Tibial component sizing and alignment of TKR components does not significantly affect patient reported outcome measures at six months. A case series of 474 participants.

Abstract

Objectives: Total knee replacement (TKR) is an effective means of alleviating the symptoms of end stage osteoarthritis. However, 20% of patients report dissatisfaction one year post-operatively. Previous literature has demonstrated contradictory evidence regarding the relationship between alignment and tibial component sizing with patient reported outcome measures (PROMs). We aim to investigate the association between alignment of TKR components and effect of tibial component sizing on PROMs.

Method: A prospective, multicentre case series was performed at six centres. Baseline characteristics were collected at recruitment. Coronal and sagittal plain films were taken day one post-operatively. Trained medical professionals blinded to outcome measured the alignment and degree of over/underhang of the tibial component in the coronal and sagittal place, with Oxford Knee Score (OKS) measured six months post-operatively.

Results: 474 patients were recruited. Malaligned TKRs caused no significant difference in mean OKS change at six months (independent t-test) ($p>0.05$). A multivariate regression model taking into account age, gender, body mass index and baseline OKS also demonstrated no significant difference ($p>0.05$). With regards to tibial component sizing, 125 (27%) of patients had appropriately sized tibial components, 120 (26%) had overhang and 219 (53%) had underhang with no significant difference in OKS between the groups ($p>0.05$).

Conclusion: Tibial component sizing and alignment does not significantly affect short-term function, as measured by OKS, after total knee replacement. Dissatisfaction after TKR is likely due to other factors other than alignment of implant.

Introduction

Total knee replacement (TKR) is a definitive means of treating symptomatic arthritis of the knee (1). An estimated 90,000 procedures take place in Great Britain per year (2), yet despite its effectiveness, 20% of patients have expressed dissatisfaction post-operatively (3).

Dissatisfaction has been shown to be associated with lower patient reported outcome measures (PROM), with a three-month Oxford knee score (OKS) shown to be a significant predictor of satisfaction (4). Factors contributing to lower PROM and dissatisfaction following TKR include infection, loosening, component sizing, and implant malalignment (5). The aim of the current study was to investigate the association between implant alignment and component sizing with PROM.

Traditionally, implant alignment in the coronal and sagittal planes has long been held a critical factor in the attainment of optimal results. An important technical objective is to achieve a perfect tri-planar component alignment (6) with a neutrally aligned limb and a mechanical axis of $180° \pm 3°$ and no tibial-femoral rotational mismatch (7, 8). Some studies have demonstrated an association between malalignment and worse PROM scores (9-11) whereas others have contradictorily demonstrated no association (12, 13). Figure 1 demonstrates radiographic evidence of tibial component malalignment.

Current evidence within literature regarding tibial component sizing suggests that tibial overhang particularly at the medial side is associated with soft tissue irritation and therefore resultant post-operative pain (5). Femoral component overhang (>3mm) has been shown to be associated with a two-fold increase in knee pain 2 years post operatively (14). Within the context of unicompartmental knee replacement an overhang of greater than 3mm has been shown to be associated with a significantly worse OKS score (15). In the case of cemented TKRs the literature provides contradictory evidence. A retrospective review of consecutive TKRs found oversizing of components was associated with worse clinical results and an increase in pain scores (16), whereas, overhang has also been shown to have no significant effect on OKS scores (17).

Aims

To investigate the association between alignment of TKR components and effect of tibial component sizing on PROMs.

Methods

Patient selection

Patient recruited to a prospective multicentre cohort study were included within this study and a full protocol is available (18). Briefly, patients were recruited from six hospitals undergoing primary TKR between April 2013 and June 2014. Three prosthesis are used across these sites; Nexgen CR, Nexgen CR flex and Nexgen medial pivot (Zimmer Biomet, Indiana, USA). Baseline measures were taken: age, body mass index (BMI), Oxford knee score (OKS) and a pre-operative radiograph. Patients were followed up at six months by postal questionnaire to determine the OKS score.

Inclusion Criteria

- Diagnosis of primary osteoarthritis listed for primary TKR
- Able to provide informed consent and complete OKS questionnaire
- Age greater than 50

Exclusion criteria

- Procedure other than total knee arthroplasty
- Delay between recruitment and operation of greater than six-months to safegaued against baseline measurements changing by the time of the operation.

Outcomes of interest

Post TKR, the following data was collected: grade of surgeon, intra-operative findings, component sizing and alignment of prosthesis (based on post-operative radiographs). Post-operatively all patients took part in a standardised enhanced recovery protocol involving mobilisation using a frame/crutches on day 1 and a combination of active or passive range of motion exercises.

The primary outcome measure of interest is the OKS (19) six months post operatively. This is a twelve point PROM used to assess both knee pain and function.

Radiographic assessment

Medical professionals, who all received identical training, performed radiographic assessment. All authors were blinded to patient reported outcome measures. Day one non-weight bearing post-operative radiographs in the anteroposterior (AP) and lateral views were used. Radiographs were reviewed electronically using the hospital digitalPACS system (Carestream Health UK Ltd., Hemel Hempstead, United Kingdom).

TKR alignment parameters are measured in both coronal and sagittal plane (Figure 2). In the coronal plane, the tibial-femoral mechanical angle is a straight line drawn from the centre of the femoral head through to the centre of ankle passing through the knee (20). Additionally, the coronal tibial-femoral anatomical angle (cTFaA) is a combination of the coronal femoral angle (cFA, α) and the coronal tibial angle (cTA, β). These are the angles between the component axes and the anatomical intramedullary long bone axes (21). Sagittal alignment is a measurement of the component relative to the intramedullary long bone sagittal axis, producing the sagittal femoral (sFA) and tibial (sTA) angles(21).

The parameters for alignment were based on previous studies (20) and were as follows:

Coronal plane

- Coronal femoral angle:
  - Aligned group – 92-98°
  - Varus <92°
  - Valgus > 98°
- Coronal tibial angle:
  - Aligned 87-93°

        - Varus <87°
        - Valgus >93°
- Coronal tibiofemoral anatomical angle:
    - Aligned 183-187.5°
    - Varus <183°
    - Valgus >187.5°

Sagittal plane

- Sagittal tibial angle
    - Aligned 0-7°
    - Misaligned 0°>x>7°
- Sagittal femoral angle
    - Flexion >3°
    - Aligned 0-3°
    - Extension <0°

Regarding component sizing, a vertical line was drawn at the most proximal part of the tibial plateau, allowing us to then measure if any component overhang or underhang was present. We accounted for magnification by measuring the mediolateral width of the tibial component and comparing this to the actual known mediolateral width provided by the manufacturers. This supplied a magnification factor that was used to provide accurate overhang/underhang compensated for magnification. Overhang and underhang was graded as follows based on previous literature (22):

- Anatomically sized 0-1mm
- Mild 1-3mm
- Severe >3mm

Power calculation

This study included reported data from patients included for a large multicentre cohort study performed in our department(18). We designed a study to have 80% power to detect associations, at the 5% level, between preoperative factors and outcome, with a correlation coefficient of 0.2. This will identify if malalignment or tibial component oversizing account for more than 4% of the variation in primary outcome measure (below the minimally clinical detectable difference for Oxford knee score. To do this we require complete data from 400 patients.

Statistical Analysis

All data and outcomes in this study will be reported in like with the PROCESS (Preferred reporting of case series in surgery) criteria (23). In order to assess the effect of alignment and tibial component sizing on OKS separate independent T-tests were performed. Alignment and over/underhang groups were separated into three categories respectively – aligned, varus and valgus for the former; anatomically sized, mild and severe for the latter.

A linear regression model was used to adjust for the variables of age, gender, deprivation (measured using the Index of Multiple Deprivation (24)), severity of arthritis (Ahlback) and BMI when comparing alignment on OKS. The Ahlback score was dichotomised according to severity with a score of 0-2 being classed as non-severe and >3 classified as severe. This approach has been used previously (25).

Inter-rater reliability was assessed between two raters using Cohens Kappa.

Results

999 Patients were screened for inclusion in the study from March 2013 to July 2014. 234 patients refused and 165 patients were excluded for reasons highlighted in figure 3.

600 patients were recruited, following recruitment, 83 participants were excluded from follow up due to delay of greater than six-months to time of surgery. . A further 11 patients with significant complications (Fracture (n=3), revision (excluding revision for pain) (n=5), patella tendon rupture (n=1), significant medical co-morbidity (e.g. dense stroke) (n=2)) were excluded from analysis.

During follow-up, a further 32 (5%) participants were lost top follow-up, leaving a total of 474 patients for analysis (92% of eligible participants) (table 1 for baseline characteristics). Of the 474 participants there was a mean age of 68.75 with a mean BMI of 34.71. For the tibial sizing group, complete data was present for 464 participants (90%) - A further 10 participants were excluded due to ambiguity regarding exact prosthesis

Alignment *vs.* OKS

Coronal tibial component

Of the 474 participants, 350 (74%) were in the aligned group (87° – 93°) with a six-month OKS score of 34.171 (95% CI 33.161 – 35.181). 110 (23%) radiographs revealed a varus alignment (<87°) with an OKS score of 35.693 (95% CI 33.929 – 37.456). There was no significant difference between the two groups (p=0.726). Similarly there was no significant difference between the valgus aligned tibial components (14 (3%) participants) and the neutrally aligned tibial components (p=0.566) (table 2).

Coronal femoral component

Of the 474 participants, 233 (49%) were in the aligned group (92° – 98°) with an average six-month OKS of 34.779 (95% CI 33.583 – 35.975). 169 (36%) radiographs revealed a varus alignment <92° with an average six month OKS of 34.446 (95% CI 33.003 – 35.888). There was no significant difference in the six-month OKS score between the two groups ($p=0.147$). Valgus alignment (72 (15%) participants) also had no significant effect on OKS score at 6 months in compared to the aligned group ($p=0.993$) (table 2).

Combined anatomical tibiofemoral component

A post-operative overall coronal anatomical tibiofemoral component provided no significant advantage in terms of OKS score change at 6 months compared to a varus or valgus aligned total knee replacement (table 2).

There were 169 (35%) neutrally aligned components (183-187.5°) with an average OKS of 34.883 (95% CI 33.512 – 36.255) compared to 236 (50%) varus aligned total knee arthroplasty (<183°) components with an average OKS of 34.441 (95% CI 33.211 – 35.671) ($p=0.641$). There was also no significant difference when comparing valgus aligned total knee arthroplasties (>187.5°) (69 (15%) patients) and neutrally aligned components ($p=0.428$).

Sagittal femoral component (table 2)

There was no significant difference in average OKS score between an aligned femoral component (192 (40%) participants) and a flexed femoral component (269 (58%) participants) ($p=0.492$). There was also no significant difference in average OKS score between an aligned femoral component and an extended femoral component (13 (3%) participants) ($p=0.065$).

Sagittal tibial component (table 2)

There was no significant difference in average OKS score between an aligned tibial components (0-7°) (324 (69%) participants) and a misaligned tibial component (0°>x>7°) (150 (31%) participants) ($p=0.957$).

Tibial Component sizing

Overhang

There were 125 (27%) anatomically sized TKRs with a six month OKS of 34.474 (95%CI 32.846 - 36.101). 120 TKRs had some degree of overhang (25%) with a six month OKS of 34.318 (95%CI 32.642 - 35.995). There was no significant difference in six-month OKS score between the anatomically sized group and the overhang group (p=0.387) (Table 3).

Medial Overhang

255 (55.9%) TKRs were well positioned on the medial side, 24 (5.2%) had evidence of minor overhang and 14 (3.0%) had evidence of severe overhang. There was no significant difference in six-month OKS score between the three groups (p>0.05) (Table 3).

Lateral Overhang

203 (44%) TKRs were well positioned on the lateral side, 64 (13.8%) had evidence of minor overhang and 77 (16.6%) had evidence of severe overhang. There was no significant difference in six-month OKS score between the three groups (p>0.05) (Table 3).

Underhang

There were 125 (27%) anatomically sized TKRs with a six month OKS of 34.474 (95%CI 32.846 - 36.101). 219 TKRs had some degree of underhang (47%) with a six month OKS of 33.967 (95%CI 32.594 – 35.339). There was no significant difference in six-month OKS score between the anatomically sized group and the overhang group (p=0.758) (Table 4).

Medial Underhang

255 (55.0%) TKRs were well positioned on the medial side, 90 (19.4%) had evidence of minor underhang and 81 (17.5%) had evidence of severe underhang. There was no significant difference in six-month OKS score between the three groups ($p>0.05$) (Table 4).

Lateral Overhang

203 (43.7%) TKRs were well positioned on the lateral side, 52 (11.2%) had evidence of minor underhang and 65 (13.7%) had evidence of severe underhang There was no significant difference in six-month OKS score between the three groups ($p>0.05$) (Table 4).

We also performed multivariate analyses comparing the 'aligned vs misaligned group', the 'aligned' vs 'varus" or "valgus' group, the 'Well positioned vs overhang group' and the 'well positioned' vs 'underhang" group. Taking into account age, gender, BMI, baseline OKS and Ahlback score which confirmed no significant difference between the respective groups ($p>0.05$).

Inter-rater reliability

Alignment data

Cohens Kappa between at this studies raters varied from 0.3-0.6 indicating a moderate to good level of agreement. The base rate for this study varied from 0.59 -0.70 providing a percentage accuracy of between 80 – 90%. The percentage agreement was 71% between the raters.

Tibial sizing data

Cohens kappa between this studies raters at the study sites varied between 0.65 – 0.75 which indicates a substantial agreement between the two raters (26). The percentage agreement was 90.3% between raters.

Discussion

For the patients within this study, attaining neutrality of coronal and sagittal alignment of tibial and femoral component does not provide any additional advantage in the context of patient reported outcome measures. This study also confirms the premise that tibial component sizing does not significantly affect patient reported outcome measures. Overall, for all parameters investigated in this study there was no significant difference in mean change in OKS six-months post-operatively.

Alignment

Although five studies have demonstrated an association between malalignment in the coronal plane and unfavourable PROMS (9-11, 27, 28) the majority of studies do not support this correlation (8, 12, 29-34). It should be noted that the five studies that demonstrated a significant association looked at the coronal tibio-femoral mechanical alignment. Additionally, these studies were subject to certain methodological flaws. Firstly, 14 of the 15 studies mentioned above were single centre studies (33) and secondly, the sample sizes were relatively small in comparison to this study. There was one case series of 600 participants (30), however, of the remainder, the largest sample size was 200 (33). There was also a significant variation in follow-up time (6 months to 5 years) and timing of radiograph acquisition. Rienmuller et al (35) looked at radiographs five years post-operatively and as a result the misalignment could potentially be due to implant migration rather than misalignment at the time of surgery. Furthermore, there were variations in both weight bearing status and standardisation of radiological technique. Studies have shown a non-standardised method of acquiring radiographs can lead to inconsistent rotation adding an additional source of bias (36).

We believe the reason for high proportions of dissatisfaction (3) could be due to reasons other than implant misalignment. Recently, there has been a trend to shift towards kinematic alignment whereby restoring the patients original anatomy is the focus of alignment. Howell et al concluded that a kinematically aligned knee replacement does not adversely affect patient function (37). These results show varying coronal anatomical alignment had no significant effect on PROMS. This could be considered consistent with the findings of Howell et al as restoring patients' own pre-operative anatomy will create a group of patients who may be kinematically aligned but anatomically misaligned or vice versa. This study suggests that where patient reported outcomes are the endpoint of interest alignment had no significant effect on PROM scores.

Tibial sizing

With respect to component sizing, it has been suggested that medial overhang of the tibial component is more problematic than lateral overhang due to irritation of the medial collateral ligament (17, 22). When results are subdivided to look at medial vs lateral overhang, we found the incidence of lateral overhang (30%) to be greater than medial overhang (8.1%). However we found that both medial and lateral overhang had no significant difference on six-month OKS. The rational for a greater incidence of lateral overhang is likely to be due to operative technique, as the intra-operative view is reduced on the lateral side through a medial parapatellar arthrotomy (17).

These results demonstrate that tibial component underhang did not significantly affect patient reported outcome measures, which is supported the literature. Component underhang is thought to be associated with implant subsidence and loosening rather than pain (38).

To the best of our knowledge this is the first multicentre study investigating the effects of tibial component sizing of cemented TKRs. A recent study found tibial component sizing of uncemented TKRs had no significant effect on patient reported outcome measures (22). Another previous single centre retrospective case series of cemented TKRs showed tibial underhang did not significantly compromise OKS score(17). However, this was a single centre study therefore results are less generalisable as they could be affected by a specific technique used in that centre. Another limitation of this study was there study group consisted exclusively of patients with overhanging tibial components and a comparison was made to the OKS of patients from another large RCT.

The strengths of this study are evidenced by the design; firstly we performed the study in six centres across a range of hospitals, secondly a broad eligibility criteria gives us a pragmatic study which is representative of current practice within the UK. As mentioned above a concern with the above studies was the lack of standardisation of radiological assessment. All study radiographs were taken day 1 post-operatively and followed a standardised format reducing the risk of bias due to inconsistent rotation (36). Given that all radiographs were taken day one post-operatively we can be confident in stating the malalignment was due to surgical placement rather than implant migration. Another strength of the study was that we assessed all parameters within the coronal and sagittal plane. Some of the previous studies did not report all the coronal parameters (11, 34): Ritter et al (39) highlighted the complex interplay between different components whereby correction of a malaligned component by aligning the second component to achieve a neutrally aligned knee was associated with increased failure rate. As a result, we reported the alignment of individual components in addition to combined anatomical angle. Assessing inter-rater reliability provided further strength to this study design. Although short leg radiographs are less accurate than long leg radiographs is assessing alignment, we think that this level of accuracy was sufficient to assess the component axis in relation to the anatomical bone axis (40).

A limitation of this study was that we did not assess coronal mechanical axis and the axial measures of alignment. Axial alignment is best assessed using post-operative CT scans, however, this was not standard practice in any of the study sites as patients are assessed with short leg radiographs and therefore we did not assess this measure. Three different prostheses were used in this study, which could affect outcome. Future work should involve assessing axial rotation using post-operative CT scans in a standardised manner, and the assessment of overhang of different implant designs to see if there is a difference in outcome. Another potential weakness of this study is that for medial overhang it may have been underpowered. Given only 14 participants had significant medial overhang this may not be a true reflection on the impact of this condition on OKS score. This could be further investigated with a study adequately designed to primarily assess the effect of medial overhang on patient related outcome. In addition, although we assessed inter-rater reliability using 4 raters, the authors acknowledge that additional raters would increase the reliability of our findings.

In conclusion, this study suggests that if PROMS is the outcome of interest for operating surgeons, then alignment and tibial component sizing does not significantly affect outcome scores. As a result, the variability in outcome following total knee arthroplasty is likely due to other factors besides alignment of implantation.

Baseline Characteristics	
Age (mean)	68
BMI (mean)	30.06
Male:Female	129:198
Baseline OKS	19.05
Arthritis severity*	178 mild 143 severe
*severity based on Ahlback score. 1-2: mild and 3-5: severe.	

Table 1: Demographics of study population

Association between alignment in Coronal tibial angle (CTA) and change in OKS score.

	Number	Six-month OKS	Confidence interval	p value	Multivariate analysis
Aligned	350	34.171	33.161 – 35.181	Ref	Ref
Varus (1)	110	35.693	33.929 – 37.456	0.147	p>0.05
Valgus (-1)	14	34.193	29.647 – 38.739	0.993	p>0.05
Association between alignment in Coronal femoral angle (CFA) and change in OKS score.					
Aligned	233	34.779	33.583 – 35.975	Ref	Ref
Varus (1)	169	34.446	33.003 – 35.888	0.726	p>0.05
Valgus (-1)	72	34.04	31.641 – 36.438	0.566	p>0.05
Association between alignment in Coronal tibial femoral anatomical angle (CTFaA) and change in OKS score.					
Aligned	169	34.883	33.512 – 36.255	Ref	Ref
Varus (1)	236	34.441	33.211 – 35.671	0.641	p>0.05
Valgus (-1)	69	33.801	31.310 – 36.292	0.428	p>0.05
Association between alignment in Sagittal femoral angle (SFA) and change in OKS score.					
Aligned	192	34.341	32.878 – 35.803	Ref	Ref
Flexion	269	34.973	33.870 – 36.076	0.492	p>0.05
Extension	13	29	23.915 – 34.085	0.065	p>0.05
Association between alignment in Sagittal tibial angle (STA) and change in OKS score.					

Aligned	324	34.495	33.437 – 35.552	Ref	Ref
Malaligned	150	34.547	33.055 – 36.039	0.957	p>0.05

Table 2: The association between alignment and OKS scores at 6 months.

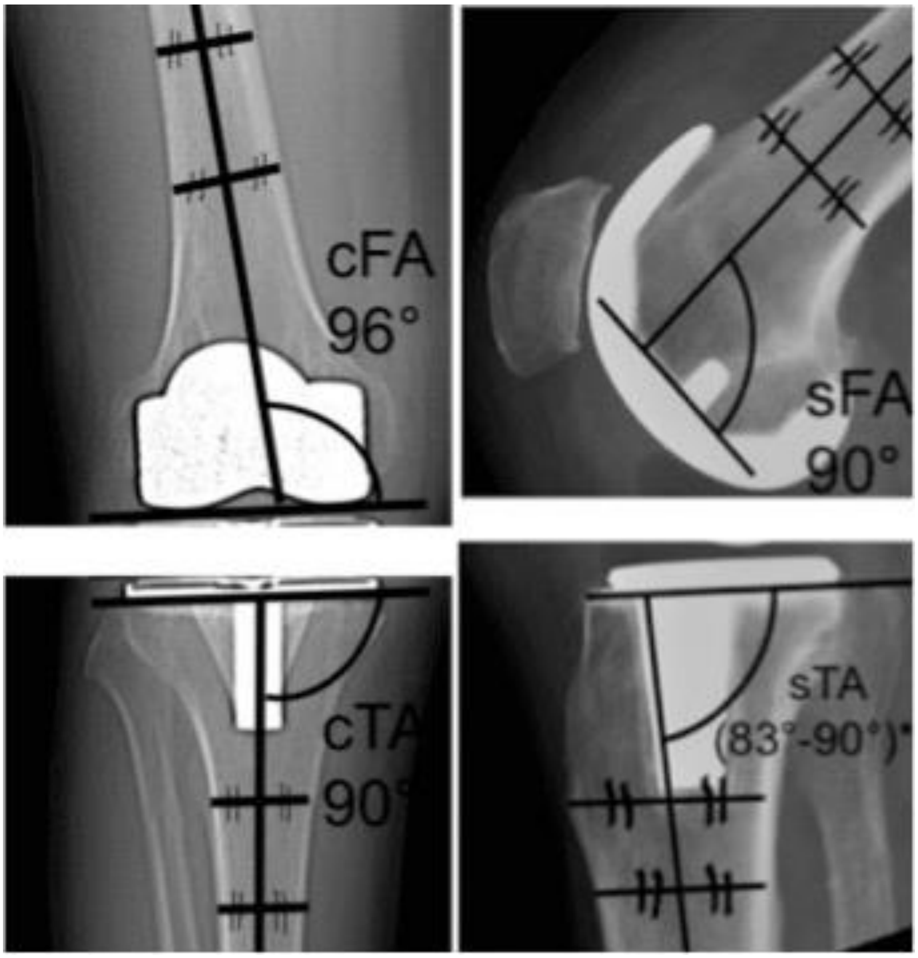
Association between tibial component <u>overhang</u> and six month OKS score				
	Number	Six month OKS	Confidence Interval	Independent t test
Any degree of overhang				
Well positioned	125 (27%)	34.474	32.846 - 36.101	
Overhang	120 (25%)	34.318	32.642 - 35.995	P=0.387
Medial aspect				
Well positioned	255 (55.0%)	34.069	32.792 - 35.346	
Minor Overhang	24 (5.2%)	34.553	30.571 - 38.534	P=0.841
Severe Overhang	14 (3.0%)	37.288	33.777 - 40.708	P=0.351
Lateral aspect				
Well positioned	203 (43.8%)	34.551	33.292 - 35.810	
Minor Overhang	64 (13.8%)	34.792	31.715 - 37.869	P=0.873
Severe Overhang	77 (16.6%)	37.818	34.220 - 41.417	P=0.11

Table 3: **Association between tibial component <u>overhang</u> and six month OKS score**

Association between tibial component <u>underhang</u> and six month OKS score				
	Number	Six month OKS	Confidence Interval	Independent t test
Any degree of underhang				
Well positioned	125 (27%)	34.474	32.846 - 36.101	
Underhang	219 (47%)	33.967	32.594 - 35.339	0.758
Medial aspect				
Well positioned	255 (55.0%)	33.992	32.699 - 35.285	
Minor underhang	90 (19.4%)	35.612	33.457 - 37.767	P=0.202
Severe underhang	81 (17.5%)	34.041	31.597 - 36.486	P=0.971
Lateral aspect				
Well positioned	203 (43.8%)	34.509	33.254 - 35.764	
Minor underhang	54 (11.6%)	33.746	30.908 - 36.584	P=0.599
Severe underhang	67 (14.4%)	33.364	30.883 - 35.845	P=0.39

Table 4: **Association between tibial component <u>underhang</u> and six month OKS score**

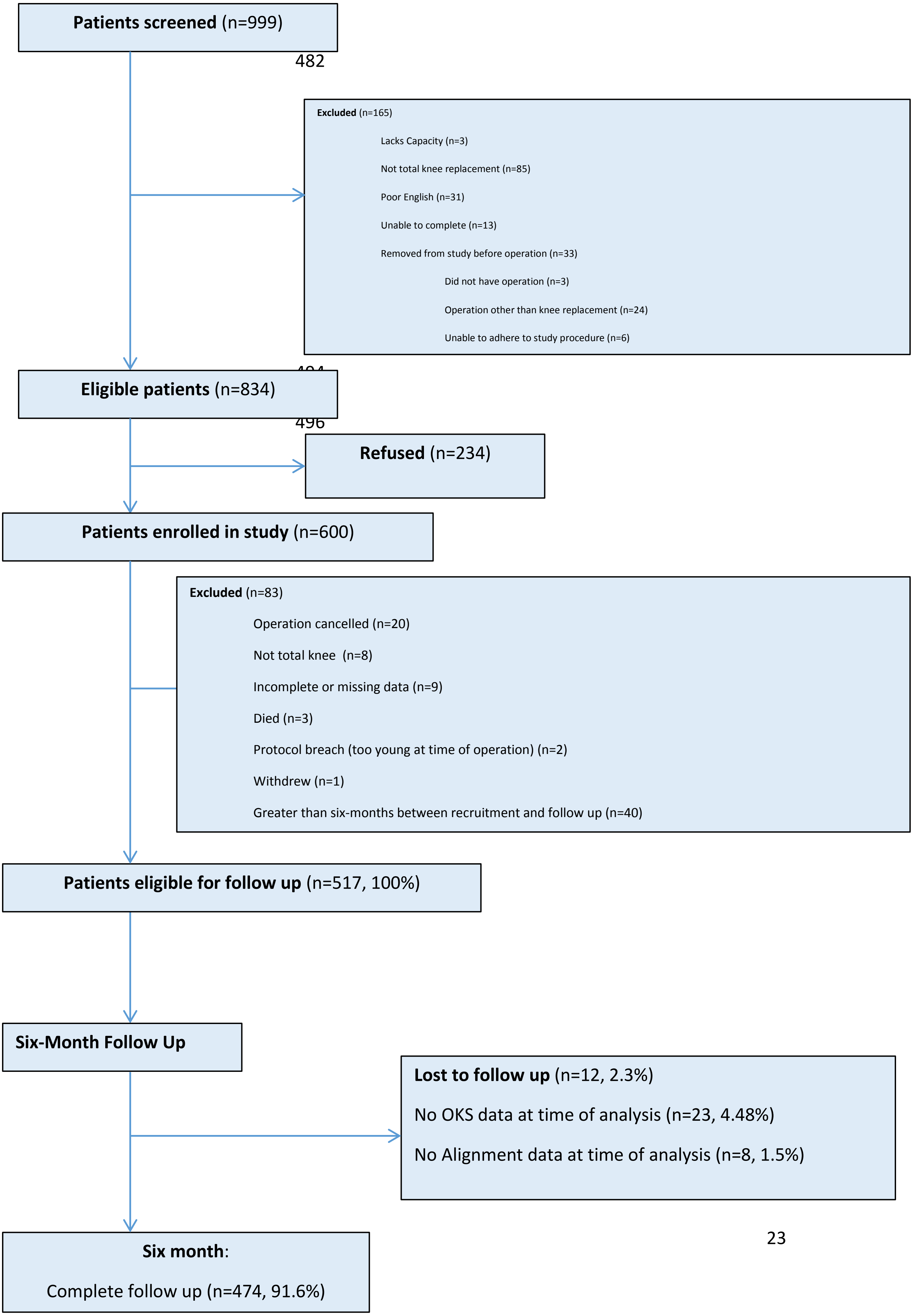
Figure 1: Malalignment of the tibial component in the coronal plane.



a b

Figure 2:
A diagrammatic representation of different alignment parameters based on The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. The coronal tibial – femoral anatomical axis (1a) is a combination of the coronal femoral axis (cFA) and the coronal tibial axis. The sFA (1b) is the angle between a where a line which bisects the medullary canal of the femur bisects a line which crosses the condyles of the femoral component. sTA represents the angle between where a line running between the centre of the tibia bisects a line drawn across the femoral component

Figure 3: Flow of patients through the study



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