COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENT

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Dissertation submitted to the Tamil Nadu Dr. M.G.R Medical
University in partial
fulfillment of the requirement for the M.S Degree Examination
Branch II (Orthopaedic Surgery)
May 2019

CERTIFICATE

This is to certify that the dissertation titled "**COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENT**" is a bonafide work of **Dr. REUBEN CEDRIC NAPPOLY**, in the Department of Orthopedic Surgery, Christian Medical College and Hospital, Vellore in partial fulfillment of the rules and regulations Of the Tamil Nadu Dr. M.G.R Medical University for the award of M.S Degree Branch II (Orthopaedic Surgery), under the supervision and guidance of **Prof. Dr. ALFRED JOB DANIEL** during the period of his post-graduate study from April 2016 to May 2019. This consolidated report presented herein is based on bonafide cases, studied by the candidate himself.

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DECLARATION

I hereby declare that this dissertation titled "**COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENT**" was prepared by me in partial fulfillment of the regulations for the award of the M.S Degree (Final) Branch II (Orthopaedic Surgery) of the Tamil Nadu Dr. M.G.R Medical University, Chennai towards examination to be held in May 2019. This has not formed the basis for the reward of any degree to me before and I have not submitted this to any other university previously.

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TABLE OF CONTENTS

AIMS AND OBJECTIVES

AIM:

Study to compare the short-term functional outcomes of patients undergoing single radius and multi radius total knee replacements.

OBJECTIVES:

- To assess the functional outcomes of patients undergoing total knee replacement at 10 and 90 days.
- To compare functional outcomes of patients in single radius and multi radius at 10 and 90 days

HYPOTHESIS

The purported advantages of the SR design include a decrease in the patellar load due to an increased extensor moment arm; a decrease in the required muscular strength for knee extension, and a better ligament stability based on a maintained isometry during the whole ROM.

We assume these design features should improve extensor strength, and knee stability should accelerate and enhance the rehabilitation after TKA.

INTRODUCTION

Knee joint is the largest joint in the body. It has two articulations, i.e., one in between the femur and the tibia and the other in between the femur and the patella. The majority of the body-weight is borne by the knee joint and hence there are repeated micro traumas, which can lead on to cause osteoarthritis later in older age. The knee joint is divided into three compartments, which includes the medial femorotibial compartment, lateral femorotibial compartment and the patellofemoral compartment. Damage, usually due to osteoarthritis, can occur to one, two or all three of the compartments of the knee joint (1).

Osteoarthritis is a chronic degenerative disorder that has a multifactorial etiology and is characterized by loss of articular cartilage; hypertrophy of bone at the margins, subchondral sclerosis and morphological changes at the synovial membrane and knee capsule (2). The various pathological changes in the late stages of osteoarthritis include softening, ulceration and disintegration of the articular cartilage. There may also be synovial inflammation (3).

Clinical symptoms include pain that can occur after prolonged activity, however stiffness is expected after inactivity. It is a degenerative arthritis that can also involve the small joints of the hand, spine and also weight-bearing joint as the hip joint (2).

Most cases of Osteoarthritis have no known cause and is referred to as primary OA knee joint(4).

Osteoarthritis is a process largely associated with aging and as the mean age of the population of the older age group is increasing, the prevalence of obesity amongst the older population has also increased. Some authors have predicted an increase in the number of patients with knee arthritis to increase by 673% by 2030 (5).

Chronic knee pain is the most commonly associated complaint amongst the older population and the incidence of the symptom affecting the general population in the UK is between 7 to 30%.

There are many non-surgical modes of intervention, which exist for example, physiotherapy and also pain relief medications. With the failure of these interventions patients are offered surgical procedures for pain relief that include osteotomy and also arthroplasty (6).

The main reason for doing a total knee replacement has been to relieve pain when all other non-surgical methods of intervention have failed. The aim of surgery is to reconstruct a joint that is pain free and also helps to maintain good proprioception and better performance. (1) Total knee replacement has been widely considered as an effective end stage surgical procedure to relieve chronic knee pain and knee deformity.

APPLIED ANATOMY

The embryological development of knee joint originates from the leg bud at 28 days with the formation of femur, tibia and fibula by 37 days. The knee joint arises from blastemal cells with the formation of patella, cruciate ligaments and menisci by 45 days. The knee joint has two components

- Condylar joints: where the medial and lateral condyles of the femur articulate with the corresponding tibial condyles
- Gliding joint between the patella and the patellar surface of the femur.

Hyaline cartilage covers all the articulating surfaces.

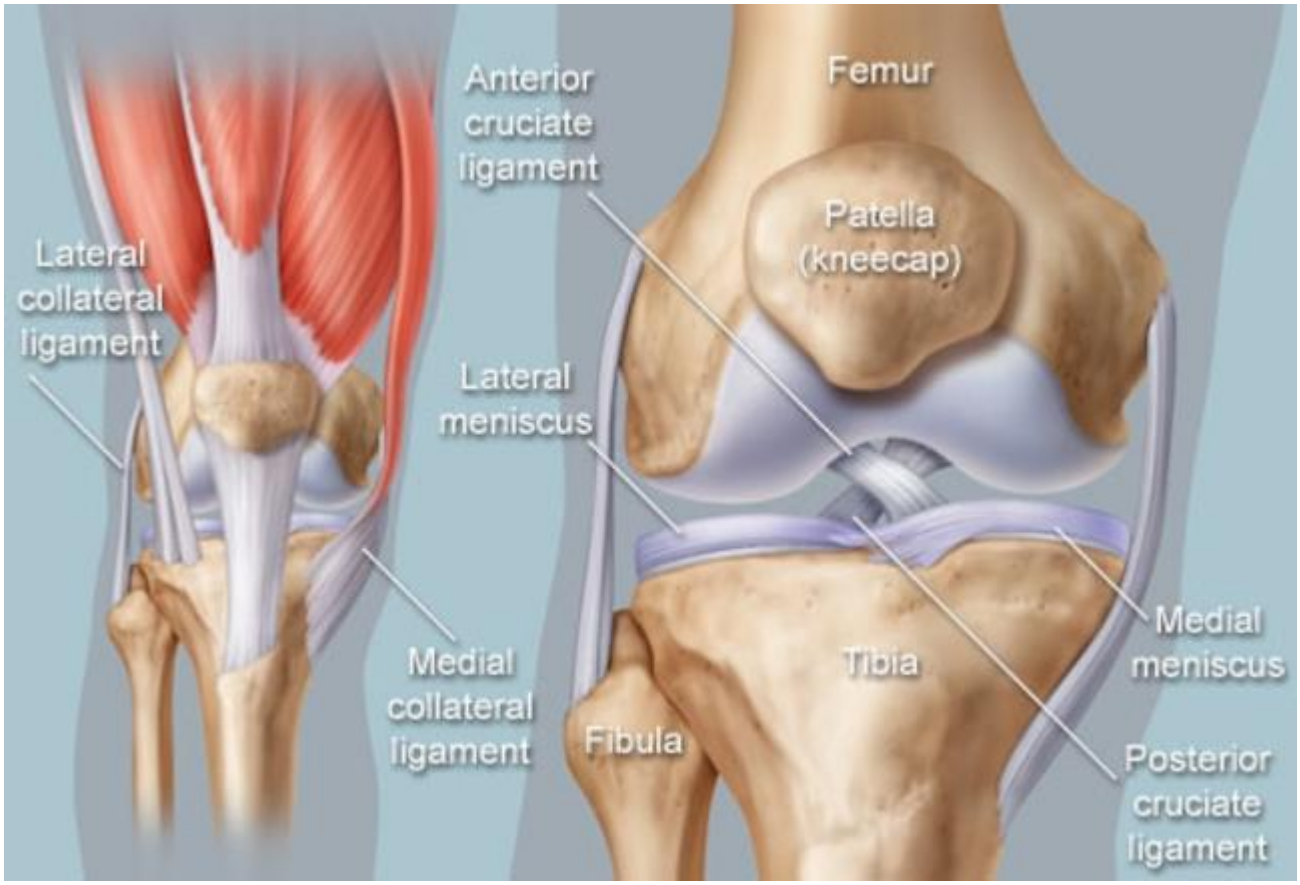


Figure 1: Anatomy of the knee joint (Source: WEB MD)

FEMUR

The femoral condyles are asymmetric in size and shape. The medial femoral condyle is relatively 1.7cm longer than the lateral condyle in its outer circumference. This asymmetry in length produces axial rotation of the tibia on the femur during flexion and extension. The width of each individual condyle is similar, with the lateral dimension being slightly wider than the medial when measured at the center of the intercondylar notch. In the sagittal axis the lateral femoral condyle extends more anteriorly than the medial femoral condyle. In the coronal plane, the medial condyle extends distally than the lateral condyle. Viewing the femur along the anatomic axis makes the valgus alignment more obvious. However, in normal weight bearing alignment, condyles appear to be equal in length. The parallel femoral condylar surfaces are created by the mechanical axis configuration of the lower extremity. The mechanical axis configuration is a straight line from the center of the femoral head that intersects the center of the knee and ankle joints. The distal femoral joint line forms a 6 degrees angle to the long axis of the femoral shaft, creating a physiological valgus of the distal femoral joint line. The sagittal curvature of the condyles has a radius that decreases posteriorly. The highest bone strength is found at the posterior aspects of the condyles, with the central area being relatively weak.

TIBIA

The medial tibial plateau is slightly concave and the lateral tibial plateau is slightly convex. In the sagittal plane the tibial condyles slope posteriorly approximately 10 degrees. In the frontal plane the condyles are essentially perpendicular to the long axis of tibia. The highest-pressure concentrations are located on the uncovered cartilage of the medial compartment and on the menisci as well as on the uncovered cartilage of the lateral compartment. Trabecular bone of the tibial epiphysis is responsible for the load transmission. The medial tibial plateau is high strength area especially centrally and anteriorly. Preservation of bone stock of the tibial plateau should be considered in total knee arthroplasty, because optimum support is achieved by resecting 10mm or less of tibial plateau. Excessive resection results in prosthetic loosening and alteration of desired component position.

PATELLA

The articular surface of the patella is divided into medial and lateral facets. Trabecular structure of the patella and the femoral trochlea is aligned normally to the joint surfaces.

EXTRACAPSULAR LIGAMENTS

The superior attachment of the ligamentum patellae is to the lower border of the patella and to the upper border of the tibial tuberosity, inferiorly. It is a continuation of the quadriceps femoris muscle tendon in the central part. The

superior attachment of the cord like lateral collateral ligament is to the lateral condyle of the femur and to the medial surface of the shaft of the tibia inferiorly. It is attached to the edge of the medial meniscus. The oblique popliteal ligament is a tendinuous expansion derived from the semimembaranous muscle, which serves to strengthen the posterior aspect of the capsule.

INTRACPASULAR LIGAMENTS

1. ANTERIOR CRUCIATE LIGAMENT (ACL)

The main function of the anterior cruciate ligament is to prevent anterior displacement of the tibia on the femur. Anteriorly, it is attached to the anterior intercondylar area of the tibia, from where it passes upward, backward and laterally, to be attached to the medial surface of the lateral femoral condyle in the posterior aspect.

2. POSTERIOR CRUCIATE LIGAMENT (PCL)

The main function of the posterior cruciate ligament is to prevent posterior displacement of the tibia on the femur. Posteriorly, it is attached to the posterior intercondylar area of the tibia and passes upward, forward abd medially to be attached to the lateral surface of the medial femoral condyle in the anterior aspect.

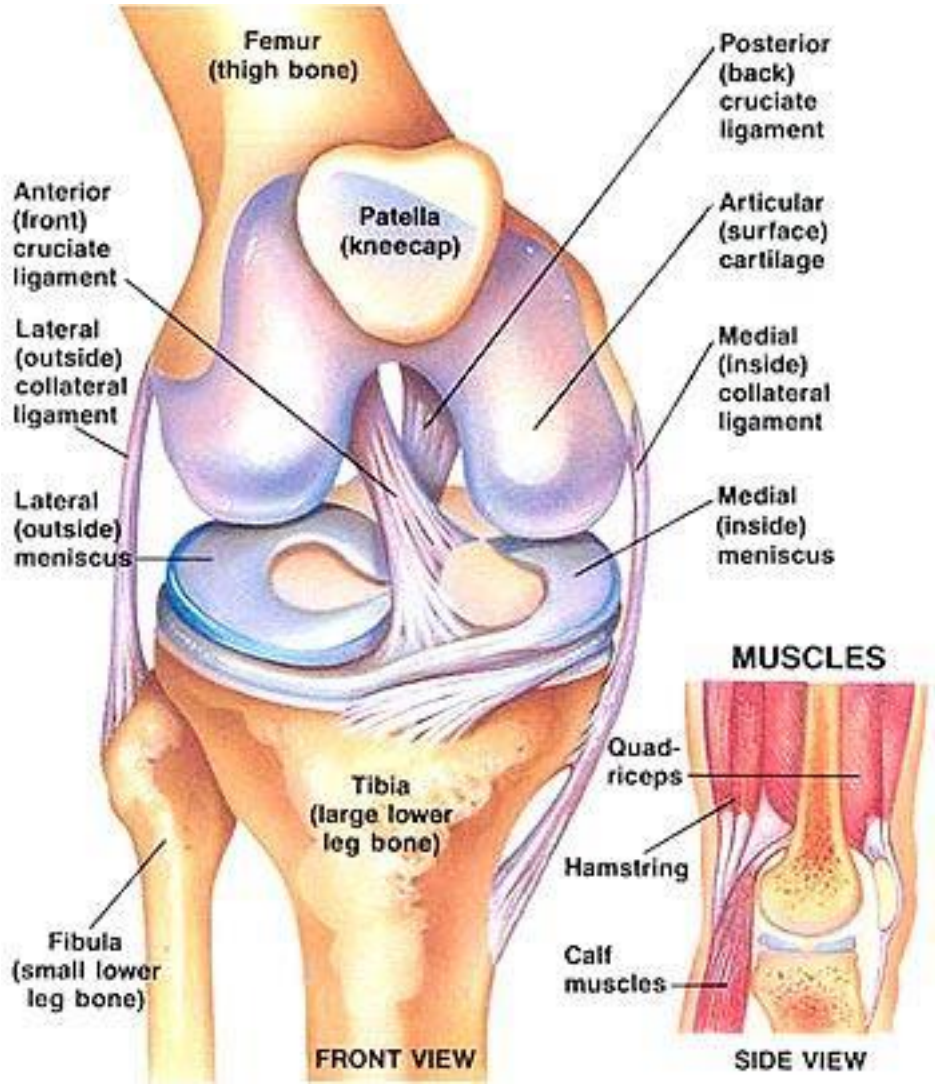


Figure 2: Anatomy of the knee with the ligaments of the knee

3. MENISCI

The menisci are made of cartilage and they are C shaped. The thick peripheral border is attached to the capsule and the thin inner border is concave and forms a free edge. The femoral condyles are in contact with the upper surface of the menisci and the tibial condyles are in contact with the lower surface of the menisci, leading to a cushioning effect between the long bones. Their function is to deepen the articular surfaces of the tibial condyles to make it more concave in order to receive the convex femoral condyles.

SYNOVIAL STRUCTURES

- **PLICA**

A remnant of embryologic development, the synovial plica is variably developed in different individuals. Its form can range from a complete septation of the suprapatellar pouch from the more inferior joint, to a band extending from the medial fat pad through the medial gutter and across the suprapatellar pouch flaring out in the lateral gutter, to a remnant or to no structure at all. In its normal state, it is tissue-paper thin but can become thickened, scarred, and contracted as a consequence of injury and causes ankylosis and painful tethering of the quadriceps tendon.(7)

EPIDEMIOLOGY

Worldwide estimates have shown that 9.6% of men and 18% of women above the age of 60 years have symptomatic arthritis(4). The incidence of Total Knee replacement has increased since its introduction in the 1960's. In the United States the prevalence of primary total knee replacement has tripled between 1990 and 2002 (8).

Total knee replacements have a survivorship of up to 10 years in situ (9). With the improved survivorship of total knee replacement designs the focus has shifted to assessing the impact of the prosthesis on the patient and also the functional ability of the patient (6).

The primary aim of total knee replacements include improved range of motion, stability, pain relief and also function. Appropriate implant selection and also implant alignment with soft tissue balancing are important in achieving this goal (10). Measured resection and gap balancing are two different techniques that are used to achieve implant alignment and soft tissue balancing (11).

PATHOGENESIS

Osteoarthritis of the knee joint is a progressive and disabling disease that results from a combination of risk factors which includes age, trauma, genetics, trauma, knee malalignment, increased biomechanical loading of joints, augmented bone density and an imbalance in physiological processes (12). The link between obesity and OA knee has been shown to be due to the presence of activated white adipose tissue that increases the synthesis of pro inflammatory cytokines, such as IL-6, IL-1, IL-8, TNF alpha, IL-18, but decreases the regulatory cytokines, such as IL-10 (13). There were increased levels of leptin, which is a product of the obesity gene, seen in the cartilage and osteophytes of people with osteoarthritis of the knee joint (14). Leptin was also found in the synovial fluid of patients that was correlated with an increased body mass index (12,15).

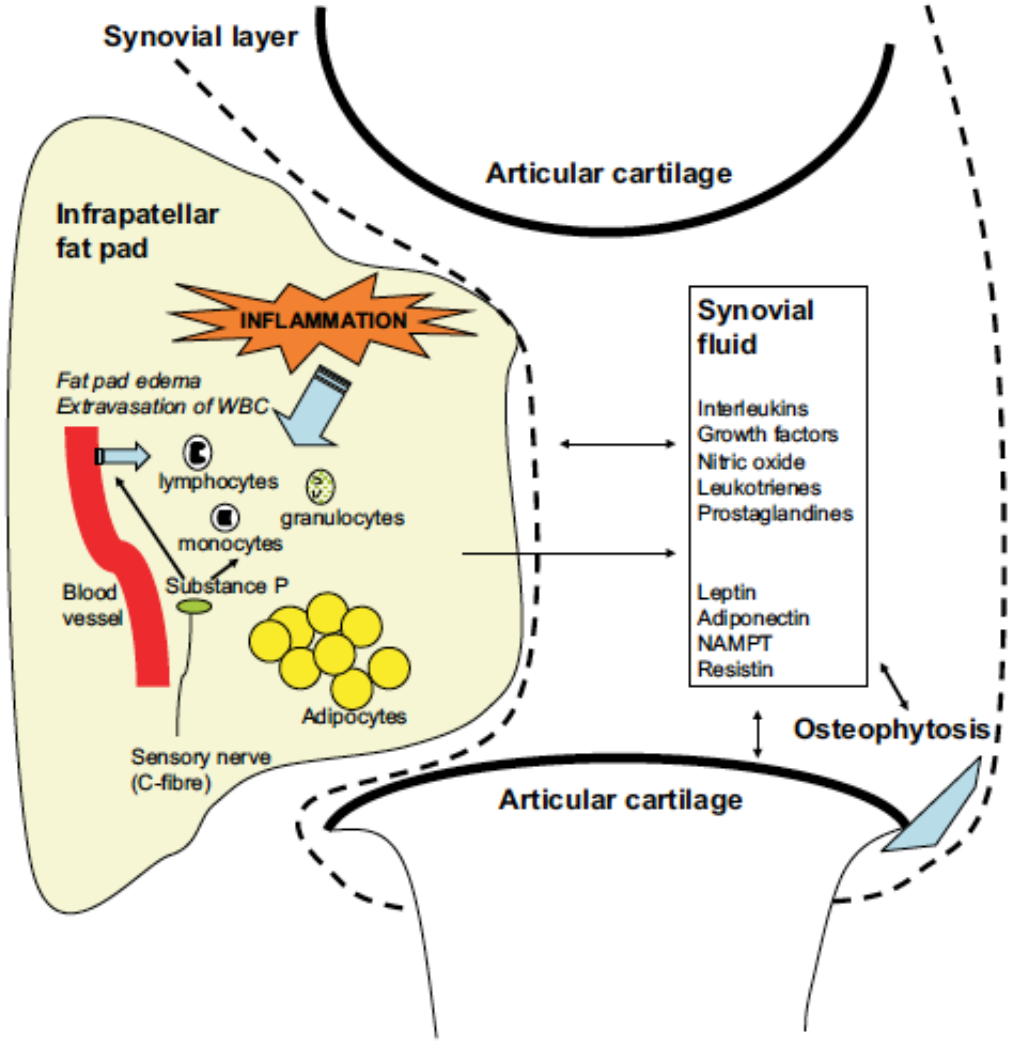


Figure 3: Pathogenesis of Osteoarthritis of the knee joint

There's a cascade of changes that can occur in the joint structure start from subchondral bone expansion, bone marrow lesions, meniscal tears and extrusion, to cartilage defects that can ultimately lead to cartilage loss and radiographic osteoarthritis at late stage. The anterior knee pain in patients with osteoarthritis of the knee joint is due to the presence of inflammatory cells in the infrapatellar fat pad (16).

CLINICAL FEATURES

The natural history of knee osteoarthritis seems to have been poorly understood (17). The symptoms of osteoarthritis knee can vary greatly amongst patients (18). The various symptoms include joint pain and stiffness, swelling of the knee joint with decreased function and there can also be cracking or grinding noise with joint movements (18). The pain mainly varies in its intensity, its quality and also its predictability. The pain can also impact the mobility of the patient, the patients' mood and also can cause disturbances in the sleep of the patient (19). The symptoms are usually gradual in progression and are later followed by periods of exacerbation (20). The pain and the functional disability for some patients can increase over time (21). The symptoms can vary from pain at weight bearing activities to symptoms that are persistent at rest . Other patients' can have an improvement in their pain after performing activities like walking after leaving the sedentary lifestyle. Based on the European League Against Rheumatism (EULAR) evidence-based recommendations, typical symptoms of knee osteoarthritis are pain, often worse towards the end of the day, relieved by rest; and the feeling of 'giving way' of the knee; only mild morning or inactivity stiffness and impaired function (21).

On physical examination, the various findings indicative of knee osteoarthritis include crepitus, painful and restricted movement of the knee joint, bony enlargement and absence or modest knee effusion (22). Other features can include deformity of the knee joint that can include fixed flexion deformity or

varus or valgus deformity (20). There can also be instability with joint line tenderness that can also be peri-articular and also pain on patella-femoral compression. There can also be sensorimotor changes and neuromuscular deficits in patients with knee osteoarthritis (18). The inhibition of the quadriceps muscle may occur due to the reduced capacity of the muscle due to swelling and pain (23).

DIAGNOSIS AND PROGNOSIS

In osteoarthritis of the knee joint both joints are usually involved, but however differentiation testing of both the joints can be performed.

The various differential diagnosis of the chronic knee pain include

Bursitis

Illiotibial band syndrome

Ligamentous instability

Meniscal pathology

Other forms of arthritis like gout and pseudogout,

Rheumatoid arthritis

Septic arthritis

Referred pain from neuropathy or radiculopathy

Avascular necrosis

Patellofemoral pain syndrome

Tumor (24)

RADIOLOGICAL CLASSIFICATION

KELLGREN-LAWRENCE CLASSIFICATION

Grade 1: doubtful narrowing of joint space and possible osteophyte lipping;

Grade 2: definite osteophytes and possible narrowing of joint space;

Grade 3: moderate multiple osteophytes, definite narrowing of joint space and some sclerosis and possible deformity of bone ends; and

Grade 4: large osteophytes marked narrowing of joint space, severe sclerosis and definite deformity of bone ends (25).

Box 1. Criteria for diagnosis of knee osteoarthritis[24, 27]

Clinical criteria
- Age older than 50 years
- Bony enlargement
- Bony tenderness
- Crepitus
- No palpable warmth
- Stiffness for < 30 minutes

Laboratory criteria
- Erythrocyte sedimentation rate < 40 mm/hour
- Rheumatoid factor < 1:40
- Synovial fluid analysis: clear, viscous, white blood cell count < 2,000/µL (2.00 x 109 per L)

Radiographic criteria
- Presence of osteophytes

	Sensitivity (%)	Specificity (%)	LR+	LR–
– Pain plus ≥ 3 clinical criteria	95	69	3.1	0.07
– Pain plus ≥ 5 clinical or laboratory criteria	92	75	3.7	0.11
– Pain plus ≥ 5 clinical or laboratory criteria, plus osteophyte	91	86	6.5	0.10

LR+ = positive likelihood ratio; LR– = negative likelihood ratio.

Table 1: Diagnostic criteria for osteoarthritis by the American College of Rheumatology(26)

BIOMECHANICS

The study of knee joint kinematics has been going on over the past decade and a half. But however there has been little change in the understanding from 1970 (27).

The popular method to mention about the knee movements has been based on the relative motions of the two bones – the femur moving bodily posteriorly on the tibia as the knee flexes which is referred to as the femoral roll back. This mechanism helps in increasing the flexion range and further increases the lever arm of the extensor mechanism.

Zuppinger first described the concept of the tibia, femur and the cruciate ligaments working as a rigid four bar linkage which act as a mechanical linkage to produce roll back (28)

The four bar linkage is based on the bars being straight, taut and in a single plane. But however the cruciate ligaments are multi planar. The posterior cruciate ligament lies in the sagittal plane, whilst the anterior cruciate ligament is triplanar(27).

METHODS OF INVESTIGATION OF KNEE MOTION

There are various methods of investigation of knee motion which include gait analysis, Roentgen stereophotogrammetric analysis (RSA), MRI scanning.

Knee flexion has been divided into three arcs:

The screw home arc

The functional active arc

Passive deep flexion arc

SCREW HOME ARC

This arc shows the movement of the knee joint between 20 degrees of knee flexion to terminal extension. There is an asymmetry in the shapes of the medial and lateral femoral condyles in the screw home arc of the knee flexion (29). The medial femoral condyle articulates with the upwardly sloping anterior tibial surface which contributes to the posterior part of the medial femoral condyle rising 1-2mm with terminal knee extension and the lateral femoral condyle moves internally in the terminal knee extension (27)

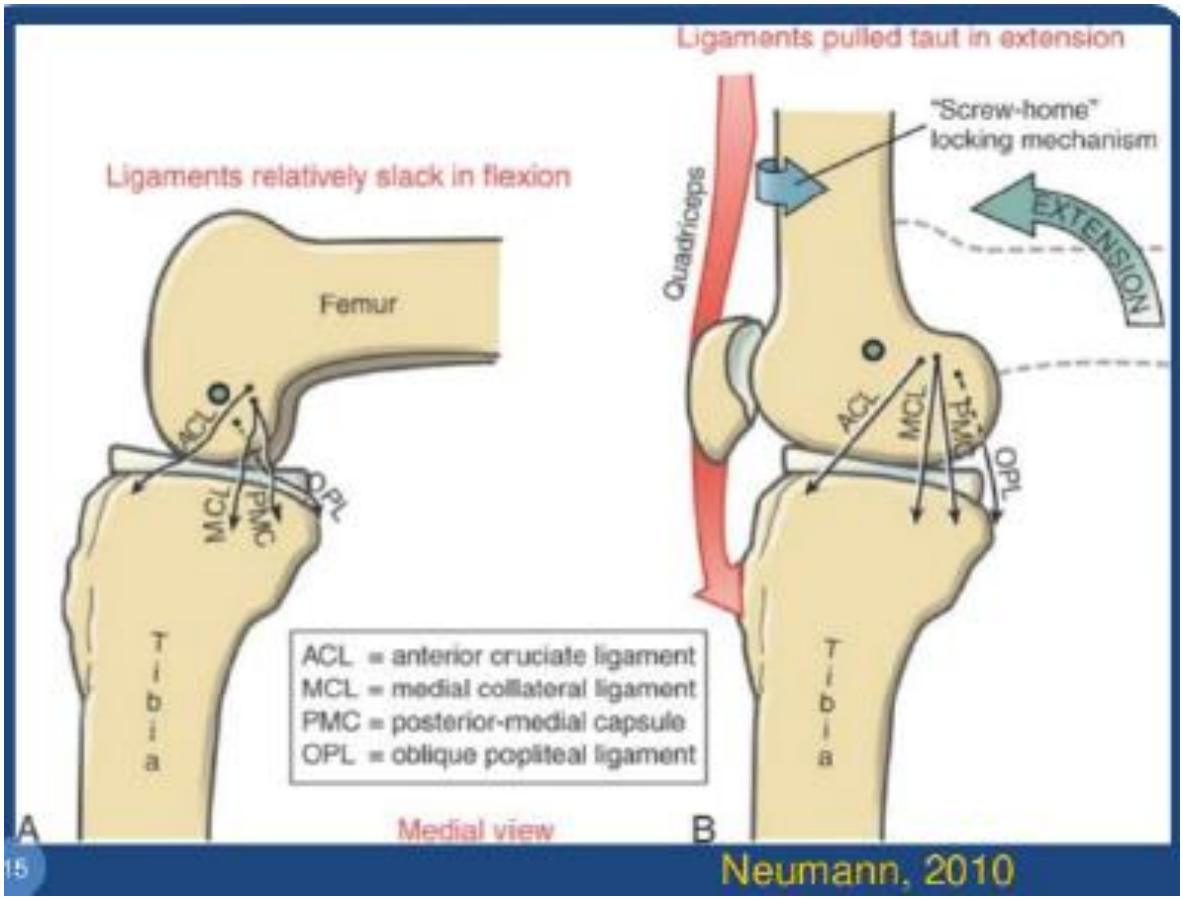


Figure 4: Screw home mechanism of knee joint

FUNCTIONAL ACTIVE ARC

This arc is between 20-120 degrees of knee flexion. In this phase the longitudinal rotation with flexion is not obligatory and can be reversed by voluntarily rotating the tibia externally. This allows the knee to function as a uniaxial hinge (30).

PASSIVE DEEP FLEXION ARC

This arc is a movement of the knee joint from 120 to 140 degrees of the knee joint. It is a passive movement, which is brought about by external forces, which is usually the body weight. The medial femoral condyle rises approximately 2mm as it moves into flexion and rides on the posterior horn of the medial meniscus. The knee in deep squat nearly subluxes but is held in position by the extensor mechanism and the posterior anatomical impingement (27).

The extensor mechanism is the most fundamental dynamic support of the knee in both stance phase and also locomotion (31).

PRINCIPLES OF TOTAL KNEE ARTHROPLASTY

There continues to be dissatisfaction over total knee arthroplasties with regard to its post op functional outcomes. This has been attributed to the mid flexion instability of multi radius knee replacement designs. Mid flexion instability has been attributed to transient ligament slackness and instability to knee flexion(32).

To achieve a successful outcome after a total knee arthroplasty and to perform daily activities it is essential to gain adequate extensor mechanism(33). The Quadriceps extensor mechanism is the major determinant of strength, which is affected by various factors in a total knee replacement. The two designs of the single radius and multi radius are believed to have different levels of influence on the recovery of the muscle strength (34).

Single radius designs have a more posterior center of rotation. This decreases the moment arm of the patella and thus requiring less quadriceps force and also decreases the load on the patella (35).

There is also a theoretical advantage of single radius designs that it decreases the ligament instability during mid flexion, based on the maintenance of the isometry of the ligaments during the entire range of motion (32).

Mid flexion instability is defined as mediolateral instability from 30 to 60 degrees of flexion of the knee joint. This is an underappreciated cause of postoperative pain, patient dissatisfaction and instability (36).

In a cadaveric study of total knee replacements mid flexion instability was identified in the coronal plane when the femur was shifted 5mm proximally and anteriorly. The position of the joint line was thus said to have a profound effect on mid flexion instability, that can occur in the presence of well-balanced flexion and extension gaps. The elevation of the joint line can alter the flexion- extension axis that subsequently leads to laxity of the posterior capsule, PCL and collateral ligaments at midflexion range i.e., 30–60 (36). The average joint line elevation in primary TKRs was from 1 to 4.3mm (37,38). Snider and Macdonald in their study showed that joint line elevation more than 8 mm was associated with lower postoperative KSS scores (38). In a randomized control trial, which compared conventional total knee replacement to computer assisted total knee replacement it was, suggested that joint line depression of over 2mm was associated with poor international knee society clinical scores at 2 years but however did not affect the quality of life (36). In a kinematic study to compare single radius and multi radius designs it was found that there was mediolateral instability in multi radius designs which coincided with the mid flexion range of movement between 30 to 45 degrees of range of movement. It was also found that there was a higher knee extensor torque in the single radius designs which was secondary to the more posterior center of rotation in the flexion extension axis in a single radius design (39). Collateral ligament instability was also better maintained in the single radius designs which suggested there was better stability in the mid flexion range of movement (39). Kessler et al (34) in their study found that there was a more

uniform movement found during stair climbing in a single radius design. But however it was found that there was increased varus-valgus laxity in the mid flexion range of movement in multi radius designs during stair climbing (34).

It was also found that the quadriceps could take more than two years to regain the pre-operative levels of strength following total knee replacement. Therefore, in the long term the difference in quadriceps activation between the single and multi radius designs may not be significant (40–42). Also, long term studies of single radius and multi radius designs have not shown to have any mid flexion instability in the multi radius designs (31).

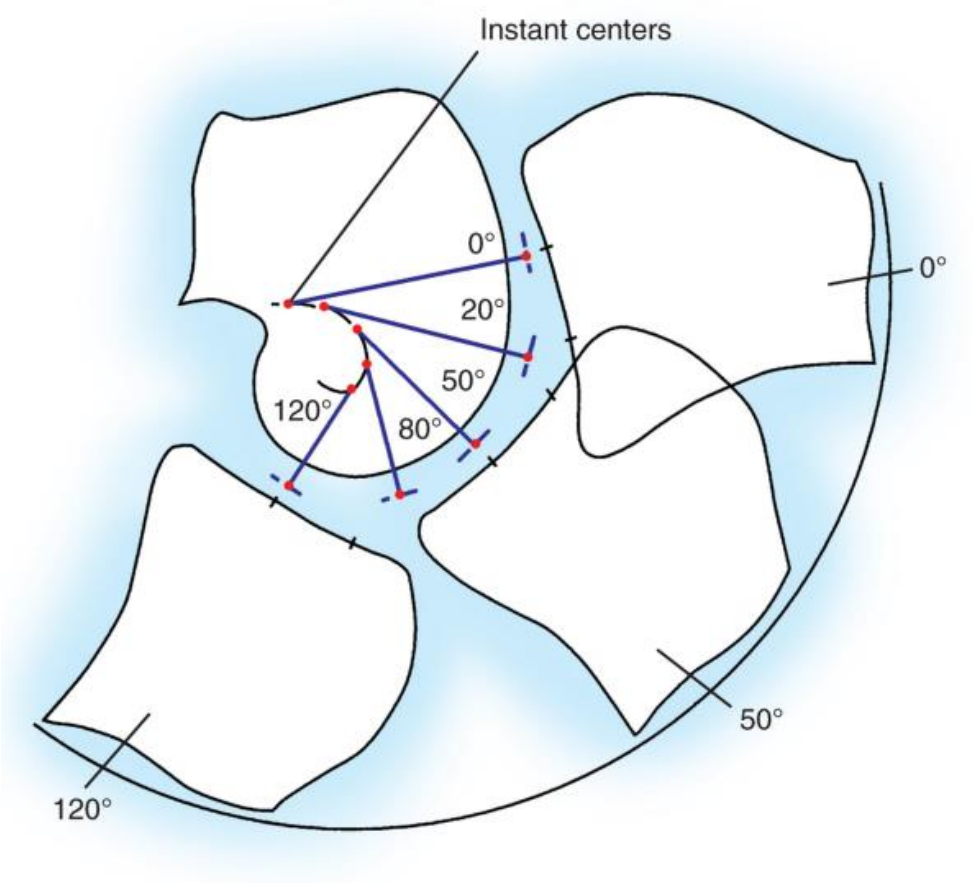
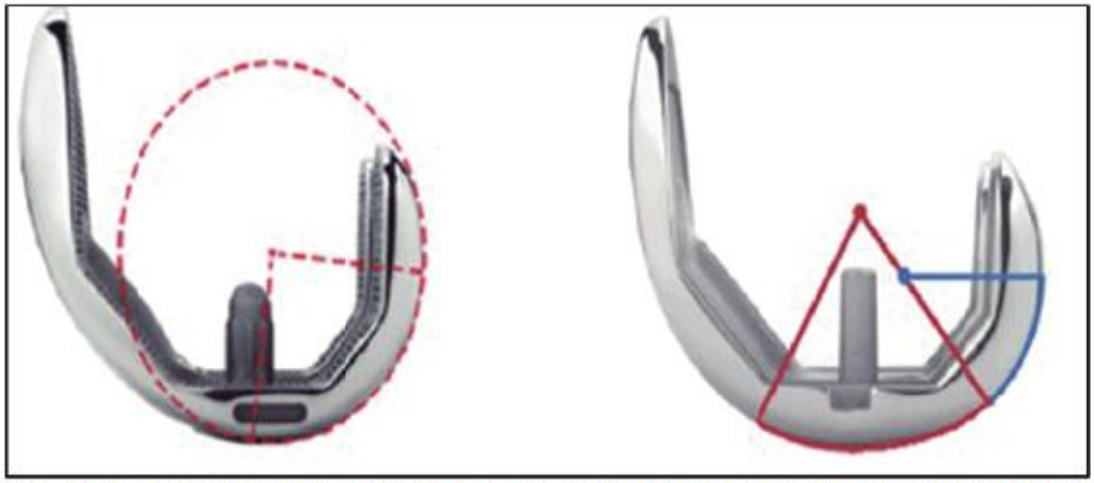


Figure 5: Multiple centers of rotation of femur in knee flexion (Source: Campbells operative orthopedics 11th edition)

The femoral components of multi radius knee replacements have shown to have a J shaped radius of curvature. The sagittal component of the radius of curvature has been shown to have a larger radius anteriorly. There was a good survivorship but there was a dissatisfaction over the function of the multi radius total knee replacement designs (43).



Schematic description of a single radius prostheses (left) and a multi radius prosthesis (right) with their rotation axis [14]. (License number: 2734170007640).

Figure 6: Single radius and multi radius implants with centers of rotation in the femur prosthesis (Source: The influence of a single-radius-design on the knee stability *M. Ezechieli*∗*, J. Dietzek, M. Ettinger, C. Becher, T. Calliess, S. Ostermeier and H. Windhagen)*

During implantation of knee prosthesis the surgeon balances the knee by a combination of alignment and ligament tensioning to ensure knee stability during flexion, which is established during 0-90 degrees of knee flexion (32). There can be a intermediate arc of flexion where the ligaments are slack and can lead to mid range instability in multi radius designs (44). This instability

can occur with both posterior cruciate ligament retaining and also sacrificing knee replacement designs (45).

The single radius total knee replacement designs have been proposed to ensure consistent tension in the collateral ligaments during the entire range of knee flexion. This is based on the superficial medial collateral ligament and its isometry during the entire range of motion. The femoral attachment of the superficial medial collateral ligament is around the flexion axis. The anterior fibres of the superficial collateral ligament extend while the posterior fibres shorten during flexion (46).

Single radius designs have been proposed to have better anterior knee function, stability and function due to a better proprioception (47).

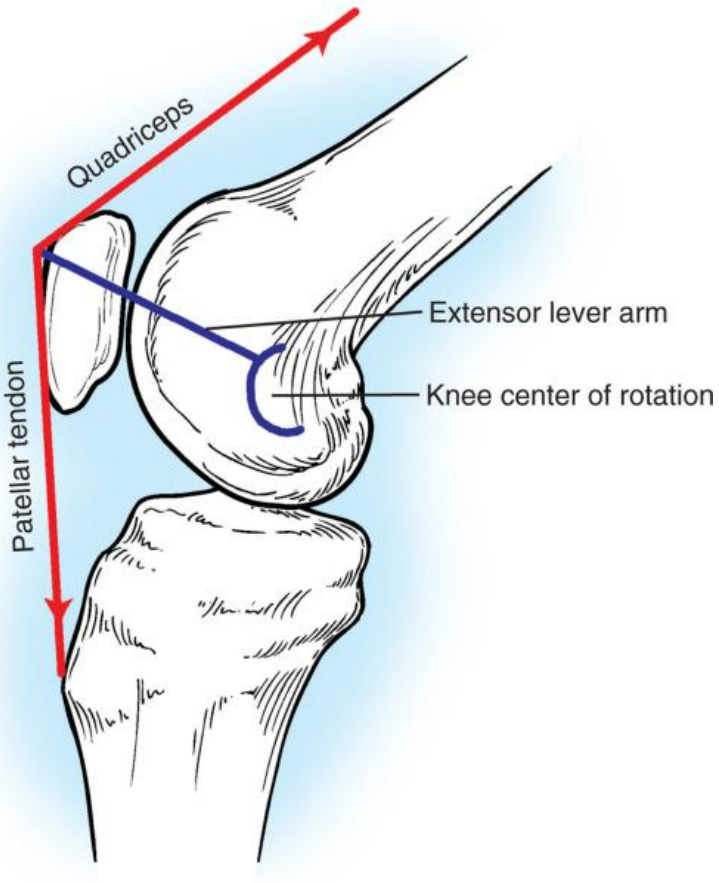


Figure 7: *Patella acts to lengthen extensor lever arm by displacing force vectors of quadriceps and patellar tendons away from center of rotation (COR) of knee. Length of extensor lever arm changes with varying amounts of knee flexion.*

(Source: Campbells operative orthopedics 11th edition)

The femur component in a single radius design showed less deviation in the flexion extension axis than compared to the multi radius design, which has multiple radii of rotation. In the single radius design the flexion and extension axis is more similar to the transepicondylar axis of the femur when compared to the multi radius designs. This in turn can lead to a longer lever arm of the quadriceps muscle and a lower retropatellar surface pressure (48)(35). In multi radius designs the axis of rotation is relatively anterior and this can lead to weaker extensor mechanism (48). In a single radius design there is a single radius of rotation in the medio lateral plane of the femur and tibia and this allows for greater contact area on flexion and extension. This helps in minimizing the edge loading and also helps in reducing the polyethylene wear debris formation. An optimization of the extensor mechanism function is important as the extensor mechanism can influence the gait pattern, joint stability and endurance following a total knee replacement (49).

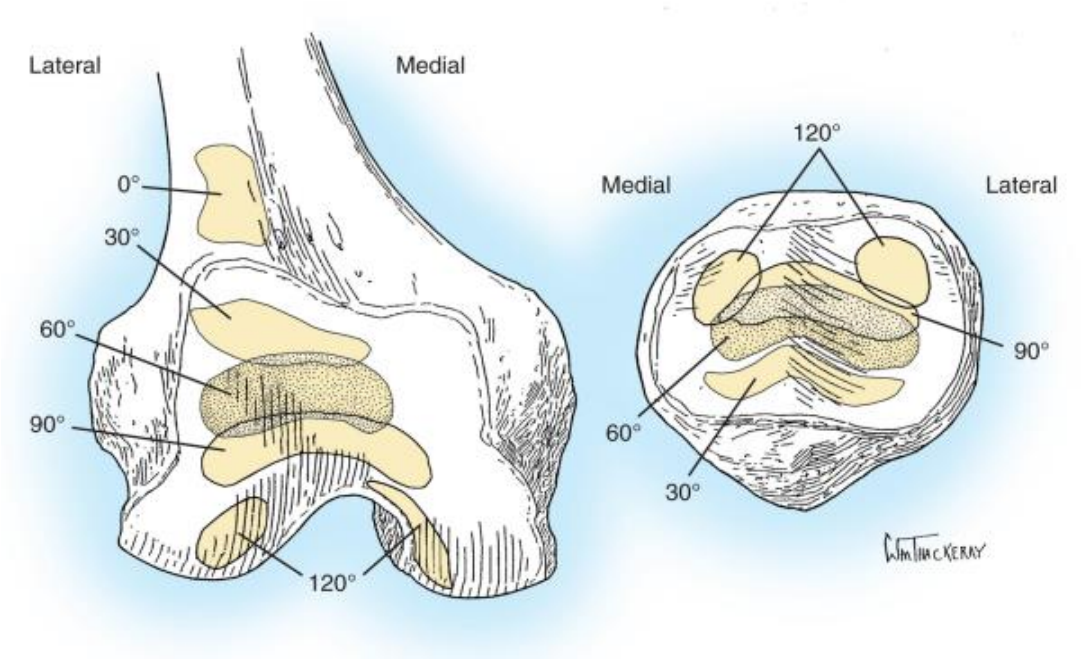


Figure 8: *Patellofemoral contact zones change with knee flexion. Source (Redrawn from Aglietti P, Insall JN, Walker PS, et al: A new patella prosthesis: design and application, Clin Orthop Relat Res 107:175, 1975.)*

The moment arm of the extensor mechanism determines the forces required for knee extension. In the post op patients who underwent total knee replacements with a single radius designs, it was found that there was a decreased quadriceps muscle activation in sitting to standing movements and decreased trunk flexion which was required for standing. This suggested that these patients would recover more readily in the post op period (32).

The single radius femoral component is supposed to have a greater range of flexion and also in achieving the natural movement of the knee joint. The single radius should achieve a flexion of up to 150 degrees with stable collateral tensioning of the ligaments (50).

INDICATIONS FOR TOTAL KNEE ARTHROPLASTY

- Primary indication for total knee arthroplasty is to relieve pain.
- Generally indicated in older patients with more sedentary lifestyles.
- In younger patients it is indicated if they have limited function due to systemic arthritis.
- Severe patellofemoral arthritis can be indicated for total knee arthroplasty in older patients.
- Deformity in patients with moderate arthritis is a principal indication for knee replacement.

CONTRAINDICATIONS FOR TOTAL KNEE ARTHROPLASTY

- Recent or current knee sepsis is an absolute contraindication for total knee arthroplasty
- Any remote source of ongoing infection is a contraindication.
- If there is an extensor mechanism discontinuity or dysfunction.
- A recurvatum deformity secondary to muscular weakness is a contraindication to performing total knee arthroplasty.
- Presence of a painless well functioning arthrodesed knee.

RELATIVE CONTRAINDICATIONS FOR TOTAL KNEE ARTHROPLASTY

- Any medical condition that can compromise the patients ability to withstand anesthesia.
- Medical condition that can impair the patients' ability to undergo rehabilitation, which can affect the outcome of the patient.
- Significant atherosclerotic disease of the operative leg.
- Skin conditions such as psoriasis, tinea within the operative field.
- Venous stasis leading to recurrent cellulitis.
- Presence of morbid obesity of the patient.
- Neuropathic arthropathy.
- Any history of osteomyelitis of the region close to the knee joint.
- Patient with recurrent urinary tract infections.

MATERIALS AND METHODS

This study was carried out to investigate if there were any advantages of the newer single radius total knee arthroplasty designs over the traditional multi radius designs. The objective of this study was to look at the functional outcomes of the total knee replacements done in our institution.

The study was carried after obtaining the approval from the Institutional Review Board.

This study was a prospective cohort based study.

SETTING:

The study was carried on in Christian Medical College; Vellore, which is a 2695, bedded multispecialty hospital. It was done under the department of Orthopedics Unit 3. The study included all patients who underwent total knee arthroplasty of a unilateral knee secondary to osteoarthritis under the department of Orthopedics unit 3.

A single surgeon carried out the surgery. The patients were selected based on the inclusion criteria and the principal surgeon chose the implant i.e. single radius or multi radius for the respective patients. All patients were assessed in the pre op period, based on the knee society scoring and also in the post op 10 days and 90 days based on the same scoring system. The patients were enrolled in the study after getting an informed consent and completely clarifying all the queries with regards to the study. The single radius designs used in the study were DJO 3DKnee™ system, Zimmer Biomet Vanguard® system.

The multi radius designs used in the study were Smith & Nephew Genesis II system and DePuy P.F.C.®SIGMA® Knee system. The patients were enrolled in the study based on the following inclusion and exclusion criteria.

INCLUSION CRITERIA

- All patients with a diagnosis of primary osteoarthritis
- No hip disorder
- Contralateral knee should be normal or have minimal symptoms
- Flexion contracture should be less than or equal to 30 degrees
- Flexion of the affected knee should be more than 90 degrees
- Should be able to ambulate independently
- No lower limb discrepancy
- Should not have neuromuscular disorders

EXCLUSION CRITERIA

- Any other indication for total knee replacement like rheumatoid arthritis
- Ipsilateral hip disorder
- Flexion contracture of more than 30 degrees
- Unable to ambulate without assistance
- Presence of lower limb discrepancy
- Loss of follow up or not adherent to the post op physiotherapy protocol
- Presence of neuromuscular disorders.

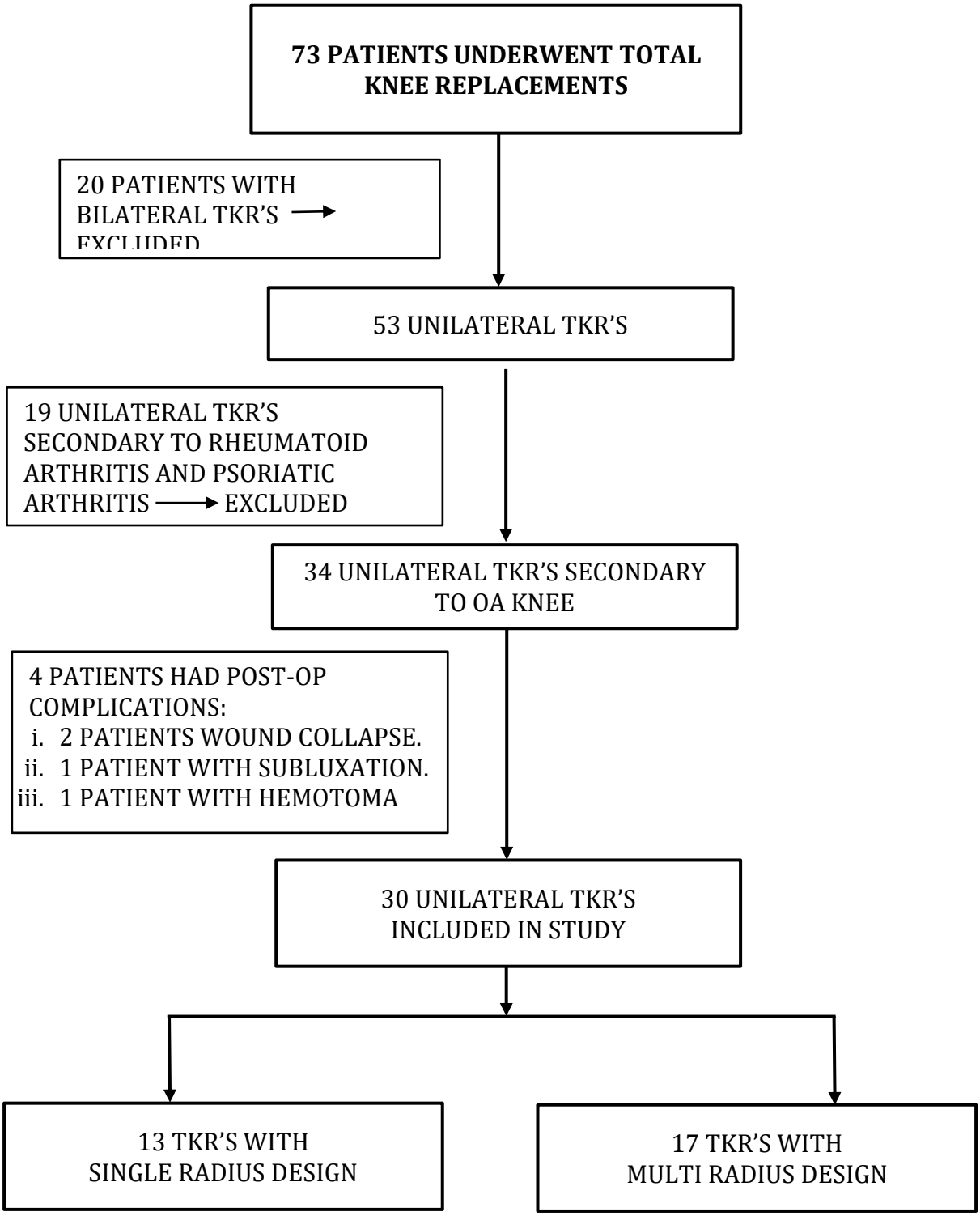


Table 2: Algorithm for selection of patients

The period of study was between July 2017 and April 2018. During this period 73 patients underwent total knee replacement. Of this there were 20 patients' who underwent bilateral total knee replacements who were excluded from the study. There were 53 unilateral total knee replacements that were done in the period of the study. In the total unilateral total knee replacements 34 were secondary to osteoarthritis of the knee joint and the rest were excluded from the study as they were due to other causes such as rheumatoid arthritis and psoriatic arthritis. 4 patients were excluded as there were complications in the post op period like wound collapse and subluxation of the knee joint. There were 30 patients who were included in the study of which 17 received multi radius total knee replacement designs and 13 received single radius designs.

The operative and postoperative protocol was paralleled in both the groups. Both the groups underwent pre anesthesia clearance and were deemed fit for the surgery after which were taken for the operative procedure. Surgical technique was paralleled in both the groups. This included usage of a tourniquet, anterior midline approach to the knee, and medial Para patellar approach to the knee joint. The surgical technique used was the measured resection technique. Wound closure was done in flexion in layers and a drain was placed. The drain was placed for a period of 48 hours in the postoperative period. A compression bandage was placed for 48 hours after which the dressing was debulked. Postoperative management was performed following the unit's clinical pathway for TKA, from immediate postoperative analgesia to discharge. Postoperative protocol in this pathway included sitting in the second

postoperative day including active and passive knee range of movements. Patient was made to stand on the third postoperative day. Gait reeducation with two crutches was taught until negotiating stairs (six steps) between the fourth and seventh postoperative days. At this point, the patient was discharged and physiotherapy continued on outpatient basis. An independent physiotherapist who was blinded to the two patient groups determined the intensity of physiotherapy required for each patient to achieve adequate range of movement and gains on gait pattern. The postoperative assessment was done on the 10^{th} and 90^{th} postoperative day and outcome measurements were done via the knee society scoring system that included both clinical and functional outcomes (51).

BIAS

Patients enrolled in the study will receive the SR or MR implants based on the surgeon's preference. In the post op evaluation patients may give positive or negative outcomes, which would be eliminated by the knee society-scoring questionnaire. In the post op rehabilitation program both groups will undergo similar physiotherapy. The physiotherapists and the principal investigator assessing the functional outcome will be blinded to the type of prosthesis used on the patient.

STATISTICAL METHODS

Data will be entered using EPIDATA software and screened for outliers and extreme values using Box-Cox plot and histogram (for shape of the distribution). Summary statistics will used for reporting demographic and clinical characteristics. t-test will be use for analysis of continuous data with Normal distribution and Mann-Whitney U test for data with non- Normal distribution with group (SR & MR). Chi-square test will be performed for categorical variables and group. Multivariable analysis will be done based on the variables, which will be significant at Univariate levels. Differences will be considered significant at $p<0.05$. All the statistical analysis was performed using SPSS 18.0.

RESULTS

During the period of study from July 2017 to April 2018 all the patients who underwent unilateral total knee replacement secondary to osteoarthritis of the knee joint were included in the study according to the inclusion criteria. There were 34 patients who underwent unilateral total knee replacements in both the groups, which included the single radius, and multi radius designs. Out of which 4 patients were not included as there were post op complications:

- 2 patients had wound collapse who had to be taken for wound debridement and secondary closure
- 1 patient had posterior subluxation of the knee joint for which closed reduction was done in day care under anesthesia.
- 1 patient had hematoma after persistent discharge from the wound for whom a wound washout and closure was done on the 10^{th} post op day.

All patients who were included in the study according to the inclusion criteria were assessed based on the same questionnaire-Knee Society Score. The various parameters that were assessed in the questionnaire included the age, sex, BMI, Pain score according to Visual Analog Scale during walking and stair climbing, range of movement and the Functional knee score and also the knee score in the pre op period and also in the post op 10^{th} day and 90^{th} day. X rays were taken in the pre op period and also in the post op period. The study was done in the Department of Orthopedics Unit 3 in CMC Vellore. All

patients underwent total knee replacement with an implant of the primary surgeons preference.

Baseline Patient Demographics and Surgical Details		
Characteristics	**Single-Radius Group**	**Multi-Radius Group**
Number Of Patients Male & Female	13	17
Male	8	2
Female	5	15
Mean Age Of Male	60.75	66.50
Mean Age Of Female	57.2	58.07
Mean BMI Male	26.83	27.85
Mean BMI Female	31.14	30.16

Table 3: Demographic details of patients

Of the 30 patients who underwent total knee replacement there were 13 patients in the single radius group and 17 patients in the multi radius group. Amongst all the patients that underwent total knee replacement who were included in the study, 67% of the patients were female whereas 33% of the patients were male, which were 20 female patients and 10 male patients.

There were 8 male and 5 female patients in the single radius group, which was 61.54% male and 38.46% female.

Similarly in the multi radius group there were 2 male patients and 15 female patients who underwent total knee replacement, which was 11.76% male and 88.2% female.

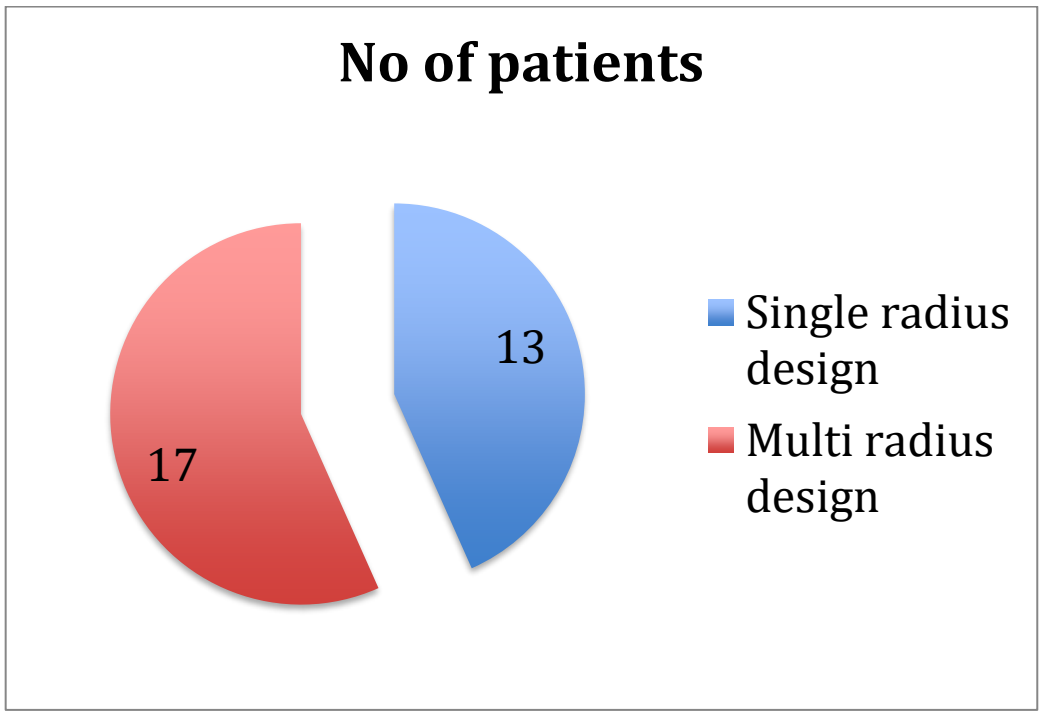


Figure 9: Distribution of patients with single radius and multi radius designs

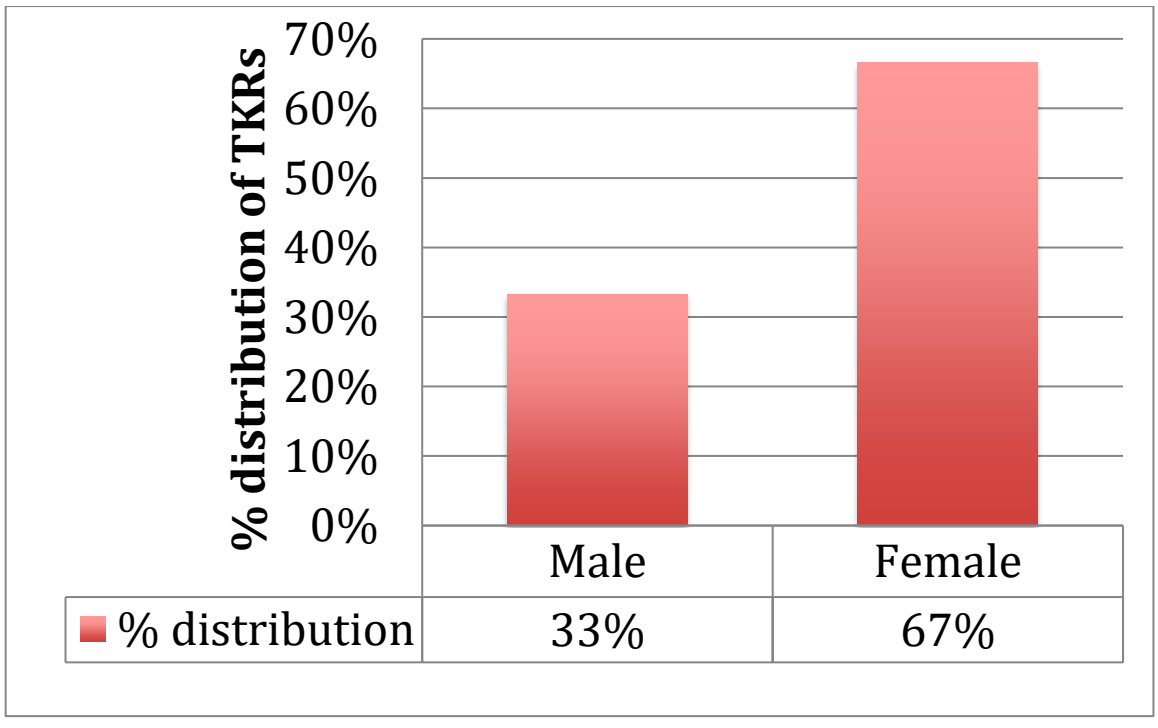


Figure 10: Percentage distribution of patients based on gender

The majority of the patients who underwent total knee replacement were mainly in the age group of 50-60 followed by the age group of 60-70.

	Male		**Female**	
	Single-Radius Group	**Multi-Radius Group**	**Single-Radius Group**	**Multi-Radius Group**
40 to 50	x	x	x	**2**
50 to 60	**3**	x	**5**	**6**
60 to 70	**4**	**1**	**1**	**6**
70 to 80	x	**1**	x	**1**

Table 4: Distribution of patients based on age and implant used

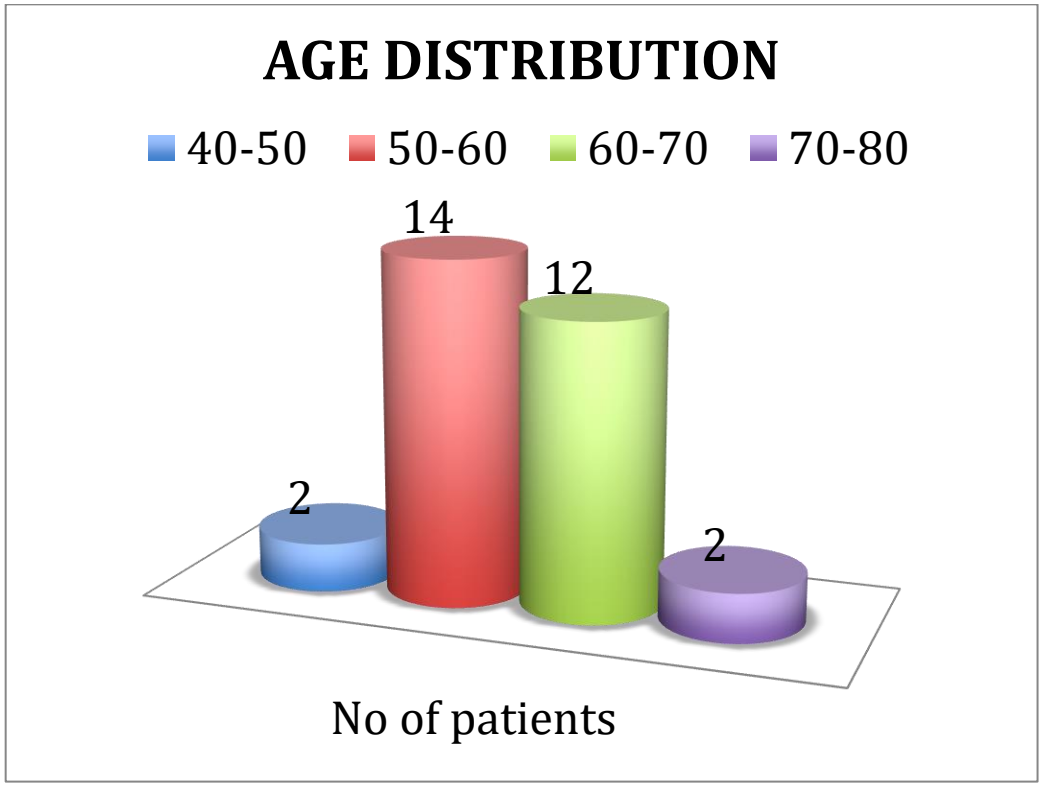


Figure 11: Age distribution of patients

The mean age of patients who underwent total knee replacement was lower in the female patients compared to the male patients. The mean age of female patients was 58.07 in the multi radius group compared to57.2 in the single radius group. Similarly, the mean age of male patients in the multi radius group was found to be 66.5 years compared to 60.75 in the single radius group.

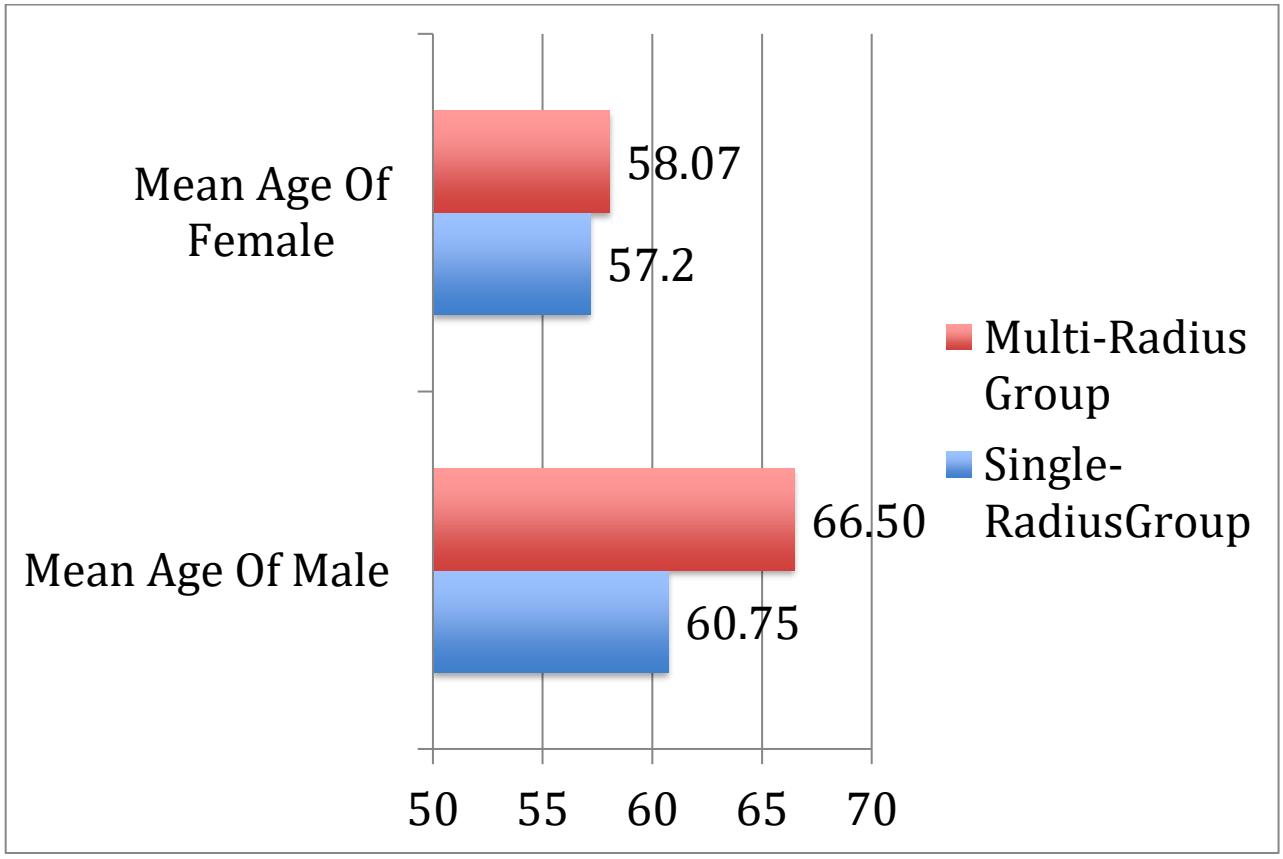


Figure 12: Age distribution of patients based on gender and mean age in single radius and multi radius groups.

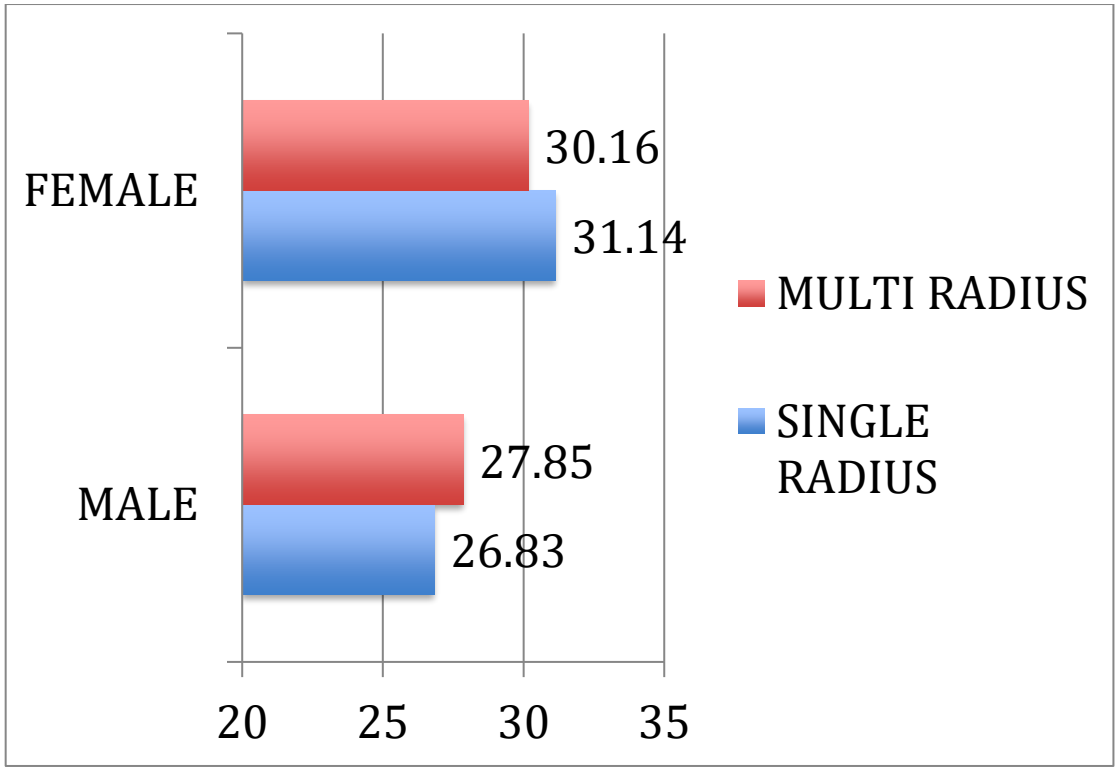


Figure 13: Distribution of patients based on BMI and gender in single radius and multi radius groups

MEAN BODY MASS INDEX

It was also found that there was a significant difference ($p<0.05$) in comparison of the mean body mass index of the female patients who underwent total knee replacement to the mean body mass index of male patients who underwent total knee replacement.

The mean body mass index amongst the female patients who underwent multi radius total knee replacements was 30.16 kg/m^2 compared to 27.85 kg/m^2 in the male group. In a similar comparison in the single radius group it was found that the mean body mass index in the female group was 31.14 kg/m^2 compared to 26.83 kg/m^2 in the male group.

Relationship of BMI VS sex	N	Mean	p value
Male	10	27.04	0.051
Female	20	30.405	

Table 5: Relationship of BMI VS sex

	Pre-Op	Post-Op 10 Days	Post-Op 90 Days
MEAN FUNCTIONAL KNEE SCORE (100)	34.50	28.33	59.17
MEAN KNEE SCORE (100)	42.47	68.33	82.00

Table 6: Mean functional knee score and Knee scores in port op 10 and 90 days

The functional knee score and the objective knee score was measured in patients in the pre op period and also at the 10 days and 90 days post op period. It was found that there was an improvement in the mean score of the patients in both the groups combined. The mean functional score had a significant improvement when compared in the pre op and post op 90 days amongst the patients that underwent total knee arthroplasty. But there was a drop in the functional score when comparing the pre op and post op 10 days as the patients in the postop period used assistance for ambulation following the surgery for a period of 6 weeks in the postop period.

But the objective knee score there was an improvement in the postop 10 and 90 days because there was an improvement in the range of motion of the knee and there was also no flexion contractures or varus-valgus deformity in the patients in the postop period.

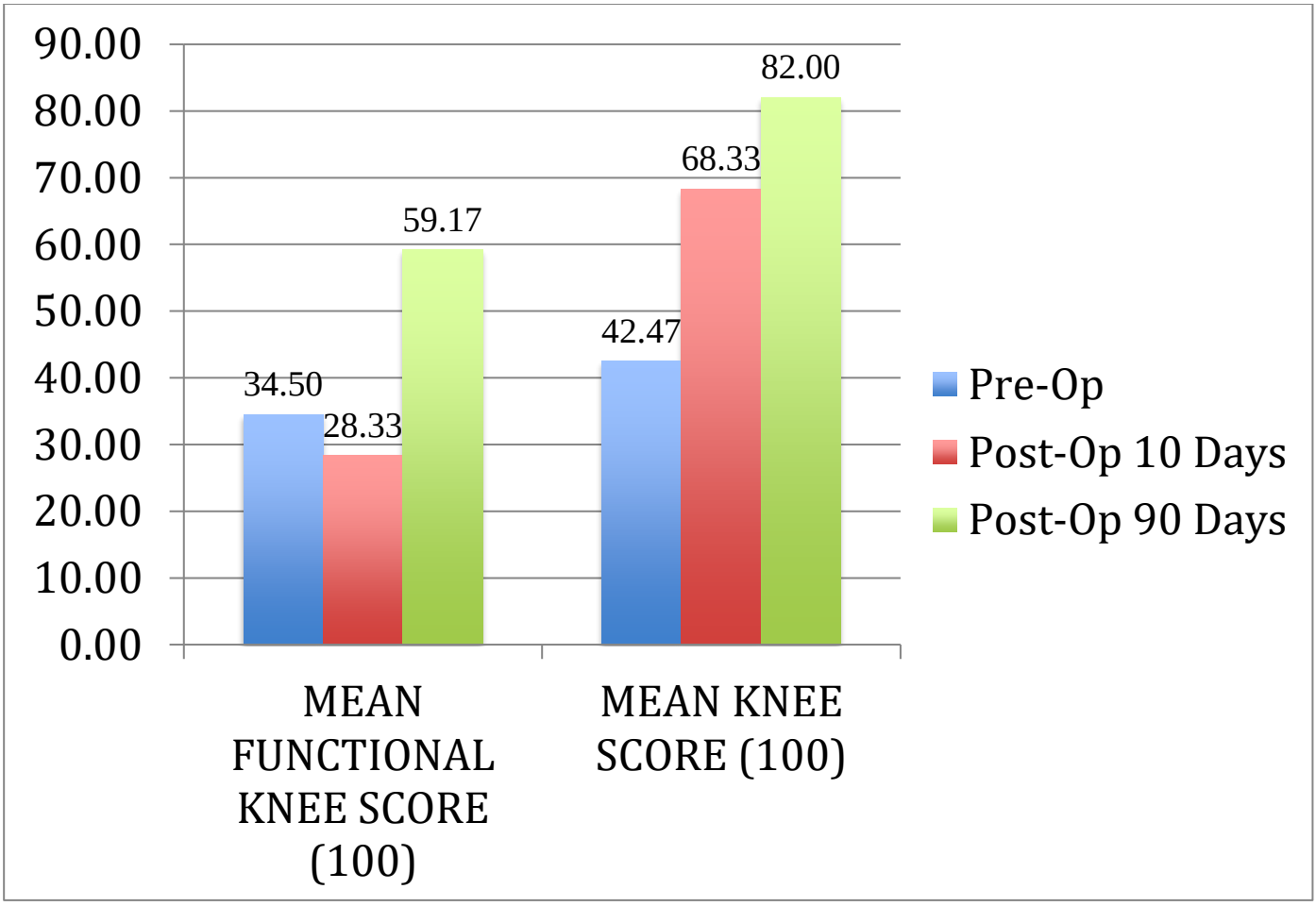


Figure 14: Analysis of mean functional knee score and knee score of patients in the pre op and post op 10 and 90 days

On comparing the mean functional knee score for patients between the single radius and multi radius it was found that there was a significant improvement in the functional knee score for patients who underwent total knee arthroplasty with a single radius design, when comparing the preop and the post op 10 days period.

But there was no significant difference in the functional knee score for patients between the single radius and multi radius designs on comparing the pre op and 90 days post op period.

	Pre-Op	Post-Op 10 Days	Post-Op 90 Days
MEAN FUNCTIONAL KNEE SCORE (100) - SR	38.84	30.88	56.92
MEAN FUNCTIONAL KNEE SCORE (100) - MR	31.17	25	60.88
MEAN KNEE SCORE (100) - SINGLE RADIUS	49	67.00	80.08
MEAN KNEE SCORE (100) - MULTI RADIUS	37.47	69.35	83.47

Table 7: Mean functional knee score and knee score in single radius and multi radius in pre op, post op 10 days and 90 days

	POST OP 10 DAYS	POST OP 90 DAYS	p value (Pre Op VS post op 10 days)	p value (Pre op VS 90 days post op)
FUNCTIONAL KNEE SCORE MR (MEAN)	25 (SD-6.9)	60.88 (SD-7.12)	0.033	0.196
FUNCTIONAL KNEE SCORE SR (MEAN)	30.88 (SD-7.36)	56.92 (SD-9.24)	0.035	0.214

Table 8: Comparison of funational knee score and knee score with tests of significance

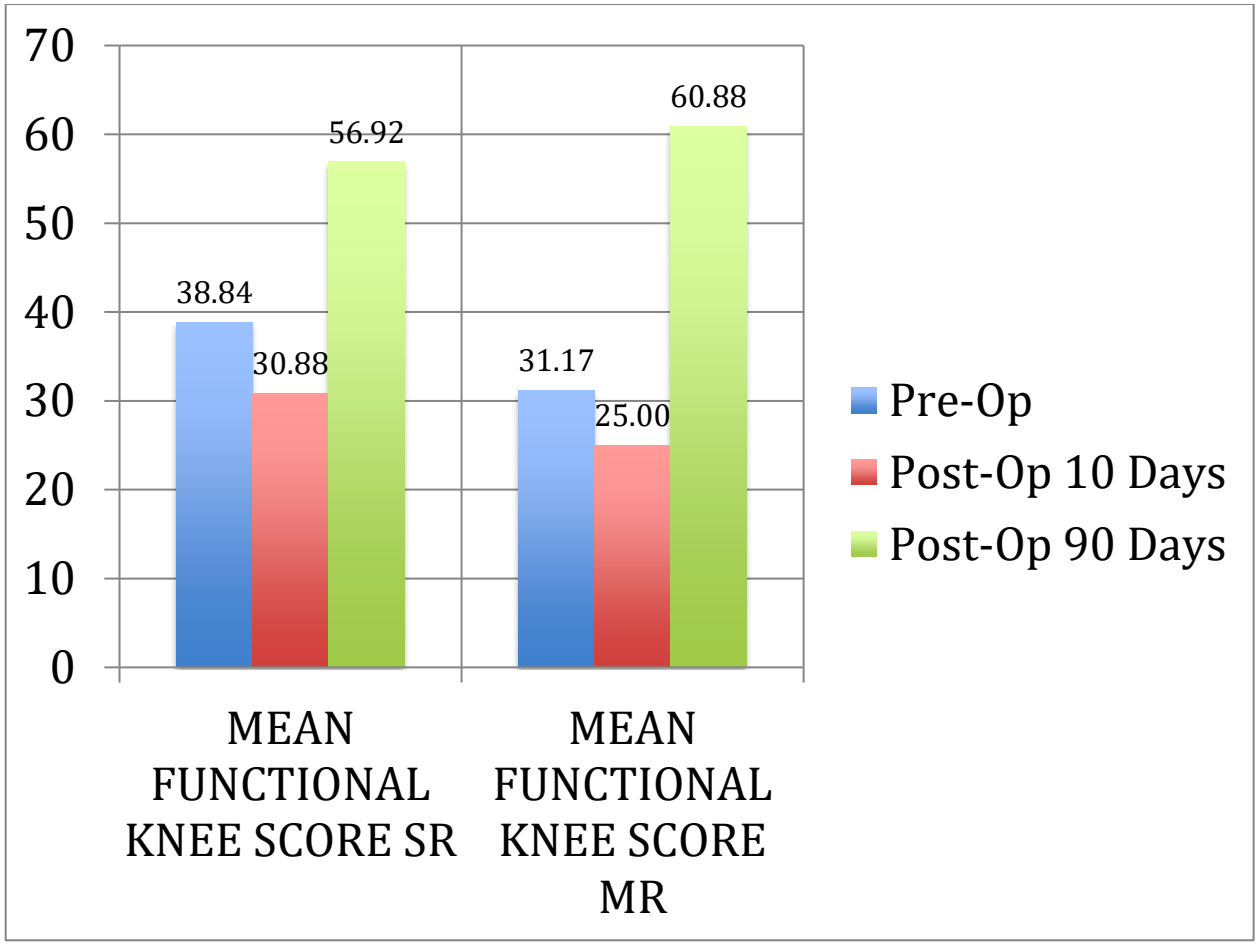


Figure 15: Comparison of functional knee score of single radius and multi radius in pre op and post op 10 days and 90 days

The knee score, which involved the calculation via the knee society score involved parameters like the range of motion, alignment, deformity and the stability of the knee joint in the pre op and post op 10 and 90 days period. There was no significant difference seen on comparing the single radius design with the multi radius designs in the pre op VS the 10 days post op and 90 days post op period. There was however an overall improvement seen in the knee score for patients when comparing the pre op and the post op 10 and 90 days period.

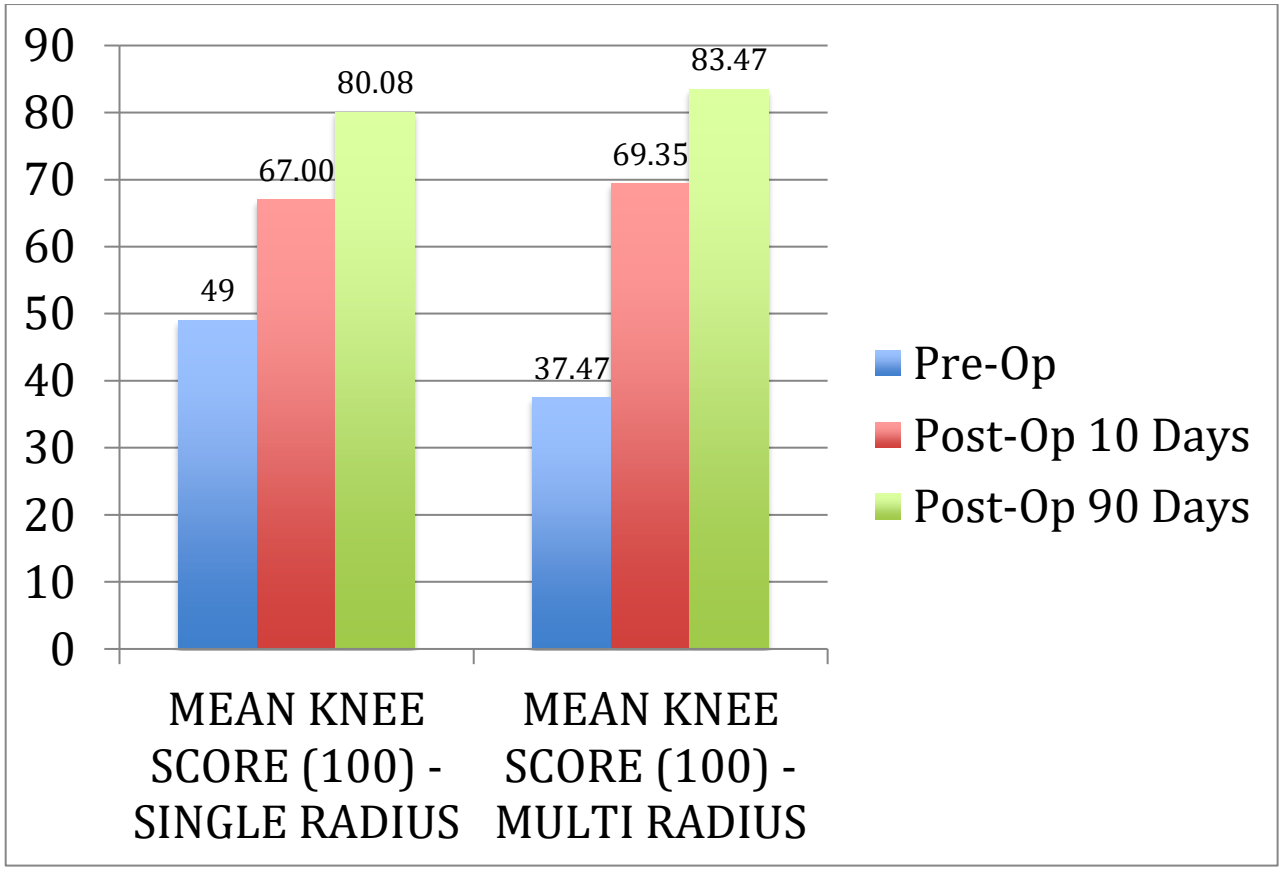


Figure 16: Mean knee scores at pre op, postop 10 days and 90 days

	POST OP 10 DAYS	**POST OP 90 DAYS**	**p value (Pre Op VS post op 10 days)**	**p value (Pre op VS 90 days post op)**
KNEE SCORE MR (MEAN)	69.35 (SD-7.43)	83.47 (SD-6.46)	0.416	0.267
KNEE SCORE SR (MEAN)	67 (SD-8.11)	80.08 (SD-9.92)	0.422	0.297

Table 9: Comparison of mean knee scores at pre op, post op 10 and 90 days with tests of significance

The visual analog score for pain was calculated for both walking and stair climbing in the pre op and post op 10 days and 90 days.

There was an improvement in the scores of the visual analog scale for pain while walking in both the single radius and multi radius design on comparing the pre op with the post op 10 days and the post op 90 days period. But however there was no significant difference seen on comparing both the groups of the single radius and the multi radius.

	POST OP 10 DAYS	**POST OP 90 DAYS**	**p value (Pre Op VS post op 10 days)**	**p value (Pre op VS 90 days post op)**
VAS WALKING MR (MEAN)	5.47 (SD- 1.06)	3 (SD- 1)	0.376	0.688
VAS WALKING SR (MEAN)	5.85 (SD- 1.21)	3.15 (SD- 1.06)	0.385	0.691
VAS STAIR CLIMBING MR (MEAN)	6.18 (SD- 1.074)	3.47 (SD- 1.068)	0.599	0.631
VAS STAIR CLIMBING SR (MEAN)	6.38 (SD- 1.044)	3.69 (SD- 1.437)	0.598	0.646

Table 10: VAS score with walking and stair climbing at post op 10 days and 90 days with tests of significance

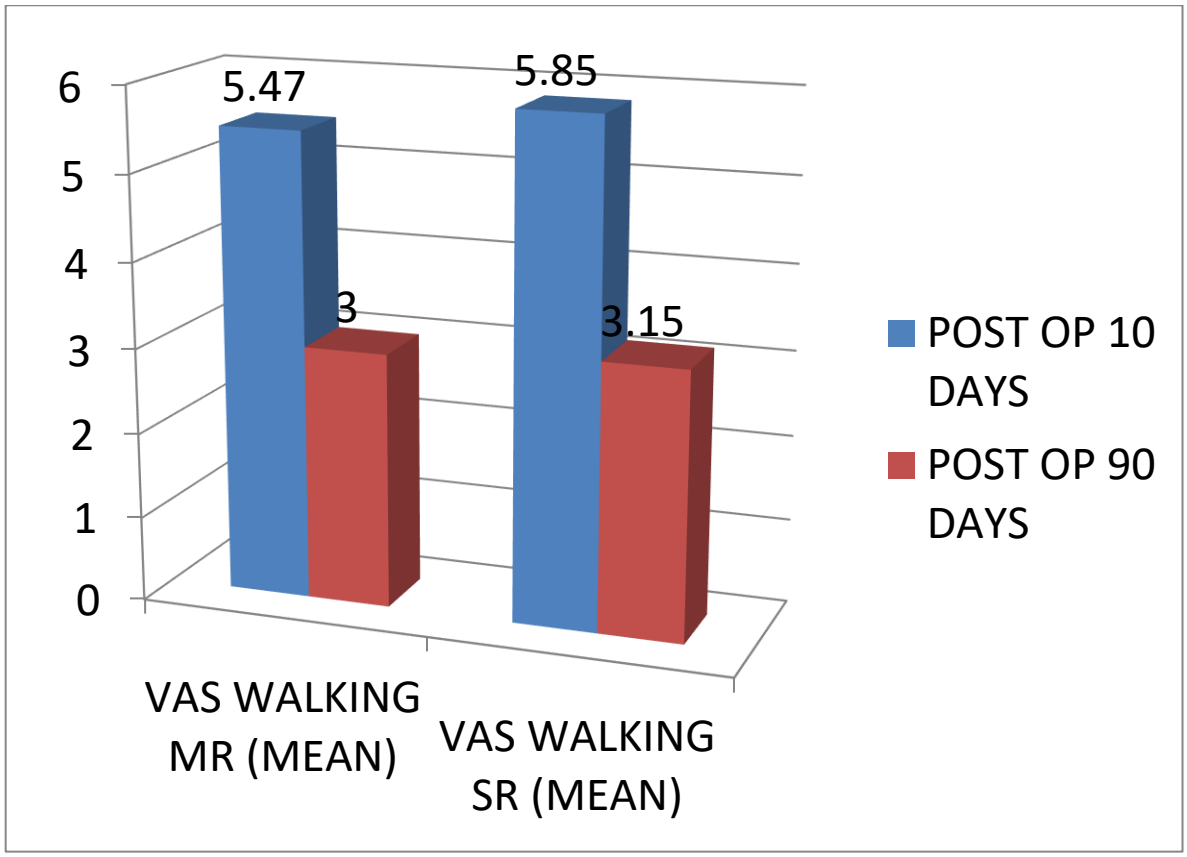


Figure 17: Comparison of VAS scores on walking at postop 10 and 90 days

Similarly there was also an improvement seen in the visual analog scale for pain for stair climbing for patients in both the single radius and multi radius designs in between the post op 10 days and post op 90 days. But on comparison of the visual analog scale for pain on stair climbing between the single radius and multi radius designs there was no significant difference seen between the pre op and the post op 10 and 90 days period.

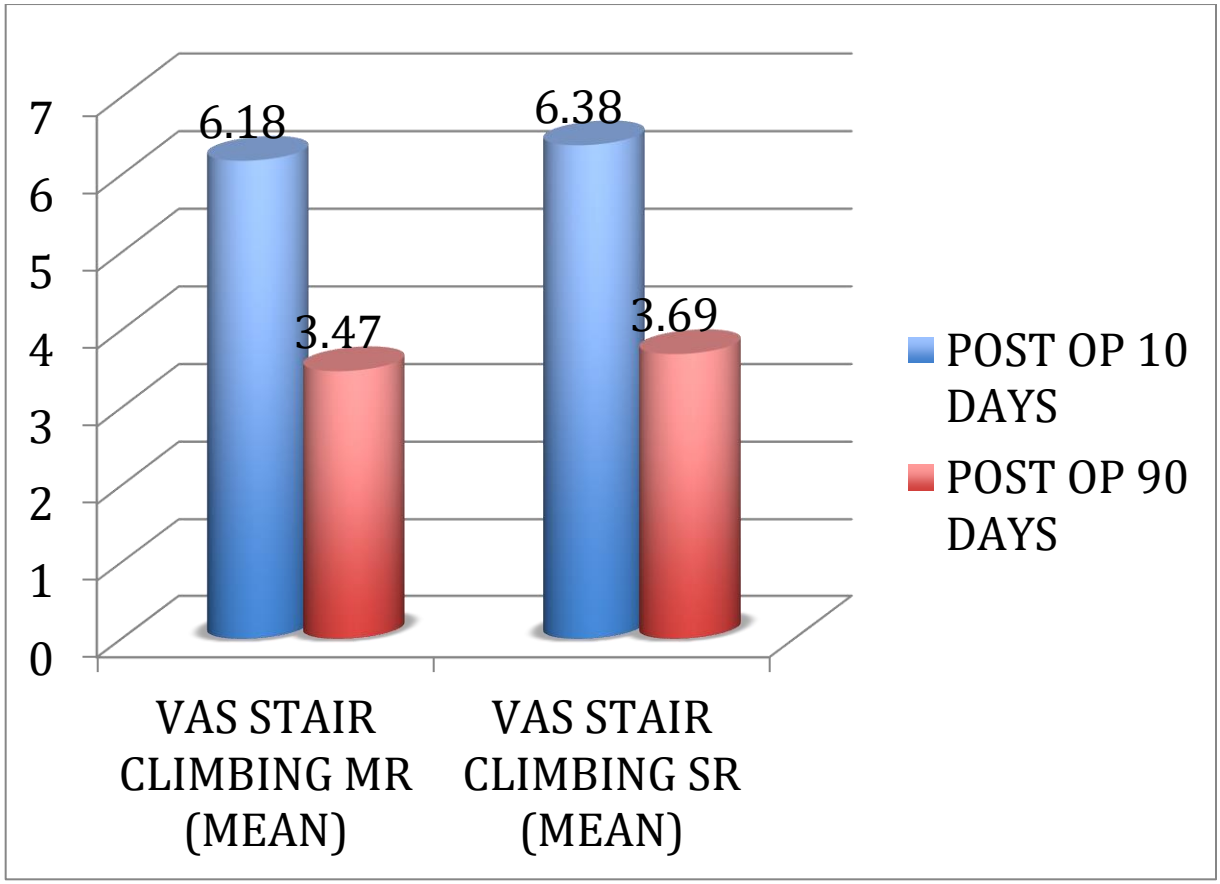


Figure 18: Comparison of VAS scores on stair climbing at postop 10 and 90 days

The range of motion was calculated for patients in the pre op and also at post op 10 days and 90 periods. The range of motion was found to be 92.94 in the post op 10 days period for patients who underwent total knee arthroplasty via the multi radius designs and was 96.15 for patients who underwent total knee arthroplasty via the single radius design. There was a minimal improvement in the mean range of movements for patients who underwent total knee arthroplasty via the single radius design but there was no significant difference seen in the patients in the pre op and post op 10 days between the single radius and multi radius designs.

Similarly the mean range of movement in patients who underwent total knee replacement via the single radius design was found to be 106.15 in the postop 90 days period. The mean range of movement in the post op 90 days for single radius designs was better than that of the multi radius design which was found to be 101.86.

But there was no significant difference seen in the pre op when compared to the post op 90 days period in between the single radius and multi radius designs.

	POST OP 10 DAYS	**POST OP 90 DAYS**	**p value (Pre Op VS post op 10 days)**	**p value (Pre op VS 90 days post op)**
ROM MR (MEAN)	92.94 (SD-8.48)	101.86 (SD-6.96)	0.439	0.129
ROM SR (MEAN)	96.15 (SD-13.86)	106.15 (SD-10.43)	0.471	0.153

Table 11: Comparison of knee range of motion in the postop 10 days and 90 days with tests of significance

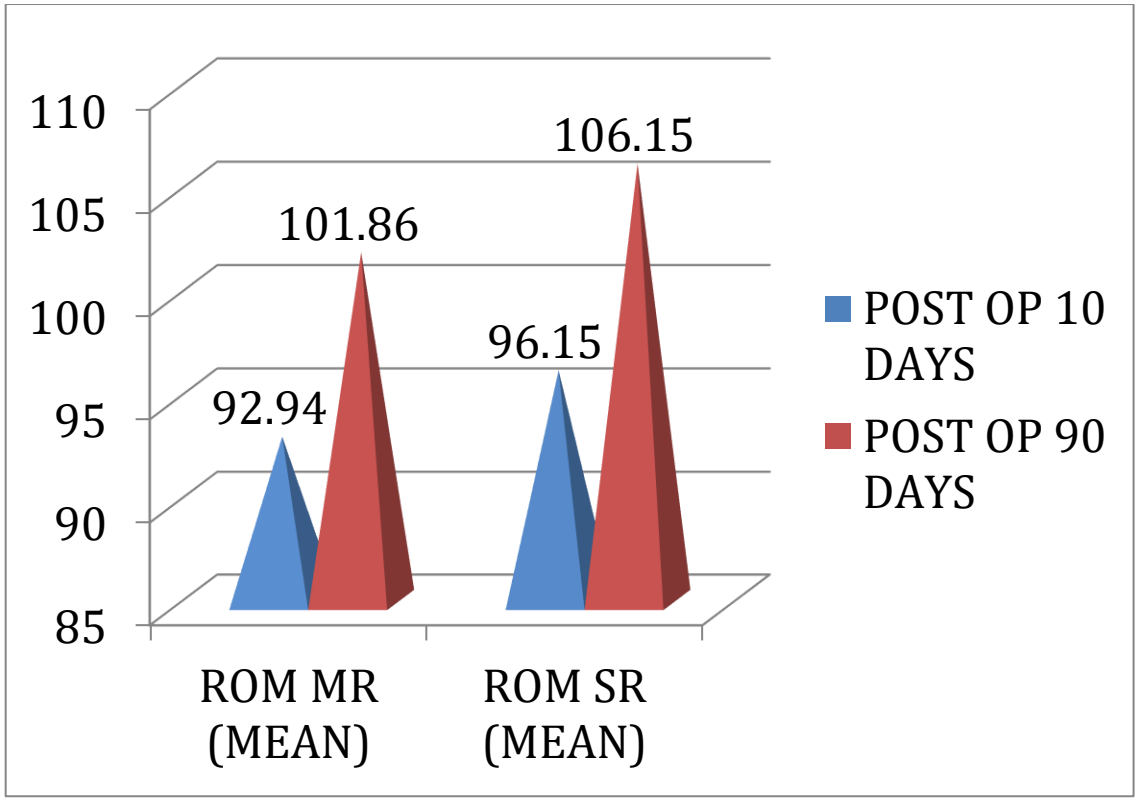


Figure 19: Mean knee range of motion at post op 10 and 90 days

CASE REPORT-1

Mrs X, 51 year old school teacher presented with complaints of pain in her left knee for the past 2 years which was aggravated on walking long distances and also on stair climbing. There were no known co morbidities.

On examination of the left knee, she was found to have a knee range of motion of 10-100 degrees with a fixed flexion deformity of 10 degrees. There was no varus valgus deformity noted.

She was diagnosed to have osteoarthritis of the knee joint and was suggested to undergo total knee replacement.

Her pre op X rays were the following:

Figure 20: Pre op AP X rays

Figure 21: Pre op lateral X rays

It was decided to place a single radius total knee design and the single raidus implant used was the DJO 3DKnee^{TM} system. The pre op scores were done according to the knee society scores and her functional score was found to be 50 and her knee score was 60. She underwent the above described post op protocol for total knee replacement and she was evaluated in the 10 days and 90 days post op period. Her 10 days post op knee score according to the knee society scoring was found to be 75 and her functional knee score was found to be 30. The range of movement in the 10 days post op was 0-90 degrees with no lag and also no fixed flexion deformity.

Figure 22: Post op X rays with AP and lateral views

In the post op 90 days period her knee score according to the knee society scoring was found to be 92 and her functional knee score was found to be 70. The range of movement was 0-110 degrees and there was also no lag and no varus deformity noted.

She was able to ambulate without the help of crutches and could also walk for a period of 15-20 minutes without difficulty.

Figure 23: Post op clinical pictures of patient with knee flexion

Figure 24: Post op Pictures with no lag and varus deformity at 90 days post op

CASE REPORT-2

Mr Y, 61 year old school businessman presented with complaints of pain in his bilateral knee with more pain in the right knee compared to the left knee for the past 4 years which was aggravated on walking and stair climbing. His ambulation was mainly restricted indoors due to the pain and there was also difficulty in using public transportation due to the pain. There were no known co morbidities.

On examination of the right knee, he was found to have a knee range of motion of 10-100 degrees with a fixed flexion deformity of 10 degrees. There was also a varus deformity of 20 degrees noted.

He was diagnosed to have osteoarthritis of the knee joint and was suggested to undergo total knee replacement.

His pre op X rays were the following:

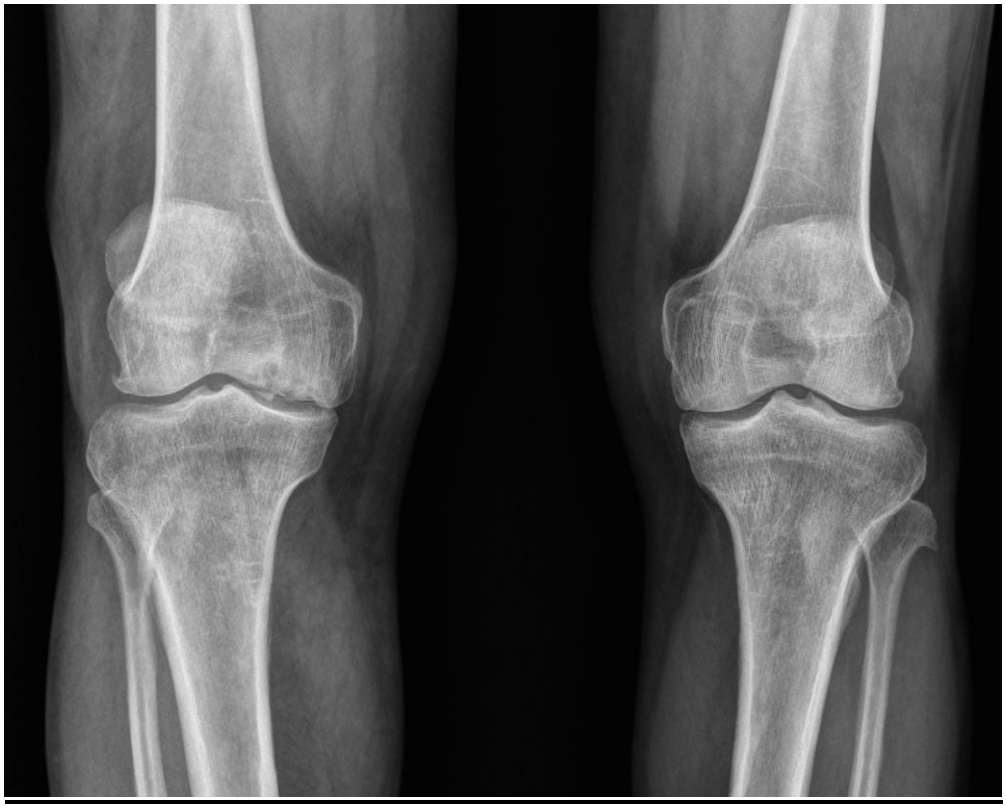


Figure 25: Pre op X rays with AP and lateral views

It was decided to place a multi radius total knee design and the implant used was the Smith & Nephew Genesis II system. The pre op scores were done according to the knee society scores and functional score was found to be 50 and knee score was 28. He underwent total knee replacement and was placed on the similar post op protocol after total knee replacement and the scoring was done in the post op period. The 10 days post op knee score according to the knee society scoring was found to be 75 and functional knee score was found to be 30. The range of movement in the 10 days post op was 0-110 degrees with no lag and also no fixed flexion deformity.

Figure 26: Post op AP X rays

Figure 27: Post op lateral X rays

Figure 28: Post op clinical pictures with no flexion deformity

Figure 29: Post op clinical picture with flexion of knee joint

Figure 30: Post op clinical pictures at 10 days with minimal lag

In the post op 90 days period knee score according to the knee society scoring was found to be 87 and functional knee score was found to be 70. The range of movement was 0-110 degrees and there was also no lag and no varus deformity noted.

He was able to ambulate without the help of crutches and could also walk for a period of 10-15 minutes without difficulty. There was also no difficulty in climbing stairs.

DISCUSSION

At present total knee replacement remains the most successful and commonly performed elective procedures in orthopedics. There is a clear evidence of a positive impact on patient satisfaction. An aging population is clearly likely to demand for an increase in arthroplasty procedures (52,53). It has also been documented that nearly 20-30% of patients are dissatisfied after total knee replacements. About 30% of patients may also have persistent knee pain at mid term follow up (54). In addition, instability is also the second most common reason for revision after total knee replacement, which is a more common reason than infection and polyethylene wear (55). Siting these above reasons there is a continuous need to evaluate the implications of change in implant design and arthroplasty technique. As a result implant manufacturers have focused on developing prosthetic knee devices that can simulate the normal knee kinematics.

The present study was an observational cohort based study and compared the functional and anatomical parameters by the knee society scoring in between the single radius total knee arthroplasty design and multi radius total knee arthroplasty design.

To ensure that the similar groups were selected both the groups had similar inclusion and exclusion criteria and both the groups followed the same surgical and post op surgical protocol. The main purpose of this study was to evaluate if there were any of the perpetrated theoretical advantages of the single radius

total knee design over the multi radius design in terms of functional outcomes by the knee society scoring.

This study failed to detect any clinically relevant difference in between the two groups of study design. However statistical difference was achieved in the functional knee score at the post op 10 days period in between the two total knee arthroplasty designs, that is the single radius and multi radius designs. But however in the post op 90 days there was no statistical difference that was noted in the functional knee scoring and also in the knee scoring by the knee society scoring system. Excellent results were achieved in both the groups involved in the study.

The multi radius arthroplasty implant was designed to match the normal femoral anatomy on the basis of anatomical studies prior to the introduction of the single radius design. In contrast the single radius design had a single radius of rotation which was designed primarily to avoid instability, by maintaining the isometry of the collateral ligaments throughout the range of motion (56). Single radius also has the potential to improve the quadriceps function compared to multiple radius by decreasing the patellofemoral moment arm. The MR knee was previously thought to be the gold standard for total knee arthroplasty as it correlated with the multiple simultaneous pivot points of knee flexion and extension that exist in a normal knee (57). The SR knee has a single point of rotation that is centered on the transepicondylar axis. This allows for uniform movement, lower contact stress on the inlay, better mid flexion stability (58).

A Meta analysis conducted by Liu et al, examined the differences in between the single radius designs and the multi radius designs with regard to the postoperative knee society scoring, range of motion, complications and also survival rate. The Meta analysis found that the single radius prosthesis in total knee arthroplasty is not significantly different from the multi radius prosthesis in terms of knee society scoring, complications and survival rate (59). In a study by Jo et al, postoperative clinical outcomes of 58 patients with a single radius design and 58 patients with a multi radius design were assessed by range of motion, Hospital for Special Surgery (HSS) score, Western Ontario McMaster Universities Osteoarthritis Index (WOMAC), and the Visual Analogue Scale (VAS) for knee joint pain during stair climbing. The study had a follow up period of 24-48 month period. It was found that there was no statistical difference in between the two patient groups (56).

This study has similarly demonstrated that the postoperative standardized knee society scores such as the knee society scoring and the functional knee scoring along with the knee range of motion and the visual analog scale for stair climbing and walking are not significantly different in between the single radius and multi radius total knee arthroplasty.

There was however a significant difference which was found in the 10 days postoperative period of patients with the functional knee scores with the patients who underwent total knee arthroplasty with a single radius design. But the there was no significant difference seen in the 90 days postoperative period. The mean range of motion was also seen to be more in the single radius designs

in both the 10 days postoperative period and at the 90 days postoperative period. But there was no significant difference noted in between the same at the end of 10 days and 90 days postoperative period. But however in agreement with findings from Tarabichi et al, this finding had no relation to the knee scoring and the functional knee scoring. Other studies examining postoperative knee range of motion have also revealed that improved knee flexion does not relate to improve clinical outcomes (60–62).

The visual analog scale for pain in stair climbing and walking did not show any significant difference in the postop 10 days and 90 days period in between the single radius and multi radius designs.

The differences in between the single radius and multi radius designs that are mainly theoretical and biomechanical, there have been several basic science studies done to examine and compare the two types of implants (39,63). However, the theoretical superiority of the single radius designs over the multi radius designs did not translate directly to an improvement in the clinical outcomes. Since there has been a shift of focus from revision surgery to patient satisfaction as an end point of arthroplasty, it is vital to measure the patient reported outcome measures (64).

There was a significant relationship found in the present study, which showed that there was a relationship with increased Body mass index in women with osteoarthritis. Women with high Body mass index showed increased incidence of osteoarthritis and also underwent total knee arthroplasty. In a cohort based study of 1420 patients by Felson et al, it was reported that the incidence of

obese individuals to develop osteoarthritis was 1.5 to 2 times more than their leaner counterparts (65). Fowler et al also found that an increase in the body mass index by 5kg/m^2 showed an increase by 32% in the probability of osteoarthritis and also letpin contributed to approximately half the total effect of obesity on osteoarthritis of the knee joint (66). Murphy et al found that the lifetime risk of osteoarthritis of the knee joint was 40% in men and was 47% for women and the risk rises by 60% if the body mass index is 30kg/m^2 or more (67).

The significant strength of this study was that a single high volume surgeon in a tertiary care institution performed all surgeries. All the patients who were included in the study satisfied the inclusion and exclusion criteria and patients with complications in the postoperative period were excluded to limit the bias while measuring the knee society scores in the postoperative period. All patients in the study underwent the similar postoperative protocol. The physiotherapist was blinded to the type of implant used to avoid bias. There was also consistent use of similar implants in the single radius and multi radius designs, that were mentioned earlier, that allowed to compare the group of implants directly in the two patient groups. The study also used a validated questionnaire to assess the outcome measures.

LIMITATIONS

A major limitation of this study was that the study was a prospective cohort based study and was not randomized. The cohort-based study could have caused bias in the selection of the patients as to which patient received which type of prosthesis and this could affect the final results in the study. But since a single surgeon recruited the patients and also performed the surgeries the chances of bias were limited.

There were also multiple implants used in the study, minor differences in the implant designs could have introduced confounding factors in the data analysis.

Furthermore another limitation of the study was that the rate of minor complications like superficial skin infections were not be reported as most of the follow up of patients were done on an outpatient basis and minor complications were not reported.

The follow up period in the postoperative period was very short and probably longer follow up studies could show significant changes in the outcome of the patients, which could also assess the polyethylene wear and tear.

Also the patients in each cohort that received the single radius or the multi radius design were not equal in number and that could also affect the outcome measures. But since the study was adequately powered it was enough to detect any changes in the outcome measures.

The study also did not include a radiographic analysis of the joint line to assess changes from the baseline values to the 90 days follow up period.

Also a multi centric study where there are primary high volume arthroplasty surgeons could bring about significant changes in measuring the outcome measures and comparing the differences in the single radius and multi radius designs.

CONCLUSIONS

- In conclusion it was found that there was no significant differences in both the prosthesis designs and there was also no superiority found in the single radius design over the multi radius design.
- In addition there were also significant changes seen in the pain scores in both stair climbing and walking during the 10 days and 90 days postoperative period irrespective of the implant chosen.
- There were also significant changes in the range of movement in both the knee designs comparing the pre op and post op periods.
- There was a positive correlation that was found to be significant established between an increased body mass index and osteoarthritis in female patients.
- Overall our study corroborated with earlier studies which showed that there was no significant differences in both the prosthesis designs (56,59).

FUTURE RESEARCH SUGGESTIONS

- A multicentre study with a larger number of patients enrolled to study the differences in between the two implant designs.
- Randomization of the groups to reduce bias in the study groups.
- Longer post op follow up period to study the effect of the implant designs on the functional outcomes.

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ANNEXURES

1. Abstract
2. Patient information sheet
3. Consent forms
4. Clinical research form
5. Scores Used
6. IRB and Fluid Grant approval
7. Thesis Data

ANNEXURE 1

ABSTRACT

TITLE OF ABSTRACT: COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENT

DEPARTMENT: ORTHOPEDICS

NAME OF CANDIDATE: REUBEN CEDRIC NAPPOLY

DEGREE AND SUBJECT: M.S. ORTHOPEDICS

NAME OF THE GUIDE: Prof. Dr. ALFRED JOB DANIEL

OBJECTIVES:

The main objective of this study was to compare functional outcome in patients who have undergone a single-radius (SR) or multi-radius (MR) total knee arthroplasty (TKA). The secondary objective was to observe changes in knee range of movement (ROM) and standardized knee scores (KSCs) in these patients. The hypothesis was that there would be a statistically significant difference between the two patient groups in functional outcome.

METHODS:

Thirty unilateral Total knee replacements were performed by a single surgeon from July 2017 till April 2018 secondary to Osteoarthritis of the knee joint. It was a prospective cohort based study that included patients from the age of 18-90 years. Preoperative and postoperative functional outcomes at 10 days and 90

days were calculated by the Knee society scoring and then analyzed. There were 13 unilateral total knee replacements done with a single radius design and 17 unilateral total knee replacements done with a multi radius design. The single radius designs used in the study were DJO 3DKnee™ system, Zimmer Biomet Vanguard® system and multi radius designs were Smith & Nephew Genesis II system and DePuy P.F.C.®SIGMA® Knee system. Analysis was done via t-test for analysis of continuous data with Normal distribution and Mann-Whitney U test for data with non- Normal distribution with group (SR & MR). Differences were considered significant at $p<0.05$.

RESULTS:

At 10 days postoperatively, there was a statistically significant difference between the SR and MR patient populations in terms of functional knee scoring by the knee society scoring ($p<0.05$). No significant difference was noted in the knee society scoring, Knee range of motion, and Visual analog scale for pain at 10 days and 90 days post op. There was a statistically significant difference between the body mass index of women who underwent total knee replacements and men who underwent total knee replacements ($p<0.05$).

CONCLUSION:

While an SR femoral implant design has several theoretical biomechanical advantages, postoperative standardized Knee Society scores in this single-surgeon series do not show a clear advantage of one design over the other.

KEYWORDS: Single radius, Multi radius, Total knee replacement, Knee Society Scoring system

ANNEXURE - 2

INFORMATION SHEET

I, Dr Reuben Cedric Nappoly, am planning to do a research study on the COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENTS. I will be studying the out comes of the single radius and multi radius total knee designs and comparing the functional outcomes in between the two groups. Through this study I will also be trying to describe if there are any differences in the outcomes in patients who receive the single radius designs in comparison to the more commonly used multi radius designs. To do this study I will be collecting information from the details provided by you after you underwent the surgery and how you have improved in terms of function, range of movement and correction of deformity. These details you will be providing will be studied along with those provided by other patients to identify if there is any difference in the functional outcome in between the two designs of the total knee replacement designs. The details you will be providing will be held in confidentiality and any mention will be with research numbers, which will be allotted to each subject. There won't be any additional cost or benefits in participating in the study. Your participation in the study is completely voluntary and you have the right to leave the study any time you chose with no change in your treatment or any loss of benefits as a patient. For more details you can contact me in the following address or mobile number.

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தகவல் தாள்

நான், டாக்டர். ரூபன் சிட்ரிக் நப்போளி, ஒற்றை ஆரம் vs பல ஆரம் மொத்த முழங்கால் மாற்று சிகிச்சையில் குறுகிய மற்றும் இடைநிலை கால செயல்பாட்டின் விளைவுகளை ஒப்பிட்டு ஆராய்ச்சி செய்ய முடிவு செய்துள்ளேன். ஒற்றை ஆரம் மொத்த முழங்கால் மாற்று சிகிச்சை மூலம் பெற்ற செயல்பாட்டு விளைவுகளையும் ஒப்பிட்டு பார்க்கபோகிறேன். இந்த ஆராய்ச்சியின் மூலம் ஒற்றை ஆரம் மொத்த முழங்கால் மாற்று சிகிச்சை பெறும் நோயாளிகளுக்கும், பொதுவாக பயன்படுத்தப்படும் பல ஆரம் மொத்த முழங்கால் மாற்று சிகிச்சை பெற்ற நோயாளிகளுக்கும் வித்தியாசங்கள் உள்ளன. எவை என்று ஆராய்ச்சி செய்யப்படும். இந்த ஆராய்ச்சி செய்ய தங்களிடம் சிகிச்சைக்கு பின்பு உங்கள் குறைப்பாடு திருத்தம், அசைவு, முன்னேற்றம் இருக்கிறதா என சில கேள்விகள் கேட்கப்படும். தாங்கள் அளிக்கும் ஒவ்வொரு தகவல்களும் மற்ற நோயாளிகளுடன் ஒப்பிட்டு பார்த்து மொத்த முழங்கால்மாற்று சிகிச்சையின் இரு ஆரத்தின் செயல்பாட்டில் வித்தியாசங்கள் உள்ளன எவை என்று கண்டறியப்படும். நீங்கள் அளிக்கும் ஒவ்வொரு தகவல்களும் தனித்தனியே ஆய்வு எண் அளிக்கப்பட்டு ரகசியமாக கண்காணிக்கப்படும். இந்த ஆராய்ச்சியில் சேர எந்த ஒரு அதிக மருத்துவ செலவோ வசூலிக்கப்படமாட்டாது. தங்களுடைய முழு விருப்பத்துடன் இந்த ஆய்வில் நீங்கள் சேரலாம், விருப்பமில்லை என்று நினைத்தால் இந்த ஆய்விலிருந்து எந்நேரமும் நீங்கள் இதைவிட்டு வெளியேறலாம், அதனால் தங்களுடைய சிகிச்சைக்கோ, மருத்துவ சலுகைக்கோ எவ்வித பாதிப்பு ஏற்படாது என்று தெரிவிக்கப்படுகிறது.

மேலும் விவரங்களுக்கு அணுக வேண்டிய முகவரி எண்.

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मैं, डॉ रूबेन सेड्रिक नाप्पोली, लघु और मध्यम अवधि के कामकाज के निष्कर्षों पर एक शोध अध्ययन करने की योजना बना रहा हूं, एकल रेडियस वी.एस. मल्टी रेडियस के कुल कन्नी प्रतिस्थापन मैं अध्ययन कर रहा हूँ | बाहर एकल त्रिज्या और बहु त्रिज्या कुल घुटने के डिजाइन की आता है और दोनों समूहों के बीच कार्यात्मक परिणामों की तुलना कर रहा हूँ । इस अध्ययन के माध्यम से मैं यह भी वर्णन करने का प्रयास करूँगा कि यदि रोगियों में परिणाम में कोई मतभेद हैं जो अधिक सामान्यतः इस्तेमाल किए गए मल्टी त्रिज्या डिज़ाइनों की तुलना में एकल त्रिज्या डिजाइन प्राप्त करते हैं यह अध्ययन करने के लिए मैं सर्जरी के दौरान आपके द्वारा दिए गए विवरणों से जानकारी एकत्र कर दूँगा और आप कार्य के संदर्भ में कैसे सुधार आया है, आंदोलन की श्रेणी और विकृति के सुधार ये विवरण जो आप उपलब्ध कराएंगे वे अन्य रोगियों द्वारा प्रदान किए गए उन लोगों के साथ अध्ययन करेंगे जिनकी पहचान कुल घुटने के प्रतिस्थापन डिजाइन के दो डिजाइनों के बीच कार्यात्मक परिणाम में कोई अंतर है। आपके द्वारा प्रदान किए जाने वाले विवरण गोपनीयता में आयोजित किए जाएंगे और कोई भी उल्लेख अनुसंधान संख्या के साथ होगा, जिसे प्रत्येक विषय के लिए आवंटित किया जाएगा। अध्ययन में भाग लेने में कोई अतिरिक्त लागत या लाभ नहीं होंगे। अध्ययन में आपकी भागीदारी पूरी तरह से स्वैच्छिक है और मरीज के रूप में आपके उपचार में कोई परिवर्तन नहीं होने या किसी भी लाभ के नुकसान के साथ आपके द्वारा चुनी गई किसी भी समय आपके पास अध्ययन छोड़ने का अधिकार है। अधिक जानकारी के लिए आप मुझसे निम्नलिखित पते या मोबाइल नंबर पर संपर्क कर सकते हैं।

डॉ रूबेन सेड्रिक नाप्पोली

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ANNEXURE-3

Consent form

Study Title: Comparison of short-term functional outcomes of single radius VS multi radius total knee replacements.
Study Number: _____
Subject's Initials: _____
Subect's Name: _____
Date of Birth / Age: _____

(i) I confirm that I have read and understood the information sheet dated _____ for the above study and have had the opportunity to ask questions. [ ]

(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]

(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]

(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree to take part in the above study. [ ]

Signature OR thumb impression of subject:

Signature of investigator:

Signature OR thumb impression of witness:

ஒப்புதல் வடிவம்

ஆய்வு தலைப்பு: பல ஆரம் மொத்த முழங்கால் மாற்றுக்களை வி ஒற்றை ஆரம் குறுகியகால செயல்பாட்டு வெளிப்பாடுகள் ஒப்பீடு.
ஆய்வு எண்: _____
தலைப்பு இன் ஆரம்பங்கள்: _____
உபதேசத்தின் பெயர்: _____
பிறந்த தேதி / வயது: _____

(நான்) மேற்கூறிய ஆய்வுக்காக _____ தேதியிட்ட தகவல் தாளை நான் படித்து புரிந்து கொண்டேன் என்பதையும், கேள்விகளைக் கேட்பதற்கான வாய்ப்பைப் பெற்றிருப்பதையும் உறுதிப்படுத்துகிறேன். []

(ஆ) இந்த ஆய்வில் பங்கேற்பது தன்னார்வமாக உள்ளது என்பதையும் நான் எப்போது வேண்டுமானாலும் விடுவிக்க முடியும் என்பதையும், என் மருத்துவ கவனிப்பு அல்லது சட்ட உரிமைகள் பாதிக்கப்படாமல், எந்த காரணமும் அளிக்காமல் இருப்பதையும் புரிந்துகொள்கிறேன். []

(III) நடப்பு ஆய்வு மற்றும் நடத்தப்படும் எந்த ஆராய்ச்சியிலும் எனது மருத்துவ பதிவேடுகளைப் பார்க்க மருத்துவ உதவியாளர், ஒழுக்கவியல் குழு மற்றும் நெறிமுறைக் குழு ஆகியவற்றில் பணியாற்றும் மற்றவர்கள், மருத்துவ பரிசோதனைக்கான ஸ்பான்சர் இது தொடர்பாக, நான் விசாரணையில் இருந்து விலகி விட்டாலும் கூட. இந்த அணுகலை நான் ஏற்கிறேன். இருப்பினும், மூன்றாம் தரப்பினருக்கு வெளியிடப்பட்ட எந்த தகவல்களுடனும் வெளியிடப்படவோ அல்லது வெளிப்படவோ வெளியிடப்படமாட்டாது என்பதை நான் புரிந்து கொள்கிறேன். []

(IV) இத்தகைய பயன்பாடு விஞ்ஞான நோக்கம் (கள்) க்கு மட்டுமே வழங்கப்பட்ட இந்த ஆய்வுகளிலிருந்து எழும் எந்தவொரு தரவு அல்லது முடிவுகளின் பயன்பாட்டைக் கட்டுப்படுத்துவதில்லை என்பதை நான் ஒப்புக்கொள்கிறேன். []

(V) மேலே உள்ள படிப்பில் பங்கேற்க நான் ஒப்புக்கொள்கிறேன். []

பொருள் கையொப்பம் அல்லது கட்டைவிரல் உணர்வை:

புலன்விசாரணை கையொப்பம்:

சாட்சி கையொப்பம் அல்லது கட்டைவிரல் உணர்வை:

सहमति फॉर्म

अध्ययन शीर्षक: बहु त्रिज्या कुल घुटने प्रतिस्थापन वी.एस. एकल त्रिज्या के अल्पावधि कार्यात्मक परिणामों की तुलना

अध्ययन संख्या: _____

विषय के आरंभिक: _____

सब्जेक्ट का नाम: _____

जन्म तिथि / आयु की तारीख: _____

(1) मैं पुष्टि करता हूं कि मैंने उपरोक्त अध्ययन के लिए _____ के सूचना पत्र को पढ़ और समझ लिया है और सवाल पूछने का अवसर मिला है□ []

(2) मैं समझता हूं कि अध्ययन में मेरी भागीदारी स्वैच्छिक है और मैं किसी भी समय बिना किसी कारण के बिना किसी भी समय वापस लेने के लिए स्वतंत्र हूं, मेरी चिकित्सा देखभाल या कानूनी अधिकारों के बिना प्रभावित हो रहा है□ []

(3) मैं समझता हूं कि प्रायोजक की ओर से काम करने वाले दूसरे, नैदानिक परीक्षण के प्रायोजक, एथिक्स कमेटी और नियामक प्राधिकरणों को मौजूदा अध्ययन के संबंध में अपने स्वास्थ्य के रिकॉर्ड दोनों को देखने की मेरी अनुमति की आवश्यकता नहीं होगी और जो आगे की शोध इसके संबंध में, यहां तक कि अगर मैं परीक्षण से वापस लेता हूं मैं इस पहुंच से सहमत हूं□ हालांकि, मैं समझता हूं कि मेरी पहचान तीसरी पार्टी के लिए जारी किसी भी जानकारी या प्रकाशित में प्रकट नहीं होगी□ []

(4) मैं इस अध्ययन से उत्पन्न होने वाले किसी भी डेटा या परिणामों के उपयोग को प्रतिबंधित करने के लिए सहमत नहीं हूं, बशर्ते ऐसा उपयोग केवल वैज्ञानिक उद्देश्य (प्रयोजनों) के लिए है□ []

(5) मैं उपरोक्त अध्ययन में भाग लेने के लिए सहमत हूं□ []

विषय के हस्ताक्षर:

ANNEXURE -4

STUDY TITLE:

COMPARISON OF SHORT TERM FUNCTIONAL OUTCOMES OF SINGLE RADIUS VS MULTI RADIUS TOTAL KNEE REPLACEMENTS

PATIENT ID:

NAME:

HOSPITAL NUMBER:

AGE:

SEX:(M/F)

HEIGHT:

WEIGHT:

BODY MASS INDEX:

OCCUPATION:

RELIGION:

ADDRESS:

DATE OF DATA ENTRY:

PHONE NUMBER:

EMAIL:

ADMISSION DETAILS

DATE OF ADMISSION:

DATE OF DISCHARGE:

WARD:

PRE OPERATIVE DETAILS

CHARNLEY FUNCTIONAL CLASSIFICATION:

SURGERY SIDE:

ANATOMIC ALIGNMENT:

RANGE OF MOTION:

LAG:

FIXED FLEXION DEFORMITY:

PAIN SCORE:

- WALKING:
- STAIR CLIMBING:

FUNCTIONAL KNEE SCORE:

KNEE SCORE:

POST OP DETAILS AT 10 DAYS AND 90 DAYS

ANATOMIC ALIGNMENT:

RANGE OF MOTION:

LAG:

FIXED FLEXION DEFORMITY:

IMPLANT USED:

PAIN SCORE:

- WALKING:
- STAIR CLIMBING:

FUNCTIONAL KNEE SCORE:

KNEE SCORE:

ANNEXURE – 5

Appendix 1

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KNEE SOCIETY SCORE: PRE-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex O Male O Female

6- Side of this (symptomatic) knee O Left O Right
If both knees will be operated on, please use a different form for each knee

7- Ethnicity
O Native Hawaiian or other Pacific Islander O American Indian or Alaska Native O Hispanic or Latino
O Arab or Middle Eastern O African American or Black O Asian O White

8- Please indicate the expected date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Will this be a primary or revision knee replacement?
O Primary O Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis
B1 Unilateral TKA, opposite knee arthritic
B2 Bilateral TKA
C1 TKR, but remote arthritis affecting ambulation
C2 TKR, but medical condition affecting ambulation
C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS

(To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

O Always (5 pts) O Sometimes (3 pts) O Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATIONS (To be completed by patient)

What do you expect to accomplish with your knee replacement:

1- Do you expect your knee joint replacement surgery will relieve your knee pain? **(5 points)**

- O no, not at all (1 pt)
- O yes, a little bit (2 pts)
- O yes, somewhat (3 pts)
- O yes, a moderate amount (4 pts)
- O yes, a lot (5 pts)

2- Do you expect your surgery will help you carry out your normal activities of daily living? **(5 points)**

- O no, not at all (1 pt)
- O yes, a little bit (2 pts)
- O yes, somewhat (3 pts)
- O yes, a moderate amount (4 pts)
- O yes, a lot (5 pts)

3- Do you expect you surgery will help you perform leisure, recreational or sports activities? **(5 points)**

- O no, not at all (1 pt)
- O yes, a little bit (2 pts)
- O yes, somewhat (3 pts)
- O yes, a moderate amount (4 pts)
- O yes, a lot (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? (0 points)

O Yes O No

2 - If no, which of the following aid(s) do you use? (-10 points)

O wheelchair (-10 pts) O walker (-8 pts) O crutches (-8 pts) O two canes (-6 pts)

O one crutch (-4 pts) O one cane (-4 pts) O knee sleeve / brace (-2 pts)

O other

3 - Do you use these aid(s) because of your knees? (0 points)

O Yes O No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? (15 points)

O cannot stand (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? (15 points)

O cannot walk (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	O	O	O	O	O	O	O	
2 - Turning or pivoting on your leg	O	O	O	O	O	O	O	
3 - Climbing up or down a flight of stairs	O	O	O	O	O	O	O	
4 - Getting up from a low couch or a chair without arms	O	O	O	O	O	O	O	
5 - Getting into or out of a car	O	O	O	O	O	O	O	
6 - Moving laterally (stepping to the side)	O	O	O	O	O	O	O	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	O	O	O	O	O	O	O	
2 - Carrying a shopping bag for a block	O	O	O	O	O	O	O	
3 - Squatting	O	O	O	O	O	O	O	
4 - Kneeling	O	O	O	O	O	O	O	
5 - Running	O	O	O	O	O	O	O	

Maximum points (25 points)

DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
- ☐ Road Cycling (>30mins)
- ☐ Gardening
- ☐ Bowling
- ☐ Racquet Sports (Tennis, Racquetball, etc.)
- ☐ Distance Walking
- ☐ Dancing / Ballet
- ☐ Stretching Exercises (stretching out your muscles)

Workout and Gym Activities

- ☐ Weight-lifting
- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	O	O	O	O	O	O	
2.	O	O	O	O	O	O	
3.	O	O	O	O	O	O	
						Maximum points (15 points)	

Maximum total points (100 points)

KNEE SOCIETY SCORE: POST-OP

DEMOGRAPHIC INFORMATION (To be completed by patient)

1- Today's date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

2- Date of birth ☐☐ / ☐☐ / ☐☐☐☐

3- Height (ft' in") ☐ ☐☐

4- Weight (lbs.) ☐☐☐

5- Sex O Male O Female

6- Side of this (surgically treated) knee O Left O Right
If both knees have been operated on, please use a different form for each knee

7- Ethnicity

O Native Hawaiian or other Pacific Islander O American Indian or Alaska Native O Hispanic or Latino

O Arab or Middle Eastern O African American or Black O Asian O White

8- Please indicate date and surgeon for your knee replacement operation

Date ☐☐ / ☐☐ / ☐☐☐☐ Enter dates as: mm/dd/yyyy

Name of Surgeon ☐

9- Was this a primary or revision knee replacement?

O Primary O Revision

To be completed by surgeon

10- Charnley Functional Classification (Use Code Below) ☐

A Unilateral Knee Arthritis	C1 TKR, but remote arthritis affecting ambulation
B1 Unilateral TKA, opposite knee arthritic	C2 TKR, but medical condition affecting ambulation
B2 Bilateral TKA	C3 Unilateral or Bilateral TKA with Unilateral or Bilateral THR

OBJECTIVE KNEE INDICATORS (To be completed by surgeon)

ALIGNMENT

1- Alignment: measured on AP standing Xray (Anatomic Alignment) — **25 point max**

Neutral: 2-10 degrees valgus	(25 pts)
Varus: < 2 degrees valgus	(-10 pts)
Valgus: > 10 degrees valgus	(-10 pts)

INSTABILITY

2- Medial / Lateral Instability: measured in full extension — **15 point max**

None	(15 pts)
Little or < 5 mm	(10 pts)
Moderate or 5 mm	(5 pts)
Severe or > 5 mm	(0 pts)

3- Anterior / Posterior Instability: measured at 90 degrees — **10 point max**

None	(10 pts)
Moderate < 5 mm	(5 pts)
Severe > 5 mm	(0 pts)

JOINT MOTION

4- Range of motion (1 point for each 5 degrees)

Deductions

Flexion Contracture — **Minus Points**

1-5 degrees	(-2 pts)
6-10 degrees	(-5 pts)
11-15 degrees	(-10 pts)
> 15 degrees	(-15 pts)

Extensor Lag — **Minus Points**

<10 degrees	(-5 pts)
10-20 degrees	(-10 pts)
> 20 degrees	(-15 pts)

SYMPTOMS (To be completed by patient)

1- Pain with level walking (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

2- Pain with stairs or inclines (10 - Score)

0	1	2	3	4	5	6	7	8	9	10

none severe

3- Does this knee feel "normal" to you? (5 points)

O Always (5 pts) O Sometimes (3 pts) O Never (0 pts)

Maximum total points (25 points)

PATIENT SATISFACTION

1- Currently, how satisfied are you with the pain level of your knee while sitting? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

2- Currently, how satisfied are you with the pain level of your knee while lying in bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

3- Currently, how satisfied are you with your knee function while getting out of bed? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

4- Currently, how satisfied are you with your knee function while performing light household duties? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

5- Currently, how satisfied are you with your knee function while performing leisure recreational activities? (8 points)

O Very Satisfied (8 pts) O Satisfied (6 pts) O Neutral (4 pts) O Dissatisfied (2 pts) O Very Dissatisfied (0 pts)

Maximum total points (40 points)

PATIENT EXPECTATION (To be completed by patient)

Compared to what you expected before your knee replacement:

1- My expectations for pain relief were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

2- My expectations for being able to do my normal activities of daily living were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

3- My expectations for being able to do my leisure, recreational or sports activities were... **(5 points)**

- O Too High- "I'm a lot worse than I thought" (1 pt)
- O Too High- "I'm somewhat worse than I thought" (2 pts)
- O Just Right- "My expectations were met" (3 pts)
- O Too Low- "I'm somewhat better than I thought" (4 pts)
- O Too Low- "I'm a lot better than I thought" (5 pts)

Maximum total points (15 points) ☐

FUNCTIONAL ACTIVITIES (To be completed by patient)

WALKING AND STANDING (30 points)

1 - Can you walk without any aids (such as a cane, crutches or wheelchair)? (0 points)

O Yes O No

2 - If no, which of the following aid(s) do you use? (-10 points)

O wheelchair (-10 pts) O walker (-8 pts) O crutches (-8 pts) O two canes (-6 pts)

O one crutch (-4 pts) O one cane (-4 pts) O knee sleeve / brace (-2 pts)

O other

3 - Do you use these aid(s) because of your knees? (0 points)

O Yes O No

4 - For how long can you stand (with or without aid) before sitting due to knee discomfort? (15 points)

O cannot stand (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

5 - For how long can you walk (with or without aid) before stopping due to knee discomfort? (15 points)

O cannot walk (0 pts) O 0-5 minutes (3 pts) O 6-15 minutes (6 pts)

O 16-30 minutes (9 pts) O 31-60 minutes (12 pts) O more than an hour (15 pts)

Maximum points (30 points)

STANDARD ACTIVITIES (30 points)

How much does your knee bother you during each of the following activities?	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	I never do this	
1 - Walking on an uneven surface	O	O	O	O	O	O	O	
2 - Turning or pivoting on your leg	O	O	O	O	O	O	O	
3 - Climbing up or down a flight of stairs	O	O	O	O	O	O	O	
4 - Getting up from a low couch or a chair without arms	O	O	O	O	O	O	O	
5 - Getting into or out of a car	O	O	O	O	O	O	O	
6 - Moving laterally (stepping to the side)	O	O	O	O	O	O	O	

Maximum points (30 points)

ADVANCED ACTIVITIES (25 points)

1 - Climbing a ladder or step stool	O	O	O	O	O	O	O	
2 - Carrying a shopping bag for a block	O	O	O	O	O	O	O	
3 - Squatting	O	O	O	O	O	O	O	
4 - Kneeling	O	O	O	O	O	O	O	
5 - Running	O	O	O	O	O	O	O	

Maximum points (25 points)

DISCRETIONARY KNEE ACTIVITIES (15 points)

Please check 3 of the activities below that you consider *most important* to you.

(Please do not write in additional activities)

Recreational Activities

- ☐ Swimming
- ☐ Golfing (18 holes)
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- ☐ Leg Extensions
- ☐ Stair-Climber
- ☐ Stationary Biking / Spinning
- ☐ Leg Press
- ☐ Jogging
- ☐ Elliptical Trainer
- ☐ Aerobic Exercises

Please copy all 3 checked activities into the empty boxes below.

How much does your knee bother you during each of these activities?

Activity (Please write the 3 activites from list above)	no bother 5	slight 4	moderate 3	severe 2	very severe 1	cannot do (because of knee) 0	
1.	o	o	o	o	o	o	
2.	o	o	o	o	o	o	
3.	o	o	o	o	o	o	
						Maximum points (15 points)	

Maximum total points (100 points)

ANNEXURE – 6

IRB GRANT

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

November 15, 2017

Dr. Reuben Cedric Nappoly,
PG Registrar,
Department of Ortho - 3,
Christian Medical College,
Vellore – 632 002.

Sub: **Fluid Research Grant NEW PROPOSAL:**
Comparison of short term functional outcomes of single radius vs muti radius total knee replacements.
Dr. Reuben Cedric Nappoly, PG Registrar, Orthopedics Unit 3, Dr. Alfred Job Daniel (Emp. No. 11140), Orthopedics Unit 3, Dr. Abel Livingston (emp. No. 31610), Orthopedics Unit 3

Ref: IRB Min. No. 10786 [OBSERVE] dated 01.08.2017

Dear Dr. Reuben Cedric Nappoly,

I enclose the following documents:-

1. Institutional Review Board approval 2. Agreement

Could you please sign the agreement and send it to Dr. Biju George, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

Cc: Dr Alfred Job Daniel, Dept. of Orthopaedics, CMC, Vellore

1 of 4

OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
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Dr. Reuben Cedric Nappoly, PG Registrar, Orthopedics Unit 3, Dr. Alfred Job Daniel (Emp. No. 11140), Orthopedics Unit 3, Dr. Abel Livingston (emp. No. 31610), Orthopedics Unit 3

Ref: IRB Min. No. 10786 [OBSERVE] dated 01.08.2017

Dear Dr. Reuben Cedric Nappoly,

The Institutional Review Board **(Blue**, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project titled "Comparison of short term functional outcomes of single radius vs muti radius total knee replacements" on August 01st2017.

The Committee reviewed the following documents:

1. IRB Application Format
2. Information Sheet and Informed Consent Form (English, Tamil, Hindi)
3. Knee Society Score
4. Cvs of Drs. Reuben Cedric Nappoly, Alfred Job Daniel, Abel Livingston
5. No. of documents 1 - 4.

The following Institutional Review Board (Blue, Research & Ethics Committee) members were present at the meeting held on August 01st2017 in the Jacob Chandy Hall, Paul Brand Building, Christian Medical College, Vellore 632 004.

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

Dr. B.J. Prashantham, M.A., M.A., Dr. Min (Clinical)
Director, Christian Counseling Center,
Chairperson, Ethics Committee.

Dr. Anna Benjamin Pulimood, M.B.B.S., MD., Ph.D.,
Chairperson, Research Committee & Principal

Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Name	Qualification	Designation	Affiliation
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, Research), Additional Vice Principal , Deputy Chairperson (Research Committee), Member Secretary (Ethics Committee), IRB, CMC, Vellore	Internal, Clinician
Dr. B. J. Prashantham	MA(Counseling Psychology), MA (Theology), Dr. Min (Clinical Counselling)	Chairperson, Ethics Committee, IRB. Director, Christian Counseling Centre, VLR	External, Social Scientist
Dr. Jayaprakash Muliyil	BSc, MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist
Dr. RekhaPai	BSc, MSc, PhD	Associate Professor, Pathology, CMC, Vellore	Internal, Basic Medical Scientist
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL.	Sr. Legal Officer, CMC, Vellore	Internal, Legal Expert
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Ms. Grace Rebekha	M.Sc., (Biostatistics)	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Sowmya Sathyendra	MBBS, MD (Gen. Medicine)	Professor, Medicine III, CMC, Vellore	Internal, Clinician
Dr. Anuradha Rose	MBBS, MD, MHSC (Bioethics)	Associate Professor, Community Health, CMC, Vellore	Internal, Clinician
Dr. Thomas V Paul	MBBS, MD, DNB, PhD	Professor,Endocrinology, CMC, Vellore	Internal, Clinician
Dr. SnehaVarkki	MBBS, DCH, DNB	Professor, Paediatrics, CMC, Vellore	Internal, Clinician
Dr. Sathish Kumar	MBBS, MD, DCH	Professor, Child Health, CMC, Vellore	Internal, Clinician

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
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Dr. Biju George, M.B.B.S., MD., DM.,
Deputy Chairperson,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Mrs. Emily Daniel	MSc Nursing	Professor, Medical Surgical Nursing, CMC, Vellore	Internal, Nurse
Dr. AjithSivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician
Dr. Balamugesh	MBBS, MD(Int Med), DM, FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay Person
Dr. Mathew Joseph	MBBS, MCH	Professor, Neurosurgery, CMC, Vellore	Internal, Clinician
Dr. Shyam Kumar NK	MBBS, DMRD, DNB, FRCR, FRANZCR	Professor, Radiology, CMC, Vellore	Internal, Clinician
Dr. Vivek Mathew	MD (Gen. Med.) DM (Neuro)Dip. NB (Neuro)	Professor, Neurology, CMC, Vellore	Internal, Clinician
Dr. John Antony Jude Prakash	MBBS, MD	Professor, Clinical Microbiology, CMC, Vellore.	Internal, Clinician.

We approve the project to be conducted as presented.

Kindly provide the total number of patients enrolled in your study and the total number of Withdrawals for the study entitled: "Comparison of short term functional outcomes of single radius vs muti radius total knee replacements" on a monthly basis. Please send copies of this to the Research Office (research@cmcvellore.ac.in).

Fluid Grant Allocation:

A sum of 20,000/- INR (Rupees Twenty Thousand Only) will be granted for 12 Months.

Yours sincerely,

Dr. Biju George
Secretary (Ethics Committee)
Institutional Review Board

Dr. BIJU GEORGE
MBBS., MD., DM.
SECRETARY - (ETHICS COMMITTEE)
Institutional Review Board,
Christian Medical College, Vellore - 632 002.

IRB Min. No. 10786 [OBSERVE] dated 01.08.2017

Ethics Committee Blue, Office of Research, 1st Floor, Carman Block, Christian Medical College, Vellore, Tamil Nadu 632 002
Tel: 0416 – 2284294, 2284202 Fax: 0416 – 2262788, 2284481 E-mail: research@cmcvellore.ac.in

ANNEXURE-7

HOSPNO	NAME	BMI	AGE	SEX	FUNCTIONAL_CLASSIFICATIOI	SURGERY_SIE	ANATOMIC_ALIGNMENT_AP_XF
879125G	Nagendra Kumar Singh	27.9	58	1	2	2	1
842979	Karthikeyan	20.5	52	1	2	1	2
475805G	Rita Bhattacharya	33.7	52	2	2	1	2
363575D	Bhanamati	24.9	52	2	2	1	1
171280H	Arun Chandra Dey	28.7	56	1	2	2	1
138303H	Md Shafi Ahmed	34.2	60	1	2	2	3
122099H	Lilawati Devi	20.8	56	2	2	2	1
097826H	Mosammat Zahanara Begum	32	46	2	2	2	2
056176H	Mansur Khalifa	24.5	69	1	1	2	2
020440H	Farhat Bano	31.3	52	2	2	1	1
882857G	Rina Koley	32.2	56	2	2	1	2
854894g	Chaman Ara Begum	30.7	58	2	2	1	2
903177D	Sasikala	35.5	51	2	2	2	1
964033G	Narayanan	28.6	72	1	2	2	4
864130G	Mahendra Pandit	27.1	61	1	2	1	3
040266H	Sumitra Gosai	27	71	2	2	1	2
958005G	Rahima Yousuf	26.5	63	2	2	1	1
458060G	Lily Saha	28.3	40	2	2	2	5
306087d	Kamatchi Ammal	42.9	70	2	2	2	3
979090G	Chandi Charan Das	26.6	61	1	2	2	2
993856G	Sipra Roy	32.9	61	2	2	1	1
053342H	MST Sultana Begum	34	53	2	2	1	1
041115H	Ruzi Barua	32.9	54	2	2	1	1
173724F	Mary	24.4	67	2	2	1	1
894547G	Valliyammal	25.6	68	2	2	1	1
455149B	Shila Rakshit	26.6	63	2	2	2	1
862150G	Haran Chandra Biswas	28.9	70	1	2	2	2
120330H	Netai Chandra Pal	23.4	61	1	2	1	2
075958H	Uttara Roy	37.3	59	2	2	1	3
015318H	Purali Karmakar	28.6	65	2	2	2	1

ROM	FFD	LAG	WALKING	STAIRS	IMPLANT	FUNCTIONAL_KNEE_SCO	KNEE_SCORI	Group
120	1	1	8	8	#NULL!	25	48	1
90	2	1	7	8	#NULL!	40	47	1
80	2	1	7	8	#NULL!	50	42	1
90	1	1	8	8	#NULL!	25	54	1
90	1	1	7	8	#NULL!	50	54	1
90	1	1	8	8	#NULL!	40	33	1
90	2	1	6	7	#NULL!	25	39	1
110	2	1	8	8	#NULL!	40	53	1
120	2	1	8	8	#NULL!	55	50	1
100	2	1	8	8	#NULL!	40	56	1
90	2	1	9	9		40	48	1
90	2	1	8	9		50	34	1
100	2	1	7	8		50	60	1
80	2	1	8	8		40	26	1
90	2	1	8	8		50	28	1
90	2	1	8	9		60	56	1
110	1	1	7	8		25	51	1
100	3	1	9	9		20	20	1
110	1	1	9	9		20	31	1
110	1	1	7	7		50	56	1
110	2	1	7	8		50	42	1
110	2	1	9	9		25	41	1
90	1	1	8	9		40	37	1
100	1	1	7	8		25	51	1
110	2	1	8	9		25	36	1
80	2	1	9	9		10	32	1
120	1	1	7	8		25	51	1
90	1	1	8	8		25	46	1
80	2	1	9	9		10	31	1
100	4	1	9	9		5	21	1

879125G	Nagendra Kumar Singh	27.9	57	1	2	2	1
842979	Karthikeyan	20.5	52	1	2	1	1
475805G	Rita Bhattacharya	33.7	52	2	2	1	1
363575D	Bhanamati	24.9	52	2	2	1	1
171280H	Arun Chandra Dey	28.7	56	1	2	2	1
138303H	Md Shafi Ahmed	34.2	60	1	2	2	1
122099H	Lilawati Devi	20.8	56	2	2	2	1
097826H	Mosammat Zahanara Begum	32	46	2	2	2	1
056176H	Mansur Khalifa	24.5	69	1	1	2	1
020440H	Farhat Bano	31.3	52	2	2	1	1
882857G	Rina Koley	32.2	56	2	2	1	1
854894g	Chaman Ara Begum	30.7	58	2	2	1	1
903177D	Sasikala	35.5	51	2	2	2	1
964033G	Narayanan	28.6	72	1	2	2	1
864130G	Mahendra Pandit	27.1	61	1	2	1	1
040266H	Sumitra Gosai	27	71	2	2	1	1
958005G	Rahima Yousuf	26.5	63	2	2	1	1
458060G	Lily Saha	28.3	40	2	2	2	1
306087d	Kamatchi Ammal	42.9	70	2	2	2	1
979090G	Chandi Charan Das	26.6	61	1	2	2	1
993856G	Sipra Roy	32.9	61	2	2	1	1
053342H	MST Sultana Begum	34	53	2	2	1	1
041115H	Ruzi Barua	32.9	54	2	2	1	1
173724F	Mary	24.4	67	2	2	1	1
894547G	Valliyammal	25.6	68	2	2	1	1
455149B	Shila Rakshit	26.6	63	2	2	2	1
862150G	Haran Chandra Biswas	28.9	70	1	2	2	1
120330H	Netai Chandra Pal	23.4	61	1	2	1	1
075958H	Uttara Roy	37.3	59	2	2	1	1
015318H	Purali Karmakar	28.6	65	2	2	2	1

120	1	2	6	6	2	35	58	2
90	1	1	6	7	2	40	70	2
100	1	2	4	4	1	30	70	2
90	1	1	8	8	1	20	79	2
120	1	1	3	5	2	20	64	2
100	1	1	7	7	2	20	68	2
90	1	1	5	6	1	40	78	2
90	1	1	6	7	1	30	70	2
110	1	1	5	5	2	20	75	2
100	1	1	6	7	1	40	56	2
90	1	1	5	5	2	25	73	2
100	1	1	5	6	2	25	75	2
100	1	1	5	6	2	30	75	2
90	1	1	4	5	1	40	73	2
110	1	1	5	5	1	30	75	2
100	1	1	4	5	1	30	76	2
100	1	2	5	6	1	35	75	2
100	1	1	5	5	1	30	74	2
90	1	2	7	7	1	15	64	2
90	2	2	7	8	2	15	57	2
90	1	1	6	7	1	30	63	2
90	2	1	6	7	1	30	58	2
80	2	1	7	7	2	30	56	2
80	2	2	7	8	2	15	54	2
100	1	1	5	6	1	30	75	2
80	2	2	5	6	1	40	72	2
80	2	1	7	7	2	25	73	2
90	1	1	6	6	2	25	73	2
80	2	1	6	7	1	30	61	2
80	1	1	6	7	1	25	60	2

879125G	Nagendra Kumar Singh	27.9	57	1	2	2	1
842979	Karthikeyan	20.5	52	2	2	1	1
475805G	Rita Bhattacharya	33.7	52	2	2	1	1
363575D	Bhanamati	24.9	52	2	2	1	1
171280H	Arun Chandra Dey	28.7	56	1	2	2	1
138303H	Md Shafi Ahmed	34.2	60	1	2	2	1
122099H	Lilawati Devi	20.8	56	2	2	2	1
097826H	Mosammat Zahanara Begum	32	46	2	2	2	1
056176H	Mansur Khalifa	24.5	69	1	1	2	1
020440H	Farhat Bano	31.3	52	2	2	1	1
882857G	Rina Koley	32.2	56	2	2	1	1
854894g	Chaman Ara Begum	30.7	58	2	2	1	1
903177D	Sasikala	35.5	51	2	2	2	1
964033G	Narayanan	28.6	72	1	2	2	1
864130G	Mahendra Pandit	27.1	61	1	2	1	1
040266H	Sumitra Gosai	27	71	2	2	1	1
958005G	Rahima Yousuf	26.5	63	2	2	1	1
458060G	Lily Saha	28.3	40	2	2	2	1
306087d	Kamatchi Ammal	42.9	70	2	2	2	1
979090G	Chandi Charan Das	26.6	61	1	2	2	1
993856G	Sipra Roy	32.9	61	2	2	1	1
053342H	MST Sultana Begum	34	53	2	2	1	1
041115H	Ruzi Barua	32.9	54	2	2	1	1
173724F	Mary	24.4	67	2	2	1	1
894547G	Valliyammal	25.6	68	2	2	1	1
455149B	Shila Rakshit	26.6	63	2	2	2	1
862150G	Haran Chandra Biswas	28.9	70	1	2	2	1
120330H	Netai Chandra Pal	23.4	61	1	2	1	1
075958H	Uttara Roy	37.3	59	2	2	1	1
015318H	Purali Karmakar	28.6	65	2	2	2	1

120	1	1	3	3	2	50	80
100	1	1	5	6	2	45	70
100	1	1	5	5	1	70	87
100	1	1	4	5	1	60	84
120	1	1	3	3	2	60	74
100	1	1	3	4	2	50	79
110	1	1	5	5	1	50	70
90	1	1	3	3	1	60	88
110	1	1	4	5	2	60	80
100	1	1	3	4	1	50	82
100	1	1	2	3	2	70	90
110	1	1	3	4	2	50	87
110	1	1	2	2	2	70	92
100	1	1	2	3	1	70	92
110	1	1	2	2	1	70	87
110	1	1	2	3	1	60	88
110	1	1	3	3	1	60	87
100	1	1	2	2	1	70	90
100	1	1	4	5	1	50	75
90	2	1	5	6	2	45	59
100	1	1	2	3	1	55	85
100	1	1	3	3	1	60	85
100	1	1	3	3	2	60	76
90	1	1	4	5	2	50	73
110	1	1	2	2	1	70	87
90	2	1	3	4	1	60	74
120	1	1	2	2	2	70	94
110	1	1	2	2	2	60	87
100	1	1	3	4	1	60	85
90	1	1	3	3	1	60	73