THE EARLY OUTCOME OF MECHANICAL VERSUS KINEMATIC ALIGNMENT OF TOTAL KNEE ARTHROPLASTY: A PROSPECTIVE RANDOMISED CONTROL TRIAL

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Abstract

We performed a prospective double-blind randomised controlled trial to compare the functional outcome of patients receiving a total knee arthroplasty (TKA) in mechanical alignment (MA) with that of kinematic alignment (KA). A total of 71 patients undergoing TKA were randomised to either MA (n=35) or KA (n=36). The knee injury and osteoarthritis outcome score (KOOS), Euro-Qol (EQ-5D), range of motion (ROM), two minute walk, and timed up and go tests were assessed pre-operatively, 6 weeks, 3 months, 6 months, and one year.

There were no significant differences in the patient demographics or pre-operative outcome scores between the two groups ($p>0.1$). There were no statistically significant differences in the KOOS (difference 1.3, 95% confidence interval (CI) -9.4 to 12.1, $p=0.80$), EQ-5D (difference 0.8, 95% CI -7.9 to 9.6, $p=0.84$), ROM (difference 0.1, 95% CI -6.0 to 6.1, $p=0.99$), two minute distance tolerance (difference 20.0, 95% CI -52.8 to 92.8, $p=0.58$), or timed up and go (difference 0.78, 95% CI -2.3 to 3.9, $p=0.62$) between the MA and KA groups at one year.

No functional difference was observed between MA and KA of TKA, however this represents the early outcome and longer follow up is required to ensure these results are observed into the long-term.

Keywords: Total knee arthroplasty, kinematic, mechanical, alignment, outcome, function

Introduction

The number of total knee arthroplasty (TKA) performed in the UK has been increasing year on year with excess of 90,000 being recorded by the national joint registry of England, Wales and Northern Ireland in 2013 (1). The 10-year revision risk for cemented, unconstrained fixed bearing TKA is just over 3% (1). TKA is now a more common procedure than total hip arthroplasty but patient satisfaction following TKA surgery remains inferior (2-5). The cause of this comparatively higher patient dissatisfaction is not clear. The knee is a complex joint involving movement in six degrees of freedom. Errors in rotation (flexion and extension, external and internal rotation, varus and valgus angulation) and translation (anterior and posterior glide, medial and lateral shift, compression and distraction) of the implant can lead to alteration in knee kinematics, potentially compromising patient outcome.

The concept of mechanical alignment (MA) was developed by Insall (6), in an attempt to improve survivorship of the early rudimentary designs of TKA. Distribution of the load evenly across the prosthesis was thought to confer mechanical advantage to the implant, ignoring the patient's natural anatomy. Due to the limitations in prosthesis design and accurate alignment analysis, the success of a TKA has historically been measured by implant survivorship, largely attributed to implant alignment in the coronal plane. Surgeons have had to rely on radiographs to analyse alignment. As a result of this, a disproportionate amount of research has focused on alignment in the coronal plane only and the relationship the implant has to the mechanical axis. Deviation from neutral overall alignment (NOA) in the coronal plane has previously been thought to contribute to reduced survivorship of the implant (7-10). As a consequence of this, recent technology has focused on ways to more accurately reproduce NOA. Computer navigated one was such innovation that has improved accuracy of alignment (11,12), but significantly this has not been translated into improvement in functional outcome or patient satisfaction (13-15). Current data from the national joint registries demonstrates that implant survivorship is no longer comparable to the early designs (1), and recent research has suggested that deviation from NOA does not have the detrimental effects on implant survivorship as previously thought (13,16,17).

Improvements in imaging have led to an increased understanding and appreciation of alignment in TKA by being able to assess the joint in three dimensions. Computerized tomography (CT) has now become the gold standard for measuring alignment (18). The concept of what constitutes normal alignment has been revisited and it has been demonstrated

that 32% of men and 17% of women have constitutional varus knees with a natural MA of three degrees or more (19). The use of more detailed imaging has called into question established reference landmarks regarding alignment. Eckhoff's studies of the knee concluded that the axis of the leg is not straight and the true flexion and extension axis does not correspond with the eipcondylar axis (20-23). Coughlin (24) established a direct correlation between the flexion and extension axis and the patella axis. The use of both magnetic resonance imaging (MRI) and CT imaging modalities has also lead to the development of patient specific instrumentation (PSI). Computer software is used to create a 3-dimensional reconstruction of the patient's knee from which custom fit cutting blocks are produced to assist the surgeon in making their desired femoral and tibial cuts. The concept of trying to implant the prosthesis in such a way as to recreate the limb alignment in the pre-arthritic state has been termed natural or kinematic alignment (KA). There is however conflicting evidence as to whether KA of TKA results in improved early functional outcome relative to traditional MA .(ref Dosset 2012/14, and Abdel 2014)

The primary aim of this study was to compare the early (one year) functional outcome, as assessed by the Knee Injury and Osteoarthritis Outcome Score, for KA TKA with that of MA TKA. Secondary aims were to compare the functional outcome of KA TKA with that of MA TKA using the University of California at Los Angeles activity score, forgotten knee score, EuroQol-5D, Short Form 36 health and quality of life forms, American knee society score, and defined functional tasks. The null hypothesis was that KA TKA was not associated with superior functional outcome results when compared to MA TKA.

Patients and Methods

Ethical approval for this study was obtained from the National research ethics service committee Cambridge East.

Patients were recruited from the waiting list of three consultant orthopaedic surgeons (KES, VIM, ADT) at the study centre between December 2011 and April 2013. The inclusion criteria for enrolment was a patient age of 18-85 years with a diagnosis of Osteoarthritis causing degenerative joint disease. Patients were exclude if they had: a varus or valgus deformity greater than 10^{o} or flexion contracture greater than 20^{o}; if they had received any orthopaedic surgical intervention to the lower extremities within the past year at the time of enrolment; a history of unsuccessful contralateral partial or TKA; any implanted device that would be

incompatible with MRI procedures; a neuromuscular or neurosensory deficiency; a diagnosis of a systemic disease or metabolic disorder leading to progressive bone deterioration. In addition patients incurring a complication thought to significantly influence their functional outcome, such as deep infection, fracture or extensor mechanism dysfunction were excluded from one year function assessment.

A flow diagram of the patients in the study, prepared according to the CONSORT Guidelines is shown in Figure 1. A total of 86 patients fulfilled the criteria and were recruited to the study. Of these 71 (83%) underwent surgery and were followed up for one year. Seven patients were recruited but were withdrawn due to a medical device class1 recall in April 2013. Four patients were lost to follow up. One patient decided against having an operation, another patient opted for a patella-femoral joint replacement. One patient decided they wanted KA TKA so withdrew. A single patient sustained a post-operative quadriceps rupture and was withdrawn from functional assessment.

Patients who fulfilled the inclusion criteria to the trial were provided with a patient information booklet outlining the details of the surgery and follow up requirements. A true random number generator program was used and cards displaying the numbers 1 (for KA) or 2 (for MA) were placed in sealed envelopes. Following signed consent from the patient's to enter the study they were allocated an envelope that was opened in sequence. All patients were seen at a pre-operative clinic and then at 6 weeks, 3 months, 6 months and 1 year post operatively by a research physiotherapist who was blinded to the patients treatment modality. At each appointment patients were asked to complete the joint specific Knee Injury and Osteoarthritis Outcome Score (KOOS) as well as the University of California at Los Angeles activity score (UCLA), the forgotten knee score, the EQ-5D and SF-36 health and quality of life forms. The physiotherapist completed the American knee society score (AKSS) measuring range of motion with a goniometer. An assessment laboratory was used to measure a number of functional tasks performed by the patient (Figure 2).

Patients who were randomised into the KA group then had an MRI scan arranged pre-operatively. Following the MRI scan the surgeon was then sent a surgical plan with the proposed alignment for that patient (figure 3). Once the plan was accepted the patient specific cutting blocks were produced. The TKAs were performed either with the patient specific cutting blocks with the aim of achieving KA or standard extra and intramedullary instrumentation to achieve MA. The Triathlon TKA design was implanted in both groups. A medial parapatellar approach without the use of tourniquet was performed. The post-operative protocol was identical for both groups. Surgery was performed by one of three consultant

orthopaedic surgeons (KES, VIM, ADT) who were familiar and experienced with both techniques.

Statistical analysis. The study was powered to demonstrated a 19 point difference in the KOOS score which has been defined as the minimal clinical important change in the score (25). Assuming a 15 point standard deviation in the score (26) a size effect of 0.66 was used to power the study. Using a one tailed analysis (assumed superior results with the KA group) and an alpha of 0.05 with a power of 0.80 the determined total sample size required was 60 patients (30 in each arm). Assuming a fifteen percent loss to follow up at one year a total of 70 patients would need to be recruited to meet the required numbers. The functional assessment and patient reported outcome scores are presented as means with standard deviations (SD), with 95% confidence intervals. Differences between the two groups of patients were analysed using unpaired t-tests and multiple analysis of variance (MANOVA) for improvement at four time points after surgery. SPSS version 17 software was used (SPSS Inc., Chicago, Illinois). A p-value of <0.05 was defined as clinically significant.

Results

The Patient reported primary outcome measures of the KOOS, AKSS, ULCA, SF-36, and EQ-5D are illustrated in Tables I to V. The KOOS score demonstrated a greater improvement in the KA group at 6 weeks when compared to the MA (p=0.05), but at 1 year there was no significant difference (p=0.42). There was no significant difference in the functional component of the AKSS, between the two groups, at any of the time periods post operatively. There was no significant difference in the UCLA scores at any of the post-operative follow up assessments. The physical function component of the SF-36 demonstrated a slight improvement in the KA group compared to the MA group at 6 months post-operatively (p=0.04), but this had been negated by 1 year (p=0.45). There was no significant difference between the two groups at any stage of the EQ-5D.

The results of the physical function tests performed in the gym demonstrated a similar trend. The TUG test demonstrated no significant difference pre-operatively or at any point during the follow-up (Figure 4). The two minute walking distance test failed to demonstrate any significant difference at one year post-operatively (0.58) (Figure 5). The timed up and down stairs test demonstrated no significant difference at any stage post-operatively between the KA and MA groups (Figure 6). The myometre measurements of peak torque in the quadriceps demonstrated that in the early post-operative period the KA group were significantly better at 6 weeks and 3 months (p=0.003 and p=0.02 respectively) although this

difference was negated by 1 year (p=0.26, Figure 7). At the 6 week and 3 month post-operative assessments the MA group decreased their quadriceps peak torque in comparison to their pre-operative strength (Figure 8). This trend was not seen in the KA group. The peak hamstring torque results demonstrated that both groups became weaker at 6 weeks, 3 months and 6 months post-operatively and only at one year post-operatively did they exceed their pre-operative peak torque. There was no significant difference in the patient's range of knee motion (Figure 9), ability to kneel, or walk across an uneven surface at any point.

Discussion

This study has demonstrate no significant difference in the early functional outcome of KA TKA over conventional MA TKA as performed on an unselected cohort of patients with endstage noninflammatory arthritis of the knee. There were however trends towards earlier functional improvement at 6 weeks for some of the outcome measures (KOOS and peak torque of the quadriceps) assessed in the KA group, but this was not maintained at the one year assessment. Significant improvements were observed in both the joint specific and generic outcome measures for both groups relative to their pre-operative scores.

A huge amount of research has been undertaken correlating patient outcome with alignment of the TKA prosthesis. Since the advent of computer navigation and subsequently PSI, the ability to implant the TKA with greater accuracy has improved (11,12). This greater accuracy of MA has not translated into improved patient outcome (13-15). More detailed pre-operative imaging techniques and a better understanding of what constitutes a patient's normal alignment and flexion axis has led to the possibility of trying alignment methods different from that of the standard MA. The expectation of a more natural alignment was to improve patient outcome. The concept of KA had been used in the US with some positive early results (27,28). In our study we used a comprehensive number of both joint specific and generic health scores in the form of the KOOS, AKSS, ULCA, SF-36 and EQ-5D to assess outcome. In addition to these patient reported outcome measures (PROMs) we used validated function tests performed in the gymnasium. The theory behind this was that, although labour intensive to perform and record, these functional tests may give more subtle variations in the patient's performance pre and post operatively and obtain more detailed information. However, despite this barrage of assessment tools no significant difference was demonstrated between KA and MA TKA.

The general trend in results was that both groups significantly improved at 1 year post operatively compared to pre-operatively but there was no significant differences between KA and MA. It is interesting to see that the PROMs of the ULCA, KOOS and SF-36 all

demonstrated a steady improvement over the course of the post-operative period. As did the 2 minute walk test and the timed get up and go test. This is in contrast to the quantifiably measured functions of range of motion and hamstring and quadriceps torque, all of which decreased during the first 3 months post operatively before then improving. This could be attributed to pain relief as a consequence of the TKA resulting in improved patient's perception of function.

Dossett et al (29,30) published 6 month and then 2 year results of a similar randomised control trial of KA versus MA and was able to demonstrate a significant improvement in the outcome of the KA group at both time points. They assessed a different TKA (Vanguard) and used differing outcome measures, which may account for the contrasting results. In addition differences in patient demographics between UK NHS patients and private USA may exist with differing expectations, which has been demonstrated to affect outcome (Clement 2015). It is interesting to note that in Dossett's paper the pre-operative scores were universally better in the KA group than the MA group. Abdel et al also published a similar randomised control trial assessing the outcome of KA versus MA, using Negev1 LPS-Flex mobile, at 3 months using similar patient reported outcome measures as presented in the current study. They also demonstrated no significant difference between the groups, but this was at an early time point and was retrospectively powered to demonstrate a difference in the Knee Society Score. Our study affirms the findings of Abdel et al are observed at one year, where functional outcome has reached the likely optimal status (Williams DP 2013), using a prospectively powered study. This study and those of Dossettet al and Abdel et al represent robust level one evidence and although offer conflicting evidence demonstrate that KA results in an early functional outcome that is equal to that of MA. This supports the assertion that accurately recreating MA does not necessarily correlate with improved outcome (14).

There are limitations with this study. A weakness of this study and the Dossett papers are that both have not assessed the accuracy of the cutting blocks. Small deviations from the desired alignment may have effected patient outcome. It is possible that a type II error could have occurred if the KA knees did not vary significantly in their alignment in comparison to the MA knee. A previous study (31) assessing KA TKA demonstrated that the average mechanical Lateral Distal Femoral Angle (mLDFA) and Medial Proximal Tibial Angle (MPTA) of 110 MRI plans for KA knees was 87.82 degrees and -87.10 degrees respectively, so the assumption was that there would be a significant difference, but there would be scope for future research to investigate this.

Follow up of one year is useful in terms of predicting long-term functional outcome (32), but longer follow up is required to assess if KA will have an effect on survivorship. This study recruited an unselected cohort of patients and was not powered to assess specific subgroups that may benefit from KA. Further research is required to see if pre-operative alignment effects outcome in KA TKA. This study was however preceded and powered by a pilot study with a low loss to follow-up, with no conflict of interest.

There were no catastrophic failures in the KA group as may have been feared from the early alignment literature (10). Theoretically trying to reproduce more naturally aligned TKAs appears a logical progression to try and improve patient outcomes, however this randomised control trial failed to demonstrate any discernible difference between TKAs implant in KA and MA. Mid to longer term follow up is required to affirm the equivocal functional outcome and that survival of the TKA is not compromised by KA relative to MA.

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