Computer-assisted total knee replacement

A CONTROLLED CADAVER STUDY USING A MULTI-PARAMETER QUANTITATIVE CT ASSESSMENT OF ALIGNMENT (THE PERTH CT PROTOCOL)

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A controlled study, comparing computer- and conventional jig-assisted total knee replacement in six cadavers is presented. In order to provide a quantitative assessment of the alignment of the replacements, a CT-based technique which measures seven parameters of alignment has been devised and used. In this a multi-slice CT machine scanned in 2.5 mm slices from the acetabular roof to the dome of the talus with the subject's legs held in a standard position. The mechanical and anatomical axes were identified, from three-dimensional landmarks, in both anteroposterior and lateral planes. The coronal and sagittal alignment of the prosthesis was then measured against the axes. The rotation of the femoral component was measured relative to the transepicondylar axis. The rotation of the tibial component was measured with reference to the posterior tibial condyles and the tibial tuberosity. Coupled femorotibial rotational alignment was assessed by superimposition of the femoral and tibial axial images. The radiation dose was 2.7 mSV.

The computer-assisted total knee replacements showed better alignment in rotation and flexion of the femoral component, the posterior slope of the tibial component and in the matching of the femoral and tibial components in rotation. Differences were statistically significant and of a magnitude that support extension of computer assistance to the clinical situation.

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doi:10.1302/0301-620X.86B6.15456 $2.00

J Bone Joint Surg [Br] 2004;86-B:818-23.
Received 15 April 2003; Accepted after revision 8 March 2004

A functioning total knee replacement has to be well aligned which implies that it lies along the mechanical axis and in the correct axial and rotational planes. Incorrect alignment can lead to abnormal wear,[1,2] premature mechanical loosening of the components,[3-5] and patellofemoral problems.[6-8] Conventionally, alignment is facilitated using mechanical jigs to position cutting blocks. In most knee replacement systems the surgeon has a choice of using either intramedullary or extramedullary jigs or a combination of the two.

However, there is debate as to the reliability of jig systems.[9-11] Computer assistance has been developed to help the surgeon, with the expectation that such systems will result in knee replacements which are better aligned, with the benefits of better function and improved longevity. Clearly, it is important to establish whether computer assistance does indeed produce better alignment, in a laboratory setting, before it is introduced clinically and disseminated on a large scale.

The aim of this study was to compare the accuracy of a computer-assisted total knee replacement (CATKR) with a conventional jig-assisted total knee replacement (JATKR) technique, in cadavers. To make the comparison objective and quantitative we have developed a CT-based technique which allows direct measurement of the alignment of the femoral and tibial components in relation to the mechanical axis or the trans-epicondylar axis. This technique measured all the parameters which the Stryker Computer Navigation System (Stryker Orthopaedics, Kalamazoo, Michigan) aimed to control, namely the alignment of the femoral and tibial prostheses in the coronal, sagittal and axial planes. In addition, it showed how the femoral and tibial components were matched in rotation.

Materials and Methods

Cadaver surgery. Twelve knee replacements were performed on six cadavers which were treated with 'soft-fix' fixative which is a technique of fixation for cadavers which avoids much of the rigidity of conventional methods. In spite of the fixative, soft-tissue releases around the hip and mid thigh had to be performed to allow sufficient mobility at the hip and knee to carry out the procedures. Two surgeons (SC and GC) performed the operations. Both had some experience in conventional total knee replacements but were relatively new to computer-assisted surgery. Six CATKR operations and six JATKR procedures were alternated. Both procedures were undertaken by one surgeon on each cadaver. The choice of which was done first was randomised. The Duracon (Stryker Corp) prosthesis was used with a cruciform tibial base plate. The jig-based operations were performed according to the manufacturer's recommendations[12] which imply intra-medullary alignment of the femoral component and extramedullary alignment of the tibial component. Pre-operative CTs using a multi-slice scanner (General Electric Healthcare, Waukesha, Wisconsin) were performed on the cadavers to determine the anatomical and mechanical axes of the limbs. The femoral valgus angle was chosen on this basis.

The CATKRs were performed using the Stryker Knee Navigation system. This is an imageless system which uses anatomical mapping of the limb to build up a working model of the patient's knee. It uses an infrared camera array to track three fixed infrared beacons or emitters which are fixed to the anterosuperior iliac spine, distal femur and proximal tibia by bicortical screws. The camera can also track the position of a pointer or attachment and relate their positions to the mapped anatomy. A process of registration is required whereby the anatomical landmarks of the limb are identified for the computer. This starts by kinematic identification of the centre of the femoral head, mapping of the lower femur, upper tibia and bony landmarks of the ankle. The mechanical axis of the limb and the trans-epicondylar axis of the femur, the most distal part of the femoral condyles, the most distal point of the tibial plateau and the long axis of the tibia are all identified and the image data stored. The algorithms used to determine the axial rotation average the readings of the trans-epicondylar axis and the estimate of the anteroposterior axis known as Whiteside's line.[7] Tibial rotation is derived from the trans-malleolar axis, the anteroposterior axis of the ankle and a line from the mid-part of tibial tubercle to the insertion of the posterior cruciate ligament. The relationships of the pointer or tool to the anatomy are shown, in real time on the computer screen.

In the CATKRs a mobile beacon was mounted directly onto a cutting block and its position was adjusted according to the image and data shown. The block was then pinned into place. No mechanical jigs or other alignment aids were used. The femoral cuts were made by a two-step process, using the two femoral cutting blocks, with the initial distal cut requiring control in flexion, valgus and depth of bone resection. Rotational alignment was subsequently established. The tibial cuts were made in one step, controlling posterior slope, valgus and depth. Tibial rotational alignment required pinning of the trial baseplate in the appropriate position but did not require a separate cut. After each cut was made it was verified with the mobile beacon to which a small plate was attached.

A preliminary study had shown that using two or three pins to stabilise the cutting blocks allowed a significant (2 to 3°) amount of movement and therefore all cutting blocks in both computer and conventional operations were fixed with three standard pins and one interlocking pin. This configuration proved stable to within 1° of movement when measured against a displacement of 30 N. The prosthetic component sizes were judged manually using the recommended techniques.

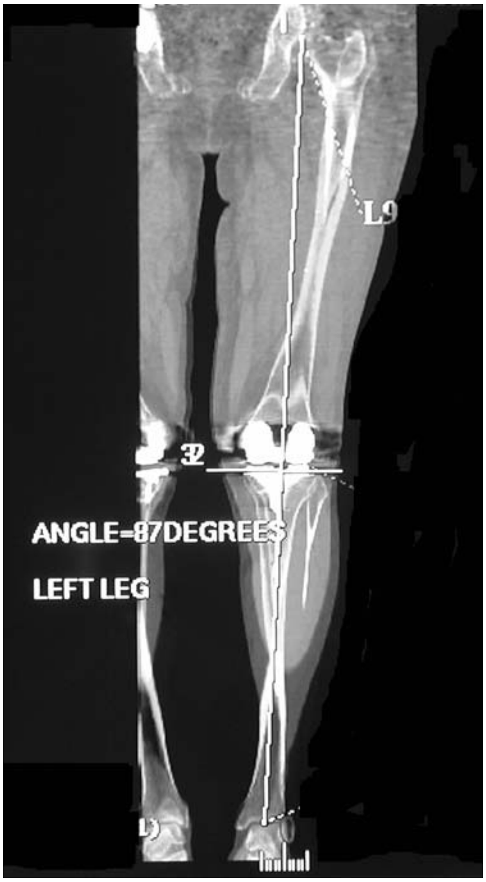

Fig. 1

The mechanical axis in the coronal plane. The alignment of the femoral and tibial components was measured by the intersection of a line drawn across the base of each component and the mechanical axis.

After implantation of the prostheses all limbs underwent CT scanning using the 'Perth CT Protocol'. The results of the two groups were compared using a two-tailed Student's *t*-test with $p \le 0.05$ considered significant.

Computer tomography

Hardware requirements. This technique involved the use of the newer generation multi-slice CT scanners, which are widely available in Europe, North America and Australasia. These scanners have the advantage over conventional helical scanners of greater speed, more data storage and decreased collimation of beams, which greatly reduce radiation exposure. All measurements can be performed using the standard scanner software and no additional software is required.

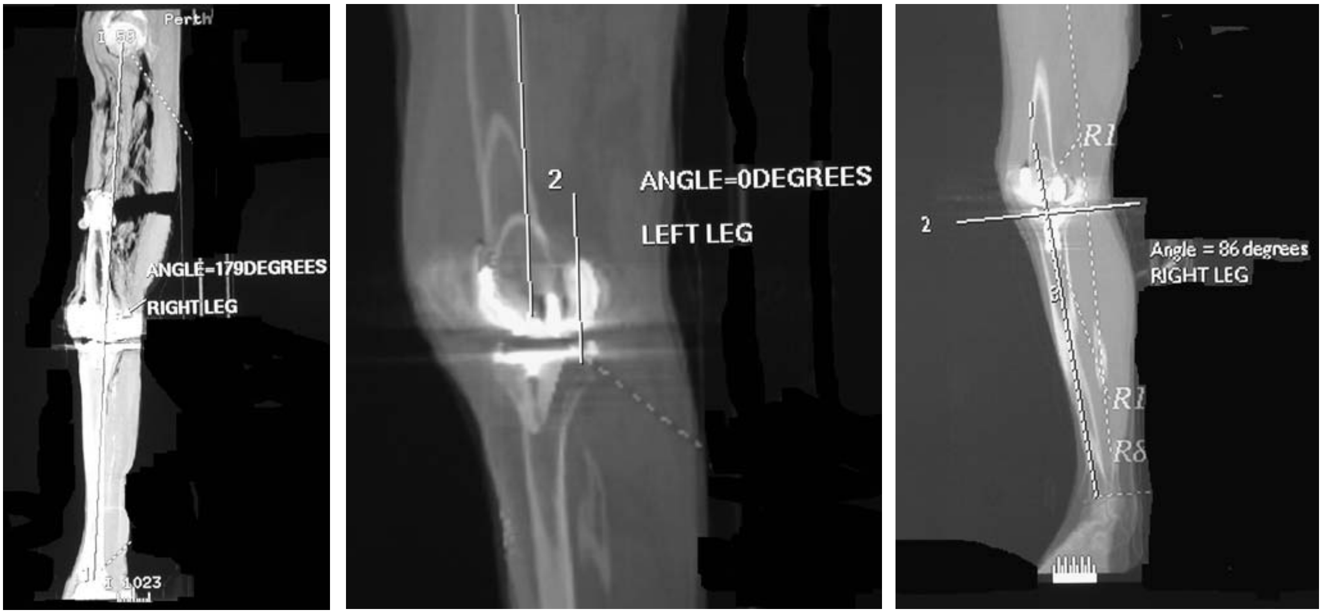

Fig. 2a Fig. 2b Fig. 2c

Figure 2a – The mechanical axis in the sagittal plane. Figure 2b – Measurement of femoral component flexion/extension. Figure 2c – Measurement of the posterior slope of the tibial component.

Scanning protocol. The cadaver was positioned supine on the scanner gantry table with the legs in a neutral position, the patellae pointing forwards and the knees in maximal extension. The legs were stabilised in this position when necessary. AP (anteroposterior) and lateral views were performed to check initial alignment. If satisfactory, a scan sequence was performed from the superior margin of the acetabulum to the talus, using 2.5 mm contiguous slices. The scan time was 40 seconds with an average kilovoltage of 140; 85 milliampere-seconds. The calculated radiation dose for the procedure was 2.5 mSV, which could have been reduced to 1 mSV by the use of a lead shield.

Measurement protocol. The centre of the femoral head, distal femur, tibial plateau and ankle were calculated by assessing the axial, coronal and sagittal images of these structures. The centre of the femoral head was initially identified on the axial image, and dynamically linked to the coronal and sagittal images. The true centre was identified using digital circles. The centre of the distal femur was determined by taking the centre of the femoral notch in the coronal plane[5] and linking this dynamically to the deepest point of the femoral notch in the sagittal plane.[13] This provided a corresponding axial centre point. The centre of the tibial plateau was determined by taking the centre points of the maximal coronal and sagittal diameters (excluding osteophytes) of the tibial plateau which were linked dynamically with the axial image. The centre of the ankle was similarly determined by finding the maximal coronal and sagittal diameters of the ankle and linking this with the axial image. Reconstructions of the full leg were produced on which the pre-determined points detailed above were plotted automatically.

From the reconstructed images and points described, the mechanical axis of the limb in the coronal, AP and sagittal lateral planes could be identified by taking a line from the centre of the femoral head to the centre of the ankle (Figs 1 and 2a). The varus/valgus positioning of the femoral and tibial components (Fig. 1) was calculated by taking a line across the distal femoral component, or the tibial base plate, and finding the angles created by the intersection with the mechanical axis. All angles were measured from the medial side.

The flexion/extension (Fig. 2b) of the posterior flange of the femoral component was determined relative to a line from the sagittal points of the centre of the femoral head to the centre of the distal femur.[13] The posterior slope of the tibial base plate was measured by drawing a line across the base of the tibial base plate so that it intersected the sagittal tibial anatomical axis as defined by a line drawn from the centre of the tibial plateau and ankle on the sagittal images (Fig. 2c).

The rotation of the femoral component (Fig. 3) was determined relative to the trans-epicondylar axis.[6] An axial image of the distal femur was chosen which most clearly demonstrated the medial epicondylar sulcus, when present, or the central point of the medial epicondyle when no sulcus was found, and the lateral epicondylar prominence. A line was drawn between these two points, which formed the surgical epicondylar axis. A second line, the posterior condylar line of the prosthesis, was drawn across the base of the femoral component. The angle between these represented the rotation of the femoral component.

The femorotibial mismatch angle was calculated with the limb in maximal extension by superimposing an axial

Fig. 3

Measurement of axial rotation of the femoral component in relation to the trans-epicondylar axis. In this case the epicondyles were marked with screws to validate the registration in one of the cadaver experiments.

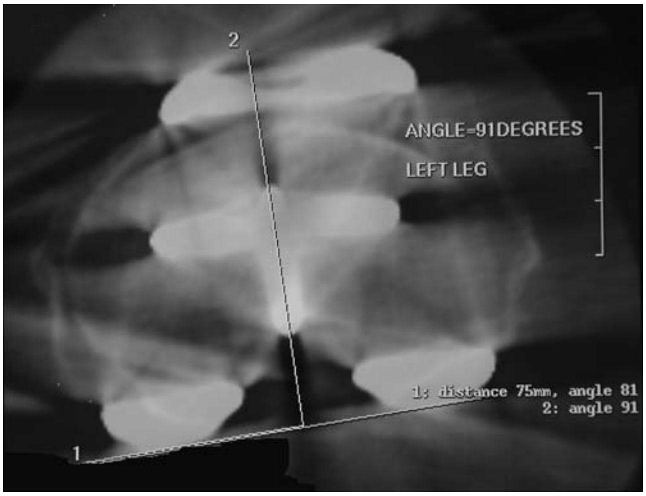

Fig. 4

Superimposition of the axial views of the femoral and tibial components to demonstrate the degree of matching of the two. In this case a cruciate stem is shown and in the ideal situation the AP fin transects the posterior condylar line of the femoral component at right angles.

image of the femoral component onto an axial image of the stem of the tibial baseplate. A line was drawn across the base of the femoral component and an intersecting line drawn through the centre of the stem of the baseplate to calculate this angle (Fig. 4).

The measurement protocol thus provided six component position parameters as well as the position of the mechanical axis in sagittal and coronal planes.

Determination of accuracy. The accuracy of the determination of the centre of the femoral head and the measurement of the anatomical axis of the femur were independently measured using the FARO-arm (FARO-arm, Model BO8/rev9; FARO Technologies, Lake Mary, Florida) technique.[14] Three balls were rigidly fixed to the shaft of each of two femora. Each femur was scanned, and the centre of the femoral head and of each ball determined by the CT technique. Each femur and its attached marker balls were then digitally mapped using the FARO-arm (FARO Technologies) to determine the centre of the femoral head and each marker ball. The relationship between the fixed marker balls and the centre of the femoral head was then calculated by each technique.

In order to determine the accuracy of the anatomical axis measurement, 11 entire femora were digitally mapped again using the FARO-arm. This determined the centre of the femoral head and distal femur. An 8 mm rod was passed 25 cm up the femoral canal from the centre of the distal femur. The distal end of the rod was mapped with the FARO-arm, and the angle between the mechanical axis and the rod determined as the anatomical axis. The results of the anatomical axis determined by the CT scan technique were compared with those produced by the FARO-arm technique.

Testing of scanning protocol. The scanning protocol was tested using 18 cadaver limbs which had knee replacements performed. The scans of six limbs were measured twice to assess intra-observer error.

Results

CT protocol validation. When comparing the accuracy of CT measurement of the femoral head with that using the FARO-arm technique, we found mean errors of 2 mm in the coronal plane, 3 mm in the sagittal plane and 1 mm in the axial plane. This gave an error of 2 mm in a three dimensional plot. Replotting the results with a 2 mm correction in the scans of the cadaver limbs produced no difference in the outcome measurements. In determining the accuracy of measurement of the anatomical axis, for eight of the 11 the difference between the CT and FARO-arm measurements was <0.5 mm. The range was -2.5 mm to 2 mm. Intra-observer error for CT scan measurements was 9% which implied errors of <1°.

Cadaver alignment outcomes

Femoral alignment. The femoral rotation angles (transverse axis of the femoral component in relation to the trans-epicondylar axis of the femur) results are shown in Table I. Perfect (0°) alignment was obtained in two CATKRs and in one JATKR. All CATKRs were within 3° of the optimum alignment. The spread of outcomes was 6° in the JATKR group. All the variations were in external rotation. The difference between the groups was significant (p = 0.02). In the CATKRs, all the components were flexed over a range of 0° to 2° (Table II) while the JATKRs ranged from 0° to 5°. The difference between the groups was significant (p = 0.04). Femoral valgus (or varus) alignments (Table III) showed that only one of the 12 operations achieved neutrality. Ten

Table I. Rotational alignment of the femoral component in relation to the trans-epicondylar axis. Positive values imply external rotation of the component

	External rotation (°)						
	0	1	2	3	4	5	5
CATKR	2	2	0	2	0	0	0
JATKR	1	1	1	0	1	1	1

Table II. Flexion/extension of the femoral component in relation to the sagittal plane of the limb. All deviations from the ideal value of 0° were in the direction of flexion

	Femoral flexion (°)					
	0	1	2	3	4	5
CATKR	3	1	2	0	0	0
JATKR	1	0	1	2	1	1

Table III. Varus/valgus alignment of the femoral component. Neutral alignment in relation to the mechanical axis of the limb is recorded as 0°. Negative values imply varus and positive values imply valgus alignment

	Femoral valgus (°)						
	-1	0	1	2	3	4	5
CATKR	4	0	2	0	0	0	0
JATKR	3	1	0	0	1	0	1

Table IV. Tibial component varus/varus alignment. Neutral alignment in relation to the mechanical axis of the limb is recorded as 0°. Negative values imply varus and positive values imply valgus alignment

	Tibial varus/valgus alignment (°)							
	-4	-3	-2	-1	0	1	2	3
CATKR	0	0	0	1	3	2	0	0
JATKR	1	1	0	2	1	0	0	1

Table V. Tibial component alignment in the sagittal plane with positive values indicating posterior slope. The recommended value for this prosthesis is 3°

	Posterior tibial slope (°)				
	0	1	2	3	4
CATKR	0	0	2	3	1
JATKR	2	3	1	0	0

Table VI. Femorotibial mismatch for the two groups

	Femorotibial mismatch (°)								
	0	1	2	3	4	5	6	7	8
CATKR	2	2	1	1	0	0	0	0	0
JATKR	0	0	1	1	0	2	0	0	2

were within 1° of the desired alignment. The two results which were out by >1° were both JATKRs, one being 3° and one 5° valgus. The differences between the two groups were not significant.

Tibial alignment. Tibial varus/valgus alignment (Table IV) showed a spread of 2°, around the ideal of 0° for the CATKRs. By contrast the JATKRs showed a spread of 7°, with errors occurring in both valgus and varus. The differences between the groups were not significant. The AP slope of the tibia (Table V) showed a spread of 2°, around the ideal of 3° for all the CATKRs. None of the JATKRs achieved the desired position and varied between 0° and 2° of alignment. The differences between the groups were highly significant ($p = 0.001$).

Femorotibial matching. The matching of the femoral and tibial components (Table VI) was much closer in the CATKR group, with all knees being matched, in rotation, to within 3°. The degree of femorotibial mismatch for the JATKRs varied between 2° and 8°. The differences between the groups were significant ($p = 0.02$).

Discussion

This cadaver study was considered necessary, by the surgeons involved, as a preliminary to the introduction of the technique into clinical practice. Working on a small number of chemically-fixed cadavers is clearly not the same as normal surgical practice and, as a result, several questions remain unanswered. Issues such as comparative soft-tissue balance, relative morbidity and functional outcomes can only be clarified by clinical studies. Nevertheless, we were able to confirm that this particular computer navigation process can be made to work and produce bone cuts which are as good or better than by a conventional jig-based operation. Great care was taken with both arms of the study as seen by the performance of pre-operative CT scans of the cadavers to determine the optimum valgus setting on the femoral jigs.

In the planning stages of this study we were faced with the challenge of deciding how to determine the quality of the alignments that resulted. Conventional radiographs, long leg films and CT scanograms were all discarded as inadequate. We therefore developed the 'Perth CT Protocol' as described. It provides an objective, sensitive, numerical technique; the results of which can undergo statistical analysis.

The speed and thinner collimation of beams in multi-slice scanners resulted in scans which were quick to perform (40 to 60 seconds), with reduction of the metallic artefact which has proved a problem with CT. Their greater data storage facility allowed the patient's entire limb to be scanned and the images reformatted. There was a significant reduction in radiation dose, such that the calculated dose when using a lead shield (1 mSV) became equivalent to three pelvic radiographs or a single CT scan of the brain.

The use of this multi-parameter assessment provided a more comprehensive evaluation of surgical technique. For the first time we have been able to look at several parameters in one subject. We could quantitate the rotational parameters of femoral rotation and femorotibial matching. This is important as internal rotation of the femoral component affects patellar tracking[15,16] and is a cause of anterior knee pain[17,18] while malalignment in the coronal plane can increase the likelihood of component loosening.[19] Sagittal alignment is also important because the degree of posterior slope of the tibial plateau affects the range of flexion of the knee and the tension in the posterior cruciate ligament.[20] The significance of femoral flexion/extension is not yet well understood. We assume that individual parameter malalignments interact and may cumulate to produce a highly clinical problem.

In interpreting the results of the cadaver study it is important to remember that the final quality of the alignment of the prosthesis is determined by several factors, of which the set-up of the cutting block is only one. We quickly became aware of the fact that the stability of the cutting block is determined by the security of the pins on which the block rests. Even with a rigidly held cutting block the final cut is affected by the quality of the bone, with skating and vibration of the saw blade being significant issues. It was our impression that the mechanics of the process were not as refined as the electronics.

The CATKRs were significantly better aligned than the JATKRs in four of the seven parameters measured (femoral rotation, femoral flexion, tibial anteroposterior slope and matching of the femoral and tibial components) representing a major advantage for the computer navigation process and, were it to be repeated in clinical practice, would almost certainly be reflected in better prosthetic performance. However, at present we are not able to quantitate the potential improvement. This is because we do not understand the quantitative aspects of malalignment and the lifespan of the prosthesis. If this relationship is linear every degree of malalignment will produce a proportional reduction of life-span. However, the relationship may not be linear and there may be a critical point beyond which the slope of the malalignment/wear graph increases. Neither do we have clear indications as to whether all directions of malalignment are equally important.

The failure of femoral varus/valgus differences to reach statistical significance is of interest. On conventional postoperative radiographs the varus/valgus alignment of the components reflects possible success or failure. In many cases a good coronal appearance may be hiding less satisfactory aspects in other dimensions. The finding that in the JATKRs there was no posterior tibial slope of the recommended 3° suggests that there is an inherent error in the recommended extramedullary tibial jigging process. The tibial rotation results raise a series of issues beyond the simple comparison of accuracy. Firstly, none of the operations produced zero tibial component rotation. In the CATKRs the modal value for rotation was 10° suggesting that the computer navigation tibial referencing is to some other anatomical landmark(s). Secondly, the range of tibial rotations, 13°, produced by the JATKRs is extremely wide when compared with the CATKRs of 3°. If tibial rotatory malalignment is important then the conventional technique is clearly inadequate, at least when used with a fixed-bearing tibial prosthesis. By contrast, the CATKR seems to have the potential for producing a more predictable tibial rotatory alignment.

Femorotibial matching, in maximal extension, was better with the CATKRs. This parameter is the result of both femoral and tibial alignments and any errors in these can and do cumulate. In the JATKRs four of six knees had a mismatch of 5° or more which seems highly undesirable.

In conclusion, this version of computer assistance provided an improved alignment when compared with a conventional jig-based system. This improvement was statistically significant in four parameters. These results support continuing interest in computer assistance in knee replacement and justify clinical trials of the technology. The ‘Perth CT Protocol’ provides the best means available so far to assess the adequacy of alignment of the components in knee replacement.

The work has been supported by research grants from the Stryker Corporation.

No other benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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