Consent in foot and ankle surgery

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Abstract

The process of consent for surgical procedures has undergone a fundamental change since the landmark Montgomery vs Lanarkshire Health Board Case. The judge in that case determined that consent should focus on the risks that are material to the patient, and not purely those that a body of expert opinion feels are prudent to mention. This is a change from a paternalistic to a patient-centred approach. Ideally the consenting process should be done by the operating surgeon, or other doctor who has adequate knowledge of the risks and potential complications of the procedure. Taking consent is a process that occurs over several patient contacts, rather than being a singular consenting event. In this article we discuss several of the particular risks of each foot or ankle procedure and their relative incidence, as well as providing guidance regarding optimizing the consent process.

Keywords ankle; bolam; complications consent; foot; Montgomery; risks

Introduction

The process by which consent for surgical procedures is obtained in the UK underwent a fundamental change in 2015. The judge in the Montgomery vs Lanarkshire Health Board case ruled that the whole focus should change. Paternalism should be replaced by a patient-centred approach. This means that the onus is on the clinician to explain all the treatment options that are available; explain the likely consequences of choosing no treatment at all; specifically highlight those risks which are important to the individual patient; and not make assumptions regarding the information that might or might not be relevant to that patient. Previously the Bolam principle had applied. Under the Bolam principle the risks that should be explained were those seen as important by 'a body of experts in the field'.

The Royal College of Surgeons of England produced a guideline in 2016 as a direct response to the Montgomery case. Within this document there is strong emphasis placed upon documenting the discussion that takes place with the patient. In addition, surgeons are encouraged to record whether any printed or web-based information is provided to the patient. The surgeon still has the freedom to act in the patient's best interests in an emergency or urgent situation, but the new guidance should always be followed in an elective setting (RCS Eng 2016).

This new guidance inevitably puts pressure on outpatient services and consultation time. In order to achieve informed consent, the patient should be provided with comprehensive and easily understandable information. They should be provided with this in advance of their procedure. Patient-centred information sources should be provided. Comprehensive documentation in the patient notes should of course be made too (this may be in the form of the clinical letter). It has been recommended that consent should not be taken on the day of surgery. It has also been recommended that consent should not be taken at the initial consultation between surgeon and patient. This has led to consent clinics where the surgeon and patient discuss the planned procedure, prior to the day of surgery and after the patient has had time to reflect upon their options.

If this process is followed, the patient should arrive for an elective procedure fully informed and content with the consent process. On the day of the surgery it will then only remain for the surgeon to confirm that the patient has no further questions and then sign the Confirmation of Consent on the previously completed consent form.

Postoperatively, disclosure to the patient of any complications is important. This is in accordance with a doctor's Duty of Candour. Acknowledging a complication does not imply negligence. Studies have shown that the patient is more likely to pursue legal action against a surgeon who fails to disclose complications. Understanding the patient's perspective and taking the time to give an accurate and understandable explanation will help prevent the breakdown in clinician-patient relationship.

Complications can be graded (Table 1) but the consequences for each patient may not be so easily categorized.

This summary of common procedures in elective foot and ankle surgery will attempt to cover the particular risks that are likely to be materially important to the patient. The list is not exhaustive. These risks relate to complications that affect the quality of life, function and recovery of the patient.

First-ray osteotomies for hallux valgus

The importance of patient assessment in the surgical planning for hallux valgus correction surgery cannot be underestimated. Hallux valgus is a complicated deformity and is multifactorial in its origin. No single operation can reliably treat all variations of the condition.

Congruent hallux valgus requires particular care. Operations for the more common causes of incongruent deformity aim to restore joint congruity. If such techniques are used for a congruent joint, incongruity is likely to result and lead to painful hallux varus.

Hypermobility of the first tarsometatarsal joint (TMTJ) has been implicated in the development of hallux valgus (Myerson), and should be considered during surgical planning. This may indicate fusion of the first TMTJ as part of the correction. Pre-existing arthritis in the first TMTJ is another reason that fusion of that joint may be required.

Metatarsus adductus is defined as a structural deformity occurring at the Lisfranc joint, with the metatarsals deviated medially. If metatarsus adductus is not recognized, **recurrence** of the deformity after surgery is common.[1,2]

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Modification of the Clavien–Dindo system by Jacobs and Babette

Grade	Type of complication	Examples
I	Deviation from the normal postoperative course without need for treatment	Non-symptomatic oedema or scarring
II	Unplanned physical or pharmacological therapy required	Stiffness, infection, transfer metatarsalgia
III	Surgical intervention required	Infection requiring incision and drainage, nerve entrapment
IV	Limb threatening	Necrotising fasciitis, compartment syndrome
V	Threatening to the quality of life	Complex regional pain syndrome, significant limb shortening
VI	Life-threatening complications	Pulmonary embolus, Organ failure

Data from Complications in Foot and Ankle Surgery. Lee MS, Grossman JP, Springer 2017.

Table 1

The distal metatarsal articular angle (DMAA) is important when planning surgical correction. If the DMAA is not corrected, then the patient is at risk from **persistent deformity**, an incongruent joint and subsequent stiffness and **pain**.

Recurrence of deformity (up to 16%)

This can be due to patient factors or surgical technique. The specific anatomical features discussed previously, such as hypermobility of the first TMTJ, metatarsus adductus and increased DMMA may lead to recurrence if the correct surgical procedures are not selected. Poor surgical technique, such as inadequate lateral soft tissue release or insufficient metatarsal translation, leading to incomplete reduction of the sesamoids, may also contribute to recurrence rates. Finally, poor compliance with postoperative protocol can also adversely affect the result. It is imperative that the surgeon explains the postoperative management plan adequately.[3]

Avascular necrosis (AVN)

AVN is a recognized, if uncommon, complication of distal metatarsal osteotomies. Careful preservation of the blood supply to the metatarsal head requires avoidance of excessive medial capsular release. Injury to the lateral capsular vessels is also important. It has been postulated that a separate incision for the lateral release might result in a lower incidence of AVN.[4,5]

Hallux varus (2–15.4%)

This is regarded as an iatrogenic complication of hallux valgus surgery, resulting from overcorrection.[6,7] Hallux varus can be avoided by ensuring that the translation of the metatarsal osteotomy is appropriate, and that the soft tissues are not released excessively. Overtightening the medial capsule may also contribute to hallux varus. The resultant deformity is accentuated by the abductor hallucis muscle and by excessive translation of the medial head of flexor brevis so that it acts as an abductor.

Transfer metatarsalgia

Excessive shortening or elevation of the first metatarsal may lead to overload of the lesser metatarsals, particularly the second. All metatarsal osteotomies may be associated with some degree of shortening and for distal chevron osteotomies this has been estimated at 2.0 mm–2.5 mm.[4,8,9] Dorsal malunion at the osteotomy site can also contribute. Intraoperatively the surgeon must strive to ensure that the osteotomy is performed in such a way as not to excessively shorten or elevate the first metatarsal.

Scar sensitivity, numbness and neuroma

Surgery for conditions affecting the hallux risks damage to cutaneous nerves. The dorsomedial cutaneous nerve, a branch of the superficial peroneal nerve, is particularly vulnerable if a dorsomedial approach is used. For this reason, mid-medial or dorsal approaches to the first metatarsophalangeal joint (MTPJ) are preferred. If small incision techniques are chosen then surface anatomy should still be respected.

Re-operation for removal of metalwork

Many modern techniques utilize screws and staples. Headless compression screws help to minimize the incidence of prominent hardware. However, once the swelling has resolved prominent screws may cause symptoms. After osteotomies have healed there are instances where the screws loosen and back out, sometimes resulting in patients re-presenting years after the original operation.

Cheilectomy

Cheilectomy for hallux rigidus of the first MTPJ involves either open or minimally invasive resection of the dorsal part of the head of the metatarsal (no more than 30% of the articular surface), removal of osteophytes and capsular release. It is a joint preserving procedure and, as such, the main risk to the patient is persistence of symptoms and subsequent need for further surgery. Large series[10] report 85% success rates. That, however, means that at least 15% of patients will have further problems and may require further treatment (most frequently arthrodesis).

A small percentage of patients develop secondary stiffness after a seemingly uncomplicated cheilectomy. Joint manipulation and injection (after a suitable interval) may serve to save the situation in selected cases.

First MTPJ arthroplasty

The total rate of complications from first MTPJ arthroplasty is relatively high when compared with arthrodesis, with 3.9% and 11% revision rates respectively.[11]

Infection (1.6%)

This can occur immediately after surgery, or it may be a late complication. In either case the initial treatment is the same as for any other infected joint arthroplasty. The implant is removed, an antibiotic spacer may be inserted and systemic antibiotic treatment is given. The overall rate of infection in MTPJ arthroplasty has been found to be 1.6%.[11] Unlike infection of a large joint arthroplasty, second stage revision is probably not indicated and the patient may be offered a salvage fusion instead.

Residual pain

Residual pain may be secondary to infection, loosening, fracture or subsidence. Loosening was found to occur in 20.9% patients in a recent systematic review.[11] A rigid foot orthotic can be used to treat pain, but most patients will opt for fusion. The bone defect left after removal of the implant often requires an interposition bone graft to preserve the length of the first ray.

First MTPJ fusion/interphalangeal joint (IPJ) fusion

Pain (16.2%)

Pain may be secondary to irritation caused by hardware, non-union, scar tissue or nerve irritation. It is important to counsel patients that there is a chance that fusion surgery will not eradicate all their pain. Preoperatively the IPJ must be assessed for any pre-existing arthritis which may be a relative contraindication to MTPJ fusion.

Non-union or delayed union (6.6%)

Union depends upon several factors, both patient and surgeon related. Patient compliance with the postoperative instructions regarding immobilization, weight-bearing and smoking are important. Intraoperatively the joint surfaces must be adequately prepared. The chosen fixation hardware should allow good compression to be achieved.

Superficial wound infection (2.3%)

The rate of superficial infection is relatively low, but it is still a significant complication that the patient should be made aware of. Sensitive handling of the tissues, avoiding prominent hardware and minimizing tourniquet time may all help. Patient-related factors such as smoking, diabetes, poor vascular supply and compliance with postoperative protocol are also relevant.

Metatarsalgia (2.7%)

Although there can be significant complications from arthrodesis, long-term follow-up has shown that these patients have less pain, are more satisfied, and have a lower rate of return to theatre than arthroplasty patients.[12]

Excision of Morton's neuroma

The management of a symptomatic interdigital neuroma is initially non-operative, with wide shoes, orthoses, injections and physiotherapy being the mainstay of treatment. In cases of severe persistent pain surgery will provide up to 85% of patients with significant relief.[10]

Ongoing pain/no symptomatic relief

There are many causes for ongoing pain after neuroma surgery. Incomplete resection of the nerve, painful stump neuroma, adhesions and incorrect diagnosis among the most important. A histological study of tissue specimens taken during revision surgery for Morton's neuroma demonstrated that 46% contained residual neuroma tissue, suggesting incomplete resection at the index procedure.[13]

Excision arthroplasty, tenotomy and IPJ fusion for the lesser toes

Paradoxically the outcome of lesser toe surgery is in many instances less predictable than surgery for the hallux. The overall satisfaction rate is, irrespective of the specific operative technique, not as high as either patients or surgeons might imagine. Residual metatarsalgia, recurrent deformity, painful non-union of the arthrodesis, malunion, numbness and late deformity of the distal IPJ should all be discussed with patients. Deep infection or ischaemia may prove hard to salvage, resulting in the need for amputation (Figure 1). Percutaneous techniques are subject to all the same complications as open surgery.

Tarsometatarsal arthrodesis

Non-union (7–8%)

The non-union rate after this surgery is consistent across the literature. There have not been enough patients studied to draw conclusions regarding specific risk factors. Patient compliance, smoking and surgical technique all play a part.[14,15]

Irritation from hardware (9–25%)

Despite the use of modern low-profile plating systems there is still a relatively high rate of hardware removal. The younger more active patient may be more likely to require re-operation for hardware removal.[15,16]

Infection (3%)

Complication with deep infection will require irrigation, thorough debridement and hardware removal, and subsequent therapeutic antibiotic treatment.[15]

Other relevant complications include broken hardware, delayed wound healing, delayed union, stress fracture and complex regional pain syndrome.

Triple arthrodesis

Triple arthrodesis is a powerful procedure that can lend itself to the treatment of significant deformity or arthritis. It has been shown that up to 93% of patients will be satisfied with the outcome, yet only 41% can perform moderate activity without significant pain in the foot and ankle postoperatively.[17]

Osteoarthritis (9–27%)

Osteoarthritis of the ankle joint has been described as a recognized long-term complication of triple fusion. The cause is unknown but is thought to be due to the loss of the 'shock absorbance' of the hindfoot and the subsequent increased stress

Figure 1 Amputation after complications for second toe.

through the tibiotalar joint.[18] Severe naviculo-cuneiform arthrosis has also been found to have a similar incidence post triple fusion.[17,19]

Persistence or recurrence of deformity (70%)

Malalignment after fusion (as assessed relative to Meary's angle) is relatively common, with up to 70% quoted in one study. It is technically difficult to prepare and fuse three joints with the hindfoot in physiological alignment. Residual varus deformity is more commonly associated with ongoing pain, due to overload of the lateral border of the foot; fifth metatarsal stress fractures may result. However, it has been repeatedly shown that malalignment does not necessarily correlate with progression to symptomatic ankle arthritis.[20]

Non-union (2–30%)

Time to union averages 10 weeks, so the patient will need to be counselled about this preoperatively.[18] Compliance with immobilization and abstinence from smoking will help decrease the time to union and reduce the chance of non-union. The non-union rates are 20% for the talonavicular joint, 17% for the calcaneocuboid joint and 9% for the subtalar joint.[21]

Debridement of Achilles insertion/flexor hallucis longus interposition[22]

Functional hallux weakness (4%)

A surprisingly small number of patients report hallux weakness affecting their balance post-procedure, despite the tendon having been harvested. It may be more important to those patients who require push-off strength as part of their occupation or recreational activity.

Peroneal tendinitis (15%)

The aetiology of this is unclear, but a significant number of patients in one study were symptomatic.

Deep vein thrombosis (4%)

This is an important risk of all lower limb procedures, but surgery involving the achilles complex, with immobilization of the ankle in equinus and consequently a loose calf, carries an extra risk. Thromboprophylaxis for an extended period should be considered in all patients.

Delayed wound healing or superficial infection (13–31%)

Wound healing problems are a recognized complication of all Achilles surgery. The risks are more common in smokers, diabetics and patients with impaired vascularity.

Lateral ligament reconstruction/repair

Synovial impingement

Synovial impingement will co-exist in a proportion of patients with chronic ankle instability. Careful assessment will determine whether true instability of functional insecurity are causing the patient's problems. Impingement be addressed by performing an arthroscopy and debridement. A mensicoid soft tissue lesion has been observed in cases of ankle instability and it is thought that this becomes trapped in the lateral gutter, leading to anterolateral ankle pain after stabilization surgery.[23] There is no published evidence surrounding the rate of residual impingement post-operatively.

Recurrence of instability/failure of repair (1–16%)

Published data vary between the patient populations studied, with a quoted figure as high as 16% in athletes. The patient's compliance with postoperative protocol, concurrent ankle pathology and expectations of the procedure will all play a part in determining success[24,25]

Stiffness (13%)

This may manifest itself as limitation of inversion/eversion and could represent overtightening of the soft tissue repair. Non-anatomic reconstructions using, for example, peroneal tendon transfer, are noted for stiffness and subsequent subtalar joint arthritis. Many authors argue the tissue will stretch with physiotherapy, and symptoms may be transient[25]

Nerve injury/entrapment (2–7%)

The superficial peroneal and sural nerves are at risk from entrapment in scar tissue, damage during the approach or stretching, leading to neuropraxia. This may lead to pain and/or sensory disturbance.[24,25]

Wound problems (2–22%)

Wound problems are more common in open repair/reconstruction than after arthroscopic techniques. The general principles of good tissue handling and patient selection apply.[24] Meticulous tissue handling, short tourniquet times and patient factors should all be considered.[25] It has been shown that the rate of wound problems is significantly higher in smokers (22%) than in non-smokers (4%).[26]

Ankle fusion[27]

Non-union (9–13.7%)

The time to union has been shown to be consistently longer in smokers than non-smokers, so patients should be counselled about giving up smoking completely before the procedure. The presence of preoperative neuromuscular imbalance has also been

implicated, so these patients may require more rigid fixation and potentially a longer period of immobilization (Jain). In general most patients achieve union between 6 and 12 weeks.[28]

Infection (6.1%)

Infection can be superficial or deep. Deep infection requires debridement, removal of internal fixation and revision fusion, sometimes with external fixation. Infected non-union may eventually lead to amputation.

Revision (10.3%)

The most common indication for revision surgery is non-union, but malalignment and infection are also implicated.

Pain from hardware (9%)[29]

The rate of hardware removal will depend on the method of fixation used, but bulky plates may be less well tolerated. If union has been achieved, then patients may regard the risk of needing future hardware removal as relatively acceptable.

Arthritis of adjacent joints (6.4%)

There is not yet enough evidence of a causal link between ankle arthrodesis and degenerative changes in other hindfoot joints, with the altered biomechanics poorly understood. However, it remains the case that a significant proportion of patients undergoing ankle arthrodesis will develop arthritis in adjacent joints. Radiological rates or arthritis are much higher than the incidence of symptoms.

Ankle arthroplasty

Wound healing problems (0.9–14.7%)[30–32]

The use of oral steroids and the presence of rheumatoid arthritis or diabetes, have been shown to be risk factors for the development of wound problems. Rheumatoid arthritis increases the risk of a re-operation for complications by 14 times.[33]

Infection

The mean superficial infection rate in the literature is 2.4%, but has been shown to increase in patients with rheumatoid arthritis and diabetes.[34] The rate of deep infection is generally lower, but can range from 0% to 5.7%.[31,34,35] Superficial infections can be treated with a course of antibiotics, but when deeper infection is present more radical treatment involving implant removal, debridement and systemic antibiotics is required.

Intraoperative fractures

Intraoperative fractures may affect the lateral or medial malleolus. The rate of Intraoperative fracture of the medial malleolus has been quoted as 3.1–9%.[31,36] The rate of fracture of the lateral malleolus varies from 0.05% to 2.1%.[37,38] There is a learning curve associated with each implant and placement of the jigs will affect the surgeon's view and consequentially the safe use of the saw. It is important to recognize this complication intraoperatively so it can be addressed.

Aseptic loosening and osteolysis (3.2–19%)[31,35,39,40]

These are major complications that potentially require revision surgery. Malalignment of the components, either due to poor positioning or residual hindfoot deformity, is thought to be an important factor.[38] The rate of loosening may vary between different implant designs.

Chronic pain

Chronic pain often manifests as medial or lateral gutter pain of unknown aetiology. The largest study to date reported a 7% rate of chronic pain that required further surgical intervention.[41] The design, sizing and alignment of the components are all contributory factors in the development of gutter pain.[42]

Revision

The revision rate in the literature is still high at 20.5% and this can be minimized by suitable patient selection.[27]

Amputation

A very small proportion of patients who suffer complications may eventually require amputation. Infected non-union of the ankle after fracture, arthrodesis or arthroplasty is very challenging to manage.[43]

The role of ankle arthroplasty vs arthrodesis is not resolved. Traditional teaching holds that patients aged 50–70 years, with adequate bone stock, normal talar alignment and preserved motion may be considered for arthroplasty. Indications are expanding and it is hoped that high-quality studies, like the TARVA study, will help to guide decision-making.

Arthroscopic procedures

The overall complication rate for ankle arthroscopy has been quoted as between 9% and 17%.[44,45] The most common significant complication is neurovascular damage and a good knowledge of anatomy is imperative in order to place portals safely.

Nerve injury (4.4%)

The superficial peroneal nerve is at risk from the anterolateral portal, and the saphenous nerve from the anteromedial portal. Blunt dissection down to the joint should help avoid this, and prevent the patient sustaining a painful neuroma.[46]

Infection (1.3%)

Infection tends to be superficial, and may be related to persistent drainage from the portals.[47]

Complex regional pain syndrome (CRPS) (1.8%)

Although it is a relatively uncommon complication of foot and ankle surgery, the consequences for the patient can be severe. CRPS has been described as a neuropathic pain syndrome, which can occur postoperative. The diagnosis is made clinically, as there are no biochemical tests that can distinguish those patients with the condition. The International Association for the Study of Pain criteria describe an initiating noxious event or immobilization, followed by disproportionate pain, allodynia or hyperalgesia, oedema, changes in blood flow and/or abnormal sudomotor activity in the region of pain. It can be divided into types 1 and 2, with type 2 being defined as secondary to a known nerve injury (causalgia). CRPS has been found to be more common in middle-aged women, particularly those with a history of anxiety or depression,[48,49] although any patient is at risk.

The diabetic patient

The overall complication rate in this population is quoted as 3.2%. The glycated haemoglobin (HbA^{1c}) reading is important, because for every 1% increase there is a 5% increase in complication rate. Also relevant is the presence of peripheral neuropathy and/or two or more related co-morbidities (1.78 and 3.08 times the risk of developing a complication respectively).[50]

Infection

Infection is the most common complication in the diabetic population (42.3% of complications), hence good perioperative blood glucose control is imperative. Poor perioperative glucose control has been shown to more than double the rate of surgical site infection (5.2% vs 11.9%).[51]

Mechanical failure (33.4% of complications)

Mechanical failure is inextricably linked to delayed or non-union. The rate of non-union is higher in diabetic patients, but the strongest association is in those patients with neuropathy.[52]

Wound breakdown (5.8% of complications)

This is multifactorial, with concurrent infection playing a part, but undoubtedly the microvascular supply to the skin (or deficiency of this) in diabetics is an important factor.

Amputation

It is important to warn all diabetic patients of this prior to performing any surgery on the foot and ankle. This can be a secondary complication of any of the above and has devastating consequences to the patient's independence and function.

Pulmonary or cardiovascular complications

Pulmonary or cardiovascular complications are important to mention, and many diabetics will have multiple co-morbidities that make them high risk for anaesthetic or prolonged surgery.[50]

Thromboembolic complications

Deep vein thrombosis/pulmonary embolism and thromboprophylaxis are very controversial topics. Guidance documents from various sources are frequently contradictory. Surgeons can cite evidence to support their personal views regarding the need for mechanical or chemical prophylaxis. The issue and the options should be discussed with the patient. As noted above, surgery to the Achilles tendon carries particular risks.

Summary

The Montgomery ruling has had a significant effect on the process of consent for surgical procedures. The focus has moved from discussion of those risks that the operating surgeon considers important, to those that are material to the individual patient. Alternatives to surgical treatment must be discussed and documented, including the possibility of conservative management, even if this decision seems illogical to the clinician. In addition, a discussion regarding the timing of surgery is crucial. To some patients, particularly the self-employed or those who care for others, the timing of the procedure and the subsequent effect on their ability to carry out duties or employment will be paramount.

Ideally the surgeon performing the procedure should consent the patient, to allow for an in-depth discussion regarding the risks, benefits and implications of proceeding. There is a risk in delegating this process to junior staff, unless they are experienced in the complexities of the procedure and aftercare.

Individualized patient information must be provided, and often written information can be a good adjunct to enable the patient to make a balanced decision. Whenever information is given to the patient this should be recorded. Websites are useful in providing up to date information, but it is the responsibility of the surgeon to ensure that the patient can access this easily. Some patients may find this harder than others.

The final consent form should be regarded as a confirmation of the overall consent process, rather than comprising a single consenting 'event'. This complies with the Montgomery ruling, the guidelines issued by the Royal College of Surgeons of England and the guidance from the General Medical Council. ◆

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