Validity of an instrumented knee brace compared to 3D motion navigation: A cadaveric investigation

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Title

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Abbreviated title

Validity of an instrumented knee brace

Authors

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Highlights :

- Reliability of an instrumented knee brace during specific tasks
- Consideration of soft tissue artifacts on knee brace with cadaveric navigation
- Validity of 3 axis kinematics of instrument knee brace compare to navigation investigation

1. Abstract

The aim of this study was to test the accuracy and the reliability of 3-dimensional angular measurements of an instrumented knee brace compared to the gold standard navigation system optoelectronic cameras-based.

Thirteen cadaveric bodies were used to calculate kinematic knee parameters. Three exercises were performed, 100° flexion (FLEX100), internal/external rotation with a 30° flexion (ROT30), and the pivot shift test (PS).

The reliability was excellent with an ICC (95%) > 0.90. The agreement between the two systems showed excellent correlation in the F/E axis for FLEX100 and PS ($\sigma_{(\text{Flex/ Ext})} > 0.95$) and strong correlation in the I/E axis for ROT30 ($\sigma_{(\text{Rot Int/ Ext})} > 0.939$). The root mean square error (RMSE) was under 5° for all exercises considering the soft tissue artifact (STA) for the F/E axis.

Consequently, the instrumented knee brace exposed high reliability and accuracy which could end up on clinical interpretations thanks to the previous measures.

2. Keywords

Connected knee brace, inertial measurement unit, joint kinematics, navigation, validity, reliability

3. Background

Knee joint function can be altered by several pathologies, such as anterior cruciate ligament rupture (ACLr) and knee osteoarthritis (OA) [1–4]. A better understanding of knee pathologies has given rise recently to new knee diagnostic and analysis tools [5–7]. Thus, motion capture and questionnaires have become the gold standard for practitioners for several pathologies [1,2,8]. The optoelectronic camera system (OCS) is the usual tool for quantifying body motion [2,9–11]. However, motion capture with OCS has few limitations. Firstly, the gait patterns can be affected by the laboratory environment compared to an ecological environment [12–14]. Secondly, the OCS is very expensive, restricted to a limited field of view in time and space [12,14] and time consuming. Finally, the OCS cannot be used in a home-based rehabilitation perspective.

To develop systems that overcome these disadvantages, recent research has focused on gait analysis using wearable sensors [15], and new systems have been developed to quantify human motion. For example, accelerometers are valid and reliable for the recording of activity, energy expenditure and acceleration data [16]. Nevertheless, the precision of kinematic measurements is poor with an accelerometer sensor only due to the presence of drift during fast accelerations [17,18]. Combining a gyroscope with an accelerometer may solve this problem. Indeed, gyroscopes can estimate sensor orientation by integrating the angular velocity on the X, Y, Z axes relative to the sensor. Yet this sensor is subject to a drift in angular velocity due to signal integration, a well-known problem in robotics and motion analysis. By mixing the complementary data from accelerometers and gyroscopes, the two drifts can be minimized with a fusion algorithm like a Kalman filter [16,19,20]. The association of the two sensors is called an inertial measurement unit (IMU). Body sensor networks with IMUs such as Xsens MVN (Xsens Technologies BV, Enschede, NL) [21] or Perception NEURON Pro (Noitom, Miami, FL, USA) [22] provide quantitative movement analysis in ecological environments.

In a home-based rehabilitation perspective, the knee motion analysis has become necessary to supervise patients through biofeedback. To deal with that, a new instrumented knee brace with two IMUs was developed. These sensors calculated the movement of the thigh relative to the shank. Moreover, this integrated system compares to simple IMU sensors described previously did not necessitate clinicians or physiotherapist for calibration or anatomical placement due to its ease of use. Indeed, once the connected knee brace is in place, it is possible to quantify knee motion in an ecological environment to reduce bias in laboratory conditions with a smartphone [23–25]. Palpation to find anatomical landmarks is not required, nor is it necessary to fix markers or IMUs with different systems, as it is the case with other systems [2,26]. Moreover, this technology offers free use of a workstation for motion computation through cloud computing on the smartphone app, and biofeedback can be displayed in real time with smartphone computation. All these data allow a quantified rehabilitation for physiotherapists or clinicians via success scores and pain scale charts. Then, this system enhance physical rehabilitation by motivating the user with visual data of progression and informative videos [27].

However, this knee brace, like IMU systems or OCS, is sensitive to soft tissue artifacts (STA), a problem inherent to all skin-mounted tracking system. A systematic review noted the effects of STA in the lower limb, finding that several factors influence the results, including sensor orientation [28]. STA was found to reach more than 30 mm of magnitude on the thigh segment and more than 15 mm on the tibia [28]. To overcome this problem, OCS investigation with bony pins would be highly accurate [29,30], but this procedure is unethical and should not be applied to living patients. Along the same lines, the fluoroscopic 3D-matching technique is invasive due to radiation exposure [31]. Recently, several studies have used commercial navigation devices to assess knee kinematics during surgical procedures for ACL reconstruction or total knee arthroplasty [32–34]. Navigation is composed of three parts: computer platform, tracking system, and rigid body marker. Tracking system visualizes the rigid body markers through OCS and calculates motion in real time with the tracking systems. Markers are fixed to the patient's bones surgical instruments to track joint motion or target objects after a referencing procedure which consists in determining bone positions compared to marker positions [35]. For example, this system via bony pins and OCS is a computer-assisted surgical navigation device to help tunnel placement during ACL reconstruction and can quantify knee laxity and validate the surgical procedure [33,36].

A more ethical solution might be considered to begin with cadaveric investigations. Indeed, tibiofemoral motion in the unloaded cadaveric knee is almost the same as that in the living knee [37,38].

Given the innovative aspect of the knee brace, its accuracy and reliability must be confirmed before the system can be used more extensively. In the present study, we thus investigated the accuracy and reliability of this new system of knee motion quantification and compared it to the gold standard during specific movements well-known to physiotherapists and orthopedic surgeons.

4. Material and methods

4.1. Subjects

Thirteen intact knees from seven frozen cadaveric males were used for this study. The specimens were thawed at room temperature for at least three hours and they showed no sign of degeneration. Exclusion criteria were signs of knee instability (Lachman test) and signs of surgical procedures on knee or hip, evidence of a knee or hip prosthesis, ACL reconstruction, etc. The mean age of the specimens was approximated at 85 years-old approximately due to a lack of anthropological information.

4.2. Material and instrumentation

Three clusters of four reflective markers were fixed by one screw on the pelvis and two screws on the femur and tibia to record the knee kinematics. The femoral and tibial screws were fixed in the bone diaphysis outside the joint capsule with a 2-cm incision to avoid influencing the soft tissue. After fixing the three clusters, seven anatomical landmarks were identified with reflective markers fixed onto the skin with cyanoacrylate glue. The medial malleolus (MM), the lateral malleolus (LM), the medial and lateral epicondyle of the femur (MF, LF), the medial and lateral epicondyle of the tibia (MT, LT) and the greater trochanter (GT) were located. Kinematic data were simultaneously obtained with seven cameras (Vicon Motion Systems Ltd. Oxford, UK): four MX-T20 and three MX-T40 and with the instrumented knee brace with a sampling frequency of 100 Hz. The instrumented knee brace is composed with two IMU ICM-20948. The knee sleeve was designed to reduce compression around the knee by using soft tissue in opposition to medical knee sleeve designed to change the knee joint kinematic [39]. The knee sleeve compression around the knee was minimal to avoid change in knee joint movement but enough to limit the movement of the IMU sensors. IMU's knee brace had a 16 bits resolution for accelerometers and gyroscope. However due to Bluetooth Low Energy communication, these resolutions were downgrade to 10 bits with respectively, a sensitivity of 7.81 mg/LSB for a ±4 g range and a sensitivity of 0.98 dps/LSB for a range of ±500 dps.

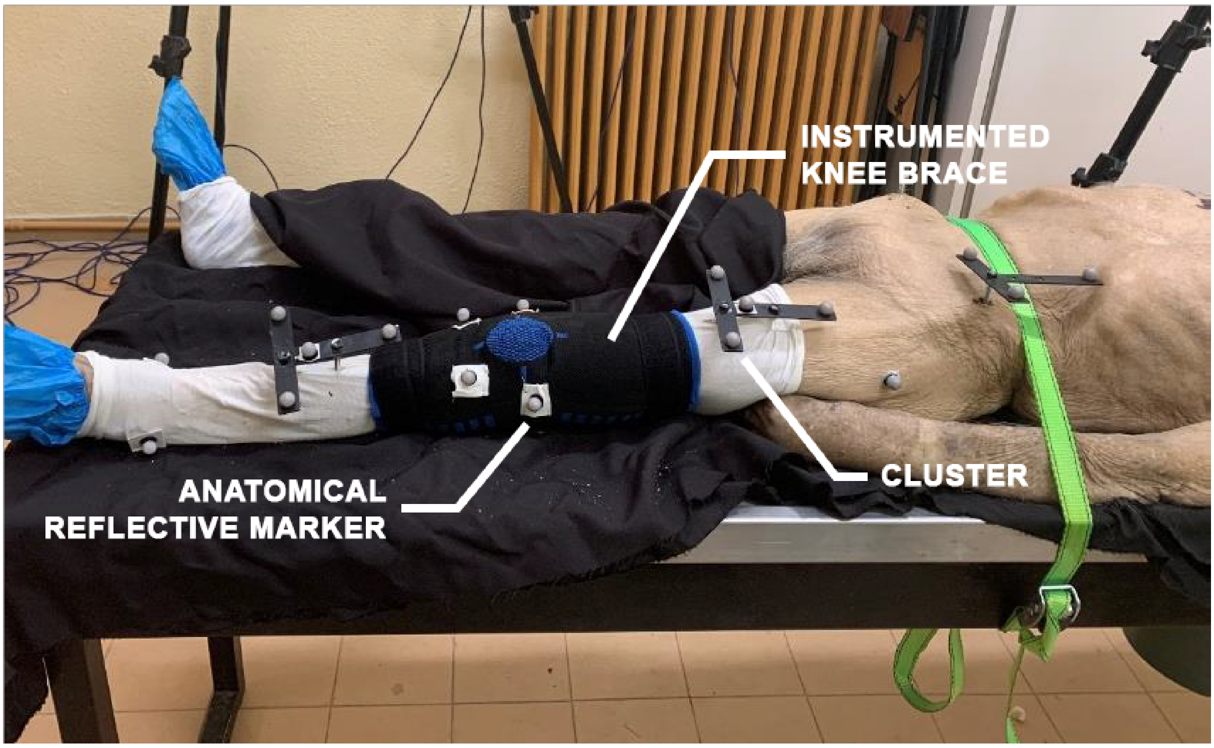

Figure 1: View of the instrumented knee brace, reflective markers and clusters placement on the cadaver's lower limb. The torso was strapped to the table to minimize artifacts on the hip cluster position.

4.3. Experimental protocol

To evaluate the position of the clusters relative to the bones, a functional movement protocol was generated with the leg extended on the table in a static position then with the leg fully extended realizing hip circular movement. The hip joint can be modeled as a ball-and-socket joint, and the hip joint center (HJC) location is characterized by a point invariant in any position of the joint [40]. The coordinates of the femoral head location were obtained by an optimization method to minimize the HJC movement in the circle movements compared to the hip reference. The distal femur location was determined at the middle of the MF and LF markers. The proximal and distal tibia locations were calculated between the MT and LT markers and the MM and LM markers, respectively.

The mechanical axis of the femur was defined by the line containing the femoral head location and the distal femur location. The femoral condylar axis was defined by the MF and LF markers. The femoral frontal plane was defined by the plane containing the mechanical axis and the femoral condylar axis. The femoral sagittal plane was defined with the femoral axis and the cross-product of the femoral axis and the femoral condylar axis [40]. The mechanical axis of the tibia was defined by the line containing the proximal and distal locations of the tibia. The tibial condylar axis was defined by the MT and LT markers. The tibial frontal plane was defined by the plane containing the mechanical axis and the tibial condylar axis. The tibial sagittal plane was defined with the tibial axis and the cross-product of the tibial axis and the tibial condylar axis. To estimate the orientation of the two IMUs of the instrumented knee brace, we used a procedure implemented in a smartphone application.

The operator performed four movements, five times each: a flexion with a full extension to 100° of flexion (FLEX100), a maximal internal/external rotation with a flexion of 30° (ROT30), a pivot shift test (PS) and a flexion from full extension to maximal knee flexion under constraint (FLEXMAX).

5. Calculation

5.1. Analysis

The synchronization of the two systems was performed by a wand with three reflective markers on it. The maximum acceleration detected when the wand hit the thigh IMU was synchronized with the trajectory of the wand's reflective markers. Data from the OCS were analyzed and the angles were computed in Python. The data from the instrumented knee brace were collected and the angles were computed in Python with a data fusion algorithm based on Valenti et al. filter applied to the accelerometric and gyroscopic data [20]. However, data analysis revealed problems with the calibration protocol for the instrumented knee brace due to the dorsal decubitus position of the cadavers. A better alternative estimation was to find the IMU orientation by comparing clusters and IMU movements when there were small flexions in FLEXMAX. This estimation of the IMU orientation was used for all other exercises. Then, some acquisitions were not processed because of the abnormal movement of some of the anatomical marker fixed on the knee brace (MF, LF, MT and LT), which resulted in the selection of only 23 acquisitions in all. Due to motion differences between operators, only 13 acquisitions for pivot shift test were selected among the 23.

5.2. Statistical analysis

Statistical analysis was performed on the FLEX100, ROT30 and PS exercises. The variables extracted for reliability were the intraclass correlation coefficient (ICC) and Bland & Altman plots. ICC was considered poor (<0.50), moderate (between 0.5 and 0.75), good (between 0.75 and 0.90), or excellent (>0.90) [41]. The variables extracted for validity were Pearson's correlation coefficient (σ), the root mean square error (RMSE), and the mean confidence interval (CI). Pearson's coefficient was evaluated as excellent (>0.95), very good (0.85-0.95), good (0.75-0.85), moderate (0.65-0.75) or weak (<0.65) [42]. Error (RMSE) <5° was considered excellent, and between 5 and 10° it was considered good [16]. RMSE was measured without offset on the abduction/adduction (A/A) axis and the internal/external rotation (I/E) axis because of the poor accuracy of the alternative IMU orientation procedure. To deal with STA [43], we extracted two types of variables for the validity: the validity on the standard knee motion and the validity on the knee motion with consideration of STA on the flexion/extension (F/E) axis through a linear regression on FLEXMAX acquisitions.

6. Results

The ICC (95%) for the kinematic parameters recorded with the instrumented knee brace showed excellent reliability for all exercises. In terms of concurrent validity, Pearson's r coefficient for the instrumented knee brace kinematics compared to the navigation kinematics showed the following for all exercises: very good to excellent correlations for the F/E angles, poor to excellent correlations for I/E rotation, and poor to excellent correlation for A/A (Table 1). RMSE was less than 5° between systems except for the F/E axis. Table 2, Figure 3, Figure 4 and Figure 5 show the impact of STA. The Bland & Altman plots showed the difference in the range of motion (RoM) between the two systems (Figure 2). 3D kinematics of the knee during the three exercises are depicted in Figure 3, Figure 4, and Figure 5. Rates of flexions for FLEX100 and PS were 78.3 ± 12.4 dps and 55.5 ± 8.9 dps, rates of rotations for ROT30 were 19.4 ± 2.8 dps. Coefficients of variation (CV) were respectively: 15.8%, 16.0%, 14.3%.

Table 1.
ICC and Pearson's correlation coefficient (σ) between instrumented knee brace and navigation. (CI = confidence interval.)

Exercise	FLEX100	ROT30	PS
ICC (CI 95%)	0.979 (0.959 – 0.990)	0.957 (0.918 – 0.980)	0.976 (0.944 – 0.992)
$\sigma_{(F/E)}$ (CI 95%)	0.999 (0.999 – 0.999)	0.888 (0.794 – 0.981)	0.991 (0.984 – 0.997)
$\sigma_{(I/E)}$ (CI 95%)	0.700 (0.621 – 0.780)	0.956 (0.939 – 0.972)	0.725 (0.506 – 0.944)
$\sigma_{(A/A)}$ (CI 95%)	0.820 (0.723 – 0.917)	0.649 (0.624 – 0.895)	0.860 (0.789 – 0.931)

Table 2.
RMSE of F/E, F/E with STA regression, I/E, and A/A with 95% confidence interval

Exercise	FLEX100 (°)	ROT30 (°)	PS (°)
F/E (CI 95%)	8.26 (6.77 – 9.77)	4.65 (3.11 – 6.18)	6.06 (4.86 – 7.27)
F/E Reg (CI 95%)	2.96 (2.31 – 3.61)	1.01 (0.83 – 1.20)	2.72 (2.08 – 3.35)
I/E (CI 95%)	2.25 (1.99 – 2.52)	3.12 (2.67 – 3.58)	3.89 (3.03 – 4.75)
A/A (CI 95%)	3.82 (3.25 – 4.38)	1.83 (1.57 – 2.10)	3.53 (2.45 – 4.61)

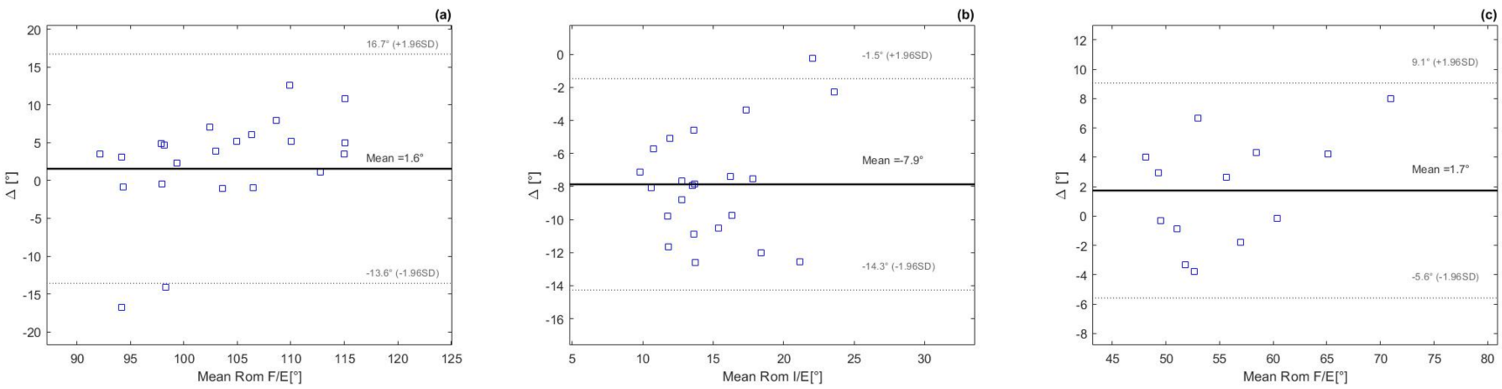

Figure 2: Bland & Altman plots of RoM from both systems for FLEX100 (a), ROT30 (b) and PS (c). Each graph represents the mean difference (black line) and the CI 95% of the difference (dashed lines) as recorded by the instrumented knee brace and navigation.

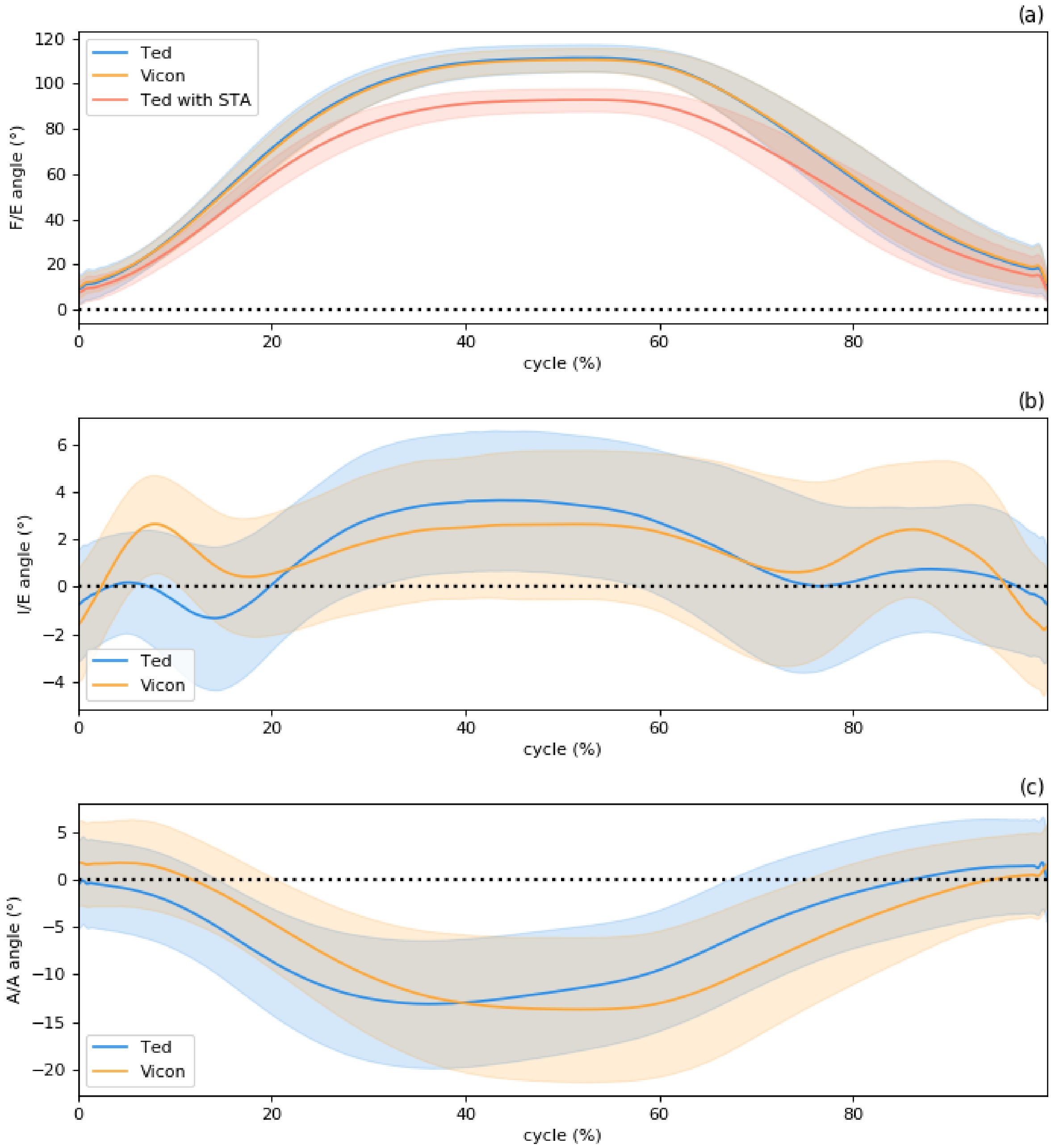

Figure 3: Mean knee joint kinematics over all trials and all subjects with a standard deviation cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace without STA regression in red, Navigation with Vicon in orange) for flexion 100° in F/E (a), I/E (b), A/A(c)

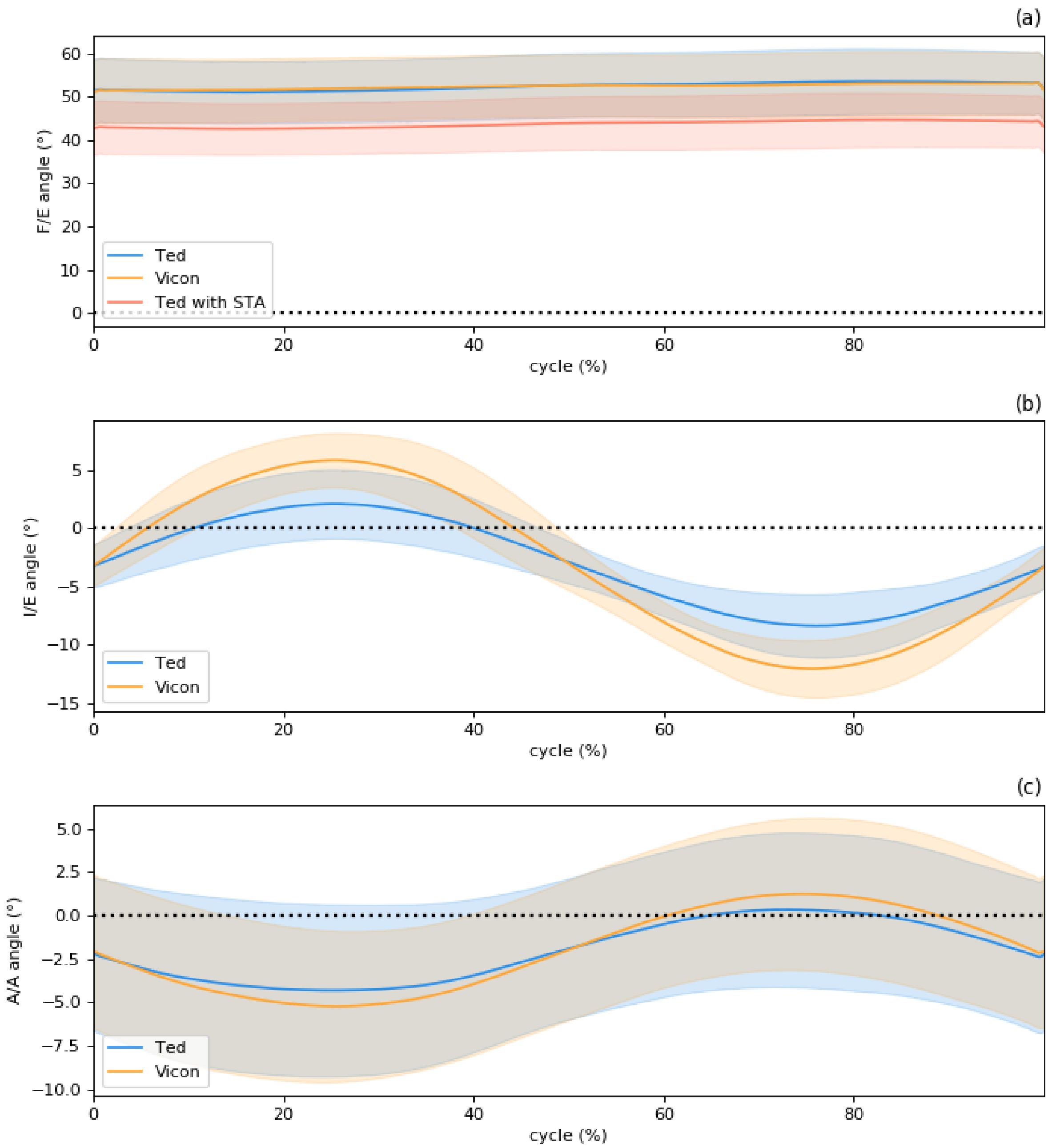

Figure 4: Mean knee joint kinematics over all trials and all subjects with a standard deviation cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace without STA regression in red, Navigation with Vicon in orange) for internal/external rotation at 30° of flexion in F/E (a), I/E (b), A/A(c)

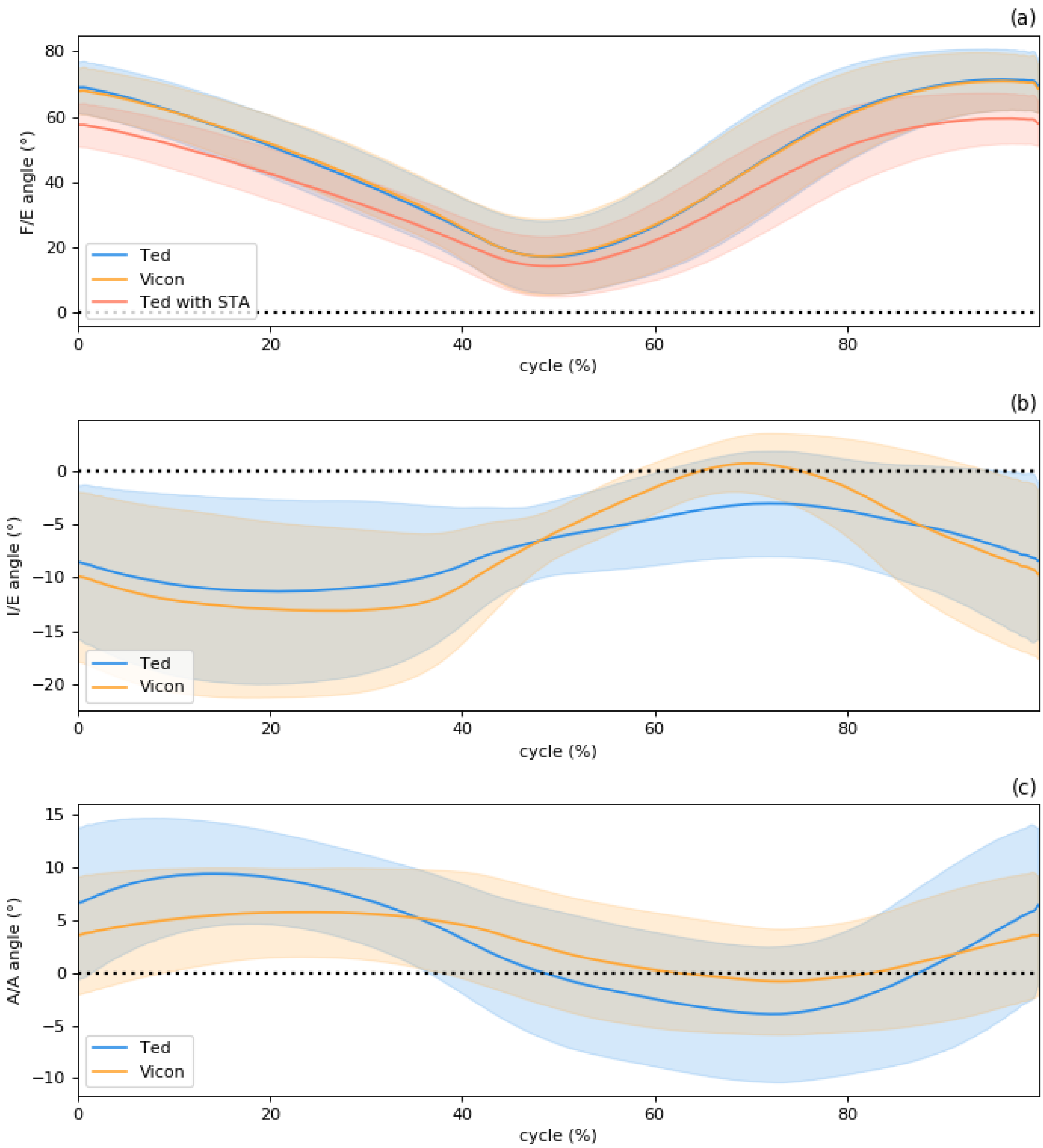

Figure 5: Mean knee joint kinematics over all trials and all subjects with a standard deviation cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace without STA regression in red, Navigation with Vicon in orange) for pivot shift test in extension in F/E (a), I/E (b), A/A(c)

7. Discussion

This study compared a new instrumented knee brace based on two IMU sensors aligned to the lateral side of the pelvis and the leg with an OCS to evaluate the accuracy and reliability of the new system during specific tasks. The study showed the excellent reliability of the knee brace and the strong concordance between the two systems. The difference in the RoMs was acceptable. The RMSE values of the OCS and the knee brace for the three angles remained under 5° for all exercises.

The reliability of the IMU system was tested for each exercise and demonstrated ICC>0.918 for all exercises, indicating excellent reliability. Moreover, the results are in line with the literature. Indeed, the ICC of the FLEX100 exercise was similar to the results found by Maderbacher's study, which showed an ICC of 0.92 for knee flexion [44]. The results for I/E rotation with our knee brace were similar to those found by Musahl et al., who reported ICCs from 0.94 to 0.99 for measured rotational knee laxity with a noninvasive system [45]. Other studies of gait analysis using IMU systems have found similar results, with excellent reliability for the flexion angle [46,47]. These studies are consistent with findings of the excellent reliability of IMU systems for several tasks.

The correlations between the two systems were excellent in the major axis of each exercise. These results are in line with the Pearson's correlation coefficient of 0.96 reported by Kayaalp et al. and the agreement between 0.82 to 1.0, depending on the task, for knee F/E reported by Lebel et al. [42,48]. However, the correlations for the minor axes were not as conclusive with Pearson's correlation coefficients ranging from weak to excellent. Favre et al. brought this trend to light with measurements of IMUs and the knee exoskeleton during a gait test, finding the major axis $\sigma = 1.00$ (0.00) in F/E and the minor axes $\sigma = 0.76(0.18)$ in A/A and $\sigma = 0.85(0.11)$ in I/E [49]. Then, additional measurements revealed agreement levels between poor and excellent, depending on the axis and joint, for squats (SQ), single-leg squats (SLS) and countermovement jumps (CMJ). For the knee joint, the minor axes for these exercises showed less agreement, ranging from poor to excellent, compared to the major axis (F/E), which showed excellent agreement [43]. These findings underline the weaker correlation of the two minor axes of the knee and the strong correlation in F/E found in this study, except for the ROT30 exercise due to a major axis in the I/E axis.

The accuracy of the instrumented knee brace as assessed by RMSE was under 5° in the three axes (F/E without STA). Lebel et al. reported comparable mean RMSE varying between 1.1° and 5.5°, depending on the segment tracked and the task performed [48]. The same results were found by Kayaalp et al., with a mean RMSE of 5.17° in F/E during a gait test [42]. A systematic review by McGinley et al. confirmed these results and noted that most studies reported error of less than 5° for all gait variables, excluding hip and knee rotation [50]. The study by Robert-Lachaine et al. was in line with these results, with RMSE between 3° and 6° for knee rotations in the F/E, I/E, and A/A axes [51]. These authors thus agreed on the clinical relevance of IMU systems with RMSE values under 5°.

Bland & Altman analysis revealed a similar RoM with a mean error under 2° in F/E due to the STA regression used in the computation angles of the instrumented knee brace. These results are similar to the findings of Teufl et al. for SQ, SLS and CMJ with a mean error of 2° [43]. Another study on Sit To Stand (STS) test with visual feedback showed a mean difference ranging from -1.7° to 3.2° in the F/E axis between the IMU system and OCS [52]. More specifically, Leardini et al. highlighted a mean RoM error of 3.9° for knee flexion between 0 to 95° [27]. However, the RoM error for our ROT30 exercise revealed an underestimation in the I/E rotation axis due to STA. Unfortunately, no significant regression was found to minimize STA on this axis. Indeed, Stagni et al. also observed a simple overestimated flexion in F/E but a more complex artifact for I/E and A/A rotations [53].

A few limitations of this study should be noted. First, the outcomes were marred by STA, which impacted each axis of rotation, but more specially the I/E and A/A rotations because there was no compensation for STA. More studies are required to identify the best approach to minimize STA and reduce RMSE between the connected knee brace and bone placement [31,54]. Indeed, the results of the ROT30 exercise contradicted the findings of Moewis et al. (Figure 2; Figure 3), who suggested a linear overestimation of I/E rotation with skin-mounted markers compared to knee fluoroscopy [55,56]. Second, the alternative procedure for estimating the IMU orientation with optimization introduced inaccuracy into the measurement of I/E and A/A rotations due to the exercise of flexion used by the optimization algorithm [57,58]. In fact, the I/E and A/A rotations had a small range of motion and were in general less valid due to the projection of the F/E rotation, caused by small errors in IMU orientation estimation during the calibration phases [16,58,59]. Further studies should elucidate the most appropriate calibration methods to estimate joint kinematics [42,57]. Third, even if navigation system allows a motion capture without STA, mechanical properties between cadaveric and living knee may differ due to difference in soft tissue tension, capsule, ligaments and neglecting the influence of muscle contractions [38,60]. Then, passive kinematics may differ from active kinematics [38,60]. Not least of all, rates of flexion and rotation for FLEX100, PS and ROT30 highlighted limitations in reliability of movements due to a CV close to or even higher than 15% [61]. Acquisition performed with a robotic arm would acquire better data with repetitive ranges and rates [62]. However, acquired data performed with clinicians is closer to field data acquisitions.

8. Conclusion

The present work investigated the reliability and accuracy of a new instrumented knee brace compared to a gold standard navigation system without STA. The new brace showed excellent reliability and sufficient accuracy for clinical interpretations. However, STA induced errors in the axes without artifact consideration algorithm. In conclusion, this study highlights the clinical validity of the instrumented knee brace. Further investigations are necessary to develop new algorithms to minimize STA in the I/E and A/A

9. Declaration of competing interest

The institutes of the Authors have received funding from the marketing company the instrumented knee brace Ted Orthopedics to cover the costs involved in the execution of this study. I, Nicolas Reneaud, declare that Zory Raphaël, Chorin Frédéric, Chavet Pascale, Coyle Thelma, Puech Stephane, Ollivier Matthieu, Chabrand Patrick, Gerus Pauline have no proprietary, financial, professional or other personal interest of any nature of kind of any product, service and/or company that could be construed as influencing the position presented in the manuscript.

10. Acknowledgements

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