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Original Research Article

A prospective study: Short-term clinical assessment of EMPK prosthesis in total knee arthroplasty

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Abstract

Background: Knee osteoarthritis (OA) is a progressive degenerative joint disease characterized by cartilage degradation and osteophyte formation, leading to chronic pain, reduced mobility, and significant impairment in daily activities. As a primary weight-bearing joint, the knee is particularly susceptible to OA, making it one of the leading causes of disability worldwide.

Methodology: This multicenter clinical study enrolled 150 patients, evaluating a total of 216 knees that underwent total knee arthroplasty (TKA) using the EMPK (EXCEL MEDIAL PIVOTAL KNEE SYSTEM) prosthesis. Clinical outcomes were assessed using validated patient-reported outcome measures (PROMs), including the Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Oxford Knee Score (OKS), both preoperatively and at three months postoperatively.

Results: The study cohort had a mean age of 65.7 ± 7.19 years, with a higher proportion of women patients. At three months postoperatively, the mean OKS increased significantly from 13.4 ± 3.5 preoperatively to 26.7 ± 4.2 ($p < 0.001$). The mean KSS improved from 52.3 ± 16.4 to 134.0 ± 15.1 ($p < 0.001$), while the mean WOMAC score decreased from 67.22 ± 8.80 to 47.21 ± 7.52 ($p < 0.001$), indicating substantial improvements in functional mobility and pain reduction.

Conclusion: The EMPK prosthesis demonstrated significant short-term improvements in knee function, pain relief, and overall quality of life in patients with end-stage knee osteoarthritis. These findings are consistent with existing literature on contemporary TKA systems, reinforcing the efficacy of EMPK as a reliable surgical option. However, ensuring optimal postoperative management, including infection control and implant longevity strategies, remains critical for sustaining long-term clinical benefits.

Keywords: Osteoarthritis, EMPK prosthesis, KSS, WOMAC, OKS.

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1. Introduction

Total knee arthroplasty (TKA) is a well-established surgical intervention for patients with osteoarthritis (OA) experiencing severe knee pain and functional impairment. OA, a chronic degenerative joint disorder, is characterized by progressive cartilage loss and osteophyte formation, ultimately leading to disability and restricted mobility. As a weight-bearing joint, the knee is particularly vulnerable to OA, affecting a significant proportion of the global population.[1,2]

Osteoarthritis affects each person differently. For some people, osteoarthritis is relatively mild and does not affect day-to-day activities. For others, it causes significant pain and disability. Joint damage usually develops gradually over years, although it could worsen quickly in some people.[3]

Osteoarthritis has often been referred to as a wear and tear disease. But besides the breakdown of cartilage, osteoarthritis affects the entire joint. It causes changes in the bone and deterioration of the connective tissues that hold the joint together and attach muscle to bone. It also causes

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inflammation of the joint lining.[4] More than 50% of individuals with knee OA present with bilateral involvement, often experiencing symptoms such as joint stiffness, quadriceps weakness, reduced range of motion, and persistent pain—typically described as a dull ache that worsens with activity. In advanced cases, severe OA can lead to genu varus deformity, further compromising mobility and quality of life.[5]

Early-stage OA is typically managed with conservative treatments, including weight management, physiotherapy, analgesics, and intra-articular injections. However, in advanced cases where conservative measures fail, TKA remains the gold-standard treatment, offering substantial pain relief and functional restoration. In India, nearly 80% of the population is affected by osteoarthritis, with approximately 20% experiencing significant disability in daily activities.[6]

This study aims to evaluate the short-term clinical efficacy and safety of the EMPK prosthesis in TKA patients.

A medial pivot joint is a type of synovial joint where one bone rotates around another in a circular motion, specifically around its longitudinal axis. This type of joint allows for rotational movement and is found in certain areas of the body.[7]

A good example of a medial pivot joint is the proximal radioulnar joint in the forearm, where the radius rotates around the ulna during pronation and supination (rotating the hand palm-up to palm-down and vice versa).[8]

In the context of human anatomy, this joint primarily permits rotation, which is a crucial motion for tasks like turning a doorknob, or in the case of the forearm, turning the palm up and down. The term "medial" refers to the direction in which the bone rotates relative to the body.

In total knee arthroplasty, the medial pivot design seeks to emulate the knee's natural kinematics by providing a highly conforming surface on the medial (inner) side of the joint. This design aims to improve clinical outcomes by restoring more natural motion and stability. Studies have shown that medial pivot implants can reproduce the physiological "medial pivoting" pattern of the knee, potentially leading to better functional results and reduced wear compared to traditional designs.[9,15]

Using validated patient-reported outcome measures (PROMs) such as the Knee Society Score (KSS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and Oxford Knee Score (OKS), the study assesses improvements in functional outcomes and pain reduction, providing valuable insights into the effectiveness of the EMPK prosthesis.[14,15,18]

2. Materials and Methods

2.1. Study design and participants

This multicentre, prospective study recruited 150 patients with moderate to severe knee OA. The study was conducted at four sites: Belle Vue Clinic, Kolkata (n = 105), K S Ortho Hospital, Coimbatore (n = 25), Shah Hospital, Ahmedabad (n = 6) and Sarvodhya Hospital, Faridabad (n = 14). Institutional ethics committee approvals were obtained for each site, and all patients provided informed consent.

2.2. Sample size calculation

The sample size was determined based on a 95% confidence level and a 9% margin of error, assuming a population proportion of 0.5. Using a standard z-value of 1.96, the minimum required sample size was calculated as 118. Accounting for a 30% dropout rate over the five-year study period, the final sample size was determined to be 150 patients.

2.3. Inclusion criteria

1. Men or non-pregnant, non-lactating women patients aged ≥18 years.
2. Patients with severe knee pain and functional impairment requiring TKA.
3. Clinical signs and symptoms corresponding to hip and/or knee OA or radiologically diagnosed OA.
4. Willingness to comply with study requirements and provide informed consent.

2.4. Exclusion criteria

1. Body mass index (BMI) ≥40.
2. Patients requiring revision knee arthroplasty.
3. Active or suspected joint infections.
4. Neurological/musculoskeletal disorders impairing ambulation.

2.5. Data collection and outcome measures of preoperative and post-operative (03 months) evaluation

Patient-reported outcome measures (PROMs) were used to evaluate functional outcomes:

1. Knee society score (KSS): Assesses knee stability, alignment, range of motion, symptoms, patient satisfaction, and functional capacity.
2. WOMAC score: Consists of 24 questions evaluating pain, stiffness, and physical function.
3. Oxford knee score (OKS): A validated tool measuring pain and functional impairment based on daily activities over the preceding four weeks.[13]

2.6. Statistical analysis

Statistical analysis was performed using chi-square and t-tests to determine the significance of preoperative and postoperative differences. p-value <0.05 was considered statistically significant.

3. Results

3.1. Patient demographics

The study cohort comprised 150 patients aged 42–85 years (mean: 65.7 ± 7.19). The majority were women (n = 118, 78%), with 32 men patients (21%). A total of 216 TKA procedures were performed, including 66 bilateral, 38 left, and 46 right knee replacements.

3.2. Clinical outcomes

The KSS, WOMAC, and OKS assessments demonstrated significant improvements at three months postoperatively: Knee Society Score (KSS). Preoperatively, 74% of patients had poor KSS scores, while 16% had fair scores. Only 9% had good or excellent scores. Post-operatively, the mean KSS improved significantly from 52.3 ± 16.4 to 134.0 ± 15.1 ($p < 0.001$) as seen in **Table 1**.

Table 1: Summary of knee society score

	Knee Society Score	
	Pre score	**Post 03 months**
N (Total number of knees)	216	216
Mean	52.3	134.0
SD	16.4	15.1
Minimum	5	85
Median	54	134
Maximum	95	179
CV	31.29	11.23
P value (T Test - Correlated Samples) Pre vs Post	<.0001*	

**P* value <0.05 shows statistically significant

3.3. WOMAC score

Preoperatively, 91.3% of patients had moderate arthritis, while 8.3% had severe OA. The mean WOMAC score decreased from 67.22 ± 8.80 to 47.21 ± 7.52 postoperatively ($p < 0.001$), indicating reduced pain and improved function as shown in **Table 2**.

Table 2: Summary of WOMAC

	WOMAC	
	Pre score	**Post 03 months**
N (Total number of knees)	216	216
Mean	67.22	47.21
SD	8.80	7.52
Minimum	48.95	25.93
Median	65.10	47.80
Maximum	92.00	75.00
CV	13.10	15.93
P value (T Test - Correlated Samples) Pre vs Post	<.0001*	

**P* value <0.05 shows statistically significant

3.4. Oxford knee score (OKS)

Preoperatively, 95.3% of patients had severe OA, while 4.7% had moderate arthritis. The mean OKS improved from 13.4 ± 3.5 to 26.7 ± 4.2 postoperatively ($p < 0.001$) as depicted in **Table 3**.

Table 3: Summary of Oxford knee score

	Oxford Knee Score	
	Pre score	**Post 03 months**
N (Total number of knees)	216	216
Mean	13.4	26.7
SD	3.5	4.2
Minimum	1	13
Median	13	27
Maximum	22	39
CV	26.02	15.56
P value (T Test - Correlated Samples) Pre vs Post	<.0001*	

**P* value <0.05 shows statistically significant

4. Discussion

This study confirms the efficacy of the EMPK prosthesis in enhancing short-term clinical outcomes following TKA. The notable postoperative improvements in KSS, WOMAC, and OKS are consistent with findings from previous studies on modern TKA implants.[11,14-17]

The EMPK design allows for some adjustability, enabling the knee to adapt to different angles of flexion. This adaptability is crucial in providing more natural movement and improving the overall function, especially in activities that require high mobility.[15]

One of the key advantages of the EMPK prosthesis is its design, which aims to optimize kinematics and patient comfort, potentially contributing to the rapid functional improvements observed within the short-term follow-up period. The significant increase in KSS and OKS scores, suggests that the prosthesis facilitates early recovery, allowing patients to regain independence and improve their overall quality of life.[18]

The EMPK prosthesis is often chosen for patients with significant knee deformities, those with severe arthritis or bone deformities, or for patients who are highly active and need a knee that provides more natural motion and stability during daily activities.

The polycentric design offers better knee flexion and extension, making walking and other movements feel more natural. Enhanced Stability provides better stability during flexion and weight-bearing, which can reduce the risk of dislocation.

The results with Medial Pivot joints are often excellent. This type of prosthesis aims to give the user more functional range and better quality of life after total knee replacement.

While short-term benefits are evident, long-term follow-up studies are needed to assess wear resistance, potential revision rates, and overall implant survival. Understanding

these factors will be essential in optimizing patient outcomes and ensuring that EMPK remains a viable and durable option for knee OA treatment.[11]

5. Conclusion

The EMPK prosthesis demonstrated excellent clinical outcomes in patients undergoing total knee arthroplasty (TKA) for end-stage osteoarthritis, with significant improvements in pain relief, functional mobility, and overall quality of life. These results highlight the effectiveness of EMPK as a reliable and well-tolerated treatment option, supporting its role in enhancing patient outcomes.

While the short-term benefits are evident, ensuring long-term success requires addressing key challenges such as implant longevity, surgical site infections, and potential revision rates. Continued research with extended follow-up periods will be essential to fully assess implant durability and long-term patient satisfaction. Additionally, optimizing postoperative care strategies, including rehabilitation protocols and infection prevention measures, will be critical in sustaining favourable outcomes.[15]

In conclusion, the EMPK prosthesis represents an effective and promising solution for knee osteoarthritis management. With appropriate patient selection, meticulous surgical technique, and comprehensive postoperative care, it has the potential to enhance surgical success rates, improve functional independence, and significantly elevate the quality of life for individuals undergoing TKA.

6. Ethical Approval

Not Applicable.

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8. Conflict of Interest

The author(s) declared no potential conflicts of interest.

9. Author's Contribution

SB: Study design, Manuscript writing, literature review, statistical analysis; SK: Manuscript Editing, literature review, Methodology; KS: Manuscript Editing, literature review, Methodology; MS: Manuscript Editing, literature review, Methodology.

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