	5	4	1	7	7	1	7	9	8	5	1	7	8	3	8	2	5	4	2	5	8	5	5	7	N	E
1	155	MA	1	8	1	9	9	7	7	4	1	7	7	1	5	6	4	9	1	3	9	2	3	7	6	1	1	6	5	1	3	5	N	E
1	156	MA	9	9	9	9	9	8	8	4	1	7	7	1	9	9	8	9	1	7	9	3	8	7	6	4	2	7	8	5	5	7	N	E
1	157	MA	6	2	6	9	6	8	6	8	1	9	7	1	9	9	9	9	5	8	8	8	9	8	6	7	9	9	9	9	6	8	N	E
1	158	MA	9	2	9	9	6	8	6	8	1	9	7	1	9	9	9	9	5	8	8	8	9	8	6	7	9	9	9	9	6	8	N	E
1	159	MA	6	9	6	9	9	9	7	8	1	9	7	1	9	9	9	9	5	9	9	9	9	8	7	7	9	9	9	9	7	9	N	E
1	160	MA	9	9	9	9	9	9	7	8	1	9	7	1	9	9	9	9	5	9	9	9	9	9	7	7	9	9	9	9	7	9	Y	A
1	161	MA	6	9	6	8	9	9	5	9	1	9	7	1	9	9	9	9	5	9	9	9	9	8	6	7	8	9	9	9	7	9	N	E
1	162	MA	9	9	9	8	9	9	5	9	1	9	7	1	9	9	9	9	5	9	9	9	9	9	6	7	8	9	9	9	7	9	N	E
1	163	MA	3	4	9	4	8	9	2	7	1	9	7	1	3	2	2	9	1	6	9	1	5	9	7	5	3	9	9	1	3	5	N	E
1	164	MA	3	4	9	4	8	9	2	7	1	9	7	1	3	2	2	9	1	6	9	1	5	9	7	5	3	9	9	1	3	5	N	E
1	165	MA	9	9	9	9	9	9	9	9	1	9	7	1	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
1	166	MA	9	9	9	9	9	9	9	9	1	9	7	1	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
1	167	MA	1	1	1	1	1	1	1	2	1	2	1	9	1	1	1	1	1	1	1	1	1	2	1	1	1	2	1	1	1	1	Y	I
1	168	MA	1	1	1	1	1	1	1	2	1	2	1	9	1	1	1	1	1	1	1	1	1	2	1	1	1	2	1	1	1	1	Y	I
1	169	MA	2	3	1	1	1	1	1	2	1	2	1	8	1	1	1	1	1	1	2	1	2	3	1	1	1	3	2	1	2	1	Y	I
1	170	MA	2	4	1	1	1	1	1	2	1	2	1	8	1	1	1	1	1	1	2	1	2	3	1	1	1	3	2	1	2	1	Y	I
1	171	MA	4	4	3	9	1	2	1	2	1	3	1	7	1	1	1	1	1	5	3	1	2	3	1	1	1	6	3	5	2	2	N	E
1	172	MA	4	5	3	9	1	2	2	2	1	3	1	7	1	1	3	1	1	5	3	1	4	3	1	1	1	6	3	5	3	3	N	E
1	173	MA	1	1	1	1	1	2	1	2	1	3	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	2	1	Y	I
1	174	MA	1	3	1	1	1	2	1	2	1	3	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	1	3	1	Y	I
1	175	MA	2	5	1	3	8	2	1	2	1	7	5	1	1	1	3	5	1	1	9	1	8	2	1	1	1	4	7	1	3	2	N	E
1	176	MA	2	6	1	3	8	3	1	2	1	7	5	1	1	1	3	5	1	1	9	1	8	2	1	1	1	4	6	1	3	2	N	E
1	177	MA	3	5	3	3	8	7	1	3	1	7	5	1	5	1	5	7	1	5	8	1	5	1	1	1	1	6	7	1	2	3	N	E
1	178	MA	3	6	5	3	8	8	1	3	1	7	5	1	7	5	5	7	1	5	8	1	5	1	1	3	1	7	8	1	2	5	N	E
1	179	MA	2	4	3	9	7	4	3	6	1	7	5	6	5	2	5	1	5	5	7	2	4	3	1	1	1	3	7	1	2	4	N	E
1	180	MA	3	8	8	9	8	4	5	6	1	7	5	6	8	7	9	5	5	5	7	3	6	3	1	3	2	6	8	5	4	5	N	E
1	181	MA	3	4	4	9	7	3	3	6	1	7	5	1	5	2	5	1	5	5	8	2	4	6	2	1	1	4	7	1	2	4	N	E
1	182	MA	4	9	9	9	9	3	4	6	1	7	5	1	8	7	8	5	5	5	8	3	6	7	2	3	2	7	8	5	4	5	N	E
1	183	MA	8	9	7	9	9	6	5	8	1	9	5	1	9	8	8	9	9	5	9	5	9	7	3	4	7	9	9	9	7	8	N	E
1	184	MA	8	9	9	9	9	6	5	8	1	9	5	1	9	8	8	9	9	5	9	5	9	8	3	4	7	9	9	9	7	8	N	E
1	185	MA	9	9	7	9	9	7	7	8	1	9	5	1	9	8	8	9	9	5	9	5	9	8	5	4	8	9	9	9	7	8	N	E
1	186	MA	9	9	9	9	9	7	7	8	1	9	5	1	9	8	8	9	9	5	9	5	9	8	5	4	8	9	9	9	7	8	N	E
1	187	MA	9	9	9	9	9	4	7	8	1	9	5	1	9	8	8	9	9	5	7	5	9	8	5	4	2	9	9	9	7	8	N	E
1	188	MA	9	9	9	9	9	4	8	8	1	9	5	1	9	8	8	9	9	5	7	5	9	8	5	4	2	9	9	9	7	9	N	E
1	189	MA	3	5	3	6	4	9	1	7	1	9	5	1	1	1	7	9	5	5	9	1	4	8	5	5	2	9	9	1	3	5	N	E
1	190	MA	3	5	3	6	4	9	1	7	1	9	5	1	1	1	7	9	5	5	9	1	4	8	5	5	2	9	9	1	3	5	N	E
1	191	MA	9	9	9	9	9	9	9	9	1	9	5	1	9	8	8	9	9	5	9	5	9	9	7	6	8	9	9	9	7	9	N	E
1	192	MA	9	9	9	9	9	9	9	9	1	9	5	1	9	8	8	9	9	5	9	5	9	9	7	6	8	9	9	9	7	9	N	E
1	193	MA	5	6	7	9	7	1	1	9	1	2	1	9	3	1	1	9	1	1	6	1	2	5	5	1	3	8	3	5	4	3	N	E
1	194	MA	5	6	7	9	7	1	1	9	1	2	1	9	3	1	1	9	1	1	6	1	2	5	5	1	3	8	3	5	4	3	N	E
1	195	MA	5	6	7	9	9	1	1	9	1	2	1	9	3	1	1	9	1	1	4	1	2	5	7	1	3	8	3	5	4	3	N	E
1	196	MA	5	7	7	9	9	1	1	9	1	2	1	9	3	1	1	9	1	1	4	1	5	6	7	1	3	8	3	5	4	4	N	E
1	197	MA	5	8	9	9	9	3	1	9	1	3	1	3	3	1	5	9	1	9	8	1	6	6	8	1	3	9	3	1	5	5	N	E
1	198	MA	5	9	9	9	9	3	3	9	1	3	1	3	3	1	8	9	1	9	8	1	6	6	8	1	3	9	3	1	5	5	N	E
1	199	MA	4	4	7	9	6	1	1	9	1	3	1	9	3	1	1	9	1	1	1	1	2	1	5	1	3	8	2	5	4	3	N	E
1	200	MA	4	5	7	9	9	2	1	9	1	3	1	9	3	1	1	9	1	1	1	1	3	1	5	1	3	8	2	5	4	3	N	E
1	201	MA	5	5	8	9	7	7	7	9	1	6	5	1	3	1	5	9	9	1	4	1	5	2	5	1	3	9	8	5	5	5	N	E
1	202	MA	5	5	8	9	7	7	8	9	1	6	5	1	3	1	8	9	9	1	4	1	5	2	5	1	3	9	8	5	5	5	N	E
1	203	MA	5	7	9	9	9	6	8	9	3	6	5	1	7	2	1	9	1	9	9	1	4	1	5	1	3	9	8	9	3	6	N	E
1	204	MA	5	8	9	9	9	6	8	9	3	6	5	1	7	5	1	9	1	9	9	1	7	1	5	3	3	9	8	9	4	6	N	E
1	205	MA	5	8	9	9	9	8	5	9	7	6	5	1	5	3	8	9	9	5	7	1	5	3	7	1	3	9	8	9	3	7	N	E
1	206	MA	5	9	9	9	9	7	7	9	7	6	5	1	7	6	8	9	9	9	7	3	7	3	7	3	4	9	9	9	6	7	N	E
1	207	MA	5	8	9	9	9	8	6	9	7	6	5	1	5	3	7	9	9	5	8	1	5	5	9	1	3	9	8	9	3	7	N	E
1	208	MA	5	9	9	9	9	8	9	9	7	6	5	1	9	6	8	9	9	8	8	3	8	6	9	3	4	9	9	9	6	8	N	E

1	209	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	7	9	9	9	9	9	9	6	9	7	9	9	9	9	6	9	Y	A
1	210	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	9	9	9	9	9	9	9	6	9	7	9	9	9	9	6	9	Y	A
1	211	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	7	9	9	9	9	9	9	6	9	7	9	9	9	9	7	9	Y	A
1	212	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	9	9	9	9	9	9	9	6	9	7	9	9	9	9	7	9	Y	A
1	213	MA	9	9	9	9	9	8	9	9	8	9	5	1	9	9	9	9	9	9	8	9	9	6	9	7	9	9	9	9	7	9	Y	A
1	214	MA	9	9	9	9	9	8	9	9	8	9	5	1	9	9	9	9	9	9	8	9	9	6	9	7	9	9	9	9	7	9	Y	A
1	215	MA	6	9	9	9	9	9	9	9	8	9	5	1	3	2	7	9	5	5	9	3	5	7	9	5	5	9	9	5	4	7	N	E
1	216	MA	6	9	9	9	9	9	9	9	8	9	5	1	3	2	7	9	5	5	9	3	5	7	9	5	5	9	9	5	4	7	N	E
1	217	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
1	218	MA	9	9	9	9	9	9	9	9	8	9	5	1	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
2	1	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	1	9	9	9	Y	A
2	2	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	3	ARC	9	9	9	9	8	8	9	9	9	9	7	9	9	9	9	9	9	9	9	9	8	9	9	8	9	8	9	9	8	9	Y	A
2	4	ARC	9	8	9	9	8	8	9	9	9	9	7	9	9	9	9	9	9	9	9	9	8	9	9	7	9	8	9	9	7	9	Y	A
2	5	ARC	7	6	5	1	8	7	9	8	9	9	7	1	8	9	9	5	9	1	2	9	8	8	5	7	8	7	7	8	8	8	N	E
2	6	ARC	6	5	5	1	8	7	9	8	9	9	7	1	8	9	7	5	9	1	2	9	6	7	5	7	8	7	8	7	7	7	N	E
2	7	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	Y	A
2	8	ARC	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	6	9	8	8	9	9	8	9	Y	A
2	9	ARC	9	8	9	9	8	8	9	8	8	8	8	9	8	9	9	7	9	9	1	9	7	8	9	8	8	8	8	9	9	8	Y	A
2	10	ARC	9	8	9	9	8	8	9	8	8	8	8	9	8	9	9	7	9	9	1	9	7	8	9	8	8	8	7	9	9	8	Y	A
2	11	ARC	8	6	8	9	3	8	9	7	6	8	7	9	7	9	9	8	8	7	1	9	5	8	8	7	8	7	7	9	7	8	N	E
2	12	ARC	7	5	8	9	3	7	7	7	6	8	7	9	7	6	9	6	8	7	1	9	5	7	7	6	7	7	8	9	6	7	N	E
2	13	ARC	8	7	9	1	4	9	5	5	6	7	7	1	7	7	5	8	9	7	7	7	6	7	6	5	9	7	7	9	7	7	N	E
2	14	ARC	7	6	2	1	1	6	2	4	6	7	7	1	2	4	4	5	5	1	7	3	4	4	2	5	5	3	4	4	4	4	N	E
2	15	ARC	7	6	9	1	4	6	3	5	8	5	1	1	7	5	5	7	9	5	1	7	5	6	2	5	9	6	7	8	7	6	N	E
2	16	ARC	3	2	2	1	2	5	1	5	7	3	1	1	3	5	3	3	7	1	1	3	4	3	1	5	5	4	5	4	4	3	N	E
2	17	ARC	1	1	5	1	2	1	2	2	3	3	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	3	1	1	1	Y	I
2	18	ARC	1	1	1	1	2	1	2	2	3	3	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	19	ARC	3	1	5	1	1	1	1	2	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	20	ARC	2	1	1	1	1	1	1	2	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	21	ARC	1	1	5	1	1	2	2	1	1	3	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	2	1	2	1	Y	I
2	22	ARC	2	1	1	1	1	2	2	1	1	3	1	1	1	1	1	1	1	1	9	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	23	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	9	9	Y	A
2	24	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	9	9	Y	A
2	25	ARC	8	9	9	9	8	8	9	8	9	9	7	1	9	9	9	9	9	7	8	9	8	9	9	9	7	9	9	9	8	9	Y	A
2	26	ARC	7	9	9	9	8	8	9	8	9	9	7	1	9	9	9	9	9	7	8	9	8	9	9	9	7	9	9	9	8	9	Y	A
2	27	ARC	8	7	4	1	9	7	7	8	9	9	7	5	9	8	8	8	9	1	7	9	8	7	7	9	7	7	7	7	7	7	N	E
2	28	ARC	7	5	4	1	5	7	9	8	9	9	7	5	9	8	6	8	9	1	7	9	6	7	7	9	7	7	8	7	6	7	N	E
2	29	ARC	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	7	8	7	9	9	9	9	Y	A
2	30	ARC	8	9	9	9	9	8	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	7	7	5	9	9	8	9	Y	A
2	31	ARC	8	7	8	9	7	8	9	8	9	8	8	9	9	9	8	5	9	9	2	9	8	8	9	9	6	9	7	8	8	8	Y	A
2	32	ARC	8	7	8	9	7	8	9	8	9	8	8	9	9	9	8	5	9	9	2	9	8	8	9	9	6	9	7	8	8	8	Y	A
2	33	ARC	7	6	8	7	6	7	9	7	6	8	7	9	8	8	7	8	9	6	3	8	6	7	7	5	7	5	8	6	7	7	N	E
2	34	ARC	5	4	8	5	4	5	7	7	6	6	7	9	5	5	5	5	9	6	3	7	6	6	6	5	5	5	6	5	6	6	N	E
2	35	ARC	8	7	9	1	6	8	3	3	8	7	7	1	7	7	4	8	1	1	5	7	6	7	5	7	7	7	7	6	7	7	N	E
2	36	ARC	5	3	1	1	4	4	1	3	4	3	7	7	1	4	2	5	1	1	5	5	3	4	3	7	4	4	4	3	6	4	N	E
2	37	ARC	6	5	9	1	5	5	2	3	7	5	5	4	7	5	3	8	1	1	1	7	5	5	3	6	7	5	6	6	7	5	N	E
2	38	ARC	4	1	1	1	1	3	1	3	5	5	5	1	3	3	1	5	1	1	1	4	2	3	2	6	4	3	5	3	4	3	N	E
2	39	ARC	1	1	5	1	4	1	2	1	1	3	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	4	1	N	E
2	40	ARC	1	1	1	1	4	1	2	1	1	3	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	2	1	Y	I
2	41	ARC	1	1	5	1	1	1	1	1	1	3	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	3	1	Y	I
2	42	ARC	1	1	1	1	1	1	1	1	1	3	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	3	1	Y	I
2	43	ARC	1	1	5	1	1	2	1	1	1	3	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	3	1	Y	I
2	44	ARC	1	1	1	1	1	2	1	1	1	3	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	3	1	Y	I
2	45	ARC	9	9	9	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	1	9	9	9	Y	A
2	46	ARC	9	9	9	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	Y	A
2	47	ARC	9	9	9	9	7	8	9	8	9	9	7	9	9	9	9	9	9	9	7	9	8	9	9	7	8	9	9	9	8	9	Y	A
2	48	ARC	8	9	9	9	7	8	8	8	9	9	7	9	9	9	9	9	9	9	7	9	8	9	9	7	8	9	9	9	8	9	Y	A
2	49	ARC	7	7	4	1	4	7	9	9	9	9	7	2	9	8	6	6	9	1	2	9	8	7	7	9	7	7	7	5	7	7	N	E
2	50	ARC	6	6	4	1	4	7	9	9	9	9	7	2	9	8	5	6	9	1	2	8	6	7	6	9	7	7	7	5	6	7	N	E
2	51	ARC	9	9	9	9	8	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	52	ARC	9	9	9	9	5	8	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	6	9	9	8	9	Y	A
2	53	ARC	8	7	8	9	7	8	9	8	6	7	5	9	9	9	9	9	9	9	9	9	8	9	9	9	8	7	8	9	8	9	Y	A
2	54	ARC	8	7	8	9	7	8	9	8	4	7	5	9	9	9	9	9	9	9	9	9	8	9	9	9	8	7	8	9	8	9	Y	A
2	55	ARC	7	6	8	9	6	7	9	7	5	7	5	9	6	9	6	5	9	8	5	9	7	7	4	9	8	5	9	9	7	7	N	E
2	56	ARC	6	4	8	9	4	7	7	7	5	7	5	9	5	7	4	5	9	8	5	9	7	7	4	7	7	5	9	7	6	7	N	E
2	57	ARC	7	7	9	1	6	8	3	8	7	7	7	1	7	8	7	8	3	8	7	8	7	7	6	9	7	7	7	8	7	7	N	E
2	58	ARC	6	3	1	1	4	5	1	8	6	7	7	1	1	3	2	8	3	5	7	7	5	5	4	9	5	5	6	5	6	5	N	E
2	59	ARC	7	6	9	1	1	8	6	8	6	5	5	1	7	8	7	8	3	8	5	7	6	7	2	9	7	7	7	7	7	7	N	E
2	60	ARC	3	3	1	1	1	3	2	8	3	5	5	1	1	3	2	8	1	1	5	6	2	3	1	9	5	3	5	3	4	3	N	E
2	61	ARC	1	1	5	1	6	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	3	1	Y	I
2	62	ARC	1	1	1	1	6	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I

2	63	ARC	1	1	5	1	1	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	2	1	Y	I
2	64	ARC	1	1	1	1	1	1	2	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	65	ARC	1	1	5	1	1	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	66	ARC	1	1	1	1	1	2	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	67	ARC	9	9	9	9	7	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	68	ARC	9	9	9	9	7	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	69	ARC	9	9	9	9	8	7	9	9	9	9	9	9	9	9	9	9	9	9	7	9	8	9	9	9	9	8	9	9	9	9	Y	A
2	70	ARC	9	9	9	9	7	7	9	9	9	9	9	9	9	9	9	9	9	9	7	9	8	9	9	9	9	8	9	9	9	9	Y	A
2	71	ARC	7	7	4	1	5	6	8	7	9	9	7	4	7	7	8	5	9	1	1	9	7	7	6	9	8	6	8	6	7	7	N	E
2	72	ARC	7	6	4	1	5	6	8	6	9	9	7	4	7	7	4	5	9	1	1	9	6	6	5	9	8	5	7	6	7	6	N	E
2	73	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	Y	A
2	74	ARC	8	9	9	9	7	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	8	9	9	8	9	Y	A
2	75	ARC	8	7	6	9	6	8	9	9	9	7	8	9	9	9	9	9	9	8	9	9	8	9	9	9	7	8	8	9	8	9	Y	A
2	76	ARC	8	7	6	9	6	9	9	9	9	7	8	9	9	9	9	9	9	8	9	9	8	9	9	9	7	8	8	9	8	9	Y	A
2	77	ARC	7	7	7	7	4	2	7	7	9	7	6	7	7	7	6	8	9	5	2	9	6	7	9	7	8	6	7	7	7	7	N	E
2	78	ARC	6	3	7	8	3	2	5	7	9	7	6	7	3	2	4	5	9	5	2	9	5	6	8	7	7	5	7	6	7	6	N	E
2	79	ARC	7	7	9	1	3	7	6	4	8	6	7	5	7	7	6	8	3	9	8	9	7	7	4	8	8	5	7	8	7	7	N	E
2	80	ARC	5	3	1	1	3	3	4	4	6	6	5	5	1	5	2	5	3	1	8	7	3	5	3	8	6	4	6	5	6	5	N	E
2	81	ARC	6	6	9	1	3	6	5	4	6	5	6	5	5	7	6	8	1	9	1	9	7	6	3	8	8	6	6	9	7	6	N	E
2	82	ARC	5	3	1	1	3	3	3	4	4	5	3	5	1	3	1	5	3	1	1	6	2	3	1	8	6	3	3	4	4	3	N	E
2	83	ARC	1	1	3	1	1	2	2	1	7	1	5	1	1	1	1	1	1	1	1	1	1	1	4	1	1	2	1	1	2	1	Y	I
2	84	ARC	1	1	1	1	1	2	2	1	7	1	5	1	1	1	1	1	1	1	1	1	1	1	4	1	1	2	1	1	2	1	Y	I
2	85	ARC	1	1	4	1	1	1	1	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	2	1	Y	I
2	86	ARC	1	1	1	1	1	1	1	1	7	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	2	1	Y	I
2	87	ARC	1	1	4	1	1	1	2	1	7	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	2	1	Y	I
2	88	ARC	1	1	1	1	1	1	2	1	7	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1	1	2	1	Y	I
2	89	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	90	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	91	ARC	9	9	9	9	9	8	9	9	9	8	9	9	9	9	9	9	9	9	8	9	8	9	9	9	9	8	9	9	8	9	Y	A
2	92	ARC	9	9	9	9	9	8	9	9	9	8	9	9	9	9	9	9	9	9	8	9	8	9	9	9	9	8	9	9	8	9	Y	A
2	93	ARC	7	8	4	1	9	7	9	9	9	7	9	5	9	9	9	9	9	1	5	9	8	8	4	9	8	8	9	8	7	8	N	E
2	94	ARC	7	7	4	1	9	7	7	9	9	7	9	5	9	9	7	9	9	1	5	9	6	7	3	9	8	7	7	8	7	7	N	E
2	95	ARC	9	9	9	9	9	9	9	9	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	96	ARC	9	9	9	9	7	8	9	9	9	7	9	9	9	9	9	9	9	9	9	9	3	9	9	9	8	7	9	9	9	9	Y	A
2	97	ARC	8	7	8	9	8	8	9	9	9	7	9	9	9	9	9	7	9	9	5	9	8	9	8	9	7	7	8	9	8	9	Y	A
2	98	ARC	8	7	8	9	8	7	9	9	9	7	9	9	9	9	9	7	9	9	5	9	8	9	7	9	7	7	8	9	8	9	Y	A
2	99	ARC	7	7	8	9	8	9	9	8	9	7	9	9	5	9	8	7	9	6	1	9	7	8	9	9	7	3	8	9	8	8	N	E
2	100	ARC	6	5	8	6	8	6	5	8	9	7	7	9	5	5	6	8	9	6	1	9	5	7	8	7	7	6	7	6	7	7	N	E
2	101	ARC	8	7	9	1	5	7	7	7	3	5	5	5	7	9	8	9	9	9	8	9	6	8	4	9	9	8	7	9	8	8	N	E
2	102	ARC	5	6	1	1	5	6	4	5	3	5	5	5	1	5	3	3	9	1	8	7	4	5	3	7	7	5	7	5	6	5	N	E
2	103	ARC	7	7	9	1	6	7	6	4	3	5	5	1	7	8	7	9	9	9	3	9	6	7	4	7	9	7	7	7	7	7	N	E
2	104	ARC	4	3	1	1	2	4	3	4	3	5	5	1	1	5	2	5	9	1	3	6	3	4	2	7	7	4	5	3	6	4	N	E
2	105	ARC	2	1	5	1	7	1	2	1	3	3	2	1	1	1	1	1	5	1	1	1	1	1	1	1	1	2	1	1	2	1	Y	I
2	106	ARC	2	1	1	1	7	1	2	1	3	3	2	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	107	ARC	3	1	5	1	1	1	1	1	3	2	1	1	1	1	1	1	5	1	1	1	1	1	1	1	1	2	1	1	2	1	Y	I
2	108	ARC	2	1	1	1	1	1	1	1	3	2	1	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	109	ARC	1	1	5	1	1	1	1	1	3	2	1	1	1	1	1	1	5	1	1	1	1	1	1	1	1	2	1	1	3	1	Y	I
2	110	ARC	2	1	1	1	1	1	1	1	3	2	1	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	111	ARC	8	7	1	9	6	1	9	8	3	1	4	1	9	9	9	5	9	9	1	9	7	8	9	7	8	8	8	9	7	8	N	E
2	112	ARC	8	7	1	9	6	1	9	8	3	1	4	1	9	9	9	5	9	9	1	9	7	8	9	7	8	8	8	9	7	8	N	E
2	113	ARC	1	1	1	1	1	1	1	1	3	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	114	ARC	1	1	1	1	1	1	1	1	3	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	115	ARC	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	116	ARC	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	117	ARC	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	5	9	8	9	9	9	9	8	9	9	8	9	Y	A
2	118	ARC	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	5	9	8	9	9	9	9	8	9	9	8	9	Y	A
2	119	ARC	7	8	4	1	9	7	9	8	9	9	9	4	9	8	9	9	9	1	2	9	8	8	4	9	8	7	8	6	7	8	N	E
2	120	ARC	6	7	4	1	9	7	9	8	9	9	9	4	9	8	7	9	9	1	2	9	6	7	3	9	8	7	7	6	7	7	N	E
2	121	ARC	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	Y	A
2	122	ARC	9	9	9	9	7	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	8	9	9	7	9	Y	A
2	123	ARC	8	7	8	9	4	7	9	9	9	7	9	9	9	9	9	7	9	9	2	9	8	9	9	9	7	7	8	9	7	9	Y	A
2	124	ARC	8	7	8	9	4	9	9	9	9	7	9	9	9	9	9	7	9	9	2	9	8	9	9	9	7	7	8	9	7	9	Y	A
2	125	ARC	7	7	8	9	2	3	9	8	9	7	6	9	5	9	7	9	9	3	2	9	7	8	9	9	7	7	8	9	8	8	N	E
2	126	ARC	5	5	8	9	2	3	6	8	9	7	6	9	4	5	5	5	9	3	2	9	5	6	7	5	7	6	7	7	7	6	N	E
2	127	ARC	8	7	9	7	1	7	8	8	7	5	5	1	7	9	8	8	1	8	7	9	6	7	5	9	9	7	7	9	8	7	N	E
2	128	ARC	5	6	1	1	1	8	3	4	6	5	5	1	1	6	3	5	1	2	7	8	4	5	4	8	6	5	6	4	5	5	N	E
2	129	ARC	7	6	9	1	1	8	7	4	7	5	7	1	7	8	7	8	1	8	5	9	7	7	6	9	9	7	7	8	7	7	N	E
2	130	ARC	4	2	1	1	1	3	4	4	6	5	4	1	1	6	3	5	1	2	5	6	5	4	2	8	6	3	6	4	5	4	N	E
2	131	ARC	3	1	5	1	7	1	2	1	6	2	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	N	E
2	132	ARC	3	1	1	1	5	1	2	1	6	2	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	133	ARC	1	1	5	1	1	1	1	1	6	2	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	134	ARC	1	1	1	1	1	1	1	1	6	2	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I

2	135	ARC	1	1	5	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	136	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	137	ARC	7	7	1	9	6	7	9	8	6	5	7	6	9	9	8	1	9	8	1	9	6	7	3	5	8	6	7	9	7	7	N	E
2	138	ARC	7	7	1	9	6	7	9	8	6	5	7	6	9	9	8	1	9	8	1	9	7	7	3	5	8	6	7	9	7	7	N	E
2	139	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	140	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	141	ARC	9	9	8	7	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	142	ARC	9	9	8	7	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	Y	A
2	143	ARC	8	9	8	7	9	8	9	9	9	9	9	9	9	9	9	9	9	9	2	9	8	9	9	9	9	9	7	9	8	9	Y	A
2	144	ARC	7	9	8	7	9	7	9	9	9	9	9	9	9	9	9	9	9	9	2	9	8	9	9	9	9	9	7	9	8	9	Y	A
2	145	ARC	8	8	4	1	8	7	9	7	9	7	9	4	9	9	9	9	9	1	1	9	5	8	4	9	8	8	9	7	6	8	N	E
2	146	ARC	8	8	4	1	8	6	9	7	9	7	9	4	9	9	5	9	9	1	1	9	5	7	3	9	8	7	7	7	6	7	N	E
2	147	ARC	9	9	9	9	9	9	9	9	9	7	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	8	9	8	9	Y	A
2	148	ARC	9	9	9	9	8	8	9	9	9	7	9	9	9	9	9	9	9	9	8	9	9	9	9	9	8	9	8	9	7	9	Y	A
2	149	ARC	8	7	6	7	7	7	9	8	7	7	7	9	9	9	9	7	9	7	1	9	7	7	9	9	7	7	7	9	8	7	Y	A
2	150	ARC	8	7	6	7	7	7	9	8	7	7	7	9	9	9	9	7	9	7	1	9	7	7	9	9	7	7	7	9	8	7	Y	A
2	151	ARC	7	7	7	8	7	6	9	8	6	6	7	9	3	8	7	9	9	2	1	9	6	7	9	9	7	7	7	9	7	7	N	E
2	152	ARC	6	5	7	7	7	6	9	4	6	6	7	9	6	5	5	6	9	2	1	9	5	6	9	7	7	6	7	5	6	6	N	E
2	153	ARC	7	7	9	1	7	6	5	3	6	5	6	4	1	8	7	8	9	8	7	9	7	7	5	8	9	7	7	5	7	7	N	E
2	154	ARC	4	5	1	1	5	4	2	4	6	5	6	4	6	1	3	5	7	2	7	6	3	5	2	8	7	4	6	8	5	5	N	E
2	155	ARC	7	6	9	1	7	3	4	3	6	5	5	3	1	8	7	8	9	8	1	9	7	7	4	8	9	6	7	5	7	7	N	E
2	156	ARC	3	2	1	1	5	2	1	6	6	5	5	5	1	1	3	5	9	2	1	6	3	4	2	8	7	3	5	8	4	4	N	E
2	157	ARC	1	1	4	1	1	2	1	1	6	1	3	1	1	1	1	1	5	1	2	1	1	1	1	1	1	1	1	3	3	1	Y	I
2	158	ARC	1	1	1	1	1	2	1	1	6	1	3	1	1	1	1	1	5	1	2	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	159	ARC	1	1	4	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	160	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	161	ARC	1	1	4	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	162	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	N	E
2	163	ARC	7	7	1	7	8	7	8	7	6	5	7	4	9	9	8	5	9	7	1	9	7	7	6	6	7	7	5	9	7	7	N	E
2	164	ARC	7	7	1	7	8	7	8	7	6	5	7	4	9	9	8	5	9	7	1	9	5	7	6	6	7	7	5	9	7	7	N	E
2	165	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	166	ARC	1	1	1	1	1	1	1	1	6	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	167	ARC	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	168	ARC	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	8	9	9	9	9	Y	A
2	169	ARC	8	8	9	9	8	8	9	9	9	8	9	9	9	9	9	9	9	9	8	9	8	9	9	9	9	8	8	9	8	9	Y	A
2	170	ARC	8	7	9	9	8	8	9	9	9	8	9	9	9	9	9	9	9	9	8	9	8	9	9	9	9	8	8	9	8	9	Y	A
2	171	ARC	7	7	7	1	7	7	9	8	9	7	7	6	9	8	8	8	9	1	2	9	8	7	6	9	8	7	7	5	7	7	N	E
2	172	ARC	7	6	7	1	7	7	9	8	9	7	7	7	9	8	7	8	9	1	2	9	6	7	6	9	8	7	7	5	7	7	N	E
2	173	ARC	9	9	9	9	9	9	9	9	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	8	9	Y	A
2	174	ARC	9	8	9	9	9	8	9	9	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	7	9	9	7	9	Y	A
2	175	ARC	8	8	9	7	8	7	9	8	9	7	8	9	9	9	9	8	9	9	1	9	8	8	9	9	7	7	8	9	7	8	Y	A
2	176	ARC	8	8	9	7	8	6	9	8	9	7	8	9	9	9	9	8	9	9	1	9	8	8	9	9	7	7	8	9	7	8	Y	A
2	177	ARC	7	6	7	7	7	7	8	8	3	7	7	5	5	9	7	6	9	2	1	9	6	7	9	8	8	6	7	9	8	7	N	E
2	178	ARC	7	5	5	7	5	5	8	8	3	7	5	5	4	5	5	6	9	2	1	9	4	6	9	8	7	5	7	9	8	6	N	E
2	179	ARC	8	6	7	1	7	6	7	3	3	6	7	3	6	9	7	8	9	8	4	9	6	7	4	8	9	7	7	9	8	7	N	E
2	180	ARC	7	3	2	1	5	5	3	3	3	5	7	3	1	3	2	5	9	2	4	6	4	4	3	8	7	4	6	4	6	4	N	E
2	181	ARC	7	6	7	1	7	8	7	3	3	5	5	2	6	9	7	8	9	8	4	9	7	7	4	8	9	7	7	9	7	7	N	E
2	182	ARC	5	3	2	1	5	4	5	3	3	5	5	2	1	3	2	5	9	2	4	6	4	4	3	8	7	4	6	3	5	4	N	E
2	183	ARC	2	1	5	1	1	1	2	1	3	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	184	ARC	2	1	1	1	1	1	2	1	3	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	185	ARC	1	1	5	1	1	1	1	1	3	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	186	ARC	1	1	1	1	1	1	1	1	3	1	5	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	187	ARC	1	1	2	1	1	1	3	1	3	1	1	1	1	1	1	1	1	1	3	3	1	1	1	1	1	1	1	1	1	1	Y	I
2	188	ARC	1	1	2	1	1	1	2	1	3	1	1	1	1	1	1	1	1	1	3	3	1	1	1	1	1	1	1	1	1	1	Y	I
2	189	ARC	7	5	8	6	7	6	8	8	3	5	6	7	9	9	7	5	9	9	5	9	6	7	5	5	8	5	1	9	7	7	N	E
2	190	ARC	7	5	8	6	7	6	8	8	3	5	6	7	9	9	7	5	9	9	5	9	6	7	5	5	8	6	1	9	7	7	N	E
2	191	ARC	1	1	2	1	1	1	5	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	192	ARC	1	1	2	1	1	1	5	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	193	ARC	8	7	7	1	8	9	9	3	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	8	9	9	8	9	9	Y	A
2	194	ARC	8	7	7	1	8	9	9	3	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	8	9	7	8	9	9	Y	A
2	195	ARC	8	7	7	1	7	9	9	3	9	9	9	9	9	9	9	8	9	9	7	9	8	9	9	9	8	3	7	8	8	9	N	E
2	196	ARC	8	6	7	1	7	9	9	3	9	9	9	9	9	9	9	8	9	9	7	9	6	9	9	9	7	3	7	8	8	9	N	E
2	197	ARC	5	5	2	1	3	6	2	3	9	7	9	4	9	7	6	7	8	1	4	7	4	6	5	8	8	5	6	5	6	6	N	E
2	198	ARC	5	4	2	1	5	6	7	3	9	7	9	4	9	7	3	7	8	1	4	6	4	6	5	8	8	5	6	5	6	6	N	E
2	199	ARC	9	8	4	1	9	9	9	4	9	7	9	9	9	9	9	9	9	9	9	9	8	9	9	9	8	9	8	3	7	9	N	E
2	200	ARC	9	7	4	1	9	9	9	4	9	7	9	9	9	9	9	9	9	9	9	9	7	9	9	9	7	9	8	3	6	9	N	E
2	201	ARC	5	7	2	1	3	6	3	3	3	4	5	6	9	9	5	5	9	9	4	9	5	5	9	7	5	5	3	6	5	5	N	E
2	202	ARC	5	6	2	1	3	6	2	3	3	4	5	6	9	9	5	5	9	9	4	9	5	5	9	7	5	5	3	6	5	5	N	E
2	203	ARC	5	4	2	1	4	4	2	3	3	4	4	3	7	8	5	5	5	2	3	8	5	4	8	6	7	3	7	1	6	4	N	E
2	204	ARC	5	3	1	1	2	4	1	3	3	4	3	3	3	3	5	5	5	2	2	6	3	3	7	6	5	2	5	1	6	3	N	E
2	205	ARC	5	5	2	1	4	6	2	1	2	4	2	2	5	7	3	2	1	8	5	9	5	4	1	6	8	1	6	1	5	4	N	E
2	206	ARC	3	1	1	1	4	3	1	1	2	4	2	2	1	4	2	1	1	2	3	8	3	2	1	6	4	1	2	1	4	2	N	E

2	207	ARC	7	5	1	1	3	4	5	1	2	4	5	1	5	7	3	2	1	8	5	8	5	5	3	6	8	2	6	1	5	5	N	E
2	208	ARC	5	1	1	1	1	2	1	1	2	4	2	1	1	4	1	1	1	2	5	5	2	1	1	6	4	1	1	1	3	1	N	E
2	209	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	210	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	211	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	212	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	213	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	214	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	215	ARC	6	1	1	1	1	1	2	1	1	1	2	4	9	9	3	1	5	9	1	6	3	2	1	2	5	1	1	5	6	2	N	E
2	216	ARC	6	1	1	1	1	1	1	1	1	1	2	4	9	9	3	1	5	9	1	6	3	2	1	2	5	1	1	5	6	2	N	E
2	217	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	218	ARC	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	1	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	2	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	3	MA	1	1	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	1	2	1	2	1	1	2	1	2	1	1	2	1	Y	I
2	4	MA	1	2	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	1	2	1	2	1	1	3	1	2	1	1	3	1	Y	I
2	5	MA	3	4	5	2	3	2	1	2	1	1	3	9	2	2	1	5	1	9	9	1	2	2	5	3	2	2	2	2	2	2	N	E
2	6	MA	4	5	5	2	3	2	1	2	1	1	3	9	2	2	3	5	1	9	9	1	3	3	5	3	2	2	2	2	3	3	N	E
2	7	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	8	MA	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	9	MA	2	2	2	2	3	2	1	2	1	2	2	1	2	1	1	2	1	1	9	1	3	2	1	2	2	2	2	1	2	2	Y	I
2	10	MA	2	2	2	2	3	2	1	2	1	2	2	1	2	1	1	2	1	1	9	1	3	2	1	2	2	2	2	1	2	2	Y	I
2	11	MA	2	4	2	2	7	2	1	4	4	4	3	1	2	2	2	2	2	6	8	1	5	2	3	2	2	2	3	2	3	2	N	E
2	12	MA	4	5	2	4	8	3	3	4	4	3	3	1	2	4	3	2	2	6	8	1	5	4	6	4	3	4	4	4	4	4	N	E
2	13	MA	2	5	1	7	7	6	7	5	4	3	5	5	3	4	5	4	4	5	2	5	4	5	6	5	1	5	4	3	4	5	N	E
2	14	MA	4	7	8	7	9	7	9	7	4	5	5	5	7	5	7	5	5	5	2	7	8	7	7	5	5	7	6	7	6	7	N	E
2	15	MA	3	5	1	5	6	6	7	7	3	7	9	5	5	5	5	4	4	8	9	5	5	5	8	5	1	5	5	3	5	5	N	E
2	16	MA	7	7	8	5	8	8	9	7	2	7	9	5	7	6	8	7	5	9	9	7	7	7	9	5	5	7	7	8	7	7	N	E
2	17	MA	8	7	5	8	8	9	9	8	8	7	9	7	6	8	8	9	9	9	1	9	8	8	9	9	9	9	8	9	8	8	Y	A
2	18	MA	9	7	9	8	9	9	9	8	8	7	9	7	7	8	8	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	19	MA	7	9	5	9	9	9	9	8	9	7	9	7	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	20	MA	8	9	9	9	9	9	9	8	9	7	9	7	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	21	MA	9	9	5	8	9	8	9	8	8	7	9	9	5	8	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	22	MA	8	9	9	8	9	8	9	8	8	7	9	9	5	8	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	Y	A
2	23	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	24	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	25	MA	2	1	1	1	4	1	1	1	1	1	3	9	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	Y	I
2	26	MA	3	1	1	1	4	1	1	1	1	1	3	9	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	Y	I
2	27	MA	1	1	6	5	1	4	1	1	1	1	3	5	1	2	1	2	1	1	4	1	3	1	1	1	1	1	2	1	1	1	N	E
2	28	MA	1	1	6	5	4	1	1	1	1	1	3	5	1	2	1	2	1	1	4	1	2	1	1	1	1	1	2	1	4	1	N	E
2	29	MA	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	30	MA	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	Y	I
2	31	MA	2	2	2	1	3	3	1	1	1	2	1	1	1	1	1	5	1	1	8	1	2	1	1	1	1	1	2	1	1	1	Y	I
2	32	MA	2	2	2	1	3	3	1	1	1	2	1	1	1	1	1	5	1	1	8	1	2	1	1	1	1	1	2	1	1	1	Y	I
2	33	MA	3	2	2	1	2	2	1	1	2	2	1	1	1	1	1	2	1	1	2	1	5	1	1	1	1	1	2	1	1	1	Y	I
2	34	MA	1	2	2	1	6	2	1	1	2	2	1	1	5	1	1	2	1	1	2	1	5	1	1	1	1	1	2	1	3	1	Y	I
2	35	MA	2	2	1	5	4	2	1	1	3	3	1	2	5	1	1	1	1	1	2	2	3	2	1	1	1	1	2	2	3	2	Y	I
2	36	MA	3	3	9	5	6	3	1	2	3	3	1	2	9	1	1	3	1	1	3	3	3	3	3	2	3	2	2	3	4	3	N	E
2	37	MA	2	3	1	5	3	3	1	2	7	5	2	5	4	1	1	1	1	1	9	2	3	2	1	2	2	1	2	2	3	2	N	E
2	38	MA	2	4	9	5	3	3	4	2	4	5	2	8	7	1	2	3	1	1	9	3	5	3	2	2	2	1	2	2	4	3	N	E
2	39	MA	5	1	5	5	4	2	1	2	9	8	2	5	9	2	1	3	1	1	9	3	3	2	1	1	2	1	1	2	5	2	N	E
2	40	MA	5	1	9	5	4	2	1	2	9	8	2	5	9	2	1	3	1	1	9	3	3	2	1	1	2	1	1	2	5	2	N	E
2	41	MA	8	2	5	5	5	3	1	2	9	8	1	5	9	1	1	3	1	1	9	3	3	3	1	1	2	2	1	2	5	3	N	E
2	42	MA	8	2	9	5	5	3	1	2	9	8	1	5	9	1	1	3	1	1	9	3	3	3	1	1	2	2	1	2	5	3	N	E
2	43	MA	5	2	5	5	5	2	1	2	9	8	2	4	9	1	1	3	1	1	4	3	3	2	1	1	2	2	1	2	5	2	N	E
2	44	MA	5	2	9	5	5	2	1	2	9	8	2	4	9	1	1	3	1	1	4	3	3	2	1	1	2	2	1	2	5	2	N	E
2	45	MA	2	1	1	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1	Y	I
2	46	MA	2	1	1	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	1	Y	I
2	47	MA	2	1	1	1	3	1	1	2	1	1	3	1	1	1	1	1	1	1	3	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	48	MA	3	1	1	1	3	1	1	2	1	1	3	1	1	1	1	1	1	1	3	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	49	MA	2	3	6	7	6	2	1	2	1	1	3	5	1	2	2	4	1	1	3	1	2	2	2	1	1	1	2	2	3	2	N	E
2	50	MA	2	3	6	7	6	2	1	2	1	1	3	5	1	2	2	4	1	1	4	1	3	2	2	1	2	1	2	2	3	2	N	E
2	51	MA	1	1	1	1	4	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	Y	I
2	52	MA	2	1	1	1	4	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	3	1	Y	I
2	53	MA	2	2	2	1	3	3	1	2	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	3	1	2	1	Y	I
2	54	MA	2	2	2	1	3	3	1	2	2	2	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	2	3	1	2	1	Y	I
2	55	MA	2	2	2	2	4	3	1	2	5	2	2	1	4	3	2	5	1	1	8	1	3	2	2	2	2	2	1	2	3	2	N	E
2	56	MA	3	2	2	2	6	3	2	2	5	2	2	1	5	5	2	5	1	1	8	1	3	2	2	2	2	2	1	2	4	2	N	E
2	57	MA	2	2	1	7	4	2	5	3	4	3	3	2	5	2	2	2	1	1	3	2	3	2	3	2	2	2	2	2	3	2	N	E
2	58	MA	3	3	9	7	6	3	7	3	5	3	3	2	9	5	2	2	1	1	3	3	3	3	3	2	3	3	3	3	4	3	N	E
2	59	MA	3	5	1	7	7	3	5	3	4	5	4	9	5	2	2	2	1	1	9	2	4	3	4	3	2	3	3	2	3	3	N	E
2	60	MA	4	6	9	7	7	3	7	3	7	5	4	9	9	2	2	2	1	1	9	4	4	4	5	3	3	4	3	2	5	4	N	E

2	61	MA	6	4	5	7	6	5	7	4	9	5	1	9	7	5	3	7	2	1	9	2	5	5	6	5	3	5	4	5	6	5	N	E
2	62	MA	6	4	9	7	6	5	8	4	9	5	1	9	7	5	3	7	2	1	9	2	5	5	6	5	3	5	4	5	6	5	N	E
2	63	MA	7	5	5	7	9	5	7	4	9	5	1	3	9	2	4	5	2	1	9	2	5	5	6	5	4	5	5	7	7	5	N	E
2	64	MA	7	5	9	7	9	8	7	4	9	5	1	3	9	2	4	5	2	1	9	7	5	6	7	5	4	7	5	7	7	6	N	E
2	65	MA	8	5	5	7	9	5	5	4	9	5	1	9	9	2	4	5	2	1	9	3	7	5	7	5	2	6	5	7	7	5	N	E
2	66	MA	8	5	9	7	9	7	8	4	9	5	1	9	9	2	4	5	2	1	9	3	7	7	7	5	2	7	5	7	7	7	N	E
2	67	MA	2	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	3	1	1	1	1	Y	I
2	68	MA	2	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	3	1	1	1	1	Y	I
2	69	MA	2	1	1	1	2	3	1	1	1	1	1	1	1	1	1	1	1	1	7	1	2	1	1	1	2	3	1	1	2	1	Y	I
2	70	MA	3	1	1	1	2	3	1	1	1	1	1	1	1	1	1	1	1	1	7	1	2	1	1	1	2	3	1	1	2	1	Y	I
2	71	MA	3	3	6	7	2	3	1	4	1	1	1	7	3	2	3	5	1	9	9	1	3	3	2	1	2	2	2	3	2	3	N	E
2	72	MA	3	3	6	7	2	3	1	4	1	1	1	7	3	2	5	5	1	9	9	1	3	3	2	1	2	2	2	3	3	3	N	E
2	73	MA	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	2	1	Y	I
2	74	MA	2	1	1	1	1	2	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	2	1	1	3	1	Y	I
2	75	MA	2	2	4	1	5	2	1	2	1	2	1	1	2	1	2	1	1	2	1	1	4	2	1	1	2	2	3	1	2	2	Y	I
2	76	MA	2	2	4	1	5	2	1	2	1	2	1	1	2	1	2	1	1	2	1	1	4	2	1	1	2	2	3	2	2	2	Y	I
2	77	MA	3	3	3	2	6	3	5	3	1	2	3	4	5	3	3	2	1	5	7	1	3	3	1	3	2	3	3	3	3	3	N	E
2	78	MA	3	4	3	2	8	3	2	3	1	2	3	4	6	3	5	7	1	5	7	1	4	3	2	3	2	3	3	3	3	3	N	E
2	79	MA	3	2	1	7	7	3	5	6	2	4	3	5	5	4	3	2	1	2	5	1	3	3	2	3	2	3	3	2	3	3	N	E
2	80	MA	4	4	9	7	7	3	7	6	4	4	5	5	7	7	5	5	1	7	5	3	5	5	3	3	4	6	4	5	4	5	N	E
2	81	MA	4	5	1	8	7	4	5	6	4	5	5	5	5	4	3	2	1	1	9	2	3	4	2	3	2	5	5	2	3	4	N	E
2	82	MA	5	6	9	8	7	5	5	6	6	5	5	5	9	7	5	5	1	7	9	3	7	5	3	3	4	6	6	5	5	5	N	E
2	83	MA	7	5	6	7	7	7	9	7	7	5	7	9	9	5	5	5	1	8	9	8	8	7	6	7	7	8	9	8	7	7	N	E
2	84	MA	7	5	9	7	7	7	9	7	7	5	7	9	9	5	5	5	1	8	9	8	8	7	6	7	7	8	9	8	7	7	N	E
2	85	MA	8	6	6	8	8	8	8	7	7	5	1	9	9	9	5	5	1	8	9	9	8	8	6	7	7	9	9	8	7	8	N	E
2	86	MA	8	6	9	8	8	9	8	7	7	5	1	9	9	9	5	5	1	8	9	9	8	8	6	7	7	9	9	8	7	8	N	E
2	87	MA	8	6	6	7	2	8	7	7	7	5	1	7	9	9	5	5	1	8	9	9	8	7	6	7	5	9	7	8	7	7	N	E
2	88	MA	8	6	9	7	2	8	7	7	7	5	1	7	9	9	5	5	1	8	9	9	8	7	6	7	5	9	7	8	7	7	N	E
2	89	MA	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	90	MA	1	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	91	MA	1	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	2	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	92	MA	1	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	2	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	93	MA	3	2	6	8	1	2	1	1	1	3	2	5	1	1	2	1	1	8	6	1	2	2	3	1	1	2	2	2	2	2	N	E
2	94	MA	3	3	6	8	1	2	1	1	1	3	2	5	1	1	3	1	1	8	6	1	2	2	4	1	1	2	2	2	3	2	N	E
2	95	MA	1	1	1	1	1	2	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	96	MA	1	1	1	1	3	2	1	1	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	1	1	1	Y	I
2	97	MA	2	4	2	1	3	1	1	1	1	3	7	1	1	1	1	3	1	1	5	1	2	1	1	1	1	2	2	1	2	1	Y	I
2	98	MA	2	4	2	1	3	1	1	1	1	3	7	1	1	1	1	3	1	1	5	1	2	1	1	1	1	2	2	1	2	1	Y	I
2	99	MA	2	6	2	2	5	2	1	2	1	3	3	2	5	1	2	3	1	6	9	1	3	2	1	1	1	2	2	1	2	2	N	E
2	100	MA	3	7	2	3	6	3	5	2	1	3	3	2	5	1	4	3	1	6	9	1	4	3	3	1	2	5	2	2	3	3	N	E
2	101	MA	3	3	1	7	7	3	5	6	1	5	5	6	6	3	2	2	3	2	7	1	4	3	5	1	2	5	4	3	2	3	N	E
2	102	MA	5	6	9	7	9	4	8	6	1	5	5	6	9	5	7	5	3	7	7	2	6	5	5	1	4	5	5	4	4	5	N	E
2	103	MA	3	5	1	7	6	3	5	6	1	5	3	8	6	2	3	2	3	3	9	1	4	4	5	1	2	4	5	4	3	4	N	E
2	104	MA	6	7	9	7	7	6	8	6	1	5	6	8	9	2	7	5	3	8	9	3	6	6	6	1	4	7	6	5	6	6	N	E
2	105	MA	7	7	5	8	3	7	8	8	1	7	7	9	9	1	9	9	6	9	9	9	7	7	7	6	7	7	8	7	7	7	N	E
2	106	MA	8	7	9	8	4	7	9	8	1	7	7	9	9	1	9	9	6	9	9	9	8	8	8	6	7	8	9	7	7	8	N	E
2	107	MA	8	9	5	8	9	7	9	8	1	7	8	8	9	3	9	9	5	9	9	9	8	8	7	6	7	8	9	8	7	8	N	E
2	108	MA	8	9	9	8	9	7	9	8	1	7	8	8	9	3	9	9	5	9	9	9	8	8	7	6	7	8	9	8	7	8	N	E
2	109	MA	7	9	5	8	9	8	8	8	1	7	8	8	9	1	9	9	5	9	9	9	9	8	6	6	5	8	9	8	8	8	N	E
2	110	MA	8	9	9	8	9	8	8	8	1	7	8	8	9	1	9	9	5	9	9	9	9	8	7	6	5	8	9	8	8	8	N	E
2	111	MA	3	3	9	3	7	4	2	3	1	5	7	6	1	1	3	5	1	2	9	1	4	3	5	6	1	3	5	2	3	3	N	E
2	112	MA	3	3	9	3	7	4	2	3	1	5	7	6	1	1	3	5	1	2	9	1	4	3	5	6	1	3	5	2	3	3	N	E
2	113	MA	9	9	9	9	9	9	9	9	1	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	9	Y	A
2	114	MA	9	9	9	9	9	9	9	9	1	9	7	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	9	Y	A
2	115	MA	2	1	1	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	116	MA	2	1	1	1	3	1	1	2	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	117	MA	2	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	6	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	118	MA	3	1	1	1	1	1	1	2	1	1	1	1	1	1	1	1	1	1	6	1	2	1	1	1	1	2	1	1	2	1	Y	I
2	119	MA	3	3	6	8	1	2	1	3	1	1	1	8	1	1	1	1	1	9	3	1	2	2	3	1	1	3	2	3	2	2	N	E
2	120	MA	3	4	6	8	1	2	3	3	1	1	1	8	1	1	3	1	1	9	3	1	3	3	4	1	1	3	2	3	3	3	N	E
2	121	MA	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	122	MA	1	1	1	1	3	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	123	MA	1	4	2	1	6	2	1	1	1	3	1	1	1	1	1	3	1	2	8	1	2	1	1	1	1	1	2	1	3	1	Y	I
2	124	MA	1	4	2	1	6	1	1	1	1	3	1	1	1	1	1	3	1	2	8	1	2	1	1	1	1	1	2	1	3	1	Y	I
2	125	MA	2	5	2	2	7	2	2	2	1	3	2	1	5	1	2	3	1	7	9	1	3	2	1	1	1	2	2	1	2	2	N	E
2	126	MA	3	6	2	2	7	2	4	2	1	3	2	1	7	2	4	3	1	7	9	1	3	2	1	1	1	2	2	1	2	2	N	E
2	127	MA	3	3	1	8	9	4	3	6	2	5	4	8	5	3	3	2	1	3	3	2	4	3	5	1	1	3	4	2	2	3	N	E
2	128	MA	5	7	9	8	9	4	6	6	5	5	4	8	9	5	7	5	3	7	3	4	6	5	5	1	3	5	5	4	4	5	N	E
2	129	MA	3	6	1	8	9	3	3	6	2	5	5	8	5	1	3	2	1	3	5	2	3	3	6	1	1	3	4	2	3	3	N	E
2	130	MA	6	8	9	8	9	5	6	6	5	5	5	8	9	1	7	5	1	7	5	4	6	5	7	1	3	5	5	5	5	5	N	E
2	131	MA	7	8	5	7	3	6	8	8	4	8	7	7	9	3	9	9	5	9	8	7	7	7	7	7	7	8	9	8	7	7	N	E
2	132	MA	2	8	9	7	4	6	9	8	5	8	7	7	9	3	9	9	5	9	8	2	7	7	7	7	7	8	9	8	7	7	N	E

2	133	MA	9	9	5	8	9	7	8	8	5	8	7	8	9	8	9	9	5	9	9	7	8	8	8	8	8	9	9	9	7	8	Y	A
2	134	MA	9	9	9	8	9	7	9	8	5	8	7	8	9	8	9	9	5	9	9	7	9	9	8	8	8	9	9	9	7	9	Y	A
2	135	MA	9	9	5	8	9	9	7	7	5	9	9	9	9	9	9	9	8	9	9	7	9	9	7	8	5	9	9	9	7	9	Y	A
2	136	MA	9	9	9	8	9	9	7	7	5	9	9	9	9	9	9	9	8	9	9	7	9	9	7	8	5	9	9	9	7	9	Y	A
2	137	MA	4	4	9	1	7	5	1	4	5	5	5	2	1	1	2	9	1	5	9	1	4	4	7	5	2	5	5	1	3	4	N	E
2	138	MA	4	4	9	1	7	5	1	4	5	5	4	2	1	1	2	9	1	5	9	1	4	4	7	5	2	5	5	1	3	4	N	E
2	139	MA	9	9	9	9	9	9	9	9	5	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	7	9	Y	A
2	140	MA	9	9	9	9	9	9	9	9	5	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	7	9	Y	A
2	141	MA	1	1	2	3	1	2	1	2	1	2	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	1	2	1	1	1	Y	I
2	142	MA	1	1	2	3	1	2	1	2	1	2	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	1	2	1	1	1	Y	I
2	143	MA	2	1	2	3	1	3	1	2	1	2	1	1	3	1	1	1	1	1	8	1	2	1	1	1	1	1	3	1	2	1	Y	I
2	144	MA	3	1	2	3	1	3	1	2	1	2	1	1	3	1	1	1	1	1	8	1	2	1	1	1	1	1	3	1	2	1	Y	I
2	145	MA	3	2	6	8	3	4	1	3	1	3	3	8	3	3	3	1	1	8	9	1	4	3	2	1	2	3	3	4	4	3	N	E
2	146	MA	3	3	6	8	3	4	2	3	1	3	3	8	3	3	5	1	1	8	9	1	5	3	2	1	2	3	3	4	4	3	N	E
2	147	MA	1	1	1	2	3	1	1	2	1	3	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	3	2	1	2	1	Y	I
2	148	MA	1	1	1	2	1	2	1	2	1	3	1	1	3	1	1	1	1	1	3	1	1	1	1	1	1	1	2	1	3	1	Y	I
2	149	MA	3	4	4	3	3	3	2	2	1	3	3	1	3	1	1	3	1	4	9	1	3	3	1	1	2	3	3	2	2	3	N	E
2	150	MA	3	4	4	3	3	3	2	2	1	3	3	1	3	1	1	3	1	4	9	1	3	3	1	1	2	3	3	2	2	3	N	E
2	151	MA	3	6	3	3	3	4	1	2	1	4	4	3	5	3	3	4	1	7	9	1	3	3	3	2	2	3	3	2	3	3	N	E
2	152	MA	4	7	3	3	3	4	1	2	1	4	4	3	5	7	5	4	1	7	9	1	5	4	4	2	3	4	3	3	4	4	N	E
2	153	MA	2	3	1	8	5	3	7	6	1	5	3	7	5	6	4	3	1	3	8	2	3	3	4	2	2	3	3	2	3	3	N	E
2	154	MA	5	7	9	8	5	7	9	6	1	5	3	7	9	9	7	5	3	7	8	4	7	6	5	2	3	6	4	5	5	6	N	E
2	155	MA	3	6	1	9	6	5	7	6	1	5	7	1	5	6	4	3	3	3	9	2	5	5	5	2	2	5	5	3	4	5	N	E
2	156	MA	5	9	9	9	6	8	9	6	1	5	7	1	9	9	8	5	4	7	9	5	8	6	6	2	3	7	6	5	6	6	N	E
2	157	MA	7	8	6	9	6	8	8	8	1	9	7	8	9	9	9	9	5	8	8	8	9	8	7	7	9	9	9	9	7	8	N	E
2	158	MA	9	8	9	9	6	8	8	8	1	9	7	8	9	9	9	9	5	8	8	8	9	8	7	7	9	9	9	9	7	8	Y	A
2	159	MA	8	9	6	9	9	9	7	8	1	9	7	8	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	9	7	9	Y	A
2	160	MA	9	9	9	9	9	9	7	8	1	9	7	8	9	9	9	9	9	9	9	9	9	9	7	7	9	9	9	9	7	9	Y	A
2	161	MA	8	9	6	8	9	9	9	9	1	9	7	9	9	9	9	9	9	9	9	9	9	9	7	7	8	9	9	9	7	9	Y	A
2	162	MA	9	9	9	8	9	9	9	9	1	9	7	9	9	9	9	9	9	9	9	9	9	9	7	7	8	9	9	9	7	9	Y	A
2	163	MA	6	4	9	5	6	5	2	5	1	5	5	6	1	2	2	5	1	6	9	1	5	5	7	5	3	5	7	2	4	5	N	E
2	164	MA	6	4	9	5	6	9	2	5	1	5	9	6	1	2	2	5	3	6	9	1	7	5	7	5	3	9	9	2	4	5	N	E
2	165	MA	9	9	9	9	9	9	9	9	1	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
2	166	MA	9	9	9	9	9	9	9	9	1	9	7	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
2	167	MA	1	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	168	MA	1	1	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	1	1	1	Y	I
2	169	MA	2	3	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	2	1	2	1	1	1	1	3	2	1	2	1	Y	I
2	170	MA	2	4	1	1	1	1	1	2	1	2	1	1	1	1	1	1	1	1	2	1	2	1	1	1	1	3	2	1	2	1	Y	I
2	171	MA	3	4	3	9	1	2	2	2	1	3	1	7	1	1	2	2	1	5	3	1	2	2	1	1	1	3	2	3	2	2	N	E
2	172	MA	3	5	3	9	1	2	2	2	1	3	1	7	1	1	5	2	1	5	3	1	4	2	2	1	1	3	2	3	3	2	N	E
2	173	MA	1	1	1	1	1	2	1	2	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	2	1	Y	I
2	174	MA	1	3	1	1	1	2	1	2	1	3	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	3	1	Y	I
2	175	MA	2	2	1	2	6	2	1	1	1	3	2	1	1	1	2	3	1	1	9	1	2	2	1	1	1	3	2	1	3	2	Y	I
2	176	MA	2	2	1	2	6	3	1	1	1	3	2	1	1	1	2	3	1	1	9	1	2	2	1	1	1	3	2	1	3	2	Y	I
2	177	MA	3	5	3	3	3	3	2	2	1	3	3	7	5	1	3	5	1	5	8	1	4	3	2	1	1	4	3	1	2	3	N	E
2	178	MA	3	6	5	3	3	4	2	2	1	3	3	7	7	3	3	5	1	5	8	1	4	3	2	1	2	4	3	1	2	3	N	E
2	179	MA	3	4	3	9	7	4	7	7	1	4	4	7	5	2	5	2	5	4	7	2	4	4	2	2	1	4	4	2	2	4	N	E
2	180	MA	4	8	8	9	8	4	8	7	1	5	5	7	9	7	8	5	5	5	7	3	5	5	4	2	3	6	5	5	4	5	N	E
2	181	MA	4	4	4	9	7	3	3	7	1	5	4	7	5	2	5	1	5	5	8	2	4	4	3	2	1	4	4	2	2	4	N	E
2	182	MA	5	9	9	9	9	3	4	7	1	5	5	7	9	7	8	5	5	5	8	3	5	5	4	2	3	7	5	5	5	5	N	E
2	183	MA	8	9	7	9	9	6	7	8	1	9	8	9	9	8	8	9	9	5	9	5	9	8	3	8	7	9	9	9	7	8	N	E
2	184	MA	8	9	9	5	9	6	8	8	1	9	8	9	9	8	8	9	9	5	9	5	9	8	3	8	7	9	9	9	7	8	N	E
2	185	MA	9	9	7	5	9	7	7	8	1	9	5	9	9	8	8	9	9	5	9	5	9	8	6	8	8	9	9	9	7	8	N	E
2	186	MA	9	9	9	9	9	7	7	8	1	9	5	9	9	8	8	9	9	5	9	5	9	9	6	8	8	9	9	9	7	9	N	E
2	187	MA	9	9	9	9	9	9	7	8	1	9	9	9	9	8	8	9	9	5	7	5	9	9	7	8	5	9	9	9	7	9	N	E
2	188	MA	9	9	9	9	9	9	8	8	1	9	9	9	9	8	8	9	9	5	7	5	9	9	7	8	5	9	9	9	7	9	N	E
2	189	MA	3	5	3	9	4	5	2	5	1	5	5	6	1	1	3	5	5	5	9	1	5	5	5	5	2	5	9	1	4	5	N	E
2	190	MA	3	5	3	9	4	5	3	5	1	5	5	6	1	1	3	5	5	5	9	1	5	5	5	5	2	5	9	1	4	5	N	E
2	191	MA	9	9	9	9	9	9	9	9	1	9	9	9	9	8	8	9	9	5	9	5	9	9	7	9	8	9	9	9	7	9	Y	A
2	192	MA	9	9	9	9	9	9	9	9	1	9	9	9	9	8	8	9	9	5	9	5	9	9	7	9	8	9	9	9	7	9	Y	A
2	193	MA	4	5	7	9	6	3	3	9	1	2	4	1	2	1	2	2	2	1	4	1	3	3	5	3	2	5	3	5	4	3	N	E
2	194	MA	4	5	7	9	6	3	3	9	1	2	4	1	2	1	2	2	2	1	3	1	3	3	5	3	2	5	3	5	4	3	N	E
2	195	MA	4	4	7	9	4	4	6	9	1	2	4	1	3	1	2	2	2	1	4	1	5	4	5	3	3	4	3	6	4	4	N	E
2	196	MA	4	5	7	9	4	4	6	9	1	2	4	1	3	1	2	2	2	1	4	1	5	4	5	3	3	4	3	6	4	4	N	E
2	197	MA	5	5	9	9	7	5	7	9	1	3	5	7	3	5	5	3	2	9	6	3	6	5	7	3	3	5	5	5	5	5	N	E
2	198	MA	5	7	9	9	9	5	7	9	1	3	5	7	3	5	8	3	2	9	6	4	6	5	7	3	3	5	5	5	5	5	N	E
2	199	MA	4	4	7	9	6	5	3	9	1	3	4	1	3	1	2	1	1	1	1	1	4	3	4	3	3	5	2	5	4	3	N	E
2	200	MA	4	5	7	9	6	5	4	9	1	3	4	1	3	1	2	1	1	1	1	1	4	4	4	3	3	5	2	5	4	4	N	E
2	201	MA	5	5	8	9	7	5	8	9	1	6	5	5	3	1	5	5	5	9	4	1	5	5	5	3	4	5	6	5	5	5	N	E
2	202	MA	5	5	8	9	7	5	8	9	1	6	5	5	3	1	8	5	5	9	4	1	5	5	5	3	4	5	6	5	5	5	N	E
2	203	MA	5	7	9	9	9	6	9	9	3	6	6	8	7	4	5	5	4	5	8	3	6	6	5	4	3	7	6	9	4	6	N	E
2	204	MA	5	8	9	9	9	6	9	9	3	6	6	8	7	7	5	5	4	9	8	4	7	7	5	4	4	8	7	9	4	7	N	E

2	205	MA	6	7	9	9	9	8	9	9	7	6	7	8	5	3	8	8	9	5	7	2	6	7	7	4	3	9	8	9	5	7	N	E
2	206	MA	6	8	9	9	9	7	9	9	7	6	7	8	9	6	8	8	9	8	7	5	7	8	8	4	4	9	9	9	6	8	N	E
2	207	MA	6	8	9	9	9	8	8	9	7	6	7	8	5	3	7	8	9	9	8	3	6	8	8	4	3	8	9	9	6	8	N	E
2	208	MA	7	9	9	9	9	8	9	9	7	6	8	8	9	6	8	9	9	9	8	6	8	9	9	4	4	9	9	9	7	9	N	E
2	209	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	7	9	9	9	9	9	9	9	9	7	9	9	9	9	8	9	Y	A
2	210	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	8	9	Y	A
2	211	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	7	9	9	9	9	9	9	9	9	7	9	9	9	9	7	9	Y	A
2	212	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	7	9	9	9	9	7	9	Y	A
2	213	MA	9	9	9	9	9	8	9	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9	7	9	9	9	9	7	9	Y	A
2	214	MA	9	9	9	9	9	8	9	9	8	9	9	9	9	9	9	9	9	9	8	9	9	9	9	7	9	9	9	9	7	9	Y	A
2	215	MA	6	9	9	9	9	9	9	9	8	9	8	7	3	2	7	9	5	5	9	3	8	8	9	8	5	9	9	7	4	8	N	E
2	216	MA	6	9	9	9	9	9	9	9	8	9	8	7	3	2	7	9	5	5	9	3	8	8	9	8	5	9	9	7	4	8	N	E
2	217	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A
2	218	MA	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	9	9	9	9	9	9	9	9	8	9	9	9	9	9	9	Y	A

APPENDIX 4

Recording sheet

SCOTTISH AUDIT OF THE SURGICAL MANAGEMENT

OF CHRONIC CRITICAL LOWER LIMB ISCHAEMIA

RECORDING SHEET

Personal details

Patient's name	....
D.O.B.	...... / ...... / ......
Age at operation	☐☐☐ years
Male / Female	*(circle one)*

Hospital details

Hospital number	☐☐☐☐☐☐☐☐☐☐☐
Hospital	....
Consultant	....

Operation details

Operation ....

Date of operation ....../......./......

Disease severity details

Rest pain yes / no *(circle one)*

Tissue loss yes / no *(circle one)*

If yes, *(tick one)*

digital ❐

superficial forefoot ❐

deep forefoot ❐

superficial heel/midfoot ❐

deep heel/midfoot ❐

Angiogram score A B C D E F G H I J K L M *(circle one)*

APPENDIX 5

Retrospective sample of operations and categorisation by appropriateness

Hospital	Sex	Operation	Rest pain	Tissue loss	Site	Severity	Vein available	Angiogram	Scenario	Appropriateness
1	F	ARC	Y	N	N/A	N/A	Y	B	3	A
1	F	ARC	Y	Y	digital	N/A	Y	A	89	A
1	F	ARC	Y	N	N/A	N/A	N	D	8	A
1	F	ARC	Y	Y	digital	N/A	Y	G	101	E
1	M	ARC	Y	N	N/A	N/A	N	G	14	E
1	M	ARC	Y	Y	digital	N/A	Y	H	103	E
1	M	ARC	Y	N	N/A	N/A	Y	D	7	A
1	F	ARC	Y	N	N/A	N/A	Y	B	3	A
1	M	ARC	Y	N	N/A	N/A	Y	H	15	E
1	M	ARC	Y	Y	forefoot	superficial	Y	G	127	E
1	M	ARC	Y	N	N/A	N/A	Y	B	3	A
1	M	ARC	Y	N	N/A	N/A	Y	D	7	A
1	M	ARC	Y	Y	heel	superficial	Y	B	143	A
1	F	ARC	Y	Y	digital	N/A	Y	G	101	E
1	F	ARC	Y	N	N/A	N/A	Y	A	1	A
1	M	ARC	Y	Y	digital	N/A	Y	D	95	A
1	F	ARC	Y	N	N/A	N/A	Y	G	13	E
1	M	ARC	Y	Y	forefoot	superficial	Y	C	119	E
1	M	ARC	Y	Y	digital	N/A	Y	J	41	I
1	M	ARC	Y	Y	digital	N/A	Y	A	89	A
1	M	MA	Y	N	N/A	N/A	Y	I	17	A
1	F	MA	Y	Y	digital	N/A	Y	D	95	I
1	M	MA	Y	N	N/A	N/A	Y	I	17	A
1	M	MA	Y	Y	digital	N/A	Y	J	107	E
1	M	MA	Y	Y	forefoot	superficial	Y	G	127	E
1	F	MA	Y	N	N/A	N/A	Y	K	21	A
1	F	MA	Y	Y	digital	N/A	Y	C	93	E
1	F	MA	Y	N	N/A	N/A	Y	D	7	I
1	F	MA	Y	Y	heel	superficial	Y	D	147	I
1	F	MA	Y	Y	heel	superficial	Y	G	153	E
1	M	MA	Y	Y	forefoot	ddep	Y	G	179	E
1	M	MA	Y	N	N/A	N/A	Y	K	21	A
1	M	MA	Y	Y	digital	N/A	Y	G	101	E
1	M	MA	Y	Y	midfoot	superficial	Y	C	145	E
1	M	MA	Y	Y	digital	N/A	Y	K	109	E
1	M	MA	Y	Y	digital	N/A	Y	D	95	I
1	F	MA	Y	N	N/A	N/A	Y	F	11	E
1	F	MA	Y	N	N/A	N/A	Y	G	13	E
1	F	MA	Y	Y	heel	deep	Y	G	205	E
1	F	MA	Y	Y	digital	N/A	Y	G	101	E
2	F	ARC	Y	N	N/A	N/A	Y	B	3	A
2	F	ARC	Y	Y	forefoot	superficial	Y	F	125	E
2	F	ARC	Y	Y	digital	N/A	Y	D	95	A
2	M	ARC	Y	N	N/A	N/A	Y	B	3	A
2	F	ARC	Y	Y	forefoot	deep	Y	D	173	A
2	F	ARC	Y	N	N/A	N/A	Y	G	13	E
2	M	ARC	Y	Y	digital	N/A	Y	F	99	E
2	F	ARC	Y	Y	digital	N/A	Y	D	95	A
2	F	ARC	Y	Y	midfoot	deep	Y	G	205	E
2	F	ARC	Y	Y	digital	N/A	Y	D	95	A
2	F	ARC	Y	N	N/A	N/A	Y	G	13	E
2	F	ARC	Y	N	N/A	N/A	Y	E	9	E
2	M	ARC	Y	Y	heel	deep	Y	G	205	E
2	M	ARC	Y	N	N/A	N/A	Y	A	1	A
2	F	ARC	Y	N	N/A	N/A	Y	G	13	E
2	F	ARC	Y	Y	midfoot	superficial	Y	G	153	E
2	M	ARC	Y	Y	digital	N/A	Y	G	101	E
2	M	ARC	Y	N	N/A	N/A	Y	D	7	A
2	M	ARC	Y	Y	digital	N/A	Y	K	43	I
2	M	ARC	Y	N	N/A	N/A	Y	A	1	A
2	F	MA	Y	N	N/A	N/A	Y	I	17	A
2	F	MA	Y	N	N/A	N/A	Y	I	17	A
2	F	MA	Y	Y	digital	N/A	Y	G	101	E
2	M	MA	Y	N	N/A	N/A	Y	D	7	I
2	M	MA	Y	Y	digital	N/A	Y	D	95	I
2	M	MA	Y	Y	heel	deep	Y	K	213	A
2	M	MA	Y	Y	digital	N/A	Y	G	101	E
2	M	MA	Y	Y	forefoot	superficial	Y	D	121	I
2	M	MA	Y	N	N/A	N/A	Y	I	17	A
2	M	MA	Y	Y	forefoot	superficial	Y	K	135	A
2	M	MA	Y	Y	digital	N/A	Y	G	101	E

2	F	MA	Y	Y	heel	superficial	Y	D	147	I
2	M	MA	Y	Y	midfoot	deep	Y	K	213	A
2	M	MA	Y	Y	digital	N/A	Y	G	101	E
2	M	MA	Y	N	N/A	N/A	Y	J	19	A
2	M	MA	Y	Y	heel	superficial	Y	G	153	E
2	F	MA	Y	Y	digital	N/A	Y	D	95	I
2	F	MA	Y	N	N/A	N/A	Y	D	7	I
2	M	MA	Y	N	N/A	N/A	Y	K	21	A
2	M	MA	Y	Y	heel	deep	Y	G	205	E
3	F	ARC	Y	N	N/A	N/A	Y	C	5	E
3	M	ARC	Y	N	N/A	N/A	Y	D	7	A
3	F	ARC	Y	N	N/A	N/A	Y	D	7	A
3	M	ARC	Y	Y	heel	superficial	Y	G	153	E
3	M	ARC	Y	N	N/A	N/A	Y	B	3	A
3	F	ARC	Y	Y	digital	N/A	Y	D	95	A
3	M	ARC	Y	Y	digital	N/A	Y	G	101	E
3	M	ARC	Y	N	N/A	N/A	Y	G	13	E
3	M	ARC	Y	Y	forefoot	superficial	Y	D	121	A
3	M	ARC	Y	N	N/A	N/A	Y	D	7	A
3	M	ARC	Y	Y	forefoot	superficial	Y	A	115	A
3	F	ARC	Y	N	N/A	N/A	Y	E	9	E
3	M	ARC	Y	N	N/A	N/A	Y	D	7	A
3	M	ARC	Y	N	N/A	N/A	Y	H	15	E
3	F	ARC	Y	Y	digital	N/A	Y	G	101	E
3	M	ARC	Y	N	N/A	N/A	Y	D	7	A
3	F	ARC	Y	N	N/A	N/A	Y	G	13	E
3	F	ARC	Y	Y	heel	superficial	Y	D	147	A
3	M	ARC	Y	Y	forefoot	superficial	Y	G	127	E
3	M	ARC	Y	Y	digital	N/A	Y	K	43	I
3	F	MA	Y	N	N/A	N/A	Y	K	21	A
3	F	MA	Y	Y	digital	N/A	Y	K	109	E
3	F	MA	Y	Y	heel	superficial	Y	B	143	I
3	M	MA	Y	Y	heel	superficial	Y	K	161	A
3	F	MA	Y	N	N/A	N/A	Y	K	21	A
3	F	MA	Y	Y	heel	deep	Y	K	213	A
3	M	MA	Y	N	N/A	N/A	Y	K	21	A
3	F	MA	Y	Y	forefoot	superficial	Y	J	133	A
3	M	MA	Y	N	N/A	N/A	Y	K	21	A
3	M	MA	Y	Y	forefoot	superficial	Y	C	119	E
3	F	MA	Y	Y	digital	N/A	Y	F	99	E
3	M	MA	Y	Y	heel	superficial	Y	G	153	E
3	M	MA	Y	Y	forefoot	superficial	Y	G	127	E
3	M	MA	Y	Y	digital	N/A	Y	K	109	E
3	M	MA	Y	Y	digital	N/A	Y	D	95	I
3	M	MA	Y	Y	digital	N/A	Y	I	105	E
3	F	MA	Y	Y	digital	N/A	Y	B	91	I
3	M	MA	Y	Y	forefoot	superficial	Y	C	119	E
3	F	MA	Y	Y	digital	N/A	Y	G	101	E
4	M	ARC	Y	Y	digital	N/A	Y	D	95	A
4	F	ARC	Y	Y	digital	N/A	Y	D	95	A
4	M	ARC	Y	N	N/A	N/A	Y	A	1	A
4	M	ARC	Y	N	N/A	N/A	Y	D	7	A
4	M	ARC	Y	N	N/A	N/A	Y	D	7	A
4	M	ARC	Y	N	N/A	N/A	Y	D	7	A
4	F	ARC	Y	Y	digital	N/A	Y	D	95	A
4	M	ARC	Y	Y	heel	superficial	Y	B	143	A
4	M	ARC	Y	N	N/A	N/A	Y	A	1	A
4	F	ARC	Y	N	N/A	N/A	Y	D	7	A
4	M	ARC	Y	Y	digital	N/A	Y	A	89	A
4	M	ARC	Y	Y	digital	N/A	Y	B	91	A
4	M	ARC	Y	Y	digital	N/A	Y	D	95	A
4	F	ARC	Y	Y	digital	N/A	Y	G	101	E
4	M	ARC	Y	N	N/A	N/A	Y	G	13	E
4	M	ARC	Y	N	N/A	N/A	Y	G	13	E
4	M	ARC	Y	N	N/A	N/A	Y	C	5	E
4	M	ARC	Y	Y	digital	N/A	Y	G	101	E
4	M	ARC	Y	N	N/A	N/A	Y	D	7	A
4	M	ARC	Y	Y	forefoot	superficial	Y	D	121	A
4	F	MA	Y	Y	heel	deep	Y	G	205	E
4	F	MA	Y	Y	heel	superficial	Y	D	147	I
4	F	MA	Y	N	N/A	N/A	Y	K	21	A
4	M	MA	Y	Y	heel	deep	Y	M	217	A

4	M	MA	Y	N	N/A	N/A	Y	G	13	E
4	F	MA	Y	N	N/A	N/A	Y	G	13	E
4	F	MA	Y	Y	digital	N/A	Y	L	111	E
4	M	MA	Y	Y	heel	deep	Y	G	205	E
4	M	MA	Y	Y	digital	N/A	Y	D	95	I
4	F	MA	Y	N	N/A	N/A	Y	D	7	I
4	F	MA	Y	Y	heel	superficial	Y	M	165	A
4	F	MA	Y	N	N/A	N/A	Y	K	21	A
4	M	MA	Y	Y	digital	N/A	Y	L	111	E
4	F	MA	Y	Y	heel	superficial	Y	I	157	E
4	M	MA	Y	Y	heel	superficial	Y	B	143	I
4	F	MA	Y	N	N/A	N/A	Y	G	13	E
4	M	MA	Y	N	N/A	N/A	Y	D	7	I
4	F	MA	Y	Y	digital	N/A	Y	D	95	I
4	M	MA	Y	Y	digital	N/A	Y	G	101	E
4	M	MA	Y	Y	digital	N/A	Y	I	105	E
5	F	ARC	Y	Y	heel	superficial	Y	D	147	A
5	F	ARC	Y	Y	forefoot	superficial	Y	D	121	A
5	F	ARC	Y	Y	digital	N/A	Y	D	95	A
5	M	ARC	Y	Y	digital	N/A	Y	D	95	A
5	F	ARC	Y	N	N/A	N/A	Y	B	3	A
5	M	ARC	Y	Y	digital	N/A	Y	G	101	E
5	F	ARC	Y	N	N/A	N/A	Y	D	7	A
5	F	ARC	Y	N	N/A	N/A	Y	A	1	A
5	F	ARC	Y	Y	digital	N/A	Y	D	95	A
5	F	ARC	Y	N	N/A	N/A	Y	D	7	A
5	M	ARC	Y	Y	heel	superficial	Y	A	141	A
5	F	ARC	Y	Y	digital	N/A	Y	G	101	E
5	M	ARC	Y	Y	digital	N/A	N	D	96	A
5	M	ARC	Y	N	N/A	N/A	Y	G	13	E
5	M	ARC	Y	Y	heel	superficial	Y	F	151	E
5	F	ARC	Y	Y	heel	superficial	Y	G	153	E
5	M	ARC	Y	N	N/A	N/A	Y	G	13	E
5	M	ARC	Y	N	N/A	N/A	Y	A	1	A
5	F	ARC	Y	N	N/A	N/A	Y	G	13	E
5	M	ARC	Y	N	N/A	N/A	Y	G	13	E
5	M	MA	Y	Y	digital	N/A	Y	K	109	E
5	M	MA	Y	N	N/A	N/A	Y	I	17	A
5	F	MA	Y	N	N/A	N/A	Y	K	21	A
5	M	MA	Y	N	N/A	N/A	Y	K	21	A
5	M	MA	Y	Y	digital	N/A	Y	F	99	E
5	F	MA	Y	Y	digital	N/A	Y	K	109	E
5	F	MA	Y	Y	digital	N/A	Y	G	101	E
5	M	MA	Y	Y	digital	N/A	Y	F	99	E
5	F	MA	Y	Y	digital	N/A	Y	D	95	I
5	M	MA	Y	Y	heel	superficial	Y	J	159	A
5	M	MA	Y	Y	heel	superficial	Y	K	161	A
5	M	MA	Y	N	N/A	N/A	Y	K	21	A
5	M	MA	Y	Y	heel	superficial	Y	K	161	A
5	F	MA	Y	Y	digital	N/A	Y	G	101	E
5	F	MA	Y	Y	heel	superficial	Y	M	165	A
5	M	MA	Y	Y	heel	superficial	Y	B	143	I
5	F	MA	Y	N	N/A	N/A	Y	G	13	E
5	F	MA	Y	Y	digital	N/A	Y	D	95	I
5	M	MA	Y	N	N/A	N/A	Y	K	21	A
5	F	MA	Y	Y	digital	N/A	Y	D	95	I
6	M	ARC	Y	N	N/A	N/A	Y	A	1	A
6	M	ARC	Y	N	N/A	N/A	Y	G	13	E
6	M	ARC	Y	Y	heel	superficial	Y	G	153	E
6	M	ARC	Y	N	N/A	N/A	Y	D	7	A
6	M	ARC	Y	N	N/A	N/A	Y	D	7	A
6	F	ARC	Y	Y	digital	N/A	Y	C	93	E
6	M	ARC	Y	Y	digital	N/A	Y	G	101	E
6	F	ARC	Y	N	N/A	N/A	Y	C	5	E
6	F	ARC	Y	Y	digital	N/A	Y	G	101	E
6	F	ARC	Y	Y	digital	N/A	Y	D	95	A
6	M	ARC	Y	N	N/A	N/A	Y	C	5	E
6	F	ARC	Y	Y	digital	N/A	Y	G	101	E
6	M	ARC	Y	N	N/A	N/A	Y	H	15	E
6	F	ARC	Y	N	N/A	N/A	Y	D	7	A
6	M	ARC	Y	N	N/A	N/A	Y	A	1	A
6	F	ARC	Y	Y	forefoot	superficial	Y	F	125	E

6	F	ARC	Y	Y	forefoot	superficial	Y	D	121	A
6	M	ARC	Y	Y	heel	superficial	Y	G	153	E
6	M	ARC	Y	Y	heel	deep	Y	G	205	E
6	F	ARC	Y	Y	forefoot	deep	Y	D	173	A
6	M	MA	Y	N	N/A	N/A	Y	I	17	A
6	M	MA	Y	N	N/A	N/A	Y	I	17	A
6	M	MA	Y	Y	forefoot	superficial	Y	K	135	A
6	F	MA	Y	Y	digital	N/A	Y	G	101	E
6	F	MA	Y	Y	digital	N/A	Y	D	95	I
6	M	MA	Y	N	N/A	N/A	Y	G	13	E
6	M	MA	Y	N	N/A	N/A	Y	F	11	E
6	F	MA	Y	N	N/A	N/A	Y	D	7	I
6	M	MA	Y	N	N/A	N/A	Y	D	7	I
6	F	MA	Y	N	N/A	N/A	Y	K	21	A
6	F	MA	Y	N	N/A	N/A	Y	I	17	A
6	M	MA	Y	N	N/A	N/A	Y	K	21	A
6	M	MA	Y	Y	digital	N/A	Y	I	105	E
6	M	MA	Y	Y	forefoot	superficial	Y	F	125	E
6	F	MA	Y	N	N/A	N/A	Y	D	7	I
6	F	MA	Y	Y	heel	superficial	Y	D	147	I
6	F	MA	Y	N	N/A	N/A	Y	K	21	A
6	M	MA	Y	N	N/A	N/A	Y	K	21	A
6	M	MA	Y	Y	digital	N/A	Y	D	95	I
6	M	MA	Y	N	N/A	N/A	Y	I	17	A
7	F	ARC	Y	Y	heel	superficial	Y	G	153	E
7	M	ARC	Y	N	N/A	N/A	Y	D	7	A
7	M	ARC	Y	Y	heel	superficial	Y	E	149	E
7	M	ARC	Y	Y	heel	superficial	Y	D	147	A
7	F	ARC	Y	N	N/A	N/A	Y	A	1	A
7	M	ARC	Y	Y	digital	N/A	Y	D	95	A
7	M	ARC	Y	Y	digital	N/A	Y	D	95	A
7	F	ARC	Y	Y	digital	N/A	Y	D	95	A
7	M	ARC	Y	N	N/A	N/A	Y	D	7	A
7	F	ARC	Y	Y	digital	N/A	Y	D	95	A
7	M	ARC	Y	N	N/A	N/A	Y	D	7	A
7	M	ARC	Y	Y	forefoot	deep	Y	B	169	A
7	F	ARC	Y	Y	heel	deep	Y	G	205	E
7	F	ARC	Y	Y	heel	superficial	Y	D	147	A
7	M	ARC	Y	Y	forefoot	deep	Y	D	173	A
7	M	ARC	Y	Y	digital	N/A	Y	D	95	A
7	M	ARC	Y	N	N/A	N/A	Y	D	7	A
7	M	ARC	Y	N	N/A	N/A	Y	H	15	E
7	F	ARC	Y	N	N/A	N/A	Y	A	1	A
7	M	ARC	Y	N	N/A	N/A	Y	D	7	A
7	M	MA	Y	Y	digital	N/A	Y	I	105	E
7	M	MA	Y	Y	digital	N/A	Y	I	105	E
7	M	MA	Y	Y	midfoot	superficial	Y	G	153	E
7	F	MA	Y	N	N/A	N/A	Y	D	7	I
7	F	MA	Y	Y	digital	N/A	Y	B	91	I
7	F	MA	Y	Y	forefoot	superficial	Y	K	135	A
7	M	MA	Y	N	N/A	N/A	Y	I	17	A
7	F	MA	Y	N	N/A	N/A	Y	K	21	A
7	M	MA	Y	N	N/A	N/A	Y	K	21	A
7	M	MA	Y	Y	forefoot	superficial	Y	I	131	E
7	F	MA	Y	N	N/A	N/A	Y	G	13	E
7	M	MA	Y	Y	forefoot	deep	Y	G	179	E
7	F	MA	Y	Y	heel	superficial	Y	D	147	I
7	F	MA	Y	N	N/A	N/A	Y	K	21	A
7	M	MA	Y	N	N/A	N/A	Y	K	21	A
7	M	MA	Y	N	N/A	N/A	Y	K	21	A
7	M	MA	Y	N	N/A	N/A	Y	F	11	E
7	M	MA	Y	N	N/A	N/A	Y	G	13	E
7	M	MA	Y	N	N/A	N/A	Y	D	7	I
7	M	MA	Y	N	N/A	N/A	Y	F	11	E
8	F	ARC	Y	N	N/A	N/A	Y	D	7	A
8	M	ARC	Y	N	N/A	N/A	Y	H	15	E
8	M	ARC	Y	N	N/A	N/A	Y	F	11	E
8	M	ARC	Y	N	N/A	N/A	Y	E	9	E
8	M	ARC	Y	Y	forefoot	superficial	Y	J	63	I
8	M	ARC	Y	Y	digital	N/A	N	K	110	I
8	M	ARC	Y	Y	forefoot	superficial	Y	D	121	A
8	M	ARC	Y	Y	digital	N/A	Y	H	103	E

8	F	ARC	Y	Y	digital	N/A	Y	F	99	E
8	F	ARC	Y	N	N/A	N/A	Y	B	3	A
8	M	ARC	Y	N	N/A	N/A	Y	D	7	A
8	M	ARC	Y	N	N/A	N/A	Y	B	3	A
8	M	ARC	Y	N	N/A	N/A	Y	D	7	A
8	M	ARC	Y	Y	digital	N/A	Y	C	93	E
8	F	ARC	Y	Y	heel	deep	Y	G	205	E
8	M	ARC	Y	N	N/A	N/A	N	G	14	E
8	M	ARC	Y	Y	digital	N/A	Y	B	91	A
8	M	ARC	Y	Y	digital	N/A	Y	D	95	A
8	F	ARC	Y	Y	heel	superficial	Y	G	153	E
8	M	ARC	Y	N	N/A	N/A	Y	C	5	E
8	M	MA	Y	N	N/A	N/A	Y	K	21	A
8	M	MA	Y	Y	digital	N/A	Y	M	113	A
8	F	MA	Y	Y	digital	N/A	Y	K	109	E
8	M	MA	Y	N	N/A	N/A	Y	G	13	E
8	M	MA	Y	Y	digital	N/A	Y	I	105	E
8	F	MA	Y	Y	digital	N/A	Y	K	109	E
8	M	MA	Y	N	N/A	N/A	Y	I	17	A
8	F	MA	Y	Y	digital	N/A	Y	K	109	E
8	F	MA	Y	Y	digital	N/A	Y	G	101	E
8	M	MA	Y	Y	digital	N/A	Y	G	101	E
8	M	MA	Y	N	N/A	N/A	Y	C	5	E
8	F	MA	Y	Y	digital	N/A	Y	D	95	I
8	M	MA	Y	Y	digital	N/A	Y	K	109	E
8	F	MA	Y	Y	heel	deep	Y	F	203	E
8	F	MA	Y	Y	digital	N/A	Y	D	95	I
8	M	MA	Y	N	N/A	N/A	Y	K	21	A
8	M	MA	Y	N	N/A	N/A	Y	F	11	E
8	F	MA	Y	Y	heel	superficial	Y	D	147	I
8	M	MA	Y	Y	heel	superficial	Y	B	143	I
8	F	MA	Y	Y	heel	superficial	Y	B	143	I
9	M	ARC	Y	Y	heel	superficial	Y	G	153	E
9	F	ARC	Y	Y	digital	N/A	Y	B	91	A
9	M	ARC	Y	N	N/A	N/A	Y	G	13	E
9	F	ARC	Y	Y	digital	N/A	Y	G	101	E
9	F	ARC	Y	Y	digital	N/A	Y	G	101	E
9	M	ARC	Y	Y	heel	superficial	Y	C	145	E
9	F	ARC	Y	N	N/A	N/A	Y	C	5	E
9	M	ARC	Y	Y	digital	N/A	N	K	110	I
9	F	ARC	Y	N	N/A	N/A	Y	D	7	A
9	F	ARC	Y	N	N/A	N/A	Y	G	13	E
9	M	ARC	Y	N	N/A	N/A	Y	F	11	E
9	M	ARC	Y	N	N/A	N/A	Y	G	13	E
9	M	ARC	Y	N	N/A	N/A	Y	F	11	E
9	M	ARC	Y	Y	forefoot	superficial	Y	C	119	E
9	M	ARC	Y	N	N/A	N/A	Y	H	15	E
9	M	ARC	Y	Y	heel	superficial	Y	G	153	E
9	M	ARC	Y	N	N/A	N/A	Y	D	7	A
9	M	ARC	Y	Y	digital	N/A	Y	H	103	E
9	M	ARC	Y	Y	heel	superficial	Y	G	153	E
9	M	ARC	Y	Y	digital	N/A	Y	C	93	E
9	F	MA	Y	Y	digital	N/A	Y	G	101	E
9	M	MA	Y	Y	digital	N/A	Y	L	111	E
9	M	MA	Y	Y	digital	N/A	Y	A	89	I
9	F	MA	Y	Y	digital	N/A	Y	F	99	E
9	M	MA	Y	Y	digital	N/A	Y	G	101	E
9	M	MA	Y	Y	heel	superficial	Y	B	143	I
9	M	MA	Y	N	N/A	N/A	Y	K	21	A
9	F	MA	Y	Y	heel	superficial	Y	K	161	A
9	M	MA	Y	Y	forefoot	superficial	Y	K	135	A
9	M	MA	Y	Y	digital	N/A	Y	K	109	E
9	M	MA	Y	Y	digital	N/A	Y	I	105	E
9	F	MA	Y	Y	digital	N/A	Y	F	99	E
9	M	MA	Y	N	N/A	N/A	Y	I	17	A
9	M	MA	Y	Y	heel	deep	Y	G	205	E
9	F	MA	Y	Y	digital	N/A	Y	D	95	I
9	F	MA	Y	N	N/A	N/A	Y	D	7	I
9	M	MA	Y	Y	heel	superficial	Y	J	159	A
9	M	MA	Y	Y	heel	deep	Y	G	205	E
9	F	MA	Y	Y	heel	superficial	Y	G	153	E
9	F	MA	Y	N	N/A	N/A	Y	D	7	I

10	M	ARC	Y	N	N/A	N/A	Y	B	3	A
10	F	ARC	Y	N	N/A	N/A	Y	G	13	E
10	F	ARC	Y	N	N/A	N/A	Y	G	13	E
10	M	ARC	Y	N	N/A	N/A	Y	G	13	E
10	M	ARC	Y	Y	digital	N/A	Y	F	99	E
10	M	ARC	Y	N	N/A	N/A	Y	H	15	E
10	M	ARC	Y	N	N/A	N/A	Y	D	7	A
10	F	ARC	Y	Y	heel	superficial	Y	D	147	A
10	F	ARC	Y	Y	digital	N/A	Y	C	93	E
10	F	ARC	Y	Y	heel	superficial	Y	G	153	E
10	M	ARC	Y	Y	heel	superficial	Y	C	145	E
10	M	ARC	Y	N	N/A	N/A	Y	G	13	E
10	M	ARC	Y	N	N/A	N/A	Y	G	13	E
10	F	ARC	Y	Y	forefoot	superficial	N	J	134	I
10	M	ARC	Y	Y	digital	N/A	Y	H	103	E
10	M	ARC	Y	Y	digital	N/A	Y	H	103	E
10	M	ARC	Y	Y	digital	N/A	Y	G	101	E
10	M	ARC	Y	N	N/A	N/A	Y	G	13	E
10	M	ARC	Y	Y	digital	N/A	Y	D	95	A
10	M	ARC	Y	Y	digital	N/A	Y	E	97	E
10	F	MA	Y	N	N/A	N/A	Y	J	19	A
10	M	MA	Y	Y	forefoot	superficial	Y	K	135	A
10	M	MA	Y	N	N/A	N/A	Y	I	17	A
10	M	MA	Y	Y	midfoot	deep	Y	K	213	A
10	M	MA	Y	Y	heel	deep	Y	D	199	E
10	M	MA	Y	Y	digital	N/A	Y	G	101	E
10	F	MA	Y	Y	digital	N/A	Y	G	101	E
10	M	MA	Y	Y	heel	superficial	Y	L	163	E
10	M	MA	Y	N	N/A	N/A	Y	G	13	E
10	F	MA	Y	Y	heel	superficial	Y	G	153	E
10	F	MA	Y	Y	digital	N/A	Y	G	101	E
10	M	MA	Y	N	N/A	N/A	N	G	14	E
10	F	MA	Y	Y	heel	superficial	Y	I	157	E
10	F	MA	Y	Y	heel	deep	Y	F	203	E
10	F	MA	Y	N	N/A	N/A	Y	F	11	E
10	M	MA	Y	Y	digital	N/A	Y	A	89	I
10	F	MA	Y	N	N/A	N/A	Y	D	7	I
10	M	MA	Y	Y	forefoot	deep	Y	D	173	I
10	M	MA	Y	Y	heel	superficial	Y	B	143	I
10	M	MA	Y	N	N/A	N/A	Y	D	7	I

APPENDIX 6

Publications arising from original data contained in thesis

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Declining Incidence of Amputation for Arterial Disease in Scotland

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Objectives: *To determine time trends and geographical variations in the incidence of major amputation for peripheral arterial disease and whether lower rates of amputation were related to higher rates of arterial reconstruction.*
Design: *Analysis of Scottish hospital discharge data.*
Setting: *Scotland 1981–1990.*
Materials: *Patients undergoing major amputation or arterial reconstruction for peripheral arterial disease.*
Chief outcome measures: *Time trends in age-sex standardised rates of major amputation and arterial reconstruction, and correlation between the rates of these operations by health board.*
Main results: *In Scotland, between 1981 and 1990, the incidence of major amputation fell by 22% ($p < 0.001$). Inconsistencies were observed within different age-sex groups. In the population under 65 years of age the incidence of amputation fell by 45% ($p < 0.001$), whereas in those over 65 years the incidence increased by 54% ($p < 0.001$). Amputation rates fell in men but a paradoxical increase was observed in women. Between 1981 and 1990, rates of arterial reconstruction doubled ($p < 0.001$), with an increase in all age-sex groups. Rates of amputation and reconstruction varied between health boards of residence, with a positive correlation ($r = 0.5$) between rates of operations within health board. Therefore areas with higher reconstruction rates tended to have higher amputation rates.*
Conclusions: *In Scotland, the incidence of amputation has fallen during a period when reconstruction rates have risen greatly. However inconsistencies in time trends by age-sex groups, and the lack of an inverse correlation by health board of residence, suggest that fewer amputations are unlikely to be due solely to an increase in reconstructive surgery.*

Key Words: Amputation; Arterial reconstruction; Peripheral arterial disease.

Introduction

Although arterial reconstruction is often used as a "limb-salvage" procedure, its value as such has not been properly assessed using randomised controlled trials. The impact of arterial reconstruction on amputation rates has therefore been inferred largely from observational studies.

If arterial reconstruction avoids the need for amputation in some patients, a negative correlation should exist between rates of amputation and arterial reconstruction within areas. However, correlational studies in both Denmark and the U.S.A. showed that, contrary to expectations, areas with high reconstruction rates also possessed the highest amputation rates.[1,2] Other studies have assessed the longitudinal impact of increased use of arterial reconstruction on amputation rates. Some single institutions have reported a decline in amputation rates.[3,4] However, population studies published to date have failed to support this decline.[2,5–7] A doubling in arterial reconstruction rates in Maryland between 1979 and 1989, had no effect on amputation rates which remained constant,[7] whilst an analysis of US national discharge data showed that increased use of reconstruction between 1979 and 1985 was associated with a paradoxical increase in amputations.[5]

Given the increasing use of arterial reconstruction in vascular surgery, the main aim of this study was to determine if a decline in the incidence of major amputation had occurred in Scotland and whether this was inversely related to reconstruction rates.

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Materials and Methods

Scottish hospital discharge data are collated by the Information and Statistics Division (ISD) of the Common Services Agency in Edinburgh. The Scottish morbidity record 1 (SMR1) documents information on all patients admitted to non-obstetric, non-psychiatric units. Unlike many national discharge datasets, SMR1 has 100% coverage. Patient details collected include age, sex and the health board area of residence. The principal underlying disease is recorded using the ninth version of the International Classification of Diseases codes (ICD9), and operations performed during the admission are recorded using the fourth version of the Office of Population Censuses and Surveys classification (OPCS4). Note is also made of whether the operation was performed as an emergency or elective procedure. SMR1 data are event-based, with each admission generating a new record. However, computerised record linkage enables extraction of patient-based information by linking all records associated with the same patient name and date of birth.[8]

Information was obtained from ISD on the numbers of major amputations and arterial reconstructions performed in Scotland between 1981 and 1990. Major amputations were defined as above-, through- and below-knee amputations. These operations are occasionally performed for trauma, deformity and malignancy, so only those operations which also had a principal disease code corresponding to peripheral arterial disease, gangrene or diabetes were included. Information on operations was further categorised according to age and sex, and whether the procedure was performed electively or as an emergency.

Record linkage was used to differentiate between primary amputations and those following failed attempts at arterial reconstruction and to obtain the numbers of patients undergoing multiple reconstruction operations. The chi-square (χ^2) test for trend was applied to assess the significance of changes in operation rates, as well as trends in the proportion of amputations performed as secondary and emergency procedures. The relationship between rates of amputation and arterial reconstruction within areas of residence was evaluated using Spearman rank correlation.

Results

In 1990, 1181 admissions to hospitals in Scotland were attributed to gangrene, with a further 9943 due to milder stages of peripheral arterial disease. The numbers of admissions due to gangrene remained remarkably stable over the past decade; the figures for 1981 and 1990 being identical. However, admissions for milder peripheral arterial disease increased by 50% (Fig. 1).

During 1990, 722 major amputations and 2224 arterial reconstruction operations had a principal disease code corresponding to peripheral arterial disease, diabetes or gangrene. These were equivalent to operation rates of 142 and 435 per 10^6 population respectively. Between 1981 and 1990, the age-sex standardised rate of major amputations for peripheral arterial disease fell by 22% (χ^2 trend $p < 0.001$), while the rate for arterial reconstructions more than doubled (Fig. 2). Standardised reconstruction rates rose steadily between 1981 and 1989 and then increased dramatically. The trend in amputation rates was also most marked after 1988. The numbers of patients undergoing reconstruction also doubled, with the trend mirroring that of reconstruction operations. Therefore, the operation:patient ratio remained between 1.1:1 and 1.2:1. The percentage of total reconstructions followed within one year by amputation fell steadily from 16% in 1981 to 11% in 1989 (χ^2 trend $p <$ 0.001).

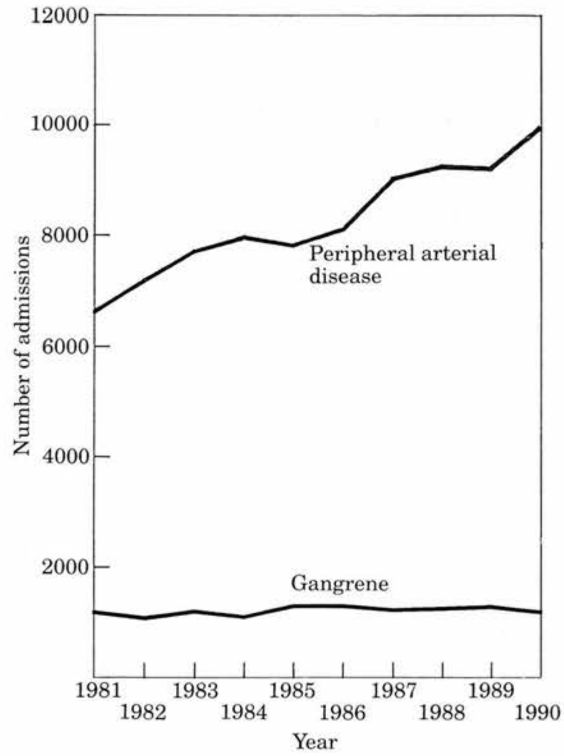

Fig. 1. Time trends in the number of admissions to Scottish hospitals with a discharge diagnosis of peripheral arterial disease or gangrene, 1981–1990

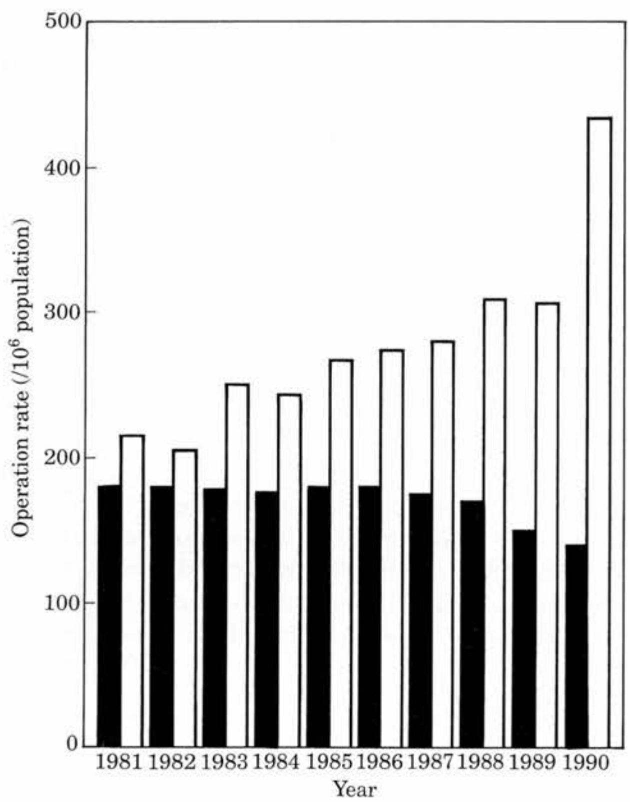

Fig. 2. Time trends in the age-sex standardised rates of arterial reconstruction (□) and major amputation (■) for peripheral arterial disease in Scotland, 1981–1990.

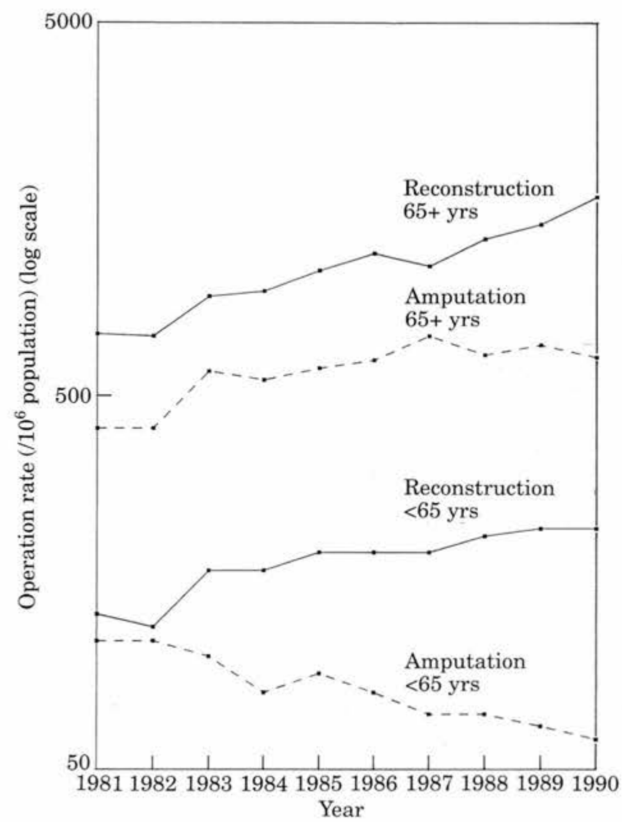

Fig. 3. Time trends in the age-specific rates of major amputation and arterial reconstruction for peripheral arterial disease in Scotland, 1981–1990.

The time trends observed in operation rates for the population as a whole were not consistent between the middle-aged and elderly. Among those under 65 years of age, the arterial reconstruction rate rose by 69% and the amputation rate fell by 45%. Despite a 132% increase in reconstruction rates in those 65 years and older, amputation rates rose by 54% (Fig. 3). Inconsistencies were also apparent between the sexes. The age-adjusted reconstruction rate doubled in both men and women, but the age-adjusted amputation rate declined by 28% in men and increased by 28% in women.

Prior attempts at reconstruction were less likely in older amputees. Twenty-nine percent of amputations in patients under 65 years of age were preceded by arterial reconstruction in the previous year, compared with only 18% in those over 65 years (χ^2 $p < 0.01$). The proportion of amputations performed as emergency rather than elective procedures also increased with age (χ^2 trend $p < 0.001$). For example, only 11% of amputations were emergency operations in patients under 45 years, compared with 37% in those over 84 years.

There were marked variations in the rates of major amputation and arterial reconstruction performed on the populations resident in the 15 different health board areas. Age-sex standardised rates of major amputation ranged from 51 to 230 per 10^6 population, and arterial reconstruction rates ranged from 174 to 997 per 10^6 population. Amputation and reconstruction rates within areas were positively correlated ($r = 0.5$, $p < 0.05$) (Fig. 4). The areas with higher rates of reconstruction therefore tended to be those with higher major amputation rates.

Discussion

Discharge data indicated that in 1990 the incidence of major amputations for peripheral arterial disease in Scotland was 142 per 10^6 population. This is of a similar magnitude to the estimates of the European Working Group on Critical Leg Ischaemia which calculated the annual incidence of critical ischaemia to be between 500 and 1000 per 10^6 population, with one quarter of these people undergoing major amputation

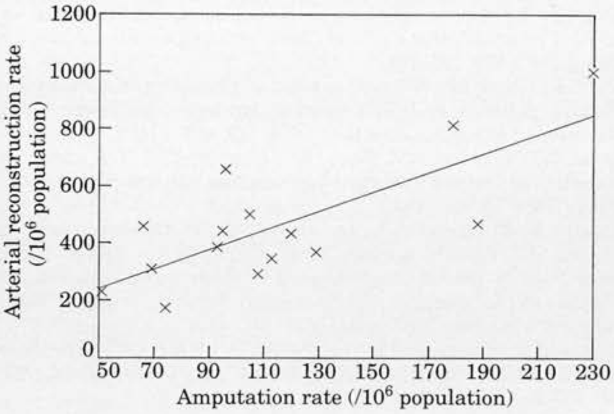

Fig. 4. Rates of major amputation and arterial reconstruction performed on populations resident in each of the 15 Scottish health board areas.

within one year.[9] The incidence of arterial reconstructions in Scotland was also of a similar magnitude to that described in other Western countries.[2,5,7]

National discharge data are sometimes criticised for being inaccurate or incomplete. ISD recently completed a validation study on Scottish vascular surgery discharge data, in which SMR1 records of vascular operations performed in eight units over a 3-month period were compared with the same data held on the units' computer databases or obtained from the operating theatre registers. Of the 3190 procedures performed, 95% were recorded centrally, and in 85% of cases the operation details were accurate (unpublished data, Clarke J).

It is unlikely that the recent decline in amputation rates in Scotland can be attributed to a fall in the incidence of disease since admissions due to gangrene did not fall, and an upward trend was observed in both total admissions and operations for peripheral arterial disease. Because arterial reconstruction rates increased over this period, it might be postulated that reconstructive surgery reduced the need for amputation, either by use in critical limb ischaemia in lieu of major amputation or by halting or retarding disease progression when used for milder cases. However, inconsistencies between the middle aged and elderly, between sexes and between areas of residence revealed that a simple beneficial effect of arterial reconstruction on major amputation rates was not apparent at the population level.

The increase demonstrated in arterial reconstruction rates more than compensated for the fall in major amputations. An increase in total operations for peripheral arterial disease has also been found in other studies.[5,7] Tunis claimed that arterial reconstruction may represent "an increasingly aggressive but ineffective interventional approach to disease which is either too mild or too advanced to be associated with an increase in limb salvage."[7] He claimed that increased use of reconstruction had so far failed to produce a beneficial effect on amputation rates because its increased use was not due to limb salvage but to expanded indications, increased diagnosis of milder disease and multiple procedures. This latter suggestion was supported by one study which showed that the average number of procedures performed per patient presenting with peripheral arterial disease rose from 1.2 in 1974 to 1.8 in 1989.[3] However, in our study the average number of reconstructions per patient remained constant, and the percentage of reconstructions followed by amputation fell significantly. The increase in total operations shown here therefore did not simply reflect an increase in the numbers of procedures per patient, but was instead due to a real increase in the numbers of patients treated. This was likely to be due, in part, to changes in the indications adopted for arterial reconstruction, resulting in increased use in patients with intermittent claudication in whom amputation would not be considered. The reassuring decline in amputation rates observed in younger patients was not mirrored in those over 65 years, in whom the incidence of amputation rose. Changes in disease incidence and natural history may play a role. However, this age differential is likely to reflect, at least in part, a less aggressive approach to the management of critical ischaemia in older patients. This is further supported by the higher numbers of emergency and primary amputations performed on the elderly. In view of current demographic trends, with the elderly accounting for an increasing proportion of the total population, consideration must be given to whether higher rates of limb-salvage could be procured among this expanding group of patients.

Also of concern is the sex difference in amputation trends. Although age-specific amputation rates in men were higher than those in women for all age-groups, male amputation rates declined considerably over the period studied, while the rate in women continued to rise. We can only speculate on whether this may reflect different trends in risk factors such as smoking or whether it reflects differences in clinical decision-making between the sexes.

A positive correlation between amputation and reconstruction rates has been described previously.[2] It is unlikely that the incidence of disease varies sufficiently within Scotland to account entirely for the observed variations in practice. Differences in clinical practice are likely and may in part reflect geographical variations in the type of surgeon performing amputation and reconstruction operations. Four of the 15

Scottish health boards contain specialist vascular surgery units. In the remaining areas, amputations are performed by a combination of general and orthopaedic surgeons.

Despite the introduction of arterial reconstruction in the early 1950s, lower limb amputations continued to increase in the U.S.A. and Western Europe into the early 1980s.[5,6] This study suggests that major amputations for peripheral arterial disease have since fallen within Scotland. In Denmark also, amputation rates appear to have declined since 1983 (unpublished communication, Eickhoff JH). Arterial reconstruction has long been used as a "limb salvage" procedure in individual patients. The recent decline in amputation rates might therefore be assumed to reflect a beneficial effect of increasing use of reconstructive surgery within the population, but our results do not support this explanation.

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Indications for Arterial Reconstruction and Major Amputation in the Management of Chronic Critical Lower Limb Ischaemia

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Objectives: *The aim of this study was to derive specific clinical indications for surgery in patients with chronic critical lower limb ischaemia and to determine the extent to which practice in Scotland conformed to these indications.*
Design, materials and methods: *Consensus on indications was achieved using a modified Delphi method in which a postal questionnaire was completed by 29 vascular surgeons on two occasions, with feedback between the rounds. Respondents indicated the appropriateness of arterial reconstruction and primary major amputation for 218 case scenarios comprising all possible combinations of clinical and angiographic findings.*
Results: *Agreement was reached on 31 appropriate indications for major amputation and 65 for arterial reconstruction. In 10 hospitals in Scotland, 400 primary amputation and arterial reconstruction operations were reviewed retrospectively and compared with the indications. The clinical findings for 7 (4%) arterial reconstructions and 48 (24%) major amputations did not conform to the indications agreed by the Delphi method. The proportion of operations conforming to the agreed indications differed significantly by size of unit (p<0.025).*
Conclusions: *This study shows that consensus can be reached on indications for surgery. However, in practice some operations performed do not conform with these indications. This discrepancy may be due to inappropriate practice.*

Key Words: Arterial reconstructive surgery; Major amputations; Variations; Indications.

Introduction

Arterial reconstruction is attempted in only one-half of all patients presenting with critical lower limb ischaemia.[1] Approximately, one-quarter undergo primary major amputation, and most of the remainder are treated conservatively.[2] However, published case series suggest that practice may vary significantly between units, with some attempting more limb-salvage procedures than others.[1] In addition, wide variations have been demonstrated in the rates of arterial reconstruction and major amputation throughout Scotland.[3] Although these operation rates are influenced by local disease incidence, referral patterns and case-mix, they may also reflect differences in clinical practice. The Second European Consensus Document on Chronic Critical Leg Ischaemia made general recommendations on the use of surgery but did not

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define specific indications.[2] In common with many diseases, studies on the management of critical ischaemia are insufficient to define precise and comprehensive indications. Also the diversity of clinical presentation does not easily permit the conduct of controlled trials.

The modified Delphi technique provides an explicit and systematic method of defining indications by consensus among a panel of specialists.[4,5] It has been used previously to determine appropriate indications for a variety of procedures, including carotid endarterectomy[6] and coronary artery bypass grafting.[7,8] In this study, the Delphi method was applied by a panel of vascular surgeons to define the appropriate indications for arterial reconstruction and primary major amputation in the management of chronic critical lower limb ischaemia. Case notes were then reviewed retrospectively in a representative sample of Scottish hospitals to determine the extent to which vascular surgical practice conformed to the indications.

Materials and methods

Modified Delphi technique

In the modified Delphi method, a questionnaire is completed by a panel of specialists who are asked to rate the appropriateness of surgery in a series of clinical situations. After completion of the questionnaire, the results are fed back to each panelist, before inviting them to complete a duplicate questionnaire amending previous responses if they so wish. The final appropriateness rating for each indication is determined by both the direction and dispersion of responses.[9]

Questionnaire and panelists

The questionnaire consisted of a series of hypothetical case scenarios covering the different clinical presentations of critical lower limb ischaemia. Following a review of the relevant literature and discussions with vascular surgeons, 218 possible case scenarios were selected for inclusion in the questionnaire. These were described in terms of combinations of the presence or absence of rest pain and gangrene, the site and severity of tissue loss, the availability of a vein for autologous grafting and the angiographic findings (13 options presented pictorially). The categories were designed to be mutually exclusive while encompassing all conceivable indications for surgery. The classification was sufficiently detailed to ensure that surgery would be equally appropriate for all patients within a category. Patients were deemed to have already undergone appropriate preoperative medical therapy and were excluded if unfit for major surgery. Appropriate preoperative treatment included: control of diabetes mellitus, hypertension and hyperlipidaemia, adequate attempts at pain relief, use of subcutaneous heparin, prostanoids, vasodilating and anti-platelet drugs where indicated, antibiotic therapy for systemic infections, debridement of necrotic tissue and advice on smoking cessation. Contra-indications to major surgery were considered to include: dementia, severely restricted functional capacity due to respiratory, cardiovascular or cerebrovascular disease, markedly reduced life-expectancy due to concomitant life-threatening conditions or markedly advanced age, patient opposition to surgery and lack of fitness for general anaesthesia. Chronic critical limb ischaemia was defined in accordance with the Second European Consensus Document.[2] A panel of 29 vascular surgeons from Scotland and North-East England completed both rounds of the questionnaire. Twelve (41%) were full-time vascular surgeons and 17 (59%) were general surgeons with a vascular interest. All major geographical areas were represented, as were both teaching and district general hospitals.

Scoring and feedback

For each indication, panelists were asked to rate the appropriateness of arterial reconstruction and primary major amputation separately using two multi-level scales ranging from 1 (extremely inappropriate) to 9 (extremely appropriate). "Appropriate" was defined as meaning that the expected health benefit, in terms of increased life expectancy, symptom relief or improved function, exceeded the expected negative consequences by a sufficiently wide margin that the procedure was worth doing; "inappropriate" was defined as the converse. The financial cost of procedures and availability of resources was not to be considered.

In analysing the results of the first round, the highest three and lowest three ratings for each possible indication were discarded. The remaining 23 scores were defined as showing "agreement" if they fell within a three-point range and "disagreement" if they did not. Indications were classified as "appropriate" if the median rating was 7–9 with agreement, "inappropriate" if the median was 1–3 with agreement, or "equivocal" if the median was 4–6 or there was disagreement. After completion and analysis of the first round, feedback was posted to respondents in the form of histogram of the group's scores for each question. Their own score and the group median were also marked on the histogram. Analysis of the second round was conducted in the same way as the first. A Chi-squared test was applied to determine if convergence of opinion between the two rounds was statistically significant.

Factors affecting ratings

Multiple linear regression analysis using dummy variables was used to assess the extent to which the presence of rest pain, degree of tissue loss, availability of a vein and angiographic findings influenced the overall appropriateness ratings for each operation. Each of these variables was divided into sub-categories. The face validity of the questionnaire ratings was assessed by the trend in median scores across these categories when ranked according to disease severity.

A Wilcoxon signed rank test was used to determine if the median scores for specialist vascular surgeons differed significantly from those for general surgeons with a vascular interest. The multiple linear regression analysis was also repeated, assessing specialists and generalists separately, to determine if their decision-making was influenced by the same clinical variables.

Comparison with actual surgical practice

Samples of primary major amputation and arterial reconstruction operations were selected using a two-stage sampling method. The 20 Scottish hospitals performing vascular surgery were stratified into three groups by size using annual numbers of vascular operations as a proxy measure. "Small" hospitals were defined as those performing less than 100 amputations plus arterial reconstructions per annum. "Medium" performed between 100 and 400 and "large" more than 400. A stratified random sample of 10 hospitals was then selected. Within each of these hospitals, the most recent 20 consecutive arterial reconstruction operations and 20 primary major amputations which satisfied the inclusion criteria (chronic critical limb ischaemia, adequate preoperative management, fitness for major surgery and preoperative angiography) were obtained from either computer databases or operating theatre registers.

The case-notes and angiograms were reviewed in order to categorise patients into one of the 218 clinical presentations contained within the questionnaire. The appropriateness of these operations could then be assessed in comparison to the indications previously defined. Chi-squared tests were used to determine whether the appropriateness of operations differed significantly between individual units and by size of unit.

Results

Between the first and second rounds opinion converged significantly on the appropriateness of indications for both primary major amputation (Chi-squared test, $p<0.01$) and arterial reconstruction (Chi-squared test, $p<0.0001$) (Table 1). In the second round, agreement was reached on 31 appropriate indications for major amputation and 65 for arterial reconstruction. Table 2 contains an example of the scores obtained for one specific scenario while, in Table 3, the 218 scenarios are allocated to 20 broad categories, for which appropriate operations are defined. This provides a general overview of the panel results.

Good face validity was demonstrated. The 218 questions were categorised by rest pain, gangrene, vein availability and angiography in turn, and the categories then ranked according to severity of disease (Table 4). As disease severity increased, the mean panel score for primary amputation rose, indicating its increasing appropriateness. Conversely, arterial reconstruction scores fell, indicating decreasing appropriateness. For tissue loss and angiography, where there were more than two categories, a consistent trend in scores was observed across the categories.

On multiple linear regression analysis, rest pain, gangrene, vein availability and angiogram findings explained 74% of the observed variation in amputation scores and 75% of that in arterial reconstruction scores. Angiogram findings were the most significant determinant of the appropriateness of both major amputation and arterial reconstruction ($p<0.0005$) (Table 5). Tissue loss was also independently associated with both scores. The availability of a vein was only significant for arterial reconstruction. Overall, specialists rated arterial reconstruction as more appropriate and major amputation less appropriate than generalists. However, the difference was only significant for arterial reconstruction (Wilcoxon signed rank test, $p=0.001$). Applying multiple linear regression analysis to vascular and general surgeons separately, vein availability was a significant determinant of arterial reconstruction score for vascular surgeons only ($p<0.01$).

In the retrospective review of case notes, clinical

Table 1. Ratings of appropriateness of case scenarios as indications for primary major amputation and arterial reconstruction following first and second rounds of completion of questionnaire.

		Number (%) case scenarios		
		Round I	Round II	Difference between I and II*
Major amputation	Appropriate	16 (7%)	31 (14%)	
	Inappropriate	53 (24%)	65 (30%)	$p<0.01$
	Equivocal	149 (68%)	122 (56%)	
Arterial reconstruction	Appropriate	45 (21%)	65 (30%)	
	Inappropriate	36 (17%)	61 (28%)	$p<0.0001$
	Equivocal	137 (63%)	92 (42%)	

* Chi-Squared test.

Table 2. Scores obtained for one specific scenario.

Example of a case scenario:
A patient who is fit for general anaesthaesia and has received maximal medical therapy presents with rest pain and superficial digital tissue loss. The angiogram demonstrates occlusion of the external iliac, common femoral and superficial femoral arteries, but patent vessels more distally and a patent profunda femoral artery. Both saphenous veins are intact.

Results:	Arterial reconstructive surgery	median = 9 range 8–9
	Primary major amputation	median = 1 range 1–2
Conclusion:	Arterial reconstructive surgery	appropriate
	Primary major amputation	inappropriate

practice was compared with the appropriateness scores of all 218 scenarios. Forty-eight percent of arterial reconstructions were judged to have conformed with the agreed indications (Fig. 1). The 49% classified as equivocal were predominantly femorodistal reconstructions. Only seven (4%) did not conform with the indications. There were significant differences in the degree of conformity for arterial reconstruction operations both between individual hospitals (Chi-squared test, $p<0.05$) and by size of unit (Chi-squared test, $p<0.025$). The percentage of arterial reconstructions conforming with the indications fell from 65% in small hospitals to 48% in large hospitals. Conversely, the percentage of reconstructions not conforming rose from 3% to 8%.

Only 31% of primary major amputations conformed with the agreed indications (Fig. 1). Twenty-four percent did not conform. These were predominantly patients with moderate degrees of tissue loss and inflow obstruction in addition to either outflow or superficial femoral occlusion. The percentage of amputations not conforming with the indications differed significantly by size of unit (Chi-squared test, $p<0.025$), although there were no clear trends apparent. The difference between individual units was not statistically significant.

Discussion

Ideally, appropriate indications for surgery should be derived from the results of randomised clinical trials, but these are lacking for many treatments. Consensus guidelines are not a substitute for experimentally derived standards, but can provide useful guidance in their absence and are preferable to arbitration by a single opinion. The Delphi method provides an explicit and systematic method of defining indications by consensus and has been used previously to develop guidelines for a number of surgical procedures.[6–8]

Some consensus methods require complete agreement and have therefore been criticised for producing "bland" recommendations which have already been widely implemented.[4,10] By contrast, the Delphi method allows for minor degrees of dissention by omitting the most atypical responses before assessing consensus. Alternative methods have also been criticised for producing results which are biased towards the views of the most vocal member of the group.[9] In the Delphi method, participating experts are polled individually and anonymously, using self-administered questionnaires. They are therefore able to express their views impersonally, while ultimately providing information generated by the entire group. The reliability of the Delphi method increases with the size of the panel,[11] and since the questionnaires can be posted, there is no geographical constraint on the selection of panelists.

The Delphi technique has been shown previously to be a reliable and valid method of deriving clinical indications for surgery.[6] As in these previous studies,

Table 3. Overview of procedures agreed as appropriate for categories of clinical presentation.

Angiographic findings	Degree of gangrene	Appropriate procedure
SFA or more proximal occlusion with patent popliteal and distal vesels	None	Arterial reconstruction
	Digital	Arterial reconstruction
	Forefoot	Arterial reconstruction
	Midfoot or heel	Arterial reconstruction in most cases
Patent SFA and proximal vessels. Complete occlusion of tibial, ankle and foot vessels	None	Major amputation in most cases
	Digital	Major amputation in most cases
	Forefoot	Major amputation in most cases
	Midfoot or heel	Major amputation
SFA and all distal vessels occluded	None	Major amputation in most cases
	Digital	Major amputation in most cases
	Forefoot	Major amputation
	Midfoot or heel	Major amputation
Inflow and distal vessels occluded. SFA and PFA patent.	None	Arterial reconstruction
	Digital	Arterial reconstruction
	Forefoot	Arterial reconstruction
	Midfoot or heel	Arterial reconstruction in most cases
Tibial vessels occluded but patent segment(s) at ankle or foot.	None	Arterial reconstruction (if vein available)
	Digital	Arterial reconstruction (if vein available)
	Forefoot	Arterial reconstruction (if vein available)
	Midfoot or heel	Arterial reconstruction (if vein available)

SFA = superficial femoral artery; PFA = profunda femoral artery.

Table 4. Mean panel score of appropriateness by sub-categories of rest pain, tissue loss, vein availability and angiogram findings.

			Mean panel score	
		Number of questions (%)	Major amputation	Arterial reconstruction
Rest pain	Absent	66 (45%)	2.7	5.6
	Present	15 (55%)	4.6	5.3
Tissue loss	None	22 (10%)	2.9	5.8
	Digital	48 (22%)	2.9	5.6
	Superficial forefoot	48 (22%)	3.5	5.6
	Superficial midfoot/heel	48 (22%)	4.2	5.6
	Deep forefoot	26 (12%)	4.4	5.4
	Deep midfoot/heel	26 (12%)	6.6	4.0
Vein availability	Vein available	109 (50%)	3.9	5.7
	No vein available	109 (50%)	4.3	5.1
Angiogram	Inflow and/or SFA occlusion	72 (33%)	1.5	8.5
	Inflow and outflow occlusion	36 (17%)	2.4	7.3
	Outflow occlusion but ankle patent	36 (17%)	4.5	5.1
	Outflow occlusion	18 (8%)	7.1	1.9
	Outflow and SFA occlusion	56 (26%)	7.6	1.0

SFA = superficial femoral artery.

Table 5. Multiple linear regression analysis of the association between operation appropriateness scores and clinical parameters.

		Odds ratio (95% C.I.)
Major amputation	Rest pain	3.7 (2.5–6.0)‡
	Tissue loss	1.5 (1.4–1.6)‡
	Angiogram	4.1 (3.7–5.0)¶
	Vein availability	1.3 (0.9–2.0)
Arterial reconstruction	Rest pain	0.7 (0.4–1.2)
	Tissue loss	0.8 (0.7–0.9)*
	Angiogram	0.2 (0.1–1.2)¶
	Vein availability	0.5 (0.3–0.8)†

* $p<0.05$.
† $p<0.01$.
‡ $p<0.001$.
¶ $p<0.0005$.

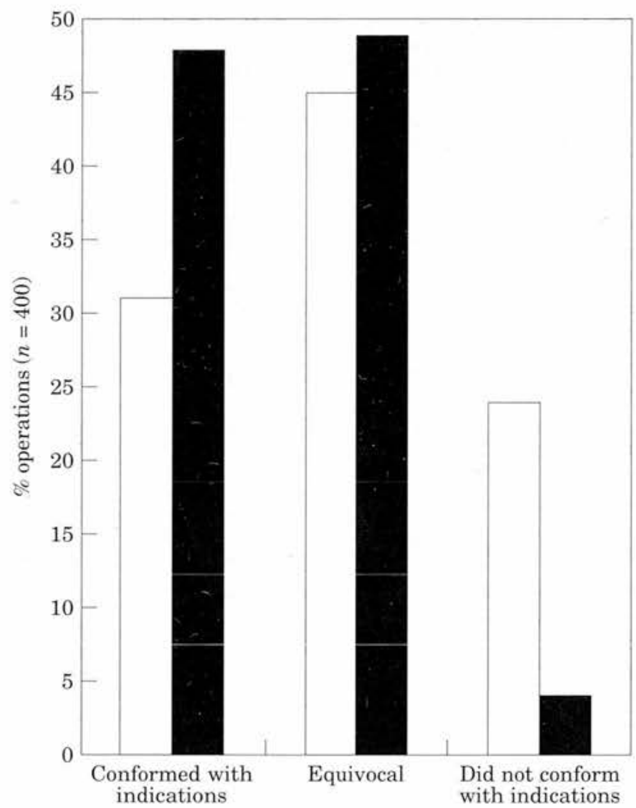

Fig. 1. Degree to which primary major amputation and arterial reconstruction operations performed in 10 Scottish hospitals conformed with agreed clinical indications. (□) major amputation; (■) arterial reconstruction.

the large number of indications classified here as inappropriate reflects the aim of making the questionnaire as inclusive as possible of all potential presentations. For those indications where agreement is good, guidelines can be formulated. Of equal importance is the identification of those clinical situations where consensus is lacking. In this study, opinion was divided on the most appropriate management of patients with occluded femoral, popliteal and proximal tibial arteries, but patent arteries at the ankle or foot level. This reflects the lack of trial information on the outcome following distal reconstruction. In such situations, some surgeons would advocate femorocrural reconstruction, especially if a suitable vein is available for autologous grafting. However, this is a time-consuming procedure requiring high levels of surgical expertise and vascular laboratory and radiological support, and it does not find unanimous support.[1,12] Highlighting areas of divergent opinion, helps direct future studies into those areas where they are most needed.

Indications derived by consensus must reflect all perspectives. In this study, the large number of panelists and their representation of all localities and types of units reduced the risk of bias. The good validation results and the ability of clinical parameters to explain most of the variability in scores further enhanced the credibility of the results. Also, the majority of surgeons performing vascular surgery in Scotland participated directly in the rating of indications, thereby increasing the likelihood that they are a good reflection of overall opinion.

The actual practice of vascular surgeons in Scotland differed from their own ratings of appropriate practice. The discrepancies found may reflect inappropriate practice. If this is the case, and the results are generalised to all units in Scotland, over 170 patients in Scotland may each year be undergoing major amputation unnecessarily.[3] However, clinical decision-making may have been influenced by factors which were not incorporated into the case scenarios, such as patients' wishes, available resources, surgical experience, the results of supplementary investigations and clinical factors unrelated to fitness for major surgery.[13] A prospective study is required to determine the extent to which such factors influence the decisions made by vascular surgeons.

Acknowledgements

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Surgical Management of 671 Abdominal Aortic Aneurysms: A 13 Year Review from a Single Centre

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Objective: *To audit the results for abdominal aortic aneurysm (AAA) repair from a single centre over a 13 year period.*
Design: *Retrospective survey.*
Setting: *Vascular unit of a major teaching hospital.*
Materials: *Six hundred and seventy-one consecutive patients divided into two groups: group A (1981–87) and group B (1988–93).*
Chief outcome measures: *Mortality rates, cause of death and major complications in patients undergoing elective, urgent and ruptured AAAs.*
Results: *Elective repair was performed in 313 (47%) patients, urgent repair in 80 (12%) and emergency repair for rupture in 278 (41%). A vascular surgeon performed the procedure in 94% of patients. The overall mortality was 21 patients in the elective group (6.7%), 13 in the urgent group (16%) and 148 in the ruptured group (53%). Mortality rates have not fallen during the study period but more patients in group B had ischaemic heart disease. Sixty patients (9%) required further operative procedures on 66 occasions: 24 elective cases (8%), 8 urgent cases (10%) and 28 ruptured cases (10%). There were 23 deaths in these 60 patients (38%) who underwent re-operation (5 elective, 2 urgent and 16 ruptured). Major postoperative complications included cardiac events in 212 (32%) patients, respiratory failure in 202 (30%) and renal failure in 90 (13%). Major causes of death included cardiac disease in 67 patients (37%), cardiac disease with coagulopathy in 22 (12%) and cardiac disease with respiratory failure in 16 (9%). Logistic regression analysis showed that in the elective group, cardiac or renal failure were significantly associated with death; and in the ruptured group cardiac, respiratory or renal failure were significantly associated with death.*
Conclusions: *More high risk patients with ischaemic heart disease are undergoing AAA repair. Postoperative cardiac, respiratory or renal failure are significant causes of death in AAA patients.*

Key Words: Abdominal aortic aneurysm; Diagnosis; Treatment.

Introduction

Abdominal aortic aneurysms (AAAs) occur in 3% of the population over the age of 50 years[1–3] and the incidence of this condition is increasing in England and Wales.[4] The majority of AAAs remain asymptomatic until complications develop; the most serious of which is rupture which accounts for 10 000 deaths in England and Wales per annum.[4] The risk of rupture is related to the size of the aneurysm, and studies have shown that aneurysms of greater than 5.5 cm are at significant risk of rupture.[5,6] Emergency surgical repair of a ruptured aortic aneurysm carries approximately a 50% mortality in those patients who reach hospital alive[7–11] and has an overall mortality of 90%.[9] In some patients warning symptoms such as abdominal pain, back pain or aneurysmal tenderness indicate that the aneurysm is rapidly expanding and urgent repair can be performed before rupture occurs. However, even in this situation, urgent repair of these acute, symptomatic aneurysms still carries a mortality of at least 10%.[12,13] The overall mortality from AAAs is rising by 4% per year mainly because more elderly patients are presenting for aneurysm repair.[14] Elective surgical repair, which carries a low mortality of around 4–8%,[8,10,12,13,15,16] appears to offer the greatest chance of reducing the mortality associated with this condition.

Over the last 2 decades, there have been major advances in the treatment of AAAs based upon changes in preoperative diagnosis and assessment; intraoperative surgical and anaesthetic techniques and postoperative care. This study examines the surgical

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APPENDIX 7

Guidelines formulated from results

SCOTTISH VASCULAR AUDIT GROUP

Guidelines for the use of major amputation and arterial reconstruction in the management of chronic critical lower limb ischaemia

The following guidelines apply to:

1. patients with chronic critical lower limb ischaemia as defined by the second European Consensus Document:

   - recurring ischaemic rest pain requiring regular analgesia for more than two weeks, with an ankle systolic pressure at or below 50 mmHg, or
   - tissue loss (ulceration or gangrene) of the foot or toes, with an ankle systolic pressure at or below 50 mmHg.

2. patients in whom treatment options are not restricted because of contra-indications to major surgery, such as:

   - dementia,
   - severely restricted functional capacity due to respiratory, cardiovascular or cerebrovascular disease,
   - markedly reduced life-expectancy due to markedly advanced age or concomitant life-threatening conditions,
   - patient opposition to surgery,
   - lack of fitness for general anaesthesia.

3. patients in whom maximum conservative treatment has already been undertaken, including:

   - control of diabetes mellitus, hypertension and hyperlipidaemia,
   - adequate attempts at pain relief,
   - use of sub-cutaneous heparin, prostanoids, vasodilating and anti-platelet drugs, where indicated,
   - antibiotic therapy for systemic infections,
   - debridement of necrotic tissue,
   - advice on smoking cessation.

Guidelines

For the clinical presentations described below, the following operations are preferable in most situations. The guidelines assume that the angiograms available to the surgeon are of good quality and enable all vessels to be visualised if patent. Although the operations are peferable for most patients within a category, we recognised that guidelines should not be prescriptive since factors other than those mentioned below may have an important role in determining the most appropriate management of individual patients. These additional factors will include, among others, patients' preferences and their general levels of fitness. Access to the radiology and vascular laboratory services differs between units and we recognise that, in some units, results from additional investigations will also influence the choice of operation.

*Please refer to the attached sheet for pictorial representations of the angiogram categories.

Angiographic findings	Angiogram categories	Preferred operation
SFA[t] and/or more proximal occlusion with patent popliteal and distal vessels	A, B, D	Arterial reconstructive surgery
Patent SFA[t] and proximal vessels but complete occlusion of tibial, ankle and foot vessels	K	Major amputation
SFA[t] and distal vessels occluded with or without occlusion of PFA[t] and proximal vessels	I, J, M	Major amputation
Proximal and tibial vessels occluded but SFA[t] and PFA[t] patent	E	Arterial reconstructive surgery

Angiographic findings	Angiogram categories	Preferred operation
SFA[†] and tibial vessels occluded but PFA,[‡] popliteal and proximal vessels patent	F	Arterial reconstructive surgery
Popliteal and tibial arteries occluded but patent segments at the ankle or foot level	G, H	Arterial reconstructive surgery (especially if vein available for grafting)

[†] SFA = superficial femoral artery
[‡] PFA = profunda femoral artery

** Where the angiograms show popliteal and tibial occlusion but patent segments at the ankle or foot level, complete consensus is lacking and therefore the choice of operation cannot be prescriptive. Where a vein is available for grafting, distal reconstruction is generally preferred. However, selection of the most appropriate operation for individual patients must also take account of surgical and technical expertise, access to vascular laboratory facilities, operating theatre time and patient preference.

Scottish Vascular Audit Group

ANGIOGRAM SCORES

Definitions

Severe inflow obstruction is defined as angiographic evidence of advanced disease of the aorto-iliac vessels, comprising major stenoses (> 10cm long or > 70% reduction in lumen) or complete occlusion.

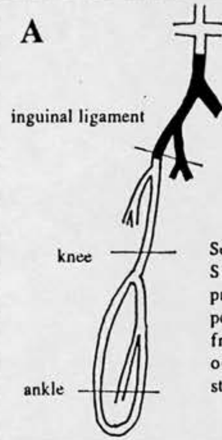
Severe outflow obstruction is defined as angiographic evidence of:

a. severe disease of the distal popliteal artery, due to either complete occlusion or long (> 10cm) stenoses resulting in > 70% narrowing of the lumen, as well as;

b. occlusion of the tibial arteries, resulting in no vessel flowing into the plantar arch which is both visibly patent on agiogram and suitable for distal anastomosis, or;

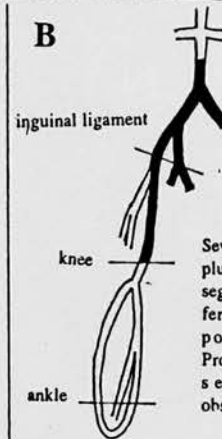
c. no other evidence of a vessel suitable for distal anastomosis by any criterion including exploration on the operating table or vascular laboratory tests.

A



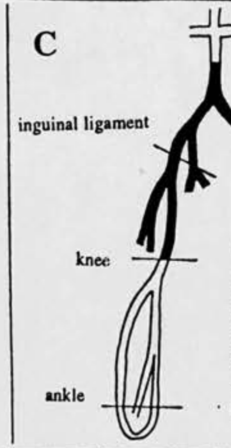
Severe inflow obstruction. Superficial and/or profunda femoral plus popliteal and tibial arteries free from complete occlusions or long stenoses.

B



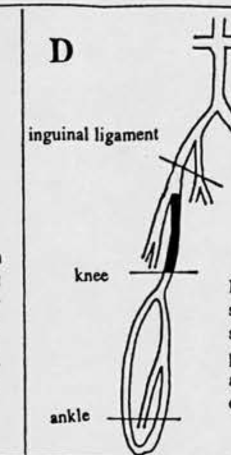
Severe inflow obstruction plus no visibly patent segment in superficial femoral or proximal popliteal arteries. Profunda patent and no severe outflow obstruction.

C



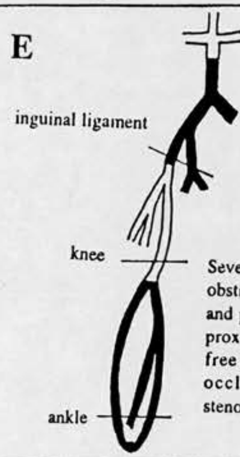
Severe inflow obstruction plus no visibly patent segment in superficial or profunda femoral arteries or proximal popliteal artery. No evidence of severe outflow obstruction.

D



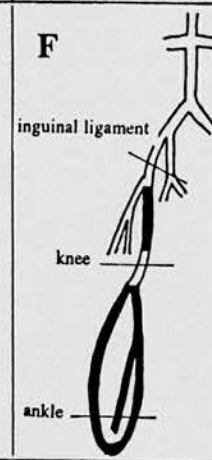
Major occlusions or long stenoses within the superficial femoral and proximal popliteal arteries. No severe inflow or outflow obstruction.

E



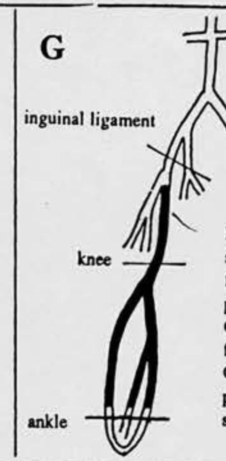
Severe inflow and outflow obstruction. Superficial and profunda femoral and proximal popliteal arteries free from complete occlusions or long stenoses.

F



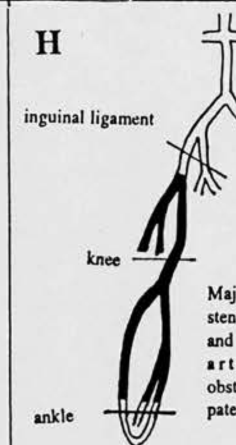
Severe outflow obstruction plus no visibly patent segment in superficial femoral artery. Profunda femoral and popliteal arteries patent and no severe inflow obstruction.

G



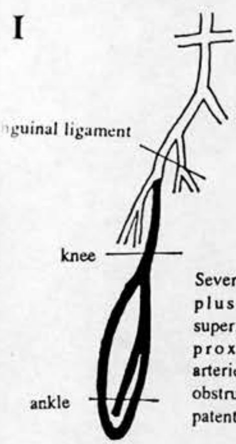
Major occlusions and long stenoses within superficial femoral and proximal popliteal arteries. Common and profunda femoral arteries patent. Outflow obstruction present but patent segments at ankle/foot.

H



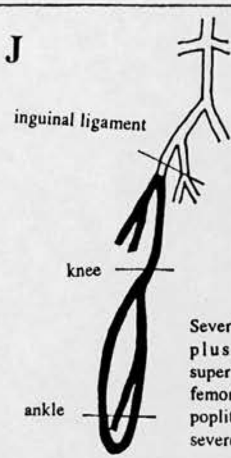
Major occlusions and long stenoses within femoral and proximal popliteal arteries. Outflow obstruction present but patent segments at ankle/foot.

I



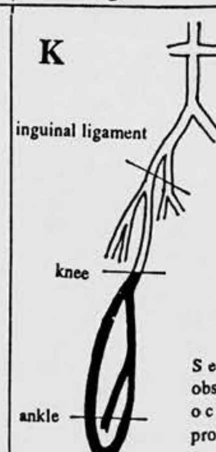
Severe outflow obstruction plus occlusion of superficial femoral and proximal popliteal arteries. No severe inflow obstruction and profunda patent.

J



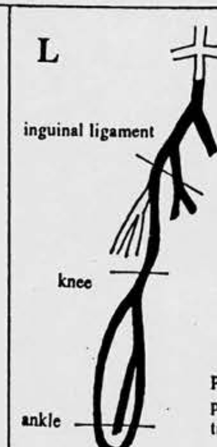
Severe outflow obstruction plus occlusion of superficial and profunda femoral and proximal popliteal arteries. No severe inflow obstruction.

K



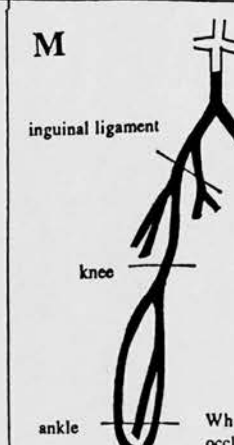
Severe outflow obstruction. No major occlusions more proximally.

L



Profunda femoral artery patent. Rest of arterial tree occluded.

M



Whole arterial tree occluded.