




Improved mediolateral load distribution without adverse laxity pattern in robot-assisted knee arthroplasty compared to a standard manual measured resection technique

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Abstract

Purpose Robot-assisted total knee arthroplasty (rTKA) remains in its infancy, is expensive but offers the promise of improved kinematic performance through precise bone cuts, with minimal soft tissue disruption, based on pre-resection soft tissue behaviour. This cadaveric study examined load transfer, soft tissue performance and radiographic indices for conventional (sTKA) versus rTKA. The null hypothesis was there would be no difference between the two modes of implantation.

Methods Whole (ten) cadaveric limbs were randomised to receive either robotic (rTKA, $N=5$) or conventional measured resection (sTKA, $N=5$) knee arthroplasty. Laxity patterns were established using validated fixed sensors (Verasense) with manual maximum displacement for six degrees of freedom. Tibiofemoral load and contact points were determined dynamically using remote sensor technology for medial and lateral compartments through a functional arc of motion (0–110 degrees of motion). Final component position was assessed using pre- and post-implantation CT.

Results No significant intergroup differences for laxity were found (n.s.). The rTKA group exhibited consistently balanced mediolateral load throughout the full arc with significantly reduced overall total load across the joint (for distinct points of measurement, $p < 0.05$). Despite using flexion–extension and mediolateral gap balancing with measured resection, the sTKA group failed to achieve balance in at least three points of the flexion arc. Post-operative CT confirmed satisfactory component alignment with no significant differences for positioning between the two groups.

Conclusion This work found improved load sharing for rTKA when compared to conventional surgery for same donor knees. Laxity and CT determined final component positioning was not significantly different. The work supports the contention that robot-assisted TKA delivers improved tibiofemoral load sharing in time zero studies under defined conditions but such offers the promise of improved clinical performance and reduced implant wear.

Keywords Robotic · Load · Knee · Laxity · Arthroplasty · Cadaveric

Introduction

As the burden of arthroplasty is expected to increase, there remains an unacceptably high rate of patient-reported dissatisfaction [3, 11, 26]. The immediate desired effect is pain relief, the medium goal is optimization of function and survivorship is a long-term objective. Intra-operative and very early clinical measurements such as time to discharge or single-plane alignment determination remain nothing more than surrogate markers for patient-relevant outcomes.

Navigated knee arthroplasty did achieve a tightening of the Gaussian distribution for mechanical alignment without demonstrating reliable improvement in functional outcome perhaps explaining the failure of widespread adoption of such expensive technology [7, 25, 40]. Patient-specific

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instrumentation was hailed as the answer to matching the anatomy to optimized soft tissue characteristics but has not been shown to consistently improve functional outcome [1, 6]. The debate between mechanical and kinematic alignment continues yet axiomatically single-view stance radiography cannot possibly be extrapolated to whole lower-limb mechanical behaviour [43]. Translation of early outcome improvements for partial may not necessarily be translated into surgery for tricompartmental disease with often more complex soft tissue deformity [13, 33, 46]. The final common pathway for alignment, intra-operative, subjective assessment such as patellar tracking is to achieve equivalence of load across the tibiofemoral joint through full arc of motion using defined axes of motion [15, 21, 30, 35, 45]. Such intra-operative assessment is increasingly being adopted through sensor technology. Such measurements have been shown to be more reliable than the use of tensor devices or standard instrumentation [29].

Headlong haphazard adoption of new technology without determining the value of such for state of the art assessment may be construed as commercially advantageous but may not necessarily be in the best interests of the patient. A key indicator of long term performance may be load distribution across the joint and its impact on the soft tissue envelope. Hence, it was considered desirable to examine through a simple comparative study the influence of robot-assisted surgery upon load distribution when compared with a conventional measured resection surgical technique. The null hypothesis was that there would be no difference for load across the tibiofemoral articulation for all ranges of motion for the two forms of knee arthroplasty.

Materials and methods

Six whole cadaveric specimens (pelvis to feet) were obtained from a tissue bank (Science Care Phoenix Az 85207). Each cadaver provided two knees upon which to perform TKA. All limbs exhibited full passive movement; documentation from Science Care (Phoenix, AZ, USA) confirmed that there was no record of previous surgery, trauma with no evidence of malalignment or gross torsional abnormality. The limbs were randomized to receive a knee implant performed through either conventional, measured resection or robot-assisted means. The median BMI of the donors was 24.1 (range 20–30) 3 female 3 male, 4 white Caucasian, 1 African–American, median age was 76 years, range 61–85. Power analyses from previous studies and again for this work based on preliminary (three separate cadaveric robotic measured procedures) had determined that five matched pairs of limbs would be sufficient to allow for identification of any significant differences with 95% confidence at 80% power. Pre-operative CT scans from hip to ankle joint were

performed on all five pairs of limbs in extension to determine coronal and rotational alignment and to exclude peri-articular or limb segment. All knees underwent the MAKO (MAKO Surgical Corp. Stryker Ft. Lauderdale) CT planning protocol (PN 200004) prior to randomization. One femur fractured beyond salvage and another component sustained significant soft tissue disruption during preparation/surgery thereby allowed for comparison of 10 specimens (5 in each group).

Specimen preparation and experiment set-up

A custom rig was built specifically to immobilize the pelvis but allow a full range of hip and knee movements. The rig consisted of two 350 mm-long/11 mm diameter upright stainless steel rods welded to table clamps. When the clamps were secured to the table (on either side of the specimen) the rods acted as vertical “outriggers” to which Hoffman III external fixator (Stryker, Kalamazoo, USA) delta clamps could be attached. A total of four, 5 mm apex half pins (180 mm long) were then driven into the ilium (two into each side) just above the acetabulum to secure the pelvis (Fig. 1). The pelvis was raised on a platform approximately 15 cm off the operating table and the lower limb was secured in a leg positioner (Fig. 2) thereby enabling the index operated knee to be positioned at any point within a full arc of motion. Skin and subcutaneous tissue were then dissected carefully from the proximal half of the thigh and the quadriceps and hamstring muscle groups were separated. Loading of the individual flexor and extensor muscle groups has been

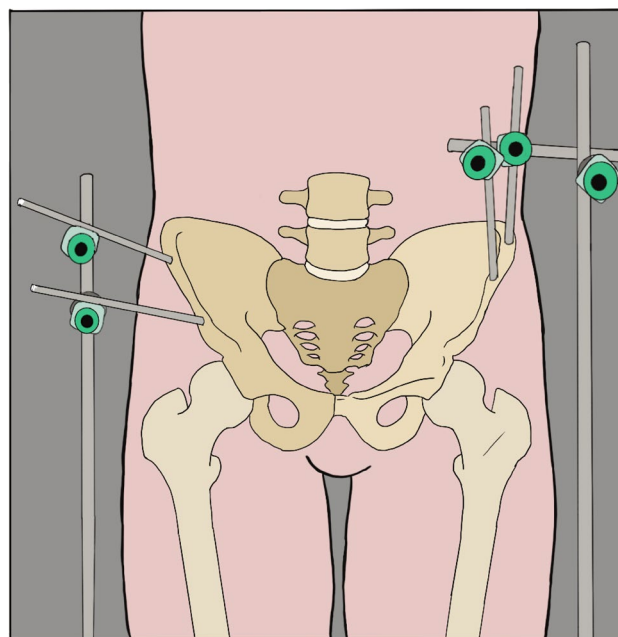


Fig. 1 Schematic image of fixation of pelvis

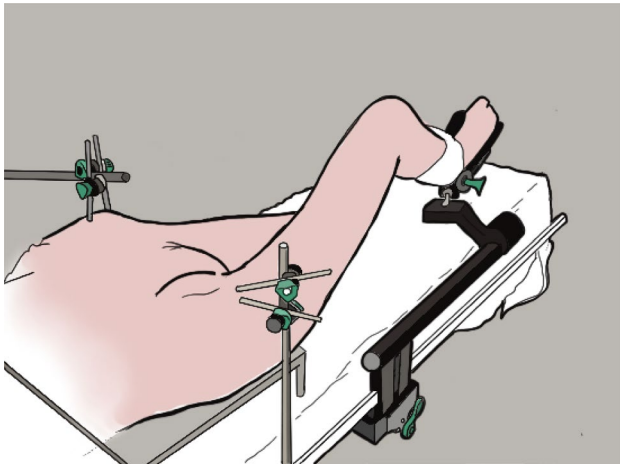


Fig. 2 Schematic image of the setup of operated limb with pelvis fixation using external mounted frame and leg holder

previously reported and was performed within previously accepted safe loads in an open chain fashion [12, 22, 28]. Navigation arrays were then secured to the tibia and femur in accordance with the MAKO TKA Surgical Guide. All knees underwent a medial parapatellar approach followed by navigation mapping of the tibial and femoral osteology. Randomization was performed using a sealed envelope technique. Three left and two right knees were randomized to receive robotic (rTKA) implantation and two left and three right knees therefore received a standard measured resection instrumented arthroplasty TKA (sTKA).

Standard total knee arthroplasty

A single radius cruciate retaining Total Knee Arthroplasty (CR-TKA) (Stryker Triathlon, Michigan USA) was performed via the medial parapatellar approach using a measured resection technique [39]. The transepicondylar axis and central trochlear sulcus were used for femoral component rotational referencing [4]. The tibial rotation for all cases was neutral with respect to a line drawn between the medial aspect of the patellar tendon and the PCL footprint [2, 36]. For all knees the senior authors subjectively deemed the knee balanced upon completion of trialing. Definitive implants were then cemented using Palacos® (Heraeus, Hanau, Germany) bone cement. A trial tibial insert of appropriate thickness was secured before closing the arthroto-

Robotic TKA

Following arthroto-

my, anatomical landmarks were referenced using a wand matching the digitised bone model to the CT. Medial and lateral gaps were evaluated in flexion and extension prior using spacer paddles to guide final soft-tissue tension. The CT screen bone model continuously updates in real time, thereby giving feedback on alignment and bone resection so as to achieve rectangular gaps in extension and 90° of flexion. Final positioning of the implant on the bone was determined through rotation of the tibial component. Bone cuts were made with the haptic-controlled arm-mounted oscillating saw guided by navigational arrays. The definitive implant was then cemented into place as per the technique for the sTKA group. No additional soft-tissue releases were required for these robot-assisted procedures.

Laxity testing

Prior to intervention the native knee was taken through 10 complete flexion/extension cycles to reduce hysteresis and ensure stable, reproducible recordings from the navigation array throughout the arc of flexion (0°–120°). The femur was then secured and fixed using two further half pins attached to the uprights. The position of femoral fixation ensured the tibia (when removed from the leg positioner) could be moved through a full arc of motion (0°–140°). Knees were manually stressed to mimic intraoperative laxity assessment, with the endpoints defined as the maximal displacement achieved [12, 22]. The TKA in extension acted as the datum from which maximal displacements of the tibia in relation to the femur were recorded in six degrees of freedom [14]. For each knee condition, maximal manual varus, valgus, internal and external rotational (IR–ER) displacements were each recorded at five angles of flexion (0°, 30°, 60°, 90° and 120°). Each recording was performed three times.

Load testing

Following laxity testing and for all knees, the arthroto-

Component position

Following laxity and load measurements all knees were re-imaged and CT scans were analysed by a blinded senior radiologist to assess component rotation using previously validated protocols [17]. Femoral component rotation was measured as the angle between the posterior condylar line of the femoral component and the trans-epicondylar axis. A positive (+ve) value was given for external rotation. Tibial component rotation was measured by the angle between a line drawn from the centre of the footprint of the PCL and the medial border of the tibial tuberosity and a line perpendicular to the line connecting the posterior fins of the tibial base plate [37]. A positive (+ve) value was given for external rotation. Tibiofemoral component divergence (matched rotation) was calculated using lines perpendicular to the femoral posterior condylar axis and a line perpendicular to the line connecting the posterior fins of the tibial base plate. A positive (+ve) value was given for external rotation of the tibial component relative to the femoral component. Radiographic measurement of divergence for femoral/tibial component alignment in the coronal plane, (α , β angles) (Fig. 3) and in the sagittal plane (γ , δ angles) (Fig. 4) were determined from each post implantation CT scan.

Statistical analysis

The numbers used were based on precedent and a pre-hoc determination was made from previous power analysis in multiple papers on laxity for defined differences in varus valgus and rotational laxity. Load analysis and differences were performed based on preliminary experiments (not included in the final numbers) examining the measured load across the tibiofemoral articulation. Effect sizes determined from previous studies indicated that eight limbs in total (for laxity and pre and post load) were sufficient to identify significant differences in load transfer and laxity with 95% confidence at 80% power. The previous studies examined a total of 8 but in this work each limb acted as a control combining pre and post laxity patterns and the changes from pre to post were examined for the two groups. In effect, each limb acted as its own control. Three replicate measurements were taken for all measurements of angle, load at each point of flexion and the median has been used for simple statistical summaries at each point of measurement through flexion arc. Linear mixed-effect models were used to model the relation between the measured outcomes (laxity angles and load) and knee flexion [34]. All three outcome measurements were used to account for uncertainty at each flexion angle. This approach accounts for the structure of these data, where values taken at each knee are expected to be more correlated than between knees, and measurements

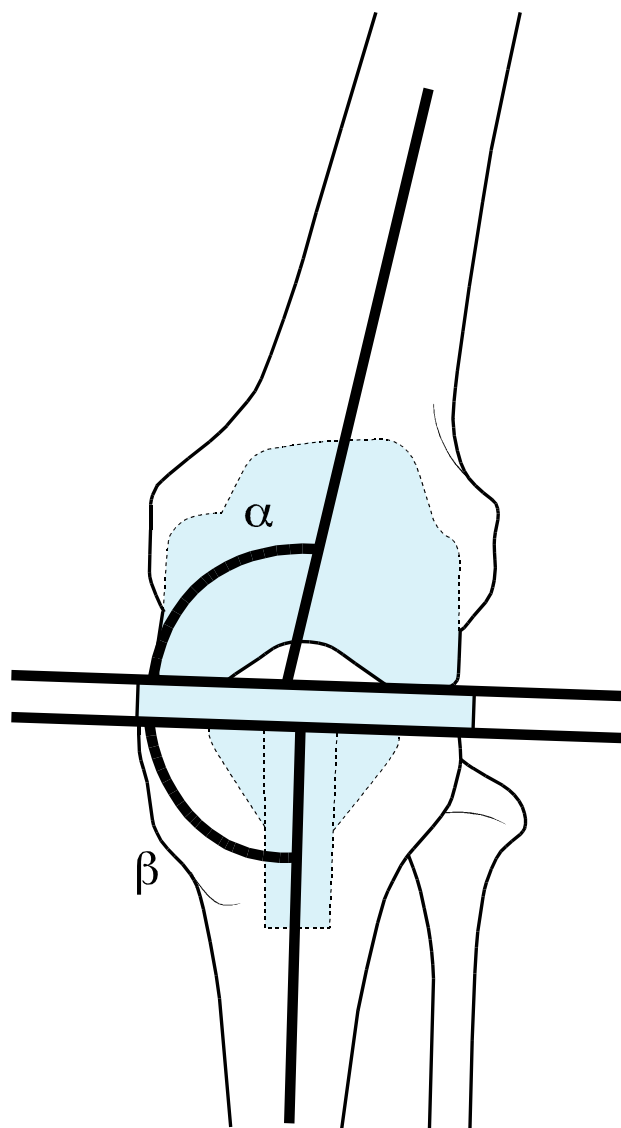


Fig. 3 Schematic representation of alpha and beta angles in frontal plane

taken at different angles within the same knee are correlated. Comparison of knees before arthroplasty was performed for varus, valgus, internal and external rotation using fixed effects for operation type (rTKA versus sTKA) and flexion. Tests of difference between MAKO and manual knees were performed post implantation thereby testing for differences in overall effect and for the change with defined point of flexion angle. Random effects for both intercept and slope (relationship of outcome variable to flexion) were included for varus, valgus, internal and external angle measurements. Quadratic random effects were included for all loading variables to account for the curvilinear relationship between all loading outcome measures and flexion which differed for each knee. General linear mixed model (GLMM) linear models

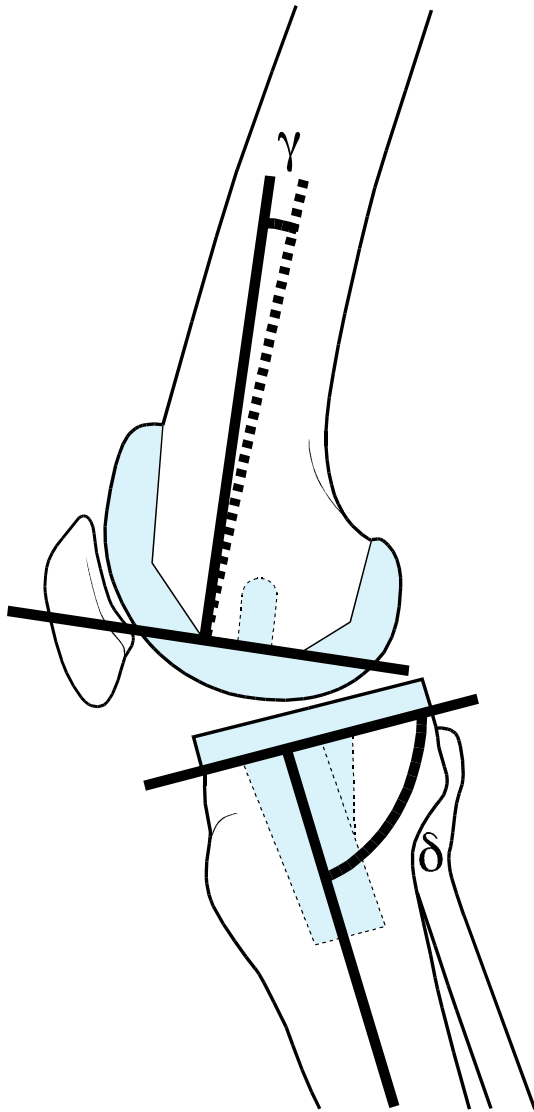


Fig. 4 Schematic representation of gamma and delta angles in sagittal plane

were fitted using maximum likelihood and statistical significance assessed using likelihood ratio tests, using a normal error model. Statistical analyses were done using R [34], the R libraries lme4 [4] and lmerTest [27]. A type 1 error probability was taken as 0.05

Results

Data are given as a mean with standard error.

Rotational laxity (Fig. 5)

Using the GLMM, no significant differences were found for rotational laxity or varus–valgus maximal laxity in the pre-operative knees randomly assigned to sTKA and rTKA. No significant difference was found for maximal internal or external rotational laxity between the two completed states (sTKA and rTKA) at any of the defined points of flexion. There was a consistently greater standard deviation for the conventionally implanted knee arthroplasty compared to the robot-assisted arthroplasty.

Varus—Valgus maximal laxity (Fig. 6)

There was no significant difference between rTKA or sTKA for maximal varus or valgus laxity for any of the points of knee flexion through the measured arc of motion.

Load (Fig. 7)

There were no significant differences between rTKA and sTKA for total loads. Near full extension there was greater load on the medial side for points of flexion 0° and 30° for the sTKA knee arthroplasty group whereas at the same points of flexion load were greater on the lateral side for the rTKA suggesting a redistribution of load in this range between the two groups of knee procedures. The change in load imbalance was significantly greater in sTKA knees at flexion of 0°–60° (s.e. 24) and decreased at a statistically significantly rate for the rTKA knees (–0.56 s.e. 0.22). This resulted in a knee that would be defined as unbalanced from 0° to 30° with < 15lbs difference in load from medial to lateral compartments. Beyond 60° of flexion the medial to lateral loading equalised to within 15 lbs of pressure for both s-TKA and r-TKS.

Contact point data

A grid reference was used to localise the point of contact on the medial and lateral side these points of contact for each position of flexion for the two states of implantation are shown in Fig. 8. For the sTKA it can be seen that the median point of contact on the lateral tibial plateau moved posteriorly incrementally with flexion where the medial point of contact remained relatively constant with flexion of the knee. In contrast, for the rTKA there was a parallel movement with flexion on the medial and lateral plateau posteriorly with no evidence of a pivot effect.

CT measurements

Raw data for each knee for all measurements are given in Table 1. No intergroup significant differences were found

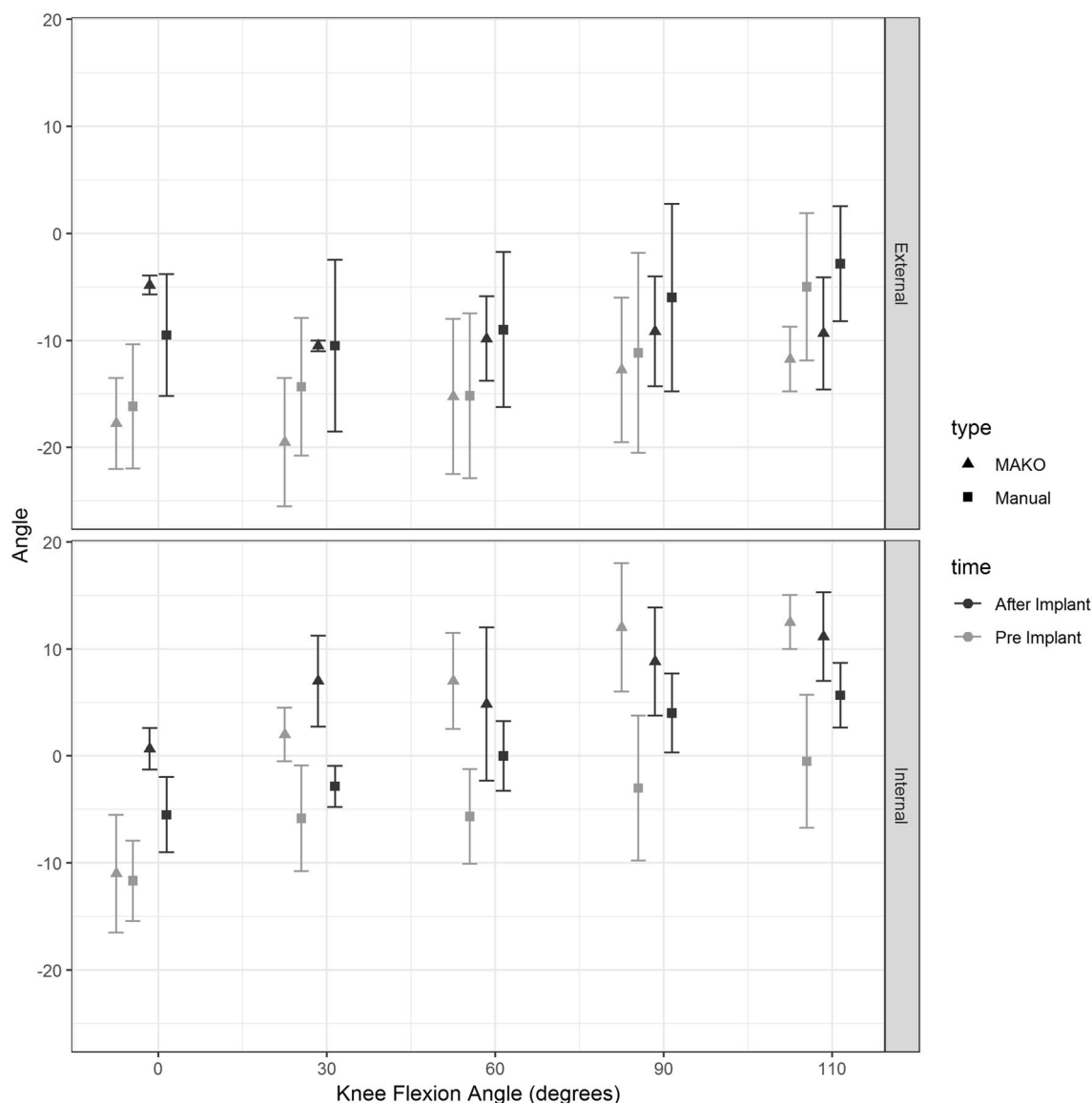


Fig. 5 Maximal external and internal rotational displacement in degrees by knee flexion angle for robot-assisted (MAKO) versus conventional (manual) total knee arthroplasty constructs. Black triangles represent MAKO and squares represent manual measurement

for component alignment or rotation positioning with very similar concordance for the α , β , γ and δ angles.

Discussion

The key findings of this work were that robotically assisted TKA (rTKA), as opposed to conventional measured resection sTKA, demonstrated consistent equal load distribution between the medial and lateral compartments through a functional arc of motion. Point of contact for the tibiofemoral articulation analysis confirmed the accepted pattern of external tibial rotation with flexion for the sTKA group with

parallel movement of the point of the contact posteriorly across the medial and lateral compartments for the rTKA.

Key limitations to the interpretation of this work are that specimens were non-arthritic with no evidence of chondral loss or soft tissue contracture. With advanced arthritic deformity, anatomical landmark identification may not be so straightforward [30, 32]. For the purposes of replicating the in vivo situation muscle loading was reduced to 66.7 N per muscle group to maintain physiological line of pull and replicate the in vivo setting [15, 22]. This is in keeping with previously published works thereby avoiding overloading the sensor. This loading was that below physiological loading but concurs with previous work confirming high loads

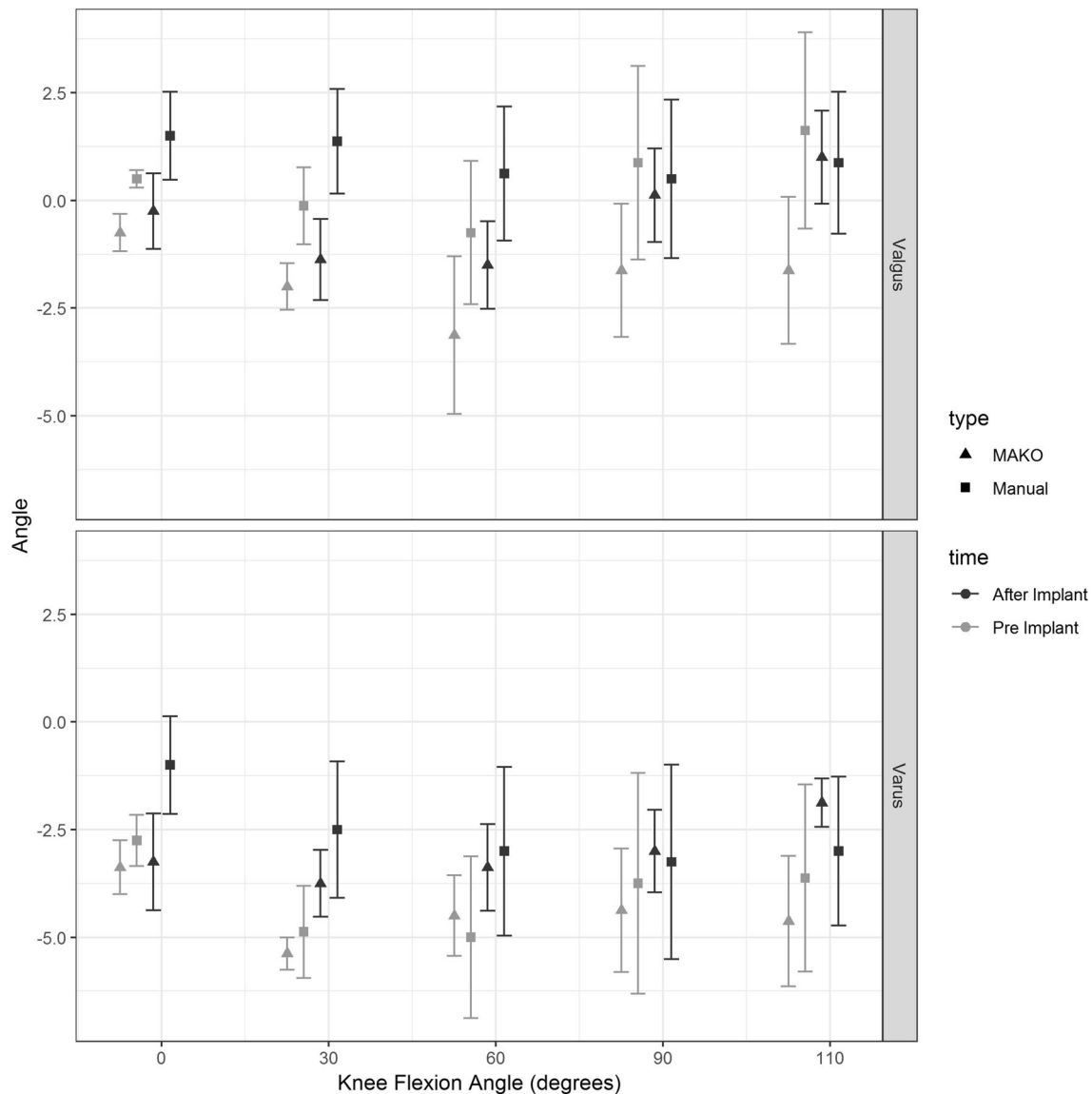


Fig. 6 Maximal varus and valgus displacement in degrees by knee flexion angle for robot-assisted (MAKO) versus conventional (manual) total knee arthroplasty constructs. Black triangles represent MAKO and squares represent manual measurement

across the medial compartment in cadaveric work particularly near extension [41].

Restoration of correct alignment with restoration of mechanical axis has been shown to reduce radiological loosening and promote implant longevity [20, 23, 26]. This experimental work found no difference using CT-based measures for component placement between conventional or robot-assisted TKA but this was a controlled cadaveric experiment with small numbers and not powered to identify such a difference. Robot-guided bone resection was promoted with the promise of limited surgical exposure, increased accuracy and better alignment and improved performance [24, 38]. Yet, debate continues as to the prognostic value of static mechanical alignment measures for PROMS

related clinical performance [25]. Alignment infers load only in the static phase but does not reflect load transfer in flexion [32]. Intra-operative pressure sensors perform real-time full arc load measurement across the two tibiofemoral compartments. Classical teaching argues for equilibration of force in the frontal plane across the two compartments [15, 19, 20]. Up to 20% of mechanically aligned knee arthroplasty cases exhibit load imbalance of greater than 66.7 N load [15, 16]. In this study, with no medial release, the majority of sTKA demonstrated significantly higher medial loads in early flexion. This figure may be even higher when examining torque forces near full extension and may reflect the preservation of the medial soft tissue envelope and in particular the deep component of the medial collateral ligament

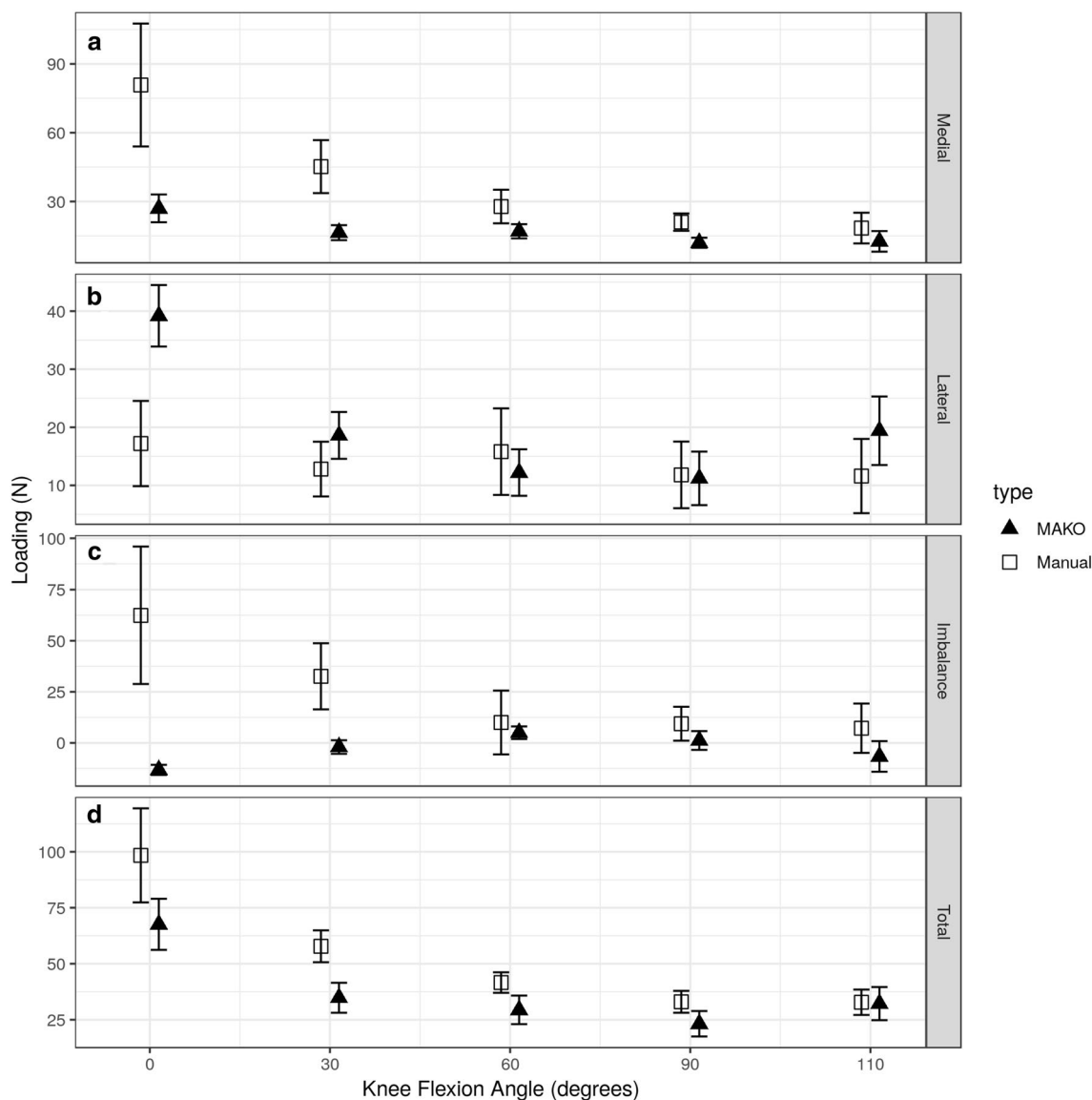


Fig. 7 Load across medial and lateral compartments and difference by knee flexion angle for robot-assisted (MAKO) versus conventional (manual) total knee arthroplasty constructs. Black triangles represent MAKO and squares represent manual measurement

near the joint margin [41]. Kinematically aligned knees aim to minimize soft tissue release but presume that the soft tissue envelope is stable and will optimize load transfer [18]. This work has confirmed the absence of mediolateral load inequality at time zero for the robotic group of cadaveric knee arthroplasty procedures. Furthermore, one could argue that the parallel movement with flexion limits the torsional effect of tibiofemoral motion as opposed to a medial pivot pattern. This work has extended our knowledge of actual load across the tibiofemoral joint and argues for robotically assisted knee arthroplasty to optimize total load across the joint.

This study found a consistent pattern, under equivalent testing conditions, of progressive axial external rotation of

the tibia through flexion for the conventional knee arthroplasty. It is known that such behaviour, whilst predictable in the native knee and desirable in the replaced knee, is inconsistently found [8]. The robot-assisted group in our study demonstrated a standard pattern of posterior sequential translation with rotation through flexion. This is not the same as reverse axial rotation, which has also been found paradoxically within subgroups of knee designs. Reverse axial rotation may expose the knee to patellofemoral instability secondary to lateralization of the tibial tubercle during deep flexion. We did not find any such pattern in any knee in this work and the current study is the first to examine the interrelationship between load transfer and point of contact for robotic total knee arthroplasty. Posterior translation of

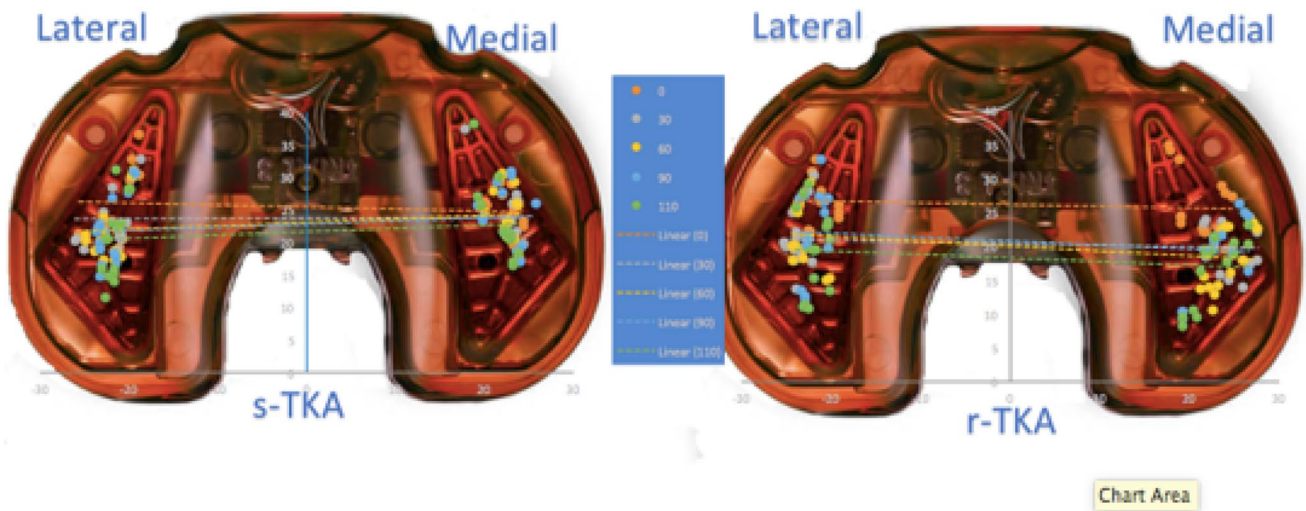


Fig. 8 Aerial view of the orthosensor fixed tibial insert with the grid overlay on which the points of contact on both the medial and lateral tibial articular surface were plotted for both rTKA and sTKA components

Table 1 The final angles for the individual knee arthroplasty CT scan measurements

Specimen	Side	PCL	Akagi	Tibial baseplate	Tibial stem	Alpha	Beta	Gamma	Delta	
NSTC180366	R	-1	-5.6	-5.4	-5.4	95.4	87.9	2.7	89	Robot-assisted
	L	-7.5	-5.3	-8.8	-7.6	98.8	88.8	-5	85.1	Conventional
NSTC180393	R	2.1	-0.3	0	-0.3	98.6	88.7	-0.8	92.5	Conventional
	L	12.6	2.7	5.5	5.7	97.4	88.5	-2.2	87.7	Robot-assisted
NSTCS180298	R	-4.5	-8.6	-4.5	-5.2	97.2	91.6	7	86.8	Conventional
	L	-0.6	-14.4	-10.1	-8.2	96.1	91.6	-0.6	87.4	Robot-assisted
NSTCS180396	R	2.1	-13.9	4.5	4.7	96	90.7	4.5	87	Robot-assisted
	L	9.6	8.7	7.2	9.8	93.6	91	-1.1	85	Conventional
NSTCS180406	R	4.1	13.7	2	1.7	101.7	90.8	3.55	87.8	Conventional
	L	-3.6	-19	-2.4	-3	92.4	90.1	0.4	86.9	Robot-assisted

Femoral Component Rotation (FCR) is the angle subtended by the transepicondylar axis and the posterior condylar line (PCL). The Akagi angle is that between the PCL and the sagittal ruler. The tibial base angle is that angle between a perpendicular to the posterior condylar axis and sagittal ruler. The tibial stem angle is that angle between a perpendicular to the transverse stem axis and sagittal ruler

the tibial point of contact was demonstrated equally with flexion for the medial and lateral compartments in the rTKA subgroup. Previous authors have argued that this pattern is akin to that found in kinematically aligned knees thereby facilitating flexion [5, 42]. The robot-assisted knee arthroplasty exhibited an almost equivalent medial and lateral compartment posterior point of contact movement. Nakamura et al. found in a modelling analysis that the amount of posterior translation at the lateral side in kinematically aligned knee arthroplasty was greater than in the mechanically aligned knee arthroplasty model [31]. However, extrapolation of such time zero behaviour to improved clinical performance remains untested [9, 19]. Furthermore, the CT rotational data suggested a more internally rotated tibial component in the rTKA group, but restoration of mechanical

alignment, and such a starting point could help explain the differing modes of femorotibial motion in flexion. Preservation of the soft-tissue envelope whilst restoring alignment and equalising load may offer the potential for improved clinical performance after TKA [44].

Conclusion

This study has compared the biomechanical behaviour under load of a robot-assisted versus measured resection knee arthroplasty. As such, the robotic group achieved equivalence of load transfer between the two compartments. Laxity was similar for the two implanted states. No significant differences were found for implant positioning determined

by CT analyses. Point of motion was parallel and there was no medial pivot in the robotic group.

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Compliance with ethical standards

Conflict of interest David Deehan as PI oversaw the administration and delivery of this project. All funds from NSTC research grant and Stryker Europe were used on consumables and technical support for this project. None of the authors received any personal funding or from a commercial partner for the delivery of this work.

Ethical approval Ethical approval was obtained (Human Tissue Act 2004, Section 16/2, license number 12148, license held by Department of Anatomy, University of Newcastle upon Tyne).

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