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A randomised controlled trial of kinematically and mechanically aligned total knee replacements

TWO-YEAR CLINICAL RESULTS

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We have previously reported the short-term radiological results of a randomised controlled trial comparing kinematically aligned total knee replacement (TKR) and mechanically aligned TKR, along with early pain and function scores. In this study we report the two-year clinical results from this trial. A total of 88 patients (88 knees) were randomly allocated to undergo either kinematically aligned TKR using patient-specific guides, or mechanically aligned TKR using conventional instruments. They were analysed on an intention-to-treat basis. The patients and the clinical evaluator were blinded to the method of alignment.

At a minimum of two years, all outcomes were better for the kinematically aligned group, as determined by the mean Oxford knee score (40 (15 to 48) *versus* 33 (13 to 48); p = 0.005), the mean Western Ontario McMaster Universities Arthritis index (WOMAC) (15 (0 to 63) *versus* 26 (0 to 73); p = 0.005), mean combined Knee Society score (160 (93 to 200) *versus* 137 (64 to 200); p= 0.005) and mean flexion of 121° (100 to 150) *versus* 113° (80 to 130) (p = 0.002). The odds ratio of having a pain-free knee at two years with the kinematically aligned technique (Oxford and WOMAC pain scores) was 3.2 (p = 0.020) and 4.9 (p = 0.001), respectively, compared with the mechanically aligned technique. Patients in the kinematically aligned group walked a mean of 50 feet further in hospital prior to discharge compared with the mechanically aligned group (p = 0.044).

In this study, the use of a kinematic alignment technique performed with patient-specific guides provided better pain relief and restored better function and range of movement than the mechanical alignment technique performed with conventional instruments.

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Reports from Canada[1] and England and Wales[2] have shown that up to 20% of patients are not satisfied after total knee replacement (TKR). Recent developments have included the individualisation of alignment of the components using pre-operative imaging and computer software, with the goal of achieving pre-arthritic alignment through restoration of the axes of rotation.[3-5] The outcomes of this alignment have been assessed in case series[6-8] but so far no randomised controlled trial has compared the clinical results of kinematic alignment with the traditional technique of mechanical alignment.

This randomised controlled trial was designed to compare kinematically aligned TKR performed with patient-specific guides and mechanically aligned TKR performed with conventional instruments, with the null hypothesis that there would be no difference in pain, function or range of movement (ROM) at two years post-operatively between the two groups.

A secondary hypothesis was that there would be no difference between the two groups as assessed by blood loss, distance walked prior to discharge from hospital, length of stay, and frequency and type of further minor and major operations.

Some early results have been previously reported for 82 patients who completed a six-month follow-up evaluation.[9] Here we have included the alignment information for the limb, knee and components for 88 patients who completed a two-year intention-to-treat follow-up, to ascertain whether a difference in alignment between the two groups is associated with a difference in pain, function and ROM.

Patients and Methods

The study had ethical approval and the patients provided informed consent. A total of 120 patients eligible for TKR with end-stage arthritis of the knee were prospectively enrolled in the study between January 2008 and August 2009. They were randomised by an opaque sealed envelope method to receive either kinematically aligned TKR with

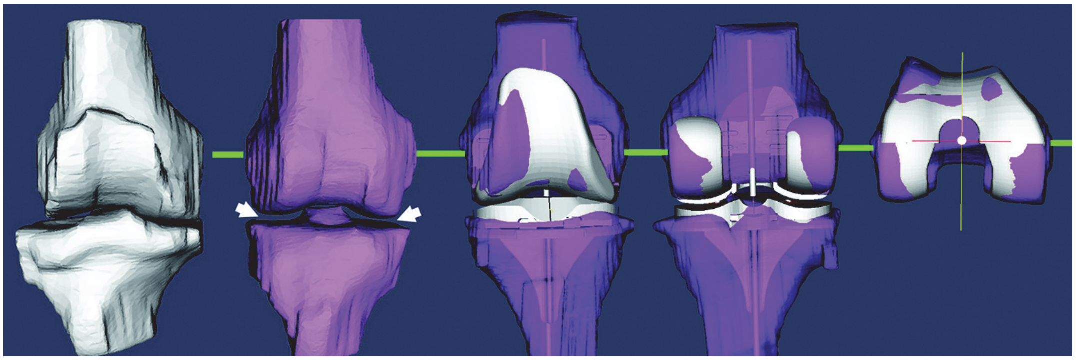

Fig. 1

Composite showing a three-dimensional model of an 'arthritic' knee (first from the left), a model of a normal knee (second from the left), and a femoral component shape-fitted to anterior, posterior and axial projections of the femur (last three to the right). Shape-fitting the femoral component aligns its flexion-extension axis in the femur, about which the tibia flexes and extends with the femoral component.

patient-specific guides or mechanically aligned TKR using conventional instruments. Exclusion criteria included previous fracture of the femur or tibia, infection, previous joint replacement or osteotomy involving the knee, or a medical condition precluding surgery. Patients who required a bilateral procedure and those who could not undergo MRI of the knee were also excluded. A total of 44 patients underwent kinematically aligned TKR and 44 underwent mechanically aligned TKR by two authors (HGD, GJS) who were trained in both approaches and who acted as surgical assistant to each other. Data were analysed on an intention-to-treat basis.

Outcome was assessed using the Oxford knee score (OKS, 0 to 48 worst to best),[10] the Western Ontario and McMaster Universities Arthritis Index (WOMAC, 0 to 96 best to worst) score[11] and the combined Knee Society score (KSS, 0 to 200 worst to best).[12]

In order to blind the patients, those in both groups had the same clinical evaluations and MRI scans of the knee pre-operatively. Standing coronal radiographs of the knee were performed with the patellae pointing forward and the anatomical alignment of the knee was recorded by the two surgeons using Picture Archiving and Communication system (PACS). A cemented posterior cruciate-retaining prosthesis with patellar resurfacing was used in all patients (Vanguard, Biomet, Inc. Warsaw, Indiana). The same length of incision, usually 16 cm and exposure were used for both groups. All patients underwent rotationally controlled post-operative CT scans of the lower limb during the hospital stay. Blood loss was calculated by subtracting the lowest post-operative haemoglobin recorded during the hospital stay from the pre-operative value. The distance walked prior to discharge was the furthest that the patient walked with a wheeled walker, as recorded by the physiotherapist. The frequency and type of further procedures were recorded. Major further operations involved the removal or revision of the components, and minor further operations included all other procedures in which the components were retained.

The concept of kinematic alignment is based on the kinematic axes of the knee and their relationship to the femoral condyles.[3,4,13] The femoral and tibial components are introduced in such a way that the angle and level of the distal and posterior femoral joint lines and the tibial joint line are restored to the natural alignment for each patient using patient-specific guides.[5,13,14] The process of creating these guides begins with a standardised MRI protocol of the knee. The projection of the knee in the MRI scanner is such that the plane of the oblique sagittal image is perpendicular to the primary axis in the femur, about which the tibia flexes and extends. Proprietary software is then used to create a three-dimensional model of the knee (Fig. 1). The 'arthritic' model is transformed into a 'normal' model by filling articular defects and equalising the gap between the medial and lateral compartments of the knee. Equalising the gap restores the joint line and the alignment of the knee and lower limb to the normal pre-arthritic state. An algorithm shape fits the best-fitting 3D model of the femoral component to the articular surface of the 3D model of the 'normal' femur, with a reproducibility of ± 0.5 mm for translations and ± 0.5° for rotations (OtisMed Inc., Alameda, California). The software sets the anteroposterior (AP) axis of the tibial component perpendicular to the flexion–extension axis of the femoral component, which kinematically aligns the two components. The tibia is centred kinematically beneath the tibial component. The guides which create the bone cuts are designed to fit onto the arthritic knee and are manufactured from medical-grade plastic.

The patient-specific guides were sterilised according to the manufacturer's instructions, opened within the sterile field, and the specific patient identifiers on the guides were visually confirmed. Two trays of instruments and trials of the correct size were required for each procedure. The guides were made to fit to the patient's knee in one specific position according to the arthritic anatomy, and were accurately placed by the surgeon on the femur and tibia. No release of the medial or lateral collateral ligaments was performed; however, the medial and lateral capsules were

Table I. Overview of the participants who were randomly assigned to each group; the number of patients who received the intended treatment or were excluded after randomisation, with reasons; the number who were lost to follow-up after the intended treatment, with reasons; and the number, who were analysed on an intention-to-treat basis.

	Participants	Participants
	Allocated to kinematically aligned group (n = 60)	**Allocated to mechanically aligned group (n = 60)**
Baseline status		
Response	60	60
Non-response	0	0
Treatment received		
Received allocated intervention	44	44
Did not receive allocated intervention	16	16
Reasons:		
Withdrawn from surgery	12	14
Crossover to other intervention	1	0
Received non-trial intervention	3	2
Two-year status		
Response	44	44
Non-response	0	0

released at the margins of the menisci. The posterior cruciate ligament was retained. The distal femoral cut was made through the slot of the patient-specific guide. The conventional 4-in-1 cutting block that matched the size of the planned femoral component was placed into the two-guide pinholes in the distal femoral articular surface. The tibial patient-specific guide was then secured by drilling two pins through the pinholes on the proximal surface of the tibial guide, and and two in the anterior surface. The tibial cut was made through the slot in the guide, and marginal osteophytes were removed. Trial components were introduced, and the ROM of the knee, stability, rotation of the components, posterior cruciate ligament tension, patellar tracking (without applying any digital pressure) and flexion–extension gaps were checked. The tibial component was aligned parallel to the pinholes which had been drilled through the proximal surface of the guide. The definitive components were introduced with cement and a final check of the ROM etc was made.

The mechanically-aligned TKR was performed with the goal of achieving a neutral coronal mechanical limb alignment by making the femoral and tibial bone cuts perpendicular to the mechanical axes. The operation was conducted according to the manufacturer's instructions (Biomet Inc). In all, nine instrument trays were used for each procedure. The distal femoral cut was made using an intramedullary alignment system, with the angle of the distal resection set at 5° valgus.[15] The posterior femoral cuts were made with a referencing guide set at 3° of external rotation. The proximal tibial cut was made with an intramedullary alignment system (n = 43). An extramedullary system was used in one patient with severe varus bowing. Significant posterior osteophytes were removed. Trial components were introduced, and the ROM of the knee and other intra-operative parameters were checked as described above. Release of the collateral and retinacular ligaments was performed when necessary to balance the flexion and extension gaps, and provide satisfactory patellar tracking, at the discretion of the surgeons. In order to reduce intra-articular bleeding, the hole for the femoral intramedullary guide was plugged with bone. The definitive components were introduced with cement, and a final check of the ROM etc was made.

Post-operative management was identical for both groups. The patients, physiotherapists and nurses were blinded to method of alignment which had been used, as also was the radiologist (JC) who analysed the CT scans and the surgeon (BGK) who recorded the OKS, WOMAC and combined KSS scores. The limits of active extension and flexion were measured with a long-arm goniometer with the patient supine.

Statistical analysis. The mean, standard deviation (SD) and 95% confidence intervals (CIs) were determined for each measure in each group. Odds ratios (OR) were determined by logistic regression using Fisher's scoring as the optimisation technique. The effect of the method of alignment (significance of the OR) was evaluated using Wald's chi-squared test with 95% CIs. The difference in the means of the primary outcome measures between the groups were determined using the non-parametric Wilcoxon's signed-rank test for non-normally distributed data, an unpaired *t*-test for normally distributed data, OR and the chi-squared test using statistical software (SPSS Inc.v20, IBM Corp., Armonk, New York, and JMP v11, SAS, Cary, North Carolina). Statistical significance was set at $p < 0.05$. A power analysis was conducted on the intention-to-treat data. Given the mean OKS of 39.5 in the kinematically

Table II. Description of the groups at the beginning of the trial

Baseline demographic and clinical characteristics	Kinematic alignment (n = 44)	Mechanical alignment (n = 44)
Demographics		
Mean Age (years, (SD)(range))	66 (7.7) (51 to 84)	66 (8.6) (47 to 86)
Sex (male) (n (%))	41 (*95.3*)	38 (*88.3*)
Body Mass Index (kg/m^2, (SD))	29 (4.1)	32 (4.9)
Anesthesia Society of Anesthesiologists score (ASA) (n, %) (1 is best, 4 is worst)	2 (10, *22.7*), 3 (34, *77.3*)	2 (10, 22.7%), 3 (33, *75.0*), 4 (1, *2.3*)
Pre-operative motion		
Mean Extension ((°) (SD))	4 (4.0)	3 (5.3)
Mean Flexion (degrees ((°) SD))	117 (12.3)	115 (12.8)
Pre-operative knee alignment		
Mean knee alignment shown in (°) (range)	1.5 (-11.4 to 9.3)	1.8 (-11.9 to 14.2)
Pre-operative clinical outcome scores		
Oxford Knee Score (48 is best, 0 is worst)(mean (SD))	20 (7.4)	18 (6.6)
WOMAC Score (0 is best, 96 is worst)(mean (SD))	53 (15.9)	58 (12.7)
Knee Society Score (100 is best, 0 is worst)(mean (SD))	46 (15.9)	45 (15.6)
Knee Function Score (100 is best, 0 is worst)(mean (SD))	51 (18.3)	46 (16.4)
Combined Knee Society Score (200 is best, 0 is worst)(mean (SD))	97 (27.9)	91 (25.2)

Table III. Clinical outcome scores and movement at two years, with coronal alignment values

	Kinematic alignment (n = 44) Mean ((SD)(range))	Mechanical alignment (n = 44) Mean ((SD)(range))	Difference = Kinematic alignment -Mechanical alignment (95% CI) p-value (Wilcoxon test)
Clinical outcome scores at two years			
Oxford Score (48 is best, 0 is worst)	40 (10.2) (15 to 48)	33 (11.1) (13 to 48)	6.2 (1.7 to 10.7) p = 0.005
WOMAC Score (0 is best, 96 is worst)	15 (20.3) (0 to 63)	26 (22.6) (0 to 73)	-10.7 (-19.8 to -1.5) p = 0.005
Knee Society Score (100 is best, 0 is worst)	84 (17.1) (43 to 100)	72 (21.2) (25 to100)	11.2 (3.1 to 19.4) p = 0.004
Knee Function Score (100 is best, 0 is worst)	77 (19.2) (45 to 100)	65 (21.1) (15 to100)	12.0 (3.5 to 20.6) p = 0.011
Combined Knee Society Score (200 is best)	160 (31.9) (93 to 200)	137 (37.9) (64 to 200)	23.3 (8.4 to 38.1) p = 0.005
Movement at two years			
Extension (°)	2 (3.8) (0 to 15)	3 (3.8) (0 to 12)	-0.4 (-2.0 to 1.2) p = 0.613
Flexion (°)	121 (10.4) (100 to 150)	113 (12.5) (80 to 130)	8.5 (3.6 to 13.4) p = 0.002
Coronal alignment			
Limb: hip–knee–ankle angle	0.1(2.8)(-7.7 to 8.5)	-0.1(2.5) (-8.9 to 4.9)	0.2 (-.9 to 1.4) p = 0.818
Knee: anatomic axis	-3.5(2.3) (-9.5 to 0.1)	-2.9(2.3) (-8.0 to 1.2)	-0.6 (-1.6 to 0.4) p = 0.233
Joint: varus/valgus Inclination of joint	-2.0(2.0) (-6.6 to 3.1)	-0.1(2.7) (-8.4 to 4.1)	-1.9 (-2.9 to -0.9) p < 0.001
Femoral component relative to mech. axis	-1.3(2.0) (-6.5 to 2.4)	0.8(2.7) (-6.3 to 5.8)	-2.2 (-3.2 to -1.2) p < 0.001
Tibial component relative to tibial mech. axis	2.2(2.6) (-4.0 to 8.7)	0.0(2.1) (-3.8 to 6.4)	2.1 (1.1 to 3.1) p < 0.001

aligned group and 33.4 in the mechanically aligned group, and a pooled SD of 10, $\alpha = 0.05$, and power of 0.80, the sample size required for each group was 43.

Results

The number of patients allocated, treated, lost to follow-up and analysed on an intention-to-treat basis in each group is listed in a flow diagram based on CONSORT guidelines (Table I).

Comparison of pre-operative characteristics of the two groups. The mean age, gender, BMI, American Society of Anaesthesiologists Score (ASA),[16] pre-operative alignment of the knee, extension, flexion, OKS, WOMAC, Knee Society, knee function and combined Knee Society scores were similar in the two groups (Table II).

Comparison of post-operative alignment of the two groups. The knee joint alignment for the kinematically aligned group was a mean of 1.9° more valgus compared with the mechanically aligned group ($p < 0.001$) (Table III). The femoral component was a mean of 2.2° more valgus in the kinematically aligned group ($p < 0.001$), and the tibial component a mean of 2.1° more varus ($p < 0.001$) in the kinematically aligned group compared with the mechanically aligned group. The alignment of the knee and limb were similar in the two groups.

Comparison of clinical results of the two groups. There was a statistically significant difference between the two groups for all the scores (Table III). The patients who underwent kinematically aligned TKR had significantly better scores for pain, function and ROM than those who underwent mechanically aligned TKR.

Those in the kinematically aligned group had less pain as assessed by the OKS and WOMAC scores (Table IV).

The mean active extension was similar for the two groups, but in the kinematically aligned group the mean flexion was greater by 8.5° ($p = 0.002$) (Table III).

Blood loss, length of stay and frequency and type of minor and major further operations was similar between

Table IV. Odds ratio of a pain-free knee replacement at two years

	Kinematically aligned TKR	Mechanically aligned TKR
Oxford Knee Score : Pain free is score of 20 on five pain questions		
Describe the pain you usually have from your knee		
How long can you walk before pain becomes severe?		
After a meal, how painful has it been to stand up from a chair?		
Have you been troubled by pain in bed at night?		
How much has pain from your knee interfered with your normal work?		
Pain-free patients (n)	17	7
Patients in randomisation (n)	44	44
Percentage of patients who were pain free:	39%	16%
Odds ratio 3.2 (95% CI 1.2 to 9.1) (p = 0.020)		
WOMAC: Pain free last 48 hours (Score of 0 on 5 pain questions)		
Walking on a flat surface		
Going up or down stairs		
At night while in bed		
Sitting or lying		
Standing upright		
	Kinematically-aligned TKR	**Mechanically-aligned TKR**
Pain-free patients (n)	23	6
Patients in randomisation (n)	44	44
Percentage of patients who were pain free:	52%	18%
Odds ratio 4.9 (95% CI 1.8 to 13.0) (p = 0.001)		

Table V. Secondary outcome measures at two years

Secondary outcome measures	Kinematic alignment (n = 44) mean (SD))	Mechanical alignment (n = 44) (mean (SD))	Difference = kinematic-mechanical (95% CI), p-value
Peri-operative outcomes			
Change in haemoglobin (g/dl)	3.4 (97)	3.3 (76)	0.06 (-0.43 to 0.31), p = 0.828
Distance walked prior to discharge (feet)	248 (120.1)	198 (120.4)	49.8 (-1.5 to 101.04), p = 0.044
Length of stay (days)	6.2 (6.8)	5.2 (2.2)	0.98 (-1.17 to 3.13), p = 0.653

the two groups. Patients in the kinematically aligned group walked a mean of 50 feet (15 to 400) further than the mechanically aligned group before discharge (Tables V and VI).

There was no statistically significant difference in the proportion of patients requiring further surgery in either group (Table VI).

Two patients in the kinematically aligned group required a manipulation under anaesthetic, one in a diabetic who had 90º of flexion at nine weeks post-operatively, and the other in a patient with chronic pain syndrome who had 85º of flexion at nine weeks post-operatively.[17,18] In one patient in the mechanical group skin sloughing occurred, which was treated with local debridement and dressing changes.

Discussion

This study shows that an alignment technique based on restoring the normal kinematics for each patient's knee can produce significantly better results two years post-operatively with regard to pain, function and ROM. We were thus able to reject the primary null hypothesis that there would be no difference in the pain, function and ROM between the two groups at two years. More patients were pain free in the kinematically aligned group at two years than in the mechanically aligned group.

The higher proportion of pain-free knees in the kinematically aligned group is important from both an individual patient and a global health system perspective, considering a recent report on the expense involved in investigating a painful TKR.[19]

With any method of alignment in TKR, there is a legitimate question about the survival of the prosthesis. Data from the New Zealand Joint Registry have shown that patients with a higher OKS are unlikely to require early revision.[20,21] It is possible that the significantly higher OKSs in the kinematically aligned group in our study may be predictive of a lower rate of revision. Previously published alignment data for these patients[9] showed that kinematic alignment did not preclude a neutral limb mechanical axis (Fig. 2). The mean alignment of both the limb and the knee in our patients was similar in both groups. The alignment of the components was different in the two groups, with a mean 2.2° more valgus for the femoral component and 2.1° more varus for the tibial component in the kinematically aligned knee group. A study of the Kinematic Condylar Prosthesis (Howmedica, Rutherford, New Jersey) with a mean varus alignment of the tibial component of 3° (SD 3) (similar to the mean 2.1° (SD 2.6) alignment of the tibial component in this study) showed a 96% survival of

Table VI. Readmission for minor or major reoperations within two years

	Kinematic re-admission (n, (%)	Mechanical re-admission (n, (%)	Odds ratio (CI)	p-value
Number allocated (n)	44	44		
Patients requiring at least one re-admission	5 (*11.4*)	4 (*9.1*)	1.25 (0.36 to 4.35)	1.00
Procedures requiring re-admission (n,%)	8 (*18.2*)	5 (*11.4)*		
One re-admission per patient	4 (*9.1*)	3 (*6.8*)		
Two re-admissions per patient		1 (*2.3*)		
Four re-admissions per patient	1 (*2.3*)			
Re-admissions not requiring further knee surgery				
One readmission	2 (*4.5*)	1 (*2.3*)	2.00 (0.19 to 21.26)	1.00
Multiple readmissions	0	0		
Minor operations				
Total (n, (%)	3 (*6.8*)	3 (*6.8*)	1.00 (0.21 to 4.69)	1.00
One minor operation	3 (*6.8)*	3 (*6.8*)		
Multiple minor operations	0	0		
Type of operation (n, %)				
Evacuation of hematoma	1 (*2.3*)	1 (*2.3*)		
ORIF patella fracture*	0	1 (*2.3)*		
Excision of lateral patella	2 (*4.5*)	1 (*2.3)*		
Major operations				
Total (n, %)	1 (*2.3*)	1 (*2.3*)	1.00 (0.06 to 15.49)	1.00
One major operation	0	1 (*2.3*)		
Multiple major operations	1 (*2.3*)	0		
Type of operation (n, %)				
Revision for instability	0	1 (*2.3*)		
Late revision for infection	1 (*2.3*)	0		

* ORIF, open reduction and internal fixation

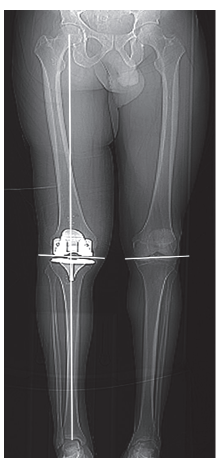

Fig. 2

Long-leg scan of a patient with a kinematically aligned total knee replacement (TKR). The line connecting the centre of the femoral head and the ankle passes through the centre of the prosthesis. The obliquity and level of the joint line in the kinematically aligned TKR are similar to those of the contralateral knee.

the prosthesis at ten years.[22] A biomechanical study of the same prosthesis in 2° of tibial varus produced 51% to 49% mediolateral force distribution, consistent with symmetrical loading of the tibial component.[23] In a study of 214 kinematically aligned knees with a mean follow up of 38 months (31 to 43), none had required revision of either component for loosening, wear or instability.[6] The rate of further operation for any reason was 1.4%.

One explanation for the better pain relief, function and flexion in the kinematically aligned TKR could be the use of patient-specific instrumentation. This explanation is unlikely, however, as clinical trials and a comprehensive review article have shown no difference in function and alignment between patients treated with a mechanically aligned TKR performed with patient-specific guides, and those treated with a mechanically aligned TKR performed with conventional instruments.[24-26]

Another explanation is that the principle of kinematic alignment results in better pain relief, function and flexion than the principle of mechanical alignment. In our study, the kinematically aligned group varus-valgus angle of the femoral and tibial components was generally anatomical or in a natural alignment, which was significantly different from the mechanically aligned group, confirming that different alignment goals were achieved.

The second (null) hypothesis of this study was that there would be no difference between the two methods for blood loss, distance walked prior to discharge from hospital, length of stay, and rates of further minor and major operations. This hypothesis was confirmed for all except the distance walked. The kinematic group walked a mean of 50 feet further, indicating an earlier functional recovery in these patients.

This study has limitations. The population was primarily male, but the results are similar to those in the literature for kinematically aligned and mechanically aligned TKR in both men and women.[6,27-29] The mean intention-to-treat OKS of 40 in the kinematically aligned group in our study is similar to the mean OKS of 43 reported in a case series of kinematically aligned TKRs in both men and women,[6] and also similar to the mean of 42 reported in a series of 93 consecutive kinematically aligned TKRs performed with manual instruments.[27]

The mean intention-to-treat OKS of 33 in the mechanically aligned group in this study is similar to the mean OKS of 34 at two years in a large registry series of both men and women,[28] and compares with a two-year mean OKS of 33 for fixed-bearing TKRs noted in the Knee Arthroplasty Trial.[29]

Another limitation of this study is that patients with post-traumatic osteoarthritic deformities were not included. The study does not show whether a kinematic alignment technique would be applicable to complex multilevel deformities.

This study involved only two surgeons at one site, and larger studies involving many sites and surgeons are needed to determine whether the results are generally applicable. Longer-term studies are also needed to investigate the survival of TKR using this technique of achieving alignment. Our findings should guide further research on kinematic alignment to assess wear, survival, clinical outcomes in women, outcomes with different designs of implant, and outcomes using different patient-specific guides.

This randomised controlled trial has shown that individualising a TKR using 3D imaging, and pre-operative computer planning to produce patient-specific guides in an attempt to replicate the kinematics of an individual's knee, can significantly reduce pain and restore better function and movement two years post-operatively than a mechanical alignment technique using conventional instruments.

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References

1. **Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD.** Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? *Clin Orthop Relat Res* 2010;468:57–63.
2. **Baker PN, van der Meulen JH, Lewsey J, Gregg PJ.** The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales. *J Bone Joint Surg [Br]* 2007;89-B:893–900.
3. **Hollister AM, Jatana S, Singh AK, Sullivan WW, Lupichuk AG.** The axes of rotation of the knee. *Clin Orthop Relat Res* 1993;290:259–268.
4. **Eckhoff DG, Bach JM, Spitzer VM, et al.** Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. *J Bone Joint Surg [Am]* 2005;87-A (Suppl):71–80.
5. **Howell SM, Hull ML.** Kinematic Alignment in Total Knee Arthroplasty. In: Scott AE. *Surgery of the knee*. Philadelphia: Elsevier, 2012:1255-68.
6. **Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML.** Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? *Clin Orthop Relat Res* 2013;471:1000–1007.
7. **Howell SM, Kuznik K, Hull ML, Siston RA.** Results of an initial experience with custom-fit positioning total knee arthroplasty in a series of 48 patients. *Orthopedics* 2008;31:857–863.
8. **Spencer BA, Mont MA, McGrath MS, Boyd B, Mitrick MF.** Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment. *Int Orthop* 2009;33:1571–1575.
9. **Dossett HG, Swartz GJ, Estrada NA, Lefevre GW, Kwasman BG.** Kinematically versus mechanically aligned total knee arthroplasty. *Orthopedics* 2012;35:160–169.
10. **Murray DW, Fitzpatrick R, Rogers K, et al.** The use of the Oxford hip and knee scores. *J Bone Joint Surg [Br]* 2007;89-B:1010–1014.
11. **Bellamy N, Buchanan WW.** A preliminary evaluation of the dimensionality and clinical importance of pain and disability in osteoarthritis of the hip and knee. *Clin Rheumatol* 1986;5:231–241.
12. **Insall JN, Dorr LD, Scott RD, Scott WN.** Rationale of the Knee Society clinical rating system. *Clin Orthop Relat Res* 1989;248:13–14.
13. **Howell SM, Howell SJ, Hull ML.** Assessment of the radii of the medial and lateral femoral condyles in varus and valgus knees with osteoarthritis. *J Bone Joint Surg [Am]* 2010;92-A:98–194.
14. **Bellemans J, Colyn W, Vandenneucker H, Victor J.** The Chitranjan Ranawat award: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. *Clin Orthop Relat Res* 2012;470:45–53.
15. **Lotke PA, Ecker ML.** Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg [Am]* 1977;59-A:77–79.
16. **No authors listed.** American Society of Anesthesiologists (ASA) Physical Status Classification System. http://www.asahq.org/Home/For-Members/Clinical-Information/ASA-Physical-Status-Classification-System. (date last accessed May 16 2014).
17. **Meding JB, Reddleman K, Keating ME, et al.** Total knee replacement in patients with diabetes mellitus. *Clin Orthop Relat Res* 2003;416:208–216.
18. **Zywiel MG, Stroh S, Lee SY, Bonutti PM, Mont MA.** Chronic opioid use prior to total knee arthroplasty. *J Bone Joint Surg [Am]* 2011;93-A:1988–1993.
19. **Kassam AM, Dieppe P, Toms AD.** An analysis of time and money spent on investigating painful total knee replacements. *BJMP* 2012;5:5261.
20. **No authors listed.** The New Zealand Joint Registry Thirteen Year Report. http://www.cdhb.govt.nz/NJR/reports/A2D65CA3.pdf (date last accessed 28 October 2013).
21. **Rothwell AG, Hooper GJ, Hobb, A, Framptom CM.** An analysis of the Oxford hip and knee scores and their relationship to early joint revision in the New Zealand Joint Registry. *J Bone Joint Surg [Br]* 2010;92-B:413–418.
22. **Malkani AL, Rand JA, Bryan RS, Wallrichs SL.** Total knee arthroplasty with the kinematic condylar prosthesis: a ten-year follow-up study. *J Bone Joint Surg [Am]* 1995;77-A:423–431.
23. **Hsu HP, Garg A, Walker PS, Spector M, Ewald FC.** Effect of knee component alignment on tibial load distribution with clinical correlation. *Clin Orthop Relat Res* 1989;248:135–144.
24. **Krishnan SP, Dawood A, Richards R, Henckel J, Hart AJ.** A review of rapid prototyped surgical guides for patient-specific total knee replacement. *J Bone Joint Surg [Br]* 2012;94-B:1457–1461.
25. **Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C.** A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. *Bone Joint J* 2013;95-B:354–359.
26. **Barrack RL, Ruh EL, Williams BM, et al.** Patient specific cutting blocks are currently of no proven value. *J Bone Joint Surg [Br]* 2012;94(11SupplA):95–99.
27. **Howell SM, Papadopoulos S, Kuznik KT, Hull ML.** Accurate alignment and high function after kinematically aligned TKA performed with generic instruments. *Knee Surg Sports Traumatol Arthrosc* 2013;21:2271–2280.
28. **Williams DP, Blakey CM, Hadfield SG, et al.** Long-term trends in the Oxford knee score following total knee replacement. *Bone Joint J* 2013;95-B:45–51.
29. **Breeman S, Campbell MK, Dakin H, et al.** Five-year results of a randomized controlled trial comparing mobile and fixed bearings in total knee replacement. *Bone Joint J* 2013;95-B:486–492.