

Midterm survivorship and clinical outcome of INDUS knee prosthesis: 5 year followup study

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ABSTRACT

Background: INDUS knee implant has been designed as per the anatomical morphology of the Indian population and has shown good clinical outcome in short term studies. The purpose of the present study was to report the midterm survivorship and clinical outcome of this implant.

Materials and Methods: Two hundred and twenty three primary total knee arthroplasties in 209 consecutive patients using the INDUS knee prosthesis were prospectively enrolled. There were 145 females (155 knees) and 64 males (68 knees) with a mean age of 69.95 years (range 42–86 years). Annual followup with clinical and radiological examination was conducted, and a survivorship analysis was done using the Kaplan–Meier analysis.

Results: Mean followup was 5.8 years (range 5–6.5 years). Eleven patients died while eight were lost to followup and a total of 204 knees were available for followup. The mean knee flexion improved from preoperative $110.4^\circ \pm 11.24^\circ$ (range 60° – 130°) to $128.17^\circ \pm 8.32^\circ$ (range 100° – 140°) at the final followup. The mean knee score improved from 40.1 ± 10.7 to 90.3 ± 5.34 while the function score improved from 44.35 ± 12.9 to 89.58 ± 7.43 . Two patient developed infection and required revision. The Kaplan–Meier analysis reported a survivorship of 98.6% (confidence interval 95.7–99.6%) at the end for 5 years for INDUS knee prosthesis.

Conclusion: INDUS knee prosthesis has excellent survivorship with a good clinical outcome and low failure rate.

Key words: INDUS knee, Kaplan–Meier, survivorship

MeSH terms: Knee joint, knee replacement, total, osteoarthritis, knee

INTRODUCTION

Total knee replacement (TKR) surgery has redefined the lives of patients with severe knee arthritis. The major refinement in the field of knee arthroplasty is in terms of introduction of new designs of the prosthesis.^{1,2} The geographical, racial and socioeconomic factors define the need for research and development of a new prosthesis that can meet these specific demands. A knee flexion of 90° – 100° can allow most daily activities to be done comfortably in the western world.³ Higher flexion is required in Asians, particularly Indians, to perform social

customs and daily habits.⁴ The geographical variation in the size of distal femur and tibia is also significant. The INDUS knee was designed to fulfill the ethnic anatomical and cultural variations in the Indian population.^{5,6} It was introduced in 2005 and has a combination of high flexion design and sizing according to anatomical sizes of the Indian population. An earlier report presented 2 years followup of INDUS knee prosthesis with an average knee range of motion of 132.9° .⁶ We present midterm survivorship and clinical outcome of INDUS knee prosthesis.

MATERIALS AND METHODS

A prospective data collection was started from 2006 and all consecutive patients operated with INDUS knee between

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2006 and 2007 were included in the study. Ethics approval was taken for the study and an informed consent was taken. Two hundred and twenty three primary total knee arthroplasties in 209 consecutive patients using the INDUS knee prosthesis were prospectively enrolled. There were 145 women (155 knees) and 64 males (68 knees) with a mean age of 69.95 years (range 42–86). 195 patients underwent unilateral TKR while 14 patients underwent bilateral surgeries. The diagnosis was osteoarthritis in 169 knees (75.6%, 8 bilateral), rheumatoid arthritis in 51 knees (22.76%, 6 bilateral) and posttraumatic arthritis in three knees (1.62%). Grade of osteoarthritis as per the Kellgren and Lawrence system⁷ was grade 4 in 72 knees, grade 3 in 85 knees, and grade 2 in 12 knees.

Implant

INDUS knee implant (Biorad Medisys Pvt., Ltd. Pune, India.) was designed taking into consideration the Indian knee morphology as per suggestions by Vaidya *et al.*⁵ It is a posterior substituting design where the radius of curvature of the posterior condyle of femoral component is reduced to increase the rollback and flexion. Tibial component is a monoblock metal backed design with inbuilt 4° slope in the tibial insert and 3° slope in the metal base plate which in turn helps in achieving greater flexion. The post and cam mechanism is modified to form a third joint with congruent surfaces. This joint engages at more than 80° flexion and allows load bearing on deep flexion. The femoral components are separate for right and left knees and the patella is a single peg anatomic design.

Operative procedure

All patients were operated using standard operative protocol and were operated by the same team of surgeons. Medial parapatellar approach was used and tourniquet was applied in all surgeries. Bony cuts were made as per standard instrumentation using preoperative radiographs as guides. Distal femoral cut was made using an intramedullary guide. The proximal tibia was prepared using extramedullary guide and parallel to the tibial cut technique was used for posterior femoral cuts. Patelloplasty was done in 98 knees where there was no cartilage eburnation of patella and the patient was young. This included peripatellar synovectomy, cauterization of the patellar rim thus effectively denervating it and removal of osteophytes. The remaining patellae were replaced. Soft tissue release was done as per needs to balance the knee. In varus knees sequential release of superficial, deep medial collateral ligaments and the semimembranosus was done so as to achieve medio-lateral stability. Antibiotic impregnated cement was used in all cases, and second generation cementing was used. Manual pressurization of the cement was done. Postoperative drain was kept for 2 days and patients were mobilized from day 2 as per pain tolerance. An annual followup schedule was explained to

the patient with both clinical and radiological examination at each followup. All patients completing 5 year postsurgery were called for a final followup where knee range of motion, flexion deformity, Knee score and function scores⁸ were evaluated. Simple subjective pain grading was used to assess anterior knee pain (Grade 0 - no pain, grade 1 - mild pain, grade 2 - moderate pain, grade 3 - severe pain). Radiographic followup included a scanogram, anterior posterior and lateral knee radiographs. All radiographs were assessed by two clinical fellows to look for signs of implant loosening. Survivorship assessment was done using the Kaplan–Meier analysis. Paired *t* test or Wilcoxon signed rank test was used to compare the data depending on normal distribution of data. The level of significance was set as $P < 0.05$.

RESULTS

The mean followup was 5.8 years in our study (range 5–6.5 years). Eleven patients expired during the course of 5 years since the date of surgery. Nine patients expired due to medical issues which included renal failure, CVA and myocardial infarction. One patient expired due to complications following a cholecystectomy, 3 years after the knee surgery. Another patient died due to septicaemia following infection in the joint. All the patients who expired had unilateral knee replacement and thus 212 knees were available for final followup. Of these, eight knees were lost to followup (address not traceable). For the remaining knees (204), the mean knee flexion improved from preoperative $110.4 \pm 11.24^\circ$ (range 60° – 130°) to $128.17 \pm 8.32^\circ$ (range 100° – 140°) at the final followup ($P < 0.0001$). Of these, 8% had a range between 100° and 120° , 72% had a range between 120° and 130° while 20% had a key motion of range of more than 130° . Preoperatively, there was a flexion contracture of $12.3^\circ \pm 10.5^\circ$ (range 0° – 30°). This improved at the final followup to a mean of $2.7^\circ \pm 2.42^\circ$ (range 0° – 5°) (P value 0.0014 for Wilcoxon signed rank test). One hundred sixty four knees had grade 0 anterior knee pain, 33 had grade 1 anterior knee pain (19 nonresurfaced and 14 resurfaced patellae), and 7 knees had grade 2 anterior knee pain (4 nonresurfaced and 3 resurfaced). No knee had grade 3 anterior knee pain and no crepitus was palpable in any of the patients. No patients demanded revision or treatment for anterior knee pain. The mean knee score improved from 40.1 ± 10.7 to 90.3 ± 5.34 while the function score improved from 44.35 ± 12.9 to 89.58 ± 7.43 ($P < 0.001$). The mean preoperative tibiofemoral alignment was $9.3^\circ \pm 8.2^\circ$ varus (range 35° varus to 20° valgus) which was noted to be $4.9^\circ \pm 2.7^\circ$ valgus (0° – 7° valgus). Two knees underwent two-stage revision because of late infection with *Staphylococcus aureus* and *Pseudomonas aeruginosa*, respectively, which was identified 7 months and 18 months after surgery, respectively. In another knee, a peri-prosthetic

Table 1: Five year survivorship analysis of INDUS knee prosthesis

Time period (year)	At risk	Number of knees enrolled at the beginning of the study=223			Survival probability estimate	95% CI	
		Unavailable (lost to followup/died)*	Revised/ failed*	Lower limit		Upper limit	
1 st	223	3	1	0.995	0.971	0.999	
2 nd	219	0	1	0.99	0.964	0.998	
3 rd	218	6	0	0.99	0.964	0.998	
4 th	212	8	0	0.990	0.964	0.998	
5 th	204	2	1	0.986	0.957	0.996	

Kaplan-Meier analysis was done accounting for failures and lost to followup cases. There were 11 deaths*, 8 lost to followup* and 3 failures* which were all unilateral cases. CI=Confidence interval

supracondylar fracture of the femur occurred 17 months after operation, and this was treated successfully with open reduction and plate fixation. The femoral component remained well-fixed. In two other knees, patients had a fall which resulted in peri-prosthetic fracture of the tibia. They were treated successfully with open reduction and plating. The tibial component remained well-fixed. Both patients are walking well now. One patient who underwent TKR for rheumatoid arthritis of the right knee developed severe fixed deformities of other joints including the left knee and is now bed ridden. The operated right knee has a range of motion of 105°. On radiographs, there were radiolucent lines seen under tibia tray in 21 cases. However, these were non progressive on sequential radiographs and no tilting of tibial tray was seen or revision required for aseptic loosening of the prosthesis. On Kaplan–Meier survivorship analysis, INDUS knee prosthesis was found to have 98.6% survivorship (confidence interval 95.7–99.6%) at minimum 5-year followup for failure due to any reason [Table 1]. There were 3 failures, two infections and one progressive rheumatoid arthritis (as detailed earlier). The survival analysis was done taking into account patient who died, patients lost to followup and failed cases, so that a worst case scenario is accounted in the calculation. Since there was no aseptic loosening or mechanical failure, survival analysis with these as end point will yield 100% survival for INDUS knee implant.

DISCUSSION

Clinical outcome and survivorship are the two most important measures that establish the usefulness of implants in arthroplasty. We present midterm followup results of INDUS knee prosthesis with a 98.6% survivorship and good clinical outcome.

INDUS knee has been designed as a high flexion implant. High flexion implants have consistently reported an average knee flexion of more than 120° [Table 2]⁹⁻¹⁷ although a clinical advantage of this higher flexion is debatable.¹⁸⁻²⁰ In an earlier study of 2 years followup,⁶ INDUS knee had reported an average range of motion as 132° while in 5-year followup the average knee range

Table 2 : Literature review of range of knee flexion for high flexion knee prosthesis

Author	Year of publication	Total knee implant	Mean knee flexion angle (degrees)
Kim YH <i>et al.</i> ⁹	2005	High flex-PS	138.6
Seon JK <i>et al.</i> ¹⁰	2005	High flex	128.5
Laskin RS. ¹¹	2007	High flex PS	133
Nutton RW <i>et al.</i> ¹²	2008	High flex PS	127
Seon JK <i>et al.</i> ¹³	2009	High flex CR	135.3
Endres <i>et al.</i> ¹⁴	2010	High flex CR	122
Kim <i>et al.</i> ¹⁵	2012	High flex PS	139
Maniar and Singh. ¹⁶	2012	PS-RPF	130
Lee <i>et al.</i> ¹⁷	2013	High flex PS	132.2

of motion was 128°. Although the mean range of motion seems to be a bit lower than the earlier study, it still is comparable to range of motion of high flexion implants reported in literature. The incidence of anterior knee pain was around 19.6% (40/204) of which 82.5% were with mild pain. This was comparable to an earlier report on Indus knee.^{6,21,22} Other authors have reported the incidence of anterior knee pain to vary from 8% to 50%.²³⁻²⁵ Systematic reviews have quoted similar rates of anterior knee pain in both resurfaced and nonresurfaced groups and same was the case in our series too.^{26,27} Some studies have implied anterior knee pain to severity of cartilage damage²⁸ while others have attributed it to dysfunctional muscular co-ordination in the thigh muscles.²⁹ In our series, we did selective resurfacing of patella according to the severity of cartilage damage and thus probably is the reason for lower rates of severe anterior knee pain. A detailed assessment of factors that affect the range of motion in INDUS knee is already published and this article does not wish to duplicate the analysis.^{21,22}

Survivorship of various implants at 5-year midterm followup ranges from 90% to almost 100%.³⁰⁻³⁷ Rand and Ilstrup³⁸ in their study of 9200 TKRs suggested that the probability of any implant surviving would be about 97% at both 5 and 10 years, while recent meta-analysis³⁷ reported pooled survivorship of 98.4% at 5 year followup. Comparing with other implants, the INDUS knee showed a comparable survivorship rate (98.6%) with these recent reports [Table 3]. Good survivorship and low revision rates

Table 3: Literature comparison of survivorship of TKA implants

Authors	Year of publication	Implant	Number of years	Survivorship (%)
Font-Rodriguez DE <i>et al.</i> ³⁰	1997	Total condylar series	21	90.77
Shen <i>et al.</i> ³¹	2009	PS-All polyethylene	5.9	93.55
Asif and Choon ³²	2006	Cemented press fit total condylar prosthesis	6	94
Dalury <i>et al.</i> ³³	2008	PFC Sigma	5	99.6
Kim <i>et al.</i> ³⁴	2007	Fixed bearing-cruciate retaining	5	94
Meftah <i>et al.</i> ³⁵	2012	RPF	5	97.7
Clayton <i>et al.</i> ³⁶	2006	Sigma TKA	5	97.00
Hopley and Dalury ³⁷	2014	Pooled survivorship of Sigma knee System	5	98.5
Present study		INDUS knee	5	98.60

PS=Posterior stabilized, RPF=Rotating platform, TKA=Total knee arthroplasty

are function of surgical technique and also implant design. INDUS knee design is developed indigenously from data of the Indian population.⁵ This helps in getting proper size of the implants and avoiding over and undersizing of the components. The modified post and cam functions as the third joint thus providing additional stability in deep function activities. Deep flexion activities are common in our country, and although our patients are advised against such activities, there are situations where they do flex the knees beyond 100°. Although we cannot always force the patients to follow our advice, the design stability of INDUS Knee does make these deep flexion activities safer as compared to conventional implants and is probably one of the most important causes of high survivorship. Again monoblock design avoiding backside wear and no cam postimpingement in rotations add to prevent total wear rates⁶ and thus add to the longevity of the implant. Wear of polyethylene and resulting osteolysis play an important role in early failure of knee implant. INDUS knee reported a survivorship of 98.6% which in turn indicates less poly wear and can be taken as a surrogate to the quality of the polyethylene. Furthermore, there were no cases of aseptic loosening again indicating less amount of wear debris and osteolysis.

Complications in our series are again comparable to other implants with 1% (2 out of 204) infection rate.^{35,36,39} No cases of early loosening or implant subsidence was noted in present cases. Peri-prosthetic fractures had the lower rate compared to other series,^{36,39} likely reason being that our patients remain less aggressive with activities even after a successful surgery. Radiolucent lines were seen under the tibia tray and were also reported in the previous study of INDUS knee.⁶ These were non progressive and are also reported by other studies,⁴⁰ however, longer followup of this series will be needed to ascertain their role in aseptic loosening.

Our study has a few limitations. There is no comparison group, however, this was purely designed to be a study for survival analysis of the implant. Few patients were lost to followup, and the survivorship could not be assessed

in those, however, we considered these patients while calculating the survivorship and accounted for them in the analysis. The sample was comparatively smaller, as this was a single-center study. However, as in early days of the implant, maximum cases were done at one center, and so proper followup could be conducted at that center. Another limitation is relative short term followup of the implant. A multicenter and larger sample study is currently undergoing with the aim to attain a longer followup of the implant.

Thus, good clinical and functional results are achieved in our cases at the end of 5 years and survivorship of the implant was 98.6%. These results are comparable to other similar implants, however, long term followup (10–15 years) with a focus on aseptic loosening and functional outcomes are necessary to study about the long term efficiency of the implant.

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Conflicts of interest

There are no conflicts of interest.

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