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ORIGINAL ARTICLE

Early Results of Bone-Conserving High Flexion Posterior-Stabilized Total Knee System in Indian Population

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Abstract

Background A number of total knee arthroplasty (TKA) systems are used across a variety of markets in which outcome will be influenced by patient factors, surgical technique and implant characteristics. The aim of the current study was to report the early functional results of a primary TKA system in support of the component design characteristics adapted for achieving increased functional expectations of the patients.

Materials and Methods A prospective, continuous series of 304 primary posterior-stabilized (PS) TKAs were performed in 208 patients by a single surgeon. Inclusion criterion was patients undergoing primary TKA with Freedom Total Knee system and willing to participate in the study. Exclusion criteria were patients undergoing revision TKA, patients not willing to participate and patients who were lost to follow-up. Patients were clinically and radiologically assessed for a minimum of 5 years post-operatively. Oxford Knee score (OKS) and range of motion (ROM) were assessed for the entire study population and by gender.

Results There were no patients who were lost to follow-up. Two patients (Two knees) required incision and secondary suturing for superficial skin wound complication. At minimum 5-year follow-up, there was no radiographic evidence of component loosening/failure. Clinical evaluation at 5 years post-operatively showed statistically significant increase in the OKS and ROM as compared to pre-operative values (OKS pre-operative 19.27 ± 1.86, post-operative 38.76 ± 1.5, p value < 0.001, ROM pre-operative 94.57 ± 3.49, post-operative 127.69 ± 3.65, p value < 0.001). There was no statistically significant difference in the clinical outcome between male and female genders as well as between unilateral and bilateral TKA.

Conclusion The study showed encouraging early results for the bone-conserving high flexion TKA system in 208 patients at minimum 5-year follow-up. The adapted design characteristics for improved functional expectations are confirmed in this reported Indian population study group cohort. Further continued evaluation is warranted for this primary TKA system across Indian and other ethnic population.

Keywords Total Knee System · Bone Conserving · High flexion · Indian population

Abbreviations

TKA Total knee arthroplasty
OKS Oxford Knee Score
ROM Range of motion

Introduction

Total knee arthroplasty (TKA) is one of the highly successful operations in Orthopaedics. TKA significantly relieves pain and function including activities of daily living [1–4]. Still a sizable percentage of TKA patients remain dissatisfied after the operation. [5] Lot of advances have happened in the implant designs, refinement of surgical technique and patient selection. Despite these various studies have shown that only

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82–89% of TKA patients are satisfied with their primary TKA [6–11].The successful long-term survival of a TKA implant depends on accurate and optimum bone resection and maximum coverage of the resected cortical bone [12, 13]. This is heavily dependent on the accurate size matching of the implant with the resected knee. Various studies have shown that current commercially available TKA implants do not cater to racial anthropometric differences [14–16]. Most of these implants are designed taking into consideration the anthropometric data of the Western population. Research has shown that the smaller build and stature of the Asian-Pacific population gives rise to TKA component mismatch [17]. Uehara et al. showed that implants designed for knees of the Anglo-Saxon population are currently being used without modifications for the Asia–pacific ethnic group. This is primarily because of paucity of data about the Asia–pacific ethnic population [18]. Research on TKA mismatching has led to the conclusion that people in Asia Pacific should have special designs of TKA implants. Vaidya et al. [16] showed that a statistically significant number of women (60.4%) had femoral anteroposterior diameters smaller than the smallest available (55 mm) femur component. They also noted the spaying of the distal femur in the mediolateral dimension (> 10 mm) for a given anteroposterior size. They recommended manufacture of additional prosthetic inventories suitable for most Asian–Pacific population who have smaller anthropometric measurements than western population. Many Asian cultures require increased flexion up to and beyond 130 degrees to accommodate activities like squatting and kneeling. Currently, available almost all high flexion TKA components are based on standard implant design prototype with additional posterior femoral condyle resection. Maxx Freedom TKA system has been designed to address these issues. It accommodates the unique bone morphology of the Asia–Pacific ethnic group with testing of the components in deep flexion without removing any additional bone leading to bone conservation. To the best of our knowledge, there are no early-midterm studies about this TKA system in Indian/Asia–Pacific population. The purpose of this non-randomized, single surgical team, prospective case series of TKA patients (both unilateral and bilateral) is to report on the early results of the Freedom Total Knee system. The main emphasize is on achievement of early flexion expectations in support of TKA system design characteristics.

Materials and Methods

This is a single surgical team, non-randomized, prospective case series of TKA patients. The sample size was estimated to be 175 for 10% improvement in the reported other system clinical outcomes with α error of 0.05, β error of 0.2 with power of study being 80%. Considering the 20% dropouts the sample size was rounded to 208 patients. Inclusion criteria were patient who underwent primary TKA (unilateral and bilateral) between 1st January 2012 and 31st December 2016 utilizing the posterior-stabilized (PS) Freedom Total Knee system (Maxx Orthopedics, Inc., Plymouth, Meeting, Pennsylvania) (Figs. 1 and 10). Exclusion criteria were patient undergoing revision TKA, patient not willing to participate in the study and patient who were lost to follow-up. There were unilateral TKA and bilateral TKA patients. The study had approval of the local ethics committee (approval letter dated 09/12/2011) and informed written consent was taken from the participants of the study. The primary objective of the study was clinical evaluation with Oxford Knee Score (OKS) and radiological evaluation every year post-TKA. The radiographs were evaluated by an independent observer (as per the modern knee society radiographic evaluation system protocol. Antero-posterior radiographs (with patient bearing full weight) and lateral radiographs (with 30º of knee flexion) were assessed for component position, prosthesis–cement–bone interface and fixation. The criteria for TKA loosening were presence of a complete radiolucent line of > 2 mm width, visible fracture of the cement mantle around the TKA component or change in the TKA component position [19]. The secondary objective of the study was analysis of pre- and post-operative range of motion (ROM). The patients were followed up at 1 month, 3 months, 6 months, 1 year and then every yearly after the TKA. The follow-up was done by an independent observer who was not part of the operative team. The primary and secondary outcomes (OKS, radiological evaluation and ROM) variables like difference between male and female gender and between unilateral and bilateral TKA are also studied.

The study population data and radiographic information were deidentified to protect patient confidentiality. The same information was compiled using Microsoft Excel

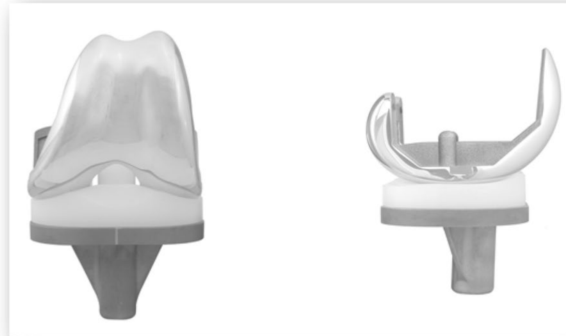

Fig. 1 Antero-posterior and lateral view of posterior-stabilized freedom total knee system

software (Microsoft Corp, Redmond, WA). The statistical analysis and comparison between the different groups were performed with the student *t* test. The *p* value < 0.05 was considered statistically significant.

Results

Total 208 study population included 166 females and 42 males. The average age of female patient was 69.49 ± 7.57 and that of male patient was 71.67 ± 6.71 years (statistically non-significant *p* value 0.0899). The pre-operative diagnosis was osteoarthritis in 94% (*n* = 156) of female patients and 100% (*n* = 42) of male patients. 6% (*n* = 10) of female patients had rheumatoid arthritis as the pre-operative diagnosis (Table 1). All the study population, i.e., 208 patients had a minimum follow-up of 5 years. The average time of follow-up was 7.15 ± 1.23 years. The range being 5.1–10.1 years (Table 2). No patient in the study population was lost to follow-up. The pre-operative OKS was 19.27 ± 1.86 which improved to 38.76 ± 1.5 at 5-year follow-up (statistically significant *p* value < 0.001). The pre-operative range of motion (ROM) was 94.57 ± 3.49 which improved to 127.69 ± 3.65 at 5-year follow-up (statistically significant *p* value < 0.001). There was no statistical difference in the pre-operative and post-operative ROM and OKS between male and female patients (*p* value > 0.05) (Table 3). Unilateral and bilateral TKA patient groups also showed no statistical difference in the pre-operative and post-operative ROM and OKS (*p* value > 0.05) (Table 4). There was no difference in the radiographic evaluation between male and female gender as well as unilateral and bilateral TKA. The male gender required larger femoral and tibial component sizes as compared to the female patients (Figs. 2 and 3). The 9 mm tibial insert was used in 47.11% (*n* = 98) patients followed by 11 mm in 39.42% (*n* = 82) of patients and 14 mm in 12.02% (*n* = 25) of patients. The 17 mm insert was used in 1.44% of patients (*n* = 3) (Fig. 4). The patella was resurfaced in 72.65% (*n* = 77) of female patients and in 27.35% (*n* = 29) of male patients (Figs. 5 and 6). Two patients (*n* = 2, 0.96%) required incision and secondary suturing for superficial skin wound complication. One patient had intra-operative tibial plateau fracture which was treated with use of cannulated cancellous screw and addition of tibial intramedullary stem. Following these additional procedures, all three patients had satisfactory clinical and radiological outcome through 5 years post-operatively (Figs. 7 and 8). Four patients (*n* = 4, 1.92%) had urinary tract infection in the post-operative period, which was treated with appropriate oral antibiotics according to the urine culture and sensitivity report. At minimum 5-year

Table 1 Pre-operative patient characteristics

	Total population (*n*)	Males	Females	*p* value
Total patients	208 (100%)	42 (20.19%)	166 (79.81%)	
Average age	67.49 ± 7.57	71.67 ± 6.71	69.49 ± 7.57	0.0899
Body mass index	29.1 ± 3.4	28.5 ± 2.9	29.4 ± .3.1	0.0902
Pre-operative diagnosis				
Osteoarthritis	95.2%	100%	94%	
Rheumatoid arthritis	4.8%	0%	6%	

Table 2 Average follow-up by gender and unilateral/bilateral TKA

	Total population	Male	Female	Unilateral TKA	Bilateral TKA
Age	67.49 ± 7.57 (*n* = 208)	71.69 ± 6.71 (*n* = 42)	66.37 ± 7.40 (*n* = 166)	66.58 ± 7.20 (*n* = 112)	68.53 ± 7.87 (*n* = 96)
Average follow-up (years)	7.15 ± 1.23 (*n* = 208)	7.01 ± 1.20 (*n* = 42)	7.18 ± 1.24 (*n* = 166)	7.16 ± 1.22 (*n* = 112)	7.13 ± 1.26 (*n* = 96)

Table 3 Pre-operative and post-operative (5 years) OKS and ROM by gender

	Total population	Males	Females	*p* value
Average follow-up	7.15 ± 1.23 (*n* = 208)	7.01 ± 1.20 (*n* = 42)	7.18 ± 1.24 (*n* = 166)	0.4253
Oxford Knee Score				
Pre-operative	19.27 ± 1.86	19.52 ± 1.76	19.21 ± 1.88	0.3349
5-year follow-up	38.76 ± 1.5	38.52 ± 1.33	38.82 ± 1.54	0.2484
Range of motion				
Pre-operative	94.57 ± 3.49	95.93 ± 3.26	95.22 ± 3.48	0.2331
5-year follow-up	127.69 ± 3.65	128.95 ± 2.82	128.37 ± 3.77	0.3522

Table 4 Pre-operative and post-operative (5 years) deformity/HKA angle, OKS and ROM by unilateral/bilateral TKA

	Total population $n=208$	Unilateral TKA $n=112$	Bilateral TKA $n=96$	P value
Pre-operative degree of deformity (coronal plane)	8.6 ± 2.9	8.5 ± 2.5	8.7 ± 3.5	0.6325
Mean post-operative knee alignment (HKA angle or FT angle) (degrees)	**181.7 ± 0.4**	181.7 ± 0.3	181.6 ± 0.9	0.2949
OKS score				
Pre-operative	19.27 ± 1.86	19.22 ± 1.84	19.33 ± 1.88	0.6709
5-year follow-up	38.76 ± 1.5	38.63 ± 1.46	39.03 ± 1.51	0.0539
Range of motion				
Pre-operative	94.57 ± 3.49	94.95 ± 3.34	94.13 ± 3.63	0.0914
5-year follow-up	127.69 ± 3.65	128.23 ± 3.39	127.36 ± 3.85	0.0846

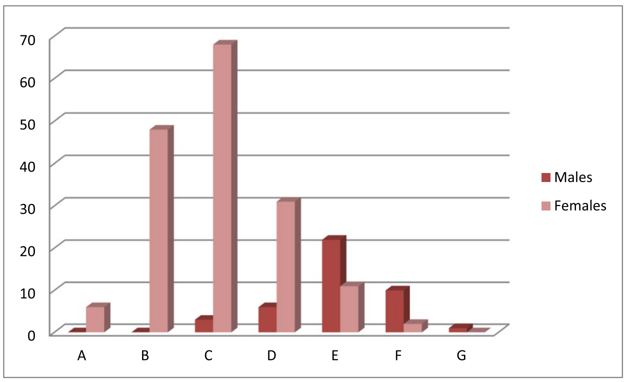

Fig. 2 Distribution of femoral component size by gender

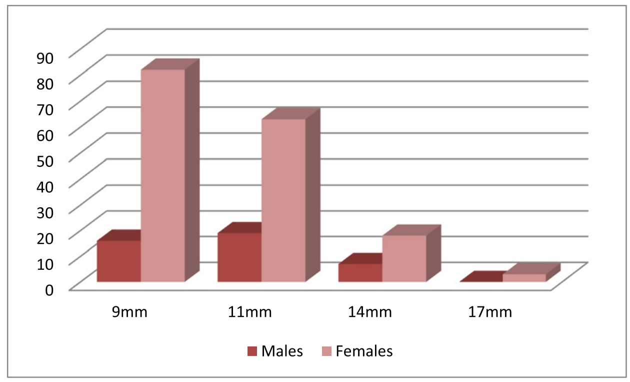

Fig. 4 Distribution of tibial insert by gender

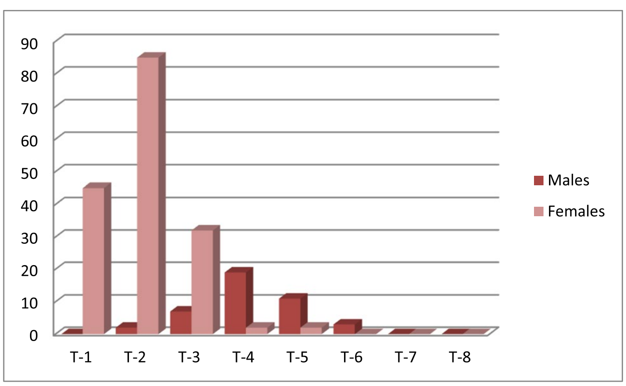

Fig. 3 Distribution of tibial component by gender

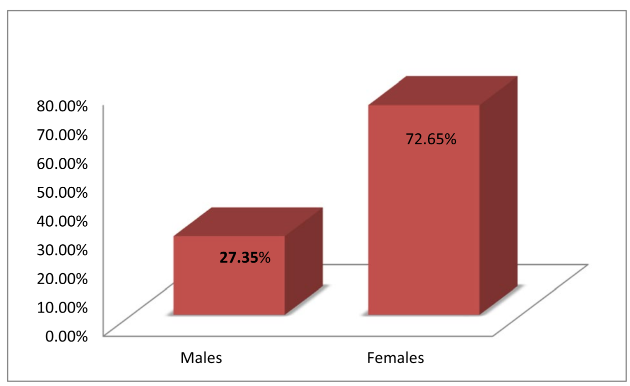

Fig. 5 Percentage of patella replaced by gender

follow-up, there was no radiographic evidence of component loosening/failure (as defined by the modern knee society radiographic evaluation protocol) in the entire study population (Fig. 9). Non-progressive radiolucent lines < 2 mm were seen in 4 TKAs. There was no difference in the radiographic evaluation between male and female gender as well as unilateral and bilateral TKA.

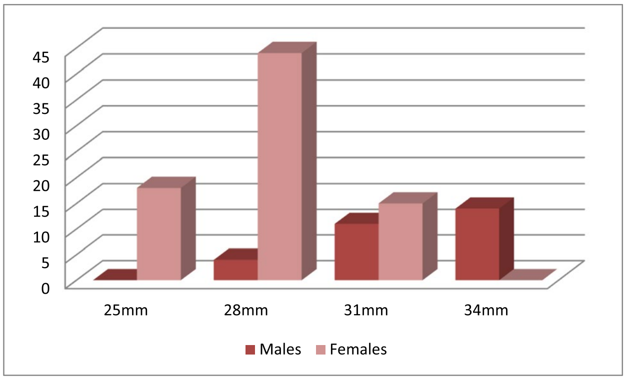

Fig. 6 Distribution of patella component by gender

Fig. 7 Patients performing high flexion activity

Discussion

The main findings of our study are there was statistically significant improvement in the OKS (the pre-operative OKS of 19.27 ± 1.86 improved to 38.76 ± 1.5, statistically significant p value < 0.001) at 5-year follow-up. There was no statistical difference in the pre-operative and post-operative ROM and OKS between male and female patients so also between unilateral and bilateral TKA patient groups (p value > 0.05). At minimum 5-year follow-up, there was no radiographic evidence of component loosening/failure in the entire study population. These findings are comparable if not slightly better than the reported outcomes of other TKA systems

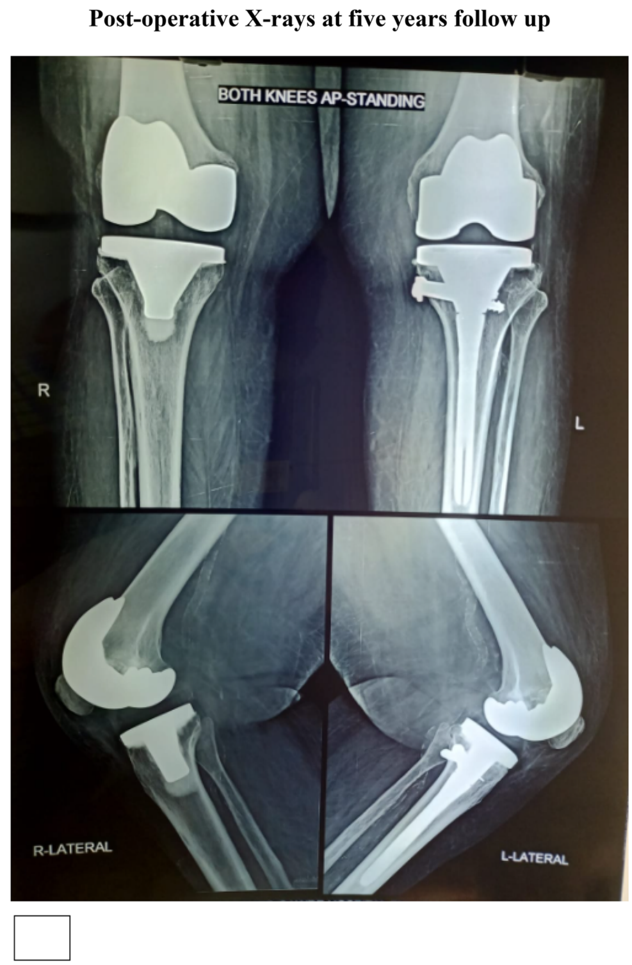

Fig. 8 Post-operative X-rays at 5-year follow-up

in Indian/Asian population [20, 21]. There is a paucity of studies with regards to the function of TKA post-operatively in Indian population. Batra et al. [20] conducted a study in which they reported preliminary clinical results of medial pivot total knee arthroplasty in an Indian population with a five-year follow-up. Our results are similar to the results of this study. Siow et al. [21] studied the outcome of TKA in Chinese, Malays and Indian patients and concluded that Chinese patients had consistently higher pre-operative and post-operative scores. Malays presented with the lowest pre-operative scores but had the greatest improvement in scores at follow-up with post-operative scores similar to Chinese counterparts while Indians had the lowest post-operative scores and worst improvement of all. In our study, we have found results better in the Indian populations in comparison to the above study.

Ability to do activities of daily living is one the most important expectation of the patient undergoing TKA. Londhe et al. [22] showed that relief of pain after TKA was the most important expectation of the patient's undergoing

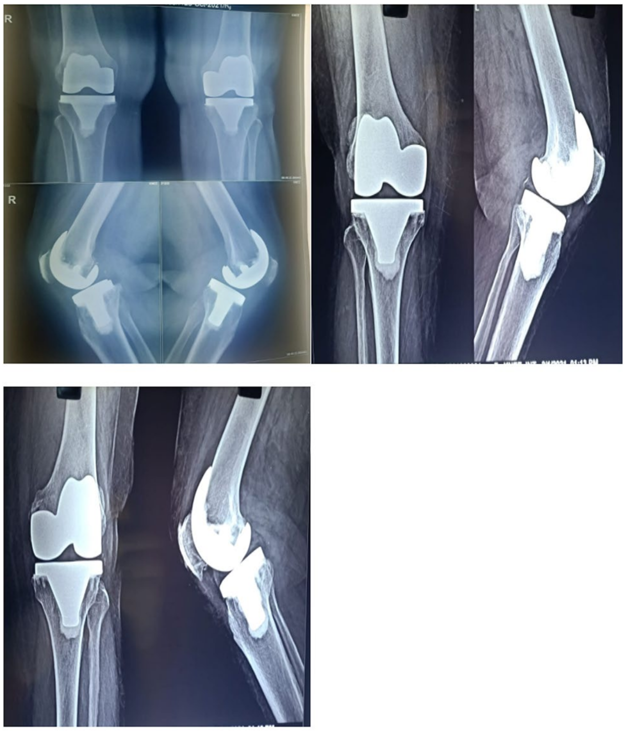

Fig. 9 Post-operative X-ray at 5-year follow-up

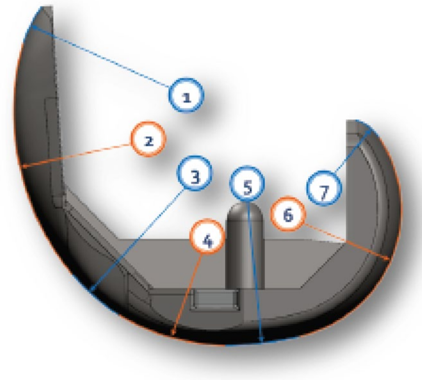

Fig. 10 Multi-radius design of the Freedom Total Knee. Radii 1, 2 and 3 are for patellofemoral contact. Radii 4, 5, 6 and 7 are for allowing femoral rollback and high flexion

TKA. Ability to do activities of daily living was ranked the second most important expectation in the same study. Weiss et al. [23] found that patients after their TKA were not able to perform deep flexion activities. They also showed that the patients were discontented with the restricted flexion they achieved post-TKA. The Maxx Freedom TKA system was introduced in India in the year 2011. Currently, available almost all high flexion TKA components are based on standard implant design prototype with additional posterior femoral condyle resection. The Maxx Freedom TKA system was devised for allowing deep flexion without removing any additional bone leading to bone conservation. The Freedom total knee system is manufactured from cast cobalt chromium while the articular bearing surface utilizes ram extruded UHMWPE (GUR1020). The intention behind the design of the Freedom TKA system is to achieve bone conservation while permitting optimal high flexion motion up to 155 degrees taking into account patient's anatomy and activities of daily living depending upon the culture (squatting and kneeling activity in Asian culture). In order to achieve and accommodate the high flexion, the femoral component is designed utilizing multi radius design. Seven tangential radii are incorporated in the femoral component design to facilitate rollback between the available surfaces through the transition from walking to deep flexion (Fig. 10). The femoral prosthesis condylar profile allows large radii or arc to inhibit significant rollback in normal gait and smaller radii for greater rollback with increasing flexion. This unique design feature allows higher flexion without sacrificing additional posterior femoral condylar bone. This also helps in achieving bone preservation [24]. As stated above achieving early and good ROM is a significant factor in maximizing patient satisfaction. Tarabichi et al. [25] showed good results with attainment of high flexion with the use of high flexion devises in Muslim population. They also concluded that the use of high flexion TKA did not result in any additional post-operative complication. This validates the concept of achieving increased kinematics with femoral condyle profile without compromising the prosthetic composite.

Systematic, unbiased, and continuous monitoring of the TKA devices is extremely important. This includes review of new materials and materials combination, new technologies and their clinical relevance. To further this cause various arthroplasty associations and societies have devised voluntary registries. These registries report their observations at regular intervals [26–28]. Continuous patient case series are also important as they provide important information regarding component performance over a period of time. For example, continuous case series studies about the Total Condylar knee replacement showed early issues with the instrumentation, femoral component sizing and single pegged cemented patella component. This knowledge leads to improvement in the component design and instrumentation. To the best of our knowledge, there are no early-midterm studies about Freedom TKA system in Indian/Asia–Pacific population. The Freedom TKA system is designed taking into consideration both the Western and Asia Pacific ethnic population. The only early reporting about the system is in the Anglo-Saxon Population. Durbhakula et al. [24, 29] have shown good results at 2-year and 5-year follow-ups with use of this system in North American population. They recommended that continued use and study is required to confirm achieving similar results across surgeons and to further study various ancestral populations namely middle Eastern and Pan Asian population. This single surgical team, non-randomized, prospective case series of TKA patients undergoing primary TKA(unilateral and bilateral) between 1st January 2012 and 31st December 2016 utilizing the posterior-stabilized (PS) Freedom Total Knee system is an attempt to further the knowledge gained through the previous studies of Dubhakula et al. [24, 29].

Our study has certain limitations. First limitation is that it is a single surgical team, non-randomized, prospective case series. However, the study has a large cohort (208 patients and 304 knees) of continuous, non-selective series of patients without any loss to follow-up patient. The second limitation is high prevalence of female patients. This is not actually a limitation as multiple studies have shown that females have a high prevalence of advanced osteoarthritis and hence need for TKA [30, 31]. The third limitation is the patients included in the study are of Indian ancestry population, so no comparison with other Asia–Pacific population (Chines/Japanese/Korean Population) is available. Going forward every effort should be made to capture similar data from Pan Asia population. This will help in comparative review of the results across different ancestral populations.

The strength of our study is that to the best of our knowledge this is the first study of its kind reporting the early functional results of this TKA system with reference to clinical function including flexion with bone conservation.

Conclusion

This study of patients receiving Freedom TKA system for primary TKA supports the design rationale taking into account the anthropometric considerations while achieving increased ROM with minimal bone resection. Primary and secondary outcome measures (OKS, ROM and radiographic evaluation) were similar in Male and female gender as well as unilateral and bilateral TKA. Further use and longer follow-up study is warranted to confirm good clinical and functional results across multiple centers and different geographies and population.

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Availability of Data and Materials All data generated or analyzed during this study are included in this published article.

Declarations

Conflict of Interest The authors declare there are no financial conflicts of interest to disclose.

Ethical Approval Local ethics committee approval was obtained before the study. In addition, all patients consented to participate.

Informed Consent Informed consent was obtained from all individual participants included in the study.

Consent for Publication We hereby give our consent for publication.

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