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Kinematic evaluation of cruciate-retaining total knee replacement patients during level walking: A comparison with the displacement-controlled ISO standard

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Abstract

Differences between wear-scar features of simulator-tested and retrieved tibial total knee replacement (TKR) liners have been reported. This disagreement may result from differences between *in vivo* kinematic profiles and those defined by the International Organization for Standardization (ISO). The purpose of this study was to determine the knee kinematics of a TKR subject group during level walking and compare them with the motion profiles defined by the ISO standard for a displacement-controlled knee wear testing simulator. Twenty-nine patients with a posterior cruciate ligament-retaining TKR design were gait tested using the point cluster technique to obtain flexion-extension (FE) rotation, anterior-posterior (AP) translation and internal-external (IE) rotation knee motions during a complete cycle of level walking. Relative ranges of motion and timing of key points within the *in vivo* motion data were compared against the same ranges and same key points from the input profiles of the displacement-controlled wear testing standard ISO14243-3. The subjects exhibited a FE pattern similar to ISO, with an insignificant difference in range of FE rotation from midstance to terminal stance. However, the subjects had a significantly higher range of knee flexion from terminal stance into swing. The subjects also exhibited a phase delay for the entire gait cycle. For AP translation, the standard profile had statistically significant lower magnitudes than seen *in vivo*. Opposite pattern of AP motion was also apparent from midstance and swing. Similarly, ISO specified a smaller IE total range of rotation with a motion pattern in complete opposition to that seen *in vivo*. In conclusion, significant differences were found in both the magnitudes and pattern of *in vivo* motion compared with ISO.

Keywords

total knee replacement; gait; wear testing; knee kinematics

Introduction

Over 450,000 total knee replacement (TKR) surgeries are performed annually in the US, with an anticipated increase to 3,480,000 surgeries by the year 2030 (Kurtz et al., 2007). During the

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Conflict of Interest Statement

Authors Ngai and Wimmer received an unrelated institutional grant from Zimmer.

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past several decades, increases in life expectancy, body weight and activity level of TKR candidates have been documented, thus necessitating improved implant endurance and durability (Crowninshield et al., 2006). With a current prosthesis survival of 10–15 year (Sharkey et al., 2002), the number of revision surgeries is projected to increase from 38,300 in 2005 to 268,200 by the year 2030 (Kurtz et al., 2007). In order to reduce the anticipated revisions, increasing implant longevity is of prime importance. A prevalent cause of implant failure has been wear of the polyethylene tibial liner (Sharkey et al., 2002; Swedish Knee Arthroplasty Registry, 2006). Knee wear simulator testing is therefore essential for pre-clinical evaluation of prosthesis performance. Physiologic testing conditions are necessary for accurate implant assessment and for the development of preventive measures to improve device longevity.

Normal knee function entails various combinations of translation and rotation between the femur and tibia (Andriacchi et al., 1986; Walker and Sathasivam, 2000; LaFortune et al., 1992). The primary motion of the knee is flexion-extension (FE) rotation, however secondary motions have been previously defined as anterior-posterior (AP) translation and internal-external (IE) rotation (Dyrby and Andriacchi, 2004). Current prostheses wear testing can be conducted using displacement-controlled simulators, which are supposed to mimic these kinematic conditions, under a standardized protocol (ISO14243-3, 2004) developed by the International Organization for Standardization. This standard defines the FE, AP, IE and axial (compressive) force patterns during an entire gait cycle as input.

Studies have used fluoroscopic imaging to track 3D knee motions of TKR patients during various activities (Banks et al., 1997; Stiehl et al., 1995; Dennis et al., 2003; Li et al., 2006; Harman et al., 2001). Due to a small field of view, these methods inhibit natural patterns of locomotion during the most frequent activities of daily living (ADL) (Andriacchi et al., 2003). There is only limited information on tibiofemoral motions of TKR patients for an entire cycle of level walking. Yet natural tibiofemoral kinematics during ADL are important for wear analysis. In particular, characterizing kinematics during walking with a high fidelity to natural movement is relevant due to the large number of loading cycles associated with this activity.

Analyses of wear scars showed bigger wear areas and more variable pattern of wear in retrieved components than in simulator tested components (Schwenke et al., 2005; Orozco et al., 2005), suggesting obvious differences between *in vivo* and simulation. Stair ascent/descent manoeuvres have been shown to affect wear scarring in TKR, which could partly explain the differing wear areas between the groups (Benson et al., 2002). However, TKR gait by itself is quite variable (Andriacchi et al., 1982) causing differences in AP forces (Wimmer and Andriacchi, 1997) and (perhaps) secondary movements. Therefore, the variable pattern observed on retrieved components may be due to motion variability from patient to patient since wear scars are linked to patient specific gait (Schwenke et al., 2005; Wimmer et al., 2003). In order to allow viable assessment of implants, the testing input should be as representative as possible.

The aims of the current study were to characterize the primary and secondary knee motion patterns during an entire cycle of level walking of cruciate-retaining TKR subjects and to compare them with the profiles defined by the displacement-controlled simulator standard. We hypothesized that the relative ranges of motion for FE, AP and IE motions of the TKR population would not be statistically different from those defined by ISO and that the pattern of motion would be similar; meaning the timing of peaks and valleys would not be different between those observed *in vivo* and those of the standard.

Methodology

Twenty-nine TKR patients, separated into two groups, were recruited to undergo gait analysis at Rush University Medical Center (Chicago, USA) to obtain knee joint motions during level walking at self-selected speeds. Patient consents were obtained for this Institutional Review Board approved study. The study inclusion criteria specified patients that had a successful primary TKR of a posterior cruciate ligament (PCL) retaining design. Group 1 had ten subjects with a Miller-Galante II (MGII) TKR and Group 2 had nineteen subjects with a NexGen Cruciate-Retaining (NGCR) TKR. Both implant types were manufactured by Zimmer, Inc. The MGII is an older design with cylinder-on-flat tibiofemoral articulations, providing minimal constraint. The MGII has a flatter tibial plateau surface and larger femoral radii of curvatures than the NGCR. The NGCR incorporates slight dishing of the tibial plateau with differing radii of curvature on the lateral and medial femoral condyles. All implants were at least 12 months in-situ and patients were actively being followed for post-operative care by an orthopedic surgeon. Patients were excluded if they required a walking aid, had undergone revision surgery or had a history of neurological disorders (ie. stroke, multiple sclerosis, Parkinson's). Patients walked with runners or standard walking shoes. Details of the TKR subjects are listed in Table 1.

To obtain the primary knee motion, FE rotation, and secondary knee motions, AP translation and IE rotation, the sample TKR populations were gait tested using the point cluster technique (PCT) (Andriacchi et al., 1998). Twenty-one reflective markers were placed on the thigh and shank, creating 2 cluster groups (Figure 1a) with corresponding orthogonal sets of axes, referred to as the cluster coordinate systems (Andriacchi and Dyrby, 2005). Palpable bony landmarks (Hoppenfeld and Huton, 1976) defined the femoral and tibial anatomical coordinate systems to which these cluster coordinate systems were then related. The femoral coordinate system was defined as the midpoint of the transepicondylar line of the distal femur (TEP axis), which is close to the instantaneous axis of motion (Andriacchi et al., 2003) and thus similar to the center of femoral rotation as defined by the knee simulator standard. AP translation and IE rotation motions were measured as previously described (Andriacchi and Dyrby, 2005), to obtain motions of the tibia relative to the femur (Figure 1b). The marker clusters allowed determination of detailed femoral and tibial motion, while minimizing non-rigid skin motion artifact (Alexander and Andriacchi, 2001). A four camera optoelectronic system (120 frames/s; Qualisys, Gothenburg, Sweden) was used to track the movement of the reflective markers and record the 3-dimensional knee motions for 3 separate walking trials per subject. A multi-component force plate (Bertec, Columbus, OH) was used to record foot-ground reaction force (GRF), which defined stance and swing phases of gait (stance was defined as forces greater than 5% body weight) Motion and force data were time-synchronized at 120 Hz. Using a rigid link model (Andriacchi et al., 2005), inverse dynamics were used to calculate three-dimensional external moments during gait (CFTC – Chicago, Illinois, USA) using the three-dimensional GRF data and sagittal plane motion as input.

Since intra-patient variability was considerably smaller than inter-patient variability (Ngai and Wimmer, 2007), primary and secondary knee motion data for all walking trials for each subject were averaged to obtain a single, subject representative walking trial. Two averaging methods were employed for both TKR groups to: a) produce representative motion curves for graphical display of each subject population and b) to allow direct, statistical comparisons with ISO in both time and spatial domains. The first method involved averaging subject representative curves every 1% gait to obtain motion curves representative of the subject populations. All motions were offset to start at the same value as ISO at heelstrike, thus permitting relative and qualitative comparisons to the standard. Since this averaging method results in attenuated peaks, it is inappropriate to identify peak values from the calculated motion curves. To allow statistical comparisons with the standard, the second averaging method matched peak

displacements and notable motion milestones for subjects in their respective groups to obtain key discrete data points of the subject populations (Figure 2). The timing of these key points and the relative ranges of motion between these points were compared with ISO. For FE rotation, motion milestones included peak knee flexion in midstance, minimum knee flexion in terminal stance and peak flexion in swing. Ranges of motion from midstance to terminal stance and from terminal stance to peak flexion in swing were then calculated and compared against ISO. For AP motion, motion milestones included the maximum posterior tibial translation in midstance, the maximum anterior tibial translation in terminal stance/near toe-off and the maximum posterior tibial translation in swing. The total ranges of posterior and anterior translation in both stance and swing were used to compare against ISO. For IE rotation, the motion milestones included the peak external tibial rotation in midstance, the peak internal tibial rotation in terminal stance and the peak external tibial rotation in swing. The total ranges of rotation in both stance and swing between these key points were calculated for comparison against the standard. All motion data were presented as mean $\pm$ standard error of the mean for both spatial and timing domains. Histograms were obtained to evaluate normality of data distribution. Levene's test for equality of variances was used prior to applying the independent samples t-test to determine if the two TKR populations were different from each other. The one-sample t-test was then used to test the hypothesis that the population means were equal to the values from ISO, with calculated p-values being considered significant for $p \leq 0.05$. All statistical analyses were carried out using SPSS (SPSS Inc., Chicago, IL).

Results

The typical motion patterns of both the MGII and NGCR TKR populations, obtained from averaging data every 1% gait, were very similar to one another. Both FE profiles displayed nearly full extension at heelstrike, 18–20° of knee flexion during midstance, and a knee flexion of 8–11° during terminal stance (Figure 3a). Peak knee flexion of 63–65° occurred during swing phase at 76% of the gait cycle for both groups. The average AP pattern (Figure 3b) of the MGII and NGCR groups showed posterior tibial travel immediately after heelstrike, followed by anteriorly directed tibial translation. On average, the AP motion tended to be smaller for the NGCR group, however, this finding was not significant. At toe-off, all subjects switched to again translate posteriorly and finally concluded swing phase with an anteriorly directed tibial movement. The averaged rotational profiles (Figure 3c) during walking indicated less than 6° of total rotation during stance, leading into an external tibial rotation from terminal stance to peak swing. Both TKR groups then displayed a final direction change to internal tibial rotation to the end of swing phase. Generally, the secondary motions for the NGCR group appeared smoother during stance phase than the MGII group.

Based on the notable motion milestones identified for all motions, the MGII and NGCR TKR groups were not statistically different in either the spatial or timing domains (Figure 3a, b, c). For this reason, the two populations were combined and the resulting average motion curves allowed for a qualitative assessment against the ISO standard. Motion milestones of the combined group were determined for subsequent statistical comparisons against ISO.

As shown in Figure 3a, the average subject FE profiles had a similar pattern to that defined by ISO; however there were significant differences. Subjects displayed an increased range of knee flexion from terminal stance to peak flexion in swing. Peak knee flexion in midstance, minimum knee flexion in terminal stance and peak flexion in swing all occurred statistically later than prescribed by ISO (Table 2).

The AP input profile for ISO initially followed a similar motion path as displayed by the average AP patterns of both subject groups (Figure 3b), with a posterior tibial travel after heelstrike and a switch to anterior tibial displacement in early midstance; however, the magnitudes

defined by ISO were much smaller (Table 2). A pattern discrepancy between the subjects and ISO began at approximately 40% gait. The TKR subjects continued to translate anteriorly from terminal stance until toe-off as the ISO profile suggested a posterior translation of the tibia. The ISO profile changed direction one final time to translate anteriorly at the end of stance phase, whereas the patients did not change translation direction until approximately toe-off, exhibiting posterior tibial translation. The subjects then displayed a final direction change, with an anterior tibial travel at the end of swing. It is notable that the subjects exhibited two tibial direction changes during swing phase where ISO did not reflect any directional changes during this phase, and continued its anterior tibial translation initiated in terminal stance. In general, both the subject groups and the ISO curve displayed 3 points of direction changes; however, the times at which these changes occurred during the gait cycle and the magnitudes differentiated the ISO profile from the subjects (Table 2).

The IE rotation pattern also reflected the AP translational findings, showing nonconformation between the ISO curve to that of the TKR subjects (Figure 3c). During stance, there was a high variability in the *in vivo* IE patterns, displaying larger rotations than defined by ISO (Table 2). At approximately 55% gait, the input motion of ISO and the *in vivo* IE rotational patterns displayed completely opposite motions, with the subjects rotating externally while the ISO defined internal tibial rotation. At the end of swing, the *in vivo* and ISO curves changed direction once more, continuing the motion contradiction. Total ranges of rotation in both stance and swing were significantly different between ISO and subjects (Table 2).

Discussion

In vivo knee kinematics of two sample cruciate-retaining TKR populations with related implant designs were obtained for one complete cycle of level walking and compared with the input motion profiles for knee prosthesis wear testing for a displacement-controlled simulator. While the movement patterns and magnitudes were similar between the two subject groups, significant differences in both the pattern and the magnitudes of movement were found for primary and secondary motions between the *in vivo* kinematics of both TKR groups and those defined by the ISO standard, contradicting our study hypothesis.

Andriacchi et al., 1982 utilized 6 marker gait analysis on TKR patients during level walking and determined that patients had a different pattern of sagittal motion when compared with a normal control population. The TKR group displayed a flexion-contraction at heelstrike, higher knee flexion during terminal stance and a time delay before reaching maximum knee flexion in swing. The current study determined similar *in vivo* FE profiles (although no flexion contraction at heelstrike was found), confirming that TKR patients walk abnormally.

Secondary motions of the knee were also determined during this study. Both subject groups displayed very similar motions, both in magnitude and pattern. The NGCR tibial compartments are slightly dished in the sagittal and frontal planes, and thus provide more constraint than the flat MGII component. The NGCR group tended to have smoother and smaller motions than the MGII group, however, no statistical difference between the two sample groups was determined though larger populations could yield otherwise. The average AP motion profiles indicated posterior tibial travel immediately after heelstrike for both groups, moving into and continuing anterior translation from early stance to toe-off, for a maximum displacement of 19.3 ± 4.82 mm and 21.5 ± 3.13 mm during stance phase for the MGII and NGCR populations, respectively. These displacements are much larger than what is suggested by the standard, but similar observations have been made in a recent cadaveric test by Sutton et al., 2008. The *in vivo* walking pattern of motion contradicts the femoral rollback theory of relative anterior tibial translation with increasing flexion, which was initially established passively with cadaver knees (Iwaki et al., 2000). Consistent findings of translations with little or no posterior femoral

rollback with flexion have been reported by numerous researchers (Nilsson et al., 1991; Nozaki et al., 2002; Hanson et al., 2006).

There was high variability in the IE profiles between the subjects during stance (coefficient of variation 60.9%) (Ngai and Wimmer, 2007). This substantial variability of axial rotation between patients has been reported previously and expressed as a common occurrence in PCL-retaining TKRs (Dennis et al., 2003). During swing phase, all the subjects exhibited a common motion pattern: external tibial rotation entering swing phase, reaching a peak external tibial rotation and changing to internal tibial rotation into the end of swing phase. The average maximum total ranges of rotation for the entire gait cycle was $13.6 \pm 2.25^\circ$ (MGII) and $16.9 \pm 2.09^\circ$ (NGCR). Dennis et al., 2003 and Karrholm et al., 1994 both found a rotational pattern that agreed with the findings of the current study. With the exception of one, twenty-eight TKR subjects had externally rotated toe-out angles during stance leading into swing, which could possibly indicate a forced external tibial rotation and help explain the observations of an internally rotating tibia at the end of swing and thus the “counter-screwhome” motion during knee extension. It is very interesting to note that secondary motions of level walking for normal subjects have similar AP and IE patterns as the TKR subjects in this study (LaFortune et al., 1992; Andriacchi et al., 1998).

When comparing the primary and secondary motions of the subjects with the motion input profiles of ISO for displacement-controlled simulators, both the patterns and magnitudes of motion were significantly different. During FE, the motion pattern between the subjects and the standard was similar. However, the subjects had significantly higher knee flexion angles during heelstrike, midstance and peak flexion in swing, with statistically significant phase delays in the occurrence of peak knee flexion in midstance, minimum knee flexion in terminal stance and peak flexion in swing than prescribed in ISO. For the secondary knee motions, ISO displayed smaller AP and IE displacements and defines a perfect “screwhome” motion throughout the entire gait cycle. The subjects had significantly larger AP translations and complete opposite AP and IE patterns to ISO in swing phase. Interestingly, if the ISO IE pattern was flipped, the conformance to the *in vivo* pattern is astounding.

DesJardins et al., 2007 conducted a study which compared fluoroscopically determined *in vivo* knee kinematics of PCL-retaining TKR patients during treadmill gait with the output motions from a force-controlled simulator wear test that followed the ISO force control standard (ISO 14243-1). Based on an “active” subgroup of 4 patients, they found good agreement in both patterns and ranges of motion throughout the entire gait cycle. Their *in vivo* motions described “screwhome” mechanism and translations with magnitudes much smaller than currently reported. The current collective TKR group walked at much faster speeds than the “active” subjects in the DesJardins et al. study (avg. $1.19\text{m/s} \pm 0.05$ vs. 0.76m/s). Walking speed has been shown to influence joint angles (Stansfield et al., 2001), knee axial loading and adduction torque (Zhao et al., 2007), altering kinematics. The higher walking speed of our patients therefore induced a higher cadence (54.7 ± 1.19 steps/s), which translated into an average gait cycle frequency of 0.9Hz, thereby encompassing the ISO specified testing frequency (1.0 ± 0.1 Hz). Also, treadmill walking was conducted while hands were rested on the handlebars, possibly affecting balance and body posture during gait. Therefore, both walking speed and the type of gait (level walking vs. treadmill) could explain variations in magnitudes and pattern between both studies.

The results of this study may be influenced by the limitations of skin-marker gait testing, which can only estimate the positions of the underlying osseous structures and may be masked by skin movement. Since the rotation axis of the knee is not fixed, overestimations of movement are possible, particularly during high flexion (ie. swing phase). Interestingly, the analysis of 67 MGII retrievals reported an average AP wear scar stretch of 21.8 ± 2.67 mm and 22.6 ± 2.76

mm for the medial and lateral plateaus, respectively (Paul, 2004), which correspond to the total AP displacement travelled during stance phase in the present study (19.3 ± 4.82 mm for MGII) very well. Additionally, the PCT method was originally validated against Lafortune et al. 1992 study, where the primary and secondary motions for normal individuals without TKR were obtained during level walking using intra-cortical bone pins. All motions were agreeable in magnitude and pattern (Andriacchi et al. 1998).

In conclusion, the knee kinematics for two sample cruciate-retaining TKR populations during a complete cycle of level walking were obtained and compared with the current standard protocol for knee prosthesis testing for displacement-controlled simulators. Significant differences were found in both the pattern and magnitudes of *in vivo* motion with the standard. This finding suggests that the most representative motion patterns have yet to be identified to better reflect the *in vivo* situation and provide more viable data for prosthesis evaluation.

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Figure 1.

a) Representative subject showing placement of the lower limb markers

b) Definition of primary and secondary motions of the knee. Note that secondary motions refer to movement of the tibia with respect to a fixed femur.

Figure 2.
Averaging Method – Peaks and Key Points

Figure 3.

Kinematic profiles of ISO compared with the mean motion curves of the subject populations, averaged for every 1% time increment of the gait cycle. Statistical analysis was performed with notable motion milestones, where motion maxima and minima for each patient were matched. Those data points are shown with error bars for both the spatial and the time domain. All error bars represent ± 1 standard error of the mean.

a) Flexion-extension rotation b) Anterior-posterior translation c) Internal-external rotation

Table 1

Subject Demographics (Average values $\pm$ 1 Standard Deviation)

Group	1	2
Implant Design	MGII	NGCR
No. of subjects	10	19
Gender: Male/Female	6M/4F	9M/10F
Average Age (yrs)	76.6 $\pm$ 5.64	61.6 $\pm$ 7.14
Body Mass Index (kg/m ²)	30.2 $\pm$ 6.06	30.1 $\pm$ 6.94
Average in-situ time (yrs)	12.0 $\pm$ 0.92	3.16 $\pm$ 2.27

Table 2

Relative Ranges of motion (including direction) and timing of motion milestones during level walking: Subject data vs. ISO standard 14243-3 (Average values $\pm$ 1 Standard Error of Mean)

Flexion-Extension			
	Subjects	ISO	P value
Total knee extension from	12.34 $\pm$ 1.01°	11°	0.198
Midstance (@ % gait)	17.7 $\pm$ 0.82%	15%	0.003
to Terminal Stance (@ % gait)	43.7 $\pm$ 1.07%	40%	0.002
Total knee flexion from Terminal Stance to	59.4 $\pm$ 1.93°	53°	0.002
Peak Flexion (@ % gait)	75.8 $\pm$ 0.45%	72%	<0.001
Anterior-Posterior Translation *			
Stance Phase	Subjects	ISO	P value
Total Posterior Tibial Translation from Heelstrike	15.2 $\pm$ 1.36 mm	4.5 mm	<0.001
to Midstance (@ % gait)	14.6 $\pm$ 1.40%	17%	0.099
Total Anterior Tibial Translation from Midstance	20.8 $\pm$ 2.59 mm	4.2 mm	<0.001
to Terminal Stance/Toesoff (@ % gait)	60.4 $\pm$ 1.72%	40%	<0.001
End of Stance Phase and Swing Phase			
Total Posterior Tibial Translation from Terminal Stance/Toesoff	27.5 $\pm$ 2.72 mm	4.82 mm	<0.001
to Peak in swing (@ % gait)	87.4 $\pm$ 0.73%	56%	<0.001
Total Anterior Tibial Translation from Terminal Stance/Toesoff to end of cycle	21.1 $\pm$ 2.11 mm	4.83 mm	<0.001
Internal-External Rotation			
	Subjects	ISO	P value
Stance Phase	6.26 $\pm$ 0.66°	2.76°	<0.001
Total Internal (Subjects)/External (ISO) Tibial Rotation from			
Midstance (@ % gait)	13.7 $\pm$ 1.35%	15%	0.340
to Terminal stance (@ % gait)	50.2 $\pm$ 1.91%	40%	<0.001
Swing Phase	17.3 $\pm$ 1.58°	7.29°	<0.001
Total External (Subjects)/Internal (ISO) Tibial Rotation from Terminal Stance			
to Peak in swing (@ % gait)	79.8 $\pm$ 1.66%	89%	<0.001

Bold - significance to a 95% confidence level,

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based on 28 subjects