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## Clinical outcome of 100 total knee replacements using Persona posterior stabilized knee implant- A prospective observational study

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### Abstract

**Background:** Total knee arthroplasty is a well accepted treatment for managing end-stage symptomatic osteoarthritis of knee. Many designs of prostheses have evolved over a period of time with almost similar clinical outcomes. The aim of this study was to evaluate the functional outcome of total knee arthroplasty using persona posteriorly stabilized knee implant (Zimmer, Warsaw, Indiana) and to investigate the effect of pre operative range of motion of involved knee on final range of motion and to observe the trends in the post op range of motion of the knee after total knee Arthroplasty.

**Methods:** This was a prospective, observational study involving 100 total knee replacements in 60 patients using Persona Posterior Stabilised Knee Implant system. All patients were assessed clinically and radiologically with respect to the improvement of function and range of motion of knee joint, grading of pain, daily routine activity modification and generalized wellbeing after surgery and Knee society score was calculated.

**Results:** During the study period, 3 patients died on follow up (due to multiple comorbidities) and one patient underwent revision surgery for late infection, all of them had unilateral knee replacement. Knee Society Score, and knee range of motion of 96 knees in 56 patients was assessed preoperatively and postoperatively at 3 months, 6 months, 1 year, 2 years and 3 years. There was a significant improvement in mean KSS, FS and Pain score post operatively upto 1 yr with no significant improvement thereafter. Range of motion reduced significantly 3 months post op with a significant improvement thereafter at 6 months and 1 year. Furthermore patients with less pre op ROM gained significantly more ROM than the patients with better pre op ROM.

**Conclusion:** Persona posteriorly stabilized knee show good functional outcome at 3 years follow up period and post operative range of motion of the knee, functional score and knee society score show improving trend with significant improvement upto 1 yr.

**Keywords:** Total knee Arthroplasty, Replacement surgery, Persona knee, Knee joint replacement, Osteoarthritis knee.

### 1. Introduction

Total Knee Arthroplasty <sup>[1, 2]</sup> is an established treatment of patients with advanced osteoarthritis of the knee joint when medical management has failed. Total knee replacement confers significant intermediate and long-term benefits with respect to both disease-specific and generic health-related quality of life, especially pain and function, leading to positive patient satisfaction <sup>[3]</sup>. Various factors that may influence the range of motion of the knee after a total knee arthroplasty have been postulated. Posterior Femoral translation has been referred to as a major factor affecting knee flexion <sup>[4-12]</sup>. Other factors known to affect knee flexion are pre-operative range of movement, status of soft tissues, knee joint stability, involvement of the ankle, hip and feet, status of the spine, as well as issues influencing the patients general health, sense of well being and expectations and last but not the least – the Implant design.

Standard designs have achieved very good results over a period of time achieving knee range of motion upto 120 degrees <sup>[13]</sup>. As we attained better knee flexion with Hiflex designs and better surgical techniques, we started aiming at the implant which matches the patient's anatomy better than existing ones. The idea behind such concept is to attain better patient

satisfaction following the surgery.

Nowadays various different designs of prosthesis available for TKA include the cruciate retaining (CR) knee design where the posterior cruciate ligament (PCL) is retained, the cruciate sacrificing knee design where the PCL is sacrificed and the posterior stabilizing (PS) knee design where the PCL is substituted [14, 15, 16]. Personalized implants feature 21 left and 21 right unique femoral shapes and further offers standard and narrow shapes to better accommodate the varying anomalies of global population. Unique anatomic tibial component enables more accurate rotational placement and maximizes proximal tibial coverage thereby minimizing risk of overhang. Vivacit –E polyethylene is believed to be stronger than conventional highly cross linked polyethylene. 2 mm increments in femoral size and 1 mm articular surface increments offer an ability to fine tune each patients soft tissue.

Current study is aimed to evaluate the functional outcome of total knee arthroplasty using Persona posteriorly stabilized knee implant (Zimmer, Warsaw, Indiana) and to investigate the effect of pre operative range of motion of involved knee on final range of motion and to observe the trends in the post op range of motion of the knee and the overall functional outcome after total knee Arthroplasty.

### Material and Methods

This was a prospective, observational study of 60 subjects with 100 consecutive Knees who underwent either unilateral or bilateral Total knee replacement using the Persona Posterior Stabilised Knee Implant system (Zimmer, Warsaw, Indiana). Patients with Post Septic Arthritis, Valgus knee, Complex Primary TKR, Revision TKR, uncontrolled diabetes, and patients with neurological deficit in ipsilateral lower limb were excluded from the study.

All patients who presented to our O.P.D. with knee pain were evaluated clinically and radiologically in the form of X rays of knees, Anteroposterior, lateral view and hip knee and ankle view. The demographic data, physical data and knee society score were noted at the time of admission. The patients have either undergone a single sitting bilateral or unilateral total knee arthroplasty. A pneumatic tourniquet was utilized, and medial parapatellar arthrotomy approach was used. In all subjects, femoral preparation was performed first, followed by tibial preparation. All implants were cemented with use of pulse lavage, drying and pressurization of the cement. Patella were not resurfaced in any patient. Drains were used in all patients and were removed after 24 hrs.

Post operatively patients were given intravenous antibiotics for 3 days. Post-operative pain was managed by intravenous Paracetamol, opioids (oral and intravenous) and as epidural top-ups. The patients started ambulation from 1st post-operative day. They stayed in the hospital for an average period of 5-6 days and continued physiotherapy at home. There may be subtle variations in post operative regimen based on patient's tolerance. All patients received identical surgical protocol and post-operative care.

Postoperatively all patients were followed in our OPD after discharge at 2 weeks for suture removal, 6 weeks, 6 months, 1st, 2nd and 3rd year.

Patients were assessed clinically with respect to the

improvement of function and range of motion of knee joints, grading of pain, daily routine activity modification and generalized wellbeing after surgery. KSS was calculated at all follow up visits and radiological assessment was done.

The data was analyzed using repeated analysis of variance. Duncan's multiple range test was used for post hoc comparison, p value < 0.05 was considered to be statistically significant.

### Observations and Results

60 patients with 100 knees (with primary osteoarthritis of knee) who underwent Total Knee Replacement with the Persona Posterior Stabilised Knee Implant system (Zimmer, Warsaw, Indiana) and fulfilled the inclusion criteria and were available for the follow up were included in the study. 20 patients underwent Unilateral Total Knee Replacement and 40 patients underwent Bilateral Total Knee Replacement. 3 patients died on follow up due to medical comorbidities and one patient underwent revision for late infection, all the 4 had undergone unilateral knee Arthroplasty and were not included in the final results.

The mean age of the patients was 62.6±8.73 years. There were 14 males (4 Unilateral and 10 Bilateral TKR) and 46 female patients (16 Unilateral and 30 Bilateral TKR). 41 patients (68.33%) were obese with 3 patients having morbid obesity (Table 1).

**Table 1:** Showing number of patients in each category as per BMI.

BMI	No. of patients	Percentage
<18.5 (Underweight)	00	-
18.5 to 24.9 (Normal)	04	6.66
25 to 29.9 (Overweight)	15	25
30-34.99(Grade I Obese)	25	41.66
35-39.99(Grade II Obese )	13	21.66
≥40 ( Morbid Obese)	03	05
Total	60	100

**BMI:** Body mass index.

Table showing number of patients in each category as per BMI.

Medical comorbidities seen in our study group were Hypertension, Diabetes Mellitus, Coronary Artery Disease, Hypothyroidism and Asthma (Table 2).

**Table 2:** Distribution of co morbidities amongst the sample.

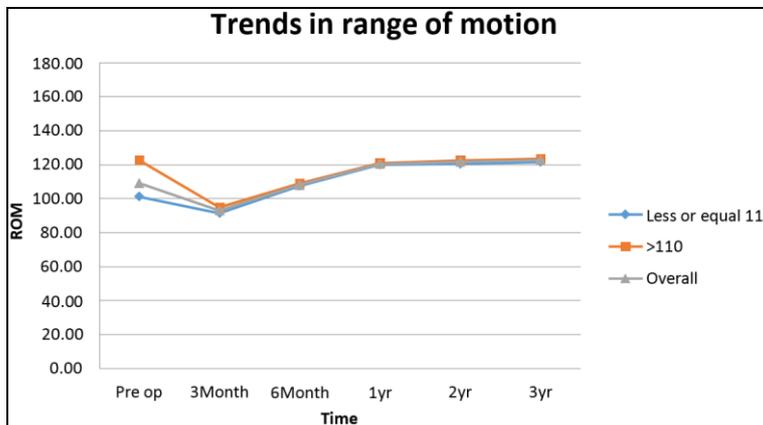
Number of comorbidities	Unilateral TKR	Bilateral TKR	Total
0	5	11	16
1	4	16	20
2	7	9	16
3	5	2	7
4	0	1	1

After initial significant fall in range of motion at 3 months, increasing range of motion was seen during subsequent follow-ups. Mean pre op range of motion of 108.958<sup>0</sup>± 14.252 improved to 107.843<sup>0</sup>±7.137 at 6 months and 120.260 ±5.588 at the end of 1st year to 121.48 ± 6.164 and 122.44±5.191 at the end of 2<sup>nd</sup> and 3<sup>rd</sup> yr respectively (Table 3).

**Table 3:** Showing trends in ROM with statistical relation

		Pre op	3 Month	6 Month	Ist Year	2 <sup>nd</sup> Year	3 <sup>rd</sup> Year
ROM ≤ 110, n=61	Mean	100.984 <sup>b</sup>	91.393 <sup>a</sup>	107.262 <sup>c</sup>	119.934 <sup>d</sup>	120.37 <sup>d</sup>	121.41 <sup>d</sup>
	Std. Deviation	11.504	5.333	6.681	5.099	5.261	5.104
ROM > 110, n=35	Mean	122.857 <sup>c</sup>	94.857 <sup>a</sup>	108.857 <sup>b</sup>	120.829 <sup>c</sup>	122.58 <sup>c</sup>	123.47 <sup>c</sup>
	Std.Deviation	4.583	8.444	7.867	6.392	6.065	6.114
Overall ROM n = 96	Mean	108.958 <sup>b</sup>	92.656 <sup>a</sup>	107.843 <sup>b</sup>	120.260 <sup>c</sup>	121.48 <sup>cd</sup>	122.44 <sup>d</sup>
	Std. Deviation	14.252	6.804	7.137	5.588	6.164	5.191

Values with different superscripts are statistically significant ( $p < 0.05$ )



**Fig 1:** Graphical representation of trends in the ROM.

Whole study sample was divided into 2 groups considering 110<sup>0</sup> as a central (median) of the group (Table 3). Patients with lower pre op range of motion gained higher on final range of motion. Patients in higher pre op range of motion group had no significant improvement in final mean Rom compared to pre op ROM.

Pain score component of Knee Society Score was used to assess pain status of the patients. Range of pain score is 0 to 50. Pain score of 0 indicates maximum pain and 50 indicated no pain. Increasing score indicated Improvement in pain symptoms.

**Table 4:** Showing changes in Pain score, KSS and Funct score with time.

	Pre op	3 Month	6 Month	Ist Year	2nd year	3
Pain Score	22.760 <sup>a</sup> (±9.784)	27.448 <sup>b</sup> (±8.335)	39.271 <sup>c</sup> (±6.688)	45.313 <sup>d</sup> (±4.280)	46.363 <sup>d</sup> (±4.872)	46.95
KSS	59.510 <sup>a</sup> (±16.070)	74.583 <sup>b</sup> (±13.682)	84.177 <sup>c</sup> (±9.905)	91.125 <sup>d</sup> (±6.619)	92.170 <sup>d</sup> (±5.903)	93.04
Funct.Score	62.802a(±18.176)	70.219b(±14.622)	81.208c(±10.515)	90.594d(±6.865)	92.310d(±6.040)	93.20

Values with different superscripts are statistically significant ( $p < 0.05$ )

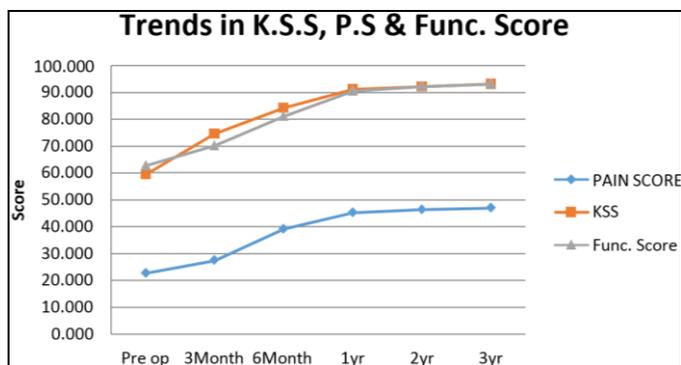
KSS, Knee society score; Funct score, Functional score; Pre op, Pre operative.

Pain score of patients was noted at pre-op visit as well as every follow up. Mean pain score improved significantly at each follow up till the end of Ist yr with no significant improvement thereafter.

significantly at each follow up till the end of Ist yr after which there was no significant improvement.

Functional score of every subject was noted at pre-op visit as well as every follow up visit. Average gain as compared to pre op functional score was assessed (Table 4).

Mean duration of surgery was 40.83±5.26 min. Mean duration of hospital stay was 6.13±0.81 days.



**Fig 2:** Representation of changes in K.S.S, P.S, and Func. score from pre op to end of 3<sup>rd</sup> year.

Preoperative Knee Society Score was compared with Knee Society Score at 3 months, 6 months and 1 year, 2 years and 3 years. The average gain as compared to pre op KSS was assessed. Mean pre op KSS of 59.510<sup>a</sup> (±16.070) improved

**Table 5:** Post op complications.

Complication	
Stiffness	4
Ant. knee pain	4
Delayed wound healing	5
Infection	1
DVT	0

Postoperative knee stiffness was seen in 4 knees. Preoperative range of motion in these patients was 30-90<sup>0</sup>, 0-80<sup>0</sup>, 0-90<sup>0</sup> and 0-130<sup>0</sup>. They underwent manipulation under anesthesia 3 months after surgery. This was followed by an intensive physiotherapy programme. Anterior Knee Pain was present in 4 patients until 3 months after surgery.

These symptoms were completely relieved at 6 months follow up.

5 patients developed delayed wound healing with slight sloughing of margins. All of them had Diabetes Mellitus with 1 or 2 other co-morbidities. They were treated with intermittent dressing under aseptic conditions. All wounds healed by 3 weeks after surgery. One patient in our study group developed infection 1 yr after surgery which required revision (Table 5).

## Discussion

Ever since Total Knee Replacement became popular in 1990's, there have been efforts to improve range of motion and survivorship of the implants. This has been made possible by improvement in implant design and surgical techniques. The improvement in implant design has been an evolving process.

Persona posterior stabilised knee implant is the latest in this evolution, The major difference being asymmetric tibia to match the asymmetric native tibia. The asymmetric tibial tray of the Persona knee has the best coverage without underhang or overhang. There have been other design modifications to match the anatomy in both male and female patients. It is difficult to ascertain in the short term whether this design changes will translate into better results in the long term.

Along with debate and discussion on the effect of gender-specific total knee arthroplasty, race specific or size specific implants are in discussion. Mismatch due to different sizes of knee and corresponding implant led to inferior results [17].

As majority of knee replacement implants are designed as per the sizes of caucasian knee, other races (chinese, korean, indian etc) experience major chances of implant mismatch and inferior results [17, 18, 19, 20].

The risk of component oversizing is increased if related aspect ratios are not taken into consideration. The smaller distal femur diameter of Chinese [48], Japanese [49], Korean [50] and Indian [51] populations compared with their Caucasian counterparts also creates a significant disparity amongst related parameters. Studies show that Chinese [18], Korean [19] and Iranian [20] patients tend to have a more asymmetrical tibial plateau, so that the central point (Cp) runs medial to the central shaft line (Cs). This requires that the tibial entry point be adjusted, because otherwise the tibial component is likely to be inserted in varus which can cause the tibial medial cortex to fracture.

Iorio R *et al.* in their study stated that most of the currently available knee prosthetics are generally designed for the Caucasian knee. In studies being undertaken to assess the impact of this historic, one size fits all approach it appears that the success of TKR in Asia has been compromised by what is, effectively, a component mismatch. Japanese patients, for example, have significantly less postoperative ROM than white patients. At least 4.1% have required revision within 7 years, whilst only 2.6% of American patients required similar work within 9 years [17].

The mean age of patients in our study was  $62.6 \pm 8.73$  years (range 45 to 79 years) which is lower than Gary Hooper *et al.* [21] study and Iliana N Ackerman *et al.* [22] study. Probably Indian patients undergo total knee replacement at much younger age.

93.33% patients were overweight to obese. They achieved excellent final outcome as measured by KSS. Paul Baker *et al.* [23] and Andy Judge *et al.* [24] had the similar results. There was no preference towards unilateral TKR in patients with obese subjects (BMI>30). Benjamin James *et al.* [25] showed that higher BMI is not a contraindication for bilateral Total Knee Replacement. Madsen AA *et al.* [26] recommended the

same. Vandana Ayyar *et al.* [27] stated that there is similar benefit from replacement surgery irrespective of BMI.

Range of motion of every subject was noted at pre-op visit as well as every follow visit so that average gain compared to pre op range of motion could be assessed. Pre op range of motion was found to be  $108.958 \pm 14.252$  Range of motion at 3 months was  $92.656 \pm 6.804$  which was significantly lower than pre-op range, Range of motion at 6 months was almost equal to pre op range of motion ( $107.26 + 7.137$ ) and was significantly higher than range of motion at 3 months. Range of motion at 1 year was  $119.93 + 5.588$  which was significantly higher than pre-op range and range of motion at 6 months. At 2nd and 3rd year follow up mean range of motion did not improve significantly and finally reached  $122.44 \pm 5.191$ . Final mean range of motion was comparable to other posterior stabilized TKR designs as shown by Wilco C H Jacobs *et al.* [28] (mean  $113^0$ ), Frank R. Kolisek *et al.* [29] (Mean  $118^0$ ) and by K. H. Sancheti *et al.* [30] ( $128 \pm 8.32$ ).

Taking whole group into consideration, there seems to be fall in range of motion at 3 months. This fall can be attributed to post op pain. Micheal J Bade *et al.* [31] in 2010 showed the same in his study. This fall in range of motion at 3 months may be due to some subjects having lower pre op range in the group. To eliminate this bias, the whole sample was divided into two groups. One with pre op range of motion less than the median (i.e.  $110^0$ ) and one with more than that.

In range of motion  $\leq 110^0$  group, mean pre op ROM was  $100.98 \pm 11.504$  and in  $>110^0$  mean pre op range of motion was  $122.857 \pm 4.583$ . At the end of 3 months, mean ROM was  $91.393 \pm 5.333$  in  $\leq 110^0$  group and  $94.857 \pm 8.444$  in  $>110^0$  degree group, which is significantly lower than corresponding pre op range of motion respectively.

At the end of 6 months mean ROM was  $107.262 \pm 6.681$  in  $\leq 110^0$  group and  $108.857 \pm 7.867$  in  $>110^0$  degree group which is not significantly different in both groups ( $p > 0.05$ ). At the end of 1 year mean range of motion was  $119.91 \pm 5.07$  in  $<110^0$  group and  $122.24 \pm 8.24$  in  $>110^0$  degree group which is not significantly different in both groups ( $p > 0.05$ ). According to Micheal J Bade *et al.* [31] it took 6 months to achieve pre op range of motion. We observed that in the patients with  $\leq 110^0$  degree pre op range of motion there is a significant gain in mean rom at each follow up till the end of first year after which there is no significant gain. Whereas in the group with pre op ROM greater than  $110^0$  degrees there is no final significant gain in ROM compared to pre op Rom.

This indicated patients with lower pre op range of motion gained more range of motion as compared to patients with higher range of motion. These finding were consistent with those of McCalden *et al.* [32], who reported that patients with lesser preoperative range of motion had higher average gain in ROM as compared to pre op range of motion  $>120^0$ , who actually lost 1-20 of mean range of motion. Similar results were given by Lucio Honorio de Carvalho Junior *et al.* [33].

It can be concluded that final range of motion in patients having lower pre op range is comparable to the patients with higher pre op range of motion.

4 knees in 3 patients (2 unilateral and 1 bilateral) out of 100 knees experienced post operative stiffness. All of these patients underwent manipulation at 3 months and achieved good range of motion at 6 months. This is proportionate with Lucio Honorio de Carvalho Junior *et al.* [33] who had 4 unilateral patients of stiffness out of 80 arthroplasties who underwent manipulation at 2.1 months to achieve functional range of motion.

Range of motion achieved in present study is consistent with

studies conducted using other TKR designs with asymmetrical tibia. Young Joon Choi *et al.* [34] reported flexion of  $116.3 \pm 27.8^\circ$  with Genesis II asymmetrical tibia TKR design. Zeh A *et al.* [35] reported flexion of  $122 \pm 8.9^\circ$  at 16 months follow up with Genesis II asymmetrical tibia TKR design.

The preoperative pain score was  $22.760^a (\pm 9.784)$  which improved to  $46.951^d (\pm 5.477)$  at the end of 3<sup>rd</sup> yr. There was no significant improvement in pain score after 1st yr. There was gradual improvement in pain symptoms of patients till 1 year of follow up. 4 patients experienced anterior knee pain until 3 months after surgery. These symptoms resolved at 6 months follow up without any intervention. Literature reports similar incidence of anterior knee pain to be 5- 10% [7], 8% [8] and 20.2 % [9]. Majority of these patients settled with conservative measures [8]. K. H. Sancheti *et al.* [30] showed that they had 7 patients of anterior knee pain out of 160 TKRs (4 unresurfaced and 3 resurfaced). None of them needed intervention.

The mean Knee Society Score improved significantly from  $59.510^a (\pm 16.070)$  to  $74.583 (\pm 13.682)$  at 3 months, to  $84.177 (\pm 9.905)$  at 6 months and  $91.125 (\pm 6.619)$  at 1 year. There was no significant improvement in KSS thereafter (Table). Final KSS in the study was comparable to those reported in literature. H. Farahini *et al.* [36] showed in their study that pre operative KSS improved from  $45.2 \pm 12.10$  to  $93.7 \pm 2.8$ . K. H. Sancheti *et al.* [30] reported improvement KSS from  $40.1 \pm 10.7$  to  $90.3 \pm 5.34$ . Young Joon Choi *et al.* [34] reported final KSS of  $92.3 \pm 7$  using Genesis II asymmetrical tibia TKR design.

The mean postoperative functional score improved from  $62.802 (\pm 18.176)$  to  $70.219 (\pm 14.622)$  at 3 months, to  $81.208 (\pm 10.515)$  at 6 months and to  $90.594 (\pm 6.865)$  at 1 year. The final score at 3 yrs was  $93.203 (\pm 5.880)$  with no significant improvement after 1 yr.

The final functional score at the end of 1 year is comparable to the study by Frank R. Kolisek *et al.* [29] who reported final functional score of  $73 (32 \pm 100)$  with posterior stabilized knee implant. K H Sancheti *et al.* [30] reported improvement in functional score of  $44.35 \pm 12.9$  to  $89.58 \pm 7.43$  with posterior stabilized knee implant. Young Joon Choi *et al.* [34] reported final functional score of  $93.6 \pm 8.2$  using Genesis II asymmetrical tibia TKR design.

Mean duration of hospital stay was  $6.13 \pm 0.81$  days which was comparable with other studies. H Farahini *et al.* [36] reported mean hospital stay of 6.1 days which is consistent with present study results. Remedios Lopez Liria *et al.* [37] reported hospital stay of  $6.59 \pm 1.58$  days which is longer than in present study. Omri Ayalon BS *et al.* [38] emphasized the importance of reducing hospital stay. He concluded that decreased hospital stay resulted in an increased capacity of patient admission. In other words, if all total knee replacements performed at the hospital during this 3-month period experienced this reduced length of stay, some additional admissions would have been possible. Shruti Raut *et al.* [39] reported mean hospital stay of 6.25 days. The need for a blood transfusion, patient age, pre-operative mobility and the use of walking aids and BMI were the factor influencing hospital stay in their study.

## Conclusion

Giant strides have been made in the past three decades in refinement of replacement arthroplasty of the knee. Although, previous implant designs showed excellent functional outcomes, implant mismatch was the major draw back about

them. Persona Posterior Stabilised Knee Implant (Zimmer, Warsaw, Indiana) is devoid of this drawback with no implant mismatch. Persona knee implant has provided good results at 3 year follow up. This was a single centre study with small sample size and short follow up period. Long follow up and bigger samples are recommended to comment whether these results are superior to the previous implants.

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