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A NOVEL NON-INVASIVE METHOD FOR MEASURING KNEE JOINT LAXITY IN FOUR DOF: *IN VITRO* PROOF-OF-CONCEPT AND VALIDATION

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Abstract

Knee joint laxity or instability is a common problem that may have detrimental consequences for patients. Unfortunately, assessment of knee joint laxity is limited by current methodologies resulting in suboptimal diagnostics and treatment. This paper presents a novel method for accurately measuring non-invasive knee joint laxity in four degrees-of-freedom (DOF). An arthrometer, combining a parallel manipulator and a six-axis force/moment sensor, was developed to be used in combination with a low-dose biplanar x-ray system and 3D image data to reconstruct tibiofemoral position and orientation of laxity measurements.

As proof-of-concept, four cadaveric knees were tested in the device. Each cadaveric knee was mounted in the device at approximately 30° of flexion and twelve monoplanar anteroposterior, mediolateral and internal/external load cases were applied. Additionally, four biplanar load cases were applied, consisting of different combinations of anteroposterior and internal/external loads. The arthrometer was limited to four DOF to address the specific measurements. For validation purposes, the pose reconstructions of tibia and femur were compared with pose reconstructions of bone pin marker frames mounted on each bone.

The measurements from the arthrometer in terms of translation and rotations displayed comparable values to what have previously been presented in the literature. Furthermore, the measurements revealed coupled motions in multiple planes, demonstrating the importance of multi DOF laxity measurements. The validation displayed an

average mean difference for translations of 0.08 mm and an average limit of agreement between -1.64 mm and 1.80 mm. The average mean difference for rotations was 0.10°and the limit of agreement were between -0.85° and 1.05°.

The presented method eliminates several limitations present in current methods and may prove a valuable tool for assessing knee joint laxity.

Introduction

The knee joint is a complex synovial joint and its non-conforming nature makes it capable of movement in multiple degrees-of-freedom (DOF) (Bull and Amis, 1998). Knee joint stability is maintained by the shape of the condyles and menisci in combination with supporting structures i.e. ligaments and muscles (Woo et al., 1999). Excessive joint laxity, also known as instability, is detrimental for the functionality of the joint and will cause pain and degradation, leading to a decrease in mobility and quality-of-life (Nevitt et al., 2016; Wheaton and Jensen, 2010). Such excessive laxity can arise from a variety of causalities e.g. ligament injuries (Brandsson et al., 2002), osteoarthritis (Van Der Esch et al., 2007) or joint replacements (Le et al., 2014).

Clinical assessment of knee joint laxity typically relies on manual tests like the Pivot-shift, Anteroposterior drawer and Lachman tests. However, these manual tests are subjective of nature, and their applicability depends on the examiners experience (Rob et al., 2003). Several studies have displayed that these tests have poor diagnostic value (Branch et al., 2015; Katz and Fingeroth, 1986; Peeler et al., 2010; Rob et al., 2003). Furthermore, manual tests are non-quantifiable and unable to identify minor changes in laxity e.g. in relation to a partial ligament tear (R.L. et al. 1996; Yoon, Rah, and Park 1997; Abat et al. 2013).

Numerous attempts have been made to quantify knee joint laxity using instrumented in vivo assessments, i.e. arthrometry. Current instrumented knee laxity measurement methods can generally be divided into two categories: clinical arthrometry and stress radiography. Clinical arthrometry is typically driven by human-imposed loadings in combination with mechanical displacement measurements. Stress radiography consists of a combination of a mechanically imposed load with simultaneous medical imaging. Arthrometers have been part of the clinical practice for many years, and are widely used as a diagnostic tool when assessing knee ligament injuries (Pugh et al., 2009). The majority of arthrometers are designed to measure monoplanar laxity i.e. anterior/posterior (AP) displacement, varus/valgus (VV) rotation or internal/external (IE) rotation (Sundemo et al., 2016). Unfortunately, handheld arthrometers are limited by low reliability (Arneja and Leith, 2009; Forster et al., 1989; Wroble et al., 1990) and soft tissue artifacts (STA) (Hewett et al., 1997; Kupper et al., 2007), making it impossible to measure true bone position and orientation. Lopomo et al., (2012) quantified STA during pivot-shift assessment and found a root-mean-square error (RMSE) of 4.9±2.9 mm.

Current stress radiography is also only assessing single plane laxity, but is not limited by low reliability (Schulz et al., 2005) or STA (Garavaglia et al., 2007). The radiation exposure from such measurements may, however, induce serious health risks for both the patient and operator making the method unsuitable for many applications (Balonov and Shrimpton, 2012).

Joint instability must be assessed in multiple DOF in order to fully understand the complexity of the joint structures and the interplay between ligaments (Hirschmann and Müller, 2015). Neither clinical tests, arthrometry nor 1D stress radiography possesses the potential to obtain this information. Furthermore, these methods potentially over-constrain the joint during measurements, by restricting out-of-plane motion, making it appear more stable and potentially shift the load distribution unnaturally in the joint (Woo et al., 1999).

Methods capable of measuring unconstrained knee joint laxity in multiple DOF not restricted by the above limitations are a prerequisite to progress the field of research in knee instability and advance current clinical assessment of joint instability. Novel methods utilizing robotics for assessing knee joint laxity has, therefore, recently emerged (Branch et al., 2015; Lorenz et al., 2015). These methods exercise high repeatability and accuracy in the application of forces, however, they are still limited by their inability to measure true bone motion due to STA.

By combining robotic technology with new medical image modalities, the aforementioned limitation can be overcome which may make it possible to conceive a laxity measurement method with high accuracy, multiplanar assessment and unaffected by STA. Therefore, this paper proposes such a novel method for measuring knee joint laxity in multiple DOF, combining parallel manipulator technology and low dose biplanar x-ray acquisition.

Methods

Development

An in vivo arthrometer was custom developed, combining a parallel manipulator (H-820, Physik Instrumente, Germany) and a six axis force/moment (F/M) sensor (Omega85 SI-1900-80, ATI Industrial Automation, USA) (see Fig. 1). The parallel manipulator has a manufacturer reported repeatability of ±1 µm and the F/M sensor has a resolution of 0.29 N (F_x, F_y), 0.43 N (F_z), 13.37 mNm (M_x, M_y) and 9.36 mNm (M_z) and were software synchronized in LabVIEW 2017 (National Instruments, USA). The arthrometer is designed to apply unconstrained multidirectional loads to the knee joint using F/M control. While performing the test, the shank is fixated to the sensor/platform using a pneumatic cast boot and the thigh is fixated to a frame restricting excessive motion. A height adjustable seat allows for measurements to be performed in multiple knee flexion angles. This setup enables application of loads similar to what is applied in clinical practices i.e. AP, VV, IE and any combinatorial loading. The arthrometer is designed to be used in combination with a low-dose biplanar x-ray system (EOS, EOS imaging, France) and 3D image data to reconstruct the

tibiofemoral pose from each load case. For this study, the segment fixations were modified to fit the requirements of an in vitro setup.

As a proof-of-concept, an in vitro test setup was established for the laxity measurement method in order to demonstrate its applicability and identify its accuracy.

Protocol

The study was approved by the Belgian National Council for Bioethics (NH019-2016-10-01-KR09). Four fresh frozen cadaver specimens were used in this study, three females (C1, C2, C3) and one male (C4) with an average age, mass and height of 75±14 years, 76±7 kg and 1.66±0.14 m, respectively. C1 had a calcification on the origin of MCL. C2 had no visible pathologies in the knee. C3 had grade 1 patellofemoral OA. C4 had grade 1 patellofemoral and tibiofemoral OA. Following thawing, the left leg from each cadaver were resected from the pelvis and down. Optical markers were attached to femur and tibia using bone pin markers. Full lower limbs were scanned using computed tomography (CT). Subsequently, the thigh was resected 320 mm proximally from the joint and the shank was resected 280 mm distally from the joint line. Soft tissue were removed from the resection site and 120 mm in, allowing the specimen to be fixated in aluminum containers using an acrylic resin (VesoCit-2, Struers Aps, Denmark). Femur was mounted in natural valgus in the coronal plane and parallel to the sagittal and transverse plane, preserving the mechanical axis of the knee joint in parallel to the containers. Tibia was mounted in parallel to the container in the sagittal and transverse plane. The orientation in the transverse plane was ensured by aligning the lateral and medial tibial condyle with mediolateral markers on the container. This operation was performed by eye measurements at a knee flexion angle of approximately 90 degrees.

Subsequently, the specimen was mounted in the arthrometer at approximately 30° of flexion with the femoral container fixated to the frame and the tibial container mounted to the sensor on top of the parallel manipulator (see Fig. 2). The arthrometer was placed inside a biplanar x-ray scanner (EOS, EOS imaging, France). A series of static loads (see Tab. 1) based on arthrometric protocols from the literature (Branch et al., 2015) were applied to the specimen using a F/M controller written in LabVIEW 2017 (National Instruments, USA). The F/M controller was based on individually in situ tuned proportional–integral–derivative control of each DOF working in parallel receiving feedback from the matched DOF from the F/M sensor recorded with a data acquisition card (NI USB-6216, National Instruments, USA). Mediolateral (ML) and AP translation of the platform were disabled, allowing the F/M controller to obtain force/moment equilibrium during tests. This leaves the parallel manipulator free to move in three rotations and distal/proximal (DP) translation. The parallel manipulator was limited to a maximum movement velocity of 2 mm/s. AP loads were obtained by applying a flexion/extension moment in the sensor equating an AP force in the knee. ML loads were obtained by applying a VV moment in the sensor equating a ML force in the knee. IE loads were obtained by

applying an IE moment in the sensor. DP forces were maintained at zero load throughout measurements, allowing tibia to hang freely, only supported by the soft tissue spanning the knee joint. For each load case, a biplanar x-ray was obtained when the specimen had become stationary and the applied load had reached its target value (see Fig. 3D). The system typically used 60 s to 180 s to reach target values to eliminate overshoot.

Validation

Bone pin marker frames were attached to femur and tibia during measurements, enabling accurate tracking of the bones in 6-DOF (Lafortune et al., 1992). Application of these markers allows validation of the bone position and orientation reconstruction by replacing the bone contour in the registration process with a known geometry that has clearly distinguishable contours. The 3D geometries of the marker frames were obtained using a 3D scanner (ATOS Triple Scan, GOM GmbH, Germany) to account for metal artifacts during CT scanning. 3D geometries of the marker frames were manually fitted onto the 3D bone geometries using Mimics Research 19.0 (Materialise, Belgium) based on their relative positions in the acquired CT images.

Post-processing

3D bone geometries of tibia and femur were segmented from the acquired CT images using Mimics Research 19.0 (Materialise, Belgium) (see Fig. 3C). Bone position and orientation for each load case were reconstructed by registering the 3D bone geometries onto the orthogonal biplanar x-ray images. The registration was done by using an iterative closest point (ICP) algorithm developed in MATLAB (Mathworks, USA) to match contours of the x-ray images and projected contours of the 3D bone geometries onto the images planes (see Fig. 3E). A similar process have been validated by Karade and Ravi(2015) on bi-planar x-ray and found a mean error of 1.2 mm.

The relative translations and rotations between the reconstructed tibia and femur were computed in the AnyBody Modeling System 7.0 (AnyBody technology, Denmark) following ISB recommendations using the inter-malleolar point defined between the tip of the medial and lateral malleolus and the inter-condylar point (Tibial axis origo) between the lateral and medial tibial condyles to define the PD axis of tibia. The ML axis of tibia was defined as being perpendicular to the PD axis pointing towards the hip joint center. The AP axis of tibia was defined as being perpendicular to both the PD and ML axis. The PD axis of femur was defined using the inter-condylar point (Femoral axis origo) between the lateral and medial femoral condyles and the hip joint center. The ML axis of femur was defined as being perpendicular to the PD axis pointing towards the medial condyle. The AP axis of femur was defined as being perpendicular to both the PD and ML axis. The rotation convention followed flexion/extension, abduction/adduction and internal/external. Translations were calculated by projecting the vector pointing from the axis origo of tibia to the axis origo of femur onto the three axes of rotations. (Grood and Suntay, 1983; Wu et al., 2002).

Likewise, relative translation and rotation of the bones were additionally reconstructed by applying the ICP algorithm and contour registration on the attached marker frames, serving as ground truth data.

Results

Primary Laxity

Primary laxity is defined as laxity in the same plane as the load is applied in. The primary tibiofemoral translation and rotation for the monoplanar measurements are presented in Fig. 4. Anterior loading of 67 N and 134 N resulted in an average tibial translation of 5.04±1.41 mm and 5.95±0.43 mm, respectively. Posterior loading of 67 N and 134 N resulted in an average tibial translation of -4.12±0.84 mm and -5.24±0.51 mm, respectively. Medial loading of 14 N and 28 N resulted in an average tibial translation of 1.00±0.65 mm and 2.43±0.62 mm, respectively. Lateral loading of 14 N and 28 N resulted in an average tibial translation of -3.68±1.20 mm and -4.93±0.51 mm, respectively. Internal rotational loading of 3 Nm and 6 Nm resulted in an average tibial rotation of 10.22±4.79° and 15.26±1.34°, respectively. External rotational loading of 3 Nm resulted in an average tibial rotation of -20.32±5.22°, respectively. External rotational loading of 6 Nm caused the parallel manipulator to reach its rotational limit in three of the specimens and will therefore be excluded from further analysis.

Secondary Laxity

Secondary laxity is defined as laxity in any other plane than the load is applied in. A graphical presentation of the relationship between primary and secondary laxity during different load cases can be seen in Fig. 5. During AP loading, a high linear coupling between AP translation and IE rotation was found (see Fig. 5A). Anterior loading of 67 N and 134 N resulted in an average tibial internal rotation of 3.11±1.77° and 8.38±1.03°, respectively. Posterior loading of 67 N and 134 N resulted in an average tibial external rotation of -9.33±4.17° and -12.20±4.19°, respectively. The average coupling between AP translation and IE rotation was between 1.23°/mm and 1.90°/mm for the four specimens. No linear coupling was found for secondary laxity during ML and IE loadings in the monoplanar load cases. However, it can be speculated that there might be a U-shaped relationship between IE rotation and AP translation during IE loading (see Fig 5B).

Multiplanar Laxity

A combination of a 134 N anterior load and a 6 Nm internal rotational moment resulted in an average anterior translation of 5.60±1.80 mm and 18.01±4.14° of internal rotation, respectively. A combination of a 134 N posterior load and a 6 Nm internal rotational moment resulted in an average posterior translation of -1.53±0.76 mm and 11.99±3.74° of internal rotation, respectively. A combination of a 134 N posterior load and a 3 Nm external rotational moment resulted in an average posterior translation of -3.08±2.85 mm and -20.31±5.14° of external rotation, respectively. A

combination of a 134 N anterior load and a 3 Nm external rotational moment resulted in an average anterior translation of 7.27±2.14 mm and -20.03±5.22° of external rotation, respectively.

Validation

The mean difference and limit of agreements (LoA) between the marker frame method and the bone method for obtaining translations and rotations in each measurement is displayed in Bland-Altman plots in Fig. 6. The average mean difference for translations was 0.08 mm and the average LoA were between -1.64 mm and 1.80 mm. The average mean difference for rotations was 0.10°and the LoA were between -0.85° and 1.05°. All translations had similar LoA, however, IE rotation displayed a considerably higher LoA than in the two other rotational DOFs. RMSE for translation and rotation were 0.88 mm and 0.49° respectively. The ICP process had a mean error and standard deviation of 0.95±0.55 mm for the bones and 0.73±0.54 mm for the marker frame.

Discussion

This study demonstrated a novel non-invasive method for measuring knee joint laxity in four DOF. The method was capable of measuring laxity with an accuracy close to what is possible with bone pin markers while not restricted by the common limitations seen in current arthrometers. The application of a six DOF parallel manipulator as a loading mechanism enables multiple and combined load cases to be investigated. Furthermore, the parallel manipulator in combination with a six DOF F/M sensor allows measurements to be unconstrained by applying force/moment control.

The presented arthrometer could in theory measure joint laxity without combining it with bi-planar x-ray by analyzing the kinematics directly from the parallel manipulator system. However, Lorenz et al. (2015) used an *in vivo* robot-aided laxity measuring method to measure anterior laxity of 70 subjects and found values of 39.14±8.01 mm anterior translation when an anterior force of 88 N were applied. The magnitude of the anterior translation measured by the robot-aided device in the study was about six times higher than what was measured using a Rolimeter (6.29±2.04 mm) in the same study, and way above the physiological limits of knee joint ligaments. The overestimated anterior translation can mainly be explained by compression of soft tissue in the interface between the shank and arthrometer. This highlights the limitations in measuring joint laxity without accounting for STA.

Coupled motion

The ability to identify and measure coupled motions in the knee is one of the advantages of the presented method. This was demonstrated by identifying IE rotation during AP loads. The coupled motion between AP translation and IE rotation has previously been established in 30° of flexion in the literature (Grood et al., 1988). They found an average internal rotation of 7.7° when an anterior load of 100 N was applied, compared to this study where an average internal rotation of 8.4° was found during an anterior loading of 134 N. Interestingly, we found indication of a U-shaped

relationship between IE rotation and AP translations during IE loading, contrary to Grood et al., (1988) that reported the motions to be linearly coupled.

It can be speculated that unidentified coupled motions could affect the outcome of surgical procedures and/or the survival rate of different prosthetic designs. By identifying coupled motions further precautions can be taken to restore healthy joint function.

Limitations

The EOS scanner used in this study is a low dose system reducing radiation expose 4 to 8 times compared to a CT scan (Ben Abdennebi et al., 2017) and 2.5 times compared to plain x-rays (Chiron et al., 2017). However, if multiple laxity measurements are conducted the total radiation exposure may become problematic. Therefore, an effort to establish which laxity measurements provides the most useful information should be made to reduce the number of measurements.

The validation method in this study was limited in the sense that we used the ICP registration for both the bone measurements and marker frame measurements. Therefore, it is possible that this process may induce an error that we cannot detect. Ideally motion-capture should have been used for tracking the motion of the marker frames, however this was not possible due to the confined space in an EOS scanner. Nonetheless, ICP is a commonly used method, and previous studies have applied and validated bone position reconstruction using ICP and found similar accuracy as presented in this paper (Stentz-Olesen et al., 2017).

Another limitation in the validation process is this position of the marker frame in relation to the joint center. An error in the registration of the frame would exacerbate the error in the position and orientation of the knee joint due to the large distance between the joint center and marker frames. A solution could have been to use tantalum marker beads, which would bring the validation points closer to the joint center.

A LoA of approximately 2 mm and 1° was found in this study, however some of the difference between the measured laxity with bone reconstruction and marker reconstruction may originate from malpositioning of the optical marker frame CAD onto the segmented CT image due to metal artifacts. This difference would be expressed as an offset error isolated to a specific specimen. Furthermore, increased operator experience may further limit the measuring error.

Finally, the constrainments of ML and AP translations of the platform could have affected the laxity measurements, particularly the coupling of motions.

Future work

VV laxity measurements were not included in this study because this would require the rotational center of the parallel manipulator to be moved inside the knee joint, whereas the remaining measurements in this study could be performed while maintaining the rotational center in the platform center of the parallel manipulator. In the future, VV load measurements should be implemented in the setup due to its prevalence and familiarity in clinical settings. Furthermore, VV measurements may be better at isolating the contribution from the collateral ligaments and may not be obstructed by a large intercondylar eminence or a posterior stabilized knee implant.

Additionally, software changes will be implemented to enable the remaining two DOF in the system. Going from four to six DOF force application will unlock the full potential of the arthrometer, making it an even more versatile tool.

Application

The ability to measure non-invasive joint laxity in multiple DOF enables multiple new applications. Accurate laxity measurements can assist clinicians when assessing complicated ligament injuries. The method could also be used in preoperative planning of e.g. knee arthroplasty where soft tissue balancing is a major concern. Furthermore, the method could be applied in post-operative evaluations and in development of subject-specific braces, prosthesis and *in silico* simulations.

Conclusion

In summary, this paper presented a novel method for measuring non-invasive knee joint laxity in four DOF. The method demonstrated proficient in preforming clinically relevant laxity measurements in multiple planes with an acceptable accuracy. The method also proved capable of capturing secondary laxity like coupled motions. Furthermore, the method eliminated many of the limitations present in previous methods e.g. over-constrainment, single-plane assessment, STA, subjectiveness and non-quantifiable.

The presented method may both be a valuable research tool for progressing the understanding of knee joint laxity, but also prove to be a clinical applicable method improving diagnostics and preoperative planning.

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Conflict of interest statement

M.S. Andersen and D. Pedersen have part in a pending patent on the presented method (PCT/DK2018/050003). V. Vanheule, R. Wirix-Speetjens, O. Taylan, H. P. Delport and L. Scheys have no conflicts to declare.

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Tables

Tab. 1 – An overview of the load cases applied to measure knee joint laxity in this study.

Measurements	Load
No load	0
Anterior loading	67 N, 134 N
Posterior loading	67 N, 134 N
Medial loading	14 N, 28 N
Lateral loading	14 N, 28 N
Internal rotational loading	3 Nm, 6 Nm
External rotational loading	3 Nm, 6 Nm
Anterior and internal rotational loading	134 N and 6 Nm
Posterior and internal rotational loading	134 N and 6 Nm
Anterior and external rotational loading	134 N and 3 Nm
Posterior and external rotational loading	134 N and 3 Nm

Figure Legends

Fig. 1 – The in vivo arthrometer based on a parallel manipulator and a six DOF force moment sensor working in force control. A pneumatic cast boot fixates the shank to the boot and a custom bracket fixates the thigh to the frame. A height adjustable seat allows for adjustment of knee flexion angle.

Fig. 2 – The modified arthrometer for in vitro setup. A cadaver specimen was mounted in the arthrometer and placed inside an EOS scanner for laxity measurements. Bone pin marker frames were mounted on femur and tibia for validation of bone position and orientation reconstruction.

Fig. 3 – Flow chart presenting the different processes in the proposed method. (A) Medical image from CT scan. (B) Arthrometer customized for in-vitro testing. (C) Segmented bones from CT scan. (D) Bi-planar x-rays. (E) Bone position reconstruction. (F) 3D Knee laxity measurement.

Fig. 4 – Graphical presentation of the measured anteroposterior translation (A), mediolateral translation (B) and internal/external rotation (C) induced by anteroposterior (A), mediolateral (B) and internal/external (C) loadings in each of the four cadaver specimens.

Fig. 5 – Graphical presentation of the relationship between primary laxity and secondary laxity, separated in three columns: Anteroposterior loadings, internal/external loadings and mediolateral loadings. Each symbol represents a specific load within the column and each color represents a cadaver specimen.

Fig. 6 – Six Bland-Altman plots displaying the difference between positions measured with bone pin marker frames and bone contour in three rotational and three translational degrees of freedom in the knee joint. Upper and lower limits of agreement are presented with dotted lines and bias is presented with a solid line. Each specimen is highlighted with different colors and symbols.

Figure 1

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Figure 2

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Figure 3

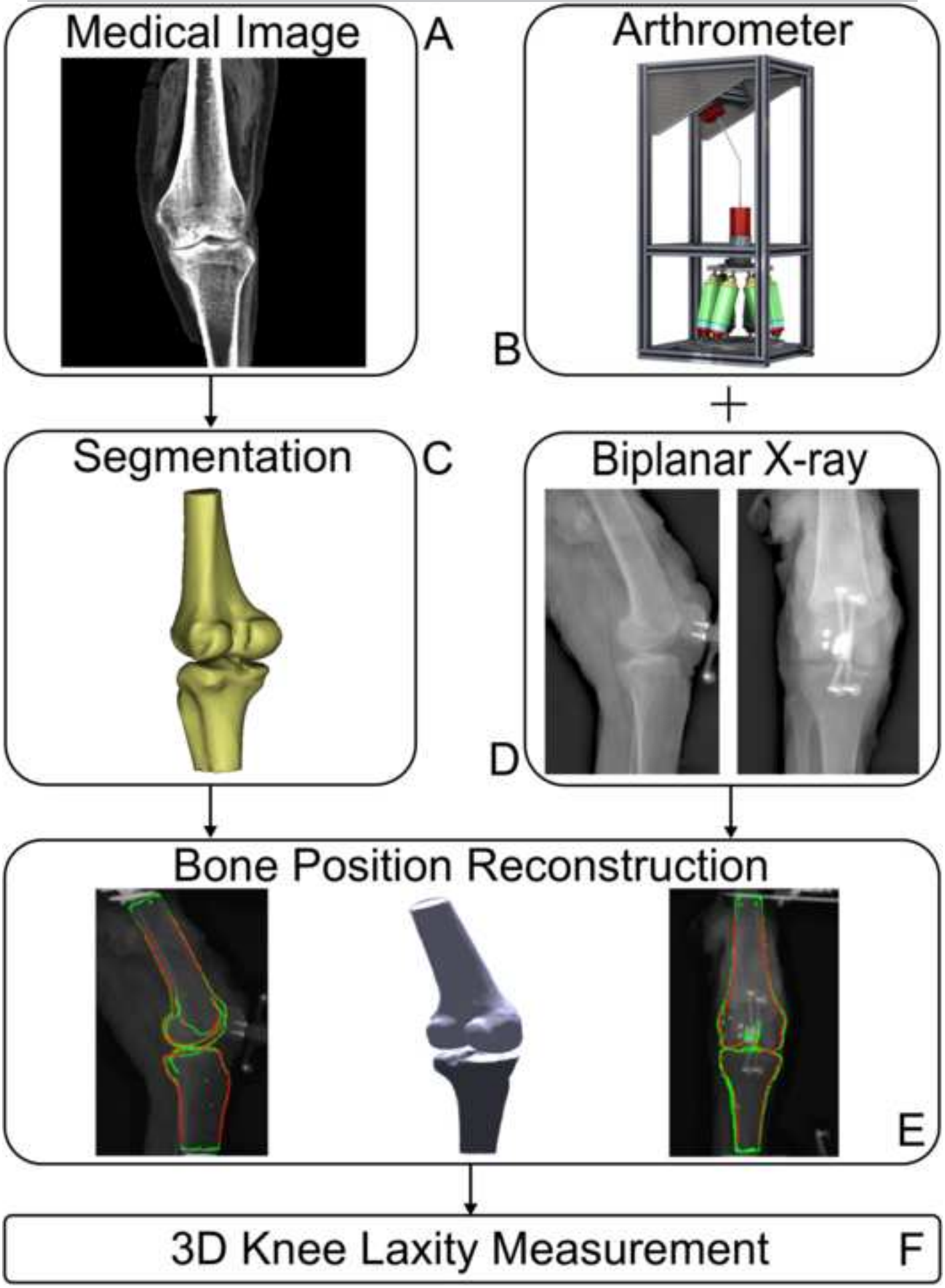

Figure 4

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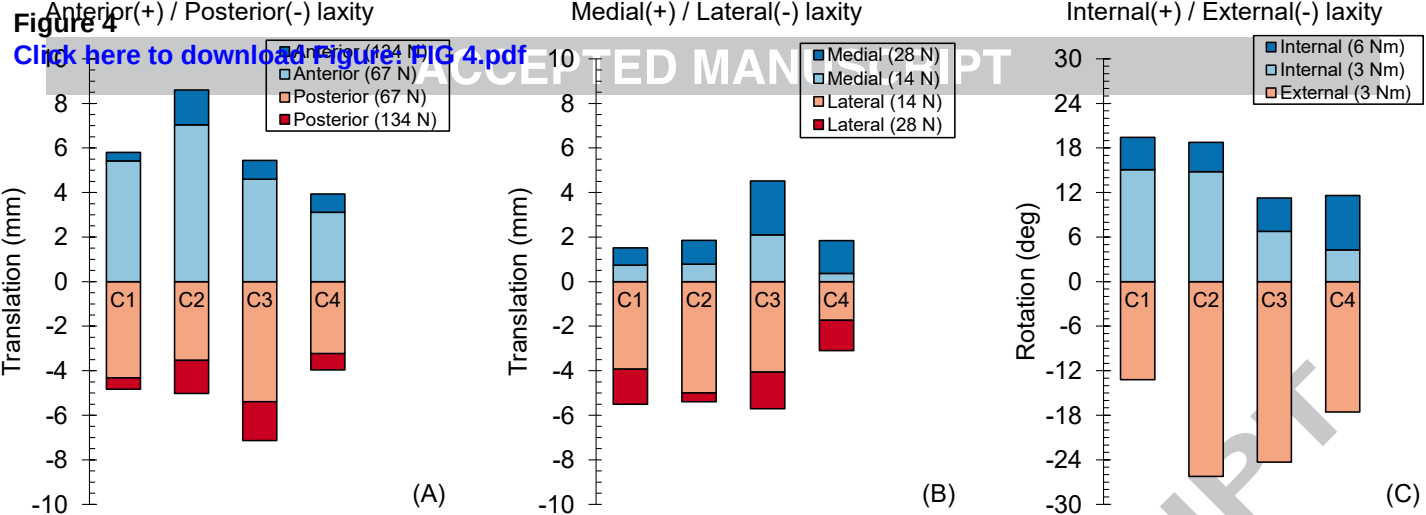

Figure 5 Anteroposterior Loading | Internal/External Loading | Mediolateral Loading

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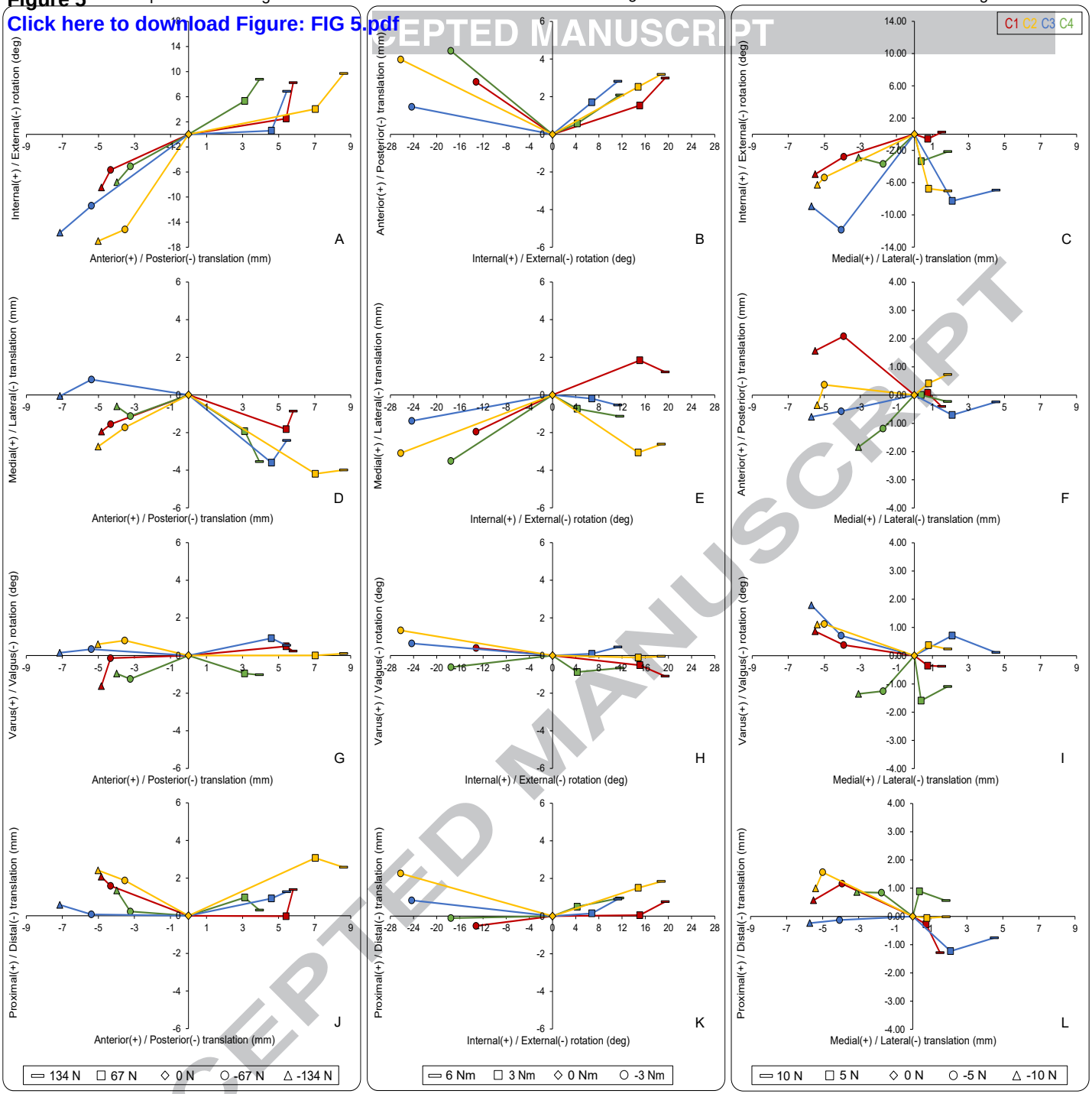

Figure 6

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