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Original Research

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☆

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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.

1. Introduction

Total knee replacement (TKR) is a definitive means of treating symptomatic end stage 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 one year 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° ± 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]. Fig. 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 (> 3 mm) has been shown to be associated with a two-fold increase in knee pain 2 years

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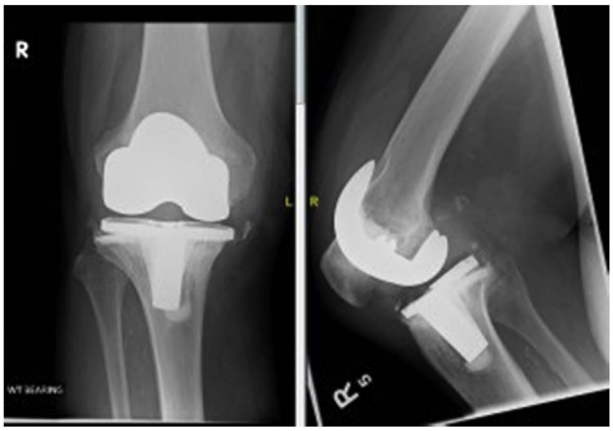

Fig. 1. Malalignment of the tibial component in the coronal plane.

post operatively [14]. Within the context of unicompartmental knee replacement an overhang of greater than 3 mm 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].

2. Aims

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

3. Methods

3.1. 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.

3.2. Inclusion criteria

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

3.3. 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.

3.4. 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.

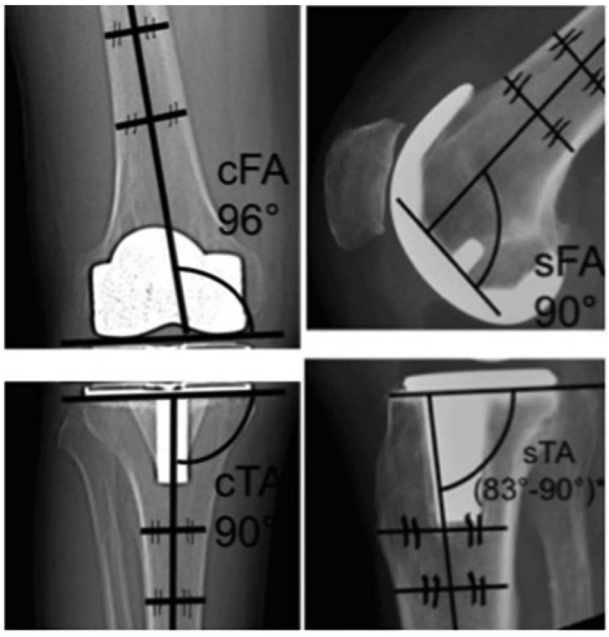

Fig. 2. A diagrammatic representation of different alignment parameters based on The Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System. The coronal tibial – femoral anatomical axis [1a] is a combination of the coronal femoral axis (cFA) and the coronal tibial axis. The 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.

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.

3.5. 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 (Fig. 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:
  - o Aligned group – 92–98°
  - o Varus < 92°
  - o Valgus > 98°
- Coronal tibial angle: