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

Reneaud Nicolas, Pierre Emma, Zory Raphaël, Chorin Frédéric, Thomas Luc, Chavet Pascale, Coyle Thelma, Truchet Eric, Puech Stephane, Ollivier Matthieu, Chabrand Patrick, Gerus Pauline

1 **Title**

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

4 **Abbreviated title**

5 Validity of an instrumented knee brace

6 **Authors**

7 Reneaud Nicolas^{1,2,3}, Pierre Emma², Zory Raphaël¹, Chorin Frédéric^{1,3}, Thomas Luc², Chavet
8 Pascale⁴, Coyle Thelma⁴, Truchet Eric², Puech Stephane⁵, Ollivier Matthieu⁵, Chabrand
9 Patrick⁶, Gerus Pauline¹

10 **Affiliations**

11 ¹ Université Côte d'Azur, LAMHESS, 261 Boulevard du Mercantour 06205, Nice, France

12 ² Ted Orthopedics, 37 rue Guibal, Marseille, France

13 ³ Université Côte d'Azur, Hôpital Cimiez, 4 Avenue reine Victoria, 06003, Nice, France

14 ⁴ Université Aix-Marseille, ISM, 163 av. de Luminy F-13288, Marseille cedex 09, France

15 ⁵ Université Aix-Marseille, Hôpital Sainte-Marguerite, 20 avenue Viton, 13274, Marseille
16 cedex 09, France

17 ⁶ SCCDS, Hôpital Timone, 264 rue Saint-Pierre 13385, Marseille cedex 09, France

18 **Address correspondence to**

19 Nicolas Reneaud, Hôpital Cimiez, bâtiment Mossa, Etage -1 – Plateforme fragilité

20 4 avenue reine victoria 06003 Nice, France

21 E-mail : nicolas@tedorthopedics.com

22 Tel : +33 04

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Highlights :

25

- Reliability of an instrumented knee brace during specific tasks

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- Consideration of soft tissue artifacts on knee brace with cadaveric navigation

27

- Validity of 3 axis kinematics of instrument knee brace compare to navigation investigation

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31 **1. Abstract**

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

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

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

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

45 **2. Keywords**

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

48

49 **3. Background**

50 Knee joint function can be altered by several pathologies, such as anterior cruciate ligament
51 rupture (ACLR) and knee osteoarthritis (OA) [1–4]. A better understanding of knee pathologies
52 has given rise recently to new knee diagnostic and analysis tools [5–7]. Thus, motion capture
53 and questionnaires have become the gold standard for practitioners for several pathologies
54 [1,2,8]. The optoelectronic camera system (OCS) is the usual tool for quantifying body motion
55 [2,9–11]. However, motion capture with OCS has few limitations. Firstly, the gait patterns can
56 be affected by the laboratory environment compared to an ecological environment [12–14].
57 Secondly, the OCS is very expensive, restricted to a limited field of view in time and space
58 [12,14] and time consuming. Finally, the OCS cannot be used in a home-based rehabilitation
59 perspective.

60 To develop systems that overcome these disadvantages, recent research has focused on gait
61 analysis using wearable sensors [15], and new systems have been developed to quantify human
62 motion. For example, accelerometers are valid and reliable for the recording of activity, energy
63 expenditure and acceleration data [16]. Nevertheless, the precision of kinematic measurements
64 is poor with an accelerometer sensor only due to the presence of drift during fast accelerations
65 [17,18]. Combining a gyroscope with an accelerometer may solve this problem. Indeed,
66 gyroscopes can estimate sensor orientation by integrating the angular velocity on the X, Y, Z
67 axes relative to the sensor. Yet this sensor is subject to a drift in angular velocity due to signal
68 integration, a well-known problem in robotics and motion analysis. By mixing the
69 complementary data from accelerometers and gyroscopes, the two drifts can be minimized with
70 a fusion algorithm like a Kalman filter [16,19,20]. The association of the two sensors is called
71 an inertial measurement unit (IMU). Body sensor networks with IMUs such as Xsens MVN
72 (Xsens Technologies BV, Enschede, NL) [21] or Perception NEURON Pro (Noitom, Miami,
73 FL, USA) [22] provide quantitative movement analysis in ecological environments.

74 In a home-based rehabilitation perspective, the knee motion analysis has become necessary to
75 supervise patients through biofeedback. To deal with that, a new instrumented knee brace with
76 two IMUs was developed. These sensors calculated the movement of the thigh relative to the
77 shank. Moreover, this integrated system compares to simple IMU sensors described previously
78 did not necessitate clinicians or physiotherapist for calibration or anatomical placement due to
79 its ease of use. Indeed, once the connected knee brace is in place, it is possible to quantify knee
80 motion in an ecological environment to reduce bias in laboratory conditions with a smartphone
81 [23–25]. Palpation to find anatomical landmarks is not required, nor is it necessary to fix
82 markers or IMUs with different systems, as it is the case with other systems [2,26]. Moreover,
83 this technology offers free use of a workstation for motion computation through cloud
84 computing on the smartphone app, and biofeedback can be displayed in real time with
85 smartphone computation. All these data allow a quantified rehabilitation for physiotherapists
86 or clinicians via success scores and pain scale charts. Then, this system enhance physical
87 rehabilitation by motivating the user with visual data of progression and informative videos
88 [27].

89 However, this knee brace, like IMU systems or OCS, is sensitive to soft tissue artifacts (STA),
90 a problem inherent to all skin-mounted tracking system. A systematic review noted the effects
91 of STA in the lower limb, finding that several factors influence the results, including sensor
92 orientation [28]. STA was found to reach more than 30 mm of magnitude on the thigh segment
93 and more than 15 mm on the tibia [28]. To overcome this problem, OCS investigation with
94 bony pins would be highly accurate [29,30], but this procedure is unethical and should not be
95 applied to living patients. Along the same lines, the fluoroscopic 3D-matching technique is
96 invasive due to radiation exposure [31]. Recently, several studies have used commercial
97 navigation devices to assess knee kinematics during surgical procedures for ACL reconstruction
98 or total knee arthroplasty [32–34]. Navigation is composed of three parts: computer platform,

99 tracking system, and rigid body marker. Tracking system visualizes the rigid body markers
100 through OCS and calculates motion in real time with the tracking systems. Markers are fixed to
101 the patient's bones surgical instruments to track joint motion or target objects after a referencing
102 procedure which consists in determining bone positions compared to marker positions [35]. For
103 example, this system via bony pins and OCS is a computer-assisted surgical navigation device
104 to help tunnel placement during ACL reconstruction and can quantify knee laxity and validate
105 the surgical procedure [33,36].

106 A more ethical solution might be considered to begin with cadaveric investigations. Indeed,
107 tibiofemoral motion in the unloaded cadaveric knee is almost the same as that in the living knee
108 [37,38].

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

114

115 **4. Material and methods**

116 **4.1. Subjects**

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

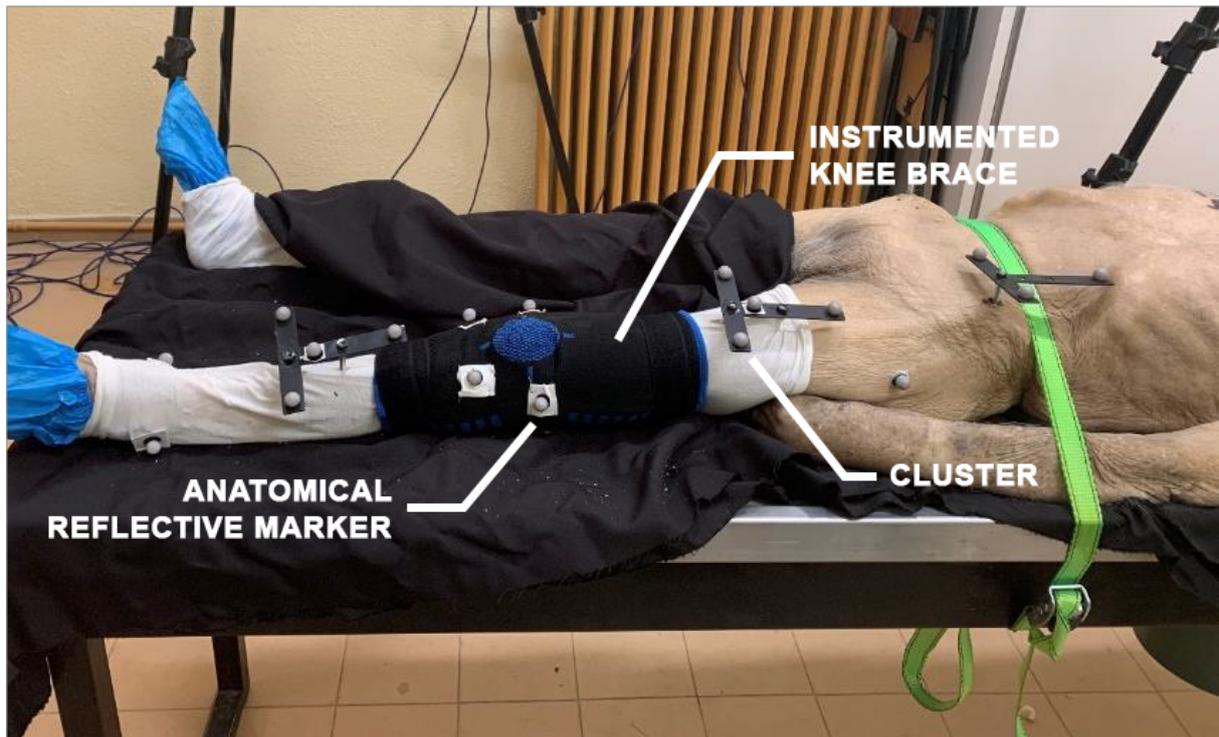
4.2. Material and instrumentation

123
124 Three clusters of four reflective markers were fixed by one screw on the pelvis and two screws
125 on the femur and tibia to record the knee kinematics. The femoral and tibial screws were fixed
126 in the bone diaphysis outside the joint capsule with a 2-cm incision to avoid influencing the soft
127 tissue. After fixing the three clusters, seven anatomical landmarks were identified with
128 reflective markers fixed onto the skin with cyanoacrylate glue. The medial malleolus (MM),
129 the lateral malleolus (LM), the medial and lateral epicondyle of the femur (MF, LF), the medial
130 and lateral epicondyle of the tibia (MT, LT) and the greater trochanter (GT) were located.
131 Kinematic data were simultaneously obtained with seven cameras (Vicon Motion Systems Ltd.
132 Oxford, UK): four MX-T20 and three MX-T40 and with the instrumented knee brace with a
133 sampling frequency of 100 Hz. The instrumented knee brace is composed with two IMU ICM-
134 20948. The knee sleeve was designed to reduce compression around the knee by using soft
135 tissue in opposition to medical knee sleeve designed to change the knee joint kinematic [39].
136 The knee sleeve compression around the knee was minimal to avoid change in knee joint
137 movement but enough to limit the movement of the IMU sensors. IMU's knee brace had a 16
138 bits resolution for accelerometers and gyroscope. However due to Bluetooth Low Energy
139 communication, these resolutions were downgrade to 10 bits with respectively, a sensitivity of
140 7.81 mg/LSB for a ± 4 g range and a sensitivity of 0.98 dps/LSB for a range of ± 500 dps.

141

142

143



144

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

148

149 **4.3. Experimental protocol**

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

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

170 The operator performed four movements, five times each: a flexion with a full extension to
171 100° of flexion (FLEX100), a maximal internal/external rotation with a flexion of 30° (ROT30),
172 a pivot shift test (PS) and a flexion from full extension to maximal knee flexion under constraint
173 (FLEXMAX).

174

175 **5. Calculation**

176 **5.1. Analysis**

177 The synchronization of the two systems was performed by a wand with three reflective markers
178 on it. The maximum acceleration detected when the wand hit the thigh IMU was synchronized
179 with the trajectory of the wand's reflective markers. Data from the OCS were analyzed and the
180 angles were computed in Python. The data from the instrumented knee brace were collected
181 and the angles were computed in Python with a data fusion algorithm based on Valenti et al.
182 filter applied to the accelerometric and gyroscopic data [20]. However, data analysis revealed
183 problems with the calibration protocol for the instrumented knee brace due to the dorsal

184 decubitus position of the cadavers. A better alternative estimation was to find the IMU
185 orientation by comparing clusters and IMU movements when there were small flexions in
186 FLEXMAX. This estimation of the IMU orientation was used for all other exercises. Then,
187 some acquisitions were not processed because of the abnormal movement of some of the
188 anatomical marker fixed on the knee brace (MF, LF, MT and LT), which resulted in the
189 selection of only 23 acquisitions in all. Due to motion differences between operators, only 13
190 acquisitions for pivot shift test were selected among the 23.

191 **5.2. Statistical analysis**

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

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209 **6. Results**

210

211 The ICC (95%) for the kinematic parameters recorded with the instrumented knee brace showed
 212 excellent reliability for all exercises. In terms of concurrent validity, Pearson’s r coefficient for
 213 the instrumented knee brace kinematics compared to the navigation kinematics showed the
 214 following for all exercises: very good to excellent correlations for the F/E angles, poor to
 215 excellent correlations for I/E rotation, and poor to excellent correlation for A/A (Table 1).
 216 RMSE was less than 5° between systems except for the F/E axis. Table 2, Figure 3, Figure 4
 217 and Figure 5 show the impact of STA. The Bland & Altman plots showed the difference in the
 218 range of motion (RoM) between the two systems (Figure 2). 3D kinematics of the knee during
 219 the three exercises are depicted in Figure 3, Figure 4, and Figure 5. Rates of flexions for
 220 FLEX100 and PS were 78.3 ± 12.4 dps and 55.5 ± 8.9 dps, rates of rotations for ROT30 were
 221 19.4 ± 2.8 dps. Coefficients of variation (CV) were respectively: 15.8%, 16.0%, 14.3%.

222 **Table 1.**

223 ICC and Pearson’s correlation coefficient (σ) between instrumented knee brace and navigation.
 224 (CI = confidence interval.)

225

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)

226

227

228 **Table 2.**

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

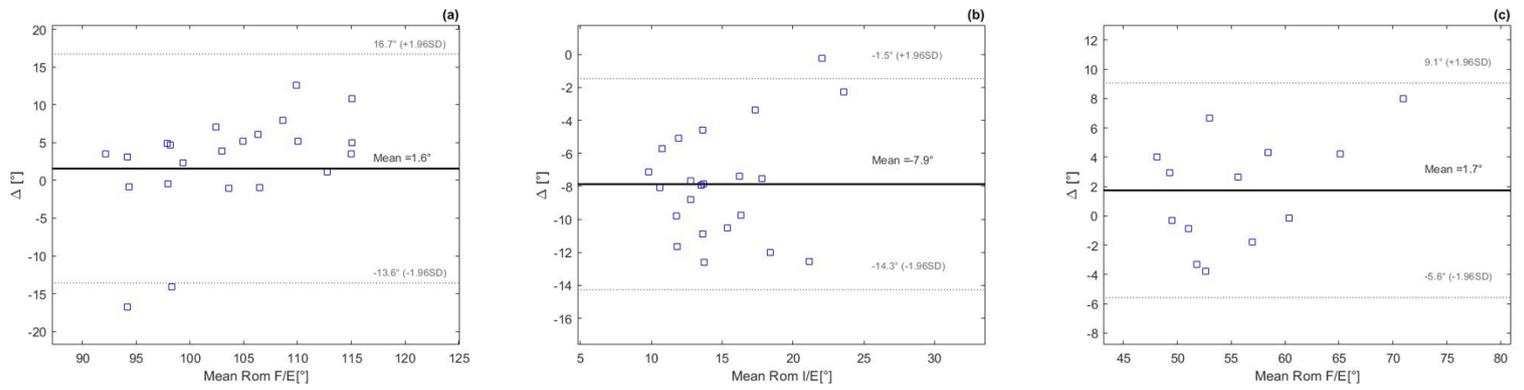
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Exercise	FLEX100 (°)	ROT30 (°)	PS (°)
F/E (CI 95%)	8.26 (6.77 – 9.77)	4.65 (3.11 – 6.18)	6.06 (4.86 – 7.27)
F/E Reg (CI 95%)	2.96 (2.31 – 3.61)	1.01 (0.83 – 1.20)	2.72 (2.08 – 3.35)
I/E (CI 95%)	2.25 (1.99 – 2.52)	3.12 (2.67 – 3.58)	3.89 (3.03 – 4.75)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

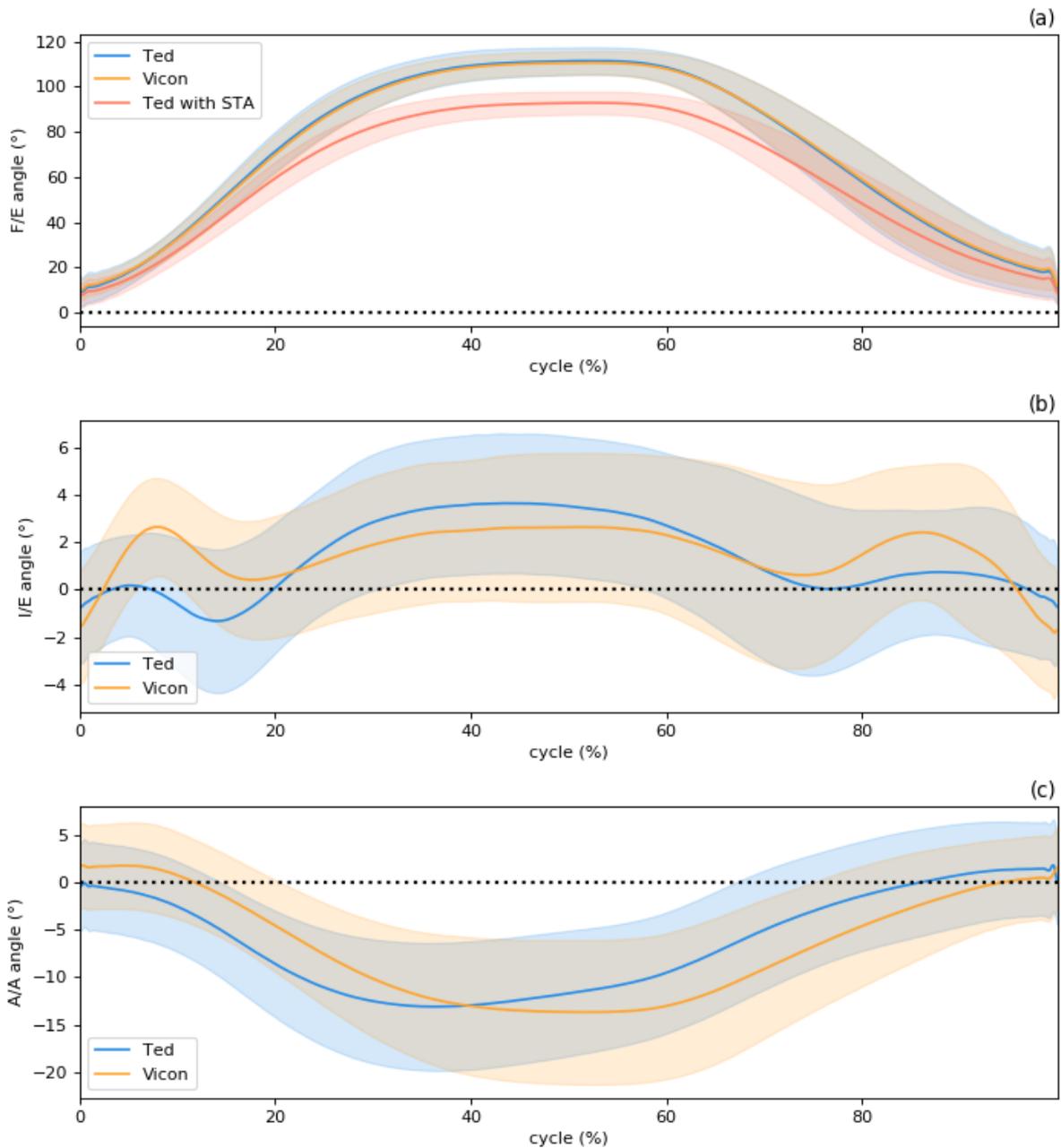
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234 **Figure 2:** Bland & Altman plots of RoM from both systems for FLEX100 (a), ROT30 (b) and
235 PS (c). Each graph represents the mean difference (black line) and the CI 95% of the
236 difference (dashed lines) as recorded by the instrumented knee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

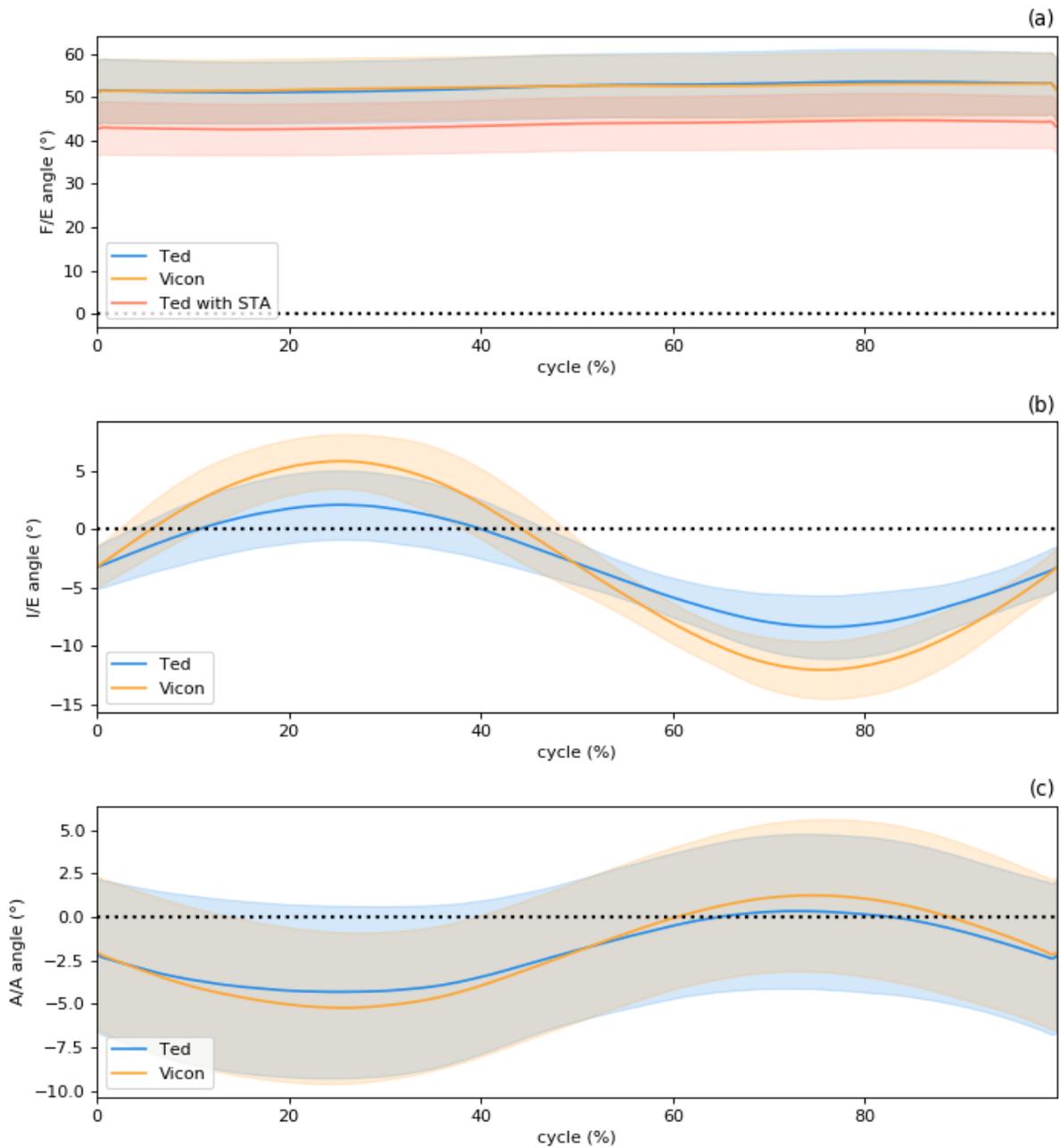


237
 238 **Figure 3:** Mean knee joint kinematics over all trials and all subjects with a standard deviation
 239 cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace
 240 without STA regression in red, Navigation with Vicon in orange) for flexion 100° in F/E (a),
 241 I/E (b), A/A(c)

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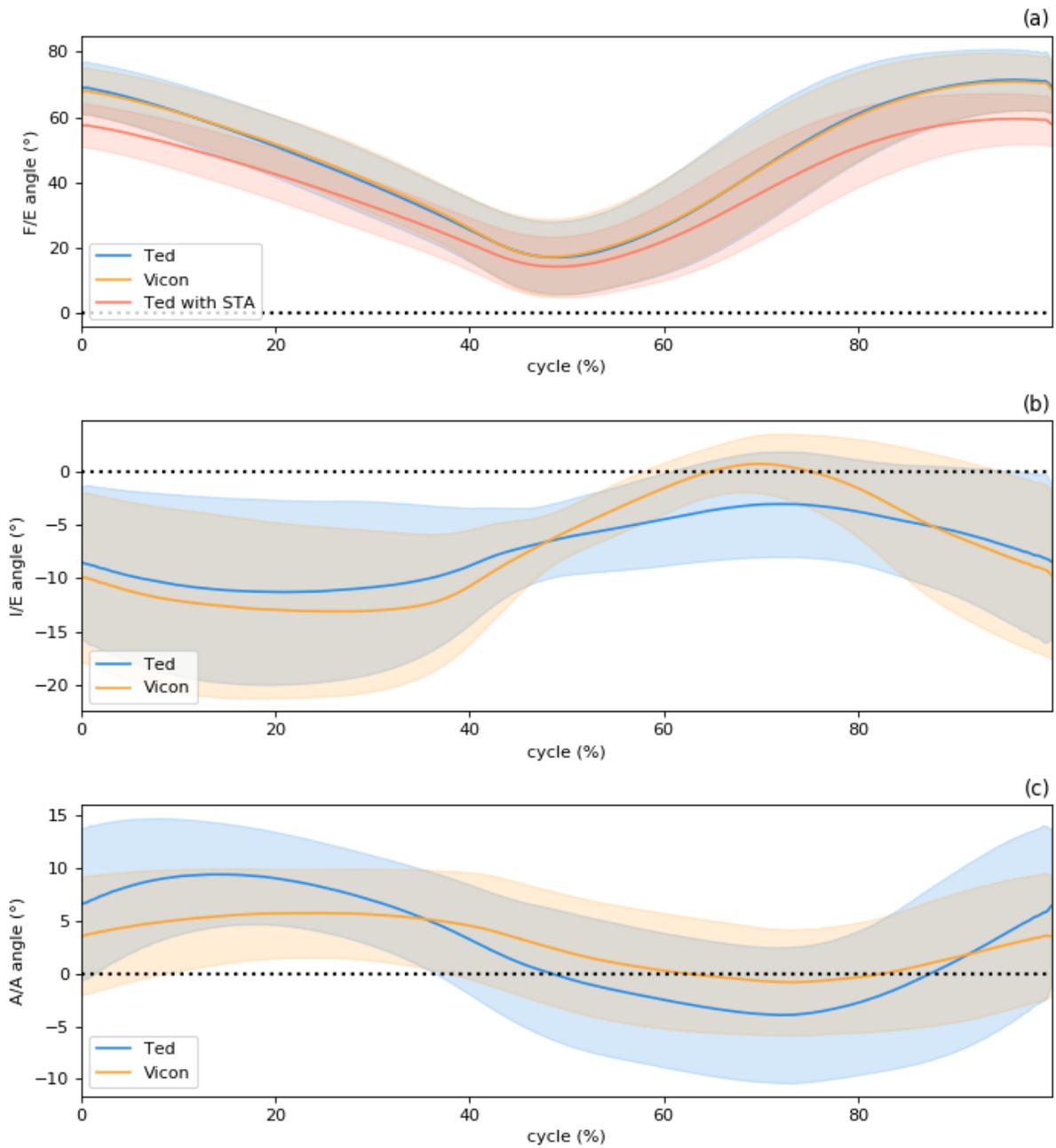
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245
 246 **Figure 4:** Mean knee joint kinematics over all trials and all subjects with a standard deviation
 247 cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace
 248 without STA regression in red, Navigation with Vicon in orange) for internal/external rotation
 249 at 30° of flexion in F/E (a), I/E (b), A/A(c)

250



251
 252 **Figure 5:** Mean knee joint kinematics over all trials and all subjects with a standard deviation
 253 cloud to compare the two systems (Instrumented knee brace in blue, Instrumented knee brace
 254 without STA regression in red, Navigation with Vicon in orange) for pivot shift test in
 255 extension in F/E (a), I/E (b), A/A(c)

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260 7. Discussion

261

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

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

277 The correlations between the two systems were excellent in the major axis of each exercise.
278 These results are in line with the Pearson's correlation coefficient of 0.96 reported by Kayaalp
279 et al. and the agreement between 0.82 to 1.0, depending on the task, for knee F/E reported by
280 Lebel et al. [42,48]. However, the correlations for the minor axes were not as conclusive with
281 Pearson's correlation coefficients ranging from weak to excellent. Favre et al. brought this trend
282 to light with measurements of IMUs and the knee exoskeleton during a gait test, finding the
283 major axis $\sigma = 1.00 (0.00)$ in F/E and the minor axes $\sigma = 0.76(0.18)$ in A/A and $\sigma = 0.85(0.11)$
284 in I/E [49]. Then, additional measurements revealed agreement levels between poor and

285 excellent, depending on the axis and joint, for squats (SQ), single-leg squats (SLS) and
286 countermovement jumps (CMJ). For the knee joint, the minor axes for these exercises showed
287 less agreement, ranging from poor to excellent, compared to the major axis (F/E), which showed
288 excellent agreement [43]. These findings underline the weaker correlation of the two minor
289 axes of the knee and the strong correlation in F/E found in this study, except for the ROT30
290 exercise due to a major axis in the I/E axis.

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

300 Bland & Altman analysis revealed a similar RoM with a mean error under 2° in F/E due to the
301 STA regression used in the computation angles of the instrumented knee brace. These results
302 are similar to the findings of Teufl et al. for SQ, SLS and CMJ with a mean error of 2° [43].
303 Another study on Sit To Stand (STS) test with visual feedback showed a mean difference
304 ranging from -1.7° to 3.2° in the F/E axis between the IMU system and OCS [52]. More
305 specifically, Leardini et al. highlighted a mean RoM error of 3.9° for knee flexion between 0 to
306 95° [27]. However, the RoM error for our ROT30 exercise revealed an underestimation in the
307 I/E rotation axis due to STA. Unfortunately, no significant regression was found to minimize
308 STA on this axis. Indeed, Stagni et al. also observed a simple overestimated flexion in F/E but
309 a more complex artifact for I/E and A/A rotations [53].

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

330

331 **8. Conclusion**

332

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

339

340 **9. Declaration of competing interest**

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

348

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353

354

355 **11. References**

356

- 357 [1] R. García-Bógalo, R. Larraínzar-Garijo, A.D. Murillo-Vizuate, J. Montoya-Adárraga, O.
358 Marín-Peña, M. Pérez-España Muniesa, L. Horna-Castañeira, Evaluation of
359 intraoperative anterior cruciate ligament laxity reconstruction &, *Rev Esp Cir Ortop*
360 *Traumatol.* 56 (2012) 267–73. <https://doi.org/10.1016/j.recote.2011.12.003>.
- 361 [2] D. Bytyqi, B. Shabani, S. Lustig, L. Cheze, N. Karahoda Gjurgjeala, P. Neyret, Gait knee
362 kinematic alterations in medial osteoarthritis: Three dimensional assessment, *Int.*
363 *Orthop.* 38 (2014) 1191–1198. <https://doi.org/10.1007/s00264-014-2312-3>.
- 364 [3] S. Ren, Y. Yu, H. Shi, X. Miao, Y. Jiang, Z. Liang, X. Hu, H. Huang, Y. Ao, Three
365 dimensional knee kinematics and kinetics in ACL-deficient patients with and without
366 medial meniscus posterior horn tear during level walking, *Gait Posture.* 66 (2018) 26–
367 31. <https://doi.org/10.1016/j.gaitpost.2018.08.007>.
- 368 [4] P. Ismailidis, C. Egloff, L. Hegglin, G. Pagenstert, R. Kernen, A. Eckardt, T. Ilchmann,
369 A. Mündermann, C. Nüesch, Kinematic changes in patients with severe knee
370 osteoarthritis are a result of reduced walking speed rather than disease severity, *Gait*
371 *Posture.* 79 (2020) 256–261. <https://doi.org/10.1016/j.gaitpost.2020.05.008>.
- 372 [5] S.S. Paul, C.G. Canning, Five-repetition sit-to-stand, *J. Physiother.* 60 (2014) 168.
373 <https://doi.org/10.1016/j.jphys.2014.06.002>.
- 374 [6] M. Ateef, S. Kulandaivelan, S. Tahseen, Test–retest reliability and correlates of 6-minute
375 walk test in patients with primary osteoarthritis of knees, *Indian J. Rheumatol.* 11 (2016)
376 192. <https://doi.org/10.4103/0973-3698.192668>.
- 377 [7] A. Gomez Bernal., R. Becerro-de-Bengoa-Vallejo, M.E. Losa-Iglesias, Reliability of the
378 OptoGait portable photoelectric cell system for the quantification of spatial-temporal
379 parameters of gait in young adults, *Gait Posture.* 50 (2016) 196–200.
380 <https://doi.org/10.1016/J.GAITPOST.2016.08.035>.
- 381 [8] P. Devita, J. Aaboe, C. Bartholdy, J.M. Leonardis, H. Bliddal, M. Henriksen,
382 Quadriceps-strengthening exercise and quadriceps and knee biomechanics during
383 walking in knee osteoarthritis : A two-centre randomized controlled trial, *Clin. Biomech.*
384 59 (2018) 199–206. <https://doi.org/10.1016/j.clinbiomech.2018.09.016>.
- 385 [9] T.A. Gerbrands, M.F. Pisters, B. Vanwanseele, Individual selection of gait retraining
386 strategies is essential to optimally reduce medial knee load during gait, *JCLB.* 29 (2014)
387 828–834. <https://doi.org/10.1016/j.clinbiomech.2014.05.005>.
- 388 [10] J. Favre, B.M. Jolles, Gait analysis of patients with knee osteoarthritis highlights a
389 pathological mechanical pathway and provides a basis for therapeutic interventions,
390 *EFORT Open Rev.* 1 (2016) 368–374. <https://doi.org/10.1302/2058-5241.1.000051>.
- 391 [11] L.D. Duffell, S.J. Jordan, J.P. Cobb, A.H. McGregor, Gait adaptations with aging in
392 healthy participants and people with knee-joint osteoarthritis, *Gait Posture.* 57 (2017)
393 246–251. <https://doi.org/10.1016/j.gaitpost.2017.06.015>.
- 394 [12] J. Huddleston, A. Alaiti, D. Goldvasser, D. Scarborough, A. Freiberg, H. Rubash, H.
395 Malchau, W. Harris, D. Krebs, Ambulatory measurement of knee motion and physical
396 activity: Preliminary evaluation of a smart activity monitor, *J. Neuroeng. Rehabil.* 3

- 397 (2006) 1–10. <https://doi.org/10.1186/1743-0003-3-21>.
- 398 [13] P.Y. de Müllenheim, S. Chaudru, G. Mahé, J. Prioux, A. Le Faucheur, Clinical Interest
399 of Ambulatory Assessment of Physical Activity and Walking Capacity in Peripheral
400 Artery Disease, *Scand. J. Med. Sci. Sport.* 26 (2016) 716–730.
401 <https://doi.org/10.1111/sms.12512>.
- 402 [14] M. Fusca, F. Negrini, P. Perego, L. Magoni, F. Molteni, G. Andreoni, Validation of a
403 wearable IMU system for gait analysis: Protocol and application to a new system, *Appl.*
404 *Sci.* 8 (2018) 1–16. <https://doi.org/10.3390/app8071167>.
- 405 [15] K. Tanimoto, M. Takahashi, K. Tokuda, T. Sawada, M. Anan, Lower limb kinematics
406 during the swing phase in patients with knee osteoarthritis measured using an inertial
407 sensor, *Gait Posture.* 57 (2017) 236–240. <https://doi.org/10.1016/j.gaitpost.2017.06.017>.
- 408 [16] I. Poitras, F. Dupuis, M. Biemann, A. Campeau-Lecours, C. Mercier, L.J. Bouyer, J.S.
409 Roy, Validity and reliability of wearable sensors for joint angle estimation: A systematic
410 review, *Sensors (Switzerland).* 19 (2019) 1–17. <https://doi.org/10.3390/s19071555>.
- 411 [17] H. Dejnabadi, B.M. Jolles, E. Casanova, P. Fua, K. Aminian, Estimation and
412 visualization of sagittal kinematics of lower limbs orientation using body-fixed sensors,
413 *IEEE Trans. Biomed. Eng.* 53 (2006) 1385–1393.
414 <https://doi.org/10.1109/TBME.2006.873678>.
- 415 [18] R. Antonello, K. Ito, R. Oboe, Acceleration Measurement Drift Rejection in Motion
416 Control Systems by Augmented-State Kinematic Kalman Filter, *IEEE Trans. Ind.*
417 *Electron.* 63 (2016) 1953–1961. <https://doi.org/10.1109/TIE.2015.2512224>.
- 418 [19] S. Šlajpah, R. Kamnik, M. Munih, Kinematics based sensory fusion for wearable motion
419 assessment in human walking, *Comput. Methods Programs Biomed.* 116 (2014) 131–
420 144. <https://doi.org/10.1016/j.cmpb.2013.11.012>.
- 421 [20] R.G. Valenti, I. Dryanovski, J. Xiao, Keeping a good attitude: A quaternion-based
422 orientation filter for IMUs and MARGs, *Sensors (Switzerland).* 15 (2015) 19302–19330.
423 <https://doi.org/10.3390/s150819302>.
- 424 [21] M. Nazarahari, A. Noamani, N. Ahmadian, H. Rouhani, Sensor-to-body calibration
425 procedure for clinical motion analysis of lower limb using magnetic and inertial
426 measurement units, *J. Biomech.* 85 (2019) 224–229.
427 <https://doi.org/10.1016/j.jbiomech.2019.01.027>.
- 428 [22] R. Sers, S. Forrester, E. Moss, S. Ward, J. Ma, M. Zecca, Validity of the Perception
429 Neuron inertial motion capture system for upper body motion analysis, *Measurement.*
430 149 (2019) 107024. <https://doi.org/10.1016/j.measurement.2019.107024>.
- 431 [23] U. Lindemann, Spatiotemporal gait analysis of older persons in clinical practice and
432 research: Which parameters are relevant?, *Z. Gerontol. Geriatr.* 53 (2020) 171–178.
433 <https://doi.org/10.1007/s00391-019-01520-8>.
- 434 [24] J.P. Stellmann, A. Neuhaus, N. Götze, S. Briken, C. Lederer, M. Schimpl, C. Heesen, M.
435 Daumer, Ecological validity of walking capacity tests in multiple sclerosis, *PLoS One.*
436 10 (2015) 1–11. <https://doi.org/10.1371/journal.pone.0123822>.
- 437 [25] B.J. McFadyen, M.È. Gagné, I. Cossette, M.C. Ouellet, Using dual task walking as an
438 aid to assess executive dysfunction ecologically in neurological populations: A narrative
439 review, *Neuropsychol. Rehabil.* 27 (2017) 722–743.

- 440 <https://doi.org/10.1080/09602011.2015.1100125>.
- 441 [26] J. Clément, R. Dumas, N. Hagemeister, J.A. de Guise, Soft tissue artifact compensation
442 in knee kinematics by multi-body optimization: Performance of subject-specific knee
443 joint models, *J. Biomech.* 48 (2015) 3796–3802.
444 <https://doi.org/10.1016/j.jbiomech.2015.09.040>.
- 445 [27] A. Leardini, G. Lullini, S. Giannini, L. Berti, M. Ortolani, P. Caravaggi, Validation of
446 the angular measurements of a new inertial-measurement-unit based rehabilitation
447 system: Comparison with state-of-the-art gait analysis, *J. Neuroeng. Rehabil.* 11 (2014)
448 1–7. <https://doi.org/10.1186/1743-0003-11-136>.
- 449 [28] A. Peters, B. Galna, M. Sangeux, M. Morris, R. Baker, Quantification of soft tissue
450 artifact in lower limb human motion analysis: A systematic review, *Gait Posture.* 31
451 (2010) 1–8. <https://doi.org/10.1016/j.gaitpost.2009.09.004>.
- 452 [29] M.A. Lafortune, P.R. Cavanagh, H.J. Sommer, A. Kalenak, Three-dimensional
453 kinematics of the human knee during walking, *J. Biomech.* 25 (1992) 347–357.
454 [https://doi.org/10.1016/0021-9290\(92\)90254-X](https://doi.org/10.1016/0021-9290(92)90254-X).
- 455 [30] D.L. Benoit, M. Damsgaard, M.S. Andersen, Surface marker cluster translation, rotation,
456 scaling and deformation: Their contribution to soft tissue artefact and impact on knee
457 joint kinematics, *J. Biomech.* 48 (2015) 2124–2129.
458 <https://doi.org/10.1016/j.jbiomech.2015.02.050>.
- 459 [31] T.Y. Tsai, T.W. Lu, M.Y. Kuo, H.C. Hsu, Quantification of three-dimensional
460 movement of skin markers relative to the underlying bones during functional activities,
461 *Biomed. Eng. - Appl. Basis Commun.* 21 (2009) 223–232.
462 <https://doi.org/10.4015/S1016237209001283>.
- 463 [32] P. Imbert, C. Belvedere, A. Leardini, Knee laxity modifications after ACL rupture and
464 surgical intra - and extra - articular reconstructions : intra - operative measures in
465 reconstructed and healthy knees, *Knee Surgery, Sport. Traumatol. Arthrosc.* 25 (2017)
466 2725–2735. <https://doi.org/10.1007/s00167-015-3653-1>.
- 467 [33] A. Grassi, C. Signorelli, G.A. Lucidi, F. Raggi, L. Macchiarola, T. Roberti Di Sarsina,
468 G.M.M. Muccioli, G. Filardo, S. Zaffagnini, ACL reconstruction with lateral plasty
469 reduces translational and rotatory laxity compared to anatomical single bundle and non-
470 anatomical double bundle surgery: An in vivo kinematic evaluation with navigation
471 system, *Clin. Biomech.* 69 (2019) 1–8.
472 <https://doi.org/10.1016/j.clinbiomech.2019.06.012>.
- 473 [34] P.Z. Feczko, B.G. Pijls, M.J. Van Steijn, L.W. Van Rhijn, J.J. Arts, P.J. Emans, Tibial
474 component rotation in total knee arthroplasty, *BMC Musculoskelet. Disord.* (2016) 1–6.
475 <https://doi.org/10.1186/s12891-016-0940-z>.
- 476 [35] D.K. Bae, S.J. Song, Computer Assisted Navigation in Knee Arthroplasty, *Clin. Orthop.*
477 *Surg.* 3 (2011) 259–267. <https://doi.org/10.4055/cios.2011.3.4.259>.
- 478 [36] A. Nakamae, M. Ishikawa, T. Nakasa, Y. Ikuta, M. Ochi, N. Adachi, Evaluation of the
479 intraoperative kinematics during double-bundle anterior cruciate ligament reconstruction
480 using a navigation system, *Asia-Pacific J. Sport. Med. Arthrosc. Rehabil. Technol.* 19
481 (2020) 11–16. <https://doi.org/10.1016/j.asmart.2019.11.002>.
- 482 [37] P.F. Hill, V. Vedi, A. Williams, H. Iwaki, V. Pinskerova, M.A.R. Freeman, Tibiofemoral

- 483 movement 2: The loaded and unloaded living knee studied by MRI, *J. Bone Jt. Surg. -*
484 *Ser. B.* 82 (2000) 1196–1198. <https://doi.org/10.1302/0301-620X.82B8.10716>.
- 485 [38] M. Worlicek, B. Moser, G. Maderbacher, R. Zentner, F. Zeman, J. Grifka, A. Keshmiri,
486 The influence of varus and valgus deviation on patellar kinematics in healthy knees: An
487 exploratory cadaver study, *Knee.* 24 (2017) 711–717.
488 <https://doi.org/10.1016/j.knee.2017.04.009>.
- 489 [39] N.A. Mohd Sharif, S.L. Goh, J. Usman, W.K.Z. Wan Safwani, Biomechanical and
490 functional efficacy of knee sleeves: A literature review, *Phys. Ther. Sport.* 28 (2017) 44–
491 52. <https://doi.org/10.1016/j.ptsp.2017.05.001>.
- 492 [40] J. Jenny, C. Boeri, F. Picard, F. Leitner, O.I.S. Leitner, Reproducibility of intra-operative
493 measurement of the mechanical axes of the lower limb during total knee replacement
494 with a non-image-based navigation system, 9088 (2010).
495 <https://doi.org/10.3109/10929080500095517>.
- 496 [41] A.I. Cuesta-Vargas, A. Galán-Mercant, J.M. Williams, The use of inertial sensors system
497 for human motion analysis, *Phys. Ther. Rev.* 15 (2010) 462–473.
498 <https://doi.org/10.1179/1743288X11Y.0000000006>.
- 499 [42] M.E. Kayaalp, A.N. Agres, J. Reichmann, M. Bashkuev, G.N. Duda, R. Becker,
500 Validation of a Novel Device for the Knee Monitoring of Orthopaedic Patients, (2019)
501 1–14. <https://doi.org/10.3390/s19235193>.
- 502 [43] W. Teufl, M. Miezal, B. Taetz, M. Frohlich, G. Bleser, Validity of inertial sensor based
503 3D joint kinematics of static and dynamic sport and physiotherapy specific movements,
504 *PLoS One.* 14 (2019) 1–18. <https://doi.org/10.1371/journal.pone.0213064>.
- 505 [44] G. Maderbacher, A. Keshmiri, H.R. Springorum, H. Maderbacher, J. Grifka, C. Baier,
506 Reproducibility of navigation based kinematic analysis of the knee – A cadaveric
507 investigation, *J. Orthop. Sci.* 24 (2019) 128–135.
508 <https://doi.org/10.1016/j.jos.2018.08.027>.
- 509 [45] V. Musahl, K.M. Bell, A.G. Tsai, R.S. Costic, R. Allaire, T. Zantop, J.J. Irrgang, F.H.
510 Fu, Development of a simple device for measurement of rotational knee laxity, *Knee*
511 *Surgery, Sport. Traumatol. Arthrosc.* 15 (2007) 1009–1012.
512 <https://doi.org/10.1007/s00167-007-0317-9>.
- 513 [46] Y.S. Cho, S.H. Jang, J.S. Cho, M.J. Kim, H.D. Lee, S.Y. Lee, S.B. Moon, Evaluation of
514 validity and reliability of inertial measurement unit-based gait analysis systems, *Ann.*
515 *Rehabil. Med.* 42 (2018) 872–883. <https://doi.org/10.5535/arm.2018.42.6.872>.
- 516 [47] D. Kobsar, S.T. Osis, A. Phinyomark, J.E. Boyd, R. Ferber, Reliability of gait analysis
517 using wearable sensors in patients with knee osteoarthritis, *J. Biomech.* 49 (2016) 3977–
518 3982. <https://doi.org/10.1016/j.jbiomech.2016.11.047>.
- 519 [48] K. Lebel, P. Boissy, H. Nguyen, C. Duval, Inertial measurement systems for segments
520 and joints kinematics assessment: Towards an understanding of the variations in sensors
521 accuracy, *Biomed. Eng. Online.* 16 (2017) 1–16. <https://doi.org/10.1186/s12938-017-0347-6>.
- 523 [49] J. Favre, R. Aissaoui, B.M. Jolles, J.A. de Guise, K. Aminian, Functional calibration
524 procedure for 3D knee joint angle description using inertial sensors, *J. Biomech.* 42
525 (2009) 2330–2335. <https://doi.org/10.1016/j.jbiomech.2009.06.025>.

- 526 [50] J.L. McGinley, R. Baker, R. Wolfe, M.E. Morris, The reliability of three-dimensional
527 kinematic gait measurements: A systematic review, *Gait Posture*. 29 (2009) 360–369.
528 <https://doi.org/10.1016/j.gaitpost.2008.09.003>.
- 529 [51] X. Robert-Lachaine, H. Mecheri, C. Larue, A. Plamondon, Effect of local magnetic field
530 disturbances on inertial measurement units accuracy, *Appl. Ergon.* 63 (2017) 123–132.
531 <https://doi.org/10.1016/j.apergo.2017.04.011>.
- 532 [52] K.M. Bell, C. Onyeukwu, M.P. McClincy, M. Allen, L. Bechard, A. Mukherjee, R.A.
533 Hartman, C. Smith, A.D. Lynch, J.J. Irrgang, Verification of a portable motion tracking
534 system for remote management of physical rehabilitation of the knee, *Sensors*
535 (Switzerland). 19 (2019). <https://doi.org/10.3390/s19051021>.
- 536 [53] R. Stagni, S. Fantozzi, A. Cappello, A. Leardini, Quantification of soft tissue artefact in
537 motion analysis by combining 3D fluoroscopy and stereophotogrammetry: A study on
538 two subjects, *Clin. Biomech.* 20 (2005) 320–329.
539 <https://doi.org/10.1016/j.clinbiomech.2004.11.012>.
- 540 [54] B.M. Potvin, M.S. Shourijeh, K.B. Smale, D.L. Benoit, A practical solution to reduce
541 soft tissue artifact error at the knee using adaptive kinematic constraints, *J. Biomech.* 62
542 (2017) 124–131. <https://doi.org/10.1016/j.jbiomech.2017.02.006>.
- 543 [55] P. Moewis, H. Boeth, M.O. Heller, C. Yntema, T. Jung, R. Doyscher, R.M. Ehrig, Y.
544 Zhong, W.R. Taylor, Towards understanding knee joint laxity: Errors in non-invasive
545 assessment of joint rotation can be corrected, *Med. Eng. Phys.* 36 (2014) 889–895.
546 <https://doi.org/10.1016/j.medengphy.2014.03.017>.
- 547 [56] C.C. Lin, T.W. Lu, H.L. Lu, M.Y. Kuo, H.C. Hsu, Effects of soft tissue artifacts on
548 differentiating kinematic differences between natural and replaced knee joints during
549 functional activity, *Gait Posture*. 46 (2016) 154–160.
550 <https://doi.org/10.1016/j.gaitpost.2016.03.006>.
- 551 [57] G. Cooper, I. Sheret, L. McMillian, K. Siliverdis, N. Sha, D. Hodgins, L. Kenney, D.
552 Howard, Inertial sensor-based knee flexion/extension angle estimation, *J. Biomech.* 42
553 (2009) 2678–2685. <https://doi.org/10.1016/j.jbiomech.2009.08.004>.
- 554 [58] X. Robert-Lachaine, G. Parent, A. Fuentes, N. Hagemeister, R. Aissaoui, Inertial motion
555 capture validation of 3D knee kinematics at various gait speed on the treadmill with a
556 double-pose calibration, *Gait Posture*. 77 (2020) 132–137.
557 <https://doi.org/10.1016/j.gaitpost.2020.01.029>.
- 558 [59] K. Manal, I. McClay, S. Stanhope, J. Richards, B. Galinat, Comparison of surface
559 mounted markers and attachment methods in estimating tibial rotations during walking:
560 an in vivo study, 2000. [https://doi.org/10.1016/S0966-6362\(99\)00042-9](https://doi.org/10.1016/S0966-6362(99)00042-9).
- 561 [60] G. Maderbacher, A. Keshmiri, H.R. Springorum, H. Maderbacher, J. Grifka, C. Baier,
562 Influence of Component Rotation in Total Knee Arthroplasty on Tibiofemoral
563 Kinematics—A Cadaveric Investigation, *J. Arthroplasty*. 32 (2017) 2869–2877.
564 <https://doi.org/10.1016/j.arth.2017.03.055>.
- 565 [61] O. Schectman, *Methods of Clinical Epidemiology*, *Methods Clin. Epidemiol.* (2013) 33–
566 49. <https://doi.org/10.1007/978-3-642-37131-8>.
- 567 [62] P.Z. Du, K.L. Markolf, D. V Boguszewski, K.T. Yamaguchi, C.J. Lama, D.R. Mcallister,
568 K.J. Jones, Effects of Proud Large Osteochondral Plugs on Contact Forces and Knee

569 Kinematics A Robotic Study, (2018) 1–6. <https://doi.org/10.1177/0363546518770415>.

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