# **A Femoral Clamp to Reduce Soft Tissue**

# **Artefact: Accuracy and Reliability in**

**Measuring Three-Dimensional Knee** 

# **Kinematics During Gait**

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**ABSTRACT**

 The accurate measurement of full six degrees-of-freedom (DOFs) knee joint kinematics is prohibited by soft tissue artifact (STA), which remains the greatest source of error. The purpose of this study was to present and assess a new femoral clamp to reduce STA at the thigh. It was hypothesised that the device can preserve the natural knee joint 42 kinematics pattern and outperform a conventional marker mounted rigid cluster during gait. Six healthy subjects were asked to walk barefoot on level ground with a cluster marker set (cluster gait) followed by a cluster-clamp-merged marker set (clamp gait) and their 45 kinematics was measured using the cluster method in cluster gait and the cluster and clamp methods simultaneously in clamp gait. Two operators performed the gait measurement. A six DOFs knee joint model was developed to enable comparison with the gold standard knee joint kinematics measured using a dual fluoroscopic imaging technique. One-dimensional paired t-tests were used to compare the knee joint kinematics waveforms between cluster gait and clamp gait. The accuracy was assessed in terms of the root mean square error, coefficient of determination and Bland-Altman plots. Inter-operator reliability was assessed using the intra-class correlation coefficient. The result showed that the femoral clamp did not change the walking speed and knee joint kinematics waveforms. Additionally, clamp gait reduced the rotation and translation errors in the transverse plane and improved the interoperator reliability when compared to the rigid cluster method, suggesting a more accurate and reliable measurement of knee joint kinematics.

#### **INTRODUCTION**

 The knee joint is one of the most complicated synovial joints [1] that primarily moves in flexion/extension and external/internal rotation [2]. Coupled motions, due to the articular



 Although technologies exist to measure bone motion directly [14–20], these are clinically impractical due to a combination of invasiveness (for example, pins inserted to the bones, or ionising radiation), cost ( advanced imaging), limited field of view (imaging), time (scanning, imaging segmentation and registration), and ethics. Therefore, other methods are preferred clinically, which infer motion of the underlying bones from the movement of overlying soft tissue. These include, for example, electromagnetic motion tracking [21], and marker-based [22] or markerless optical motion tracking [23,24], and include techniques to minimise the effect of soft tissue artefact (STA), which is the relative movement of soft tissue to the underlying bones due to inertial effects, skin stretching/sliding, and muscle contractions [25–27]. At the knee joint, STA particularly affects the measurement of subtle movements such as abduction/adduction, external/internal rotation, anterior/posterior and lateral/medial translations: the tracking errors between the surface markers and the underlying bone can be up 40 mm at the thigh and 15 mm at the shank [28–31], resulting in rotation errors of up to 20° and translation errors of 20 mm in both the frontal and transverse planes. For planes of motion other than the sagittal plane, STA remains the main limitation of these measurement technologies.



- natural knee joint kinematics pattern and outperform a conventional marker mounted rigid
- cluster in accuracy and reliability during gait.

## **METHODS**

**The femoral clamp design and fabrication** 

 The device functions on two key principles, where the first is that the femoral epicondyles are very close to the surface of the skin and clamping at the epicondyles will reduce errors in all planes of motion, except flexion/extension which will cause twisting and shear on the surface that is difficult to control. The flexion/extension motion between surface and bone is then resisted by a stabilising bar that straps along the anterior aspect of the thigh. However, the thigh soft tissue can rotate around the bone. A fixed bar would then transmit this rotation to the epicondyles and result in the device separating from its attachment points. Therefore, the stabilising bar is attached to the clamp with a rotational bearing that permits axial rotation without changing the flexion/extension position of the bar.

 The femoral clamp consists of two femoral pads, a femoral arch, a stabilizing bar and the distal and proximal Velcro straps (Fig.1). The 40.0-mm-diameter, 8.0-mm-thick circular femoral pads are 3D-printed (Ultimaker 2, Ultimaker B.V., Geldermalsen, Netherlands) using PLA (PolyLactic Acid). They are placed over the medial and lateral femoral epicondyles and are interconnected over the front of the knee via an 8.0-mm-thick femoral arch, made of moulded Polycaprolactone (PCL), designed to have an appropriate stiffness to apply a compressive force to the epicondyles. To further minimise the movement between the femoral pads and the underlying bone, they are attached posteriorly by a distal Velcro strap. The stabilizing bar consists of a proximal part and a distal part angled 160° to the proximal

128 part. The proximal part rests on the anterior aspect of the thigh, restricting the rotation of

the device in the sagittal plane. The distal part inserts into the femoral arch through a pivot

- bearing. The mass of the whole device is 63 g.
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## 131 Insert figure 1

### **Validation experiment**

133 Six healthy subjects (three male and three female; age  $31.4 \pm 4.0$  years; height  $1.76 \pm 1.76$ 134 0.10 m; mass 74.3  $\pm$  16.8 kg; body mass index 23.8  $\pm$  3.5 kg/m<sup>2</sup>) with no self-reported lower limb musculoskeletal pain or impairments were recruited. Institutional ethics approval and informed consent were obtained. Subjects were asked to walk barefoot at a self-selected speed on level ground with a cluster-based marker set (cluster gait) followed by a clusterclamp-merged marker set (clamp gait) on their pelvises and right legs. Knee joint motion was measured using the cluster method in cluster gait and the cluster and clamp methods simultaneously in clamp gait. In the cluster-based marker set, reflective markers were placed on the anterior/posterior superior iliac spine, medial/lateral femoral epicondyles, medial/lateral malleoli, second/fifth metatarsal head, and lateral and posterior calcaneus. Additionally, two clusters of three markers were placed onto the lateral and frontal aspects of the thigh and shank (Fig. 2) [43]. Three walking trials were recorded for cluster gait, as well as a standing reference trial of subjects standing in a neutral position before the walking trials. In clamp gait the markers on the medial/lateral femoral epicondyles were removed and five markers were placed on the clamp (Fig.1d). Once the clamp was aligned and stable, subjects were given several practice trials (including walking and standing up from a chair) to familiarise themselves with the device. Similar to cluster gait, three walking trials and a standing reference trial were recorded. The protocol was

 performed by two separate operators with experience in palpating bony landmarks. The order of the operators was randomised. Following completion of the protocol the first time, the whole marker set was removed, and subjects were given a break; then the second operator repeated the identical protocol. Marker trajectories were measured with a 10- camera optical motion capture system (Vicon Motion Systems Ltd, Oxford, UK, 100 Hz). Measured kinematics was initially processed in Vicon Nexus (V2.6.1), including labelling, gap filling and heel strikedetection (using the vertical component of the posterior calcaneus marker [44]), and then lower-pass filtered using a fourth-order, zero-lag Butterworth filter with a cut-off frequency of 6 Hz [45] in MATLAB (The MathWorks Inc., USA). Insert Figure 2

#### **Knee model**

 The knee is described with full six DOFs with the anatomical geometry scaled from an MR-based musculoskeletal (MSK) model (female, 43 years, 1.84 m, 78 kg [46]), implemented in an open source musculoskeletal modelling software, FreeBody (v2.1, [47,48]). To enable the comparison with knee joint kinematics in the literature measured using the gold standard dual fluoroscopic imaging technique [49], the coordinate system of the thigh and shank and rotations and translations at the knee are defined as follows (see Fig.3): the thigh origin is the midpoint between the medial and lateral femoral epicondyles, the superior - inferior (SI) - axis points from the thigh origin to the hip joint centre (centre of a sphere fitted to the femoral head), the temporary lateral - medial (tempLM) - axis points from the medial to lateral femoral epicondyle, the anterior - posterior (AP) - axis is the cross product of the SI and tempLM axes, pointing anteriorly and the LM - axis is the cross product of the AP and SI axes, pointing laterally; the shank origin is the midpoint between the centres of

 two circles fitting the medial and lateral plateaus separately, the SI - axis points from the midpoint of medial and lateral malleoli to the shank origin, the tempLM - axis connects the centres of plateau circles, the (AP) - axis is the cross product of the SI and tempLM axes, pointing anteriorly and the LM - axis is the cross product of the AP and SI axes, pointing laterally. The bony landmarks on the anterior/posterior superior iliac spine from the MSK model and the same landmarks from the standing reference trial were used to construct the hip joint centre and similarly, the landmarks on the femoral epicondyles and malleoli from the MSK model and from the reference trial were used to construct the shank origin, based on the method described by Soderkvist and Wedin [32, 48]. Knee rotations are calculated as the orientation of the shank with respect to the thigh, resolving the Cardan angles in the sequence of flexion/extension, abduction/adduction and external/internal rotation [2]; knee translations are calculated as the displacement of the thigh origin with respect to the shank origin, represented in the shank LCS [8]. The location and orientation of the thigh and shank segments are determined based on the method described by Horn et al.[35]: for the thigh segment constructed using three markers from the thigh cluster in the cluster method and three markers from the femoral arch in the clamp method; for the shank segment using three markers from the shank cluster in both methods. All markers are visible during the analysed gait cycles. The resulting knee kinematics was normalised to 100% of the gait cycle with 101 sample points.

## Insert Figure 3

**Data analysis** 

 To test whether the device changes the walking pattern, walking speed and knee joint kinematics were compared. Walking speed, was calculated as the distance of the







 measurement reliability. As there was a reduction in errors in tracking the femur, this might 266 result in an improvement in the measurement of hip joint kinematics, although this wasn't assessed in this study.

 The new device still showed considerable knee superior/inferior translation and this amount of translation is not seen in direct measures using bone pins and imaging [25, 37]. This DOF also had the lowest ICC. Therefore, the method should not be used to comment on absolute values and patterns of superior/inferior translation at the knee.

 The intra-operator reliability of the custom-made cluster used in the study has been reported previously [43]. Other researchers also investigated inter-operator reliability using 274 the cluster method for knee rotations [55]. Although the use of different reliability index impedes the direct comparison, similar findings have been obtained: the reliability was low 276 in the non-sagittal plane with the lowest value for knee abduction/adduction. The use of the 277 clamp provided a more reliable measure of knee joint kinematics in the non-sagittal plane, which may partly be due to the reduced STA. Furthermore, the femoral clamp appears to have less uncertainty in reinstallation than the thigh cluster, as it will only stabilise on the thigh when it is properly positioned. However, the mean and the range of ICCs for knee rotations were slightly lower in this study when compared to other similar clamps (i.e., the KneeKG with ICCs ranging from 0.89 to 0.94, compared to 0.84 to 0.90 here [57]). The mass 283 of the clamp made from PCL presented here (63 g) is significantly less than other similar clamps (with mass ranging from 125 g [1] to 180 g [42]). Therefore, it is expected that, an improved fixation of the stabilising bar with the femoral clamp may further reduce the effect of gravity and improve its reliability; this is being investigated.



## 1 **NOMENCLATURE**











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## 1 **Figure Captions List**

# Fig. 1

The femoral clamp (a) and its lateral (b) and frontal (c) view on the thigh segment; the lateral femoral pad is placed at the posterior aspect of the lateral epicondyle and the medial femoral pad is placed at the superior aspect of the medial epicondyle; (d) the soft tissue can move around the axis of rotation without affecting the clamp attachments.

## Fig.2

Marker placement for the cluster-based gait methodology. Markers are placed on: right anterior superior iliac spine (RASIS), left anterior superior iliac spine (LASIS), right posterior superior iliac spine (RPSIS), left posterior superior iliac spine (LPSIS), medial femoral epicondyle (MFE), lateral femoral epicondyle (LFE), medial malleolus (MM), lateral malleolus (LM), second metatarsal head (MTHII), fifth metatarsal head (MTHV), lateral calcaneus (LCAL) and posterior calcaneus (PCAL).

## Fig.3

Local coordinate systems of the thigh and shank segments: the lateral – medial (LM) axis is the cross product of the anterior – posterior (AP) and superior – inferior (SI) axes, pointing laterally. The red dots represent the origins; the black dots represent the medial/lateral femoral epicondyles; and the white dots represent the centres of two circles fitted to the medial and lateral plateaus.

Fig. 4 Data analysis flowchart.

Fig. 5 Comparison of mean (solid line) and standard deviation (shaded area)

knee joint kinematics waveforms between cluster gait and clamp gait for one representative subject. Knee flexion(+)/extension(-), abduction(+)/adduction(-), external(+)/internal(-) rotation,

anterior(+)/posterior(-), superior(+)/inferior(-) and lateral(+)/medial(-) translations are measured using the cluster method. The horizontal dashed line indicates the critical thresholds ( $t^* = 31.757$ ,  $\alpha = 0.05$ ). Regions of the gait cycle for which SPM {t} exceeded the critical threshold are considered as statistically significant differences.

Fig. 6 Knee joint kinematics (mean in solid line and standard deviation in shaded area) measured using the cluster method and the clamp method during clamp gait (left panel) for one representative subject, compared to the literature [44]. The differences in eleven data points digitised from the ensemble average kinematics during stance (0-60% of gait, starting from 0% of gait with 6 percentage point intervals) in comparison with the literature are represented in the Bland-Altman plots (right panel) with the corresponding root mean square error (RMSE) and coefficient of determination  $(r<sup>2</sup>)$ .

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## 2 **Table Caption List**

Table 1 The accuracy of knee joint kinematics as measured using the cluster method and the clamp method during clamp gait, in comparison with the literature data [44]. Bland-Altman bias (B) and confidence interval (CI) are expressed as range; room mean square error (RMSE) and coefficient of determination  $(r^2)$  are expressed as mean (standard deviation) across six subjects. The non-parametric Wilcoxon signed rank test is performed to compare the differences in RMSE and  $r^2$ between the two methods.

Table 2 Inter-operator reliability to measure knee joint kinematics using the cluster method in comparison with the clamp method during clamp gait. The intra-class correlation coefficients (ICCs)are calculated for the range of motion (ROM), peak, eleven points during the gait cycle (starting from 0% of gait with 10 percentage point intervals) and expressed as mean across six subjects. The non-parametric Wilcoxon signed rank test is performed to compare the differences in ICCs between the two methods.

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- lateral femoral pad is placed at the posterior aspect of the lateral epicondyle and the medial
- femoral pad is placed at the superior aspect of the medial epicondyle; (c) the soft tissue can
	- move around the axis of rotation without affecting the clamp attachments.
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- 



**Fig.2** Marker placement for the cluster-based gait methodology. Markers are placed on: right

anterior superior iliac spine (RASIS), left anterior superior iliac spine (LASIS), right posterior

superior iliac spine (RPSIS), left posterior superior iliac spine (LPSIS), medial femoral

epicondyle (MFE), lateral femoral epicondyle (LFE), medial malleolus (MM), lateral malleolus

(LM), second metatarsal head (MTHII), fifth metatarsal head (MTHV), lateral calcaneus

(LCAL) 7 and posterior calcaneus (PCAL).



- **Fig.3** Local coordinate systems of the thigh and shank segments: the lateral medial (LM) axis
- is the cross product of the anterior posterior (AP) and superior inferior (SI) axes, pointing
- laterally. The red dots represent the origins of the thigh and the shank; the black dots
- represent the medial/lateral femoral epicondyles; and the white dots represent the centres
- of two circles fitted to the medial and lateral plateaus.



**Fig.4** Data analysis flowchart.





2 **Fig.5.** Comparison of mean (solid line) and standard deviation (shaded area) knee joint kinematics



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5 anterior(+)/posterior(-), superior(+)/inferior(-) and lateral(+)/medial(-) translations are measured

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as

8 statistically significant differences.



 **Fig.6.** Knee joint kinematics (mean in solid line and standard deviation in shaded area) measured using the cluster method and the clamp method during clamp gait (left panel) for one representative subject, compared to the literature [44]. The differences in eleven data points digitised from the ensemble average kinematics during stance (0-60% of gait, starting from 0% of gait with 6 percentage point intervals) in comparison with the literature are represented in the Bland-Altman plots (right panel) with the corresponding root mean 8 square error (RMSE) and coefficient of determination ( $r^2$ ).

Table 1. The accuracy of knee joint kinematics as measured using the l cluster method and the clamp method during clamp gait, in comparison with the literature data [44]. Bland-Altman bias (B) and confidence interval (CI) are expressed as range; room mean square error (RMSE) and coefficient of determination ( $r^2$ ) are expressed as mean (standard deviation) across six subjects. The non-parametric Wilcoxon signed rank test is performed to compare the differences in RMSE and  $r^2$ between the two methods.



Fle/ext = flexion/extension, Abd/add = abduction/adduction, Ext/int = external/internal rotation, Ant/pos = anterior/posterior translation,

Sup/inf = superior/inferior translation, Lat/med = lateral/medial translation. \* indicates significantly different (*p* ≤ 0.05).

Corresponding: Ding; BIO-19-1284 (Technical Brief) 30 Table 2. Inter-operator reliability to measure knee joint kinematics using the cluster method in comparison with the clamp method during clamp gait. The intra-class correlation coefficients (ICCs) are calculated for the range of motion (ROM), peak, eleven points during the gait cycle (starting from 0% of gait with 10 percentage point intervals) and expressed as mean across six subjects. The non-parametric Wilcoxon signed rank test

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