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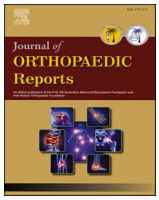

A multicentre retrospective study of the impact of body mass index on clinical and functional outcomes of total knee arthroplasty: An Indian prospective

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ABSTRACT

Objective: To study the impact of body mass index (BMI) on the outcomes of total knee arthroplasty (TKA) in primary osteoarthritis (OA) patients with CR/PS TKS.
Methods: We conducted a retrospective analysis of data from the ongoing, prospective Freedom 400 study, involving 259 patients. Patients were grouped based on the BMI (WHO categorization): Cohort 1 (normal weight, BMI 18.5 kg/m^2 to 25.00 kg/m^2), Cohort 2 (overweight patients, BMI 25.00 kg/m^2 to 29.99 kg/m^2), and Cohort 3 (class 1 and 2 obese patients, BMI 30.00 kg/m^2 to 39.99 kg/m^2). The primary endpoint was implant survivorship and cumulative revision rates. Secondary endpoints included Knee Society score (KSS), Range of Motion (ROM), Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores, SF-36 questionnaire for assessing quality of life (QoL), and radiographic analysis up to a 3-year follow-up period. Results were considered significant at $p < 0.05$.
Results: A total of 252 patients completed the 3-year follow-up. Women dominated each group (79 %, 78 %, and 83 %, respectively). Average BMIs (Kg/m^2) were 22.11 ± 1.78, 27.09 ± 1.39, and 33.08 ± 2.67, respectively. Adverse events were significantly low. Clinical KSS scores improved significantly at 6 weeks ($p < 0.001$) and continued to improve up to 3 years. Similar patterns were observed in functional KSS scores. WOMAC scores showed significant improvements in pain, stiffness, and degree of difficulty across all groups at 3 years ($p < 0.001$). Also, ROM improved post-operatively, reaching 122.42° ± 6.43°, 122.67° ± 5.34°, and 122.21° ± 5.68° in Groups 1, 2, and 3, respectively. Radiographical assessments at 12 months ($n = 211$) and beyond showed no wear or osteolysis. X-ray images displayed favourable functionality of the CR/PS TKS.
Conclusions: This study affirms that BMI does not adversely affect TKA outcomes in primary OA patients. The CR/PS TKS demonstrates high clinical effectiveness, safety, and notable improvements in functional and QoL outcomes across all BMI groups over a 3-year period.

1. Introduction

Total knee arthroplasty (TKA) is a frequently performed elective surgical intervention aimed at mitigating the symptoms of knee osteoarthritis (OA), including pain and functional impairment.[1] In comparison to the year 2020, it is anticipated that there would be a 74.9 % rise (ranging from 59.4 % to 89.9 %) in instances of knee OA by the year 2050. The age-standardised prevalence rates in 2020 exhibited a consistent pattern throughout all global regions, surpassing 5.5 %. These rates varied between areas, with the lowest observed in southeast Asia at 5677.4 [5029.8–6318.1] per 100,000 individuals, and the highest in high-income Asia Pacific at 8632.7 [7852.0–9469.1] per 100,000 individuals. The knee joint was identified as the most often affected anatomical location. The presence of a high body-mass index (BMI) was found to be a contributing factor to 20.4 % of OA cases.[2] The elevation in body weight has been identified as a potential risk factor in the development of knee OA, due to heightened mechanical loads experienced by

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List of abbreviation:

BMI	Body mass index
KSS	Knee society score
OA	Osteoarthritis
QoL:	Quality of life
ROM	Range of motion
SF-36	Self-reported questionnaires
TKA	Total knee arthroplasty
TKS	Total knee system
WHO	World health organization
WOMAC	Western Ontario and McMaster Universities Arthritis Index

the joint.[3–5] Indeed, there exists a fourfold decrease in the strain applied to the knee during daily activities for each pound of weight loss observed in individuals with OA.[6] Furthermore, obesity is correlated with a range of metabolic disruptions that may lead to systemic complications for OA.[5] The World Health Organization has developed a classification system for adults that is based on BMI. According to the classification system, those with a BMI falling within the range of 30–34.9 kg/m^2 are categorized as having obesity class I. Those with a BMI ranging from 35 to 39.9 kg/m^2 are classified as having obesity class II. Finally, individuals with a BMI equal to or over 40 kg/m^2 are categorized as having obesity class III.[7] The presence of obesity is associated with an elevated susceptibility to OA, which subsequently leads to a heightened need for TKA.[8] An elevated BMI exerts greater pressure on the supporting bone and implant material, leading to negative consequences for the durability of prosthetic devices and the achievement of functional improvements.[9] The escalating worldwide prevalence of obesity within TKA population has prompted apprehension regarding the surgical results for obese individuals, which can ultimately damage the longevity and functional outcomes of prosthetic interventions.[9] The inquiry on whether individuals with obesity who undergo TKA are more susceptible to experiencing negative outcomes has been previously investigated, with inconsistent findings. Several researchers have examined the impact of obesity, defined as a BMI greater than 30 kg/m^2, on patient outcomes. Some of these studies have found no significant difference in results between obese and non-obese patients.[10–14] However, other studies have revealed that obese patients experience inferior outcomes in terms of postoperative complications, functional recovery, and rates of revision surgery.[15–17] These studies assess the functional outcomes based on patient's oriented functional questionnaires, knee society scores (KSS), range of motion (ROM) and very few of these studies report Western Ontario and McMaster Universities Arthritis Index (WOMAC) scores, radiographic including full-length scanograms measuring hip-knee-ankle axis.

Based on current knowledge, there is a lack of available research regarding the influence of BMI on the efficacy of the Cruciate Retaining (CR)/ Posterior Stabilized (PS) Total Knee System (CR/PS TKS). The present study aims to address this research gap by investigating the potential impact of BMI on the performance of CR/PS TKS over a span of three years. Our hypothesis posited that obesity would exert a detrimental effect on the implant, leading to misalignment, reduced functional capacity, and diminished clinical results.

2. Method and population

2.1. Study design

This is a retrospective analysis of a prospectively enrolled patients of an ongoing, single-arm, open label, real-world study "Freedom 400 study".

2.2. Study population

A cohort of 259 individuals were monitored during the initial three-year period after undergoing unilateral TKA for primary OA. The surgical procedures were performed by skilled orthopaedic surgeons affiliated with a nearby orthopaedic practice. The study's exclusion criteria encompassed several factors: (1) uncontrolled hypertension, (2) diabetic nephropathy, (3) the presence of symptomatic OA in the opposite knee determined by the occurrence of reported pain in the knee, as measured by a visual analogue scale with a score of 4 or above on a 10-point scale, (4) other lower-limb orthopaedic issues that restricted functionality, (5) neurological disorders, and (6) BMI exceeding 40 kg/m^2. Inclusion criteria were patients suffering from end-stage knee OA; male and female aged 18 years and above indicated for TKA with CR/PS TKS; those able to provide written informed consent.

The study received approval from the local ethical committee review board at each site. Prior to their participation, all individuals submitted the written informed consent.

The utilization of BMI in this investigation was driven by its frequent application to evaluate obesity and its strong correlation with implant survivorship and revision rate regarded as primary endpoint of the study. Baseline and demographic characteristics, medical history of all enrolled patients was assessed after enrolment. Self-reported questionnaires (SF-36) evaluating the pain, functional limitation due to physical health, quality of life (QoL) was all assessed at baseline as well as at all follow-up time points of 6 weeks, 6 months, 1- and 3 years. Preoperative ROM, KSS, WOMAC and radiographic analysis was also performed which were also evaluated for all follow-ups, as secondary endpoints.

2.3. Study device description

The CR/ PS TKS (Freedom TKS, Maxx Orthopaedics Inc., Plymouth Meeting, Pennsylvania, USA), is an artificial prosthetic device designed for TKA. The femoral components of this device are crafted from a biocompatible Cobalt–Chromium–Molybdenum (CoCrMo) alloy. It presents clinicians with a selection of femoral component configurations, including the CR and PS variants, in addition to tibial component choices encompassing metal-backed and all-polyethylene designs. Notably, the polymer constituents including all-polyethylene tibial component, tibial insert, and patellar component, are constructed from Ultra-High-Molecular-Weight Polyethylene powder explicitly intended for "surgical implants" designated for human deployment. Regulatory approvals for these systems encompass clearance from the Drugs Controller General of India (DCGI), a 510(k) clearance by the United States Food and Drug Administration (US-FDA), and conformity with the Conformité Européene (CE) marking.[18]

2.4. Statistical analysis

The findings are presented in terms of the mean value along with the standard deviation for continuous variables, while categorical variables are expressed as the numbers and percentages. The comparison of continuous variables is conducted through the utilization of the 2 Sample *t*-test for independent samples. The dependent samples paired *t*-test is employed when it is expected that the data follows a normal distribution, whereas the Wilcoxon signed rank test is utilized when the assumption of normal distribution cannot be made. The chi-square test is employed to compare categorical variables. The obtained result demonstrates statistical significance at a significance level of $p < 0.05$.

3. Results

A cohort of 259 participants were included in the study and were classified according to their BMI range, as illustrated in Fig. 1. The study population was divided into three groups based on BMI values. Group-1 consisted of individuals with a BMI ranging from 18 Kg/m^2 to 25.00 Kg/

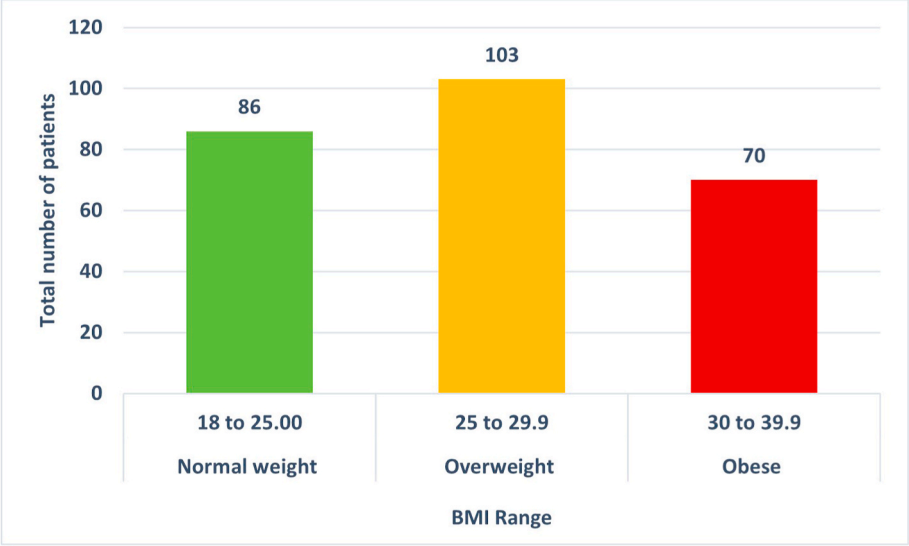

Fig. 1. Total number of patients across all groups categorized based on range of body mass index (BMI).

m^2, with a total of 86 participants. Group-2 included individuals classified as overweight, with a BMI ranging from 25.00 Kg/m^2 to 29.99 Kg/m^2, and a total of 103 participants. Lastly, Group-3 comprised individuals classified as obese, with a BMI ranging from 30.00 Kg/m^2 to 39.99 Kg/m^2, and a total of 70 participants. In each of the three groups, women exhibited a higher level of dominance, with percentages of 79 %, 78 %, and 83 % seen, respectively (Figure A1). The average BMI indices were 22.11 ± 1.78 Kg/m^2, 27.09 ± 1.39 Kg/m^2, and 33.08 ± 2.67 Kg/m^2, respectively, as shown in Table 1. End-stage OA was shown to be the prevailing disease in all three groups. Table 1 and Table A1 provide a comprehensive overview of the additional baseline characteristics and medical history of the patients, respectively.

During a span of three years, a total of 252 patients successfully completed the designated follow-up period. The withdrawal of consent occurred in the following manner: two patients from group 1, one patient from group 2, and two patients from group 3. Additionally, one patient from group 3 was lost to follow-up. There were no instances of lost to follow-up or withdrawal throughout the first one-year period in any of the groups. The incidence of adverse events up to the 1-year follow-up period was shown to be significantly low. At 6-month, a suture line abscess was documented in a patient classified as obese (group 3). Additionally, during the 3-year follow-up period, a 66-year-old female in overweight group who underwent left TKA, experienced an unrelated death (informed by the close relative).

The clinical effectiveness and safety of the CR/PS TKS have been validated by the 100 % rate of successful functioning of the implanted knees for three-year follow-up period, with no instances of revision observed during the trial.

A comprehensive evaluation was conducted to analyse the functional outcomes of the CR/PS TKS, utilizing the KSS and WOMAC scoring. The results demonstrated a notable enhancement in these outcomes at the 6-week, 6-month, 1-year, and 3-year follow-up intervals, as compared to the baseline measurements. The pre-operative clinical KSS scores in three groups were 29.86 ± 16.59, 35.55 ± 15.65, and 30.80 ± 15.84, respectively. These scores showed a significant improvement to 67.64 ± 14.9, 74.69 ± 14.89, and 72.84 ± 16.12, respectively, after a 6-week follow-up period, with a p-value of <0.001. Furthermore, these scores continued to improve to 92.86 ± 7.94, 92.03 ± 7.78, and 91.62 ± 8.00 ($p < 0.001$) after a 3-year follow-up period. A comparable pattern was identified in the functional Knee Society Score (KSS), wherein noteworthy post-operative 3 years values were recorded as 97.57 ± 5.85 (group 1 baseline: 25.41 ± 19.96), 99.22 ± 2.22 (group 2 baseline: 28.54 ± 21.47), and 98.08 ± 4.81 (group 3 baseline: 29.21 ± 22.35) across all three groups, with a $p < 0.001$ (Fig. 2).

Among the 252 patients, the WOMAC score evaluating the pain, stiffness, and degree of difficulty, showed no significant baseline score variations among the group. For pain: significant improvement in scores from baseline was observed— group 1–25.67 ± 3.42 (3 years: 1.05 ± 1.39), group 2–25.60 ± 4.59 (3 years: 1.38 ± 2.06) and group 3–25.00 ± 4.26 (3 years: 1.29 ± 2.15) p-value<0.001. Similar trend was observed in stiffness score and degree of difficulty with significant improvement for 3 years from their baseline — stiffness score: group

Table 1
Baseline characteristics of patients undergoing TKA with CR/PS total knee system.

Patient characteristics	Normal Weight (n = 86) Subjects	Overweight (n = 103) Subjects	Obese (n = 70) Subjects	Normal Weight Vs Overweight p-value	Normal Weight Vs Obese p-value
Age, years, mean±SD	66.34 ± 9.74	64.75 ± 8.01	64.01 ± 6.85	0.219	0.093
Body Mass Index, kg/m^2, mean±SD	22.11 ± 1.78	27.09 ± 1.39	33.08 ± 2.67	<0.001	<0.001
Heart rate, beats per minute, mean±SD	82.33 ± 9.91	82.38 ± 11.83	81.39 ± 13.2	0.973	0.612
Primary diagnosis					
Osteoarthritis	83 (96.51)	100 (97.09)	69 (98.57)		
Rheumatoid arthritis	2 (2.33)	1 (0.97)	1 (1.43)		
Other	1 (1.16)	2 (1.94)	0 (0.00)		
Advanced degenerative disease both the knee	0 (0.00)	0 (0.00)	0 (0.00)		
Advanced degenerative joint disease right knee, left TKR in situ	0 (0.00)	1 (0.97)	0 (0.00)		
Advance degenerative disease of left knee	0 (0.00)	1 (0.97)	0 (0.00)		
Advanced degenerative disease right knee	1 (1.16)	0 (0.00)	0 (0.00)		

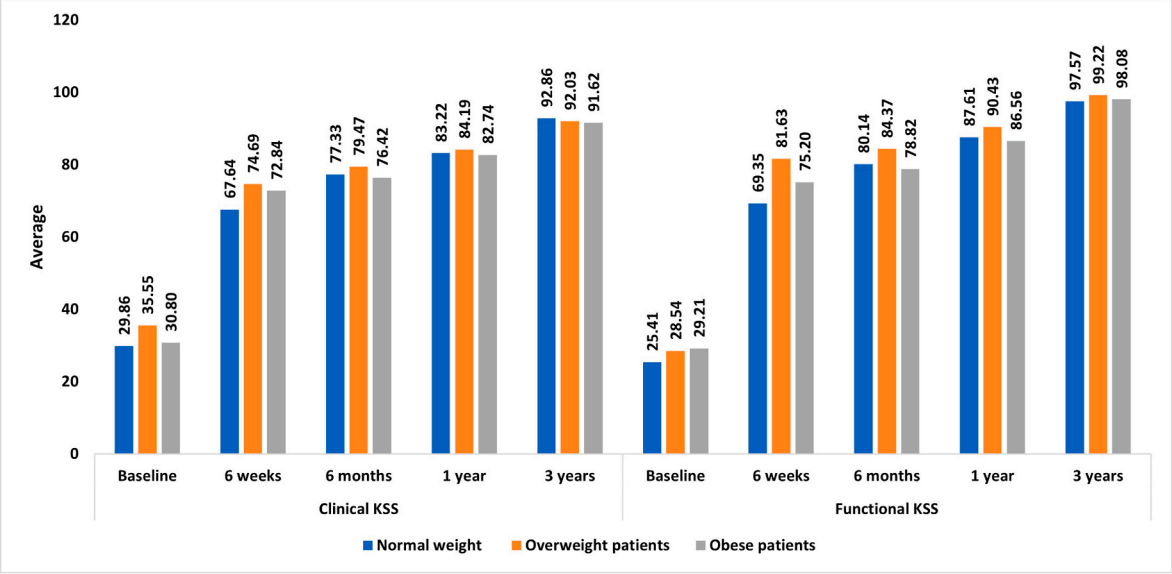

Fig. 2. Pre-operative and follow-up outcomes related to clinical and functional Knee society scores across all groups categorized based on range of body mass index (BMI).

1–0.54 ± 0.63 (baseline: 6.66 ± 0.9), group 2–0.52 ± 0.8 (baseline: 6.69 ± 1.19) and group 3–0.55 ± 0.81 (baseline: 6.49 ± 1.43) p-value<0.001; degree of difficulty score: group 1–2.49 ± 3.94 (baseline: 54.47 ± 7.84), group 2–2.88 ± 4.70 (baseline: 54.81 ± 10.09) and group 3–3.23 ± 5.13 (baseline: 53.99 ± 9.01) p-value<0.001 (Fig. 3).

The comprehensive examination of ROM shown a clear enhancement in post-operative follow-up flexion and extension among patients, regardless of their BMI range. The initial ROM significantly improved achieving a flexion of 122.42° ± 6.43°, 122.67° ± 5.34°, and 122.21° ± 5.68° in group 1, 2 and 3, respectively (Table A.2, Figure A2).

The assessment of QoL was conducted using the SF-36 questionnaire, revealing suboptimal baseline scores for role limitation related to both emotional and physical health. These detailed values are presented in Table A.3 and Fig. 4. The general health, changes in health, and emotional well-being were observed to be suboptimal at the initial assessment, characterized by heightened pain levels and reduced capacity to engage in activities without assistance. The patients who received the CR/PS TKS demonstrated notable improvements in their QoL, as evidenced by their high scores. These improvements were observed regardless of the patients' BMI range.

During the course of a 12-month period, no instances of radiographical wear or osteolysis were detected in the cohort of patients under study (n = 211). Due to the optional nature of post-1-year follow-up radiography studies, our sample size was limited to a total of 73 patients at 3 years. However, our observations revealed favourable functionality of the CR/PS TKS, as seen by the lack of any notable occurrences as indicated by radiographic images. Fig. 5 (Panel i, ii, iii) displays pre-operative and post-operative X-ray images of patients belonging to different groups (normal, overweight, and obese).

4. Discussion

In terms of joint-related patient-oriented outcomes following TKA, our experience with CR/PS TKS has been exemplary over the course of three years. We compared the clinical and functional outcomes of overweight and obese patients undergoing TKA to those of normal-weight patients and found no significant differences between the groups. Regardless of the potential impact of BMI, patients in all three groups demonstrated significant post-operative improvement compared to their pre-operative evaluation.

There is some disagreement in the scientific literature regarding the influence of BMI on pain and functional results following TKA. Multiple studies have demonstrated that outcomes following TKA are poorer in patients who are obese as compared to people who are not obese.[19–21] In a study by single surgeon (Koray Başdelioğlu, 2020), retrospective evaluation of 588 patients undergoing TKA based on their BMI, age and

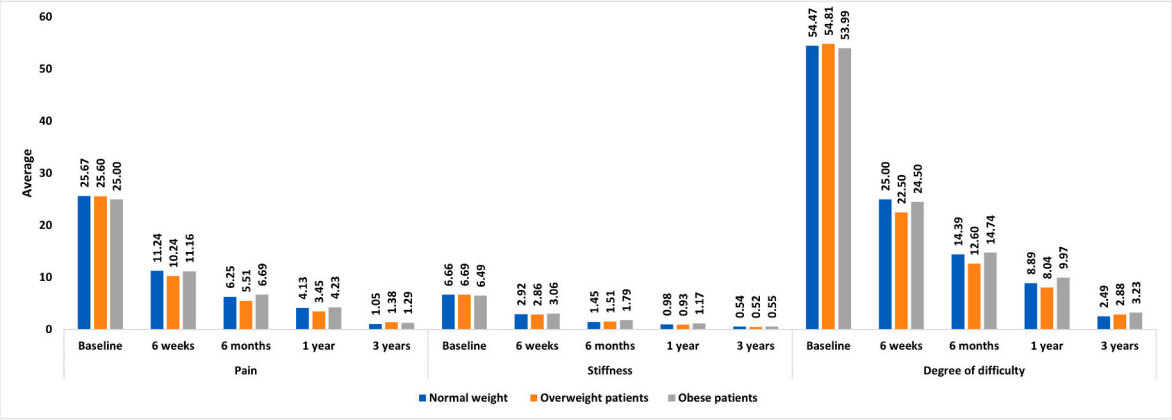

Fig. 3. Pre-operative and follow-up outcomes related to WOMAC scores across all groups categorized based on range of body mass index (BMI).

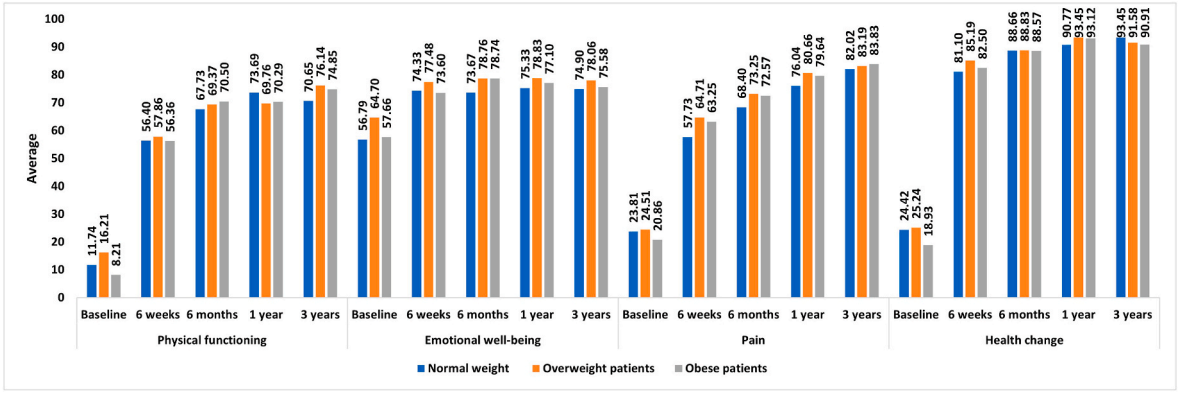

Fig. 4. Pre-operative and follow-up outcomes related to SF-36 assessing quality of life across all groups categorized based on range of body mass index (BMI).

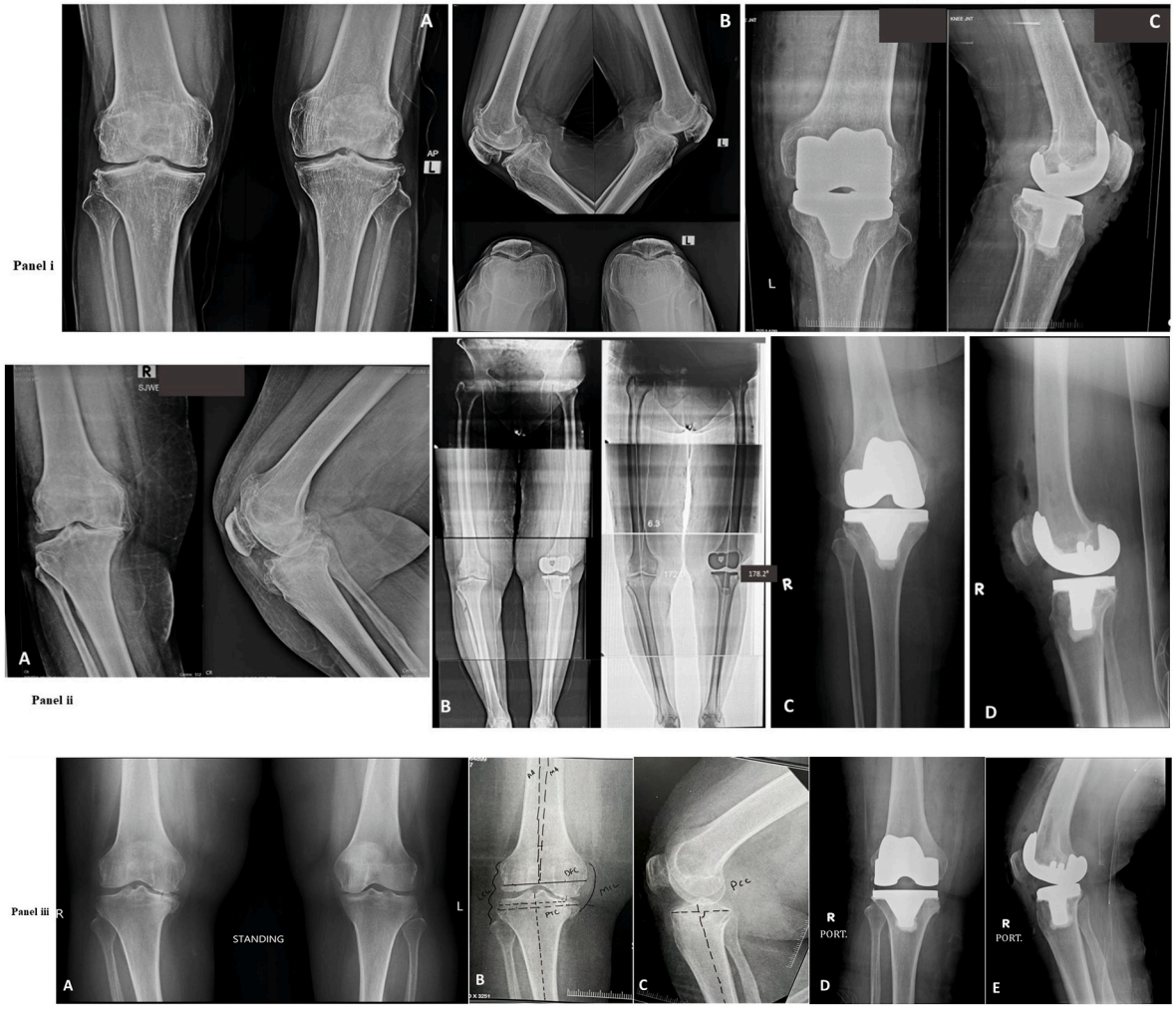

Figure 5. (Panel i): Group-1: Normal weight patient-representative radiograph of patient undergoing unilateral TKA with Freedom total knee system (TKS). Panel A shows anteroposterior diseased knee and panel B shows the lateral and flexed view. Panel C shows the post-operative knee implanted with Freedom TKS.
(Panel ii): representative radiograph of overweight patient (group 2) undergoing unilateral TKA with Freedom TKS. Panel A shows anteroposterior (AP) and lateral views of diseased knee and panel B shows the Orthoscanogram of post-TKA knee with improved HKA axis of 178.2°; Panel C is the AP view and panel D shows the lateral view of the post-operative knee implanted with Freedom TKS.
(Panel iii): representative radiograph of obese patient (group 3) undergoing unilateral TKA with Freedom TKS. Panel A shows AP view of the diseased knee and panel B shows the measured AP and panel C shows the lateral views. Panel D and E shows the AP and lateral views of post-operative knee implanted with Freedom TKS, respectively.

sex determined that with increase in BMI there was poorer outcomes in terms of both clinical and functional outcomes.[21] Similarly, another retrospective data of 688 patients showed greater risk of misalignment and poor long-term outcomes post-TKA.[22] However, these studies have a mean follow-up period of 50.29 months and 8.1 years where the osteolysis of implant is rather high and shows the poor outcomes in these patients. Lash and his colleagues suggest that the impact of BMI >35 kg/m^2 exhibited inferior preoperative and post-operative functional scores, as measured by the WOMAC, Oxford Knee Score (OKS), and High-activity Arthroplasty Score, compared to those with a BMI below 30 kg/m^2. However, the study did not find any disparity in the improvement of functional scores following surgery between these two BMI groups.[23] According to Chen et al.,[24] there is evidence to support more substantial recovery in patient groups with higher levels of obesity. Specifically, the average improvement in the OKS and Knee Society Knee Score after a two-year follow-up period was shown to be considerably greater in the morbidly obese group compared to the normal weight group. Li et al.,[25] conducted a study which found a positive correlation between higher levels of obesity and increased pain during the initial assessment. However, they also observed that those with greater obesity experienced greater remission from postoperative pain.[25] Contrary to these findings we observed significant improvement in terms of pain reduction and functional scorings in patients with higher BMI: 30.00 Kg/m^2 to 39.99 Kg/m^2 (obese group) and overweight patients (BMI: 25 kg/m^2 to 29.99 kg/m^2) which were comparable to normal weight patients. During the study duration of three years, we did not notice any aseptic loosening, wound infection or any other implant or access site related complications. When assessing the therapeutic advantages of TKA, it is imperative to prioritize the improvement rather than relying solely on broad evaluations of follow-up data. This is because the latter approach may predominantly represent pre-operative disparities across patients. The patient primarily perceives a change in the symptoms, which can serve as the benchmark for evaluating the efficacy of the surgery and implant. Patients with a greater poor pre-operative QoL may potentially experience a more substantial improvement following surgery, which may be the cause for higher SF-36 and WOMAC scores observed in our study.

In a study conducted by Haifeng Li et al.,[26] evaluating 157 patients in a prospective analysis reported that obesity may not necessarily lead to early post-operative complication and these cohort may have reduced pain post-TKA surgery. Our results resonate with Haifeng Li et al., as we observed improved ROM across all three cohorts, reduction in post-operative pain, improved QoL, clinical and functional KSS score which all had statistically significant change from their baseline values.

Radiological wear and osteolysis has been recorded in the majority of the studies that have been discussed thus far[20,21,25,26] and long-term wear and osteolysis has been detected in the majority of the patients. Because this was a study that took place over the course of three years, we did not find any instances of this happening. Nevertheless, it would be fascinating to notice any such report during the course of the study (between 8 and 10 years).

5. Limitations of the study

Our study has certain limitations inherent to its retrospective design. Data accuracy and completeness are dependent on medical records, and the potential for selection bias cannot be entirely eliminated. Furthermore, the follow-up duration may not capture the very long-term outcomes of TKA. Future prospective studies with larger sample sizes and longer follow-up periods could provide more robust evidence to elucidate the complex relationship between BMI and mid-to-long-term TKA outcomes. Additionally, investigating the impact of lifestyle modifications and preoperative weight management interventions on TKA outcomes may offer further insights into optimizing results for patients with higher BMI.

6. Conclusion

Obesity represents a significant risk factor in the context of prosthesis infection and aseptic prosthesis loosening, both of which are recognized consequences following TKA. A notable observation is the absence of incidences such as prosthesis infection and aseptic prosthesis loosening in patients belonging to the BMI>35 kg/m^2 category in this study. Elevated BMI is also associated with negative impacts on both clinical and functional outcomes. However, based on our observations, it is possible that obesity does not have a significant impact on patients' function and discomfort, and may not lead to an increased occurrence of problems after primary TKA. This study demonstrates that the use of CR/PS TKS can lead to favourable functional rehabilitation outcomes in individuals who are obese.

Funding sources

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Statement of informed consent

Written informed consent was obtained from all enrolled patients and the Local ethics committee at each site approved the study to be conducted at their centers.

Submission declaration

"The work described here has not been published previously, it is not under consideration for publication elsewhere, and its publication is approved by all authors and tacitly or explicitly by the responsible authorities where the work was carried out. If accepted, it will not be published elsewhere in the same form, in English or in any other language, including electronically without the written consent of the copyright-holder."

Table A.1
Medical history of patients undergoing TKA with CR/PS total knee system.

Medical history	Normal (n = 86) Subjects	Overweight (n = 103) Subjects	Obese (n = 70) Subjects
Diabetes mellitus	13 (15.12)	18 (17.48)	11 (10.68)
Hypertension	32 (37.21)	49 (47.57)	44 (42.72)
Smokers	1 (1.16)	1 (0.97)	0 (0.00)
Dyslipidemia	2 (2.33)	4 (3.88)	1 (0.97)
Chronic renal insufficiency	0 (0.00)	1 (0.97)	3 (2.91)
Pulmonary edema	0 (0.00)	1 (0.97)	1 (0.97)
Ischemic heart disease	3 (3.49)	3 (2.91)	4 (3.88)
Osteoarthritis	83 (96.51)	100 (97.09)	68 (66.02)
Osteonecrosis	0 (0.00)	0 (0.00)	1 (0.97)
Inflammatory arthritis (IA)	4 (4.65)	5 (4.85)	1 (0.97)
Rheumatoid arthritis	2 (2.33)	1 (0.97)	2 (1.94)
Previous joint surgery	15 (17.44)	12 (11.65)	11 (10.68)
Other illness			
Spinal fixation	1 (1.16)	0 (0.00)	0 (0.00)
spine surgery	1 (1.16)	0 (0.00)	0 (0.00)
Hypothyroidism	6 (6.98)	10 (9.71)	14 (13.59)
CAD	0 (0.00)	2 (1.94)	0 (0.00)
Asthma	0 (0.00)	1 (0.97)	0 (0.00)
Hyperuricaemia	0 (0.00)	0 (0.00)	1 (0.97)
MI	0 (0.00)	1 (0.97)	0 (0.00)
Angina	0 (0.00)	1 (0.97)	0 (0.00)
Seizures	0 (0.00)	0 (0.00)	1 (0.97)

Table A.2
Radiographic analysis of patients in different groups categorized based on range of body mass index (BMI).

Parameters	Time	Normal (n = 86) Subjects	Overweight (n = 103) Subjects	Obese (n = 70) Subjects	*Normal Weight Vs Overweight p*-value	*Normal Weight Vs Obese p*-value
Anterior-Posterior View (weight bearing knee)						
Tibio femoral angle (degrees)	Baseline	9.45 ± 4.29	9.98 ± 4.	11.03 ± 4.9	0.401	0.033
	6 weeks	1.38 ± 2.25	2.13 ± 2.47	1.62 ± 2.39	0.052	0.571
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	1.18 ± 2.12	2.19 ± 3.91	1.61 ± 3.79	0.048	0.402
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	0.9 ± 1.91	1.32 ± 2.2	1.13 ± 2.06	0.215	0.505
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	0.33 ± 0.95	0 ± 0	0.3 ± 1.11	0.053	0.938
	p-value (Baseline vs 3 Year)	**<0.001**	**<0.001**	**<0.001**		
Anterior-Posterior View (with varus/valgus stress)						
Tibio femoral angle (°), (n = implant)	Baseline	8.7 ± 4.06	8.83 ± 3.66	10.03 ± 4.69	0.807	0.059
	6 weeks	1.38 ± 2.25	2.11 ± 2.48	1.54 ± 2.39	0.061	0.704
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	1.18 ± 2.12	2.13 ± 3.49	1.72 ± 3.92	0.042	0.311
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	0.87 ± 1.91	1.38 ± 2.23	1.18 ± 2.12	0.136	0.380
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	0.48 ± 1.63	0 ± 0	0 ± 0	0.103	0.168
	p-value (Baseline vs 3 Year)	**<0.001**	**<0.001**	**<0.001**		
Upper tibial varus, (n = implant) Upper tibial bone loss, (n = implant)	Baseline	5.49 ± 3.65	5.15 ± 2.21	5.77 ± 2.72	0.428	0.591
	6 weeks	0.1 ± 0.65	0.05 ± 0.44	0.04 ± 0.28	0.547	0.529
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	0.09 ± 0.62	0.06 ± 0.55	0.19 ± 1.03	0.713	0.498
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	0 ± 0	0.02 ± 0.22	0.08 ± 0.64	0.357	0.289
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	0.14 ± 0.65	0 ± 0	0 ± 0	0.220	0.300
	p-value (Baseline vs 3 Year)	**<0.001**	**<0.001**	**<0.001**		
	Baseline	3.55 ± 2.16	3.92 ± 2.33	4.14 ± 2.8	0.255	0.135
	6 weeks	0 ± 0	0.04 ± 0.33	0 ± 0	0.363	NA
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	0 ± 0	0.06 ± 0.55	0.09 ± 0.66	0.346	0.256
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	0 ± 0	0 ± 0	0 ± 0	NA	NA
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	0.1 ± 0.3	0 ± 0	0 ± 0	0.077	0.136
	p-value (Baseline vs 3 Year)	**<0.001**	**<0.001**	**<0.001**		
Lateral view, (n = implant)	Baseline	12.03 ± 5.27	13.25 ± 5.35	11.34 ± 5.56	0.118	0.427
	6 weeks	0.22 ± 1.34	0.14 ± 0.8	0 ± 0	0.678	0.253
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	0.27 ± 1.41	0.18 ± 1.65	0.37 ± 2.21	0.716	0.757
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	0 ± 0	0.09 ± 0.6	0.08 ± 0.64	0.230	0.289
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	0 ± 0	0.16 ± 0.88	0.3 ± 1.11	0.423	0.214
	p-value (Baseline vs 3 Year)	**<0.001**	**<0.001**	**<0.001**		

Table A.3
SF-36 questionnaire assessing the quality of life of patients in different cohorts categorized based on their BMI.

Study Endpoints	Time	Normal Subjects	Overweight Subjects	Obese Subjects	Normal Weight Vs Overweight	Normal Weight Vs Obese
					p-value	p-value
Role limitations due to physical health, (mean ± SD)	Baseline	3.49 ± 14.93	5.34 ± 21.19	2.86 ± 10.02	0.496	0.762
	6 weeks	57.56 ± 45.55	57.52 ± 47.72	64.64 ± 44.94	0.996	0.332
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	77.91 ± 36.06	78.4 ± 38.2	85.36 ± 29.94	0.928	0.168
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	92.86 ± 19.62	88.35 ± 27.07	87.68 ± 28.32	0.203	0.185
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	81.25 ± 25.11	87.62 ± 22.26	86.36 ± 26.01	0.068	0.224
	p-value (Baseline vs 3 Years)	**<0.001**	**<0.001**	**<0.001**		
Role limitations due to-emotional problems, (mean ± SD)	Baseline	30.62 ± 44.34	24.92 ± 41.15	6.67 ± 22.41	0.361	<0.001
	6 weeks	60.08 ± 46.25	58.25 ± 47.31	65.71 ± 43.95	0.789	0.44
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	80.23 ± 34.82	78.96 ± 37.34	82.86 ± 34.86	0.81	0.64
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	92.86 ± 22	88.67 ± 26.63	86.47 ± 30.42	0.25	0.134
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	87.3 ± 17.85	91.75 ± 17.26	91.41 ± 18.77	0.087	0.173
	p-value (Baseline vs 3 Years)	**<0.001**	**<0.001**	**<0.001**		
Energy/fatigue, (mean ± SD)	Baseline	44.07 ± 22.12	46.65 ± 20.16	41.71 ± 23.39	0.402	0.52
	6 weeks	60.93 ± 14.58	66.26 ± 14.26	64.93 ± 18.05	0.012	0.127
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	62.21 ± 13.43	67.62 ± 13.26	69.29 ± 15.61	0.006	0.002
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	63.75 ± 13.82	68.3 ± 13.77	66.45 ± 14.4	0.025	0.24
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	66.07 ± 15.43	69.8 ± 16.12	69.55 ± 15.78	0.111	0.177
	p-value (Baseline vs 3 Years)	**<0.001**	**<0.001**	**<0.001**		
Social functioning, (mean ± SD)	Baseline	37.35 ± 26.6	37.38 ± 24.78	29.64 ± 23.23	0.994	0.058
	6 weeks	64.68 ± 16.74	68.81 ± 14.63	65 ± 16.7	0.071	0.905
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	70.64 ± 14.57	75 ± 16.23	75.71 ± 16.05	0.055	0.04
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	75.6 ± 16.57	79.61 ± 19.65	78.26 ± 16.7	0.137	0.325
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	82.29 ± 14.02	84.16 ± 14.02	83.52 ± 16.43	0.368	0.621
	p-value (Baseline vs 3 Years)	**<0.001**	**<0.001**	**<0.001**		

(*continued on next page*)

Table A.3 (*continued*)

Study Endpoints	Time	Normal Subjects	Overweight Subjects	Obese Subjects	Normal Weight Vs Overweight	Normal Weight Vs Obese
					p-value	p-value
General health, (mean ± SD)	Baseline	49.53 ± 17.48	46.65 ± 17.79	40.86 ± 15.49	0.264	0.001
	6 weeks	68.78 ± 11.53	69.76 ± 13.03	67.79 ± 14.08	0.588	0.628
	p-value (Baseline vs 6 Weeks)	**<0.001**	**<0.001**	**<0.001**		
	6 months	72.33 ± 9.72	71.94 ± 12.39	72.93 ± 12.2	0.815	0.731
	p-value (Baseline vs 6 Months)	**<0.001**	**<0.001**	**<0.001**		
	1-year	72.62 ± 10.34	71.89 ± 12.76	71.67 ± 11	0.674	0.582
	p-value (Baseline vs 1 Year)	**<0.001**	**<0.001**	**<0.001**		
	3-year	77.86 ± 12.06	75.74 ± 11.82	76.06 ± 14.64	0.231	0.411
	p-value (Baseline vs 3 Years)	**<0.001**	**<0.001**	**<0.001**		

Ethical statement

The study received approval from the local ethical committee review board. Prior to their participation, all individuals submitted the written informed consent.

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Statement of informed consent

Written informed consent was obtained from all enrolled patients and the Local ethics committee at each site approved the study to be conducted at their centers.

CRediT authorship contribution statement

Kunal Aneja: Conceptualization, Data curation, Formal analysis, Funding acquisition, Investigation, Methodology, Project administration, Resources, Software, Supervision, Validation, Visualization, Writing – original draft, and, Writing – review & editing. **Ponnanna Karineravanda Machaiah:** Data curation, Formal analysis, Methodology, Software, Writing – review & editing, of the, Writing – original draft. **Supreet Bajwa:** Data curation, Formal analysis, Methodology, Software, Writing – review & editing, of the, Writing – original draft. **Ravi Teja Rudraraju:** Data curation, Formal analysis, Methodology, Software, Writing – review & editing, of the, Writing – original draft.

Declaration of competing interest

The author declare that the research was conducted in the absence of any commercial or financial ties that could be construed as a potential conflict of interest. Hence, there are no conflicts of interest to disclose.

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Appendix A. Supplementary data

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