ORIGINAL ARTICLE

Comparative Analysis of the Clinical and Functional Outcome of High Flex Indus Knee and Conventional Posteriorly Stabilized Total Knee Prosthesis – Results of a Prospective Study.

K H Sancheti[1], Parag Sancheti[1], Surendra Patil[1], Rajeev Joshi[1], Ashok K Shyam[1], Amol Waghmare[1]

ABSTRACT:

Introduction: Total knee arthroplasty has become treatment of choice in severe osteoarthritis. High flexion designs have been recently promoted as offering better range of motion; however clinical significance of the improved range is still debatable. The purpose of this study was to compare clinical, functional and radiological outcome following TKA done with high flex (INDUS Knee) and conventional posteriorly stabilized prosthesis.

Material and methods: One Hundred patients were entered between Jan 2007 to April 2008 into a prospective non-randomised trial in which 50 patients received Indus knee TKA prosthesis and 50 patients received PFC sigma (conventional posteriorly stabilized TKA prosthesis).

Results: On follow up of 1 year, there was no difference in pain, flexion deformity, and knee score in both the groups. There was significant difference in Range of motion with final range of motion achieved of Indus knee much better than the conventional posteriorly stabilized group and better final functional score of Indus group ($p < 0.01$).

Conclusion: In summary this prospective non-randomised trial demonstrated the INDUS group has better range of motion and function score as compared to the conventional posteriorly stabilized TKA prosthesis group. The improvement in the pain score, flexion deformity and knee score were comparable in both the groups. Long-term evaluation will be required to comment on differences in implant longevity.

Keywords: knee arthroplasty, non-randomised trial, Indus knee, PFC Sigma, range of motion, outcome scores.

INTRODUCTION

Total Knee Arthroplasty (TKA) is a very successful and a low risk treatment option. It is a safe and cost effective treatment for alleviating pain and restoring physical function in patients unresponsive to non-surgical modalities of treatment.[1, 2] Though the success story of TKA is known well, questions remain concerning which material and implant design are most effective for specific patient population. Demands of the knee and expectations of Indian patients are different as compared to the western world.[3-,7]. Armamentarium of implants is available but technical familiarity, needs of the patient etc. have to be kept in the mind prior to surgery.

The design of the standard posterior stabilised Press-Fit Condylar (PFC) total knee prosthesis (Johnson and Johnson, Raynham, Massachusetts, USA) was based on earlier successful implants such as the Total Condylar and Kinematic knees. [8-11]. The Press Fit Condylar (PFC) was later changed to PFC Sigma with the main design changes being a deep and extended trochlear groove with a matching single radius dome all polyethylene patella. The average flexion achieved by this prosthesis was 107–115° [12-15] similarly, cruciate retaining designs achieve a flexion of around 110–112°. [16-17] Although this was a significant improvement, it may not be enough for daily habits like cross-legged sitting and squatting that are so common in Indian subcontinent. The INDUS knee is a cruciate substituting posterior stabilized design with numerous modifications done to achieve high flexion at the knee joint.[18,19]

We hypothesized that an indigenous INDUS knee prosthesis will offer a better clinical and functional outcome in Indian patients as compared to the foreign standard implant. The present study aims to follow-up patients who had undergone Total Knee replacements and to compare the clinical, functional and radiological outcome after arthroplasty with standard versus indigenously designed high flex INDUS implant.

Materials and method:

One hundred patients were entered into a prospective non-randomised trial from Jan 2007 to April 2008 in which 50

Table 1: Comparison of demographic data

Variables	Indus Group		Conventional Group	
	Mean	SD	Mean	SD
Age	63.5	5.34	65.2	5.04
Weight	67.93	9.82	68.8	7.45
BMI	25.9	2.13	27.1	3.18

[1]Department of Orthopaedics, Sancheti Institute for Orthopaedics and rehabilitation, Pune Maharashtra, India.

Address for correspondence: Dr Ashok K Shyam, Sancheti Research department, Sancheti Institute for Orthopaedics and Rehabilitation, first floor, Shivaji nagar, Pune, Maharashtra, India. Email: drashokshyam@yahoo.co.uk

patients received Indus knee TKA prosthesis and 50 patients received PFC sigma TKA prosthesis having a minimal follow up of 1 year was reviewed and studied. Informed consent was taken from all patients. Clearance of ethical committee of the institute was taken. Exclusion criteria included patients requiring revision knee surgery, a prior septic process to the knee, or knee flexion of less than 50°, Non osteoarthritis knee pathology and patients with BMI > 40. In addition, we excluded patients with previous knee surgery, ASA>grade II and prior neuromuscular and vascular disease.

All patients received the identical operation, that is, a cemented knee arthroplasty through a medial parapatellar approach. All patients had their patella resurfaced with a cemented biconvex all-polyethylene patella. Every aspect of their care, including intraoperative and postoperative management, was identical. None of the patients were placed on continuous passive motion postoperatively. All patients received routine in-hospital physiotherapy followed by outpatient therapy

The patients were enrolled preoperatively and observed postoperatively by one of the authors who measured clinical performance with a number of different validated clinical outcome tools including The Knee Society scores (KSS) for function and knee score. The patients were also assessed for anterior knee pain using visual analog scale. All ROM measurements were done in a blinded fashion, using a goniometer with the patient in supine position.

Preoperative & postoperative data collection was done by one of the authors. For comparison of the pre operative and post operative variables within each group paired t test was used. For comparison among means for continuous variables in between two groups was done by unpaired t test. The level of statistical significance was taken as p value<0.05, i.e. whatever difference was observed (mean/distribution) was real and can be attributed to the intervention in the study.

RESULTS:

There were 50 patients in each of the two groups viz, high flex and conventional group. The mean age in High flex INDUS group was 63.5±5.34 (range 72-58) while mean age in the conventional group was 65.2±5.4 (range, 72-56). There were 31 females and 19 males in the INDUS group while conventional group had 33 females and 17 males. All hundred patients were Osteoarthritis. In INDUS group surgery was performed on the left knee in 29 patients and on right knee in the remaining 21 patients. In the conventional group there were 30 right and 20 left knees that were operated upon.

The average weight of the patient in the INDUS group was 67.93± 9.82 (54-90) Kgs and the pre operative BMI was 25.9±2.13 (range 23.6 -28.9). In the conventional group the average weight of the patient was 68.85 ±7.6 (range, 62 to 80) Kgs and the mean BMI was 27.1±3.18 (range, 21.7 to 32) [Table 2].

Table 2: Comparison between two groups

Variables	High Flex Group		conventional Group		p value
	Mean	SD	Mean	SD	
Pain	43.75	-	45.25	-	0.5
Knee-ROM	128	16.1	107.5	25.15	0.001
Flexion deformity	3.95	3.77	2.8	3.4	0.26
Knee score	87.7	8.5	86.9	7.09	0.35
Function score	89.75	10.67	85.25	7.23	0.01

Pain– Post operatively the mean pain score in the INDUS Group was 43.75 (30 to 50) and the mean pain in the conventional group was 45 (30 to 40). Although it appears as if the conventional group patients had less pain, this difference was not statistically significant (p<0.5).

Range of motion- At one year follow up the mean ROM of the INDUS Group was 128± 16.1 (115 to 135) which was significantly better than the ROM of conventional group which was mean 107.5±25.15 (90 -120) (p<0.001), thus the final ROM achieved by INDUS group was much better than the conventional group.

Flexion deformity- Post operatively the mean flexion deformity in the INDUS group was 3.95± 3.77 (0-13) which was comparable to the correction achieved in the conventional group where the final flexion deformity was 2.8±3,4 (0 to 12). Both had a comparable flexion deformity at the final follow up (p value 0.26).

Alignment - Post operatively the alignment in both the groups improved with alignment in INDUS group to be mean of 4.8±8.5 (6.7 to 9.5) degrees of varus and in conventional group the alignment was 6.85±1.38 (5 to 9) degrees of varus.

Knee score - Post operatively the mean knee score in the INDUS group was 89.7±8.5 (67 to 95) while that in the conventional group was 86.9±7.09 (69 to 95). This difference was not statistically significant between the two groups (p 0.35).

Function score - Post operatively the function score in the INDUS group was 89.75±10.67 (65 to 100) while in the conventional group it was 85.25±7.23 (70 to 100) and this difference was significant (p <0.01) indicating that the INDUS group had a better final functional score.

DISCUSSION

Total joint replacement is the highly effective solution for arthritic pain, however a search for a better functional and durable prosthesis still continues. The original Total Condylar design was very successful in terms of pain relief and durability but the average post op flexion achieved was only around 900 to 950 [1-7]. Even though this may be enough for most of the daily activities in the western world, 23 Indian population requires higher flexion for most of their daily

social habits and customs like sitting cross legged and squatting [24]. In 1978, the posterior stabilized condylar prosthesis was introduced, as a modification of the total condylar prosthesis, by Insall et al [25]. In this prosthesis a post and cam mechanism was used to achieve femoral rollback. The average flexion achieved by this prosthesis was 1070 – 1150 12-14,25,26. PFC sigma is the most common implant used in India while Indus Knee prosthesis is gaining popularity as an indigenous, high flexion implant with cost advantage.

Comparison between the standard conventional and high flex implants has been reported recently by few authors. Minoda et al [2009] analysed range of motion of standard and hi-flex cruciate retaining prosthesis prospectively.[9] They had 89 knees with standard and 87 knees with high flexion CR total knee prostheses [both Next Gen brands]. At 12-month follow-up, average ROM was 112.0° ± 12.6° for standard, and 115.3° ± 13.4° for high-flexion CR prosthesis (P = 0.101). They found no significant differences between groups with regard to ROM, clinical, or radiographic parameters. Seon et al [2009] analysed 100 knees with 50 knees in each category of Hi-flex and standard total knee prosthesis.10,27 At the time of the final follow-up, the average maximal non-weight-bearing flexion was 135.3° for the knees in the high-flexion group and 134.3° for the knees in the standard group; the difference was not significant. Moreover, no significant difference was found between the groups in terms of weight-bearing flexion (124.8° in the high-flexion group and 123.7° in the standard group) and the number of knees that allowed kneeling and sitting cross-legged. The average Hospital for Special Surgery knee score was 94.4 points in the high-flexion group and 92.4 points in the standard group; the difference was not significant. The Western Ontario and McMaster Universities Osteoarthritis Index scores also showed no significant difference between the groups. Thus no functional difference was noted in two groups. Nutton et al [2008] performed prospective randomised comparison of the functional outcome in patients receiving either a NexGen LPS-Flex or the standard design. [11] The study included total of 56 patients, half of whom received Hi-flex and standard knee prosthesis each. They found that there was no significant difference in outcome, including the maximum knee flexion, between patients receiving the standard and high flexion designs of this implant. Gupta et al [2006] reported a significant improvement in the post-operative range of movement using a high flexion rotating platform design when compared with a standard design of rotating-platform TKR.[27] Similarly, Bin and Nam [2007] found a significant improvement in knee flexion at one year after operation in patients receiving a high flexion design compared with a standard knee replacement, particularly in patients with a pre-operative range of flexion of less than 90°.[28] Kim, Sohn and Kim [2005] were unable to show a significant improvement in knee flexion using a NexGen LPS-Flex knee replacement.[29] In their study, the standard design was used in one knee and high flexion prosthesis in the other. After a mean of 2.1 years the mean range of movement was 136° in the standard design and 139° in the high flexion design, compared with a mean preoperative range of movement of 126° and 127°, respectively. In their Asian population, the pre-operative range of movement was greater than in the present series, despite which they were unable to demonstrate any advantage in using a high flexion design over the standard version. Other studies from Asian centres have failed to show an improvement in knee flexion using a high flexion design.[30, 31] this is in contrast with expectations that the Asian population will be more satisfied with the Hi-flex designs.

Menegheni et al [2007]retrospectively reviewed 511 TKAs in 370 patients fitted with posterior cruciate ligament–substituting prosthesis of a traditional design (not designed for high flexion).[32] Regression analysis determined the effect of obtaining high flexion (>125°) on Knee Society, stair, function, and pain scores. Of 511 TKAs, 340 (66.5%) obtained range of motion greater than 115°, and 63 (12.3%) TKAs obtained high flexion greater than 125°. There was no difference between the patients who obtained flexion greater than 115° and those who obtained high flexion greater than 125° in Knee Society scores (P = 0.34) and function scores (P = 0.57). Patients with greater than 125° of flexion were 1.56 times more likely to demonstrate optimal stair function (P = 0.02). They concluded that obtaining flexion greater than 125° after TKA does not offer a benefit in overall knee function; however obtaining a high degree of flexion appears to optimize stair climbing.

First metaanalysis done by Gandhi et al was published in 2009 January. [33] They studied 6 studies that met with their inclusion criteria. They concluded that High-flexion implant design improves overall ROM as compared to traditional implants but offers no clinical advantage over traditional implant designs in primary knee arthroplasty. Murphy et al [2009] performed a systematic review of published trials designed to determine if there is a significant increase in ROM or function in patients who receive a high-flexion TKA compared to those who receive a standard TKA.[34] Nine studies fitting the inclusion criteria were analysed. They concluded that there was insufficient evidence of improved range of motion or functional performance after high-flexion knee arthroplasty[30,31,32,33,34.].

In our study we found that post operatively both groups had similar pain relief, flexion deformity. Alignment was also similar n both the implant groups with similar knee society score. The range of motion was better in the Indus High flex Indus knee than the conventional prosthesis and this results was similar to the studies mentioned above. The functional outcome in our series was better in the Indus knee group. This may be because of high flexion features of the INDUS knee and also because it is designed to fit the sizes of the knee of indigenous population. This higher functional acceptance of Indus Knee by the patients did not mean that high flex activities are promoted. In a recent article by Sancheti et al[35]

the authors made it clear that the patients were adequately warned against high flexion activities and this was also the case in this study. Thus improved range of motion, pain relief and indigenous design may be a reason for better subjective acceptance of the Indus Knee by our patients. A randomised controlled trial is however essential to prove the findings of the present study.

CONCLUSION;

Comparing the INDUS and conventional group we found that; Post operatively the INDUS group had better ROM and function score as compared to the conventional group. The improvement in the pain score, flexion deformity and knee score were comparable in both the groups.

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