Kinematic and Neuromuscular Deficiencies Phenotypes Associated With Patellofemoral Pain Syndrome : a Cross-sectional Interventional Study Protocol.

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ABSTRACT

Background: The physiopathology of Patellofemoral Pain Syndrome (PFPS) is multifactorial and includes static and dynamic dysfunctions which are still not fully understood. Among the available classifications, a pragmatic classification distinguishes three major clinical phenotypes: PFPS with objective displacement of the patella, PFPS with extra-patellar alignment problems, and PFPS without alignment problems or displacement of the patella. The relationships between the clinical and biomechanical factors involved are still unclear. **Objective**: The primary aim of this study is to describe and compare the 3D knee rotation range of motion specifically associated with each of the three main clinical phenotypes. The secondary aim is to describe and compare neuromuscular postural and proprioceptive deficiencies associated with each of the three phenotypes. **Method**: PHENOPAT is a comparative, non-randomized study. We will use the KneeKG device (EMOVI) to assess 3D knee rotations during gait, EOS Imaging to assess femorotibial alignment and an isokinetic device to measure hip abductor, quadriceps and hamstrings muscle strength and endurance. Unipodal static and dynamic stability will be assessed with the Y test and posturography. We will compare the kinematic deficiencies using a rank comparison or a mean comparison test between groups, according to participant distribution. A multivariate regression model will allow us to explore kinematic parameters associated with each clinical phenotype. **Discussion**: We expect that specific biomechanical factors will be associated with each main clinical phenotype. A better understanding of PFPS should enable more targeted treatment.

Trials registration: NCT05441332 (ClinicalTrials.gov).

KEYWORDS: clinical phenotypes, dynamic deficiencies, patellofemoral pain syndrome, 3D Kinematics assessment.

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Background

Patellofemoral Pain Syndrome (PFPS) is defined as anterior knee pain located behind and/or around the patella. This definition excludes femorotibial (FT) osteoarthritis and peri-articular pathologies [1]. The prevalence of PFPS varies from 4% to 33% with an over-representation in the young, athletic and female populations [2]. PFPS is a pathology with high rates of chronicity and recurrence [3]. Two-thirds of patients still have symptoms one year after their initial diagnosis [4].

The PFPS diagnosis is based on clinical examination and standard imaging. Frontal, lateral and skyline x-rays can be used to rule out the pathology but also to identify contributing factors [5]. There are several PFPS classifications [6] and previous studies defined four clinical phenotypes: PFPS with movement coordination deficits, PFPS with mobility Impairments, PFPS with muscle performance deficiencies, and overuse/overload without other Impairment [6]. Other authors underscore the morphological deficiencies associated to PFPS [7, 8]. Based on these classifications, the current study will focus on three main clinical phenotypes: Phenotype 1: PFPS with objective displacement of the patella; Phenotype 2: PFPS with static and/or dynamic lower limb alignment problems; Phenotype 3: PFPS without alignment problems or objective displacement of the patella.

The physiopathology of PFPS is multifactorial and includes static and dynamic dysfunctions of the hip, knee and foot that have not been fully explained. Indeed, questions remain on the interaction between the clinical and biomechanical aspects of PFPS, and the kinematics and neuromuscular deficiencies associated with the three main clinical phenotypes [9, 10]. Accurate clinical assessment of 3D knee movements is difficult. The KneeKG (EMOVI) is an optical tracking device that uses non-invasive sensors and measures 3D FT rotations in real-time while walking on a conventional treadmill. Several studies have demonstrated the accuracy, reliability, and validity of this device [11, 12]. A study assessing intra and inter-observer reliability showed that both were excellent (ICC values were 0.92, 0.94 and 0.88 for intra-observer agreement and 0.94, 0.92 and 0.89 for inter-observer agreement for knee flexion/extension, abduction/adduction and internal/external tibial rotation, respectively) [13].

A biomechanical study compared data obtained with the KneeKG and with fluroroscopy and found that mean accuracy was 0.4º for abduction/adduction, 2.3º for axial rotation, 2.4 mm for anteroposterior translation, and 1.1 mm for axial translation [14]. The present study will assess the 3D FT rotations of the participants with this device, and also complete kinematic, neuro-muscular, postural, and proprioceptive assessments to improve our understanding of the physiopathology of PFPS. This information will make it possible to reach a more specific diagnosis and identify the best treatment option for each patient.

The primary aim of this study is to describe and compare the kinematic deficiencies (increased or decreased femorotibial 3D rotation angles during stance) specifically associated with each of the three main clinical phenotypes.

The secondary aim is to describe and compare neuromuscular, postural and proprioceptive deficiencies associated with each of the three main clinical phenotypes.

Our primary hypothesis is that there are kinematic deficiencies specifically associated with each of the three PFPS phenotypes. More specifically, we expect that patellar mobility deficiency (Phenotype 1) will be associated with knee flexion or extension deficiency during stance. We also expect that limb alignment anomaly (phenotype 2) will be associated with altered range of motion (ROM) for tibial rotation or increased knee valgus during stance. We do not expect to find any specific kinematic deficiencies in the last group (phenotype 3: without alignment problems or objective displacement of the patella). Finally, we expect that participants categorized as phenotypes 1 and 3 will show quadriceps strength deficits and/or hypoextensibility (quadriceps and hamstrings), while participants categorized as phenotype 2 will show poor motor control (assessed with posturography and the Y test) and a deficit in gluteus medius strength.

Methods

Study design and setting

PHENOPAT is a comparative, non-randomized study. It was developed in the Physical Medicine and Rehabilitation (PMR) department of the ***** Hospital, which is part of **********, an organization that also promotes this study.

Participants

Eligibility The inclusion criteria are based on the medical definition to diagnose PFPS [4, 6, 7].

Inclusion criteria: a) 18 $\leq$ age, $\leq$ 70 years old; b) Diagnosis of patellofemoral pain syndrome with mechanical anterior knee pain lasting more than one month, and rated more than 3/10 on the simple numerical scale when performing at least one of the following activities: climbing/descending stairs, squatting, jumping, jogging, prolonged sitting, crouching; c) social insurance coverage; d) signing the consent form.

Exclusion criteria: a) neurological disorders affecting the lower limbs; b) femorotibial osteoarthritis on x-Ray; c) surgery or trauma to the lower limbs during the past year; d) intra-articular knee injection in the past 2 months; e) cognitive or behavioral disorders; f) participation in another interventional study; g) inability to speak, read and write French, h) patients under guardianship or curatorship; i) patients receiving AME (French state medical aid).

Recruitment Patients will be recruited from the orthopaedic and rheumatology departments, as well as the two PMR departments (tertiary care units) of the *****and ***** hospitals, (*****), and the offices of general practitioners and physiotherapists in private practice at the time of medical consultation . Potential participants in the study will contact the principal investigator who will provide detailed explanations. Within one week to two months, an appointment will be made for enrolment in the study. If the volunteer meets the inclusion criteria, he/she will be asked to sign a written consent after a reflection period. Participants will be excluded from the study if they withdraw their consent to participate, or if they cannot be contacted anymore.

Experimental Protocol

Inclusion and all assessments will take place on the same day, but the assessment can be spread over 2 days according to patient preference. The entire assessment is expected to last approximately 4 hours. Study duration is estimated to be 7 months (corresponding to the duration of the inclusion period). The assessments will be carried out in the Department of Rehabilitation of the Musculoskeletal System and Pathologies of the Spine at ***** Hospital. X-rays will be taken at the Imaging Department of ***** Hospital.

The physician will check the inclusion criteria and will obtain written consent from the patient before collecting sociodemographic and clinical data. The participants will be asked about previous and current treatments including supervised physiotherapy, home based exercise programs, brace use, orthopaedic soles (if available, the type of sole used will be noted), and drug use. The following scores will be collected: pain at rest and during activities using a numeric rating scale (0 — 100; 0: no pain, 100: most severe pain imaginable), patellofemoral specific symptoms using the Anterior Knee Pain Scale (AKPS) (0 — 100; 0: maximal symptoms, 100: no symptoms), and quality of life using the 12-Item Short Form Survey (SF—12) (Physical component summary score 9.95: minimum quality of life, 70.02: maximum quality of life, and mental component summary score: 5.89: minimum quality of life, 71.97: maximum quality of life).

Participants will be classified according to morphological parameters that

are routinely assessed by physicians. The following clinical tests will be completed by the physician to determine the participant's phenotype:
Phenotype 1: PFPS with objective displacement of the patella (positive apprehension test, lateral hypermobility $\geq$ 10 mm, positive J sign).
Phenotype 2: PFPS with static and/or dynamic lower limb alignment problems (genu valgum, recurvatum of the knee, Q angle >15º, lower limb length discrepancy, and excessive pronation of the rear foot).
Phenotype 3: PFPS without alignment problems or objective displacement of the patella (positive eccentric step-down test).
In the event that a participant does not fall into the phenotype 1, 2 or 3 category, we created two additional categories: a combination of phenotypes 1 and 2 and other phenotypes in order to reflect the potential heterogeneity of the PFPS.
EOS imaging of the lower limbs will be used to measure femorotibial alignment, the Q angle (angle between the line from the anterior superior iliac spine (ASIS) to the center of the patella, and the line from the center of the patella to the anterior tibial tuberosity) and lower limb lengths. The EOS system is a low-dose bi-planar X-ray system allowing the simultaneous acquisition of sagittal and coronal X-rays in a standing position [15, 16].
The principal investigator (MC) will perform all the clinical examinations (bilateral assessments).
The tests included in the physical and functional assessments are routinely used in clinical practice to asses PFPS patients [6]. To prepare for this study, the principal investigator (MC) completed multiple training sessions on healthy subjects and patients with various knee pathologies.

Physical examination We will measure hip, knee and ankle ROM, as well as hamstring and calf muscle tightness with a goniometer. We will assess quadriceps tightness with a measuring tape, and we will use Ober's test to measure iliotibial band tightness [17]. Patellar mobility will be assessed with the lateral apprehension test, glide test, lateral tilt test and J sign [6, 17, 18, 19]. The J sign and the apprehension test will be used to classify the participants as positive or not. The glide test will be used to detect lateral hypermobility. We will measure lower limb length, intermalleolar distance and intercondylar distance. We will use the foot posture index and navicular drop test to quantify foot pronation [6, 20].

Functional tests The participants will perform the Y balance test [21], as well as the lateral and the frontal step down tests [17].

Knee 3D kinematic assessment The kinematic assessment will be performed with the KneeKG device (Knee3DTM Software, EMOVI), an optoelectronic device designed for 3D knee movement analysis. It includes a 3D infrared camera (Polaris Spectra, Northern Digital) and three tripod reflectors located on arches above the femoral condyles and medial side of the tibia, on a belt facing the sacrum. Before starting data acquisition, the participant will walk for 5 to 10 minutes on the treadmill, in order to get used to the speed and the equipment and ensure that the sensors are well-attached and can always be detected by the camera. Data acquisition will be done at 60 Hz and will last 1 minute at a comfortable and usual gait speed. The principal investigator trained for one year with EMOVI's engineers to prepare for the study. EMOVI's engineers confirmed that the measurements taken were correct and usable.

Muscle strength and endurance assessment Computerized isokinetic assessments of the hip and knee muscles will be performed on a Humac NORM isokinetic dynamometer (CSMi, Stoughton, MA, Software HUMAC 2009, v.9.7.1). Before the isokinetic test, all subjects will warm up for 5 min on a stationary bicycle or/ and with bodyweight exercises (squats, lounges, steps), according to their preference.
Knee flexion–extension (range 0º-70º) will be assessed seated at 60º.s^{-1} (5 trials) and at 180º.s^{-1} (20 trials) to measure the quadriceps and hamstring muscles' strength and endurance, respectively. Isometric hip abduction (4 trials, 5 s/trial) will be assessed in a side-lying position at 5º of hip abduction. The hip abductor isometric test is simpler to perform and more comfortable for participants than the isokinetic measurement [22]. The participants will have two to five trials in each position to become familiar with the test. The participants will have a 30 s rest period between each assessment. Data will be analyzed without gravity correction. To take into consideration the neuro-muscular fatigue potentially involved with this test, it will be the last one completed by participants.

Myoelectric activity assessment Surface EMG (EMG Zerowire, Aurion) will be used to measure the activation times of the vastus medialis obliquus (VMO) and vastus lateralis (VL) of the quadriceps muscle in a closed muscle chain, while standing up from a chair three times. We will use a 2000 Hz sampling frequency. According to the recommendations for EMG electrode placement [23]: the VMO electrode will be placed 4 cm above the superior border of the patella and 3 cm medially. The VL electrode will be placed 10 cm above the superior border of the patella and 7 cm laterally to the reference line.

Posturography The unipodal stability test will be completed using a posturography platform (Posture Win paired plates, Technoconcept). In agreement with recommendations, the platform will be placed 90 cm from a uniform wall with a vertical marker [24].
The unipodal test will be performed twice, with the eyes opened and the eyes closed, with a 15º lateral hip rotation and one foot at a time (less symptomatic side will be tested first). The participants will be instructed to remain "as still as possible" on a single leg during one trial of 10 s [24, 25]. If a participant is unable to remain on a single leg for 10 s, he/she will be categorized as unable to perform the unipodal test.
For the duration of the assessment, participants can rest as much and as often as needed.

Outcomes

Primary outcome The primary outcome will be the 3D knee rotation ROM measured by KneeKG during stance for all the gait cycles: differences between the three clinical phenotypes in mean valgus/varus thrust (increase in the femorotibial medial/lateral angle), knee flexion/extension ROM and knee tibial medial/lateral rotation ROM will be recorded.

Secondary outcomes Some secondary outcomes will compare biomechanical factors measured by KneeKG between the clinical phenotypes. Namely, the difference in mean: varus/valgus thrust at initial contact, in external tibial rotation ROM during initial contact, internal tibial rotation ROM during loading, minimum and maximum 3D rotations during the entire gait cycle.
Other secondary outcomes:
Neuro-muscular activity: the delay in VMO activation (mean differences in contraction time between VL and VMO measured by EMG), strength and endurance of hip and knee muscles measured with the peak torque (N.m^{-1}) for hip abductors, quadriceps and hamstrings, the total work (N.m^{-1}) for quadriceps and hamstrings and the hamstrings to quadriceps ratio, using the isokinetic device.
Postural stability: unipodal static and dynamic stability will be assessed by the length (cm) and speed of displacement (mm.s^{-1}) of the center of pressure on posturography and the Y test score.
Foot posture: the foot posture in pronation will be assessed using the Navicular Drop test (cm) and the Foot Posture Index (−12, +12; −12: high supination, +12: high pronation).
Knee posture: femorotibial alignment, Q angle and lower limb lengths will be measured using the EOS system.
The clinical assessments used for joint ROM and muscle extensibility are presented in Tables 1 and 2.

Table 1 Clinical assessment of lower limb range of motion

Joint	Movement	Testing position	Goniometer Placement
Hip	Abduction (°)	Supine hip and knee in extension	Axis: Anterior superior iliac spine (ASIS)
	Adduction (°)	Supine hip and knee in extension Opposite hip and knee in flexion	Stationary arm: parallel to a line between the two ASIS Mobile arm: along the femur to the center of the patella.
	Flexion (°)	Supine hip and knee in flexion	Axis: femoral greater trochanter Stationary arm: parallel to the trunk Mobile arm: parallel with longitudinal axis of the femur in line with the lateral femoral condyle.
	Extension (°)	Supine hip and knee in extension Opposite hip and knee in extension at the beginning and in flexion at the end	Axis: femoral greater trochanter Stationary arm: to ASIS Mobile arm: parallel with longitudinal axis of the femur in line with the lateral femoral condyle Final angle is the difference between the initial and final angles (movement from the opposite hip)
	Medial/lateral rotation (°)	Supine: hip and knee in 90° flexion.	Axis: ASIS Stationary arm: parallel to a line between the two ASIS Mobile arm: along the tibia to the center of the tibiofibular joint
Knee	Flexion/ extension (°)	Supine	Axis: lateral epicondyle of the femur Stationary arm: along the femur to the greater trochanter Mobile arm: along the fibula to lateral malleolus
	Medial/lateral rotation (°)	Seated: hip and knee in 90° flexion	Foot on a sheet of paper with a protractor printed out on it.
Foot	Extension (°)	Supine	Axis: Lateral malleolus Stationary arm: Parallel to fibula Mobile arm: Parallel to 5th metatarsal
	Flexion (°)	Standing, in front of a wall. Front knee is in flexion. The front ankle is measured.	Axis: Lateral malleolus Stationary arm: Parallel to fibula Mobile arm: Parallel to 5th metatarsal

Knee function: knee function will be assessed with the Y test (% of the length of the lower limb), the frontal (qualitative pain assessment during movement) and lateral step-down tests (0−6, 0 and 1: good quality movement, 2 and 3: average quality movement, and 4 to 6: poor quality movement).
Some parameters will be collected without comparative analysis: pain (NS), knee function (AKPS), quality of life (SF−12), muscle hypoextensibility of the main muscles of the hip, knee and ankle using a goniometer (degrees) and a measuring tape (centimeters).

Sample size calculation The FT biomechanical deficiencies between patients with different PFPS phenotypes have never been compared, making it problematic to accurately determine the sample size. Based on recent studies comparing 3D FT kinematics between asymptomatic and OA knees with the KneeKG device [26], and a literature review on biomechanical femorotibial parameters during gait in PFPS participants [10], an estimated sample size of 15 participants per group (45 participants in total) seems appropriate.

Statistical analysis

Statistical analyses will be performed in the Clinical Research Unit Paris Descartes Cochin/Necker using SAS software version 9.4 or R version 4.0.3.
All tests will be bilateral with p=5%. No interim analysis is planned and all statistical methods used will be described in the statistical analysis plan before data analyses.

Data description Continuous data will be presented as means (standard deviations), medians and ranges, while categorical data will be presented as counts and percentages.

Primary and secondary endpoint analyses Depending on the normal distribution of the quantitative variables of interest and the homogeneity of the samples, data will be compared using a rank comparison test (Wilcoxon test) or a mean comparison test between two groups (Student's t-test for independent samples) or between three or more groups (Kruskal-Wallis or ANOVA tests) according to participant distribution between groups. A multivariate regression model will allow us to explore kinematic parameters associated with each clinical phenotype, with and without adjusting for confounding factors (sex, duration of symptoms etc.).

Table 2 Clinical assessment of lower limb muscle extensibility

Muscle	Testing position	Goniometer Placement
Quadriceps (cm)	Prone position. Knee passively goes to maximal flexion	Heel to buttock measurement
Hamstrings (°)	Supine: Hip flexed and 90°, the knee goes to its maximal passive extension	Axis: lateral epicondyle of the femur Stationary arm: along the femur to the greater trochanter Mobile arm: along the fibula to lateral malleolus
Calves (°)	Standing, in weight-bearing lunge position in front of a wall. The rear leg is measured in full extension.	Axis: Lateral malleolus Stationary arm: Parallel to the ground Mobile arm: Parallel to the fibula

Discussion

This observational study aims to shed new light on PFPS. The results of this study will improve our knowledge and understanding of kinematic, neuromuscular and postural deficiencies in people with PFPS. Specifically, it will explore the associations between clinical presentation and the biomechanical factors at work in PFPS. In this way, this study will assess if a pragmatic clinical classification is representative of different biomechanical profiles and how PFPS participants are distributed between the three clinical phenotypes. This, in turn, will shed light on whether other phenotypes need to be described and if a different classification system is required. The data collected will also be useful to identify which assessments are essential to determine the PFPS phenotype and which are unnecessary and redundant. In the longer term, better phenotyping will contribute to the design of more personalized rehabilitation programs for people with PFPS.

Statement and declaration

Acknowledgments

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Data availability statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Competing Interests

The authors declare they have no conflicting interests with the content of the article.

Ethics

The authors declare they have no conflicting interests with the content of the article. The study complies with the guidelines of the Declaration of Helsinki. The protocol of the study was approved by our institutional review board (CPP EST-3, n°21-12-03). Any substantial modification to the protocol will be sent to the Committee for approval prior to its implementation. The study will be carried out in accordance with French (modified Data Protection Act) and European regulations (General Data Protection Regulations – GDPR), and follows the MR-001 reference methodology.

Trial Status

The trial is currently in the recruitment phase. We have enrolled 37 out of the 45 targeted participants in the study and collected their data.

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