



**Journal Club:** 18 August 2015

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**Theme:** Kinematic alignment in total knee arthroplasty

**Dowsett HG, Estrada NA, Swartz GJ, LeFevre GW, Kwasman BG.** A randomised controlled trial of kinematically and mechanically aligned total knee replacements. *Bone Joint J* 2014;96-B:907-913.

### **Importance**

Kinematic alignment (KA) describes the positioning of the implants during total knee arthroplasty, to reflect the patient's pre-arthritis anatomy and reduce the need for soft-tissue releases. As opposed to the more traditional principles of mechanical alignment (MA), which aims to position all TKAs perpendicular to the mechanical axis of the limb, KA recognises that there is great variation in the natural alignment of the knee, with less than 4% of patients having a knee that is naturally aligned in the position resultant from a MA procedure.

Our unit has trialled the use of KA with mixed results. However, there is a belief that many of the principles could have importance to our continued understanding of the optimal joint arthroplasty.

### **Summary**

- This single-centre, double-blinded RCT from Phoenix, Arizona compares the outcomes of a group of kinematically-aligned TKAs (performed with patient-specific instrumentation) with a mechanically-aligned group

- A total of 88 patients (44 in each group) are presented with a minimum follow-up of 2 years
- The main findings are of improved function (Oxford Knee Score 40 vs 33, WOMAC 15 vs 26, KSS 160 vs 137), improved flexion (121 vs 113 degrees), and greater walking distance prior to discharge in the kinematically-aligned group
- They also demonstrate an improved odds ratio of having a pain-free knee with a kinematically-aligned knee using the pain questions of the OKS (OR = 3.3) and WOMAC (OR = 4.9)

## REVIEW

### **Purpose of this paper**

- This paper has clearly-defined intentions to look for a difference between the two techniques
- The primary aim is well-defined with the null hypothesis suggesting no difference in pain, function and range of motion between the groups at two-years
- The secondary hypothesis is also included, which seems to look for any other difference (in a range of outcomes from blood loss to need for further surgery) between the groups

### **Methodology**

- Ethical approval was achieved. This RCT had been performed using robust methods with clear definition of the randomisation process, and blinding of both patients and the observer
- A retrospective power calculation had been performed suggesting that the groups were appropriately-sized to demonstrate a difference
- The statistical methods appeared thorough with consideration of the distribution of data and the appropriate tests applied
- An intention-to-treat analysis had been performed (although only one patient changed groups)
- The groups appeared well-matched with similar descriptive statistics displayed in a table
- The methods were described in detail, with both groups having pre-operative MRI scans (for patient-specific implants), the MA group performed using intramedullary guides (5-degrees

valgus, 3-degrees external rotation), and both groups receiving the same implants (Vanguard, Biomet)

- The post-operative alignment was judged on CT

## RESULTS

- Summary statistics are presented with means and standard deviations
- Overall the KA group's implants were found to be aligned with the femur in 2-degrees of valgus and the tibia in 2-degrees of varus. However the individual data is not shown
- Significant differences are highlighted with p-values  $< 0.05$
- There is no mention of the accuracy of the KA group (intended alignment vs achieved alignment)

## CRITIQUE

This paper is well-considered and provides a valid answer to a relevant question. The methods are robust, and therefore the differences found are likely to be true. The functional scores used are appropriate and, with differences found in all scores used, the findings are persuasive. However, some deficiencies are identified. It is not clear whether these were not considered, or were simply unreported.

### **Strengths of the study**

- Single implant and small number of surgeons
- Blinding of participants and reviewers
- Standardised pre-operative investigations (MRI for both groups) and post-operative rehabilitation programme
- Power calculation (retrospective)
- Functional scores used relevant to condition
- Complete follow-up of both groups

- Intention-to-treat analysis performed

### **Weaknesses of the study**

- Lack of information about reasons for patient drop-out prior to procedure
- No consideration of minimum clinically-important difference for scores or differences in flexion achieved
- Definition of 'Pain-free' (0 scored for all pain questions) may not be the same as patient being 'untroubled' by pain
- Some of the secondary variables (drop in haemoglobin level, distance walked prior to discharge) seem fairly non-specific and it is unclear how many other such variables were considered
- No recording of how accurately KA and MA achieved

### **CONCLUSIONS**

The authors make valid conclusions about the superiority of the KA group and the relevance of their findings. They also acknowledge limitations of their study – mainly male population, limited follow-up, exclusion of post-traumatic patients. They discuss the potential for differences to be attributable to the patient-specific implants used in the KA group (rather than the difference in alignment).

The reported short-term results suggest a clinically-relevant improvement in patient outcomes with KA in total knee arthroplasty. However, the longer-term implications of an oblique joint-line in terms of wear and failure are not answered by this paper. Therefore this seems a promising concept but the full implications cannot yet be assessed fully.

### **Additional queries and discussion by Mr Jonathan Phillips**

How many outliers were in the KA group?

- Mean values presented with small variance from the MA group

- How many were positioned further away from an MA position? What was the effect of this on their function?

Is an Oxford Knee Score of 33 low for 2 years post-TKA?

- Although comparison is made with previous studies using OKS as outcome, 33 seems a low mean score for the MA group. Is there a reason for this? Are there significant outliers in either group that affect this data?

Were there problems with the patient-specific instrumentation?

- How did pre-operative templates compare to the post-operative alignment found?
- What was the effect of differences in this?
- A limitation of previous studies has been inaccuracy of instrumentation – Are the authors reporting more accurate reproduction of KA or better function despite the limitations of this?

Use of retrospective power calculations

- Recognised methodology with some relevance to validity of results
- Pilot study needed to determine alpha and beta values for calculation prior to commencing the trial – not described in this paper
- Power calculation in this study only with reference to OKS. Other variables may require separate consideration

### **Overall conclusion**

- A well-designed study with excellent follow-up
- Appropriate end points selected
- Although it shows a benefit of kinematic alignment, it only has a follow-up of 2 years, and long-term survivorship of non-mechanically aligned TKAs is unknown
- This is clearly a good starting point for investigating kinematically-aligned TKAs