Management of Diabetic Foot Complications

Clifford P. Shearman
Patrick Chong
Editors

Second Edition

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Preface

Since the publication of the First Edition in 2015, it is encouraging to see improvements in this field. The publication of NICE Guidelines in 2015 has re-enforced the importance of the multidisciplinary foot care team in early diagnosis and management of diabetic foot complications to prevent amputation. Despite this, the service is not universal and outcomes vary depending on geographical location which cannot be acceptable. The poor outcomes for some patients who develop foot complications are reflected in the increased litigation.

The Second Edition has been completely updated to reflect recent changes. A number of new authors have joined the team and shared their expertise and to whom we are very grateful.

We hope this publication will continue to be a useful aid to all health care professionals involved with treating and supporting patients who have diabetes and are at risk or have developed a foot complication.

Southampton, UK — Cliff P. Shearman
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Chapter 1
Foot Complications in Diabetes: The Problem

Clifford P. Shearman

Background

There are currently over 3.7 million people registered with diabetes in England and Wales and the prevalence continues to rise. That amounts to more than 7.2% of the adult population and there will be more who are currently undiagnosed. Despite increased recognition of the benefit of management of the condition and its complications, access to services across England and Wales remains variable for area to area [1].

Foot complications are a common and costly cause for admission to hospital and are strongly associated with the risk of amputation. The cost of foot complications has been estimated at £1 billion annually, or approximately 1% of the NHS budget [2].

The At-Risk Foot

People with diabetes are prone to foot complications due to neuropathy, arterial disease, and infection. Neuropathy is found in up to 28% of people with diabetes and is more common in those who have had the condition for over 10 years, or whose control has been poor. Sensory neuropathy will reduce awareness of injury to the foot, especially due to repetitive trauma such as ill-fitting footwear. It may also affect proprioception and gait, which alters biomechanical load distribution

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resulting in the unprotected foot being more vulnerable to injury from ambulation. Autonomic neuropathy will reduce sweating, resulting in dry and cracked skin, allowing bacteria into the soft tissues resulting in infection. Autonomic regulation of skin blood flow may be lost with shunting through arteriovenous fistulae, producing the pink, warm, but ischaemic foot with reduced nutritional blood flow to the tissues. Most importantly, men with diabetes have a 2.6 relative risk of developing peripheral arterial disease (PAD) compared to non-diabetic men. This risk increases with the duration of diabetes. It is estimated that even at the time of diagnosis, 8% of type 2 diabetics have PAD and one-third of those over the age of 40 years have PAD. The presence of PAD is associated with a 10–16-fold risk of amputation, but also a 70–80% risk of dying from cardiovascular disease (mainly myocardial infraction and stroke) compared to a person with diabetes but no PAD [3].

The immune response of patients with diabetes may be obtunded and neutrophil phagocytosis is impaired due to chronic hyperglycemia. This will not only make the individual more prone to infection in a foot wound, but their systemic response may be reduced and only about one third of patients with a foot infection will have a temperature. The patient may not be aware of infection until advanced and clinicians often underestimate the extent of the infection.

In the person with diabetes, then, it is easy to see how the foot is more vulnerable to damage and injury, often resulting in skin damage and an ulcer. Reduced blood supply due to PAD results in either slow, or non-healing of the wound and infection will ensue.

Diabetic Foot Ulcers

Diabetic foot ulcers (DFUs) are extremely common. The prevalence varies across different populations, but the lifetime risk of a patient with diabetes developing a foot ulcer may be as high as 30%. At any one time between 2.2 and 6% of the diabetic population will have an ulcer, being more common in those over 60 years of age. Based on this it can be extrapolated that in England and Wales at any one time there will between 81,400 and 222,000 people with an active DFU.

Around two-thirds of DFUs will heal with treatment, but it can be a slow process, often taking more than a year, and over half will get recurrent ulceration within 12 months [4]. DFUs have a significant impact on the quality of life of the patient. Up to 84% of people reported a major impact of a DFU on their lives including reduced mobility, pain and anxiety and depression [5]. The inability to stand or walk was found to be the most important determinant of their quality of life.

Perhaps most worryingly, the development of a DFU is a major prognostic indicator of mortality risk. Over half of patients who develop a foot ulcer will be dead within 5 years, largely from cardiovascular disease and complications of diabetes [6].

Foot Complications and Amputation

The most feared complication of a DFU is the progression to limb amputation. This is either due to failure to heal the primary ulcer, recurrent ulceration, or chronic infection. Many patients with foot complications who are admitted to hospital require minor amputation (below the ankle, usually digits or trans-metatarsal) as part of the treatment to control infection or remove dead tissue. Although often an essential part of their treatment, the change in foot architecture caused by the amputation will put them at increased risk of further problems.

Between 2007 and 2010 there were 34,104 lower extremity amputations in England, of which 48.9% were in people with diabetes. This was a rate of 2.51 for those with diabetes compared to a 0.11 risk for non-diabetics per 1000 person years (23.3 relative risk) [7]. In this study it was observed that the amputation rate varied eightfold across different health care providers, suggesting a variation in the quality of the service provided. In a similar study between 2003 and 2008, 25,578 major amputations were identified in England of which 39.4% were in diabetic patients. The adjusted in-hospital mortality rates for major amputation varied between geographical areas from 14.0 to 20.2% with a median of 16.8%. Over 50% of patients had no recorded attempt at revascularisation prior to amputation [8]. A more recent study suggests a fall in the rate of major amputation in people with diabetes by 17% and an increase in minor amputations by 23% between 2003 and 2013. However, major amputation remains 6 times higher in people with diabetes compered to non-diabetics [9].

Although amputation may be looked on as a final solution for a chronic, often debilitating problem, the evidence does not seem to bear this out and only 37% will become ambulant to the level they were before [10]. Having lost one leg, the risk to the remaining limb increases and around 50% suffer a contralateral amputation within 5 years. Amputation, although a marker of more advanced disease, has a major impact on the persons general health and 50% will be dead within 2 years.

Diabetic Foot Ulcers: The Economic Impact

Managing patients with DFUs is extremely costly and includes those with less severe ulcers in the community and primary care, requiring regular dressing changes and visits to podiatry together with patients who may require hospital admission for treatment including amputation. The estimated costs in England for treatment of diabetic foot ulceration and amputation for 2014–2015 was between £837 and £962 million. Community and primary care costs were £627 million and inpatient care for ulceration and amputation was £315 million, which represents between 0.78 and 0.90% of the NHS budget. It was estimated that around 90% of these costs were incurred managing ulceration. Although amputation was expensive, the very large numbers of foot ulcers outweighed the expenditure on amputation [11].

Targeted preventative services (Multi-Disciplinary Diabetic Foot Care Teams) can identify those at risks of ulceration and have been shown to improve outcome and reduced amputation. Preventing one amputation has a major impact not only on the patient but also on the health economy. Based on the published evidence and 2010–2011 costings, Kerr calculated that one quality adjusted life year (QALY) cost £25,000, which is below cost threshold supported by NICE.

The Solution

The pathway to amputation is a long one and begins with the foot at risk due to neuropathy and ischaemia. The potential to prevent the initial development of complications and the progression of those that are inevitable is apparent but often missed. The screening of people with diabetes will identify those at increased risk and if appropriate, supportive action is taken, such as regular review by a specialist foot care team, ulceration and amputation can be reduced [12].

Rapid referral of people who have developed complications is essential and delay is strongly associated with increased risk of amputation. Patients who are seen within 2 weeks of ulceration have more rapid healing and less risk of amputation compared to those seen after 2 weeks. In the most recent data from the National Diabetes Foot Audit, 71% of health care providers indicated that they provided access to the multidisciplinary team on the same day or next working day. However, overall, only 46% of patients referred to these teams were seen within 2 weeks [13].

Where services have been organized across primary and secondary care to facilitate the care pathway, with a multi-disciplinary foot care team and network, hospital admissions and amputation rates have been shown to fall, with a considerable cost saving to the local health economy. Despite this being known for at least a decade, the NHS Diabetes Inpatient Audit (2019–2020) found that although foot risk surveillance was undertaken in a median of 72.5% of people with type 1 diabetes and 84% of people with type 2 diabetes, this ranged from 38 to 87% and 63 to 91% respectively, depending on geographical location [14]. Encouragingly 82% of hospitals treating patients with complications of diabetes reported that they had a multidisciplinary foot care team [15].

It appears that not only can considerable improvements in quality of life be achieved by organizing services for diabetics who are at risk or who have developed foot complications, but considerable cost savings can also be made. It is disappointing that despite this evidence being apparent, over the last decade there still remains wide variation in commissioning the multidisciplinary foot care team, resulting in continued variation in amputation rates, most likely reflecting varying levels of interest and care available to these patients.

Key Points

- Up to 30% of people with diabetes will suffer a DFU in their lifetime.
- DFUs have a significant impact on quality of life and increase the risk amputation.
- DFUs are a major marker of cardiovascular risk, which can be reduced.

- The cost of managing foot complication of diabetes representing 0.6–0.7% of all NHS health care spending in England.
- Substantial reductions in hospital admissions and amputations can be made with multidisciplinary foot care teams and networks, which are highly cost-effective.
- Delay in diagnosis and treatment is the commonest cause of deterioration in DFUs resulting in amputation.

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Chapter 2
Screening and Treatment of Early Complications in the Diabetic Foot

Graham C. Bowen

Introduction

Foot disease is a potentially devastating complication of diabetes and, as a consequence, a lower limb is lost every 20 s somewhere in the world. In the UK, diabetes-related foot complications are the largest single reason for patients with diabetes to be admitted to hospital [1].

It is estimated that one in three people diagnosed with diabetes will experience a foot ulcer during their lifetime [2]. For those people with diabetes who have a foot ulcer and go on to have an amputation, these amputations could be avoided if the foot ulcers are effectively detected, assessed, referee and rapidly treated in order to optimise healing [3].

Foot ulceration and infection places a huge burden on healthcare systems, in terms of expenditure and resources to support hospital in-patients and outpatients being managed by primary care and community care services. The financial costs to the NHS are large and increasing. A recent study estimated the cost of healthcare for ulceration and amputation in diabetes in England in 2014–2015 at £837–£962 million [4]. This is equivalent to almost £1 in every £100 spent by the NHS in England, and is higher than estimated NHS expenditure on breast, prostate, and lung cancers combined [5].

Community care for the diabetic foot is delivered primarily by podiatry services whose aim is to prevent foot ulceration in the first instance, manage foot complications and prevent hospital admission and amputation. However, patients commonly present late or the significance of early complications is not fully recognised. It has

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been suggested that 85% of limb amputations could be prevented by early intervention.

The United Kingdom Department of Health Quality Improvement, Innovation and Prevention (QIPP) agenda highlights that if strategic goals are not implemented now, the NHS will end up providing crisis intervention to the population, rather than active chronic disease management. Diabetic foot disease clearly characterises this approach. There are few conditions in which prevention and early intervention play such a major role in the prevention of major complications such as amputation.

However, all too often the patient's condition is allowed to reach an advanced state before treatment is initiated, by which time the outcome is poor. This chapter illustrates how foot care services can be delivered to improve clinical outcomes for patients with diabetes and foot disease.

Need for Foot Care Service

The 2021 prevalence of diabetes in England was 6% of the population; 20–40% of patients with diabetes will develop neuropathy and a similar number develop peripheral arterial disease (PAD). These conditions are the two strongest predictors of the risk for developing foot ulceration. Identification of a patient's foot risk is essential and all patients with diabetes should be aware of their risk for developing diabetes related foot disease and fully understand the consequences of this.

For those patients with diabetes who will suffer at foot ulcer at some stage in their lives, approximately 10% of these ulcers lead to lower limb amputation. Approximately 80,000–100,000 people with diabetes in England and Wales are thought to have foot ulcers at any given time, i.e. approximately 2.5% of the diabetes population [4]. It is important to acknowledge that patients with diabetes who have a foot ulcer and/or go on to have a diabetes related amputation have poor survival rates. 50% of foot ulcer patients will die within 5 years and 80% of those having a diabetes related amputation will die within 5 years [6].

Apart from the increased risk of amputation, the indirect and often intangible costs of ulceration to the patient are also high. Many individuals with foot ulceration are unable to work, experience social isolation, develop depression and have a poorer quality of life than those without an ulcer [7].

There is evidence that dedicated multidisciplinary diabetes foot clinics are clinically effective and reduce amputation rates [4]. These multi-professional specialist teams include podiatrists, diabetologists and orthotists, and can access a wider range of healthcare professionals who may be called upon for specialty input, depending on the condition of the foot. Those without active diabetic foot disease must also be considered; strategies should be in place to educate and empower patients and carers on self-management strategies. These models form the basis of national guidelines and continue to be the recommended approach to diabetes foot care [8].

In 2009, investigation of diabetes with foot ulcers on a single vascular ward, identified that 48% of patients were not known to podiatry prior to admission (personal observation). Late referrals are one of the major factors that contribute to poorer outcomes. This results in a delay in targeted management of foot ulceration and can be the cause of a preventable amputation. Late and delayed referrals can be overcome with a clear communication between teams via a dedicated diabetes foot pathway.

The aim of a dedicated diabetic foot pathway is to

- Reduce incidence of foot ulceration by early identification of foot risk and what that means to a patient.
- Support ongoing education of all patients who are at risk, informing them about self-care and measures they can take to reduce the risk of foot complications.
- Support the prevent escalation of patient from "low risk" to "moderate risk" to "high risk" and on to "the acute foot".
- Ensure a dedicated diabetes foot pathway is utilised effectively for all patients.
- Raise awareness amongst healthcare professionals of the extent of diabetes foot problems, possible actions and the consequences of not managing these patients promptly.
- Reduce the number of foot-related hospital admissions, both non-elective and electives.
- Promote healthy lifestyles, mobility, independence and optimise quality of life for all patients.

Podiatry Foot Risk Guidance

Prevention is the one of the key aspect of Podiatry, creating a culture to prevent end stage diabetes foot complications. However, this is a significant challenge as many Podiatry services are "firefighting" the already established burden of diabetes foot disease fueled by late presentations and over stretched health care systems managing diabetes.

Every patient with diabetes should receive healthy lifestyle assessment. This assessment will look at lifestyle choices with detrimental effects on health, such as, smoking, obesity and alcohol misuse, along with topics of footwear advice and skin care. Any lifestyle choice that falls outside of the national recommendations will be identified and brief intervention provided (see Chap. 6). Intervention will involve opportunistic advice, discussion, negotiation and encouragement to modify lifestyle. The aim is to motivate individuals to modify lifestyle choice rather than to promote total abstinence. Each Intervention is designed around a customised approach to each public health initiative detailed in this document. Patients requiring specialist intervention will be referred to appropriate organisations. Local health trainers can be utilised when patients who do not need specialist referral would like support in changing their behaviour.

Early identification of people at moderate risk and high risk of developing diabetes foot complications is achieved through the use of a Diabetes Foot Assessment (DFA) tool. The DFA tool will indicate the foot risk in accordance with NICE Guidelines [8] and suggests the care pathway the patient should follow. All referrals for diabetes patients into podiatry should be accompanied by a completed DFA. This will enable patients to be directed appropriately to the correct clinic and health care professional.

General Management Approach

The approach should be a partnership with shared decision-making between the patient and healthcare professionals. This encourages and supports the patient to take control of their diabetes and modify their lifestyle appropriately. Patients should have an annual review with this can be done predominately within primary care. However, personnel carrying out this review should be trained to examine the feet and recognise risk factors for ulceration [8]. It is helpful to use a traffic light system red indicating high risk/acute foot, Amber indicating moderate risk and green low risk, to rate the risks as these are easily understood by all involved (see Appendix).

Examination of patients' feet should include

- Testing of foot sensation using a 10-g monofilament or vibration
- Palpation of foot pulses
- Ulceration
- Callus
- Infection and/or inflammation
- Deformity
- Charcot arthropathy
- Inspection for any foot deformity and footwear

Based on this the foot should be classified as one of the following

- At low current risk
- Moderate risk
- High risk
- Acute foot—ulcerated foot/charcot/infection/critical limb ischaemia/tissue loss

At Low Risk

These patients have no evidence of neuropathy, arterial problems or any other risk factor (such as deformity) so are at low risk of foot ulceration. It has been estimated that this group will be 99.6% ulcer-free after 2 years, i.e., they have a 1 in 500 risk of foot ulceration per year [9]. It is suggested that low risk patients comprise

60–65% of the adult diabetes population. With such a low risk of foot ulceration, this group do not require routine podiatry, but require annual screening. They should also be given help to modify their cardiovascular risk factors.

Routine screening may be carried out in primary care and does not need to be carried out by podiatrists. A diabetes foot training programme for medical staff, practice nurses and clinical support workers should be provided to ensure that those involved are competent to carry out screening. Patients should be made aware of their risk stratification.

These patients with no significant risk factors should have access to urgent podiatry appointments within 24 h if an ulcer or other foot pathology develops. The local podiatry service should accept referrals for patients categorised as low risk with minor complications such as callus, minor skin abrasions or minor infections and offer a short-term management and empowerment programme for the foot condition, particularly increasing the patient's awareness of good foot-care and prevention of further problems. Patients should be empowered and given the confidence to take charge of their own foot health.

Moderate Risk

Patients with deformity, neuropathy or non-critical limb ischaemia detected on screening but who have not had a foot ulcer, are at moderate risk of future foot ulceration. This group comprises around 25–30% of the adult diabetes population and patients have a 3–7% annual risk of ulceration [9]. National guidelines recommend that this group of patients has regular podiatry care depending on individual need; some may need up to a 3-month review. These patients must have immediate (next working day) access to the foot protection team if they develop a new active foot complication, such as ulceration.

It is important to ensure these patients have access to structured education regarding foot health and advice on good diabetes management. Strategies such as enhanced screening, determining foot pressures and bespoke footwear may provide benefit and prevent ulceration. Often this group is neglected, resulting in them progressing into the high-risk group.

Podiatry should lead on the enhanced assessment of these patients and arrange a regular review every 3–6 months by the diabetes foot protection team. At each review, the patient's feet should be inspected by a podiatrist trained in diabetes foot care and may include foot biomechanical assessment for review for orthotics/insoles. Careful vascular assessment and assessment of cardiovascular risk should be undertaken. Most importantly, current footwear should be evaluated, and advice and help given regarding this, as foot-wear is a major factor in both preventing and causing foot problems. They should also be given help to modify their cardiovascular risk factors. Finally, it is important to re-enforce foot care education and ensure the patient understands what moderate risk means.

At High Risk

High risk means that a patient with diabetes will have one of the following

- previous ulceration or
- previous amputation or
- on renal replacement therapy or
- neuropathy and non-critical limb ischaemia together of
- neuropathy in combination with callus and/or deformity
- non-critical limb ischaemia with callus and/or deformity

This group of patients comprises 8–12% of the adult diabetic population and patients have a 40–50% annual risk of foot ulceration [9]. For this reason, they should have close follow-up by podiatrists in the diabetes foot protection team. Due to the high rate of re-ulceration, it is recommended that these patients have direct access to services with appropriately skilled diabetes-specialist podiatrists. These services should have direct involvement with a multidisciplinary diabetes foot team. Podiatry should lead on the assessment of these patients by arranging frequent reviews by the foot protection team (1–3 monthly). At each review a full examination of the patient's feet should be made and the need for more detailed vascular assessment by a vascular surgeon considered. There should be provision of intensified foot care education and specialist footwear and insoles. Skin and nail care should also be addressed. Many of these patients will have other disabilities or will be immobile and it is essential to ensure they get adequate access to this service. They should also be given help to modify their cardiovascular risk factors. Finally, it is important to re-enforce foot care education and ensure the patient understands what high risk means.

Ulcerated/Acute Foot Complication

At any one time 1–5% of diabetes patients will have an active foot ulcer or other foot disease. Considerable resource and time are spent dealing with this group and the re-ulceration rate can be frustrating. These patients should be reviewed frequently in a specialist multidisciplinary diabetic foot clinic with a network of community podiatry foot protection teams that link with primary care and nursing teams to provide continuity of care in between specialist clinic visits.

The model for ulcer care should be led by these multidisciplinary teams (MDT) who are able to provide the appropriate clinical skills, orthotic service, surgical access and radiological support. The expected model is as follows

- All new foot ulcers to be managed by appropriately skilled and competent health care professional
- Complex diabetes related foot ulcers (DFUs) requiring MDT input should be referred for urgent care
- Prevent emergency hospital admissions for DFUs
- Prevention of avoidable amputations
- Identified lead for delivering care using NICE guideline NG19 [8].

Initial Presentation: Time is Tissue

Rather too frequently, patients with diabetes commonly present late in seeking care for the foot complications. Late presentation can be due to lack of awareness of the foot problem, lack of pain from neuropathy and underpinned by poor symptoms recognition. This delay can unfortunately vary from days to weeks to months, as patients are unaware of the complication and the damage it is doing to their foot. Patients frequently report a failure to understand the severity of a foot problem and that this can lead to a lack of urgency to seek help. This will then lead to a delay in accessing a health care professional for specialist care and/or accessing the diabetes foot pathway/Multi Disciplinary Diabetes Foot Team in a timely manner [10].

Due to ongoing educational requirements, it is clear that both patients with diabetes and healthcare professional may not appreciate the warning signs that precede the need for an amputation, thereby reinforcing the requirement for foot problems to receive urgent attention [11].

Even after appreciation of the need for specialised care, the pathway to treatment may be compromised due to poor communication, difficulty in referral between healthcare professionals across sectors and reduced access to specialised care because of actual lack of multidisciplinary foot teams (MDFTs). An association has also been noted between the number of healthcare professionals in the referral pathway and increased delays in patient with diabetes reaching specialised care. The more complex the referral pathway, the greater the delay [10].

ACTNOW!, (Fig. 2.1) is a key initiative developed in 2021, by the iDEAL group (a multidisciplinary team of specialists with a key interest in improving diabetes care outcomes across the UK). The acronym ACTNOW! Is a simple and straightforward way of highlighting the need for a patient or a health care professional to take action if they have one or more of the following, outlined in the picture below.

This guide is a very practical and innovative approach to encourage people with diabetes with a foot problem to seek help. ACTNOW has been endorsed by Diabetes UK, the International Diabetes Federation (Europe), D-Foot International, the Royal College of Podiatrists, the Foot in Diabetes UK, the English Diabetes Footcare Network, Diabetic Foot Network Wales, Diabetes Network Northern Ireland, the Juvenile Diabetes Research Foundation and the Primary Care Diabetes Society, who all recognise its valuable contribution to footcare services [10].

Management of the Diabetic Foot

The structure of the service across primary and secondary care can be confusing for the patient and for those who work in the service. The structure of the teams is illustrated in Fig. 2.1.

Multi-disciplinary Foot team (MDFT) management is essential to ensure diagnosis and management of the most complex of the acute foot conditions. All patients identified as acute foot or high risk should be given emergency contact details. MDFT clinics should consist in the main of a diabetes consultant and

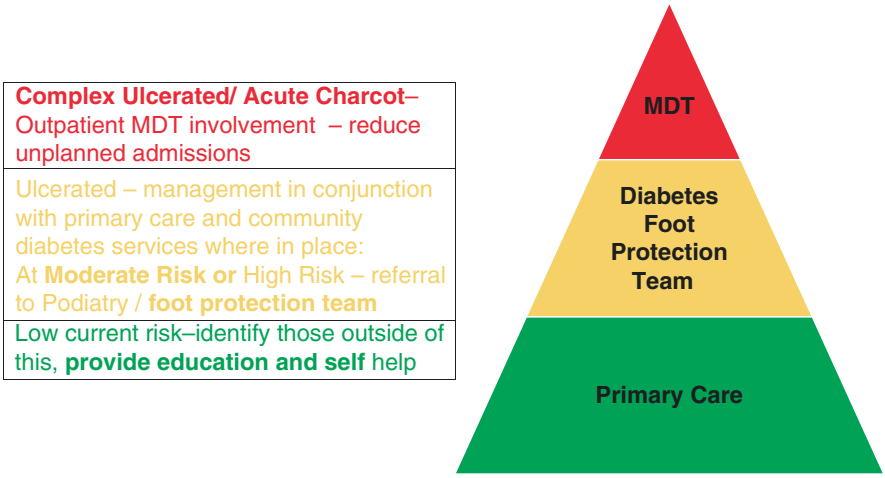

Fig. 2.1 Pyramid of teams who manage foot risk – Adapted from National Institute for Health and Care Excellence. NICE clinical guideline: NG19 type 2 diabetes—prevention and management of foot problems. London: NICE; 2019

podiatrist both with specialist expertise in this field to provide expert opinion on the management of complex neuropathic ulceration including medical management, infection control, offloading and imaging. The MDFT works well where there is rapid seamless access into vascular surgery, orthopaedics, orthotics, diabetes specialist nursing, microbiology, radiology, and pharmacy although this list is not exhaustive.

Systems must be in place to allow rapid access to see and access new patients presenting with complex foot disease (including suspected Charcot) and to manage complex acute foot conditions which can be complicated by concomitant PAD, renal failure and other co-morbidities where diagnosis, management and treatment options are unclear or limited due to the complex nature of the condition.

Diabetes Foot Protection Team

Community Podiatry services are ideally placed to form and coordinate the Diabetes Foot Protection Team (DFPT). This team needs to be fully integrated with Primary Care and support the delivery of the Quality Outcome Framework (QoF).

It is clear that podiatry plays a significant role in the management of the diabetes foot and podiatry services should be funded and commissioned appropriately with a focus of delivering a dedicated DFPT as a priority.

The DFPT should use the "Capability Framework For Integrated Diabetic Lower Limb Care: A User's Guide" [12] that clearly describes the skills, training and capabilities the any members of the DFPT require to deliver the correct

intervention, assessment and education. All appropriate health care professionals can be utilised in this team, which supports primary care and the hospital multidisciplinary team so that there is a comprehensive and seamless pathway in place for any patient with diabetes who presents with a foot concern or problem. This structure and information on how to access the team should be widely publicised so that all patients and members of the health care team are aware of who to contact for varying degrees of foot problems (Fig. 2.2). Many services are not available out of hours and at weekends. This can cause problems, as patients may require help and advice during these times. It is likely that services will be challenged to address this with increasing pressure for health care in the UK to be provided 7 days a week.

The rapid increase in the diabetes population is stretching existing diabetes foot services and an increase in the multi-disciplinary workforce may be required to meet demands. There are considerable efficiencies to be achieved in good team working, ensuring there is no duplication of activity. Information technology too may be harnessed to enable information about the patient and their condition to be available to the health care professionals managing these patients across health care systems. Fundamentally, the real gain is that well-structured and organised foot care services with easy access, not only brings significant benefit to patients by improving clinical outcomes, reducing amputation rates and improving patients quality of life, but they benefit the wider health care systems by saving precious time and resources.

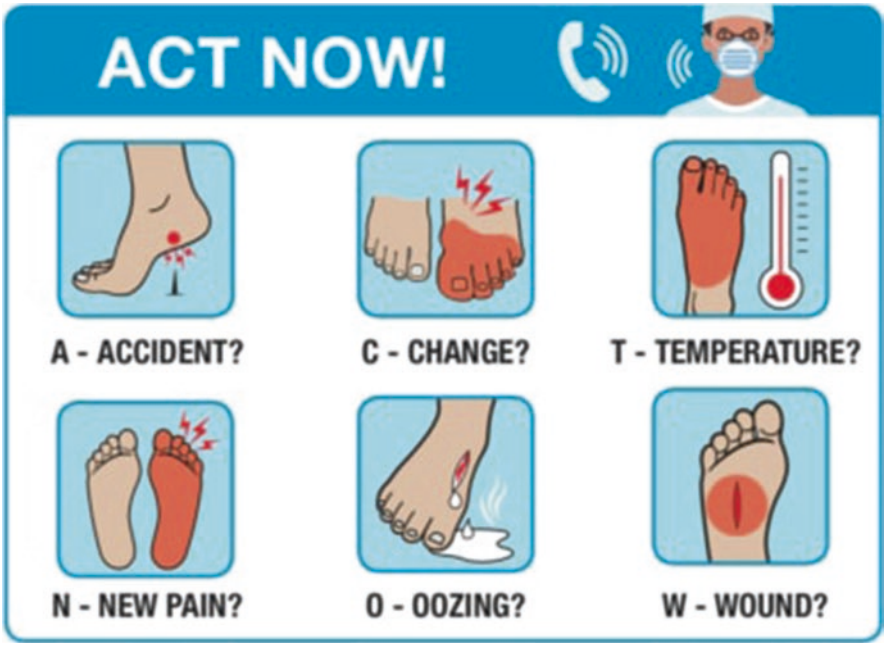

Fig. 2.2 ACTNOW—situations which should prompt immediate action

Key Points

- Use a risk identification system on clinical records systems (electronic or paper) to identify all patients so that they can have timely access when needed.
- ACTNOW/use a Red, Amber and Green approach for risk identification.
- Ensure all patients are informed of their risk and the impact this has on their foot health.
- Seek enhanced assessment for the increased risk group—the biggest benefit will be gained with these patients.
- Ensure appropriate pathway into podiatry (Diabetes Foot Protection Team) that has a dedicated assessment tool that identifies risk to allow for the quick identification from referral.
- Ensure ongoing education for both patients and health care professionals. This should include audit of outcomes such as amputations, admissions to hospital and new ulcer development.
- Foot care networks support and drive change and improvements in pathways but must be well structured, managed and resourced.

Appendix

See Fig. 2.1.

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Chapter 3
Emergency Management of the Acute Diabetic Foot: Foot Attack

Sarah Jane Messeder and Robert S. M. Davies

Introduction

Diabetic foot ulceration (DFU) is the most common diabetic complication requiring hospitalisation. It results in significant morbidity and mortality and is the leading cause of non-traumatic lower limb amputations. Up to 25% of patients with diabetes will have a diabetic foot ulcer during their lifetime with 17% of individuals undergoing an amputation within 1 year of developing an diabetic foot ulcer [1]. Individuals with diabetes are at an increased risk of injury and subsequent ulceration due to the synergistic effects of peripheral neuropathy and impaired tissue perfusion; neuroischaemic ulceration.

Diabetic peripheral neuropathy is present in up to 50% of individuals with diabetes and effects the somatic (sensorimotor) and autonomic nervous systems.

Peripheral sensorimotor neuropathy often follows an insidious onset: initially affecting the feet before progressing proximally in a symmetrical manner (stocking distribution). The sensory component predominates in the early phase with patients complaining of numbness and paraesthesia or dysesthesia. As an individual's protective nociceptor reflexes diminish, they become at an increased risk of unappreciated foot integumental injury and subsequent ulceration.

Charcot neuropathic osteoarthropathy is an extreme consequence of somatic dysfunction whereby the peripheral sensorimotor neuropathy has caused the loss of proprioception and nociceptor reflexes within the joints of the foot. This leads to chronic joint subluxation, instability, and bony destruction, Charcot foot. In its acute phase the associated inflammatory response may be mistaken for infection

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and contributes to further deterioration of normal foot architecture. Motor neuropathy may alter the normal biomechanics of the foot through the creation of an imbalance between the flexors and extensors muscle groups of the foot. The resultant clawing of the toes and exaggeration of the longitudinal plantar arch exacerbates abnormal pressure loading over the plantar metatarsal heads, toe pulps and interphalangeal joints increasing the risk of injury and ulcer formation. Damage to the autonomic nervous system may further compound the effects of sensorimotor neuropathy through the loss of sweating, rendering the skin more prone to fissures and infection. Concurrently reduced sympathetic tone increases microvascular arterio-venous shunting exacerbating ischaemia caused by macrovascular peripheral arterial disease; paradoxically the arterio-venous shunting may lead to pink, warm foot despite underlying tissue ischaemia.

Peripheral arterial disease (PAD) is common in patients with diabetes and the length of affliction and level of glycaemic control is proportional to the risk and severity of PAD. For every 1% increase in haemoglobin A1c (HbA1c) there is a 25% increase in the relative risk of PAD [2, 3]. Seldomly causing DFU in isolation, PAD works synergistically with neuropathy causing neuroischaemic ulceration and is implicated in the aetiology of 50% of diabetic foot ulcerations.

The pattern of PAD in diabetes is macrovascular and diffuse, characteristically affecting the crural vessels whilst sparing portions of the plantar arch [4]. Concomitant microvascular dysfunction potentiates the effects of macrovascular disease with microcirculatory arteriolar shunting and impaired capillary vasoreactivity exacerbating tissue ischaemia. The combination of macrovascular disease and microvascular dysfunction has considerable implications on treatment strategies with relatively innocuous PAD in the non-diabetic population having the potential to significantly impact on tissue healing in patients with diabetes. In turn the presence of PAD is a predictor of non-healing and amputation and is implicated as a contributing factor in 90% of major lower limb amputations in diabetics [5]. Thus, even when only mild in severity, the early recognition of PAD is vital for limb salvage.

Diabetic foot infection is a common and potentially limb threatening problem often being the cause for emergency or urgent presentation. Traditionally thought to be integral to the initial formation of DFU, infection is now recognised as occurring because of ulceration or other types of foot wounds e.g. paronychia. Polymicrobial in nature, aerobic gram-positive cocci and gram-negative bacilli are the commonest causative organisms.

Infection may be initially limited to the ulcer or local integumentum, however a superficial diabetic foot infection can quickly spread from the subcutaneous tissues along the deep fascia impacting upon tendons, muscles, and bone. The anatomy of the foot makes it particularly prone for spread of infection due to its separate but intercommunicating compartments; as infection spreads compartment pressures elevate from the resultant oedema exacerbating ischaemia and tissue necrosis. This rapidly progressive diabetic foot infection requires prompt recognition and treatment without which deterioration may occur over a matter of hours leading to a non-salvageable foot and often life-threatening systemic sepsis. In this chapter, we focus on the emergency management of a patient with an acute diabetic foot infection—the ‘diabetic foot attack’.

Initial Management

Initial Assessment

Initial assessment begins with managing the individual according to the Resuscitation Council UK Guidelines with an A–E approach [6]. Blood glucose levels and the presence of ketones in the urine must be assessed urgently to diagnose metabolic derangements, diabetic ketoacidosis and hyperglycaemic hyperosmolar syndrome. Initial management and treatment should be done in accordance to guidelines ([7], also see Chap. 4). Other potential sources of sepsis should also be identified and treated accordingly.

History

A clear and focused history should be taken to determine onset, duration and extent of symptoms. Treatment prior to admission, including type and duration of antibiotic(s), should be recorded to reduce ineffective antibiotic prescribing. It is important to note that systemic symptoms (rigors, fevers and chills) are uncommon in patients with diabetic foot infection [8]. Preceding glycaemic control can provide an indicator of infection severity with hyperglycaemia a marker of severity of illness and predictor of poor outcome [8]. Cardiovascular co-morbidities such as hypertension, cerebrovascular accident, myocardial infarction and hypercholesterolaemia should be documented alongside other co-morbidities such as chronic kidney disease. History of previous surgery is useful to ascertain previous peri-operative complications and fitness for anaesthesia. Additionally, it is important to record the time of last oral intake, medications (particularly anticoagulants), allergies and a social history to determine timing and type of surgery if appropriate.

Examination

Basic observations should be recorded; respiratory rate, oxygen saturation, pulse, blood pressure and temperature to determine systemic response to infection. Fluid status can be determined by assessing skin turgor, mucus membranes, capillary refill time, peripheral temperature and pulse character.

To examine the foot all dressings must be removed including on the unaffected limb. Erythema, ulceration, pus, swelling and calluses should be noted and documented with particular attention paid between the toes and on the heel. The authors recommend taking photographs of the affected foot for accurate clinical documentation.

Changes in temperature, pain or tenderness, oedema and crepitus should be recorded. The finding of crepitus is significant as it indicates the presence of

gas-producing organisms (gas gangrene) in the soft tissues requiring urgent surgical debridement. 'Milking' of the foot along tendons may produce pus in the wound distally, suggesting proximal tracking of infection.

Osteomyelitis may underly diabetic foot ulceration and is frequently observed in ulcers that are chronic, extensive, overlying a bony prominence e.g., first or fifth metatarsophalangeal joints, or accompanied by a swollen "sausage" toe (Fig. 3.1). In these circumstances the clinician should undertake a 'probe to bone' test to establish bony involvement: a sterile metal probe is inserted into the ulcer with a positive test recorded upon encountering bone. A positive 'probe to bone' test is an accurate and inexpensive bedside test for osteomyelitis and widely used by the authors.

Pulse status throughout the leg and foot should be recorded alongside objective tests for peripheral arterial disease. An ankle brachial pressure index (ABPI) <0.9 indicates the presence of peripheral arterial disease however, a third of patients with diabetes produce an incompressible or falsely elevated ABPI due to calcification of the arterial wall. Toe pressures are more reliably used as they are rarely affected by atherosclerosis with a pressure <50 mmHg indicative of significantly impaired perfusion.

Validated scoring systems should be used to determine the severity of infection and need for revascularisation. The Infectious Diseases Society of America/International Working Group on the diabetic foot classification scheme is used to determine the presence and severity of a diabetic foot infection (Table 3.1). The Wound, Ischemia, and foot Infection (WIfI) is used to estimate the risk of major limb amputation and benefit of revascularisation in individuals with a threatened limb (Table 3.2).

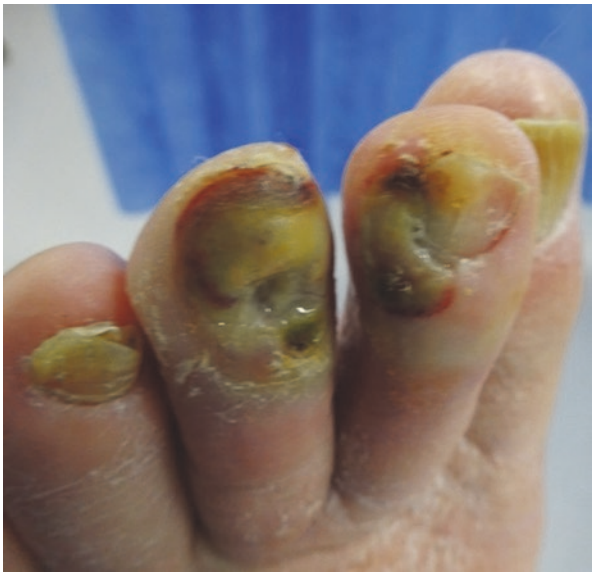

Fig. 3.1 "Sausage" toe indicative of underlying osteomyelitis

Table 3.1 The Infectious Diseases Society of America/International Working Group on the diabetic foot classifications of diabetic foot infection [8]

Clinical classifications of infection	IDSA infection severity
No symptoms or signs of infection	1 (Uninfected)
Infection defined as ≥2 of: • Local swelling or induration • Erythema >0.5 cm^2 around wound • Local tenderness/pain • Local increased warmth • Purulent discharge Excludes other causes (e.g. trauma, gout, acute Charcot, fracture, thrombosis, venous stasis)	
Infection confined to skin and subcutaneous tissue with no systemic manifestations	2 (Mild)
Infection with erythema ≥2 cm^2 and/or involving structures deeper than skin and subcutaneous tissues and with no systemic manifestations	3 (Moderate)
Infection with systemic manifestations defined as ≥2 of: • Temperature >38 °C or <36 °C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min or $PaCO_2$ <4.3 kPa • White blood cell count >12 × 10^9/L, or <4 × 10^9/L, or ≥10% immature (band) forms	4 (Severe)

Table 3.2 Society for vascular surgery lower extremity threatened limb classification: wound, ischemia, and foot infection system [9]

Component	Score	Description		
Wound	0	No ulcer (ischemic rest pain)		
	1	Small, shallow ulcer on distal leg or foot without gangrene		
	2	Deeper ulcer with exposed bone, joint or tendon ± gangrene changes limited to toes		
	3	Extensive deep ulcer, full thickness heel ulcer ± calcaneal involvement ± extensive gangrene		
Ischemia		ABPI	Ankle pressure (mmHg)	Toe pressure or $TcPO_2$
	0	≥0.8	>100	≥60
	1	0.60–0.79	70–100	40–59
	2	0.40–0.59	50–70	30–39
	3	<0.40	<50	<30
foot Infection	0	No symptoms/signs of infection		
	1	Local infection involving only skin and subcutaneous tissue		
	2	Local infection involving deeper than skin/subcutaneous tissue		
	3	Systemic inflammatory response syndrome		

Investigations

Initial blood tests are required to help determine severity of infection and initiate management plans. It is important to note that half of patients with a diabetic foot infection have a normal white cell count [8]. However, a C-reactive protein level or other inflammatory marker level can help guide initial management and act as an adjunct in the diagnosis of osteomyelitis. A full blood count is also useful in determining baseline haemoglobin level and platelet function with anticipated serum grouped and saved. In patients with a history of cardiovascular disease a haemoglobin >80 g/L should be targeted. A coagulation screen should be carried out for clotting function with an INR ≤1.4 being acceptable for an individual to undergo regional anaesthesia [10].

Measuring urea and kidney function is useful to assess for organ dysfunction due to sepsis and to help guide suitable antibiotic choice and doses. A venous blood gas allows a quick immediate assessment of lactate, pH and glucose level. A HbA1C should also be sent concurrently. Blood cultures are required in those with pyrexia to determine micro-organisms involved.

Samples for microbiology culture and sensitivity should be taken; however, this should ideally be done aseptically by curettage or biopsy from the ulcer to determine the true causative organism as wound swabs are often positive for contaminants. Bony fragments evident in the wound should be biopsied and sent for culture and histopathology analysis.

Patients with a diabetic foot infection require an AP and lateral foot X-ray view to assess for osteomyelitis. It is important for the clinician to note that X-ray evidence of osteomyelitis may not be evident during the first 4–6 weeks of infection or could be mimicked by a Charcot osteoarthropathy. X-rays should also be assessed for the presence of soft tissue gas; an indicator of severe foot infection (Fig. 3.2). Advanced imaging techniques such as MRI may be useful following initial measures to control the foot control. However, they have little benefit during the emergency setting where the combination of accurate clinical history and examination, blood tests and plain radiographs are more useful in directing emergency treatment of the diabetic foot attack.

Management

Emergency management of a patient with an acute diabetic foot infection also requires management of diabetes and other co-morbidities. Those awaiting emergency surgery with normoglycaemia (capillary blood glucose <10 mmol/L), no metabolic derangement and who will only miss one meal due to surgery should receive a reduced insulin dose. Those who will miss more than one meal or who have hyperglyacemia (blood glucose >10 mmol/L) without metabolic derangement require a variable rate intravenous insulin infusion (VRII). Where there are risk factors for hypoglycaemia (chronic kidney disease, acute kidney injury, low body weight, low total daily dose of insulin,

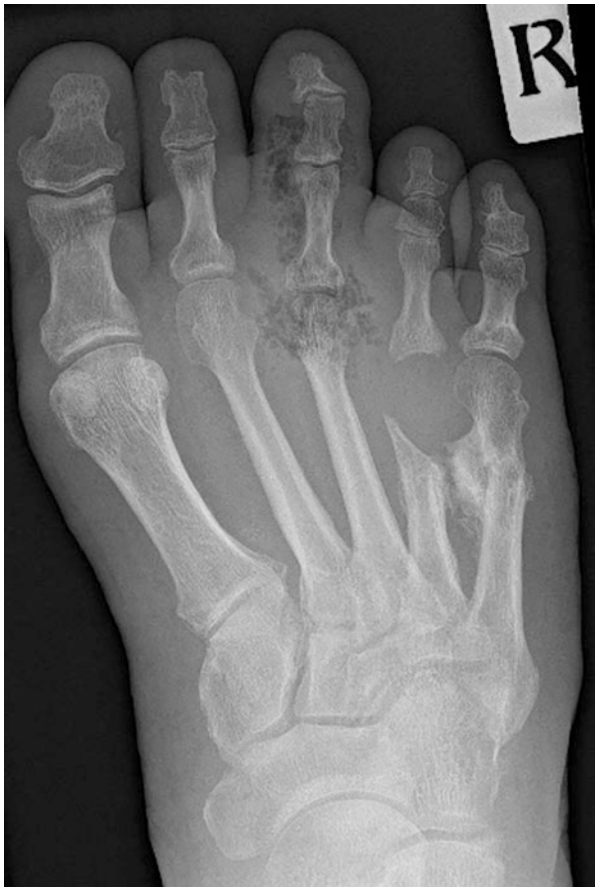

Fig. 3.2 Plain AP foot X-ray demonstrating locules of gas around the third toe. Previous partial resection of the fourth toe and through the distal interphalangeal joint of the second toe

insulin naïve), then a reduced VRIII should be used. Diabetic ketoacidosis and hyperosmolar hyperglycaemic states should be managed with a fixed rate intravenous insulin infusion according to local institute guidelines (see Chap. 4). Intraoperative blood glucose levels should be maintained between 6 and 12 mmol/L [11].

500 mL of crystalloid fluid should be used for immediate fluid resuscitation and broad-spectrum antibiotics given promptly. Antibiotics should be continued for 1–2 weeks and initially parenteral for severe infection. It is important to remember that diabetic foot infections are often polymicrobial in nature. The most common causative organisms are aerobic gram-positive cocci and gram-negative bacilli; therefore, antibiotics should be targeted accordingly. No antibiotic class or agent has been shown to be superior to others and so prescribing according to local policy, previous sensitivities and consideration of allergies should be undertaken.

Consideration is required for patients on anticoagulation and antiplatelet therapy who need surgery. Warfarin should be withheld for 5 days for patients undergoing surgery. If emergency surgery is required in 6–8 h then 5 mg of IV vitamin K for immediate reversal should be given. If emergency surgery is required sooner, then warfarin should be reversed with 25–50 μ/kg of four-factor prothrombin complex

concentrate. Direct oral anticoagulants should be withheld for 48 h prior to surgery. However, for those requiring emergency surgery, reversal agents exist. Idacrucizumab should be used to reverse dabigatran and andexanet for the reversal of apixaban, rivaroxaban or edoxaban. The management of anticoagulation in the emergency setting is complex and requires careful co-ordination and discussion with the anaesthetic and haematology teams. Regarding antiplatelet therapy, aspirin can be continued peri-operatively including those awaiting neuroaxial anaesthesia. Ideally Clopidogrel and Ticagrelor should be withheld for 5 days and Prasugrel for 7 days pre-operatively, however this may not always be possible in the emergency setting of a foot attack and rapid debridement should take priority with haematological input to reduce bleeding peri-operatively [12].

Surgery

Many diabetic foot infections remain above the subcutaneous fascia and can be managed with antibiotics alone. However, deep soft tissue involvement requires emergency surgical management. Purulent discharge, fullness in the plantar space, pain or tenderness in a previously insensate foot, infected and necrotic tissue, presence of an abscess or radiological evidence of gas are all indications for emergency surgical intervention. The aim of surgery for most patients is to facilitate the control of infection, and in turn limb salvage, through the drainage of compartmental pus and debridement of necrotic tissue. However, for the patient in fulminant diabetic foot sepsis the priority of surgery is preservation of life rather than limb salvage and on occasion a major limb amputation is required.

Surgery

Surgery is aimed at targeting all pockets of infection and this requires a detailed understanding of the nine compartments of the foot (medial, lateral, four interosseous and 3 central; superficial, intermediate and deep).

The Loeffler–Ballard incision is the most widely described technique and commences proximally from behind the medial malleolar extending distally and laterally across the medial longitudinal arch, ending between heads of the first and second metatarsals [13]. This allows good access to the medial, central and 1–2 interosseous compartments. Modifications of this technique have been widely described and the authors use a modified technique (Fig. 3.3). The incision commences between the two metatarsal heads corresponding to the maximal distal extent of infection and progresses proximally towards the medial malleolus until healthy tissue is identified or all infection has been drained. In our experience, this rarely progresses to the level of the medial malleolus thereby reducing the

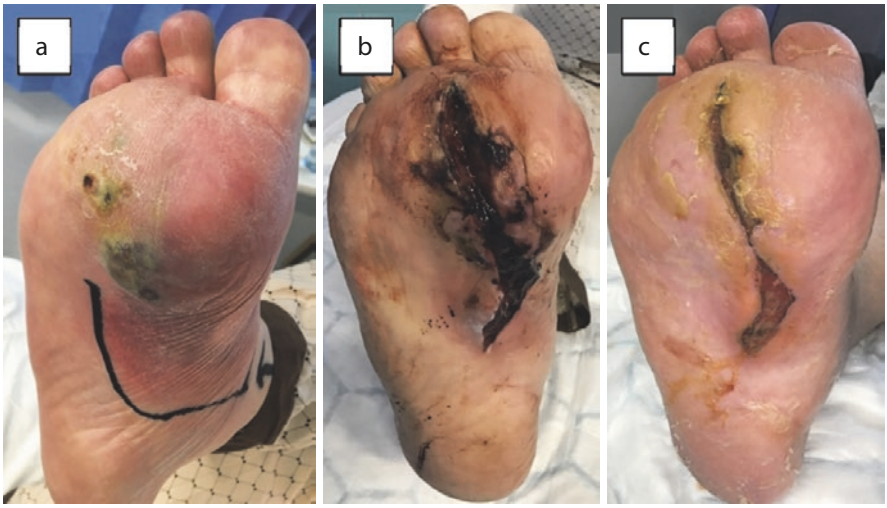

Fig. 3.3 (**a**) Diabetic foot infection; black mark demonstrating degree of erythema. (**b**) 5 days post modified plantar incision. (**c**) 4 weeks post modified plantar incision

morbidity of the surgery particularly in those patients with concomitant ischaemia. In cases of fulminant foot infection access to all nine compartments of the foot is vital. In these situations, the authors combine a standard Loeffler–Ballard incision with two longitudinal dorsal incisions commencing immediately proximal to the second and fourth webspace and extending the length of the adjacent metatarsal bone. When combined with a plantar incision, this facilitates access and lavage of all nine compartments.

Upon accessing the fascial spaces and drainage of pus, debridement of all non-viable tissue and bone should be undertaken regardless of size and extent. Exposed tendons should be resected to prevent future tracking of infection/pus. It is vitally important to document and send superficial, deep soft tissue, and bone samples for microbiological culture and sensitivity. This allows targeted peri-operative antibiotic therapy as pus samples alone are inadequate for this purpose.

Once the infection has been drained and all non-viable tissue excised, the incision(s) should be left open. Multiple surgical debridements are often required for the severely infected diabetic foot. The use of drains is at the operator's discretion, but the authors have found little benefit to their usage and believe them to be no substitute for aggressive debridement and planed 'relook' surgery.

In some cases, it may be appropriate to undergo a primary amputation to manage the diabetic foot infection. Limited toe amputations can be carried out for individuals with wounds limited to the middle or distal portion of the toe. Incisions ensuring complete drainage of infection and tension-free coverage should be chosen. Fish-mouth or transverse incisions are traditionally used for partial amputation of the toe and Racket incisions for complete amputation (Fig. 3.4). Ray

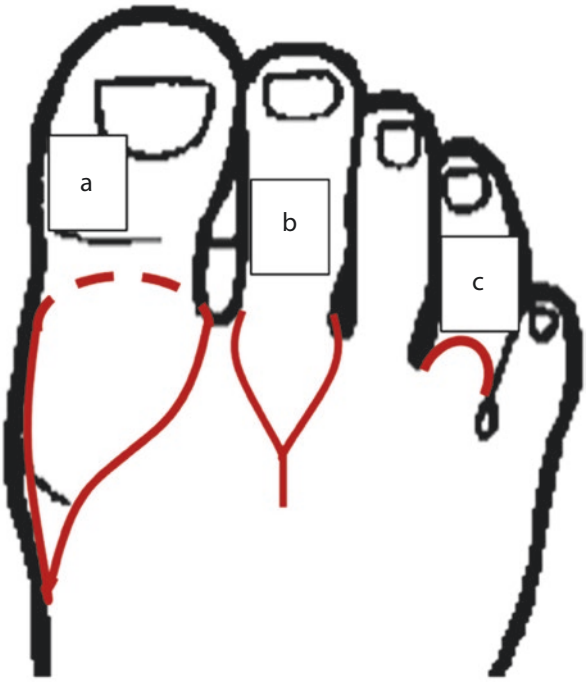

Fig. 3.4 (**a**) Racket incision. (**b**) Ray amputation. (**c**) Fish-mouth incision

amputations involve an amputation through the metatarsal head and may be necessary in severe diabetic foot infection where the entire digit is involved (Fig. 3.4). For the patient with a non-salvageable foot in fulminant diabetic foot sepsis (Fig. 3.5) it may be appropriate to undergo a guillotine amputation as a life-saving measure (Fig. 3.6). When the patients' condition is stabilised, a formal amputation can then be carried out.

Wounds should be dressed with a non-adherent dressing and padding and inspected within 48 h. If there are concerns regarding tissue viability or residual infection, then they should be inspected within 24 h. Patients should undergo strict bedrest for the first 24 h to allow for initial wound healing and prevent post-operative bleeding. Post-operative ward destination depends on the level of cardiovascular/organ support required and the authors have a low threshold for seeking high dependency level care. All patients should be encouraged to eat and drink as soon as able to reduce morbidity associated with prolonged fasting.

Revascularisation

All patients with suspicion of PAD should undergo formal imaging as described in Chap. 6. The need for revascularisation can be guided by intra-operative findings. Patients with known PAD but with good bleeding during initial surgery may be able

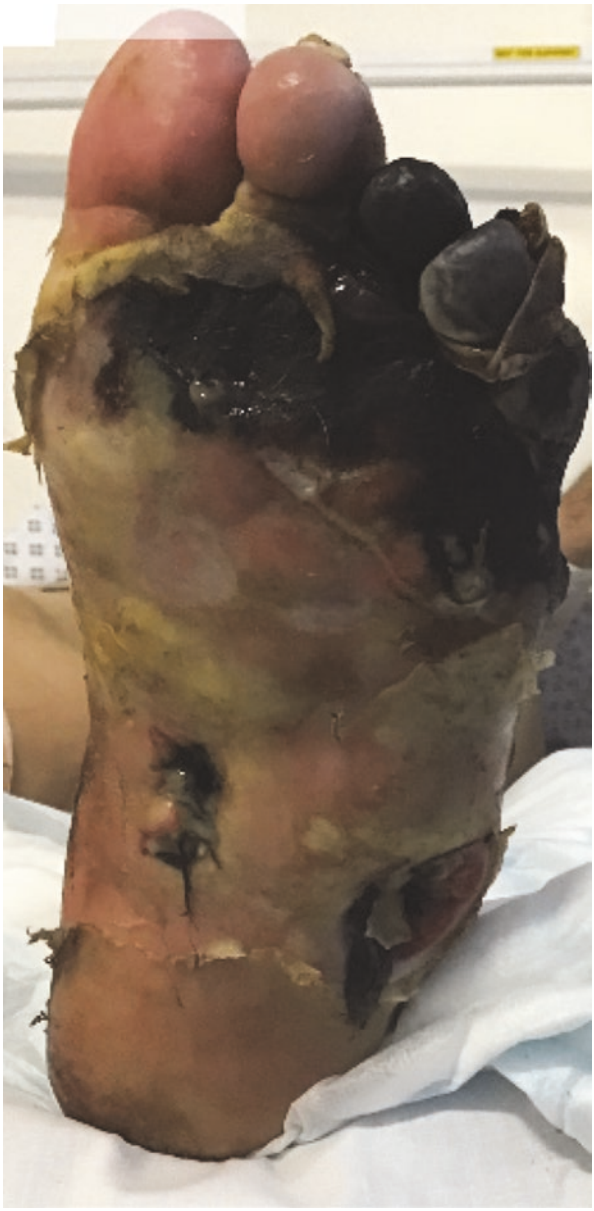

Fig. 3.5 Patient with a non-salvageable foot presenting with fulminant diabetic foot sepsis

to undergo a 'watch and wait' approach. However, if the wound fails to heal then prompt revascularisation should be arranged. Those with poor bleeding intra-operatively may be required to undergo emergency revascularisation once cardio-vascularly stable and source of infection removed. Revascularisation options available are discussed in detail in Chaps. 8 and 9.

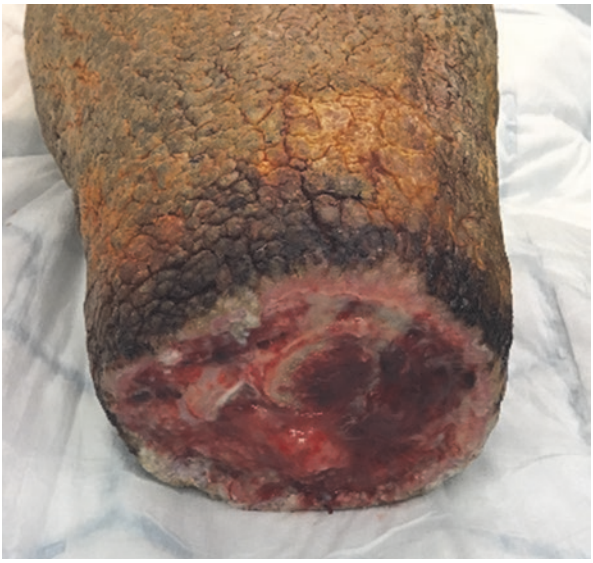

Fig. 3.6 One week post below the knee Guillotine amputation of limb for fulminant diabetic foot sepsis. This was revised to a through knee amputation at a later date

Ongoing Care

Antibiotics should be targeted to microbiology culture results and continued for 1–2 weeks for severe infection. Patients with diagnosed osteomyelitis and residual bone should be managed with a prolonged course of antibiotics. However, if no clinical improvement in infection within the first 2–4 weeks then further surgical resection or an alternative antibiotic regimen may be required. Treatment with antibiotics should ideally not exceed longer than 6 weeks [8].

Wound healing relies on optimisation of circulation and a multidisciplinary approach. Wounds should primarily be managed by vascular nurses and podiatrists to improve outcome. Regular wound inspection is imperative to assess for healing and prevent infection. Careful dressing management is required to control excess exudation and maintain a moist environment. Promotion of wound healing has been suggested by negative pressure wound therapy and systemic hyperbaric oxygen therapy however, there remains insufficient evidence to determine their benefit. The authors routinely utilise a topical negative pressure dressing with or without a lavage function for plantar wounds as we feel it facilitates exudate control and wound healing.

Appropriate footwear is necessary to offload the foot to reduce, redistribute and remove detrimental forces, preventing further ulcers. Custom-made footwear can be used to accommodate deformity and relieve pressure. Non-removable knee-high offloading devices can be used for plantar, midfoot or forefoot ulcers and the use of other offloading devices depends on the position of the ulcer [14]. All of these rely on the expertise of podiatrists and orthotic services.

Poor glycaemia control increases risk of infection and so all individuals should have their diabetic control optimised and referred to diabetic specialists as appropriate.

Upon discharge, all patients should be followed up in the community to ensure sufficient wound healing and to prevent further diabetic foot infections. The continued management of a patient with a diabetic foot infection requires a multidisciplinary approach to prevent further morbidity and mortality.

Summary

Patients presenting with an acute diabetic foot infection should be managed as a surgical emergency as early assessment and intervention is imperative to prevent morbidity and mortality. Diabetic foot infections remain the commonest diabetic complication requiring hospitalisation. Delays in management result in a higher risk of major limb amputation and potential for severe organ dysfunction due to sepsis. Therefore, the management of the patient presenting with a diabetic foot infection is complex and should be carried out in a multidisciplinary setting within a dedicated vascular unit. More should be done to prevent ulcer development with the use of community services such as podiatry and diabetic foot clinics. These services help identify the at-risk foot as well as regularly inspect and examine for ulcers. Additionally, the use of podiatry and orthotic services will ensure the routine wearing of appropriate footwear and prevention of ulcers. Lastly, educating the patient, family and healthcare professionals helps to recognise pre-ulcerative signs leading to the reduction in the associated morbidity.

Key Points

- Initial assessment should begin with Resuscitation Council UK Guidelines with an A–E approach and address sepsis, diabetic ketoacidosis, and hyperglycaemic hyperosmolar syndrome as appropriate.
- Clinical assessment must include a medical history, clinical examination, blood tests and assessment of the arterial circulation.
- Validated scoring systems should be used to determine the severity of infection and need for revascularisation.
- Surgical debridement requires understanding of the anatomy and compartments of the foot and should be carried out by a surgeons experienced in management of diabetic foot complications.
- Successful wound healing requires a multidisciplinary approach, addressing antibiotic therapy, offloading and optimisation of the patients diabetes care.

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Chapter 4
Managing Diabetes in Patients with Foot Complications

Venkatram Subramanian and Edward Jude

Introduction

Diabetes mellitus is a metabolic condition characterised by hyperglycaemia which when uncontrolled leads to several effects on various organ systems with subsequent complications.

Traditionally referred to as a lack of insulin, the term diabetes now encompasses the syndrome of polyuria and polydipsia, which are the results of the osmotic effects that elevated blood sugars cause on the body's metabolism.

We know about the types of diabetes being defined as either type 1 or type 2 but there are more recent figures and studies suggesting a third type called type 3c. In all forms of diabetes, the common pathology is related to the body's inability to metabolise glucose secondary to a lack or inefficient effect of insulin.

Type 1 diabetes is caused due to autoimmune mediated destruction of the beta cells of the pancreas resulting in absolute insulin deficiency. Type 2 diabetes on the other hand refers to the syndrome of insulin resistance and is part of the metabolic syndrome contributing to a rise in cardiovascular morbidity and mortality. Type 3c is a newer description which refers to individuals who have had normal pancreatic function previously but have lost the function because of an acute or other chronic illness such as pancreatitis or haemochromatosis.

Neuropathy is more commonly associated with type 2 diabetes as it has traditionally been a scenario of later diagnosis by which time the effects of the disorder have already started, with the focus on delaying the progress towards full organ

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dysfunction. Innovations in technology and healthcare including pharmaceuticals have resulted in type 1 diabetes patients having longer lifespans and consequently more time to potentially develop a pattern similar to type 2 diabetes in terms of cardio-metabolic complications.

The mainstay for treatment is early detection and once recognised, effective treatment to stall the progress of the disease and prevent the long-term consequences resulting from prolonged hyperglycaemia. We will focus mainly on the medical methods of managing diabetes the subsequent parts of the chapter.

Available Medications

Table 4.1 shows a sample of the current pharmacopeia of medications used in diabetes management. Earlier, type 1 diabetes was restricted to insulin therapy alone with oral agents reserved for type 2 patients. Following recent studies however, there have been amendments and some oral medications can be used for type 1 patients as adjuncts to try and improve sugar control and provide cardiovascular protection.

Glucagon-like peptide-1 (GLP-1) agonists are gaining a lot of traction these days due to greater information from various research studies such as the LEADER, SUSTAIN and PIONEER studies [1].

There are also more medications being developed at present, such as GLP-1 and GIP (glucose-dependent insulinotropic polypeptide) co-agonists [2] which are

Table 4.1 Current medicines for treatment of diabetes

Medications	Type 1/type 3c	Type 2
Non-insulin therapies		
Oral		
Biguanides—metformin	Can be used	Used
Sulphonylureas—gliclazide/glipizide/glibenclamide	NA	Used
Thiazolidinediones—pioglitazone	NA	Used
Alpha-glucosidase inhibitors—acarbose	NA	Used
Dipeptidyl peptidase 4 inhibitors—sita/alo/lina gliptins	NA	Used
Sglt 2 inhibitors—dapagliflozin, canagliflozin, empagliflozin, ertugliflozin	Unknown	Used
Meglitinides—repaglinide, nateglinide	NA	Used
Injectables GLP 1 agonists—liraglutide, semaglutide, dulaglutide	Unknown at present	Used
Insulins Fast acting—Fiasp, Novorapid, Actrapid Intermediate—Humulin I, NPH insulin Long—Glargine, Degludec Mixed—Humulin M3, Novomix 30, Humalog Mix 25/50	Used	Used

showing promising results in diabetes management but are yet to provide evidence to show an effect in managing patients with foot disease.

It is important to know that while SGLT2 (sodium/glucose cotransporter 2) inhibitors are an excellent group of drugs for managing diabetes, recent studies have led to the recommendation to not use these medications in patients with active foot ulcers. However, further trials are in progress to clarify the use of these drugs in people with diabetic foot disease [3].

Diabetes Foot and Diabetes Management

The medical management of the acute diabetic foot ulcer revolves around a combination of biomechanical aspects, medical management of the diabetes and surgical input in the form of debridement or, in the worst-case scenario, amputation.

Diabetes management requires a multi-disciplinary approach with focus on lifestyle changes along with therapy. Given that most patients who present with a diabetic foot ulcer may have already had diabetes and associated foot disorders (e.g. DPN, PAD) for a prolonged period, the acute diabetic foot patient may require insulin therapy to improve the diabetes control rapidly.

Recommendations are in place for the role of the multidisciplinary team approach in diabetic foot management with involvement of a diabetes specialist, a specialist nurse and dietitian forming the main medical members of the team involved in the patient's journey. This in turn, is then supported by a robust podiatry service and the integration of vascular surgeons and orthopaedic surgeons for the surgical aspects. The tissue viability service can also be a useful adjunct in this regard.

Ultimately, the focus is on wound healing as ischaemia and infection are the main reasons for limb loss. Diabetes control will also be affected in an acute diabetic foot attack, and prompt action to improve diabetes control goes a long way in the salvage of the foot.

The Acute Presentation

Whichever ward or department to which a patient with acute active foot disease is admitted, the process of medically stabilising the patient should be consistent. The pathway of resuscitation (airway, breathing, circulation, etc.), as well as local protocols for managing sepsis should always be available and followed. The unwell patient with diabetes and hypotension should have anti-hypertensive medication suspended where relevant, to promote more effective fluid resuscitation. Attention must also be given to aspects of diabetic control. The presence of acute hepatic or renal impairment can reduce drug metabolism, which can result in prolonged drug action. A comprehensive drug review of other medications will need to be done to

identify any other potential risks. In the event of a rising lactate in the event of a septic patient or rapidly deteriorating renal function, it may is advisable to suspend metformin temporarily.

Management of Hyperglycaemia

Hyperglycaemia, in the acute setting, may be a sign of acute infection. However, it is good practice to check an HbA1c level on arrival and to review blood glucose testing equipment to ascertain recent trends in diabetes control. This has become easier since the advent of flash and continuous glucose monitors which can be either purchased or funded by the health services. Any patient with hyperglycaemia must have diabetic ketoacidosis (DKA) or a hyperosmolar state (HHS) ruled out as a routine practice as these will need urgent treatment and stabilisation alongside the active foot ulcer.

Patients may present with acute diabetic and life-threatening complications in the event of severe sepsis arising from an infected diabetic foot. A fixed rate insulin infusion is advocated in DKA along with aggressive fluid resuscitation to correct the osmolar effects of hyperglycaemia and improve circulation.

DKA treatment involves drawing up 50 units of Actrapid insulin in 50 mL of 0.9% saline solution and administer on an hourly basis based on the weight of the patient [4]. Following the resolution of DKA or HHS, the patient may be stepped down to either a variable rate insulin (formerly termed as sliding scale) or on to subcutaneous insulin therapy. When using the variable rate insulin infusion, the amount of insulin required is calculated based on either the amount required to recover from DKA or on the amount of insulin injected normally by the patient. It is imperative to monitor for hypoglycaemia (low blood glucose) during treatment. There should be a policy in place for treatment of hypoglycaemia in patients on an insulin infusion.

Having good glucose control during the acute and recovery phases helps in promoting immune system activity and allows for better wound healing.

Recovering from Acute Diabetic Foot Disease

Patients who are hospitalised for acute diabetic foot disease can find themselves having lengthy hospital stays, with foot disease accounting for a significant percentage of inpatient stays. Hospital Episode Statistics in England recorded 72,459 inpatient spells for 2010–2011 in which diabetes and foot ulcer or amputation codes were recorded; this represented almost 9% of all admissions with a diabetes code [5].

It is good practice for inpatients with diabetic foot complications to receive regular review from the diabetes foot MDT. Aside from the vascular surgical team, this MDT includes a diabetes consultant, specialist nurse, dietician, and pharmacist.

It is easy to focus on the foot healing process, but in terms of diabetes care, a holistic approach is needed. Much can be done to optimise diabetes care that will greatly impact on recovery from acute foot disease. Managing cardiovascular risk is of huge importance in individuals with diabetic foot disease. Young et al. showed the relative risk of death within 5 years of foot ulceration was 48.5% lower in a group of patients treated aggressively for cardiovascular risk compared to a group of individuals before the policy was introduced (see Chap. 15).

A large part of supporting care involves taking a non-judgmental and empathetic approach in empowering a patient who may previously have neglected their usual diabetes care, which may in part have contributed to the acute foot presentation. An admission to hospital may be the first time that a patient with diabetic foot disease is reviewed by a specialist diabetes team. Being able to see the same team repeatedly over the course of an inpatient stay can help to instil confidence and build trust, enforce key educational messages, and promote a greater focus on diabetes than prior to admission.

An inpatient with foot disease also provides an opportunity for the team to give precise guidance on nutrition, diet, and lifestyle, as well as suggesting weight management measures. Foot disease and obesity do not coexist well together. Plantar pressures in gait can be decreased significantly by weight loss, which can also improve general cardiovascular fitness, lipid profiles and blood pressure.

If it transpires that pre-admission diabetes control had been sub-optimal, through the combination of reflections by the patient, medical records, and review of HbA1c, a hospital stay can also be the time when glucose-lowering treatment regimens can be reviewed. Patients are often not made aware of the progressive nature of type 2 diabetes, meaning that that the endocrine function of a failing pancreas is less responsive to usual anti-hyperglycaemic agents over time.

It is not uncommon for patients who were admitted on oral medications for diabetes to find themselves discharged on insulin. Those new to insulin will need ongoing support and education around self-monitoring of blood glucose, the risk of hypoglycaemia, as well as Driver and Vehicle Licensing Agency (DVLA)/local driving authority guidance on safe driving practices when on insulin where applicable.

A post-hospital discharge follow-up appointment with the local diabetic foot clinic/service should be made before discharge, and the patient should be discharged with appropriate pressure-relieving footwear. It is also a good policy to reassure the patient that following the healing of the wound, provided glucose control remains optimal, it may be possible to use other injectables such as GLP1 agonists to reduce the dependence on insulin as well as counter the anabolic effects of the latter.

New wearable technology has made large strides in diabetes management especially since the COVID pandemic. This can be either flash glucose sensors (Freestyle Libre—Abbott Healthcare) or continuous glucose monitors (Dexcom or Medtronic).

There are also various applications available for both computers and smartphones which can be utilised in monitoring and advising on diabetes management which were not available previously [6].

Remote working has also become a reality allowing for more distant patients to have similar care from a diabetes perspective, but this cannot substitute for the assessment and management of the active or healing ulcer and ensure forward progress for the wound.

Utilising the newer medications available has also improved diabetes control and assist with weight management which goes far into aiding in wound healing as a medical means to reduce pressure on the wounds [1, 2].

Post Hospital Discharge

Post-hospital discharge, for a patient to live well with diabetes and foot disease, it is essential that they are given all the support and knowledge that they need to enable this. Basic foot care education is of vital importance, so patients know how to recognise potential problems before they become acute. Daily foot inspections and regular podiatry appointments are the key to preventing acute episodes. Wearing appropriate accommodative footwear and being familiar with the signs and symptoms of a "foot attack" [7] can ultimately save a patient's leg. Issues around the need for treatment compliance should be explored before simply increasing medication doses or starting new agents. To reduce subsequent cardiovascular risk, antihypertensive and lipid-lowering therapy should be considered, with agents and doses reviewed periodically as appropriate, based on tolerability and clinical response. Antiplatelet agents should also be considered [8].

Smoking cessation and alcohol reduction and a conversation around exercise may be appropriate, once the wounds heal, are all important.

A large subgroup of patients who are at increased risk of foot problems, are those with diabetic renal disease [9]. It is well documented that there is a close association between renal failure, foot ulceration, peripheral vascular disease, Charcot foot and amputation. Individuals with renal disease and diabetes are highly susceptible to foot ulceration and should be monitored closely. Where applicable, appropriate renal protective medications should be initiated and any medicines that are deemed unsafe at lower renal function levels must have dose alterations or stopped as applicable.

Local guidelines should be considered when antibiotic therapy is required. When managing the diabetic patient with foot disease, whether it is recovering from an acute admission or living with chronic foot problems, the focus must be on aiming to maintain a good quality of life.

With that in mind, it needs to be recognised that the pursuit of lower blood pressure and lower blood glucose levels may increase the risk of symptomatic

hypotension and hypoglycaemia, respectively, with an associated decrease in quality of life, as well as reduced treatment compliance. Conversely, allowing a patient to live with uncontrolled hyperglycaemia is not without risk either, increasing both a risk of infection and dehydration through osmotic diuresis. Individual targets for both blood pressure and glucose levels need to be agreed upon and the rationale behind decision-making explained to patients. The adoption of wearable technology may aid in these patients as one of the key factors in later detection of poor diabetes control is the hesitancy in patient blood glucose testing. The Freestyle Libre sensor provides a lot of information for the assessing clinician to identify trends in blood glucose levels to intervene more accurately to improve control.

Although in most circumstances every effort should be made to save a limb through gold-standard multidisciplinary treatment, there are occasions when amputation is the treatment of choice. This may be when individuals have a diminished quality of life with multiple foot ulcers or regular episodes of infection undergoing constant hospital visits. It is important for clinicians to recognise this and know when and how to have an informed conversation with the individual.

Disability through life-affecting foot disease can contribute to social isolation, with individuals becoming increasingly house-bound, as they may have lost the ability to drive, for example, or become more carer-dependent. Healthcare professionals should be vigilant for signs of mental illness in this patient group and there is a role for a clinical psychologist or a psychiatrist in supporting these individuals.

Living with diabetes can be daunting but doing the key things well can help reduce the risk of associated problems later. The themes of the protective checklists created by societies such as Diabetes UK are around ensuring that patients are reviewed at least once a year by a healthcare professional who is proficient in providing diabetes care. All healthcare professionals managing patients with diabetes should explain the benefits of having these health-checks, in that potential problems may be developing (asymptomatic proteinuria for example), despite patients feeling well. Appropriate intervention can then be considered earlier rather than later.

Guidelines for Management

Diabetes management has various guidelines in place depending on the country. These guidelines serve to help clinicians aim for specific targets which help in reducing the frequency of micro and macrovascular complications in association with diabetes [10].

The commonly referred guidelines include the NICE guidelines in UK, EASD guidelines in Europe and ADA guidelines for the Americas. There may be more separate regional guidelines respective to the availability of drugs and cost factors depending on the region.

Overall, the recommendations are aimed based on HbA1c targets. The ideal target HbA1c for remission of diabetes is set at 48 mmol/mol but it is recognized that this is not always achievable. Hence the general recommendation is to achieve HbA1c levels as close to 53 mmol/mol to suggest good control from a diabetes perspective. This is recommended by nearly all global organisations involved in diabetes care. The ADA/EASD consensus document from 2019 suggests the same and has clear recommendations as well the choice of anti-diabetic agents depending on the presence or absence of macrovascular complications. Safety levels for the usage of GLP 1 analogues and for the SGLT2 inhibitors have also been recommended [11].

A summary of diabetes management is provided from the latest NICE guidelines which also reflects a similar pattern to that from the EASD in the form of a visual flowchart linking into the various technology appraisals involving individual medications [12].

All guidelines recommend Metformin as initial therapy as well as lifestyle managements.

The second line agent can be determined based on the individual benefit required the patient such as weight loss, glycaemic control or in the event of intolerance to any of the medications.

EASD recommendations showcase the following chart which clearly gives a simple means of identifying what treatment is required for the patient (Fig. 4.1).

Blood pressure management is also part of the overall strategy. While foot disease does not directly impact on the choice of treatment, there is definite benefit from achieving blood pressure targets from a renal perspective. It is to be emphasised that aiming for a BP of 140/90 mmHg in the absence of macrovascular complications is suggested but this target is made stricter in the presence of end organ damage but can be relaxed in the elderly [13]. A summary of these recommendations is below (Fig. 4.2).

The ideal medications used for slowing of diabetic kidney disease are the ACE inhibitors and angiotensin receptor blocking agents. Further medications are added after these have been initiated as per local protocols. Blood pressure management is also to be augmented by incorporation of appropriate lifestyle management such as salt restriction, losing weight, incorporation of exercise as appropriate and reducing other modifiable factors such as smoking and alcohol intake.

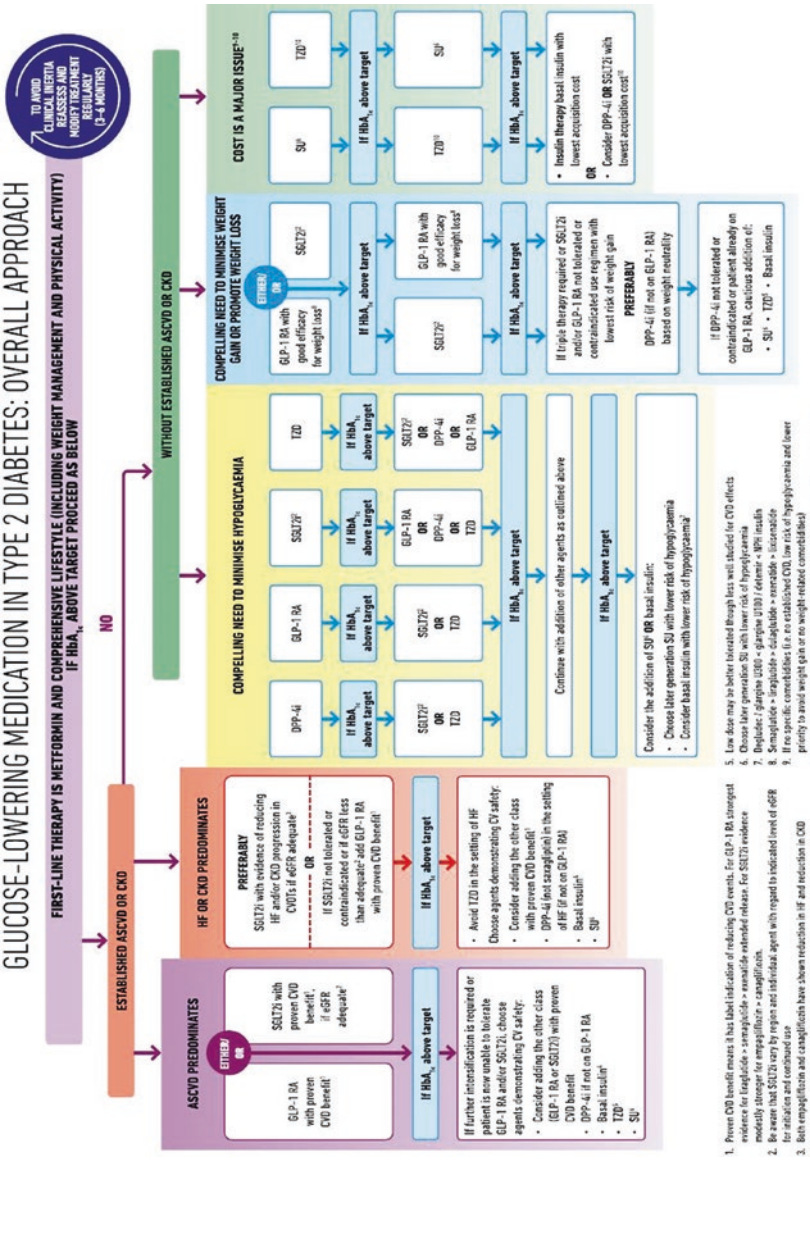

Fig. 4.1 EASD recommendations shown as management algorithm

	Stage of kidney function impairment				
	Normal kidney function, normo-albuminuria	Normal kidney function, micro-albuminuria	CKD stages 1–3	CKD stages 4–5 (non-dialysis)	CKD stage 5 (dialysis)
Type 1 diabetes in mmHg (evidence grade)	<140/80–90 (2D) <120/80 (2D)^	≤130/80 (1B) 120/80 (2D)^	≤130/80 (1B) 120/80 (2D)^	≤140/90 (1B) ≤130/80 for albuminuric(2C)	≤140/90 (2D)*** (interdialytic BP)
Type 2 diabetes in mmHg (evidence grade)	<140/90 (1D) <150/90 (2B)** (for ≥75 years)	<130/80 (2D)	<130/80 (2D)	<140/90 (1B)* <130/80 for albuminuric (2C)	<140/90 (2D)*** (interdialytic BP)

CKD=chronic kidney disease; BP=blood pressure
*For adults >65 years a higher target >140/90 may be appropriate
**For frail adults >75 years a higher target >150/90 may be appropriate to avoid side effects
***Monitor and target interdialytic home BP for people on haemodialysis
^ Lower targets for younger adults aged <30

Fig. 4.2 Summary of targets for treatment of blood pressure in people with diabetes

Summary

The increasing prevalence of diabetes means that there will be an increased burden of diabetic foot disease. All healthcare professionals who encounter patients with diabetes should be familiar with the basic signs that suggest acute foot problems. Acute diabetic foot disease is a serious issue that requires prompt assessment by an appropriate specialist team. It is important to optimise all aspects of diabetes care to increase the chance of favourable outcomes for this high-risk patient group.

An acute diabetic foot problem, particularly infection, can affect diabetes control and the patient's usual diabetes medications may need to be reviewed.

There is a need for on-going support for this patient group to enable them to feel empowered to manage day-to-day diabetes well. The increased cardiovascular risk they face should also be addressed, through appropriate lifestyle measures and medication-related means. It is essential that all people with diabetes are familiar with the principles of good foot care. They need to know what an 'at risk foot' means or looks like, so that they can seek medical advice promptly, rather than risking amputation through delayed presentation.

Key Points

- Acute diabetes foot disease is common and must be detected early and promptly to avoid limb loss.
- Morbidity and mortality increase with the advent of diabetic neuropathy and foot disease.
- Insulin therapy is more likely to support in the early recovery of the acute diabetic foot and promotes healing.

- A multi-disciplinary approach is required when treating the acute diabetic foot.
- Glucose management can be supplemented by use of advancing diabetes monitoring technology.
- Effective post discharge management plays an equally important role as the acute stage in preventing further ulceration/limb loss.
- Lifestyle measures should be encouraged where possible including use of medications such as Metformin and GLP 1 agonists if applicable to aid in weight loss and support in offloading measures.

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Chapter 5
Predicting Wound Healing in the Diabetic Foot: Measuring Tissue Perfusion

Robert J. Hinchliffe and Luke Hopkins

Introduction

In patients with diabetic foot ulceration, the presence of peripheral arterial disease (PAD) significantly increases the risk of failure of wound healing, major lower limb amputation and of cardiovascular mortality [1–3]. The Eurodiale study, a prospective cohort of 1088 patients with a new diabetic foot ulcer, found that patients with PAD, were significantly less likely to heal their wounds (69% vs. 84%) and require major amputation (8% vs. 2%) than those without PAD [1]. Although the clinical severity of PAD is variable, patients with diabetes usually present with a distinct pattern of PAD. It is characterised by diffuse, distal atherosclerotic lesions with medial sclerosis and few collaterals [4]. Crural vessel occlusions tend to be long and in combination with extensive calcification make revascularisation challenging. Interestingly, the peroneal and pedal arteries tend to be spared [5]. The presence of arterial lesions ultimately leads to a reduction in the delivery of blood to the capillary bed leading to malperfusion. The consequent shortage of oxygen, reduction in nutrient delivery and insufficient removal of waste products results in ischaemia. To overcome ischaemia either the cause of inadequate oxygen delivery must be removed or the demand for oxygen reduced [6].

The role of microvascular dysfunction in diabetic foot ulceration is controversial. It is generally accepted that people with diabetes do not have a specific arteriolar or capillary occlusive disease [7]. Microcirculatory changes include thickening of the

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capillary basement membrane and reduction in capillary size. This may result in reduced migration of leucocytes to the tissues in response to infection. Reduction in capillary size is thought to be related to sympathetic denervation resulting in increased flow and shunting through arteriovenous anastomoses. This results in reduced skin nutrition and subsequent impairment of ulcer healing [8]. With regards to foot complications and ulceration the interplay between microcirculatory dysfunction and neuropathy is important. There is decreased availability of endothelial derived nitric oxide and an abnormal response to acetylcholine, altering endothelial vasodilation. As a result, the foot cannot increase blood flow in response to stress producing a functional ischaemia. Patients with diabetes have an abnormal response to tissue ischaemia. Consequently, the foot does not produce the same healing response to infection and inflammation. Arterial wall calcification reduces the ability of the body to increase blood flow to the foot at times of increased demand. The diabetic foot also suffers from impaired angiogenesis (new capillary formation) and arteriogenesis (preventing collateralisation). This means that progression of large vessel ischaemia can quickly result in compromised blood flow into the foot, compounding already altered wound healing, reperfusion of the foot now becomes essential to prevent amputation.

Assessment of Tissue Perfusion

The assessment of any patient with suspected foot disease should commence with history and examination [9]. Detecting PAD in people with diabetes can present a challenge. Co-existing neuropathy and the distal distribution of the disease means the many patients will not have preceding symptoms such as intermittent claudication or rest pain even in the presence of severe ischaemia. People with diabetes and health professionals may confuse symptoms of ischaemia with neuropathy. Although the presence of palpable foot pulses has been suggested to predict an increased likelihood of ulcer healing, absent pulses do not necessarily predict failure of wound healing [10]. The foot may have prominent veins, be warm and pink because of arteriovenous shunting, falsely giving the impression of good tissue perfusion. Bedside tests that are commonly used and will be discussed below, can produce unreliable results because of arterial calcification, oedema and neuropathic changes or deformity.

Investigational tools commonly used to investigate whether patients with diabetic foot ulceration require revascularisation can be divided into two groups, those that map the anatomical distribution of peripheral arterial disease and those that measure the perfusion deficit resulting from stenotic or occlusive arterial disease. Imaging modalities such as computed tomography angiography (CTA), magnetic resonance angiography (MRA) and digital subtraction angiography (DSA) provide the anatomical distribution and severity of arterial disease. Tools such as the Bollinger score can quantify the burden of disease and higher scores have been associated with poorer outcomes [11].

Ankle brachial pressure index (ABPI) is performed with the patient supine, using a blood pressure cuff and a handheld Doppler probe. The ankle systolic blood pressure is measured over the dorsalis pedis and posterior tibialis arteries, as well as the

brachial systolic blood pressure. The ratio of the highest ankle pressure to the highest brachial pressure is calculated to produce the ABPI. An ABPI between 0.8 and 1.2 suggests that there is no significant arterial disease. It is however recognised that in many patients with diabetes ABPI may be falsely elevated owing to incompressible arteries due to arterial wall calcification. Patients with high ABPI are known to have an increased risk of mortality. The utility of ABPI to predict wound healing is limited, a recent systematic review suggested that a low ABPI (<0.6) predicted an increased risk of major amputation in a patient with a diabetic foot ulcer by >25% [12]. The same systematic review found that ABPI was unable to predict ulcer healing.

Digital arteries are often spared from the calcification seen in the tibial arteries meaning that absolute toe pressure or toe brachial pressure indices (TBPI) can be used to measure foot perfusion. These are measured using a small cuff and either photoplethysmography or laser Doppler. A TBPI of <0.7 or an absolute toe pressure of <55 mmHg is strongly suggestive of PAD. A threshold of an absolute toe pressure of ≥30 mmHg has been found to predict an increased likelihood of wound healing by at least 25%, although it should be noted that this test has poor sensitivity (15–60%) for predicting wound healing but excellent specificity (90–97%) [12].

Skin perfusion pressure uses either laser Doppler, radioisotope clearance or photoplethysmography in combination with external compression to measure the minimal pressure at which skin blood flow ceases. Yamada et al. demonstrated that the combination of skin perfusion pressure >40 mmHg and absolute toe pressure of >30 mmHg is able to provide a more accurate prediction of wound healing than either method in isolation [13].

Transcutaneous oxygen measurement ($TcPO_2$) measures the levels of oxygen in the tissues below the skin and is therefore an indirect measure of blood flow in the tissues. Electrodes can be placed close to the wound edge allowing reasonable approximation of perfusion at the ulcer site. The electrode warms the surrounding skin, causing localised hyperaemia, facilitating oxygen diffusion. $TcPO_2$ measurements can be affected by localised oedema, infection and inflammation which can reduce its reliability in some patients, however in the cohort of patients who have had previous digital amputation it has a clear advantage of TBPI. A systematic review found that a $TcPO_2$ >25 mmHg increased the probability of healing by >25%, whilst amputation risk increased by a similar percentage if $TcPO_2$ <25 mmHg [12].

Intravenous indo-cyanine green (ICG) dye can be used in combination with near-infrared fluorescence imaging to assess skin and tissue perfusion. ICG is injected intravenously, and an infra-red camera is used to record the area being assessed. The changes in the intensity of the fluorescence over time can be used to produce a time-intensity curve. Two values can be derived from the time-intensity curve, T1/2, the time needed to achieve half of the maximum fluorescence intensity, and PDE10, the fluorescence intensity 10 s after the starting point of the uprising of the time-intensity curve [14]. The measurements obtained reflect perfusion in the tissues approximately 3–5 mm below the skin. Advantages of ICG measurement include that several areas of interest can measured simultaneously. It is also unaffected by prior tissue loss, unlike TPBI which may not be possible if there has been previous digital amputation. The costs of the equipment are similar to high quality laser Doppler used for ABPI and TBPI (approximately €60,000), whilst ICG dye itself

costs approximately €10 per test [15]. Like $TcPO_2$, ICG values can be affected local inflammation causing falsely elevated readings [15]. It has been found to only have a small ability to predict ulcer healing, but will more reliably detect those who will not heal or are at increased risk of amputation [16].

Significant progress has been made in treating PAD in patients with DFU, however, neither endovascular nor open surgical revascularisation procedures are without risk. Not every patient who presents with a DFU requires vascular imaging. However, the clinician needs to be able to identify those patients with a greater likelihood of healing without revascularisation if a conservative approach is to be adopted in the first instance. Similarly, if a higher likelihood of major amputation is identified, urgent investigation and revascularisation should be considered.

A recent systematic review identified that the most useful perfusion assessment findings to inform on the probability of healing were skin perfusion pressure ≥40 mmHg, toe pressure ≥30 mmHg or $TcPO_2$ ≥25 mmHg [12]. At these thresholds, all these tests increased the probability of healing by >25% in at least one study. They suggested that when such results are obtained, an initial period of conservative management could be considered, particularly if the patient has a relatively high pre-test probability of healing, for example, in the presence of a small, superficial wound with no evidence of infection. When they reviewed tests to predict major amputation, that the same team found that the most useful tests were ankle pressure <50 mmHg, ABPI <0.5, toe pressure <30 mmHg, $TcPO_2$ <25 mmHg and fluorescein toe slope <18 units [12]. All these tests increased the likelihood of major amputation around 25%. They concluded that patients with a perfusion deficit such as this could be considered at higher risk of amputation and should therefore have urgent imaging to plan revascularisation. It is Important to note that low ABPI or ankle pressures increased the probability of amputation, but that normal results are unable to help predict wound healing.

Assessing Tissue Perfusion After Revascularisation

Following revascularisation, it is important to objectively reassess perfusion, however the timing and the effective figure to achieve healing is unclear [9]. Perfusion angiography is a recently developed technique that uses software to produce a two-dimensional reconstruction of the foot before and after intervention. The image is captured during a digital subtraction angiography (DSA) run, meaning that no additional radiation or iodinated contrast is required [17]. The software calculates time-density curves, arrival time and time to peak for each pixel of the DSA image. Both time-density curves and a colour image of the foot can be displayed allowing objective assessment of perfusion at the time of endovascular intervention [18]. At present, there is no evidence that this technology can aid prediction of wound healing success or failure. It has been demonstrated that TBPI does increase immediately after revascularisation and that an increase of at least 0.2 was associated with wound healing [19]. In contrast $TcPO_2$ has been shown in some studies to decrease during endovascular procedures but will continue to rise for up 10 weeks following the procedure [20, 21]. Given the uncertainty regarding the how much perfusion must be improved

to aid wound healing it is difficult to offer cut-off values that should be used to guide clinical decisions. Ultimately wound healing is dependent on a variety of other factors such as the size of wound, the presence or absence of infection and patient co-morbidity, meaning that perfusion is only part of the clinical picture that must be formed.

Emerging Methods for Assessing Tissue Perfusion

Given the limitations of the methods of perfusion assessment described above it is unsurprising that novel methods of assessing perfusion continue to be developed. Recognising that ABPI, TBPI or $TCPO_2$ all have their limitations in the assessment of perfusion in patients with DFU, Sommerset and colleagues developed a novel assessment, the Pedal/Plantar Acceleration Time (PAT) [22]. Using arterial duplex ultrasound to image the pedal vessels they obtain the acceleration time in the vessel thereby providing an estimation of blood flow to the area. They have found that this correlates with ABPI and can be used as a predictor of limb salvage in patients with CLTI (70/72 patients had diabetes) [23]. PAT therefore could provide an alternative, non-invasive method of perfusion assessment in patients with incompressible calf vessels using equipment already present in most units. Its major limitation is the dependence on a trained operator to perform the assessment.

The detection of tissue oxygen concentration using injectable microsensors is another recent development. Montero-Baker et al. found that a hydrogel coated microsensor was able to provide real-time assessment of tissue oxygen concentration, particularly useful during and following revascularisation [24]. Their sensor continued to function for at least 4 weeks after implantation avoiding the need for repeated device insertion. Such technologies may be useful particularly in patients with undetectable toe pressures and characteristics that make $TCPO_2$ less reliable such as oedema or infection although does require an invasive procedure that not all patients may tolerate. The utility of such devices remains to be seen, at present costs would be prohibitive for routine clinical use and it's clinical usefulness unproven.

The Role of Perfusion Assessments in the Classification of Diabetic Foot Ulcers

Traditional methods of classifying patients with chronic ischaemia such as Rutherford or Fontaine have focused solely on ischaemia. This is of limited applicability to the patient with a diabetic foot ulcer where interplay between neuropathy, infection and ischaemia is more relevant. Perfusion is only a single element and without addressing wound factors and the severity of infection, prediction of healing or limb loss is challenging. Indeed, even when severe ischaemia is present, revascularisation is not always necessary to achieve wound healing or avoid limb loss. Elgzyri et al. investigated a large population of patients with diabetic foot ulceration and ischaemia (defined as toe pressure <45 mmHg or ankle pressure

<80 mmHg) who did not undergo revascularisation. They found that half the wounds healed with wound care alone and/or minor (digital) amputation [2]. Revascularisation is also not a guarantee of avoiding limb loss. For example, in patients who had a lower limb bypass due to chronic limb threatening ischemia (59% had diabetes), more than half of the major amputations during follow-up were performed in patients with a patent bypass [25]. Clearly there is a need for classification systems that consider all factors that influence wound healing rather than treat them in isolation. Many diabetic foot ulcer classification systems treat perfusion as a dichotomised variable with no grading of severity. Often wound classification systems fail to differentiate between ulceration and necrosis. The desire to create a classification system that considers the wound, perfusion and infection lead to the development of the Society for Vascular Surgery Lower Extremity Threatened Limb Classification System more commonly known as WIfI [26]. It synthesises other classification systems to include both diabetic foot ulcers and isolated chronic ischaemia in a single system. Each of the major factors influencing wound healing (**W**ound, **I**schaemia and **f**oot **I**nfection) are graded on a scale of 0–3 (see Table 5.1). A consensus process was then used to produce the perceived risk of amputation and perceived benefit of

Table 5.1 Society for Vascular Surgery (SVS) Wound, Ischaemia and foot Infection (WIfI) grades

Wound grade		Ischaemia grade		Infection grade	
0	No wound No gangrene	0	TP/$TcPO_2$ >60 mmHg ABPI >0.8 ASP >100 mmHg	0	No symptoms or signs of infection
1	Small, shallow ulcer No exposed bone, unless limited to distal phalanx No gangrene	1	TP/$TcPO_2$ 40–59 mmHg ABPI 0.6–0.79 ASP 70–100 mmHg	1	Local infection involving only skin or subcutaneous tissue
2	Deeper ulcer with exposed bone, joint or tendon; generally not involving heel; shallow heel ulcer, without calcaneal involvement Gangrenous changes limited to digits	2	TP/$TcPO_2$ 30–39 mmHg ABPI 0.4–0.59 ASP 50–70 mmHg	2	Local infection with erythema >2 cm, or involving structures deeper than skin, subcutaneous tissue (e.g. abscess, osteomyelitis, septic arthritis, fasciitis)
3	Extensive, deep ulcer involving forefoot and/ or midfoot; deep, full thickness heel ulcer +/− calcaneal involvement Extensive gangrene involving forefoot or midfoot; full thickness heel necrosis +/− calcaneal involvement	3	TP/$TcPO_2$ <30 mmHg ABPI ≤0.39 ASP <50 mmHg	3	Local infection with signs of SIRS, as manifested by two or more of the following: • Temperature >38 °C or <36 °C • Heart rate >90 beats/min • Respiratory rate >20 breaths/min • White blood cell count >12 × 10^9/L or <4 × 10^9/L

Adapted from *Mills JL, Sr., Conte MS, Armstrong DG, Pomposelli FB, Schanzer A, Sidawy AN, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). J Vasc Surg. 2014;59(1):220–34 e1–2*

TP toe pressure, *$TcPO_2$* transcutaneous oximetry, *ABPI* ankle-brachial pressure index, *ASP* ankle systolic pressure, *SIRS* systemic inflammatory response syndrome

Table 5.2 Consensus expert estimates of 1 year amputation risk and benefit from revascularisation based upon Wound, Ischaemia and foot Infection grades

a,Estimated risk of amputation at 1 year for each combination

	Ischaemia- 0				Ischaemia- 1				Ischaemia- 2				Ischaemia- 3			
W-0	VL	VL	L	M	VL	L	M	H	L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H	L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H	M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimated benefit of revascularisation (assuming infection can be controlled first)

	Ischaemia- 0				Ischaemia- 1				Ischaemia- 2				Ischaemia- 3			
W-0	VL	VL	VL	VL	VL	L	L	M	L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M	M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H	H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

Adapted from *Mills JL, Sr., Conte MS, Armstrong DG, Pomposelli FB, Schanzer A, Sidawy AN, et al. The Society for Vascular Surgery Lower Extremity Threatened Limb Classification System: risk stratification based on wound, ischemia, and foot infection (WIfI). J Vasc Surg. 2014;59(1):220–34 e1–2*
W wound, *fI* foot infection

revascularisation for each WIfI class (see Table 5.2) [26]. Subsequent studies have validated the WIfI classification system in both non-diabetic and diabetic populations [27–30]. Hicks et al. were able to demonstrate that as WIfI stage increased the risk of poor wound healing increased. Their multivariable analysis found that WIfI stage 3 or 4 was able to more accurately predict poor wound healing than wound size, the presence of peripheral arterial disease and other patient risk factors [30].

Conclusion

In patients with diabetic foot ulceration and PAD, impaired perfusion is rarely the only risk factor for non-healing and amputation. The outcome of the ulcer and patient does not rely simply on improving foot perfusion. Greater understanding of the influence of any perfusion deficit to the prognosis of patients with a diabetic foot ulcer and the interaction with other local and systemic factors is necessary. Perfusion assessments should not be used in isolation and the most recent guidelines from the International Working Group of the Diabetic Foot recommend using multi-factorial tools to assess prognosis, which also include other important contributing factors such as infection and wound characteristics [9]. Classification systems, such as the

WIfI classification, require each domain to be graded according to severity, allowing an overall risk category to be calculated [26], and although initially based upon expert consensus have been externally validated in the diabetic foot ulcer population [30].

Perfusion assessments are a vital tool in the prediction of wound healing in the patient with diabetic foot ulceration, knowledge of advantages and limitations of each test allows accurate assessment. Combining perfusion measures with other factors such as infection and wound characteristics allows for improved prediction of wound healing and/or major amputation. Having identified a patient with ulceration and a perfusion deficit further anatomical evaluation should be performed to plan potential revascularisation.

Key Points

- The presence of peripheral arterial disease is associated with increased failure of wound healing.
- ABPI can be falsely elevated in people with diabetes. A low APBI is associated with increased risk of amputation although does not predict wound healing.
- Perfusion may be assessed by several techniques to predict the risk of amputation. Ankle pressure <50 mmHg, ABPI <0.5, toe pressure <30 mmHg, $TcPO_2$ <25 mmHg and fluorescein toe slope <18 units are associated with a higher risk of amputation.
- Perfusion should be reassessed after revascularisation.
- When predicting wound healing perfusion assessment must be considered with other factors such as infection and the nature of the wound.

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Chapter 6
Imaging the Patient with Foot Complications

Kunal Khanna and Vincent Helyar

Tissue Evaluation

Plain X-ray

X-rays play a crucial role in the early investigation of diabetic foot complications and assessment of disease progression. All patients presenting with new or recurring diabetic foot complications should have X-rays, even if more advanced imaging techniques are being utilised. X-rays are readily available and allow rapid assessment of the area of interest including depth of ulceration, the presence of soft tissue gas, bone lucency/destruction in established osteomyelitis and bone disorganisation, destruction, and deformity in neuropathic (Charcot's) arthropathy.

The most common indication for an X-ray request in this group of patients is to assess the bones for the presence of infection. The area of interest related to clinical examination and ulceration should be indicated on the clinical request as spread of infection to bone is most commonly deep to a visible soft tissue ulcer. Following this, careful assessment of the common 'pressure point' regions should be made on the X-ray. These include the heel or hind-foot, metatarsal heads and the interphalangeal joints. It is important to note that pressure points will alter post-surgical intervention or autoamputation of the toes or foot. Hallmark features of osteomyelitis on X-ray are abnormal bone lucency, periosteal reaction, bony destruction and any bone changes adjacent to soft tissue gas (Fig. 6.1a, b).

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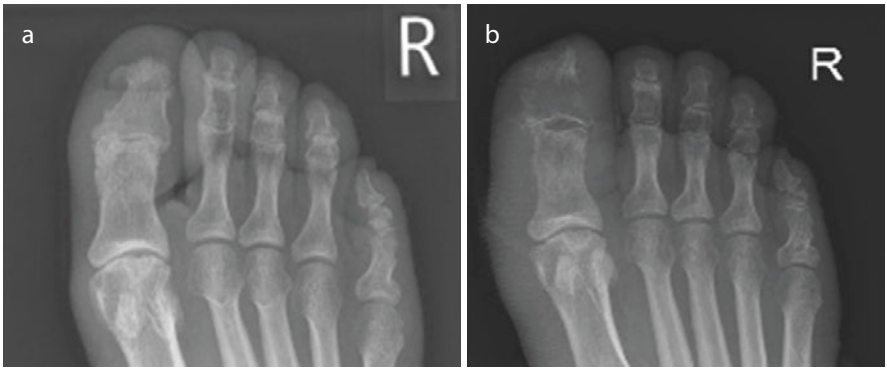

Fig. 6.1 (**a**) Subtle lucency seen in the right first toe distal phalanx. Clinical examination stated this to be the site of a worsening soft tissue ulcer. Features are, therefore, consistent with osteomyelitis. (**b**) The same patient seen after 2 months of attempted treatment. The 1st toe distal phalanx now demonstrates severe resorption/erosion demonstrating the value of serial X-rays. Note X-ray also demonstrates the worsening first toe soft tissue ulcer

As MRI is becoming more readily available and scan times reducing, the role of X-ray is also changing. It is well documented that X-ray has poor specificity and sensitivity for early detection of osteomyelitis and neuropathic arthropathy [1]. Where possible, X-ray should now be used as a complementary triaging tool to clinical history/examination to determine urgency of management and/or further investigation. Serial X-rays over time also continue to have a useful role in assessing progression of bony changes or destruction. Therefore, standalone X-rays should not be used as a definitive evaluation of a foot with suspected osteomyelitis or early neuropathic arthropathy.

The second most common indication for foot X-rays in the diabetic patient is to assess for neuropathic (Charcot's) arthropathy. This is defined as bone and joint changes due to recurrent, minor trauma in an individual with loss of sensation. The '6 Ds' of a Charcot joint are distention, destruction, dislocation, disorganisation, debris and (increased) density. More specifically, X-ray changes are seen as destruction of articular surfaces, opaque subchondral bones, joint debris, deformity, and dislocation (Fig. 6.2).

Magnetic Resonance Imaging

Diagnosis of osteomyelitis and differentiation between osteomyelitis, soft tissue infection, and Charcot arthropathy can be extremely difficult to achieve. Magnetic resonance imaging (MRI) remains the gold standard and most accurate tool for diagnosis and problem solving [2].

MRI provides excellent visualisation of bony changes and bone marrow infiltration. Furthermore, MRI allows assessment of soft-tissue infection, sinus tracts,

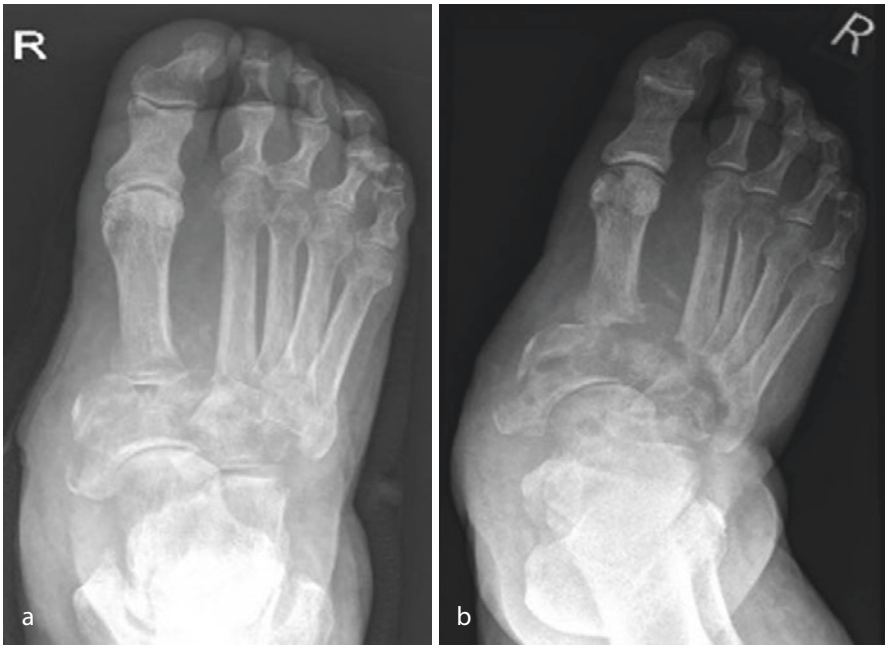

Fig. 6.2 Two X-rays 3 months apart demonstrating significant worsening of Charcot arthropathy in the midfoot of a 63 year old diabetic patient. (**a**) Destruction and erosion of the midfoot (Lisfranc joint). (**b**) The same patient seen after 3 months after poor compliance with conservative management. The Lisfranc joint is now severely disrupted with progressive erosion of the navicular

collections and features of septic arthritis. The hallmarks of osteomyelitis are increased fluid signal (T2/STIR sequences) and corresponding low signal on T1-weighted imaging. These two sequences should be assessed in conjunction, with the T1 weighted sequence being the most specific for infection. T2-weighted sequences are highly sensitive for bone oedema (which may or may not be related to infection) but should not be used to diagnose osteomyelitis in isolation. Secondary findings of collections or subcutaneous oedema/cellulitis may be identified by high signal intensity fluid signal (T2/STIR) sequences. If contrast is administered in these patients, rim enhancement may be seen consistent with abscess formation.

As stated above, differentiating between acute infection and active Charcot's arthropathy can be near impossible. However, some soft signs have been described to aid in providing a primary differential diagnosis. The presence of widespread changes, 'regional' involvement (e.g. the midfoot), significant disorganisation and debris, all favor Charcot's arthropathy (Fig. 6.3). In addition, florid subcutaneous oedema and fluid may be seen in the acute/subacute phases of Charcot's arthropathy and less so with infection. These findings are not definitive, of course, and correlation with the clinical findings along with multi-disciplinary discussion are highly beneficial to developing a diagnosis and management plan for these complex patients.

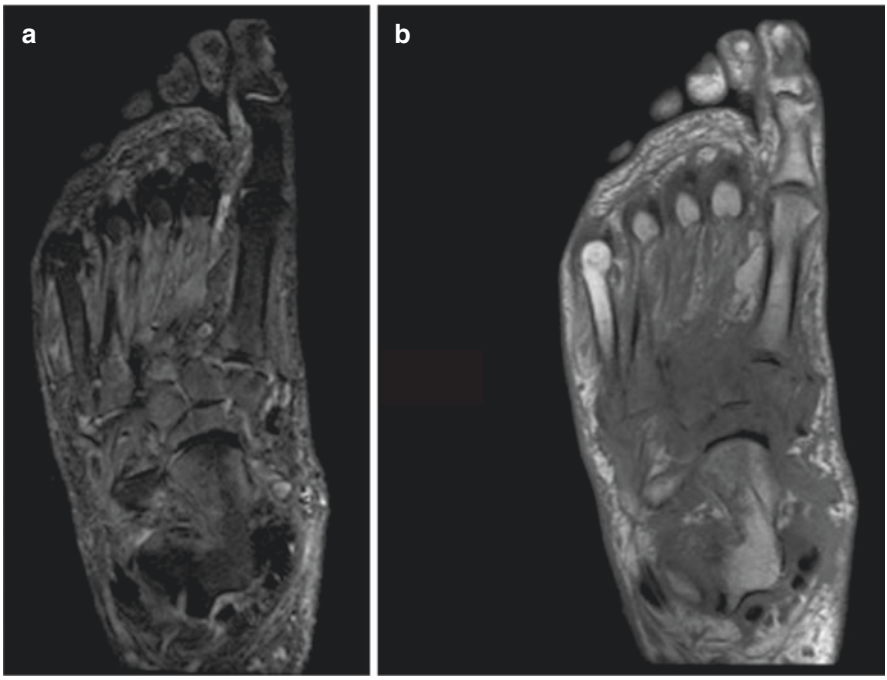

Fig. 6.3 T2 weighted (**a**) and T1 weighted (**b**) MRI of the foot demonstrating midfoot bone marrow oedema and associated fluid, suggestive of Charcot's arthropathy. No radiographic evidence of established osteomyelitis

The importance of MRI in assessing a patient with diabetic foot complications has increased further over time as surgical options and techniques have been developed. MRI should still be utilised in patients with known osteomyelitis or neuropathic arthropathy, for example, to determine the extent of disease, degree of debridement/amputation and surgical approach [3].

Nuclear Medicine Scintigraphy

Nuclear medicine using gamma camera planar/SPECT system is not readily available but can have a role in the diagnosis of osteomyelitis. This technique is a functional examination based on accumulation of radiopharmaceuticals at the site of infection. The studies generally have high sensitivity and specificity for identifying a site of infection but with poor anatomical identification and spatial resolution. Radiopharmaceuticals that have been utilised include 111In-HMPAO, 99mTc-HMPAO leukocyte, 99mTc 3-phase bone scan, WBC with 3-phase bone scan, non-specific polyclonal 99mTc-IgG, Leukoscan, 99mTc-nanocolloid and 18F-FDG-PET/CT.

Bone scintigraphy is commonly used in oncology and readily available in many centers. Technetium-99m-labeled phosphonates are most commonly used as they demonstrate a high bone-to-soft tissue ratio, ideal for bone imaging. Bone scintigraphy is a highly sensitive method for demonstrating infection/inflammation in bone, with the potential for earlier diagnosis or demonstrating more lesions than are found by X-ray or even MRI. These methods may have sensitivity approaching 100% but often demonstrate low specificity due to the high incidence of neuroarthropathy, fracture or dislocation. The low specificity of these investigations can be mitigated significantly through radiolabeled leukocyte scintigraphy. This is currently regarded as the nuclear medicine technique of choice to diagnose osteomyelitis in the diabetic foot. SPECT/CT technology develops this further by improving anatomical definition and resolution. The SPECT/CT system uses a planar gamma camera along with low dose CT to provide three-dimensional anatomical information.

Finally, PET/CT scanning has been utilised in the setting of the diabetic foot. As in conventional PET/CT in the oncology setting, 18F-7 FDG (fluorodioxyglucoce) is the radiopharmaceutical of choice, mimicking glucose in its uptake by any cell with high metabolic activity. It has been hypothesised that 18F-FDG PET/CT may have advantages over SPECT/CT such as shorter acquisition time and higher anatomical detail. However, further research and data is required to fully assess the suitability of 18F-FDG-PET/CT as an investigative modality in the diabetic foot.

Computed Tomography

CT is not routinely utilised in the investigation of diabetic foot complications but is readily available, has a rapid acquisition time and provides increased detail when compared to X-rays. The use of CT should be considered not as an alternative to MRI in the diagnosis of infection, but in cases where further evaluation of lucency, fracture/dislocation or identification of foreign bodies is required. CT could also be considered for patients where MRI is not possible due to inability to lie still secondary to pain, claustrophobia or the presence of a pacemaker. This must always be considered with the awareness that CT has a considerably lower specificity for diagnosis of infection than MRI.

Ultrasound

Ultrasound is generally limited to Doppler assessment of vascular supply and the presence of ischaemia, as discussed below. However, ultrasound is readily available and can be utilised as a complementary modality to assess and mark the presence of a foreign body, detect the presence of joint effusions in associated septic arthritis and guide fine-needle aspiration of joints and collections for microbiology.

Vascular Investigation

Patients with diabetic complications affecting the lower limb frequently present with signs of advanced vascular compromise, chronic limb threatening ischaemia (CLTI). The affected segment is typically the distal femoropopliteal arterial segment, the tibial arteries and the arterial microvasculature.

As demand for imaging generally outstrips supply, patients should be directed to the imaging modality which is most likely to assist in decision making. The clinical picture is crucial in selecting the appropriate test and directing the Radiologist in their interpretation of the imaging. There is little benefit in performing imaging if the patient is not a candidate for treatment of some kind.

Grading Disease

Various systems are in use to grade the severity of peripheral vascular disease; most are not specific to diabetic patients. In the context of the multi-disciplinary team meeting (MDTM), there is a need to make a pragmatic decision by weighing the basic clinical presentation with the appearance on imaging, the patient's fitness and their likely ability to tolerate or recover from a procedure. The Fontaine, Rutherford and TASC systems are all useful in organising the clinical picture and then prioritising clinical workload. Detailed grading systems may be used and integrated with technology to assist with decision making, such as 'WIfI' and 'GLASS.'

In 2014 the Society of Vascular Surgery proposed a new grading system to account for foot wounds, limb perfusion and infection, known as WIfI [4] Detailed grade scores are made under each heading and combined to estimate the risk of an amputation and the possible benefit of limb revascularization. The Global Limb Anatomic Staging System (GLASS, Conte et al. 2019) builds on the holistic approach of WIfI adding in a new anatomic scheme for the threatened limb. Its aim is to bring the evidence base together to assist revascularisation decision making, from the groin to the ankle. Factors considered in this model include patient risk, severity of the limb and the anatomic pattern of disease.

Nephrotoxicity

Patients with vascular compromise arising from diabetes are very likely to have underlying chronic kidney disease. This may well deteriorate further as their disease progresses and with exposure to contrast agents.

Iodinated contrast agents used for CT angiograms and conventional digital subtraction angiography (DSA) may result in an acute kidney injury if used in patients with an eGFR <40 mL/min. Where possible, these patients should be optimised

prior to contrast imaging with fluid resuscitation, suspension of nephrotoxic medications and by consulting with the nephrology team. There is insufficient evidence to support prophylactic pharmacological treatment as a protective measure against contrast induced nephropathy (CIN). It is important that a hydration regime is continued after contrast administration and that renal function is monitored in the following days. Contrast imaging for patients with an eGFR 30–40 mL/min or less is performed following consideration of individual risk factors and the potential benefits of the test.

Magnetic resonance angiography (MRA) is generally performed using a gadolinium-based contrast agent (GBCA), these have an excellent safety profile and are associated with a lower incidence of allergic reaction and nephrotoxicity than iodinated contrast agents. GBCAs are relatively contraindicated in patients with severe CKD (eGFR <30 mL/min) due to an association with nephrogenic systemic fibrosis (NSF). Recent data suggests that even in patients with stage 4 or 5 CKD (GFR <15) the risk of NSF is very small (<0.07%) with the administration of GBCA [5]. It is possible to perform non-contrast MR angiography using time of flight (TOF) sequences, depending on the capability of the scanner, its software package and radiographers.

DSA may be performed with iodinated contrast, carbon dioxide, gadolinium or a combination of these contrast agents. Poor renal function is rarely an absolute contraindication to DSA since good quality images can be obtained with a total volume of no more than about 20 mL.

Ultrasound

A Doppler ultrasound scan is a useful tool to begin vascular imaging assessment, it may indeed be sufficient in certain clinical circumstances. The iliac segment is routinely assessed or inferred from flow velocity in the common femoral artery. The common femoral, proximal profunda femoral, superficial femoral and popliteal arteries may all be imaged by an appropriately trained vascular sonographer. A duplex ultrasound report will usually include some assessment of vessel morphology (plaques, calcification, dilatation) and flow dynamics (increased velocities through stenoses, damping of waveforms, occlusion).

The tibial arteries are also readily assessed with ultrasound. Vascular calcification common in diabetic patients below the knee causes shadowing on ultrasound and may prevent accurate assessment of vessel patency. Oedema, dressings and patient immobility also present a challenge to the sonographer. Ultrasound is operator dependent, and this means that the quality of imaging is only as good as the person using the equipment. Stored images are selected by the operator and are usually chosen to demonstrate abnormalities referred to in the report.

Many centres will opt for cross-sectional imaging to complement ultrasound, usually as a precursor to intervention.

CT Angiography

CT angiography (CTA) for the lower limbs is a performed in the arterial phase after intravenous administration of iodinated contrast and includes the vessels from the abdominal aorta to the feet. The images are gathered in a few seconds, this is especially useful for patients with rest pain who are unable to lie still easily. Data is presented as a series of thin axial slices (typically <1 mm) which may be reconstructed either at the time of image acquisition or reporting. Software to assist with vessel analysis is widely available and may be particularly useful for subtracting vessel calcification. CTA is accessible and reproducible; it requires less technical skill than ultrasound or MRI to produce good quality images.

CTA provides very valuable information where intervention is being considered concerning the vascular segment/s requiring treatment, the approach to treatment (endovascular, surgical, hybrid) and procedural considerations (access, plaque morphology, outflow etc.). CTA will show the burden of vascular calcification common in diabetic patients and provides information about plaque morphology (Fig. 6.4). This is especially useful for separating acute/chronic occlusion, stable/unstable plaque and calcified/non-calcified stenoses.

The CTA relies on good contrast opacification of the artery, this can be affected by reduced cardiac output, vascular disease and image acquisition too early or too late after contrast injection. The tibial vessels are frequently poorly opacified in patients with CLTI, sometimes this can be optimised by performing a second scan from the knee down immediately after completion of the first. Heavy calcification in the vessel wall may also preclude assessment of vessel patency, particularly below the knee and in some cases a diagnostic angiogram may be required.

MR Angiography

Magnetic resonance (MR) angiography is typically performed following intravenous contrast; however it may also be performed without contrast using time of flight (TOF) sequences. Standard lower limb angiography covers the same regions

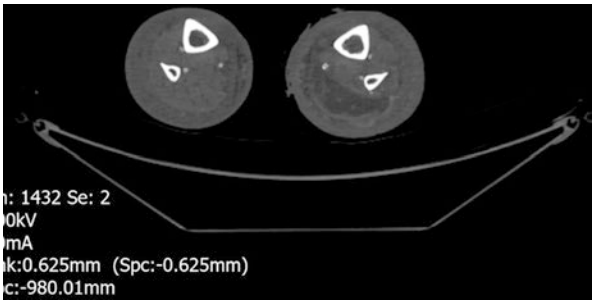

Fig. 6.4 CT angiogram showing dense calcification of the tibial arteries and little luminal contrast opacification. This is commonly seen in diabetic patients, a further scan immediately after the first from the knees down may help to optimise arterial opacification

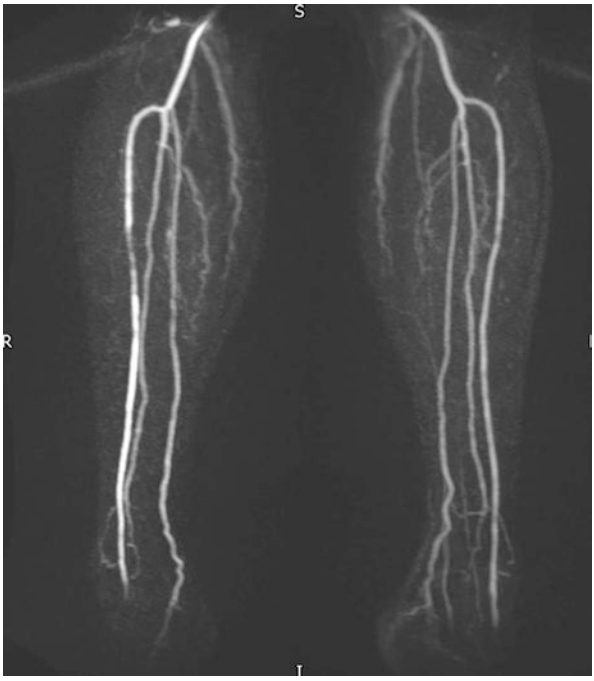

Fig. 6.5 MRA showing intense arterial opacification and excellent signal to noise ratio, useful for the depiction of the small vessels below the knee. Note stenosis in the proximal right anterior tibial artery

as a CTA, images are usually acquired in the coronal plane and may be reconstructed to axial using a multi-planar reformat (MPR). Maximum intensity projection (MIP) images may be provided on image acquisition, while these are useful to provide an overview of the vascular anatomy, they lack detail and should not be used in isolation (Fig. 6.5). MRA is considerably slower to acquire than CT and patients must lie still during image acquisition as movement and poor arterial opacification commonly result in non-diagnostic images.

The signal to noise ratio of MRA is superior to CT, this can be advantageous for demonstrating the vascular anatomy of the small vessels below the knee, especially in the presence of mural calcification (Fig. 6.6). Unlike CT, a MR angiogram depicts the lumen of the vessel only, little information is provided about the vessel wall, or plaque and even large femoral calcifications are easily overlooked. Implanted metalwork results in artifact on MRA and it is not suitable for assessing stent patency.

Digital Subtraction Angiography

DSA is an invasive test requiring the placement of a catheter into an artery, usually the common femoral artery. For diagnostic purposes a 4F sheath or catheter is sufficient to provide good quality imaging. The best quality images of the femoropopliteal segment and tibial arteries are gained by anterograde access, this also provides

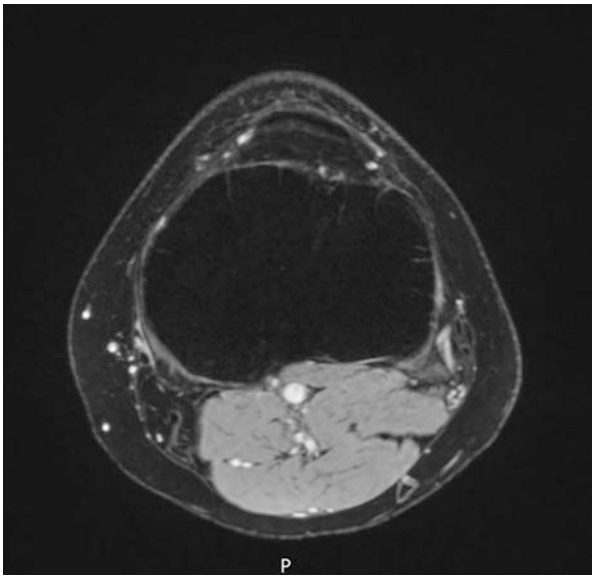

Fig. 6.6 TOF MRA showing the popliteal artery clearly without the need for contrast administration

Fig. 6.7 Angiogram of the foot using iodinated contrast which illustrates the superior spatial resolution of this technique. Illustrated here is single-vessel run-off via the peroneal with collateral supply to the distal posterior tibial artery, plantar arch and digital vessels

the flexibility to proceed to treatment if required (Fig. 6.7). Hostile groins (e.g. scarred post endarterectomy) or occlusions may be better approached from the contralateral CFA using a cross-over sheath.

Patent vessels, stenoses, occlusions and collateral supplies are very well depicted using a small volume of iodinated contrast. DSA has a high spatial resolution and is the best test to depict the small vessels below the knee and in the foot. CO_2

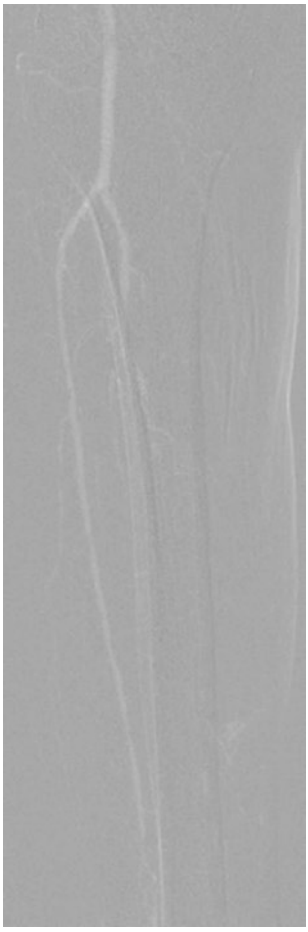

Fig. 6.8 Angiogram performed using carbon dioxide as a contrast agent, injected selectively into the popliteal artery to optimise image quality. Images are acquired with a higher frame rate and the limb elevated slightly

angiography is a useful adjunct, although the contrast opacification is considerably less than iodinated contrast (Fig. 6.8). Patients with rest pain usually find CO_2 angiography painful as the gas penetrates the tissue below the knee, this may result in movement and non-diagnostic imaging. Gadolinium DSA may be used in conjunction with CO_2 for patients with a history of severe allergy to iodinated contrast, contrast opacification is of a similar density to CO_2 (Fig. 6.9).

Given the invasive nature of an arterial puncture, DSA is reserved for patients needing intervention, either at the same sitting or as subsequent surgical bypass. Patients need to be able to lie flat with their leg extended for the procedure, which lasts about 20 min. The patient should be cooperative and also able to comply with 2–4 h bed rest after the procedure.

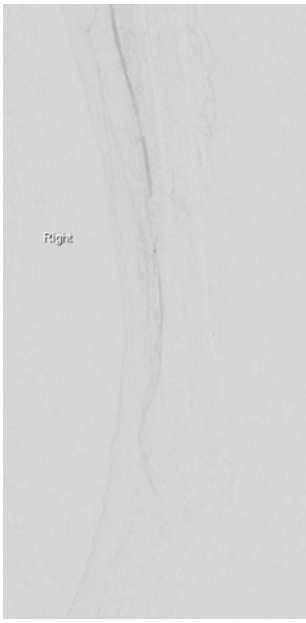

Fig. 6.9 Further angiogram performed prior to intervention for the same patient as Fig. 6.3b, using gadolinium as a contrast agent

Key Points

- An X-ray of the foot is mandatory in patients presenting with a foot complication due to diabetes, in order to assess the integrity of the soft tissue, bones, joints and presence of destructive osteomyelitis.
- MRI with or without contrast is the imaging modality of choice for diagnosing and characterising osteomyelitis. It is increasingly used for planning prior to debridement or reconstructive surgery.
- Vascular compromise is common in patients with diabetes and foot complications. Initial assessment may be with ultrasound, followed by CT or MR angiography if revascularisation is being considered. Conventional angiography is also used for problem solving in selected cases.

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Chapter 7
Diagnosis and Management of Diabetic Foot Infections

Melanie Manjula Pathiraja

Step 1: Is it Infected? Definition and Challenges

DFI is said to be present when an infra-malleolar infection (cellulitis, foot abscesses, infected collections, tendonitis, myositis, necrotising fasciitis, osteomyelitis and septic arthritis), with or without an ulcer, is found in a patient with diabetes.

However, diagnosing DFI can be challenging as a diabetic foot can be markedly functionally and anatomically impaired without infection being present. Associated peripheral vascular disease and Charcot's neuroarthropathy can radically distort foot appearance with erythema, ulceration, heat and swelling without the presence of infection. As a result, DFI is both under-diagnosed through the omission of appropriate foot assessments and over-diagnosed when inflammatory changes are too readily presumed to be infection, or skin culture results are used in isolation to guide treatment, in the absence of other signs of infection.

The presence of pathogenic flora is a necessary but not sufficient criteria for the diagnosis of infection. Diabetic ulcers are colonised with both pathogenic and non-pathogenic flora that will grow on culture without any ongoing infective process in the tissue sampled. This is because the hyperglycaemic, ischaemic and neuropathic microenvironment does not facilitate a host immune response. This is why the presence of surface bacteria on culture is not diagnostic of infection.

Bacteria sited in wounds exist in a complex arrangement of protective bacterial layers known as a biofilm. The outer layers are composed of senescent bacteria that form a protective shell for the active bacteria beneath. This facilitates bacterial survival through enhanced cell to cell signalling influencing protective gene expression

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and isolation of the bacteria from host immune defences [1]. The biofilm reduces the efficacy of antibiotics by limiting antibiotic penetration to active bacterial layers.

Biofilm bacteria also influence wound healing through inter cellular signalling between host tissue and bacteria. This phenomenon is dependent on bacterial species and strain, with some (e.g. Staph aureus SA 10757) associated more with infection and poor wound healing than others [1]. The biodiversity of the microbiome can also have a positive or negative impact on wound healing, so that supporting healthy commensal flora is as important as tackling harmful biofilms [1]. However, given the reduced growth rate in the protective biofilm, treating with antibiotics does not eliminate organisms, nor does it promote wound healing, but drives further colonisation with resistant bacteria. Hence the mere presence of bacteria in a wound should not be used in isolation, rather in combination with the clinical signs to trigger antibiotic treatment.

Hence the definition of DFI reflects the dynamic state of microbiological activity and requires the presence of at least two or more signs of inflammation: redness, swelling, heat, pain or increased purulence.

The inflammatory response to infection depends on the patient's ability to produce a systemic and or local immune response to infection/ injury. This can be altered in patients with poorly controlled diabetes, peripheral neuropathy and peripheral vascular disease resulting in minimal signs of inflammation, even in the presence of infection. Therefore, some experts also consider secondary signs such as friable granulation, wound undermining, enlarging ulcer, change in the characteristic of exudates, and foul odour as indicators of infection [2]. Even more challenging is the diagnosis of chronic osteomyelitis, which may show very few surface changes.

Biological Markers

In patients whose clinical diagnosis of DFI remains uncertain, inflammatory markers may be used. Procalcitonin (PCT) has been found to differentiate between infected and non-infected wounds if raised [3]. C-reactive protein (CRP) is more widely available, and is raised in infection, as well as non-infected diabetic wounds hence should be evaluated in combination with other clinical, radiological and microbiological information. Erythrocyte sedimentation rate (ESR) is perhaps the best biological marker in the setting of osteomyelitis (>70 mmHg) but lacks specificity and can be influenced by non-infective reasons such as azotaemia and anaemia [3].

Step 2. Clinical Evaluation: What Is the Extent and Severity of DFI?

Once infection is suspected the next step is to assess the extent (which compartment is affected) and severity (mild, moderate or severe). Greater the extent and severity poorer the outcome. DFI can spread from the skin to bone and can affect one or

more compartments of the foot at any given time, so it's important to evaluate this alongside severity assessment. Combination of severity and extent will help guide the next steps in management, such as the need for hospitalisation, urgency of investigations and surgical intervention, diagnostic sampling and imaging, route of antibiotic administration and spectrum of empirical therapy.

IWGDF (International Working Group on the Diabetic Foot) guidance provides an easy to use tool to rapidly assess severity. The extent of erythema can be expressed as <0.5 cm (non-infected), <2 cm (mild), >2 cm (moderate to severe);

Severity Classification of DFI (+/– 'O' Which Indicates Osteomyelitis)

- Category 1: erythema <0.5 cm (no infection)
- Category 2: erythema 0.5–2 cm (mild)
- Category 3: erythema >2 cm without sepsis (moderate)
- Category 4: erythema >2 cm with sepsis (severe)

Absence of accurate description of the site, size, location and appearance of ulcers is a frequently encountered challenge during infection consultations. Therefore in addition to noting severity, delineating this information when requesting cultures and radiological investigations is essential for the interpretation of results, especially when there are multiple ulcers at different stages of healing. It is also important to appreciate the proximity to bone as chronic ulcers failing to heal after appropriate off loading and wound care overlying bony prominences may indicate underlying osteomyelitis and should be further evaluated with imaging.

Assess the Risk to the Limb

Rapid inflammation during infection can complicate pre-existing vascular impairment leading to acute limb ischemia. The presence of necrosis, gangrene, crepitation, bullae, devitalised tissue, should be assessed for, because it could indicate necrotising fasciitis, imminent compartment syndrome and acute limb threatening infections and the need for urgent vascular and or orthopaedic surgical intervention.

Assess the Risk to Life

Sepsis can sometimes be masked in this group of patients, so a high index of suspicion is required to act fast with appropriate supportive care, urgent antibiotic escalation and surgical intervention. Currently systemic inflammatory response syndrome

(SIRS) criteria are used to identify severe sepsis. Although not very sensitive, the features of tachycardia, tachypnea, fever/hypothermia, leukocytosis or leukopenia when, present may indicate severe life-threatening infection [3].

Debride and Probe the Wound

This is both a clinically and microbiologically therapeutic and diagnostic step. There is commonly a mixture of infected viable and dead tissue, pus, slough, eschar and callosity in infected diabetic ulcers. To establish a better healing environment and allow antibiotics to function optimally, debridement of the infection, by removing devitalised tissues, is an important early step. This can be undertaken by a podiatrist, tissue viability nurse, or surgeon, provided they have been appropriately trained in sharp debridement and understand the anatomy of the foot. In densely neuropathic feet, debridement can often be undertaken without anaesthetic, but caution must always be exercised especially when more extensive debridement is planned. When there is doubt about the extent of infected and dead tissue after an initial superficial debridement, a more formal surgical procedure will be necessary.

Probing of the wound, using a blunt sterile metal probe, is a valuable technique that allows better evaluation of wound depth and the wound edges. Allow the detection of the involvement of tendons and facilitate the direct palpation of bone. The "probe to bone" (PTB) test, has a good predictive value for diagnosing osteomyelitis[1]. The probe should be grasped between thumb and index finger with a pinch grip and applied to the wound with sufficient force so that the probe will penetrate slough but will slide back through the thumb and finger if intact soft tissue or bone is encountered. In the latter case, a distinctive "rock-like" sensation is felt. IWGDF guidelines recommend using the PTB test to diagnose osteomyelitis in high-risk patients with DFI and to rule out osteomyelitis in those with a low risk of DFI.

Step 3: Diagnostic Evaluation: Radiological and Microbiological Diagnosis

Radiological Evaluation

Imaging should be considered when the Probe To Bone test (PTB) is positive to look for presence of osteomyelitis. PTB test has good sensitivity (0.87) and specificity (0.83) [3] to use as screening test for osteomyelitis. Plain X-rays should also be considered in all moderate to severe DFI and in chronic, wide deep ulcers or ulcers overlying bony prominences which are slow to heal after good wound care and offloading which could indicate underlying chronic osteomyelitis. However diagnostic changes in plain X-rays can be delayed by few weeks to appear [4]. Serial

imaging could be used in conjunction with clinical review for evaluation of underlying bone infection.

In addition to evaluating the foot for osteomyelitis plain X-rays can also provide useful information on soft tissues, vascular calcification, radio-opaque foreign bodies such as fragments of insulin needles trodden on, unawares by a neuropathic patient, gas in the soft tissues and fractures. Plain X-rays however could be non-diagnostic for osteomyelitis when Charcot neuro-osteoarthropathy is present, since many of the changes of infection; sclerosis, lucency, and bone destruction, are also seen in the diabetic Charcot foot [5]. Ultrasound may help localise foreign bodies, fluid collections, show inflammation (e.g., around tendon sheaths) and identify if a sinus extends to bone. MRI scans are a further useful option for the assessing of osteomyelitis, purulent collections and when gauging for Surgery. However, their reliability may decrease with chronic infection and following multiple surgeries, where presence of sclerotic bone may not signal changes of inflammation and where some signal changes may persist longer after infection has been treated and also for non-infective reasons such as mechanical stress. Therefore, when clinical signs of infection has subside, infection should not be considered cured until year of remission [5].

Microbiological Sampling and Aetiological Diagnosis

Microbiological diagnosis is essential for appropriate use of antibiotics in DFI treatment. Principles of stewardship can be applied to microbiological sampling with the **Right patient, Right sample at the Right time** being critical for high quality results. Cultures should be obtained whenever there is clinical suspicion of infection regardless of severity, prior to starting antibiotics, in order to customise appropriate, highly bioavailable oral or parenteral options, targeting relevant pathogens. This would also enable local surveillance of resistance in order to develop local empirical antibiotic guidelines for DFI given the significant geographical variation in resistance patterns.

Microbiological sampling should not be done in non-infected diabetic foot ulcers, as it could erroneously prompt commencing antibiotics in reaction to positive cultures of colonising flora. Treating uninfected diabetic foot ulcers does not improve wound healing, nor does it prevent development of infection. Therefore, culture is unnecessary in this setting.

What Is the Most Evidence-Based Sample Type?

Cultures ideally should be obtained off antibiotics as there is a risk of reduced sensitivity while on antibiotics, and reduce specificity due to over growth of less virulent more resistant colonising flora.

Tissue is preferred to swabs in soft tissue infections. Tissue specimens obtained from a clean base by curettage following debridement of all devitalised tissue are more representative of true pathogens, capable of invading deep tissue and biofilm formation than those less virulent flora colonising surface debris. Tissue samples also have increased sensitivity in that the culture methodology includes enrichment and longer incubation period, with more isolates worked in detail for reporting.

The most appropriate specimen for aetiological diagnosis of osteomyelitis is less well defined. Organisms yielded from deep wound cultures may only partially reflect deep bone sample isolates. Lack of concordance varies in literature with some reporting less than 50% while others reporting this method as correlating well with osseous cultures [6]. On the plus side, deep wound samples are easier to obtain, less invasive and can give a reasonable reflection of bone microbes but generally may have more organisms than need to be considered in the treatment of osteomyelitis. Thus tissue cultures may isolate some surface colonising/infecting flora that could be dealt with debridement and short course of antibiotics. Osteomyelitis on the other hand could require a longer duration of treatment. Hence the downside to unnecessary broad regimes include; limited therapeutic options for oral step down, longer intravenous antibiotics, as a result longer hospital stay, health care associated infections, line sepsis and thrombophlebitis, promote further resistance, and potentially less optimised cover for more relevant, frequently infecting bacteria such as Staphylococcus aureus and beta haemolytic streptococci. Hence thoughtful consideration should be given when deciding the most appropriate sample type for individual patients balancing diagnostic ease and accuracy vs overall patient risk and care.

What is consistently observed however is that surface swabs correlate poorly with bone samples and should not be used for microbiological diagnosis of osteomyelitis, except in the presence of a sinus tract or if a virulent pathogen well known to cause bone infection, e.g., *Staphylococcus aureus*, is isolated [6].

In summary, deep tissue samples could be of value when deciding antibiotic therapy for chronic osteomyelitis, where obtaining bone biopsy is not readily available or considered high risk. When the risk balance and practical aspects are in favour of bone biopsy this should be pursued as the preferred option especially in the context of treatment failure or where therapeutic options are narrow.

Bone biopsies are best obtained via fluoroscopy guidance through clean intact skin. The procedure is considered low risk but new ulcer formation is a feared complication impeding the technique from being used more routinely, even though this is not widely reported [3].

Intra-operatively obtained infected bone samples are also useful to guide therapy in the initial postoperative period. Sampling of clean bone from the stump, obtained with strict aseptic technique (using a new set of instruments) combined with histology, could give further information on adequate debridement, residual infection and facilitate decision making on subsequent duration and targeted therapy [7].

In addition to obtaining high quality specimens, attention should be given to appropriate labelling of the type and anatomical site of the sample and prompt delivery to the laboratory. This will help facilitate recovery of all pathogens including fastidious organisms which may perish during delayed transport and for the accurate interpretation of culture results.

Step 4: What Are the Main Considerations in the Management of DFI

Appropriate Location of Management

Not all patients with DFI require hospital admission. Hospital admission can be costly and can be associated with unwanted health care infections. It is usually reserved for moderate to severe infections which require close monitoring of progressions, needing parenteral antibiotics, urgent diagnostic investigations, and Surgical input.

Table 7.1 summarises management location based on severity of infection.

Table 7.1 Severity based suggested clinical setting for management of DFI

Category and severity	Clinical features	Location of DFI management
Category 1: No infection	Erythema <0.5 cm	No cultures or antibiotics required. Supportive wound care and other diabetic foot measures delivered in a setting prioritised by other medical or surgical needs. (see other indications for admission)
Category 2: Mild	Erythema 0.5–2 cm Confined to skin and subcutaneous tissue	Empirical cover for Gram positive organisms adequate pending culture results. Can be managed as outpatient provided the patient will be able to self-care or be supported at home, be able to comply with antibiotic treatment and required wound care measures including ulcer offloading
Category 3: Moderate	Erythema >2 cm without sepsis Can be uncomplicated involving only skin and soft tissue or complicated involving deeper structures; muscles, tendon, or bone >50% limb threatening infections will not have sepsis, therefore should be assessed for signs independent of SIRS (systemic inflammatory response)	Infections are usually poly-microbial hence empirical treatment should cover broadly using prior microbiological history pending fresh cultures. IV vs PO depends on the extent of infection and available antibiotic options. Can be managed as an outpatient even in the presence of OM if there is no surgical or other hospital admission indication. Will need diabetic foot MDT review prior to discharge for careful follow up and safety netting. Outpatient parenteral antibiotic therapy (OPAT) if available, could facilitate safe discharge while providing multidisciplinary input If hospitalisation is needed, it should be cared for with regular diabetic foot team input
Category 4: Severe life threatening infection	Erythema >2 cm with sepsis Temperature >38 °C or <36 °C Heart rate >90 beats/min Respiratory rate >20 breaths/min White blood cells >12000/mm^3 or <4000/mm	All patients should be managed in a hospital with access to specialist vascular and orthopaedic surgery, with a low threshold to request high dependency or critical care admission. Involvement of the diabetic foot team is essential Microbiological sampling including blood cultures should be done even without pyrexia Broad spectrum antibiotics and fluid resuscitation is essential. Antibiotics should not be delayed, and administered immediately while obtaining cultures IV antibiotics with optimum dosing should be guided by the infection specialist and antibiotic pharmacist

Other Indications for Hospital Admission

- Diabetic team and acute medical input for improved metabolic control; hyperglycaemia, acidosis, azotaemia, electrolyte abnormalities and management of sepsis.
- Podiatry input for wound debridement, dressing and offloading measures that cannot be provided in the outpatient setting.
- Urgent assessment for vascular surgery and revascularization.
- Orthopaedic surgery (foot and ankle specialist) for foot-sparing surgery.
- Specialist antimicrobial advice from the infection team.
- Need for urgent Radiology: progressive osteomyelitis
- Failure of outpatient management.
- Selected comorbidities such as renal failure or immunocompromised.
- Unsuitable for outpatient treatment due to social, physical or psychological vulnerabilities or lack of compliance with outpatient treatment.
- Lack of appropriate outpatient antibiotic options.
- Presence of a foreign body.

Antibiotic Therapy

Antibiotic stewardship is essential in managing DFI as patients can have more than one episode of infection, therefore minimising the antibiotic resistance is beneficial for overall patient care. **Start smart with the Right Drug for the Right Patient and then Focus on targeted therapy for appropriate duration duration is a simple easy to follow basic principle of antibiotic stewardship.** The first step as already described involves clinical assessment of severity and extent of infection thereby assessing likely pathogen or pathogens, then choosing antibiotic/antibiotics that have the most appropriate coverage, bio-availability and penetration in the relevant compartment affected. Targeted therapy will follow adequate debridement and revascularization if indicated and/or when appropriately obtained culture results are available. This should be for the shortest duration required to achieve the desired outcome (curative vs suppressive).

Pathogens are generally predictable depending on two factors; severity of infection and prior colonising flora. Mild to moderate uncomplicated infections are predominantly caused by aerobic Gram-positive organisms such as Staphylococcus Aureus and Haemolytic Group B streptococci. Anaerobes are fastidious and may not always be recovered from cultures however it's been demonstrated that anaerobes can play a significant co-infecting role alongside primary Gram positive bacteria in DFI especially at the tipping point of infection [8]. Moderately complicated to severe infections will need poly-microbial cover as it can often be associated with significant devitalised tissue allowing less virulent opportunistic pathogens such as anaerobes (Prevotella, Peptostreptococcus, Bacteroides) and aerobic and

facultatively anaerobic Gram negatives (Pseudomonas aeruginosa, E. coli, Klebsiella sp.) to cause co-infection.

Local guidelines and patient's past microbiology results would reflect both geographical and individual resistance patterns, hence both should be used when deciding empirical therapy. Treatment can be targeted after source control, allowing better coverage of more virulent pathogens capable of causing deep tissue infection. The timing of step down therapy and choice of antibiotics should be decided by the diabetic foot team.

Table 7.2 summarises potential empirical options for each category of infection.

Surgery Versus Antibiotic Management Alone for Osteomyelitis and Skin and Soft Tissue Infections

Debridement is typically needed in moderately complicated or severe DFI when there is a significant amount of devitalised tissue or uncontrolled soft tissue spread of infection with or without underlying osteomyelitis. Presence of prosthesis which would readily form biofilm should also have debridement or complete removal of prosthesis for eradication of infection. Bacteria can divide rapidly in devitalised, poorly perfused hyperglycaemic environments, protected by host's immune response and antibiotics. Hence creating a clean wound bed free from debris and reduced bioburden, is critical for a good clinical outcome.

The benefits of local debridement is less clear in chronic diabetic foot osteomyelitis. Bacteria form a biofilm in these settings with slow growth rate, and are relatively less susceptible to antibiotic killing effect than rapidly dividing bacteria. However in some settings antibiotics with limited debridement has shown comparable outcomes to extensive debridement and amputation[4]. Local debridement has the advantage of disruption and physical removal of biofilm. There by reducing bioburden and facilitating effective delivery of antibiotics and influx of host immune cells. However, too extensive surgical debridement can alter biomechanics of the foot resulting in new ulcer formation which could subsequently act as a new foci of infection. On the other hand limited debridement in order to preserve biomechanics can result in relapse of infection at the same site. Stump bone histology and cultures may be of value but there is no clear evidence/ guidance on how to determine adequate margins. Hence the benefit of foot sparing surgical debridement has to be carefully evaluated against effective management of infection by the Orthopaedic Surgeon in consultation with the patient and diabetic foot team.

Useful steps when deciding antibiotics vs Surgical debridement strategy:

- Define the starting point of infection and what would be considered as remission for the selected patient. In practice, 3 months follow up is usually considered as treatment success, but in infections involving biofilm, relapse may occur up to one year later in the same site.

Table 7.2 Suggested Empirical antibiotic therapy

Infection severity	Pathogen assessment	Pathogens to consider	Suggested empirical therapy	Bugs-drug-tissue dynamics [4, 9]
Mild-moderately uncomplicated	No previous antibiotics: Cover for Gram positives:	Methicillin Sensitive Staphylococcus aureus (MSSA) Beta Haemolytic Streptococci group A, B, C, G (BHS)	Flucloxacillin PO 500 mg–1 g 6 hourly	Effective against MSSA, BHS except Group B Strep (GBS) No anaerobic or Gram negative cover 50 ± 20% bioavailable after ingestion Should be taken 1 h before food for best bioavailability Distributes well in inflamed tissue but to a lesser extent in the absence of inflammation Highly protein bound therefore could also affect tissue bioavailability PO administration is effective for skin and soft tissue infections Bone and joint concentration is relatively less needing clinical monitoring for relapses especially once acute inflammation has subsided
			Cephalexin PO 250–500 mg 6 hourly	Effective against MSSA, BHS and some Gram positive anaerobes (peptostreptococcus) Almost completely absorbed after ingestion Only 15% protein bound Effective for skin and soft tissue infection Detectable in bone but data on treatment for adult osteomyelitis is lacking
	Prior antibiotic treatment failure, recent hospital admission	Cover predominantly for Gram positives; MSSA, BHS and MRSA if prior colonisation. Additionally anaerobes and to a lesser extent Gram negatives	Co-Amoxiclav PO 625 mg 6–8 hourly depending on severity	Effective against MSSA, BHS, some anaerobes and Gram negatives Good coverage for Gram negatives ***without*** multi-drug resistance such as ESBL/ApmC 60 ± 23% bio-available after oral absorption Widely distributed in skin and soft tissue, synovial fluid and bone
			Clindamycin PO 300 or 450 mg 6 hourly. Can be increased to 600 mg 8 hourly under guidance of infection team	Effective against MSSA, MRSA, BHS And anaerobes (subject to testing). No Gram negative activity Effective anti-toxin production in Group A and PVL (Panten Valentine Leucocidin toxin) producing Staph aureus Resistance can vary geographically. Resistance is screened using Erythromycin. If resistant to Erythromycin, this could indicate clindamycin resistance Well absorbed (90%) after ingestion Penetrates well into infected diabetic tissue, decubitus ulcers and moderately well into bone and joint
			Septrin PO 960 mg 8 hourly	Effective against MSSA, MRSA, BHS and Some Gram negatives (subject to testing) Not adequate for anaerobes 100% bioavailable when ingested Reaches therapeutic levels for management of skin and soft tissue, bone and joint infections primarily by Gram positive organisms
			Doxycycline PO 200 mg stat followed by 100 mg 12 h	Effective against MRSA, MSSA, BHS, some anaerobes but not effective against enteric Gram negatives Completely absorbed after oral administration Lipid soluble with good tissue penetration into soft tissue. Bone concentration can reach therapeutic levels for Staphylococci

Moderately complicated to severe DFI (Discuss with infection specialist)	Macerated ulcer Ischaemic limb necrosis, soft tissue crepitus	Poly-microbial cover for Gram positives and Gram negative rods (GNR) and anaerobes. Anti-Pseudomonas cover indicated in active immunosuppression, failed treatment in the last 90 days Prior colonisation with multi-drug resistant isolates AmpC, ESBL should also be taken into account	Tazocin 4.5 g 6–8 hourly IV (6 hourly for Pseudomonas)	Effective against MSSA, BHS and anaerobes. GNR coverage including pseudomonas, dependent on susceptibility. Unreliable for AmpC and ESBL in severe sepsis Well established efficacy for complicated diabetic foot infections including bone infections
			Ceftriaxone 1–2 g IV 12–24 hourly	No Pseudomonas or anaerobic cover, but has good MSSA, BHS, and non-pseudomonas enteric Gram negative cover except for AmpC and ESBL Reaches therapeutic concentrations for both Gram positive and Gram negative bone infections. Should use higher doses if treating Staph aureus
			Meropenem 1 g 8 hourly	Broad spectrum Gram negative, including ESBL, Amp C, MSSA, BHS and anaerobic cover. No MRSA cover Reaches good therapeutic concentrations in soft tissue, bone and joint but as with other beta lactams depend on degree of ischaemia
			Metronidazole IV or PO	100% bioavailable when given orally. Anaerobic cover only, should be used in combination Poor bone penetration
			Glycopeptide (Vancomycin and Teicoplanin) Requires loading	Broad spectrum including MSSA, MRSA, Streptococci, enterococci and some Gram-positive anaerobes Should be considered as part of combination treatment if prior isolation of MRSA Penetrates to bone poorly in the presence of ischaemia
			Daptomycin 6–8 mg/kg	Broad spectrum including MSSA, MRSA, Streptococci, enterococci Should be considered as part of combination therapy if prior isolation of MRSA High therapeutic concentrations in bone and joint
			Linezolid 600 mg 12 hourly	Broad spectrum Gram positive and anaerobic cover including MRSA and Enterococci Effective for skin soft tissue and bone Diffuses well into tissues regardless of perfusion

- Consider if bony debridement or biopsy would be of value both diagnostically and therapeutically prior to starting antibiotic therapy
- Patients who are medically unstable for surgery or there is a high risk of operative and post-operative complications could trial a course of antibiotics with ward based debridement
- Presence of significant devitalised soft tissue or progressive infection despite antibiotics should be considered for surgical debridement.

Intravenous Versus Oral Therapy

The OVIVA study assessed the long-held belief that IV was superior to PO in complex bone and joint infections including DFIs. The results showed no significant difference in IV versus PO for patients with peripheral arterial disease, retention of metal and whether or not antibiotic impregnated cement was used. This study found that when appropriate source control is achieved, custom selected oral antibiotics taking into account culture results and bio-availability are of similar efficacy to intravenous in terms of relapse rates [10].

However as a general principle moderately complicated or severe infections should usually start with intravenous antibiotics and be stepped down to oral therapy when clinically stable.

Duration of Therapy

The optimum duration of antibiotics is an important unmet area of debate and it is also closely linked to how clinicians should monitor resolution or progression of DFI treatment (clinical Vs radiological). In general, severity and extent of infection, response time to clinical improvement, source control, presence of foreign body are useful clinical considerations for deciding duration. Serial monitoring of radiology or assessing for radiological resolution of OM, which can lag clinical resolution has not been shown to be superior to clinical assessment hence should not be routinely recommended but can be considered case by case basis.

Mild to moderate uncomplicated soft tissue infections can be treated with 2–3 weeks of antibiotics [3]. If all infected necrotic bone is excised to healthy bleeding bone 3–7 days [3] of antibiotics is sufficient. In foot sparing surgery eradication of infection is difficult especially if prosthesis salvation is attempted, hence will need a longer course of treatment. Traditionally 6–12 weeks. However new data suggests 3 weeks in some settings as having similar remission rates as 6 weeks [11]. (not applicable if prosthesis is present). Ultimate duration should be decided with close clinical follow up of the patient.

In summary

The principles underlying antibiotic selection are therefore:

(a) Choose antibiotics that are narrow in spectrum for mild infections and uncomplicated moderate infections and start with broader spectrum for complicated moderate and severe infection.
(b) Rationalise antibiotic use as soon as cultures are available and good source control is achieved with debridement where necessary.
(c) Give oral therapy for mild infection unless there are unusual host circumstances (e.g., allergies, unable to tolerate oral medication)
(d) Give initial intravenous therapy for severe and complicated moderate infections in in-patients, stepping down to oral therapies as soon as clinical progress, and culture results, permit
(e) Use antibiotics rationally and consistently, ideally using the IWGDF guidance, to create local guidelines that can take into account local factors (resistance patterns, cost, availability, hospital formulary).

Key Points

- Diabetic Foot infections are heterogeneous affecting a clinically diverse group of patients with multi system comorbidities. Hence an individual patient tailored approach is preferred and is best delivered through a multidisciplinary diabetic foot team
- Half of diabetic foot ulcers are infected, but the presence of surface bacteria does itself mean infection
- Infection is diagnosed by the presence of at least 2 or the following: redness, swelling, heat, pain and increased purulence.
- Inflammatory markers may help with diagnosis of infection.
- Severity and extent of a DFI should be determined and this should guide antibiotic therapy
- Antibiotic therapy should be guided by a multidisciplinary diabetic foot care team with infection specialist involvement.

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Chapter 8
Endovascular Revascularisations: When and How

Lorenzo Patrone and Hany Zayed

Diabetic Vascular Disease

According to the UK Prospective Diabetes study, a 1% increase in HbA_1C, is associated with about 28% increased risk of PAD [1]. The presence of neuropathy precludes the common presentation of intermittent claudication, therefore diabetic patients are more likely to present with a foot ulcer or with gangrene first.

Diabetes leads to multiple metabolic abnormalities, which promote atherogenesis, such as dyslipidaemia, hypertension, hyperglycaemia and insulin resistance. These contribute to endothelial cell dysfunction, resulting in vasoconstriction, inflammation and ultimately atherogenesis. In addition, abnormal platelet function is thought to lead to a heightened thrombotic potential.

Diabetic macrovascular disease is associated with florid calcification of the intimal plaque and media. The disease tends to be diffuse with poor collateral circulation particularly between the infra-geniculate vessels. Perfusion defects are consequently more severe in diabetic patients.

Non-diabetic PAD predominantly affects the aorto-iliac, femoral and popliteal arteries. The pattern in diabetic vasculopathy is different with increased prevalence of disease in the below knee vessels. The below knee vessels, referred to as 'the runoff vessels', include the anterior tibial, posterior tibial and peroneal arteries. A study by Graziani et al. analysed the angiographic findings in 417 diabetic patients with CLI [2]; they demonstrated that the vascular involvement is extremely diffuse,

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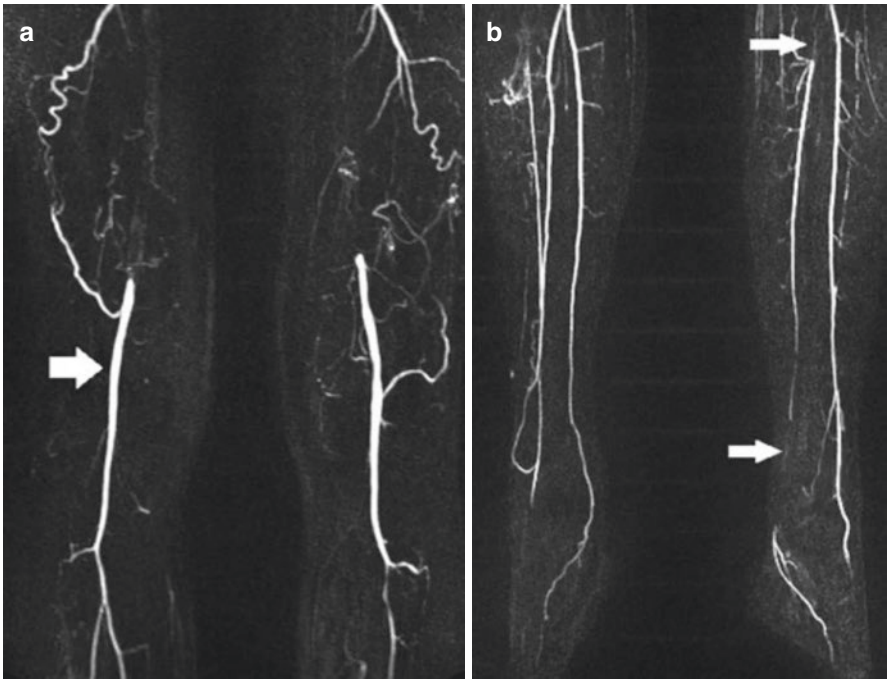

Fig. 8.1 Reconstructed MRA images demonstrating the typical combination of SFA and infra-geniculate disease found in diabetic PAD. (**a**) Bilateral SFA occlusions with collateral reconstitution of the popliteal artery (*arrow*). (**b**) Bilateral proximal occlusions of the anterior tibial artery and multi-level occlusive disease of the left posterior tibial artery (*arrow*)

and particularly severe in the tibial arteries with a high prevalence of long occlusions. The most common pattern of disease found in diabetic patients is a combination of stenotic and occlusive disease of the superficial femoral artery (SFA) and multifocal infra-geniculate occlusions (Fig. 8.1).

Treatment Options

Multiple factors need to be taken into account before considering revascularisation. These include clinical findings, degree of tissue loss, degree of ischaemia, the age of the patient, life expectancy, co-morbidities and the level and extent of arterial disease.

It must be ensured that all patients are on best medical therapy; this includes optimising glycaemic control and treatment of hypertension, in addition to smoking cessation, antiplatelet and statin therapy. Optimal wound care, treatment of infection and good foot care are also vital, both pre- and post-procedure. This should ideally be achieved with input from a multi-disciplinary team involving

diabetologists, podiatrists, infectious diseases specialists, interventional radiologist, vascular surgeons with access to specialist input from orthopaedic foot surgeon, orthotics and patient appliances teams.

The global vascular guidelines document proposed a detailed framework for classifying and staging limbs affected by CLTI to guide decision making: the need and the options for revacularisation. This framework, which is referred to as ***PLAN*** (**P**atient, **L**imb staging, **AN**atomical staging), starts by considering patient factors first, including: their comorbidity profile, perioperative risk, likelihood of long-term survival, ambulatory function and suitability for rehabilitation, in addition to their hopes and expectations on what difference any treatment is likely to offer.

This is followed by a detailed description of Limb Staging utilising the WiFi classification of the affected foot (Fig. 8.2) [3]. This relatively new tool is thought to correlate with wound healing and limb salvage probability following adequate revascularisation. It is simple to assess, and using a tabulated structure analogous to the TNM classification for cancer, the 'Grades" will be charted into 64 possible

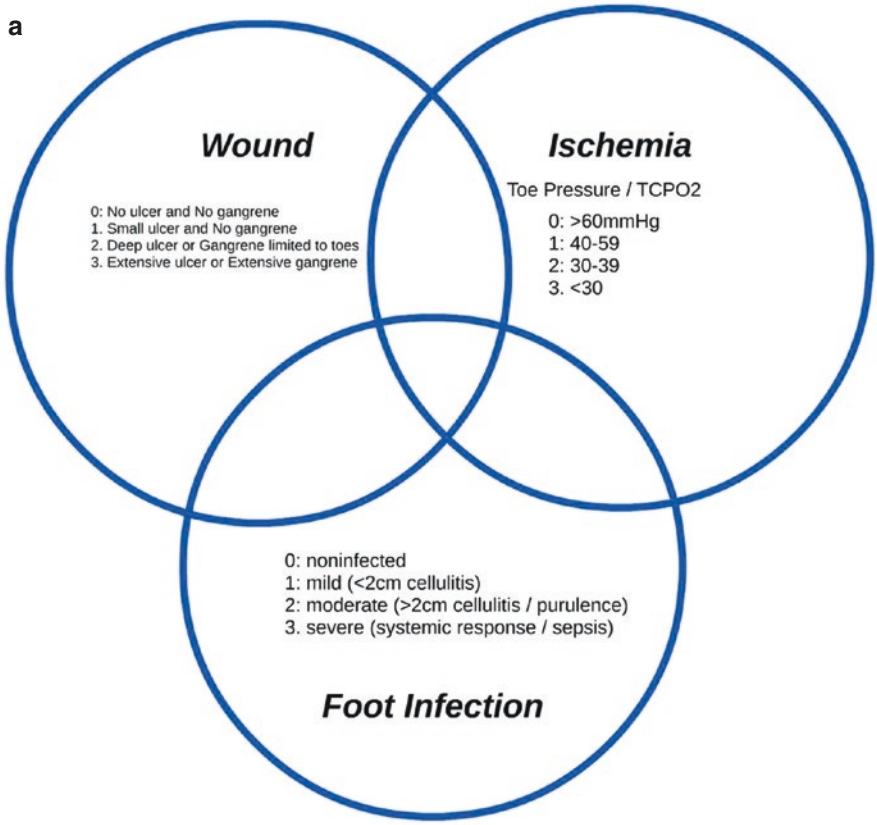

Fig. 8.2 (**a**) The WiFi Score. (**b**) Clinical stages of WiFi score

b

	Ischemia – 0				Ischemia – 1					Ischemia – 2				Ischemia – 3			
W-0	VL	VL	L	M	VL	L	M	H		L	L	M	H	L	M	M	H
W-1	VL	VL	L	M	VL	L	M	H		L	M	H	H	M	M	H	H
W-2	L	L	M	H	M	M	H	H		M	H	H	H	H	H	H	H
W-3	M	M	H	H	H	H	H	H		H	H	H	H	H	H	H	H
	fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3		fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

b, Estimate likelihood of benefit of/requirement for revascularization (assuming infection can be controlled first)

	Ischemia – 0				Ischemia – 1					Ischemia – 2				Ischemia – 3			
W-0	VL	VL	VL	VL	VL	L	L	M		L	L	M	M	M	H	H	H
W-1	VL	VL	VL	VL	L	M	M	M		M	H	H	H	H	H	H	H
W-2	VL	VL	VL	VL	M	M	H	H		H	H	H	H	H	H	H	H
W-3	VL	VL	VL	VL	M	M	M	H		H	H	H	H	H	H	H	H
	f-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3		fI-0	fI-1	fI-2	fI-3	fI-0	fI-1	fI-2	fI-3

fI, foot Infection; I, Ischemia; W, Wound.

Premises:

1. Increase in wound class increases risk of amputation (based on PEDIS, UT, and other wound classification systems)
2. PAD and infection are synergistic (Eurodiale); infected wound + PAD increases likelihood revascularization will be needed to heal wound
3. Infection 3 category (systemic/metabolic instability): moderate to high-risk of amputation regardless of other factors (validated IDSA guidelines)

Four classes: for each box, group combination into one of these four classes

Very low = VL = clinical stage 1
Low = L = clinical stage 2
Moderate = M = clinical stage 3
High = H = clinical stage 4
Clinical stage 5 would signify an unsalvageable foot

Fig. 8.2 (continued)

Classes, and these are further Staged according to the level of risk of limb loss: from 1 to 4; 4 being most severe. This helps in determining the estimated 1-year risk of amputation and the potential benefits from revascularisation. It is worth mentioning that within the WiFi system, more emphasis is placed on the value of assessing for ischaemia in diabetic patients presenting with tissue loss, namely by utilising more reliable tools of perfusion and pressure assessment specific to this patient

population, i.e., Toe pressures, and Toe-brachial indices (TBI), and perfusion assessment, i.e., $TCPO_2$. In recent years, WiFi has become widely adopted globally, and this risk assessment process is simplified by utilising readily available WiFi calculators via mobile phone applications.

The new global guidelines also provide a detailed schematic representation of the Global Limb Anatomical Staging System (GLASS) tool, which is designed to replace the Transatlantic Society Consensus Classification (TASC) for more accurate and evidence-based guidance on revascularisation. High quality imaging, intact inflow to femoropopliteal segment and assessment for availability of venous conduit are mandatory.

In theory, the GLASS grading for femoropopliteal and infrapopliteal segments, can be put into the provided matrix to provide guidance on:

– Estimated peripheral endovascular outcomes
– Estimated technical failure rates
– 1-year limb-based patency rates

Further description of the process is beyond the scope of this chapter and readers are advised to review the full document, published in 2019 [4].

Once a decision is made to proceed to revascularisation, there are two options: endovascular treatment or surgical bypass.

Endovascular revascularisation was first performed in 1964 by Charles Dotter [5]. Since then, there has been continued development of techniques and equipment particularly for infra-popliteal disease and the indications for endovascular intervention continue to expand.

There is limited level 1 evidence comparing endovascular treatment with open bypass. The BASIL trial was published in 2005 [6] and demonstrated that at 1 year that there was no difference in amputation rates or overall survival between patients with severe limb ischaemia treated initially with bypass surgery or endovascular treatment performed by angioplasty only (patients who received stenting or other adjuncts were not included in the endovascular group). At 2 years there was a survival advantage in the bypass group and a trend towards improved amputation-free survival. More recent non-randomised evidence seems to also suggest favourable outcomes for bypass when it comes to longevity and amputation-free survival, at the expense of higher perioperative major complication rates as expected [7, 8].

BASIL, however, comprised a heterogeneous group of patients with both above- and below-knee disease, and no sub-group analysis for diabetic patients was performed. This data has been used to suggest that angioplasty may confer benefits with short-term revascularisation, and bypass surgery is more suitable if the patient has reasonable life expectancy and suitable anatomy (including venous conduit). However, since the conduction of the BASIL trial, more advanced techniques and tools have been developed and are now widely used in endovascular therapy e.g. Intravascular lithotripsy, atherectomy and new stent designs. Endovascular therapy has been further evaluated in 2 further contemporary studies in the BASIL-2 and BEST-CLI trials which have finished recruiting. The

BEST-CLI is a landmark trial that randomised over 1800 patients to either surgical bypass or endovascular therapy in two separate cohorts of patients. Cohort 1 examined patients with a good quality venous conduit for bypass versus endovascular therapy and Cohort 2 looked at patients without a venous conduit versus endovascular therapy. BEST-CLI found that patients with a good quality venous conduit receiving a surgical bypass, had a 32% reduction in Major Adverse Limb Events (MALE) or death compared to endovascular therapy including 65% fewer major re-interventions and 27% fewer amputations. For patients who had only an alternative non-venous bypass conduit available, there was no difference in these outcome measures. It is therefore important that patients who are fit and eligible for either therapy is guided by input from a multidisciplinary team so that evidence based shared decision making takes place with regards to treatment. Endovascular therapy should be favoured in the more elderly, less fit patients and patients lacking a suitable venous conduit. Results from the BASIL-2 trial are awaited.

Endovascular Treatment

Endovascular treatment techniques are now widely adopted for the treatment of CLTI. They are minimally invasive, and the technology has largely progressed in the last two decades.

Pre-procedure

There are several important pre-procedural considerations. The patient needs to be able to lie flat and still for the procedure (possibly for several hours) and if they are unable to do this, then anaesthetic support for sedation and possibly general anaesthesia may be required. Pre-procedural imaging and previous endovascular interventions must be carefully reviewed. Recent blood tests should be available, particularly renal function.

Considerations should be made with enough time prior to intervention regarding withholding the following common medications:

- **Antiplatelet agents**: Aspirin is usually continued and has been shown to reduce the incidence of peri-procedural thromboembolic events. If the patient is on dual antiplatelet therapy, then the indication for that therapy should be reviewed and a multi-disciplinary decision made, based on the risks and benefits, on how to proceed. Aspirin is usually continued whilst the other antiplatelet agent held for approximately 5–7 days pre-procedure.
- **Anticoagulants:** If the patient is on warfarin this should be stopped, aiming for an INR <1.5 before intervention is performed. Similarly, if the patient is on a

Direct Oral Anticoagulant (DOAC), a review of the indication should be made and this should be held in time, and in both cases, bridging with Heparin is sometimes required.

– **Metformin**: This is usually stopped for 48 h prior to intervention and restarted after if creatinine levels are stable.

It is good practice to involve a nephrologist early if the patient suffers from severe Chronic Kidney Disease (CKD; i.e., glomerular filtration rate < 30). For patients with CKD, perioperative hydration with oral and/or intravenous fluids is indicated, with careful assessment of renal function and urine output. Iso-osmolar contrast is usually used (e.g. iodixanol).

Operators and team members should be familiar with utilising negative contrast agents, i.e. Carbon dioxide (CO_2), for angiography. CO_2 is used for renal protection or in the presence of documented contrast allergy. It requires special equipment: A disposable cylinder of medical-grade CO_2, standard filter from an IV giving set, a high-pressure connector, a three-way tap and a lockable stopcock with every syringe (Luer-lock syringes). In addition, a dedicated pump can be used to inject CO_2.

Preoperative checklists and a safety check for all equipment should be standard practice in all centres performing endovascular interventions.

Treatment Site

The principle of any vascular intervention is to first ensure that inflow is restored (i.e., the most proximal level of disease is treated), before considering more distal intervention. Whilst much emphasis is placed on the below-the-knee (BTK) disease in patients with diabetes it is important to remember this principle and ensure that proximal iliac or femoral disease is adequately treated. It is also important to relate the severity of the clinical presentation to the planned endovascular treatment. For example, patients with intermittent claudication and combined SFA and BTK disease may derive sufficient benefit from treatment of the SFA disease alone, whereas patients with tissue loss usually require multi-level intervention to restore an in-line flow to the foot.

The angiosome concept always attracts debate. In general, the evidence when it comes to the outcomes of BTK revascularisation is poor and suffers from considerable heterogeneity in reporting standards and outcome measures.

The foot is divided into distinct vascular territories or angiosomes, one each; from the anterior tibial artery (ATA) and peroneal arteries (PA) and three from the posterior tibial artery (PTA). The ATA supplies the dorsal side of the foot and toes, the PA supplies the lateral ankle and lateral heel, and the PTA perfuses the plantar surface of the foot and the medial heel. This varies however, and a proper angiographic assessment of the foot with lateral and anteroposterior views at the time of angiography is mandatory in a patient with tissue loss. It is also important to note

that most foot wounds spread across multiple angiosomes which can affect the planning for angiosome-guided revascularisation.

In addition, the status of the pedo-plantar foot arch has been shown to play an important role for optimal healing of foot ulceration [9], as are the small collateral vessels in the foot, known as choke vessels, which are often compromised in diabetic patients.

It is therefore logical that the operator considers all these variables in CLTI patients with foot lesions.

An updated review of observational studies showed that overall, there appeared to be a benefit to direct angiosomal revascularisation in relation to endovascular interventions, but the authors highlighted that most studies suffered from selection bias [10]. Another review specific to diabetic patients with tissue loss, found that both direct angiosomal and indirect revascularisation appeared to be equally effective [9]. From a practical point of view, it is often not possible to achieve angiosome-targeted perfusion due to severe disease of the target vessels. Similarly, the evidence is poor when considering the clinical benefits of revascularizing more than a single tibial vessel, and some observational studies found that it did not improve outcomes [11, 12].

Case Planning

We would recommend that all endovascular lower limb interventions are planned carefully prior to the procedure. Careful assessment of good quality imaging is essential. The operator is clearly advised to document this planning clearly on a dedicated sheet in a similar fashion to planning endovascular aortic interventions.

First, full assessment of inflow and access vessels is required. Assessment of inflow may require dual modality imaging (including duplex ultrasound) to ascertain it is adequate. The access vessel should be assessed, in addition to the access route to reach the target lesion(s) to be treated.

When it comes to the lesion, the following lesion characteristics should be assessed: occlusive vs stenotic, length, adequacy and diameter of healthy vessel segments above and below, the severity of calcification, location of important branches and distance from the access point.

The outflow should be also assessed all the way down to the foot, however, in the presence of multilevel disease, this can sometimes be challenging as most imaging modalities have a degree of limitation for assessing crural vessels distally, and a diagnostic angiogram at the time of intervention will aid in better evaluating runoff.

The operator should then determine what approach and what tools they will need and ensure these are available. The lengths and diameters of devices should be checked, as well as the profiles of sheaths and catheters required to safely deliver the treatment. It is advisable to have alternative plans and bail-out kits ready, as well as colleagues to support if the cases are complex.

Arterial Access

Ultrasound guided access is strongly recommended in all cases. The operator must be familiar with retrograde and antegrade approaches and these procedures should be performed at centres able to manage access site complications such as bleeding and false-aneurysm formation.

After planning the intervention, the operator decides what access route is most suitable for their individual patient. A retrograde route describes puncture and access against the direction of blood flow. In relation to infrainguinal disease, there are 2 options:

A retrograde common femoral artery access from the contralateral side, with 'up and over' access to the target lesion(s). This approach is useful for treating inflow disease (Iliac, common femoral) at the same time. It is also helpful when treating flush SFA occlusions or PFA disease, especially with high bifurcation of the ipsilateral CFA. However, this approach requires longer guidewires, sheaths and catheters. The operator must be mindful of the tortuosity and the presence of arterial disease in the contralateral and access vessels. Additionally, retrograde CFA access could be a convenient approach when treating ipsilateral iliac disease.

The other retrograde option is via the popliteal or below knee vessels (including pedal access), i.e. reaching the vessel from a distal access site. The access to these vessels can be performed by ultrasound or fluoroscopic guidance and the need for a bidirectional approach is becoming increasingly common especially in challenging cases. Dedicated micropuncture kits are available on the market.

Antegrade access is now the preferred option in suitable patients, especially for Below The Knee (BTK) disease. This approach allows better control of guidewires and catheters to cross distal lesions due to better support and pushability with straight-line access and relatively shorter lengths of wires and catheters required. It can be challenging in obese patients, patients with short or diseased common femoral arteries, or in the presence of scarring.

As discussed previously, having a plan is essential. The first step once access is secured, would be to obtain adequate angiographic imaging from the common femoral artery all the way down to the foot. The operator should be familiar with radiation safety principles and cautious with the use of contrast media. Some angulations are required to obtain adequate views, especially to open the vessel bifurcations at the level of the common femoral and below knee popliteal arteries. We recommend obtaining magnified foot views in 2 projections (antero-posterior and lateral) in patients with tissue loss.

Once the disease pattern is identified, the treatment strategy should be confirmed. Intravenous or intra-arterial heparin should be administered before proceeding to crossing the lesion. The level of anticoagulation should be regularly checked. We recommend using Activated Clotting Time (ACT) to achieve an adequate anticoagulation with a target between 200–300 especially in long and BTK procedures. In this patient population, multilevel disease and long occlusions are common. In practice, crossing lesions can be achieved either intra-luminally or in the sub-intimal plane.

This is often dictated by three factors: The type of lesion (occlusive vs stenotic, long-vs short, heavily calcified vs soft), the guidewires used, and the experience of the operator. Staying intra-luminal allows exploring adjunct modalities for treatment (e.g. atherectomy, intravascular lithotripsy). However, there is no evidence to clearly differentiate between the two in terms of patency rates and clinical outcomes, and both are considered valid treatment approaches.

Sub-intimal Approach

This alternative recanalization approach was described in 1990 by Bolia et al. [13] To create a sub-intimal channel, a guide catheter is pointed towards the arterial wall at the proximal aspect of the occlusion and a hydrophilic guide-wire is introduced into the space between the intima and media. This looped guide-wire is used to dissect a sub-intimal tract and then passed back into the true lumen at the distal end of the occlusion. Angioplasty then displaces the atheromatous and calcified intimal and medial layers to the contralateral side of the lumen, thus creating a neo-lumen. Care should be taken not to extend the created sub-intimal tract too distally, so as to preserve collaterals as well as possible distal targets for bypass. Re-entry into the true lumen may not be possible, particularly in extensively calcified vessels (reported up to 10–15% of cases). Specialised re-entry devices are available such as the Outback® (Cordis) and Offroad® (Boston Scientific, Natick, MA, USA) devices. The Outback device is a 6F compatible catheter with a sharp, hollow 22G needle that can facilitate targeted re-entry into the true lumen at the desired level.

Intra-luminal approach is the preferred approach in tibial vessel occlusive disease if possible. The intra-luminal approach may require the use of dedicated wires (CTO), which have weighted tips, providing the necessary force to break through occlusions.

Retrograde recanalisation is an effective and increasingly utilised technique when an antegrade approach has proved unsuccessful. As previously described, access is obtained either in the tibial vessels or popliteal artery and the occlusion is crossed from below.

The advent of lower profile balloons and narrow calibre wires and catheters has allowed effective treatment of complex distal tibial and pedal disease. There are numerous complex techniques that have been described for the treatment of below the knee disease including trans-collateral retrograde recanalisation and pedal loop retrograde recanalisation. The pedal loop technique is of particular value when a proximal occlusion stump is unavailable or when distal disease makes retrograde puncture impossible. The dorsalis pedis and the lateral plantar arteries (distal PT branches) communicate through the deep perforating artery. A low-profile guidewire can be navigated through these collaterals, resulting in a loop connecting the anterior and posterior tibial arteries. From this position, retrograde tibial recanalisation and angioplasty can be performed.

Vessel preparation

It is becoming increasingly common to use a variety of modalities to deliver the most durable treatment, especially in calcified CTO, with or without the use of drug-coated devices. It is accepted that adequate vessel preparation can maximise luminal gain, reduce the risk of dissections and optimise the vessel for stenting and other devices such as drug eluted devices. Consequently, it is thought to have a favorable mid- and long-term outcome, however, there is no high quality evidence to demonstrate that at the moment.

In modern practice, the tools for vessel preparation range from pre-dilatation with an undersized balloon, to more sophisticated and costly techniques such as atherectomy and intravascular lithotripsy [14].

Angioplasty or Stent

The two main options when it comes to endovascular treatment of stenotic or occlusive lesions are balloon angioplasty with or without stenting. When it comes to these options, there are many adjuncts that were developed recently with the aim of improving patency and long-term outcomes.

It is worth mentioning that there is a lack of high-level evidence to support one over the other, especially in the diabetic patient population with CLTI. It is therefore common to treat complex lesions (long occlusive diseased, calcified diseased) with angioplasty and stenting, or to reserve stenting as bail-out option when the outcome following angioplasty is not satisfactory, e.g., suboptimal luminal gain, flow-limiting dissection, rapid recoil.

Iliac Disease

The STAG trial comparing primary stenting for iliac occlusive disease demonstrated a reduction in major procedural complications, predominantly distal embolisation, in the stent group [15]. Some data suggest that covered stents have better outcomes than bare metal stents (BMS). The COBEST trial comparing covered stents with bare metal stents for iliac disease demonstrated a benefit in terms of freedom from restenosis in the covered stent group; at 18 months 95.4% in the covered stent group were free of binary restenosis compared with 82.2% in the BMS group [16].

The use of stents has been shown to improve the immediate haemodynamic and clinical results of iliac angioplasty. However, for short non-occlusive iliac disease, stand-alone angioplasty is still reasonable, with primary stent placement reserved for more complex or occlusive disease.

Femoro-Popliteal Disease

The RESILIENT trail demonstrated better 1-year patency rates, and lower target lesion revascularisation (TLR) in patients who had nitinol stents in comparison to angioplasty alone [17]. Of note, the study population were claudicants, which makes the extrapolation of these outcomes to the more advanced disease often seen in CLTI undetermined.

Bare metal stents have evolved in recent years to allow for certain properties (resistance to external forces, elastic and thermal memory, confirmability). A new-generation biomimetic braided nitinol alloy stent (Supera, Abbott) had an overall 1-year patency approaching 90% in an observational study that included 147 patients (67% CLTI, 63% Diabetic) [18]. In addition, its results were found to match drug coated stents in patients with calcific femoropopliteal disease [19].

Similarly, covered stent grafts offer another option especially for lesions in the femoropopliteal region, however they were associated with higher stent thrombosis rates in some series [20]. The evidence to support one modality over the other is, again, limited to observational studies. One randomised study included 148 patients (44% diabetic) showed no difference in 3-year patency outcomes to bare-metal stents [21].

Below the Knee Interventions

Both angioplasty with or without stenting have been widely used for treatment of infrapopliteal disease. The outcomes are widely variable in the literature. A Cochrane review suggested that stenting may be associated with improved technical success, however, this was not clearly reflected in the 6-month patency outcomes, which did not differ [22]. Again, the heterogeneity and variation in outcome reporting, limits conclusions from the numerous studies that were done in the last 2 decades. Notably, only few studies are powered to clinically relevant outcomes: namely: amputation-free survival.

Drug-Eluting Technologies

The leading cause of endovascular failure is recurrent stenosis due to neointimal hyperplasia. This is analogous to scar formation at the angioplasty site or in the stent and is due to inflammatory mediator release from damaged endothelial cells, leading to smooth muscle cell proliferation.

Drug-coated balloons (DCB) and drug-eluting stents (DES) have been shown to significantly reduce neointimal hyperplasia and restenosis rates. The two most commonly used agents, which are bonded to the balloon or stent, are Paclitaxel and Sirolimus. Paclitaxel is a plant alkaloid and inhibits mitogen-activated protein

kinase, thus halting the cell cycle in the M phase. Sirolimus is a macrolide antibiotic and immunosuppressive agent and is a potent inhibitor of smooth muscle migration and proliferation.

Different studies evaluated Paclitaxel-coated stents versus laser-cut bare metal nitinol stents, and the results demonstrated superior primary patency and reduced restenosis rate with the Paclitaxel-coated stents [23–25]. The use of Sirolimus coated balloons has recently been studied and the short term results look promising [26], but further studies need to prove their long term efficacy and safety.

Drug-eluting technologies are also used in the treatment of BTK vessels, and the evidence regarding their efficacy continues to grow. A trial by Schmidt et al. demonstrated reduced early restenosis rates using drug-coated balloons [27]. The DEBATE-BTK study, looking specifically at treatment of BTK disease in diabetic patients, demonstrated reduced restenosis rates and target vessel occlusion rates in the DEB group [28]. On the other hand, drug-eluting stents the evidence seems to favour using drug eluted stents in this region compared to BMS [29].

Drug-eluting technologies are significantly more expensive, but a number of studies have shown that the initial higher index costs are offset in time, due to reduced rates of re-intervention. As drug-eluting technologies improve and costs decrease, it seems likely that they will play an increasing role, particularly in diabetic patients, who are known to have a higher incidence of restenosis. However, the clinical benefit to patients in terms of wound healing and prevention of amputation has yet to be established.

However, drug eluted technology has been a subject of world-wide debate in recent years after the publication of a meta-analysis in December 2018 that suggested higher mortality beyond 2 years in PAD patients receiving paclitaxel -eluted therapies [30]. As a result of this meta-analysis, both the MHRA and FDA temporarily suspended the use of these devices. They are now back in use, especially for CLTI patients. Multiple subsequent multicentre registries and metanalyses failed to show the same mortality signal associated with Paclitaxel use in femoropopliteal segment [31, 32].

Atherectomy

Atherectomy devices aim to improve luminal gain at the time of recanalization, they utilise mechanical technologies (rotational, directional, and orbital) to fracture the calcified plaque, debulk the lesion and prepare the vessel for treatments such as drug coated or plain balloon angioplasty with or without stenting. Atherectomy shows some promise particularly as a preparation for drug eluting therapy [33], and decreasing the need to leave a stent.

DEFINITIVE LE was a multicentre registry that included about 600 patients undergoing directional atherectomy. No CLTI patients were included, however. There was no clear difference in terms of TLR or primary patency in patients who were diabetic or not. And the technical outcomes appeared encouraging [34].

More recently, peripheral artery angioplasty with adjunctive orbital atherectomy has been demonstrated to be safe and associated with low major amputation rates after 3 years of follow-up [35]. Despite some encouraging studies, strong evidence of proper benefits correlated to vessel preparation using atherectomy is still lacking [36].

Complications

Complications following endovascular intervention include access-site haemorrhage, major medical complications and distal thromboembolism or vessel occlusion. Accurate assessment of true complication rates is hampered by varying definitions of what constitutes a major or minor complication. Moreover, the ongoing improvement in angioplasty techniques, means conclusions about current outcomes cannot always be obtained from older literature.

The rate of major medical complication (stroke, myocardial infarction and renal failure) is low and has been reported between 1.8 [37] and 2.4% [38]. Access vessel complications include pseudoaneurysm, arteriovenous fistula formation and access-vessel dissection or occlusion. A study by Dick et al. reported an access-site complication rate of 4.9% [37].

Access-site pseudoaneurysms can often be treated with either ultrasound-guided compression or thrombin injection. On-going access-site haemorrhage usually requires surgical repair. A 2002 study by Axisa et al. showed that emergency surgical intervention was required in 2.3% of cases, with the commonest aetiologies being haemorrhagic complications and acute limb ischaemia [38]. Retroperitoneal bleeding may be amenable to endovascular treatment with stent placement.

Distal vessel occlusion can occur as a result of flow limiting dissection or a thromboembolic event. Flow-limiting dissection can usually be treated with prolonged balloon inflation or stent placement. Occlusion due to thromboembolism can be treated with either aspiration thrombectomy or thrombolysis. Some cases may require surgical embolectomy.

Post-procedure Care

Immediate post-operative care comprises access site care to ensure haemostasis; this can be achieved with manual compression (usually 10 min in duration) followed by a period of bed rest and observation. Various closure devices are available which reduce time to achieve haemostasis and allow earlier ambulation. Closure devices are usually reserved for larger sheath sizes, with manual compression used for 4F systems. Closure devices are particularly useful in non-compliant patients who will be unable to lie still and flat.

Stents should undergo regular duplex surveillance to identify in-stent restenosis and enable re-intervention before occlusion occurs.

No Option Patients

A real challenge to the endovascular clinician, is the subgroup of patients who have non-reconstructable lower limb disease, commonly due to the absence of a distal target vessel. The incidence of major amputation in these patients is high.

In recent years, the concept of venous arterialisation has been revisited. First described by Halstead and Vaughan in 1912, this technique aims at diverting arterial blood in the venous circulation in an attempt to enhance tissue perfusion in critically ischaemic tissue. In 2016, the first dedicated endovascular system; Limflow© was granted the CE mark, and recently, its 1-year early feasibility results showed a 70% amputation-free survival rate using this technique [39].

On the other hand, pedal artery recanalization, and restoration of an intact pedal arch is regarded by many as essential for optimal distal wound healing. This, however, can involve a variety of advanced endovascular techniques; e.g. Subintimal Arterial Flossing with Antegrade and Retrograde Intervention (SAFARI), and the evidence to support its role in enhancing amputation-free survival is still unclear.

Summary

Diabetic vascular disease commonly affects the tibial arteries and careful assessment, and planning is required before any endovascular intervention. Medical therapy should be optimised before intervention. A number of endovascular techniques are available and should be used depending on the location and nature of the diseased arterial segment.

Key Points

- In people with diabetes arterial disease is diffuse but with particularly severe disease with long occlusions in the tibial arteries.
- Before intervention medical therapy should be optimised.
- Patient should be able to lie flat for duration of treatment.
- Inflow should be restored before considering any distal intervention.
- Pre-intervention planning should consider occlusion versus stenosis, length of diseased segment, condition and diameter of proximal and distal vessels, severity of calcification, location of important side branches and distance from access point.
- Ultrasound guidance should be used for atrial access.
- Drug eluting technologies have been shown to reduce fibrointimal hyperplasia.

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Chapter 9
Surgical Revascularisation of the Diabetic Foot

Paul Moxey and Patrick Chong

Background

Peripheral arterial disease (PAD)) affects 50% of patients presenting with a diabetic foot ulcer. If PAD is left untreated, non-healing wounds will occur and in many cases will deteriorate threatening both the patient's limb and their life. PAD gives rise to stenoses or occlusions of the lower limb arteries by the accumulation of atherosclerotic plaques within the vessel lumen preventing optimal perfusion of the affected limb. Procedures to either bypass or re-open the diseased arterial segment are termed revascularisation and can take the form of either endovascular radiological guided intervention (angioplasty or stenting) or open surgical bypass. To date, a few landmark randomised trials have compared the outcomes of open versus endovascular treatment for critical limb ischaemia. The BASIL study concluded that if a patient had more than a 2-year life expectancy and extensive tissue loss they should be offered surgical revascularisation in the first instance [1]. However, BASIL was not performed exclusively in patients with diabetes and the last patient was randomised 10 years ago in 2004. In that time exciting endovascular techniques have evolved with drug eluting balloons and drug eluting stents promising to overcome the problem of early re-stenosis in the tibial vessels following intervention in

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diabetic patients. However, despite advances in endovascular techniques and technologies, the BEST-CLI study has underscored the superiority of surgical bypass over endovascular therapy in the setting of chronic limb threatening ischaemia (CLTI) when a patient has a suitable venous conduit for bypass [2, 9]. Results demonstrate that surgical bypass patients have less major adverse limb events (MALE), deaths and re-interventions compared to endovascular therapy. Even in the setting of patients without a suitable venous conduit, non-venous surgical bypass had similar outcomes to endovascular therapy. It is vital therefore for clinicians or vascular teams looking after diabetic patients with foot tissue loss and CLTI to be proficient in providing both treatment modalities and to develop evidence based treatment algorithms that take into account patient fitness or frailty, the availability of suitable venous conduit and the anatomical features of the peripheral arterial disease that may render endovascular therapy technically challenging with increased kit costs but limited clinical durability. The most recent BASIL-2 trial, a smaller scale randomised controlled study compared to the BEST-CLI trial reported better outcomes for major amputation, all-cause mortality and amputation free survival in favour of an endovascular therapy first strategy over bypass surgery. 30-day mortality rates were high for both bypass surgery (6%) and for endovascular therapy (3%) underlining the need for careful medical pre-optimisation and patient selection [3].

Introduction

Goals of Revascularisation

The main goal of revascularisation in the diabetic foot patient is to help the patient achieve successful limb salvage with restored limb function and patient quality of life. Revascularisation in the diabetic foot with ischaemia and tissue loss should be carried out as soon as possible as further delays may lead to irretrievable tissue loss and major amputation.

Indications for Revascularisation

The main indication for revascularisation in the diabetic foot patient is critical limb ischaemia causing rest pain and tissue loss with either non-healing wounds or gangrene. It is important to appreciate that the presence of peripheral neuropathy may cause some patients to present late to the multidisciplinary diabetic team because of a lack of pain symptoms despite advanced tissue loss in the foot. In some emergency patients with severe foot sepsis and extensive tissue loss, it may be expedient to debride and drain the foot even before any attempt at investigation or treatment for any underlying arterial disease. Delays may lead to irreversible foot tissue loss and

consequent major amputation. Analysis of UK Hospital Episode Statistics data revealed that more than half of patients that underwent major lower limb amputation between 2003 and 2008 had no attempt at revascularisation prior to losing their limb [4].

Diagnosis of PAD

The diagnosis of peripheral arterial disease (PAD) can be confirmed clinically by bedside examination of the patient's lower limb arterial pulses and also with the use of non-invasive modalities in the vascular lab and imaging of the arterial blood supply to the limb.

Non-invasive Techniques in the Vascular Lab

Ankle brachial pressure index (ABPI) recordings are performed with the aid of a hand-held Doppler probe or with automated ABPI recording systems. A reduced ABPI value of less than 0.9 suggests the presence of Peripheral Arterial Disease (PAD) . ABPI recordings are often falsely elevated in diabetic patients due to medial sclerosis of the ankle arteries rendering them incompressible. This is the reason why automated ABPI recording systems are not recommended in the assessment of diabetic patients with PAD and even manual ABPI recordings can be inaccurate. However, the audible waveforms obtained with a hand-held Doppler can be helpful and an incompressible monophasic waveform character suggests the presence of significant PAD. Toe pressures are more accurate than ABPI values in the setting of elevated ankle pressures but often outside of research settings toe pressures recordings are difficult to obtain as expertise is not available. Absolute ankle systolic pressures of less than 50 mmHg or toe systolic pressures of less than 30 mmHg suggest the presence of critical ischaemia which may lead to potential limb loss unless revascularisation takes place.

An alternative non-invasive option for the assessment of lower limb perfusion is transcutaneous oximetry ($TCpO_2$). $TCpO_2$ measurement is not universally accepted due to a perceived variability in obtaining accurate $TCpO_2$ values which may be affected by limb and ambient temperatures. Generally, a $TCpO_2$ value of less than 35 mmHg suggests the presence of significant PAD and can be a helpful adjunct in the decision-making process when there is a need to optimise major amputation levels or in deciding whether conservative wound management in less fit patients with tissue loss is likely to succeed. Low $TCpO_2$ values of less than 35 mmHg should prompt further investigation of the limb for PAD with vascular imaging.

Vascular Imaging Options

Diabetes produces a typical pattern of multilevel disease that is particularly aggressive below the knee in the tibial arteries. This presents a challenge for angiography as the below knee vessels and pedal arch in particular are difficult to clearly image on all but invasive catheter angiography. Imaging of the arterial blood supply to the limb prior to any intervention for revascularisation is required in order to establish the anatomical distribution of PAD in the affected limb and to ensure that there is an adequate inflow vessel proximally and target outflow or run off vessel distally to aid the long-term durability of any endovascular or open surgical bypass technique. Vascular imaging techniques can be non-invasive or invasive. Computer Tomography Angiography (CTA), Magnetic Resonance Angiography (MRA), duplex ultrasound and digital subtraction angiography (DSA) are the methods available.

Non-invasive Vascular Imaging

Duplex Scan

The simplest approach to vascular imaging is duplex scanning in the Vascular Lab. This quick, non-invasive technique for the assessment of the lower limb arterial blood supply is safe and acceptable to most patients. It provides both anatomical and haemodynamic information regarding the severity of PAD in the affected limb and its suitability for endoluminal treatment. However duplex scanning is an operator dependant technique that can be limited by bowel gas when evaluating the supra-inguinal aorto-iliac segment and also by calcification present in the infra-geniculate tibial arteries. It can also be used for vein mapping prior to a surgical reconstruction to assess for venous conduit suitability for bypass and used for the surveillance of existing vein bypass grafts in patients who have had previous surgery for PAD. The added advantage of duplex scanning is that it allows the avoidance of contrast agents in patients with renal function impairment.

Computer Tomography Angiography (CTA)

CTA allows accurate assessment of the lower limb arterial supply from the thoracic aorta down to the level of the ankle vessels but often visualisation of the distal foot arteries is not clear. It is also preferred when there is concomitant aneurysmal disease suspected in the aorta and the lower limb peripheral arterial system. The degree of calcification of the aorta and peripheral arteries is also noted on CTA. CTA is the preferred vascular imaging modality in patients with end stage renal failure or

chronic kidney disease (CKD) as gadolinium contrast used in Magnetic Resonance Angiography (MRA) can potentially cause contrast induced nephropathy (CIN) and in rare cases nephrogenic systemic fibrosis. Patients with an eGFR <30 mL/min/1.73 m^2 will require prior intravenous normal saline infusions before and after the CTA to prevent CIN.

Magnetic Resonance Angiography (MRA)

MRA is a useful non-invasive technique for arterial imaging of the lower limb. It provides useful imaging of the distal tibial arteries and is easier to interpret compared to CTA especially in severely calcified arteries. MRA requires Gadolinium contrast and may not be suitable for patients with chronic kidney disease (CKD) and renal function impairment who are susceptible to contrast induced nephropathy (CIN). MRA is also contraindicated in patients with cardiac pacemakers, implantable cardioverter defibrillator (ICD) devices and metallic implants such as cerebral aneurysm clips and cardiac metallic heart valves. A small proportion of patients are also MRI intolerant due to claustrophobia. It is important to appreciate that turbulent blood flow within diseased or stented arteries may sometimes cause a loss of signal and thus an overestimation of disease severity when using MRA imaging.

Invasive Vascular Imaging

Digital Subtraction Angiography (DSA)

Pragmatically the mode of imaging used is often dictated by local availability and expertise but in our opinion a DSA is essential to planning successful bypass surgery in diabetic patients. DSA remains the gold standard in pre-operative vascular imaging and provides accurate information about the tibial arteries even the pedal arch in the foot. Due to the availability of non-invasive imaging, a DSA is usually performed in conjunction with concomitant endoluminal intervention or if the anatomy or disease severity of the best arterial target vessel for intervention remains unclear after CTA or MRA. DSA is contrast mediated and diabetic patients with CKD and renal impairment will require prior intravenous normal saline infusion before and after the DSA in order to avoid CIN. Access for angiography is often obtained via a 4F sheath through the common femoral artery in the patient's groin. There is a small risk of complications such as bleeding or false aneurysm formation at the site of access. DSA allows accurate assessment of the deep plantar arch vessels and identification of the best artery in communication with this arch across the ankle joint.

Principles of Revascularisation

In our practice, the patient's clinical findings and results of their arterial investigations and vascular imaging are discussed in a multidisciplinary meeting prior to making the final decision regarding the optimal approach to revascularisation of the limb. The patient's fitness and co-morbidities are reviewed as a whole so as to assess the surgical risks involved and their suitability for either endoluminal intervention or open surgical bypass. This section will discuss the pre-treatment patient workup and optimisation, operative planning and consent and the techniques of surgical bypass or endovascular therapy and finally post-operative follow up and surveillance.

Pre-treatment Workup

The majority of diabetic patients with PAD will also have ischaemic heart disease, renal impairment and respiratory disease and these must be taken into consideration before proceeding with treatment. A patient presenting with foot sepsis is also likely to have grossly elevated blood sugar levels and will require optimisation of glycaemic control. Acute severe sepsis in the diabetic foot is a surgical emergency requiring early diagnosis and urgent debridement and drainage of sepsis. This is paramount to foot preservation and successful limb salvage with subsequent revascularisation. The patient should be started on broad spectrum intravenous antibiotics and deep tissue cultures including bony specimens sent to microbiology to allow more specific targeting of antimicrobial therapy. An anaesthetic review is required for optimisation of the patient's co-morbidities in order to stratify their risk from intervention for revascularisation so that a fully informed consent process can take place prior to treatment. It should always be borne in mind that symptomatic palliation with or without primary amputation is a valid and acceptable treatment option. This may be in the patient's best interests if the risks of intervention are unacceptably high in frail, unfit patients or if there is extensive irreversible tissue loss extending into the proximal foot and calf.

Poor glycaemic pre-operative control is associated with a higher mortality and morbidity in diabetic patients. All patients undergoing revascularisation should have their HbA1c levels checked for an indication of long-term glycaemic control over the preceding 2–3 months. Multidisciplinary team input is needed to the gauge severity of the PAD and foot disease, urgency of intervention and whether it is worthwhile delaying surgery to improve glycaemic control. In the acute setting rapid stabilisation of the patient's blood sugar levels using sliding scale infusions of insulin is needed but must be monitored and adjusted appropriately with the patient transferring to a more formal insulin regime as early as possible. Any

renal impairment should also be identified and optimised prior to intervention. Patients who are undergoing renal replacement therapy are a high-risk group and are three times more likely to die following a surgical bypass procedure compared to those without renal impairment. Early renal review with input from renal medicine is therefore advised. Patients with renal replacement therapy requirements should only undergo surgical revascularisation if there are onsite renal replacement facilities such as haemodialysis available. Likewise, patients with symptomatic cardiac disease will require urgent cardiology review and an ECG and cardiac echocardiogram prior to definitive treatment. It is also often possible to perform revascularisation with a regional anaesthetic if patients have severe respiratory disease.

The vascular anaesthetist should review the patient before treatment can proceed. Ideally this assessment should occur in advance before the day of planned intervention to allow anaesthetic recommendations to be implemented in the preoperative period. In particular new beta-blockade should not be started immediately before surgery but if required at least 6 weeks prior to commencing surgery. Many diabetic patients with extensive tissue loss cannot wait 6 weeks and this reinforces the need to involve anaesthetic colleagues early in the process for guidance and advice.

Surgical Bypass

Open surgical bypass to the distal tibial vessels or the pedal vessels remains the gold standard for revascularisation in diabetic limb salvage. The principle aim of open surgical revascularisation is the restoration of 'straight line" pulsatile blood flow to the foot via a native anatomical tibial artery crossing the ankle joint but not via collaterals. If "straight line" blood flow can be achieved the patient stands the best chance of wound healing with an 85% limb salvage rate at one year [5]. Longer term follow-up data for surgical bypass shows that durability for target vessel patency and limb salvage rates are superior to endovascular techniques. However surgical bypass procedures are often time consuming with longer inpatient stays and in-hospital morbidity and mortality is higher than endovascular intervention.

Therefore, unfit patients who are not suitable candidates for surgical bypass should be considered for an endovascular approach. Most open surgical bypass procedures are done under a regional anaesthetic which also allows for foot tissue loss debridement following revascularisation at the same sitting. Patients usually stay for 5–10 days post-operatively and require extensive physiotherapy and occupational therapy input in order to regain lower limb function.

Figure 9.1 is a flow chart outlining the decision-making steps that should be considered when managing a diabetic patient with a foot ulcer.

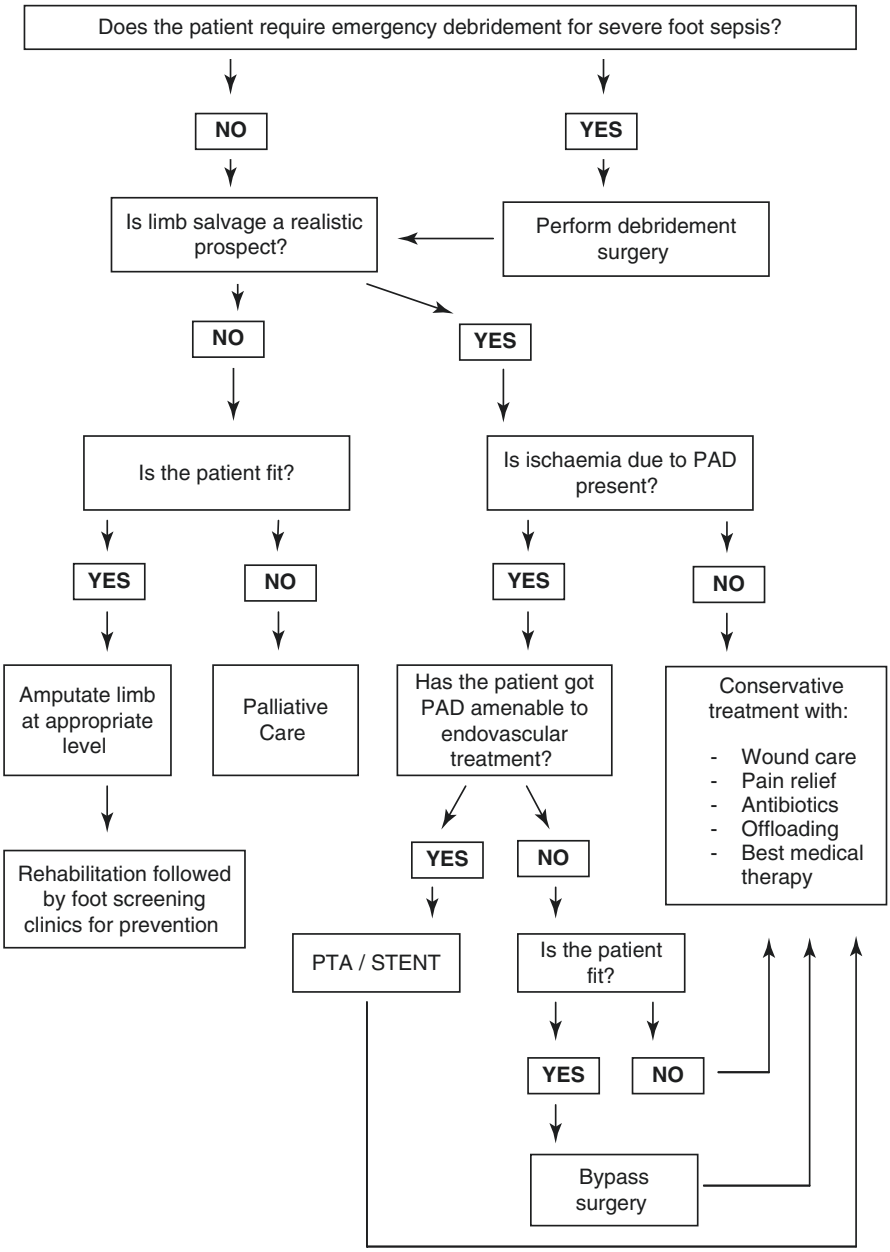

Fig. 9.1 Algorithm for revascularisation in diabetic limb salvage

Choice of Bypass Conduit

There are three choices when considering a conduit for bypass surgery. By far the superior choice is the patient's own vein as outlined by the BEST-CLI study findings. Second is synthetic man-made grafts composed of either ring supported 'Dacron' or ePTFE. Both will usually be reinforced on the outside with spiral plastic supports to prevent kinking. A recent development are ePTFE grafts 'rifled' on the inside to produce spiral flow of blood within the conduit to reduce neointimal hyperplasia at the anastomoses and increases longevity. Although early results for these grafts are encouraging no long-term data exists at present. The final option is cadaveric vein that has been cryopreserved after harvest from a post-mortem donor. Cadaveric vein use in the UK has been limited, largely due to cost and the limited outcome data available.

A pre-operative duplex scan for vein mapping is essential as it allows the assessment of the venous conduit quality (>3 mm is considered acceptable) and also aids accurate intraoperative conduit harvesting avoiding complications with skin flap necrosis. Vein is the preferred gold standard conduit for bypass procedures as they have more durable patency rates and are less likely to suffer infection compared to prosthetic Dacron or ePTFE conduits. As well as the greater saphenous vein and the short saphenous vein, the basilic and cephalic arm veins can also be harvested to good use.

The Inflow Vessel

The proximal inflow vessel must be as disease free as possible and is usually the infra-inguinal common femoral artery but it can be derived from the supra-inguinal external iliac artery or the infra-inguinal Profunda Femoris or superficial femoral artery. In diabetic patients it is often possible to perform shorter bypasses using the popliteal artery behind the knee as an inflow vessel. This obviates the need for a longer venous conduit required to perform femoral distal bypass with equally good long-term results achieved for the shorter bypasses. In some patients, angioplasty and stenting of the iliac arterial segment may be required beforehand to allow the use of the common femoral artery as the inflow vessel. This can be performed before bypass surgery as a staged procedure or concomitantly as a hybrid combined open with endovascular revascularisation (COWER) procedure.

The Outflow Target Vessel

The distal outflow target vessel for graft anastomosis is typically the most disease-free tibial artery identified on angiography. Ideally it should cross the ankle into the plantar pedal arch to provide a realistic chance of ulcer healing. The distal outflow target vessel can be the popliteal artery above or below the knee or the best quality

infra-geniculate tibial artery crossing the ankle joint which may or may not be in continuity with the plantar pedal arch in the foot. The nomenclature of lower limb bypass surgery reflects this.

Popliteal target—femoro-popliteal bypass
Tibial vessel target—femoro-distal bypass
Plantar pedal arch target—femoro-ultra distal bypass

Technical Considerations During Bypass Surgery

The small size of distal target arteries makes the anastomosis in fem-distal bypass more technically challenging with a greater chance of early failure from surgical error. Wherever possible the most proximal landing zone in the target vessel should be used. Magnifying surgical eyewear e.g. Loupes should be worn by the operating surgeon performing the distal anastomosis. This enables accurate small evenly spaced suture bites to be taken and the identification of debris or small intimal flaps that will doom a graft to be cleared.

Prior to venous conduit harvesting it is helpful to mark the course of the vein pre-operatively using ultrasound to facilitate accurate skin incisions during vein harvest and also to confirm the vein size (>3 mm in diameter ideally) and that the quality of the vein is free from thrombophlebitis. The greater saphenous vein (GSV) is most commonly used and arises in the foot and passes anterior to the medial malleolus at the ankle ascending the leg medially and superficial to the muscles within its own facial envelope and before diving deep in the groin to join the common femoral vein at the sapheno-femoral junction. The GSV is 'harvested' or disconnected from the venous system and instead used to carry higher pressure oxygenated arterial blood distally. Over time the thin walled GSV becomes 'arterialised' to the point that at revision surgery it can be difficult to tell a vein graft from a native artery. Vein grafts are more infection resistant and more durable compared to prosthetic grafts. An infected graft is usually a complication associated with limb loss for the patient as revision surgery is often difficult and risky. Vein grafts do not develop the impervious bio-layer of bacteria that an artificial graft does making antibiotic treatment feasible in the first instance. Occasionally the contralateral greater saphenous vein or the basilic and cephalic veins in the arm are harvested as conduits in preference to prosthetic grafts. If an individual segment of vein is not of sufficient length to complete the bypass then two or even three segments of vein can be harvested and 'spliced' together to produce one long conduit. Veins taper up in size from 2 to 3 mm at the ankle to around 8–10 mm at the sapheno-femoral junction in the groin as more tributaries drain into them. They also contain one-way valves that prevent blood returning to the foot under the effects of gravity when a patient is upright and stationary. These two points must be borne in mind when deciding on how to anastomose the vein graft onto the arteries. If the vein is reversed in direction to counter the effects of the valves a size mismatch occurs with a large diameter artery proximally but a small diameter vein and vice-versa at the distal

end. This can usually be corrected for in the popliteal segment but more distal than this and it can be technically challenging to join a 10 mm diameter vein graft to a 2 mm tibial artery. In these cases, it may be preferable to leave the vein 'in-situ' but pass a valvulotome instrument down the vein that cuts and destroys the valve leaflets allowing reverse flow of blood within the vein. There are no differences in long term outcomes between reversed or in-situ vein techniques for bypass. An in-situ bypass may help to avoid a size mismatch between smaller target vessels and the venous conduit but may take slightly longer to harvest and prepare with a valvulotome. There is also a small risk of injury to the venous conduit as the valvulotome is passed. The authors recommend using an expandable valvulotome which can prepare vessels as small as 1.5 mm in diameter.

The decision to perform either a reversed vein bypass or an in-situ vein bypass boils down to surgeon experience and choice. We favour the in-situ technique for distal bypass onto the tibial vessels and reverse vein grafting in the more proximal popliteal or tibio-peroneal trunk. At the end of any revascularisation procedure, it is important to quality control the operation by ensuring the aim of increasing perfusion to the foot has been achieved. This consists of a visual examination of the foot to confirm it has 'pinked up' with capillary refill combined with a handheld Doppler check for flow in the vessel distal to the graft. You must be prepared at this stage to explore a graft that is not running as a small intimal flap or thrombus blocking the graft can be easily rectified. Occasionally an on-table angiogram maybe necessary to establish if or why a graft is not running and it is standard practice in our unit to have the patient on an x-ray compatible operating table.

If wound debridement or minor amputation is needed then the surgical wounds should be completely dressed and the foot re-prepared and draped before this takes place to protect against surgical site infection.

Other non-bypass surgical procedures for groin level PAD such as femoral endarterectomy and patchplasty may also be performed as a hybrid procedure in combination with either retrograde angioplasty and stenting of the ipsilateral iliac inflow artery or antegrade downstream angioplasty and stenting of the femoral and popliteal run off vessels.

Endovascular Therapy

The use of endovascular techniques either exclusively or in combination with open surgical bypass should form part of the modern armamentarium for revascularisation for multidisciplinary diabetic limb salvage teams. Endovascular therapy consists of balloon angioplasty to restore luminal patency in a diseased artery and the placement of stents to keep a diseased artery patent via a percutaneous approach. Although there are risks associated with angioplasty and a tenting such as contrast allergy, CIN and complications associated vessel related injury at the access site and the treated target vessel, endovascular therapy is now the preferred choice of treatment in the more elderly and unfit patient. In general, endovascular therapy is

associated with lower morbidity and mortality rates and improved in hospital length of stays with most cases feasible as day cases even in diabetic patients. There is now greater enthusiasm and advocacy for an endovascular first approach if there is anatomical equipoise between open bypass surgery or endoluminal therapy even with patients fit for bypass surgery, but this consideration must be balanced by the BEST-CLI study findings that bypass surgery is a good strategy when there is a good venous conduit in a medically fit patient.

It is unusual for above knee level SFA disease to require a surgical bypass due to the rapid advances in the endoluminal therapeutic options available. Angioplasty of the SFA and popliteal segment can be achieved either via a subintimal or intraluminal route. This is often combined with concomitant SFA stenting and long term dual antiplatelet therapy for improved outcomes. Recent advances in the endovascular armamentarium include retrograde vessel access, dedicated wires and catheters for intraluminal crossing of challenging disease, debulking options for vessel preparation such as atherectomy devices and intravascular lithotripsy for severely calcified disease.

Proponents of an "endovascular first" approach to treating PAD in diabetic patients state that even if initial endoluminal therapy fails, it is still often feasible to salvage the limb with a subsequent surgical bypass procedure [6].

Advances in guide wire, balloon and stent technologies have allowed the expansion of indications for endoluminal therapy in infra-geniculate arterial disease. The advent of novel endoluminal therapies such as drug eluting balloons, drug eluting stents and even bioabsorbable stents have produced short term data for target lesion restenosis rates that are less than 10% at 12 months. However, a lack of longer-term data regarding clinical outcomes such as wound healing rates and limb salvage rates means that the outcomes of these fast-evolving therapies should be recorded in registries and future endovascular research studies should include clinical and quality of life outcomes in addition to vessel patency measures.

Post-operative Surveillance and Follow Up

Regular surveillance of a surgical bypass graft is essential for the early detection of haemodynamically significant graft threatening stenosis with a peak systolic velocity ratio (PSVR) of more than 2.5. These usually occur at the proximal and distal anastomoses as a result of neointimal hyperplasia but can occur within the graft itself. The narrowing reduces flow velocity within the graft and ultimately will lead to thrombosis and graft occlusion. Identification of haemodynamically significant lesions at an early stage allows them to be angioplastied thus preserving the graft, a process called assisted primary patency. There is debate as to the frequency with which these surveillance scans should be performed but we would suggest every 6 months for the first 2 years and then annually thereafter. In addition to regular graft surveillance, it is essential that patients be advised to stop smoking and they be

prescribed a statin and anti-platelet medication provided there are no contraindications. Risk factor modification and best medical therapy will play a vital role in preventing the patient representing with further critical ischaemia.

Novel Concepts in Revascularisation

Advances in endovascular access have also led to the feasibility of retrograde pedal access for infrageniculate tibial arterial disease or retrograde popliteal artery access for long length Superficial Femoral artery disease. These arterial access techniques will help to expand the indications for endovascular therapy in otherwise previously inaccessible lower limb arterial disease.

Recently there is increased advocacy for revascularisation of the target vessel feeding the relevant angiosome with tissue loss. Data from studies supporting this angiosome concept of revascularisation in the diabetic foot suggests that ulcer healing may be speeded up if blood flow in the relevant infrageniculate tibial artery disease is improved. Those who argue against the angiosome concept point to the greater importance of ensuring that the target vessel is in continuity with an intact deep plantar arch to support the durability of any surgical bypass or endovascular procedure for infrageniculate arterial disease [7, 8].

Of late, there has been increasing interest in the role of deep venous arterialisation as a final resort for limb salvage in the "no-option" patient cohort for conventional revascularisation techniques. In the absence of a conventional arterial target vessel for revascularisation, the lower limb deep venous system is arterialised either with an open technique or via a percutaneous deep venous arterialisation (PDVA) procedure with intentional destruction of the deep venous valves to help support arterial flow. Outcomes are mixed and there is not enough data to support the routine use of this technique for diabetic limb salvage [9].

Autologous stem cell therapy is also an exciting area of promise for the treatment of ischaemia in the diabetic patient with tissue loss and no treatment options left for revascularisation either via endovascular therapy or surgical bypass. Following stem cell therapy improvement is seen in $TCpO_2$ measurements and in patient reported pain scores. A lack of convincing limb salvage data to date means that stem cell therapy remains a research tool with conventional methods of revascularisation remaining the main stay of treatment for diabetic patients with tissue loss and PAD.

Finally, it is important for clinicians to classify their patients according to severity of arterial disease clinically (e.g. Rutherford classification) and anatomically (e.g. TASC classification) together with classification of the degree of severity of foot tissue loss and the presence of infection in order to allow meaningful comparison of outcomes for future studies comparing different modalities of treatment for PAD in the diabetic foot patient. The authors recommend the validated WIfI classification which assesses wound depth, ischaemia and infection. It has been shown to be a useful predictor of amputation risk and identifies the potential benefit of revascularisation in at risk patients.

Key Points

- Early and accurate assessment of arterial limb perfusion using clinical examination, toe and ankle pressures, $TcPO_2$ and non-invasive imaging modalities is vital for successful diabetic limb salvage.
- A diagnostic digital subtraction angiogram (DSA) is essential for planning distal arterial bypass surgery
- Emergency surgery for the debridement of severe foot threatening sepsis and tissue loss should be prioritised before limb revascularisation.
- Extensive infra-geniculate tibial PAD is best treated with surgical bypass in fit patients with a good quality venous conduit and distal target arterial vessel with endovascular therapy reserved for higher risk patients. Treatment should be expedited as delays to revascularisation lead to adverse limb outcomes.
- Post treatment surveillance should include optimisation of best medical therapy no matter what form of revascularisation was used. Haemodynamic assessment of vein bypass grafts with duplex scanning is vital to detect and treat graft threatening problems early.

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Chapter 10
Amputation Below the Ankle: How to Ensure the Best Outcome for the Patient

Hani Slim and Venu Kavarthapu

Since limb function following a minor amputation is often dictated by the level of tissue loss in the foot, care should be taken to preserve the remaining viable foot and achieve good stump healing in order to provide the patient with optimal standing balance in comfortable footwear. This in turn results in a reduced risk of foot ulceration and a better quality of life. Therefore, careful assessment on the extent of tissue loss and its effect on foot mechanics, and planning of the procedure are required, while taking into consideration the patient's expectations and functional requirements.

Contrary to a major lower extremity amputation where the resection levels are agreed, minor amputation levels vary widely depending on the clinical presentation. Even though, there is a wide spectrum of presentations that warrant a minor amputation, a standard set of principles are applicable that help the clinician chose the correct level and technique. Minor amputations, defined as amputations below the ankle level, are important surgical procedures when indicated, as they can prevent a major limb loss and provide the patients with the best functional outcome to maintain their independence. Minor amputations carry less post-operative mortality in comparison to a major amputation. Contrary to a major amputation that carries a high 30-day mortality in the elderly population of up to 17.5% [1] and 1 year mortality rate of 66% [2], minor amputations, especially when done under local anesthesia have a significantly low mortality level. In this chapter we focus on the presentations, assessment and principles of surgical treatment when performing a diabetic foot minor amputation procedure.

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Common Causes of Minor Amputation in Diabetic Foot

The incidence of minor foot amputations is 10–15 times higher in people with diabetes mellitus (DM) compared to those without [3]. Although the leading causes of minor amputation are related to neuropathy and ischaemia, other presentations include infected ulcer, non-healing ulcer, osteomyelitis, diabetic foot attack, severe toe deformities, Charcot neuroarthropathy (CN) resulting in deformity and or instability, deformed forefoot not amenable to offloading, severely infected ingrown toenail, burn injuries (common in winter in patients with diabetic neuropathy) and chronic fungal infection of toenails. Patients with such pathologies often present late to the treating clinician, frequently due to the lack of adequate primary care or access to specialised units with multi- disciplinary teams (MDT). An MDT is ideally placed to perform a detailed assessment, determine the cause behind the tissue loss, plan management and consider the degree of urgency needed for the intervention.

Most minor foot amputations are performed on patients with a diabetic foot problem [4]. Although a regional variation is noted, most of these procedures are done by general, vascular, or orthopedic surgeons (particularly those sub-specialising in foot and ankle surgery); in some countries, physicians, podiatrists and podiatric surgeons deliver this treatment. There are three broad categories of indications for amputation of any body part, as described below [5].

1. Dead
2. Deadly
3. Dead loss

A “dead” distal part of the foot is directly related to completely infarcted tissue which results in dry gangrene. This is a common complication of diabetic foot syndrome due to a combination of macrovascular and microvascular disease [6].

The “deadly” category generally refers to a process that can result in life-threatening systemic sequelae if untreated in a timely manner. As such, this constitute a true surgical and medical emergency and dealing with it should be prompt due to a potential limb and life-threatening situation. The presentations in “deadly” category include:

– Diabetic foot attack
– Wet Gangrene
– Gas Gangrene
– Necrotising fasciitis
– Foot Abscess

A “dead loss” is when the foot part is diseased to the point where the tissue is irreparable due to sepsis (as with chronic osteomyelitis) or ischaemia [7], if it ceases to be functional (as with significant trauma or severe bone loss), or it impedes the function of the limb (as with neuropathic pain).

Before any amputation, the clinician should ensure that the patient’s medical comorbidities have been optimised, with a particular emphasis on glycaemic control, cardiovascular support, infection control and revascularization (in the presence of ischaemia).

Minor amputation involves resection of distal part of foot by performing a disarticulation through a joint or osteotomy of a bone. The method of resection and the level of amputation depends on the extent of the disease and the anatomy involved. As such the degree of postoperative functional loss is generally proportional to the amount of tissue taken. The great toe is considered the most important of the toes in functional terms. Nevertheless, great-toe amputation can still be performed with little resulting functional deficit [7, 8] if certain principles are adhered to.

History

Detailed present and past medial history with an emphasis on the acuity of presentation, duration, progression, and any rapid deterioration is taken. Previous surgeries, especially revascularisation or orthopaedic foot reconstruction procedures should also be noted.

Specific history of vascular ischaemic symptoms such as claudication or rest pain should be carefully excluded. Emphasis should be made to distinguish acute limb ischaemia from the infected and chronically ischaemic foot. Acute ischaemia (pain, pulselessness, perishing cold, paresthesia, paralysis and pallor) should prompt immediate referral to a vascular unit for emergency revascularisation. Where there is tissue loss secondary to chronic foot ischaemia with symptoms of progressive claudication and rest pain and clinical signs of extensive atrophic skin and nail changes such as shiny dry skin, thickening of the toenails, open sores, skin infections, long standing ulcers and dry gangrene, it is indicative of a slow deterioration due to occlusive arterial disease that requires a planned revascularisation rather than an emergency procedure. In such cases the minor amputation can be delayed, if the clinical presentation allows, until after the revascularisation to ensure adequate tissue healing response following the amputation procedure.

Any history of fever or rigors and clinical signs of spreading redness, swelling and tenderness, along with evidence of local tissue loss or purulent discharge should raise the possibility of a diabetic foot attack. On the other hand, a history of change in foot shape is indicative of loss of mechanical integrity of the bone and joints in the foot. The foot shape can change acutely due active CN or trauma, or slowly and progressively due to muscle imbalance from motor neuropathy or tendon contractures.

Medical Assessment

Patients with DM presenting with complicated foot infection often present with challenging medical comorbidities. The prevalence of ischaemic heart disease in patients with diabetic foot ulcer (DFU) ranged from 6.83 to 60.61% with a pooled mean of 25.85% (95% CI, 24.28–27.32%) [9]. In addition, up to 40% of patients with DM are expected to develop chronic kidney disease (CKD), with 19–34%

expected to suffer from DFU during their lifetimes [10]. A thorough and detailed medical assessment in an MDT set up is conducted to identify, assess and optimise the medical comorbidities, where possible, prior to the surgical procedure.

Foot Examination

General foot examination includes the assessment of the tissue loss,infection, foot deformities, neuropathy and vascular status. Care should be taken to identify any deadly pathologies. In the presence of spreading cellulitis, the erythematous area with swelling usually feels firm to touch indicating reactive tissue oedema or deep-seated abscess. This can be associated with skin crepitus, scolding of tissues, dark blotches on the skin that turn into fluid-filled blisters and malodor. The foot infection often spreads proximally along the tendon sheaths. The clinical examination should include palpation along the course of tendons for tenderness and swelling. The presence of spreading cellulitis, swelling and tenderness along the course of tendons may be indicative of a 'deadly' category and warrant prompt and thorough assessment for possible emergency surgical exploration, debridement, and a minor or major amputation. The MDT team foot assessment should include adequate examination of vascular status, peripheral nerves including motor function and tendon contractures, and associated foot deformity, including features consistent with a CN.

Investigations

In addition to performing a full set of observations, the following clinical investigations are routinely performed:

Capillary blood glucose
HbA1c
Full blood count
Renal and liver function tests
C-reactive protein
Blood cultures

Wound tissue specimens of Ultrasound guided aspirates from the infected area for microbiology analysis.

Imaging: Foot radiographs are routinely obtained in the dorso-plantar and oblique views. However, if possible, weight bearing dorso-plantar, weight bearing lateral and non-weight bearing oblique views of the foot are performed in all patients for a more detailed mechanical assessment of the foot. The foot radiographs will

reveal the presence of bone destruction, soft tissue swelling, foot deformity and gas in the soft tissues. If deep soft tissue collection is suspected, ultrasound examination will not only identify this, but also allow aspiration of the fluid for microbiological analysis. If time permits, an MRI imaging of the foot and ankle can identify the presence and spread of infection in the soft tissues and the underlying bone parts.

Vascular investigations: All patients with a history of diabetes presenting with tissue loss, even with palpable foot pulses should undergo an urgent formal vascular assessment such as arterial duplex ultrasound scan, to rule out peripheral arterial disease (PAD). CT/MR angiogram will only be required in certain individual cases where arterial duplex scan cannot be done. We do not recommend the use of ankle brachial pressure measurement (ABPI) in these group of patients as it has been shown that APBI is often falsely raised due to heavily calcified crural vessels, particularly in those with diabetes and chronic kidney disease [11, 12]. Another reason is that a high proportion of patients with such presentations suffer from infra-malleolar level ultra-distal arterial occlusive disease that otherwise cannot be detected with ABPI but can be revealed on a duplex scan.

Medical Management

It's important to realise that most patients with diabetes have an underlying plethora of medical comorbidities. The prevalence of diabetic kidney disease particularly, in type 2 diabetes mellitus (T2DM) ranges between 25% in patients younger than 65 years old to nearly 50% with age older than 65 years [13]. Globally, overall cardiovascular disease (CVD) affects approximately 32.2% of all persons with T2DM [14]. To complicate things further a significant number of geriatric patients with diabetes have underlying malnutrition [15]. Associated medical comorbidities contribute to poor outcomes following minor amputations and need to be optimised to reduce surgical complications and ensure quick post-operative recovery.

Timing of Minor Amputation

The timing of the surgical procedure is crucial for not only ensuring successful outcome, but also rapid healing and recovery.

There are two basic categories that determine the speed of intervention.

(a) The deadly category conditions that present with tissue loss and spreading foot sepsis. Such presentation in the background of diabetes is labelled as 'diabetic foot attack' [16]. This is a true surgical and medical emergency where aggressive foot debridement should be done promptly due to the potential limb and

life-threatening situation. Diabetic foot attack should be considered during the following clinical presentations:

- Foot abscess
- Wet gangrene
- Gas gangrene
- Necrotising fasciitis.

(b) The dead or dead loss categories often present with slow deterioration of tissue loss with or without a background ischaemia. In such cases the minor amputation can be done as a planned urgent procedure after reversing or improving the underlying ischaemia.

Technical Considerations

Foot Anatomy and Biomechanics

Based on its anatomy and function, the foot is divided to hindfoot, midfoot and forefoot. The hindfoot include talus and calcaneus, and the joint between these bones is the subtalar joint. This joint contributes to the inversion and eversion movements of the foot. Midfoot includes the navicular, cuneiforms and cuboid, and these contribute to the transverse plantar arch of the midfoot. Midfoot articulations work with the subtalar joint and contribute to the midfoot and hindfoot flexibility during wright bearing and parts of the gait cycle. The forefoot includes the metatarsals and phalanges. The shape of the body of proximal phalanx is similar to the metatarsals in being convex dorsally and concave on the plantar side. The articular surface of the base of proximal phalanx is concave for articulation with the metatarsal head, whereas the distal part has a trochlear surface for articulation with the phalanx distal to it.

The foot mechanically is divided into three columns. The medial column includes the first metatarsal, medial cuneiform, and navicular. This column is a slightly flexible unit and takes most of the weight while standing. The middle column is rigid and includes the second and third metatarsals, middle cuneiform and lateral cuneiform. The fourth and fifth metatarsals articulate with cuboid to form the lateral column which is very mobile and allows for flexibility when walking on uneven ground. The medial column is the main contributor of the medial longitudinal arch.

The load bearing in the foot is through the heel posteriorly and the balls of the large and little toes anteriorly, forming a tripod that provides better stability and load distribution [17].

As such some important anatomical and biomechanical points need to be considered during minor amputations as given below:

- The ankle Joint. Utmost care should be taken not to expose the ankle joint while performing debridement for foot infection, as any possible infection spread to the ankle as a result can lead to a major amputation.

- The Heel. It plays a very important role in load bearing, as the first contact point to the ground during the gait with the foot landing on the posterolateral aspect of the heel. In addition, the plantar heel pad has a key role in weight transmission and load dissipation. Hence, it is extremely important to protect the heel to maintain the integrity and functionality of the foot.
- The big toe with the first metatarso phalangeal joint is important for foot stability and forefoot function. The main function of the big toe is to direct body weight through the foot in the direction of travel [18]
- The peroneus brevis tendon is attached at the base of the fifth metatarsal that provides forefoot abduction movement and resists foot supination. A minor amputation that includes the base of the fifth metatarsal bone defunctions peroneus brevis leading to a progressive forefoot adduction deformity. Hence, it is recommended to perform a peroneus brevis tendon transfer in such situations, where the tendon is inserted into cuboid or base of fourth metatarsal, in an effort to provide continued balance between the supinatory and pronatory muscle forces [19]
- Achilles tendon tightness is noted in some chronic presentations. It is important that the tendon lengthening is performed at the time of minor amputation procedure to improve the foot alignment and reduce forefoot overload.

Preprocedural Planning

The minor foot amputation should be performed at a level that makes an anatomic sense, preserves load bearing ability of the foot and minimises the risk of further surgical interventions. Each minor amputation should be planned individually according with the location and extent of the tissue loss. The following principles are followed in all cases,

Equipment

The materials required for toe amputation include the following:

– Skin marker pen
– Povidone-iodine, chlorhexidine, or a similar surgical disinfectant
– Scalpel with No. 15 blade for toe amputation and 10 blade for larger minor amputations such as transmetatarsal amputations
– Heavy toothed forceps
– Bone cutter, such as Jacobson or Liston bone cutter that comes with sharp edges and small blade.
– Bone nibbler
– Curette

- Diathermy
- Absorbable and non-absorbable suture materials such as vicryl and Nylon for wound closure
- Needle holder
- Dressings (including gauze, bandages)

Patient Preparation

- Informed consent is obtained for the planned debridement and minor amputation.
- Antibiotic should be considered for each individual case. For cases requiring intravenous (IV) antibiotics, and when prior microbiology culture sensitivities are not available, we recommend empirical antibiotic therapy of IV Tazocin 4.5 g 8 hourly for patients with diabetes with normal kidney function or 12 hourly when it is impaired. Alternatively, the local hospital guidelines for such clinical presentations can be followed when available. When microbiological culture and sensitivities are available from the intraoperative specimens, the antibiotics can be adjusted accordingly. After an appropriate period of intraoperative antibiotic therapy, the patient can be discharged on oral antibiotics, usually on Augmentin 625 mg 8 hourly. Suitable alternative antibiotics are chosen for patients with Penicillin allergy.
- Anaesthesia: It is understood that there is a wide variation on the choice of anaesthesia used for minor foot amputations. From our experience, the majority of minor amputations can be safely done under local anaesthetic ankle block. As most of the patients present with DM and associated comorbidities, avoidance of general anaesthesia is preferable whenever possible. However, even under local anaesthetic, patients should be monitored during the procedure and in post-operative recovery for any adverse effects such as bleeding from the amputation site. Those patients with suspected severe infections such as necrotising fasciitis or gas gangrene may require extensive debridement that requires extension to or above ankle level, and in these situations general anaesthesia may be a more appropriate.
- The patient is positioned supine, and a sandbag is placed under the ipsilateral hip for lateral column surgery. In the absence of proximal peripheral arterial disease, or any other contra-indication, the surgeon can choose to use a high thigh tourniquet during the procedure. Intra-operative fluoroscopy is useful for more proximal minor amputations.

The sterile field is set up so that the surgeon has access to the entire lower leg and foot on the affected side.

Surgical Techniques

Following the minor amputation procedure if the wound is clean, primary skin closure using interrupted nylon suture will achieve a quick and predictable healing and prevent further wound infection. Tension free skin and soft tissue coverage can

be obtained by removing an adequate amount of bone. Small case series have shown that primary closure following aggressive debridement and wound irrigation is better than leaving the wound open, even in the presence of infection [20, 21].

However, in actively infected cases, the wound can either be partially closed or left open. In such cases many dressing options are available. Small wounds are commonly managed with loosely packed alginate dressing, fibrillar hemostat agents, paraffin gauze or with dressing gauze soaked in saline or povidone-iodine. Cotton wool wrapping with or without crepe bandage can be applied. However, care should be taken for any adjacent bypass grafts so the dressings will not cause compression of the grafts and result in occlusion. Larger wounds are ideally managed with negative pressure wound therapy (NPWT).

Amputation of Toe

Incision lines are marked on the skin as appropriate for the planned amputation. In partial toe amputations, different types of skin flaps can be raised to help with the wound coverage. These include plantar-based flap (Fig. 10.1), dorsal flap, side-to-side flap, fish-mouth flap and occasionally a toe filleting flap from a healthy distal part of the toe or the adjacent toe that might help cover a larger defect. It is critical to ensure that the flap is viable before closure and perform a tension-free closure. For a disarticulation or a transmetatarsal amputation, a long plantar flap is the best choice.

All necrotic tissue should be debrided back to healthy bleeding surfaces. If infection is present, the tendon sheaths must be drained from any possible purulent material and thoroughly washed with normal saline or 50% diluted iodine solution. Samples should be sent for microbiology culture and sensitivity testing.

Dissection is carried down to the periosteum, and a bone cutter or pneumatic saw is used to perform the osteotomy at the appropriate level. It is important to be mindful of tendon insertions and to consider the biomechanical effects that sacrificing these will have.

Disarticulation of Toe

Dissection is carried down to the joint capsule, the capsule is completely incised, and the distal segment is removed. For amputation of one of the medial two toes, preservation of the base of the proximal phalanx is beneficial, but for different reasons in each toe. In amputation of the big toe (hallux) toe, preservation of the base of the phalanx preserves the flexor hallucis brevis insertion and function, and this helps to maintain stability during terminal gait phase [22]. In a second-toe

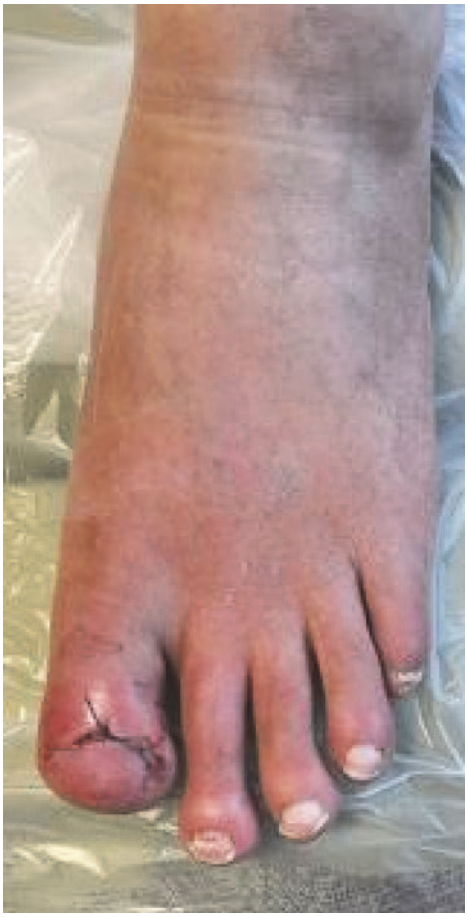

Fig. 10.1 A clinical photograph showing a partial amputation of hallux with primary wound closure done using a plantar flap

amputation, the retained segment helps maintain the position of the hallux and prevent the development of secondary hallux valgus.

For the lateral three toes, virtually no functional loss is experienced with either partial amputation or disarticulation, and foot architecture is minimally disturbed [23].

Classically a bone nibbler is then used to smoothen the surface of the remaining bone and remove any sharp edges. It is the common practice of the authors to excise the hyaline cartilage of the metatarsal head since the cartilage is avascular and its presence may delay wound healing. However, we acknowledge that some authors prefer not to remove the hyaline cartilage.

Neurovascular bundles are ligated or cauterised as they are dissected. Before closure care should be taken to remove any devitalized or foreign material such as bone wax, bone chips, excessive amounts of suture material, fascia or tendon to improve stump healing and prevent wound infection.

Ray Amputation

The operation is tailored to the removal of a single toe and its corresponding metatarsal. Ray amputation of the second, third or fourth toes results in a V-shaped defect between the retained metatarsals (Fig. 10.2a–c). The associated soft tissue defect is better managed with NPWT dressing. Ray amputation of the hallux disrupts the medial column of the foot and should be performed only after careful consideration. If there is skin loss on the plantar aspect of the head of first metatarsal, due to an infected ulcer, dorsal skin can be used to fill this defect (Fig. 10.2d). Ray amputation of the little toe may result in peroneus brevis dysfunction if the metatarsal resection is too proximal. A well performed ray amputation to the lateral four toes and their metatarsals in a V-shaped wedge flap is functionally superior to a transmetatarsal amputation [20].

Transmetatarsal Amputation

Transmetatarsal amputation is suitable when the toes are non-viable with little or no extension of the pathology to the midfoot [24]. A slightly curved dorsal incision is made at the level of the resection margin, with the plantar flap designed to extend more distally, just proximal to the plantar crease. This long plantar flap is later utilised for the wound closure. An osteotomy is performed through each of the metatarsals, between the neck and the base, depending on the extent of tissue necrosis. The metatarsal osteotomies are performed, using a narrow oscillating saw, in a parabola fashion such that the first and second metatarsals are of equal length, followed by about 5 mm shortening in each of the lateral metatarsals compared to its immediate medial one (Fig. 10.3a). Careful beveling of the metatarsal resected margins is done, particularly on the plantar side, medial and lateral cortices of the first and fifth metatarsals correspondingly, to prevent sharp edges and pressure

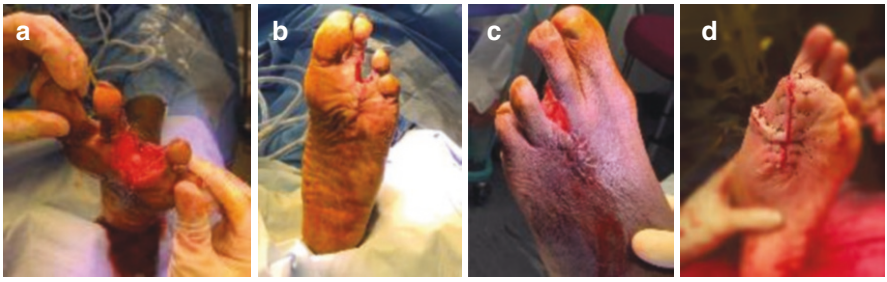

Fig. 10.2 (**a**) Clinical photograph showing a ray amputation of the third toe showing the V-shaped defect. (**b**) Clinical photograph showing partial wound closure on the plantar aspect. (**c**) Clinical photograph showing partial wound closure on the dorsal aspect. NPWT was applied. (**d**) Clinical photograph showing wound closure of first ray amputation using a dorsal flap

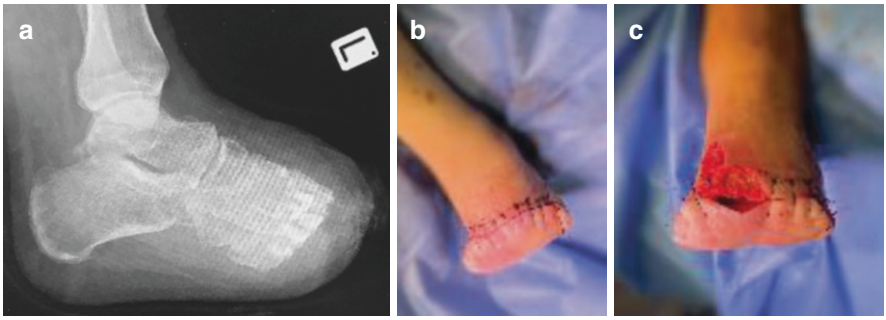

Fig. 10.3 (**a**) Post-operative lateral radiograph of the foot following a trans-metatarsal amputation at the proximal shaft level. In this case example, a local antibiotic eluting injectable calcium preparation was injected into the medullary cavities of all metatarsal stumps, to prevent recurrence of infection. (**b**) Clinical photograph showing complete wound closure of trans-metatarsal amputation stump using a plantar flap. (**c**) Clinical photograph showing partial wound closure of trans-metatarsal amputation stump using a plantar flap. NPWT was applied

areas. The long plantar flap is then rotated dorsally to and closed in layers after adequate debulking (Fig. 10.3b). If full skin closure is not possible, partial closure is performed and the residual wound is managed with dressings or NPWT (Fig. 10.3c). A concomitant Achilles tendon–lengthening procedure may be required to achieve a neutral position of the shortened foot. The Hoke's method of triple hemisection of the Achilles tendon and controlled lengthening can be performed using 3 percutaneous stab incisions over the tendon [25]. A well-padded below-knee plaster cast is applied to maintain the correction achieved with Achilles tendon lengthening.

Chopart Amputation

Chopart amputation is a minor amputation that removes the forefoot and midfoot from the hindfoot through the talonavicular and calcaneocuboid joints, saving talus and calcaneus. This surgery was named after François Chopart, a French surgeon who popularised this procedure because it essentially keeps the total length of the limb. This amputation results in an instability as most of the tendons which act around the ankle joint, apart from Achilles tendon, have lost their insertion into foot. The intact Achilles tendon results in a tendency to develop equinus or varus deformity. To prevent these deformities, Achilles tendon lengthening and transfer of tibialis anterior to the neck of talus is required. In addition, the extensor tendons can be carefully sutured to the metatarsal stumps and fascia and soft tissues of the sole of the foot.

Pirogoff, Boyd and Syme Amputations

These are less commonly performed minor amputation for infection in patients with diabetes.

The Syme's amputation is the most proximal minor amputation and involves resection through the ankle joint. Here, the ankle is disarticulated, and malleoli are removed, followed by suturing of the heel pad to distal tibia to allow load bearing. This procedure provides better energy efficiency than a transtibial amputation and can allow limited weight bearing on the stump without the use of prosthesis.

Pigeroff and Boyd amputations are suitable alternatives to Syme's amputation in certain situations. Both utilise part of the plantar heel pad to allow weight bearing. The Boyd amputation involves excision of talus and part of calcaneus, with preservation of plantar tuberosity of calcaneus along with plantar heel pad. The preserved calcaneal fragment is fixed to distal tibia, that can eventually allow some load bearing. A Pigeroff amputation involves excision of talus and part of calcaneus, with preservation of posterior calcaneal tuberosity along with its plantar heel pad attachment. The calcaneal tuberosity fragment is rotated 90° and fixed to distal tibia so that the fusion mass can allow some load bearing.

Complications

Common complications following minor amputations include the following:

- Bleeding—this often starts with early weight bearing mobilisation, leading to either active bleeding or a tense hematoma, sometimes necessitating wound exploration. Undrained haematoma can potentially form a nidus for infection and should be swiftly addressed
- Wound infection—If there are any concerns of possible spreading infection or deep collection, early wound exploration, debridement and repeat microbiology cultures are essential to achieve adequate infection control.
- Flap necrosis or flap gangrene—This is caused by interruption of the arterial blood supply to the flap or due to excessive tension in the flap closure. Providing the rest of the wound is not ischemic, management involves repeat debridement and excision of the non-viable flap and application of NPWT.
- Failure to heal—In such cases, a careful reassessment of the arterial blood supply should be considered, and any ischæmic causes should be corrected. Also, deep seated infections, such as undrained collections or remaining osteomyelitis need to be addressed.

Post Operative Management

Wound Management

Following the minor amputation, the patient is reviewed, and the amputation site inspected by the surgical and multidisciplinary team within 24–48 h, depending on the severity of infection at the time of amputation. Minimising post-operative limb oedema is very important in the healing process. Hence patients are instructed to keep leg elevated as much as possible and mobilise non-weight bearing for 2–4 weeks postoperatively. Some authors also caution against mobilisation if cellulitis is present [5]. Any underlying medical illness such as decompensated cardiac failure or renal failure should be addressed and optimised by the relevant subspecialty team. Other key aspects of wound management include:

- Infection control. Antibiotics should be targeted towards the pathogens isolated and repeated cultures should be obtained during regular clinic visits
- Adequate perfusion is essential in the healing process, and any occlusive PAD should be ruled out with repeat assessments, and corrected, if there is any delay in wound healing.
- Offloading of the operated leg is routinely followed to ensure rapid healing of the wounds and improve foot mechanics.
- Adequate control of blood glucose levels and optimisation of any other medical comorbidities are also critical.
- Larger wounds are ideally managed with negative pressure wound therapy (NWPT) (Fig. 10.4).

Long-term Outcomes

Achieving full wound healing and obtaining optimal foot mechanics are critical for better long-term outcomes following a minor amputation. However, well healed minor amputation stumps can still develop problems in the medium and long-term. As the peripheral neuropathy, and its associated mechanical problems, and vascular compromise are progressive in people with diabetes, the patients that undergo minor amputations should be monitored for any complications such as foot stump deformity or instability and new ulcerations requiring further amputation. Vassallo et al., showed that following toe amputations in patients with diabetes, 59.3% of participants underwent further surgery ($n = 31$ to revise the original amputation site and $n = 17$ to amputate a new site) at a 12-month follow-up, 45.7% of participants presented with a new ulcer at a different site. At 12 months, 80.2% of the study cohort had a completely healed amputation site, where as the mortality was 7.4% [26].

Regular visits to the foot clinic to be reviewed by the multidisciplinary team and podiatrist should be encouraged to ensure good wound healing and functional

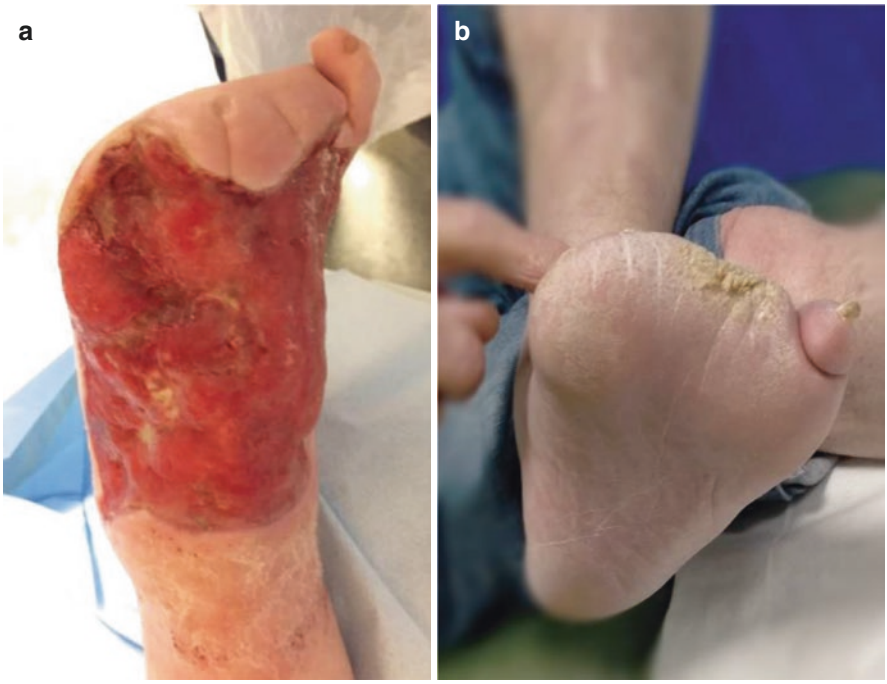

Fig. 10.4 (**a**, **b**) Clinical photograph showing 1st–4th toes amputation with extensive dorsal foot debridement, following treatment with NPWT and after complete healing

recovery. Also, regular inspection of foot ware by podiatric and orthotic teams and education on foot care is crucial to prevent further problems. In addition, patients should be encouraged to perform daily self-inspection of the minor amputation stump to detect the skin lesions at an early stage.

Summary

The number of minor amputations below the ankle has increased. These procedures can prevent the need for major amputation and give good functional outcome. The majority can be performed with local anaesthetic techniques with no mortality. However, to achieve optimal outcomes careful consideration of the extent of tissue loss and its effect on foot mechanics is required when planning the procedure which should be done in a multidisciplinary team setting. The method of resection and the level of amputation depend on the extent of the disease and the anatomy involved and any surgeon undertaking amputation below the ankle should be familiar with these techniques.

Key Points

- Minor amputation involves resection of the distal part of the foot by performing disarticulation through a joint or osteotomy of a bone.
- Indications for minor amputation include irreversible damage secondary to ischaemia, neuropathy, non-healing ulceration, infection including osteomyelitis and severe deformity.
- Careful pre-operative planning is essential and should be done within the context of an MDT.
- Understanding of the foot anatomy is essential to carry out appropriate the appropriate amputation and to achieve healing.
- Following healing of minor amputations patients should be seen regularly in the multidisciplinary foot clinic to ensure they gain good function and to prevent further problems.

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Chapter 11
Amputation Above the Ankle: Achieving the Best Outcome for the Patient

Tim Nash and Keith G. Jones

Who and When to Offer Amputation?

Diabetic patients present to primary, secondary, and tertiary care with a diverse range of complaints affecting the lower limb including chronic limb threatening ischaemia and fulminant diabetic foot sepsis. It is difficult to be prescriptive about who to amputate and when. Broadly amputation should be considered in the event:

- The patient's own limb is no longer viable and is a threat to life because of ischaemia or infection
- There is uncontrolled pain and alternative treatment such as revascularisation is not possible or feasible
- The patient's functional status will be improved with a prosthetic limb rather than their own

In the very acute situation of life-threatening foot sepsis, especially in clinically unstable young patients with good chances of post amputation ambulation we consider the option for a two-stage amputation with an initial guillotine of the foot to clear sepsis and allow oedema to settle and then go on to perform the definitive operation after an interval of a few days [1].

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Patient Preparation

Aside from the notable exception of life-threatening emergencies it is recommended that those having a major amputation undergo pre-operative optimisation of medical conditions and nutrition, specialist physiotherapy and occupational therapy assessment and frank discussion regarding predicted functional outcomes [2]. The process of rehabilitation should start prior to surgery.

Short term outcomes for those having major amputations have been poor in the UK with reported mortality as high as 17% between 2003 and 2008 [3]. The effect of multi-disciplinary care cannot therefore be overstated with current 30-day mortality rates falling to well below 10% in 2019 [4].

Clearly there is still room for improvement in terms of morbidity and mortality outcomes. The 2014 NCEPOD report entitled 'Lower limb amputation: Working together' seeks to highlight standards for audit by the multidisciplinary diabetic foot team at pre, peri and post operative time points. The ambition echoing that of the Vascular Society of Great Britain and Ireland to reduce mortality from amputations to less than 5% [5]. Key points from this document include performing amputations on planned lists within 48 h of the decision to operate, involvement of a wide multi professional team and the involvement of a consultant or post CCT surgeon in theatre at the time of operation.

Patient Preparation: Pre-operative Assessment

If time allows, all patients identified as needing major lower limb amputation should be assessed prior to operation in a multimodal fashion. In practice this means obtaining input from the following specialists:

- Vascular surgeons
- Anaesthetists
- Intensive care specialists
- Diabetes/Endocrine specialists
- Dietician
- Specialist amputee physiotherapist
- Occupational therapist
- Psychologist/support groups for patient and family

The goal of pre-operative assessment is to identify and correct abnormal physiology and control factors that place a patient at higher risk of an adverse surgical outcome.

An additional goal that warrants special mention is to assess functional status and make a reasoned prediction as to the probability of ambulation with a prosthetic limb (The input of physiotherapy and occupational therapists is of paramount importance helping to determine the level of amputation, providing access to rehabilitation and limb fitting services post operatively and to make adjustments to the

patient's living conditions in a timely manner in order to facilitate safe discharge and maintain independent living.

In addition to the specialists outlined above, input from others such as cardiologists, respiratory or renal teams may be sought as indicated in the peri-operative period. Definitive treatment however should not be delayed any longer than is necessary and often a judgement must be made between the acuity of threat to the patient posed by the limb and the margin of gain expected from further modification of co-morbidities.

Determination of Amputation Level

Superficially, selection of amputation level would seem straight forward, especially in the context of treating extensive tissue loss or gas gangrene.

Most patients present before such advanced manifestations of their condition are present and so require more nuanced consideration weighing up the potential for rehabilitation and ambulation versus the likelihood of healing as distal a stump as possible.

Several tools are available to aid in determining probability of successful prosthetic use. Simple history and examination, taking into account pre-morbid mobility, and the status of the contralateral limb should always be a starting point. The Blatchford Leicester, Allman Russell tool (BLARt) is a validated decision aid that seeks to stratify the likelihood of ambulation using numerical scales over several clinical and demographic domains [6].

When there is expectation to rehabilitate with a prosthesis, preservation of the knee joint with a trans-tibial amputation is preferable to trans-femoral or through knee amputations owing to the reduction in additional energy expenditure needed to walk. 63% additional energy expenditure is required with a trans-tibial amputation versus 117% additional energy with a trans-femoral operation [7].

Trans-tibial amputation is not always possible. It may be precluded by the presence of infection or tissue loss in the area needed to raise flaps. Ischaemia may also hamper attempts at below knee amputation. Adjunctive information provided by tissue oxygenation ($TcPO_2$) or photoplethysmography have been evaluated, but not yet validated as tools to determine the probability of stump healing. Studies into the use of $TcPO_2$ to determine the appropriate level of lower limb amputation have failed to provide a consensus on a $TcPO_2$ value that can guarantee healing. The $TcPO_2$ is therefore only a helpful adjunct for clinical decision making. Calf $TcPO_2$ values greater than 40 mmHg are associated with a high percentage of successful wound healing after below-knee-amputation, whereas values lower than 20 mmHg indicate an increased risk of non-healing [8]. The presence of a femoral pulse and patent profunda femoris remain the most reliable clinical determinant of success. It may sometimes be appropriate to perform surgical or endovascular 'inflow' procedures to help support trans-tibial amputation rather than subject the patient to a higher-level stump. An additional consideration is the status of the knee joint. Patients with fixed flexion of the knee struggle to rehabilitate and are at increased

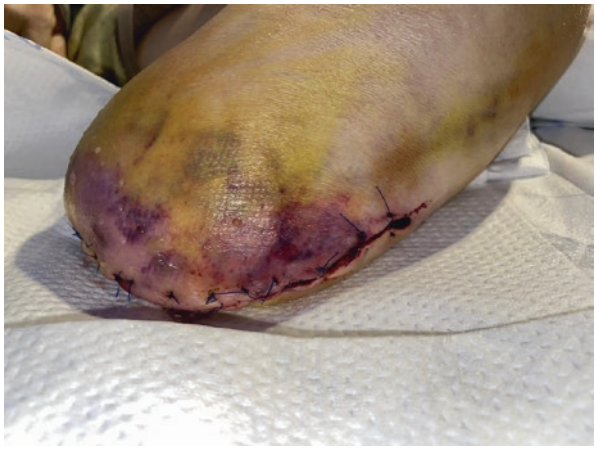

Fig. 11.1 This patient developed a flexion contracture of the knee following trans tibial amputation. Note how pressure damage has affected the stump. Adjuncts such as rigid stump dressings, back slabs and intensive physio can help to correct fixed flexion and prevent complications such as this

risk of wound complications because of pressure on the stump (Fig. 11.1). Flexion of up to 15° can normally be tolerated. Thorough assessment by the surgeon considering all of these findings is therefore vital to success.

Trans-femoral and through knee amputations.

Previously through knee amputations were offered to those with no expectation of prosthetic rehabilitation. The longer length, compared to an above knee stump, giving increased stability in the sitting position and better proprioception aiding transfers. Trans-femoral amputation has been more commonly offered to patients with rehabilitation potential but without suitable tissues for a below knee stump. Whilst this practice continues it is worth noting that improvements in lower limb prosthetics no longer render through knee stumps a lost cause with regards to walking. They may instead be viewed as a viable alternative to trans-femoral amputation. Given the dismal long-term prospects of continued limb use for trans-femoral amputees [8], the advantages of through knee amputation outlined previously may be realised after the cessation of prosthetic limb use. As a caveat to this, however, is the cosmetic appearance of the through knee prosthesis since it makes the leg more prominent anteriorly in the sitting position which patients should be counselled about.

Amputation Procedure: General Tips

Wherever possible amputation procedures should take place on elective operating lists within 48 h of the decision to operate [2, 5].

General factors such as careful tissue handling and meticulous attention to detail will improve the outcomes for any operation, amputation included.

Specific details that improve amputation outcomes include:

- Input/supervision in theatre from a consultant surgeon [5]
- Minimal use of diathermy to reduce the burden of devitalised material in the wound

- Optimisation of the quality of tissues used for flaps (with elevation if oedematous, nutrition support, eradication of infection and improvement in perfusion wherever possible)
- Removal of devitalised tissue from the stump
- Tourniquet use, while not widely established, may convey some improvement in outcome [9]
- Liberal use of nerve infusion catheters to reduce post operative pain and aid early physiotherapy.

Amputation Procedure: Trans Femoral amputation

With the patient supine a sandbag or gel bolster may be placed behind the ipsilateral buttock in order that the hip is held in a neutral position to facilitate a myodesis should this be desired. It also ensures that the closure occurs in the neutral position and prevents the uneven tension created by closure of the stump in flexion as created by using an upturned bowl under the stump.

Every effort should be made to leave the femur as long as possible with the caveat that roughly 12 cm of space is needed above the knee joint to allow placement of the prosthetic knee unit. Flaps are most commonly marked and cut in an anterior-posterior (fish-mouth) configuration (Fig. 11.2).

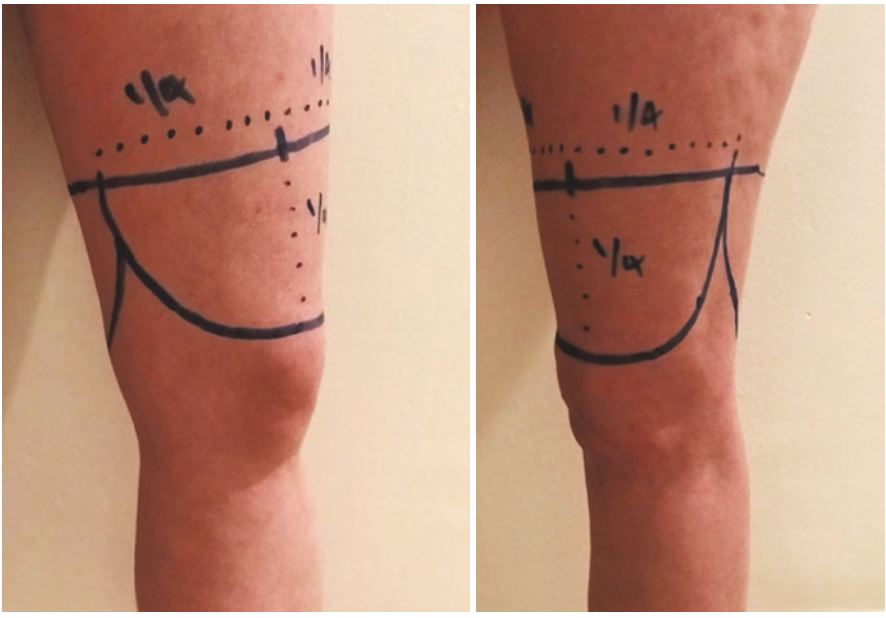

Fig. 11.2 Anterior-Posterior 'Fish Mouth' flaps. Note that the circumferential line denotes the level of bone division. The flap is 1/4 the circumference A/P and 1/2 the circumference medio-lateral

Sharp dissection with scalpel blade or Liston knife is normally possible without excessive bleeding. In the case of vigorous bleeding, positioning the patient head down can help control this until cut ends are ligated. If a myodesis is desired, then the adductor muscle group (medial) is left long. If not, then it is cut in the line of the flaps.

The vessels are divided as high as possible, and the sciatic nerve cut short under tension with a blade to reduce incidence of neuroma. In our practice a perineurial analgesic catheter may be inserted prior to transection of the nerve and this is brought out laterally through the skin.

The wound is washed after the bone is divided and the edges rasped smooth. A suction drain is placed prior to closure.

If a myodesis is performed, then a 2.5 mm drill is used to bore a hole on the lateral side of the femur. Thick braided sutures such as size 0 or 1 ethibond fix the adductors across the cut bone end to this hole. Remaining muscle groups are opposed antero-posterior by suturing fascia to fascia. Depending upon the quality of skin and presence or absence of infection the final layer is closed with either continuous subcuticular or interrupted prolene sutures.

Care is taken not to place adhesive dressings on the wound. A non-adhesive strip such as jelonet is reinforced with gauze, wool and crepe bandages to complete the operation.

Amputation Procedure: Knee Disarticulation

Many variations exist for flaps used in knee disarticulation. The Gritti-Stokes pattern no longer seems widely endorsed with many groups advocating slight adjustments on either an equal medio-lateral flap or a modified long posterior flap. Here we will describe both.

Equal Flaps

With the patient supine a line is drawn around the leg at the level of the tibial tuberosity. With the tuberosity as the central point the circumference is divided into four quarters using a nylon tape. A length of one sixth the circumference is then marked caudally from the circumferential line at the medial and lateral points and a fasciocutaneous flap raised from there (Fig. 11.3).

We recommend using gastrocnemius to cover the uncut bone end. The patella tendon is sewn to the posterior cruciate ligament with the hip in flexion, but the patella is not necessarily brought all the way round to form a weight bearing end.

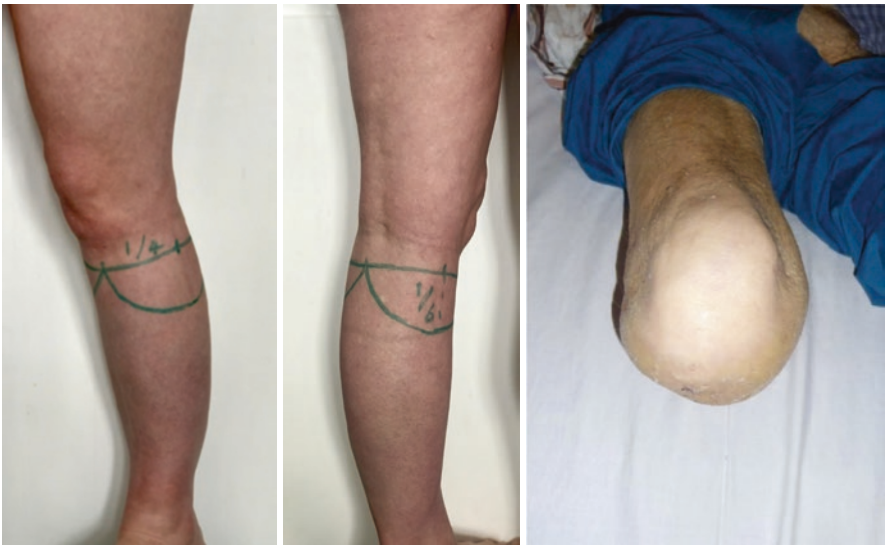

Fig. 11.3 Equal flaps for knee disarticulation. A line of circumference is drawn with the tibial tuberosity as its central point. Fascio-cutaneous flaps of 1/6 circumference are raised. Gastrocnemius is preserved for coverage of the femoral condyles

This preserves the ability to crawl. A suction drain is inserted before closure to deal with removal of synovial fluid as well as haemo-serous ooze. We recommend this drain remains in place for review at 48 h.

Long Posterior flap

The circumference of the leg is marked along the joint line and divided into quarters from a central anterior point with a half circumference long flap raised from the posterior skin of the calf akin to a Burgess flap for trans-tibial amputation (Fig. 11.4). Once again, a fascio-cutaneous flap is raised but in this instance only the medial head of gastrocnemius is preserved for eventual joint coverage. The approach to fixation of the patella and synovial fluid drainage is the same in this approach as to that already described. After disarticulation of the joint the remnants of the joint capsule are preserved as much as possible to allow fixation of gastrocnemius across the femoral condyles, the articular surface of which are disrupted with a rasp or diathermy to reduce production of synovial fluid.

The advantages of through knee amputation have been outlined previously however it is not always feasible. Fixed flexion at the hip, inadequate posterior or medio-lateral calf skin, previous surgery in the popliteal fossa or poor vascularity are all factors that may preclude healing.

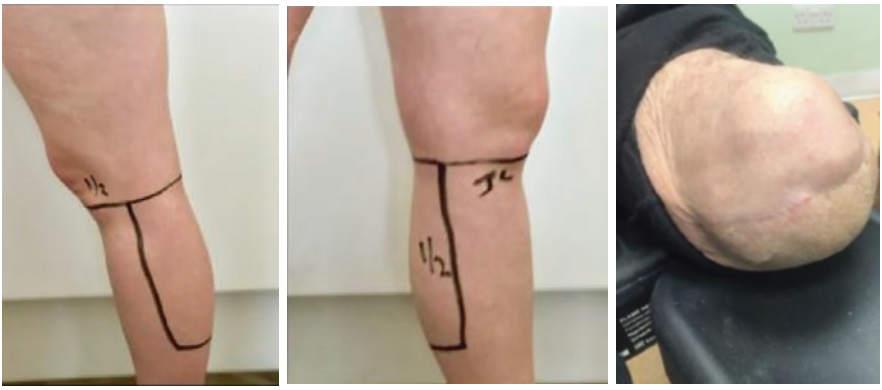

Fig. 11.4 Long posterior flap for knee disarticulation. The circumference is marked around the level of the joint line. A posterior flap of 1/2 the circumference is raised. The medial head of gastrocnemius is preserved and used for bone coverage

Amputation Procedure: Trans Tibial amputation

The long posterior and skew flaps are the most commonly utilised patterns for transtibial amputation. No evidence exists to favour one over the other in terms of healing and revision [10]. Different prosthetists have views on which stumps they prefer and accommodating members of the patients' rehabilitation team can pay dividends especially when there is surgical equipoise about which flap to use.

Previous long saphenous vein harvest can disrupt the blood supply to the skin over the medial calf and as a skew flap is reliant on this blood supply for the perfusion of the antero-medial flap previous surgery or scars in this area are a relative contraindication and in this situation we prefer to use the long posterior pattern.

Skew flap: An antero-medial/postero-lateral equal flap that makes use of the skin perfusion afforded by the saphenous and sural arteries. The tibia is marked for division 12–15 cm distal to the joint line and fasciocutaneous flaps of one quarter the circumference are raised from a central point 2 cm lateral and 2 cm proximal to the tibia (Fig. 11.5) [11].

The anterior bone and muscle division is the same in each technique, with care to ligate the anterior tibial vessels after division of the anterior compartment muscles. The gastrocnemius is used in a similar fashion to the long posterior flap for bone coverage. Several variations using parts of soleus or tibialis anterior have been described to aid coverage when the gastrocnemius is slender but our experience to date has been poor with these variations.

Prior to bone division the anterior periosteum is raised, in our practice with a blade to create a defined layer with which to attach the gastrocnemius fascia.

An anterior bevel should be cut into the tibia and the fibula divided 2 cm proximal to this.

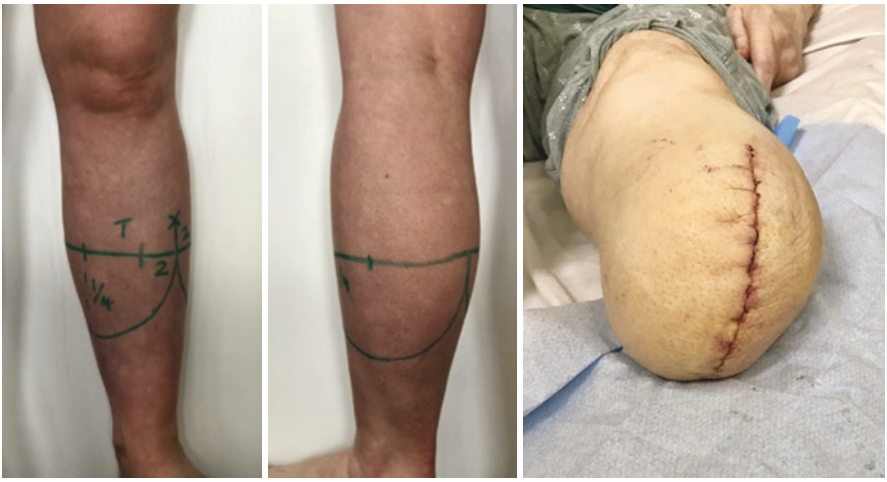

Fig. 11.5 A skew flap is marked using the pattern described by Kingsley Robinson 14. Often the finished result will appear quite floppy at the end of the operation. After 5 days healing however, the result can be seen in the picture on the right

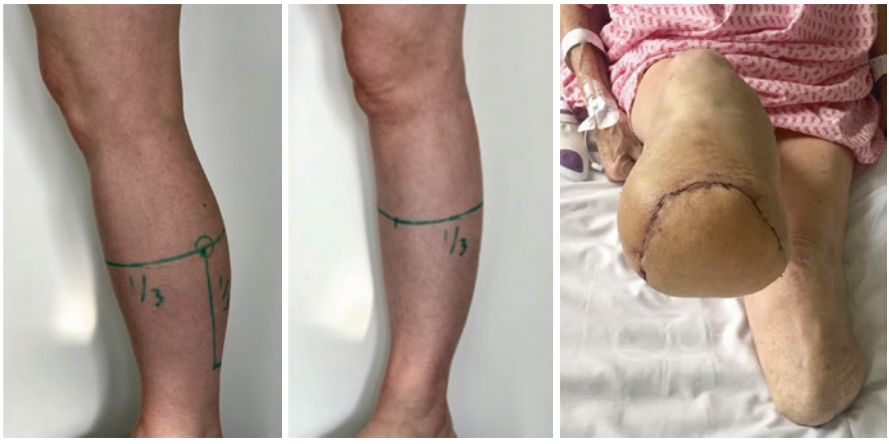

Fig. 11.6 The long posterior flap marked in 1/3rds. By excising a small amount of skin in the 'corner' a dog ear can be avoided and day 5 like the picture on the right achieved

A suction drain and tibial nerve catheter are placed before closure.

Long posterior (Burgess) flap: Relies upon the skin of the posterior calf to raise a myo-cutaneous flap. The tibia is marked for division 12–15 cm distal to the joint line and the circumference of the leg marked in thirds with the tibia considered the central point. The skin and muscle from the posterior third is left long to form the flap (Fig. 11.6).

As previously described the tibia should be beveled and fibular divided proximal to this level. A suction drain and nerve catheter should be placed before closure and application of non-adherent dressings.

If a tourniquet is being used, it is released at the end of the dissection/tissue amputation to check haemostasis prior to flap and skin closure.

Post Operative Care: General Considerations

Most patients can be safely returned to a ward environment following amputation. Some may need higher levels of care or an extended recovery stay depending upon the acuity of their presentation and any ongoing organ dysfunction. In most cases this is predictable.

It is optimal that a Physiotherapy assessment occurs on day 1, including a review of respiratory function.

Wherever possible we advocate a period of roughly 5 days before the wound is reviewed unless there is suspicion of ongoing infection, possibly indicated by unexpected pain, or if the wound has been left open.

Suction drains can be safely removed when daily output falls below 50 mL and, in our practice, are not fixed with a suture. This allows for removal without the need to disrupt the dressing.

Perineural infusion catheters can be safely left for up to a week post insertion but may need supplementary analgesia to reach maximum effectiveness. Input from pain specialists is valuable. In our practice we remove them after 5 days.

Post Operative Care: Wound Management

In the event that amputation wounds fail to heal the following must be considered:

- Has infection been eradicated? Extended post-operative antibiotics may be indicated for those in whom doubt exists following the advice of microbiologists. Intra-operative tissue samples should be sent for microbial analysis to focus antibiotic therapy. If a collection is suspected, then prompt drainage is essential to reduce the chance of revision. For open wounds the routine use of negative pressure dressings should be considered standard
- Is the stump ischaemic? Clinical history and examination as well as obtaining transcutaneous oxygen measurements will aid diagnosis. Cross sectional imaging such as CT or MR angiography as well as ultrasound duplex scanning may demonstrate lesions suitable for revascularisation which should be addressed by a suitable method. Below knee stumps are more at risk but through or above knee stumps may also require intervention in order to heal.

- Swelling and oedema can be dealt with by elevation but treating the underlying cause such as heart failure or hypoalbuminaemia must continue in the post operative period
- The effects of pressure damage can be catastrophic (Fig. 11.6). Offloading the stump and the use of pressure relieving mattresses can help mitigate this. For those who develop flexion contracture at the knee after trans tibial amputation intensive physiotherapy and the use of a plaster of Paris back slab or a rigid stump dressing can aid stump salvage.

Some stumps cannot be saved and require revision surgery to a higher level of amputation. Those that do well should be put into a stump shrinker such as a Juzo sock after about a week in preparation for limb fitting.

Post Operative Care: Rehabilitation

The objective of rehabilitation is to restore as much function as possible and attempt to maintain independence. This is achieved through a process of physiotherapy, occupational therapy, psychological counselling, and specialist limb fitting.

In the immediate post operative period patients are taught skills in transfer, contralateral and upper limb strengthening, wheelchair and toilet skills. Home visits allow for adaptation plans to be made and executed by occupational therapists.

After this initial period patients can be encouraged to use of early walking aids such as the PPAM aid or femurette prior to definitive custom limb manufacture.

It is important to be realistic with patients. Many diabetic and vascular amputees are frail with poor pre-operative mobility. It is highly unlikely that amputation will improve upon pre-operative function in these cases. Rehabilitation then should be tailored to the patients' own goals and is a dynamic process that is responsive to changes in their physical abilities [12].

Key Points

- Amputations should not be viewed in a negative sense. A good stump can provide durable pain relief, the basis for successful rehabilitation and the maintenance of independence for a wide variety of people with lower limb complications of diabetes.
- Morbidity and mortality outcomes after major amputation are improving, but there is some way to go. Adopting the recommendations of NCEPOD and the Vascular Society quality improvement framework as well as regular audit of local outcomes and engagement with the national vascular registry may improve things further.
- Multi-professional working to pre-optimise patients and select the best level of amputation is proven.
- Open or endovascular inflow procedures can prevent proximal amputations.

- Wherever possible amputations should be performed on planned lists with senior supervision for both surgeons and anesthetists. Meticulous technique and attention to detail will pay off.
- Early intervention in at risk or failing stumps helps to reduce the need for revision.
- Pre-operative rehabilitation planning and early commencement of physiotherapy shortens length of hospital stay and helps patients to realise their full rehabilitation potential sooner.

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Chapter 12
Neuro-osteoarthropathy: The Charcot Foot—Pathology, Diagnosis, and Treatment

William J. Jeffcoate

Description

The Charcot foot is a syndrome, and has no definition. It is, however, a condition in which subacute or chronic inflammation of the soft tissues and of the skeleton of the foot is associated with increased bone breakdown and joint dislocation—with a consequent increased risk of fracture and deformity. The deformed foot may develop secondary ulceration at points of increased pressure and friction, and the resultant ulcers may become infected. Infection of the ulcer may lead in turn to infection of the bone (osteomyelitis)—leading to further skeletal damage.

History

Jean-Martin Charcot was an eminent physician active in Paris in the second half of the nineteenth century. In 1868 he described the occurrence of painless inflammatory arthritis of the spine and larger joints of the lower limb in people with tertiary syphilis, and the condition was later named "Charcot's disease" by Sir James Paget. The first cases involving the foot were described by an English surgeon, Herbert William Page, in 1881, and by Charcot himself in 1883. It was first reported as a complication of diabetes by Jordan in 1936.

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Names

The Charcot foot is known by a variety of medical terms, variously including the words/roots "neuropathic," "osteo" (affecting bones), "arthro" (affecting joints), and "-pathy." Strictly, it should include the term "sarco-" to indicate that the soft tissues are also affected. It is, however, simplest to refer to the condition simply as the "Charcot foot." When it first presents it is often described as being "acute," even though the history may be of several weeks or months at the time of presentation. The term "chronic" is used with imprecision. It is more precise to use the terms "active" and "inactive" instead of "acute" and "chronic."

Causes

Neuropathy

It is thought that the presence of some form of neuropathy is essential for the Charcot foot to develop. It is, however, not clear which particular modalities of denervation are most important. It is possible that none is obligatory but that each contributes to a varying extent in different individuals. This would explain why very similar disease of the foot may occur in people with distal symmetrical neuropathy (as in diabetes, leprosy, or alcohol abuse), with disease of the spinal cord (tabes dorsalis from tertiary syphilis; syringomyelia) or with traumatic denervation.

Sensory Neuropathy

Loss of pain sensation—whether loss of sensation of deep pain (as in tabes dorsalis) or more superficial pain (as is usual in distal symmetrical neuropathies)—is significant because the patient is unaware of the severity of the disease, and may continue to walk on the affected foot and cause further damage.

Motor Neuropathy

Loss of innervation of the long flexors and extensors to the foot, as well as the intrinsic small muscles, causes abnormalities of the spread of forces through the foot during normal gait, leading to points of increased pressure. This is made worse by the glycation and shortening of connective tissue that occurs in diabetes.

Vasomotor Neuropathy

Abnormal regulation of flow through small blood vessels may potentiate the inflammation, which is a central feature of the acute Charcot process.

Loss of Neuropeptide Release

It is possible, but not proved, that failure of nerve terminals to release neuropeptides (including calcitonin-gene related peptide, CGRP) may also play a part since these peptides may modulate the inflammatory process.

Inflammation

It is currently thought that the key change that triggers the onset of the Charcot process is the onset of inflammation in the foot. Inflammation is marked by the increased expression of pro-inflammatory cytokines, principally TNF-α and IL-1ß, by leucocytes. Pro-inflammatory cytokines then trigger increased expression of the nuclear transcription factor, NFkappaB, which has a number of effects, including stimulation of the maturation of osteoclasts—which results in local bone breakdown [1].

The onset of inflammation may be caused by one of a number of events, including minor trauma, an episode of infection and the occurrence a preceding ulcer. Such inflammation would normally be short-lived, but the inflammation in the Charcot foot is not self-limiting, and persists. The persistence of the inflammation results in continuing activation of the NFkappaB pathway, which in turn causes continuing bone breakdown and makes the foot increasingly vulnerable to trauma.

Predisposition to Inflammation in Diabetes

A number of aspects of diabetes may predispose to the onset of inflammation through pre-existing potentiation of the RANKL-NKkappaB signaling pathway. These include the influence of glucose, reactive oxygen species and lipids.

Factors Encouraging Persistence of Inflammation

It is likely that the dominant factor is loss of protective sensation as a result of sensory neuropathy. Because painlessness renders the person unaware of the extent of the damage, it will predispose to continuing trauma through inappropriate weight-bearing.

Other Factors Linked to the Onset of Charcot Disease

People with renal failure are at increased risk of developing a Charcot foot. Amongst those with renal failure, the subgroup at particularly high risk includes those that undergo renal transplantation and especially combined kidney-pancreas transplantation.

Epidemiology

There are no reliable data on either the incidence or prevalence of Charcot foot disease in diabetes. It is usually said that the lifetime risk is of the order of 3 per thousand (i.e., approximately 1% of all people with diabetes related neuropathy), but it is likely that it is very much higher than this. A town or city in England with a total population of 500,000 will have about 25,000 people with known diabetes and the experience of a specialist foot care centre serving such a population is that they will see some 15–20 new cases of Charcot disease each year. The *annual* risk is therefore just less than one per thousand of all people with diabetes and the lifetime risk may be 10–20 times higher.

Diagnosis

It is essential that the condition is suspected in any person who has diabetes complicated by neuropathy and who presents with unexplained inflammation in the foot (Fig. 12.1). At the moment it is rarely considered—simply because the condition is thought by most clinicians to be rare. The result is the diagnosis is frequently delayed by weeks or months and the condition of the foot may deteriorate considerably during this time. Delayed diagnosis may lead to limb loss.

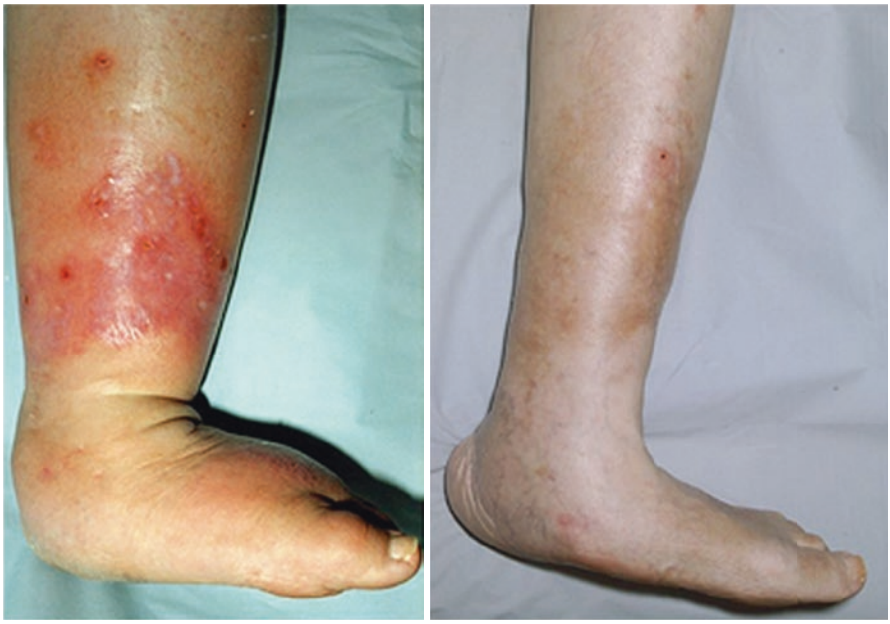

Fig. 12.1 Inflammation of the foot and lower leg in the acute phase of Charcot foot (left image). Residual deformity apparent in the same leg after the swelling has regressed (right image)

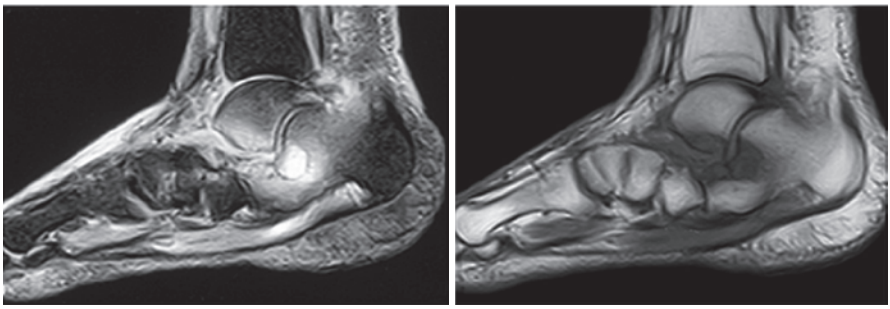

Fig. 12.2 The MRI appearance of Charcot foot in the acute phase, with inflammation of the bone marrow and soft tissue being apparent as enhancement on the left (T2-weighted) image, and as suppression on the right image

Once the condition is suspected, the person should be referred promptly to an expert in the field and should have a plain x-ray (taken weight-bearing to exaggerate any radiological signs of loss of integrity of the skeleton of the foot). If the x-ray is normal and the disease is still suspected, the person should have an MRI of the foot as soon as possible and should remain non-weight bearing until it is done (Fig. 12.2). The MRI will highlight inflammation of both soft tissue and bone, even in the absence of overt fracture or dislocation. A CT scan may also highlight small fractures that are not apparent on a plain x-ray. It is possible that newer imaging techniques will prove to have added diagnostic value.

Treatment

There is no specific treatment that has been proved to be of benefit. In the absence of any specific therapy, there is only one therapeutic option available, and that is immobilisation of the foot (called "off-loading"). Immobilisation (which should ideally be achieved with a non-removable, below knee fibreglass cast) has two aims: (1) to interrupt the cycle of persistent inflammation by splinting the foot, and (2) to protect the foot from traumatic injury at a time when the bones and joints are susceptible.

When an inflamed foot is immobilised in a fibreglass cast, the inflammation settles within days. Indeed, the inflammation and soft tissue swelling settle so quickly that the cast will usually need to be replaced within a week because it will no longer fit the foot sufficiently snugly. In cases of doubt, this rapid resolution of inflammation with immobilisation provides strong suggestive evidence supporting the diagnosis. In established disease, casts need to be changed each 1–3 weeks until the disease enters remission. This frequent change of cast also enables the foot to be frequently checked to ensure that its condition of the foot has not deteriorated from, for example, ulceration caused by rubbing.

Casting should be continued until the Charcot process is thought to have entered remission. Remission may be judged simply by regression of the clinical signs of residual inflammation (including comparison of skin temperature on the two sides) but there are no other objective measures. Repeat MRI may give an indication of resolution of bone marrow oedema but it is expensive. Overall, casting is continued for a period of months. For reasons that are not clear, the reported duration of casting may vary from less than 6 months (reported in the USA and Denmark) to 12 months or more (reported in the UK).

Surgery

Active Phase

Surgery involving exostosis and arthrodesis of one or more bones and joints may be adopted in the active phase by some specialist units, especially when there is acute, gross deformity, such as dislocation of the ankle joint. Such surgery may be associated with the use of external fixation using a frame in order to protect the foot. However, the majority of surgeons are reluctant to operate in the active phase.

Inactive Phase

When the inflammatory phase has entered remission, surgery may be considered in an attempt to correct residual deformity and to make foot more functional.

Major Amputation

Sometimes the deformity and complications of the condition are such that the best option for long term function and well-being is to undertake major amputation. In developing nations and in impoverished populations, early amputation may sometimes be the only option for the care of people with more severe disease.

Complications

Ulceration and Infection

The Charcot foot occurs in people with neuropathy and people with neuropathy are the group who are most susceptible to ulceration of the foot. Ulceration is more likely if there is deformity and this is obviously a common consequence of the Charcot process. Ulceration may also be more likely if the foot is enclosed within a fibreglass cast.

When ulceration is complicated by infection, there is a very high risk of osteomyelitis developing in the underlying bone. Such osteomyelitis can be very difficult to eradicate and may be a factor leading to loss of the limb.

Psychosocial

It is becoming increasingly apparent that people who have a Charcot foot are very likely to become depressed, and to suffer a major reduction in quality of life. Part of this relates to the inevitable restriction in usual daily activities resulting from both the disease and its treatment, and is obviously worsened by the long course of the disease, the need for frequent specialist surveillance and the lack of clear markers to indicate progress.

Aspects of Long-term Management

Prevention of Late Ulceration

People who have residual deformity are at high risk of ulceration and ideally require long term surveillance by an expert podiatrist or physician, combined with long-term provision of effective orthoses, i.e. fitted footwear [2]. People who have had one Charcot foot should be alerted to the possibility of contralateral disease and should be urged to seek expert advice if suggestive inflammation occurs on the other side.

Cardiovascular Risk

People with neuropathy and foot disease (whether Charcot foot or neuropathic ulcer) have been reported to have a life expectancy which is reduced by an average of 14 years. The most likely cause for this is cardiovascular disease and hence long term specialist surveillance is needed to reduce cardiovascular risk as much as possible.

Key Points

- Charcot foot is uncommon but all health care professionals should be aware of it. The diagnosis should be seriously considered in any person with diabetes-related neuropathy who presents with inflammation of the foot.
- Charcot foot is an inflammatory condition involving the bones, joints and soft tissues and is closely linked to diabetic neuropathy.
- Weight bearing must be avoided if the diagnosis is suspected.

- Treatment is focused on off-loading and avoidance of weight bearing. The role of surgery is unclear and should be undertaken only by experts.
- Long-term follow-up is essential in view of the risk of foot ulceration, further episodes and increased associated cardiovascular risk.

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Chapter 13
The Role of an Orthopaedic Surgeon in the Management of Diabetic Foot Complications

Alexander Wee

General Assessment of Diabetic Feet

An orthopaedic history is elicited from the patient. The following lines of enquiry should be pursued: swelling, pain, recent trauma, abnormal sensation, history and duration of foot ulcer, history and progression of deformity. The surgeon should ask about proximal joint problems—of the knee and hip, as often these can exacerbate foot deformities, or lead to gait problems, predisposing the patient to abnormal shear stresses in the plantar foot skin. The examination of the patient will involve a rudimentary assessment of the hip and knee looking for obvious deformity and contractures and stiffness of the joints.

Examination of the feet involves the following steps:

1. Footwear and insoles—custom or proprietary, wear pattern of the sole.
2. Hind foot alignment on standing—is the heel in anatomical valgus.
3. Gait pattern
4. Loss of medial arch
5. Integrity of plantar fascia
6. Tightness of the Achilles tendon and Gastrocnemius muscle.
7. Quality of the skin—healthy and pliable or dry cracked, presence and location of ulcers and their depth.
8. Ankle and hind foot deformity—are the deformities correctible?
9. Midfoot deformity and presence of exostoses

   Forefoot deformity and mobility: presence of claw, hammer and mallet toes

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10. Pulses, including doppler insonation and recording the signal quality—triphasic is normal; biphasic or monophasic indicates a degree of arthrosclerosis and loss of normal vessel wall elasticity. Recording the Ankle Brachial Pressure index which may also be falsely elevated in the diabetic patient
11. Sensation to light touch and protective sensation with the Semmes Weinstein 10 g monofilament
12. Temperature of the foot either by simple palpation, or with a handheld cutaneous thermometer

The standard X-ray imaging required is a weight bearing foot and ankle series. This is an AP, mortice and lateral view of the ankle and foot with an oblique and AP of the foot. Other specialist views can be useful such as an axial calcaneal view to localise a posterior tuberosity lesion.

More recently weight bearing computerised tomography has been used. This can identify any prominences in the loaded foot that might not be apparent on two dimensional radiographs such as plantar displaced or subluxed intermediate and lateral cuneiforms. Three-dimensional reconstruction views are helpful in allowing the surgeon to visualise a complex deformity as part of reconstructive planning process, to work out the shape and orientation of corrective osteotomies. There are certain centres that use 3D printers to create models of the deformed foot so the surgeon can plan and rehearse the orientation of the osteotomy required for corrective surgery [1, 2].

Ultrasound is useful in localising collections of pus in the foot or the tendon sheaths, directing surgical drainage.

MRI has a high sensitivity for confirming infection in the foot. A normal MRI virtually excludes infection. The diagnostic accuracy is 95%, with 95% sensitivity, and 80% specificity. It does not differentiate between infection and oedema, and therefore will not distinguish between an infective process or a Charcot neuroarthropathy. PET and SPECT scans have a role in identifying infections with similar diagnostic accuracy, sensitivity, and specificity. The wider availability of MRI scanners and the lack of exposure to ionising radiation leads to MRI being the investigation of choice [3, 4].

Other useful adjuncts include transcutaneous oximetry. This measures the partial pressure of oxygen in the skin at the site of the incision, usually in the foot. This investigation modality is usually employed by the vascular team and can be used as a predictor for ulcer and wound healing and likelihood for lower limb amputation [5, 6]. A partial pressure of greater than 30 mmHg in the subcutaneous tissue at the ankle indicates healing potential of wounds in the foot, with reported healing rates of 92% [7].

A panel of blood tests are useful: these include a full blood count, C reactive protein (CRP), bone profile, and glycosylated haemoglobin.

A leucocytosis and elevation of the CRP suggests an infection. An abnormal bone profile suggests bone involvement. The glycosylated haemoglobin is an indicator of metabolic control. Poor diabetic control is an unfavourable prognostic indicator of wound healing and wound complications following surgery [8–10].

Off-Loading Surgery for Diabetic Foot

Diabetic feet are vulnerable to ulceration, due to a combination of peripheral neuropathy, ischaemia, and deformity leading to loss of the normal load bearing structure of the foot. Patients have a distal symmetrical polyneuropathy resulting in a sensory loss in a stocking distribution with large fibre involvement causing tingling, paraesthesia, and eventually numbness. Vibration and touch pressure sensation are also impaired. Deterioration of the polyneuropathy gradually spreads to autonomic fibres resulting in loss of sudomotor function. There is small muscle atrophy of the intrinsic foot muscles; the imbalance between these and the long flexors leads to flexion deformities of the toes, and hyperextension at the metatarsophalangeal joints, causing claw and hammer toes in the forefoot.

The sensory neuropathy causes the loss of protective sensation resulting in the patient being unable to detect minor injury to the foot. The loss of sweating causes the foot to lose its natural pliability and the skin becomes cracked and fissured. The skin is vulnerable to minor trauma, which can lead to inoculation of the wound with microbes, resulting in an ulcer which if left undetected will deteriorate and become infected. Protective sensation can be assessed using the 10 g Semmes Weinstein monofilament [11, 12].

Subluxation of the metatarsophalangeal joints and the metatarsal head fat pad atrophies, leading to increased pedal pressure on the metatarsal heads, as demonstrated in pedobarographic studies. The skin is susceptible at the apex of the toe flexion deformity or at the subluxed metatarsal heads and is extremely vulnerable to injury and ulceration from direct contact with the floor or shoes (Fig. 13.1). Patients often develop calf tightness with gastrocnemius contractures which creates an equinus contracture at the ankle joint and resulting in increased forefoot pressures [13]. The ulceration may develop initially in the soft tissue; if the bone or joint becomes involved, osteomyelitis may ensue. The situation can deteriorate and potentially lead to a septic diabetic foot emergency requiring urgent surgical debridement.

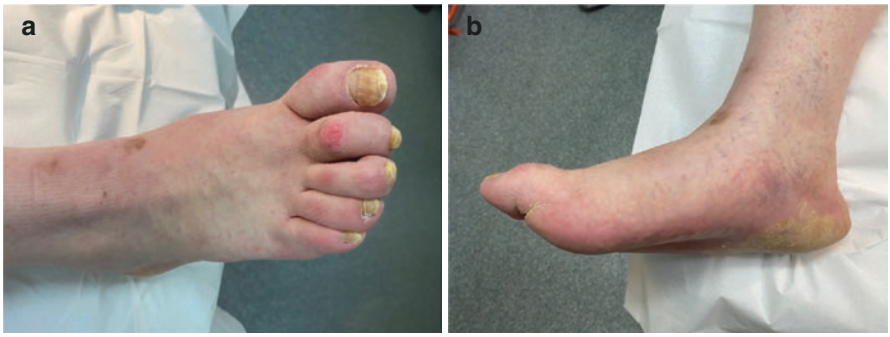

Fig. 13.1 (**a**) Hammer toe with ulcer on proximal interphalangeal joint; (**b**) Hammer toe of Hallux with associated swelling of digit, and trophic skin changes on heel

The aim of prophylactic offloading surgery is to reduce the risk of ulceration in this group of patients. The surgical armamentarium includes soft tissue releases and bony procedures. Gastrocnemius muscle can be released to reduce forefoot pressure on the metatarsal heads [14, 15]. This can be undertaken proximally at the level of the medial head of gastrocnemius, or in the midcalf aponeurosis with a Strayer's procedure [16, 17].

This procedure can be done under sedation with a local anaesthetic field block just distal to the popliteal crease, over the medial head of the gastrocnemius muscle belly. A midcalf release of the triceps surae aponeurosis can be undertaken if the proximal operation is inadequate. Lastly, if there is a significant contracture of the tendoachilles, the tendon can be lengthened with a Hoke triple hemisection [18, 19]. This results in slowing the Charcot process and reduces plantar pressures (Fig. 13.2). The percutaneous technique can be performed in an outpatient setting. Release of the Achilles tendon can cause weakness of the calf muscle and lead to loss of push off power during the gait cycle, as well as a calcaneus deformity of the posterior tuberosity of the heel and subsequent ulceration. It needs to be done with caution bearing those points in mind [20].

The imbalance between the long flexors of the foot and the intrinsic foot muscles contribute to an extension deformity at the metatarsophalangeal and interphalangeal

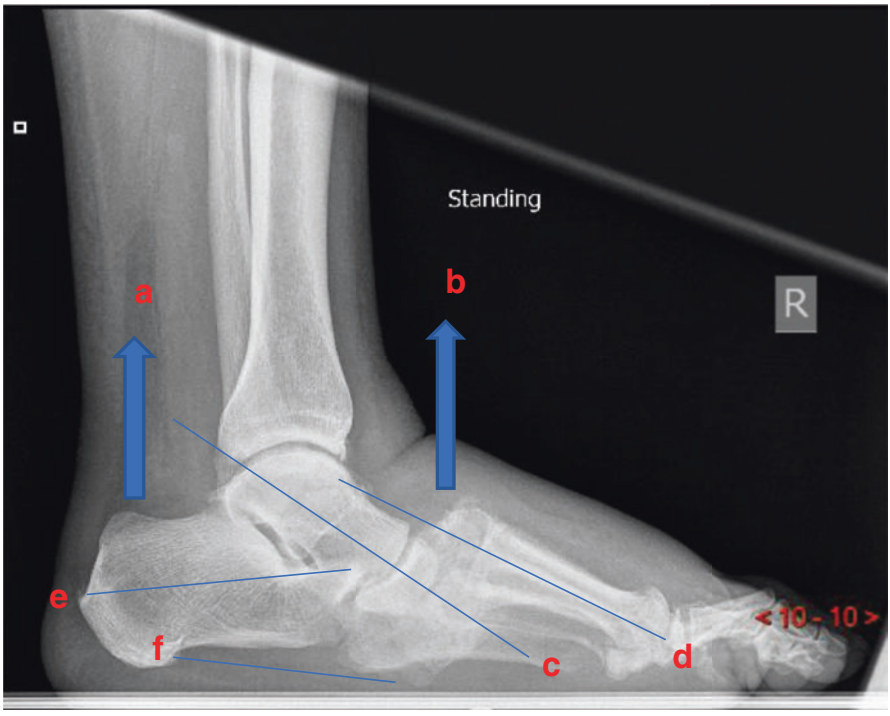

Fig. 13.2 Direction of pull of tendons. (**a**) Pull of tendoachilles; (**b**) pull of tibialis anterior; (**c**, **d**) loss of first metatarsal-talar alignment; (**e**) loss of calcaneal pitch leading to a rocker bottom deformity of a Charcot foot; (**f**) 'dropped' cuboid height

joints, resulting in claw, hammer, and mallet toes respectively. There is no direct physical evidence for this causal relationship, and it is thought that there are other factors involved with this pathological process. There is an increased plantar pressure on the affected skin and as a result the toes are vulnerable to ulceration on the dorsum of the proximal interphalangeal joint, at the pulp of the toe or under the metatarsal head where there is atrophy of the plantar fat pad [21, 22]. The dry, fissured skin is more vulnerable to ulceration and creates a portal of entry and inoculation of the deeper soft tissues, joint and eventually bone. The added complication of a microvascular angiopathy results in a poor environment for healing and the ulcer deteriorates.

This situation can be avoided with careful skin care and provision of shoes with a total contact insole, wide and high toe box. Patients often present to the orthopaedic surgeon with these deformities and a neuropathy. Release of the flexor digitorum longus tendons can be undertaken using a percutaneous needle tenotomy technique in outpatients. Studies have shown that this is a safe and effective treatment for diabetic patients with ulcer healing rates of 93% and no complications following treatment [23, 24].

Patients with long standing neuropathic ulcers beneath the subluxed metatarsal heads can be treated with osteotomies to shorten the metatarsals. Historically open techniques with screw fixation have been used, but fell out of favour because of the high rate of complications with infection of the wound, and failure of fixation [25]. A minimally invasive surgical osteotomy using a burr minimises the soft tissue insult to the foot. The osteotomy is at the level of the neck and is not stabilised with an implant. This way the risks of wound and implant infection are mitigated, however the toes can end up ‘floating’ with the pulps of the digits not engaging the ground [26, 27]. Metatarsal osteotomies are more effective in leading to ulcer healing than standard non operative offloading treatments, with 96% of ulcers healing within 1 month of surgical off-loading compared to 68% healing after standard non-surgical offloading treatment [28].

The midfoot can develop a rocker bottom deformity with a plantar medial bony prominence caused by a loss of relationship between the navicular, medial cuneiforms and first metatarsal base (Figs. 13.3, 13.4, and 13.5). This creates a plantar

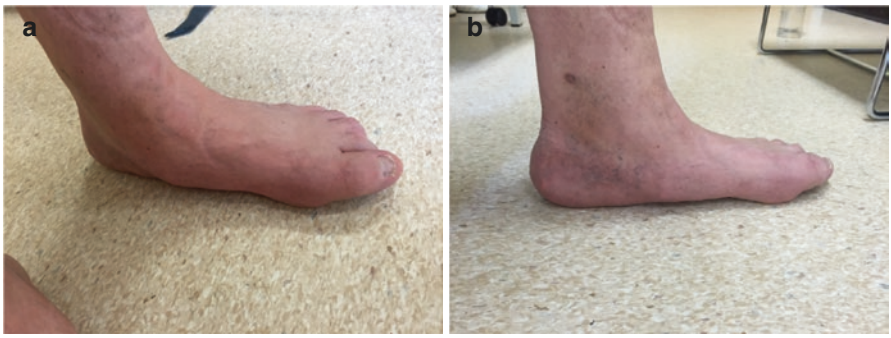

Fig. 13.3 (**a**) Medial rocker bottom Charcot foot deformity; (**b**) loss of medial arch

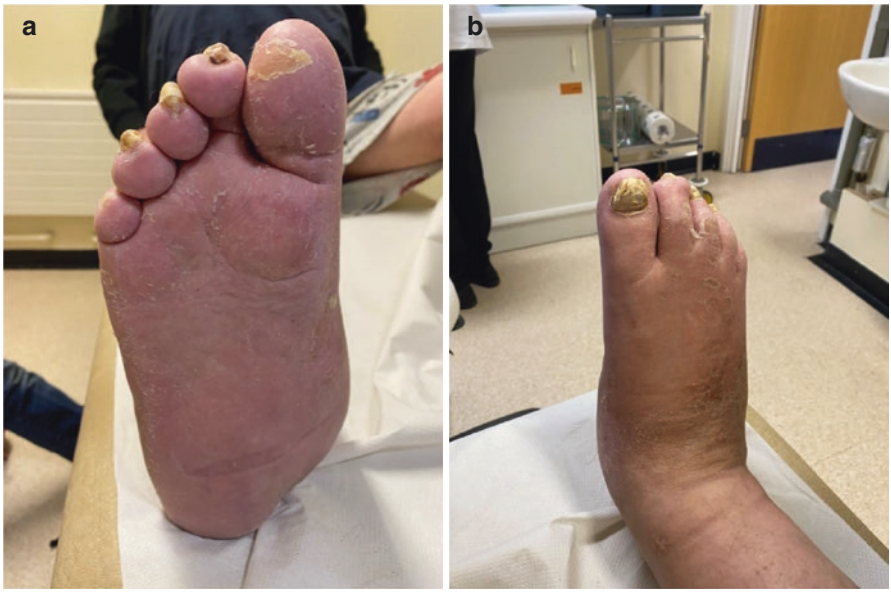

Fig. 13.4 Charcot foot with medial prominence and rocker bottom. (**a**) Trophic skin changes due to autonomic neuropathy; (**b**) dorsal foot swelling

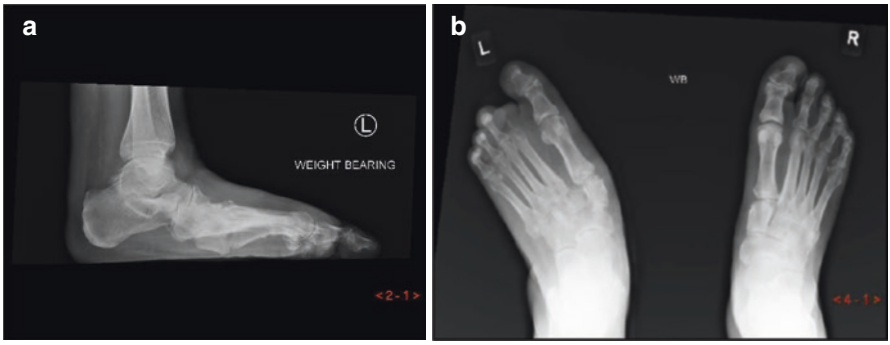

Fig. 13.5 Charcot foot XR with midfoot failure. (**a**) Loss of alignment between first ray and talus resulting in rocker bottom and abduction deformity; (**b**) failure of Lisfranc ligament complex leading to dissociation of second metatarsal from first ray with abduction of the forefoot

medial apex as the medial cuneiform is pushed out in the same direction. Pressure and friction on the skin leads to ulceration and eventually infection of the soft tissues and the underlying bone.

The bony exostosis can be surgically removed to reduce pressure on the overlying skin, therefore preventing ulceration or resulting in healing of the ulcer (Figs. 13.6 and 13.7) [29–31]. Bony prominences on the plantar lateral aspect of the foot secondary to a 'dropped' cuboid, with disruption of the lateral plantar arch are more pernicious, and have a poorer prognosis. Simple exostectomy does not have

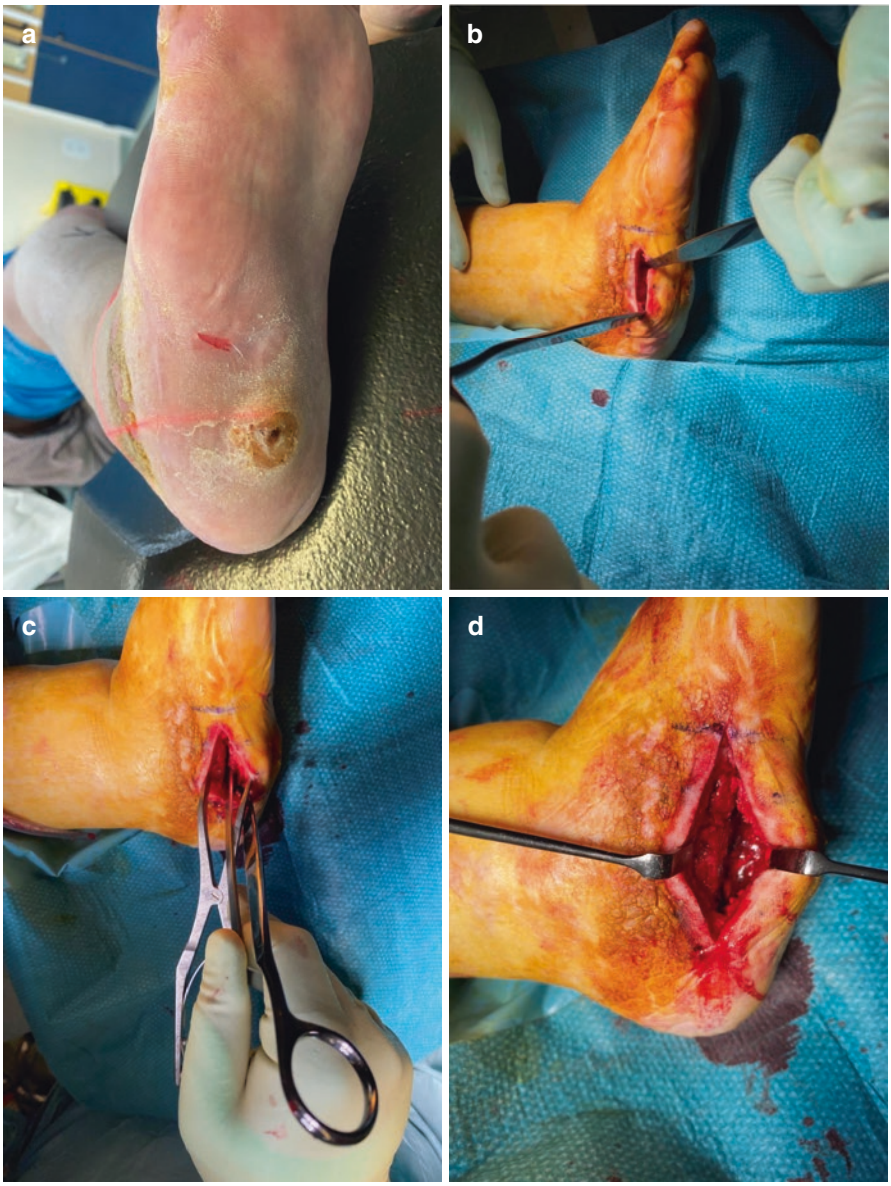

Fig. 13.6 Exostectomy. (**a**) Plantar ulcer; (**b**) lateral approach to exostosis; (**c**) exostectomy with osteotome; (**d**) completed exostectomy

the same effect and the foot deformity continues to deteriorate and the skin remains at high risk of re-ulceration. The foot needs reconstruction with restoration of the lateral and medial longitudinal arches with beams and plates. Studies have shown a negative association with loss of cuboid height and progression of the Charcot deformity [32, 33].

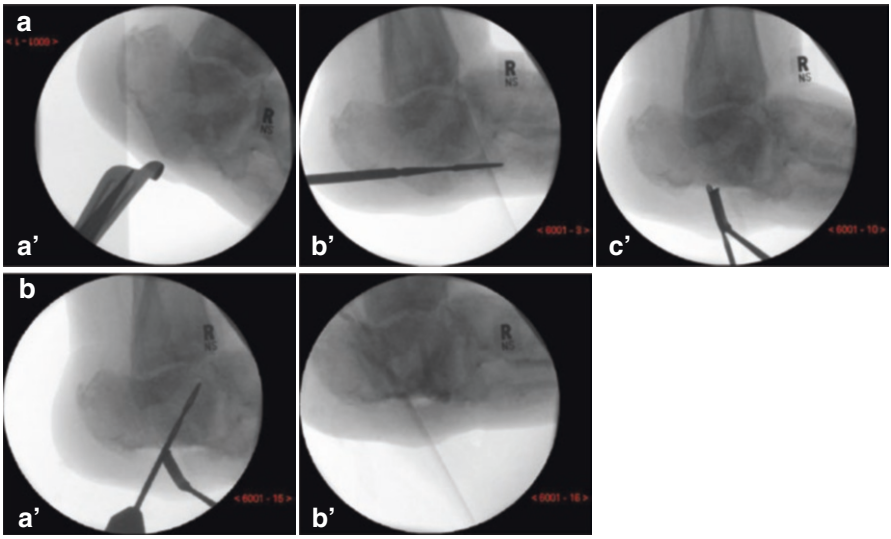

Fig. 13.7 (**a**) Intraoperative images of exostectomy: (**a′**) plantar exostosis; (**b′**) level of exostectomy; (**c′**) post exostectomy. (**b**) Calcaneal silo technique: (**a′**) drilling of calcaneum for SILO technique; (**b′**) injection of antibiotic bone void filler into calcaneal drill holes

Surgical Management of Bone Infection

A neglected ulcer diabetic foot ulcer will lead to soft tissue infection and eventually deeper structures, joint and bone, will become infected. Patients present with swollen digits, joints, redness, systemic malaise, cellulitis, septic arthritis, and osteomyelitis. The surgical strategies for treatment are radical debridement of the infected tissue back to a healthy margin, and systemic antibiotics. The rational for debridement is source control, and removal of biofilm. The bacteria accumulate in the biofilm and are immunologically privileged. They take refuge in a hyperglycaemic and poorly perfused environment, beyond the reach of white blood cells and the action of systemic antibiotics. These colonies are commonly polymicrobial. The surgical debridement disrupts the biofilm and disperses the bacterial colonies to their planktonic form, rendering them more susceptible to systemic antimicrobial therapy [34, 35]. Diabetic wounds demonstrate deregulated angiogenesis, and a suppressed inflammatory response. The hypoxic environment results in a poor wound healing prognosis [36].

Patients commonly present to the podiatrist or the foot protection team in hospital with an indolent non-healing ulcer, and a swollen digit or foot. There is erythema, and the foot is warm. The foot needs a full assessment including an X-ray and MRI. Occasionally if there is an occult collection of pus, an ultrasound scan of the foot and the tendon sheaths around the ankle can be useful. The blood tests are sometimes helpful with a raised white cell count and elevated inflammatory markers [35]. The patient's blood glucose is often deranged and those with the most severe infections or presenting with foot sepsis will have very unstable metabolic control.

Clinically the patient may demonstrate a general malaise, and sometimes demonstrate signs of confusion.

A deep bone biopsy should be acquired before commencing systemic antibiotics in accordance with local microbiology guidelines. The most commonest microbes are Staphylococcus aureus and epidermidis and Escherichia coli [37]. Streptococcus is also present in very severe skin infections [35, 38, 39].

The decision to operate is based on the presence of pus or wet gangrene, and the severity of the patient's clinical condition. If the patient is septic, urgent debridement is required for source control [40, 41]. The patient is taken to theatre for an emergency debridement and removal of the infected tissue back to a healthy bleeding margin [42]. Lavage of the wound is carried out with high volume saline, and aqueous chlorhexidine for a local bactericidal effect [43].

Specimens are taken from the infected tissue, and a marginal specimen is sent following debridement and washout. If a local debridement is performed, and there is concern that the margins have not been cleared of infection, it is sometimes necessary to preserve potentially infected bone to maintain the functional anatomy of the foot, then the bone can be treated with a topical local antibiotic bone void filler (BVF) [44, 45]. Following surgery the wound can be closed primarily if the skin is healthy, and a tension free closure can be achieved. If there is a defect application of negative pressure wound therapy (NPWT) dressing can be applied. If BVF has been deployed in the wound, the NPWT dressing is put on 24–48 h later. This allows the BVF to cure and reduces the risk of all the antibiotics eluting prematurely into the NPWT dressing.

Patients with deep bone infections without severe soft tissue involvement or in the absence of a septic presentation can be considered for a more planned approach. A bone specimen is required for targeted antibiotic treatment. If the focus of osteomyelitis is deep to an ulcer caused by a bone prominence, an exostectomy should be considered, and the underlying residual infected bone can be treated with antibiotic impregnated BVF. The BVF can be deployed using a silo technique which involves drilling the residual bone with holes, taking care to avoid penetration into neighbouring unaffected bone, and injecting the BVF into the holes (Fig. 13.8). A sucker can be placed into one of the adjacent drill holes and the suction pressure will draw

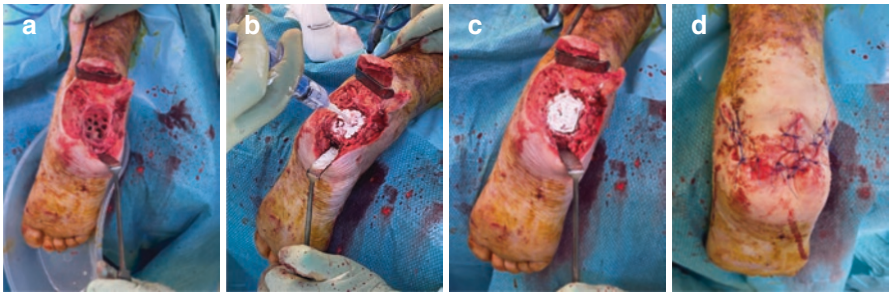

Fig. 13.8 Calcanectomy and silo technique. (**a**) Partial calcanectomy with drill holes; (**b**) filling drill holes with bone void filler; (**c**) filling of all holes; (**d**) closure of skin

the BVF, in its liquid phase, into the surrounding bone trabeculations, facilitating a deeper and wider penetration of the filler into the residual bone [45]. This technique can also be used for emergency debridements. It allows hindfoot osteomyelitis to be treated with local resection of infected tissue and avoiding radical resection of the bone to maintain the function of the lower limb.

Bone infections of the digits confined to the distal or intermediate phalanx can be treated with radical debridement of the toe at either the middle or proximal phalanx level to remove the infection completely (Figs. 13.9, 13.10, and 13.11). Antibiotic impregnated BVF is rarely required for these cases. Infection of the metatarsal heads are dealt with by removing the infected bone with a ray amputation and filling the residual stump with BVF. If the surrounding soft tissues are healthy the wound can be closed immediately, otherwise a larger defect can be treated with a NPWT dressing [46, 47].

Following surgery, the patient's inflammatory markers and glycaemic control are monitored. Patients who have undergone massive emergency debridement with large open soft tissue defects may require further washouts and debridement. If a

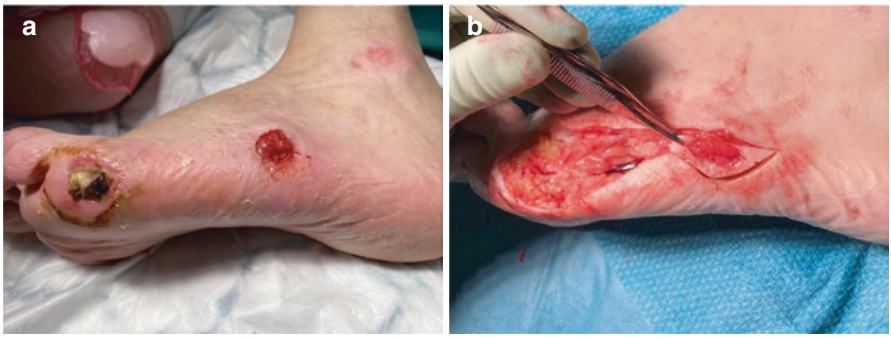

Fig. 13.9 Fifth metatarsal ulcers. (**a**) Fifth metatarsal head and base ulcers; (**b**) elliptical excisions of both ulcers

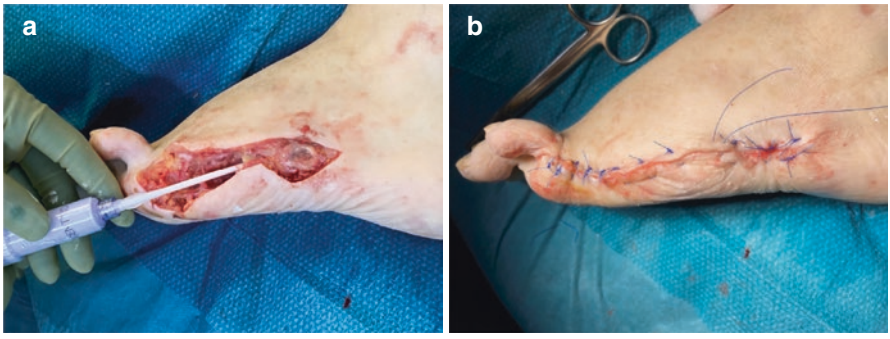

Fig. 13.10 Fifth ray amputation. (**a**) Fifth metatarsal ray amputation and injection of antibiotic impregnated bone void filler. (**b**) Direct skin closure

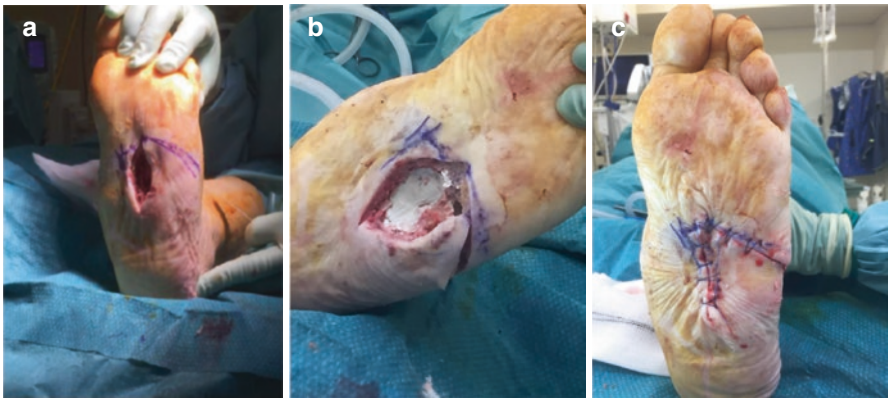

Fig. 13.11 Local flap. (**a**) Plantar central ulcer excised and local flap design; (**b**) exostectomy with bone void filler in residual bone; (**c**) closure of local flap

large soft tissue defect remains and cannot be closed by delayed secondary closure with NPWT, the patient can be referred to plastics for consideration of alternative means of wound coverage [48, 49]. Patients will require systemic antibiotics as per local microbiology guidelines with regards to duration and method of delivery—intravenously or oral [50].

Successful outcome following conservative treatment of diabetic foot infections is reported in some studies at around 63% [51]. The outcome following surgical treatment of diabetic foot infection varies between surgical reports with a long-term limb salvage rate between 70–90%; the recent use of antibiotic impregnated bone void filler has shown promising early results in some series [44, 52, 53]. The main criterion influencing the long-term outcome is the vascular status [54].

Charcot Foot Reconstruction

The structure of the foot can be described as a complex of a medial, and lateral arch connected by a transverse arch. The medial arch consists of the first metatarsal, medial cuneiform, navicular, talus, and calcaneum. The keystone of the medial arch structure is the talus, which is supported by a sling of soft tissue with the spring ligament, tibialis posterior and anterior tendons, and the peroneus longus tendon insertion at the base of the first metatarsal on its plantar aspect.

The lateral arch comprises of the fifth metatarsal, cuboid, and calcaneum, with soft tissue support from the calcaneocuboid ligaments and the shape of the joint. The peroneus longus forms a support beneath where it enters the plantar aspect within the cuboid groove.

The transverse arch is made up by the navicular cuneiform joint complex and metatarso-cuboid joints of the fourth and fifth rays, supported by the midfoot

ligaments, and the Lisfranc ligament locking the base of the second metatarsal shaft into the intermediate cuneiform as the key stone of this arch.

The plantar fascia takes origin from the base of the anterior calcaneal tuberosity into the plantar aponeurosis extending to the metatarsophalangeal joint level. This structure contributes to foot stability and maintenance of the arches by acting as a windlass mechanism.

The arrangement of the three arches creates a vault—an architectural construct which allows a load to supported by a dome ceiling, transferring the weight to each of the supporting pillars. In the foot this corresponds the weight of the tibia through the talus and into the base of the calcaneum and the five metatarsal heads, with the loaded dome of the talus being supported by the medial, lateral and transverse arches. Failure of the bones or supporting ligaments will lead to collapse of the arch and deformity of the foot.

Charcot neuroarthropathy is a relatively rare condition which affects 1% of diabetics. It is painless in 80% of cases, and often preceded by minor trauma. It can affect the other side in 10% of cases. The pathophysiology of Charcot foot is created by a combination of a neurotrophic and neurotraumatic mechanisms. The autonomic neuropathy results in smooth muscle relaxation of the arterial wall leading to failure of local vasoregulation and arteriovenous shunting of the local microcirculation. With the hyperdynamic local blood flow, there is an increase in monocytes and osteoclasts, causing resorption of the bone. There is loss of bone density and osteopaenia.

This results in the bone being easier to fracture. The loss of proprioception and protective sensation results in unrecognised microtrauma, and fractures. There is loss of joint congruity with ligament injury, leading to subluxation and failure of the structural integrity of the three arches (Fig. 13.12) [55].

Diagnosis of the Charcot foot is a combination of clinical assessment and radiological investigations (Fig. 13.13). The skin quality, foot posture and joint deformity, signs of neurological and vascular deficiency are assessed. Callosities, loss of sudomotor response, loss of protective sensation, skin temperature, redness, paraesthesia, and dysaesthesia are noted. The redness in a Charcot foot diminishes in

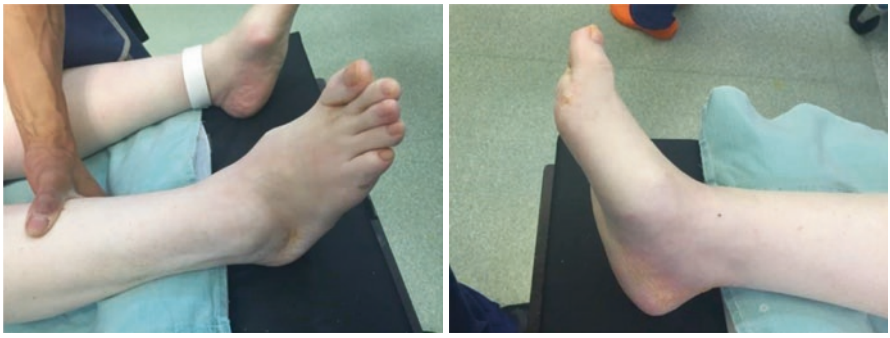

Fig. 13.12 Clinical photo of charcot foot

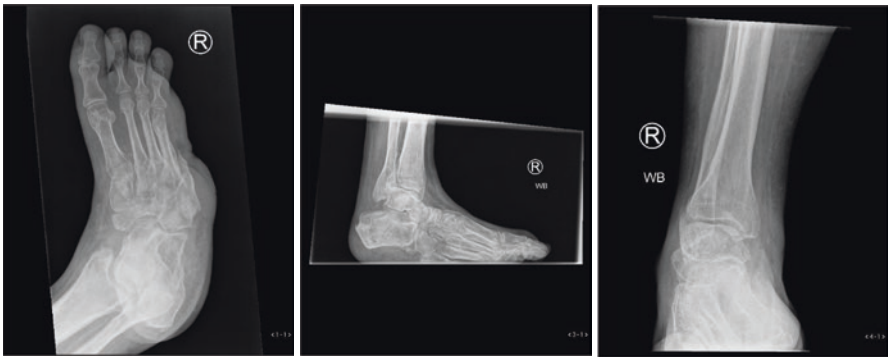

Fig. 13.13 Charcot foot X-ray

colour upon elevation suggesting a reactive hyperaemia. Vibration sense can also be diminished.

There are no serological criteria for Charcot foot. The inflammatory markers might be elevated if there is concurrent infection of a diabetic foot ulcer or underlying bone infection.

The modified Eichenholtz classification [56] for the staging of Charcot is as follows:

Stage 0: (Shibata)

Patients present with swelling erythema and warmth of the foot without any radiological changes. Management of the condition involves education, protected weight-bearing, and serial radiographic monitoring.

Stage 1: Inflammation

The acute Charcot process is a localised inflammation to a traumatic incident which precipitates the response in a vulnerable foot. This is caused by an imbalance between pro and anti-inflammatory cytokines. The bone responds with an acute phase release of pro-inflammatory cytokines, TNFα, and interleukin 1β, and interleukin 6, with a corresponding decrease in interleukin 4 and 10—anti-inflammatory cytokines. TNFα and interleukin 1β together initiates increased expression of receptor activator nuclear transcription factor κB (NF-κB) ligand (RANKL), activating monocytes and osteoclastic maturation, resulting in localised bone resorption. There is an intense and protracted inflammatory response of the bone as a result of the alteration of these cytokines, which results in bone destruction, and loss of structural integrity [55, 57]. Collapse of the medial arch at either the naviculocuneiform or talonavicular level creates an abduction deformity of the midfoot, and eventually the actions of tibialis anterior and tendoachilles causes a rocker bottom foot

deformity. As a result, a plantar medial bone prominence develops and becomes vulnerable to ulceration. (see Fig. 13.2).

The lateral arch integrity relies on the relationship between the cuboid and the calcaneum. As the calcaneocuboid ligament fails the cuboid drops, as the posterior tuberosity of the calcaneum is pulled proximally, and a prominence develops on the plantar lateral aspect of the foot.

Management of this stage involves protection in a total contact cast, which is changed initially weekly until the swelling settles and then every 2 weeks. The cast treatment can take between 2–4 months, or until the skin temperature settles to within 2° of the uninvolved foot, and there is evidence of radiographic resolution of bone fragmentation.

Stage 2: Coalescence

Absorption of bone debris, sclerosis, and bone consolidation and new bone formation occurs during this stage. This can be noted on the plain radiographs with increased bone density, and bony ankylosis of some of the larger bone fragments. Clinically the foot swelling and erythema decreases, and the temperature equalises to that of the unaffected foot. The foot is managed in a total contact plaster or a Charcot restraint orthotic walker (CROW).

Stage 3: Reconstruction/Remodelling

The foot now is the same temperature as the other foot, with an absence of swelling and redness. The joints are no longer collapsing, and the deformity is stable. The radiographic appearance is one of arthrosis or fibrous ankylosis. Fragments of bone appear rounded and smoothed off. For the plantigrade foot custom shoes with total contact insoles, a rigid shank and a rocker bottom sole are indicated. In a deformed foot with skin at risk of ulceration, exostectomy, or reconstruction with internal fixation may be necessary. Some patients complain of arthritic pain from their Charcot deformity—another indication for surgical reconstruction.

The intra and interobserver reliability of the Eichenholtz classification has not been validated, and it is difficult to identify the transition phases of the three stages. The lack of anatomical localisation makes the Eichenholtz classification difficult to apply in the treatment decisions for Charcot feet.

The goal of Charcot foot reconstruction is plantigrade with no bone prominences. At the end of the treatment the foot should fit into a custom shoe with a total contact insole. The surgical principles are rigid long segment reconstruction with beams and plates [58, 59].

External fixation can also be used to achieve long multisegment fixation [60]. Sammarco, in 2008, popularised long segment fixation, creating a "superconstruct"—in which the zone of collapse or injury is bypassed by anchoring the implant in healthy bone either side of the pathological joint segments [61–63].

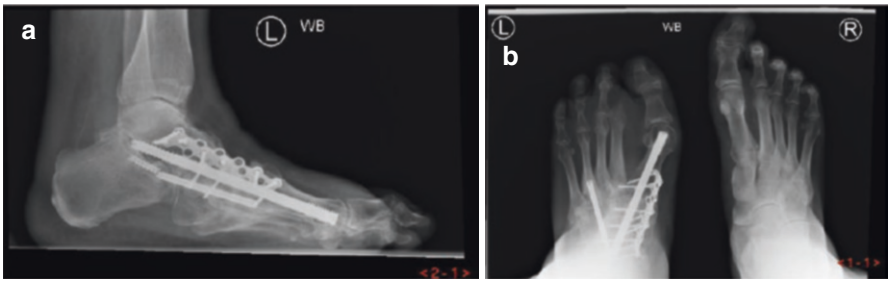

Fig. 13.14 Charcot reconstruction. (**a**) Reconstruction of medial arch by restoring alignment of first metatarsal and talus, and fusing with an intramedullary beam, neutralised with a medial plate. (**b**) Locking fourth tarsometatarsal joint to prevent collapse and failure of the lateral arch

Applying this principle, the medial ray is fixed from the head of the first metatarsal to the talus to reconstruct a midfoot Charcot rocker bottom deformity. The lateral arch is stabilised with fixation from the fourth or fifth metatarsal into the calcaneum. The intervening bones are fully prepared with removal of the articular cartilage, bone is resected with corrective osteotomies to restore the alignment of the arch, and to decompress the soft tissue. Incisions should be restricted to a single angiosome, to avoid disruption and mitigate the risk of wound breakdown (Fig. 13.14).

The implant design has gone through several iterations, with the current third generation of screws and plates giving the surgeon the best chance of creating a stable mechanical environment allowing the bones to fuse. The plate is applied to add further rigidity and neutralise rotational forces. The ankle and hindfoot joint can be fused using an intramedullary nail device augmented with a lateral or anterior plate for rigidity [63]. The literature reports an overall fusion rate of 86%, with a complication rate of 36%, and 95% of patients returning to weight bearing ambulation. The overall amputation rate is 5.5% [58].

In the infected Charcot deformity, reconstruction can still be a surgical option. The infection is initially treated, and the ulcer must be in remission before surgery is undertaken. Surgery is done in two stages. At the first stage the ulcer and infected bone are excised, and the residual bone treated with antibiotic impregnated bone void filler. The foot is temporarily stabilised with large diameter K wires, and the ankle placed in a plaster. The wound is dressed and monitored. Systemic antibiotics, as guided by local microbiology protocols, are given. The inflammatory markers and white blood cells are serially monitored for 2 months. Once these have normalised, the second stage definitive fixation can take place, utilising the principles of long segment rigid fixation, creating a superconstruct to bypass the zone of abnormal bone. The rate of fusion is 83% in the hindfoot and 60% in the midfoot for these two stage procedures as shown in recent series [64].

Healing of the bone takes approximately 3–4 months, and the patient is protected in a plaster for that time. Following removal of the plaster, the patient can be fitted with a custom-made shoe with a total contact insole and allowed to ambulate.

Key Points

- The role of the orthopaedic surgeon is to perform an orthopaedic foot and ankle examination and assessment of the patient presenting with diabetic foot complications.
- To undertake emergency debridement of foot infections. This depends on the organisation of services in the hospital. In some centres this responsibility falls to either the General or Vascular surgeons.
- Offloading surgery for diabetic feet to prevent ulceration of skin, or promote healing of ulcers, with a combination of soft tissue releases, and bony procedures
- Treatment of diabetic foot ulceration and bone infection. This should be done urgently to treat the septic foot and to preserve tissue, and ultimately function. "Time is tissue".
- Non-surgical management of Charcot foot is indicated for a deformity without bony prominences making the skin vulnerable to ulceration. The limb can be managed in a custom shoe with a total contact insole or a CROW boot.
- Surgical management of Charcot deformity:

  The bone exostoses predisposing vulnerable neuropathic skin to ulceration should be removed, and tendon releases performed to neutralise the forces driving the deformity.

  Surgical reconstruction to realign the medial and lateral rays, and restoration of the hindfoot alignment in relation to the tibiotalar axis. The aim is to create a rigid multisegment fusion.

  Fusion rates are reported to be between 60% and 80%, and overall amputation rate is 5.5%.

  Infected Charcot can be managed with two stage surgical reconstruction.

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Chapter 14
Foot Deformity and Pressure Management in the Diabetic Foot

Alexander D. Jones and David A. Russell

Introduction

The foot is a versatile organ whose functions include the ability to absorb shock on heel strike, being malleable to adapt to uneven surfaces, whilst at the same time acting as a rigid lever for propulsion during toe off. This normal function is reliant on the complex interplay between the joints of the hind-foot and mid-foot, in particular movements at the sub-talar and mid-tarsal joints. The combination of dorsiflexion/plantarflexion, abduction/adduction and inversion/eversion leads to the triplanar movements of pronation (dorsiflexion, abduction and eversion) and supination (plantarflexion, adduction and inversion).

During the gait cycle the foot is initially supinated on heel strike, with initial contact on the lateral plantar aspect of the heel. However, it rapidly moves into pronation and in this position the foot is malleable and therefore able to absorb the initial strike but also to accommodate variation in terrain. As the body moves over the foot during the stance phase of the gait cycle the foot moves from pronation to supination as the pressure loading on the foot transfers from the lateral heel across the foot to the first metatarsal. The move to supination is accompanied by a change in the biomechanics of the foot to the rigid lever which continues as the load is transferred from the first metatarsal to the hallux for toe off.

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Foot Deformity in the Diabetic Foot

Neuropathy

Although sensory neuropathy is the most commonly described element in neuropathic ulcers, the motor component of diabetic peripheral polyneuropathy plays a key role in the development of foot ulcers. Motor neuropathy causes wasting of the intrinsic muscles of the foot (lumbricals and interossei), leading to deformities such as claw or hammer toes. Unopposed action of the long extensor tendons also leads to plantar retrograde forces on the metatarsal heads, causing prominence of the metatarsal heads, pulling these proximal to the plantar fat pads. This leads to the classical neuropathic foot appearance with high pressure areas dorsally over the proximal interphalangeal joints (PIPJs) and on the plantar aspect over the metatarsal heads.

Tissue Glycosylation

Glycosylation of tendons and joint capsules leads to reduction in joint mobility and tendon contracture. Tightening of the Achilles tendon is often associated with the development of plantar forefoot ulcers. Achilles contracture raises the posterior portion of the calcaneum, leading to a negative calcaneal inclination angle and increased plantar forefoot pressures. This phenomenon is also associated with risk of lateral plantar ulcers following transmetatarsal amputation.

Charcot Neuropathic Osteoarthropathy

Charcot neuropathic osteoarthropathy classically affects the tarso-metatarsal joints but may occur anywhere in the foot. Still poorly understood, the disease starts with an acute phase characterised by hyperaemia, swelling and joint destruction secondary to increases in osteoclastic activity. This is followed by a period of stabilisation with absorption of bone fragments, fusion and coalescence of the joints. Finally, there is a period of remodelling. If untreated during the acute phase there is collapse of the normal bony architecture, classically leading to rocker bottom deformity of the midfoot.

Minor Amputations

All minor amputations disturb the normal biomechanics of the foot, and the consequences should be considered in any decisions regarding surgical debridement in the diabetic foot.

Minor toes tend to buttress the neighbouring toes and minor toe amputation may lead to valgus drifting of the medial toes. Amputation of the second toe will lead to hallux valgus deformity with increased risk of subsequent ulceration of the first metatarsophalangeal joint (MTPJ). Leaving a residual stump of toe where possible will allow the adjacent toes to remain supported and minimise this.

The hallux plays a major part in the propulsive phase of the gait cycle. Hallux amputation causes transfer of weight to the second toe and metatarsal with risk of transfer ulceration over these sites. Further, the hallux supports rotation of the first metatarsal head and thus hallux amputation also minimises the ability of the first metatarsal to bear weight. This increases pressure under the second and third metatarsal heads but also along their shafts with risk of fractures. Maintaining the attachment of the Windlass mechanism by preserving the proximal 1 cm of the proximal phalanx of the hallux minimises this risk.

Partial ray amputations can lead to increase in pressure under adjacent metatarsal heads. The axis of rotation means that the first and fifth metatarsals act as isolated rays whilst the central three rays act as a functional unit. Thus, amputation of the first or fifth ray has higher risk of transfer ulceration in the adjacent ray than amputation of a single central ray. Amputation of two central rays (with or without an outer ray) leads to significant biomechanical disturbance, very high risk of transfer ulceration and should lead to consideration of primary transmetatarsal amputation [1]. Furthermore, the insertion of the tibialis anterior tendon into the base of the first metatarsal, and the peroneus brevis tendon into the fifth metatarsal, should be preserved where possible. If this bone must be excised then the tendon should be preserved for future tendon transfer to prevent the development of pronation and supination deformities respectively.

Transmetatarsal amputation leads to unopposed action of the Achilles tendon due to division of the long extensors. This leads to an equinovarus deformity and subsequent risk of ulceration under the end of the remnant fifth metatarsal. The risk is increased as the amputation site moves proximally in the forefoot. Several techniques have been described to minimise this risk including rebalancing of the flexor and extensor tendons, or Achilles tendon lengthening, but none have good evidence of efficacy [2].

Pressure Management in the Diabetic Foot

All of the aforementioned conditions can lead to focal areas of maximum peak pressure in excess of 1000 kPa on weight bearing. It is this repetitive pressure insult, combined with shear forces, which leads to eventual tissue breakdown and foot ulceration, the precursor to major amputation in patients living with diabetes. In addition, sensory neuropathy removes the protection of pain resulting from a high-pressure stimulus.

One of the key components in management of patients with either high-risk diabetic feet or those with established ulceration is peak pressure off-loading. Although predominantly performed with footwear, surgical methods or adjuncts can also be applied. “Off-loading” is a misnomer as all methods aim to redistribute pressure rather than truly remove all pressure from the foot.

Off-Loading Footwear

Standard footwear, particularly fashion footwear, has poorly cushioned insoles which offer little in the way of pressure redistribution from high pressure areas. It is well established that pressure relief with therapeutic off-loading footwear is an integral part of the management of diabetic foot ulcers. The adage of prevention is better than cure is applicable in this setting; with 40% of ulcers recurring within 1-year of healing. Prevention requires a holistic approach encompassing risk stratification, patient education, regular foot screening and risk factor modification. As described previously, elevated plantar pressure is a key contributor to ulcer formation. Whilst there is less evidence to confirm the benefit off-loading footwear as a prophylactic measure, patients at moderate to high risk for ulcer formation should wear therapeutic footwear designed to reduce plantar pressure.

There is a wide range of off-loading footwear available, fitting largely into three categories: simple off-loading shoes, with or without total contact insoles; more complex off-loading shoes such as forefoot off-loaders and cast shoes; devices which extend above the ankle which have a calf load bearing component such as walkers (e.g. Aircast boot) and total contact casts (TCCs). The degree of off-loading varies widely between categories with simple devices achieving as little as 16% pressure reduction whilst TCCs can reduce peak pressure in the forefoot as much as 87% (Fig. 14.1) [3]. It can be seen from Fig. 14.1 that the workhorse devices used first line in many diabetes limb salvage clinics in the UK lie towards the least effective end of the spectrum, whilst forefoot off-loading shoes and those with a calf component are much more effective.

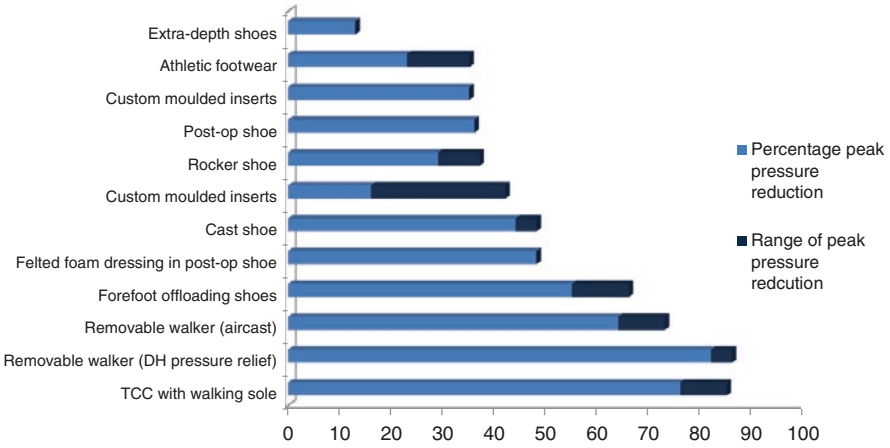

Fig. 14.1 Pressure reduction by commonly used off-loading footwear. Modified from Cavanagh PR et al. JVS 2010; 52(12S): 37S–43S

Efficiency of footwear in off-loading and patient adherence correlates directly with ulcer healing rates and the duration to ulcer healing. A recent meta-analysis found no difference between ulcer healing rate and time to ulcer healing between TCCs and non-removable walker boots. However, it was found that 3-month ulcer healing rates between 68% and 83% with TCCs compared with rates between 22% and 80% with removable walkers, and an absolute increase of 17% (risk difference 0.17, 95% CI 0.00–0.33) in the percentage of healed ulcers with TCC compared with removable walker boots. When TCCs were compared with therapeutic shoes, TCCs were associated with an increase in healing rate of 25% (95% CI 0.04–0.46) [4]. Patient adherence to off-loading is vital. One RCT demonstrated this relationship; the removable walker yielded a significantly greater peak pressure reduction at the forefoot compared with TCC (92% versus 84%), yet the TCC healed 82% of ulcers compared with 42% in the removable walker [5].

This data suggests that the off-loading strategies employed in the majority of patients, certainly within the authors unit, are less effective than available alternatives. Both the National Institute for Health and Care Excellence (NICE) and the International Working Group on the Diabetic Foot (IWGDF) recommend use of non-removable knee-high off-loading devices for neuropathic forefoot or midfoot ulcers [6, 7]. Application of TCC requires skilled technicians to minimise the risk of ulceration from ill-fitting casts, and can take up to 60 min fitting time, which would overwhelm many diabetes limb salvage clinics. These reasons may explain why TCC is only used routinely for neuropathic ulceration in 2% of US centres [8]. Conversion of a removable walker to a non-removable device, either with a cohesive bandage which takes a fraction of the time, or specific locking mechanisms in newer devices, and with data showing non-removable knee high walker boots being as effective as TCCs, we may see a trend towards these “instant” TCCs. In addition, non-removable devices were previously contraindicated in patients with infection or ischaemia; however the IWGDF now consider non-removable devices to be the first line treatment in patients with either mild infection or mild ischaemia.

The issue remains that persuading patients to agree to non-removable devices, particularly if this affects the ability to work or drive, can be very difficult. The literature suggests patient acceptability is perhaps misunderstood, with two RCTs showing no difference in patient satisfaction between removable and non-removable devices and a patient engagement review demonstrating a high tolerance for burdensome interventions if they are successful [4, 9, 10]. The authors’ experience does not reflect this however; our unit has occasionally had to resort to treatment contracts for non-concordant patients with deteriorating ulcers despite best removable off-loading who refuse TCCs. Off-loading is a balance between acceptability of the footwear to maximise compliance versus the effectiveness of that footwear in ulcer healing. Because of this we continue to use a policy of simple off-loading footwear or forefoot off-loaders as a primary modality, reserving walkers or TCC for the more complex or resistant cases.

Future Directions in Off-loading

Digital and smart technology may offer several solutions to identify at risk patients, optimise off-loading and improve patient adherence. Foot-health telemedicine platforms offer clinical teams the prospect of monitoring the status of the foot to detect early signs of ulcer development. Promising systems include temperature sensitive smart-mats and smart-socks, designed to detect the early signs of inflammation. The drawbacks of temperature assessment are its low specificity and the subsequent intervention is a wholesale reduction in activity, as opposed to targeted intervention.

A more directed approach is utilising technology to customise off-loading based upon plantar load assessment. Off-loading to reduce peak plantar pressure by 25% or to an absolute value of <200 kPa has been shown to reduce re-ulceration [11]. Despite this, due to expense and time pressures, plantar pressure assessment rarely makes it into clinical practice. The focus in many centres is to develop wearable plantar load monitoring devices, to transfer assessment from the clinic to the community. In addition, this enables the assessment of cumulative plantar load through all activities, rather than several steps within a gait lab. The emphasis moving forward is the assessment of the cumulative stress endured by the plantar tissues; this encompasses plantar pressure, shear stress and the volume of weight bearing activity performed.

Targeted off-loading is ineffective if not worn; a previous study has shown that patients only wear their off-loading device for only 29% of steps per day, despite believing that they are being highly compliant [12]. Biofeedback devices have the potential to modify behaviour to improve adherence and reduce harmful activity. Several studies have demonstrated the effectiveness of direct patient feedback from a smart insole via a smart watch, with ‘cues’ to trigger the wearing of offloading devices and reduce episodes of elevated plantar pressure [13, 14].

Surgical Off-Loading

The most important surgical consideration is the impact of minor amputations on future risk of ulceration. Data from the US has shown in patients subjected to a hallux or first ray amputation 42.1% underwent further ipsilateral amputation within 1 year, with 12.6% of those major amputations [15]. This has led to some suggesting that those requiring a first ray amputation should have a primary transmetatarsal amputation.

A number of surgical strategies to off-load specific diabetic foot abnormalities have been described. These can be useful in specific circumstances but it must be remembered that infection rates in patients with neuropathy undergoing curative corrective procedures for ulceration is approximately 20%.

Digital Ulcers

Flexible claw toe deformities of the hallux or lesser toes with associated apical ulcers can be treated by flexor tenotomy with healing rates in excess of 95% reported in the literature. Similarly dorsal IPJ ulcers in a flexible clawed toe can be treated with extensor tenotomy, again with excellent healing rates [16].

Arthroplasty of the hallux or lesser toes can be performed to correct deformities. More commonly the hallux ulceration is related to reduction in movement of the first MTPJ in which a Keller-type arthroplasty is more appropriate but can be associated with high peri-operative infection rates in this setting.

Plantar Forefoot Ulcers

For non-tunnelling ulcers metatarsal head osteotomy may be considered but more commonly ulcers are undermined, and either a single dorsal metatarsal head excision or pan-metatarsal head excision may be considered, particularly if the toes are normal. If a pan-metatarsal head excision is considered then it is important to maintain the normal metatarsal parabola. Metatarsal head excision has been shown to be superior to conservative treatment to improve rates of healing, reduce time to heal and reduce recurrence in one RCT, with more recent observational data supporting this [17–19].

Achilles tendon lengthening does not improve ulcer healing versus TCC for plantar forefoot ulcers, but there is evidence to suggest this does reduce recurrence rates [20].

Augmentation of the forefoot plantar fat pad, whether using silicone or autologous fat has been shown to increase tissue thickness and reduce forefoot peak plantar pressures [21, 22]. Further work is required to determine whether this translates to reduced incidence of DFU.

Charcot Foot

Surgical intervention for Charcot is primarily reserved for correction of abnormalities after the stabilisation phase. Exostectomy may be performed to reduce plantar pressures in those with a rocker bottom deformity. Similarly midfoot and hindfoot corrective disorders can be helpful and should be discussed with an interested foot and ankle surgeon.

Key Points

1. Foot deformity is a common sequel of diabetes and its complications
2. Off-loading is a key component in the management of all patients with diabetic foot disease. Patient education is a mandatory to maximise compliance.

3. Off-loading devices are more effective, both in ulcer healing, and time to ulcer healing, if irremovable an extending above the ankle.
4. Surgical off-loading should be considered in patients failing to respond to off-loading footwear provided conditions for ulcer healing have otherwise been optimised.
5. It is vital these patients are managed within a multi-disciplinary team with skilled orthotists, and that any associated ischaemia or infection are identified and treated promptly.

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Chapter 15
Prevention of Recurrent Ulcers: Protecting Lives and Limbs

Martin Fox and Jodi Binning

Overview

Recurrence of diabetic foot ulceration (DFU) is high and is reported to be 40% at 1 year, nearly 60% at 3 years and 65% at 5 years [1]. Diabetic foot ulceration precedes amputation which is found to be 10–20 times more likely for those with diabetes [2]. The cost on healthcare systems and society is significant, with diabetic foot disease alone utilising 0.6% of national healthcare expenditure [3, 4].

Many of the devastating outcomes from DFU are modifiable with 75% of recurrent ulcerations being suggested as being preventable [5]. In practice, there is insufficient evidence to support which preventative interventions are effective for an individual at risk of DFU although a few interventions have been shown to be useful in reviews of studies [6, 7]. Alongside the morbidity of DFU, peripheral arterial and cardiovascular disease are common in people with a history of foot ulcers and diabetes, and are causative in poor healing rates, amputations and early deaths. Cardiovascular risk management is an equally essential component of prevention for those at risk of ulcer recurrence.

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Education is cited within the literature as an essential component to improve outcomes and for life and limb protection. However, the effectiveness of education is low (under 15% effectiveness), and highly variable [8, 9]. Very little is known about what types of health education are most effective, when to offer them, and how to effectively support and influence health behaviour change. Education or behaviour change strategies require to focus on an individual's needs for support and information and also requires addressing any barriers to change [10, 11]. A personalised approach has the potential to improve the effectiveness of the clinical interventions we provide to prevent ulceration.

Mortality and Cardiovascular Risk Within Prevention Strategies

A significant challenge facing people with diabetic foot disease and for clinicians is understanding which risks to life and limb are modifiable. The emphasis of prevention and treatment for people experiencing DFU is most often limb protection, wound healing and amputation prevention. Whilst 15% of people with diabetic foot ulcers may have lost a leg at 10 years, the reality is that up to 70% will have died and over half of these deaths will be cardiac or cerebrovascular-related [12]. If we can view intermittent claudication as 'angina of the leg' and foot ulcers as life-threatening conditions, this may further assist understanding and prioritisation for timely treatment including life-long aggressive and tailored cardiovascular risk management [13, 14]. Studies have shown a positive impact on mortality rates with increased use and adherence to cardiovascular medicines for people who have a history of diabetic foot ulcers [15]. Larger studies have shown specific cardiovascular medicines, Rivaroxaban and Aspirin to improve event-free survival and amputation rates [16].

One of the challenges in broadening our preventative strategies to include cardiovascular risk management for those with DFU is the question of whose role is it? The National Institute for Health and Clinical Excellence (NICE) guidelines widely advocate CV risk management. However, it remains unclear which professions within our MDT are discussing CV risk for those who develop DFU. There is a possibility that assumptions are made between professions that another provider is managing it. GPs and primary care services are largely responsible for CV risk management aligned to Quality and Outcomes Framework (QOF) targets in the general population. Whilst the association between diabetes and CV risk is well known in primary care, the need to escalate to even more aggressive and preventative CV management for those who develop DFU may be less well known. Increased awareness of these links may be facilitated in the future by greater emphasis in clinical guidelines of cardiovascular treatment and prevention approaches alongside those focused on wound prevention and limb salvage.

Effective Interventions to Prevent Recurrent Ulceration

Despite the impact on individuals and society there is little high-quality evidence available to date on effective interventions and strategies that can help prevent recurrence of diabetic foot ulceration [6, 7]. Only five types of intervention have been demonstrated in reviews and research to prevent foot ulcers. These are:

1. Custom made footwear and offloading devices
2. Dermal infrared thermometry (skin temperatures),
3. Digital silicone devices
4. Access to and care delivery from integrated foot care services
5. Foot surgery

It still stands that providing timely access via defined local foot protection pathways to orthotists, thermography technology, podiatrists, podiatric, orthopaedic and vascular surgeons, will help to ensure these effective evidence-based interventions can be offered and tailored to individual patient needs.

Instinctively, alongside these interventions, clinicians continue to deliver patient education and advice on self-management to further reduce risk of developing a first or recurrent ulceration. This advice commonly includes:

- Accessing and wearing prescribed footwear daily
- Checking feet daily and taking quick action for new and early injury signs
- Avoiding walking barefoot to reduce risk of new injury
- Attending regular foot health appointments

For those who are engaged with their care and able to respond to early warning signs of re-ulceration, timely access to expert treatment forms an important element of their foot protection plan. Creative examples exist of prompts and reminders of when and how people at risk of DFU should access services. ACT NOW (Fig. 15.1) is one such initiative which involved people with experience of DFU designing credit cards, key rings and fridge magnets containing key messaging to support self-recognition, contact with local MDT or specialist foot services and rapid access for assessment and appropriate treatment to avert amputation risk in people with diabetes and high-risk feet [17].

Education, Advice and Adherence

Despite effort to tailor advice and make it accessible, evidence consistently demonstrates that patient education alone has minimal effect on ulceration rates [6, 8, 9, 18]. Most education to prevent ulceration is based on clinicians giving knowledge in the form of leaflets and verbal advice. This is often coupled with compassionate support and encouragement on how and why to adhere to advice given. When people are able to adhere to advice or an intervention, better outcomes are achieved

Fig. 15.1 The 'ACT NOW' cards, sized for purses, wallets and keyrings

with improvements of up to 50% across all interventions when compared to people who are non-adherent [9]. However, adherence in people with diabetic foot ulceration is frequently reported as low [5, 9, 19]. This aligns with observations from clinical practice where many of the same people are found to repeatedly return to clinics with recurrent ulceration.

It seems that however important advice and adherence may be in order to prevent recurrent ulceration or to reduce mortality from cardiovascular event, our current education strategies remain insufficient to influence what patient's do [10]. It is often cited that the absence of pain due to sensory neuropathy is the cause of non-adherence in the diabetic foot population and hinders preventative strategies from being effective [1]. Without the protective function of pain, patients are thought to not adhere to wearing prescribed footwear or checking their feet because they do not perceive there to be a problem. However, behavioural research suggests that solely attributing non-adherence in those with recurrent DFU to sensory neuropathy overlooks the vast number and complexity of determinants of non-adherence, many of which can be with improved with behavioural interventions. It remains the case that people with recurrent ulceration are often those who also find it difficult to adhere to other aspects of diabetes self-management such as blood glucose monitoring, dietary advice, medication; all of which are unrelated to pain perception.

Adherence to self-management or advice is likely to occur if it is considered important by the person, they are confident they can do it, they have the knowledge and skills and there are no serious environmental constraints to doing and maintaining it [20]. The barriers that have been demonstrated to prevent adherence for people at risk of recurrent diabetic foot ulceration include an array of competing needs involving work, family, social norms and socio-economic constraints [21]. These

barriers mean that the simplest of health behaviour changes such as wearing prescribed footwear or checking feet are challenging to incorporate into daily lives, for life. Furthermore, there is an increasing acknowledgement of the impact of emotions, sense of control, and the incidence of depression and distress on the motivation and capability to self-care for those with complications associated with diabetes. Going forward, the likelihood is that our approaches require a greater focus on a personalised and targeted approach to improve or maintain adherence in order to enable clinical interventions to have their best effect. Some of the developments in approaches to improve adherence and an individualised approach is described in subsequent sections in this chapter.

Effective Interventions to Manage Cardiovascular Risks and Tackle Mortality for Those with DFU

Cardiovascular (CV) risk management involves a variety of specific activities and interventions, from information giving, negotiating changes in health behaviours and beliefs, medication review, prescribing, referrals to support services, continuity, and follow-up. Put together well, these interventions are perhaps best demonstrated in cardiac rehabilitation service models, the likes of which have been widely set up and made available for people with cardiac disease [22]. Such programs integrate exercise into the overall treatment plan that includes lipid management, blood pressure control, smoking cessation, nutrition education and weight reduction, diabetes mellitus treatment, and psychosocial intervention. The American Heart Association has widely promoted the seven modifiable components of ideal CV health [23].

These are:

- Not smoking
- Regular exercise
- Healthy diet
- Body mass index
- Cholesterol
- Blood pressure
- Blood glucose

These modifiable factors are not always well understood by those at risk of developing CV disease. Studies have shown that 63% could not identify the seven modifiable components of CV health and hat 37% of respondents did not know that diabetes is a CV risk factor [23].

With the use of a multifaceted approach, cardiac rehabilitation and secondary prevention programs have been associated with up to a 56% improvement in survival among patients after myocardial infarction and a 28% reduction in risk of recurrent myocardial infarction [24]. There is some evidence that a focus on cardiovascular risk management can improve amputation free survival in those with

diabetes. Where multidisciplinary diabetes foot teams have systematically introduced aggressive CV risk factor management in people with foot ulcers, outcomes around 5-year mortality rates have been observed to dramatically improve, from 48 to 26.8% [15]. Success in CV risk factor reduction in people with diabetes has also been demonstrated where nurse-led clinics have been set up to focus on the key modifiable risks [25]. Successful smoking cessation has also been shown to be associated with decreased mortality and improved amputation-free in people with peripheral arterial disease, in a study that included people with diabetes [26].

Exercise Versus Rest

CV exercise as part of a structured and supervised cardiac rehabilitation programme has been shown to be highly effective in reducing cardiac-related and total mortality [24]. In people with diabetes, exercise has also been shown to have broad benefits in relation to CV reduction, morbidity and mortality [27] and in people with diabetes and peripheral neuropathy, exercise has helped with reducing pain and improving neuropathic symptoms [28]. Similarly in people with peripheral arterial disease, it is broadly recommended for all people diagnosed with symptomatic disease (intermittent claudication), to help improve pain-free walking distances [13]. Studies have also shown improvements thought to be due to improved cardiovascular functioning in people with peripheral arterial disease, from upper body exercise plans [29], which has relevance for the people with diabetes, at risk of ulcer recurrence.

Difficulty arises in those who develop DFU or those who are at risk of recurrence after healing. The evidence for reducing load over an ulcerated area is well established and people are therefore advised by clinicians to rest, often for weeks, months or years, in attempts to support ulcer healing and prevent recurrence. However, the type of load, time of load, and role of offloading devices are all factors that affect outcome and the general advice to rest may require to be balanced for people with or at risk of DFU, against the impact on quality of life and the known associated mortality risks from CV events. Clinical evidence does not appear to fully support the current ‘embargo on exercise’ for people with diabetic foot disease, to achieve offloading. Some studies have shown that exercise does not appear to increase the incidence of diabetic foot ulcers in people with existing peripheral neuropathy [30] and has not been shown to increase re ulceration in people who have healed from foot ulcers [31].

The complexities and uncertainty of introducing exercise therapy and deciding when to move from non-weightbearing exercise to weightbearing exercise in people with diabetes and significant lower limb disease remain. With weight-bearing exercise, current discussions include determining a ‘safe’ range of load stress during and after healing to increase plantar tissue strength and reduce re-ulceration risk and the role of plantar pressures and adherence [32]. Although increased weight-bearing activity can be associated inversely with DFU healing, evidence is weak and there is also an acknowledgement that suggests weight-bearing activity can be considered for people at moderate & high risk of ulceration [32]. Safety of exercise,

participation, drop-out rates, provision of accessible home-based and supervised support are all other considerations that need to be addressed [33].

A recent systematic review of the exercise in people with DFU identified insufficient evidence to conclusively support exercise as an intervention to improve healing. It did however state that there were no negative consequences identified and that given the potential benefits on health and well-being, non-weight bearing exercise should be encouraged. Further investigation to determine type, frequency and types of exercise supervision is needed [34].

The current norm of actively withdrawing or advising against exercise as an intervention for people with high-risk lower limbs is a key priority for further priority research, in view of the negative impact of prolonged inactivity in diabetes generally. Arguments for and against increasing exercise have been discussed but are not yet clearly resolved [35]. Studies for people with diabetes and risk of ulcer recurrence will likely need to include designing and prescribing low tissue stress, chair-based CV exercises for people with DFU or those who have already had an amputation. Partnerships with existing cardiac or cardiovascular rehabilitation services may assist pathways to offer people with diabetes foot complications safe, supervised, effective bespoke exercise interventions. There are current studies in progress to research the effects of seated moderate intensity exercise on people with DFU [36].

Communication and CV Risk

For the Individual

Inaccurate perceptions of CV risks by clinicians and the challenges of communicating them in an understandable and patient-centred way has also been suggested as a key barrier to patients taking on cardio-protective changes [37].

Guidance from the American College of Cardiology [38] notes the strong emotions and impact of conversations on CV risks. The college suggests an individual can be supported by:

- Explaining risk in simple terms
- Making it meaningful to the person and their individual circumstances
- Assessing their understanding of what they need to manage their risks

Simply discussing CV risks with people may have an impact on their perceptions, understanding and adherence to initiate risk reducing health changes [37]. All providers of diabetes foot care services from foot screening, podiatry, wound care and multidisciplinary foot teams have an opportunity to discuss CV risk and to signpost people towards medicine review (e.g., antiplatelet agents or intensified blood pressure control) or lifestyle change support (e.g., smoking cessation or weight management) and reviewing these issues. Using every opportunity to ask people with diabetic foot disease for permission to discuss their modifiable life and limb risk awareness and available risk reduction options, will clinicians be

able to assess modifiable risk awareness and readiness to engage in or change risk reducing health behaviours. Ongoing support by clinicians for people who then make positive changes can help people to keep people on track and allow them to continue to incorporate their preferences and motivations into individually tailored CV care plans and agreed CV risk reduction targets.

Co-production for Awareness Raising

The development of resources and information for individuals and groups remains important for those who are ready and required to understand and manage their own condition. Co-production of resources with people who have experienced DFU, amputation or CV events can improve the utility of posters and guidance being developed. Figure 15.2 below shows an example of a co-produced DFU mortality and amputation awareness poster and a CV risk discussion leaflet developed with input from a support group for people who had undergone amputations. This project aimed to raise awareness around DFU associated mortality and amputation risks and to enable focused discussions with people on modifiable CV risks to generate individualised care plans. The use of the information resources has been reported in a multi-site small pilot, involving interested diabetic foot clinics from around the UK [35].

Initial findings from people who evaluated these resources was that the majority found them useful in raising awareness, prompting discussion and setting personal DFU risk reduction plans. 88% of patient respondents indicated that they wanted clinicians to continue to use the posters and leaflets with patients. Twelve percent of responding patients however, indicated they didn't want clinicians to continue to use the resources. Concerns were expressed by some clinicians, about the potential for fear-inducing messaging in the pilot poster [35]. Fear-based messaging as discussed below, warrants ongoing rigorous investigation and exploration, around the impact on people with significant foot disease. In particularly those people who may find adherence to mortality and amputation risk reduction associated with their foot disease more challenging.

Fear-Based Messaging

Whilst resources may be co-produced, factually correct, and aim to support prevention of DFU and cardiovascular events, the messages contained can be 'hard hitting' as observed in the diabetes foot risk awareness poster in Fig. 15.2 above, which reflects the emerging parlance of likening DFU seriousness to cancer.

Five-year survival rates are comparable between DFU and some cancers, yet the impact of articulating this risk to people may not have the intended consequence of improving adherence. The reasoning behind fear-based messaging is that when

a

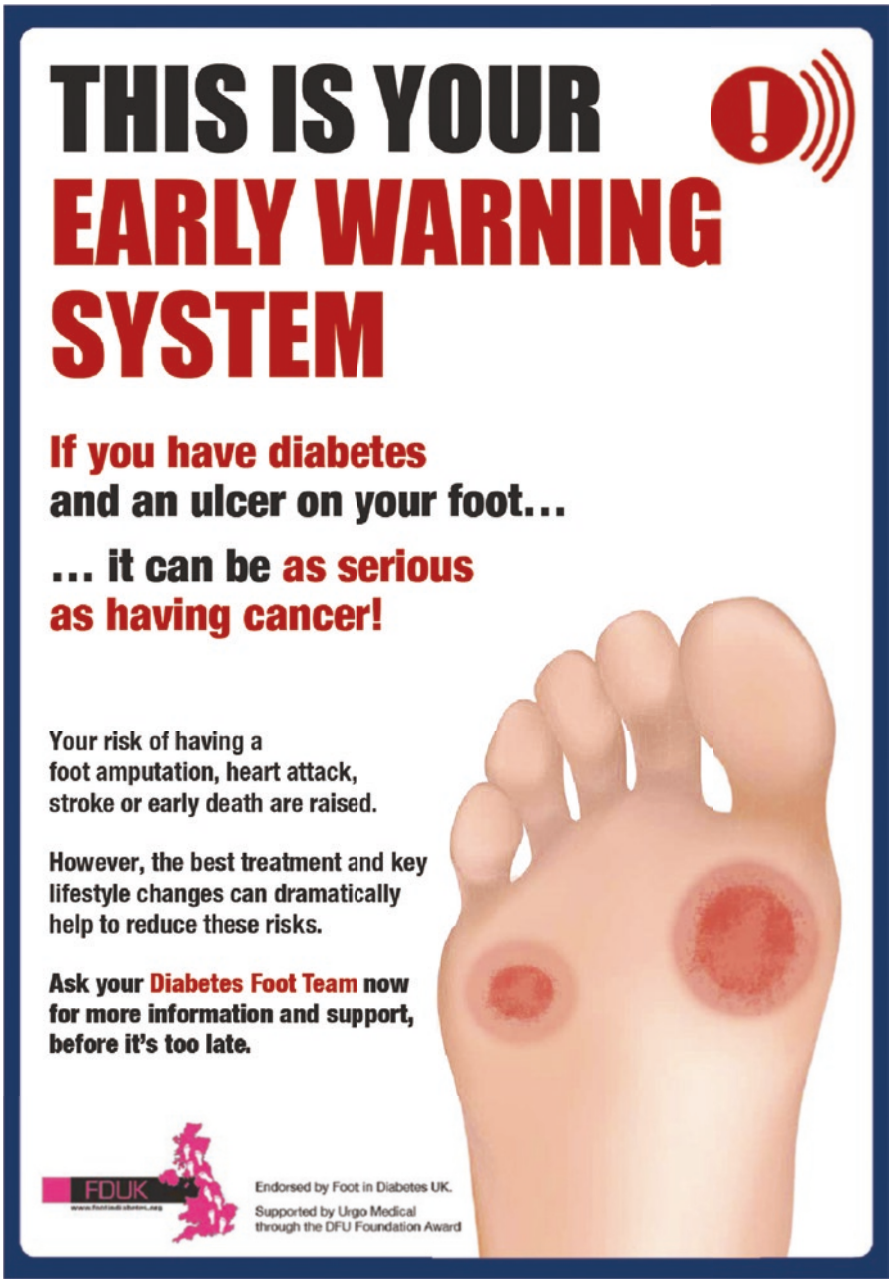

Fig. 15.2 (**a**) Diabetic foot ulcer, CV & modifiable mortality risk awareness poster example. (**b**) CV risk reduction messaging example, for people with diabetic foot ulcers

b

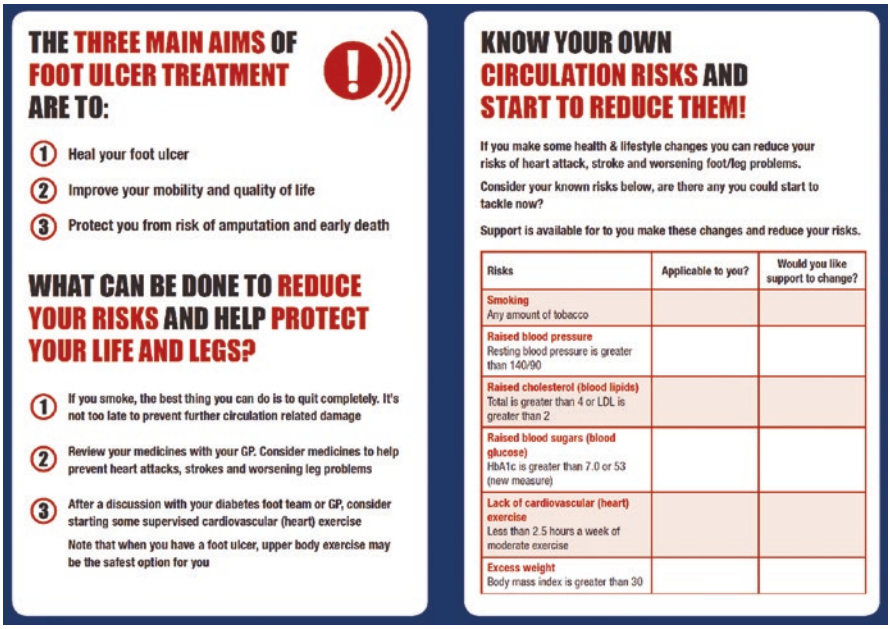

Fig. 15.2 (continued)

people are confronted with the negative effects of their behaviour, they will change their behaviour [39]. However, evidence from meta-analyses demonstrate that for people to respond positively to fear-based messaging they need to have high self and treatment efficacy [39]. Findings show that people need to believe that they can change and also need to believe that the change will make a difference to their outcome. Conversely, in the presence of high emotion and residual fear about risk, further threat posed from fear-based messaging has been found to push people further into resistance and denial [39].

For people at risk of recurrent DFU and cardiovascular events there is a known high level of emotion, fear of amputation, and a likelihood that they hold beliefs that whatever they do the consequences are at out with their control. To this effect the use of preventative materials and messages that further increase fear and emotion is unlikely to produce behaviour change and adherence and in fact may have a counterproductive effect. This evidence guides us further towards personalised approaches to prevention, education and behaviour change whereby resources can be selected judiciously based on a person's readiness.

In consultations whether and how to communicate associated mortality and amputation risks to support informed decision-making is a complex decision for clinicians. The potential for inducing fear or distress with patients and families requires consideration. This is particularly the case with people who have had foot ulcers and those where recurrence has occurred, as the burden for this at-risk group is often already high. Before electing to raise associated modifiable mortality and

amputation risks, an approach that enables the person to take control includes asking permission to raise risks and discussion about them. Careful listening for responses will indicate whether the person is ready and willing to hear about potential consequences and ways that they can mitigate risk with their behaviours and choices. A structured approach to this sort of consultation has been developed in other areas of complex healthcare, using a model called SPIKES [40, 41]. The principles may hold some relevance for diabetic foot teams and clinicians.

The SPIKES 6 step protocol for breaking difficult or bad news:

- STEP 1: SETTING UP the consultation
- STEP 2: Assessing the person's PERCEPTION of the illness and how serious it is
- STEP 3: Obtaining the person's INVITATION to discuss the diagnosis
- STEP 4: Giving KNOWLEDGE and Information to the person to support their agenda
- STEP 5: Addressing the person's EMOTIONS with empathic responses
- STEP 6: STRATEGY for what next and SUMMARISING an agreed plan

Behaviour Change Strategies to Reduce Recurrent DFU and CV Risk

A common theme in this chapter is the potential for supporting behaviour change to positively improve prevention of ulceration and CV risk. Currently, services do not appear to have access to a stepped approach to supporting behaviour change and the need to support strategies to improve adherence is not widely included in clinical guidelines. Access to psychology teams is available for some clinical teams but is reserved for those with psychopathology including moderate or severe depression and anxiety. Psychology services are suggested to be less accessible or even appropriate for working with people on their motivation, beliefs to improve adherence [42].

A wide range of behaviour change techniques and strategies are available that do not require specialist psychology or counselling training. A range of supportive techniques are reported that aim to actively engage each person based on their beliefs and needs [43–45]. Behaviour change strategies can be enabled by the positive relationships with people who are at risk of ulceration and CV event who have been attending clinical services over many years [46].

Motivational Interviewing

Motivational interviewing is an umbrella term for a range of techniques that assists people to become more aware of their reasons for change through non-judgemental conversation and collaboration [47]. The two phases of motivational interviewing are summarised below [45, 48, 49]:

Phase 1: Evoke and strengthen motivation and change talk by:
– Building a relationship/use of empathy
– Understanding motivation level as a starting point
– Supporting autonomy
– Raising doubt, pros and cons of change and risks of not changing
– Exploring alternatives
– Exploring optimism and strengths
– Exploring resistance and barriers
– Defining if there is sufficient readiness to move to commitment
Phase 2: Articulate and strengthen commitment to change by:
– Defining the specific behaviours to be targeted and the starting point
– Identifying goals and actions
– Identifying self-monitoring mechanisms
– Identifying own measures of success
– Identifying who can provide ongoing support
– Identifying who can review

Fig. 15.3 Language that is consistent with motivational interviewing

Motivational interviewing looks and feels different to usual clinical conversations with an emphasis on the participant doing most of the talking (Fig. 15.3). The clinician in motivational interviewing is a helper and does not come with the perspective or language of an expert professional. The clinician uses reflections and curiosity with permissions to encourage and guide personal exploration of motivations towards change. As an intervention, motivational interviewing is not easy to include as a 'bolt on' within usual clinical and wound care practice. In busy clinics active listening and time to explore barriers to change without distraction is rarely possible amongst clinical tasks [50].

The implication of introducing motivational interviewing or similar techniques into clinical practice is that additional appointments may be required out with usual appointment schedules. Ideally the intervention would be carried out in a different, non-clinical room to avoid distraction for both the clinician and participant. Motivational interviewing has been found to take 2–3 sessions to have an impact and has been demonstrated to outperform usual patient education methods where behaviour change and adherence are the desired outcomes [47, 51]. Whilst there are insufficient studies currently on the impact of motivational interviewing to improve adherence in those at risk of DFU specifically [52], motivational interviewing has

been demonstrated to be effective in supporting behaviour change in a wide range of populations including those considered resistant to change [45]. This includes those attending addiction services, those with chronic musculo-skeletal conditions, obesity and those living with HIV [53].

Meta-analyses have shown that 75% of participants gained some improvement from motivational interviewing and 25% gained a strong effect [53]. If these results were able to be replicated for those at risk of DFU recurrence, as well as the positive impact on people's lives, there would significant savings to services. With the costs of treating an unhealed ulcer been reported to be £8800 per year compared to £2140 for a DFU that heals, then an increase in behavioural adherence that delays or enables healing for a year would save £6540 per person per year. Where amputation can be prevented the savings would be an excess of £16,000 per person per year would be saved [54].

Conclusion

The development of preventative strategies for effective offloading, foot surgery, thermometry, early and accurate risk diagnosis, and the combined skills of integrated teams is key to prevention of recurrent DFU and cardiovascular events. The need for ongoing work upstream for primary prevention and lifestyle changes also remains high. The challenge of how best to consult with people at risk of foot ulcer recurrence to encourage optimum adherence to risk reducing behaviours and interventions is a vital area for further research. This chapter has posited that alongside the expertise in assessment, diagnosis and management of those at risk of DFU recurrence and cardiovascular events, that a greater focus is required on adherence and person related factors. With understanding the strategies and conditions that enable adherence to be better supported, improvements in self-management, ulcer & amputation prevention and early mortality from limb-based and cardiovascular interventions, may be realised. The potential to unlock significantly more life and limb improvements for people, with wound and amputation free survival, is very real.

Key Points

- Does your service offer the five interventions shown to help prevent foot ulcers?
- Has your service involved people with diabetes foot disease in the design and introduction of any patient rapid access resources (e.g. the ACT NOW initiative)?
- What training have your diabetes foot had in consultation and health behaviour change techniques such as motivation interviewing?
- Who is responsible in your team for CV risk management assessment /review, for people with diabetes and foot disease?
- Is prescribed 'rest', if prolonged, depriving people at risk of recurrent foot ulcers from healthy activity and CV exercise and contributing to frailty and early deaths?
- How can we best communicate with people about their modifiable CV associated amputation & mortality risks, and their survival opportunities, without inducing fear?

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Chapter 16
The Role of the Multidisciplinary Team in the Management of Diabetic Foot Complications and Organisation of Regional Networks and Data Collection

Andrew Schiro and Arun D. Pherwani

Overview

Across the UK, major amputations pose a significant burden on the NHS with a considerable disparity depending on geographic locations. It was shown 10 years ago that the rates of major amputation varied a staggering tentimes between localities [1], and a recent review suggested that it appeared to be only slightly less so in more recent years [2].

The National Vascular Registry

The 2020 National Vascular Registry (NVR) report logged 10,022 patients who underwent major amputation surgery in the UK between 2017–2019. These comprised 52% below knee amputations (BKA) and 48% above knee amputations (AKA). The majority of patients were men who presented with tissue loss and over half had already undergone a previous ipsilateral lower limb amputation. Nearly 80% of these patients presented acutely and over 90% suffered one or more common co-morbidities. Diabetes Mellitus (DM) was the major co-morbidity in 70% of patients undergoing BKA. These patients often stay long in hospital with a median stay of 23 days (IQR 13–39 days) with an overall in hospital mortality of 8% [3].

There have been major improvements seen in the care of these patients following recommendations from the NCEPOD report on major amputations with in-hospital mortality reported at just under 5% for below-knee amputations and under 10% for above-knee amputations compared to an overall mortality at nearly 13% in the 2014 NCEPOD publication [4].

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However, there still remain areas where care of these patients can improve along with more accurate recording of data on national audits such as the NVR with case ascertainment rates >85% recommended in the 2018 GIRFT Vascular report [5]. The case ascertainment rates for major amputation on NVR remain around 80% when compared to HES (Hospital Episode Statistics) data [6].

The importance of data collection cannot be overstated. Many NHS Trusts are still failing to record a large proportion of their major lower limb amputations in the NVR. Furthermore, the NVR records a very small number of minor amputations (*n*-3335, 23.5%) during the same period, grossly under representing the activity and the burden of disease. This is particularly important in terms of outcomes for these and the potential for prevention, given that over half of the patients undergoing major amputation have undergone a previous ipsilateral minor amputation.

The National Diabetic Foot Audit

Since its establishment in 2014 The National Diabetic Foot Care Audit (NFDA) measures the volumes outcomes and treatment structures/processes for newly occurring foot ulcers affecting diabetic patients. The NDFA aims to record every new foot ulcer, measure healing rates and record the numbers amputations in patients with diabetic foot ulceration Their aim was to determine the variation in clinical outcomes across England and Wales and the extent to which the differences could be explained by differences in patient care. NFDA consistently found a strong link between ulcer severity and worse outcomes in diabetic patients. Early referral meant better outcomes [7].

The NDFA team aims to support foot care for patients with diabetes through consultations with health care professionals and policy makers. They have identified the need to reduce the time of referral and assessment of such patients to improve outcome. With its access to the NVR and Hospital Electronic Statistics (HES) database the NFDA audit team can identify regions in the UK which are faring poorly and in so doing could aid and suggest measures to improve outcomes. However, the problem with the NDFA remains relatively poor case ascertainment and a recent editorial highlighted the need for reliable data on outcomes in the management of diabetic foot disease [8].

Shared data and linkage between the NVR the NDFA both commissioned under the HQIP programme of national audits with HES data correlation will help determine the scope of the problem and drive the quality improvements required in the care of patients with diabetic foot disease along with the priorities of the PAD-QIF [9].

Diabetic Patient in the Community-Prevention and Management

Patients with diabetes mellitus attending community GP surgeries should undergo a thorough assessment to provide an all-round person evaluation to determine and understand the factors that are affecting health and quality of life. Diabetes is

Assessment should include: - *Medical and psychosocial history, dietary*
- *Physical assessment*
- *Assessment of complications - retinopathy, foot ulcers*
- *Cardiovascular risk status – BP, smoking cessation*
- *Investigations- Blood work including HbA1c*

Fig. 16.1 A healthcare professional seeing high risk diabetic foot patients should be competent able to undertake these assessments

Foot Ulcer Prevention

1. Identifying the foot at risk
2. Regular foot inspection
3. Educating of patient, family and healthcare professionals
4. Ensuring appropriate footwear
5. Treating risk factors for ulceration

Fig. 16.2 Key features of diabetic foot ulcer prevention

commonly associated with hypertension, dyslipidaemia, obesity and physical inactivity all of which predispose to a high cardiovascular risk which should be addressed.

Patient education presented in a structured and repeated manner plays an important in the role in diabetic foot ulcer prevention. A well-educated patient will have proper foot self-care knowledge and is able to flag up any abnormalities to their GP, practice nurse or podiatrist. Patients need to learn how to identify foot ulcers and signs of infection before problems arise. Likewise, healthcare professionals should periodically be improving their skills on how to identify and manage high risk diabetic foot patients (see Fig. 16.1).

Individualised planning for ongoing care should also be developed at this stage, including negotiated goals and expectations. Secondary prevention to prevent complications of macrovascular disease in the form of smoking cessation, appropriate antiplatelet, statin and antihypertensive therapy and ACE (Angiotensin converting enzyme) inhibitors/ARB's (Angiotensin Receptor Blockers) to prevent renal complications and nephropathy requires to be initiated early in the disease [10–12]. In the ideal scenario diabetic patients should have all their co-morbidities well controlled, have proper foot wear and advice to prevent them from developing foot ulcers/ischaemia in the first place (Fig. 16.2). However, we know that this is virtually impossible as patients slip through the system. Patients with diabetic foot ulcers should be referred to and followed up by the local podiatry team on a regular basis

to constantly flag new changes in their feet. When infection sets in, ulcers fail to heal, or limbs become ischaemic patients should be referred urgently to the local vascular team for evaluation.

Diabetic Foot Service in Hospital

A diabetic foot service should be co-ordinated through diabetic foot clinics and include multidisciplinary team (MDT) who review new and follow-up patients. The ideal MDT should consist of a podiatrist, dietician, orthotist, diabetologist, microbiologist, orthopaedic foot and ankle surgeon, vascular scientist, vascular surgeon and a vascular interventional radiologist. Following the initial assessment, a plan is actioned which is patient centred (Fig. 16.3). Patients should be either be followed up in the podiatry clinic in the community if they have minor issues or in joint multidisciplinary clinics for more complex patients. Follow-up should consist of regular patient education, foot care, bypass graft surveillance and secondary prevention of cardiovascular and renal disease [13]. The pathway ensures early detection of complications and provides aggressive management of ulcers.

Diabetic patients with severe foot problems should be admitted to hospital under the medical or vascular teams and cared for in an MDT approach. Vascular specialists, in particular interventional radiologists, can then guide the teams appropriately with required imaging such as pre-operative magnetic resonance angiography (MRA), computerised tomographic angiography (CTA), or catheter angiography when surgical intervention is required or intervene endovascularly. A 24 h on call service for accepting referrals of patients with diabetic feet, whether urgent or chronic is important in that it helps avoid missing or delaying treatment [14].

The Vascular Society of Great Britain & Ireland (VSGBI)'s Provision of Vascular Services (POVS) 2021 document recommends that patients admitted as an emergency should have specialist review, WIFI score and vascular imaging performed

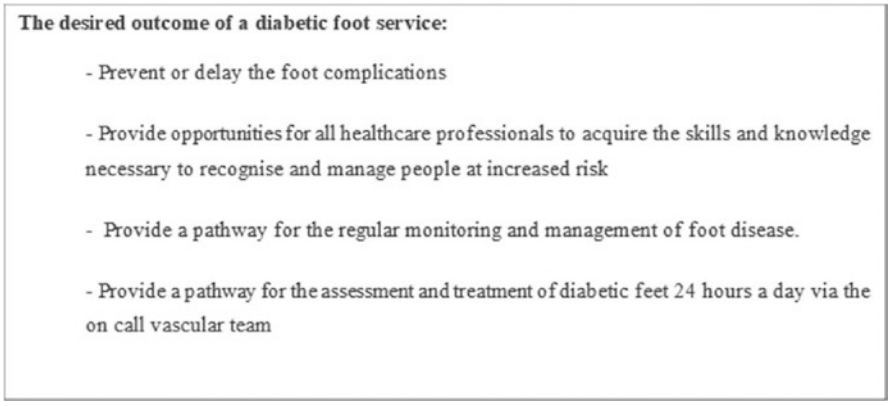

Fig. 16.3 Key components of a diabetic foot service

within 48 h of referral irrespective of whether admitted to the arterial centre or a network hospital whereas the non-admitted patients should have specialist review, WIFI score, and vascular imaging performed within 7 days of referral, ideally at a network hospital close to where they live [15].

The GIRFT DM Report

The issues we raise in this chapter were highlighted in the findings and recommendations of the GIRFT (Getting it Right First Time), report on DM published in November 2020 [16]. It was noted that one in six hospitals in England did not have a multidisciplinary foot care team; A quarter of hospitals diabetes inpatient MDTs did not have a single diabetes inpatient specialist nurse and were woefully understaffed [17].

Recommendations were made that trusts should have a dedicated diabetes inpatient MDT, including nurses, pharmacists, dietitians, psychologists and podiatrists. These also should include the right expertise in medical teams with diabetologists, foot and ankle surgeons and vascular surgeons all with a keen interest in the prevention and management of diabetic foot ulceration [18].

The report further recommended that trusts should work towards providing a seven-day service with at least one MDT team member, such as a specialist diabetes inpatient nurse, available for part of the day on weekends so that urgent cases can be seen by a diabetes specialist within hours.

For outpatient services, the report recommended having a community-based footcare protection service (FPS) to screen people and help prevent diabetes-related problems in the community, along with rapid access to specialist hospital-based MDTs to reduce rates of ulceration and amputation. Community-based staff should be trained to carry out foot screening examinations.

As has been noted previously, the GIRFT also reported a wide variation in the quality and coordination of these services across the country. In many areas, hospitals still do not have a fully established MDTs, and in some areas, there is no FPS. They also recommend that all trusts should have a dedicated MDT's well integrated with the FPS.

The GIRFT team identified vascular impairment as a key contributor to diabetic foot ulceration and amputation and therefore suggested it was vital for at risk diabetes patients to have access to good vascular services. It was noted that in particular the smaller non arterial spoke hospitals found difficulty in obtaining urgent vascular opinion. Hence, their recommendation was every patient with a diabetic footcare emergency requiring admission should be assessed the same day by the hospital-based MDT, and if vascular impairment is identified, they should have same day access to a vascular opinion either with surgeons who have dedicated sessions at spoke site and if not, then there may the need for urgent transfer to the vascular arterial hub site.

The GIRFT report reviewed the importance of data and coding and made recommendation that every acute trust should submit data to the National Diabetes Audit, the National Diabetes Inpatient Audit and the National Diabetes Footcare Audit including reporting of harms, quarterly review of results and national benchmarking

with peers [19]. The report clearly recommends adequate IT support for these tasks identifying the importance of data analysts and coders.

An area that remains to be addressed is the disconnect between traditional Clinical Commissioning Groups (CCG), derived community based diabetic foot services and Specialised Commissioned in-patient arterial services which have posed significant challenges to the establishment of robust, reliable, well-resourced and nationally reproducible integrated diabetic foot care services between community FPS and hospital based inpatient diabetic food MDT's.

Rapid access to vascular surgeons in 24–48 h has been highlighted in the GIRFT DM 2020 report and in POVS 2021 and this calls for renewed efforts to integrate vascular and diabetes services. One would hope future commissioning intentions with Integrated Care Services (ICS's) would meet healthcare needs across regions, coordinate services and reduce inequality and variation [20].

Furthermore, there should be unified and widely adopted recommendations about aggressive early medical management and preventative therapies to avoid macrovascular complications, provide early recognition and prevent or treat diabetic foot ulceration long before they approach vascular shores as we commonly see with end stage diabetes, poor glycaemic control, unaddressed vascular risk factors, and a "foot attack" that often culminates in amputation with a significant risk of death [21].

Key Points

- The ideal MDT consists of a podiatrist, dietician, orthotist, diabetologist, microbiologist, orthopaedic foot and ankle surgeon, vascular scientist, vascular surgeon and a vascular interventional radiologist.
- Early referral and involvement of the MDT in diabetic foot care improves outcomes.
- Every Acute Trust providing Diabetic Foot care should enter data to the National Diabetic Foot Ulcer Audit (NDFA) and the National Vascular Registry (NVR).
- A community based Footcare protection service (FPS) should be in place to screen patients and help prevent diabetes-related problems with rapid access care pathways to specialist hospital-based Diabetic Foot MDTs.
- All patients with diabetic foot complications requiring emergency care should be admitted and assessed on the same day by a member of the MDT diabetic foot services and those with vascular impairment reviewed by the vascular team within 24–48 h.

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Chapter 17
How to Measure Success

Naseer Ahmad and Frank L. Bowling

What Is the Published Prevalence of Amputation and the Pitfalls of Its Analysis?

To determine the number and epidemiology of diabetic foot amputations (in the UK), data is available from two sources: published peer reviewed journals and freely available national/local databases. This data can then be used to compare outcomes across both geographic areas and individual services.

Published Data Regarding Amputations

The published prevalence of major lower limb amputation has been reviewed systematically and found to vary between 5.6 and 600 per 100,000 population in people with diabetes [1]. The reasons for this huge variation were subject to another systematic review which concentrated on the methodological difficulties of reported studies [2]. Davies et al. [3] reviewed publications describing major lower limb amputation rates in England over a 30-year period (1988–2018) and found that

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variation could be explained by the failure to comply with the STROBE criteria [3] for reporting epidemiological studies. This was because basic demographic details such as the number, age and gender of both the numerator and denominator populations used to calculate rates were not given. Additionally, the overall population rate was rarely standardised to a recognised population e.g., England and Wales 2001. This resulted in 'comparable' studies not measuring 'like for like' thereby not allowing analysis of temporal trend.

The main pitfall of analysing such data, particularly that which reports only one homogenised rate, is that whilst it makes interpretation easy, it hides variation. Indeed, it is the difference between groups (geographic/population) and the inherent unfairness this represents that drives change.

How Do Amputation Rates Vary?

Davies et al. [2] noted that Ahmad et al. [4, 5] published amputation rates using the same dataset (HES and Census data) to describe amputation rates as many previous reports, but as demographic data of both the numerator and denominator populations was provided (as well as the overall age standardised with specific rates across geographical, age, gender, ethnic and diabetic groups) variation could be commented upon.

Their analysis showed major lower limb amputation rates were 2.7 times higher in men, 30% higher in the North of England and 70% higher in the black population (Fig. 17.1). Further, half of all major lower limb amputations were in the population that did not have diabetes. Additionally, major amputation rates were noted to be coming down in all groups, but at a faster rate in the diabetic population compared with the non-diabetic population - but the inequalities across groups remained. It was also noted that minor amputation rates were rising faster in the non-diabetic population [4]. The main cause for amputation in those without diabetes is peripheral arterial disease (a common factor also in diabetes-related amputations). Such analysis provides a completely different interpretation of the problems and solutions that are needed to address them.

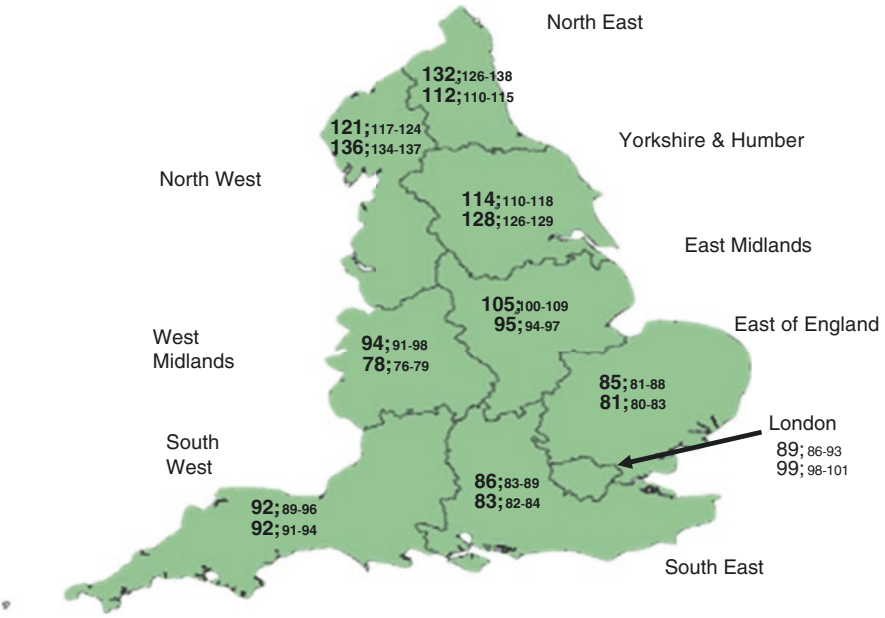

Fig. 17.1 Proportional rate of amputation (upper value) and Revascularisation (lower value). (95% confidence intervals) by English region (England Rate = 100). This diagram highlights the North/South divide for all major lower limb amputations across England [4]

Use of Freely Available Non-peer Reviewed Databases to Measure Success

Although much of the published data for England uses national databases such as Hospital Episode Statistics (HES), it is possible to go directly online to this source where data for individual areas and service providers is available at no cost (ref). There is a wealth of diabetes foot care data available from NHS Digital (ref) and whilst this is not broken down by age, gender or ethnic group, it is a starting point for comparisons across geographical areas and services.

There are, however, two specialist national databases that have published analyses pertinent to diabetes foot care and outcomes. These are The National Diabetes Foot audit (NDFA) [6] and National Vascular Registry (NVR) [7]. Whilst they rely on voluntarily submitted data from individual units rather than mandated national collection, the data provides unique insights about the importance of service set up and outcome.

Measuring Success Through the Structure of Care

The NDFA is part of the National Diabetes Audit Programme and allows services to measure their performance against NICE guidelines and peer units. The key message from this database is that 'being alive and ulcer free at 12 weeks is associated with having a 'Foot Protection Service (FPS)' and step-down care between Multidisciplinary Foot Care Teams and the FPS'. [6] Further, best outcomes are seen in those who received their first expert assessment within 2 weeks of ulcer onset [6]. This audit has shown that structure of services and time to first assessment is a crucial measure of success. However, this database only covers those patients with diabetes.

The National Vascular Registry records all procedures undertaken by vascular surgeons and includes amputations and revascularisations in those with and without diabetes. This database has published data for individual units allowing peer comparison, but again does not provide age or gender specific variation. Nevertheless, it has shown significant variation in time to revascularisation and subsequent amputation and has driven the development of the Peripheral Arterial Disease Quality Improvement Framework (PAD-QiF) [8]. This new framework recognises that better outcomes are associated with faster revascularisation, with a drive to reduce the time from presentation to revascularisation to 5 days for inpatients and 2 weeks for outpatients (ref). Both of these databases have emphasised the principle of 'time is tissue'.

An example of NICE guidelines regarding structured care practically applied to service design is given in Fig. 17.2:

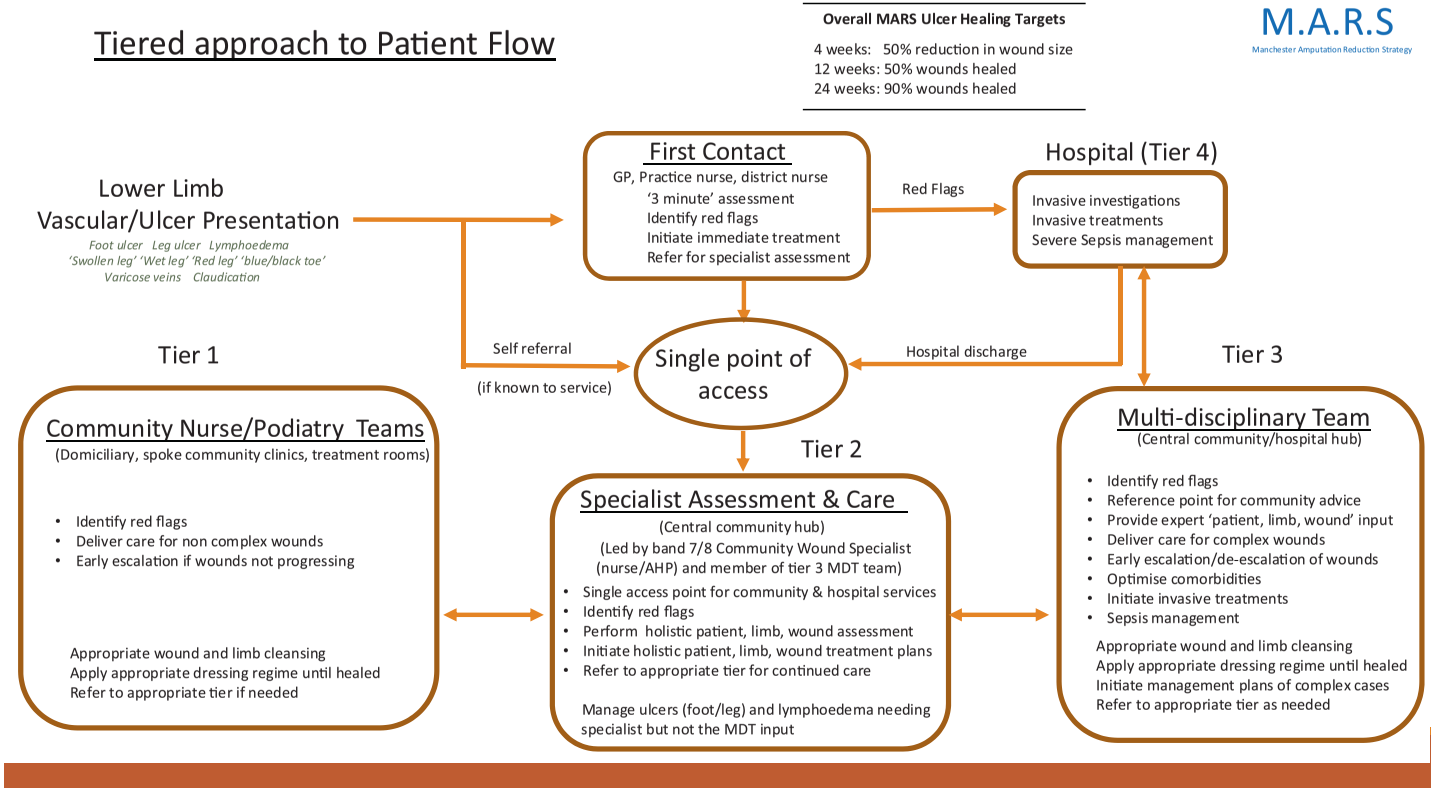

Fig. 17.2 An example of structured care with step down from multi-disciplinary clinics as per NICE guidelines

The definition of a Multi-disciplinary foot service and skills required have been defined by NICE [9] and listed in Table 17.1. It is important to note that not all patients will need to see every specialty every time they access the service.

In addition to the broad structure of care, the individual care patients receive should also be defined and measured using the best evidence (where available). An example of a system wide pathway for foot ulcer care is given in Fig. 17.3.

Table 17.1 Composition of a diabetic multi-disciplinary team as per NICE guidelines [9]

Make up of a multidisciplinary foot service	Diabetology Podiatry Diabetes specialist nursing Vascular surgery Microbiology Podiatric and/or Orthopaedic surgery Prosthetist/Orthotist Interventional radiology Wound Care & Casting Specialist

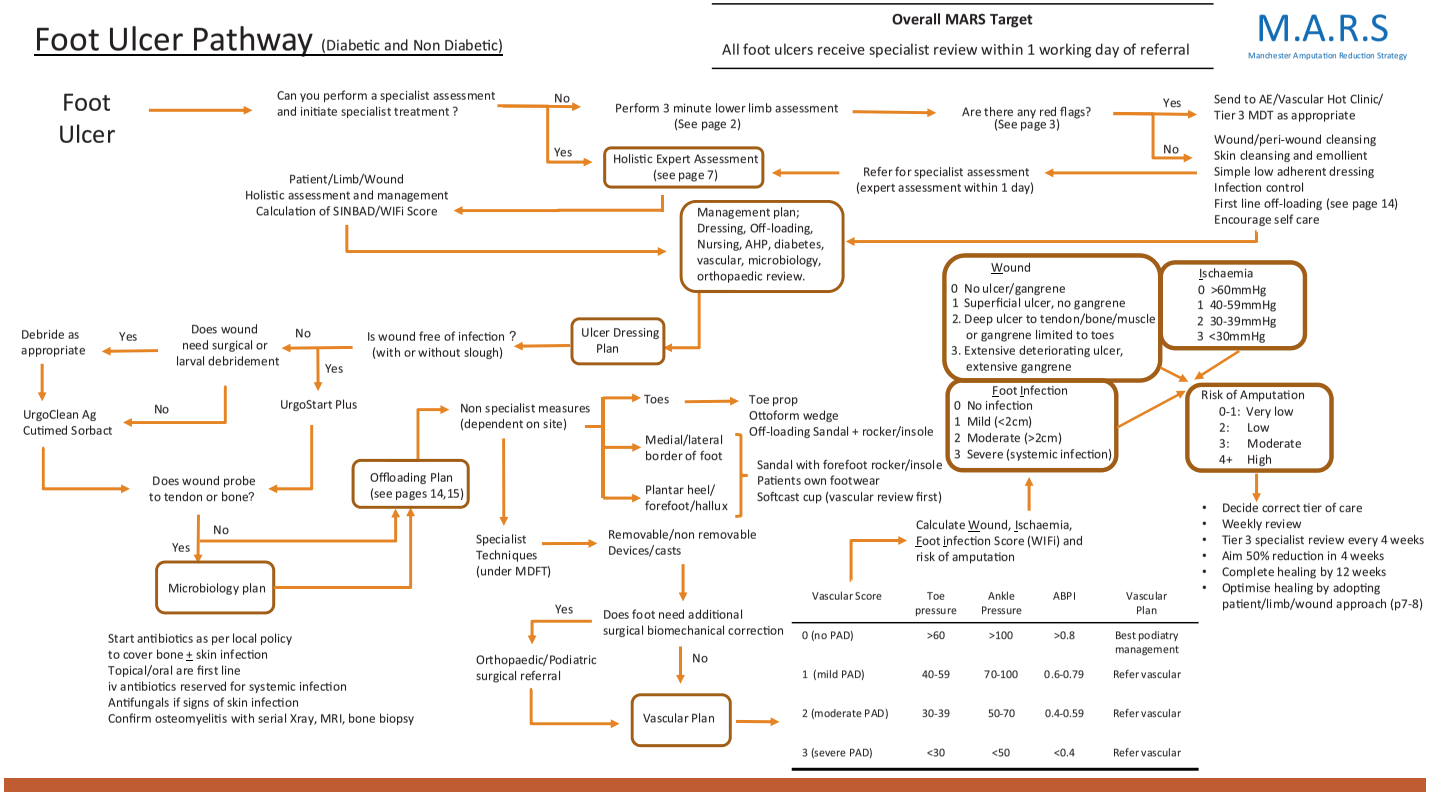

Fig. 17.3 An example of a system wide pathway for foot ulcer care

Wider Definitions of Success

Diabetic Foot Care as Part of a Wider Wound Care Strategy

The National Wound Care Strategy [10] has acknowledged the inequality between diabetic and non-diabetic foot wounds with regards to service access as well as the wider problem of leg ulcers i.e., they would all benefit from a multidisciplinary approach. To address this, in 2021 they began recruiting sites to develop local strategies to address this inequality of access. The outcomes are eagerly awaited.

Social Determinants of Care

A holistic approach to improving care involves addressing factors not directly related to wounds or chronic disease management. A holistic approach requires access to psychological therapies and exercise programmes, as well as addressing differences in socioeconomic circumstances and increasing access to digital care. The newly developing Integrated Care Systems where each neighbourhood's (defined as a population of 30–50,000) health and social care system work together to address the social determinants of health is an example of how a 'whole system' can work together to improve outcomes. A holistic approach to improving outcomes, therefore, requires planners across Public Health, Health and Social Care and the Council to work together and integrate strategies.

Patient and Staff Experience of Care

In addition to provision of and access to care, the experience of it is an important measure of success. Many services now have patient experience teams who can be deployed to gain patient views to help improve service delivery. Allied to this is staff wellbeing, which if done properly benefits morale, which in turn then drives engagement with education/training and therefore improves standards.

Clinical Measures of Success

It is no longer adequate to document clinical outcomes in studies involving the diabetic foot in terms of minor or major amputation rates. Attention should be given to the use of the more clinically meaningful composite outcome measure of ulcer free,

amputation free, survival in patients with diabetic foot ulcers given that this cohort of complex patients also suffer from high rates of cardiovascular events resulting in premature death.

Few studies assess the return to function of patients following treatment for diabetic foot ulcers. Regaining mobility and the ability of patients to carry out their activities of daily living should be a measure of successful care. Examples of instruments used for measuring this outcome in research or clinical practice are the Dependence/Daily Life subscale of the Diabetic Foot Ulcer Scale-Short Form (DFS-SF) and the Impact of Weight on Activities of Daily Living Questionnaire (IWADL). Both have been extensively used to measure physical functioning in studies for patients with type 2 diabetes.

Future clinical studies should also consider the impact of diabetic foot ulcers on patient quality of life (QOL). In addition to generic instruments for the assessment of QOL such as the SF-36 or EQ-5D, patient reported outcomes measures (PROMS) are now available for patients with Diabetic Foot Ulcers and the use of validated condition specific patient reported health related QOL tools such FHSQ (foot health status questionnaire) should be encouraged [11].

Conclusion

It is important to define the correct problem in order to define success. The inequalities of outcomes i.e., how different people experience care is central to understanding why amputation rates and or complications are different. Unfairness is often at the heart of this variation and therefore the provision of, access to and experience of services is central to understanding how to improve them. Working with teams to co-design a solution is central to sustainability and scalability of any change. Clinical studies in diabetic foot care should also evolve beyond the utilisation of amputation rates to measure success to adopting more meaningful outcomes for patients such as ulcer free survival, return to function and assessment of quality of life.

Key Points

1. Peer reviewed epidemiological data should meet STROBE guidelines.
2. Variation in epidemiological outcomes is central to understanding inequalities.
3. Success needs to measure the structure and processes of care not just the ‘bottom line’ of amputation numbers.
4. Time to first expert assessment and speed of intervention is a critical measure of success.
5. Clinical studies in diabetic foot care should aim to utilise meaningful outcomes such as ulcer free, amputation free survival, assess patient return to function and measure the impact of illness and treatment on patient quality of life.A holistic approach to patient care requires a holistic approach to planning and implementation of services.

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Chapter 18
Medicolegal Aspects in Diabetic Foot Disease: How to Keep Patients Safe, What to Do When Things Go Wrong and How to Avoid Litigation

Prash Vas and Victoria Butler-Cole KC

Over the last 10 years the number of claims and the annual cost of litigation across the UK have increased significantly. Current costs to the national health service (NHS) related to ligation are shockingly high, especially in England, even though only a small proportion of individuals who may have suffered harm choose to pursue litigation. The most recent estimate for clinical negligence claims in England and Wales during 2020/2021 was £7.9 billion, a staggering increase from £863 million in 2010/2011 [1]. This amounts to approximately 4.5% of the entire NHS budget of £176 billion for 2021.

The percentage of individuals treated by the NHS pursuing litigation is unclear, however it is understood that increases in claims and associated costs have been much greater than increases in NHS activity. Furthermore, the factors that drive individuals to consider litigation remain unclear [2–4]. Evidence from studies from outside the United Kingdom suggest that several factors can influence decisions related to consideration of medico-legal action with the extent of perceived harm being only one of them. A recent report by the Partnership for Responsive Policy Analysis and Research (PREPARE) collaboration did not identify features suggestive of a 'typical claimant' [2]. One consideration, however, is that when life changing injuries or major harm occurs (for example during childbirth or amputation of a

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major limb as relevant to this chapter), it is possible that the need to litigate may be driven by need for, and the considerable costs associated with future care [3, 5].

In England the rate of diabetes related lower limb amputations continues to rise with 21,738 minor amputations and 7957 major amputations being undertaken between 2017/18 and 2019/20 [6]. Furthermore, there were 171,759 admissions to hospitals related to diabetic foot disease during the same period and foot related admissions account for the highest percentage of diabetes specific hospitalisations [7]. It has been recognised that many amputations, both major and minor, are potentially preventable. Often, it is either an unexpected rapid sequence of events or a protracted period of care, which is likely to be (or may appear as) disorganised and confusing, culminating in loss of a limb that is likely to trigger the instruction of litigation. Recently, a thematic review of diabetic foot related clinical negligence claims has been published by NHS resolution which for the first time, characterises the individual and structural factors in care delivery associated with diabetic foot litigation.

Thematic Review of Diabetic Foot litigation Cases

NHS Resolution undertook a retrospective review of closed claims between 2013/14 and 2018/19 listed on their claims management system and published its findings in June 2022. These included claims where both liabilities were accepted or denied by the various NHS trusts, although no specific information was provided. Of the 92 claims analysed, the authors found that individuals were overwhelmingly male (>75%) and 78% were over the age of 50 years. Claims around major amputation accounted for the highest proportion (55/92, 60%) followed by minor amputation (30/92, 33%). The review highlighted certain recurrent themes, one or all of which could independently contribute to suboptimal outcome in diabetic foot disease (Box 18.1)**.**

Box 18.1 Themes from the NHS Resolution Thematic Review of Diabetes and Lower Limb Complications Clinical negligence Claims (June 2022)

Identification and screening: High risk patients were not identified and received very minimal preventative care.

Delays in Care: Delays in being seen by a specialist footcare team.

Lack of specialist foot input: Specialist footcare input was found to be irregular and relied on general practice for ongoing input.

Paucity of PAD recognition: In assessing for and managing PAD, patients experienced delays at every stage of the pathway.

Use of guidelines: Evidence-based DFU assessments and interventions were often absent. The extent and severity of the pathology was realised late or not at all.

Lower limb and pedal biomechanics were rarely considered. Pressure relieving (offloading) interventions were not evidence-based, provided late in the progression of pathology, or not performed at all.

Pathways to admit patients into hospital were complicated and time consuming.

Patients did not show sufficient evidence of healing of foot ulcers prior to discharge from hospital.

Lack of adjuvant supportive care: There were high levels of non-compliance, but there was also evidence of emotional and social factors that were not addressed, and limited evidence of diabetic lower limb education provided.

It identified that there were significant challenges in risk stratification and front-line foot protection with 91% of the individuals not having their foot-ulcer risk status documented in the community, leading to a pre-morbidity capture of only 5% as high risk for foot ulceration (85% were true high-risk in the sample). Once a foot problem was identified, there were significant delays in accessing specialist foot services as recommended by NICE NG19 with 64% not having regular specialist team input and 52% never having received multidisciplinary foot team (MDfT) input at any stage. Once referred to a specialist service, there was a paucity in the quality of standard care provided with lack of quality, regular debridement (70%), wound microbiology assessment (50% did not microbiology sample sent at any stage) and delays in performing radiological investigations—indeed, 34% did not have an x-ray at any stage. Perhaps the most important concerning factor was that vascular assessment in these complex cases were brief, potentially inaccurate (51% of pulse palpation readings were deemed incorrect), missed (33% where known vascular history was ignored) and delayed. Individuals waited an average of 90 days between identification of tissue loss and vascular investigations and 50 days between investigations and revascularisation. Furthermore, the review identified a severe lack in quality offloading provision (58% no offloading, 11% saw an orthotist) and in addition to paucity of psycho-social support. Another recurrent theme was the lack of standardised access to hospital admissions, indeed the review identified 25 different methods of hospitalisation. While anecdotally the number of claims related to Charcot neuroarthropathy and its sequelae are increasing, this was perhaps under-recognised within the thematic review.

Taken together, findings from the NHS Resolution thematic review and the annual National Diabetic Foot Audit (NDFA) [8] underscore the shortcoming of diabetic foot care provision, their clinical impact and the medico legal implication in a clear and succinct manner. The NDFA has clearly identified that there is a lack of cohesive care process (and significant variation in care delivery) within England. The NDFA also clearly establishes a clear association between time to specialist input, severity of diabetic foot ulcers and outcomes at 12 and 26 weeks. The thematic review, as it was set out, only explored clinical

and structural themes and did not report on the total cost to the NHS trusts from claims related to the management of diabetic foot or the ultimate judicial outcome of claims where liability was denied.

This chapter considers two different ways in which the courts in England and Wales might become involved in decisions about patients with diabetes and foot problems. The first—decisions by the Court of Protection—take place during the course of treatment. The second—proceedings for clinical negligence—take place after treatment. The focus here is the law in England and we recognise that the law in the devolved countries and internationally may vary. A brief overview of inquest is also considered as healthcare professionals may also be called to give witness at the Coroner's court.

Court of Protection

The Court of Protection has jurisdiction to make decisions about whether patients have mental capacity to consent to medical treatment, and, if they lack that capacity, what treatment is in their best interests. The Court of Protection applies the provisions of the Mental Capacity Act 2005 [9]. These are explained fully in the Mental Capacity Act Code of Practice [9], which should be read by every professional working with patients who may lack capacity to make their own medical treatment decisions. Adding a layer of complexity in diabetic foot disease, is the emerging appreciation that many individuals experience cognitive dysfunction [10], and many of the most complex, and presumed non-compliant individuals also have severe mental health disorders [11, 12] which may impair their ability to consent.

The Mental Capacity Act contains a presumption that people have capacity to make their own decisions and requires professionals to take all reasonable steps to assist people to acquire or demonstrate mental capacity. If, despite taking these steps, a patient is unable to make a decision for because of an impairment of, or a disturbance in the functioning of, their mind or brain, then they lack capacity to make that decision for themselves. A patient can lack capacity permanently or on a temporary basis, for example because they are unconscious, or suffering from delirium. Capacity can be assessed by a health or social care professional, although psychiatric input may be required to determine whether a patient has a mental disorder or disability, and whether it is the cause of their inability to decide. When assessing whether a patient is unable to make a decision, the test is whether the patient can understand information relevant to the decision, retain it, use or weigh it as part of the process of making the decision, and communicate the decision.

If a patient lacks capacity to give or refuse consent to proposed medical treatment, then a decision must be taken in their best interests, unless it can be postponed until they regain or acquire capacity. If the patient has appointed a lasting power of attorney for health and welfare decisions, the attorney is the decision-maker. Attorneys may or may not have the authority to make decisions concerning life-sustaining treatment: it will depend on what powers the patient gave them when the lasting power of attorney was created. If the patient has a health and welfare deputy appointed by the Court of Protection, then that person is the decision-maker, but

cannot make decisions about life-sustaining treatment for the patient. If there is no appointed substitute decision-maker, then the treating health professionals are required to make a decision.

The Mental Capacity Act 2005 says that when deciding what is in a patient's best interests, decision-makers must consider the patient's wishes, feelings, values and beliefs (including prior to their loss of capacity) and must encourage the person to participate in the decision as fully as possible. Consultation must also occur with people who care for the patient or have an interest in the patient's welfare—this includes family members, friends, carers and anyone else identified by the patient as someone who should be consulted. Best interest decisions are wider than clinical decisions about which treatments to offer:

"decision-makers must look at [the patient's] welfare in the widest sense, not just medical but social and psychological; they must consider the nature of the medical treatment in question, what it involves and its prospects of success; they must consider what the outcome of that treatment for the patient is likely to be; they must try and put themselves in the place of the individual patient and ask what his attitude to the treatment is or would be likely to be; and they must consult others who are looking after him or interested in his welfare, in particular for their view of what his attitude would be." [13]

The Court of Protection has issued guidance about when best interests decisions should be referred to the court for a decision to be made by a judge [14]. If the decision concerns life-sustaining treatment, and it is finely balanced, or there is a difference of medical opinion, a lack of agreement about what should happen, or a potential conflict of interest, then an application **must** be made to the court. This would apply to decisions about amputation where the clinical view is that without amputation, the patient is likely to die. Even if the decision does not concern life-sustaining treatment, then an application to the court may be required if any of those factors is present [15]. If providing treatment would require the patient to be sedated or physically restrained in order to prevent them objecting, then court authorisation is extremely likely to be needed. A brief overview of the process to be followed is outlined below (Fig. 18.1)**.**

The Court of Protection has made numerous decisions about limb amputation for patients with diabetes who are at risk of sepsis. The court prefers applications to be made in good time, not when there are only hours or days left for surgery to be carried out. The Official Solicitor [16] is appointed by the court to act for the patient, and the NHS Trust responsible for the patient's care is required to pay 50% of the costs of the patient's legal representation. The Official Solicitor will often seek a second opinion. Where patients are found to lack capacity to consent to medical treatment, most often the court will authorise amputation where it is necessary to save or substantially extend the patient's life, even if the patient strongly objects. This is not a foregone conclusion, however. In one case, the court decided that amputation was not in the best interests of a mentally ill 73-year-old man [17], saying that it would "*take away his little remaining independence and dignity in order to replace it with a future for which he understandably has no appetite, and which could only be achieved after a traumatic and uncertain struggle that he and no one else would have to endure.*"

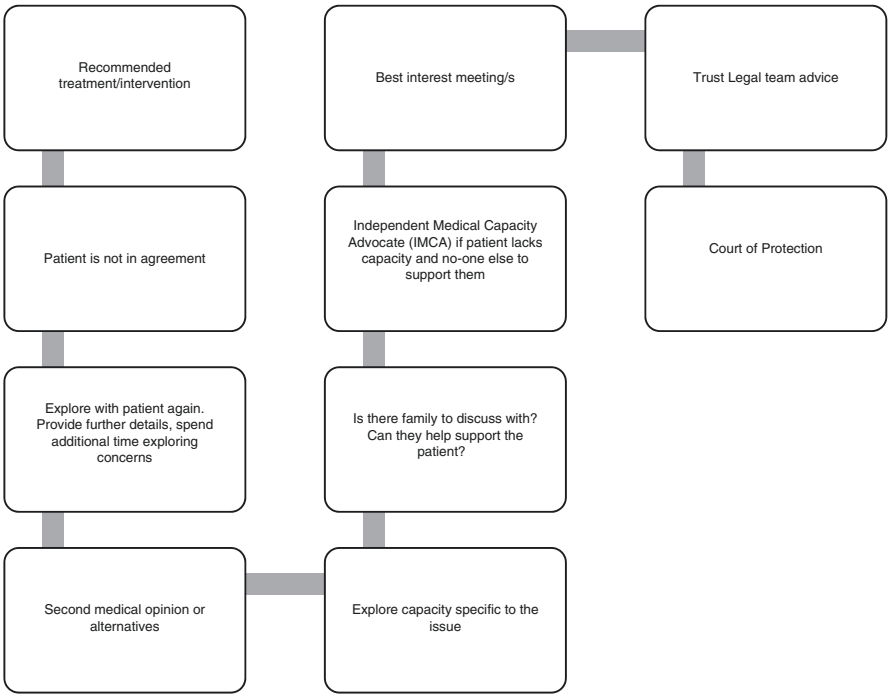

Fig. 18.1 Process before applying to the Court of Protection for treatment guidance

Clinical Negligence

Negligence is the breach of a legal duty of care owed to one person by another which results in damage being caused to that person. Clinical negligence (often called medical negligence) is concerned with claims against healthcare providers, doctors or other responsible clinicians [18]. Proceedings for clinical negligence may be instigated by a patient if they believe that the treatment they were offered was not of an adequate standard, was provided at the wrong time, or was the wrong type of treatment. A claim is a formal request for compensation because of single or multiple issues which are alleged have gone wrong in relation to a patient's healthcare. It is usually made in writing by a lawyer or representative of the patient or their family. The majority of claims are usually resolved without resorting to formal court proceedings and, often in early stages many claims are resolved without payment of any damages [19]. There has been a 25% increase in claims notified by volume in 2020/21 (n = 12,629) in comparison to 2012/13 (n = 10,129) and a doubling in the value of damages settled during the same time period (Fig. 18.2) [19]. In 2017/18, just under one third of claims ended being litigated with less than 1% going to a full trial and the latter figure was even lower at 0.36% in 2020/21 [19].

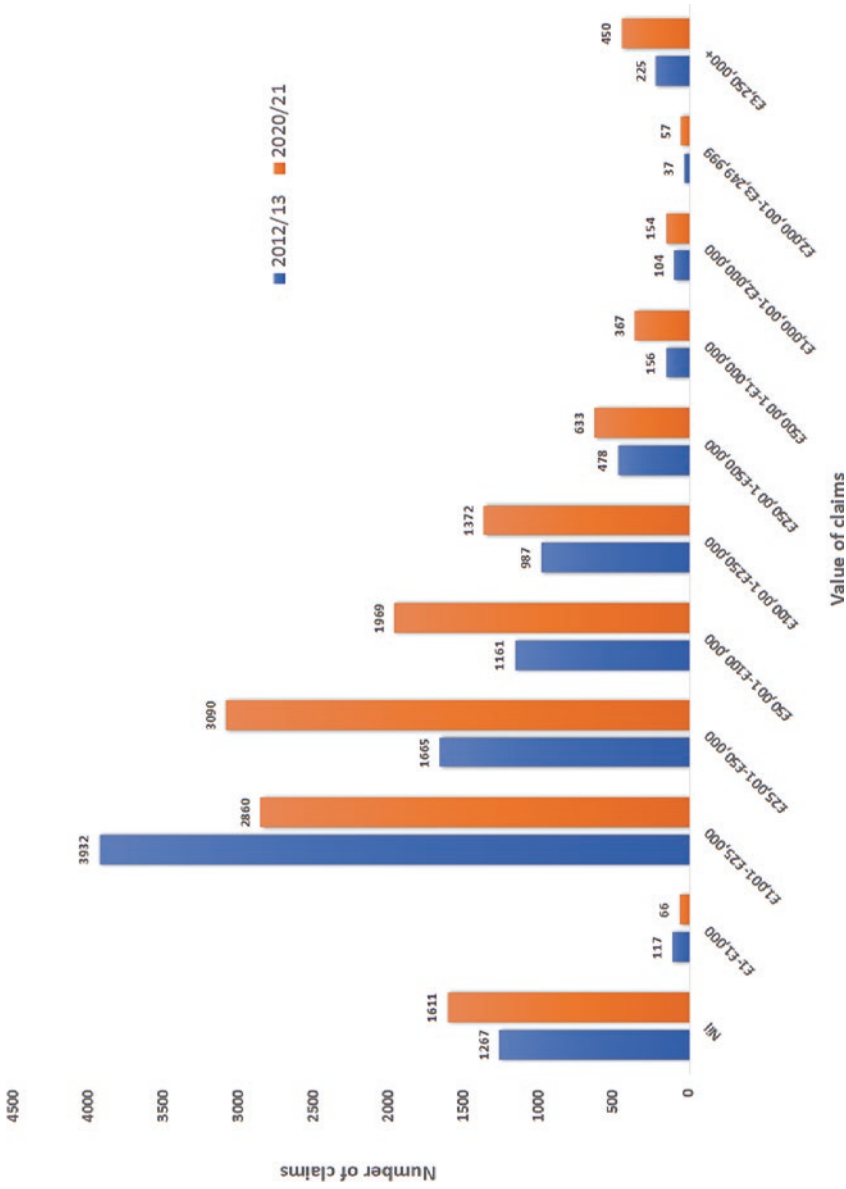

Fig. 18.2 Claims settled by cost volume–2012/13 to 2020/21. Data courtesy NHS Resolution [19]

Negligence Test

Medical negligence is part of a legal branch called tort (delict in Scotland) which comes from the Latin verb tortere, meaning to hurt. To succeed in a claim for negligence, the claimant (individual patient or their family) needs to prove that:

- The Trust owed a duty to take care of the claimant;
- There was a breach of that duty to take care;
- That the breach of duty has caused legally recognisable harm to the claimant

The majority of tortious claims for medical negligence that fail do so because they are unable to prove direct harm caused by the act or the failure to act[20]. Medical negligence is proved if all components of the three-part test are established on the balance of probabilities. In cases of negligence caused by carelessness, and where that carelessness is so severe that it is deemed 'gross', the doctor or health professional may be charged with *criminal negligence*. In such an event, the standard of proof is beyond reasonable doubt rather than the balance of probabilities, and the punishment is also considerably more severe, including a custodial sentence. In addition, doctors and health professionals found guilty of criminal negligence are likely to be subject to fitness-to-practice proceedings by the General Medical Council or their equivalent [20].

Claims Liability

The NHS trusts are legally liable for any clinical negligence rather than their individual employees. When liability is admitted or where directed, they must pay compensation to the claimant, and pay their legal fees. This requirement does not cover general practitioners, or private practice as they are considered private contractors and are legally liable for any clinical negligence claims they may receive.

Dealing with Negligence Claims

The initial letter of claim is usually sent to the Trust by the claimant and/or their representatives. The typical pathway of how any claim is handled by the NHS trust along with NHS Resolution is shown alongside (Fig. 18.3). The trust initially has 4 months to respond and will simultaneously report the claim to NHS Resolution, which has been indemnifying the NHS trusts since 1995. NHS Resolution is responsible for dealing with any claim on behalf of its members, which currently include all NHS trusts, including funding defence costs, and forthwith any resultant legal costs or damages that become payable [19]. NHS

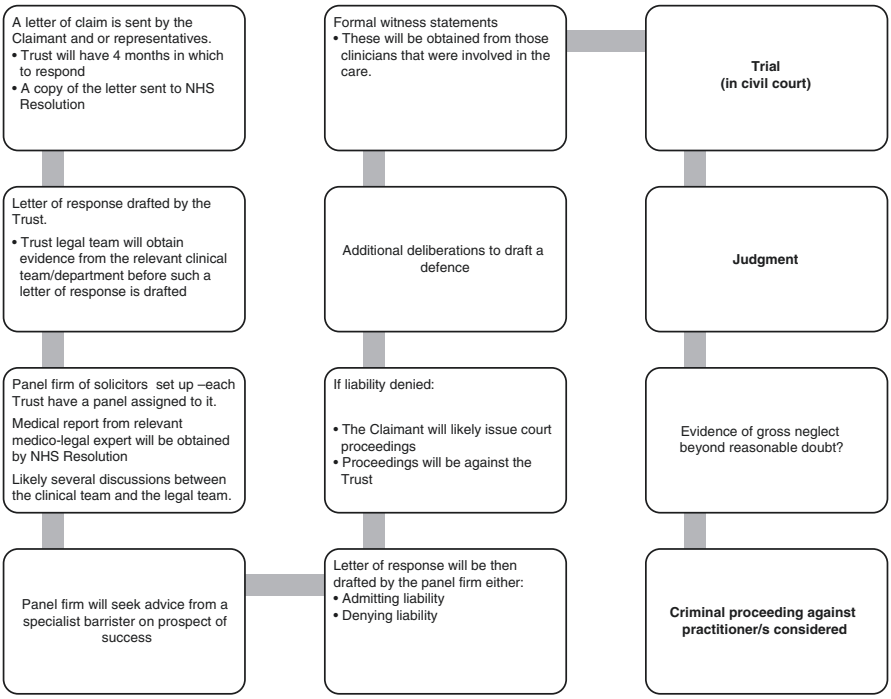

Fig. 18.3 The clinical negligence claims process

Resolution, along with the Trust, will aim to ensure that claims deemed to be valid (liability admitted) after a thorough internal enquiry appropriately compensated, by settling valid claims fairly and quickly [19], and will work with the Trust to defend any claim deemed to lack merit (liability denied). Claims that are resolved without proceeding to court are handled by NHS Resolution using a combination of methods including negotiation in correspondence, meetings between the parties, or using some form of mediation.

Undoubtedly, any claims process can be very challenging to the healthcare professional, and the wider team involved. As civil court rules apply at the outset, a claim can be made up to 3 years from the alleged event. If a claim progresses to court proceedings, cases can last an average of 5.5 years from start to conclusion with 22% of cases taking 10 years or longer [20]. It is therefore important at the outset to recognise (a) that there has been a problem and (b) engage with the trust legal team, NHS Resolution and the panel firm of solicitors in a supportive and constructive manner.

A few common features of successful litigation have been recognised [21]. Failure to diagnose or early inaction, non-instigation of the appropriate investigations in a timely manner, or delays in the treatment pathway (lack of urgency in

reviewing routine referrals, protracted wait times for treatment) are often commonly cited. Other features include failure to document adequately (examination findings, decisions, reasons for treatment decision) and importantly, poor communication (of consent, candour surrounding adverse event, engagement with patient and/or family after such event) [21]. Lack of adherence to guidance is another important theme, as both claimants and courts now have easy access to clear, considered medical pathways. Many organisations do not or are slow to implement guidance documents—and there may be need to explain why they were not followed [21]. The recent published thematic review on litigation episodes in diabetic foot disease overwhelmingly captures these features.

Inquests

An inquest is an inquiry into the circumstance and of causes death as detailed under the Section 5 of the Coroners and Justice Act 2009 [22]; it is not a trial and the questions are directed solely to ascertain:

- Identity of the deceased;
- How, when and where the deceased came by his or her death; and,
- The particulars (if any) required by the Births Deaths and Registrations Act 1953 to be registered concerning the death [23].

A Coroner is an independent judicial officer (lawyer or doctor, sometimes both) whose function is to investigate deaths reported to them where the cause is unclear, violent, or presumed unnatural. Their role is to make the necessary enquiries to determine the cause of death, including ordering a post-mortem examination, obtaining witness statements and medical records, and if required holding an inquest.

Typically, when notified that a body belongs to a deceased person (the 'deceased'), a Coroner will initiate a legal investigation (geographical 'jurisdiction'). With the introduction of the Coroners (Investigations) Regulations 2013, the Coroner will no longer be restricted to holding inquests within their own districts and will be able to relocate if it is in the best interests of the bereaved family [22, 24].

Common circumstances when the death will be reported are in Box 18.2. Most doctors will report the death to the Coroner if certain circumstances are met; if not, the registrar of death has a statutory duty to do this. Rather than dealing with the complexities of a case that should have been reported, it is better to have a short conversation with the Coroner's Office that concludes with "The Coroner does not have an interest in this death".

Box 18.2 Reasons to Refer a Death to the Coroner before Providing a Medical Certificate of Death

The death was unnatural.

Deaths due to an accident, violence, neglect, abortion or any kind of poisoning or at work or related to industrial disease.

Death was in other suspicious circumstances, or the cause of death is unknown.

Death occurred in prison, police custody or other state of detention (including a sectioned patient in a psychiatric institution).

No doctor attended the deceased during their last illness.

The deceased was not seen by a doctor within 14 days of death (amended to 30 days since CVOID-19), nor after death.

Death occurred during surgery or recovery from anaesthetic. It is normal to discuss cases that occur with 30 days of surgery or an invasive procedure, even when the circumstances do not cause concern.

It is normal to discuss all deaths occurring in the Accident and Emergency Department, and any deaths within 24 h of admission with the Coroners office.

Reducing the Risk of Litigation in Diabetic Foot

Clinical practice often imposes multiple barriers to good practice. The workload for clinicians is constantly increasing, and there are significant disruptions and temporal evolutions in the care process pathway that we practice in. Furthermore, many regions in the United Kingdom do not have robust Multidisciplinary Diabetic Foot Teams (MDFT) [25] and exhibit wide variation in adopting NICE guidance and best practice algorithms [26] which are likely to impact on clinical outcomes and the risk of potential litigation. It is therefore crucial to develop a systemic wide approach in addition to clinician level behaviour to reduce the risk of litigation (Fig. 18.4). Decisions on the management of diabetic foot disease must be done through a MDFT ('no one person or speciality can manage the diabetic foot'), and at a system level, provider services should develop pathways that adopt this and provide care within the time frame recommended in the guidance documents. Timing is key to outcomes in diabetic foot disease, to prevent or contain limb threatening problems [26, 27], and all reasonable efforts should be made to ensure this. MDFTs should clearly document their findings, decisions and rationale while ensuring quality follow-up is put in place. Such units should also aim to demonstrate good clinical practice through a refined clinical governance structure (regular service and adverse

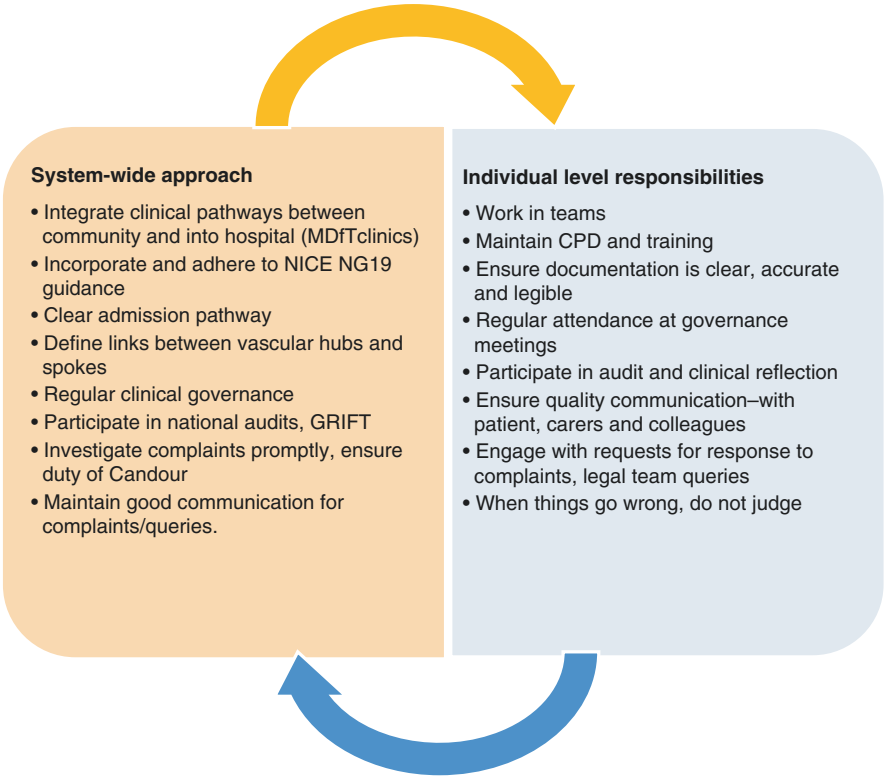

Fig. 18.4 Reducing the risk of litigation: System-wide and individual level approaches. It is important to remember that these two aspects are inter-linked

incident reviews, reflection), quality audit (local audit cycles; contribute to the National Diabetes Foot Audit) and ensure safe pathways are designed between hubs and their connected spokes. Adherence to guidelines, such the NICE NG19 for diabetic foot ulceration is very important and should be consistent between sites. At an individual level, it is important to ensure that every decision or plan is carefully explained to the patient and clearly documented at the time. Where a patient lacks capacity to make a decision about treatment, the requirements of the MCA 2005 must be followed, and if relevant, an application made to the Court of Protection. Doctors and health professionals should always consider the implications of deviations from accepted practices in light of the greater availability of practice guidelines for court guidance. The documentation should include a clear documentation of the reason for such a deviation, and it should also be clearly explained to the patient. Clinicians-in-training should be aware that they are expected to seek advice and assistance in scenarios where they lack experience [20]. Every practitioner should also ensure they are fully complaint with their employers' mandatory requirements, participate proactively within the appraisal and continuing education processes. It is important, both at a system and individual level, to maintain good

lines of communication with patients and their carers/families. When an adverse event occurs, ensure a duty of candour is performed, that apologies are offered, and that learnings from the investigation are relayed to the involved team and the patient and their carers/families in an emphatic, timely manner.

Every organisation, doctor and healthcare professional should be encouraged to familiarise with the role of NHS Resolution and engage with the 'Getting It Right the First Time' (GIRFT) initiative. The GIRFT programme was developed to improve the treatment and care of patients through a recurring in-depth review of services, benchmarking, and data-driven evidence presentations to support change within healthcare organisations. For diabetic foot disease, GIRFT triangulates around the specialties of vascular surgery, diabetes and orthopaedic surgery. In collaboration with NHS Resolution, GIRFT has produced the Learning from Litigation Claims: best practice guide for clinicians and managers document [28] which should be essential reading for healthcare providers and professionals likewise. When things go wrong, it is important to recognise and acknowledge. Saying sorry to the patient and family as soon as possible in a sincere way, is the right approach and as per the Compensation Act 2006 does not itself amount to an admission of breach of duty or negligence [29]. Such an early intervention may, as part of a wider coordinated communication initiative allow the patient and/or family to understand what went wrong without resorting to complaining or taking legal action.

In summary, clinicians and service providers are likely to see an increase in litigation related to diabetic foot care. The recent NHS resolution review has identified a number of themes which, individually or collectively, can increase the likelihood of sub-optimal outcomes and expose the system to litigation. When litigation occurs, it can be a long process with significant personal stress to individual members involved. A system wide approach is necessary to improve the patient pathway when a DFU occurs, and it is essential that individuals are cared for within a MDFT environment. Furthermore, it is important that doctors and healthcare professionals, involved in managing diabetic foot disease, continue to demonstrate best practice behaviour, clear documentation, and reflection, even within the constraints imposed on them.

Key Points

Litigation has significantly increased and most commonly occur after major and minor amputation.

Common themes of litigation include lack of screening, delays/failure in diagnosis and accessing specialist foot care services, failing to order appropriate investigations and variable quality of the care.

When a patient lacks capacity to consent to treatment the Court of Protection should be involved early.

Most clinical negligence claims are resolved without formal court proceedings.

A successful negligence claim needs to prove a duty of care was owed to the claimant by the Trust or Practioner and that there was a breach of that duty of care which resulted in harm.

It is essential that a Healthcare Practioner are involved early with clinical negligence claims and the multidisciplinary teams discuss these cases to identify learning.

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