

**A COMPARATIVE ANALYSIS OF THE CLINICAL AND
FUNCTIONAL OUTCOME OF HIGH FLEXION AND
STANDARD TOTAL KNEE REPLACEMENT
PROSTHESIS**

DISSERTATION FOR MCH ORTHOPAEDICS

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INTRODUCTION

Total Knee Replacement Arthroplasty today is the final treatment option provided to patients with unsalvageable, severely arthritic, painful and deformed knees [1, 2].

First used in late 1950s, early Total Knee Replacement implants poorly mimicked the natural motion of the knee and resulted in high failure and complication rates. Advances in Total Knee Replacement technology over the past 10 year have enhanced the design and fit of knee implant resulting in improved short and long term results [3-11].

Every year, approximately 300,000 Total Knee Replacement Arthroplasties are performed in United States alone for end stage arthritis. In India, the number in comparison is significantly lower but rapid progress is being made in this direction.

Total Knee Replacement Arthroplasty is a very successful and a low risk treatment option. It is a safe and cost effective treatment for alleviating pain and restoring physical function in patients unresponsive to non-surgical modalities of treatment [12,13].

Though the success story of Total Knee Replacement Arthroplasty is known well to us, questions remains concerning which material and implant design are most effective for specific patient population and which surgical technique is optimal for a successful outcome.

Physical, social and psychological issue may influence the success of Total Knee Replacement Arthroplasty and understanding patient difference could facilitate the decision making process before, during and after surgery thereby achieving the greatest benefit from Total Knee Replacement Arthroplasty. The requirements and the expectations of patients of the asian population are different as compare to the western world [14,15]. Armamentarium of implants is available but cost, technical familiarity and the needs of the patient have to be kept in the mind prior to surgery.

The original total condylar design was very successful in terms of pain relief and durability, but the average post-operative flexion achieved was only around 90–95° [16-22]. In 1978, the posterior stabilized condylar prosthesis was introduced, as a modification of the total condylar prosthesis by Insall et al [23]. In this prosthesis, a post and cam mechanism was used to achieve femoral rollback. The average flexion achieved by this prosthesis was 107–115° [22-27]. Similarly, cruciate retaining designs achieve a flexion of around 110–112°[28-29].

Although this was a significant improvement, it was not enough for daily habits like cross-legged sitting and squatting that are so common in Indian subcontinent. Keeping these cultural and ethnic variations in mind indigenous implant(Indus) were manufactured. These are cruciate substituting posteriorly stabilized design with numerous modifications done to achieve high flexion at the knee joint [14,30]. A recently published article showed excellent two year follow up for this implant [14]. Also INDUS knee ethnocentricity and high flex features might offer advantage over the PFC Sigma implant. Along with these advantages a need is also felt in terms of cost effectiveness

and affordability and requirement of an ideal artificial knee that would suit not only the Indian market, but also the Eastern world [31].

On the other hand PFC sigma is the most widely used foreign implant in this country and has shown to have good mid to long term results. [32,33,34]. The design of the Press-Fit Condylar (PFC) Total Knee Prosthesis (Johnson and Johnson, Raynham, Massachusetts, USA) was based on earlier successful implants such as the Total Condylar and Kinematic knees [25]. The Press Fit Condylar (PFC) was later changed to PFC Sigma with the main design changes being a deep and extended trochlear groove with a matching single radius dome all-polyethylene patella.

The present study aims to follow-up patients who had undergone total knee replacements and to compare the clinical and functional outcome after arthroplasty with standard versus hi flex designed implant. The current literature produces a very conflicting picture with most of the independent studies concluding that the Hi flex design features do not translate into improved function. However a study in population such as Indian population, for whom squatting and cross legged sitting is quite important, will be more indicative.

AIMS AND OBJECTIVES

- 1) To compare the functional outcome of standard knee with high flexion prosthesis
- 2) To study the advantages of high flexion knee over the standard prosthesis

REVIEW OF LITERATURE

A review of literature was performed to understand the current literature and evidence.

Following headings were used for review.

I] Anatomy of the knee joint

II] Biomechanics of the knee joint

III] Evolution of TKR

IV] High Flex and Standard implants

V] Design specification of study implants

I) Anatomy

Knee joint is a hinge joint between the lower end of Femur and the upper end of Tibia and a saddle joint between the Patella and the Femur, rightly called a compound synovial joint. Knee joint is the most remarkable joint in the body by any engineering standards. During complete extension, it is very stable, and during flexion, it is very mobile.

Knee motion occurs in flexion and extension, abduction and adduction and rotation about the long axis of the limb. Knee flexion, which occurs about a varying transverse axis, is a function of both the articular geometry of the knee and the ligamentous restraints.

TIBIA

Medial Tibial Plateau is slightly concave and the Lateral Plateau is slightly convex. In the sagittal plane, the tibial condyles slopes posteriorly approximately 10 degrees.

Trabecular bone strength is significantly reduced at distances greater than 5 mm from the surface.

FEMUR

The femoral condyles are asymmetric with medial condyle being smaller in the anteroposterior and mediolateral dimension. This accounts for the normal rotation of the tibia during extension. The sagittal curvature of the condyles has a radius that decreases posteriorly during extension. In contrast to the tibia, femoral trabecular bone strength is greater with increased distance from the subchondral plate. Medial femoral condyle is slightly broader and projects more anteroinferiorly than the lateral condyle.

PATELLO FEMORAL JOINT

The primary function of the patella is to increase the lever arm of the extensor mechanism about the knee, thus improving the efficiency of quadriceps contraction. The quadriceps and patellar tendons insert anteriorly on the patella, with the thickness of the patella displacing their respective force vectors away from the center of rotation of the knee. This displacement or lengthening of the extensor lever arm changes throughout the arc of knee motion. The length of the lever arm varies as a function of the geometry of the trochlea, the varying patellofemoral contact areas and the varying center of rotation of the knee.

According to Grood et al [35] the extensor lever arm is greatest at 20 degrees of flexion and the quadriceps force required for knee extension increases significantly in the last 20 degrees of extension.

II) Biomechanics of knee joint

Anatomically, knee is classified as diarthrodial or freely mobile joint of ginglymus (hinge) and trachoid (pivot) joint. However several kinematics studies have confirmed that knee motion is not that of a simple hinge but is an extremely complex series of movements about variable axes in 3 separate planes during course of normal gait cycle.

MOVEMENTS

Flexion and Extensions in the sagittal plane are about a constantly changing centre of rotation. When plotted, the path of this changing centre of rotation describes a J shaped curve around femoral condyles. Flexion and Extension are accomplished by both rolling and gliding motions about femoral condyles.

Abduction-Adduction occurs in coronal plane and internal and external rotation in a transverse plane.

Motion in knee occurs in three separate planes during course of normal gait cycle and is therefore referred to as tri-axial motion.

KINEMATICS

Static Stabilizers

Stabilizers of knee joint can be explained by Nicola's Quadruple complexes

A. Medial Quadruple Complex-

- a) Tibial collateral ligament
- b) Semi-Membranous (medial Hamstring)
- c) Pes Anserinus
- d) Oblique Popliteal Ligament

B. Lateral Quadruple complex-

- a) Fibular collateral ligament.
- b) Biceps femoris (lateral hamstring)
- c) Popliteus tendon
- d) Arcuate ligaments.

C. Cruciate ligaments provide anteroposterior stability.

Locking and Unlocking Of The Knee

On account of the medial condyle projecting more anteriorly than the lateral condyle, when the knee extends, the femur rotates on tibia internally to get total articular alignment and locks on to it (screw home movement). When the knee flexes, the femur externally rotates to unlock the joint and flexion proceeds.

Polycentricity

Flexion and extension of the knee as mentioned earlier do not take place about a fixed transverse axis but a constantly changing centre of rotation which when plotted describes a 'J' shaped curve around femoral condyles.

The magnitude of functional load, which is produced during the gait cycle at a given point, is dependent upon the centre of rotation to be located along the line that is perpendicular to joint surface at the point of contact (instant centre of rotation). During flexion the first 20° of motion is of the rocking type, which meets the stabilizing function in a relatively extended knee and gliding in the remaining part of flexion to permit more freedom during motion. In osseous or ligamentous damage to the knee joint, the instant centre of rotation lies off this perpendicular line further increasing the wear and tear.

Mechanical Axis of the lower limb

It extends from the centre of the head of femur to the centre of ankle joint passing nearly through the centre of knee. Vertical axis of body passes from centre of gravity to

the ground. Mechanical axis of lower limb is 3 deg valgus to the vertical axis of body as hips are wider than the knees.

Anatomical Axis of Femur

It is a line passing through centre of medullary canal and is in 9 deg valgus to true vertical axis and 6 deg valgus from the mechanical axis of lower limb.

Anatomical Axis of Tibia

It is in 3° varus to mechanical axis of lower limb thus coinciding with true vertical axis

III) Evolution of total knee replacement:

Orthopaedic surgeons the world over have been constantly working towards replacing the joint with an artificial one over last four decades after having faced the limitation of various surgical modalities of for the arthritic joint viz., like high tibial osteotomy, joint clearance procedures and finally arthrodesis.

History of total knee arthroplasty can be conveniently divided into several stages according to reports available in literature.

STAGE I : INTERPOSITIONAL ARTHROPLASTY

In this stage there were attempts at resection of joint surfaces and interposition of either living or dead material.

In as early as 1861, Fergusson reported performing a resection arthroplasty of the knee for arthritis [36].

Verneuil generally is credited with performing the first interposition arthroplasty of the knee in 1863, when he inserted a flap of joint capsule between the two resected joint surfaces to prevent them from growing together [37].

Various surgeons subsequently tried many other substances as interposition material including skin, muscle, fat and even chromatinized pig bladder.

Campbell (in 1920-30) popularized the use of free fascial grafts as an interposition material [38]. These grafts had limited success in ankylosed knees but not in arthritic joints. However no consideration was given towards stability in those attempts and as such met with failures.

STAGE II : SURFACE/MOULD ARTHROPLASTY

Stage of advent of foreign materials tolerated by tissues and use of mainly partial or unicompartamental replacement of damaged joint surface.

Campbell (1940) gave a new approach to replacement of damaged joint surface, when he inserted vitallium mould to cover the femoral condyles with screws [39].

Townley (1964) described a procedure using stainless steel plated platform which was fixed to tibial plateau with screws [40].

McIntosh (1966) of Toronto designed prosthesis to replace one or both tibial articular surfaces with metal blocks [41]. This provided significant relief of pain.

Lowe, Kates and Kay (1972) presenting a study of 83 McIntosh Tibial Plateau Arthroplasty found long term pain relief as most striking feature[42].

The Femoral mould and the Tibial Plateau Prosthesis dealt with only one half of joint surface and were not suitable for all knee joints especially with systemic affections e.g. Rheumatoid Arthritis which affected all three compartments of knee.

STAGE III: HINGED PROSTHESIS

In this era stability was added by incorporating mechanical hinges in prosthetic design. Hinged implants with medullary stems for fixation were developed to replace both joints surfaces, to provide stability and to restore limb alignment.

Magnoni (1943) was first to report a successful Hinge Arthroplasty[43].

Walldius B (1953) designed an acrylic material prosthesis inserted for first time in October 1954[44].

Shiers (1954) for first time in Great Britain reported use of stainless steel hinge prosthesis designed by him on two patients [45].

Walldius (1960) on a review with maximum follow up of 8 years reported excellent results in 64% cases, good in 10% and poor 26% and failure were attributed mainly to infection[46].

Young (1963) working at Mayo clinic used own hinge design on 19 patients [47]. 8 cases had good results, 4 fair and 7 failures. 8 years later (1971) Young published long term study with 10 years follow up. In 12 failed cases on removal of prosthesis, tissues showed corrosion reaction and joints were filled with metallic sludge.

The Stanmore Hinged Knee Prosthesis was developed in 1968 from a hinged knee replacement made substantially of an acrylic polymer with a nylon axle [48].

Mazas and Guepar (1973) in Paris developed a new prosthesis with its axis of rotation placed more posteriorly, also incorporating good results of Walldius, Shiers and Young and also considered following points [49]. It should be of minimum bulk, should not limit flexion through contact of two parts, should enable patellar motion preservation and should establish normal knee axis by a valgus tilting of femoral stem.

STAGE IV : NON-HINGED PROSTHESIS

Metal on plastic era – the era when the concept of resurfacing the patello-femoral joint came into vogue. Viewing the limitations of hinge prosthesis, there came the need of a prosthesis to be evolved which would provide rotatory movement in flexion and yet stability in extension.

Gunston(1971), then resident in orthopaedics, in Charlney Bio-Mechanical Laboratory at Wrightington developed the first non-hinged prosthesis (polycentric knee) cemented into slots made on articular surface of femoral condyles[50]. He also recognized that the knee does not rotate on a single axis like a hinge, but rather the femoral condyles roll and glide on the tibia with multiple instant centers of rotation. This concept has become known as Femoral Roll-back. Gunston's prosthesis consisted of four part: two Vitallium femoral components (available in three sizes), which replaced the posterior portions of the femoral condyles and two polyethylene flat tibial component (available in a single width. The components were fixed to the bone with polymethylmethacrylate and attempted to reproduce the complex knee motion he had described. The Polycentric knee enjoyed early success with its improved kinematics over hinged implants, but it tended to fail because of inadequate fixation of the prosthesis to bone.

C.S. Ranawat and Dr. John Insall both surgeons at The Hospital for special surgery, New York developed Duo-condylar prosthesis in 1971 and implanted for first time in December 1971. First report on Duo-Condylar was published by Ranawat, Insall and Shine (1975) [51]. It had 2 separate units - the femoral condyles connected by an anterior metal bridge and a flat high density polyethylene tibial plateau without patello-femoral groove.

STAGE V: GEOMETRIC KNEE ARTHROPLASTY

Coventry et al (1973) introduced the concept of geometric knee arthroplasty[52]. The polyethylene tibial plateau component was one piece with an articular geometry that closely conformed to the femoral condyles in the sagittal plane for increased stability. This design was intended to be used with retention of the cruciate ligaments, thus ignoring the kinematic principles described by Gunston.

Accordingly, attaining motion was problematic with the Geometric Knee unless the cruciate ligaments were removed. The Imperial College London Hospital (ICLH) design by Freeman and Swanson (1976) was developed as a “Roller-in-Trough” design with the one-piece femoral component constrained within the sagittally concave, one-piece tibial component by the existing tension of the capsule and the collateral ligaments [53]. The first prosthesis was inserted at the London Hospital in 1970. Both cruciate ligaments were routinely sacrificed. The tibial component had no intramedullary stem to minimize the consequences of possible infection and to maximize the potential for knee fusion as a salvage procedure. Tibial component loosening was subsequently its major shortcoming.

Skolnick, Coventry and Istrup (1976) reported on 119 geometric arthroplasties with a two year follow up with pain as primary indication in 84% cases[54]. Relief was achieved in 92% cases. Total range of motion postoperatively increased and added to stability.

Theodore et al (1972) designed a prosthesis, which permitted full rotation, adduction-abduction as well as 130 degree of flexion and inserted it in to knees all of which had

intact collateral and posterior cruciate ligaments [55]. The average overall preoperative score was 41 and postoperative score was 71.

Attenborough (1976) put forth a new constrained design with metal on plastic articulation [56]. It was a stabilized gliding prosthesis and intrinsically stable. It is a compromise between the restrained hinges and the unconnected surface prosthesis. It is a two-piece prosthesis with the normal gliding movements of flexion and extension and has a stabilizing rod between the femoral and tibial components, which allows some lateral and rotational laxity whilst acting in place of the cruciate ligaments. The components are so designed that when rotation or lateral movements occur the joint “opens” and tightens the soft tissues. This produces a gradual deceleration of the movements instead of a sudden block, which might be a cause of loosening. Only a minimal length of bone has to be removed. The implant has a self-lubricating mechanism.. He published a report in 1978 of 240 arthroplasties (1973-1977) and showed results equal to hinged or Duo-Condylar designs. He concluded that this implants could be used in patients with severe deformities and instability where condylar prosthesis was unsuitable.

Matthews et al (1973) put forth the spherocentric knee, which met all criteria of knee endoprosthesis for grossly unstable knees with ligamentous laxity[57].

Walker and Shoji (1973) reported the design of a stable-condylar prosthesis adopted after condylar replacement principle incorporating a stabilizing mechanism within the inter-condylar notch [58]. The prosthesis was made to load condyles, retain normal

motion, minimize and simplify bone resection and control rotation with stability in full extension.

STAGE VI: THE TOTAL CONDYLAR PROSTHESIS

The concept of Total Condylar Prosthesis arose out of experience with duo-condylar, Freeman-Swanson and Geometric prosthesis. This prosthesis followed the philosophy that mechanical considerations should outweigh the desire to anatomically reproduce the kinematics of normal knee motion. It is a non hinged unit working on the 'Roller in Trough' principle with replacement of patello-femoral Articulation and improved fixation of tibial component by a stout central peg. In addition to the original prosthesis, two subsequent modifications were made. The Total Condylar Prosthesis II is a cruciate substituting prosthesis in which complete anteroposterior stability is achieved by means of a tapered tibial post articulating within a femoral recess. The Total Condylar III (also called as Constrained Condylar Knee) is future constrained version meant primarily for difficult revisions. The femoral component has a longer stem and the tibial peg enlarged. The tibial post is not tapered and fits within the femoral recess, so that both medio-lateral and antero-posterior stability are provided. Varus-Valgus stability is controlled by this mechanism with a small amount of Varus-Valgus toggle allowed.

Insall, Ranawat, Scott and Walker et al (1976) studying on first 100 arthroplasties reported that tibial placement was accurate in 99% in AP view and 92% accurate in

lateral view [19]. Femoral component placement was accurate in 82% in AP and 73% in lateral view. Overall alignment was 94% accurate.

Oglesby and Wilson (1984) on comparing the results of 160 replacements [59] concluded that the standard prosthesis for most of arthritic condition is a Tri compartmental type and proper alignment is critical for proper functioning and survival of arthroplasty.

Donaldson, Sculco, Insall and Ranawat (1988) published long term follow up study of total condylar III knee prosthesis [60]. 31 knees were implanted in 25 patients. There were 17 primary arthroplasties and 14 revisions. Average follow up period was 3.8 years. The average arc of motion improved from 63 to 97 degrees. This resulted in 77% good and excellent results. There were 5 failures (26%) all of which occurred in revision group. The results compare favorably with results of constrained prosthesis.

STAGE VII: MOBILE BEARING KNEE/ HIGH FLEX DESIGNS

Goodfellow and O'Connor in 1976 proposed the Oxford meniscal-bearing total Knee replacement as a more kinematically sound design [61]. In an original Oxford implant, the medial and lateral tibiofemoral joints but not the patellofemoral joint, were resurfaced the anterior and posterior cruciate ligaments were preserved. The four-bar

linkage created by the anterior and posterior cruciate ligaments directed the movements of the meniscal bearing forward in extension and back-ward in flexion.

Buechel and Pappas developed the Low Contact Stress (LCS) total knee replacement [62]. The Low Contact Stress device resembled a condylar knee replacement that not only allowed replacement of the patellofemoral joint, but also could be inserted in either a meniscal or rotating-platform configuration. First implant was done in June 1977 and known as “the New Jersey Knee”. This modification of the Oxford design decreases the posterior excursion of the menisci in flexion, helping to decrease the incidence of posterior extrusion of the menisci.

Long (2008) described the various aspects of a high flexion knee prosthesis [63]. He mentioned that Component design modifications focus on lengthening the radius of curvature through the posterior condyles, increasing the posterior condylar offset, recessing the tibial insert, lengthening the trochlear groove, and altering the cam-post design. These changes allow increased femoral rollback, translation, and thus clearance in deep flexion.

IV) High flex vs standard implant

Minoda et al [2009] analysed range of motion of standard and hi-flex cruciate retaining prosthesis prospectively [64]. They had 89 knees with standard and 87 knees with high flexion CR total knee prostheses [both Next Gen brands]. Differences in age, gender, diagnosis, preoperative ROM of the knee, and Knee Society Score between the 2 groups were not statistically significant. At 12-month follow-up, average ROM was $112.0^{\circ} \pm 12.6^{\circ}$ for standard, and $115.3^{\circ} \pm 13.4^{\circ}$ for high-flexion CR prosthesis ($P = .101$). They found no significant differences between groups with regard to ROM, clinical, or radiographic parameters.

Seon et al [2009] analysed 100 knees with 50 knees in each category of Hi-flex and standard total knee prosthesis [65]. At the time of the final follow-up, the average maximal non-weight-bearing flexion was 135.3° for the knees in the high-flexion group and 134.3° for the knees in the standard group; the difference was not significant. Moreover, no significant difference was found between the groups in terms of weight-bearing flexion (124.8° in the high-flexion group and 123.7° in the standard group) and

the number of knees that allowed kneeling and sitting cross-legged. The average Hospital for Special Surgery knee score was 94.4 points in the high-flexion group and 92.4 points in the standard group; the difference was not significant. The Western Ontario and McMaster Universities Osteoarthritis Index scores also showed no significant difference between the groups. Thus no functional difference was noted in two groups

Nutton et al [2008] performed prospective randomised comparison of the functional outcome in patients receiving either a NexGen LPS-Flex or the standard design [66]. The study included total of 56 patients, half of whom received Hi-flex and standard knee prosthesis each. They found that there was no significant difference in outcome, including the maximum knee flexion, between patients receiving the standard and high flexion designs of this implant.

Gupta et al [2006] reported a significant improvement in the post-operative range of movement using a high flexion rotating platform design when compared with a standard design of rotating-platform TKR [67].

Bin and Nam [2007] found a significant improvement in knee flexion at one year after operation in patients receiving a high flexion design compared with a standard knee replacement, particularly in patients with a pre-operative range of flexion of less than 90° [68].

Kim, Sohn and Kim [2005] were unable to show a significant improvement in knee flexion using a NexGen LPS-Flex knee replacement [69]. In their study, the standard

design was used in one knee and high flexion prosthesis in the other. After a mean of 2.1 years the mean range of movement was 136° in the standard design and 139° in the high flexion design, compared with a mean preoperative range of movement of 126° and 127°, respectively. In their Asian population, the pre-operative range of movement was greater than in the present series, despite which they were unable to demonstrate any advantage in using a high flexion design over the standard version.

Separate studies done in Asia in 2005 by Seon JK et al(70) and Huang HT et al(71) have failed to show an improvement in knee flexion using a high flexion design. This is in contrast with expectations that the Asian population will be more satisfied with the Hi-flex designs.

Menegheni et al [2007] retrospectively reviewed 511 TKAs in 370 patients fitted with posterior cruciate ligament–substituting prosthesis (NexGen Legacy, Zimmer, Warsaw, Ind) of a traditional design (not designed for high flexion) [72]. The mean follow-up was 3.7 years (range, 2-8 years). Regression analysis determined the effect of obtaining high flexion (>125°) on Knee Society, stair, function, and pain scores. Of 511 TKAs, 340 (66.5%) obtained range of motion greater than 115°, and 63 (12.3%) TKAs obtained high flexion greater than 125°. There was no difference between the patients who obtained flexion greater than 115° and those who obtained high flexion greater than 125° in Knee Society scores ($P = .34$) and function scores ($P = .57$). Patients with greater than 125° of flexion are 1.56 times more likely to demonstrate optimal stair function ($P = .02$). Obtaining flexion greater than 125° after TKA does not offer a benefit

in overall knee function. However, obtaining a high degree of flexion appears to optimize stair climbing.

First meta analysis done by Gandhi et al was published in 2009 January [73]. They studied 6 studies that met with their inclusion criteria. They concluded that High-flexion implant design improves overall ROM as compared to traditional implants but offers no clinical advantage over traditional implant designs in primary knee arthroplasty.

Murphy et al [2009] performed a systematic review of published trials designed to determine if there is a significant increase in ROM or function in patients who receive a high-flexion TKA compared to those who receive a standard TKA [74]. Nine studies fitting the inclusion criteria were analysed. They concluded that there was insufficient evidence of improved range of motion or functional performance after high-flexion knee arthroplasty.

V] Design specification of study implants

Salient Design features of posteriorly stabilized Standard knee replacement prosthesis (PFC Sigma)

1. Patented cam and spine design provides true mechanical substitution for the PCL to produce component rollback. Its central location transfers shear forces into compression through center stem of tibial component.
2. Cam and post Provide high lift off value (16.3mm) before femoral component subluxates over tibial spine.
3. Uniform femoral box/tibial spine dimensions across size range provide for interchange-ability, one size up and down.
4. Same component can be used for primary CS or revision procedures with the addition of modular stems and augments.

5. Rounded coronal shape of posterior stabilized tibial insert maximizes contact area and reduces peak stresses avoiding edge loading with rounded femoral condyles.
6. Reinforcement pin helps reinforce against high varus/valgus loads insert is subjected to when collateral support is lacking.
7. The modular construct of CoCr Tray, along with its highly polished surface provides an environment that is more polyethylene-friendly than a rough titanium tray to minimize abrasion and increase long-term durability.
8. Finally, the tray and insert have a secure fit with a locking mechanism, achieving two important goals: 1) decreased micromotion and 2) maintaining the system's modular flexibility.

Salient Design features of posteriorly stabilized Hi Flexion knee replacement prosthesis
(INDUS)

1. The radius of curvature of the posterior condyle of the femoral component has been reduced thereby increasing the posterior condylar offset. This helps in gaining more roll back and more flexion.
2. A 4° slope is incorporated in the tibial insert and a 3° slope in the metal base plate to increase flexion.
3. The deep flexion achieved prompted certain modification in the post and cam mechanism to offer stability in deep flexion and to allow for rotational freedom in deep flexion. A third joint was designed between the post and the cam with the post engaging the cam at around 80° of flexion and thereafter acting like a load bearing surface in flexion. The articulating surface of the post is convex and that of the cam is concave thus allowing a more congruent surface for rotation to occur. The post does not impinge on the side walls of the box during rotations.
4. Also as the bar of the cam articulates with the post at a lower level, the jumping distance is 16mm, another indicator of enhanced stability in flexion.
5. The posterior edges of the tibial polyethylene insert are chamfered to avoid impingement in deep knee bending.
6. There is an anterior cut out in the tibial polyethylene insert to accommodate the patellar tendon during deep flexion.
7. The tibia is Monoblock so backside wear is reduced to minimal.
8. The tibial polyethylene insert has a deep dish design to prevent point loading and polywear.
9. Introduction of the post and cam mechanism involves removal of extra bone from the intercondylar region of the femur to accommodate the box. This results in

bone loss. In the INDUS design the femoral box is designed so as to cut minimal bone. Thus INDUS knee also incorporates the bone sparing principle.

10. The intercondylar box of the femoral component is open to enable nailing in case of periprosthetic fractures.

11. The patella is a single peg anatomic design.

12. A thorough anatomic study of the Indian knee joints was done to before designing the components. The components are made in sizes that are more suited to the Indian population.

13. The femoral components are separate for right and left with an anatomic deep trochlear design for better patellar tracking and avoiding the patellar clunk syndrome.

MATERIALS AND METHODS

Type of Study: Prospective study and retrospective.

Conducted At: Sancheti Institute of Orthopaedics and Rehabilitation

Duration of Study: Jan 2010 to May 2011

Case Selection Criteria: During this period patients undergoing total knee replacement will be screened using the inclusion and exclusion criteria. Informed consent will be taken for all patients that fit the inclusion criteria and all patients willing to undergo the trial will be included.

INCLUSION CRITERIA:

- 1) Primary Osteoarthritis of the knee joint
- 2) Rheumatoid arthritis of the knee
- 3) Patients undergoing primary total knee replacement with High flexion knee prosthesis [Group A]

4) Patients undergoing primary total knee replacement with Standard posterior-stabilized knee prosthesis [Group B]

EXCLUSION CRITERIA:

- 1) Non Rheumatoid/Osteoarthritis knee pathology
- 2) Previously operated cases for fractures or deformities around the knee
- 3)Revision arthroplasty cases
- 4)Primary complex knees
 - a) fixed flexion deformity more than 30
 - b) varus or valgus deformity of more than 10
 - c)range of motion less than 50
 - d) bony defect

History

The detailed history was taken in the form of chief complaints, onset, duration and progress of the complaints. Past history related to medical illness or any surgical treatment was also asked and noted. History suggestive of rheumatoid arthritis or any other types of arthritis and neuropathic joint were also assessed in details. Past history of any infection in the body was also taken. It was also enquired whether any kind of

anti-coagulant therapy is going on for previous thrombo-embolic disorder. Histories related to our exclusion and inclusion criterion were taken in detail.

Physical Examination

Detailed clinical examination was done to see presence or absence of tenderness, swelling and abnormal mobility in the concerned knee. Passive and active range of motion of affected knee joint was noted. Any flexion deformity or instability in knee was noted pre-operatively. Knee circumference was taken at mid patellar level for all patients preoperatively. Amount of varus / valgus deformity, flexion contracture and range of movements of the joint were noted. We had checked for any distal neurovascular deficit in the particular limb. The condition of surrounding soft tissues was also evaluated. The pre-operative pain in visual analogue scale (VAS score), Knee Society Score and Functional Knee Score were calculated preoperatively for each patient.

Radiological Assessment

Radiologically, AP view (load bearing-standing), lateral view in 90 degrees of flexion of the affected limb and full-length extremity roentgenograms to know the mechanical and anatomical axis were taken. Radiologically following points were emphasized - collateral laxity and subluxation of tibia, presence of osteophytes (femoral, tibial, patellar), quality of bone and bony defects, curvature of femur and tibia, etc. Mediolateral and anteroposterior sizing of femoral and tibial component were done. Radiographic templates were used to estimate the appropriate size of the prosthesis.

Pre-Operative Hematological Tests

All patients were evaluated with all relevant pre-operative hematological investigations including HIV and HBsAg tests. Serum urea, creatinine, blood sugar levels, serum electrolytes, coagulation profile were checked. Electrocardiogram, chest x-ray and if indicated echocardiography, were done for every patients. In some situations arterial and venous Doppler study of the lower limb was done to evaluate the vascular status of the particular limb. Preoperative Anesthetic and Physician's fitness for surgery were obtained before surgery.

Preparation of Patient

Patients were given thorough wash with soap and Microshield (at 8 hours interval) for three times; last one the night prior to surgery along with shaving of parts. Following the last event the limb was covered with autoclaved sheet and kept till the time of surgery.

Prophylactic Antibiotics

During pre operative period (approximately 12 hr prior to surgery) and during induction a dose of a III generation Cephalosporin with Sulbactam 1gm I.V. + Amikacin 500 mg IV was given.

Anesthesia

All cases were done under combined spinal and epidural anesthesia with the patient in supine position and under tourniquet control. During the course of surgery, entry and

movement of personnel were restricted in the operation theater as per the protocol of Joint Replacement Surgery. After proper painting and draping, surgery was begun.

Surgical Details

All patients were operated by anterior midline incision. Joint approached through the medial parapatellar capsular approach extended proximally to the inferior margin of the rectus femoris and distally to the medial margin of the tibial tubercle. The medial side of the knee was exposed by subperiosteally stripping the anteromedial capsule and deep medial collateral ligament off the tibia to the posteromedial corner of the knee.

Patella was then everted with knee in extension. If needed, lateral patellofemoral plicae release and release of adhesions were done. Knee was again flexed, ACL along with anterior horn of both menisci were removed (posterior horn of menisci was removed after both bone cut made); meniscus was removed leaving a 2 mm rim to prevent damage to the capsular sleeve. Now tibia was subluxated anteriorly and externally rotated.

Further exposure and soft tissue balancing were done based on patient's preoperative deformity and soft tissue stability. Soft tissue balance was assessed and reassessed several times during the whole procedure. Since many of our patients had varus deformity, release of the medial structures (superficial and deep parts of medial collateral ligament, semi-membranous tendon, pes anserinus and part of posterior capsule) as per demand of the individual case, was done. For every centimeter of release, the knee was stressed into valgus to see if varus had been fully corrected or

not. All osteophytes were removed. In majority of the above varus knee PCL, was found to be short and contracted and were sacrificed.

Bone cuts were made using appropriate jigs. Tibial preparations were followed by femoral. Three degrees of posterior slope was maintained while making tibial cut. In the femur in case of Indian Implants we used transepicondylar axis as a base line to cut distal femur and cuts were made parallel to it, whereas in case of imported implants femoral cuts were made using intramedullary aiming device. The femoral bone cut was always maintained in 5 to 7 degrees of valgus. After this anterior and posterior Chamfer cuts was made by using jigs in both groups. Aim was to achieve a rectangular space between the femur and tibia (extension / flexion) after bone cuts, was fulfilled in all cases. Final alignment was checked with spacer blocks; with less than 5 degrees of varus/ valgus stress.

As appreciable number of our patients had associated flexion contractures, special attention was paid to the removal of posterior osteophytes and elevation/release of posterior capsule. For final equalization of flexion and extension space, additional distal femoral resections had to be done (8-10 mm). Following these resections not only the correction of the flexion contracture but also the mediolateral stability with spacer in place was ascertained.

Patellar resurfacing was done in all cases following removal of peripheral osteophytes. Patellar tracking over the femoral component was noted and found satisfactory. Trial components were then fixed. Reduction was done stability and range of movement was rechecked in extension and flexion.

Now trial component were removed and prosthesis were placed and fixed to bone. First the femoral and patellar component with help of one packet of cement (CMW III), then the tibial component using another packet of cement (CMW III) were fixed. Extra cement was removed with help of knife and curette. Tourniquet was deflated. Hemostasis was achieved. Wound washed with normal saline and closure was done in layers with knee in extension under negative suction drain. Appropriate noting, documentation as regards implant specification used, etc were done.

Post-operative Protocol

1 gram of III generation Cephalosporin with Sulbactam I.V. + Amikacin 500 mg IV twice a day for 5 days followed by oral antibiotics till suture removal was adhered to during the post operative period. Suture removal was done on 10-12th postoperative day.

Post-operative Rehabilitation and Physiotherapy

Static Quadriceps exercises were started on 2nd post operative day. Hamstrings exercises were started as soon as pain subsided. Straight leg rising was encouraged from 2nd post operative day. Gentle knee flexion was started from 2nd day. Weight bearing walking was from 2nd-3rd day. Stair climbing was encouraged from 5th post-operative day.

Follow-up Data Collection

Follow-up was done on 1st, 3rd, 6th months and 1 year post operatively. Clinical evaluation was done using Knee Society Score. Pain score and functional score were noted for all patients at regular follow up. Flexion at knee was measured using the goniometer. During post-operative and follow-up period, serial x-rays were taken.

Data collection & method of statistical analysis

Preoperative & postoperative data collection was done.

For comparison of the pre operative and post operative variables within each group paired t Test was used.

For comparison among means for continuous variables in between two groups was done by unpaired t test.

The level of statistical significance was taken as p value <0.05 , i.e. whatever difference was observed (mean/distribution) was real and can be attributed to the intervention in the study.

OBSERVATIONS AND RESULT

There were 100 patients in each of the two groups.

The mean age in group A was 62.83 ± 8.63 (range 41-86) while mean age in the group B was 62.0 ± 9.15 (range, 34-87). (Table 1)

There were 72 females and 28 males in group A while in group B had 25 males and 75 females. (Table 2)

The average BMI in group A was 27.09 ± 3.93 (range 20 -40) while in group B the mean BMI was 27.22 ± 4.15 (range 19-39)(Table 3)

Table 1 Comparison of patients in Group A and Group B with respect to age (years).

Group	Number of patients	Age (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	62.83 \pm 8.63	(41, 86)	0.145
Group B	100	62.00 \pm 9.15	(34, 87)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between age (years) in Group A and Group B.

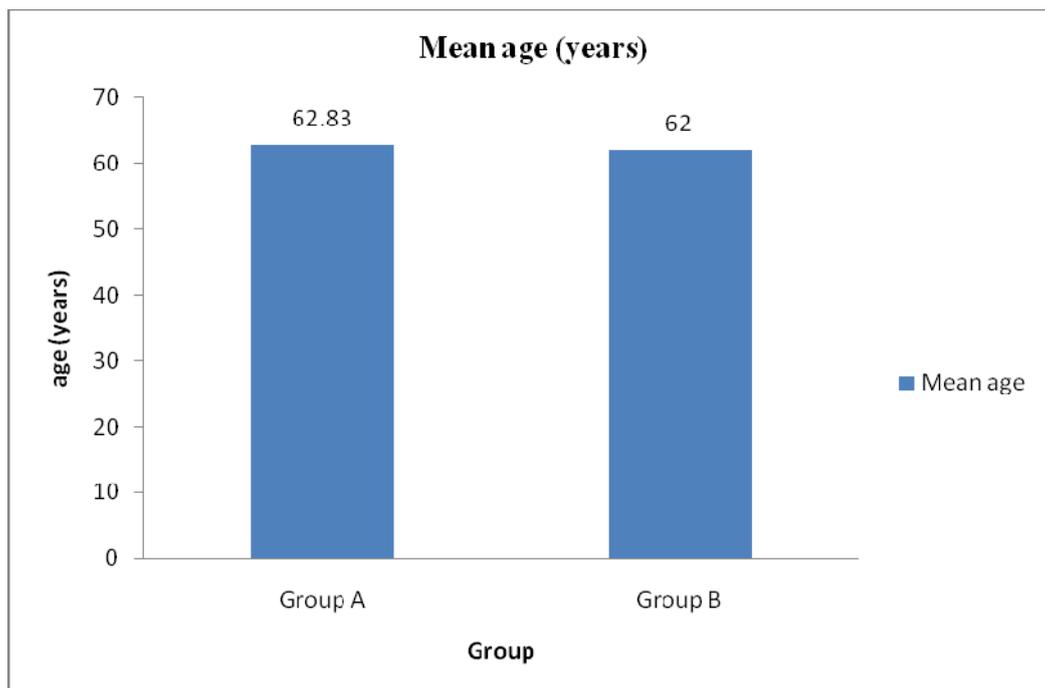


Table 2 Gender wise distribution of patients in Group A and Group B.

Gender	Group		Total	p-value
	Group A	Group B		
Male	28	25	53	
Female	72	75	147	

Conclusion :- By using 2 independent sample proportion test $p\text{-value} > 0.05$ therefore there is no

significant difference between the proportion of gender in Group A and Group B.

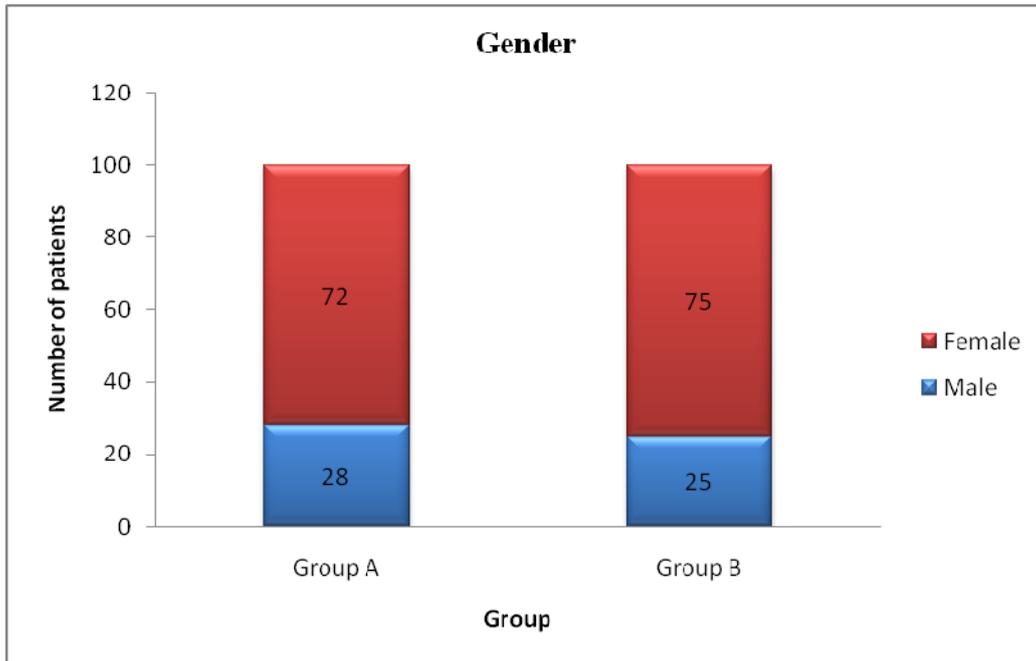
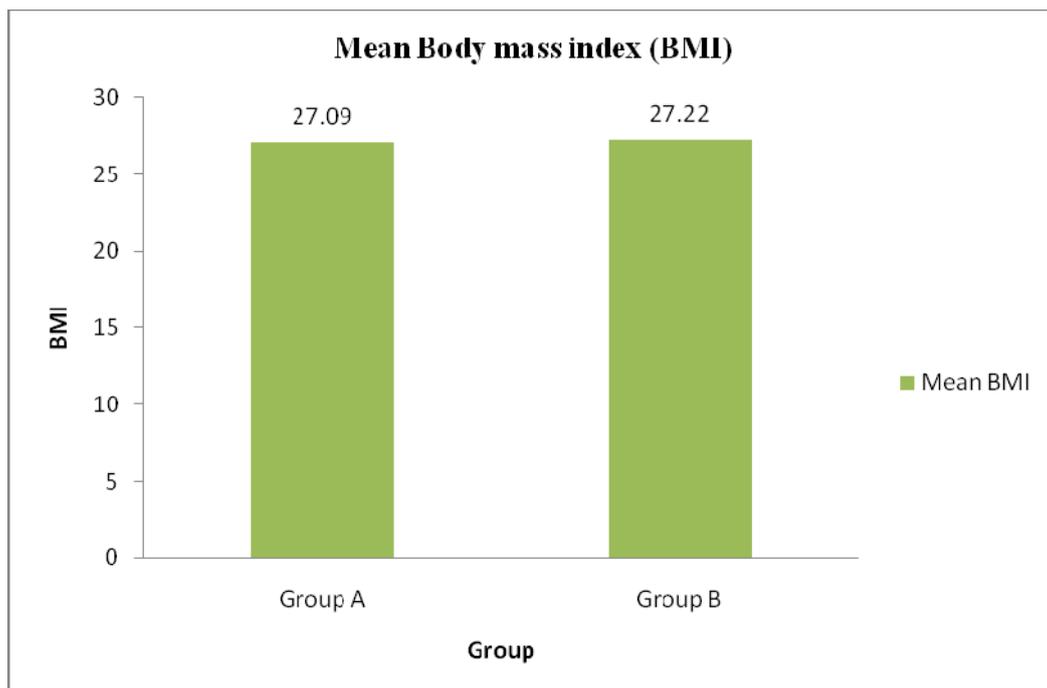


Table 3 Comparison of patients in Group A and Group B with respect to body mass index (BMI).

Group	Number of patients	BMI (Mean \pm SD)	Range (Min, Max)	p-value

Group A	100	27.09 ± 3.93	(20, 40)	0.829
Group B	100	27.22 ± 4.15	(19, 39)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between body mass index (BMI) in Group A and Group B.



Group A –

The mean pre operative ROM was 103.40 ± 18.37 (30-135) and mean post operative ROM improved to 108 ± 15.85 (range 70-140).

The flexion deformity too improved from mean of 10.40 ± 7.41 (range, 0-35) to mean of 2.15 ± 3.12 (range 0 to 10).

The mean pre operative knee score and function score were 37.92(range 18-55) and 27.80(range 0-50) which improved to a mean of 74.5(range 58-90) and 39.75(range 0-60) post operatively

Group B -

The range of motion was a pre operative mean of 106.10 ± 15.69 (range, 60-140) to post operative mean of 105.6 ± 13.88 (range 80-140).

The flexion deformity improved from mean of 9.20 ± 6.88 (range, 0-40) to mean of 2.35 ± 3.86 (range 0 to 10).

The mean pre operative knee score and function score were 40.74(range 22-55) and 27.70(range 0-50) which improved to a mean of 73.67(range 55-90) and 40.55(range 0-70) post operatively

Comparison between the Groups

Comparison between the two groups was performed with respect to pre operative and the post operative variables.

PAIN (Table 4)

Pre operative the mean pain score in group A was 8.03(3 - 9) which was similar to the mean pain score of 7.89 (6-9) in the group B (p-value 0.163). Post operatively the mean pain score in the Group A was 3.65 (range 2-6) and the mean pain in the group B was 3.47 (2-6). Thus the pre operative pain score and the final follow up score, there was no significant difference in the pain scores of both the groups.

RANGE OF MOTION(Table 5)

Mean preoperative range of motion in the group A was 103.4 (30-135) which was similar to the mean pre operative ROM of group B, 106.10 (60-140) (p value- 0.265). At one year follow up the mean ROM of Group A was 108.80(70 - 140) which was also similar to the ROM of group B which was mean 105.60 (80 - 140) (p value 0.13). Thus the ROM pre operatively and the final rom achieved was similar in the 2 groups.

FLEXION DEFORMITY (Table 6)

The mean pre operative flexion deformity in group A was 10.40 (0 -35) which was similar to the flexion deformity in group B which was mean 9.20(0 to 40) (p value 0.237). Post operatively the mean flexion deformity in group A was 2.15 (0-10) which was

comparable to the correction achieved in group B where the final flexion deformity was 2.35 (0 to 10)(p value 0.687).

KNEE SCORE (Table 7)

The mean pre operative knee score in group A was 37.92 ± 7.47 (018 - 55), while that in the group B was 40.74 ± 6.22 (22 - 55). This was statistically significant which indicated that patient in group A were having poor knee score preoperatively (p value 0.004). Post operatively the mean knee score in group A was 74.5 ± 8.72 (58 to 90) while that in group B was 73.67 ± 8.47 (55 to 90). This difference was not statistically significant between the two groups (p value 0.503).

FUNCTION SCORE (Table 8)

The group A had pre operative function score of 27.80 ± 15.41 (0 to 50) while the function score in group B was a 27.70 ± 15.95 (0 to 50) and this difference was not statistically significant (p value 0.964). Post operatively the function score in group A was 39.75 ± 10.50 (0 - 60) while in group B it was 40.55 ± 10.82 (0-70) and this difference was not significant (p value 0.496) indicating that both the groups had a similar functional score

COMPARISION

There was no significant difference in any of the factors between the final post-operative measurements in both the groups.

Table 4 Comparison of Group A and Group B with respect to visual analogue score (VAS) at pre

operative and at post operative.

a. Pre operative

Group	Number of patients	VAS (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	8.03 \pm 0.83	(3,9)	0.163

Group B	100	7.89 ± 0.55	(6, 9)	
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Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative visual analogue score in group A and group B.

b. Post operative

Group	Number of patients	VAS (Mean ± SD)	Range (Min, Max)	p-value
Group A	100	3.65 ± 1.26	(2,6)	0.282
Group B	100	3.47 ± 1.10	(2,6)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative visual analogue score in group A and group B.

Mean VAS

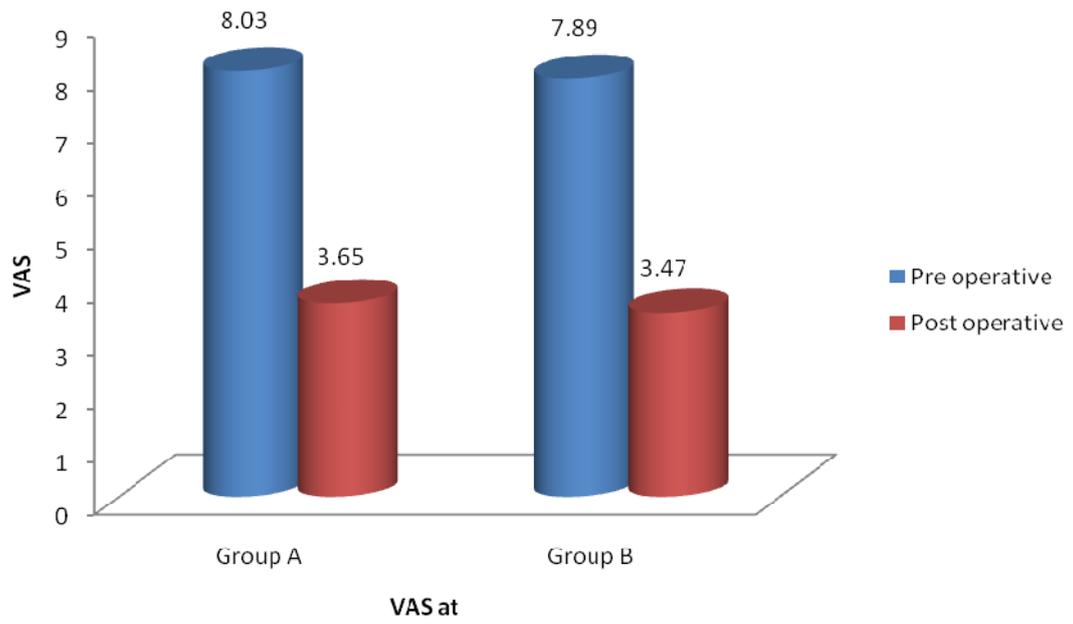


Table 5 Comparison of Group A and Group B with respect to FF at pre operative and at post operative.

a. Pre operative

Group	Number of patients	FF (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	103.40 \pm 18.37	(30, 135)	0.265
Group B	100	106.10 \pm 15.69	(60, 140)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between pre operative FF score in group A and group B.

b. Post operative

Group	Number of patients	FF (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	108.80 \pm 15.85	(70, 140)	0.13
Group B	100	105.60 \pm 13.88	(80, 140)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative FF score in group A and group B.

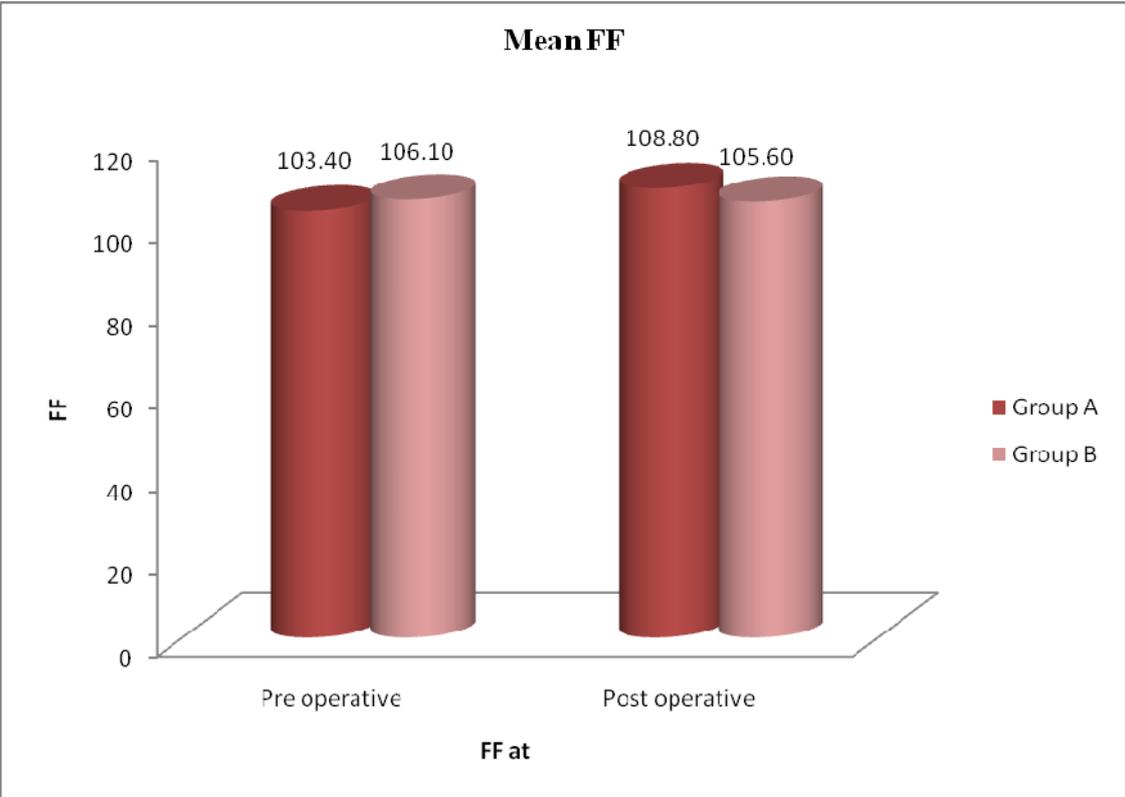


Table 6 Comparison of Group A and Group B with respect to FFD at pre operative and at post

operative.

a. Pre operative

Group	Number of patients	FFD (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	10.40 \pm 7.41	(0, 35)	0.237
Group B	100	9.20 \pm 6.88	(0, 40)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between pre operative FFD score in group A and group B.

b. Post operative

Group	Number of patients	FFD (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	2.15 \pm 3.12	(0,10)	0.687
Group B	100	2.35 \pm 3.86	(0, 10)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative FFD score in group A and group B.

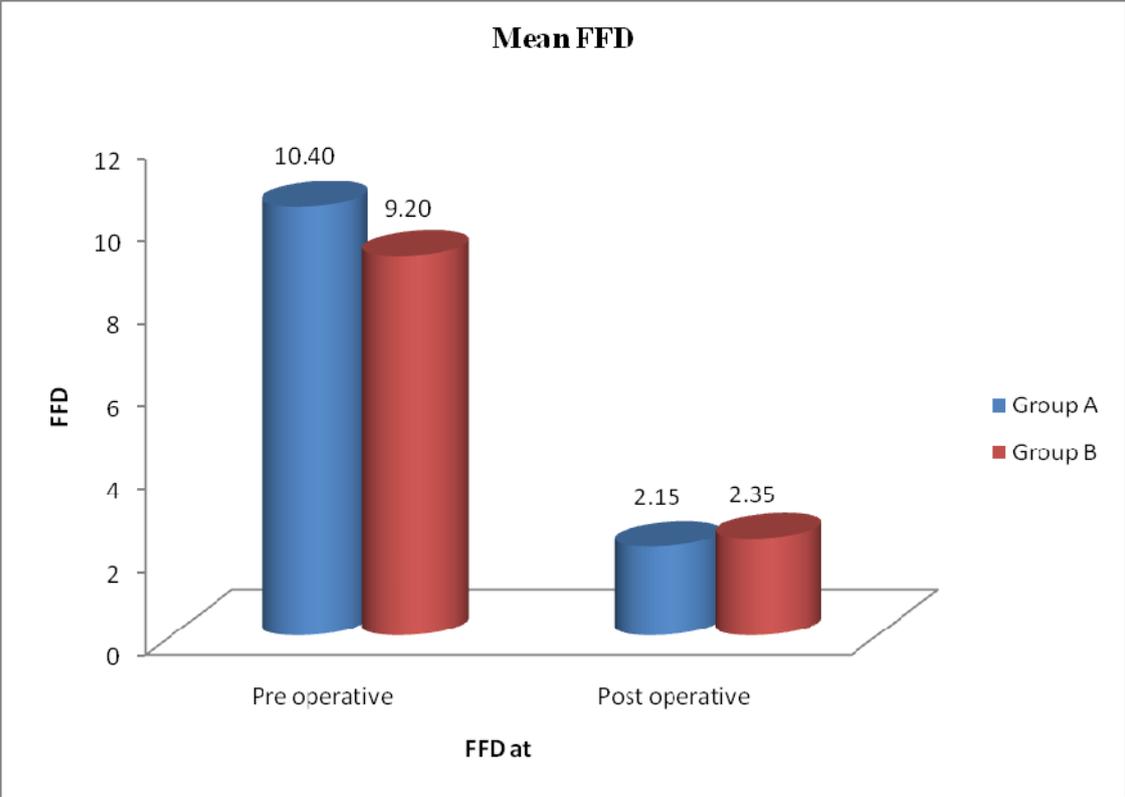


Table 7 Comparison of Group A and Group B with respect to FFD at pre operative and at post

operative.

a. Pre operative

Group	Number of patients	FFD (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	10.40 \pm 7.41	(0, 35)	0.237
Group B	100	9.20 \pm 6.88	(0, 40)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between pre operative FFD score in group A and group B.

b. Post operative

Group	Number of patients	FFD (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	2.15 \pm 3.12	(0,10)	0.687
Group B	100	2.35 \pm 3.86	(0, 10)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative FFD score in group A and group B.

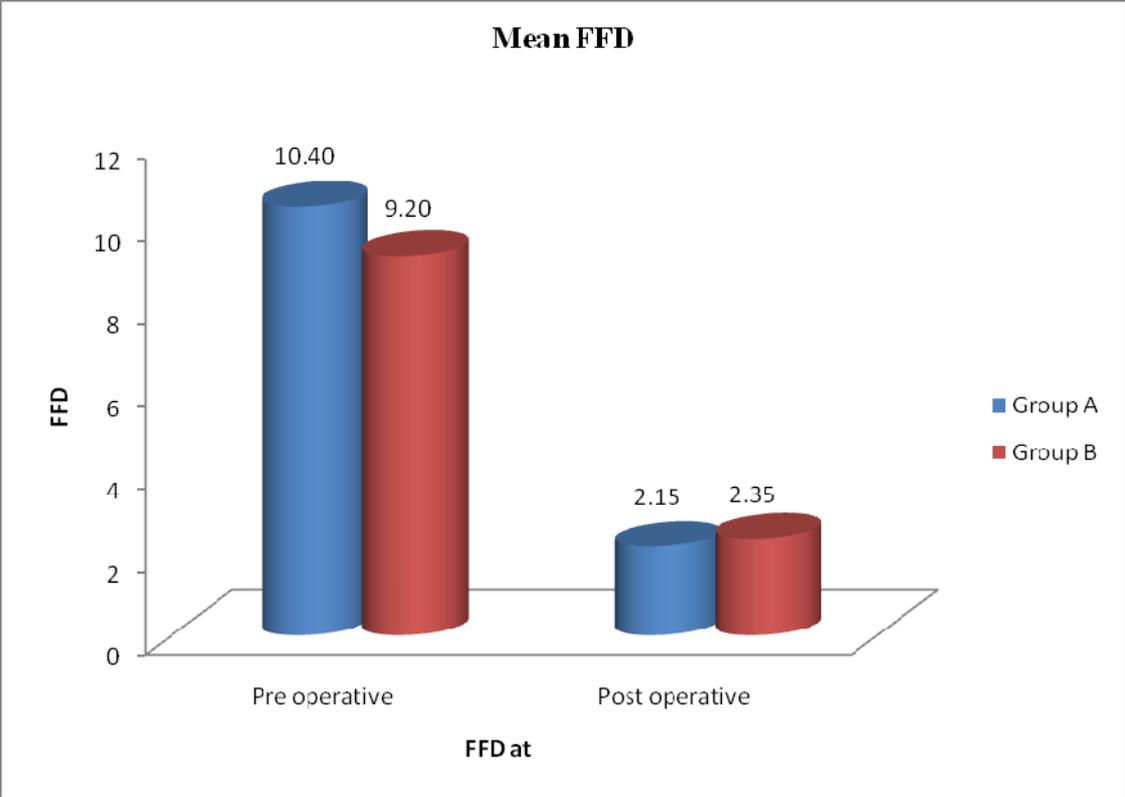


Table 8 Comparison of Group A and Group B with respect to KS at pre operative and at post operative.

a. Pre operative

Group	Number of patients	KS (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	37.92 \pm 7.47	(18,55)	0.004
Group B	100	40.74 \pm 6.22	(22, 55)	

Conclusion :- By using 2 independent sample t-test p-value < 0.05 therefore there is significant difference between pre operative KS in group A and group B.

b. Post operative

Group	Number of	KS (Mean \pm SD)	Range (Min, Max)	p-value
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	patients			
Group A	100	74.50 ± 8.72	(58, 90)	0.503
Group B	100	73.67 ± 8.47	(55, 90)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative KS in group A and group B.

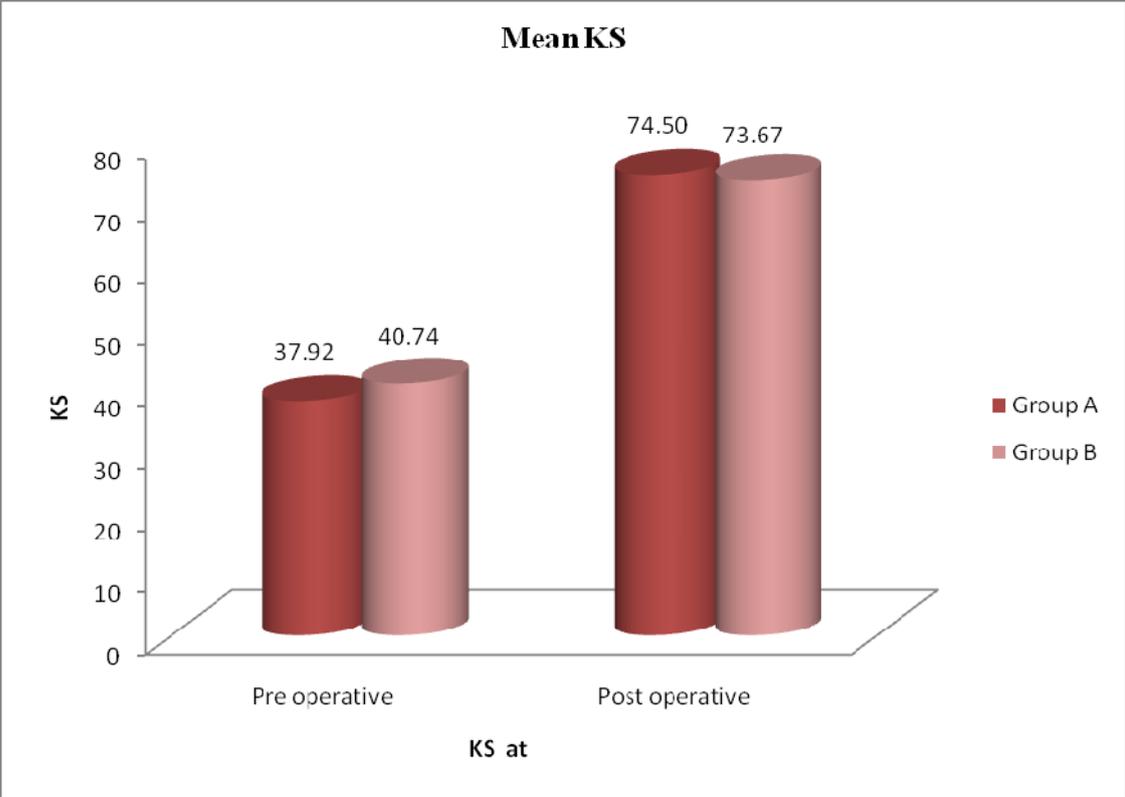


Table 8 Comparison of Group A and Group B with respect to FS at pre operative and at post operative.

a. Pre operative

Group	Number of patients	FS (Mean \pm SD)	Range (Min, Max)	p-value
Group A	100	27.80 \pm 15.41	(0, 50)	0.964
Group B	100	27.70 \pm 15.95	(0, 50)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between pre operative FS in group A and group B.

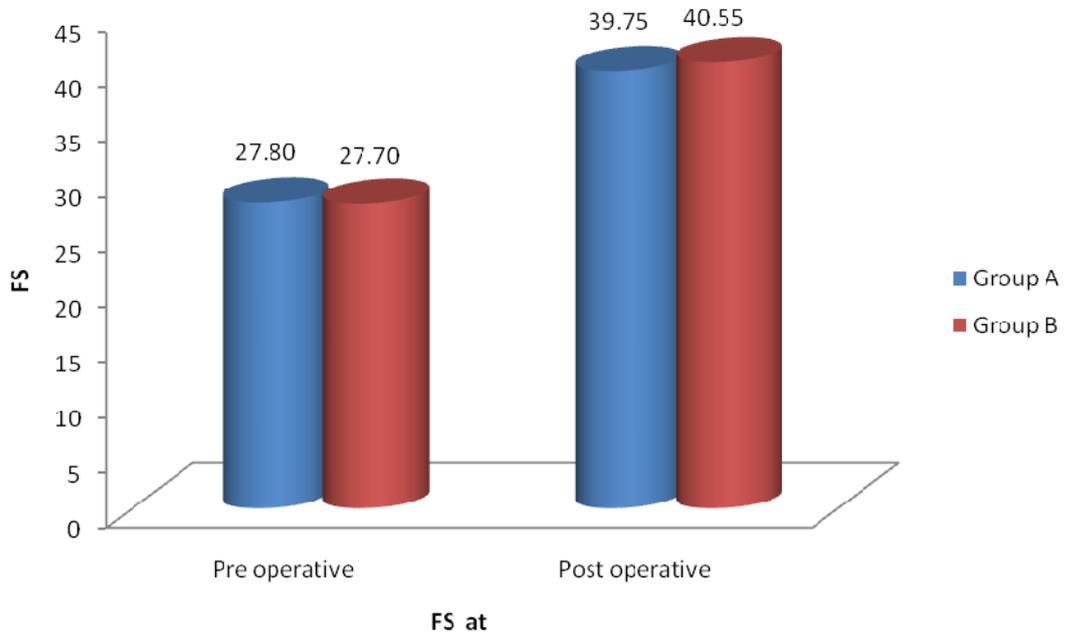
b. Post operative

Group	Number of	FS (Mean \pm SD)	Range (Min, Max)	p-value
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	patients			
Group A	100	39.75 ± 10.50	(0, 60)	0.496
Group B	100	40.55 ± 10.82	(0, 70)	

Conclusion :- By using 2 independent sample t-test p-value > 0.05 therefore there is no significant difference between post operative FS in group A and group B.

Mean FS



DISCUSSION

Total joint replacement is the most technologically advanced solution for arthritic pain, however a search for a better functional and durable prosthesis still continues. The original Total Condylar design was very successful in terms of pain relief and durability but the average post op flexion achieved was only around 90° to 95° [16-21]. Even though this may be enough for most of the daily activities in the western world [22], Asians and particularly Indians require higher flexion for most of their daily social habits and customs [75]. In 1978, the posterior stabilized condylar prosthesis was introduced, as a modification of the total condylar prosthesis, by Insall et al [23]. In this prosthesis a post and cam mechanism was used to achieve femoral rollback. The average flexion achieved by this prosthesis was 107° – 115° [23-27]. Similarly Cruciate Retaining (CR) designs achieve a flexion of around 110° – 112° [28,29].

Hi flexion Knee Implant-

Two prospective series have been published on the INDUS knee prosthesis. First a multicentric trial of 276 patients performed at six centers across India [14]. This cohort was followed prospectively for two years and was analysed to clinical and functional outcome. Of the 276 patients (297 knees), 79 knees had flexion above 140° , 167 had a flexion range of 130 – 140° , 27 had a flexion range of 100 – 130° , and 24 knees had a flexion $<100^{\circ}$, with the mean range of movement being 132.9° . Improvements in the range of movement were retained over time and a total of 205 patients (224 knees,

75.7%) could squat or sit cross-legged at the final follow-up. The mean knee score and the mean function score were significantly improved from a pre-operative value of 39.4 points and 46.7 points to a post-operative value of 87 points and 86 points, respectively. The mean tibiofemoral angle was $8.5^{\circ} \pm 6.9^{\circ}$ of varus pre-operatively and $5.4^{\circ} \pm 2.2^{\circ}$ of valgus ($3-7^{\circ}$ of valgus) at the final follow-up, with no loss of alignment noted in any case. Second was again a prospective cohort of 208 knees and results published in 2010[30]. The patients were followed up for average 3.5 years (range, 2.8 years to 4.3 years). The mean knee score and mean function score were significantly improved from preoperative value of 38.6 points and 47.7 points to postoperative value of 90 points and 89 points respectively (p value <0.05). Out of 208 knees, 60 knees had flexion above 140° , 96 had flexion range 130° to 140° , 32 had flexion range 100° to 130° and 20 knees had flexion less than 100° with mean range of movement being 133.90° . The mean tibiofemoral angle was $7.9^{\circ} \pm 5.4^{\circ}$ of varus pre-operatively and $5.2^{\circ} \pm 2.2^{\circ}$ of valgus (3° to 6° of valgus) at final follow-up.

In our series, the follow up was of one year with mean pre operative ROM was 103.40 (30 -135) and mean post operative ROM improved to 108.8 (range 70 - 140).

The flexion deformity too improved from mean of 10.40 ± 7.41 (range, 0-35) to mean of 2.15 ± 3.12 (range 0 to 10).

The mean pre operative knee score and function score were 37.92(range 18-55) and 27.80(range 0-50) which improved to a mean of 74.5(range 58-90) and 39.75(range 0-60) post operatively

Standard total knee implant

Midterm result of PFC sigma has been reported by many authors. Asif et al [34] studied 87 knees retrospectively and at final follow-up, the mean Oxford Knee Score was 22. Using the American Knee Society Score, 88% of the knees were rated excellent, 4% good, 2% fair, and 6% poor.¹³⁵ Range of motion and other variables was not reported in this series. Clayton et al [76] studied 180 patients and reported that five-year survival with an endpoint of revision for any reason was 97.0%; with an endpoint of revision for aseptic failure it was 99.5%. The median American Knee Society knee rating score was 93 out of 100 at 5 years compared with 25 out of 100 at admission in their series.

Zaki et al studied 145 patients and reported 94% survival [33]. They reported mean preoperative Knee score to improve from 45 (30-65) to 84 (45-92), Functional score from 38 (25-55) to 73 (50-95) and Oxford score from 43 (33-52) to 17 (14-29). Dalury et al [32] Knee Society pain scores significantly improved from a median of 20 (interquartile range, 10-45) to 50 (interquartile range, 45-50). Knee Society function scores significantly improved from a median of 50 (interquartile range, 45-61) to 100 (interquartile range, 62-100). There was a significant improvement in the range of knee motion at a minimum of 6 years ($P = .014$). The median preoperative range of motion was 0 (interquartile range, -5 to 4) to 120 (interquartile range, 110-130); the median postoperative range of motion at 6 years was 0 (interquartile range, 0-0) to 125 (interquartile range, 120-130). Hanusch et al [77] reported improvement in range of motion from 95.7° to 101° in a prospective study of 55 patients. The knee core and function

score improved from 36 and 43 to 84 and 76 respectively. Pain score improved from 7.3 to 41.7 according to Knee society score.

In our series, the range of motion was a pre operative mean of 106.10 ± 15.69 (range, 60 to 140) to post operative mean of 105.6 ± 13.88 (range 80 to 140)).

The mean pre operative knee score and function score were 40.74(range 22-55) and 27.70(range 0-50) which improved to a mean of 73.67(range 55-90) and 40.55(range 0-70) post operatively

Comparison between the standard and high flex implants has been reported recently by few authors. Minoda et al [2009] analysed range of motion of standard and hi-flex cruciate retaining prosthesis prospectively [64]. They had 89 knees with standard and 87 knees with high flexion CR total knee prostheses [both Next Gen brands]. Differences in age, gender, diagnosis, preoperative ROM of the knee, and Knee Society Score between the 2 groups were not statistically significant. At 12-month follow-up, average ROM was $112.0^\circ \pm 12.6^\circ$ for standard, and $115.3^\circ \pm 13.4^\circ$ for high-flexion CR prosthesis ($P = .101$). They found no significant differences between groups with regard to ROM, clinical, or radiographic parameters. Seon et al [2009] analysed 100 knees with 50 knees in each category of Hi-flex and standard total knee prosthesis [65]. At the time of the final follow-up, the average maximal non-weight-bearing flexion was 135.3° for the knees in the high-flexion group and 134.3° for the knees in the standard group; the difference was not significant. Moreover, no significant difference was found between

the groups in terms of weight-bearing flexion (124.8° in the high-flexion group and 123.7° in the standard group) and the number of knees that allowed kneeling and sitting cross-legged. The average Hospital for Special Surgery knee score was 94.4 points in the high-flexion group and 92.4 points in the standard group; the difference was not significant. The Western Ontario and McMaster Universities Osteoarthritis Index scores also showed no significant difference between the groups. Thus no functional difference was noted in two groups.

Nutton et al [2008] performed prospective randomised comparison of the functional outcome in patients receiving either a NexGen LPS-Flex or the standard design [66]. The study included total of 56 patients, half of whom received Hi-flex and standard knee prosthesis each. They found that there was no significant difference in outcome, including the maximum knee flexion, between patients receiving the standard and high flexion designs of this implant. Gupta et al [2006] reported a significant improvement in the post-operative range of movement using a high flexion rotating platform design when compared with a standard design of rotating-platform TKR [67]. Similarly, Bin and Nam [2007] found a significant improvement in knee flexion at one year after operation in patients receiving a high flexion design compared with a standard knee replacement, particularly in patients with a pre-operative range of flexion of less than 90° [68]. Kim, Sohn and Kim [2005] were unable to show a significant improvement in knee flexion using a NexGen LPS-Flex knee replacement [69]. In their study, the standard design was used in one knee and high flexion prosthesis in the other. After a mean of 2.1 years the mean range of movement was 136° in the standard design and 139° in the high flexion design, compared with a mean preoperative range of movement of 126° and

127°, respectively. In their Asian population, the pre-operative range of movement was greater than in the present series, despite which they were unable to demonstrate any advantage in using a high flexion design over the standard version. Other studies from Asian centers have failed to show an improvement in knee flexion using a high flexion design [70,71]. This is in contrast with expectations that the Asian population will be more satisfied with the Hi-flex designs.

Menegheni et al [2007] retrospectively reviewed 511 TKAs in 370 patients fitted with posterior cruciate ligament–substituting prosthesis (NexGen Legacy, Zimmer, Warsaw, Ind) of a traditional design (not designed for high flexion)[72]. The mean follow-up was 3.7 years (range, 2-8 years). Regression analysis determined the effect of obtaining high flexion (>125°) on Knee Society, stair, function, and pain scores. Of 511 TKAs, 340 (66.5%) obtained range of motion greater than 115°, and 63 (12.3%) TKAs obtained high flexion greater than 125°. There was no difference between the patients who obtained flexion greater than 115° and those who obtained high flexion greater than 125° in Knee Society scores (P = .34) and function scores (P = .57). Patients with greater than 125° of flexion are 1.56 times more likely to demonstrate optimal stair function (P = .02). Obtaining flexion greater than 125° after TKA does not offer a benefit in overall knee function. However, obtaining a high degree of flexion appears to optimize stair climbing.

First metaanalysis done by Gandhi et al was published in 2009 January [73]. They studied 6 studies that met with their inclusion criteria. They concluded that High-flexion implant design improves overall ROM as compared to traditional implants but offers no

clinical advantage over traditional implant designs in primary knee arthroplasty. Murphy et al [2009] performed a systematic review of published trials designed to determine if there is a significant increase in ROM or function in patients who receive a high-flexion TKA compared to those who receive a standard TKA [74]. Nine studies fitting the inclusion criteria were analyzed. They concluded that there was insufficient evidence of improved range of motion or functional performance after high-flexion knee arthroplasty.

In our study we found that post operatively the mean pain score, the flexion deformity, the further flexion and the knee and function score were all comparable in each of the groups.

Thus our study shows no definite advantage of hi flexion knee prosthesis over the standard knee prosthesis.

CONCLUSION

Thus on a whole, the conclusion of this work can be divided into four sections.

I] Role of Total Knee Replacement in Osteoarthritis and Rheumatoid Knee:

Our results show that all the patients improved not only clinically but functionally too.

The decrease in flexion deformity and increased range of motion lead to a better quality of life in all our patients. Correction of flexion and angular deformities with alignment of the mechanical axis leads to better gait and walking ability. Thus for patients of severe osteoarthritis total knee replacement is a life-quality enhancing option.

II] Performance of Hi flex Knee Prosthesis:

In our study the patients showed significant improvement in all the outcome measures.

As thought, the hi flexion knee does not give significant improvement in range of motion as compared to a standard knee implant.

III] Performance of PFC Sigma:

All the patients showed significant improvement in both the clinical and functional outcome measures with significant decrease in pain. These implants performed equally well showing similar functional outcomes as compared to hi flexion implants

IV] Comparison between High Flex with conventional design prosthesis:

The comparison showed that high flex implant does not have any advantage over the conventional implant with respect to range of motion, pain relief ,functional outcome and quality of life. This indicates that either implant can be used.

Thus from the above conclusions we can sum up the recommendations from our study.

1. Total knee replacement not only improves the clinical range of motion of the patients and provides pain relief, it also significantly improves the quality of life and should be undertaken for patients with severe osteoarthritis.

2. High flexion implants as hypothesized do not offer any advantage over the standard knee implant at the end of 1 year follow up period

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ANNEXURES

Annexure 1 - Proforma for evaluation:

A	Personal Details	
	Name	
	Reg no	
	Age	
	Sex	
	Contact	
	Date Of Admission	
	Date Of Surgery	
	Date Of Discharge	
	Side : Right/Left	
	Diagnosis	
	Contralateral knee	
	Body Mass Index	
B	Pre Operative Details	
	Range of Movement	
	Flexion Deformity	
	Knee Score	

	Functional Score	
	Pain Score	
	Ligament Laxity	
C	Post Operative Factors	
	Knee score	
	Function Score	
	VAS Score	
	SLR	
	90 Degree Flexion	
	Range Of Motion	
	Flexion Deformity	
	Walking	
	Complications	
D	Final Follow Up	
	Range of Motion	
	Gain in Flexion	
	Squat/Sit Cross Legged	

	Flexion Deformity	
	Knee Score	
	Functional Score	

Annexure 2 - Knee Society Score

1. Pain

	Pts	Pre-op	1 yr
None	50		
Mild or occasional	45		
Stairs only	40		
Walking and stairs	30		
Moderate	20		
Occasional			
Continual	10		
Severe	0		

2. Range of Motion

5 degree = 1 point	25		
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3. Stability (maximal movement in any position)

Anteroposterior			
< 5mm	10		
5-10 mm	5		

> 10mm	0		
Mediolateral			
< 5 degree	15		
6-9 degree	10		
9-14 degree	5		
> 15 degree	0		
Subtotal			

Deductions (minus)

5-10 degree	2		
10-15 degree	5		
16-20 degree	10		
< 10 degree	5		
10-20 degree	10		
>20 degree	15		
5-10 degree	0		
0-4 degree	3 pts each degree		
11-15 degree	3 pts each degree		
Other	20		
Total Deduction			

Knee Score			
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(If total in a minus number, score is 0)

4. Function

Unlimited	50		
> 10 blocks	40		
5-10 blocks	30		
< blocks	20		
House bound	10		
Unable	0		
Normal up & down	50		
Normal up; down with	40		
Rail			
Up with rail; down unable			
Unable			
Subtotal			
Deduction (minus)			
Cane	5		
Two cane	10		
Crutches/walker	20		

Total Deductions			
Function Score			

