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BIOMEDICAL PAPER

Non-invasive quantification of lower limb mechanical alignment in flexion

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Abstract

Objective: Non-invasive navigation techniques have recently been developed to determine mechanical femorotibial alignment (MFTA) in extension. The primary aim of this study was to evaluate the precision and accuracy of an image-free navigation system with new software designed to provide multiple kinematic measurements of the knee. The secondary aim was to test two types of strap material used to attach optical trackers to the lower limb.
Methods: Seventy-two registrations were carried out on 6 intact embalmed cadaveric specimens (mean age: 77.8 ± 12 years). A validated fabric strap, bone screws and novel rubber strap were used to secure the passive tracker baseplate for four full experiments with each knee. The MFTA angle was measured under the conditions of no applied stress, valgus stress, and varus stress. These measurements were carried out at full extension and at 30°, 40°, 50° and 60° of flexion. Intraclass correlation coefficients, repeatability coefficients, and limits of agreement (LOA) were used to convey precision and agreement in measuring MFTA with respect to each of the independent variables, i.e., degree of flexion, applied coronal stress, and method of tracker fixation. Based on the current literature, a repeatability coefficient and LOA of ≤3° were deemed acceptable.
Results: The mean fixed flexion for the 6 specimens was 12.8° (range: 6–20°). The mean repeatability coefficient measuring MFTA in extension with screws or fabric strapping of the baseplate was ≤2°, compared to 2.3° using rubber strapping. When flexing the knee, MFTA measurements taken using screws or fabric straps remained precise (repeatability coefficient ≤3°) throughout the tested range of flexion (12.8–60°); however, using rubber straps, the repeatability coefficient was >3° beyond 50° flexion. In general, applying a varus/valgus stress while measuring MFTA decreased precision beyond 40° flexion. Using fabric strapping, excellent repeatability (coefficient ≤2°) was observed until 40° flexion; however, beyond 50° flexion, the repeatability coefficient was >3°. As was the case with precision, agreement between the invasive and non-invasive systems was satisfactory in extension and worsened with flexion. Mean limits of agreement between the invasive and non-invasive system using fabric strapping to assess MFTA were 3° (range: 2.3–3.8°) with no stress applied and 3.9° (range: 2.8–5.2°) with varus and valgus stress. Using rubber strapping, the corresponding values were 4.4° (range: 2.8–8.5°) with no stress applied, 5.5° (range: 3.3–9.0°) with varus stress, and 5.6° (range: 3.3–11.9°) with valgus stress.
Discussion: Acceptable precision and accuracy may be possible when measuring knee kinematics in early flexion using a non-invasive system; however, we do not believe passive trackers should be mounted with rubber strapping such as was used in this study. Flexing the knee appears to decrease the precision and accuracy of the system. The functions of this new software using image-free navigation technology have many potential clinical applications, including assessment of bony and soft tissue deformity, pre-operative planning, and post-operative evaluation, as well as in further pure research comparing kinematics of the normal and pathological knee.

Keywords

Image-free navigation, mechanical femorotibial alignment, total knee arthroplasty

History

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Introduction

When planning and carrying out primary and revision total knee arthroplasty, lower limb alignment, knee joint laxity, and whether a varus/valgus deformity is correctable by manual stress are all crucial pieces of information. Visual assessment of flexion angle and coronal alignment is difficult and unreliable [1, 2]. Laxity of the knee and the ability to correct coronal deformity completely with manual stress can be estimated by an examiner performing standard clinical tests; however, these rely on clinician experience and are highly subjective.

The gold standard in estimating mechanical alignment of the lower limb is the ''long-leg radiograph'' or ''hip-knee-ankle'' (HKA) radiograph. For many years, the

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definition by Moreland et al. [3] has been used: mechanical femorotibial alignment (MFTA) of the lower limb is given by the lesser angle intersecting the mechanical femoral axis (the line from the center of the femoral head to the knee center) and the mechanical tibial axis (the line from the knee center to the ankle center). However, radiographs may be prone to rotational error and do not permit dynamic quantification of knee laxity or kinematics in flexion [4, 5]. As yet, surgeons in the out-patient setting do not have a validated method of establishing MFTA throughout flexion which allows dynamic assessment of the soft tissues using standardized force application. These parameters would allow superior patient assessment and planning of knee reconstruction.

Recently, non-invasive image-free navigation techniques have been introduced and validated for quantifying MFTA in extension [6]. These techniques use similar frames of reference to those used in navigation, for the first time allowing the pre- or postoperative assessment to be matched to the intraoperative evaluation. Preoperative non-invasive kinematic assessment also overcomes the disadvantages inherent in using intraoperative navigation-based MFTA measurements to guide soft-tissue algorithms, including unquantified influences of anesthesia, non-standardized passive examination forces with the patient supine and non-weight/non-physiological load bearing, and the unknown effect of arthrotomy on alignment and laxity measurements.

Non-invasive attachment of optical trackers and their movement relative to and representative of the bony anatomy of the lower limb is an area of ongoing research [7, 8]. Various materials have been proposed for attachment of non-invasive trackers, including the fabric strapping validated by Clarke et al. [6] and rubber strapping [9]. Rubber strapping has the advantage of being less expensive, allowing new strapping to be used on each subject, and is used in some commercially available image-free navigation systems as a means of fixing optical trackers to the foot. Fabric strapping may be more expensive and may therefore have to be used on multiple individuals, which has implications for infection control in a clinical setting [10, 11].

The primary aim of this study was to compare a non-invasive system with a validated and commonly used intraoperative computer navigation system in terms of repeatability of MFTA measurement and agreement with the invasive system. This non-invasive system uses novel software designed to quantify MFTA in flexion. The novel workflow is based on validated software currently used during computer-assisted high tibial osteotomy. We aimed to observe the effects of knee flexion and application of coronal force on MFTA measurement repeatability and agreement. The secondary aim was to compare proposed methods of non-invasive tracker attachment; firstly using a previously validated fabric strap [6], and then using a rubber strap.

Materials and methods

A single investigator trained in clinical examination of the knee carried out all testing on 6 knees using 4 intact embalmed cadaveric specimens. Average age of specimens was 77.8 years (range: 57–90 years); two were female.

The image-free OrthoPilot navigation system (B. Braun Aesculap, Tuttlingen, Germany) was used with passive optical trackers. The optical camera was positioned two meters from the specimen. Experimental software allowed registration of the centers of the hip, knee and ankle following a series of prescribed lower limb movements and localization of key bony landmarks. The registration algorithms in this software are identical to those in validated, commercially available software used in computer-assisted surgery (KneeSuite, B. Braun Aesculap), with changes being made only to the measurement sequence.

The limbs were put through 24 full cycles of flexion and extension to minimize systematic error due to progression of tissue elasticity. The experiments were carried out over 6 days during which the temperature of the laboratory was controlled and constant. The specimens were not refrigerated between experiments. Several runs of the protocol were performed on a specimen unsuitable for the experiment due to stiffness.

Three separate methods of tracker fixation were used: standard bone screws, a previously untested rubber strap securing a standard baseplate, and a fabric strap securing the baseplate. Both methods of strapping included eyelets through which baseplate studs secured the strap. The fabric strap and baseplate used in this study had been validated previously [6]. Trackers were secured 6–8 cm proximal to the proximal pole of the patella overlying the distal vastus medialis obliquus muscle, and 3–4 cm distal to the tibial tuberosity, again on the medial aspect of the lower limb. Registration was then carried out as described above. Following this, measurements of coronal alignment were taken, initially with no coronal stress applied, and then with applied valgus and varus stress. The load applied was equivalent to that used during routine clinical examination of the knee soft tissues – this method has demonstrated reproducible results [12]. These three measurements of coronal alignment were recorded by the system at the point of maximum knee extension, then at 30°, 40°, 50° and 60° of knee flexion. One specimen had a maximum mean flexion of 58.8°, not reaching 60°. Maximum flexion angle was recorded.

The experiment protocol was repeated four times on each of the 6 knee specimens with each type of tracker mounting (bone screws, rubber strapping and fabric strapping). Between each run of the protocol the trackers were taken off and relocated, and a new registration performed. This created 72 separate episodes of registration, during each of which 25 data points were recorded. The protocol design allowed analysis of the effect of knee flexion and type of tracker mounting on repeatability as four values were obtained with all independent variables of degrees of knee flexion, tracker mounting and knee specimen remaining constant. The only change between these four points was a new system registration to minimize potential random error from a single erroneous registration [13].

Calculation of the intraclass correlation coefficient (ICC) was performed using IBM SPSS® Statistics 17.0 software (IBM Corp., Armonk, NY); other simple calculations were performed using Microsoft Excel® (Microsoft Corp., Redmond, WA). Reliability within each method of tracker fixation used in measuring MFTA was analyzed by calculating the ICC [14]. A coefficient of ≥ 0.75 demonstrates very

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good reliability [15, 16]. The repeatability coefficient was calculated to demonstrate repeatability between test–retest measurements for each method of tracker fixation [17]. The four recorded data points with all variables constant across the 6 specimens were divided into two pairs (tests 1 and 2, tests 3 and 4) to allow calculation. The repeatability coefficient defines the interval within which 95% of test–retest differences lie, i.e., within two standard deviations of the test-retest differences [17].

According to the manufacturer, in measuring coronal alignment the device and software are expected to have a precision of 1° when repeatedly measuring a fixed point in space. We therefore determine a repeatability coefficient of ≤2° (i.e., ±1°) as demonstrating excellent precision in line with the manufacturer's standard. In the clinical setting, the accepted range for satisfactory postoperative function and implant survivorship following total knee arthroplasty is ±3°. It is therefore critical that the device be able to measure MTFA precisely within this range. A repeatability coefficient of 3° conveys that 95% of all measurements are within a range of ±1.5°.

To compare the reliability of measurements between the invasive and two non-invasive methods of tracker mounting, the ICC was calculated. Bland-Altman plots were generated as a visual representation of the limits of agreement. To calculate the standard deviation of the differences, the 95% limits of agreement, calculated using the corrected standard deviation of the differences (SD_c) [17] (mean difference ±1.96 SD_c), were calculated to analyze agreement between the invasive and non-invasive methods of tracker fixation. Acceptable limits of agreement were once again set at 3° for measurements of MFTA.

Table I. Mean and range of the repeatability coefficient for measuring MFTA using three methods of tracker fixation and applying three conditions of coronal stress throughout the range of knee flexion tested. All kinematic parameters measured in the study are summarized in this table and identified in the first column. (No range is given for maximum extension/flexion as this is a single point of measurement.)

	Repeatability coefficient (°)		
Condition	Screws	Fabric	Rubber
MFTA (no stress applied)	2.0 (0.8–2.8)	1.7 (1.3–2.3)	2.3 (0.8–5.3)
MFTA varus stress	2.0 (0.9–3.2)	2.2 (1.6–3.7)	3.1 (1.3–6.6)
MFTA valgus stress	2.2 (1.5–2.9)	2.1 (0.8–3.7)	3.1 (1.4–7.6)
Max. extension	1.3	1.6	2.0
Max. flexion	1.6	1.8	1.5

Results

Each specimen exhibited some degree of fixed flexion deformity when measured using the invasive method. The mean fixed flexion for the 6 specimens was 12.8° (range: 5–18°). The mean maximum flexion using invasive trackers was 68.2° (range: 58–95°). All measurements of maximum flexion using invasive trackers for specimen 1 were 58°, therefore we could not measure kinematics at 60° knee flexion in this specimen.

Table I shows the mean repeatability coefficient for the range of flexion tested in this experiment (12.8–60°). The bone screw and fabric strap fixation provided superior precision compared to rubber straps in all conditions of applied coronal stress. Precision in repeatedly measuring maximum extension and flexion was satisfactory using all methods of tracker fixation.

Flexion of the knee and application of coronal stress appears to reduce precision (Figures 1–3). Precision in measuring MFTA using bone screws or fabric strapping to secure trackers was acceptable throughout the tested range of flexion when no coronal stress was applied (Figure 1). Repeatability of measurements using rubber strapping became unacceptable beyond 50° knee flexion.

Applying varus/valgus stress at ≥30° flexion decreased the precision of measurement using all methods of tracker fixation; however, fabric strap fixation remained within the limits of acceptable precision until 40° of knee flexion when

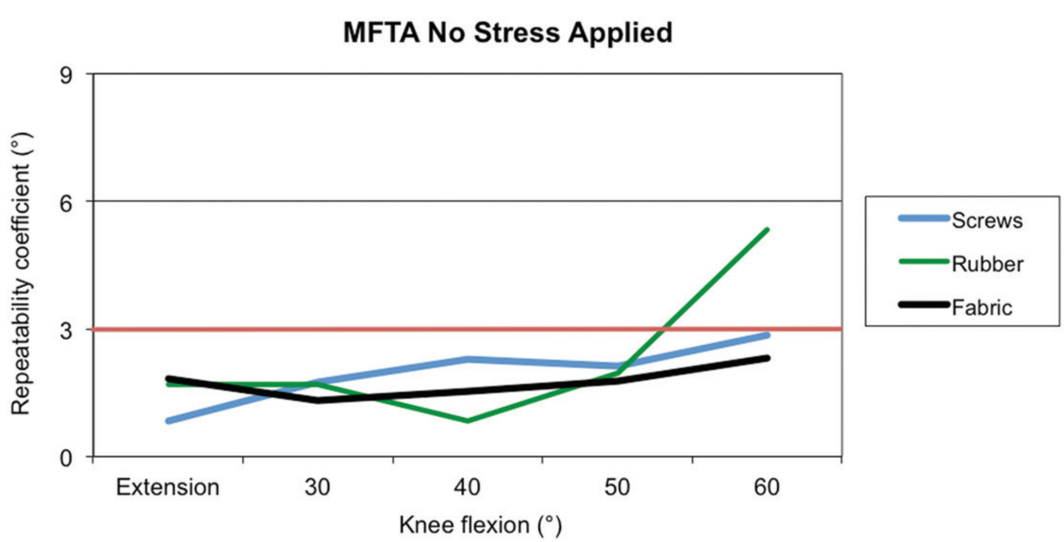

Figure 1. Repeatability coefficient at each 10° interval of knee flexion for all three methods of tracker mounting (bone screws, rubber strapping and fabric strapping). Repeatability was acceptable (<3°, indicated by red line) throughout flexion for bone screws and fabric strapping, but unacceptable for rubber strapping beyond 50°.

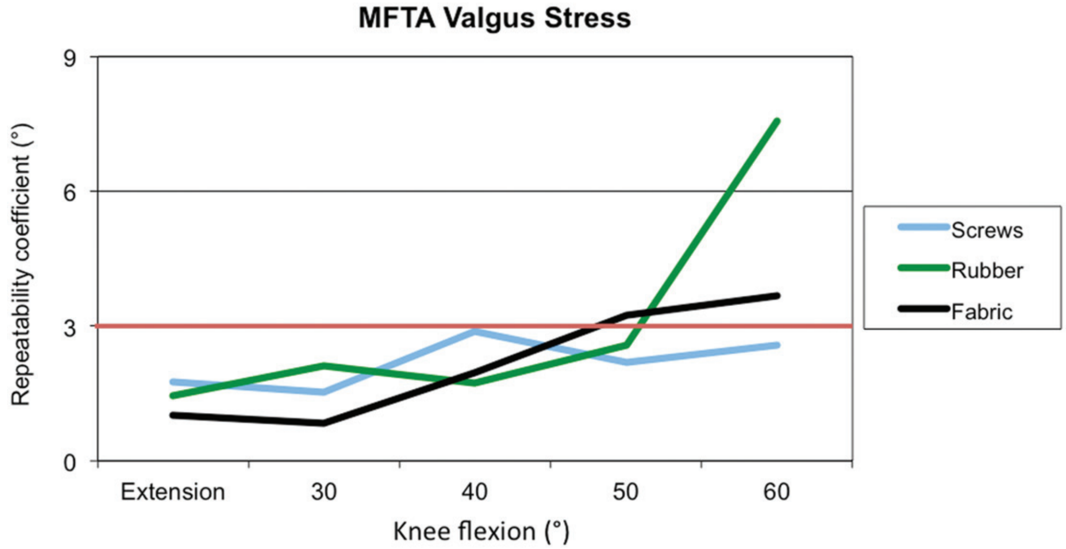

Figure 2. Repeatedly measuring MFTA with application of valgus stress resulted in a repeatability coefficient of >3° when flexing the knee beyond 40° when using fabric strapping and beyond 50° when using rubber strapping. Bone screw fixation of trackers resulted in satisfactory repeatability throughout.

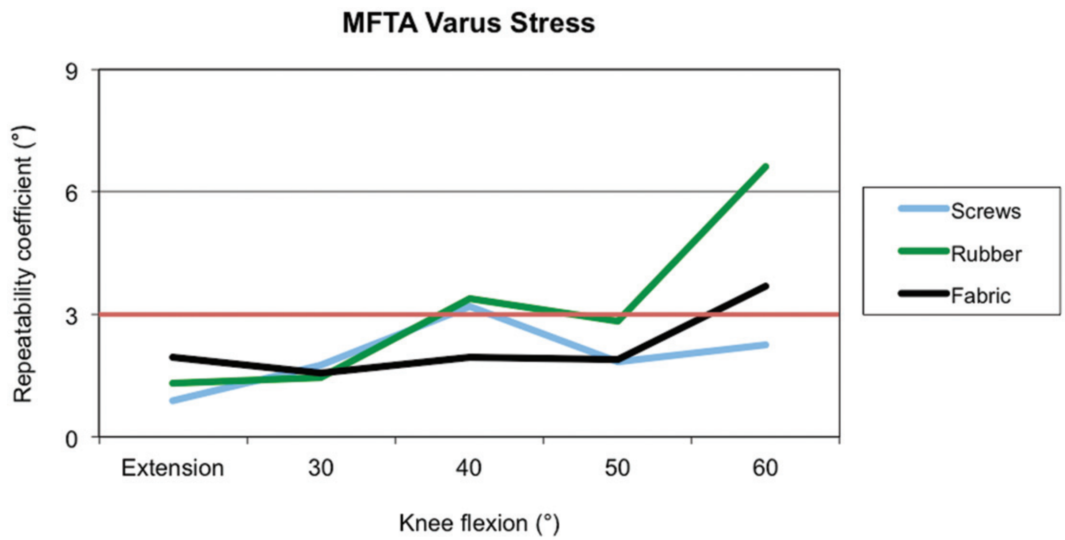

Figure 3. Repeatability of measuring MFTA with application of varus stress was again worsened by flexion. Fabric strapping remained acceptable until >50° knee flexion, rubber strapping until 30° knee flexion. Bone screw fixation gave a repeatability coefficient of 3.1° at 40° knee flexion, then remained acceptable.

applying valgus stress (Figure 2), and 50° when applying varus stress (Figure 3).

Bland-Altman plots demonstrated no systematic error when plotting screw fixation versus fabric strap fixation (Figure 4) and screw fixation against rubber strap fixation (Figure 5). This is true for other conditions of flexion.

Generating limits of agreement for each condition created a large amount of data, which is summarized in Table II.

The fabric strapping performed consistently better than the rubber strapping in measuring MFTA. Agreement between fabric strapping and screw fixation of the trackers was acceptable (LOA <3°) in extension and at 30° knee flexion with no coronal stress and with varus/valgus stresses applied. Agreement generally worsened with increasing knee flexion for all conditions, but especially when comparing screw fixation and rubber strapping at 60°.

The agreement measuring the maximum extension between values obtained using screw fixation and fabric strapping was 3.4°, and for rubber strapping it was 3°. The limits of agreement when measuring maximum flexion were 3.8° and 4.7°, respectively.

Discussion

Precision in measuring MFTA with no coronal stress applied to the leg was well within the limits of accepted repeatability throughout flexion using screw and fabric strap fixation. Repeatability using rubber strapping was poor beyond 50° in measuring MFTA and rotation. Precision of MFTA measurement was uniformly worse with coronal stress applied. Subjectively, movement of the trackers fixed

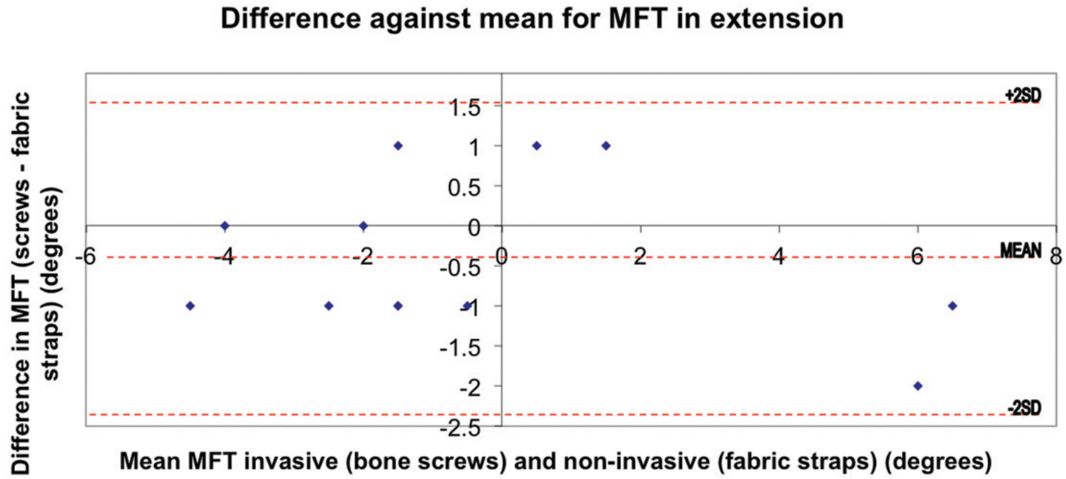

Figure 4. Bland-Altman plot displaying the mean difference between MFTA measurements with trackers secured using bone screws and fabric strapping against mean MFTA measurements.

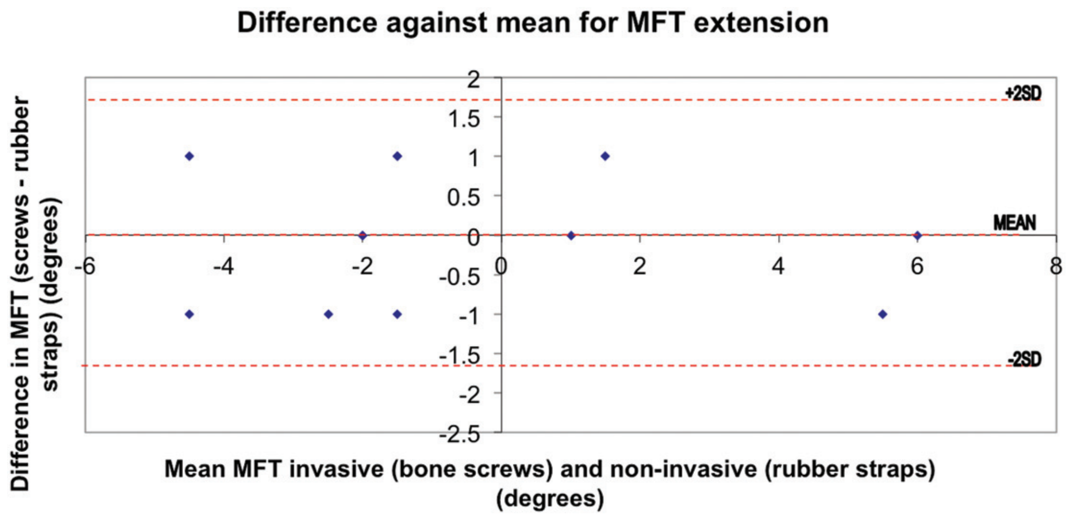

Figure 5. Bland-Altman plot displaying the mean difference between MFTA measurements with trackers secured using bone screws and rubber strapping against mean MFTA measurements.

Table II. Mean limits of agreement and range for screws versus rubber straps and screws versus fabric straps for the entire range of flexion tested. All kinematic parameters measured in the study are summarized in this table and identified in the first column. (No range is given for maximum extension/flexion as this is a single point of measurement.).

	Limits of agreement (°)	
Condition	Screws vs. fabric straps	Screws vs. rubber straps
MFTA (no stress applied)	3.0 (2.3–3.8)	4.4 (2.8–8.5)
MFTA varus stress	3.9 (2.8–5.2)	5.5 (3.3–9.0)
MFTA valgus stress	3.9 (2.9–5.2)	5.6 (3.3–11.9)
Max. flexion	3.9	4.7
Max. extension	3.4	3.0

with rubber strapping was observed during the experiment, and we have demonstrated that passive trackers should not be secured with this material. Establishing a reliable method of tracker fixation is very important before moving forward with further laboratory-based and *in vivo* testing of the device.

Applying varus and valgus stresses to the leg uniformly decreased repeatability for all methods of tracker fixation and reduced agreement between the invasive and non-invasive methods, particularly beyond 30° of knee flexion. This is most likely due to soft tissue artefacts; however, further laboratory-based work is required to prove this statement quantitatively.

No deleterious effects of strapping optical trackers to the leg were noted on the cadavers. Clarke et al. reported no complications such as tourniquet effect or intolerance of strapping when using fabric strapping on patients, as assessment can be carried out sufficiently quickly to prevent such occurrences [6, 18].

Limitations of this study include the use of embalmed cadaveric specimens, in which soft tissue artefact, joint hydration and laxity differ from those in *in vivo* studies. We acknowledge that performing four repeated measurements and creating two pairs of values for analysis from each of the 6 knee specimens is not the same as having 12 sets of independent pairs of measurements from 12 knee specimens. However, having access to only 6 cadaveric lower limbs, choosing to record two pairs of repeated measures on each specimen, rather than only one pair, provided more opportunity to uncover measurement error, resulting in more robust validation of the non-invasive method. By performing the experiment over 6 specimens, we obtained variation in the conditions of measurement, rather than repeating all the experiments on a single cadaver. The fact that repeatability of measurements taken using screw fixation of trackers was borderline at 40° knee flexion when applying varus/valgus stress points to a source of systematic error within the experiments; it is highly likely that this is because the varus/valgus force applied during testing was not standardized. Use of transducers to dictate force application during coronal and sagittal stress would have standardized the variable of applied varus/valgus stress [6, 19, 20]. The lack of a quantified coronal stress when assessing knee laxity on the operating table is a limitation of current computer-assisted surgery systems and the majority of the current literature [19, 21, 22]. Further work must attempt to standardize these forces and will be included in our future protocols validating the use of non-invasive navigation instruments to measure knee kinematics in flexion.

Clarke et al. [18] assessed the repeatability of measuring MFTA in extension whilst applying a standardized force using fabric strapping to secure the non-invasive trackers identical to that used in this study, and using a similar software and optical camera. Three clinicians performing 6 examinations on one volunteer gave standard deviation within 1.1° for each clinician, and similar values between clinicians. Further work by the group [6] using this non-invasive device on 30 volunteers gave inter-registration agreement limits of ±1.6°, 1.3° and 1.1° for measuring MFTA with no applied stress, varus stress, and valgus stress, respectively. Levels of agreement between registrations using the non-invasive system were encouraging and similar to those in this study; however, we have gone on to analyze the effect of knee flexion on the accuracy of non-invasive limb alignment measurement.

Establishing the ‘‘normal’’ static and dynamic alignment of the lower limb is an area of ongoing research [23–27], with authors noting ethnic variance [25] and questioning what is ‘‘normal’’ mechanical alignment [26]. Bellemans et al. [26] revealed that 32% of males and 17% of females from a cohort of 250 young adults had varus alignment of $\geq$3° measured on long-leg standing radiographs. Non-invasive, non-radiological methods of determining MFTA in both supine and weight-bearing conditions [6] may help in determining variation in ‘‘normal’’ alignment and whether this relates to development of osteoarthritis [28], and in evaluating current aims in restoring neutral versus ‘‘constitutional’’ alignment in total knee arthroplasty [29, 30]. Controversy also exists with regard to the recommendation that final alignment of the lower limb following total knee replacement to within ±3° of neutral [31, 32] affects clinical outcome [33] or survivorship [34]. These studies are based on static measurements of MFTA, and a method allowing dynamic assessment of MFTA in the early functional range may help establish the relationships between final mechanical alignment, function and survivorship in total knee arthroplasty.

The ability to develop a standardized method of coronal knee laxity quantification which is available in the out-patient setting prior to surgery would be a major advance in operative planning, and would allow further development of soft tissue balancing algorithms based on the presence of deformity and whether this is fixed or correctable [21, 22, 35–38]. This technology would also be of use in treatment of sports injuries. As mentioned previously, current assessment of knee collateral ligament injury relies on subjective clinical examination and stress radiographs [39–41]. Quantification of lower limb mechanical alignment in dynamic weight bearing and clinical examination would aid diagnosis and follow-up, as well as research evaluating treatment modalities.

Our data adds to the existing literature an analysis of the effect of knee flexion on non-invasive measurement of MFTA, a comparison in terms of levels of precision and agreement with a validated computer navigation system which uses standard invasive hardware, and reveals the importance of appropriate strapping for non-invasive optical trackers.

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Declaration of interest

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