TOTAL KNEE REPLACEMENT: A GUIDE TO GOOD PRACTICE

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1. INTRODUCTION

1.1 This document is a statement of good practice in primary knee replacement . This document is based on similar guidelines developed by the British Orthopaedic Association and is designed primarily for Public Hospital practice

1.2 Many studies of knee replacement identify its cost effectiveness 1, 2 and high patient satisfaction rates in the short term 3. The majority of patients are relieved of the pain and disability from knee arthritis, which may have compromised their quality of life and their independence before operation. 4,5,6 which claims to be applicable to all patients or in all circumstances. Each consultant and those working under the supervision of a consultant must continue to take into account the individual requirements of the patient.

2. THE INDICATIONS FOR THE OPERATION

2.1 Severe pain and disability with accompanying radiological changes in the knee are almost always the indications for the operation, in patients where conservative treatment has failed or is futile. Occasionally there may be an indication to replace a knee because of progressive deformity and/or instability, and pain may not necessarily be the most significant factor. Where comorbidities exist, risk benefit considerations may rule out the operation in an individual patient.

3. THE OUTPATIENT CONSULTATION

- 3.1 The pain and suffering of patients waiting for treatment is self-evident.
- 3.2 Patients should be referred from their General Practitioner. Discussion regarding operative management of knee arthritis should ideally involve an Orthopaedic Surgeon vocationally registered with the New Zealand Medical Council with appropriate training in Total Knee arthroplasty or a Trainee in orthopaedics with supervision from a consultant Orthopaedic Surgeon .
- 3.3 15-20 minutes is regarded as the appropriate time allowed for the first consultation.
- 3.4 A confidential environment with access for relatives and the reliable availability of notes and radiographs are needed for the consultation.
- 3.5 After clinical examination and general medical assessment the surgeon should provide the patient with an explanation of the problem in understandable language and discuss the available treatment options.

- 3.6 The Surgeon must offer information on the risks and benefits of any suggested treatment and the outcomes of performance of any proposed knee replacement where appropriate. The precise reasons for the operation should be given.
- 3.7 The letter to the General Practitioner should confirm that these discussions have taken place and that the patient wishes to proceed with surgery. Informed consent must be obtained.

4. WAITING FOR THE OPERATION

4.1 In a cash-limited service, there is likely to be a delay before elective operations can be carried out. Consultants are expected to manage their waiting lists ethically and patients should be admitted for operation according to clinical priority and social circumstances.

5. **PRE-OPERATIVE ASSESSMENT**

- 5.1 A managed system of pre-operative assessment is recommended as good practice, and as with hip replacement such arrangements are now commonplace 9 They allow the most efficient use of scarce resources.
- 5.2 Pre-operative assessment clinics staffed by Doctors and Nurses working to guidelines with the ability to involve Anaesthetists and Professions Allied to Medicine guard against cancellations, identify co-morbidities and allow discharge planning. There is also an opportunity for patient education.
- 5.3 Routine investigation of blood, urine, blood pressure and an ECG are best carried out at the pre-operative assessment.
- 5.4 Provisional discharge planning should take place in the pre-operative assessment clinic. The planning takes into consideration age, co-morbidities, home circumstances and the availability of care-givers.
- 5.5 Access to rehabilitation beds should be available particularly for the elderly and the more severely disabled. It is anticipated that 80% of patients admitted for Total Knee replacement will be discharged within 5-7 days.

6. THE ADMISSION TO HOSPITAL

6.1 All patients should be admitted to hospital under the care of a named vocationally registered Consultant Orthopaedic Surgeon. There should be sufficient time before

their knee replacement to allow pre-operative and pre-anaesthetic Procedures to be completed. The limb for operation should be marked in an area which is still visible after draping, and an explanation of anaesthesia be given by the anaesthetist involved. Appropriate arrangements for blood transfusion should be in place prior to surgery.

7. HOSPITAL FACILITIES REQUIRED FOR THE OPERATION OF PRIMARY KNEE REPLACEMENT

- 7.1 Primary knee replacement operations are best carried out in appropriately credentialed hospitals.
- 7.2 In order to reduce the risk of infection, knee replacement patients should be nursed in orthopaedic wards in areas separate from patients who pose a potential risk of cross infection and which are staffed by a team experienced in the management of arthroplasty patients.

8. **REQUIRED THEATRE RESOURCES**

- 8.1 The operating Theatre should be dedicated to clean elective orthopaedic surgery or joint replacement. Shared facilities with other clean surgical disciplines is acceptable practice when using ultra clean air, but data supporting this practice are not available.
- 8.2 The surgeon should have trained assistance during the operation, and a trained scrub nurse fully familiar with the required complex instrumentation is mandatory. In the absence of junior medical staff, additional nursing assistants or specifically trained Surgeon's Assistants must be available. Sometimes more than one assistant is required.
- 8.3 A full range of specialised implants and instruments must be readily available.
- 8.4 Appropriate impenetrable clothing and drapes are essential.

9. THE SURGEON

9.1 The surgeon must be vocationally registered as an Orthopaedic surgeon in New Zealand and have maintained an interest in arthroplasty. The surgeon should participate and comply with requirements of the relevant CPD program

- 9.2 The theoretical and practical skills of the Consultant Surgeon performing primary replacement operations must be maintained by continuous professional development.
- 9.3 Knee replacement operations performed by other surgeons must be supervised by Consultants. The level of supervision should be appropriate for the level of skill and experience of the operating surgeon. In the absence of consultant supervision, prospective arrangements must be made for on-site consultant cover.
- 9.4 The operation requires an anaesthetist with the appropriate skills and techniques for Total Knee Replacement.

10. RECORD KEEPING AND THE OPERATION NOTES

Clinical Records

- 10.1 Good records are a basic tool of clinical practice, and should be legible.
- 10.2 The records must include the name, date of birth and address of the patient, and the referring general practitioner should be identified. The hospital number should be clear. The hospital and surgeon with responsibility of care should be named.
- 10.3 The admission note should record the general medical condition of the patient as well as fitness for operation. It should contain a clinical history, the full clinical examination findings, pre-existing medical history, and all current disabilities. The purpose of the operation should be stated. All medication should be listed.
- 10.4 An explanation of the proposed procedure as well as the risks and benefits should be recorded. The type of implant to be used should be explained to the patient together with the success and failure rates of the implant if known. The operating surgeon should ideally complete the consent form with the patient. If this is done in outpatients, only a short delay should take place before the operation is undertaken. In certain circumstances (for example medial uni-compartmental replacement) patients must be made aware of the fact that if peri-operative findings indicate that a certain procedure would be inappropriate then an alternative procedure (usually total knee replacement) may be performed. This should be recorded.
- 10.5 It is best practice that operative notes be made in writing, or dictated for immediate typing and signature by the operating surgeon. If a pre-arranged pro forma is being used the operating surgeon should personally complete the pro forma.
- 10.6 A record of the operation should be made immediately following surgery and should include: 12

- The name of the operating surgeon, assistants and the name of the consultant responsible.
- The diagnosis and the procedure performed.
- Details of the incision and any additional procedures to achieve satisfactory exposure.
- Description of the findings.
- Details of all soft tissue release procedures.
- Details of significant tissue excision, transposition or augmentation.
- Details of serial numbers of prostheses and other implanted materials.
- Details of bone grafting.
- Details of component alignment and rotation.
- Post surgery flexion range.
- Tourniquet time.
- Details of sutures used.
- An accurate description of any difficulties or complications encountered and how these were overcome.
- Immediate post-operative instructions.
- The surgeon's signature and the date of the operation.
- Data forms for the National Joint Register must be checked for completeness and accuracy and signed by the surgeon before he/she leaves the operating theatre.
- 10.7 The anaesthetic record, signed by the anaesthetist, should contain:
 - The name of the anaesthetist and, where relevant, the name of the consultant anaesthetist responsible.
 - Pre-operative assessment by the anaesthetist, and the date the assessment was performed.
 - Drugs and doses given during anaesthesia and route of administration.

- Type and site of any regional anaesthetic used.
- Monitoring data
- Intravenous fluid therapy, if given.
- Post-anaesthetic instructions
- The anaesthetic record should be filed with the clinical notes.
- 10.8 Progress after operations, including early complications, should be listed. The date of discharge and arrangements for continuity of care should be recorded.
- 10.9 All notes should be contemporaneous and should not be altered; errors should be identified. Orthopaedic records within general hospital records should be easily identified within the case notes.
- 10.10 Follow-up notes should allow another doctor to assume the care of the patient at any time.
 - All doctors referred to in an entry must be identified by name and designation.
 - Details of written and verbal information given to general practitioners, patients, relatives and carers, whether at admission or later, must be recorded.
 - Details of all investigations considered and whether the investigation has actually been requested should be noted.
 - Ideally, at least one entry each day recording the patient's progress, but it is recognised that with pressures of work this is not always achievable particularly at weekends.
 - An entry when the management of the patient is changed or when there is an additional procedure.
 - An entry should be made whenever a doctor is called to see a patient.
 - Deletions should be made with a single line and signed and dated.
- 10.11 All patients should have good quality antero-posterior and lateral radiographs, and ideally a 25 degree skyline radiograph ideally before discharge from hospital, or at the first post operative outpatient visit.

- 10.12 There should be an agreed protocol for the retention of all documents and radiographs.
- 10.13 In Private Practice the whole process should follow the same high standard.

11. THE CHOICE OF IMPLANT AND MODE OF FIXATION.

- 11.1 Orthopaedic Surgeons have large numbers of knee devices from which to choose 7,
 13. Many of these devices have not been subject to studies of outcome for as long as 10 years 7
- 11.2 Care should be taken when using the term "total knee replacement" as this implies that all articular surfaces in the knee have been replaced including resurfacing of the patella. The issue of patellar resurfacing remains controversial as there is no strong data to support resurfacing or non-resurfacing. 14, 15, 16, 17. Surgeons practising knee replacement therefore fall into three groups, those who always resurface, those who never resurface and those who selectively resurface. In primary knee replacement implants may be unconstrained i.e. there is no direct mechanical linkage between the tibial components. Some prostheses have varying degrees of constraint and at present there is no compelling evidence to support the use of any particular design. Degenerative joint disease may be confined to one compartment and in these circumstances implants are currently available which replace both sides of the single diseased compartment 18, 19, 20
- 11.3 Concerns about the long term effect of polyethylene wear debris have resulted in the development of implants which involve the use of mobile polythene bearings in both total knee replacement and uni-compartmental tibio-femoral knee replacement 21, 22, 23, 24
- 11.4 Many factors determine surgeon preference for an individual implant. Influences include their trainers, consultant colleagues, a desire to improve their own results or the perceived outcomes of existing devices. The manufacturers of knee devices can also have a significant effect on choice through the service they provide.
- 11.5 Published results of many knee implants offer little help to the surgeon wishing to make an informed choice. Most outcome research is short term, non-comparative and does not take into account case-mix and variations in the operative technique of the operating surgeon. Importantly, there is no agreed standardisation of outcome measures for knee replacement.
- 11.6 A further confounding factor for the surgeon is that knee devices with apparently good published results have in the meantime been modified by the manufacturers and the clinically tested design is no longer available. There has been a failure to realise that even minor modifications to design, material, surface finish, or fixation techniques can dramatically alter the performance of a knee replacement.

- 11.7 The selection of knee prostheses for general use should normally be based on evidence published in peer reviewed journals. A clinical follow-up at least 10 years with a published life table and survivorship curve calculated according to best statistical practice are recommended criteria in support of the use of a particular knee prosthesis. 7 There should be at least a 90% ten year survival for knee prostheses.
- 11.8 In the absence of peer reviewed evidence of outcome at ten years, a device must be subject to ongoing surveillance. The use of such devices should have ethical approval.

Notwithstanding the comments above it is the responsibility of the surgeon to use the finite health resources in the most cost-effective way. It is anticipated the departments will have policies in place to limit the inventory of prostheses available.

12. PROPHYLAXIS AGAINST VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

- 12.1. It is well recognised that thromboembolism does occur after primary knee replacement but there is debate regarding the precise incidence of this complication. Recent evidence suggests that the prevalence of fatal pulmonary embolism, even in the absence of chemical prophylaxis, is very low following both knee and hip replacements, and much lower than quoted in historical papers. 25, 26
- 12.2 There is no doubt that deep venous thrombosis occurs fairly commonly after primary knee replacement and can be demonstrated, by venography, in between 30 and 60% of cases at any level and 10 to 20% of cases proximally. Only a very few of these develop a clinical event causing death or morbidity.
- 12.3 There is no good evidence to suggest that the use of chemical prophylaxis reduces either overall mortality or fatal pulmonary embolism, and there is a known morbidity from the use of chemical prophylaxis. In contemporary practice knee replacement should be regarded as "moderate risk" for death from pulmonary embolism. Chemical prophylaxis may reduce the risk of non-fatal pulmonary embolism, but rigorous scientific evidence is not available. There are usually no long-term sequelae from this condition.
- 12.4 There is strong evidence for the effectiveness of low dose heparin, low molecular weight heparin and Warfarin in reducing radiological DVT by 40 to 60% 27, 28 but death from other causes may be increased. There is also concern regarding possible bleeding complications, which may put the knee replacement at considerable risk.
- 12.5 There are widely divergent opinions regarding the precise role of chemical prophylaxis in Knee replacement. The surgeon should consider current evidence and advise the patient appropriately.
- 12.6 Under normal circumstances, early mobilisation (24 to 48 hours) after surgery

should always be considered as should the use of mechanical methods of reducing deep venous thrombosis although rigorous scientific evidence that these are effective is also lacking. These measures are free of significant side effects.

13. PROPHYLAXIS AGAINST INFECTION

- 13.1 Patients, prior to knee replacement, should be clinically screened for active infection.
- 13.2. Although there is no specific data relating to knee replacement, we believe that as with hip replacement, all patients should receive an intravenous broad spectrum antibiotic at induction of anaesthesia.29

13.3 Gentamycin impregnated bone cement may also reduce the overall revision burden as has been shown with THR.

13.4 In the absence of any specific data relating to knee replacement, we believe that evidence from hip replacement studies support the administration of an appropriate antibiotic in the event of peri-operative urinary catheterisation.³¹

14. SURGICAL TECHNIQUE

- 14.1 Any anterior incision which allows adequate exposure of the distal end of the femur, proximal end of the tibia and the posterior articular surface of the patella is acceptable.
- 14.2 The recognised complications of particular approaches should be explained to the patient.
- 14.3 Implants may be inserted with or without cement. In cemented knee replacement the bone surfaces should be cleaned, irrigated and dried before application of bone cement and cement should be compressed where possible.
- 14.4 For cementless knee replacement, adequate preparation of the bone and stable fixation of the implants must be achieved at operation.
- 14.5 Where possible tension in the medial and lateral soft tissue structures should be balanced in both flexion and extension and excessive tension on one side in either flexion or extension should be avoided.
- 14.6 After implantation the patellar tracking should be checked and appropriate adjustment made if not satisfactory. It is essential to check the integrity of the extensor mechanism before closure.
- 14.7 Leg length equality cannot be achieved in every case.

- 14.8 Flexion deformity should always be corrected at the time of surgery, but may still be noted at follow-up despite appropriate post-operative rehabilitation.
- 14.9 In appropriate cases, bilateral simultaneous or sequential knee replacement may be performed under the same anaesthetic. There is evidence to suggest that rehabilitation is more rapid than after staged procedures, 32,33, but there are some concerns about the morbidity of such major surgery.34 Patients undergoing bilateral surgery may in some cases be best managed in a high dependency unit.

15. EARLY POST-OPERATIVE CARE

- 15.1 It is important to confirm neurovascular integrity in the operated limb at an early stage.
- 15.2 Mobilisation, the achievement of full extension and an increasing flexion range should be supervised by the Surgeon. Patients should have access to physiotherapy as required. Outpatient physiotherapy may also be required.

16. THE FOLLOW-UP OF PATIENTS AFTER TOTAL KNEE REPLACEMENT

- 16.1 The follow-up arrangements that surgeons make for total knee replacement patients vary across New Zealand. Many surgeons discharge patients within one year .
- 16.2 Primary knee replacement may fail between five and ten years but the
- 16.3 majority fail after ten years. For best practice, patients should be followed up clinically and radiologically in the long term. We believe that ideally a minimum requirement is an AP and Lateral x-ray at five years, and each five years thereafter. This surveillance may be performed by a nurse practitioner under the supervision of the Orthopaedic surgeon.
- 16.3 Failure from aseptic loosening of a knee replacement is often silent the patient does not complain. Regular follow-up identifies the patient at risk of progressive failure. Exchange or revision operations should be planned and performed before massive bone destruction occurs, as delay may result in the need for much more extensive surgery which is more demanding of resources and has a greater risk of failure. Revision procedures are less successful than primary operations. All patients undergoing Knee Replacement in New Zealand must be entered into the National Joint Register.

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