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Fluoroscopic assessment of lumbar total disc replacement kinematics during walking

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Structured Abstract

Study design. Descriptive.

Objective. The purpose of this study was to determine the in-vivo kinematics of functional spinal units, during gait, in individuals with a single-level lumbar total disc-replacement (TDR).

Summary of background data. TDR is a motion preservation technology that offers an alternative to spinal fusion for treatment of degenerative disc disease. The aim of TDRs is to replicate motion of the functional spinal units, which may protect adjacent intervertebral discs against accelerated degeneration. At present there is limited understanding of the in-vivo motion of TDRs, particularly during dynamic activities such as gait. Such information is important for understanding the wear characteristics of TDRs and furthering design rationale of future implants.

Methods. TDR motions were obtained from 24 participants implanted with single level L4-5 or L5-S1 Charité or In Motion TDRs. Video fluoroscopy was used to obtain measurements in the frontal and sagittal planes during fixed speed treadmill walking.

Results. The mean ranges of motion between the upper and lower lumbar TDR endplates during walking was 1.6 and 2.4 degrees in the frontal and sagittal planes respectively. These values were significantly different from zero and corresponded to 19% of the maximum static range of motion in each plane.

Conclusions. Lumbar TDRs provide a degree of motion preservation at the operative level during moderate-speed walking. The distribution of lumbar TDR motions during walking presented here will inform relevant standards for conducting standardised tests of lumbar TDRs, particularly wear assessments, and, hence, enable more realistic mechanical and computer-based wear simulations to be performed.

Mini abstract/précis

Lumbar TDRs provide a degree of motion preservation at the operative level during moderate speed walking. The characterisation of lumbar TDR motions during walking provides new information on which to base realistic wear simulations which may aid the identification of adverse wear scenarios.

Introduction

Low back pain secondary to lower lumbar spine degenerative disc disease causes a significant disease burden to the patient and a substantial economic burden to wider society, estimated to be as high as $100 billion per year in the US[1]. Failure of conservative interventions in alleviating symptoms almost inevitably leads to some form of surgical approach. The gold standard of the spectrum of possible invasive procedures is anterior inter-body spinal fusion, where the disc is excised and replaced with a construct comprising an implant and bone graft. However a potential iatrogenic complication associated with spinal fusion is accelerated adjacent disc disease[2,3], which is believed to arise because global spinal motions are delivered through motion of fewer discs[4-6]. Total disc replacements (TDR) have subsequently developed in which the disc is replaced by an artificial bearing which retains the potential for some form of inter-vertebral motion[7-9].

Mimicking total hip and knee arthroplasty, the most widely used TDRs have been those based upon metal-on-polyethylene articulating models such as the Charité[7], or metal-on-metal designs[10], with a predominance of the former. These devices have demonstrated some success in terms of both increased return-to-work and reduced patient disability when compared to spinal fusion surgery[11]. However, as with other articulating, artificial bearing systems, the longer term concerns are focused on the possibility of wear related failure, principally mediated through inappropriate immune response to the debris released into the joint space[12]. Indeed, case reports and retrieval programmes have highlighted evidence for osteolytic failure in lumbar TDRs as the implant periods move to those timescales associated with this type of performance degradation in other joints, that of 10-15 years[13-15].

An important aspect of both the pre-clinical testing of these devices and understanding the underpinning tribological conditions that effect implant performance has been the use of mechanical multi-axial joint simulators[16,17], and more recently, computational models based on the Archard wear equation to predict long-term wear[18,19]. Wear studies to date have been limited in number with input parameters for load and motion being those specified by either the ISO standard for conducting wear tests of lumbar TDRs[20] or ASTM guidance document[21] or variations thereof[16,22,23]. However, the representative nature of these input conditions has not been verified, nor is there sufficient information on the variance in these parameters to allow a comprehensive modelling approach with which to deliver population based distributions of predicted wear performance. Studies have demonstrated that changes in wear rate depend on the device design and may only be discerned with kinematic input parameters going beyond that suggested in the standard[16,22]. Hence it is important to have comprehensive understanding of the motion of the TDR, which is one of the key factors that affects implant wear.

The primary purpose of this study was to investigate the in-vivo motion of the Charité (recently renamed In Motion) lumbar TDR in a patient cohort using video fluoroscopy. In light of studies that demonstrate motion preservation following TDR during static lumbar range of motion assessment relative to spinal fusion[24,25], we hypothesized that lumbar TDRs would similarly facilitate motion preservation relative to theoretical fusion during walking. A secondary purpose was to to evaluate the correspondence between measured lumbar TDR ROM during walking and the lumbar kinematics recommended in the ISO standard for conducting wear tests of lumbar TDRs.

Materials and methods

Participants

Twenty four adults participated in the study. The inclusion criteria were at least six weeks and up to 5 years since implantation of a single lumbar level TDR (Charité or In Motion) at L4-L5 or L5-S1. Potential participants were excluded if they reported neurological, cognitive, proprioceptive or musculoskeletal disorders that would affect their ability to walk normally on a treadmill for 5 minutes, or reported pain at time of testing (Visual Analog Score > 3). The study was approved by the Institutional Human Research Ethics Committee and all ethics guidelines, including obtaining written informed consent, were followed. Participant characteristics are reported in Table 1.

<Insert Table 1 about here>

Design and protocol

Participants attended a local Radiology Clinic for testing on one occasion. Following collection of demographic data and completion of medical screening, participants underwent fluoroscopic assessment of their lumbar TDR to establish their static and dynamic range of motion (ROM), in the sagittal and frontal planes respectively.

Static ROM protocol. Frontal plane images of the lumbar spine were obtained with the participant in three static poses: flexed right, upright standing, and flexed left. Sagittal plane images were obtained with the participant in two static poses: upright standing and flexed forward. For all static trials participants were instructed to stand comfortably with feet shoulder width apart and facing forward. Additional instructions to participants were as follows: (1) Upright standing: place hands by sides and to look at a target on the wall located at eye height, (2) Lateral flexion: rotate trunk to the side by sliding hand down the outside of the thigh, and (3) Forward flexion: rotate trunk forwards while allowing the arms to hang vertically. For all flexion tasks the participants were instructed to flex as far as possible without causing excessive pain or discomfort. All participants were given standardised verbal cues by the same investigator (CA) to minimise out of plane motion.

Dynamic ROM protocol. Following completion of the static trials, participants walked on a motorized treadmill while fluoroscopic images of their lumbar spine were recorded. The treadmill speed was set to 0.7 statures per second, which corresponded to 1.23±0.07 m/s (4.43±0.24 km/hr), and is intermediate between self-selected slow and preferred walking speeds adopted by young healthy adults[26]. Due to the space constraints imposed by the fluoroscopic hardware it was not feasible to evaluate faster walking speeds where a longer stride length was required. The treadmill was initially positioned to record images in the frontal plane and was subsequently repositioned to record images in the sagittal plane. Following a period of familiarization, a minimum of 10 consecutive gait cycles was recorded in each plane for each participant.

Instrumentation

Fluoroscopic images were recorded using the Philips MultiDiagnost Eleva x-ray device (1250 by 925 pixels resolution, sampling frequency 8 Hz). For gait trials a pair of tri-axial accelerometers (Analog Devices ADXL202, range ± 2 g) mounted on the treadmill were used to determine foot-ground contact events. Accelerometer data were recorded at 1000 Hz on a laptop computer via a DAQ card (National Instruments) utilizing custom written software (LabView Version 9.0).

Data analysis procedures

TDR kinematics. A custom computerised tracking algorithm (Matlab Version 7.10.0.499, R2010a, The MathWorks) was used to record the x-y coordinates of the lateral endpoints of each endplate for each frame in the cine loops obtained for the frontal and sagittal planes. Each successive image was moved within a search window until the best match with the previous image, as determined by cross-correlation, was obtained. The offset in coordinates between successive images represents the displacement of the endplate over the period between images. This approach has been successfully used to track intervertebral kinematics[27]. Coordinate data were filtered using a Butterworth low pass filter with a cut-off frequency of 3 Hz and used to compute the upper and lower endplate angles in the frontal and sagittal planes with respect to the right hand horizontal. Positive endplate angles were defined as counterclockwise. The relative angle between the upper and lower endplate was subsequently computed from the difference between the upper and lower endplate angles.

The Static ROM of the upper and lower endplate angles and the relative endplate angle was defined as the difference between the respective angles in the flexed right versus flexed left pose for the frontal plane, and between the upright and forward flexed position in the sagittal plane. The Dynamic ROM of each angle during walking was calculated as a function of the root mean square (RMS) of the time series of the respective angles ($\theta(t)$) across the sampling period using equation 1.

$$Dynamic\ ROM\ = 2\sqrt{2} \times RMS\big(\theta(t)\big) \qquad \text{Equation 1}$$

The mean upper and lower endplate angle and the mean relative angle during gait were also computed and contrasted with the corresponding angles from the upright static pose.

Representative static pose and gait data for a single representative participant are displayed in figure 1 (frontal plane) and figure 2 (sagittal plane). Corresponding video files of raw fluoroscopy data with endplate angle estimates overlaid for these examples are provided as Supplemental Digital Content. The effect of fluoroscopic image distortion on the endplate angles was assessed to be insignificant and so no image corrections were performed.

<Insert figure 1 and 2 about here>

In order to test the repeatability of the tracking algorithm we tracked endplates and calculated endplate angles during walking for three participants on three occasions, and then computed the repeatability of the upper and lower endplate angles using the Coefficient of Multiple Correlation (CMC). The CMC is a waveform similarity statistic that approaches 1 when waveforms are similar and 0 when dissimilar [28]. CMCs for the upper and lower endplate angles in the sagittal and frontal exceeded 0.98, indicating high levels of waveform repeatability.

Cadence and step length. Cadence was measured from accelerations associated with vibration of the treadmill at each foot contact. Lloyd and Svensson [29] demonstrated this method to have an RMS error of 1% compared to footswitch systems. Average step length was subsequently computed as a function of the pre-set gait speed and the measured cadence. Cadence and step length were 128 ±11 steps per minute and 0.58±0.05 m respectively for frontal plane trials, and 125 ±12 steps per minute and 0.58±0.06 m respectively for sagittal plane trials.

Statistical analysis

Paired t-tests were used to determine the effect of operative level (L4-5 versus L5-S1) and gender on the relative endplate angles and ROM under static and dynamic conditions in the frontal and sagittal planes. One-sample t-tests were used to determine whether the dynamic ROM between the upper and lower endplates in the sagittal and frontal planes during walking were significantly different from zero (i.e. theoretical intervertebral fusion). Pearson product moment correlations were used to determine the relations between dynamic ROM and age, height, time since implantation, static ROM, cadence and gait speed. Statistical analysis was performed using SPSS (Version 20) and significance was accepted for $p < 0.05$. All data are reported as the mean and one standard deviation.

Results

No significant differences in relative endplate angles or static and dynamic ROM were detected by operative level or sex (Table 2). The Dynamic ROM in the frontal plane during gait for all participants was 1.6±1.1 degrees, which was significantly different from zero ($t = 6.97$, $p < 0.001$) and corresponded to 19% of the Static ROM in the frontal plane (8.3±4.2 degrees). The corresponding Dynamic ROM in the sagittal plane during gait for all participants was 2.4±1.2 degrees, which was significantly different from zero ($t = 6.72$, $p < 0.001$) and corresponded to 19% of the Static ROM in the sagittal plane (12.5±5.6 degrees). Dynamic ROM in the frontal plane was significantly correlated with static ROM in the frontal plane (Table 3).

<Insert table 2 and 3 about here>

Discussion

This study provided the first description of in vivo kinematics of lumbar Charité (now In Motion) total disc replacement (TDR) during gait. The main findings of the study were that (1) motion preservation was evident at the operative level during gait relative to what might be anticipated from intervertebral fusion[24], (2) the amount of lumbar motion preservation during walking was at the low end of the lumbar motion reported for young, healthly participants[30,31], and (3) the measured lumbar ROMs were lower, and the mean sagittal angle during walking was larger compared to values used in the ISO standard for conducting wear tests of lumbar TDRs[20].

Static ROM

The mean static ROM between endplates of the lumbar TDR in the frontal plane (8.3±4.2 degrees) and sagittal planes (12.5±5.6 degrees) were in general agreement with previous reports for in vivo ROM of the Charité TDR. For example, McAfee et al[32] reported a mean sagittal lumbar ROM at L4-5 and L5-S1 of approximately 7.5 degrees at 2 years, follow-up and Lemaire et al.[33] reported mean frontal and sagittal plane ROMs of 5.4 and 10.3 degrees respectively for L3-4, L4-5 and L5-S1 TDRs at 10 years follow-up. In accordance with observations from in vitro testing of Charite devices[34], the majority of the static ROM was due to a greater range in the upper compared to the lower endplate as the upper body moved relative to a stable base. It was also notable that frontal plane ROM of the lower endplate was negative for two participants because, unlike the upper endplate angle, which decreased when moving from right to left lateral flexion, the lower endplate angle marginally increased in these participants. This illustrates the complex nature of spinal motion, and supports previous reports of high variability between segments and between participants who are performing the same task[35]. No abnormal core positions as identified by O'Leary et al.[36] were noted during any of the static poses.

Dynamic ROM during gait

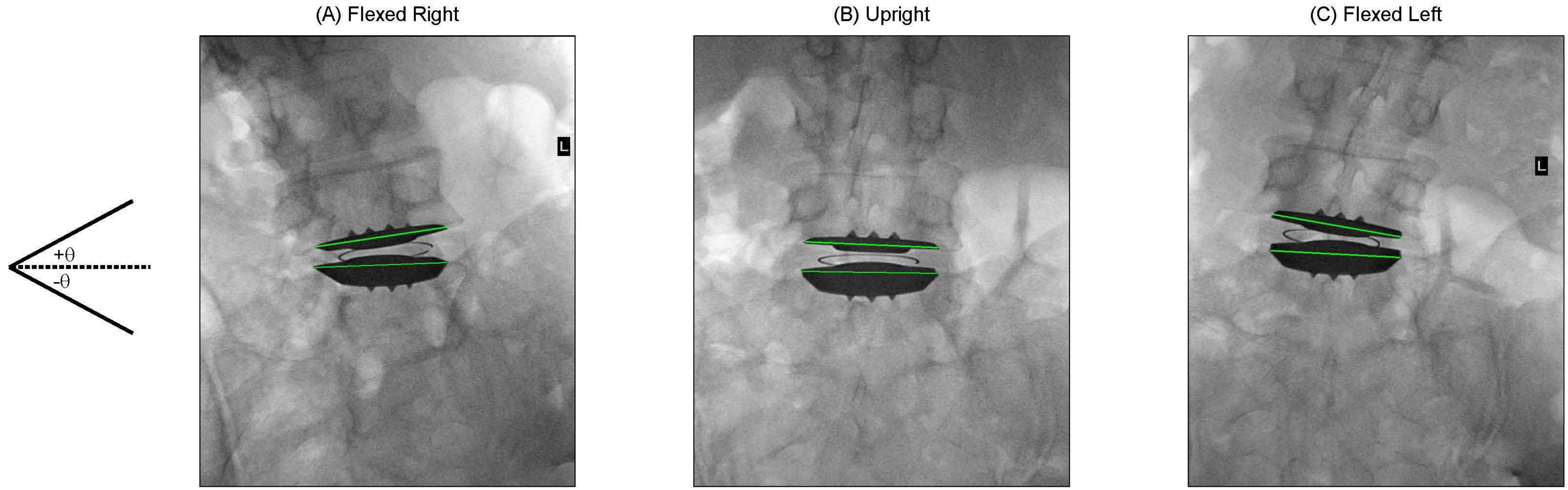
The mean dynamic ROM of the TDR during walking was 1.6±1.1 degrees in the frontal plane and 2.4±1.2 degrees in the sagittal plane, which in both instances corresponded to

19% of the static ROM in each plane. Previous studies in lumbar TDR have demonstrated that motion is preserved at the operative level during performance of static lumbar ROM relative to lumbar fusion[24,25]. The finding that our estimates of lumbar ROM were significantly different from zero during gait indicates that lumbar TDRs afford a degree of spinal motion during locomotion that would not be expected following successful intervertebral fusion.While no other studies to our knowledge have examined spinal kinematics during walking in TDR, the ranges of motion reported here are at the lower end of values reported elsewhere for healthy young participants. For example, Rozumalski et al.[31] reported a frontal ROM of 3.68±1.81 degrees and a sagittal ROM of 4.38±2.31 degrees for L4/L5 using motion capture of markers fixed to the lumbar vertebra using bone pins. Similarly, Callaghan et al.[30] reported a frontal plane lumbar ROM of 1.12-7.13 degrees and a sagittal plane lumbar ROM of 2.72-10.25 degrees using a skin mounted motion capture-based approach. The reason for the lower dynamic ROM in the present study compared to studies in healthy participants is likely due to some combination of greater age, slower walking speed and altered neuromotor coordination for our TDR participants.

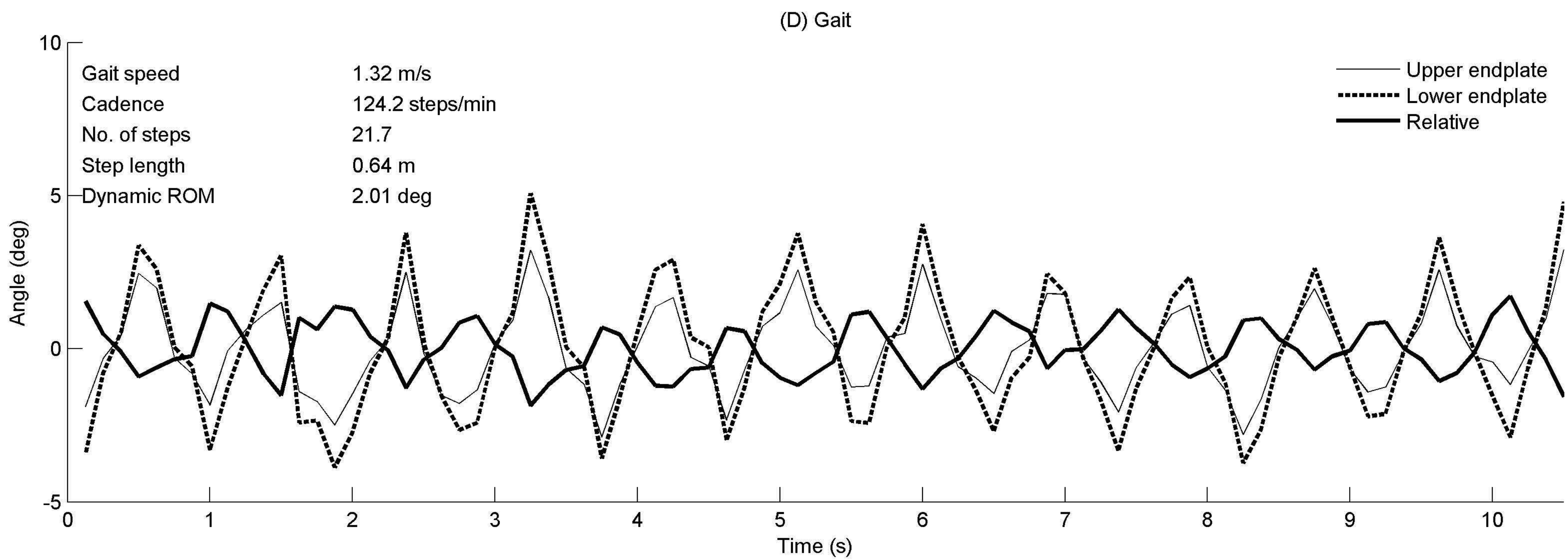
The lack of significant differences in dynamic ROM by sex and operative level, together with the lack of correlation between dynamic ROM and factors such as age, height and time since implantation suggest that other factors, such as the individuals own neuromotor strategy, are more influential in explaining variability in dynamic ROM during gait. Further, the lack of association with cadence and gait speed is probably explained by the relatively narrow range of cadences and gait speeds evaluated in our study. In contrast, the significant correlation bewtween dynamic and static ROM in the frontal plane (r = 0.47), suggests that static ROM may be a factor that has an effect on dynamic lumbar function in individuals following TDR.

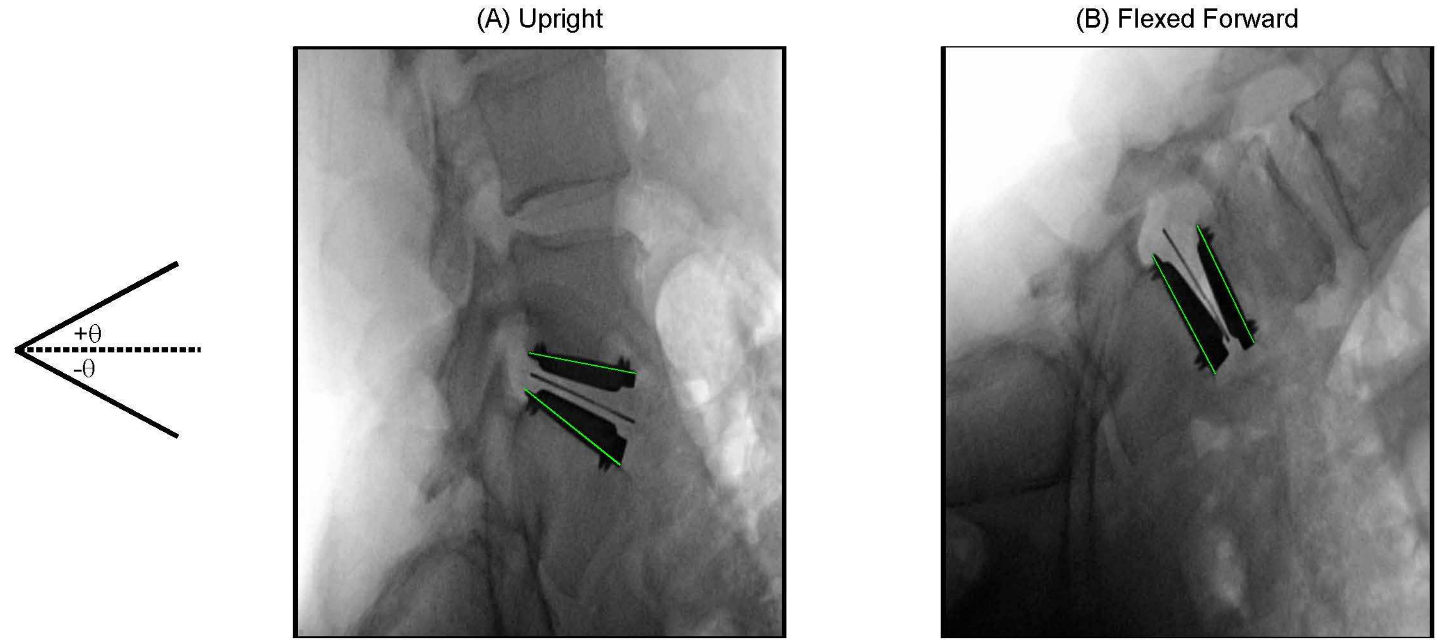
One of the aims of this paper was also to evaluate the correspondence between measured lumbar TDR ROM during walking and the lumbar kinematics recommended in the ISO standard for conducting wear tests of lumbar TDRs[20]. The prescribed kinematics from the ISO standard, which were informed by the study of Callaghan et al.[30], are periodic (sinusoidal) waveforms with minimum and maximum values of -2 and 2 degrees for the lateral bending, and 6 and 3 degrees for flexion and extension respectively. Our mean frontal and sagittal plane ROM estimates of 1.6 and 2.4 degrees were therefore approximately 40% of the corresponding peak to peak flexion angles from the ISO standard. According to the Archard equation a reduction in ROM would be expected to decrease the wear in terms of purely sliding considerations alone. However, as in all complex tribological systems, other factors may come into play such as an increase in the cross-shear subjected to the UHMWPE surface that may tend to increase the wear or the reduced stroke length making lubricant entrainment an issue. A further difference between our measurements and the ISO standard was in relation to the mean sagittal plane angle throughout the gait cycle, which we estimated to be 17.1±6.6 degrees, compared to 1.5 degrees in the ISO standard. This finding may have implications for wear because a larger mean angle in the sagittal plane during gait would be expected to alter the load distribution across the TDR compared to the current configuration used in wear tests where the endplates are near parallel. This result may also contribute to the edge loading and rim damage observed in explanted components[34,37,38]. Such conditions could be further investigated using mechanical or computational wear simulations.

The main limitations of the present study were that analyses were restricted to two rather than three dimensions and at a single walking speed, that transverse plane motions were not assessed, and that the 8 Hz sampling frequency, which was the peak sampling frequency of the fluoroscope, precluded detailed assessment of the patterning and timing of TDR motions within consecutive gait cycles. Further, we did not report core motion relative to the endplates in our study because they were small in magnitude and thus difficult to quantify (i.e. low signal to noise ratio). We also did not observe any separation of the core from the upper or lower endplates during walking and therefore believe that the principal TDR motion during walking was angular motion between the respective endplates and the core. Finally, all participants in our study were recruited via a single spine surgeon, which may have introduced a sampling bias. Irrespective, the distribution of lumbar TDR motions during walking presented here will inform relevant standards for conducting wear tests of lumbar TDRs, enable more realistic mechanical and computer based wear simulations to be performed, and thereby inform the design of future TDRs through identification of potential adverse wear scenarios.



Angle (deg)			
Upper endplate	9.8	-2.9	-11.5
Lower endplate	2.4	-1.0	-3.5
Relative	7.3	-2.0	-8.0





Angle (deg)		
Upper endplate	-8.4	-57.9
Lower endplate	-31.6	-55.6
Relative	23.1	-2.3

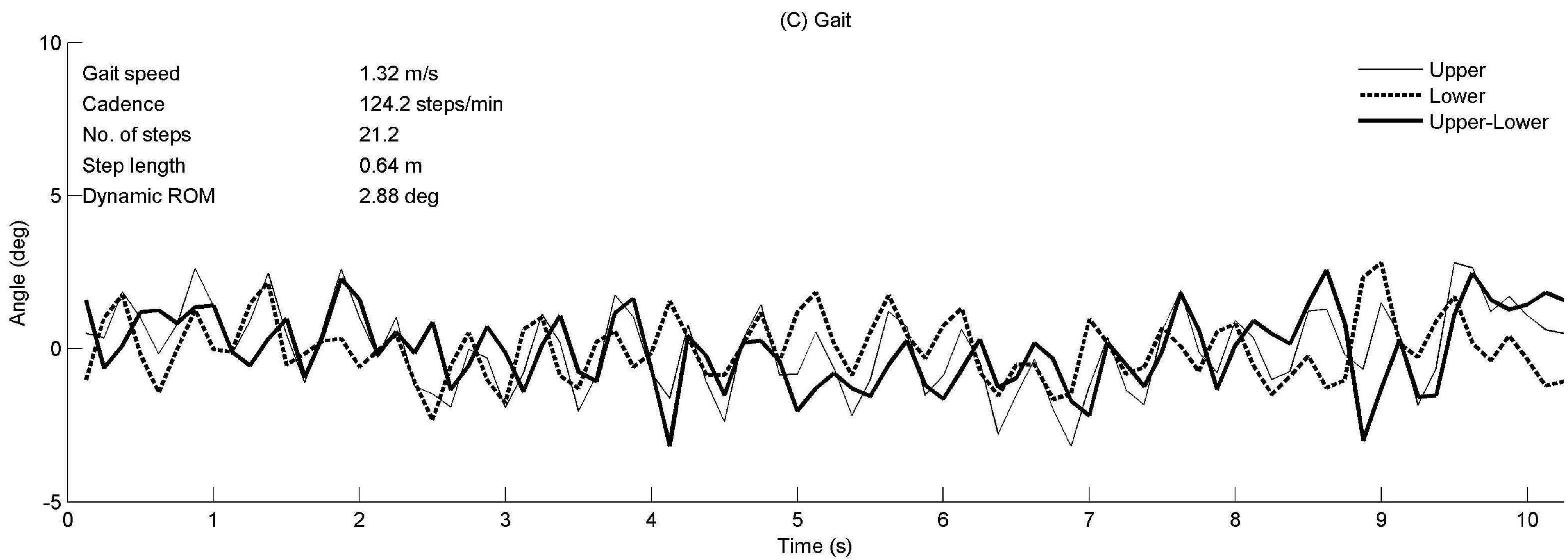


Figure legends

Figure 1. Frontal plane lumbar radiographs for three static poses (A-C) and frontal plane endplate angles during walking (D) for a representative participant (Male, aged 51 years, Charité TDR at L5-S1, 5 years post implantation). Radiographs show the participant Flexed right (A), Upright (B) and Flexed left (C). Superimposed lines (A-C) indicate the upper and lower endplate orientation (θ) expressed relative to the horizontal axis of the fluoroscope. Planar angles for the upper and lower endplates and the relative angle between the upper and lower endplate are given below each image. Upper and lower endplate angle data during walking are displayed with the mean angle removed in order to facilitate comparison between the amplitudes of upper and lower endplate motion.

Figure 2. Sagittal plane lumbar radiographs for two static poses (A-B) and sagittal plane endplate angles during walking for a representative participant (C). Data are from the same participant as figure 1. Radiographs show the participant Upright (A) and Flexed forward (B). Superimposed lines (A-B) indicate the upper and lower endplate orientation (θ) expressed relative to the horizontal axis of the fluoroscope. Planar angles for the upper and lower endplates and the relative angle between the upper and lower endplate are given below each image. Upper and lower endplate angle data during walking are displayed with the mean angle removed in order to facilitate comparison between the amplitudes of upper and lower endplate motion.

Table 1. Participant characteristics (Mean±SD).

Parameter	Value/s
Participants	24 (11 female, 13 male)
Age (yrs)	43.7±9.3 (Range 23-64)
Height (m)	1.76±0.10
Operative level	7 L4-5, 17 L5-S1
Device	7 Charité, 17 In Motion
Time since implantation (yrs)	2.5±1.7 (Range 0.3-5.0)

Table 2. Relative endplate angles and range of motion (ROM) under static and dynamic conditions in the frontal and sagittal planes for all participants (n = 24) and by operative level (n = 7 L4-L5, n = 17 L5-S1) and sex (n = 11 female, n = 13 male).

Plane	Upright pose (deg)	Mean angle during gait (deg)	Static ROM (deg)	Dynamic ROM during gait (deg)
Frontal plane				
L4-L5	1.7±6.0	3.1±6.1	10.6±5.3	1.9±1.6
L5-S1	-0.4±2.9	0.2±2.9	7.1±3.2	1.4±0.7
Female	1.8±5.2	2.1±5.1	8.7±4.3	1.7±1.5
Male	-0.1±2.7	0.4±2.8	7.9±4.2	1.5±0.7
All participants	**0.3±4.2**	**1.2±4.4**	**8.3±4.2**	**1.6±1.1***
Sagittal plane				
L4-L5	20.7±1.4	19.9±2.6	10.8±3.7	2.5±1.2
L5-S1	18.0±7.9	14.4±8.5	14.1±6.9	2.3±1.3
Female	17.6±5.5	15.9±7.3	10.9±4.1	2.3±1.2
Male	22.9±4.0	19.6±5.0	15.6±7.4	2.6±1.5
All participants	**19.4±5.6**	**17.1±6.6**	**12.5±5.6**	**2.4±1.2***

* indicates significantly different from zero ($p<0.05$).

Table 3. Correlations between dynamic range of motion (ROM) during gait in each plane and selected participant characteristics, static ROM and gait variables.

	Dynamic ROM	
Variable	Frontal plane	Sagittal plane
Age	0.21	0.06
Height	-0.07	0.07
Time since implantation	0.39	0.10
Static ROM (Frontal plane)	0.47*	-
Static ROM (Sagittal plane)	-	0.01
Cadence	0.01	0.45
Gait speed	-0.09	0.10

* indicates significant correlation (p<0.05).