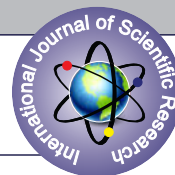


INTERNATIONAL JOURNAL OF SCIENTIFIC RESEARCH

IN FEMALE PRIMARY OSTEOARTHRITIC PATIENTS, UNDERGOING TOTAL KNEE ARTHROPLASTY, IS GENDER-SPECIFIC CRUCIATE RETAINING HIGH-FLEXION KNEE, SUPERIOR TO STANDARD CRUCIATE RETAINING FLEXION KNEE, FROM THE VIEW OF CLINICO-FUNCTIONAL OUTCOMES.



Orthopaedics

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ABSTRACT

Anthropometric measurements of the human knee, have differences in the women's and the men's knee. Total Knee Arthroplasty (TKA), aim is to relieve pain in an osteoarthritic knee, to improve the functional range of movements, and thereby improve the quality of life, of the patient. In this study, which was specifically done for women patients with primary tri-compartmental osteoarthritis of the knee, the implant design for total knee arthroplasty was either "Standard CR Flex Knee" or "Gender-Specific CR High-Flex Knee". This prospective study had a recruitment period of 2 years and a minimum follow-up period of 1 year and was done between March 2018 to February 2021. 23 female subjects aged between 51 to 80 years, were recruited in the "Standard CR Flex Knee" group and 25 female subjects aged between 51 to 80 years, were recruited in the "Gender-Specific CR High-Flex Knee" group. 60.42% (n=29) had a right sided involvement and remaining 39.58% (n=19) had a left sided involvement. Post-operative Knee Society Clinical Rating System (KSS), mean clinical outcome for "Standard CR Flex" and "Gender-Specific CR High-Flex Knee" were scored as 87.5 and 92.0 points respectively. With regard to the mean functional outcome, as per KSS both the groups averaged 85.0 points. Thus, this study could not establish any potential additional benefits, by opting for the "Gender-Specific CR High-flex knee prosthesis". Both the "Standard CR Flex Knee" and the "Gender-Specific CR High-Flex Knee" TKA yielded nearly similar clinico-functional outcomes.

KEYWORDS

Total Knee Arthroplasty, Standard CR Flex Knee, Gender-Specific CR High-Flex Knee.

INTRODUCTION:

According to Rand J.A et al; (1) in a knee that is arthritic, a factorial influence by the surgical procedure of Total Knee Arthroplasty (TKA), is to achieve the following,

- Relief of pain.
- Improve the functional range of movement of the diseased knee joint.
- With an aim to improve, the overall quality of life (QOL).

Arthroplasty is a procedure that surgically resurfaces the sub-adjacent bones, forming a di-artrodial joint, and are replaced by appropriately fitting prosthesis. In practicality, it is akin to "Joint Replacement Surgical Intervention". This is however an option exercised after all other non-invasive methodologies of treatment, like physiotherapy and pain managements have failed to yield positive results, after a suitable length and period of treatment. Modern day arthroplasties rely pretty much on the nature of replacement prosthesis. Technically "Arthro" denotes the joint and the term "Plasty" denotes to form. Therefore, the procedure of arthroplasty is that of "(Re) forming of the joint".

Themistocles Gluck (2) in 1890, used a hinged joint made of ivory, for knee arthroplasty resembling a constrained variant of the prosthesis and had emphasised the fact that prior joint infections, did not yield satisfactory results.

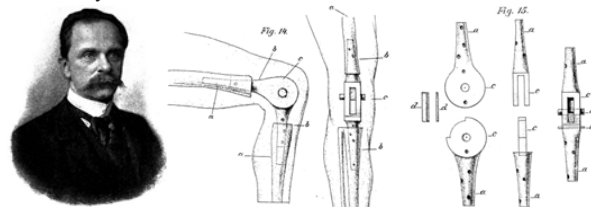


Fig. 1: (a) Themistocles Gluck, (b) Illustrations of joint constructs as suggested by Gluck.

Robertson O et al; (3) pointed at that the main hindrance to any replacement arthroplasty was infection. Verneuil performed the first interposition arthroplasty. In the 1940's the first artificial implants were introduced, which comprised of moulds that were fitted in the femoral condyles that were proposed by Campbell and Smith - Peterson. Later, Mc Keever and Mac Intosh proposed hemi-arthroplasty of tibia. All these attempts had faced many a complication, so these procedures, never became so popular. In the 1950's replacing the femoral and tibial

joint surfaces, Walldius (4) had developed a hinged variant of the prosthesis. In the 1950's and 1960's, hinged knee prosthesis started providing some satisfactory results. These hinged prostheses, due to their mechanical and structural stability, had their intra-medullary stem to align with the axis of the knee joint and were technically and surgically easy to perform. Metal on plastic knee replacement was introduced in 1971 by Frank Gunston (5) and he also presented the concept of femoral roll back. Bi-compartmental prosthesis was designed by Freeman and Lewack joining two uni-compartmental components, initially on the femoral side and then on the tibial side, which was converted into a tri-compartmental design by adding a patellar flange. The prototype of the current total knee arthroplasty was popularised by John Insall in 1973 (6). Insall and Walker in 1974 designed the unconstrained total condylar prosthesis using a metal femoral and HDPE tibial component, secured to bone with PMMA cement. Insall then designed a Constrained condylar prosthesis which has a significantly more valgus and varus stability and has been useful for revision arthroplasty, when there is a bone loss, valgus deformity and MCL insufficiency.

Good fellow and O'Connor (7) in 1976 introduced meniscal bearing prosthesis or Oxford knee. It is a bicondylar knee replacement design which contains a single sagittal radius of curvature on the femoral condyles that coapt with totally congruent tibial polyethylene inserts or menisci, that move freely on a polished metal tibial plate. It had complications of posterior extrusion of the polyethylene menisci. Use of various types of prosthesis for varying amounts of arthritic involvement, deformity laxity and bone loss are the "Graduated system concept". An example of graduated system is the Genesis knee system, with varying constraints, and metal augmentation, fixation surfaces for different clinical indications. The implant designs are classified as,

- Constrained (Hinged) variant.
- Semi-Constrained / Cruciate Substituting variant.
- Unconstrained / Cruciate Retaining variant.

Total Knee Arthroplasty (TKA) is primarily indicated to decrease pain caused by severe arthritis with or without significant deformity. The common causes include Primary Osteoarthritis followed by Rheumatoid arthritis. Osteoarthritis of the knee, is a common affliction of the middle aged and elderly, characterized by pain, swelling, stiffness and deformity.

Total knee arthroplasty in osteo-necrosis and in patello-femoral arthritis have been documented by Mont MA et al; (8). Ashraf T et al have described uni-compartmental joint arthroplasty in post-traumatic arthritis.

Anatomical and morphometric differences between the knee of the men and the women is well established. The height/width ratio of the distal femoral condyle, the quadriceps angle (Q Angle) and the shape of the distal femur are different among the genders. Women have a narrower "Medial to Lateral" dimension of the femoral condyle, for any given "Anterior to Posterior" dimension. Q Angle is significantly higher in the female population than in the male population. A gender-specific femoral component was introduced for better fit and range of motion, among the female population. It has a narrower medio-lateral dimension for a given antero-posterior dimension, to match the aspect ratio of female knees more aptly. It also has a recessed and a lateralised patellar sulcus, to accommodate for a larger Q Angle and reduced anterior condylar height.

This prospective study is to compare the clinico-functional outcomes of female patients who had undergone Primary Total Knee Arthroplasty (TKA) with two variants of the implants – "Standard Posterior Cruciate Retaining Flex Knee" and "Gender-Specific Posterior Cruciate Retaining High-Flex Knee" total knee prostheses.

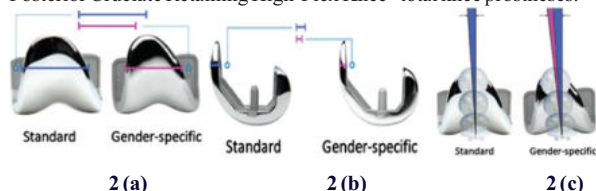


Fig. 2: Differences between "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" - (a) Increased Trochlear Groove, (b) Reduced Anterior Flange Thickness, (c) Recessing the patellar sulcus.



Fig. 3: Images of (a) the design features of a NexGen standard CR flex (left) and a NexGen gender-specific CR high-flex (right) knee prosthesis, (b) the lateral view of the standard CR flex (left) and the gender-specific CR-high flex (right) prostheses.

MATERIALS AND METHODS:

This prospective study was done at Trichy SRM Medical College Hospital and Research Centre, Irungalur, Trichy, Tamil Nadu, from March 2018 to February 2020 (24 months). Recruitment of patients stopped in February 2020, but the follow-up was done till February 2021, so that the minimum follow-up period, was for at least 12 months. Written consent was obtained from all patients to publish their clinical and radiological data, without infringing upon their privacy.

Inclusion Criteria:

Female patients between the age 51 to 80 years with Primary tri-compartmental osteoarthritis of the knee with grade-III to grade-V Ahlbäck criteria (9).

Exclusion Criteria:

1. Any old history of Musculo-skeletal sepsis, in the vicinity of the knee joint, to be operated upon.
2. Paralytic joints and in patients with neuro-muscular disorders.
3. Old treated trauma to ipsilateral femur or tibia.

Pre-operative and post-operative assessments were done with Knee Society Clinical Rating System (KSS) - Knee Clinical score, Functional score and radiological analysis, X rays of the affected knee AP and Lateral were done.

The functional outcome in these patients were evaluated and tabulated when they came for their 12th month follow-up in the OPD. The patients were given a study proforma to answer. The X rays of the surgical side were taken during each follow-up visit which were during 6 weeks, 3 months, 6 months and 12 months of the post-operative period.

Pre-operative and post-operative Hb, PCV and blood loss during and after surgery were recorded.

Intra-Op Protocol: The numbers of people inside the operation theatre were restricted to 7 and the duration of surgery was less than 2 hours in all the cases. Peri-operative antibiotic coverage was given with Ceftriaxone and Sulbactam. Combined epidural and subarachnoid anaesthesia were used in all the cases. The surgical technique for both the TKA groups were same. Anterior Knee Midline skin incision and Medial parapatellar approach used for all the surgeries. ACL, both menisci were removed, and PCL was preserved. Soft tissue release and excision of osteophytes were done according to the prevalent deformity. Femoral component was aligned using intra-medullary alignment system and extra-medullary system was used to position the tibial component. The femoral prosthesis was inserted in 3° of external rotation in relation to the posterior femoral condyles or perpendicular to Whiteside's line or parallel to the trans-epicondylar axis. Patellar osteophytes were addressed and excised. Thorough wash was given with pulse lavage. Components were cemented after drying, and pressurisation of cement.

Post-Op Protocol:

Ankle and toe exercises were given in the evening of the day of surgery. Mechanical prophylaxis against DVT began on the day of surgery. Passive Knee mobilization was started after drain removal on POD-1. This was improved by quadriceps exercises and active knee movements by the patient. Full weight bearing mobilisation with the help of a walker was started by POD-2.

Follow-up: Patients were followed up at POD-12 for suture removal and at the end of 6 weeks, 3 months, 6 months and 12 months. Post-operative results were tabulated and evaluated using Knee Society Clinical Rating System (KSS) (10) at the end of 12th month post-op.

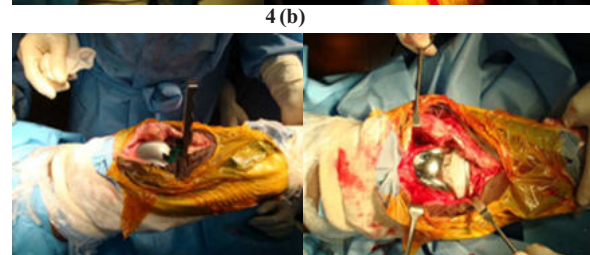
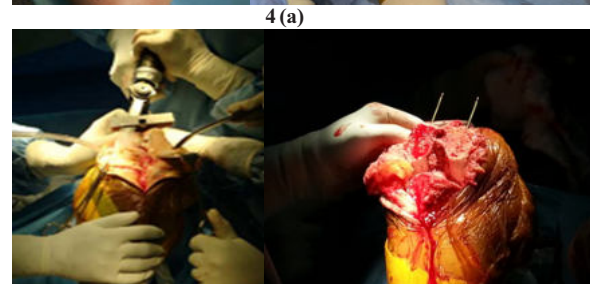
Outcome Assessment:

In this study the Knee Society Clinical Rating System (KSS) (10) is used to evaluate the clinical and functional assessment following a total knee arthroplasty. It has two components,

- A) Knee score (Clinical).
- B) Function score (Functional).

For both the knee score and function score a maximum of 100 points are given. The outcome is categorized as per score evaluated (11).

Outcome Grade	Score Evaluated
Excellent	80 to 100
Good	70 to 79
Fair	60 to 69
Poor	<60



4 (c)



4(d)

Fig. 4: Intra-op pictures - (a) Surgical incision marking, (b) Femoral preparation, (c) Implantation of components, (d) Extensor repair and Closure.

RESULTS:

In conformation to our inclusion criteria, in the 24 months of our recruitment period we could recruit 48 female patients with primary tri-compartmental osteoarthritis of the knee requiring "Total Knee Arthroplasty" (TKA). 23 female patients, among them underwent Standard Posterior Cruciate Retaining Flex Knee Total Knee Arthroplasty and the remaining 25 female patients underwent Gender-Specific Posterior Cruciate Retaining High-Flex Knee Total Knee Arthroplasty. The follow-up was for a minimum period of 12 months (range: 12-35 months, mean 16.5 months). The Knee Society Clinical Rating System (KSS) was adopted to evaluate the clinico-functional outcomes of the pre-operative cases and the post-operative cases, at the 12th month post-operative follow-up period.

With regard, to the age of the patients, 58% (n=28) fell in the age bracket of 61 to 70 years. The other two age groups were equally distributed at 21% (n=10) each.

Table 1: Demographic And Procedural Distribution:

Age group (in years)	Standard CR Flex TKA 'n'	Gender-specific CR High-Flex TKA 'n'	Total 'n' (% age)
51-60	6	4	10 (21%)
61-70	12	16	28 (58%)
71-80	5	5	10 (21%)
Total 'n' (% age)	23 (48%)	25 (52%)	48 (100%)

In all 48 female patients with regard, to the sidedness of the Total Knee Arthroplasty done knees, 60.42% (n=29) were right sided, while the remaining 39.58% (n=19) were of the left side.

Table 2: Sidedness of the Knee Operated Upon:

Surgically Intervened Knee Sidedness	Standard CR Flex TKA 'n'	Gender-specific CR High-Flex TKA 'n'	Total 'n' (% age)
Right	13	16	29 (60.42%)
Left	10	9	19 (39.58%)
Total 'n' (% age)	23 (48%)	25 (52%)	48 (100%)

With regard, to the predominant knee deformity prevailing at the time, prior to the Total Knee Arthroplasty surgical intervention, 89.58% (n=43) patients had a Genu-varum deformity and the remaining 10.42% (n=5) had a Genu-valgum deformity. Thus, as is expected, in primary osteoarthritis of the knee, Genu-varum is the predominant deformity.

Table 3: Pre-operative Predominant Knee Deformity In The Surgically Intervened Groups:

Type of Knee Deformity	Standard CR Flex TKA 'n'	Gender-specific CR Flex-TKA 'n'	Total 'n' (% age)
Genu-Varum Defomity	21	22	43(89.58%)
Genu-Valgum Deformity	2	3	5(10.42%)
Total 'n' (% age)	23(48%)	25(52%)	48(100%)

The various parameters, used for evaluation of Knee Society Clinical Rating System (KSS) - mean Knee score for Standard CR flex and Gender-specific CR high flex Total Knee arthroplasty pre-op and post-op, has been summarised in Table-4. The positive gain in points post-operatively at the 12th month follow-up was by 50.5 points for the Standard CR flex TKA. The same evaluation for the Gender-specific

CR high flex TKA yielded a marginally better positive gain score of 54 points.

Table 4: Knee Society Clinical Rating System (KSS) - Knee Score:

Parameter	Standard CR Flex TKA Mean Points		Gender-specific CR High-Flex TKA Mean Points	
	Pre-op	Post-op 12 th Month	Pre-op	Post-op 12 th Month
Pain	15	42.5	15	45
Range of Movements	12	20	13	22
Anteroposterior Stability	5	10	5	10
Mediolateral Stability	15	15	15	15
Deductions	10	0	10	0
Mean Knee Score	37	87.5	38	92

With regard, to the assessment of the functional score by the Knee Society Clinical Rating System (KSS), at the 12th month post-op evaluation the data as summarised in Table-5, yielded similar results with a gain of 47.5 points in both the groups.

Table 5: Knee Society Clinical Rating System (KSS) - Function Score:

Parameter	Standard CR Flex TKA Mean Points		Gender-specific CR High-Flex TKA Mean Points	
	Pre-op	Post-op 12 th Month	Pre-op	Post-op 12 th Month
Walking	30	45	30	45
Stairs	22.5	40	22.5	40
Deductions	15	0	15	0
Mean Function Score	37.5	85	37.5	85

In both the groups, the mean pre-operative Haemoglobin (Hb) was at 11.2gm% (range: 10.2 to 12.4). The mean post-operative Haemoglobin was at 9.3gm% (range: 7.3-10.1). 20.83 % (n=10) patients required blood transfusion.

In Standard CR flex Total Knee arthroplasty, we had 21.74% (n=5) patients with anterior knee pain and in the Gender-specific CR high flex Total Knee arthroplasty we had 16% (n=4) patients with anterior knee pain. No patients in either of the group had infection, peri-prosthetic fracture, deep venous thrombosis or patellar instability.

In the 12th month follow-up, the KSS clinical outcome Knee score was excellent in 78.26% (n=18), good in 21.74% (n=5) in the Standard CR flex Total Knee arthroplasty. In the Gender-specific CR high flex Total Knee arthroplasty 80% (n=20) had excellent and 20% (n=5) had good outcomes.

Table 6: Knee Society Clinical Rating System (KSS) - Clinical Outcome:

Grade and Points	Standard CR Flex TKA 'n' (% age)	Gender-specific CR High-Flex TKA 'n' (% age)
Excellent (80-100)	18 (78.26%)	20 (80.00%)
Good (70-79)	05 (21.74%)	05 (20.00%)
Fair (60-69)	00	00
Poor (<60)	00	00
Total	23	25

Similarly, in KSS functional outcome score was excellent in 86.95% (n=20), good in 13.05% (n=3) in the Standard CR flex Total Knee arthroplasty. In the Gender-specific CR High-flex Total Knee arthroplasty 92% (n=23) had excellent and 8% (n=2) had good outcomes.

Table 7: Knee Society Clinical Rating System (KSS) - Functional Outcome:

Grade and Points	Standard CR Flex TKA 'n' (% age)	Gender-specific CR High-Flex TKA 'n' (% age)
Excellent (80-100)	20 (86.95%)	23(92.00%)
Good (70-79)	03 (13.05%)	02 (08.00%)
Fair (60-69)	00	00

Poor (<60)	00	00
Total	23	25

CASE ILLUSTRATION (1):**5 (a)****5 (b)**

Fig. 5: Standard Posterior Cruciate Retaining Flex Knee Total Knee Arthroplasty - (a) Pre-operative clinical picture and X-ray showing Grade III Ahlbäck (9) Osteoarthritis (b) 12th Month post-operative follow-up clinical picture and X-ray.

CASE ILLUSTRATION (2):**6 (a)****6 (b)**

Fig. 6: Gender-Specific Posterior Cruciate Retaining High-Flexion Knee Total Knee Arthroplasty - (a) Pre-operative clinical picture and X-ray showing Grade IV Ahlbäck (9) Osteoarthritis (b) 12th Month post-operative follow-up clinical picture and X-ray.

DISCUSSION:

This prospective study was intended to compare the improvement in the clinico-functional outcome of "Standard Posterior Cruciate Retaining Flex Knee" and "Gender-Specific Posterior Cruciate Retaining High-Flex Knee" in the osteoarthritic females of age group 51 to 80 years with primary tri-compartmental osteoarthritis knee, based upon Knee Society Clinical Rating System (KSS) (10).

The functional outcome in these patients were assessed, when they came for the 12th month follow-up to the OPD. Clinical and functional outcome were calculated and tabulated according to the score based upon Knee Society Clinical Rating System (KSS) (10).

1. Comparing Age Distribution:

In our study 28 patients were of age group 61-70 years, mean age being 65.5 years and in the range 52-76 years.

Singh et al; (12) compared 100 Indian female patients in whom NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis were implanted and the mean age was 66 years (range 60-80 years).

Elsayed et al; (13) compared between Standard and Gender-Specific Knee Designs in Total Knee Arthroplasty in 34 Female Patients with the mean age 63 years old (range from 50 to 72 years).

Y.H Kim et al; (14) studied 138 female patients with a mean age of 71.2 years (51 to 82) in whom NexGen CR-flex prosthesis in one knee and a gender-specific NexGen were implanted.

Nutton et al; (15) performed a study in whom mean age was 69 (52-87) and patients received either a standard or a high flexion version of the NexGen legacy posterior stabilised total knee replacement.

Table 8: Comparing Age Distribution:

Study Group	Mean age (in years)
Vijayaselvan et al;	65.5
Singh et al; (12)	66
Elsayed et al; (13)	63
Y.H Kim et al; (14)	71.2
Nutton et al; (15)	69

Our age distribution, closely matched with that of Singh et al; (12) and Elsayed et al; (13).

2. Comparing Pre-operative And Post-operative KSS Knee Score (Clinical):

In our study the mean pre-operative KSS Knee Clinical score was 37 (32-40) and 38 (33-41) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively. Post-operatively, at the 12th month follow-up the mean score was 87.5 (72-92.5) and 92 (72-95) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively.

In Singh et al; (12) study the mean pre-operative KSS Knee Clinical score was 36.3 (± 13.4) and 34.2 (± 11.5) for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 24th month follow-up the mean score was 95.8 (± 3.6) and 94.9 (± 4.7) for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively.

In Elsayed et al; (13) study the mean pre-operative KSS Knee Clinical score was 25 and 27 for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 12th month follow-up the mean score was 84 and 83 for standard and gender-specific respectively.

In Y.H Kim et al; (14) study the mean pre-operative KSS Knee Clinical score was 35.3 (0 to 50) and 39.8 (10 to 70) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively. Post-operatively, at the 3 years follow-up the mean score was 94 (70 to 100) and 93 (70 to 100) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively.

Table 9: Comparing Pre-Operative and Post-Operative KSS Knee Score (Clinical):

STUDY GROUP	MODALITY	PRE-OPERATIVE MEAN KSS KNEE SCORE	POST-OPERATIVE MEAN KSS KNEE SCORE
Vijayaselvan et al;	NexGen STD CR Flex	37	87.5
	NexGen Gender-specific CR High-Flex	38	92

Singh et al; (12)	NexGen STD LPS Flex	36.3	95.8
	NexGen High LPS Flex	34.2	94.9
Elsayed et al; (13)	STD Flex	25	84
	High flex	27	83
Y.H Kim et al; (14)	NexGen STD CR Flex	35.3	94
	NexGen Gender-specific CR Flex	39.8	93

3. Comparing Pre-operative And Post-operative KSS Function Score (functional):

In our study the mean pre-operative KSS Function score was 37.5 (25-50) and 37.5 (20-45) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively. Post-operatively, at the 12th month follow-up the mean score was 85 (70-90) and 85 (70-90) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively.

In Singh et al; (12) study the mean pre-operative KSS Function score was 38.7(±10.2) and 37.6(±14.0) for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 24th month follow-up was the mean score was 79.9(±13.0) and 80.2(±10.6) for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively.

In Elsayed et al; (13) study the mean pre-operative KSS Function score was 26 and 28 for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 12th month follow-up was the mean score was 82 and 83 for standard and gender-specific respectively.

In Y.H Kim et al; (14) study the mean pre-operative KSS Function score was 44.2 (20 to 70) and 44.2 (20 to 70) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively. Post-operatively, at the 3 years follow-up was the mean score was 83 (60 to 100) and 84 (60 to 100) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively.

Table 10: Comparing Pre-operative And Post-operative KSS Function Score (Functional):

STUDY GROUP	MODALITY	PRE-OPERATIVE MEAN KSS FUNCTION SCORE	POST-OPERATIVE MEAN KSS FUNCTION SCORE
Vijayaselvan et al;	NexGen STD CR Flex	37.5	85
	NexGen Gender-specific CR High-Flex	37.5	85
Singh et al; (12)	NexGen STD LPS Flex	38.7	79.9
	NexGen High LPS Flex	37.6	80.2
Elsayed et al; (13)	STD Flex	26	82
	High flex	28	83
Y.H Kim et al; (14)	NexGen STD CR Flex	44.2	83
	NexGen Gender-specific CR Flex	44.2	84

4. Comparing of Range of Movement (ROM):

In our study the mean pre-operative ROM was 104(55-120) and 103 (55-120) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively. Post-operatively, at the 12th month follow-up the mean ROM was 113 (90-130) and 117 (90-135) for "Standard CR Flex Knee" and "Gender-Specific CR High-Flex Knee" group respectively.

In Singh et al; (12) study the mean pre-operative ROM was 110.5° (±13.7°) 111.7° (±13.5°) for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 24th month follow-up the mean ROM was 119.9°(±8.7°) and 122.8°(±8.0°) for standard and gender specific respectively.

In Elsayed et al; (13) study the average pre-operative ROM was 108° and 110° for NexGen LPS prosthesis and the gender-specific NexGen LPS High-Flex prosthesis respectively. Post-operatively, at 12th month follow-up the mean ROM was 113° and 115° for standard and gender-specific respectively.

In Y.H Kim et al; (14) study the average pre-operative ROM was 123° (80 to 150) and 127° (100 to 150) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively. Post-operatively, at the 3 years follow-up the mean ROM was 126° (85 to 140) and 124° (85 to 140) for NexGen CR-flex prosthesis and a gender-specific NexGen prosthesis respectively.

Table 11: Comparing of Range of Movement (ROM):

STUDY GROUP	MODALITY	PRE-OPERATIVE MEAN ROM	POST-OPERATIVE MEAN ROM
Vijayaselvan et al;	NexGen STD CR Flex	104	113
	NexGen Gender-specific CR Flex	103	117
Singh et al; (12)	NexGen STD LPS Flex	110.5	119.9
	NexGen High LPS Flex	111.7	122.8
Elsayed et al; (13)	STD Flex	108	113
	Hiflex	110	115
Y.H Kim et al; (14)	NexGen STD CR Flex	123	126
	NexGen Gender-specific CR Flex	127	124

Thus, from our study as per the results elucidated above, there was no significant differences between the "Standard Posterior Cruciate Retaining Flex Knee" and "Gender-Specific Posterior Cruciate Retaining High-Flex Knee" TKA, with regard to the clinical and the functional outcomes. Since the 'p' value is greater than 0.05 in both, there was no significant differences, that could be accounted for either in favour or otherwise.

Total Knee Arthroplasty is a major surgery with significant amount of blood loss. Pagnano et al; showed a mean pre-op Hb of 12.9g% (10.4-15.1g%) and the post-op Hb of 9.6g% (7.7- 12.2g%). In our study mean pre-operative Hemoglobin (Hb) was at 11.2gm% (range: 10.2 to 12.4). The mean post-operative Hemoglobin was at 9.3gm% (range: 7.3-10.1). 20.83 % (n=10) patients required blood transfusion. There was no significant difference in the blood loss between "Standard Posterior Cruciate Retaining Flex Knee" and "Gender-Specific Posterior Cruciate Retaining High-Flex Knee" in our study.

Anterior knee pain was the most common post-operative complication seen in our study. In Standard CR flex Total Knee arthroplasty, we had 21.74% (n=5) patients with anterior knee pain and in the Gender-specific CR High-Flex Total Knee arthroplasty we had 16% (n=4) patients with anterior knee pain. No patients, in either of the group had infection, peri-prosthetic fracture, deep venous thrombosis or patellar instability.

The limitation of our study was the short duration of follow up. Long term studies are needed to infer the superiority of one prosthesis over the other.

Hitt K et al; (16) in 2003 by their anthropometric measurements of the human knee, have reiterated what Ranawat CS et al; and others have said about anatomical differences in women's and men's knee. "Gender-specific High - Flex Knee Replacement Implants"

compensate for the most important differences between the men and women knee. According to Chin KR et al; (17) orthopaedic surgeons needed to do considerable intra-operative adjustments while doing a TKA in order to accommodate the women's knee anatomical differences. In accordance with the US Department of Health and Human Services, 75 % of the knee replacements are being done for women. High flexion prosthesis for arthroplasty of the knee, was introduced with the objective of achieving improved knee flexion and enhanced survivorship in subjects who have a significantly higher demand functionally or best to suit common Asian needs which requires kneeling, squatting and sitting cross legged. The TKA demand, according to Kurtz et al; (18) in patients aged less than 65 years, have being projected to in excess of 50%, year after year. Younger patients have higher demands of function, which sometimes the conventional TKA may fail to achieve. Park KK et al; (19) highlighted the enhanced functional flexion needs of the knee by the Asian population. Conventional TKA, according to Schurman DJ et al; (20) and Ritter MA et al; (21) does not exceed the flexion limits beyond 110°-120°. According to Dennis DA et al; (22) and Sultan PG et al; (23) Flexion of TKA outcomes depends on Prosthetic design, Body Mass Index, the Gender, the Causative of knee arthritis, the Extensor mechanism efficacy, Intra-op Implant positioning, achievement of ligamentous balance and the condition of the femoro-patellar joint. The so-called high flexion TKA knee implants are designed so that there is a higher contact zone and a lower contact stress, whilst maintaining, throughout the range of movement, a factor of stability. These high flexion designs have a smaller radius of curvature of the femoral component and a thick condylar posterior component. It also has a modified post and cam mechanism, with an enhanced distance of jump in order to achieve a decrease in stress at the zone of contact and prevent dislocations, at a higher angles of knee flexion, according to Li G et al; (24). According to Sanjeev Jain et al; (25) for the success of a high knee flexion, the patient should be non-obese, with pre-op knee flexion of minimum 100°, a calf to thigh index of less than 90 degrees and above all the collateral ligaments should be intact. Further, there should not be a deformity beyond 20° in any plane. Sanjeev Jain et al; (25) have also raised a concern about the quantum of bone resected, in Indians with a small stature, which the high flexion knee arthroplasty requires. Similarly, Mehini et al; Kim et al; Mc Calden et al; Nutton et al; Wohlrab et al; Sumino et al; and Bollars et al; have all reported against the use high flexion knee prosthesis. Those who favoured the high knee flexion prosthesis included, Nam et al; Argenson et al; Lee et al; Hepinstall et al; Huang et al; Sancheti et al; (26) Maniar et al; (27) Endress et al; and Weedon et al;

CONCLUSION:

With the foregoing discussion, we humbly submit and conclude that Total Knee Arthroplasty (TKA) clinico-functional results are not just depended exclusively on the implant design. Our result analysis failed to prove beyond reasonable doubt, that for female TKA, that "Gender-Specific Posterior Cruciate Retaining High-Flex Knee" has a better clinico-functional outcome, when compared to "Standard Posterior Cruciate Retaining Flex Knee" implantation. Larger studies and longer follow-up studies would be necessary to substantiate this debate.

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