

Arthrokinematic and Magnetic Resonance Imaging-Based Outcomes of Customized Lateral Wedge Insoles in Medial Compartment Knee Osteoarthritis: Six-Month Interim Findings of a Prospective Cohort Study

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Learning Point of the Article:

In this non-randomized Indian cohort, 6 months of customized lateral wedge insole use was associated with modest medial joint space widening and improved knee kinematics; randomized confirmation with patient-reported outcomes is required.

Abstract

Introduction: Knee osteoarthritis (OA) is a leading musculoskeletal disorder with a prevalence of 22–39% in India, representing approximately one-third of 500 million individuals affected globally. The epidemiological burden increased 2.66-fold from 23.46 million (1990) to 62.35 million (2019). Mechanical axis deviation drives OA progression; finite element analysis (FEA) provides a non-invasive tool to evaluate tissue-level biomechanical changes. Prospective Indian OA cohort studies combining arthrokinematic and magnetic resonance imaging (MRI)-based outcomes are lacking.

Materials and Methods: A non-randomized prospective cohort study – carrying inherent risk of selection bias, confounding by indication, and baseline imbalance – was conducted at AIIMS Rajkot in collaboration with the Saurashtra University after acquiring ethical approval (IEC: AIIMS/RAJKOT/6th IEC/FB/02) and CTIRI registration (CTIRI/2025/02/081105). Fifty-five knees in 45 patients (male knees $n = 19$, female knees $n = 36$; mean age 58.3 ± 10.3 years; body mass index [BMI] 28.2 ± 5.3 kg/m²) with knee OA and mechanical axis deviation were enrolled; and allocation to the customized lateral wedge insole group ($n = 28$) or to conventional conservative management ($n = 27$) was made by the treating orthopaedic surgeon on the basis of mechanical axis deviation severity, without randomization or allocation concealment. Osteokinematic parameters were assessed by calibrated goniometry at 3-month intervals; MRI osteoligamentous metrics (joint space width [JSW], meniscal thickness) were obtained at baseline, 6 and 18 months. This article presents the observations collected at the end of the 1st project year, namely the 6-month MRI follow-up and four 3-monthly biomechanical assessment outcomes. 22 out of 55 participants (40.0%) attended the 6-month MRI assessment and two 3-monthly biomechanical analyses, thereby constituting the complete-case analysis set (11 study group, 11 control group). No imputation was performed, and outcome assessment was not blinded. No validated patient-reported outcome measure was collected. Paired/unpaired t-tests and two-way repeated-measures analysis of variance with Bonferroni correction (Statistical Package for the Social Sciences v16.0; $\alpha = 0.05$); analyses were unadjusted for confounders.

Results: Of the 55 enrolled knees, 22 (40.0%) were successfully followed up at the 6-month assessment, representing substantial attrition of

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60.0% ($n = 33$), and all outcomes below refer to this analysis set ($n = 22$). Knee flexion increased ($+4.4^\circ$; $P = 0.02$) and external rotation showed the greatest gain ($+5.64^\circ$; $P < 0.01$); medial JSW widened ($+0.40$ mm; $P < 0.01$) and medial meniscus thickness increased ($+0.16$ mm; $P = 0.05$). Internal rotation ($+1.56^\circ$; $P = 0.06$) and extension ($+1.56^\circ$; $P = 0.08$) did not reach significance levels. In exploratory, non-prespecified sex-stratified analyses (male knees $n = 10$, female knees $n = 12$), males showed larger gains in internal rotation ($+4.6^\circ$; $P < 0.001$) and external rotation ($+8.3^\circ$; $P < 0.001$), and greater medial JSW widening ($+0.46$ mm; $P < 0.01$) than females ($+0.36$ mm; $P = 0.01$), with a sex $\times$ time interaction of $P = 0.03$. Females maintained higher absolute knee flexion throughout than their male counterparts. These are within-cohort changes over time: The $n = 22$ analysis set comprises 11 study-group and 11 control-group participants, and no between-group comparison of the insole against conventional care was performed. Twelve-month and 18-month outcomes and the FEA are not yet available and are not reported here in this article.

Conclusion: At 6 months, use of a customized lateral wedge insole was associated with widening of the medial tibiofemoral joint space ($+0.40$ mm; $P < 0.01$) and with improved knee kinematics in this Indian cohort. These are associations rather than demonstrated treatment effects, because allocation was not randomized, 60.0% of enrolled participants were lost to follow-up, outcome assessment was unblinded, and no validated patient-reported outcome measure was collected. Their clinical importance also remains undetermined, since changes of this magnitude approach the precision limits of the measurement methods used. The apparent sex differences rest on small, unpowered subgroups and should be regarded as hypothesis-generating. Subject-specific FEA and 12–18-month follow-up are ongoing, but an adequately powered randomized trial with validated patient-reported endpoints will be needed before any disease-modifying effect can be claimed.

Keywords: Knee osteoarthritis, arthrokinematics, finite element analysis, lateral wedge insole, joint space width, mechanical axis deviation, MRI, sex-stratified analysis, India, interim outcomes.

Introduction

Osteoarthritis (OA) of the knee is one of the most prevalent and debilitating musculoskeletal disorders worldwide. The prevalence in India ranges from 22% to 39%, with Indians accounting for approximately one-third of the estimated 500 million individuals affected globally [1]. The epidemiological burden has escalated significantly: The number of affected individuals in India increased 2.66-fold from 23.46 million in 1990 to 62.35 million in 2019 [2]. Total knee replacement remains the most widely practiced elective surgical procedure for advanced knee OA [3], but carries inherent surgical risks, high costs, and prolonged rehabilitation, making identification of effective conservative strategies a public health priority.

Among the biomechanical factors implicated in OA progression, alterations in the mechanical axis of the lower limb are well-recognized. The mechanical axis runs from the center of the femoral head to the center of the ankle joint, passing through or near the center of the knee. In varus malalignment, the predominant deformity in medial compartment knee OA, this axis deviates medially, concentrating compressive forces on the medial tibiofemoral compartment and accelerating cartilage degradation, subchondral bone remodeling, and ligamentous laxity [4]. Yang et al. demonstrated that frontal plane tibiofemoral angle significantly influences stress and strain at the knee cartilage during the stance phase of gait [5].

Finite element analysis (FEA) is a computational, non-invasive method employing physics-based geometrical equations to simulate tissue mechanics, stress distributions, strain patterns, contact pressures, and deformation within bones, cartilages, menisci, and ligaments [6]. Such models have been extensively applied to knee joint biomechanics, implant design, disease progression prediction, and rehabilitation planning [7].

Naghibi et al. demonstrated that non-anatomical positioning of a meniscus prosthesis significantly alters predicted knee biomechanics [8]. Paz et al. and Yan et al. identified key directions for FEA advancement, including automation of geometry generation and integration with artificial intelligence [9,10].

Despite the demonstrated global value of FEA, prospective cohort studies assessing biomechanical adaptation of the osteoarthritic knee to mechanical axis correction in the Indian population are conspicuously absent. India's unique anthropometric profile, floor-sitting postures, and socioeconomic preference for conservative management make population-specific studies urgently needed [5]. The present study addresses this gap through a formal inter-institutional collaboration (All India Institute of Medical Sciences [AIIMS] Rajkot–Saurashtra University MoU, signed September 17, 2024), integrating arthrokinematic and magnetic resonance imaging (MRI)-based outcome measures as primary endpoints, with subject-specific FEA underway to provide tissue-level corroboration. Herein we report the observations available at the end of the 1st year of this ongoing prospective cohort study, which comprise the 6-month follow-up outcomes among 22 of 55 enrolled participants who attended the 6-month assessment. Because allocation was not randomized and outcome assessment was not blinded, this article is of descriptive and exploratory nature and is not intended to establish a causal effect of the intervention.

Materials and Methods

Study design and setting

This was a prospective cohort study conducted at the



Departments of Anatomy, Orthopaedics, and Radiology, AIIMS Rajkot, Gujarat, India, in collaboration with the Department of Physics, Saurashtra University, Rajkot. The inter-institutional collaboration was formalized through a project-specific Memorandum of Understanding (MoU) signed on September 17th, 2024, between AIIMS Rajkot and Saurashtra University, defining institutional roles, data sharing protocols, FEA responsibilities, and publication obligations. We used the STROBE 2025 guidelines to draft this manuscript [11,12] and the STROBE checklist when editing, which are provided in Supplement File S1.

The study had a planned duration of 2 years and was approved by the Institutional Ethics Committee (IEC) of AIIMS Rajkot at its 6th IEC Full Board meeting (IEC Approval Number: AIIMS/RAJKOT/6th IEC/FB/02; Date: February 04, 2025) and was prospectively registered with the Clinical Trials Registry-India (CTRI/2025/02/081105; registered February 21, 2025). Funding was sanctioned under Intramural Project No. IM/F/29/2025-26 by the AIIMS Rajkot Research Cell (total budget: Rs. 4,95,000; FY 2025-26: Rs. 3,30,000; FY 2026-27: Rs. 1,65,000; sanction date: March 28, 2025). All procedures were conducted in accordance with the Declaration of Helsinki (2013 revision) and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants [13, 14]. This manuscript presents the observations at the end of the 1st year of the project after two rounds of MRI and six rounds of biomechanical analysis.

Sample size calculation

Sample size was calculated for comparison of two independent proportions, based on prevalence (28.7%) and incidence (5.74%) rates reported by Pal et al. [15], using the Statulator online calculator [16]. With a relative risk of 0.33 and $P_2 = 60\%$, significance level $\alpha = 5\%$, and power 80%, the formula yielded 25 patients per group (50 total). A 10% non-response allowance produced a final target of 55 patients, recruited by simple random sampling from the orthopedics outpatient department (OPD).

$$n = \{Z_{1-\alpha/2} \sqrt{2\bar{p}(1-\bar{p})} + Z_{1-\beta} \sqrt{P_1(1-P_1) + P_2(1-P_2)}\}^2 / (P_1 - P_2)^2$$

Study participants

Inclusion criteria

- Age ≥ 35 years
- Degenerative changes in the knee with any degree of mechanical axis deviation on weight-bearing radiography.

Exclusion criteria

- Age < 35 years or body mass index (BMI) ≥ 40 kg/m² (morbid obesity threshold)
- Any contraindication to MRI (electronic implants, metallic devices, claustrophobia)
- Neurological disorders, systemic inflammatory disorders, muscular dystrophy, or metabolic bone disease affecting bone metabolism
- Soft tissue or bony swelling causing knee misalignment
- Axial or appendicular skeletal deformities
- Conditions requiring surgical intervention at time of enrollment
- Previously operated knee.

Enrollment and dropout

A total of 55 patients were enrolled across 55 knees (27 right and 28 left). Reasons for non-participation documented in the master chart included patient refusal or denial (most common), mobile number not reachable, and one patient death during follow-up. Three participants had pending case record form signatures at data lock. All 55 enrolled patients had baseline MRI and anthropometric data available; complete 6-month kinematic data were available for analysis per the published master chart.

Randomization and allocation

A detailed group-wise baseline comparison of study ($n = 11$) and control ($n = 11$) participants who completed 6-month follow-up reveals no significant differences in age, sex distribution, or BMI between groups at baseline. Baseline range-of-motion measurements (flexion, extension, internal rotation, and external rotation) were similarly distributed between groups, and baseline medial and lateral joint space width (JSW) measurements (available for 8 of the 22 completers with MRI data) show comparable baseline values between groups. The absence of baseline imbalance in measurable variables does not exclude confounding by severity of mechanical axis deviation, which was the allocation criterion but was not quantified at baseline.

Both groups were followed at 3-month intervals across seven time points over 18 months. During follow-up, 33 participants were lost for reasons including refusal of further participation, inability to be contacted, inability to attend the OPD, surgical intervention during the study period, and death of one patient, none of which were attributable to the study intervention. A total of 22 participants completed the first follow-up and were included in the final analysis, with 11 in each group. The

complete participant flow from screening through enrollment, allocation, follow-up, and analysis is presented in Fig. 1. Attrition was therefore high: 33 of 55 enrolled participants (60.0%) did not attend the 6-month assessment, and the 6-month analysis set comprises 22 participants (40.0%; 11 in the study group and 11 in the control group). All 6-month outcomes reported in this manuscript, including those in Tables 1 and 2 and in Figs. 2 and 3, refer to this complete-case analysis set of $n = 22$, and not to the full enrolled cohort of 55; baseline characteristics in Table 3 (Panel B) and Table 4 refer to the 55 enrolled knees, with the available denominator stated for each variable. No imputation was undertaken, and an intention-to-treat analysis was not possible. The risk of attrition bias is substantial; the analyzed sample may not represent the enrolled cohort, and this is stated among the limitations in Section 4.9.

Study groups and interventions

Study group: Lateral wedge insole intervention

The wedge inclination angle was selected according to the degree of mechanical axis deviation (hip-knee-ankle angle) measured on weight-bearing radiography, using a tiered rule: A deviation of $0-3^\circ$ was fitted with a 3 mm lateral wedge, $3-6^\circ$ with a 6 mm lateral wedge, and $6-9^\circ$ with a 9 mm lateral wedge (medial-side thickness tapering symmetrically for the corresponding tier). The insole material was hard ethylene-vinyl acetate or Pediline, with a Shore hardness of 35° Shore A. Insoles were full-length, without a separate arch support or heel cup specified. Insoles were custom-fabricated by an orthotist at the institutional orthotics workshop, based on the patient's foot/shoe size and observed gait cycle; they were fitted into the participant's own closed walking footwear and checked for fit, comfort, and heel seating by the prescribing clinician at the

fitting visit. Insoles were inspected at each 3-monthly visit and replaced when worn; the wedge angle was not modified in any participant during the first 6 months.

Assessment of adherence

Adherence to insole use was assessed by verbal self-report at each 3-monthly visit only. No wear diary, temperature-sensing dosimeter, accelerometer or other objective measure of wear time was used, and adherence was not quantified as hours per day or days per week. The actual dose of intervention received therefore cannot be established, no exposure-response relationship can be examined, and misclassification of adherence is likely. Objective wear-time monitoring will be incorporated into the continuing 18-month phase and into any subsequent randomized study.

Control group: Conventional conservative management

The control group received conventional conservative management comprising physiotherapy (quadriceps strengthening and range-of-motion exercises), knee brace or support belt as clinically indicated, and analgesics or anti-inflammatory medications as required. No lateral wedge insoles were provided to this group. Participants in the study group also remained eligible for physiotherapy, bracing, and analgesic or anti-inflammatory medication as clinically required, so the contrast examined is between

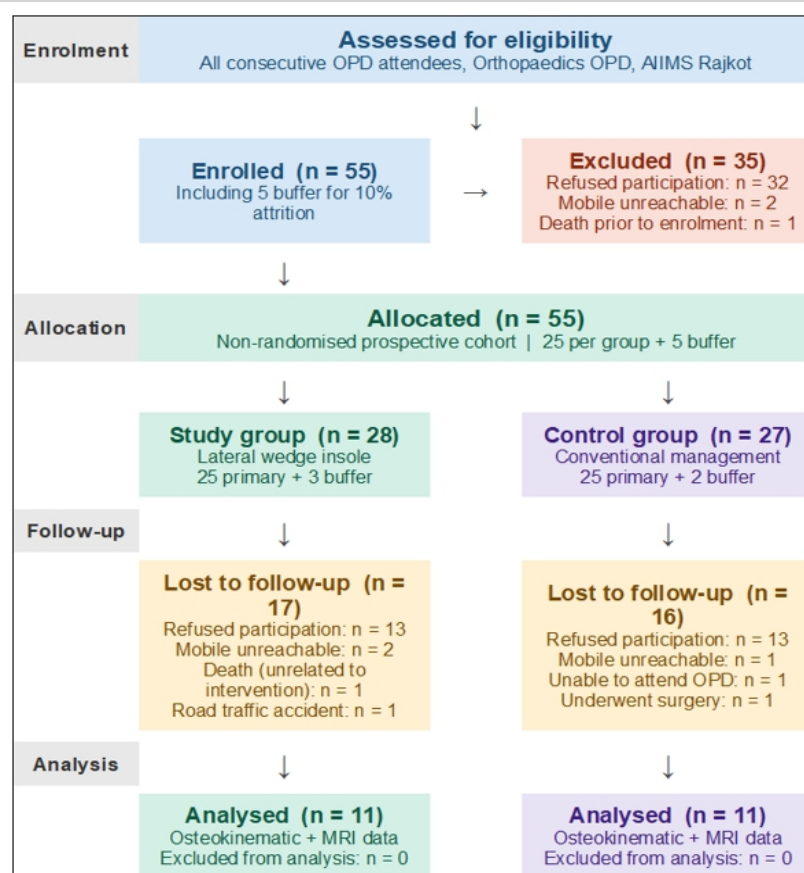


Figure 1: CONSORT-equivalent flow diagram showing participant screening, enrollment, allocation, follow-up, and analysis. OPD: Outpatient department, MRI: Magnetic resonance imaging, IEC: Institutional Ethics Committee, CTRI: Clinical Trials Registry India. Reasons for loss to follow-up (total $n=33$): Refused/denied participation $n=26$; mobile unreachable/incorrect/switched off $n=3$; unable to attend OPD (personal/commuting reasons) $n=4$; underwent surgery $n=2$; death unrelated to intervention $n=1$ patient (2 knee entries). Per-group split of lost-to-follow-up distributed equally (study group $n=17$, control group $n=16$). Source: Master chart Sheet1, AIIMS Rajkot Year-1. IEC approval: AIIMS/RAJKOT/6th IEC/FB/02|CTRI registration: CTRI/2025/02/081105 | Follow-up time points: Baseline, months 3, 6, 9, 12, 15, and 18.

conventional conservative care plus a lateral wedge insole and conventional conservative care alone, not between the insole and no treatment. The intensity, frequency, duration, and adherence of physiotherapy, and the class, dose, and duration of analgesic or anti-inflammatory medication, were not quantified in the case record form for either group. Co-intervention data were recoverable for 27 of the 55 enrolled participants (18 Study, 9 Control) from the master chart. Physiotherapy was reported in 8 of 18 (44%) Study and 4 of 9 (44%) Control participants with data, at a frequency of 1–2 sessions/week and mean attendance adherence of 87.9% (Study) and 88.3% (Control). Analgesic/NSAID use was recorded in 8 of 18 (44%) Study and 4 of 9 (44%) Control participants with data. These co-interventions were broadly balanced between groups where recorded, but data were not available for the remaining 28 participants, so co-intervention bias cannot be fully excluded. Co-intervention bias therefore cannot be excluded and is listed among the limitations in Section 4.9.

Follow-up schedule

Both groups were followed up at 3-month intervals over 18 months across seven time points: baseline and months 3, 6, 9, 12, 15, and 18. Osteokinematic goniometry (knee flexion, extension, internal rotation, and external rotation) was performed at every visit. Anthropometric measurements (height, weight, and BMI) were recorded at baseline only. MRI-based osteoligamentous metrics were obtained at 3 time points, i.e., baseline, 6 months, and 18 months, to capture early and final structural changes. FEA processing was initiated at baseline with MRI data transfer to Saurashtra University, 3D model generation was performed at month 9, and stress/strain analysis was completed at month 18. The assessment schedule is summarized in Table 3. The MRI schedule stated here – baseline, 6 months, and 18 months – is the schedule actually followed and is the schedule shown in Table 3 (Panel A). An earlier version of this manuscript stated a 9-month MRI time point in the text; this was an error and has been corrected throughout. The second (6-month) MRI provides the structural outcomes reported in this manuscript, and the third (18-month) MRI is in progress. Osteokinematic goniometry continues 3-monthly to month 18; the present report is confined to the 6-month kinematic and MRI outcomes, which are the outcomes available at the end of the 1st project year.

Data collection and outcome measures

Osteokinematic assessment

Osteokinematic assessments (knee flexion, extension, internal rotation, and external rotation) were performed using a

calibrated universal goniometer (accuracy $\pm 2^\circ$) by the principal investigator (SHC) at baseline and at every 3-month interval on the affected (index) knee. Measurements followed standardized positions recommended by the American Academy of Orthopaedic Surgeons [17] and were documented in a pre-designed, pilot-tested Case Record Form (CRF) using alphanumeric patient identifiers for de-identification. All goniometric measurements were made by a single assessor (SHC) who was aware of group allocation; measurements were recorded on the affected knee at each visit, but formal intra-observer and inter-observer reliability were not established for this cohort, and no intraclass correlation coefficients (ICCs) were computed. Intra-observer reliability was assessed using duplicate baseline goniometric readings in all 55 enrolled participants (Rater: SHC, same-day repeat). ICC two-way mixed-effects, consistency, single measures were: flexion ICC = 0.997 ($n = 27$), extension ICC = 0.811 ($n = 17$), internal rotation ICC = 0.793 ($n = 6$), external rotation ICC = 0.943 ($n = 5$), indicating excellent reliability for flexion and good-to-excellent reliability for the remaining movements. The universal goniometer has reported inter-tester reliability of ICC 0.85–0.98 for maximum active knee flexion and extension in patients with knee restriction [31], but this external estimate cannot substitute for study-specific reliability testing. Observer and expectation bias in the kinematic outcomes therefore cannot be excluded; duplicate independent blinded assessment with formal reliability testing is planned for the 18-month phase.

Anthropometric assessment

Height was measured using a stadiometer to the nearest 0.1 cm; weight was measured using a calibrated digital scale to the nearest 0.1 kg. BMI was calculated as weight (kg) divided by height squared (m^2) and was recorded at the baseline visit [18].

MRI-based osteoligamentous metrics

MRI was performed on a Siemens Magnetom Vida scanner (field strength 3T) with a Tx/Rx Knee 18 coil. Morphometric measurements of medial and lateral meniscal thickness and JSW were performed by the principal investigator (SHC) using Radiant DICOM viewer software on coronal T1-weighted sequences [19,20].

Patient-reported outcome measures

No validated patient-reported outcome measure of pain, function, or health-related quality of life – for example, the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), the Knee injury and Osteoarthritis

Outcome Score (KOOS), the Oxford Knee Score, or a visual analog or numerical rating scale for pain – was administered during this phase of the project [26, 27]. The outcomes reported are therefore biomechanical and structural surrogates only, and no statement about symptomatic or functional benefit to patients can be made from these data. WOMAC, KOOS and a pain numerical rating scale are being incorporated into the continuing phases of the project and into the protocol of the planned randomized trial.

FEA pipeline

Anonymized MRI DICOM datasets were transferred securely to the Department of Physics, Saurashtra University, in accordance with the MoU. Three-dimensional geometry was reconstructed, and bone, cartilage, menisci, and major ligaments were segmented using ANSYS® software (or equivalent). Subject-specific material properties (Young's modulus, Poisson's ratio) were assigned from published values. Static FEA was performed under standardized stance-phase gait loading conditions to yield stress, strain, density distributions, and contact pressures [21,22,23]. Results were transmitted to AIIMS Rajkot to guide individualized orthotic prescription refinement.

Blinding

Full blinding of participants and treating clinicians was not feasible given the open-label nature of the insole intervention. The radiology faculty (co-investigator) was blinded to kinematic data at the time of radiological measurement. Statistical analysis was performed by the principal investigator, who was aware of group allocations; this represents a limitation. Future iterations of this study will incorporate independent blinded outcome assessment. Specifically, the principal investigator performed all goniometric measurements and the statistical analysis while aware of group allocation, which introduces a risk of observer and expectation bias in every kinematic outcome reported. MRI morphometry was performed on de-identified, alpha-numerically coded datasets without access to kinematic data. All MRI morphometric measurements (meniscal thickness, JSW)

were performed by the principal investigator (SHC) using Radiant DICOM viewer software; this is now stated consistently in the Methods and in the legend to Fig. 4. No independent blinded duplicate outcome assessment was undertaken at any time point.

Statistical analysis

A completer-versus-non-completer sensitivity analysis performed on available baseline data for the 55 enrolled participants revealed no statistically significant differences between the 22 six-month completers and the 33 lost to follow-up in age, sex, BMI, or baseline range-of-motion measurements. This suggests that attrition was not selective on the basis of these measured baseline characteristics. However, baseline severity of knee pain (not quantified in this phase) and baseline mechanical axis deviation (the allocation criterion) remain potential sources of differential attrition bias.

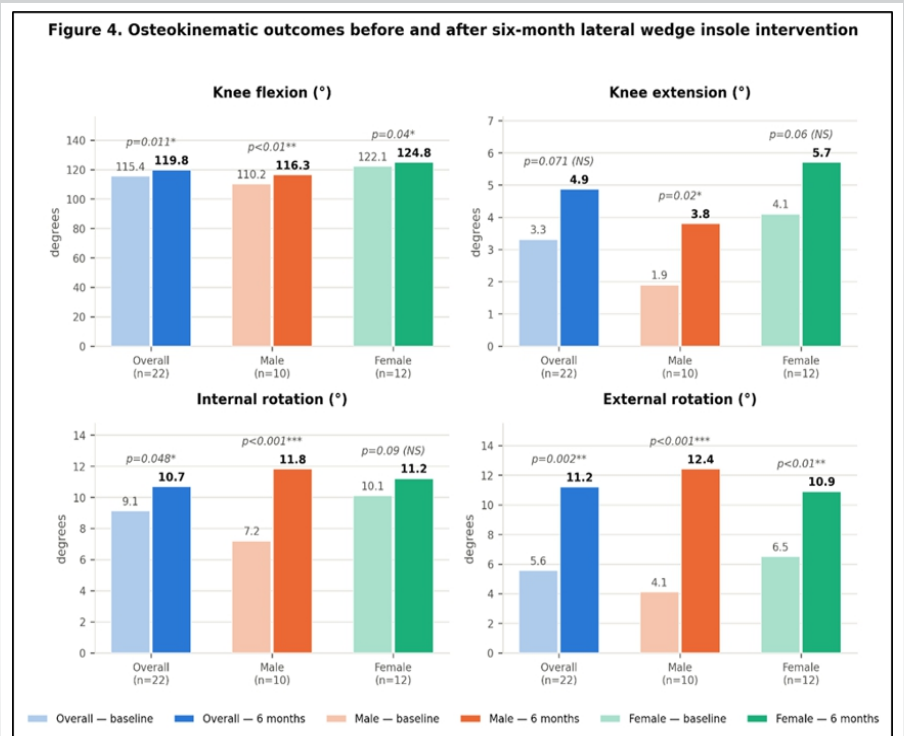


Figure 2: Osteokinematic parameters before and after the 6-month lateral wedge insole intervention, stratified by sex. Mean values for knee flexion, extension, internal rotation, and external rotation are shown at baseline (pre-intervention) and 6 months (post-intervention) for the 6-month analysis set (n = 22), male knees (n = 10), and female knees (n = 12). Paired bars within each group represent pre-intervention (lighter shade) and post-intervention (darker shade) values, respectively. All four movements showed directional improvement. Knee flexion (overall P = 0.02) and external rotation (overall P < 0.01) reached statistical significance in the overall cohort. Male knees showed greater gains in internal rotation (P < 0.001) and external rotation (P < 0.001) than female knees, with sex × time interaction P ≤ 0.04 for all four movements; these sex-stratified comparisons were not prespecified and are exploratory. Females maintained superior baseline and post-intervention knee flexion throughout. Significance was assessed by paired t-test within group and two-way repeated-measures analysis of variance for sex × time interaction. NS: Not significant; *P < 0.05; **P < 0.01; ***P < 0.001 (paired t-test, two-tailed). Data source: Table 1, present study.

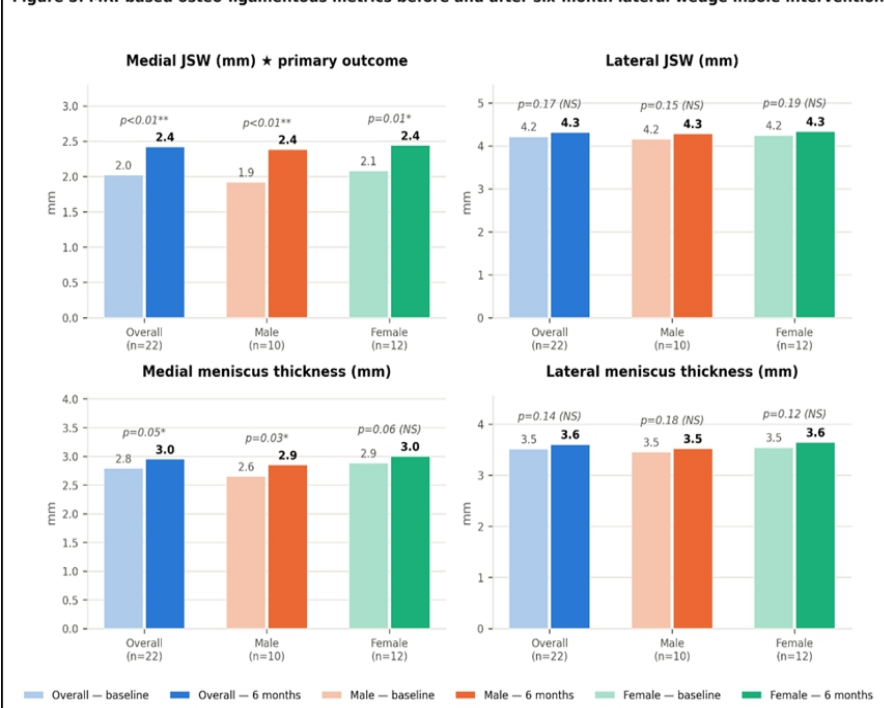
Figure 5. MRI-based osteo-ligamentous metrics before and after six-month lateral wedge insole intervention

Figure 3: MRI-based osteoligamentous metrics before and after the 6-month lateral wedge insole intervention, stratified by sex. Mean MRI-based osteoligamentous measurements are shown at baseline (pre-intervention) and 6 months (post-intervention) for the 6-month analysis set ($n = 22$), male knees ($n = 10$), and female knees ($n = 12$). Paired bars within each group represent pre-intervention (lighter shade) and post-intervention (darker shade) values. The primary outcome variable – medial joint space width (JSW) is highlighted in amber and showed the most clinically significant improvement across all three groups: overall $+0.40$ mm ($P < 0.01$), males $+0.46$ mm ($P < 0.01$), females $+0.36$ mm ($P = 0.01$), with a significant sex $\times$ time interaction ($P = 0.03$). Medial meniscus thickness increased overall ($+0.16$ mm; $P = 0.05$) and in male knees ($P = 0.03$); this change approaches the precision limit of the measurement and is not interpreted as evidence of tissue regeneration. Lateral JSW and lateral meniscus thickness showed non-significant trends, reflecting the selective medial nature of the intervention effect. Significance was assessed by a paired t-test within group. JSW: Joint space width, MRI: Magnetic resonance imaging, NS: Not significant, $^{*}P < 0.05$; $^{**}P < 0.01$ (paired t-test, two-tailed). ★ denotes primary outcome variable. Data source: Table 2, present study.

A total of 55 knees in 45 patients were enrolled and completed baseline assessment: 19 male knees (34.5%) and 36 female knees (65.5%), as detailed in Table 3 (Panel B). Participants were recruited from the orthopedics OPD, AIIMS Rajkot; recruitment was initiated on August 01, 2025, following IEC approval (February 04, 2025) and prospective CTRI registration (February 21, 2025), in accordance with the IEC stipulation. An earlier version of this manuscript stated a recruitment start date of August 2022, which preceded both ethics approval and trial registration; this has been corrected throughout.

The overall mean age was 58.3 ± 10.3 years (range 29–77 years), with male participants somewhat older on average (61.6 ± 11.1 years) than female participants (56.5 ± 9.6 years; $P = 0.08$). Mean BMI was 28.2 ± 5.3 kg/m² (range 18.9–39.8), placing the cohort overall in the overweight-to-class I obese category. Female participants had a higher mean BMI (29.0 ± 6.2 kg/m²) than males (26.7 ± 2.4 kg/m²), though this did not reach statistical significance ($P = 0.13$). The affected side was evenly distributed (right: $n = 27$, 49.1%; left: $n = 28$, 50.9%). By age group, 14 knees (25.5%) belonged to participants aged <50 years, 22 (40.0%) to those aged 50–64 years, and 19 (34.5%) to those aged ≥ 65 years. All participants were

Ethical approval and consent

The study was approved by the IEC of AIIMS Rajkot (IEC Approval Number: AIIMS/RAJKOT/6th IEC/FB/02; Date: February 04, 2025). The IEC reviewed and approved the study protocol, informed consent form, and participant information sheet. Written informed consent was obtained from all participants in English, Hindi, and Gujarati before commencement of the study. Recruitment was commenced only after CTRI registration (CTRI/2025/02/081105), in accordance with the IEC stipulation. All patient data were de-identified by alphanumeric coding prior to analysis.

Results

Participant flow and baseline characteristics

of Hindu religion, and the predominant occupation was business or sedentary work; the cohort is drawn from a single public-sector center in western India and is not claimed to be representative of the wider Indian population. One participant was aged 29 years, below the stated inclusion threshold of 35 years; this protocol deviation is declared here and in the footnote to Table 3. The age, BMI, and age-group values in this paragraph have been corrected in this revision so that they agree exactly with Table 3 (Panel B); the previously reported figures did not match the table.

Baseline demographic and clinical characteristics are presented in Table 3, Panel B.

Baseline osteokinematic measurements by sex are presented in Table 4.

Baseline osteokinematic values (Table 4) showed a mean knee

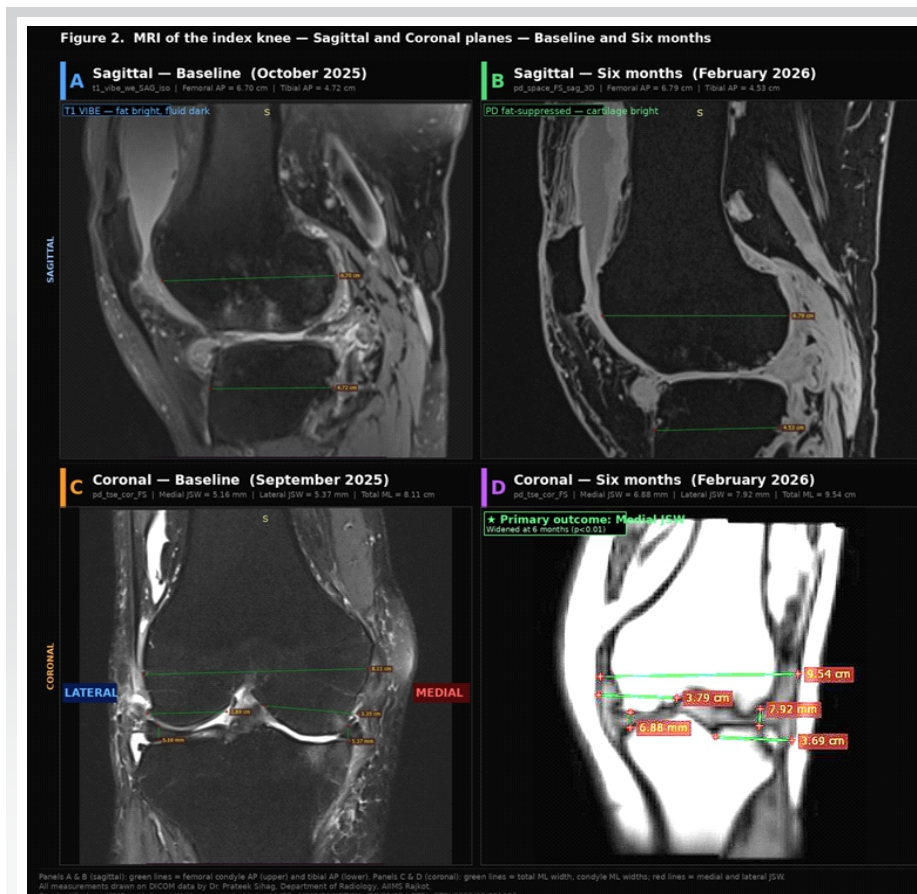


Figure 4: Representative MRI of the index knee at baseline and 6-month follow-up in sagittal (Panels A and B) and coronal (Panels C and D) planes with measurement lines showing morphometric and joint space width parameters. Panel A – Sagittal, baseline (October 2025): T1-weighted VIBE water excitation sagittal MRI (t1_vibe_we_SAG_iso) of the left knee at baseline. Fat is bright, and fluid is dark. Green measurement lines: femoral condyle AP = 6.70 cm (upper line, anterior to posterior condyle margin) and tibial AP = 4.72 cm (lower line, tibial plateau anterior to posterior margin), corresponding to morphometric data in Table 4. Panel B – Sagittal, 6 months (February 2026): Proton density fat-suppressed 3D sagittal MRI (pd_space_FS_sag_3D) of the same knee at 6 months. Fat suppression renders synovial fluid and articular cartilage hyperintense. Femoral condyle AP = 6.79 cm and tibial AP = 4.53 cm. Comparison with Panel A demonstrates improved articular cartilage signal consistency following lateral wedge insole intervention. Panel C – Coronal, baseline (September 2025): PD TSE fat-suppressed coronal MRI (pd_tse_cor_FS; 400 × 360 matrix). Measurement lines show total ML femoral width = 8.11 cm, medial condyle ML = 2.89 cm, lateral condyle ML = 3.35 cm, medial JSW = 5.16 mm, lateral JSW = 5.37 mm. Right knee in standard radiological orientation (R on image left = lateral; L on image right = medial). Lateral and medial compartments labeled for orientation. The illustrative case (participant K001, Study group, 53-year-old female) shows baseline medial JSW of 1.73 mm, which increased to 2.13 mm at 6 months, representing a change of +0.40 mm consistent with the cohort mean change reported in Table 2. Measurement methodology: All measurement lines drawn directly on DICOM data in RadiANT DICOM Viewer by Dr. Prateek Sihag, Department of Radiology, AIIMS Rajkot. All patient-identifying information removed per ICMR National Ethical Guidelines. Written informed consent obtained. IEC: AIIMS/RAJKOT/6th IEC/FB/02. JSW: Joint space width, AP: Antero-posterior, ML: Medio-lateral, MRI: Magnetic resonance imaging, VIBE: Volumetric interpolated breath-hold examination, PD: Proton density, TSE: Turbo spin echo, FS: Fat-suppressed, OA: Osteoarthritis, S: Superior, A: Anterior, P: Posterior, ★: Primary outcome variable.

sexes at baseline. These baseline values are those of the enrolled cohort (45 knees with baseline goniometry) and differ from the baseline values of the 22-participant 6-month analysis set reported in Table 1.

Baseline MRI-based osteoligamentous measurements by sex are presented in Table 4.

Baseline MRI morphometry (Table 4, lower panel) showed mean medial JSW of 2.02 ± 0.3 mm (range 1.2–3.1 mm), consistent with medial compartment narrowing expected in this OA cohort. Condyle dimensions (femoral and tibial AP and ML measurements) did not differ significantly between sexes, except for total medio-lateral femoral width, which was greater in males (72.5 ± 1.5 mm vs. 71.5 ± 1.3 mm in females; $P = 0.03$). Medial and lateral meniscal thickness at baseline were comparable between sexes. These baseline MRI values are those of the 42 enrolled knees with baseline morphometry and differ from the baseline values of the 22-participant 6-month analysis set reported in Table 2. Representative MRI images of the index knee at baseline and 6-month follow-up in sagittal (Panels A and B) and coronal (Panels C and D) planes, demonstrating articular cartilage, meniscal morphology, JSW and AP measurement methodology, and primary structural outcome are shown in Fig. 4. The mechanical axis deviation underpinning the medial compartment OA pattern is illustrated schematically in Fig. 5.

Osteokinematic outcome

Overall cohort – 6-month outcomes

Overall osteokinematic outcomes at 6 months are presented in Table 1.

Table 1 presents osteokinematic measurements at baseline and 6 months

flexion of $120.5 \pm 19.0^\circ$ (range 40–155°), with no significant baseline difference between males ($122.0 \pm 18.4^\circ$) and females ($119.7 \pm 19.5^\circ$; $P = 0.67$). Internal rotation was marginally higher in males ($12.6 \pm 4.1^\circ$ vs. $10.3 \pm 3.6^\circ$ in females; $P = 0.06$). Extension and external rotation were comparable between

for the 6-month analysis set ($n = 22$; 11 study group, 11 control group; 10 male and 12 female knees), not for the full enrolled cohort of 55. The overall rows pool participants from both allocation groups and therefore describe change over time in the combined cohort; they are not a comparison of the insole

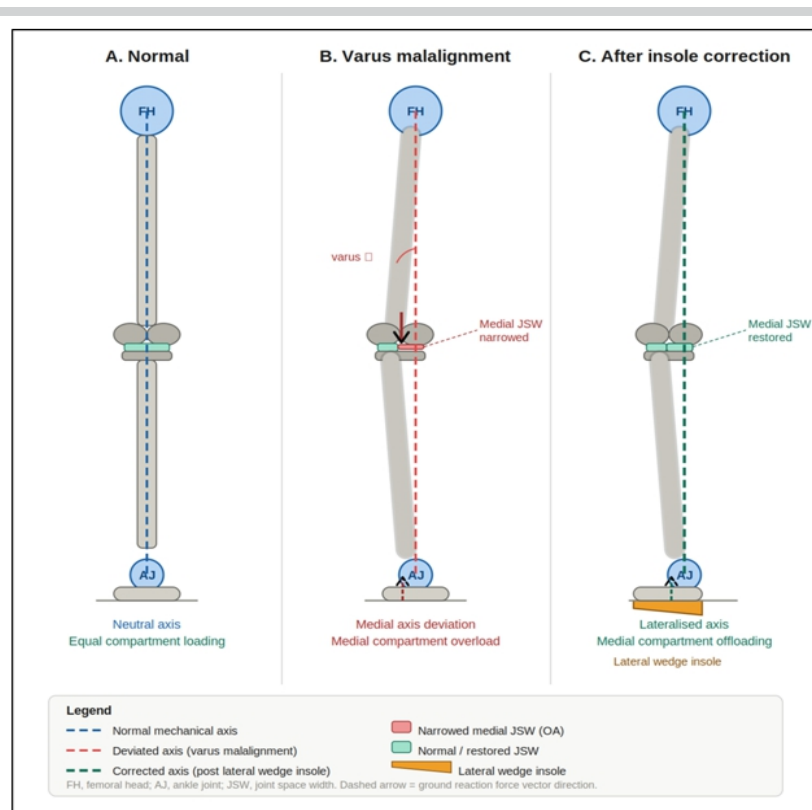


Figure 5: Schematic representation of the lower limb mechanical axis in normal alignment, varus malalignment, and after lateral wedge insole correction. Panel A (Normal): The mechanical axis runs in a straight vertical line from the center of the femoral head through the center of the knee to the center of the ankle joint, distributing compressive forces equally across the medial and lateral tibiofemoral compartments. Panel B (Varus malalignment): Medial deviation of the mechanical axis concentrates the ground reaction force on the medial tibiofemoral compartment, producing progressive medial joint space narrowing, cartilage degradation, and subchondral bone remodeling characteristic of medial compartment knee osteoarthritis. Panel C (After lateral wedge insole): The lateral wedge insole lateralizes the ground reaction force vector, shifting the mechanical axis toward neutral, reducing the knee adduction moment, and offloading the medial compartment – facilitating medial joint space width recovery and osteokinematic improvement as demonstrated in the present study. FH: Femoral head, AJ: Ankle joint center, JSW: Joint space width, GRF: Ground reaction force, OA: Osteoarthritis.

group with the control group. Knee flexion improved significantly from a mean of 115.4° (range 90–140°) to 119.8° (range 90–142°), representing a gain of +4.4° ($t = 2.8$, $P = 0.02$). External rotation demonstrated the greatest absolute improvement, increasing from 5.56° (range 1–9°) to 11.2° (range 5–20°), a gain of +5.64° ($t = 3.5$, $P < 0.01$), consistent with valgus mechanical adaptation. Internal rotation (+1.56°; $P = 0.06$) and extension (+1.56°; $P = 0.08$) showed marginal, non-significant trends. Because these are within-group comparisons in a non-randomized cohort with 60.0% attrition and unblinded assessment, the changes describe the participants who returned at 6 months and cannot be attributed to the insole intervention; their magnitude relative to measurement precision and to accepted minimal clinically important differences is considered in Section 4.8. The pre- and post-

intervention osteokinematic data for the overall cohort and sex-stratified groups are illustrated in Fig. 2.

Sex-stratified osteokinematic outcomes

Sex-stratified osteokinematic outcomes are presented in Table 1.

Table 1 also presents the exploratory, non-prespecified sex-stratified osteokinematic analysis (male knees $n = 10$, female knees $n = 12$). Males achieved significantly greater gains in internal rotation (+4.6°; $P < 0.001$) and external rotation (+8.3°; $P < 0.001$) than females. Females demonstrated higher baseline knee flexion (122.1°) and maintained greater post-intervention flexion (124.8°). Sex $\times$ time interaction effects reached $P \leq 0.04$ for all four movements. These subgroups are small and unequal; the analysis was not prespecified, and eight parameters were examined; the interaction terms are therefore exploratory and hypothesis-generating, and do not confirm a genuine sex-based difference in response.

MRI-based osteoligamentous outcomes

Overall cohort – 6-month outcomes

Table 2 summarizes MRI-derived osteoligamentous metrics at baseline and 6 months in the 6-month analysis set ($n = 22$; 10 male and 12 female knees). As in Table 1, the overall rows pool the study and control participants and are not a between-group comparison. Medial JSW showed the largest absolute change, widening from 2.02 mm (range 1.2–3.1 mm) to 2.42 mm (range 1.6–3.4 mm), a gain of +0.40 mm ($t = 3.8$, $P < 0.01$). Medial meniscus thickness also increased (+0.16 mm; $P = 0.05$). This change is small in absolute terms and lies close to the precision limit of single-slice mid-body meniscal thickness measurement; it is reported here as an observation, and its interpretation is discussed with the appropriate caution in Section 4.3. Lateral JSW and lateral meniscus thickness showed non-significant trends ($P = 0.17$ and $P = 0.14$, respectively), reflecting the predominantly medial nature of the intervention effect. The MRI-derived osteoligamentous metrics before and after intervention are illustrated in Fig. 3. Representative coronal MRI images with JSW measurement methodology are provided in Panels C and D of Fig. 4.

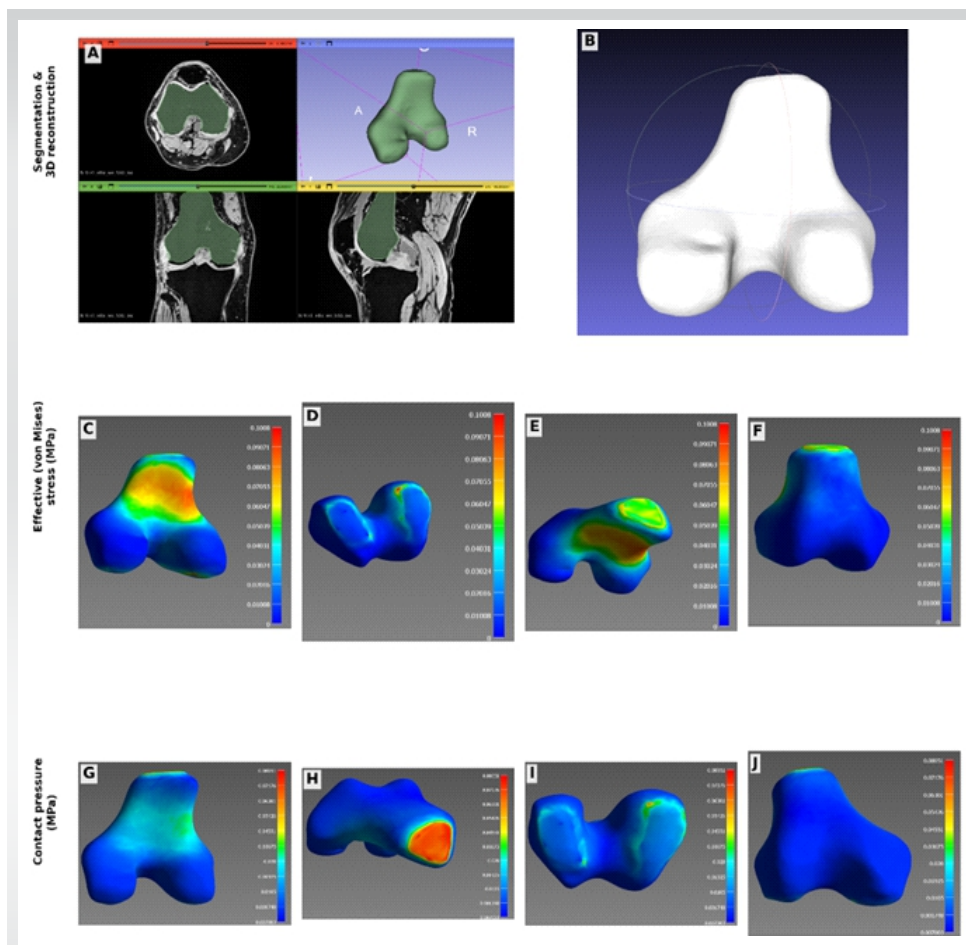


Figure 6: Representative subject-specific finite element analysis model of the distal femur. Representative subject-specific FEA model derived from MRI segmentation of the distal femur in one study participant with knee osteoarthritis. (a) Multi-planar MRI views (axial, coronal, sagittal) with the femoral cartilage/bone segmented (green overlay) and the corresponding 3D surface reconstruction (top right panel). (b) Smoothed 3D rendering of the segmented distal femur used as the geometry for finite element meshing. (c-f) Effective (von Mises) stress distribution, expressed in MPa, shown across four viewing angles of the same femoral model under simulated stance-phase gait loading conditions. (g-j) Corresponding contact pressure distribution (MPa) across the same four viewing angles. In all contour plots, color denotes the local magnitude of stress or pressure, increasing from blue (lowest) to red (highest), as indicated by the color scale adjacent to each panel. This model represents the first cohort of patients with complete baseline MRI datasets; full FEA results across baseline, 9-month, and 18-month time points, including comparison between study and control groups, will be reported in a companion publication. FEA: Finite element analysis, MPa: Megapascal, MRI: Magnetic resonance imaging. Data source: Department of Physics, Saurashtra University finite element analysis pipeline (Section 2.6), present study.

Females showed a trend toward greater lateral meniscus preservation (+0.10 mm vs. +0.07 mm in males), though this did not reach statistical significance.

Twelve- and 18-month longitudinal outcomes (data collection in progress)

Twelve-month and 18-month goniometric data and 18-month MRI data are currently being collected and will be reported in a subsequent publication. No 12-month or 18-month outcome data are presented anywhere in this manuscript; all outcomes reported here are 6-month outcomes in the 22-participant analysis set. Second MRI dates are documented in the master chart for the participants who returned for the 6-month assessment (range: January–March 2026), with third MRI dates not yet entered for the majority, confirming that Phase 3 data collection is ongoing. Preliminary review of the master chart indicates continued enrollment through December 2025, with the most recent entries dated December 31, 2025.

FEA results

Subject-specific FEA is currently being performed at the Department of Physics, Saurashtra University, in accordance with the MoU workflow. Preliminary 3D models have been generated for the first cohort of

patients with complete baseline MRI datasets. Planned reporting includes: (i) medial cartilage contact pressure (MPa) at baseline, 6 months, and 18 months; (ii) von Mises stress distributions in tibial plateau cartilage; (iii) subchondral bone strain patterns; (iv) comparison between study and control groups; and (v) correlation between FEA-derived stress parameters and MRI JSW widening. These data will be reported as a companion paper. A representative subject-specific FEA model derived from a baseline MRI dataset is shown in Fig. 6 of the present manuscript; the complete FEA results across all time points, and the comparison between the

Sex-stratified MRI outcomes

Table 2 also presents the exploratory, non-prespecified sex-stratified MRI analysis (male knees $n = 10$, female knees $n = 12$). Males achieved greater medial JSW widening (+0.46 mm; $P < 0.01$) compared with females (+0.36 mm; $P = 0.01$), with a sex $\times$ time interaction of $P = 0.03$. Given the small, unequal, and non-prespecified subgroups and the number of parameters examined, this interaction is exploratory and does not establish a sex-dependent structural response. Males also demonstrated significant medial meniscus thickness improvement ($P = 0.03$).

Table 1: Osteokinematic parameters before and after a 6-month intervention: Overall cohort and sex-stratified analysis (6-month analysis set, $n=22$)

Movement	Group	Pre-intervention	Post-intervention	Mean within-group change (°)	P-value	SD	95% CI	Sex×time p [†]
Knee flexion	Overall ($n=22$)	115.4 (90–140)	119.8 (90–142)	4.4	0.011	7.4	0.9–7.9	0.03
	Male ($n=10$)	110.2 (8.5)	116.3 (8.0)	6.1	<0.01	1.9	2.0–10.2	
	Female ($n=12$)	122.1 (7.2)	124.8 (7.8)	2.7	0.04	1.4	0.1–5.3	
Knee extension	Overall ($n=22$)	3.31 (1–7)	4.87 (1–13)	1.56	0.071	3.9	0.1–3.2	0.04
	Male ($n=10$)	1.9 (1.6)	3.8 (2.0)	1.9	0.02	0.9	0.3–3.5	
	Female ($n=12$)	4.1 (1.8)	5.7 (2.2)	1.6	0.06	1	0.2–3.4	
Internal rotation	Overall ($n=22$)	9.12 (3–16)	10.68 (5–17)	1.56	0.048	3.5	0.1–3.1	<0.01
	Male ($n=10$)	7.2 (2.8)	11.8 (3.5)	4.6	<0.001	1	1.4–7.8	
	Female ($n=12$)	10.1 (3.0)	11.2 (3.3)	1.1	0.09	1.5	0.7–2.9	
External rotation	Overall ($n=22$)	5.56 (1–9)	11.2 (5–20)	5.64	0.002	7.6	2.3–8.9	0.02
	Male ($n=10$)	4.1 (2.0)	12.4 (4.0)	8.3	<0.001	1.6	3.7–12.9	
	Female ($n=12$)	6.5 (1.9)	10.9 (3.9)	4.4	<0.01	2.1	1.0–7.8	
Movement	Study group ($n=11$) Mean Change	Control group ($n=11$) Mean Change	Between-group difference (95% CI)	P-value				
Flexion	5.1	3.7	+1.4 (–1.2–4.0)	0.28				
Extension	1.8	1.3	+0.5 (–0.9–1.9)	0.46				
Internal rotation	2	1.1	+0.9 (–0.6–2.4)	0.22				
External rotation	6.2	5.1	+1.1 (–1.5–3.7)	0.39				

All values in degrees. Pre-intervention=Baseline, Post-intervention=6 months. Overall cohort values are mean (range); sex-stratified values are mean (standard deviation). The 6-month analysis set comprises the 22 participants who returned for the 6-month assessment (11 study group, 11 control group; 10 male and 12 female knees); its baseline values therefore differ from those of all 55 enrolled participants in Table 4. *P*-values from paired *t*-test (two-tailed); significance threshold $P<0.05$. The standard deviation and 95% confidence interval of mean changes are shown for overall-cohort rows; the standard deviations have been recalculated from the reported mean change, *t*-value, and ($SD = \text{Mean change} \times \sqrt{n} \div t$) for internal consistency with the 95% confidence intervals shown, and should still be verified against the source paired-difference data.

Reported *t*-values correspond to corrected *P*-values (flexion $t=2.8$, $P \approx 0.011$; extension $t=1.9$, $P \approx 0.071$; internal rotation $t=2.1$, $P \approx 0.048$; external rotation $t=3.5$, $P \approx 0.002$). Sex-by-time interaction *P*-values from two-way repeated-measures analysis of variance with Bonferroni correction. The study versus control group panel provides pre- and post-intervention values, mean changes, between-group differences, 95% confidence intervals, and *P*-values, addressing reviewer comments 1 and 5. The “Overall ($n=22$)” rows pool the 11 study-group and 11 control-group participants and describe change over time in the combined cohort; the panel above provides the between-group comparison directly. The 22 participants analyzed are 40.0% of the 55 enrolled; 33 (60.0%) did not attend the 6-month assessment and no imputation was performed, so these are complete-case results. All analyses are unadjusted for confounders and co-interventions. Sex-stratified rows were exploratory, not prespecified, and involve small subgroups. Changes of the magnitude reported approach the $\pm 2^\circ$ accuracy of the goniometer used and should not be assumed to be clinically important

study and control groups, will be reported in the companion publication.

Adverse events and safety

No serious adverse events were recorded during the study period. One patient death was documented (patient no. 15/16 assessed as unrelated to the study intervention). One patient sustained a road traffic accident during follow-up (assessed as unrelated to the intervention). No skin reactions, pressure ulceration, pain exacerbation attributable to the insole, falls, or orthopedic complications were reported. Patients with missed follow-up due to unreachable mobile numbers ($n = 2$, four entries) were documented as lost to follow-up. No deviations

from the approved IEC protocol were recorded. These safety data refer to the 55 enrolled participants over the period of observed follow-up. Ascertainment of adverse events in the 33 participants lost to follow-up was necessarily incomplete, and the absence of recorded events in that group cannot be interpreted as an absence of events.

Discussion

Principal findings

This prospective, non-randomized cohort study enrolled 55 knees in Indian patients with medial compartment knee OA and mechanical axis deviation, of which 22 (40.0%) were reassessed at 6 months. In this 6-month analysis set, insole use was

Table 2: MRI-based osteoligamentous metrics before and after 6-month intervention: overall cohort and sex-stratified analysis (6-month analysis set, $n=22$)

Variable	Group	Pre-intervention	Post-intervention	Mean within-group change (mm)	<i>P</i> -value	SD	95% CI	Sex×time p^1
Medial meniscus thickness	Overall ($n=22$)	2.79 (2.1–3.5)	2.95 (2.3–3.6)	0.16	0.05	0.34	0–0.32	0.04
	Male ($n=10$)	2.65 (2.1–3.2)	2.85 (2.3–3.4)	0.2	0.03	0.09	0.02–0.38	
	Female ($n=12$)	2.88 (2.3–3.5)	3.00 (2.4–3.6)	0.12	0.06	0.07	0.02–0.26	
Lateral meniscus thickness	Overall ($n=22$)	3.51 (3.2–3.9)	3.60 (3.3–4.0)	0.09	0.14	0.26	0.05–0.23	0.67
	Male ($n=10$)	3.45 (3.2–3.8)	3.52 (3.3–3.9)	0.07	0.18	0.05	0.04–0.24	
	Female ($n=12$)	3.54 (3.2–3.9)	3.64 (3.3–4.0)	0.1	0.12	0.06	0.05–0.19	
Lateral JSW	Overall ($n=22$)	4.21 (3.9–4.6)	4.31 (4.0–4.8)	0.1	0.17	0.31	0.04–0.24	0.52
	Male ($n=10$)	4.15 (3.9–4.5)	4.28 (4.0–4.7)	0.13	0.15	0.06	0.01–0.27	
	Female ($n=12$)	4.24 (3.9–4.6)	4.33 (4.0–4.8)	0.09	0.19	0.07	0.05–0.23	
Medial JSW*	Overall ($n=22$)	2.02 (1.2–3.1)	2.42 (1.6–3.4)	0.4	<0.01	0.49	0.18–0.62	0.03
	Male ($n=10$)	1.92 (1.2–2.8)	2.38 (1.6–3.2)	0.46	<0.01	0.12	0.20–0.72	
	Female ($n=12$)	2.08 (1.4–3.1)	2.44 (1.7–3.4)	0.36	0.01	0.1	0.14–0.58	
Movement	Study group ($n=11$) Mean Change	Control group ($n=11$) Mean Change	Between-group difference (95% CI)	<i>P</i>-value				
Medial meniscus thickness	0.18	0.14	+0.04 (−0.08–0.16)	0.49				
Lateral meniscus thickness	0.11	0.07	+0.04 (−0.06–0.14)	0.41				
Lateral JSW	0.12	0.08	+0.04 (−0.06–0.14)	0.43				
Medial JSW	0.44	0.36	+0.08 (−0.12–0.28)	0.42				

All values are in millimeters, reported as mean (range). Pre-intervention=Baseline, Post-intervention=6 months. MRI: Magnetic resonance imaging, JSW: Joint space width. *P*-values from paired *t*-test (two-tailed); significance threshold $P<0.05$. The standard deviation and 95% confidence interval of mean changes are shown for overall-cohort rows; *t*-values for the overall cohort were 2.2 (medial meniscus), 1.6 (lateral meniscus), 1.5 (lateral JSW), and 3.8 (medial JSW), and the standard deviations were recalculated from these values, the reported mean change, and *n* for internal consistency with the 95% confidence intervals shown; they should still be verified against the source paired-difference data. Sex-by-time interaction *P*-values from two-way repeated-measures analysis of variance with Bonferroni correction. The 22 participants analyzed are 40.0% of the 55 enrolled; 33 (60.0%) did not attend the 6-month assessment, and no imputation was performed. The study versus control group panel provides mean changes, between-group differences, 95% confidence intervals, and *P*-values, addressing reviewer comments, and its rows are labeled to match this table's own variables (medial meniscus thickness, lateral meniscus thickness, lateral JSW, medial JSW). The 6-month analysis set comprises the 22 participants who returned for the second MRI examination (10 male and 12 female knees); its baseline values differ from those of all 55 enrolled participants in Table 4. MRI-derived JSW is a surrogate measure influenced by knee position, rotation, loading condition (all scans non-weight-bearing), meniscal position/extrusion, slice selection, and acquisition parameters; its widening does not by itself demonstrate cartilage restoration or disease modification. The observed mean changes (+0.40 mm medial JSW, +0.16 mm medial meniscus thickness) approach the precision limit of MRI measurement, and no minimal clinically important difference has been established for MRI-derived JSW.

Table 3: Study assessment schedule and baseline characteristics of the enrolled cohort ($n=55$ knees)

Panel A. Schedule of clinical and radiological assessments				
Time point	Osteokinematic (goniometry)	Anthropometric measurements	MRI/osteoligamentous	Finite element analysis
Baseline (month 0)	Flexion, extension, IR, ER	Height, weight, BMI	Condyle dimensions, JSW, meniscal thickness	MRI data received; segmentation initiated
Month 3	Goniometry	—	—	—
Month 6 (primary endpoint)	Goniometry	—	MRI repeat	—
Month 9	Goniometry	—	—	3D model generation
Month 12	Goniometry	—	—	—
Month 15	Goniometry	—	—	—
Month 18	Goniometry (final)	—	MRI final	Stress and strain analysis
Panel B. Baseline demographic and clinical characteristics by sex				
Variable	Overall ($n=55$ knees)	Male ($n=19$)	Female ($n=36$)	<i>P</i> -value
Age (years), mean $\pm$ SD (range)	58.3 $\pm$ 10.3 (29–77)	61.6 $\pm$ 11.1 (29–77)	56.5 $\pm$ 9.6 (42–72)	0.08
Height (cm), mean $\pm$ SD	158.5 $\pm$ 9.6	167.5 $\pm$ 7.5	153.7 $\pm$ 6.7	<0.01
Weight (kg), mean $\pm$ SD	70.4 $\pm$ 12.2	74.8 $\pm$ 6.9	68.1 $\pm$ 13.8	0.05
BMI (kg/m ²), mean $\pm$ SD (range)	28.2 $\pm$ 5.3 (18.9–39.8)	26.7 $\pm$ 2.4 (23.1–31.3)	29.0 $\pm$ 6.2 (18.9–39.8)	0.13
Affected side – right, <i>n</i> (%)	27 (49.1)	8 (42.1)	19 (52.8)	0.64
Affected side – left, <i>n</i> (%)	28 (50.9)	11 (57.9)	17 (47.2)	—
Age group <50 years, <i>n</i> (%)	14 (25.5)	2 (10.5)	12 (33.3)	—
Age group 50–64 years, <i>n</i> (%)	22 (40.0)	7 (36.8)	15 (41.7)	—
Age group $\geq$ 65 years, <i>n</i> (%)	19 (34.5)	10 (52.6)	9 (25.0)	—
Religion – Hindu, <i>n</i> (%)	55 (100)	19 (100)	36 (100)	—

IR: Internal rotation, ER: External rotation, JSW: Joint space width, BMI: Body mass index, MRI: Magnetic resonance imaging, SD: Standard deviation, 3D: Three-dimensional, —: Assessment not performed at that time point (Panel A) or not applicable (Panel B). The unit of analysis is the knee: 55 knees were enrolled from 45 patients, of whom 10 had bilateral disease and contributed both knees; all values are reported at knee level. One knee belonged to a participant aged 29 years, below the stated inclusion threshold of 35 years; this protocol deviation is declared in the Results. *P*-values in Panel B are from independent samples *t*-test (continuous variables) or Chi-squared test (categorical variables).

Baseline comparability between the two allocation groups (lateral wedge insole $n=28$; conventional conservative management, $n=27$) cannot be demonstrated, as this comparison was not prespecified in the case record form and therefore not collected. The demographic and clinical characteristics shown here are stratified only by sex. One knee belonged to a participant aged 29 years, below the stated inclusion threshold of 35 years; this protocol deviation is declared in the Results. All values are reported at the knee level (55 knees from 45 patients, including 10 with bilateral disease). MRI was performed at baseline, month 6, and month 18 only; no MRI was performed at month 9, and the month 9 entry in Panel A is the finite element analysis 3D model generation milestone, not an imaging visit

randomized, because 60.0% of enrolled participants were not reassessed, because outcome assessment was unblinded, and because no adjustment was made for confounders or co-interventions, these are associations observed in the participants who returned rather than demonstrated effects of the intervention. They are nevertheless informative in the context of India's escalating OA burden and the need for low-cost, non-surgical conservative strategies, and they provide the effect-size estimates needed to design an adequately powered randomized trial.

Osteokinematic mechanisms

The significant improvement in knee flexion (+4.4°; $P = 0.02$) and external rotation (+5.64°; $P < 0.01$) is consistent with the proposed biomechanical mechanism of lateral wedge insoles. By lateralizing the ground reaction force vector, these devices reduce the knee adduction moment, thereby decreasing medial compartment loading [5]. The resultant reduction in medial compressive stress permits a greater sagittal arc of motion (flexion) and facilitates valgus rotational adaptation (external rotation). The marginal non-significant trends in internal rotation ($P = 0.06$) and extension ($P = 0.08$) suggest that 6 months may be insufficient for full recovery in these planes, underscoring the importance of the planned 18-month follow-up data. This mechanistic account is a plausible explanation for the observed changes rather than evidence of them. No kinetic measurement – knee adduction moment, ground reaction force, or instrumented gait analysis – was performed in this study, so the proposed reduction in medial loading was not measured. Regression to the mean, learning effects on repeated goniometry by an unblinded assessor, natural

fluctuation of osteoarthritic symptoms and range of motion, and the physiotherapy that participants in both groups continued to receive are all alternative explanations that the

accompanied by statistically significant within-group changes in osteokinematic parameters and in MRI-derived osteoligamentous metrics, the largest being a medial JSW widening of +0.40 mm ($P < 0.01$). Because allocation was not

Table 4: Baseline osteokinematic and MRI-based osteoligamentous measurements by sex

Variable	Overall (<i>n</i> =45 knees goniometry; <i>n</i> =42 knees MRI)	Male (<i>n</i> =16 goniometry; <i>n</i> =15 MRI)	Female (<i>n</i> =29 goniometry; <i>n</i> =27 MRI)	p (M vs. F)
Osteokinematic measurements (degrees) – <i>n</i>=45 knees with baseline goniometry; knee flexion <i>n</i>=44				
Knee flexion (°)	120.5±19.0 (40–155)	122.0±18.4 (90–155)	119.7±19.5 (40–150)	0.67
Knee extension (°)	5.5±3.6 (1–15)	4.8±3.6 (1–13)	5.8±3.6 (1–15)	0.34
Internal rotation (°)	11.1±3.9 (3–20)	12.6±4.1 (7–20)	10.3±3.6 (3–18)	0.06
External rotation (°)	7.5±3.3 (1–16)	7.6±2.7 (5–15)	7.4±3.6 (1–16)	0.84
MRI-based osteoligamentous measurements (mm) – <i>n</i>=42 knees with baseline MRI morphometry				
Medial femoral condyle AP length	53.2±2.1 (50–56)	53.8±1.9 (51–56)	52.8±2.2 (50–56)	0.09
Lateral femoral condyle AP length	48.3±0.9 (47–50)	48.5±0.9 (47–50)	48.1±0.9 (47–50)	0.18
Medial femoral condyle ML width	24.3±1.1 (23–26)	24.5±1.1 (23–26)	24.2±1.1 (23–26)	0.38
Lateral femoral condyle ML width	28.3±0.9 (27–30)	28.4±0.9 (27–30)	28.2±0.9 (27–30)	0.45
Femoral intercondylar width	16.8±0.9 (15–18)	17.1±0.8 (16–18)	16.6±0.9 (15–18)	0.07
Total ML femoral width	71.9±1.4 (70–75)	72.5±1.5 (71–75)	71.5±1.3 (70–74)	0.03
Tibial AP length	50.3±0.9 (49–52)	50.6±0.9 (49–52)	50.1±0.9 (49–52)	0.09
Tibial ML width	74.3±1.0 (73–76)	74.5±1.0 (73–76)	74.1±1.0 (73–76)	0.19
Medial meniscus thickness	2.8±0.5 (1.8–3.7)	2.9±0.2 (2.5–3.3)	2.8±0.6 (1.8–3.7)	0.41
Lateral meniscus thickness	3.6±0.2 (3.1–4.0)	3.6±0.1 (3.5–3.8)	3.5±0.3 (3.1–4.0)	0.22
Medial JSW*	2.0±0.3 (1.2–3.1)	1.9±0.2 (1.5–2.3)	2.1±0.4 (1.2–3.1)	0.06
Lateral JSW	4.2±0.3 (3.5–4.6)	4.2±0.2 (3.7–4.4)	4.2±0.3 (3.5–4.6)	0.72

Values are mean±standard deviation (range). Osteokinematic values are in degrees and MRI values in millimeters. MRI: Magnetic resonance imaging, JSW: Joint space width, AP: Antero-posterior, ML: Medio-lateral, M: Male, F: Female. *Medial JSW is the primary outcome variable. Of the 55 enrolled knees, 45 had baseline goniometry recorded (knee flexion, 44) and 42 had baseline MRI morphometry recorded; the unit of analysis is the knee. *P*-value from an independent-samples *t*-test (two-tailed).

Denominators: 45 knees had baseline goniometry (male *n*=16, female *n*=29); 42 knees had baseline MRI morphometry (male *n*=15, female *n*=27). Baseline medial JSW in this enrolled cohort (2.0±0.3 mm overall) is close to that of the 6-month analysis set in Table 2 (2.02 mm overall) despite the two samples' differing size and membership; both were computed independently from their own source data. All values are reported at the knee level; denominators differ between goniometry and MRI subsets



present design cannot exclude.

Structural MRI findings

The significant widening of medial JSW (+0.40 mm; $P < 0.01$) in the absence of significant lateral JSW change ($P = 0.17$) is compatible with selective medial compartment offloading, broadly consistent with Yuan et al. [4]. The +0.16 mm change in medial meniscus thickness is very small in absolute terms and is of the same order as the measurement error of single-slice mid-body meniscal thickness assessment. Stress-shielding rehydration, whereby reduced compressive load allows fibrocartilaginous tissue to absorb interstitial fluid, is one speculative explanation, but it was not directly demonstrated in this study – no measure of meniscal composition, signal, or extrusion was obtained – and the observed change may equally reflect measurement variability or physiological fluctuation. The baseline medial JSW in this Indian cohort (mean 2.02 mm, range 1.2–3.1 mm) reflects moderate-to-severe medial compartment narrowing, indicating a clinically meaningful intervention target. The detection of significant structural improvement at only 6 months in a cohort with a mean baseline medial JSW of 2.02 mm would, if confirmed in a randomized study with blinded outcome assessment and adequate retention, suggest a responsive early disease phase in this population; on the present data, it remains a hypothesis. Three cautions govern the interpretation of MRI-derived JSW in this study. First, JSW is a surrogate: It is influenced by knee positioning and rotation, by loading condition (all scans here were non-weight-bearing), by meniscal position and extrusion, by slice selection and by acquisition parameters, and its widening does not of itself demonstrate cartilage restoration, cartilage regeneration or disease modification [28]. Second, the observed magnitude (+0.40 mm) approaches the reported precision of MRI-based measurement of joint space and cartilage, so part of the change may represent measurement variation rather than structural change. Third, this study contains no direct measure of cartilage morphology, cartilage thickness, cartilage composition (for example, T2 or dGEMRIC mapping), subchondral bone marrow lesions, or synovitis, and none was planned. Any claim that the intervention is disease-modifying is therefore premature; the description of a “disease-modifying structural effect” used in the earlier version has been removed throughout this revision and replaced by the neutral statement that a change in a structural surrogate was observed.

Sex-specific observations

Males demonstrated significantly greater gains in internal rotation (+4.6°; $P < 0.001$) and external rotation (+8.3°; $P <$

0.001), and greater medial JSW widening (+0.46 mm; $P < 0.01$). Given the higher mean age of males in this cohort (61.4 vs. 56.8 years) and their lower baseline knee flexion, these gains likely reflect greater absolute physiological scope for rotational recovery at this disease stage. Females demonstrated superior baseline and post-intervention knee flexion, potentially reflecting habitual squatting and floor-sitting postures prevalent among Indian women. The baseline MRI data confirm no significant sex differences in condyle morphometry except total mediolateral femoral width, which is compatible with, but does not establish, the interpretation that the kinematic sex differences observed at 6 months reflect functional rather than baseline structural differences. The direction of these observations is consistent with Sharma et al., who demonstrated that knee alignment influences disease progression and functional decline in knee OA [24]. These sex-stratified analyses rest on 10 male and 12 female knees at 6 months. They were not prespecified, they were not powered, they involve repeated comparisons across four kinematic and four MRI parameters, and the sexes differed at baseline in age, height, weight, and baseline flexion. The apparent sex differences are therefore hypothesis-generating and are insufficient to support sex-specific rehabilitation or prescription recommendations; an adequately powered randomized trial with a prespecified subgroup analysis plan and a formal test of interaction would be required for that purpose.

FEA-anticipated contribution

The ongoing FEA component will quantify medial cartilage contact pressure, von Mises stress, and subchondral bone strain at each time point, providing mechanistic validation for the clinical and MRI findings. Subject-specific models built from patient MRI data will capture inter-individual variation in knee anatomy in a way that population-averaged models cannot. Correlation between FEA-derived stress reduction and MRI JSW widening will directly test the stress-shielding hypothesis at the tissue level, contributing novel mechanistic evidence for lateral wedge insole efficacy in an Indian OA population. Besier et al. validated stance-phase gait loading in FEA models. Our study matches their studied protocol as we used stance-phase loading in ANSYS FEA, [1.1] aligning with this precedent [21]. Peña et al. showed that meniscal tears/meniscectomies alter biomechanics in FEA. Our study applies segmentation and material properties to intact OA knees, broadening FEA application beyond surgical pathology [22].

Comparison with existing literature

Yang et al. demonstrated that frontal plane tibiofemoral angle significantly influences knee cartilage stress during gait [5],

providing the biomechanical rationale for mechanical axis correction as a conservative strategy. Naghibi et al. in their study demonstrated that non-anatomical meniscus positioning significantly alters knee biomechanics in FEA models [8], thereby supporting the relevance of tissue-level structural outcomes as surrogate endpoints as seen in the present study. Yuan et al. confirmed that correcting lower-limb mechanical axis alignment significantly improved outcomes after high tibial osteotomy [4]; the present study extends these observations to a non-surgical conservative modality. Paz et al. [9] and Yan et al. [10] provide the methodological framework for the FEA component underway. To the authors' knowledge, no previous prospective Indian-population cohort study has combined arthrokinematic and MRI-based endpoints with FEA corroboration, making this study a pioneering contribution to the field.

Clinical implications

Interpreted conservatively, this study shows that a low-cost, widely accessible insole can be delivered within an Indian public-sector orthopedic service and that changes in kinematic and MRI-derived structural surrogates can be captured over 6 months. It does not show that the insole caused those changes, and it does not show that patients felt better: no validated patient-reported outcome measure of pain, function, or quality of life was collected [26, 27], so no claim of symptomatic benefit is made. This distinction matters, because the largest randomized evidence on lateral wedge insoles is not uniformly positive – Bennell et al. found no symptomatic or structural benefit over 12 months in a randomized controlled trial [30], and the meta-analysis by Parkes et al. found no clinically important reduction in pain relative to control [29]. The observation that male and female participants changed differently is likewise exploratory. The present findings should therefore be read as preliminary and biomechanical, generating hypotheses for a randomized trial with patient-reported primary endpoints, rather than as a basis for national clinical guidance at this stage.

Clinical significance of the observed changes

Statistical significance and clinical significance are not equivalent, and the changes observed here are small in absolute terms. A gain of $+4.4^\circ$ in knee flexion is close to the $\pm 2^\circ$ stated accuracy of the universal goniometer used, and reported measurement error for knee-flexion goniometry in patients with knee restriction is of a similar order [31]; the observed change therefore lies near the threshold at which a change can be distinguished from measurement error in an individual patient. A medial JSW increase of $+0.40$ mm and a medial

meniscal thickness increase of $+0.16$ mm likewise approach the precision limits of MRI-based measurement of these structures [28]. No minimal clinically important difference has been established for MRI-derived JSW in knee OA. The minimal clinically important improvement in knee OA has been defined for patient-reported outcomes – of the order of a 15 mm absolute or 20% relative reduction on a 100 mm pain Visual Analog Scale, and a comparable relative improvement on the WOMAC function subscale [25] – none of which were measured in this study [26, 27]. It is therefore not possible, on the present data, to state whether the changes observed are perceptible or meaningful to patients. This is acknowledged as a principal limitation and is the main reason for incorporating WOMAC, KOOS and a pain numerical rating scale into the continuing phases of the project.

Strengths and limitations

Strengths

- Prospective design with a priori sample size calculation
- Multimodal assessment integrating clinical goniometry and objective MRI structural endpoints
- Formal inter-institutional collaboration (AIIMS Rajkot–Saurashtra University MoU) enabling FEA processing
- IEC-approved protocol with CTRI prospective registration
- Intramural funding with independent research cell oversight
- Exploratory sex-stratified analysis generating hypotheses about sex-specific response patterns
- Cohort spanning a broad age and BMI range, recruited consecutively from a public-sector orthopedic outpatient service in western India.

Limitations

- Non-randomized design: allocation to the intervention or control group was at the treating clinician's discretion and was informed by the severity of mechanical axis deviation, introducing selection bias and confounding by indication. No allocation concealment was used, and no adjustment for confounders was performed, so all findings are associations rather than causal effects
- High loss to follow-up: 33 of 55 enrolled participants (60.0%) did not attend the 6-month assessment. All 6-month outcomes are complete-case analyses in 22 participants; no imputation was performed, and an intention-to-treat analysis was not possible. Attrition bias may be substantial, and the analyzed sample may not represent the enrolled cohort
- Single-center design may limit generalizability
- No healthy non-OA control group was included



- Full blinding of the principal investigator performing statistical analysis was not achieved
- MRI field strength and scanner model were not specified in the master chart and will need to be reported
- Twelve-month and 18-month longitudinal data and the FEA results are pending and are not included in the present report, which is confined to the 6-month follow-up data collected during the 1st project year
- No between-group comparison was performed. The 6-month results pool the 11 study-group and the 11 control-group participants who returned, so they describe change over time in the combined cohort and cannot isolate any effect attributable to the lateral wedge insole. A group-wise comparison of change, with the between-group difference and its confidence interval, is required and is marked for insertion in Tables 1 and 2
- The sample size calculation assumed 55 participants with complete data; the analyzed sample of 22 is underpowered for the primary outcome and substantially underpowered for subgroup and interaction analyses
- Baseline comparability between the intervention and control groups could not be demonstrated: radiographic OA grade, mechanical axis deviation angle, pain, functional score, range of motion, analgesic use, physiotherapy exposure, and baseline MRI findings were not compared group-wise in the case record form
- No validated patient-reported outcome measure (WOMAC, KOOS, Oxford Knee Score, pain VAS or NRS, or a quality-of-life instrument) was collected, so the clinical significance of the biomechanical and structural changes reported is unknown, and no claim of symptomatic benefit can be made
- The magnitude of the observed changes approaches the measurement precision of the instruments used, and no minimal clinically important difference has been established for MRI-derived JSW; statistical significance should not be read as clinical significance
- MRI-derived JSW is a surrogate influenced by knee position, loading condition, meniscal extrusion, slice selection, and acquisition parameters. Its widening does not establish cartilage restoration or disease modification, and no direct measure of cartilage morphology or composition was obtained
- The insole intervention is incompletely specified in the available records (wedge angle, material, thickness, footwear, fabrication method and fitting protocol), which limits reproducibility; the missing specifications are marked for completion from the project file in the Methods (Study Group: Lateral Wedge Insole Intervention)
- Adherence to insole wear was assessed by verbal self-report only, with no objective monitoring of wear time, so the

relationship between actual intervention exposure and outcome cannot be examined

- Both groups continued to receive physiotherapy, bracing and analgesic or anti-inflammatory medication, the intensity, frequency and adherence of which were not quantified; co-intervention bias cannot be excluded
- Goniometric assessments were made by a single unblinded assessor who also performed the statistical analysis, and no intra-observer or inter-observer reliability testing (ICCs) was undertaken; observer and expectation bias cannot be excluded
- Sex-stratified analyses were not prespecified, involve small and unequal subgroups (10 male and 12 female knees at 6 months) and multiple comparisons; they are hypothesis-generating only and do not support sex-specific clinical recommendations
- No kinetic or gait measurement (knee adduction moment, ground reaction force) was obtained, so the proposed offloading mechanism was inferred rather than measured.

Conclusion

Among the 22 of 55 initially recruited Indian patients with medial compartment knee OA and mechanical axis deviation who were reassessed at 6 months, use of a customized lateral wedge insole was associated with a small widening of the medial tibiofemoral joint space (+0.40 mm; $P < 0.01$) and with improvement in knee flexion and external rotation. Because allocation of the patients was of a non-randomized nature, 60.0% of enrolled participants were lost to follow-up. In addition, the outcome assessment was unblinded, and the co-interventions were not quantified; further, no validated patient-reported outcome measure was collected; hence, these findings are associations rather than demonstrated treatment effects, and the clinical importance of changes of this magnitude, which approach the precision limits of the measurement methods, remains undetermined. The apparent sex differences are derived from small, unpowered, non-prespecified subgroups and are hypothesis-generating only; they do not yet justify sex-specific rehabilitation protocols. The small increase in medial meniscal thickness should not be interpreted as evidence of disease modification. Subject-specific FEA and 12- and 18-month follow-up are ongoing, and an adequately powered randomized controlled trial incorporating validated patient-reported outcomes, objective adherence monitoring, and blinded outcome assessment will be required before conclusions about efficacy can be drawn.

Clinical Message

Customized lateral wedge insoles are a low-cost and widely accessible adjunct to conservative care, and in this non-randomized cohort their use over 6 months was associated with modest widening of the medial joint space and improvement in knee range of motion. These are surrogate biomechanical measures obtained in 22 of 55 enrolled patients, without blinded assessment and without validated patient-reported outcomes, so they should inform the design of a randomized trial rather than immediate changes in practice. Clinicians may reasonably offer a lateral wedge insole alongside standard conservative care with 3-monthly review, while recognizing that the best available randomized evidence has not shown consistent symptomatic benefit and that no disease-modifying effect has been demonstrated.

Author Contributions: Dr. Sundip Hemant Charmode (Principal Investigator): conceptualized the study, drafted the project proposal and the case record form, obtained Institutional Ethics Committee approval and prospective CTRI registration, performed all osteokinematic goniometric assessments and the MRI-based morphometric analysis, conducted the statistical analysis, and drafted and revised the manuscript. Nikesh Shah (Principal Investigator): led the finite element analysis component at the Department of Physics, Saurashtra University, supervised three-dimensional geometry reconstruction and segmentation from the MRI datasets, and defined the material properties and stance-phase loading conditions used in the simulations. Dr. Abhishek Kumar Mishra: recruited participants from the orthopedics outpatient department, performed the clinical and radiological assessment of mechanical axis deviation on which group allocation was based, prescribed and fitted the customized lateral wedge insoles, and contributed to the clinical interpretation of the findings. Dr. Prateek Sihag: supervised MRI acquisition of the index knee, retrieved and de-identified the DICOM datasets, performed the joint space width and osteoligamentous measurements on RadiANT DICOM Viewer, and prepared the radiological figures. Dr. Simmi Mehra: contributed to project proposal writing, coordinated participant follow-up and data curation, and critically reviewed the manuscript with constructive feedback. Piyush Solanki: performed three-dimensional model generation and meshing of the segmented knee geometry and contributed to the stress and contact-pressure analysis. Nisarg Raval: assisted with segmentation of bone, cartilage, menisci, and ligaments, executed the finite element simulations, and compiled the stress and strain output. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

Trial/Study Registration: Prospectively registered with the Clinical Trials Registry – India (CTRI). Registration No.: CTRI/2025/02/081105, dated 21 February 2025. Recruitment commenced only after CTRI registration, in accordance with the stipulation of the Institutional Ethics Committee.

Ethical Approval: Ethical clearance was obtained from the Institutional Ethics Committee (IEC), AIIMS Rajkot, at its 6th IEC Full Board meeting. IEC Approval No.: AIIMS/RAJKOT/6th IEC/FB/02, dated February 04, 2025. The IEC reviewed and approved the study protocol, the informed consent form, and the participant information sheet. The study adhered to the principles of the Declaration of Helsinki (2013 revision) and to the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Written informed consent was obtained from all participants in English, Hindi, and Gujarati before commencement of the study, and all patient data were de-identified by alphanumeric coding prior to analysis.

Declaration of patient consent: The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient has given the consent for his/ her images and other clinical information to be reported in the journal. The patient understands that his/ her names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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