

Protocol

Title

Does Correction of Pronated Foot Posture Alter Patellofemoral Alignment? A Weight-Bearing Cone Beam CT Proof-of-Concept Study in Individuals with Flexible Flatfoot

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List of Abbreviations

PFPS, Patellofemoral Pain Syndrome
CBCT, Cone-Beam Computed Tomography
MRI, Magnetic Resonance Imaging
FPI, Foot Posture Index
BMI, Body Mass Index
PAO, patellar articular overlap
TT–TG, Tibial Tuberosity–Trochlear Groove
LTI, Lateral Trochlear Inclination
SD, Standard Deviation
IQR, Interquartile Range
CI, Confidence Interval
DLP, Dose-Length Product
GDPR, General Data Protection Regulation

Background

Patellofemoral pain syndrome (PFPS) is a common knee condition characterized by retro- or peripatellar pain aggravated by loaded knee flexion and associated with reduced function and quality of life.^{1–3}

The etiology of PFPS is multifactorial. A frequently proposed mechanism involves altered patellofemoral alignment, including lateral patellar displacement and tilt. Excessive internal rotation of the tibia and femur may reorient the extensor mechanism and thereby increase lateral patellofemoral joint loading.^{1,4–6}

Foot posture has been suggested as a distal contributor to this proximal rotational alignment. Increased foot pronation has been associated with greater internal rotation of the tibia and femur, indicating a biomechanical coupling along the lower-limb kinetic chain.^{5,7–10} Several observational studies have reported associations between pronated foot posture and PFPS, although these studies did not directly assess whether distal foot posture alters proximal patellofemoral alignment under load.^{2,6,11–14}

Interventions targeting foot posture, such as foot orthoses and short foot exercises, have demonstrated improvements in pain and function in PFPS.^{15–18} However, it remains unclear whether measurable changes in patellofemoral alignment mediate these effects or primarily reflect distal or neuromuscular adaptations.^{19,20} In a weight-bearing radiographic study, Klingman et al. reported a medial shift of the patella following correction of excessive rearfoot pronation, supporting a mechanical coupling between foot posture and patellofemoral alignment. However, the assessment was limited to two-dimensional imaging.²¹

Weight-bearing cone-beam computed tomography (CBCT) enables high-resolution, three-dimensional assessment of skeletal alignment under physiological load and allows simultaneous evaluation of foot posture and patellofemoral alignment.^{22,23} CBCT measures of foot posture correlate strongly with the Foot Posture Index (FPI),²⁴ and the modality is increasingly used in patellofemoral research.²²

To isolate the mechanical coupling between distal foot posture and proximal patellofemoral alignment, this proof-of-concept study recruits individuals with pronounced, flexible flatfoot rather than individuals with symptomatic PFPS. Studying an asymptomatic yet structurally responsive foot type reduces confounding from pain-related motor adaptations and maximizes the likelihood of detecting alignment changes induced by controlled foot posture correction. Demonstrating such changes would establish a mechanistic basis and generate preliminary effect-size estimates to guide future studies in symptomatic PFPS populations, including assessment of whether alignment modification translates into clinically meaningful changes in pain and function.

Aim of study

To quantify the immediate within-subject effect of correcting a pronated foot posture on patellofemoral alignment under weight bearing at 0° and 20° knee flexion using CBCT.

Primary endpoints and hypothesis

Primary endpoints are lateral patellar tilt (degrees) and bisect offset (percent). We hypothesize that foot posture correction reduces lateral patellar tilt and bisect offset compared with the natural foot posture condition.

Secondary endpoints and hypotheses

Secondary endpoints are lower-limb axial rotation measures relative to a foot-based reference (femoral, tibial, transmalleolar, and patellar rotation), and CBCT-based foot posture metrics (navicular plantar position and navicular medial displacement). We hypothesize that distal correction is measurable on CBCT and is accompanied by concurrent changes in lower-limb axial rotation.

Methods

Study Design

This is a cross-sectional, within-subject experimental imaging study. No longitudinal follow-up is planned.

Setting

The study will be carried out at the Sports Medicine Center in Frederikshavn, a specialized outpatient facility at North Denmark Regional Hospital in Denmark. The center receives referrals for a wide range of musculoskeletal conditions and has access to advanced imaging modalities, including CBCT. Patient recruitment and data acquisition are expected to take place over 6 months, from June 2026 to November 2026.

Inclusion will take place during the outpatient consultation; imaging examinations will be scheduled separately.

Participants

Participants will be consecutively recruited from consultations at the Sports Medicine Center.

Inclusion criteria

- Age 18–35 years
- Pronated foot posture, defined as a Foot Posture Index (FPI) score of $\geq +6$, including a calcaneal frontal plane position sub-score of $+2$.^{25,26}
 - A trained examiner will assess FPI; inclusion is based on the right foot.
- Flexible flatfoot deformity, defined as restoration of the medial longitudinal arch during lift of the first toe.

Exclusion criteria

- Knee pain during standing or at 20° knee flexion
- Clinical signs of tibiofemoral instability
- Previous knee or foot surgery
- History of patellar dislocation
- Neuromuscular disease
- Pregnancy
- Inability to perform full weight bearing during scans

Recruitment and Informed Consent

Eligible participants will be identified consecutively during routine outpatient consultations at the Sports Medicine Department, regardless of the referral reason. As part of the standard

sports medicine examination, foot posture is routinely assessed. Patients presenting with pronounced flexible flatfoot will be screened for study eligibility according to predefined inclusion and exclusion criteria. All physicians in the department will receive standardized instruction on the screening procedure to ensure consistent identification of potential participants.

If an individual is deemed eligible and expresses interest in participation, both verbal and written information about the study will be provided. The information will focus on the study's aim, procedures, potential risks and inconveniences, radiation exposure, possible side effects, and ethical considerations. Participants will be informed about the possibility of incidental findings on the imaging examinations (including degenerative/inflammatory arthropathy, neoplastic lesions, and crystal arthropathy, etc.), that such findings may have potential health implications and could require further clinical evaluation, and will have the option to decline receiving such information if they so wish. Participants will also be informed about which data will be collected for the study, including contact information, demographic data (age and sex), basic clinical characteristics (e.g. body mass index (BMI), foot posture classification and eligibility criteria), and CBCT imaging data acquired specifically for the study. No information will be obtained from medical records. All data will be processed by authorized personnel for legally required monitoring and quality control.

The information will be provided after the consultation in a quiet, undisturbed setting within the clinic, or on a separate day if preferred by the participant. Participants will be explicitly informed of their right to bring a relative or other support person to the information meeting.

The information will be provided by the primary investigator or by a delegated physician who has received appropriate training. The study will be explained in clear, non-technical language, adapted to the individual's level of understanding, and presented in a neutral manner, without undue influence. Participants will be given ample opportunity to ask questions.

Participants will be encouraged to take sufficient time to consider their participation and will be offered at least 24 hours to decide, unless they feel fully confident in making an immediate decision. Written informed consent will be obtained only after the individual has had adequate time for reflection and to ask questions. No imaging procedures or data collection will take place until written informed consent has been signed.

For participants of childbearing potential, pregnancy status will be assessed by self-report prior to imaging. Participants will be asked whether they are pregnant or suspect pregnancy. If there is any uncertainty, imaging will be postponed, and the participant will be advised to confirm pregnancy status before inclusion. Pregnant individuals will be excluded from participation.

If new information arises during the study, including information regarding risks or incidental findings, the participant will be informed without undue delay.

Participants will be informed of the overall study results, provided that the participant has expressed a wish to receive such information. If the study is prematurely terminated, participants will be informed of the reason for discontinuation.

Use of Medical Records

Eligibility criteria will be assessed solely on participant-provided information during the consultation, while imaging-based criteria will be evaluated exclusively from scans obtained as part of the study; no retrospective use of medical records or prior imaging will be permitted.

Imaging Procedures

CBCT

All participants will undergo 6 standardized weight-bearing CBCT (CurveBeam HiRise, CurveBeam, USA) acquisitions combining three foot postures and two knee flexion angles:

1. Natural foot posture – knees fully extended
2. Barefoot orthotic correction to neutral alignment – knees fully extended
3. Orthotic in neutral running shoe – knees fully extended
4. Natural foot posture – knees flexed to 20°
5. Barefoot orthotic correction to neutral alignment – knees flexed to 20°
6. Orthotic in neutral running shoe – knees flexed to 20°



Figure 1. Weight-bearing CBCT acquisition setup

Participant positioned in the CBCT scanner in a standardized standing posture during image acquisition.

Bilateral scanning is performed to ensure stable and reproducible weight-bearing positioning and standardized alignment of the pelvis and lower limbs during image acquisition. Unilateral positioning may compromise positioning accuracy. Measurements will, however, be performed only on the right leg to ensure standardization.

Scan 1 will include the hip, knee, and foot, with intentional gaps (non-imaged segments) at the mid-femoral and mid-tibial levels to reduce radiation exposure. Scan 2-6 will include the knee and foot, with an intentional gap at the mid-tibial level.

To minimize radiation exposure to radiosensitive organs, shielding of the external genital region will be applied during all CBCT acquisitions using lead-equivalent protective material.

To minimize motion artifacts and the need for repeat scans, participants will be carefully instructed and positioned by trained personnel prior to each acquisition. Standardized positioning, visual fixation, and verification of load distribution will be applied. Participants will be allowed rest between scans to reduce fatigue-related movement. Repeat scans will be avoided whenever possible and will only be performed if image quality is insufficient for analysis.

Detailed Positioning

- Participants stand on the HiRise platform with feet positioned hip-width apart.
- The pelvis is aligned centrally over the feet, with the arms resting lightly on the side rails.
- Participants are instructed to remain still and to look at a wall-mounted target to minimize motion artifacts.
- Passive contact with stabilizing surfaces is maintained without applying active force, thereby minimizing compensatory postural sway.

Foot position

To minimize rotational bias, foot axial rotation is fixed at 10° of external rotation during all scans, thereby avoiding artificial restriction of physiological pronation and tibial internal rotation.²⁷ Participants will be instructed to distribute their body weight evenly between both feet and to maintain equal loading between the forefoot and rearfoot during all image acquisitions. Load symmetry will be verified using pressure plates immediately before each acquisition. A left–right load difference within $\pm 5\%$ of total body weight will be considered acceptable. If the criterion is not met, the participant will be repositioned, and the load distribution reassessed before proceeding.

Foot posture will be standardized according to the following definitions:

- **Natural foot posture**
 - The participant stands in a relaxed bipedal stance without any external correction.
- **Barefoot orthotic correction to neutral alignment**
 - Neutral rearfoot alignment is defined as a calcaneal frontal-plane angle of 0° ($\pm 2^\circ$) relative to the tibial longitudinal axis assessed in standing with knees extended.
 - The angle is defined as the angle between a posterior calcaneal bisection line and a vertical tibial reference line and is measured using standard goniometric techniques.
 - The posterior calcaneal bisection is established by connecting two skin markers placed on the proximal and distal thirds of the posterior calcaneal surface. The tibial reference line is defined by the vertical midline of the distal third of the tibia^{21,28}.
 - Rearfoot correction will be performed using standardized prefabricated orthoses (Bauerfeind) with predefined design characteristics, including a stable heel cup (≥ 25 mm), a uniform thickness of 3.5 mm, and a flat underside to

ensure stable contact during barefoot weight-bearing. Three orthosis configurations will be available, differing in medial longitudinal arch height and degree of lateral calcaneal tilt: (1) 30 mm arch height with 3 mm lateral calcaneal tilt, (2) 35 mm arch height with 4 mm lateral calcaneal tilt, and (3) 40 mm arch height with 5 mm lateral calcaneal tilt. All orthoses will have a neutral forefoot configuration. See figure 2. For each participant, the orthosis that best achieves neutral rearfoot alignment will be selected. See figure 3.

- If a forefoot varus deformity is present and prevents neutral rearfoot alignment, an additional wedge under the first metatarsal will be applied. See figure 4. The use of such wedges will be recorded and applied consistently across all scan conditions for the individual participant.
- The selected orthosis configuration (including any forefoot wedge) will be maintained across all relevant scan conditions. No further adjustments will be made during image acquisition.
- **Orthotic in neutral running shoe**
 - The participants will wear a standardized neutral running shoe (Nike Pegasus) fitted with the same rearfoot posting configuration as used in the barefoot correction condition, thereby maintaining identical rearfoot correction across barefoot and shod conditions.

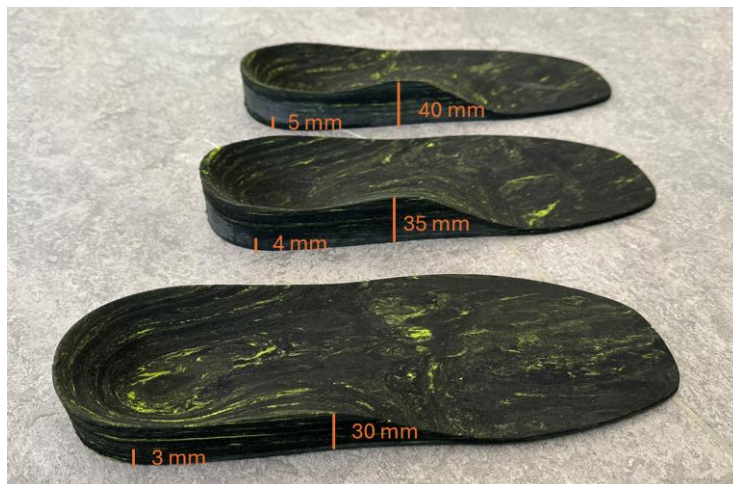


Figure 2. Orthosis design and configurations

Standardized prefabricated orthoses with a stable heel cup (≥ 25 mm), uniform thickness (3.5 mm), and flat underside. Three configurations are shown with increasing medial arch height and lateral calcaneal tilt (30/3 mm, 35/4 mm, 40/5 mm).



Figure 3. Rearfoot correction to neutral alignment

Illustration of rearfoot correction using the orthosis, demonstrating alignment of the calcaneus toward a neutral frontal-plane position relative to the tibial axis.



Figure 4. Forefoot varus compensation

Application of a medial forefoot wedge under the first metatarsal to compensate for forefoot varus and enable neutral rearfoot alignment.

Knee position

Alignment changes are most pronounced between full extension and early flexion; therefore, knee flexion is standardized to 20°. ^{4,22,29,30}

1. Extended knee:

- Knees in full extension without voluntary quadriceps activation, permitting the joint to rest in the passive screw-home locking mechanism.
- Thighs are gently placed on the vertically adjusted Short Spacer.

2. Knee flexed 20 degrees:

- Participants maintain 20° knee flexion, verified using a digital goniometer.
- Symphysis resting passively against a mounted yoga block on the knee plate.
- Knees aligned with the second toe during knee flexion.

Standardized multiplanar reconstruction CBCT

To ensure standardized image planes before measurements, the original image datasets will be aligned according to a predefined image-plane alignment protocol.

For foot measurements, image planes will be standardized using a previously described method.³¹ First, the transversal plane will be aligned with the foot tripod, defined by the lowest point of the calcaneal tubercle and the most caudal aspects of the first and fifth metatarsal heads. Second, the sagittal plane will be adjusted to approximate the long axis of the foot by aligning it to intersect both the center of the third metatarsal head and the lowest point of the calcaneal tubercle. Third, the midpoint of the forefoot will be identified as the halfway distance between the most medial point of the first metatarsal head and the most lateral point of the fifth metatarsal head, after which the sagittal plane will be translated—without altering its orientation—to intersect this midpoint.

For knee measurements, image planes will be standardized using a previously described method.³² First, on the transverse dataset, the slice demonstrating the most posterior contours of both femoral condyles will be identified, and the coronal reference plane will be oriented tangentially to these posterior surfaces to establish a consistent mediolateral alignment. Second, on the coronal dataset, the slice showing the most caudal extent of the femoral condyles will be identified, and the axial reference plane will be adjusted to lie tangential to the caudal condylar margins. Third, on the sagittal dataset, the femoral longitudinal axis will be identified, and the coronal reference plane will be realigned to run parallel with this axis.

For hip measurements, image planes will be standardized using a previously described method.³³ First, the distal femur will be aligned in the transverse dataset by identifying the slice demonstrating the most posterior contours of both femoral condyles, and the axial reference plane will be oriented tangentially to these posterior condylar surfaces to establish a consistent posterior condylar reference. Second, on the sagittal dataset, the femoral longitudinal shaft axis will be identified, and the coronal reference plane will be adjusted to run parallel with this axis to ensure neutral femoral alignment.

Outcomes and Variables

Baseline clinical characteristics and static bone morphology variables will be collected for each participant. Femoral anteversion will be recorded to account for proximal anatomical differences that might affect rotational knee alignment, regardless of foot posture correction. Knee flexion measurements will be taken to confirm the effectiveness of the knee flexion intervention. Alterations in foot posture will be assessed to verify the specific distal alignment adjustments.

The primary outcomes include changes in patellofemoral alignment variables, while secondary outcomes involve other foot–leg alignment change parameters.^{24,34}

Clinical data:

- Contact data (Email, phone)
- Age at inclusion
- Sex
- Body mass index (BMI)
- Baseline foot posture assessed using FPI²⁵
- Baseline calcaneal frontal-plane angle measured in standing

Hip and knee morphology variables:

These variables will be measured only on Scan 1, as they represent static osseous morphology and will not vary across experimental conditions.

- Femoral anteversion:
 - *Femoral anteversion will be defined as the angle between the femoral neck axis and the posterior condylar axis of the distal femur. Positive values will indicate increased anteversion.* ³³
 - *The femoral neck axis will be defined as the line connecting the center of the femoral head and the center of the femoral neck on three-dimensional reconstruction. The posterior condylar axis will be defined as the line tangential to the most posterior aspects of the medial and lateral femoral condyles.*
- Patellar height:
 - *Measured using patellar articular overlap (PAO), defined as the proportion of the patellar articular surface in actual contact with the trochlear groove, expressed as a percentage. PAO was selected because it has been shown to reflect better patellofemoral alignment under weight-bearing conditions than traditional patellar height ratios.* ³⁵
- Lateral trochlear inclination:
 - *Slope of the lateral trochlear facet in relation to the posterior condylar line.*
- Sulcus angle:
 - *Angle formed between the highest points of the medial and lateral trochlear facets and the deepest sulcus point.*

Foot posture and knee flexion variables (intervention-defining):

- Navicular plantar position
 - *The perpendicular distance between the lowest point of the navicular bone and the tripod-adjusted axial plane*
- Navicular medial displacement
 - *The distance from the most medial point of the navicular bone to the adjusted sagittal plane as perpendicular distance.*
- Foot axial rotation
 - *The angle between the adjusted sagittal and the global sagittal plane.*
 - *Positive values indicate external rotation (toe-out), and negative values indicate internal rotation (toe-in).*
- Knee flexion angle:
 - *Angle between the longitudinal axes of the femur and tibia.*

Primary outcomes:

- Lateral patellar tilt:
 - *Angle formed by the transverse axis of the patella relative to the posterior condylar axis of the femur.*
- Bisect offset (mediolateral shift):
 - *The proportion (%) of lateral displacement of the patellar midpoint from the trochlear groove midpoint.*

Secondary outcomes:

- TT–TG distance:
 - *Transverse offset between the tibial tubercle and the trochlear groove center.*
- Transmalleolar rotation (relative to foot axial rotation):
 - *The angle between a line through the malleoli and the foot axial rotation reference.*
- Tibial rotation (relative to foot axial rotation):
 - *The angle between a line tangent to the posterior surface of the proximal tibia and the foot axial rotation reference.*
- Femoral rotation (relative to foot axial rotation):
 - *The angle between a line tangent to the posterior femoral condyles and the foot axial rotation reference.*
- Patellar rotation (relative to foot axial rotation):
 - *Angle formed by the transverse axis of the patella relative to the foot axial rotation reference.*

Positive values indicate external rotation relative to the foot; negative values indicate internal rotation.

Feasibility and acceptability outcomes:

- Perceived comfort of the selected orthosis assessed immediately after completion of the scanning protocol using a 10-point numeric rating scale (NRS), where 1 indicates “not comfortable at all” and 10 indicates “maximally comfortable”

Prior studies inform these measurements; however, a study-specific foot reference plane will be applied in the present protocol. ^{5,30,36,37}

All measurements will be performed using 3D DICOM-compatible software.

Sample size

Klingman et al. reported a mean reduction in lateral patellar displacement of 1.08 mm (SD = 0.52 mm) following subtalar joint posting, corresponding to a large within-subject effect size (Cohen’s $d = 2.08$). ²¹ Based on a paired t-test with $\alpha = 0.05$ and 80% power, a sample size of 5 participants would theoretically be sufficient to detect a change of similar magnitude.

To account for uncertainty in effect size estimates and differences in imaging modality, including the use of three-dimensional weight-bearing CBCT, the planned sample size is set at 10 participants. This fixed sample size is considered sufficient to demonstrate feasibility and detect alignment-related changes in this proof-of-concept study.

Bias and Mitigation Strategies

- **Selection bias:**
 - Mitigated by consecutive recruitment from a single predefined clinical setting using explicit inclusion and exclusion criteria.
- **Measurement bias:**

- Standardized imaging protocols, positioning procedures, and predefined image-plane alignment applied across all participants and scan conditions.
- Participants will be allowed brief unloading between acquisitions to reduce postural fatigue or adaptation effects.
- Predefined anatomical landmarks and axis definitions used for all measurements.
- Intra-rater reliability assessed by re-measurement ≥ 48 hours later with re-randomized image order.
- Rater blinded to previous measurements during repeat assessments.
- **Confounding:**
 - Foot posture and knee flexion are fixed by design.
 - Static morphological variables (e.g., femoral anteversion) will be recorded to account for anatomical variation in sensitivity analyses.

Statistical plan

The study will employ a within-subject experimental design with each participant serving as their own control. The natural foot posture condition will serve as the reference condition.

Primary analysis

Primary analyses will focus on changes in patellofemoral alignment variables (patellofemoral tilt and bisect offset). These outcomes will be analyzed using linear mixed-effects models with subject-specific random intercepts to account for repeated measurements within individuals. Fixed effects will include foot condition (natural foot posture, corrected barefoot posture, orthotic in neutral running shoe), knee flexion angle (0° and 20°), and their interaction.

Pre-specified contrasts will be used to compare:

1. Natural foot posture vs corrected barefoot posture
2. Natural foot posture vs orthotic in neutral running shoe
3. Corrected barefoot posture vs orthotic in neutral running shoe

These contrasts will be evaluated separately at 0° and 20° knee flexion.

Given the proof-of-concept sample size, inference will emphasize effect estimates and 95% confidence intervals.

Secondary and exploratory analyses

Secondary foot–leg alignment outcomes will be analyzed using the same modelling framework but interpreted as exploratory.

Verification of intervention conditions

Changes in foot posture variables (navicular plantar position, navicular medial displacement, foot axial rotation) and knee flexion angle will be analyzed descriptively to verify and quantify the imposed distal alignment conditions across foot and knee-flexion states.

Effect modification analyses

Given the limited sample size, no formal subgroup analyses will be performed. Instead, exploratory effect modification analyses will be conducted using two predefined baseline variables: femoral anteversion (reflecting proximal alignment) and baseline calcaneal frontal-plane angle (reflecting severity of foot pronation).

Each variable will be entered separately into the linear mixed-effects model as an interaction term with foot condition. The variables will not be included simultaneously in the same model to avoid overfitting.

These analyses will explore whether individuals with greater proximal or distal malalignment demonstrate different magnitudes of alignment change following foot posture correction. All results will be interpreted as exploratory.

Distributional assumptions and reporting

Model assumptions will be evaluated using residual diagnostics. If substantial deviations from normality are observed, appropriate data transformation or non-parametric sensitivity analyses will be considered.

Results will be reported as estimated marginal means with 95% confidence intervals. For descriptive purposes, continuous variables will be summarized as mean (standard deviation, SD) or median (interquartile range, IQR), as appropriate. Effect sizes will be reported as standardized mean differences derived from model estimates where applicable.

Risks, Discomforts, and Radiation Safety

Participation in the study involves minimal risk. No invasive procedures, contrast agents, or pharmaceuticals will be used. Temporary discomfort may occur during standing or maintenance of knee flexion during CBCT acquisition; however, all procedures are brief and non-invasive, and participants may rest between scans as needed. Incidental findings unrelated to the study purpose may occur and could require further clinical evaluation.

All scans are performed using the manufacturer's low-dose light-scanning protocol on the CurveBeam HiRise CBCT system. Radiation dose parameters are summarized below.

Scan Series	CTDIvol (mGy)	DLP (mGy·cm)	DAP (dGy·cm²)	K-value (mSv/mGy·cm) ³⁸	Effective Dose (mSv)
Hip	2.75	53.72	33.65	0.00730	0.392
Knee	2.23	43.61	21.34	0.00044	0.019
Foot	1.06	20.52	11.10	0.00023	0.005
Scan 1 (Hip + Knee + Foot)	–	117.85	66.09	Weighted	0.416
Scan 2–6 (Knee + Foot, each)	–	64.13	32.44	Weighted	0.024
Total (All 6 scans)	–	438.50	228.29	Weighted	0.536

Total (Scan 1–6 with-out hip)	–	384.78	194.64	Weighted	0.143
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Table 1: Radiation dose parameters

The estimated effective dose will be approximately 0.42 mSv for Scan 1 (hip–knee–foot) and 0.024 mSv per acquisition for Scans 2–6 (knee–foot), resulting in a total cumulative effective dose of approximately 0.54 mSv. This corresponds to approximately 18% of the average annual background radiation in Denmark (3 mSv/year).³⁸

According to Danish national guidelines for the use of ionizing radiation in health research (Appendix 2)³⁹, the cumulative effective dose of 0.54 mSv places the study within Risk Category IIa (0.1–1 mSv).

Protective measures, including shielding of radiosensitive organs, will be applied.

Data Protection and Management

All processing of personal data in this study will comply with the EU General Data Protection Regulation (GDPR) and the Danish Data Protection Act. The project will be registered in accordance with the internal requirements of the North Denmark Region (Region Nordjylland). It will also be officially registered on ClinicalTrials.gov to ensure transparency and adherence to international research standards.

All study data will be pseudonymized and stored on secure, access-controlled servers provided by the North Denmark Region. A unique study ID will be assigned to each participant, and the key linking ID numbers to personal identifiers will be stored separately with restricted access. Only study personnel with a direct role in data analysis will have access to de-identified data.

No personal data or imaging data will be transferred outside Denmark. All participants will be informed of their rights under GDPR, including the right to access, rectify, and request deletion of their data. Data will be retained for up to 5 years following study completion for analysis, publication, and potential auditing purposes, after which they will be deleted in accordance with regional guidelines.

Ethical Justification

The protocol will be submitted to the Regional Committee on Health Research Ethics in North Denmark for approval before the study begins.

The study involves non-invasive imaging procedures that are standard in clinical practice. The radiation dose from the CBCT protocol falls within the low-dose range for extremity imaging (see Radiation Safety section).

Participants will not be expected to gain direct clinical benefits. However, participants will be allowed to retain the custom-made orthotic insoles used during the study after completion. Currently, it is unclear which individuals, if any, show measurable biomechanical responses

to foot posture correction and might thus benefit from orthotic interventions. The study aims to determine if controlled foot posture correction results in measurable changes in patellofemoral alignment under weight-bearing conditions. The results will help clarify this mechanistic relationship and guide future clinical studies to identify potential responders to orthotic treatment. Due to the low radiation exposure and non-invasive procedures, the radiation risk is considered proportionate to the expected knowledge gain.

CBCT imaging may reveal incidental findings unrelated to the study aim. Such findings may lead to participant anxiety and, in some cases, additional clinical evaluation. All scans will be reviewed by a qualified radiologist. Findings considered potentially clinically relevant will be communicated to the participant and, when appropriate, referral for further evaluation will be arranged according to standard clinical practice. Findings assessed as without clinical relevance will not be routinely reported. Participants will be informed about the possibility of incidental findings during the consent process.

Compensation and Insurance:

No financial compensation will be provided to participants. Participants will, however, be allowed to retain the custom-made orthotic insoles used during the study after completion.

The study is covered by the Danish Patient Compensation Association (Patienterstatningen), which applies to all research activities conducted within public hospitals in Denmark.

Funding and Conflicts of Interest

The study has been initiated by the primary investigator, Mads Kjeldbjerg Hilligsøe, as part of a clinical research initiative at the Sports Medicine Center.

At the time of protocol submission, applications for external funding are ongoing.

The present proof-of-concept study will primarily be supported by existing institutional resources at the Sports Medicine Center, North Denmark Regional Hospital. External funding of approximately DKK 40,000 is being sought to cover study-related expenses, including custom-made orthotic insoles (DKK 35,000) and neutral running shoes (DKK 5,000).

A larger confirmatory study will require external funding, which will be sought based on the results of the present study.

None of the investigators reports financial ties to imaging equipment manufacturers or other commercial interests related to the study.

Perspective

This proof-of-concept study will investigate whether controlled correction of a pronated foot posture induces measurable changes in patellofemoral alignment under weight-bearing conditions. By applying standardized distal alignment manipulation and three-dimensional CBCT assessment, the study aims to isolate the mechanical coupling between foot posture and proximal joint orientation.

If consistent alignment changes are observed, the findings will provide quantitative effect-size estimates and methodological feasibility data to inform future studies in symptomatic PFPS populations. These studies should incorporate dynamic assessments and clinical outcome measures to evaluate whether the observed biomechanical effects persist during movement, translate into clinically meaningful improvements, and identify subgroups of patients more likely to benefit from orthotic interventions.

In addition, the protocol may contribute to the ongoing standardization of weight-bearing CBCT methodology for integrated assessment of foot and knee alignment.

Dissemination of Results

The results of this study will be disseminated regardless of outcome. Findings will be presented as a poster or oral presentation at the Danish Rheumatology Society's Annual Meeting (*Dansk Reumatologisk Selskabs Årsmøde*). Results may also be submitted for publication in relevant peer-reviewed journals. All data will be reported in aggregate form, ensuring that no individual participant can be identified.

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