Monitoring the kinematics of Walking and Running Gait after total knee replacement using a new generation of prosthetic knee implants.

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Keywords: Gait cycle monitoring. gait analysis, Knee kinematics, joint arthroplasty

Abstract:

Gait analysis has its role in rehabilitation medicine, orthopaedics, kinesiology, sports science, and other related fields of human locomotion. The use of gait analysis in the evaluation of the efficacy of joint replacement has increased over the last two decades due to the advancement of computer technology and the requirements of more quantitative data which can allow for better and more reference-able assessment of the performance of in-service knees. This study was designed to investigate and monitor the kinematics of running and walking gait after a total unilateral knee implant operation using the new-generation high-performance kinematic retaining prosthesis. This type of post-operation running gait analysis had never been performed previously. It is designed to identify other kinematic data about the knee that may not be possible to observe using walking gait analysis alone. The kinematics of running gait in a group of 12 patients were monitored and the results are presented here. The cost and resources required to do this were also questioned and the possibility of a more controlled image capture using cheaper mobile devices was examined.

1. Background reviews and Introduction:

Osteoarthritis is the most common form of arthritis and is associated with degenerative changes of articular cartilage along with underlying bones, mainly affecting the knee, hip, spine, great toe, and hand joints.[1] Total knee replacements (TKRs) are commonly used for the treatment of knee osteoarthritis. The prevalence of knee osteoarthritis has increased in recent years and has led to more burden of expenditure on modern society.[2] The use of a TKR aims to relieve pain and improve the functional ability of the patient. Subjective outcome measures suggest that a TKR can improve the activities of daily living.[3] Despite the positive subjective outcomes, differences are still found when objectively comparing TKR patients with healthy controls using techniques such as gait analysis.

The use of observational methods and questionnaires in the follow-up of post-operative patients have been used as traditional methods to analyse the in-service performance of the joints. Looking at the demographics of patients it is obvious that the average age of those needing a TKR is reducing and not all due to osteoarthritis. Sports and other injuries are also contributing factors, Therefore, there is a need for appropriate and objective assessment methods due to the increasing number younger of TKR patients who demand more from their implants/prostheses. Gait analysis is now being commonly used to monitor the rehabilitation rate of human locomotion because it is considered an acceptable tool for the analysis and monitoring of any movement disorders. The only drawback of current methods and tools are the cost and need for a dedicated space. Also, it is used for orthopaedics, kinesiology, sports science, and other related fields of human locomotion.[4] The use of gait analysis in the evaluation of the efficiency of joints before and after a replacement has increased substantially in the last two decades. This is mainly due to more advancements in computer and software technology[5]. Smaller, mobile, and more portable systems using image tracking and/or IMU (Inertial measurement units) now exist that go a long way toward making gait analysis both affordable and accessible.

They can be used by all clinicians who need to monitor the rate of change or improvement of the patient on daily basis. Gait analysis is a tool that has also been used by other researchers to quantitatively measure functional outcomes following TKRs. It has been proposed greater use of a low-cost gait analysis system will be valuable in a clinical setting for the management of patients undergoing TKRs through its ability to monitor displacement, velocity, and acceleration of the limb as well as the forces passing through the knee joint. It can also inform and maybe modify surgical techniques.[6,7]

2. Methodology

This is a knee joint-specific kinematics monitoring exercise with the focus being the in-service performance/function of the knee at different conditions of ambulation. The effect of the knee on another joint kinematics such as hip or ankle can also be studied. The best way to assess knee performance is to either compare the operated knee with the non-operated knee or to compare the operated knee with that of normal healthy controls. Within this study, both were observed.

The gait kinematic monitoring was an exploratory study that was carried out on twelve patients who volunteered. They all underwent unilateral TKR using Physical KR Kinematic retaining Prosthetic Knees. NHS ethical approval was granted before starting the study. Informed consent was taken from all subjects before performing the gait analysis. All the case study subjects fully understood the purpose and the content of this study and agreed to participate in all the test cases conducted in this study. No inclusion or exclusion criteria were applied during the recruitment or use of control participants. They were healthy individuals with no pain or reported/visible walking or running disorder issues or problems. However, very strict inclusion and exclusion criteria, as stated in the ethics document, were applied when recruiting the participants and were applied throughout this study.

3. Test procedure

SSU's gait lab facility was selected for these tests. A test protocol was then developed and implemented. A series of gait monitoring tests were performed using Vicon (VICON, Oxford Metrics, England), a 3D video capture and gait analysis system. The Vicon systems used in these experiments consisted of 10 cameras, with their functions synchronized with (Triggered by) two Kistler force platforms (Kistler Instrument Ltd, Hampshire, England). A total of 8 control participants and 12 TKR patients' gaits were analysed a minimum of one-year post-operation.

The tests included walking and running gait, turning right and turning left, and performing a static lunge (squatting) to assess the active maximum angle that can be achieved in the knee.

It was understood that running and walking are performed at self-selected speeds and turning was based on their natural ability to turn left or right. It was difficult at the time to specify how to turn, and it was left to the individual to turn the way it best suited their knees or based on natural behaviours.

In this knee-specific study, the angles, forces, and moments of all three main joints in both legs were collected but only the kinematics for the operated knee was compared with that of the non-operated knee or that of the controls. It must be noted that the study was based on unilateral TKRs but out of the 12 TKR participants, two of them were bilateral TKRs.

3.1 Walking and running gait instructions

Each participant was asked to warm up initially by walking or running normally. Some training was necessary to ensure that the correct leg hit the correct force plate at the correct location. Once training was over, the participants were asked to walk/run in a straight line, which was repeated several times. This process was continued if the subject was comfortable performing these activities in the laboratory environment. The data for six successful walking trials per participant were collected for subsequent data analysis. Of the 6 or more trials, the best 3 were selected and used for all other subsequent post-processing such as time normalization and statistical analysis.

3.2 Test tracks

Figure (1) shows the floor paths/tracks used for multiple gait analysis activities and experiments, ranging from a) walking, and running in a straight line, b) walking through a 90-degree left and/or right turn, and c) performing squatting or lunging. At each stage of these case studies, both the participant and the controls were asked to follow a predefined path/track as shown in Figure (1). The continuous black straight line represents the path patients followed when walking or running. It must also be noted that running was performed in one direction (left to right) only. The volunteer participants were asked to walk around to the start position every time. Here, running is defined as the state of the walk when at one moment in time both feet are off the ground, unlike normal walking when one foot is always in touch with the ground. it was necessary to use this diagram because it was part of the submission of the ethics approval application documents. This diagram clearly shows the combined running, walking, and turning gait analysis paths planned and conducted as part of this investigation.

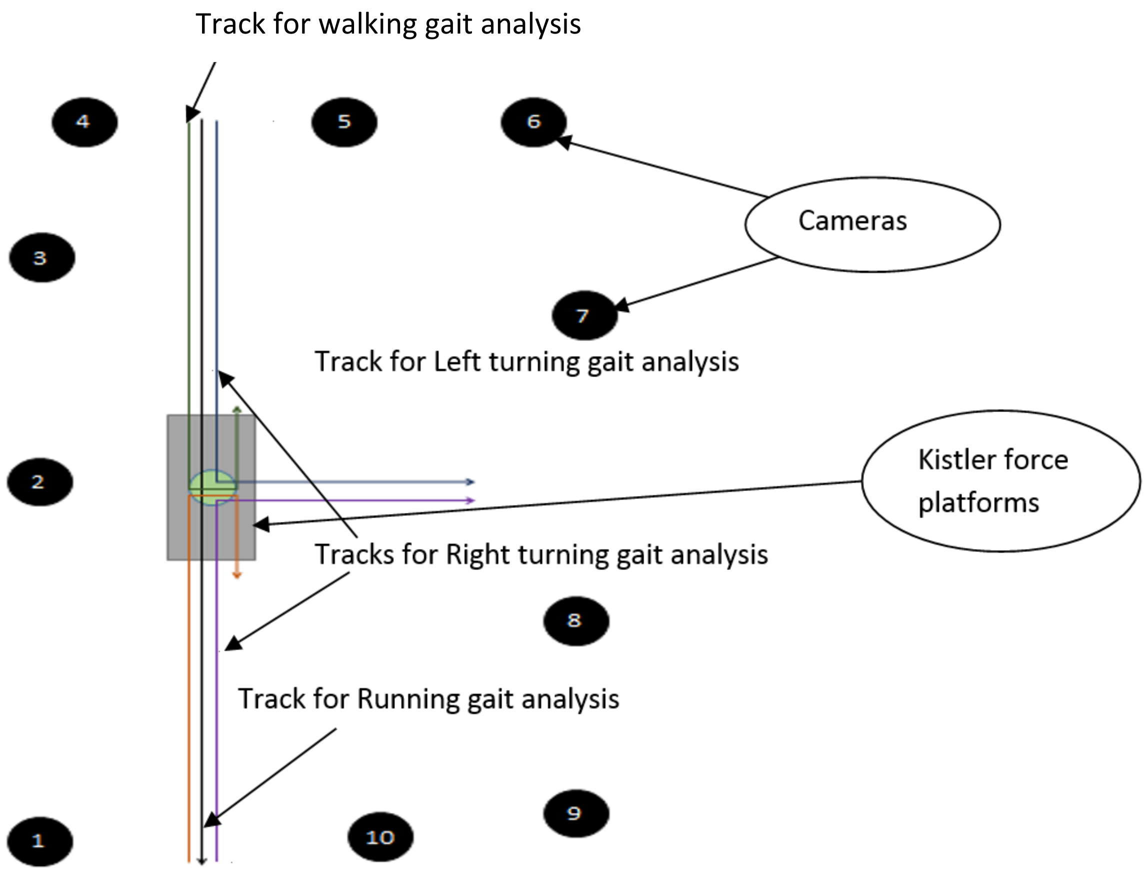


Figure 1: Setup for running gait analysis

4. Data Acquisition

Running, unlike walking, is defined in this case as displacement/ambulation at a faster speed where at some point during one cycle either one or both feet must be off the ground or not touching the ground. One cycle is defined as the time between two successive strikes of the same heel, or the time from one heel strike and when the same heel strikes again. Figure (2) shows the walking and running gait cycle definition and distinct differences.

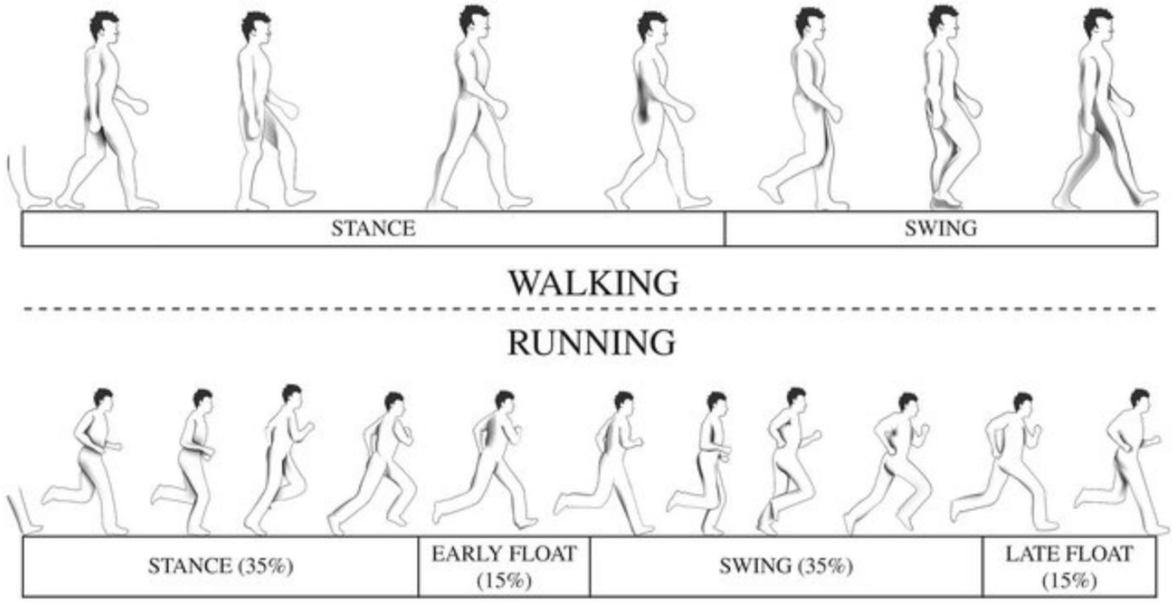


Figure (2) walking and running gait. Research Gait[22]

Every individual has a different gait cycle or beats frequency when walking or running. The Vicon system is used to automatically collect the coordinates of the markers at 250 Hertz (Hz). The number of points collected between each gait cycle varies from person to person. Here a data normalization algorithm was developed to map out one gait cycle onto 100 fixed data points per cycle to make superposition possible. To do this a normalization routine was developed in MATLAB that read the raw data for one gait cycle and normalized it to 100 points per cycle so that an objective comparison between the kinematics of a joint per one cycle can be made.

The modern version of the Vicon system now comes with reporting tools that make post-processing significantly easier. The system uses image tracking, fourteen-millimetre-wide spherical retro-reflective markers as shown in Figure (6) and were attached all over the body at key locations or landmarks following the VICON, “Helen Hays” seen in Figure (3a), plug-in-gait guidelines. Overall, 39 markers were used during these 20 case studies. Prior calibration of the camera using a standard calibration artefact made it possible for the system to measure the exact distance, displacement, and orientation of limbs relative to each other. Here, the assumption is that there is zero marker displacement relative to the joint centre of rotation. This implies that the contact point between the marker and skin is a fixed point and does not change during tests or due to the shear force experienced by the skin because of movements. During the test, the absolute marker position data (X, Y, Z) for all the markers were sampled at 250 Hz. The force platform data were sampled at 2000 Hz. The foot contact force passing through the foot centre of pressure and its orientation in 3D space was detected and measured by the force plate.

Vicon required some exact measurements of the length of body parts, needed to normalize the kinematics in terms of scale, relative distances, and absolute displacement. Once the anatomical measurements of each participant had been taken for the Vicon system, the subject was marked up as seen in Figure (3b) following the Helen Hayes plug-in-gait model, Figure (3a), which is one of the standard digital mannequin models representing a typical anatomical body or figure that can be resized to fit every participant's anatomical dimensions. A static and dynamic calibration trial was conducted and processed to assess and check to ensure every marker can be seen by at least 3 cameras at any one time and to identify any blind spots.

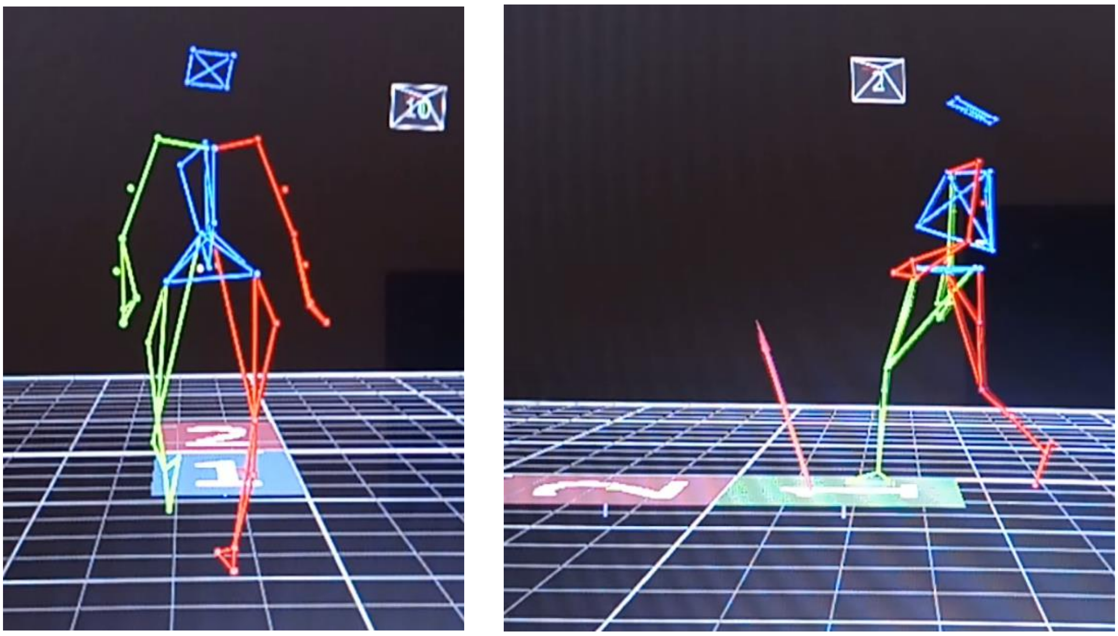


Figure (3a) Helen Hays Plugin model.

Figure (3b) The Markers attached are based on Helen Haze's plug-in gait model.

5. Data Processing

Three out of the six successful trials were post-processed for the running. The same was done for walking. All data were initially processed, and raw kinematic data was extracted using Nexus 2.0. Nexus-2.0 is the software system that comes with the Vicon system used in these trials. The raw data is usually in ".CSV" format but for ease of use, they were converted and stored in excel. Each gait cycle data was time normalized with 0% being the heel strike and 100% being the second heel strike of the same leg. The time normalization allows for direct comparison between trials within every case study. It can also be used for proportional timing or phase of each event within one cycle. The joint angles at initial contact, maximum flexion, and extension in both the operated and non-operated during the stance swing phases were sampled and recorded at 250Hz. This was done for all the main joints in the body (such as the hip, knee, and ankle) but only the knee-specific data were analysed in this report. It is envisaged that running generates higher inertia forces in various limbs. That can result in overextension and over-flexion in the knee joints, and this is one of the main research questions in this paper. To investigate if TKRs running and walking gait differences correlate well with that of the healthy knee or that of the controls.

6. A low-cost alternative proposal for daily application during daily clinics.

In addition, below is a view of a proposed novel low-cost basic gait monitoring system developed as part of the investigation. It is to be used in parallel with the Vicon system to establish its accuracy compared to Vicon. It must be noted that this system was only used with healthy controls and not TKR patients. This system uses a combination of IMU (Inertia Measurement Units), optical markers, and a mobile camera designed to monitor kinematics in a single plane. The idea was to investigate if a cheaper and more accessible system can give good enough data to allow adequate assessment of the improvement in the range of motion after a TKR. Figure (6) shows a demonstration of such equipment and Figure (7) shows the close agreement between optical and IMU-based trackers.

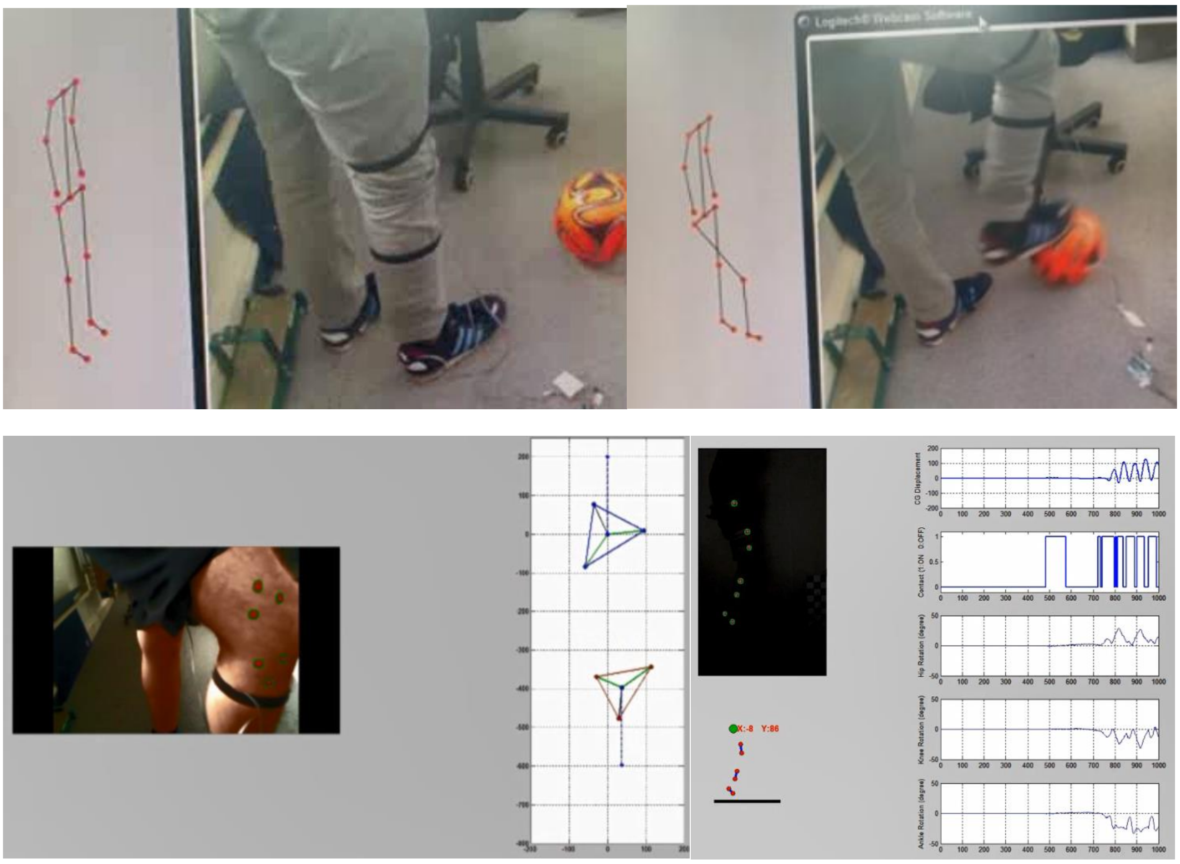


Figure (6) The proposed low-cost lotion tracking and kinematic assessment system using a combination of IMU and optical measurements using a mobile camera.

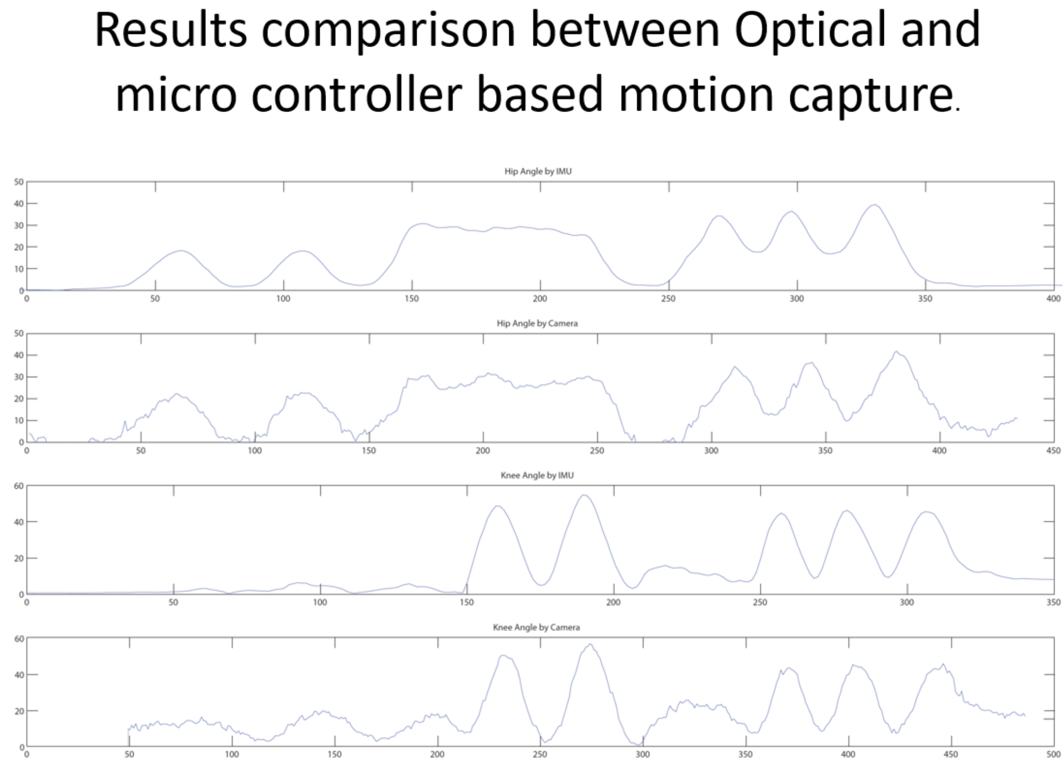


Figure (7) results of comparison between optical and IMU-based trackers

7. Analysis and Results:

A total of 8 healthy control and 16 TKR patient volunteers were initially recruited and included in this Physica KR case study. Of the 16, only 12 patients managed to complete the study; one patient could not run due to other underlying medical conditions and the other three did not attend the data collection session. The age range was from 57-75 and the mean age of the patients was 66.67±5.45 years. There were 6 males and 6 females. The mean weight and height of the patients were 83.5±8.63 kg and 1.72±0.1 m respectively. In this report, it was decided to compare the kinematics of the knee for the 12 participants, since in-service knee kinematics was the subject of this investigation. Here, we compared knee joint angles/kinematics at different stages of ambulation.

The baseline graphical analysis of the gait cycle was used to study the kinematic differences. All graphs show knee angles during both the stance and swing phases. They were plotted for all the participants to search for any evidence of significant differences between knees. Overall, there were no significant differences found within the working envelopes of the knees, such as the initial contact, maximum flexion, maximum extension, stance phase, and swing phase between all participants with ($P > 0.05$). It was therefore concluded that the implanted knee post-TKR performed very similarly to the normal controls and/or the non-operated knees. The standard deviation for the group at each normalized time interval was evaluated and the error band/estimation against one STD was calculated.

7.1 Knee-specific data analysis.

The key moment defining a single gait cycle is the time between the initial heel contact with the ground and the next time the same heel contacts the ground again. The key parameters usually used in gait analysis are a) the initial contact b) the maximum dorsiflexion c) maximum plantar flexion during the stance phase d) maximum dorsiflexion during the swing phase. The following graphs show that although there are significant differences between everyone's gait pattern during each repeat, the overall behaviours of the knee joint and the leg pretty much remain the same. Averaging the results of 3 repeats of the same activity per individual will minimize the effects of any random variation in an individual's gait during each repeat. This shows that the knee performs repeatedly well within the 1-STD significant error band (which is the mean +/- 1 standard deviation). This also indicates that simple averaging of specific kinematic data for all participants again will significantly reduce the effects of random variation in an individual's overall gait kinematics for given knees, such as all the right knees, all the left knees, all the TKR knees, or even all the control's left and/or the right knees. If the variance was to be extended to 3 STD (as used in industry) then all or 99.9% of all variations fall within the normal range of mean +/- 3 STD). This shows that no significant differences can be found between all knee kinematics (angles) at a) the initial contact, b) the maximum knee flexion, c) the maximum knee extension during stance d) the Maximum knee extension during the swing phase. This was done for both the operated and non-operated knee as well as the controls. The P value may not be that indicative of the outcome as there are too few participants for more meaningful statistical inferences. However, P value and standard T-test calculations can be carried out within Excel ($P < 0.05$) which again shows that there are no significant differences between the overall kinematics of the left and right knees making it difficult to differentiate between the operated and non-operated legs.

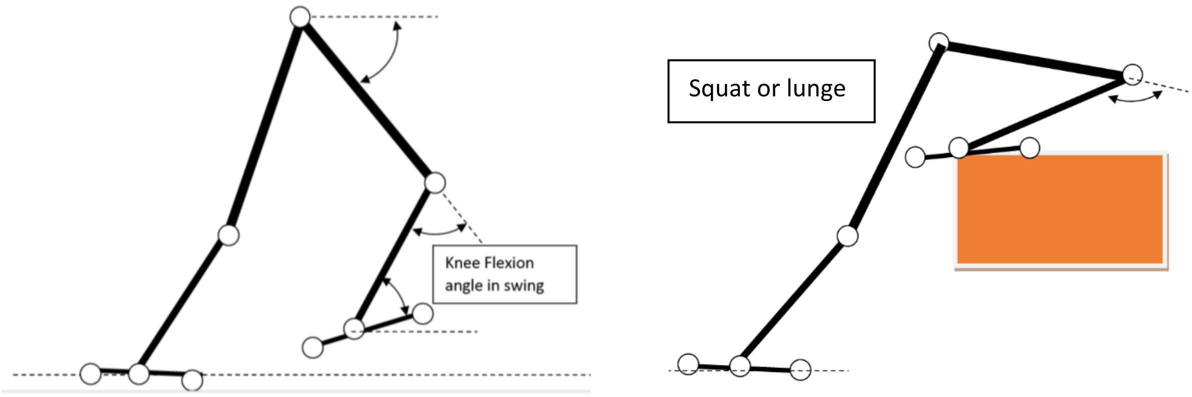
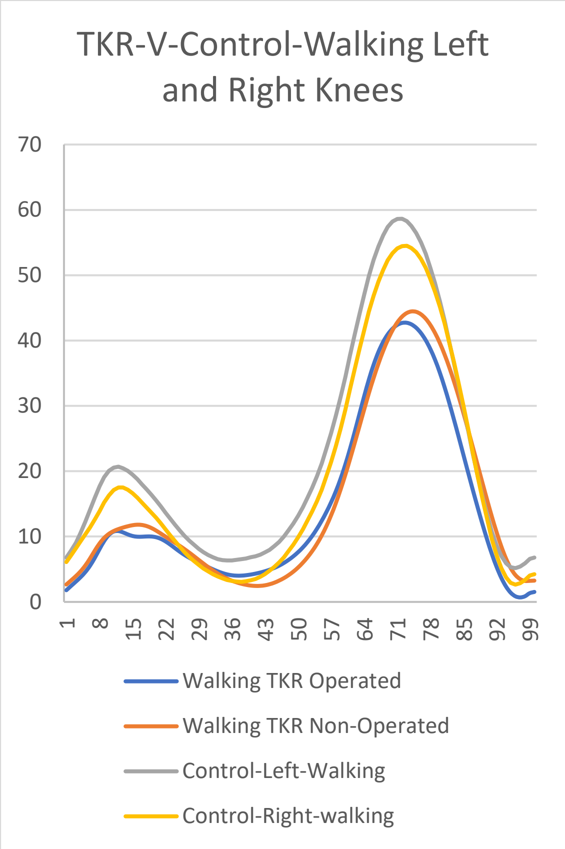


Figure (8) Schematic model of a leg showing the knee angle

7.2 Walking/Running left and right knees

The graphs in Figure (9) and Figure (10) show the comparison of the normalized walking and running knee kinematics between controls and TKR participants' left and right knees.



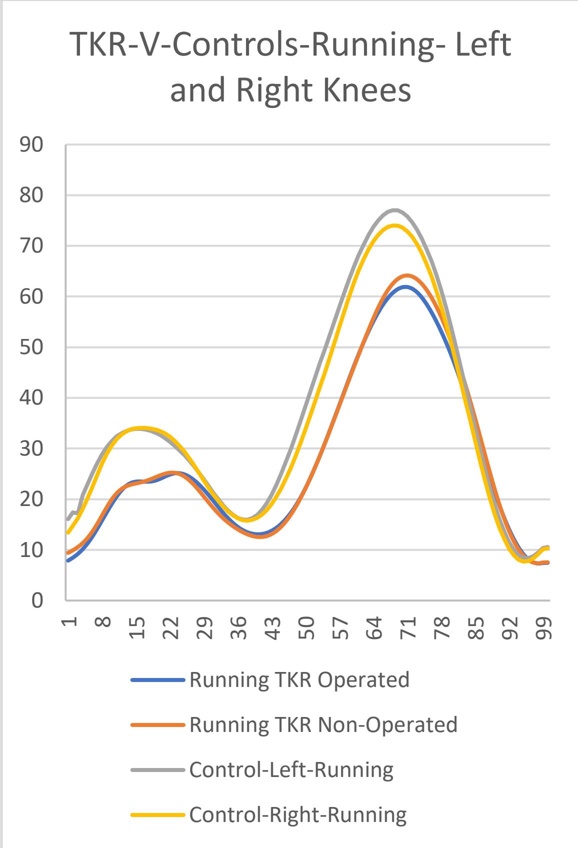


Figure (9) Walking TKR vs. Control both knees Figure (10) Running TKR vs. Control both knees

	Operated knee (Mean ±SD)	**Non-operated knee (Mean ±SD)**	**P value***
Knee Angles (Degrees)			
Angle on initial contact	7.60±4.72	9.41±7.42	0.48
Maximum flexion during stance	25.97±5.38	25.22±10.91	0.83
Maximum extension during stance	13.76±4.19	12.55±8.06	0.65
Maximum flexion during swing	61.83±11.50	64.15 ± 7.92	0.57
Maximum extension during swing	7.39±5.52	7.35±7.99	0.99

Table 1: Knee, angles variance after total knee arthroplasty during stance and swing phase of gait cycle

*p value > 0.05 for all variables (non-significant)

8. Discussion:

The lower limb joints such as the hip, knee, and ankle should coordinate during running or walking with the involvement of the neuromuscular system under the control of the central nervous system.[13] This study was designed to evaluate whether the operated knee performed well in coordination with hip and ankle joint movement to produce normal gait when compared to the non-operated knee and that of the controls. Running in general appears to be more stable than walking due to heightened levels of control by the runner and the shorter duration of the knee being in action as well as the natural gyroscopic behaviour of the body's dynamic. There have been improvements in the design of the TKR prosthesis to meet the higher demanding activities. At the time of this investigation, there was no published material on running gate analysis post-TKR operation and this was needed if the influence of the new design changes can be better realized. This study was initiated to investigate the kinematics of running in TKR patients. The knee interfacial force balancing and equilibrium during the fitting can also play a role, and various technology may be the necessary to better measure and track the knee joint contact points on the surface of the joint during implant operation.

Manual artefacts or robotic manipulator arms may be able to assess the overall laxity or the overall tension in the knee joint that is needed for stability, but they cannot accurately identify any contact force or tractions on the joint surface during a joint operation. Previous researchers have compared knee joint angles only with some other parameters such as moments and velocity.[14-16] In the present study, mean angles of flexion and extension of all the knee joints in the operated knee were similar to the non-operated knee during running and walking, after a minimum of one-year post total knee arthroplasty.

Here it has been shown that the TKR knees are also on par with normal controls. No significant differences were found between the overall behaviour of the operated knee and non-operated knee and the controls. These qualitative findings suggest that the time displacement pattern of the gait cycle in the operated knee is like that of the non-operated knee and that of the controls. This was also true for the controls. A total of 8 control volunteers were tested for this study and their left knee kinematics were compared with their right knee kinematics for both running and walking. Although the samples are small for thorough statistical analysis, it was enough to notice that there was no significant difference observed between the mean knee angle in controls and the TKR during both walking and running. The mean values are used because it is quite difficult for the individual to repeat themselves exactly, even with a treadmill or amongst controls. Therefore, individual gait patterns can be significantly different from the overall mean time displacement pattern of knee kinematics. This investigation showed that the overall kinematics of the TKR knee is similar to healthy knees. Earlier studies have reported significantly reduced maximum knee flexion and extension during the stance and swing phase as compared to controls after a two-year follow-up period.[17,18] This could be due to increased work of the hip muscle leading to a decrease in the work of the operated knee joint.[19] But in the present study, no significant difference was found between the operated and non-operated lower limbs. The muscle activities were significantly decreased compared to non-operated knees or the controls, but that is subject to future research. A systemic review that looked at walking gait patterns in TKR has also reported non-significant differences between test and control groups and found that patients with a TKR walk with less total knee motion during gait and with less knee flexion during swing than controls.[21]

The similarity of the kinematics can be due to the latest design features of the prosthesis used. The new prosthesis used has been developed to restore physiological kinematics to promote fast functional recovery and pain relief, even in high-demand patients. This means the new joint is designed to reproduce the natural knee joint kinematics. The present study was carried out to investigate running gait due to the lower mean age of the participants. Many earlier studies reported a mean age of more than 67 years in arthroplasty patients.[16] The limitation of this study was the low participant numbers. Further studies are required with higher participant numbers and the investigation of more synchronous joints. As well as other parameters such as symmetry, moments, and energy transformation rate differences.

9. Conclusion:

No significant differences were found between the operated and non-operated limbs for all the knee joint angles. These findings suggest that this new-generation prosthesis is capable of mimicking near-normal knee kinematics during walking and running making them difficult to distinguish between TKR and healthy controls during both walking and running.

10. Acknowledgments:

The authors would like to acknowledge Southampton Solent University for allowing for the use their Gait lab and for providing the control participants and data. Also, to Lima Corp for their support of this research project and Prof. Adrian Harvey for his passion and drive for research.

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