Original Article

A CT Based assessment of femoral component external rotation in TKA for osteoarthritic varus knees

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Abstract

Objectives: A CT based comparative assessment of the femoral component axial rotation (FCAR) achieved in two different design rationales compared to desired distal femoral axial rotation in balanced knees. **Methods**: 19 males and 31 females randomized in 02 groups of 25 patients each underwent unilateral TKA using two different implant designs (Genesis II & PFC). Posterior Condylar Axis (PCA) Trans-epicondylar Axis (TEA) open angle used to assess axial placement of femoral components per-operatively. CT based evaluation of the TKA done at 06 weeks to assess the FCAR achieved compared to desired value. **Results**: Mean FCAR for Genesis II group was 3.63 degrees with no difference among the males and females. In PFC group the mean FCAR achieved was 4.07 degrees the mean value was lower in males 3.95 degrees (2.8-6.5) and higher in females 4.16 (2.5-5.2). Mean achieved FCAR achieved in the study is 3.85 degrees. **Conclusion**: Mean achieved FCAR for the two design rationales showed no statistically significant difference. Mean FCAR in Genesis II group was more than inbuilt 3 degrees and is statistically significant. In a well-balanced knee the mean achieved FCAR in the study is significantly higher (3.85 degrees) than conventional desired 3 degrees.

Keywords: Osteoarthritis (OA), Posterior Condylar Axis (PCA), Surgical Trans-epicondylar Axis (sTEA), Total Knee Arthroplasty (TKA)

Introduction

Total knee arthroplasty (TKA) is a common surgery more than 1,324,000 primary and revision TKA implantations are done worldwide[1]. Various successful implant designs and techniques are available for a primary TKA. Femoral component rotation in total knee arthroplasty (TKA) is known to have a direct impact on the patella-femoral tracking, knee flexion gap symmetry, knee ROM and mid flexion stability of the implant thereby affecting clinical outcomes and long term survival of a TKA[2-4]. Placing the implants in correct coronal and sagittal planes, and achieving the optimum axial and longitudinal rotation of the femoral and tibial components in the replaced knee are known to significantly affect the final outcome of a TKA surgery[5,6]. Although femoral component axial rotation as a singular modifiable parameter is known to have a significant impact on the biomechanics of the knee joint throughout the range of motion[7-10] the native distal femoral rotation is not routinely measured preoperatively and surgeons usually rely on various parameters like the surgical trans-epicondylar axis (sTEA), anatomical trans-epicondylar axis (aTEA), posterior condylar axis (PCA), Whiteside's line and at times some specific instrumentation to decide the final femoral component rotational placement in TKA. Although most implant systems allow for the femoral component rotation during the course of the surgery, interestingly on the contrary there are implant designs with a fixed inbuilt external rotation in the femoral component with no option to change it per-operatively. It is indeed intriguing that both types of TKA design rationales have had good clinical long term results and survival rates. Aim of the study was to ascertain and compare the axial rotation of the

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implanted femoral component achieved using two different design rationales PFC sigma & Genesis II in comparison to the desired femoral external based on the sTEA in OA varus knees using a CT based protocol.

Materials and methods

Study carried out between Sept 2014 and Jan 2016. Fifty consecutive patients who satisfied the study criteria were recruited and assigned randomly to 02 groups of 25 patients each, Inclusion criterion were full extension of knee at 06 weeks, no deformity of thigh and leg, no limb length discrepancy, primary osteoarthritis, varus deformity less than 10 degrees, flexion deformity less than 20 degrees; Exclusion criterion were inflammatory arthritis, BMI more than 35 kg/m^2, ASA Grade III or above, neurological problems, valgus deformities, ligamentous, grade 4 OA with significant bone loss and deformity. All the necessary clinical details were recorded in a pro forma prepared for this study. Baseline weight bearing antero-posterior views, lateral view in 30 degrees knee flexion and skyline view radiographs of the knee were obtained preoperatively. All the patients gave written informed consent and there was no patient lost to follow up. Patients included in the study underwent Total Knee Arthroplasty (TKA) surgery with measure resection method in which **Group A** of 25 patients were implanted Genesis II Total Knee System PS (Smith & Nephew Inc., Memphis, TN, USA) in this group the desired external rotation referenced from the PCA was a fixed 03 degrees as determined by the fixed inbuilt external rotation incorporated in the implant in the other **Group B** of 25 patients implanted with PFC Sigma PS (DePuy Orthopaedics Inc., Warsaw, United States), of which there were 11 patients in which a per operative 5 degrees of femoral component external rotation was desired and 14 patients in which the desired external rotation was 3 degrees.

Patients were assessed during their visit to the OPD at 03 weeks and 06 weeks, postoperatively. A repeat weight bearing antero-posterior view, lateral view in 30 degrees knee flexion and skyline view radiograph of the knee and a CT scan as per modified *Perth CT protocol* was done at 06 weeks as per after assessing full extension of knee has been done at 06 weeks as per protocol (Figure 1).

Figure 1. Full extension of knee at the time of CT scan at 06 weeks follow up visit

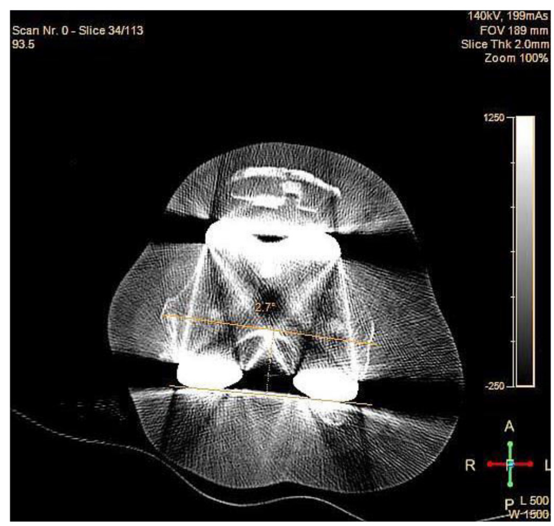

Figure 2. Measurement of external rotation of femoral component using surgical trans-epicondylar Axis (sTEA) and Femoral Prosthesis Posterior Condylar Line (FPPCL) after post-operative using CT Protocol.

Scanning Protocol

The patient is positioned supine on the scanner gantry table with the legs in a neutral position, the patellae pointing forwards and the knee in full extension. The legs were stabilized in this position when necessary. AP (antero-posterior) and lateral views were performed to check initial alignment. If satisfactory, a scan sequence was performed for knee joint, using 2.5 mm contiguous slices. The scan time was 20 seconds with an average kilo voltage of 70; 85 milliampere-seconds. The calculated radiation dose for the procedure was 0.641 mSV which is less than the radiation exposure of X-ray of Lumbosacral spine (1.3 mSV).

Measurement Protocol

An axial image of the distal femur was chosen which most clearly demonstrated the medial epicondylar sulcus and the lateral epicondylar prominence. The surgical epicondylar axis (sTEA) was defined as line connecting the lateral epicondyle identified by its prominent appearance, and the center of the medial epicondyle that was identified as the base of the medial sulcus. A second line the *femoral prosthesis posterior condylar line* **(FPPCL)** was defined as a line that connected the

Distribution of patients according to age in two groups			
	Number of patients	Mean Age	Std. Deviation
Group A (Genesis II)	25	65.04	7.133
Group B (PFC Sigma)	25	63.52	5.796

Table 1. Distribution of patients according to age.

Gender distribution in two groups			
	Male	Female	Total Cases
Group A (Genesis II)	09	16	25
Group B (PFC Sigma)	10	15	25
Total	19	31	50

Table 2. Gender distribution in two groups.

	Right knee	Left knee	
Group A Genesis II	15	10	25
Group B PFC Sigma	14	11	25
Total	29	21	50

Table 3. Distribution of patients according to Left and Right knee.

lowest point on both posterior femoral prosthetic condyles. The angle between these represented the axial rotation of the femoral component (Figure 2).

Results

Statistical Analysis

All the collected data was entered into an Excel master sheet which contained no identifiable records. Each patient had been given a unique identifiable number by which they could be traced if necessary. Data analysis was conducted on an intention to treat basis sstatistical analysis for distributions of the gender, age, side of knee using SPSS windows software. External rotation was assessed using paired t-test for both groups of patient. The present randomized prospective study compares the external rotation of femoral component in both groups of patients undergoing total knee replacement with two different implant design rationales, PFC Sigma PS (DePuy Orthopaedics Inc., Warsaw, United States) & Genesis II Total Knee System PS (Smith & Nephew Inc., Memphis, TN, USA).

Mean age in the study was 64.28 yrs (47-77yrs), in Genesis II group 25 patients mean age was 65.04 yrs. (47-76) and in PFC Group 25 patients were operated mean age was 63.52 yrs. (55-77) (Table 1).

There were 19 males and 31 females, In Genesis II implant group among 25 patients 09 were male and 16 were female and out of 25 patients in PFC Sigma group 10 were male and 15 were female (Table 2).

In the study 29 right knees and 21 left knees were operated, in Genesis II group 15 patients were with right knee and 10 with left knees. In PFC Sigma group 14 patients were with right knee and 11 with left knees (Table 3).

Mean external rotation of femoral component achieved for Genesis II group of 25 patients was 3.63 degrees (2.1-6.4) as compared to desired inbuilt value of a fixed 3 degrees($p<0.0011$) and was equivalent in males (n=9) 3.633 degrees (2.3-5.3) and females (n=16) 3.637 degrees (2.1-6.4). In PFC sigma group of 25 patients the mean external rotation of femoral component value was 4.07 degrees (2.5-6.50) compared to the desired mean external rotation of femoral component of 3.88 degrees ($p=0.4888$). The mean external rotation of femoral component achieved differed among the sexes in the PFC sigma group in males (n=10) achieved mean external rotation of femoral component was 3.95 degrees (2.8-6.5) and mean desired value was 3.4 degrees, in females (n=15) mean achieved external rotation

Group	Number of Patients	Mean desired FCAR	Std. Deviation	Mean FCAR achieved	Std. Deviation	p value #	Mean achieved FCAR in the study (n=50)/ P value
Group A (Genesis II)	25	3	.000	3.63	0.95088	0.0011	3.85 degrees. (p=0.1259)
Group B (PFC Sigma)	25	3.88	1.01325	4.07	0.90980	0.4888	
# p value determined by Independent t test [Significant (<0.05) ; highly Significant (0.001) ; Not Significant (>0.05).							

Table 4. Comparison of External Rotation in two implant designs (Genesis II and PFC Sigma) at 06 weeks.

of femoral component value was 4.16 (2.5-5.2) and mean desired value was 4.2 degrees. In PFC group mean achieved external rotation of femoral component in 11 patients (m=2, f=9) where 5 degrees external rotation of femoral component was desired the achieved external rotation of femoral component was 4.76 (3.8-6.5), as compared to 14 patients (m=8, f=6) where 3 degrees of external rotation of femoral component was desired, the mean achieved external rotation of femoral component achieved was 3.51 (2.5-4.5). The mean achieved external rotation of femoral component in 50 cases of the study was 3.85 degrees (Table 4).

Discussion

Over the years various design rationales have been tried and tested world over in the practice of knee arthroplasty. Theoretically a TKA implant design that closely recreates the native knee anatomy and achieves good ligament balance throughout the knee ROM should have good long term outcome and survival rates. For a successful outcome TKA prosthesis should be well aligned along the sagittal and coronal mechanical axis and placed in the correct axial and rotational planes as well. Inaccurate implantation of the TKA prosthesis leads to instability, patella-femoral mal-tracking, accelerated poly wear, loosening, and overall poor outcomes[1,6-11]. Using conventional techniques of surface referencing in TKA only about 75% of the femoral components are likely to be placed within the desired femoral external rotation of 3 degrees[12,13]. It is well reported in the literature that about 10-15% of the patients are unhappy after TKA[14-15], TKA instrumentation sets are equipped with tools to align the TKA component placement in the correct mechanical axis in the sagittal and coronal planes however the axial rotation is usually at the surgeons own discretion based on surface landmarks, and are thereby prone to high inter observer error, and could be directly linked to a poor outcome in TKA patients; with this background it is reasonable to deduce if the accuracy rate of femoral component placement in axial rotation is improved it can reduce a certain percentage of unhappy patients after TKA. It is at times difficult for the surgeon to truly ascertain the exact cause of the unhappy knees in the absence of overt clinical signs and symptoms especially in the early postoperative period. Corona et al[2] in a systematic review of literature of articles published between 1996 and 2019 examined the effect of the TKA femoral component mal-rotation on clinical outcomes; they concluded that although the femoral mal-rotation does not automatically correlate to poor clinical outcome after TKA but strongly recommended surgeons should consider the anatomical variability of femur in each knee and take a more accurate approach to shed light on unanswered questions in unhappy TKA[2]. The distal femoral anatomy is greatly influenced by the sex, age, race and region of the patients[1,3,16,17], moreover in OA patients the longstanding deformity, mal-alignment and articular erosion is also known to induce morphological deformation and asymmetric anatomical changes of distal femoral condyles and proximal tibia[18-20] these OA induced changes may superimpose and further accentuate on the existing variations of the distal femoral anatomy. In our opinion this altered sagittal, coronal and rotational alignment and asymmetric dimensions of the osteoarthritic knee joint makes a strong case for a thorough preoperative assessment of the altered distal femoral and proximal tibial anatomy, Routine radiological assessment prior to TKA does not measure the distal femoral anatomy with respect to the rotational alignment and this aspect is left to surgeon's discretion who usually keeps it at 3 degrees or uses various conventional surface referencing methods like TEA, PCA, AP Axis to achieve a balance between femoral axial rotation and a rectangular flexion gap, however the distal femoral anatomy is highly variable and may require more or at times even less external rotation depending on the soft tissue releases, orthogonal accuracy of the tibial cut, femoral axial deformation, and anatomy of the trochlear notch. Victor J.[1], recommend a preoperative CT scan, Trung DT et al[17] an MRI prior to surgery to assess the native distal femoral anatomy.

Various conventional surface referencing methods use the posterior condylar axis (PCA), "*Whiteside's line*" (AP-axis), trans-epicondylar axis (TEA) or the gap balancing technique to decide the femoral component rotation[11,20,21] however, it is not yet clear which method is superior for femoral rotational component axial rotation[2] and is also highly prone to inter-observer errors[22]. With no standard parameter to follow and multiple variables at the time of surgery affecting femoral component rotation, the number of outliers in postoperative axial alignment of the femoral component with respect the desired femoral external rotation are likely to be high[12,13,23] and has long been overlooked[1]. This degree of mismatch in the femoral component placement can have a graded, multifaceted, subtle or subclinical effect on the tibio-femoral and patella-femoral biomechanics and stresses and may contribute significantly towards 10 to 20% unhappy patients after TKA[24].

Femoral component axial rotation is specifically implicated in patella-femoral joint mal-alignment, anterior knee pain and reduced knee flexion[7-9,25,26], Berger RA, Crossett LS, Jacobs JJ, Rubash HE in there study compared 30 patients with isolated patella-femoral complications after total knee arthroplasty to 20 patients with a well-functioning total knee replacement without patello-femoral complications; the group with patella-femoral complications had excessive combined (tibial plus femoral) internal component rotation. This excessive combined internal rotation was directly proportional to the severity of the patella-femoral complication[11]. Data is sparse on the aspect of actual femoral component rotation achieved in TKA using the conventional reference methods for the implantation of femoral component with respect to the desired distal femoral anatomy[1,5,12,27,28]. In a PS fixed bearing design the significant influence of distortion of the proximal tibial anatomy is neutralized by a perpendicular coronal proximal tibial cut[22], however the distal femoral anatomy alterations specially the femoral rotation in patients of OA for TKA is still not fully addressed. As a standard measure most TKA techniques recommend a 3 degrees of axial rotation of the femoral component, mainly to adjust for the correction of the 3 degrees varus in the proximal tibial joint line , however the variations in the femoral axial anatomy are not catered to and this can cause disruption of the patella-femoral kinematics while focusing on the tibio-femoral flexion gap balance; this disruption of the patella-femoral kinematics in our opinion will be more significant in deep flexion and may be a significant contributor to the unhappy knee TKA patients. A variety of implants with differing design rationales are available for implantation, in our study we compared two different fixed bearing PS designs; Genesis II Total Knee System PS (Smith & Nephew Inc., Memphis, TN, USA), having a fixed inbuilt external rotation of 3 degrees and PFC Sigma PS (DePuy Orthopaedics Inc., Warsaw, United States) in which there is an option to change the femoral axial rotation during the course of the surgery. Both are well established implant designs for last 20 yrs., with survival rate over 90 % at 15 yrs[29,30]. Results of this study showed that statistically there is no significant difference between the femoral component rotation after primary total knee arthroplasty of both implant designs incorporated in this study (Genesis II and PFC Sigma) as measured by Post-operative CT scan at 06 weeks using modified Perth CT Protocol (p value determined by independent T test for comparing femoral component rotation is 0.1259). Similarly statistically there is no significant difference in femoral component rotation of PFC Sigma at 06 weeks post operatively (p value determined by independent t test for comparison of femoral component rotation is 0.4888). In case of Genesis II implant design there is a statistically significant difference (p value-0.0011) in femoral component rotation as measured at 06 weeks post operatively. The mean value of external rotation achieved is 3.63 degrees even in an implant with fixed 3 degrees of external rotation. The overall mean external rotation achieved in the study is 3.85 degrees (rounded off to 4 degrees) which is significantly higher than the conventional 3 degrees recommended in most TKA surgical techniques. In our series the results point that a higher desired external rotation of the femoral component of 4 degrees referenced from the PCA may be one of the key parameters to restore the native patella-femoral kinematics and at the same time maintain adequate collateral ligament balance throughout the range of motion of the TKA.

Conclusion

This study has some limitations as it was not a randomized controlled blinded trial, sample size was small, and follow up period was short. The study showed that in a well-balanced knee the two different Implant designs (Genesis II and PFC sigma) showed no statistically significant difference in the mean FCAR achieved and converged to a higher value of 3.85 degrees which is significantly more than the routine 3 degrees used for component external rotation. We conclude that a that a higher degree of external rotation 4 degrees (3.85 degrees rounded off) of external rotation of the femoral component referenced from the PCA as a more suitable option in Grade 3 & 4 OA knees to achieve a balanced flexion gap in the entire range of motion of TKA and at the same time restore native patella-femoral kinematics and has potential to greatly reduce the percentage of unhappy knees after TKA.

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Annexure

Master chart

S NO	AGE	SEX	KNEE (R/L)	RANGE OF MOTION	DEFORMITY (NONE, VARUS, VALGUS)	APPROACH (MEDIAL PARAPATELLAR)	IMPLANT	FEMORAL ROTATION ATF SX (DEGREE)	CT BASED MEASUREMENT (DEGREE)	WOMAC SCORE	POST-OP INFECTION (NONE/ SUPERFICIAL/ DEEP)	DVT	PRESSURE SORES (Y/N)	NEUROVASCULAR DEFICIT	LENGTH OF HOSPITAL STAY
1.	60	F	R	0-100	N	Y	GENESIS II	3	2.6	35	NONE	N	N	N	14 days
2.	66	F	R	0-120	5 deg	Y	GENESIS II	3	4.2	30	NONE	N	N	N	14 days
3.	60	M	R	0-110	5 deg	Y	GENESIS II	3	3.8	28	NONE	N	N	N	14 days
4.	55	F	R	0-10	10 deg	Y	GENESIS II	3	3.6	30	NONE	N	N	N	14 days
5.	47	F	R	0-110	10 deg	Y	GENESIS II	3	2.1	40	NONE	N	N	N	14 days
6.	68	F	L	0-90	10 deg	Y	GENESIS II	3	2.6	35	NONE	N	N	N	14 days
7.	60	F	R	0-110	N	Y	GENESIS II	3	3.5	30	NONE	N	N	N	14 days
8.	72	M	L	0-110	N	Y	GENESIS II	3	2.3	35	NONE	N	N	N	14 days
9.	73	F	R	0-110	N	Y	GENESIS II	3	2.6	32	NONE	N	N	N	14 days
10.	58	F	L	0-100	30 deg	Y	GENESIS II	3	3.8	28	NONE	N	N	N	14 days
11.	58	F	R	30-100	30 deg	Y	GENESIS II	3	3.5	27	NONE	N	N	N	14 days
12.	74	F	R	10-100	10 deg FFD	Y	GENESIS II	3	5	30	NONE	N	N	N	14 days
13.	74	F	L	10-100	10 deg FFD	Y	GENESIS II	3	6.4	28	NONE	N	N	N	14 days
14.	76	M	R	0-100	N	Y	GENESIS II	3	3.5	30	NONE	N	N	N	14 days
15.	74	F	L	0-100	N	Y	GENESIS II	3	4	29	NONE	N	N	N	14 days
16.	61	F	R	5-110	5 deg FFD	Y	GENESIS II	3	3.1	28	NONE	N	N	N	14 days
17.	61	F	L	10-100	10 deg FFD	Y	GENESIS II	3	3.1	28	NONE	N	N	N	14 days
18.	66	M	L	15-90	15 deg FFD	Y	GENESIS II	3	3.9	30	NONE	N	N	N	14 days
19.	66	M	R	0-120	15 deg Var	Y	GENESIS II	3	3.5	33	NONE	N	N	N	14 days
20.	65	M	R	0-110	N	Y	GENESIS II	3	5.3	30	NONE	N	N	N	14 days
21.	68	M	R	5-110	5 deg FFD	Y	GENESIS II	3	3.2	29	NONE	N	N	N	14 days
22.	69	F	L	15-100	15 deg FFD	Y	GENESIS II	3	4.2	38	NONE	N	N	N	14 days
23.	60	M	R	0-100	N	Y	GENESIS II	3	4	36	NONE	N	N	N	14 days
24.	63	F	L	0-90	N	Y	GENESIS II	3	4.1	35	NONE	N	N	N	14 days
25.	72	M	L	5-100	5 deg FFD	Y	GENESIS II	3	3.6	32	NONE	N	N	N	14 days
26.	60	F	R	0-90	5 deg FFD	Y	PFC SIGMA	5	5.2	26	NONE	N	N	N	14 days
27.	66	F	R	0-100	N	Y	PFC SIGMA	5	4.5	30	NONE	N	N	N	14 days
28.	55	F	L	15-100	15 deg FFD	Y	PFC SIGMA	5	4.8	32	NONE	N	N	N	14 days
29.	70	M	L	20-110	20 deg FFD	Y	PFC SIGMA	5	5.1	30	NONE	N	N	N	14 days
30.	69	M	R	0-70	10 deg	Y	PFC SIGMA	3	4.5	35	NONE	N	N	N	14 days
31.	66	M	R	0-100	N	Y	PFC SIGMA	3	4	29	NONE	N	N	N	14 days

(cont. from previous page)

S NO	AGE	SEX	KNEE (R/L)	RANGE OF MOTION	DEFORMITY (NONE, VARUS, VALGUS)	APPROACH (MEDIAL PARAPATELLAR)	IMPLANT	FEMORAL ROTATION ATF SX (DEGREE)	CT BASED MEASUREMENT (DEGREE)	WOMAC SCORE	POST-OP INFECTION (NONE/ SUPERFICIAL/ DEEP)	DVT	PRESSURE SORES (Y/N)	NEUROVASCULAR DEFICIT	LENGTH OF HOSPITAL STAY
32.	55	F	R	0-90	10 deg FFD	Y	PFC SIGMA	3	4	26	NONE	N	N	N	14 days
33.	60	F	R	0-110	N	Y	PFC SIGMA	3	3.2	28	NONE	N	N	N	14 days
34.	66	M	L	0-120	N	Y	PFC SIGMA	3	3.5	30	NONE		N	N	14 days
35.	60	F	L	15-100	15 deg FFD	Y	PFC SIGMA	5	3.8	38	NONE		N	N	14 days
36.	59	F	R	0-90	N	Y	PFC SIGMA	5	5	26	NONE		N	N	14 days
37.	77	M	R	0-100	N	Y	PFC SIGMA	3	3.5	26	NONE		N	N	14 days
38.	65	M	L	0-100	N	Y	PFC SIGMA	3	2.8	35	NONE		N	N	14 days
39.	62	F	L	0-90	N	Y	PFC SIGMA	3	3.5	30	NONE		N	N	14 days
40.	65	F	L	Oct-50	10 deg FFD	Y	PFC SIGMA	5	4.5	32	NONE		N	N	14 days
41.	55	F	L	0-100	N	Y	PFC SIGMA	3	3.6	29	NONE		N	N	14 days
42.	68	M	R	0-100	N	Y	PFC SIGMA	3	3.1	28	NONE		N	N	14 days
43.	60	F	R	0-100	N	Y	PFC SIGMA	5	4.6	33	NONE		N	N	14 days
44.	57	F	L	5-130	5 deg FFD	Y	PFC SIGMA	3	4.5	30	NONE		N	N	14 days
45.	72	M	R	0-110	N	Y	PFC SIGMA	3	3.8	28	NONE		N	N	14 days
46.	70	F	L	0-100	N	Y	PFC SIGMA	5	4.5	32	NONE		N	N	14 days
47.	65	M	L	0-100	N	Y	PFC SIGMA	5	6.5	30	NONE		N	N	14 days
48.	65	M	R	0-100	N	Y	PFC SIGMA	3	2.7	32	NONE		N	N	14 days
49.	56	F	R	0-110	N	Y	PFC SIGMA	5	4.2	32	NONE		N	N	14 days
50.	65	F	R	0-110	N	Y	PFC SIGMA	3	2.5	30	NONE		N	N	14 days