

Guidelines for Best Practice in Primary Hip Replacement Surgery in South Africa 2016

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1. INTRODUCTION

1.1 This document is a statement of best practice in primary Total Hip Replacement (THR) surgery 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 in all circumstances and is not a protocol but a guideline to assist the Surgeon, aiming to improve patient outcomes.

1.2 These guidelines are based on the British Orthopaedic Association Primary Hip Replacement Guidelines and the New Zealand adaptation thereof and adapted to suit South African circumstances

1.3 They have been compiled by the SA Arthroplasty Society (SAAS) and endorsed by the SA Orthopaedic Association (SAOA).

2. THE INDICATIONS FOR REFERRAL FOR THR

2.1 Pain and disability arising from predominantly degenerative (osteoarthritis) or inflammatory arthritis in the hip joint are the commonest indications for the operation. Pain may not necessarily be the most significant factor. In most cases other non-operative treatment will have failed or proved to be futile.

2.2. Increasingly, fracture of the proximal femur (particularly of the intra-capsular part of the neck) and osteonecrosis of the femoral head are indications for the operation. These standards apply equally to the care of such patients.

2.3. Where co-morbidities exist, risk benefit considerations may rule out the operation in an individual patient.

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 consultation with the orthopaedic surgeon should include history taking, examination, and provision of good quality X-rays films or images. As well as a routine anterior-posterior view of the hip and pelvis, the surgeon should also have a lateral view of the hip. In complex cases a 3-D reconstructed CT Scan is valuable for pre-operative planning.

The SAAS regards 15-20 minutes as the minimum time allowable for a first consultation. The patient must feel that adequate time has been allowed for this consultation.

3.3 A suitable environment for discussion with the patient and relatives should be provided, and all relevant notes and investigations, including imaging, should be available.

3.4 Patients should have the risks and benefits of the operation explained in understandable language. 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 Patients should be aware that they make the decision whether or not to undergo surgery. Failure of the hip joint as a result of arthritis is not a life or limb-threatening disease, but patients should appreciate that the operation generally carries a 30 day mortality rate of about 0.2% and a 90 day mortality of 0.5% and that these rates vary by age and gender. Furthermore, the observed medium and long-term mortality is significantly higher in patients who are older than 80 years at the time of surgery when compared to younger counterparts. It is however difficult to determine how much of this excess mortality in octogenarians is associated specifically with undergoing surgery since these patients generally have a higher risk of death nevertheless.

3.6 The patient should be made aware that there is the option of not having an operation, and some other procedures may be possible in appropriate circumstances.

3.7 A letter to the patient's General Practitioner and/or referral HCP (Health Care Professional) 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 best practice. This assessment should take place within six weeks of the operation.

4.2 Routine investigations of blood, urine, blood pressure and relevant microbiological assessment are best carried out at this assessment and there should be enough time to optimise the patient prior to surgery.

Routine screening for Methicillin Resistant Staphylococcus 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 Mupirocin ointment and chlorhexidine or betadine body wash.

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

4.4 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.

4.4 Provisional discharge planning should take place. This takes into consideration age, co-morbidities, home circumstances and availability of carers after discharge from hospital. To avoid last minute cancellations, patients should be telephoned shortly before admission to exclude factors that may prevent surgery such as change of mind, colds and inter-current infections.

4.5 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

4.6 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

4.7 A process should be in place to ensure that all patient-related information is available at the time of admission. This applies especially to any investigations that may have been deemed necessary at the pre-admission assessment.

5. HOSPITAL ADMISSION

5.1 Patients should be admitted to hospital with adequate time before operation to allow routine pre-operative and pre-anaesthetic procedures to be completed.

5.2 The limb on the operation side should be indelibly marked by the surgeon, or a member of the surgical team, in an area which should be visible during preparation in the operating theatre.

6. HOSPITAL STAFF AND IN-PATIENT FACILITIES

6.1 The operation is most safely carried out in hospitals where consultant support from other medical and surgical disciplines is readily available.

6.2 Access to a high care unit or intensive care unit (ICU) is desirable. Such units should have nursing staff trained in the management of arthroplasty patients.

6.3 Adequate numbers of trained orthopaedic nurses and members of Allied Health Professional's, especially physiotherapists, must be available.

6.4 Patients should be nursed in dedicated orthopaedic wards away from potential sources of cross-contamination from patients with infections and staffed by a team experienced in the management of patients with musculoskeletal disease.

6.5 The risk of cross-infection in hospital should be reduced to a minimum. Facilities must be available for isolating patients known to be infected with, or carrying, pathogenic organisms.

7. 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 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

7.3 THR should be performed in ultra-clean air theatres. The quality of ultra-clean air should be checked regularly.

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

7.7 A full range of implants and instruments 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.

7.8 Impenetrable sheets/drapes are essential.

7.9 A full range of implants and instruments 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 THR 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 THR's per year should be aware that 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 THR's

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

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 14 and 15]

9.2 The SA Society of Anaesthetists (SASA) will shortly be issuing their guidelines for Hip and Knee Replacements and these will then be incorporated into this document.

10. RECORD KEEPING

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 Hip Resurfacing 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 THR) 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 and leg length.
- 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 (if practical) radiographs of the operated hip 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 many devices from which to choose.

11.2 Many factors determine the surgeon's preference for an individual implant. These include their training, consultant colleagues' preference, and a desire to improve their own results. The manufacturers of such devices can have a significant effect on choice through the service they provide

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

11.4 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

11.5 A Surgeon should not gain financially from the choice of a particular implant. The SA Medical Association (SAMA) 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.

11.6 Surgeons should be aware of information published by manufacturers in relation to each implant.

11.7 Surgeons should ensure that the implants being inserted are compatible. This applies particularly to bearing surface dimensions, but also to Morse tapers and the variety of femoral head components available. It is generally safer to use components from the same manufacturer.

11.8 The selection of a prosthesis for general use should normally be based on evidence published in peer-review journals or other acceptable resources. These include national arthroplasty registers such as the NJR in England and Wales, the Scandinavian, Australian and New Zealand registries. Published evidence of satisfactory clinical follow-up of more than ten years with published life-table and survivorship curve is considered to be good supporting evidence for selection of an implant.

11.9 A confounding factor for the surgeon is that implants with apparently good published results have been modified subsequently by the manufacturers and the clinically tested design is no longer available. Company mergers may provoke such changes. There has been a failure to realise that even minor modifications to design, material, surface finish or fixation technique can dramatically alter the performance of the implant.

11.10 In the absence of peer-reviewed evidence of outcome to ten years, a device must be subject to on-going surveillance and preferably part of a properly conducted, prospective trial. The use of such devices should have ethical approval.

11.11 Indications for the use of metal-on-metal implants have changed over the past six years. While such implants are generally used for fewer patients, certain metal-on-metal resurfacing implants remain an acceptable option for younger males, with appropriate bone geometry, who are determined to undertake vigorous sporting activity. Patients should be fully informed about the risks of metallosis and adverse reaction to metal debris (ARMD) where metal on metal devices are used.

12. PROPHYLAXIS AGAINST VENOUS THROMBOEMBOLISM (VTE)

12.1 Although deep vein thrombosis (DVT) can be demonstrated by venography in 50-60% of patients after THR, it is symptomatic in approximately 2%. The most severe consequence of DVT is fatal pulmonary embolism (PE). In the 21st century, with anti-coagulants, early mobilisation and mechanical compression devices, the incidence is 0.1% or less.

Thromboprophylaxis reduces fatal PE by 70% and DVT by 50%. Accordingly, the National Institute for Health and Clinical Excellence (NICE) recommends that all patients undergoing THR be risk assessed for DVT and PE and unless contraindicated, thromboprophylaxis be prescribed.

12.2 The risks of developing DVT or PE are increased in patients with a previous history of DVT or PE, varicose veins with phlebitis, active malignancy, chemotherapy and radiotherapy, a first degree relative with a history of DVT or PE, inherited thrombophilia, previous pelvic or acetabular surgery, age > 50 years, obesity, hip surgery lasting longer than 1 hour and oestrogen containing oral contraceptive pills, hormone replacement therapy and Tamoxifen. The most important risk factors are proven thrombophilia and a personal history of proximal DVT or PE. The duration of risk of PE is 4 weeks and proximal DVT 6 weeks.

12.3 Prophylactic measures are pharmacological and mechanical. Pharmacological agents comprise anticoagulant or antiplatelet drugs. Mechanical measures include foot pumps and graduated compression stockings. Both strategies reduce death from PE but not overall mortality after THR because anticoagulants may cause death from bleeding.

12.4 Foot and calf pumps are as effective as low molecular weight heparin (LMWH), do not cause bleeding, are tolerated by over 95% of patients. Below knee stockings are better than above knee and are effective if the pressure gradient from distal to proximal is maintained. As legs swell after

THR, stockings need to be checked regularly to ensure the garter that suspends them does not indent the calf proximally reversing the pressure gradient.

12.5 After risk assessment, patients without an increased risk of bleeding should undergo THR under spinal anaesthesia if feasible. This should be combined with 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. In patients with proven thrombophilia, or a history of proximal DVT or PE full 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 and failure of primary healing are strongly associated with an increased rate of deep infection

13. PROPHYLAXIS AGAINST INFECTION

13.1 Patients should be clinically screened for infection prior to the operation.

13.2 All patients should receive, intravenously, an antibiotic at induction of anaesthesia or preferably within an hour of induction and should be continued for a 24 hour period post-operatively. Each unit performing the operation should have a locally-agreed policy which should include advice from microbiologists.

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

13.4 When bone cement is used, antibiotic-impregnated cement further reduces the risk of infection.

13.5 Surgery should not be unduly prolonged, soft tissues should be handled gently and excessive traction avoided.

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

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

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

14. SURGICAL TECHNIQUE

14.1 The benefits and risks of the operation must be discussed with the patient prior to the operation and written consent from the patients should be sought.

14.2 Preoperative templating, using templates provided by the implant manufacturer, is advised to predict the likely implants to be used and to plan for the restoration of offset and leg length. The use of digital templating software allows accurate planning to be carried out using digital X-rays.

- 14.3 Prior to starting the operation, the surgeon should ensure that the required surgical instruments and selected prostheses are available and sterile.
- 14.4 The surgical approach selected for a THR should provide a clear 360° view of the rim and face of the acetabulum. The approach should facilitate delivery of the femur into the wound to allow unimpeded instrumentation of the femoral canal.
- 14.5 The surgical approach selected should achieve these aims without the need to apply excessive forces to skin, soft tissue or bone.
- 14.6 For cemented components, the bone surface should be prepared for optimum cement penetration. Articular cartilage should be removed where present and strong cancellous bone should be exposed and preserved. The bone surfaces should be irrigated and dried before the introduction of bone cement.
- 14.7 Multiple drilled fixation pits in the acetabulum may improve fixation. Acetabular cement should be pressurised into the clean dry bone surface before introduction of the cup.
- 14.8 The distal femoral canal should be occluded with a plug and retrograde injection of cement carried out, followed by pressurisation with a proximal seal.
- 14.9 For cementless implants, the bone surfaces should be prepared with dedicated instruments for the prostheses to be inserted. The surgeon should ensure optimum fit and stability of the component in the recipient bone bed. Careful inspection should be done to ensure no intra-operative fractures have occurred, especially of the calcar.
- 14.10 Efforts should be made to restore the correct leg length and offset, to optimise the biomechanics of the hip replacement. To assist with this process, intra-operative trial reduction prior to the insertion of definitive prostheses is recommended.
- 14.11 Every effort should be made to ensure stability of the hip joint by correct implant selection, appropriate bone resection, accurate placement of the implants and assessment and correction of soft tissue tension. Repair of soft tissues at the conclusion of the operation reduces the risk of post-operative dislocation.
- 14.12 Intra-operative navigation using imageless and CT guided techniques have been developed with the intention of improving the accuracy with which components are positioned. There is little evidence that patient outcomes are improved through the use of navigation techniques.
- 14.13 Minimally invasive techniques have been applied to the posterolateral, anterolateral and anterior surgical approaches. The use of multiple incision minimally invasive technique has also been described for hip replacement. The claimed benefits of minimally invasive hip replacement have not been reproduced in randomized clinical trials and concerns have been raised about increased complication rates using these techniques.
- 14.14 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.
- 14.15 There is variation in the use of wound drains and suture materials. Current evidence does not support the use of drains.

15. POST-OPERATIVE MANAGEMENT AND DISCHARGE FROM HOSPITAL

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 Mobilisation following the operation should include significant input from the physiotherapy team, and patients should only be discharged from hospital when considered capable of coping in the environment at their destination.

15.4 Discharge planning should start before the patient's admission and is one of the important functions of a pre-admission assessment.

15.5 Patients should be given information about telephone numbers or other methods of contacting the hospital or the orthopaedic service, should problems occur.

15.6 Patients should be followed up by the Surgeon or a trained wound care professional at 10-14 days post-operatively in uncomplicated cases and as clinically indicated where there have been concerns.

16. THE FOLLOW UP OF PATIENTS AFTER THR

16.1 THR's require revision for aseptic loosening most frequently in patients who were under 60 years of age at the time of their primary THR, in males and when uncemented polyethylene lined sockets have been implanted. Patients in their mid-seventies at primary hip replacement have a 90% chance of dying before revision is required whereas the converse applies in those under fifty. Most revisions occur in patients under 65 years at the time of primary THR. Follow up should be targeted at this population who should be seen periodically as aseptic loosening is often silent and exchange or revision surgery should be performed before massive bone loss occurs. A delay may result in the need for much more extensive surgery which is expensive and has a greater risk of failure.

16.2 Most of the revision burden occurs seven years after primary hip replacement. Silent lysis is responsible for 30%. Progressive silent lysis may result in peri-prosthetic fracture which carries increased mortality and cost compared with revision for aseptic loosening.

16.3 Implants that have a good clinical track record of at least 10 years should be followed up in the first year, once at seven years and three yearly thereafter if patients are asymptomatic and have no adverse radiographic signs. All other, novel or modified implants should be followed annually for the first five years, two yearly to ten and three yearly thereafter.

16.4 Symptoms predict revision less accurately than radiographs and radiographic assessment is essential with AP and lateral views.

16.5 Routine follow up by the GP or other non orthopaedic surgeon HCP's is not advised as they frequently rely on reports which may be produced by radiologists who lack expertise in the failing hip arthroplasty.

16.6 The establishment of a national joint arthroplasty register must be seen as a priority and be adequately funded. Every Surgeon should make it his responsibility to ensure that his arthroplasties are captured on the South African Joint Registry.

17. DOCUMENT REVIEW DATE

17.1 This document should be reviewed every five years from the date of publication and amended at any stage by the SAAS Committee should circumstances require it.

18. STEERING COMMITTEE 20rd August 2016

SA Arthroplasty Society

Dr Rob McLennan-Smith (President)

Dr Jan de Vos (Incoming President 2017)

Dr Lipalo Mokete (Secretary)

Dr Allan van Zyl (Past President)

SA Orthopaedic Association

Dr Robert Fraser (President 2015/16)