



NON-INVASIVE COMPUTER-ASSISTED MEASUREMENT OF KNEE ALIGNMENT

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3 **Title page**
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7 **NON-INVASIVE COMPUTER-ASSISTED MEASUREMENT OF KNEE**
8 **ALIGNMENT**
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Abstract

The quantification of knee alignment is a routine part of orthopaedic practice and is important for monitoring disease progression, planning interventional strategies and follow-up of patients. Currently available technologies such as radiographic measurements have a number of drawbacks. The aim of this study was to validate a potentially improved technique of measuring knee alignment under different conditions. An image-free navigation system was adapted for non-invasive use through the development of external infra-red tracker mountings. Stability was assessed by comparing the variance (F Test) of repeated mechanical femoro-tibial (MFT) angle measurements for a volunteer and a leg model. MFT angles were then measured supine, standing and with varus-valgus stress for asymptomatic volunteers who each had two separate registrations and repeated measurements for each condition. The mean difference and 95% limits of agreement were used to assess intra-registration and inter-registration repeatability. For multiple registrations the range of measurements for the external mountings was 1° larger than the rigid model with statistically similar variance ($p=0.34$). Thirty volunteers were assessed (19 males, 11 females) with mean age 41 years (20-65) and mean BMI 26 (19-34). For intra-registration repeatability, consecutive coronal alignment readings agreed to almost $\pm 1^{\circ}$ with up to $\pm 0.5^{\circ}$ loss of repeatability for coronal alignment measured before and after stress manoeuvres and a $\pm 0.2^{\circ}$ following stance. Sagittal alignment measurements were less repeatable overall by an approximate factor of two.

Inter-registration agreement limits for coronal and sagittal supine MFT angles were $\pm 1.6^{\circ}$ and $\pm 2.3^{\circ}$ respectively. Varus and valgus stress measurements agreed to within $\pm 1.3^{\circ}$ and

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3 $\pm 1.1^\circ$ respectively. Agreement limits for standing MFT angles were $\pm 2.9^\circ$ (coronal) and
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5 $\pm 5.0^\circ$ (sagittal) which may have reflected a variation in stance between measurements.
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8 The system provided repeatable, real-time measurements of coronal and sagittal knee
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10 alignment under a number of dynamic, real-time conditions offering a potential
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12 alternative to radiographs.
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17 **Key words:** knee alignment, non-invasive, infrared tracking, computer-assisted
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Introduction

Knee joint alignment is an important parameter that has been extensively investigated in the context of osteoarthritis (OA). Radiographic and magnetic resonance imaging (MRI) studies have provided evidence that coronal malalignment is associated with an increased incidence [1] of tibiofemoral OA and risk of progression [2-5]. The importance of coronal alignment in reconstructive surgery of the knee has been widely accepted with the recognition that malpositioning can lead to early prosthesis loosening [6], with reported failure rates of 67% for varus knee prostheses versus 29% for knee prostheses in a neutral position [7], together with increased polyethylene wear and poor overall function [8,9]. Accurate measurement of knee alignment is therefore important for the monitoring of patients with OA, the subsequent planning of surgical interventions and the assessment of treatment outcomes.

The standard measurement of knee alignment often relies on clinical evaluation in conjunction with radiographs that centre on the knee joint. However, human assessment of angles is known to be poor [10] and the accuracy of alignment estimates under these circumstances may be no better than the order of $\pm 5^\circ$ [11]. The use of knee radiographs has been found to be an inaccurate measure of mechanical lower limb alignment [12] and so its role in assessing knee alignment for planning intervention strategies and for post-operative evaluation may be limited. Full-length hip-knee-ankle radiographs have therefore been increasingly adopted to provide more reliable pre- and post-operative information and are widely considered the gold standard for measuring knee alignment. In spite of enabling measurement of the mechanical femoro-tibial (MFT) angle these

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3 radiographs are susceptible to limb positioning errors with apparent variations in
4 alignment produced as a result of knee flexion or rotation [13,14]. Computed tomography
5 (CT) imaging can overcome these positional artefacts by providing a 3D evaluation of
6 lower limb anatomy but is unable to provide weight-bearing information as subjects are
7 required to be supine. Further drawbacks of both imaging modalities include limited
8 availability, exposure of the pelvis to ionising radiation and the lack of more normal
9 physiological control data from populations not typically exposed to them such as
10 children and non-arthritic subjects with knee ligament injuries.
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24 Due to the limitations of radiographs and CT scans, several alternative clinical measures
25 of alignment have been reported and include techniques ranging from direct visual
26 estimation to measurement adjuncts such as callipers, manual goniometers and plumb-
27 line methods [15,16]. These methods are inexpensive, avoid radiation exposure and are
28 relatively quick to perform with instant measurement results. However the reported errors
29 are potentially too large for use in planning and follow-up of surgical interventions such
30 as replacement arthroplasty and corrective osteotomy where higher levels of accuracy are
31 often required [16].
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46 Out with the clinic situation a number of new technologies using infrared tracking have
47 been introduced intra-operatively to provide surgeons with quantitative measurement
48 tools that permit real time assessment of lower limb kinematics [17-19]. These systems
49 have high levels of precision and can achieve angular and tibiofemoral gap measurements
50 of within 1° or 1mm respectively [20,21]. At present these quantitative measurement
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3 techniques have restricted scope due to their reliance on the rigid bony fixation of
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6 trackers. Adapting this technology for non-invasive patient assessment is challenging due
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8 to the soft tissue artefacts associated with the external mounting of trackers. Previous
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10 investigations to quantify the relative movement of external marker sets relative to
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12 underlying bones have reported large potential errors and questioned the value of these
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14 methods for accurate kinematic analysis [22,23]. However these functional methods of
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16 determining rotational joint centres and resultant mechanical lower limb alignment are
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18 often in the context of gait analysis or involve active joint movement with contraction of
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20 the underlying muscles. A more recent study sought to minimise [24] these potential
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22 artefacts by measuring static standing lower limb alignment with position capture and
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24 skin markers along with external anatomical landmarks. The reliance on anthropometric
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26 measurements to predict joint centre location may have accounted for only a moderate
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28 correlation with corresponding long-leg radiographs in an experimental set-up not readily
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30 adaptable to an out-patient clinic.
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39 Given the subjective nature of clinical examination and the limitations of different
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41 measurement techniques reported to date, there is potential to improve current methods of
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43 assessing knee joint alignment. This paper reports the validation of a non-invasive system
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45 for measuring lower limb alignment based on a commercially available infrared tracking
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47 technology with kinematic registration. Our hypothesis was that repeatable, real-time
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49 measurements of mechanical knee alignment under a number of conditions could be
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51 obtained in a clinic situation.
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Materials and Methods

Infra-red tracking system

An image-free navigation system (Orthopilot[®], BBraun Aesculap, Tuttlingen, Germany), that consisted of an optical localiser, active infrared (IR) trackers, a pre-calibrated probe to digitise anatomical landmarks and a foot pedal that enabled 'hands-free' data recording was chosen due to its current clinical use. High tibial osteotomy (HTO) software (Orthopilot[®] HTO version 1.5, BBraun Aesculap, Tuttlingen, Germany) was used for the kinematic determination of hip, knee and ankle centres and resultant generation of coronal and sagittal MFT angles. Coronal alignment was defined with varus negative and valgus positive, whilst sagittal alignment was defined with hyperextension negative and flexion positive.

Rigid tracker mounting model

A metal lower limb model was designed and manufactured to provide optimum conditions for measuring knee alignment. This consisted of metal rods representing a femur, tibia and a foot with rigidly attached tracker mounts and mechanical hip, knee and ankle joints with the required range of movement for registration of their rotational centres (Figure 1).

Non-invasive tracker mounting

Tracker mountings for the thigh, calf and mid-foot regions were developed using metal base plates and broad straps made from standard strength elastic webbing (542, E&E

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3 Accessories, UK). A variety of lengths were made with a sequence of eyelets at either
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5 end to connect to the base plate and enable further adjustment of strap size (Figure 2).
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10 *Tracker stability testing*

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12 In order to quantify the soft tissue artefacts of the non-invasive mountings, the
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14 repeatability of the measurement of coronal knee alignment for both the leg model and
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16 for the right lower limb of a slim, female volunteer was determined. The volunteer was
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18 asked to relax whilst lying supine on an examination couch to ensure that all movements
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20 were passive. The registration process followed that which would be employed intra-
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22 operatively in the normal use of the software. It began with the identification of the
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24 kinematic centre of the hip joint which required a slow, controlled circumduction of the
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26 thigh. The manoeuvre was performed in this manner to avoid moving the pelvis and
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28 subsequently altering the location of the rotational centre of the femoral head. If there
29
30 was excessive movement of the pelvis or the trackers, then this could have resulted in a
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32 wider, “non-spherical” spread of acquired hip joint centre (HJC) points that was out with
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34 the required precision of the system [25]. This would result in rejection of the HJC
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36 acquisition and the instruction to repeat the circumduction manoeuvre until the spread of
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38 measured points was within the required threshold. The kinematic ankle centre was
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40 determined next by attaching a tracker to the dorsum of the foot and then dorsi-flexing
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42 and plantar-flexing the ankle. The rotational centre of the knee joint was then acquired by
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44 flexing and extending the knee between 0 and 90° as well as rotating the tibia on the
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46 femur at 90° of flexion. Following a single registration the trackers were left in position
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48 and 20 consecutive MFT angle recordings were made with the rigid leg model stationary
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3 and with the volunteer instructed to remain as still as possible. The full registration
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5 process was then repeated a further 20 times on 13 different days to quantify additional
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7 soft tissue artefacts associated with removal and re-attachment of the trackers. Statistical
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9 analysis was performed using SPSS version 17 (SPSS Inc, Chicago, IL, USA) and F tests
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11 used for comparison of the variances of the repeated data sets
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15 16 17 18 *Repeatability testing*

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20 All experimental procedures were approved by the University Ethics Committee and,
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22 after giving informed consent, 30 volunteers were recruited (19 males and 11 females)
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24 with a mean age of 41 years (range 20-65) and a mean body mass index (BMI) of 26
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26 (range 19-34). Participants confirmed no acute knee symptoms and no history of joint
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28 replacement. Basic demographic data were recorded prior to assessment of the right
29
30 lower limb. Two kinematic registration processes were performed using the appropriate
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32 passive clinical manoeuvres described above. After each registration, the immediate
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34 coronal and sagittal alignments in full extension were recorded with the lower limb
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36 supported at the heel and the subject told to relax. Following this, coronal and sagittal
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38 alignment was measured with subjects asked to assume their normal bipedal stance.
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40 Returning the participant to the supine position, the coronal and sagittal alignment
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42 measurements were then performed twice and subsequent to this five manual stresses
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44 were applied to the knee joint by a single clinician to determine varus and valgus angular
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46 displacements. During these stress manoeuvres, the knee was held between 0° and 5° of
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48 flexion as indicated by the on-screen measurement of sagittal MFT angle. If the knee
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50 could not extend to 0° then the stress measurements were performed within a 5° window of
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3 flexion from the maximum extension angle. Following this, the coronal and sagittal
4 alignment measurements were finally repeated twice again. Thus five coronal and sagittal
5 MFT angles were determined, before and after standing and before and twice after five
6 bouts of varus-valgus stressing. The clinician was blinded to all the recorded alignment
7 measurements except for the initial supine coronal MFT angle following registration.
8 Occasionally, this measurement after the second registration did not agree to within 2° of
9 the first registration and if this occurred, the registration process was repeated. The limit
10 of 2° was based on the acceptance of small anticipated loss of accuracy due to soft tissue
11 artefacts in comparison to the reported 1° accuracy for invasive use [21].
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25 The mean difference and Bland-Altman 95% limits of agreement [26] of supine coronal
26 MFT angles taken consecutively, and before and after standing and collateral stress
27 within each trial were measured. This was used as an indirect measure of any intra-
28 registration tracker movement that may have occurred during manipulation of the lower
29 limb or from the subject actively moving between supine and standing positions. The
30 mean difference and 95% agreement limits were also used to assess inter-registration
31 agreement of MFT angles measured supine, standing and following applied collateral
32 stress. Bland-Altman plots were generated for the inter-registration comparative data sets.
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When more than one measurement of a variable was taken within a trial the median value was used.

Results

Tracker Stability

Comparison of the rigid and non-invasive mounts is shown in Table 1. Consecutive readings of coronal alignment following a single registration demonstrated standard deviations of 0.07° and 0.13° for the rigid leg model and volunteer respectively and the variances were found to be statistically different ($p < 0.01$). For multiple registrations on different days the overall range was 1° larger for the non-invasive volunteer mounting but the SD was still less than 1° for both tracker mounting methods with no statistically significant difference in the variance of the groups.

Repeatability

The overall cohort had a mean supine coronal MFT angle of $0.1 \pm 2.5^\circ$ and corresponding sagittal MFT angle of $-1.7 \pm 3.3^\circ$ (mean \pm SD). The intra-registration agreement of MFT angle measurements is shown for each of the two sets of registrations in Table 2. Repeat coronal alignment readings with the volunteer lower limbs stationary agreed to almost $\pm 1^\circ$ for both the first and second registrations. For the first registration there was an approximate $\pm 0.5^\circ$ loss of repeatability for coronal alignment measured before and after collateral stress manoeuvres and a less significant loss of $\pm 0.2^\circ$ following stance trials. These small losses in coronal MFT angle repeatability were not seen for the second registration with a consistent agreement of approximately $\pm 1^\circ$. Sagittal alignment measurements were less repeatable overall by an approximate factor of two and were generally no more precise for consecutive stationary readings.

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3 The agreement between the two registrations (Table 3) indicated a repeatability of
4 approximately $\pm 1^\circ$ for all the supine coronal alignment measurements including change
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6 with applied stress. On three occasions, a third registration process was required to obtain
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8 two registrations with a difference in supine coronal MFT angle of 2° or less.
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12 Standing alignment measurements showed less agreement for both coronal ($\pm 3^\circ$) and
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14 sagittal ($\pm 5^\circ$) MFT angles. These results are illustrated in Bland-Altman plots (figures 3a-
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Discussion

The quantification of knee alignment is a routine part of orthopaedic practice and is important for the monitoring of disease progression, the planning of interventional procedures and the follow up of patients. Currently available technologies and measurement techniques have a number of drawbacks including inaccuracy, limb positioning artefacts and radiation exposure. This study developed a system that has addressed some of these issues.

The stability of the IR tracker mountings permitted non-invasive kinematic measurement of knee alignment. For a single volunteer, the non-invasive attachments compared well with the rigid mountings of the leg model. The variance of volunteer measurements for repeated consecutive MFT angles on one registration was statistically greater than that of the rigidly fixed mounting but this difference is of doubtful clinical significance given that both set-ups were well within a precision of 1° . For repeated registrations, the SD of the non-invasive mounting was a third higher than the leg model and the actual range was 1° larger with no statistical difference between the two. This result was perhaps surprising given that the leg model had a rigid hinge for a knee joint with no collateral movement and therefore a more consistent MFT angle. The only minor source of variation between trials on different days was the coupling mechanism between the trackers and fixation screws. In comparison, the volunteer straps would not have been identically applied in terms of both position and tightness. Furthermore, the small amount of natural collateral laxity of the volunteer knee could potentially have resulted in real differences in alignment on different days.

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6 Further evaluation of the non-invasive tracker mountings was provided by the assessment
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8 of multiple volunteers. Following registration the lower limb coronal and sagittal MFT
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10 angles could be repeatedly measured in real-time permitting an intra-registration
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12 assessment of tracker stability following stance and varus-valgus stress. These limb
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14 movements could have potentially modified tracker position but qualitatively they
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16 appeared stable throughout and remained in position for the duration of the measurements
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18 with no complaints of discomfort. This observation of stability was reflected in the results
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20 for consecutive coronal MFT angle measurements in comparison to those taken before
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22 and after stance and collateral stress of the knee. All repeatability was within levels of
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24 clinical relevance. For sagittal alignment the measurements were less repeatable overall
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26 within both sets of registrations with the poorest agreement of up to almost $\pm 3^\circ$ seen
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28 before and after stance. However this may reflect a true difference in sagittal MFT angles
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30 rather than a change in tracker position. Some volunteers were noted to have poor
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32 relaxation which often improved throughout the course of the assessment with less
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34 resistance to full extension from the hamstring muscles. This resulted in a tendency for
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36 knees to become more extended towards the end of the trials which could potentially
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38 explain the greater variation in sagittal measurements in comparison to coronal MFT
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40 angles which were less likely to be affected by muscle tone.
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50 The limits of agreement between the two sets of registrations were approximately $\pm 1^\circ$ for
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52 all supine alignments including change with applied stress. For the initial supine coronal
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54 alignment measurements only three gave inconsistent results that required repetition. All
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3 repetitions were acceptable. Therefore although the registration process was open to error
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5 it was an infrequent occurrence and a simple repeat protocol enabled it to be identified
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7 every time. The potential variation in applied manual load to the knee did not result in a
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9 loss of repeatability that would perhaps have been anticipated. This may be explained by
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11 the consistency of the clinician performing the collateral stress manoeuvres [27] which
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13 may have shown greater inter-observer variation if different examiners were assessed.
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15 Standing alignment measurements showed less agreement for both coronal ($\pm 3^\circ$) and
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17 sagittal ($\pm 5^\circ$) MFT angles. This may represent a true difference in alignment as a result of
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19 stance variation between trials as volunteers were only instructed to stand on both legs as
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21 normal rather than to assume a position of maximum extension with their knees “locked”
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23 straight. Therefore the variation in standing knee extension angle could be due to this
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25 lack of control of limb position. In comparison the supine measurements were performed
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27 in a more reproducible manner by supporting the lower limb under the heel and this was
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29 reflected in the narrower agreement limits illustrated with Bland-Altman plots. The $\pm 5^\circ$
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31 scale of the vertical axis (except for standing sagittal measurements) was chosen to
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33 reflect typical repeatability of other methods of assessing both sagittal [10] and coronal
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35 [24] knee alignment including human variations of joint angle estimation [11]. However
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37 it should be noted that considerably greater intra-observer estimates of knee flexion and
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39 extension angles have been reported with critical differences between measurements of
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41 7.1° to 21.4° [28].
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53 The use of externally mounted markers and a motion capture system was not an entirely
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55 novel approach to measuring lower limb alignment. Mündermann et al. [24] used
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3 reflective marker sets and four high-speed cameras to measure static mechanical lower
4 limb alignment but reported only a moderate correlation ($R^2=0.544$) with the
5 corresponding long-leg radiographs and a discrepancy of more than 5.3° for 10% of
6 cases. However, the hip, knee and ankle joint centres were determined from
7 anthropometric measurements which are widely accepted as being inaccurate, particularly
8 for the hip joint [29-32]. The experimental set up in terms of anatomical landmark
9 identification, marker placement, multiple camera positioning and data capture analysis
10 also presented several limitations as a clinically adaptable measurement tool. In contrast,
11 the system developed in this study consisted of a single portable camera unit with
12 corresponding IR trackers that should be secure and visible but without the requirement
13 of specific anatomical placement. The kinematic registration process was approximately
14 five minutes with on-screen guidance for performing simple joint movements to
15 determine their rotational centres. The subsequent MFT angle was generated from
16 kinematic data alone without the potential associated errors of anatomical landmark
17 registration [33]. Hip joint centre location errors were minimised by a software algorithm
18 that rejected the points in space acquired during thigh circumduction if their spread was
19 too large or the distribution was non-spherical [25]. The passive movements for
20 kinematic registration were therefore required to be slow and controlled, which contrasts
21 to other studies of functional joint centre determination using active movements or gait
22 [22,23].

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53 The immediate generation of real-time on-screen coronal and sagittal MFT angles
54 presented a number of potential advantages over other measurement systems. Firstly it
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3 enabled dynamic measurements of alignment to be made following applied stress or
4 weight bearing with immediate visualisation of angular displacement. The ability to
5 measure the resultant change in coronal MFT angle from a supine resting position when a
6 collateral stress is applied has a potential clinical application for improving the
7 measurement of relative varus and valgus knee laxity. Current methods are either
8 subjective [34] or rely on adjuncts such as X-ray measurements of tibiofemoral gap
9 opening [35] which are prone to potential radiographic errors associated with limb
10 positioning [13,14]. For weight-bearing conditions the measurements did not require
11 strict rotational control of the lower limb and the coronal MFT angle was recorded with
12 the associated knee flexion angle. This IR system could therefore potentially offer a
13 viable alternative to long-leg radiographs whilst also overcoming some of the previously
14 discussed limitations.
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34 This validation study also has its limitations. The measurements were made by a single
35 clinician involved in the development of the system without an assessment of inter-
36 observer variation. The true volunteer knee alignments were unknown and so validation
37 of the measurement tool was based on repeatability rather than comparison to a
38 measurement standard. However, the IR measurement system is validated for use with
39 rigid tracker attachments. It could therefore be inferred that repeatable measurements are
40 also accurate, as for measurements to be repeatable, soft tissue artefacts must be minimal.
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51 In addition, it could be argued that the acknowledged long-leg radiographic gold standard
52 has more potential variation [14] than the IR system and that disagreement between
53 measurements may not reflect true inaccuracies [36]. Although there were several obese
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3 subjects, there were none who were morbidly obese and no subject reported discomfort
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5 when performing the necessary kinematic manoeuvres. The registration process may be
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7 less reliable in a typically more obese osteoarthritic population [37,38] with potential pain
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9 on joint movement.
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15 In summary, a non-invasive tool for measuring coronal and sagittal knee alignment under
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17 a number of dynamic, real-time conditions was developed and validated. The portability
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19 of the system offers potential as an out-patient assessment tool and provides an
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21 alternative to long-leg radiographs without exposure to radiation. The measurement of
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23 supine, standing and stress alignment on both asymptomatic and osteoarthritic subjects
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25 may help to further our understanding of the complex kinematics of the knee.
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Declaration of interest statement

One of the authors (FP) has patents/licensing agreements with BBraun Aesculap. JVC, PER and AHD certifies that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article. Our department has received research funding from BBraun Aesculap.

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Table 1 The mean and standard deviation (SD) of each set of tests was used to compare the difference in repeatability of the rigid model and the non-invasive tracker mounting (measurements in degrees)

	Single registration		Multiple registrations	
	Leg Model: Rigid mounting	Volunteer: Non-invasive mounting	Leg Model: Rigid mounting	Volunteer: Non-invasive mounting
n	20	20	20	20
Mean (SD)	2.1 (0.07)	1.4 (0.13)	1.6 (0.5)	1.5 (0.7)
range	2.0 – 2.3	1.1 – 1.6	0.9 – 2.8	0.3 – 2.5
F Test	p = 0.008		p = 0.34	

Table 2 Mean difference and 95% limits of agreement of repeat supine alignment measurements in extension with leg stationary and before and after both standing and collateral stress manoeuvres (measurements in degrees)

	Registration 1		Registration 2	
	Mean difference	$\pm 1.96SD$	Mean difference	$\pm 1.96SD$
Coronal MFT angle consecutive	0.03	1.2	-0.02	1.1
Coronal MFT angle before and after stance	-0.1	1.4	0.07	1.1
Coronal MFT angle before and after stress	0.2	1.7	0.2	1.0
Sagittal MFT angle consecutive	0.2	2.2	-0.1	2.1
Sagittal MFT angle before and after stance	0.5	2.8	0.7	2.6
Sagittal MFT angle before and after stress	-0.3	2.2	-0.9	1.7

Table Error! No text of specified style in document. Inter-registration agreement of supine and standing coronal and sagittal MFT angles, and relative change following varus-valgus stress (measurements in degrees)

MFT angle	Mean difference	±1.96SD
Supine coronal	-0.2	0.8
Supine sagittal	0.2	1.2
Change with varus stress	-0.3	1.3
Change with valgus stress	-0.2	1.1
Standing coronal	0.2	2.9
Standing sagittal	0.1	5.0

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3 **Figure legends**
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8 **Figure 1:** Leg model with rigid tracker mountings
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12 **Figure 2:** External tracker mountings with adjustable straps
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17 **Figures 3a-f:** Bland-Altman plots showing the mean difference (solid black line) and
18 95% limits of agreement (dotted grey lines) of MFT angular measurements for two trials
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20 a) supine coronal, b) supine sagittal, c) with varus stress, d) with valgus stress, e)
21 standing coronal, f) standing sagittal
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Leg model with rigid tracker mountings
160x107mm (150 x 150 DPI)

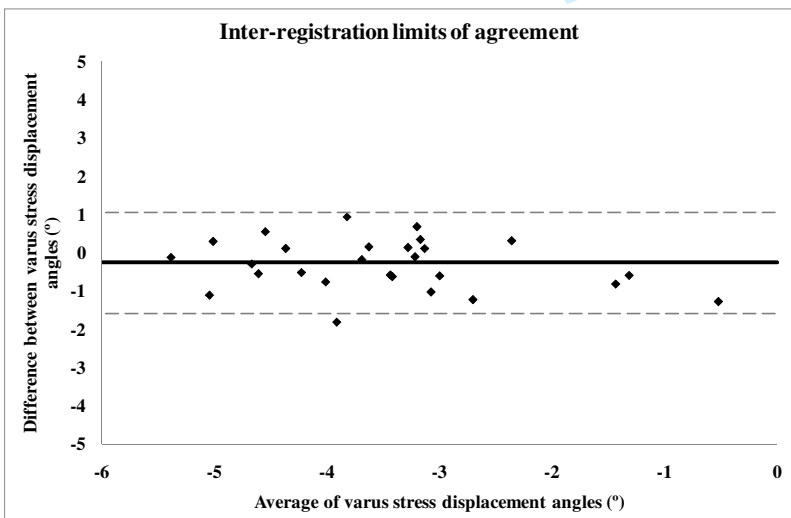
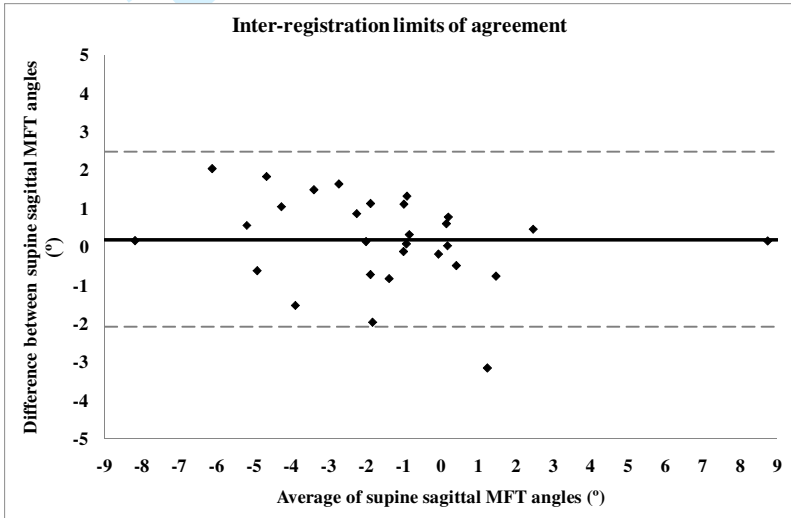
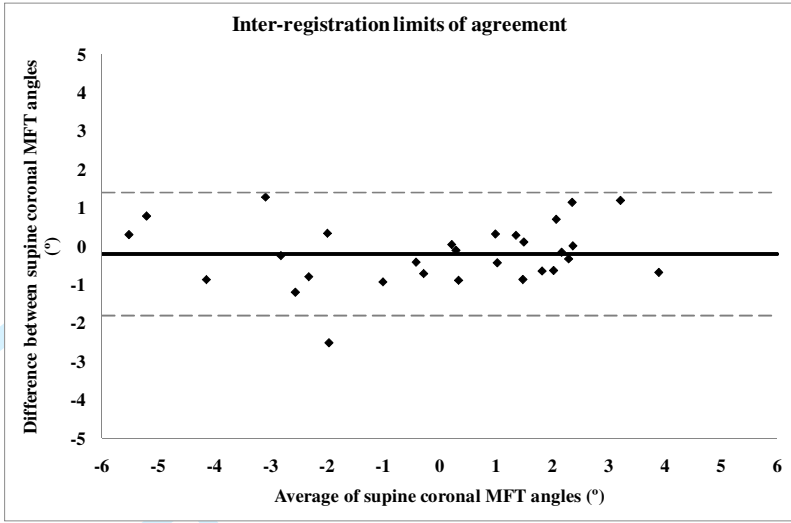
Review Only



External tracker mountings with adjustable straps
100x66mm (150 x 150 DPI)

Review Only

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