



Noninvasive navigated assessment of the lower limb axis prior to knee arthroplasty: a feasibility study

Jean-Yves Jenny^{1,2} · Gauthier Dillmann¹ · Vincent Gisonni¹ · Henri Favreau¹

Received: 19 October 2018 / Accepted: 7 January 2019 / Published online: 10 January 2019
© Springer-Verlag France SAS, part of Springer Nature 2019

Abstract

The purpose of the study was to assess accuracy and repeatability of a noninvasive navigated (NIN) measurement of the lower limb axes by comparison with the conventional, invasive navigated (IN) technique. The tested hypothesis was that NIN measure will significantly differ from IN measure when performed on a supine patient under general anesthesia just prior to knee arthroplasty. The accuracy study involved 20 cases. The following measures were performed with both systems: maximal extension angle, coronal mechanical femoro-tibial angle at the previously assessed maximal extension angle, coronal mechanical femoro-tibial angle at 30° of knee flexion. NIN and IN measures were compared with the appropriate statistical tests. The repeatability study involved 14 cases. The same measures were performed with the NIN system twice by two independent observers. The intra- and inter-observer variability was assessed by the calculation of the intra-class correlation coefficient. After correction for the systematic biases, the differences between the two systems were not significant. A good correlation, a good coherence and an excellent agreement between NIN and IN measures of maximal extension angle and coronal femoro-tibial mechanical angle at maximal extension. But measures at 30° of flexion were inconsistent. The NIN system can be considered as an accurate and precise tool for the assessment of the knee extension angle and the coronal deformation at maximal extension prior to knee arthroplasty. But this system is less accurate and less repeatable when measuring coronal femoro-tibial mechanical angle at 30° of flexion and should not be used for this purpose.

Keywords Lower limb axis · Assessment · Navigation · Noninvasive

Introduction

Coronal deformation of the lower limb is a significant factor for progression of osteoarthritis [1]. Assessment of the lower limb axis is a routine procedure for several orthopedic procedures used to address knee osteoarthritis, such as high tibia osteotomy [2], unicompartmental (UKA) or total knee arthroplasty (TKA) [3]. There is unfortunately no accepted gold standard for this measurement. CT scan may be the most accurate technique [4], but is not routinely performed in a standard clinical setting. Assessment on long-leg X-rays is recommended in clinical practice [5], but it involves several biases, especially because of the inconsistent flexion and

rotational positioning of the leg when X-rays are taken [6, 7]. Navigated techniques are considered to be accurate and precise [8–10], but most of the systems used involve direct fixation of arrays to the bone (Fig. 1), making this technique invasive and dedicated to operating room only [9, 11].

A noninvasive navigated (NIN) technique has been developed to assess the lower limb axes prior to TKA, replacing the conventional invasive array fixation by a noninvasive one [12]. The purpose of the current study was to assess accuracy and repeatability of this technique by comparison with the conventional, invasive navigated (IN) measurement technique. The tested hypothesis was that NIN measure of the lower limb axes will significantly differ from IN measure when performed on a supine patient under general anesthesia just prior to TKA. The secondary goal was to assess the intra- and inter-observer repeatability of the NIN system.

✉ Jean-Yves Jenny
jean-yves.jenny@chru-strasbourg.fr

¹ Centre de Chirurgie Orthopédique et de la Main, Hôpitaux Universitaires de Strasbourg, 10 Avenue Baumann, 67400 Illkirch-Graffenstaden, France

² Université de Strasbourg, Strasbourg, France



Fig. 1 Invasive tracker fixation



Fig. 2 Noninvasive tracker fixation

Materials and methods

Prior to starting the study, acceptance from the institutional review board was obtained. All procedures performed were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. No calculation of the sample size was made prior to the study, as it was designed as a feasibility study only.

All patients scheduled for UKA or TKA from May 2015 to June 2015 were eligible for the study. Inclusion criteria were:

- an end-stage knee osteoarthritis scheduled for primary unilateral or bilateral UKA or TKA,
- intra-operative assistance of the navigation system routinely used at the institution during surgery,
- availability of the resident performing the study.

Exclusion criteria were:

- a previous surgery on the same knee (excepting knee arthroscopy),
- unavailability of the noninvasive navigated system,
- a revision arthroplasty.

IN assessment

The OrthoPilot® (Aesculap, Tuttlingen, FRG) navigation system was used. It is a validated navigation system for the assessment of the lower limb axis during TKA [13], which is routinely used for more than 10 years during partial or total knee arthroplasty in the daily practice of the institution. All procedures were performed by a single, high-volume knee surgeon (JYJ) not involved in the development

of either invasive or noninvasive navigated systems. The complete operative technique has been described in detail elsewhere [9]. Briefly, reflecting trackers are fixed by metallic wires to the distal femur and the proximal tibia (Fig. 1), and their three-dimensional position is tracked by an infrared camera (Polaris, Northern Digital, Waterloo, Canada). Data registration involves kinematic registration of hip circumduction and knee flexion and anatomic registration with a navigated stylus of several landmarks of the knee and ankle joints. A dedicated software (OrthoPilot® TKA v5.0, Aesculap, Tuttlingen, FRG) calculates the coronal and sagittal angles between the mechanical axes of the femur and the tibia, which are displayed on a monitor.

NIN assessment

The same hardware was used. However, the trackers were secured to the soft tissue of the thigh and the calf by two industrial straps (542, E&E Accessories, Surbiton, UK) without skin perforation (Fig. 2). Kinematic registration of the hip and knee joints was not modified. Anatomic registration of the ankle joint was not modified. Anatomic registration of the knee joint was performed by transcutaneous palpation, as intra-articular palpation was not possible. Consequently, a modified software was developed from the previous one (Physiopilot® v3.0, Aesculap, Tuttlingen, FRG) to calculate the coronal and sagittal angles between the mechanical axes of the femur and the tibia.

Data collection

Demographic data were recorded prior to surgery: age, gender, body mass index (BMI). Coronal deformation was measured on long-leg standing radiographs as the hip-knee-ankle (HKA) angle [14] and categorized as varus (HKA angle $\leq 180^\circ$) or valgus (HKA angle $> 180^\circ$). Respective diameters of the thigh (15 cm above the knee joint) and of the calf (10 cm below the knee joint) were measured with a measuring tape.

Navigation data registration was performed on the patient supine after general anesthesia by a single observer not involved in surgery (GD). The following measures were performed with the NIN system:

- coronal mechanical femoro-tibial angle at the maximal extension angle without stress (values inferior to 180° denote varus angle);
- coronal mechanical femoro-tibial angle at 30° of knee flexion without stress (values inferior to 180° denote varus angle).

The accuracy study involved the first 20 cases, with one NIN registration followed by one IN registration for each case, both performed by a single observer not involved in surgery (GD). The repeatability study involved the following 14 cases; NIN registration was performed twice by the first observer (VG) and once by the second observer (HF), both not involved in surgery.

Then, the limb was prepared for surgery. The knee was opened and the IN registration was performed. The set of NIN measures was repeated by the same observer with the IN system prior to any bone cut. Finally, the standard navigated TKA was performed by the senior surgeon (JYJ).

Statistical analysis

Descriptive data analysis involved percentage categorization for qualitative items and median-range calculation for numerical items. For the accuracy study, comparison between NIN and IN measures was made with a paired Wilcoxon test. The mean paired difference was calculated; the difference was considered as an outlier if it was $> \pm 3^\circ$, and the equivalence test was performed. Correlation between NIN and IN measures was assessed by the calculation of the Spearman correlation test. Coherence between NIN and IN measures was assessed by the graphic Bland–Altman method with the definition of the systematic bias and subsequent correction of the paired differences. Agreement between NIN and IN measures was assessed by the calculation of the intra-class correlation coefficient (ICC) and its 95% confidence interval (CI). $P < 0.05$ was considered significant. For the repeatability study, intra-observer repeatability of the first observer was assessed by the calculation of the ICC and its 95% CI. Inter-observer repeatability was assessed by comparing the mean value of each item from the first observer to the value of the second observer by the calculation of the ICC and its 95% CI. $P < 0.05$ was considered significant.

Results

Accuracy study

Sixteen patients with 6 UKAs and 14 TKAs have been included after having given their informed consent. There were 5 men (31%) and 11 women (69%) with a median age of 65 years (range 55–90 years). The median body mass index (BMI) was 34.8 kg/m^2 (range $23.0\text{--}48.0 \text{ kg/m}^2$). On preoperative long-leg standing radiographs, 18 knees (90%) had a varus deformation (median 173.0° , range $138^\circ\text{--}177^\circ$), and 2 knees (10%) had a valgus deformation (median 184.5° , range $184^\circ\text{--}185^\circ$). Median thigh diameter was 51.0 cm (range 40–68 cm). Median calf diameter was 40.5 cm (range 31–57 cm).

There was a significant difference between NIN and IN measures of coronal mechanical femoro-tibial angles at maximal extension ($p = 0.01$) and at 30° of flexion ($p = 0.02$). Six differences (30%) at maximal extension and 12 differences (60%) at 30° of flexion were considered as outliers. There was a good correlation between both measures at maximal extension ($\rho = 0.80$, $p < 0.05$) and a weak correlation between both measures at 30° of flexion ($\rho = 0.43$, $p < 0.05$) (Fig. 3). There was a good coherence between both measures at maximal extension ($\rho = -0.05$) with a systematic bias of -1.6° (Fig. 4). There was a good coherence between both measures at 30° of flexion ($\rho = 0.10$) with a systematic bias of -3.1° (Fig. 5). There was an excellent agreement between both measures at maximal extension (ICC = 0.88, CI 0.71–0.95) and a poor agreement between both measures at 30° of flexion (ICC = 0.52, CI 0.11–0.78). After correction

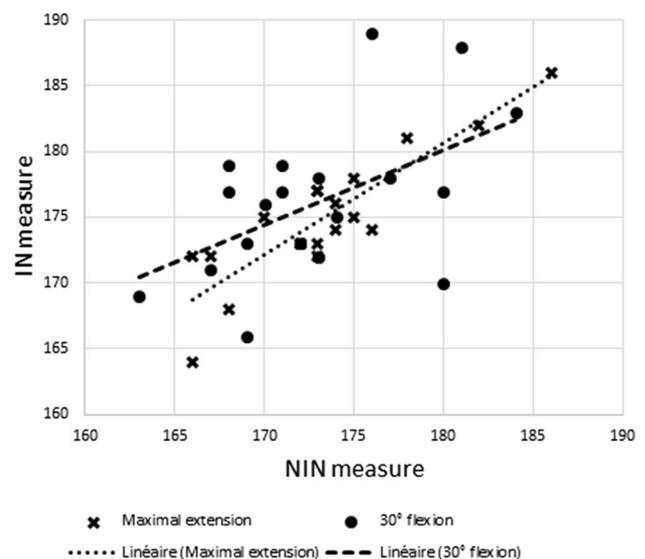


Fig. 3 Correlation between NIN and IN measures (in degrees) of the coronal mechanical femoro-tibial angle at maximal extension

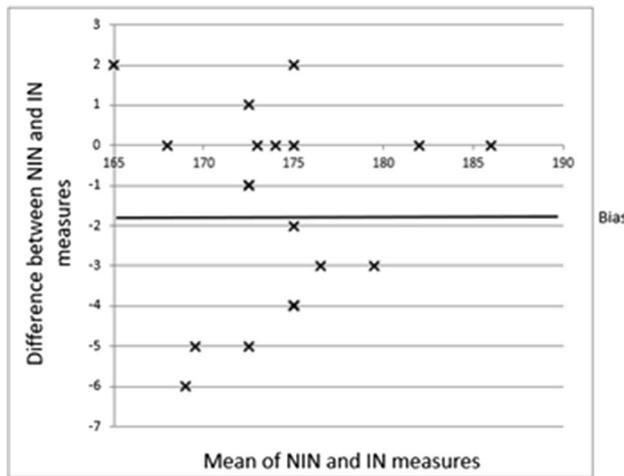


Fig. 4 Bland–Altman analysis of the NIN and IN measures at full extension (in degrees)

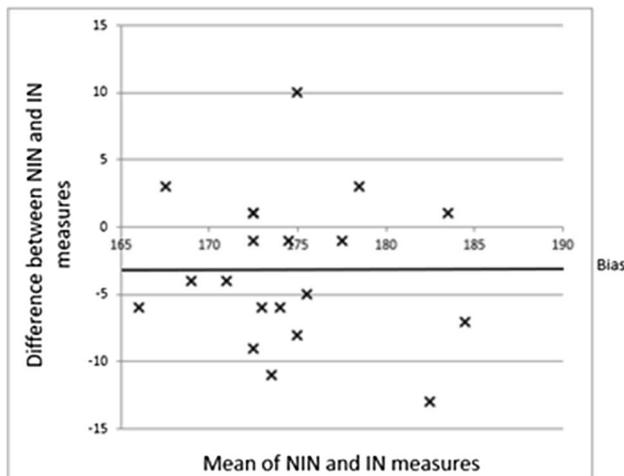


Fig. 5 Bland–Altman analysis of the NIN and IN measures at 30° of flexion (in degrees)

of the systematic bias, the differences were not significant and only five differences at maximal extension (25%) and 11 measures at 30° of flexion (55%) were considered as outliers.

There was no influence of age, gender, BMI, radiographic deformation, thigh diameter or calf diameter and type of arthroplasty on the differences between NIN and IN measures.

Precision study

Thirteen patients with 4 UKAs and 10 TKAs have been included after having given their informed consent. There were 5 men (38%) and 8 women (62%) with a median age of 72 years (range 52–86 years). The median body mass index (BMI) was 28.4 kg/m² (range 20.7–41.0 kg/m²). Twelve

knees (86%) had a varus deformation (median 178.0°, range 172°–180°), and 2 knees (14%) had a valgus deformation (median 187°, range 185°–189°). Median thigh diameter was 50.0 cm (range 41–66 cm). Median calf diameter was 39.5 cm (range 31–55 cm).

Concerning intra-observer repeatability, there was an excellent agreement for the measures of maximal extension angle (ICC = 0.86, CI 0.62–0.95), a good agreement for the measures at maximal extension (ICC = 0.70, CI 0.29–0.89) and a poor agreement for the measures at 30° of flexion (ICC = 0.49, CI 0.00–0.80). Concerning inter-observer repeatability, there was an excellent agreement for measures of maximal extension angle (ICC = 0.79, CI 0.47–0.93), an excellent agreement for measures at maximal extension (ICC = 0.84, CI 0.58–0.95) and a poor agreement for measures at 30° of flexion (ICC = 0.55, CI 0.05–0.83).

Discussion

The main conclusion of the accuracy study was that the NIN measure of the coronal femoro-tibial mechanical alignment is possible with the system used. However, the null hypothesis was rejected. NIN measures differed significantly from IN measures for both items analyzed. However, after correction for the systematic biases, the differences were not significant, and the rate of outliers was acceptable for measures of maximal extension angle and coronal femoro-tibial mechanical angle at maximal extension. Other results were consistent, with good correlation, good coherence and excellent agreement between NIN and IN measures of maximal extension angle and coronal femoro-tibial mechanical angle at maximal extension. But measures at 30° of flexion were inconsistent. Similarly, the repeatability of the NIN system was acceptable for the measures of the knee extension angle and the coronal deformation at maximal extension, but low for the measure of the coronal deformation at 30° of flexion. Consequently, the NIN system can be considered as an accurate and precise tool for the assessment of the knee extension angle and the coronal deformation at maximal extension prior to TKA. But this system is less accurate and less precise when measuring coronal femoro-tibial mechanical angle at 30° of flexion and should not be used for this purpose. One may hypothesize that the main cause of inconsistency may be the soft tissue artifact between the tracker and the bone [15], which may be minimal at maximal extension but increased during knee flexion.

Accurate measure of knee flexion and varus/valgus angles is the critical point when evaluating knee function. These angles may be measured by several techniques. Visual assessment is not accurate for flexion angle and varus/valgus angles [16]. Mechanical goniometers are easy to use and inexpensive, but this technique may involve a significant

lack of precision (up to 20°) and of accuracy (up to 18°) [17, 18]. Radiographic measurement is generally considered as the current reference technique, but besides its well-documented inaccuracy [6], radiation exposure prevents from extensive and repeated use. 3D imaging (CT scan or MRI) is not routine procedures for this purpose. Digital goniometers [19] or gait analysis [20] is still experimental and laboratory devices. The use of a new device derived from gait analysis has been suggested [21], but only few devices are currently available worldwide (company information). NIN technique might represent a good compromise between modern technology, accuracy and convenient use.

The current NIN system has been developed through a cadaver study [22]. Reliability and precision were considered satisfactory up to 40° of knee flexion when measuring antero-posterior translation. Another study from the same team reported a good precision of the NIN system when measuring coronal femoro-tibial mechanical angle up to 40° of flexion [23]. One might postulate that the different behavior of soft tissue between cadaver and living people might lead to different results in a clinical setting. An extensive study reported analysis of 585 TKAs by measuring coronal femoro-tibial mechanical angle at different angles of flexion with the same invasive system used in the current study and showed that this measurement might be relevant, but accuracy and precision were not evaluated [24].

Clinical validation of this system was performed on young, healthy volunteers [12] by measuring coronal femoro-tibial mechanical angle at maximal extension. Precision was considered acceptable, with test–retest variability about 2°. The present study confirmed these results. However, no accuracy validation was reported.

This literature analysis confirmed the results of the present study: The NIN system is accurate and precise for measurement at maximal extension, but measures in flexion should be considered with caution.

There are several limitations to the current study. The unavailability of the noninvasive navigated system prevented to include only one patient throughout the study, and this feature is unlikely to have produced a significant bias. Only few patients were included, resulting in a lack of power, and the results observed may be different from the general population. A more extensive study may have detected subtle differences between NIN and IN measures. However, previous validation studies of this system reported also few cases only [12, 15, 22] and observed small differences which may have little clinical impact. NIN and IN measures were not performed simultaneously. Both general anesthesia and surgical approach of the knee joint may modify the results in comparison with measurements on a native joint by an awake patient. But the NIN fixation device cannot be sterilized, and an intra-operative use is not possible. Invasive trackers are fixed to the bone and can track its position accurately.

The method of fixation of the NIN trackers was not optimal, as it cannot avoid uncontrolled displacement of the tracker with respect to actual bone position [25]. However, the authors were not aware of a more effective noninvasive fixation technique at the time of the study. The measures were performed after general anesthesia: The same process on an awake patient may be modified by muscular activity, and this point should be investigated in a subsequent study.

Despite these limitations, the present study may induce some relevant improvements in the clinical practice. There is a definite need for accurate and precise measures of leg alignment for arthritic patients, especially when a TKA is considered. The appropriate type of implant and the need for ligamentous releases may be detected prior to surgery when analyzing deformities. NIN systems may help the surgeon to address these points at least as accurately as with the conventional radiographic techniques without exposure. But validation of the NIN system used was only performed experimentally, and the present study is the first step of clinical validation.

Conclusion

The NIN system used was validated as an accurate and precise measurement tool for assessing lower limb axes and knee flexion angle at maximal extension by a supine patient under general anesthesia. Measurements at 30° of flexion in the same conditions may be less accurate and less precise. The possibility of using this system on awake and standing patients without the loss of accuracy and precision should be further investigated.

Funding Nothing of value has been received for the purpose of this manuscript.

Compliance with ethical standards

Conflict of interest JYJ receives royalties from Aesculap, was a paid consultant for Exactech, is an paid consultant for FH Orthopedics, is member of the Board of CAOS-International, International Society for Technology in Arthroplasty and Société Française de la Hanche et du Genou. GD, VG and HF declare that they have no conflict of interest.

References

1. Brouwer GM, van Tol AW, Bergink AP, Belo JN, Bernsen RM, Reijman M, Pols HA, Bierma-Zeinstra SM (2007) Association between valgus and varus alignment and the development and progression of radiographic osteoarthritis of the knee. *Arthritis Rheum* 56:1204–1211
2. Brinkman JM, Lobenhoffer P, Agneskirchner JD, Staubli AE, Wymenga AB, van Heerwaarden RJ (2008) Osteotomies around the knee: patient selection, stability of fixation and bone healing in high tibial osteotomies. *J Bone Joint Surg Br* 90:1548–1557

3. Zahn RK, Fussi J, von Roth P, Perka CF, Hommel H (2016) Post-operative increased loading leads to an alteration in the radiological mechanical axis after total knee arthroplasty. *J Arthroplasty* 31:1803–1807
4. Boonen B, Kerens B, Schotanus MG, Emans P, Jong B, Kort NP (2016) Inter-observer reliability of measurements performed on digital long-leg standing radiographs and assessment of validity compared to 3D CT-scan. *Knee* 23:20–24
5. Holme TJ, Henckel J, Hartshorn K, Cobb JP, Hart AJ (2015) Computed tomography scanogram compared to long leg radiograph for determining axial knee alignment. *Acta Orthop* 86:440–443
6. Khare R, Jaramaz B (2016) Accuracy of leg alignment measurements from antero-posterior radiographs. *Biomed Tech (Berl)* 62:315–320
7. Sorin G, Pasquier G, Drumez E, Arnould A, Migaud H, Putman S (2016) Reproducibility of digital measurements of lower limb deformity on plain radiographs and agreement with CT measurements. *Orthop Traumatol Surg Res* 102:423–428
8. Chauhan SK, Clark GW, Lloyd S, Scott RG, Breidahl W, Sikorski JM (2004) Computer-assisted total knee replacement: a controlled cadaver study using a multi-parameter quantitative CT assessment of alignment (the Perth CT Protocol). *J Bone Joint Surg Br* 86:818–823
9. Jenny JY, Boeri C, Picard F, Leitner F (2004) Reproducibility of intra-operative measurement of the mechanical axes of the lower limb during total knee replacement with a non-image-based navigation system. *Comput Aided Surg* 9:161–165
10. Kobayashi H, Akamatsu Y, Kumagai K, Kusayama Y, Aratake M, Saito T (2017) Influence of coronal bowing on the lower alignment and the positioning of component in navigation and conventional total knee arthroplasty. *Orthop Traumatol Surg Res* 103:251–256
11. Desseaux A, Graf P, Dubrana F, Marino R, Clavé A (2016) Radiographic outcomes in the coronal plane with iASSIST™ versus optical navigation for total knee arthroplasty: a preliminary case-control study. *Orthop Traumatol Surg Res* 102:363–368
12. Clarke JV, Riches PE, Picard F, Deakin AH (2012) Non-invasive computer-assisted measurement of knee alignment. *Comput Aided Surg* 17:29–39
13. Jenny JY, Clemens U, Kohler S, Kiefer H, Konermann W, Miehle RK (2005) Consistency of implantation of a total knee arthroplasty with a non-image-based navigation system: a case-control study of 235 cases compared with 235 conventionally implanted prostheses. *J Arthroplasty* 20:832–839
14. Siu D, Cooke TD, Broekhoven LD, Lam M, Fisher B, Saunders G, Challis TW (1991) A standardized technique for lower limb radiography. Practice, applications, and error analysis. *Invest Radiol* 26:71–77
15. Potvin BM, Shourijeh MS, Smale KB, Benoit DL (2017) A practical solution to reduce soft tissue artifact error at the knee using adaptive kinematic constraints. *J Biomech* 62:124–131
16. Shetty GM, Mullaji A, Lingaraju AP, Bhayde S (2011) How accurate are orthopaedic surgeons in visually estimating lower limb alignment? *Acta Orthop Belg* 77:638–643
17. Lavernia C, D'Apuzzo M, Rossi MD, Lee D (2008) Accuracy of knee range of motion assessment after total knee arthroplasty. *J Arthroplasty* 23(Suppl 1):85–91
18. Lenssen AF, van Dam EM, Crijns YH, Verhey M, Geesink RJ, van den Brandt PA, de Bie RA (2007) Reproducibility of goniometric measurement of the knee in the in-hospital phase following total knee arthroplasty. *BMC Musculoskelet Disord* 8:83
19. Bennett D, Hanratty B, Thompson N, Beverland D (2009) Measurement of knee joint motion using digital imaging. *Int Orthop* 33:1627–1631
20. Mündermann A, Dyrby CO, Andriacchi TP (2008) A comparison of measuring mechanical axis alignment using three-dimensional position capture with skin markers and radiographic measurements in patients with bilateral medial compartment knee osteoarthritis. *Knee* 15:480–485
21. Lustig S, Magnussen RA, Cheze L, Neyret P (2012) The KneeKG system: a review of the literature. *Knee Surg Sports Traumatol Arthrosc* 20:633–638
22. Russell DF, Deakin AH, Fogg QA, Picard F (2013) Non-invasive, non-radiological quantification of anteroposterior knee joint ligamentous laxity: a study in cadavers. *Bone Joint Res* 2:233–237
23. Russell DF, Deakin AH, Fogg QA, Picard F (2014) Quantitative measurement of lower limb mechanical alignment and coronal knee laxity in early flexion. *Knee* 21:1063–1068
24. Deep K, Picard F, Baines J (2016) Dynamic knee behaviour: does the knee deformity change as it is flexed—an assessment and classification with computer navigation. *Knee Surg Sports Traumatol Arthrosc* 24:3575–3583
25. Sangeux M, Marin F, Charleux F, Dürselen L, Tho MCHB (2006) Quantification of the 3D relative movement of external marker sets vs. bones based on magnetic resonance imaging. *Clin Biomech* 21:984–991