

Original Research Article

A comprehensive comparative study on mid-term clinical and functional outcomes in Indian patients following bilateral total knee arthroplasty: assessing the impact of body mass index on post-total knee arthroplasty results

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Received: 01 March 2024

Revised: 12 March 2024

Accepted: 14 March 2024

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ABSTRACT

Background: Limited research exists on Indian obese patients undergoing simultaneous bilateral total knee arthroplasty (bTKA), necessitating a comprehensive and comparative analysis with non-obese counterparts. This study presents an observational and prospective assessment of Indian patients who underwent cruciate retaining/posterior stabilized (CR/PS) metal-backed implant surgeries from 2016 to 2019.

Methods: The study encompassed 190 patients (380 knees) undergoing bTKA, classified by World Health Organization (WHO) weight stratification: normal weight (cohort 1, n=51), overweight (cohort 2, n=85), and obese (cohort 3, n=54). Primary endpoints were implant survivorship and revision rates, with secondary endpoints including range of motion (ROM), knee society score (KSS), Western Ontario and McMaster Universities osteoarthritis index (WOMAC), and SF-36 scores.

Results: Female representation dominated all groups (88.24%, 87.06%, and 90.74%). End-stage osteoarthritis occurred in 94.12%, 96.47%, and 98.15%, respectively. Over the 3-year follow-up, four fatalities occurred, with 186 patients completing the study. ROM showed significant improvement after three years, with baseline values increasing from $93.29^{\circ} \pm 18.29^{\circ}$ (cohort 1) to $123.97^{\circ} \pm 2.28^{\circ}$, $122.86^{\circ} \pm 5.03^{\circ}$, and $122.67^{\circ} \pm 4.77^{\circ}$, respectively ($p < 0.001$). KSS demonstrated substantial improvement (cohort 1: 89.87 ± 6.48 , cohort 2: 90.47 ± 8.40 , cohort 3: 90.52 ± 8.07) after three years. A 100% success rate and no revisions indicated implant durability. WOMAC and SF-36 questionnaires exhibited significant improvements in pain, stiffness, and overall well-being ($p < 0.001$) after bTKA.

Conclusions: This mid-term CR/PS knee survival analysis underscores 100% implant functionality, improved knee function, and enhanced quality of life for all patients, irrespective of their body mass index (BMI). Simultaneous bilateral TKA with CR/PS implants demonstrates favourable outcomes, affirming its efficacy as a viable treatment option.

Keywords: Bilateral total knee arthroplasty, Cruciate retaining/posterior stabilized total knee system, Body mass index, Obesity, Range of motion, Radiography

INTRODUCTION

End-stage knee osteoarthritis (OA) has a severe impact on the daily activities of the individuals and chances of knee OA increases six-fold in obese individuals with body mass index (BMI) $>30 \text{ kg/m}^2$ playing the major contributor to the disease.¹ With increased BMI chances of bilateral disorder increases requiring patients to undergo total knee arthroplasty (TKA).² Approximately 40% of the patients who had primary unilateral TKA has shown to undergo contralateral TKA within the period of 8-10 years.^{3,4} Furthermore, the mechanical stress imposed by excess body weight on knee joints can accelerate the degenerative processes leading to OA, necessitating joint replacement surgery. The rise in global obesity rates has led to a surge in the number of individuals with elevated BMI seeking TKA. Bilateral TKA (bTKA), the simultaneous replacement of both knee joints, has emerged as a viable option for patients regardless of their BMI.⁵

The bilateral TKA is an appealing alternative due to the high prevalence of severe, bilateral OA in up to 19% of patients upon initial presentation.⁶ This approach effectively tackles the issues related to phased operations. Nevertheless, prior research examining the efficacy of simultaneous bTKA has documented higher death rates and an elevated incidence of vascular complications, including deep vein thrombosis and pulmonary embolism, in contrast to unilateral TKA. While the prolonged exposure to a single anaesthetic is commonly associated with these consequences, there is less understanding of other contributing factors, such as obesity.⁶⁻⁸

Although many retrospective analyses of obese patients undergoing TKA has been reported from Western population, paucity of the same with Indian obese patients undergoing bTKA has created a gap in decision making for these individuals suffering from bilateral knee OA.^{9,10} None of the literature available on cruciate retaining (CR)/posterior stabilized (PS) total knee system (TKS implant) has evaluated the efficacy and safety of the device in obese patients undergoing bTKA. Studies available has lacked in assessing the impact of BMI on implant survivorship, rates of revision and other clinical and functional parameters in obese patients.

Therefore, this study was designed to evaluate the effect of BMI and present the comparative analyses of obesity with normal weight patients undergoing bTKA with CR/PS TKS including the implant safety, stability, and efficacy.

METHODS

This study conducted a prospective observation between November 2016 and January 2019 utilizing CR/PS metal-backed (MB) total knee systems (TKS), as part of the ongoing Freedom 400 study (CTRI no: CTRI/2016/11/007455). It is a multicenter investigation involving prominent institutions such as Ramaiah Medical College and Hospital and Ramaiah Memorial Hospital in

Bangalore, Karnataka, India; Apollo Hospital, Hyderabad, SVS Medical College in Mahbubnagar, Telangana, India; Wockhardt Hospitals, Mumbai Central, India; Max Superspeciality Hospital, Shalimar Bagh, Delhi and Naveda Healthcare Centre, Delhi, India. The study received approval from the Institutional Review Board at each local centre. Prior written informed consent was obtained from all patients and was conducted in accordance with The code of ethics of the World Medical Association (Declaration of Helsinki). A total of 190 individuals (comprising 380 knees) who underwent simultaneous bTKA at various institutions were identified. The inclusion criteria for this study encompassed cases of primary bTKA that were conducted for end-stage knee OA/rheumatoid arthritis, all of which were carried out under a single anaesthesia. The inclusion criteria also encompassed bTKA patients who had substantial structural deterioration in both knees, resulting in equivalent levels of pain, and expressed a strong desire to have bTKA. The patients were classified into three categories based on their BMI values, stratified according to World Health Organization (WHO) definition: normal weight (cohort 1, BMI 18.5 kg/m^2 to 25.00 kg/m^2), overweight (cohort 2, BMI 25.00 kg/m^2 to 29.99 kg/m^2), or obese (cohort 3, class 1 and 2 obese patients, BMI 30.00 kg/m^2 to 39.99 kg/m^2). Exclusion criteria included patients with revisional bTKA, unilateral TKA patients, patients with less than 5 years of survival rate suffering from end-stage chronic disorders (cancer and AIDS), patients suffering from auto-immune disorder and patients unable to provide written informed consent.

Clinical evaluation

Demographic information about patients from electronic medical records, including variables such as age, gender, BMI, length of hospitalization, and existing medical comorbidities were pre-operatively noted. The BMI was derived by the utilization of height and weight measurements, which were consistently obtained by healthcare professionals using a calibrated electronic scale at baseline. The patients underwent preoperative assessment and were then evaluated at follow-up intervals of 6 weeks, 6 months, 1 year, and 3 years. The collection of patient-reported outcome measures (PROMs) was conducted during each visit by physical therapists who were not affiliated with the study. The evaluated measures encompassed the knee society score (KSS), Western Ontario and McMaster Universities (WOMAC) scores, and the 36-item short form health survey (SF-36). These measures were subsequently converted into two overarching summary scores: the physical component score (PCS) and the mental component score (MCS). The measurement of range of motion (ROM) was conducted. Radiographic images were obtained both before and after the surgical procedure and up to a duration of three-years post-surgery, to comprehensively evaluate the disease status, as well as the extent of wear and osteolysis of the implant subsequent to TKA.

Statistical analysis

The study findings are presented as the mean±standard deviation for continuous variables, and as counts (percentages) for categorical variables. Comparative analyses of continuous variables employ the 2-sample t-test for independent samples. Categorical variables are compared using the chi-square test. Statistical significance is determined at a p value threshold of <0.05.

RESULTS

Baseline characteristics

Total of 190 patients were enrolled and 380 knees were implanted with CR/PS TKS at various centres between November 2016 to January 2019. Of the 190 subjects, there were high ratio of overweight patients (cohort 2: n=85) with mean BMI of 27.24±1.39 kg/m² followed by obese (cohort 3: n=54) with mean BMI of 33.73±2.89 kg/m² and normal patients (cohort 1: n=51) with mean BMI of 22.94±1.39 kg/m². High proportion of female patients were seen in all 3 cohorts, 88.24%, 87.06% and 90.74% respectively. Table 1 displays the comprehensive data regarding the total count of patients, their respective genders, and age distribution, depiction of notable diseases and additional disease-related information. End-stage OA was the dominant disorder seen in 94.12%, 96.47% and 98.15% of cohort 1, 2 and 3 respectively as shown in Table 1.

A total of 186 patients successfully completed the 3-year follow-up period. No instances of consent withdrawal were observed in any of the categories during the initial year of the study. However, three patients in the Obese category withdrew their consent, and one patient in the normal cohort was lost to follow-up after three years of observation. A total of four fatalities during 3 years' follow-up were recorded, with two occurring within the normal weight cohort and two among the overweight cohort. There were no recorded instances of mortality within cohort 3 (obese patients). In cohort-1, one male patient, aged 82.6 years, succumbed to a multitude of factors culminating in cardiac arrest 6 weeks post-operatively, while at 3-year follow-up, one female patient,

aged 65.2 years, succumbed to natural causes of death. Among cohort 2, an instance of mortality at 3 years attributable to a pulmonary infection was observed, involving a female patient aged 67.1 years, additionally during the same follow-up duration, 60.5 years old also a female patient, died of pulmonary pneumonia.

One patient in the normal group suffered from deep vein thrombosis for which conservative management was employed and the resulting impact was deemed insignificant. In the immediate post-operative period, acute urine retention was observed in four patients, with two individuals in each group, overweight and obese. In the study, it was observed that four patients from the obese group and one patient from the overweight group experienced superficial wound infection. Thorough wound debridement was done, and culture specific antibiotic cover was given for post op 3 to 4 weeks for all patients. Post-operatively, there was no statistically significant difference (p>0.05) in the occurrence of patellofemoral problems among all three groups. Four patients underwent a surgical procedure patella resurfacing in the overweight (n=2) and obese group (n=2) and one patient in normal weight group.

Among the total cohort of 190 patients, three patients (1.6%) necessitated tibial stem extension during bTKA. One case involved the application of a tibial stem extension due to insufficient bone stock, while two cases required the extension to address compromised bone quality in the tibia.

The radiographic assessment conducted post-TKA, demonstrated satisfactory placement, alignment, and performance of the implant at multiple time points, including 3 years' study duration. Subsequent evaluations at the 3-year mark were performed selectively, based on patient consent and surgeon discretion, and were limited to cases deemed necessary. These findings are depicted in Figure 1, showcasing a series of radiographs and orthoscanograms (pre-operative and post-operative 3 years). No signs of wear or osteolysis were detected, and the implants were well aligned and remained functional in both right and left knee throughout the duration of the follow-up study period.

Table 1: Baseline characteristics and distribution of the disease in the study cohort.

Patient characteristics	Normal cohort	Overweight cohort	Obese cohort
Total number of patients, N	51	85	54
Age, years, mean±SD	66.27±7.75	64.73±6.64	62.95±7.12
Gender, N (%)			
Male	6 (11.76)	11 (12.94)	5 (9.26)
Female	45 (88.24)	74 (87.06)	49 (90.74)
Body mass index, kg/m², mean±SD	22.94±1.39	27.24±1.39	33.73±2.89
Heart rate, beats per minute, mean±SD	80.98±10.41	81.44±11.58	78.81±10.06
Systolic blood pressure, mmHg, mean±SD	135.49±19.71	136.41±18.06	132.72±20.53
Diastolic blood pressure, mmHg, mean±SD	78.88±8.32	81.31±9.62	80.15±9.54

Continued.

Patient characteristics	Normal cohort	Overweight cohort	Obese cohort
Primary diagnosis, N (%)			
Osteoarthritis	48 (94.12)	82 (96.47)	53 (98.15)
Rheumatoid arthritis	1 (1.96)	2 (2.35)	1 (1.85)
Other	2 (3.92)	1 (1.18)	0 (0.00)

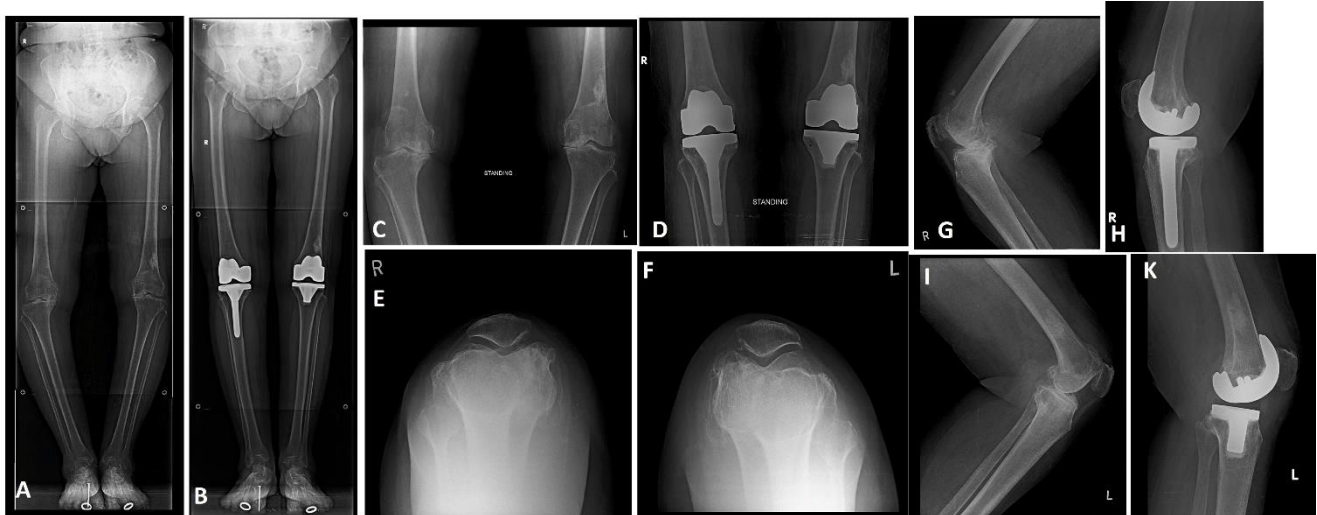


Figure 1: (A and B) Shows the representative pre-operative and post-operative orthostanograms, (C and D) shows the antero-posterior radiographs of pre-operative and post-operative radiographs, (E and F) skyline radiographs, (G and H) lateral radiographs, (I and J) lateral radiographs (pre-operative and post-operative 3 years).

Functional and clinical outcomes

The findings from a comprehensive three-year evaluation on the durability of implants revealed a 100% success rate, with no occurrences of revision necessary for the entirety of the investigation. The investigators performed a comparative analysis of the ROM measurements acquired during each subsequent assessment session and the initial baseline scores across all three cohorts. The study yielded a statistically significant alteration within each group, with a $p < 0.001$. Nevertheless, no statistically significant differences were seen across the groups. The baseline scores for the cohorts were initially measured as $93.29^\circ \pm 18.29^\circ$ (cohort 1), $97^\circ \pm 18.83^\circ$ (cohort 2), and $97.21^\circ \pm 14.98^\circ$ (cohort 3). These scores showed a substantial improvement after 6 weeks, with values of $103.89^\circ \pm 15.33^\circ$ (cohort 1), $108.77^\circ \pm 13.4^\circ$ (cohort 2), and $108.78^\circ \pm 11.5^\circ$ (cohort 3). Additionally, after three years, there was a notable increase in the scores seen ($123.97^\circ \pm 2.28^\circ$ for cohort 1, $122.86^\circ \pm 5.03^\circ$ for cohort 2, and $122.67^\circ \pm 4.77^\circ$ for cohort 3) (Figure 2).

Clinical assessment through KSS revealed significantly poor baseline scores in cohort 1 (29.86 ± 15.77) than overweight (34.74 ± 15.97) with p value of 0.02 and obese patients (37.84 ± 13.85) with $p < 0.001$ and the difference was noted during 6 weeks' follow-up where cohort 2 and 3 showed significant improvement when compared to normal BMI patients 67.73 ± 13.39 (cohort 1), 71.35 ± 13.75 (cohort 2) with $p = 0.05$ and 72.27 ± 14.28 (cohort 3) with $p = 0.03$. At the three-year mark, patients demonstrated

improvement in their scores regardless of their BMI. There was no notable difference found across the three groups. However, within each group, there was a statistically significant improvement in patients' evaluations. The study observed scores of 89.87 ± 6.48 (cohort 1), 90.47 ± 8.40 (cohort 2) and 90.52 ± 8.07 (cohort 3) was noted. A comparable pattern was noted in the case of functional KSS, wherein cohort 1 exhibited lower baseline scores (mean score of 25.34 ± 19.17) compared to cohort 2 (31.88 ± 22.11) with a significant difference ($p = 0.01$), as well as cohort 3 (35.83 ± 18.95) pre-operative scores with a highly significant difference ($p < 0.001$). The results demonstrated a statistically significant improvement in scores when compared to their pre-operative scores. Cohort 1 exhibited an average score of 98.67 ± 2.92 , cohort 2 had an average score of 98.68 ± 4.42 , and cohort 3 showed an average score of 98.69 ± 3.14 over a span of three years. These findings indicate that the scores remained relatively consistent across the three cohorts during this period. Figure 3 displays the clinical and functional KSS among these bilateral cohorts. Furthermore, no disparities in functional outcomes were seen between the left and/or right knees of any individual patient.

Quality of life assessment

The assessment of QoL was conducted using the WOMAC and SF-36 questionnaires, which utilize PROMs to measure changes in QoL before and after TKA. The examination of WOMAC characteristics, encompassing pain, stiffness, and degree of difficulty, employed a three-

point scoring system. Comparatively poorer baseline pain scores were observed in both overweight and obese patients when compared to normal BMI patients. Specifically, the baseline pain scores were as follows: normal weight patients had a mean score of 24.85 ± 4.97 , overweight patients had a mean score of 23.52 ± 6 and obese patients had a mean score of 22.57 ± 5.16 . Following TKA, there was a significant improvement in pain scores for all groups at the 6-week mark. The 6 weeks' pain scores were as follows: normal weight patients had a mean score of 10.14 ± 4.48 , overweight patients had a mean score of 9.64 ± 5.02 and obese patients had a mean score of 9.80 ± 5.45 (Figure 4).

Figure 4 provides a comprehensive evaluation of the 3-year follow-up WOMAC results for bTKA, demonstrating a decrease in pain, stiffness, and functional limitations following the TKA procedure.

A comparable trend was noted in the SF-36 parameter, wherein various aspects such as pain, emotional well-being, role limitations due to physical and emotional health, and overall general health were evaluated. We observed a remarkable enhancement in these factors following TKA at the 6-week, 6-month, 1-year, and 3-year time points (Figure 5).

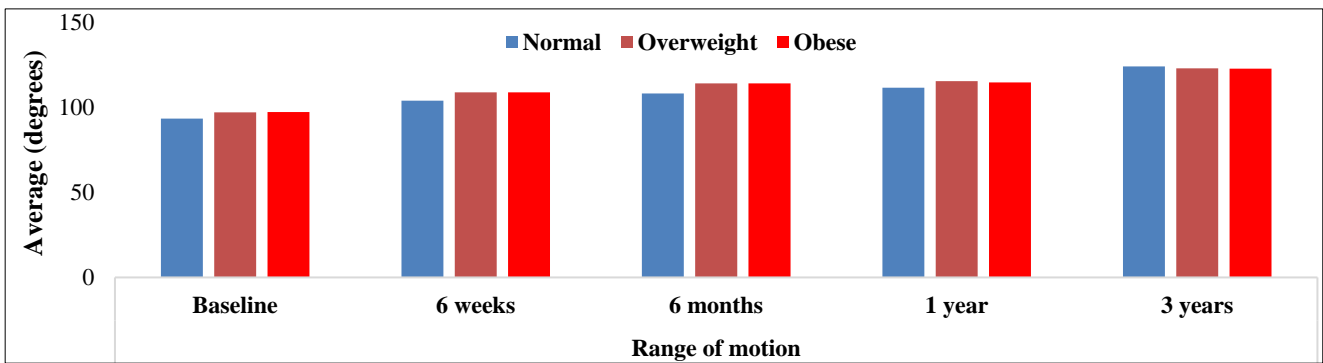


Figure 2: Preoperative and post-operative different follow-up time points showing statistically improved range of motion.

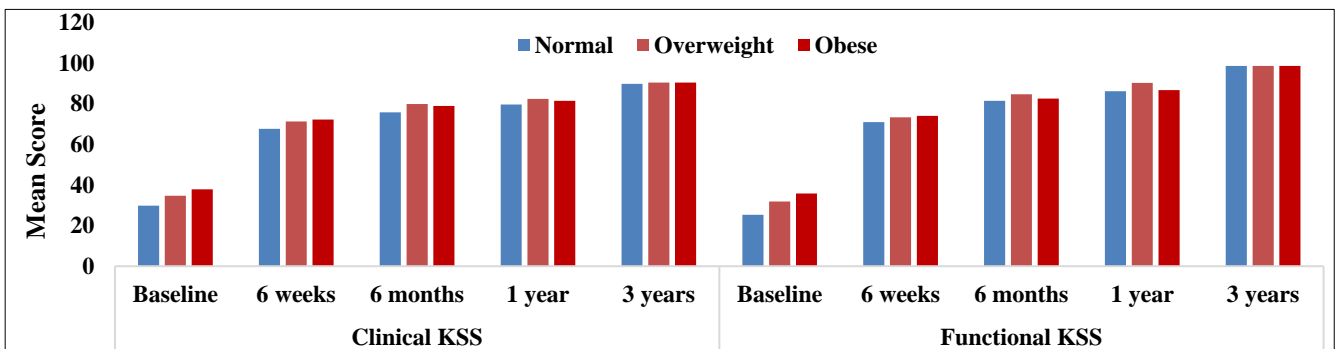


Figure 3: Clinical and functional knee society scores at different follow-up timepoints showing statistically improvement.

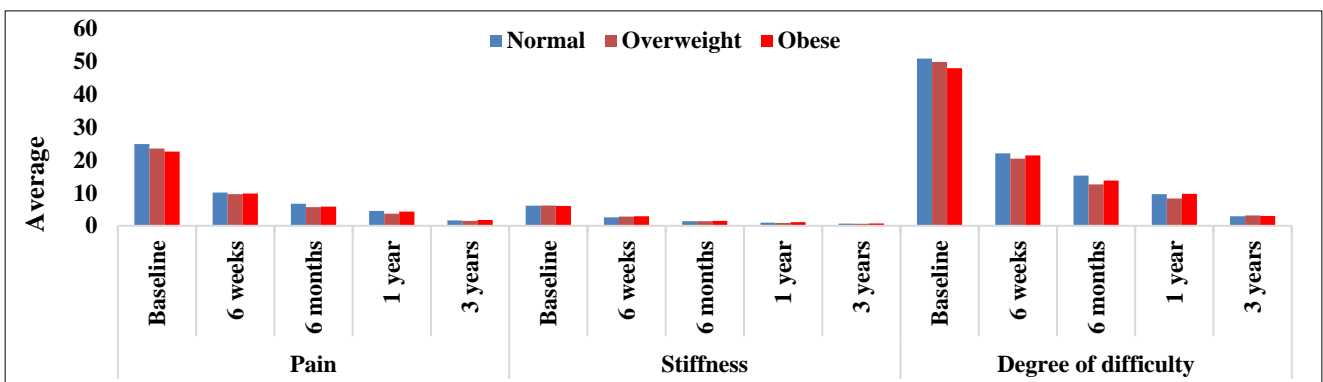


Figure 4: A comprehensive evaluation of the 3-year follow-up WOMAC results for bTKA, demonstrating a decrease in pain, stiffness, and functional limitations following the TKA procedure.

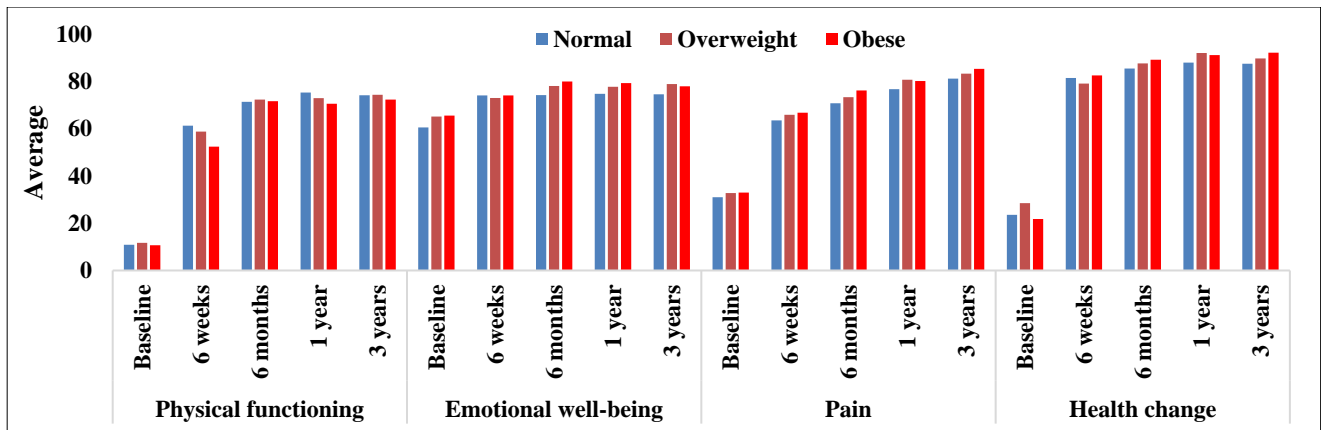


Figure 5: Shows the pre-operative and follow-up scores assessed based on patient-reported outcome evaluation of SF-36 questionnaire in patients undergoing bilateral TKA.

DISCUSSION

In our study, we observed a diverse patient population, with varying BMI categories, predominantly consisting of overweight individuals, which aligns with the growing global trends of obesity. The main medical rationale for choosing bTKA as a treatment option for these patients is the high prevalence of end-stage bilateral knee OA, and this treatment modality emphasizes the critical need for simultaneous bilateral joint replacement surgeries to address the substantial burden of OA.

It is noteworthy that patient attrition, withdrawal of consent, and loss to follow-up were relatively low, reflecting the overall compliance and engagement of the study participants. The recorded fatalities, though unfortunate, were not directly attributed to the TKA procedure and appeared to be influenced by underlying health conditions.

The durability and success rate of the CR/PS TKS implant in our study are consistent with the findings from Durbhakula et al who in a prospective, continuous series of 176 primary posterior stabilized (PS) TKAs, reported a similarly high success rate with no revisions required during a two and five-year follow-up.^{11,12} Another study by Londhe et al reports no revision rate and safety and stability of the same implant.¹³ These studies along with our observations, reiterates that the CR/PS TKS implant offers reliable, stable and a long-term performance.

In few studies reported, various authors believed that the risk of complications to be higher following bTKA compared to unilateral or staged procedures with BMI found to be a contributing factor.^{5,14} In our study we did not observe any such post-TKA complication, influenced by BMI during the study duration. The unrelated, unfortunate mortality reported can be influenced by weight however, BMI seems to act as non-factor as no complications were observed in our cohort 1 and 2 and no death was reported among obese patients. The study resonates the observation of researchers, who claimed that

BMI cannot be considered as an “exclusionary factor” for patients needing bTKA and patients with bilateral knee OA can be a candidate for TKA.¹⁵ Based on the investigation conducted by Spicer et al no substantial discrepancy was identified in the functional outcome of patients undergoing bTKA in obese versus non-obese patients.¹⁶ The aforementioned conclusion was derived from an evaluation of the Oxford knee score, utilizing a mean follow-up duration of 75.9 months. Griffin et al did a study wherein they noticed that there was no noticeable discrepancy in post-operative outcomes between normal weight patients and obese patients after a period of 10 years.¹⁷ The researchers specifically highlighted that there were comparable results in terms of post-operative knee scorings and revision rates between both patient groups. A study conducted by Amin et al has found that there are similar outcomes obtained in patients receiving TKA, regardless of their obesity status.¹⁸ In our study, we examined a cohort of 190 individuals who underwent a total of 380 TKAs. The findings from our study indicates and re-affirms that the functional ratings and implant survivorship observed in obese and overweight patients are comparable to those reported in a historical control group consisting of non-obese patients with CR/PS TKS and BMI has the least effect post-TKA. Meehan et al conducted a study comparing the incidence of periprosthetic infections and malfunction rates in patients who underwent simultaneous vs. staged bilateral arthroplasty. The findings revealed that the former group saw reduced rates of periprosthetic infections and malfunction within the first year. However, it is worth noting that the incidence of cardiovascular complications was found to be higher within the initial month following the procedure.¹⁹ However, no such complications in the initial year were noted in our study in any cohort including the obese patients. Similarly, Restrepo et al conducted a study in which they observed that simultaneous bTKA were associated with elevated rates of cardiac problems, pulmonary embolism, and mortality.²⁰ Previous studies have indicated that the performance of simultaneous bTKA is a safe procedure, with no observed elevation in postoperative mortality and morbidity rates.^{21,22} Our study

resonates with these studies as no post-TKA related mortality or post-operative complications were reported.

In this investigation into the impact of BMI on Indian patients undergoing bTKA with the CR/PS TKS, we have gained valuable insights into the postoperative outcomes associated with this innovative implant. The World Health Organization's BMI classification, recognized as a significant determinant of surgical success, prompted our exploration into this underexplored domain. Our findings reveal several noteworthy observations. First, the implant, with its adaptability and proven success, demonstrated its capacity to deliver consistent and robust post-TKA outcomes. Implant survivorship was impeccable, with no instances of post-TKA revision within the study cohort.

Furthermore, the prosthesis facilitated substantial improvements in both functional and clinical parameters across all BMI categories. We observed that regardless of BMI classification, patients experienced enhanced ROM, KSSs, WOMAC scores following bTKA with the CR/PS TKS. Notably, the improvements were consistent across all BMI groups, suggesting that the device's adaptability effectively addressed the unique needs of patients with varying degrees of obesity.

Limitations

The study is constrained by a limited three-year follow-up, potentially overlooking extended outcomes and complications. Augmenting the sample size could strengthen the statistical significance, facilitating discernment of nuanced effects. The influence of patient selection and implant type on outcomes may introduce potential bias. Notably, the absence of comparisons with alternative TKA systems impedes a comprehensive evaluation of device performance. The study's focus on an Indian cohort may limit generalizability to diverse populations. Despite these constraints, the investigation underscores favourable post-TKA outcomes, particularly with the CR/PS TKS, even among individuals with elevated BMI.

CONCLUSION

In conclusion, our study contributes to the growing body of evidence supporting the favourable performance of the prosthesis in the context of bTKA, transcending the conventional boundaries imposed by BMI. These findings hold implications for both clinicians and patients, providing a rationale for considering this implant as a viable option for a broader spectrum of individuals, including those traditionally considered high-risk due to elevated BMI. Further research with extended follow-up, is warranted to corroborate and expand upon these promising results.

ACKNOWLEDGEMENTS

Authors would like to acknowledge Dr. Dolly Singh for her valuable contributions in drafting, reviewing, and finalizing the manuscript.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

Disclaimer: Implant utilized in the study is Freedom total knee system (Maxx Orthopaedics Inc. Plymouth Meeting, Pennsylvania, USA)

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Cite this article as: Ponnanna KM, Rudraraju RT, Bajwa S, Aneja K. A comprehensive comparative study on mid-term clinical and functional outcomes in Indian patients following bilateral total knee arthroplasty: assessing the impact of body mass index on post-total knee arthroplasty results. *Int J Res Orthop* 2024;10:559-66.