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TITLE PAGE

Article title: THE KNEE PROSTHESIS CONSTRAINT DILEMMA: BIOMECHANICAL COMPARISON BETWEEN VARUS-VALGUS CONSTRAINED IMPLANTS AND ROTATING HINGE PROSTHESIS. A CADAVER STUDY.

Running Title: KNEE PROSTHESIS CONSTRAINT DILEMMA

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Authors' contributions:

Víctor Estuardo León Román designed the study, collected the data, undertook the surgeries, measured tibial rotation, performed the statistical analysis and wrote the manuscript.

David García Mato designed the inertial sensors software, collected the data with inertial sensors and motion capture cameras, processed the data and reviewed the manuscript.

Irene Isabel López Torres undertook the surgeries, performed the statistical analysis and reviewed the manuscript.

Javier Vaquero Martin reviewed the manuscript and coordinated the experimental study.

José Antonio Calvo Haro coordinated the inertial sensor project.

Javier Pascau designed the inertial sensors software and coordinated the instrumentation of the experimental study.

Pablo Sanz Ruíz is the general coordinator who designed the study, undertook the surgeries and reviewed the manuscript.

All the authors have read and approved the final version of the manuscript.

THE KNEE PROSTHESIS CONSTRAINT DILEMMA: BIOMECHANICAL COMPARISON BETWEEN VARUS-VALGUS CONSTRAINED IMPLANTS AND ROTATING HINGE PROSTHESIS. A CADAVER STUDY.

ABSTRACT

The real degree of constriction of rotating hinge knee (RHK) and condylar constrained prostheses (CCK) is a matter of discussion in revision knee arthroplasty. The objectives of this study are to compare the tibial rotation of both implants and validate the use of inertial sensors with optical tracking system as movement measurement tools. A total of 16 cadaver knees were used. Eight knees were replaced

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using a RHK (Endomodel LINK), and the remaining 8 received a CCK prosthesis (LCCK, Zimmer). Tibial rotation range of motion was measured in full extension and at 30°, 60°, and 90° of flexion, with 4 continuous waveforms for each measurement. Measurements were made using 2 inertial sensors with specific software and compared with measurements obtained using the gold standard technique - the motion capture camera. The comparison of the accuracy of both measurement methods showed no statistically significant differences between inertial sensors and motion capture cameras, with $p > 0.1$; the mean error for tibial rotation was 0.21°. Tibial rotation in the RHK was significantly greater than in the CCK (5.25° vs. 2.28°, respectively), $p < 0.05$. We have shown that RHK permit greater tibial rotation, being closer to physiological values than CCKs. Inertial sensors have been validated as an effective and accurate method of measuring knee movement. **The clinical significance:** RHK appears to represent a lower constriction degree than CCK systems.

Keywords: tibial rotation, rotating hinge knee (RHK), condylar constrained prostheses (CCK), inertial sensors, motion capture cameras.

INTRODUCTION

The number of total knee prostheses (TKA) implanted annually has tripled in the last decade due to the increase in life expectancy^{1,2}. This has, in turn, led to an increase in the number of revision surgeries performed. Primary TKA is now associated with excellent survival outcomes (around 95% at 10 years)^{2,3} compared with TKA revision surgery (79%-81% at 10 years)^{4,5}. This success rate has led to technological improvements in prostheses implanted during revision surgery. Prostheses with a higher level of constraint are needed in patients with greater ligament instability or bone stock loss⁶⁻⁸.

Constraint, is determined by degrees of freedom that an implant allows, compared to physiological movement⁹. The implants most commonly used in revision surgery are constrained condylar knee (CCK) and rotating hinge knee (RHK) implants. The greater constraint of RHKs is classically accepted due to the lower number of movements allowed¹⁰. The tibial rotation associated with flexion-extension movement of the knee joint is almost completely restricted by CCKs, due to the high congruence and trapezoidal shape of the post that limits this movement¹¹⁻¹³. For these reason, nowadays more surgeons are questioning the lesser constraint of these constrained condylar implants and choosing the RHKs as the first option for revision surgery knee prosthesis¹⁴⁻¹⁶.

Early hinged models, due to their rigidity, obtained poor 5-year survival rates close to 75%¹⁷. However, the latest RHK models have achieved survival rates beyond 80% 10-years survival, depending on the series consulted^{6,18,19}. These results have led to the expansion of the classic indications for RHKs to the extent that they now share indications with CCK¹⁸⁻²⁰. There is no randomized clinical trial comparing outcomes in varus-valgus constrained condylar knee and RHK that has been published. No study comparing the rotational constriction in tibial rotation in CCK and RHK has yet been published.

We hypothesized that RHK revision prostheses provide more physiological tibial rotation ("screw home") than CCKs¹³, and therefore have a lower, or at least an equal,

level of constraint. The objective of this study is to compare tibial rotation in varus-valgus constrained condylar knee and RHK and to validate the inertial sensors as an accurate measurement tool of the knee range of movement.

MATERIALS AND METHODS

This is a cadaveric study performed in accordance with the principles of the 1964 Declaration of Helsinki as revised in 2013 and was approved by the research ethics committee of our center (VERL-COT-2017).

Sixteen cadaver knees were used, 8 left and 8 right, divided into 2 study groups of 8 knees, 4 right and 4 left, to study tibial rotational kinematics. In the first group (RHK group), a rotating hinge prosthesis (Endomodel; Waldemar Link GmbH and Co.KG, Hamburg, Germany) was implanted, and in the second group (CCK group) a Legacy constrained knee (LCCK; Zimmer, Warsaw, Indiana, USA) was used. Knees with at least 20 cm of tibial and femoral diaphysis on which to anchor the support of the measuring devices were chosen. We specifically selected knees with no ligament instability and with a complete extensor mechanism. We fixed the femoral part of the knee (including bone and soft parts) to a metal claw and we leave the tibia and fibula free, in order to recreate the intraoperative environment during the knee prosthetization, in which we can test the stability of the prosthesis and the joint mobility.

In all cases, surgery was performed using a standard medial parapatellar approach. The medial and external lateral ligaments were released in the RHK group and left intact in the CCK group. Knees in the RHK group were replaced with a size small monobloc Endomodel® prosthesis, and those in the CCK group were replaced with a LCCK® implant, femoral size D, tibia 3, and 145 mm femoral and tibial stems without offset (Figure 1). In all cases, the tibial and femoral components were cemented using standard bone cement with gentamicin (Palacos R + G®, Heraerus, Hanau, Germany). Finally, the incision was sutured in three different layers.

Two instruments were used to measure differences in the range of motion in the rotation and flexion-extension between the prosthetic models: inertial sensors and motion capture cameras. We used 2 MARG (Magnetic, Angular Rate, and Gravity) sensors (PhidgetSpatial Precision 3/3/3 High Resolution Inc®, Alberta, Canada), which provide a full estimation of orientation by combining the information of tri-axis gyroscope, accelerometer and magnetometer. To avoid magnetometer measurement artifacts caused by magnetic field distortions, the sensors were calibrated for the magnetic field of the geographical area in which the study was conducted. To determine the accuracy of the inertial sensors to estimate the range of motion, knee mobility measurements were compared with those obtained using dual-camera optical motion tracking cameras (NaturalPoint Inc., OR, USA), implanting 4 spherical optical markers on each bone. The cameras were located at a distance of 2 metres from the side of the knees.

We designed a 3D printed tools for anchoring the inertial sensor and the 4 motion capture marker spheres to the cadaver femur and tibia diaphysis, consisting of a flat base on which the inertial sensor and 4 motion capture markers were mounted (Figure 2). The tools were printed on a desktop 3D printer using polylactic acid material and attached to the bone tissue using pins. This allowed us to obtain real rotational

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measurements without having to account for soft tissue mobility¹³. The base was anchored on the tibia immediately distal to the anterior tuberosity, while on the femur it was placed 5 cm proximal to the superior pole of the patella (Figure 3).

The range of motion of flexion and extension was measured on all knees by taking 4 measurements of the same movement per knee studied. Following this, tibial rotation range of motion was determined at 0°, 30°, 60° and 90° knee flexion, also taking 4 measurements from each knee. We began to record the range of tibial rotational from maximum internal rotation to maximum external tibial rotation at all flexion angles. All movements were recorded simultaneously by the inertial sensors and motion capture cameras, allowing us to determine the accuracy of the inertial sensor as a measuring instrument.

The data from both measurement systems were recorded using a customized software application developed on the 3D Slicer medical imaging platform²¹ and PLUS toolkit²². The application was designed to record flexion, extension and rotational movements²³ of the knee using a stationary fixed coordinate system on the femur and computing the three-dimensional movements of the tibia. Knee motion was computed by taking the femur position as a reference and measuring angular movement from the rotation matrix relating the tibia and femur bones. The mean rotation axis of each knee movement was computed using quaternions and the knee rotation was estimated using this rotation axis as a reference. A median filter was applied to remove noisy samples. Finally, the peaks of the rotation signals were identified and the range of motion was estimated for each movement using both systems.

The software provides a 3D visualization of the knee movement in real-time and enables recording knee flexion-extension and tibial rotation simultaneously and in real-time using both inertial sensors and motion capture cameras (Figure 4). After recording, the software displays to the user the measured movement in a graph, computes the range of motion, and stores the recorded values into CSV files.

Statistical analysis

Statistical analyses were performed with SPSS 23.0 (IBM, Chicago, IL, USA). The Shapiro-Wilk test was used to test the normality of variables. Quantitative variables were compared using the paired samples t test. The Pearson correlation coefficient was used to validate inertial sensor measurements. A value of $p < 0.05$ was considered significant.

RESULTS

A comparison of the accuracy of the inertial sensor vs the motion capture camera (Table 1) showed an average difference of 0.21° (SD 0.22°) between the 2 instruments; these differences were not statistically significant ($p > 0.05$). The analysis of Pearson's correlation index between the measurements made by the inertial sensors and those made with the motion capture camera, considered the gold standard for this type of study showed a correlation index of 0.992 (Figure 5).

The data obtained from the inertial sensors showed an average tibial rotation of 5.18° (SD 2.61°) in the RHK group and 2.25° (SD 0.99°) in the CCK group; these differences were statistically significant ($p < 0.001$). The greatest measurement of

tibial rotation was obtained at 60° flexion in the RHK group, with 5.72° (SD 3.14 °), vs. 2.53° (SD 1.03) in the CCK group; these differences were statistically significant ($p = 0.02$). Tibial rotation was higher in the RHK group vs the CCK group in all degrees of flexion, with statistically significant differences (Table 2).

Similar results were obtained by the motion capture cameras: the average tibial rotation in the RHK group was 5.25° (SD 2.78) vs. 2.28° (SD 1) in the CCK group; these differences are statistically significant ($p < 0.001$). Also in this case, the greatest magnitude of tibial rotation was recorded at 60°, with 5.82° (SD 3.23) in the RHK group vs. 2.66° (SD 1.13) in the CCK group; these differences are statistically significant ($p = 0.02$). We also observed that tibial rotation was greater in the RHK group vs. the CCK group, with statistically significant differences at all flexion angles (Table 3).

DISCUSSION

The widespread notion that rigid hinged implants give poor functional outcomes needs to be reviewed in the light of the performance of the latest rotating hinge prostheses. No randomized clinical trial comparing the clinical and radiological outcomes of rotating hinge implants vs valgus-varus constrained prostheses has yet been published, although Hommel et al. are currently conducting a trial to explore these differences⁶. Any comparison of these 2 models of high constraint prostheses thus far must predate 1982, when the hinged prosthesis was modernized to today's rotating hinge prosthesis. Pure hinged knee prostheses with a fixed axis gave poor functional outcomes, and were at high risk of loosening due to their excessive constraint^{6,17}.

At present, outcomes with both prosthetic models in revision or instability surgery are excellent. Siqueira et al.²⁴ report outcomes from 685 CCKs: 10-year survival in 88.5% of primary arthroplasties, 75.8% in aseptic revision, and 54.6% in septic revisions. Wilke et al.⁵ reported similar findings, with a 10-year survival rate of 80% in aseptic revisions. This confirms the excellent outcomes achieved in primary arthroplasties, good outcomes in aseptic revisions, and regular outcomes in septic revisions²⁵⁻²⁷. Recent clinical studies in rotating hinged implants show similar survival results^{20,28-30}.

Cottino et al.¹⁸, in a study of 408 rotating hinge implants, including primary arthroplasties and septic and aseptic revisions, found a 10-year survival rate of over 95%, findings that are consistent with the 90% 10-year survival rate reported by Gehrke et al.¹⁹. These results appear to be similar to those observed with CCK in primary TKA, but are better in cases of both septic and aseptic revision.

There are few studies with a good level of evidence that compare outcomes in CCK vs. RHK. In their meta-analysis, Malcolm et al.³¹ conclude that both implants have similar survival and functionality, although the revision rate in CCKs is 9% higher. Yoon et al.³² published similar results, but highlight the higher 5-year survival rate of RHKs (87.4%) vs. CCKs (75%). Many retrospective studies have found similar results in both prostheses in terms of joint mobility, functionality, survival and complications, but in most of these studies, TKA in the RHK group was more complex^{7,10,33}. These studies are prone to bias, since the RHK groups generally include more complex cases, with greater bone destruction and more ligament instability^{7,10,31,33,34}.

Overall, the aforementioned studies show that clinical outcomes in RHK prostheses are similar to CCKs, these might be because the level of constraint in both implants is more similar than expected⁶. Varus and valgus are stabilization movements, and recent biomechanical studies suggest that this mobility is so reduced that it does not increase bone stress in either RHK or CCK prostheses. Samiezadeh et al.¹⁵, using the finite element method to compare both prosthetic models, found that they are similar when the varus and valgus force is removed, but not when rotational stress is removed. Tibial rotation is probably the most difficult movement to reproduce due to the anatomical difference found in the femoral condyle³⁵. When flexing the knee, the external condyle moves from anterior and posterior, producing the internal rotation of the tibia. When the knee is extended, the tibia rotates externally to its full extent, and the last 20° of extension with maximum external rotation is called the “screw home” movement. This is the moment of maximum stress, since in normal gait the knee supports the body at this time. In a normal person, the tibia rotates between 7° and 30°¹³. When starting to walk with the load in extension and starting flexion, a new external rotation is made, called the “paradoxical screw home”³⁶. These results are consistent with our study, which shows that rotating hinge prostheses allow greater tibial rotation and thus, less constraint, than CCK. We have also shown that rotating hinge prostheses give a more physiological tibial rotation than varus-valgus constraint models (5.25° vs. 2.28°).

During the study, we validated inertial sensors as an instrument for measuring joint kinetics by comparing them with measurements obtained with motion capture cameras, considered the gold standard for the study of joint movement and gait^{37–40}. Inertial sensors are nearly 10 times less expensive than motion capture cameras, and far easier to use.

As a limitation we have to comment that although full extension produces a physiological lock in which the knee appears to have virtually no movement, we were able to identify rotational movement at this point. This could be due to taking the measurements in models with no axial load, and the absence of the full lower limb could have limited our results, as knee stability depends indirectly on the status of the nearby joints.

CONCLUSIONS

The use of inertial sensors to measure knee flexion, extension and tibial rotation has been validated, showing rotation data is nearly equivalent ($\pm 0.2^\circ$) to those recorded by motion.

Rotating hinge knee prostheses have shown greater tibial rotation than CCK prosthesis with values more close to the physiological tibial rotation. In this way, our study provides evidence on the need to review the classic concepts of constraint associated with these two implants.

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CONFLICT OF INTEREST STATEMENT:

“Each author certifies that he or she has no commercial associations (eg, consultancies, stock ownership, equity interest, patent/licensing arrangements, etc) that might pose a conflict of interest in connection with the submitted article.”

Figures:

Figure 1: **A:** Condylar constrained implant (CCK), **B:** Rotating hinge.

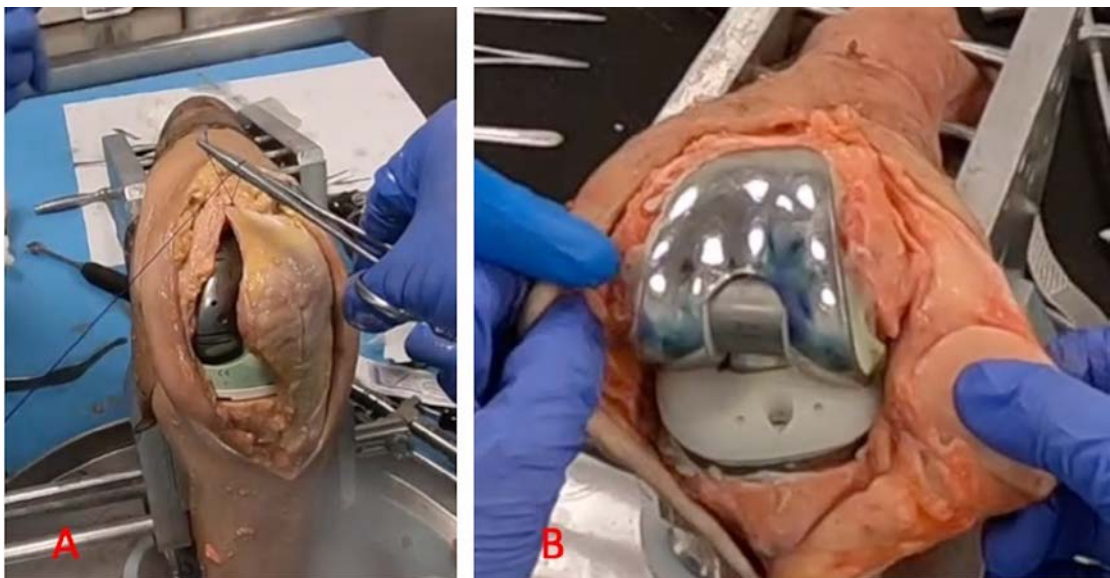


Figure 2: Left side, the 3D tool in Meshmixer ®. Green base, inertial sensors (green arrow) and motion capture markers (yellow arrow). The red arrow indicates the holes for the bone pins.

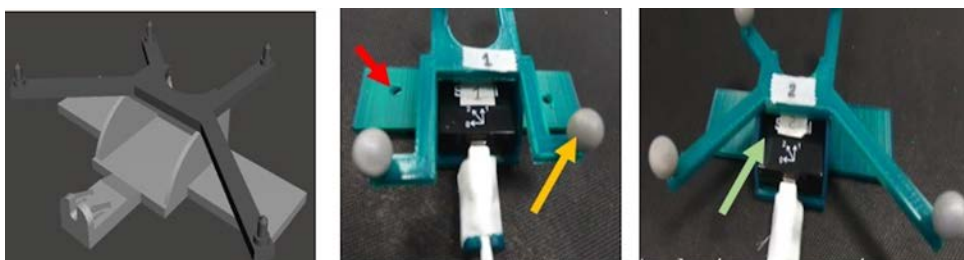


Figure 3: Base 1 on upper femur, base 2 on lower tibia. Motion capture markers (red arrow). The inertial sensors are inside the green base.



Figure 4: 3D Slicer motion capture software. The waveforms obtained from the motion capture cameras are shown in green, and the data obtained from the inertial sensors are shown in red.

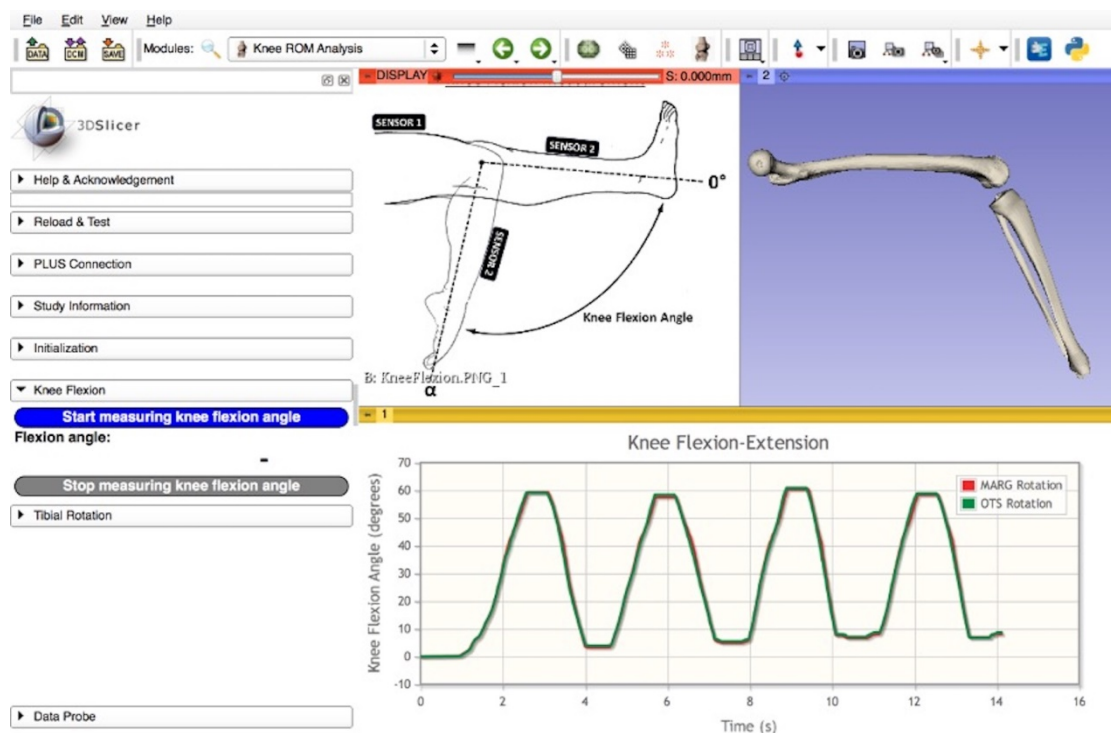


Figure 5: Example of live data recording of flexo- extension motion 0-60° with the inertial sensor (blue line) vs the motion capture camera in four oscillations (red line). OTS: Optical tracking system. MARG: Magnetic, Angular Rate, and Gravity

(Inertial sensor).

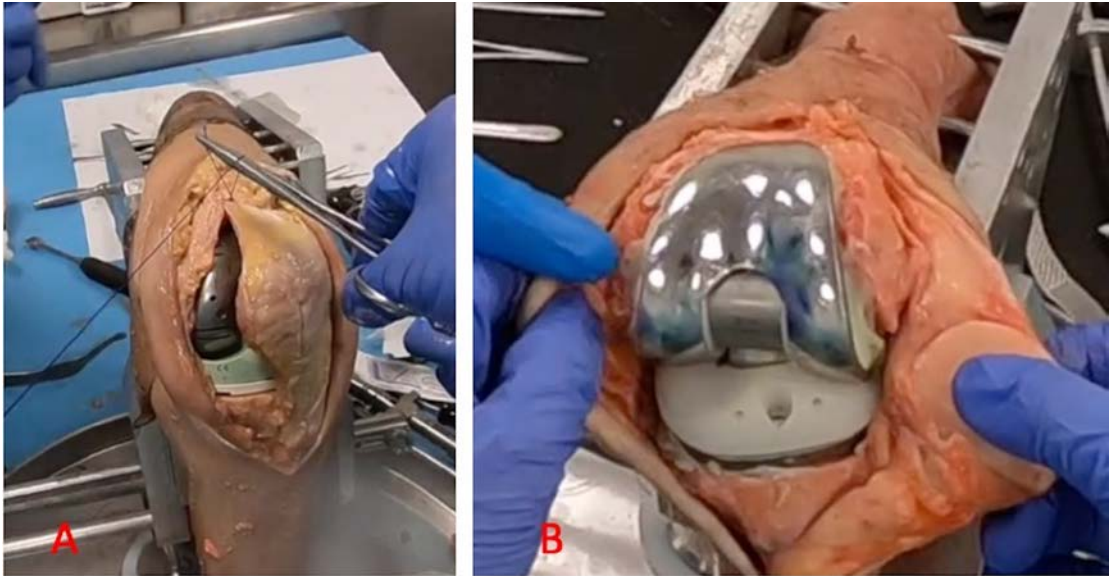


Table legends:

Table 1: Mean tibial rotation measured by motion capture cameras and inertial sensors. MCC: Motion capture cameras

Table 2: Tibial rotation in both study groups measured with inertial sensors.

Table 3: Tibial rotation in both study groups measured with motion capture cameras.

Table 1: Mean tibial rotation measured by motion capture cameras and inertial sensors. MCC: Motion capture cameras

KNEE FLEXION ANGLE	INERTIAL SENSORS	MCC	DIFFERENCE
0°	3.76 (SD 2.54)	3.83 (SD 2.58)	0.23 (SD 0.2)
30°	3.25 (SD 1.66)	3.24 (SD 1.66)	0.12 (SD 0.11)
60°	4.12 (SD 2.79)	4.24 (SD 2.85)	0.21 (SD 0.17)

90°	3.74 (SD 2.8)	3.76 (SD 3.06)	0.28 (SD 0.41)
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Table 2: Tibial rotation in both study groups measured with inertial sensors.

Inertial sensors			
KNEE FLEXION ANGLE	RHK Group	CCK Group	P
0°	5.28 (SD 2.71)	2.23 (SD 1.08)	0.01
30°	4.11 (SD 1.94)	2.39 (SD 0.68)	0.03
60°	5.72 (SD 3.14)	2.53 (SD 1.03)	0.02
90°	5.62 (SD 2.72)	1.87 (SD 1.18)	0.005
Total movement	5.18 (SD 2.61)	2.25 (SD 0.99)	<0.001

Table 3: Tibial rotation in both study groups measured with motion capture cameras.

Motion capture cameras			
KNEE FLEXION ANGLE	RHK Group	CCK Group	p
0°	5.38 (SD 2.79)	2.28 (SD 1.02)	0.01
30°	4.07 (SD 1.95)	2.40 (SD 0.7)	0.04
60°	5.82 (SD 3.23)	2.66 (SD 1.13)	0.02
90°	5.74 (SD 3.15)	1.78 (SD 1.09)	0.009
Total movement	5.25 (SD 2.78)	2.28 (SD 1.00)	<0.001