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Quantitative measurement of lower limb mechanical alignment and coronal knee laxity in early flexion

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ABSTRACT

Background: Non-invasive quantification of lower limb alignment using navigation technology is now possible throughout knee flexion owing to software developments. We report the precision and accuracy of a non-invasive system measuring mechanical alignment of the lower limb including coronal stress testing of the knee.

Methods: Twelve cadaveric limbs were tested with a commercial invasive navigation system against the non-invasive system. Coronal mechanical femorotibial (MFT) alignment was measured with no stress, then 15 Nm varus and valgus applied moments. Measurements were recorded at 10° intervals from extension to 90° flexion. At each flexion interval, coefficient of repeatability (CR) tested precision within each system, and limits of agreement (LOA) tested agreement between the two systems. Limits for CR & LOA were set at 3° based on requirements for surgical planning and evaluation.

Results: Precision was acceptable throughout flexion in all conditions of stress using the invasive system ($CR \leq 1.9°$). Precision was acceptable using the non-invasive system from extension to 50° flexion ($CR \leq 2.4°$), beyond which precision was unacceptable ($>3.4°$). With no coronal stress applied, agreement remained acceptable from extension to 40° ($LOA \leq 2.4°$), and when 15 Nm varus or valgus stress was applied agreement was acceptable from extension to 30° ($LOA \leq 2.9°$). Higher angles of knee flexion had a negative impact on precision and accuracy.

Conclusion & clinical relevance: The non-invasive system provides reliable quantitative data in-vitro on coronal MFT alignment and laxity in the range relevant to assessment of collateral ligament injury, pre-operative planning of arthroplasty and flexion instability following arthroplasty. In-vivo validation should be performed.

1. Introduction

Understanding lower limb alignment in health, disease and in the surgical setting is crucial to lower limb reconstruction, both in sports medicine and knee arthroplasty. The ability to quantify lower limb alignment in both coronal and sagittal planes is important to pre-operative decision making, planning and post-operative evaluation. 'Long-leg radiographs' or 'hip-knee-ankle' radiographs remain the gold-standard using the definition by Moreland et al. [1] for mechanical alignment in the coronal plane, allowing measurement of the mechanical femorotibial (MFT) angle. Long-leg radiographs whilst far superior to short leg radiographs [2] are prone to rotational error [3,4] especially in patients with flexion contracture [4]. Other methods used routinely in a clinical setting to assess alignment may provide a means of appreciating disease progression but are not reliable enough for surgical planning; these include visual assessment with use of a goniometer [5], and other landmark based methods [6–8].

Image-free navigation technology has been thoroughly validated in acquisition of coronal and sagittal mechanical alignments [9,10]. Clinical studies, have demonstrated that image-free navigation gives consistent accurate placement of components and limb alignment [11–13], supporting the intra-operative use of navigation systems [14]. However computer navigation presently depends on invasive placement of trackers meaning that it is limited to the operating theatre. The ability to use this type of system to quantify these parameters in a non-invasive manner with minimal adverse consequence to the patient would allow accurate assessment in a clinic situation.

Clarke et al. validated a non-invasive adaptation of image-free navigation for measuring the MFT angle in extension and with applied stress, and for early flexion–extension measurement [15–17]. These early results are promising but do not include validation of the measurement of the MFT angle with the knee beyond 10° of flexion. Initial

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results from a pilot study on cadavers were repeatable in measuring the MFT angle and knee laxity from extension to 40° [18]; however, the methodology in this study was limited in terms of consistency in limb positioning and forces applied and use of embalmed cadaveric materials. Therefore the primary aim in this study was to determine the reliability, precision and accuracy of a non-invasive adaptation of image-free navigation technology in determining the MFT angle of the lower limb in flexion. A secondary aim was to determine the reliability, precision and accuracy of the non-invasive measurements of maximum extension and flexion.

2. Materials and methods

Twelve fresh cadaveric lower limbs were used. A similar experiment setup used to test anteroposterior laxity in the knee has already been reported and was carried out on the same specimens [19]. A single investigator (DFR) performed all tests. A FDA, CE validated image-free navigation system was used for the study (Orthopilot, BBraun Aesculap, Tuttlingen, Germany). The hip, knee and ankle centres were registered during both invasive and non-invasive testing using the same software; algorithms used to register the lower limb were identical to those of validated, commercially available software currently used in image-free computer-assisted high tibial osteotomy surgery which permits non-invasive registration of anatomical landmarks of each joint. Using this software, all points requiring digitisation were located on the skin without the need for incision(s), and the kinematic centres of the hip, knee and ankle were identified through recording a series of prescribed lower-limb movements [20].

Two methods of passive tracker fixation were used: commercially available bone screws and a baseplate secured by fabric strapping (Fig. 1). In order to minimise soft-tissue artefacts from the limb resting on the laboratory table, it was necessary to suspend the limb. A bicortical eyelet screw (length of 20 mm, width of 75 mm, manufacturer part no. N330, B&Q, UK) was inserted into the proximal femur to suspend the thigh from a stand, maintaining a hip flexion of 20° (Fig. 2). To create a foot support, a loop of cord was secured proximal to the metatarsal heads; this maintained knee flexion angle (Fig. 3). In order to apply a standardised varus/valgus moment of 15 Nm, unicortical 7.5 mm eyelet screws were inserted in the medial and lateral sides of the distal tibia, aligned in the coronal plane, and at a set distance from the joint line, depending on the length of the lower limb (Fig. 3). Side supports (Fig. 2) and manual support (Fig. 3) were both employed during coronal stress testing to stabilise the knee. Fifteen Nm varus/valgus stress is similar to that exerted during clinical examination [21–23]. A force transducer (model 251066, Silverline, Somerset, UK, CE certified) was attached to these eyelet screws in order to apply a discrete force in the coronal plane (Fig. 3).

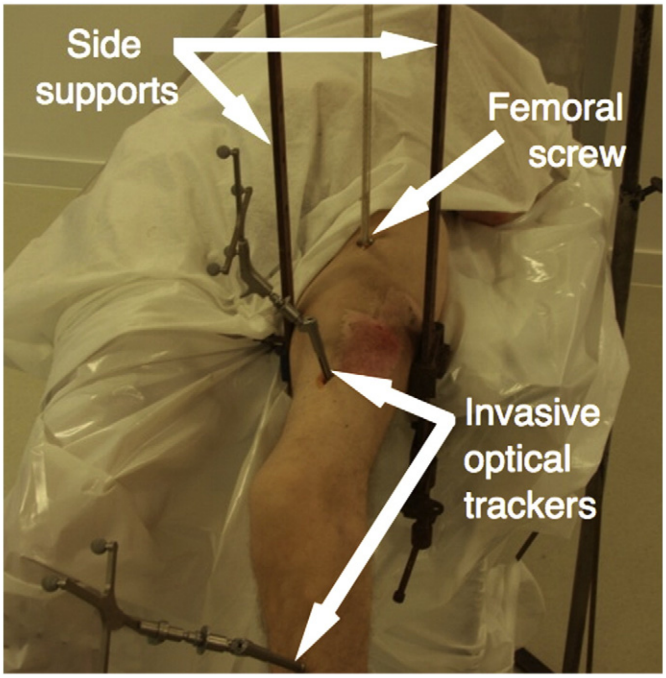

Fig. 2. Photograph of limb set up, side supports to supplement manual support against varus and valgus stress and the femoral pin used to suspend the thigh are labelled. Trackers present in this photograph are placed on mounts secured by bone screws.

To minimise soft tissue creep throughout the experiment a protocol of 24 hip circumductions, 24 full flexion and extensions of the limb & 24 manual varus/valgus stresses was performed prior to testing.

Experiment protocol (given below) was first performed using invasively mounted trackers, then repeated using non-invasively mounted trackers. The invasively mounted trackers were secured using bicortical bone screws, one in the anterior distal femur, and one in the anterior proximal tibia as is standard practise during intraoperative image-free navigation (Fig. 2). The non-invasive trackers were secured 8 cm proximal to the proximal pole of patella overlying the distal vastus medialis obliquus muscle, and 4 cm distal to the tibial tuberosity, again on the medial aspect of the lower limb to maximise tracker exposure to the localising camera (Fig. 1). The only difference in the protocol when using the non-invasive method was that the trackers and fabric strapping were removed and replaced between registrations.

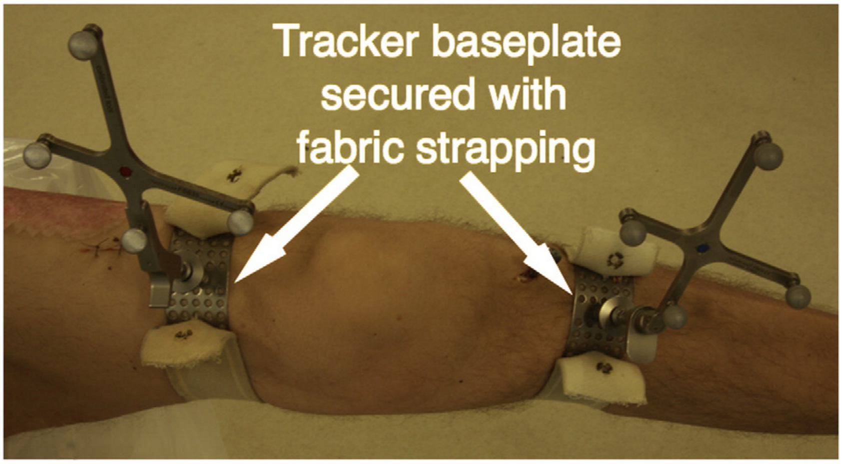

Fig. 1. Photograph showing the non-invasive method of optical tracker mounting secured with fabric strapping.