Best Practice for Knee Arthroplasty Surgery Documentation

GIRFT
GETTING IT RIGHT FIRST TIME

BRITISH ASSOCIATION FOR SURGERY OF THE KNEE

British Orthopaedic Association

Working in partnership with NHS Resolution

Introduction

As part of ongoing work both to improve patient outcomes and to reduce litigation costs within the NHS, a large series of knee arthroplasty cases in which complaints were made, have been reviewed. A number of common denominators and concerns, both in technique and documentation, have been identified. The Getting It Right First Time (GIRFT) programme, in association with the British Association for Surgery of the Knee, British Orthopaedic Association and NHS Resolution, aims to reduce the frequency of such occurrences by bringing these common denominators to the attention of surgeons who perform knee surgery. Throughout this guidance, real cases are used as a tool to stress the importance of adequate documentation of knee surgery.

To ensure patients can have confidence in their surgery, they should be reassured by a series of professional standards to ensure that knee replacements are planned, performed and supervised in a safe and thorough way, with attention to detail in all these areas. Additionally, it is important for patients to know that the prostheses used have either a proven track record (via an ODEP rating), or are undergoing a rigorous prospective evaluation through clinical trials or via processes such as Beyond Compliance.[1]

The various components of the joint arthroplasty should be clearly documented providing evidence of safe clinical practice, in addition to providing important information should a review or revision of the replacement ever be required.

This guidance illustrates the standard of practice that should be followed in modern knee surgery in the UK. The document is not a comprehensive guide to knee surgery, nor is it expected that surgeons will follow all the advice it covers. Ultimately the responsibility for patient care is with the treating surgeon, but the British Association for Surgery of the Knee and British Orthopaedic Association endorse the content of this guidance.

Theatre briefing

A brief gathering at the start of any surgical list has become standard within all sectors of healthcare. It is essential that this takes place. It is the surgeon's responsibility to ensure that all the required instrumentation and prostheses are available and that the requirement for any additional equipment, is communicated by the surgical team prior to any surgery taking place.[2] Evidence that the WHO surgical safety checklist including sign-in, time-out and sign-out has been performed should be clear and available in the record.[3] As part of that, the administration of pre-operative prophylactic antibiotics and other peri operative medication, (e.g. tranexamic acid) should be detailed as well as evidence of patient warming, plans for VTE prophylaxis during the procedure and post-operatively should be recorded. It is important that any unusual or additional steps in the procedure are identified.

Pre-operative planning

A record detailing the conclusions of any pre-operative multi-disciplinary team (MDT) meetings should be documented and thereafter made available to justify the indications for surgery and the procedure planned. In addition, the results of preoperative templating, if used, should be noted. A record of implant selection and rationale for that implant choice should be documented at the time of consent. Any potential bone grafting, whether autologous or non-autologous, should be discussed in the consent process and specifically referenced in the record of consent.

Prior to the start of the operation, the pre-operative range of movement, deformity, skin, and neurovascular condition of the limb should be documented.

The procedure

The names and grades of the lead surgeon and any assistants present during the operation should be documented. Similarly, the details of the anaesthetist(s) should be noted along with the type(s) of anaesthetic used.

With regard to the operative detail, the following should be recorded: patient position, skin preparation, and surgical approach utilised. The use of tourniquet should be noted, including any protective steps utilised to prevent spirit burns. The total tourniquet time and pressure should be recorded.

The degree of chondral surface wear in all 3 compartments and status of cruciate ligaments must be noted, as well as the sequence and extent of releases required to achieve soft tissue balancing. Any anatomical variations and steps to overcome these should be noted.

Preparation of the Femur, Tibia, and Patella

With regard to the femur and tibia, a record of the referencing technique, intra/extramedullary jigs used, cutting block sizes, use of stems or augments should be noted. Methods of assessing the flexion/extension gaps, rotational alignment, varus/valgus stability, and tibial slope should be recorded.

Details of the preparation of the patella, including thickness resected and remaining bone stock, should also be recorded.

The use of trials for all components is recommended and should be recorded alongside any reason why the definitive components are a different size to the trials that were used. Justification for uncommon prosthesis sizes or position, such as allowing anteroposterior or lateral overhang, should be documented.

Case Vignette

TKR – Rationale for uncommon prosthesis sizes

A 75-year-old lady had a total knee replacement, using a size 2 femoral and tibial implant with a 17mm insert. Following the surgery, the patient continued to experience pain and restricted movement in her knee. Upon further review it was identified that the femoral joint was a little "overstuffed" and she was eventually offered revision surgery, where the implant was replaced with a smaller size. Following this, the patient's pain fully resolved, and she made a reasonable recovery.

She alleged negligence in relation to the first procedure and specifically, the use of the larger implant.

While the defendant trust's expert evidence did not consider that the decision to use the larger implant size was necessarily negligent, there was no evidence in the records of any consideration of appropriate implant size pre-operatively or evidence of any discussion with the patient to support the surgeon's judgment call. The claimant's expert was entirely critical of the use of the larger implant.

The claim was settled and damages were agreed at £30,000. The claimant's solicitors' costs were £43,000.

Justification for the use of prosthesis sizes and positions must be documented.

Cementation

The quantity and brand of cement should be recorded and any additives (e.g. antibiotics) in the cement must be noted. Methods to optimise cementation in the femur, tibia, and patella must be noted. A check for cement debris and its removal should be performed prior to closure. The manufacturer's label for the cement detailing the batch number should also be attached.

Case Vignette

TKR - Failure to Document Cementing Technique

A patient underwent a right total knee replacement, which proceeded uneventfully. Within three years of the procedure being performed the patient developed ongoing knee pain and it was felt that the knee replacement had failed. A direct exchange revision was therefore performed. The patient's condition improved but he continued to suffer with discomfort.

The patient brought a clinical negligence claim alleging that the original knee replacement was performed inadequately. His allegations focussed around the cementing technique, which the operating surgeon did not document in his note of the procedure.

The case proceeded to trial and was successfully defended by the NHS. However, the operating surgeon spent four hours in the witness box being cross-examined on his cementing technique given the absence of any information about this in his operative note.

Methods to optimise cementation in the femur, tibia, and patella must be noted.

Implants

The choice of implant used should be based upon the best available evidence from sources such as the National Joint Registry, the Scandinavian and Australian registries, ODEP ratings, and other high-quality published literature. In all circumstances, the surgeon should be aware of the manufacturer's information for use and the operative technique manual. It is the surgeon's personal responsibility to ensure that any components that are implanted are compatible and used according to the manufacturer's recommendation. Any justification for ignoring the manufacturer's guidance must be very clearly recorded.

It is mandatory that any and all implants that are opened are checked by the surgeon and scrub team prior to implantation. Any and all components opened, checked and implanted should be recorded on a board in theatre. The component identification labels should be secured within the patient record, in an appropriate location. Appropriate information required for National Joint Registry submission should be secured within a purpose-specific document or electronically linked to the National Joint Registry.

'Stop' moment

It should be considered standard practice for there to be a 'stop moment', prior to the wound being closed, to ensure that the components that have been implanted are checked against the theatre board, that they are compatible in size, laterality, material, and manufacturer prior to the end of the operation.

Final assessment prior to closure

It should be considered standard practice to record a range of movement achieved, any injury or additional repair to the extensor mechanism or collateral ligaments, and comment on the achievement of equal flexion/extension gaps and varus/valgus stability of the knee throughout the range of motion, with particular reference to mid-flexion. Patella tracking should be recorded, including any solutions to maltracking.

Details of the closure should be recorded, in addition to the position of drains.

Case Vignette

TKR – Checks prior to closure

A patient alleged failure to remove a bead of cement during knee replacement surgery resulted in a further procedure and subsequent infection and medical complications.

Patient alleged NHS Trust was in breach of duty by failing to (i) remove operation cement; and (ii) thoroughly inspect wound to ensure that no cement had been left behind.

The case was eventually resolved for £10,000. Claimant's solicitors' costs were £50,000.

The use of cement, its type and any antibiotics contained within it, alongside technique used in application, should be noted. A thorough check for cement debris should be undertaken prior to closure during surgery.

Post-operative instructions

Any drugs given to the patient peri-operatively should be recorded clearly.

At the end of the operation the vascular status of the limb should be checked and recorded.

Case Vignette

TKR – Assessment of neurovascular status post-op

A patient underwent a total knee replacement. During the procedure, the popliteal artery was injured. Unfortunately, this was unrecognised for a number of days post operatively. By the time the complication was recognised, it was too late to salvage the claimant's leg.

The Trust admitted liability prior to the issue of pleadings. Assessment of damages is outstanding, but it is anticipated that damages will be agreed in the region of £1,000,000. The issue between the parties is the claimant's likely life expectancy. The claimant's costs are estimated to be in the region of £500,000.

The neurovascular status of the limb should be checked and documented immediately post operatively.

Clear and readily accessible post-operative instructions should detail the antibiotic prophylaxis regime, plans for VTE prophylaxis (commonly via a separate VTE risk assessment), timing of haemoglobin check and X-rays, instructions for the timing of removal of any drains, alongside the appropriate timing for removal of sutures. It is important to detail the planned weight-bearing status and any specific instructions or limitations to be observed in rehabilitation.

Post-operative care

Within the initial course of post-operative care, it should be considered standard practice for an anterior/posterior and lateral x-ray to be performed. This is to ensure that the position of the components is satisfactory, that there is no evidence of bony injury or any unexpected concern with regard to component orientation or fixation, component mal-position, and an unexpected fracture.

Case Vignette

TKR – Critical analysis of postoperative radiographs

A patient underwent a right total knee replacement. The prosthesis was found to be loose and misaligned 2 years later, resulting in revision surgery.

The patient alleged NHS trust was in breach of duty by (i) placing the knee implant in suboptimal alignment during the right total knee replacement; (ii) failing to repeat post-operative X-rays; and (iii) failing to diagnose knee pain as being caused by suboptimal alignment.

The patient argued that had the implant been placed with correct alignment, then she would have made a good recovery following the primary knee replacement and avoided further treatment.

The patient accepted the NHS Trust's offer of settlement in the sum of £70,000. Claimant's solicitors' costs were £20,000.

The use and critical analysis of AP and lateral imaging would have ensured the position of components checked as appropriate. Duty of candour should be exercised to inform the patient of any complications which meet the harm threshold, at the earliest opportunity following detection.

It is important that a neurological assessment of the sciatic and femoral nerve is performed and accurately recorded once any regional spinal or local anaesthetic has worn off.

It is sensible that a post-operative haemoglobin check should be performed, specifically if there has been more blood loss than expected, or in circumstances where the patient had a low starting haemoglobin level. This can be repeated as clinically indicated.

A daily record of progress with mobilisation should be made detailing any wound concerns. Similarly, any deviation or concern with routine post-operative VTE prophylaxis should be identified.

Duty of candour

It is important that appropriate duty of candour be exercised informing the patient of any events or peri-operative complications which could cause harm or compromise their outcome, at the earliest opportunity following detection and as deemed appropriate by the treating team. This should be carried out in accordance with local policy and should include a clear apology, an offer of an appropriate remedy (if possible) and/or support. The communication should detail the short and long-term effects of what has happened, to the patient.[4]

Bilateral surgery

When a surgeon is to carry out the second of staged bilateral knee replacements, either in a staged or simultaneous procedure, it should be considered standard practice for the surgeon to be aware of the components used on the first side. The surgeon should record any reason for the use of significantly different sized components. Where evidence of the size of the index side components is unavailable, this should be documented.

Other common issues in Knee Arthroplasty that have been identified within the case review:

Knee revision surgery

In addition to the principles described for primary surgery above, if a revision surgery is to be considered, the indications for revision, together with an explanation as to why it is felt that the index procedure has failed and an explanation of how this is to be corrected, should be undertaken and recorded in the notes. Careful attention to detail regarding the procedure planned and the techniques involved, should be described to the patient and steps taken to ensure the patient understands the situation and that their expectations are consistent with the relative complexity of the procedure required.

Possible infection after knee surgery

It is important that appropriate prophylactic antibiotics are given pre-operatively and, according to a pre-determined protocol, post-operatively. This should be discussed with the patient pre-operatively and should be clear from the patient's record.

An appropriate clinical response should be made to any early signs of concern, such as wound ooze, erythema or swelling. If there is any uncertainty as to whether there may be infection, an early second opinion from a consultant colleague should be obtained. Appropriate haematological investigations such as FBC and Differential, CRP, ESR should be performed. When there is concern, a high index of suspicion consideration should be given to returning the patient to theatre for aspiration to allow additional information to be gathered from culture and other synovial analyses such as alpha-defensin, synovial white cell count, leukocyte esterase, synovial CRP, and polymorphonuclear percentage. From that series of tests, a clear diagnosis should be made with a detailed treatment pathway determined and recorded in the records. This should be communicated with the patient and their family clearly.

At the time of any further open surgery for infection, it is considered best practice that at least five tissue samples should be taken, using a specific sample tray with a number of sets of forceps. Further recommendations can be found in the International Consensus of Musculoskeletal Infection, 2018.[5,6] The samples should be put into separate containers to prevent cross-contamination. Antibiotics given prior to this should be discussed with the microbiologists and the rationale discussed with the patient. It is considered good practice for the microbiology team to be aware that samples are to be sent, particularly 'after hours', so that they can be processed early.

In the presence of an early infection, any such surgery should be performed by a suitably-qualified surgeon with the ability to exchange all modular components of the recently-implanted knee replacement as well as to perform extensive debridement, back to healthy tissue, with additional and thorough lavage and wound closure as part of a DAIR (Debridement Antibiotics and Implant Retention) procedure.

Arthroscopic surgery has no role in the definitive treatment of acute or chronic prosthetic joint infection of the knee.

The procedure and the rationale behind any decisions taken alongside the formal microbiological advice given should be recorded clearly in the records. In essence, where there is a positive diagnosis of infection, a clear description of the management planned, including the microbiological diagnosis and antibiotic regime determined appropriate, should be recorded. It should be stressed that the investigation and successful treatment of Prosthetic Joint Infection relies significantly upon a multi-disciplinary approach.

Unicondylar Knee Replacement (UKR) or Patella Femoral Replacement (PFR)

When considering a PFR a second opinion is recommended before operating as the patient group who benefit from this procedure is known to be very specific and difficult to identify. Patients consented for UKR or PFR should also be consented for TKR in case the intra-operative findings determine that wear of other joint surfaces is greater than anticipated or other requirements for a partial knee replacement are no longer met.

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References

[1] The Beyond Compliance Advisory Group is an independent panel of experts who assist implant manufacturers with the assessment of risk of new products.

[2] National safety standards for invasive procedures, https://improvement.nhs.uk/resources/national-safety-standards-invasive-procedures/

[3] WHO Surgical safety checklist, http://www.who.int/patientsafety/safesurgery/ss_checklist/en/

[4] https://www.gmc-uk.org/-/media/documents/DoC_guidance_englsih.pdf_61618688.pdf

[5] Parvizi J, Tan, TL, Goswami K, Higuera C, Della Valle C, Chen A, Shohat N. The 2018 Definition of periprosthetic hip and knee infection: an evidence-based and validated criteria. J of Arthroplasty. 2018. May:33(5). 1309-1314

[6] Parvizi J, Gehrke T. Second international consensus meeting on musculoskeletal infection. 2018: July. Philadelphia.

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