**A Comparison of Different Patellar Implant Designs in Total Knee Replacement.: A Prospective Randomized Comparative Trial. (Study Protocol)**

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Aim

To compare the intra-operative and post-operative outcome measures between three different patellar implant designs in patients undergoing total knee arthroplasty (TKA) surgery with regards to patellar bone coverage and tracking, patient-reported outcomes and post-operative radiological and scintigraphic analysis.

Background

Controversy remains regarding whether the patella should be resurfaced in total knee arthroplasty. However, at present the scientific literature supports patellar resurfacing with regards to reduced re-operation risk and improved long term patient satisfaction.[[1](#_ENREF_1)]

Two basic techniques present for resurfacing the patella[[2](#_ENREF_2)]; either onlay or inset. In the inset design, a round domed implant is reamed in the patella and fixed with a single central pig. On the other hand, the onlay design has either round (symmetrical) or oval (asymmetrical) shaped patellae with three small peripheral pegs fixed on the cut surface of the patella. When using a round patellar implant, either onlay or inset, some surgeons perform a lateral facetectomy to avoid lateral compression syndrome and enhance patellar tracking[[3](#_ENREF_3)]. However, neither method has proved to be superior.

A wide range of complications are associated with patellar resurfacing[[4](#_ENREF_4)]. These patellar fracture, osteonecrosis related to devascularisation, patellar polyethylene (PE) wear, aseptic loosening, instability, dislocation, overstuffing and rupture of the extensor mechanism. Many of these can be catastrophic. One should always consider the peculiar blood supply to the patella during TKA and patellar resurfacing as iatrogenic disruption of supplying vessels has been identified as a major contributing factor in post-operative patellofemoral complications[[5](#_ENREF_5)].

This study will compare three different types of patellar implant designs commonly used for resurfacing in TKA. The trial will be conducted in compliance with the protocol laid out, GCP and the ethics regulations. The study will look at patients who are undergoing elective TKA for osteoarthritis.

Trial Objectives:

To prospectively compare intra-operative observed measures, patient-reported outcome measures and radiological results between inset, onlay round and onlay oval designs of patellar implants in patients undergoing total knee arthroplasty surgery. Specifically, we will compare patellar surface bone coverage, pain and functional scores together with patellar tracking and vascular status of the patella postoperatively.

Trial Design

This trial will be a prospective, patient-blinded, randomized comparative study with the end-points being directly observed patellar bone coverage, patient-reported outcome measures and radiological results. Patient consent and ethical approval will be obtained prior to trial commencement.

Intra-operative Outcome Measures

Intraoperative photograph will be taken after setting of the patellar implant to determine percentage of bone coverage for the three groups. In addition, the requirement for facetectomy (removal of the lateral bone not covered by the implant) will be recorded.

Patient-Reported Outcome Measures

Clinical outcome measures would be assessed via the Knee Society Score (KSS), the Knee Injury and Osteoarthritis Outcome score (KOOS) and Kujala score (validated questionnaire for patellofemoral symptoms) which are all validated patient reported outcome measures following knee arthroplasty. These questionnaires will be taken at the time of standard appointments (pre-surgery, 6 months and 12 months).

Radiographic Measures

Radiological outcomes will be assessed via weight bearing patellar (merchant) view x-ray validated by Baldini A et al[[6](#_ENREF_6)]. The other standard views (AP erect, lateral, and routine non-weight bearing merchant) will also be performed. Patellar tilt, subluxation and height will be recorded. Radiographic signs of implant fixation will be recorded. Bone scan with SPECT/CT will be taken at 6 months postoperatively to assess patellar vascularity.

Study Group

Patients will be recruited at the time when a decision to proceed with a knee arthroplasty is made during consultation. Based on power analysis, a sample size of 20 patients in each cohort would provide appropriate power (beta level = 0.80, alpha level = 0.05) to detect an 80% improvement in percentage of patellar surface coverage (as oval onlay design proposed to provide nearly full coverage) and in risk of osteonecrosis by preserving the lateral facet with the oval onlay design. There will be a midterm analysis when 30 patients are recruited to assess whether significance has been reached and whether or not, further patient enrolment is necessary. Means, ranges, and standard deviations will be recorded for percentage of patellar surface coverage, pre-operative and postoperative scores in all groups. ANOVA will be used to compare differences in means between continuous variables. ANOVA will be used to statistically assess pre-operative demographic factors. Fisher's exact test will be used to test for significance in osteonecrosis difference (proportions) between the groups. Statistical significance set at p = 0.05.

Inclusion criteria will be patients between the ages of 50-85 years undergoing unilateral total knee arthroplasty for degenerative osteoarthritis. Exclusion criteria includes revision TKA surgery, bilateral simultaneous TKA, prior osteotomies around the knee or extra-articular deformities, systemic inflammatory disease (e.g. rheumatoid arthritis, Systemic lupus erythematosus, etc), medial and lateral knee ligamentous instability, prior surgery specific to this, TKA for acute trauma and need for allograft, prior patellar fracture, ruptured extensor mechanism, constrained implants, stemmed components or metal augmentation during surgery.

Patients will be routinely followed-up at 2 weeks, 8 weeks, 6 months and 12 months. Any complications that develop will be documented and addressed as appropriate. All patient data will be recorded and documented as per protocols set via the institution of practice and only the researchers will have access to the data specific to the trial.

Methodology

1. **Population to be studied:** 
   * Patients undergoing routine total knee arthroplasty (TKA) surgery at St. George Private Hospital (Kogarah) performed by fellowship trained arthroplasty surgeons (Dr Samuel MacDessi and Dr Darren Chen)
2. **Type of study:**
   * Prospective, patient-blinded, randomised comparative study
   * Intraoperative digital photographs, patient-reported outcome measures and radiological results.
   * Patient consent required
   * Ethical approval required
3. **Eligibility criteria:**
   * Age 50 - 85
   * No racial nor gender bias
   * Undergoing unilateral TKA for degenerative osteoarthritis
4. **Elimination criteria**
   * Revision TKA surgery
   * Bilateral simultaneous TKA
   * Prior osteotomies around the knee or extra-articular deformities
   * Systemic inflammatory disease (e.g. Rheumatoid arthritis, Systemic lupus erythematosus, etc)
   * Medial and lateral knee ligamental instability & prior surgery specific to this
   * Knee replacement for acute trauma
   * Prior patellar fracture
   * Previous extensor mechanism rupture
   * Need for allograft, , constrained implants, stemmed components or metal augmentation during surgery
   * Patients unable to provide consent by themselves
5. **Surgical Protocol**
   * Pre-operative randomisation to have TKA with patellar resurfacing by either inset, round onlay or oval onlay design.
   * Standard anaesthetic protocol (spinal anaesthesia)
   * Administration of tourniquet, tranexamic acid (to minimise blood loss), peri-articular injection (local anaesthetic and steroid), post-operative intra-articular bolus dose (local anaesthetic), post-operative analgesia and thromboprophylaxis administration according to standard institution protocol
6. **Ascertaining data:**
   * Data to be collected pre-operatively and post-operatively with times shown below:
     1. Primary outcome measure
        + Intraoperative photograph to assess the percentage of bone coverage using the patellar implant.
        + 6 months postoperative weight bearing patellar view based on Baldini protocol to assess implant position and patellar tracking.
        + 6 months postoperative SPECT scan to assess vascularity of the patella and presence or absence of osteonecrosis.
     2. Secondary outcome measures
        + Patient-reported outcome measure reported pre-operatively, 6 weeks post-operatively, 6 months and 12 months post-operatively namely:
          1. Knee Society Score (KSS)
          2. Knee Injury and Osteoarthritis Outcome Score (KOOS)
          3. Kujala Patellofemoral score
7. **Safety factor**
   * All adverse effects that may occur (e.g. protracted pain, infection, stiffness, immobility, neuropraxia etc.) will be recorded. These effects will be classified based on their duration and severity at the 6 week and 6 month follow-up.
8. **End-point**
   * To assess whether different patellar implants have different bone coverage that reflects on postoperative outcomes based on patients feedback.
   * To determine whether there is a difference in postoperative complications, specifically patellar maltracking and osteonecrosis with different designs and techniques.
9. **Study design**
   * After fulfilling inclusion/exclusion criteria, patients will be randomised prior into 3 groups (Inset, round onlay or oval onlay patellar implant)
   * Outcomes measures to be documented and data kept securely using password protected programmes (only the investigators to have access to the study data)
   * The patient will be completely blinded until 12 months after surgery (end of study duration)

References:

1. Schindler, O.S., *The controversy of patellar resurfacing in total knee arthroplasty: Ibisne in medio tutissimus?* Knee Surgery, Sports Traumatology, Arthroscopy, 2012. **20**(7): p. 1227-1244.

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4. Panni, A.S., et al., *Patellar resurfacing complications in total knee arthroplasty.* International orthopaedics, 2014. **38**(2): p. 313-317.

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6. Baldini, A., et al., *PATELLO-FEMORAL EVALUATION AFTER TOTAL KNEE ARTHROPLASTY: VALIDATION OF A NEW WEIGHT-BEARING AXIAL VIEW AND SCORING SYSTEM.* Journal of Bone & Joint Surgery, British Volume, 2006. **88**(SUPP I): p. 111-111.