A Guideline to Good Practice in Total Knee Replacement in South Africa 2016

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1. INTRODUCTION

1.1 This document is a statement of best practice in primary Total Knee Replacement (TKR) and from available data, the document identifies current best practice in general terms. It is not a statement which claims to be applicable to all patients or in all circumstances and is not a protocol but a guideline to assist the Surgeon, aiming to improve patient outcomes.

1.2 It has been adapted for South African circumstances from the Guide to Good Practice in Knee Replacement Surgery from the British Association for Surgery of the Knee and the amendments thereof in the New Zealand Guidelines.

1.3 The Guideline has been drawn up by the SA Arthroplasty (SAAS) and SA Knee Societies(SAKS) and is endorsed by the SA Orthopaedic Association (SAOA).

2. THE INDICATIONS FOR THE OPERATION

2.1 Severe pain and disability arising predominantly from osteoarthritis or inflammatory arthritis 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.

2.2 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.

2.3 Occasionally periarticular fractures of the distal femur in elderly patients

2.4 Tumors about the knee

3. THE OUTPATIENT CONSULTATION

3.1 Usually the patient will have consulted their General Practitioner (GP) or Health Care Professional (HCP) who will seek the opinion of an Orthopaedic Surgeon.

3.2. The SAAS/SAKS regards 15-20 minutes as the minimum time allowed for the first consultation

3.3 A confidential environment with access for relatives, and the reliable availability of notes and radiographs are essential for the consultation.

3.4 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. An individual patient may have added risk factors present (such as cardio-vascular disease, obesity, predisposition to venous thromboembolism, neurological disease or diabetes) and should be made aware of the added risks when these factors are present. The surgeon should try to verify that the patient has understood the information.

3.5 The Surgeon must offer information on the risks and benefits of any suggested treatment and the outcomes of performance of any proposed knee arthroplasty where appropriate. The precise reasons for the operation should be given.

3.6 A letter to the patient's GP and/or the referring HCP should confirm that these discussions have taken place and that the patient wishes to proceed with surgery.

4. PRE-ADMISSION ASSESSMENT

4.1 A managed system of pre-admission assessment is recommended as good practice and should take place within six weeks of the operation.

4.2 Routine investigation of blood, urine, blood pressure and relevant microbiological assessment are best carried out at the pre-admission assessment which should allow enough time to optimise the patient prior to surgery.

4.3 There is strong evidence that obese patients have poorer outcomes after TKR and a delay of up to 8 months will not worsen outcomes, thus allowing time for weight control programmes.

4.4 Routine screening for Methicillin Resistant Staphlococcus Aureus (MRSA) should be considered in patients that have been transferred from other health care facilities, patients with a history of recent admission to a health care facility and patients with a prior history of MRSA infection. All patients with a positive test should be decolonised with Mupurocin ointment and chlorhexidine or betadine body wash.

4.5 Disease-modifying agents for Rheumatoid Arthritis should be stopped prior to elective TJA (although this is not universally accepted, with current controversy relating mainly to biologics.) The timing of drug discontinuation should be based on the specific medication and the individual patient. The cessation of immunosuppressant medications should be performed in consultation and under the direction of the treating physician.

4.6 The knee should be assessed for previous surgical and other scars and if necessary a Plastic Surgeon should be consulted

4.7 The X-Rays must be fully evaluated for any difficulties that may be encountered and in particular any hardware that may need to be removed.

4.8 Provisional discharge planning should take place in the pre-operative assessment. The planning takes into consideration age, co-morbidities, home circumstances and the availability of carers.

4.9 Access to rehabilitation beds should be available particularly for the elderly and the more severely disabled.

4.10 As same-day admission and early discharge has become more frequent, all these arrangements become vital for the safe passage of the patient through the peri-operative phase

4.11 Information about the operation may be given to the patient or relatives in leaflet, pamphlet or electronic format. It should be constructed in language that is understandable to the patient

5. HOSPITAL ADMISSION

5.1 All patients should be admitted to hospital with sufficient time before their knee replacement to allow pre-operative and pre-anaesthetic procedures to be completed.

5.2 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

5.3 The patient must give consent to the operation which may be given in the outpatients, the pre-admission clinic, or in the ward.

6. HOSPITAL FACILITIES REQURIED FOR TKR

6.1 Primary knee replacement operations are best carried out in hospitals where back-up from other medical and surgical disciplines is readily available.

6.2 Access to a High Care Unit and/or Intensive Care facilities is desirable. Such units should have staff trained in the management of arthroplasty patients.

6.3 Adequate numbers of trained nurses and the skills of Allied Medical Professionals, especially Physiotherapists, must be available.

6.4 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 wards which are staffed by a team experienced in the management of arthroplasty patients.

7. REQUIRED OPERATING THEATRE RESOURCES

7.1 Infection following operation is catastrophic for the patient and surgeon as well as very expensive to the Health Care provider.

7.2 The use of ultra clean air theatres is considered to be best practice for units performing knee replacement operations. The quality of ultra-clean air should be checked regularly.

7.3 The operating theatre should be dedicated to clean elective orthopaedic surgery or joint arthroplasty. Shared facilities with other clean surgical disciplines is acceptable practice when using ultra clean air, but data supporting this practice is not available.

7.4 In ultra-clean air theatres, interposition of theatre personnel between the air source and wound can increase rates of infection so provision of efficient occlusive clothing is critical

7.5 A combination of ultra-clean air theatres, systemic antibiotics active against coagulase negative staphylococci and, where applicable antibiotic impregnated cement with occlusive theatre clothing provides the most effective prophylaxis against infection. These reduce the rate of deep infection by a factor of 18 compared to conventional theatres without additional prophylactic measures. A combination of all these prophylactic measures is recommended.

7.6 Appropriate impenetrable clothing and drapes are essential.

7.7 The surgeon should have trained assistance during the operation, and a trained scrub nurse fully familiar with the required complex instrumentation is mandatory. Sometimes more than one assistant is required.

7.8 A full range of specialised implants and instruments must be readily available to address intra-operative complications such as fracture must be readily available. Non-orthopaedic emergencies such as vascular injury may occasionally occur and specialised instrumentation should be available to manage such situations.

8. THE SURGEON

8.1 Knee Replacement surgery may only be performed by a qualified Medical Professional registered with the Health Professionals Council of SA (HPCSA) and should have had sufficient training to perform the procedure to an acceptable standard.

8.2 The theoretical and practical skills of the Surgeon performing primary arthroplasty operations must be maintained by continuous professional development.

8.3 Surgeons who perform few TKR’s per year should be aware than they have a statistically significantly higher risk of complications, re-admissions and revisions. They should consider having a higher volume or experienced Surgeon assist them in their TKR’s

8.4 The operation requires an anaesthetist with the appropriate skills and techniques for TKR.

9. THE ANAESTHETIST AND THE ANAESTHETIC TECHNIQUE

9.1 The surgeon and anaesthetic team should collaborate to define the most appropriate local hospital protocol for patients including prophylactic antibiotic policy and policies for venous thromboembolism prevention. [See Sections 12 and 13]

9.2 The SA Society of Anaesthesiology (SASA) will shortly be drawing up their guidelines for Knee Replacement Surgery which will then be incorporated into this document.

10. RECORD KEEPING AND THE OPERATION NOTES

10.1 Good clinical records are a basic tool of clinical practice, are absolutely essential and should be comprehensive and legible

10.2 Regardless of the medium in which clinical data is recorded or stored, good clinical practice necessitates communication of clinical information and immediate access for postoperative instructions. It is essential that clinical records be reproducible and transmittable without delay, information loss or inaccuracy.

10.3 Within the record the general medical condition of the patient as well as fitness for operation should be recorded. It should contain the clinical history, the full clinical examination findings, pre-existing medical history and all current disabilities and complaints. The diagnosis of the condition and the purpose of the operation should be stated and all medication should be listed

10.4 The process of fully-informed consent should be recorded correctly and the patient's signature witnessed as appropriate. The process should ensure that the patient is aware of the risks and benefits of the procedure being offered, as well as the option of not performing any procedure.

10.5 The operating surgeon should ideally complete his/her own consent form with the patient. In certain circumstances (for example Unicompartmental Replacement surgery) patients must be made aware of the fact that if intra-operative findings indicate that the procedure would be inappropriate then an alternative procedure (usually TKR) may be performed. This should be recorded.

10.6 A second consent is signed by the patient as part of the Hospital's pre-operative process and should be checked by the Surgeon before the procedure.

10.7 It is best practice that operative notes be made in writing, or dictated for typing and signed by the operating surgeon. If a pre-arranged pro forma is being used the operating surgeon should personally complete the pro forma.

10.8 A record of the operation should be made immediately following surgery and should include:

• The name of the operating surgeon, anaesthetist and assistant/s

• 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

• Post implantation stability.

• Details of method of closure and sutures used.

• An accurate description of any difficulties or complications encountered

and how these were overcome.

• Immediate post-operative instructions.

10.9 Progress after operations, including early complications, should be listed. The date of discharge and arrangements for continuity of care should be recorded.

10.10 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.

10.11 Follow-up notes should allow another doctor to assume the care of the patient at any time.

• 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.

10.12 All patients should have good quality antero-posterior and lateral (and if applicable a skyline Merchant view) radiographs of the operated knee before discharge from hospital, or at the first post-operative outpatient visit

10.13 Records and images should be retained to permit long-term follow-up and facilitate revision should it be required although this is not legally required according to HPCSA rules.

10.14 Patient, operative and prosthesis details should be entered into the South African Joint Registry

11. THE CHOICE OF IMPLANT

11.1 Orthopaedic Surgeons have large numbers of knee devices from which to choose. Many of these devices have not been subject to studies of outcome for as long as 10 years and should be used with caution and the patient must be made aware of this.

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.

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 arthroplasty implants may be unconstrained i.e., there is no direct mechanical linkage between the tibial and femoral components. Most 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 of the three compartments and in these circumstances implants are currently available which replace both sides of the single diseased compartment.

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. Both fixed and mobile bearing devices have good long term records but can be device dependant.

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 The choice of prosthesis should be governed by evidence of the effective performance of that implant

11.6 The choice of implant may be influenced by cost. Surgeons and their teams should ensure that the cost of the implant does not result in the use of an unproven or sub-standard implant

11.7 A Surgeon should not gain financially from the choice of a particular implant. The HPCSA Ethical rules state:

7. Fees and commission

(1) A practitioner shall not accept commission or any material consideration, (monetary or otherwise) from a person or from another practitioner or institution in return for the purchase,

sale or supply of any goods, substances or materials used by him or her in the conduct of his or her professional practice.

11.8. 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.

11.9 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.

11.10 The selection of knee prostheses for general use should normally be based on evidence published in peer reviewed journals. These include national arthroplasty registers such as the NJR in England and Wales, the Scandinavian, Australian and New Zealand registries. A clinical follow-up of 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. There should be at least a 90% ten year survival for knee prostheses.

11.11 In the absence of peer reviewed evidence of outcome at ten years, a device must be subject to ongoing surveillance and be part of a properly conducted controlled prospective trial. The use of such devices should have ethical approval.

12. PROPHYLAXIS AGAINST VENOUS THROMBOSIS AND PULMONARY EMBOLISM.

12.1. It is well recognised that venous 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 replacement, and much lower than quoted in historical papers.

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 TKR should be regarded as “moderate risk” for death from pulmonary embolism. Chemical prophylaxis may reduce the risk of non-fatal pulmonary embolism (PE), but rigorous scientific evidence is not available. There are usually no long term sequelae from a non-fatal PE.

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% but death from other causes may be

increased. There is also significant concern regarding possible bleeding complications which may put the knee replacement at considerable risk.

12.5 There should be a combination of mechanical and pharmacological prophylaxis. Mechanical prophylaxis encompasses either well-fitting stockings, foot or calf pumps and walking as soon as feasible. Pharmacological prophylaxis includes any of LMWH, Fondaparinux, Dabigatran, Rivaroxaban or aspirin started after 12 hours and continued for 4 to 6 weeks

12.6 Under normal circumstances, early mobilisation (6 to24 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.

12.7 In patients with proven thrombophilia, or a history of proximal DVT or PE full prolonged anticoagulation with oral agents is recommended. If the risk assessment indicates that the consequences of bleeding outweigh the benefits of pharmacological prophylaxis, surgeons may choose not to prescribe them but the reasons should be documented fully. Wound haematoma, significant haemarthrosis and failure of primary healing are strongly associated with an increased rate of deep infection

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 TKR, we believe that all patients should receive an intravenous broad spectrum antibiotic within an hour of induction of anaesthesia and with a further 24 hours of post-operative antibiotic administration.

13.3 The TKR should be performed in ultra clean air theatres with minimisation of personnel and foot traffic through theatre

13.4 A combination of systemic antibiotics active against coagulase negative staphylococci, ultraclean air theatres and either body exhaust suits or occlusive theatre clothing provides the most effective prophylaxis against infection.

13.5 Surgery should not be unduly prolonged and soft tissues should be handled gently. Haemostasis should be meticulously obtained pre closure, especially if no drain is to be used.

13.6 There does not appear to be an increased risk of urinary tract infection if an indwelling urinary catheter is used for only a short time in the immediate post-operative period.

13.7 There is strong evidence to support the use of Tranexamic Acid as it decreases postoperative blood loss, reduces haematomas and the necessity of postoperative transfusions and has no known contraindications.

14 SURGICAL TECHNIQUE

14.1 There is strong evidence that the use of a tourniquet in TKR increases short-term postoperative pain and, if used, should be for as short a period as possible and at the lowest effective pressure.

14.2 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.

14.3 The surgical approach selected should achieve these aims without the need to apply excessive forces to skin, soft tissue or bone.

14.4 The recognised complications of particular approaches should be explained to the patient.

14.5 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. Current evidence does not support the use of antibiotic loaded cement.

14.6 For cementless knee replacement, adequate preparation of the bone and stable fixation of the implants must be achieved at operation.

14.7 Where possible, tension in the medial and lateral soft tissue structures should be balanced in both flexion and extension whilst excessive tension or laxity on one side in either flexion or extension should be avoided.

14.8 Rotation of the femoral and tibial components must be thoroughly checked and internal rotation of either should be avoided unless in exceptional circumstances.

14.9 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.

14.10 Leg length equality cannot be achieved in every case and is dictated by ligament tension which is more important, except in fully constrained prostheses.

14.11 Pre-operative flexion deformity should always be corrected at the time of surgery to gain full extension, but may still be noted at follow-up despite appropriate post-operative rehabilitation. Patients with marked limitation of flexion pre-operatively should be informed that they may not achieve full range of movement post-operatively.

14.12 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, but there are some concerns about the morbidity of such major surgery. Patients undergoing bilateral surgery should ideally have no co-morbidities and be managed post-operatively in a high care unit.

14.13 Patient Specific Instrumentation, intra-operative navigation using imageless and CT guided techniques have been developed with the intention of improving the accuracy with which components are positioned. No differences in outcomes or complications have been shown compared with conventional instrumentation.

14.14 The use of minimally invasive (minimal incision) techniques have been described for TKA. The claimed benefits of minimally invasive TKR have not been reproduced in randomized clinical trials and concerns have been raised about increased complication rates using these techniques.

14.15 Surgeons should ensure that, when using new techniques or techniques new to them, they are capable and competent to perform these. Any specific risk associated with these new techniques, together with the surgeon's own experience in them, should be shared with the patient as part of the informed consent process.

14.16 There is variation in the use of wound drains and suture materials. Current evidence does not support the use of drains

15. EARLY POST-OPERATIVE CARE

15.1 It is important to confirm neurovascular integrity in the operated limb at an early stage.

15.2 Drains, catheters and other indwelling access should be removed as soon as clinically indicated.

15.3 Strong evidence supports that rehabilitation started on the day of TKR reduces the length of stay in the hospital.

15.4 Mobilisation, the achievement of full extension and an increasing flexion range should be supervised by a physiotherapist experienced in the management of patients following knee replacement. Patients undergoing knee replacement at the end of the working week should have access to physiotherapy at the weekend. Adequate provision for outpatient physiotherapy is also required.

15.5 There is no evidence to support the use of continuous passive motion (CPM) machines.

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

16.1 Patients should be followed up by the Surgeon or by an HCP experienced in TKR follow up at 10-14 days post –operatively in uncomplicated cases and as clinically indicated where there have been concerns. An assessment should be made at 6 weeks to ensure rehabilitation is progressing adequately

16.2 Primary TKR may fail between five and ten years but the 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.

16.3 Failure from aseptic loosening of a TKR 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.

16.4 Follow-up by using questionnaires with X-ray checks by non-medically qualified practitioners is used in some centres, but there is no audit evidence of the efficacy of such arrangements.

16.5. The establishment of a national knee arthroplasty register must be seen as a priority and must be adequately funded. Every Surgeon should make it his responsibility to ensure that his TKR's are captured on the South African Joint registry.

17. DOCUMENT REVIEW DATE

17.1 This document should be reviewed five years from the date of publication or more frequently should the situation arise.

STEERING COMMITTEE 20th August 2016

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