

Association of medial longitudinal arch height and stiffness with lower extremity alignment, pain, and disease severity in knee osteoarthritis: A cross-sectional study

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ABSTRACT

Objectives: This study aimed to investigate the association of medial longitudinal arch (MLA) height and stiffness with lower extremity alignment, pain, and disease severity in patients with knee osteoarthritis (OA).**Patients and methods:** This cross-sectional study included 90 patients (75 females, 15 males; mean age: 63.6±9.4 years; range, 50 to 90 years) diagnosed with knee OA according to the American College of Rheumatology criteria between December 2022 and June 2024. Medial longitudinal arch height and stiffness were assessed using the arch height index (AHI) method in both sitting and standing positions. The arch stiffness index (ASI) was calculated. The OA-related clinical outcomes included pain severity (numeric rating scale), Western Ontario and McMaster Universities Osteoarthritis Index scores, Kellgren-Lawrence grade, and tibiofemoral angles. Associations between MLA characteristics and OA parameters were examined.**Results:** Low and high arch rates were 10% and 16%, respectively. No significant differences in OA clinical and radiological parameters were observed across different MLA types. Within-patient comparisons showed higher MLA height in the extremity with greater knee pain and more advanced OA. Correlation analyses indicated that increased ASI was associated with higher arch height and knee varus angles, suggesting a biomechanical interplay between MLA structure and knee joint alignment in advanced OA patients. In the early OA group, ASI was negatively correlated with knee pain severity.**Conclusion:** A higher medial arch and increased midfoot stiffness were associated with knee pain, radiological severity, and knee varus in patients with OA. These findings support the complex relationship between the foot arch structure and knee OA through the perspective of the lower extremity kinematic chain.**Keywords:** Arch height index, arch stiffness, knee, medial longitudinal arch, osteoarthritis.

The foot plays a crucial role in lower extremity alignment, facilitating interaction between the body and the ground during gait and postural control. Variations in foot morphology, such as flat feet (pes planus) and high arches (pes cavus), can significantly impact lower extremity alignment and function, potentially leading to overpronation or supination and affecting gait mechanics and stability.¹ The growing interest in understanding the kinetics and kinematic chain of the lower extremities has sparked curiosity about the relationship between foot morphology and knee joint pathologies, prompting further investigation into cause-and-effect dynamics.^{2,3}

Current research indicates several significant findings regarding the relationship between foot posture and knee pathologies. Young adults experiencing anterior knee pain tend to have pes planus more often than those without knee pain.⁴ Adolescents with increased heel valgus and low medial arch show a higher quadriceps angle, suggesting an elevated risk of patellar subluxation.⁵ Previous studies have suggested that one-third to one-half of knee OA patients have a pronated foot posture.^{6,7} Additionally, individuals diagnosed with medial compartment knee osteoarthritis (OA) tend to exhibit a more pronated foot posture compared to healthy controls.^{8,9} However, studies on the link between

foot morphology and OA-related clinical outcomes are lacking. Gross et al.¹⁰ proposed that pes planus is associated with increased pain intensity and medial tibiofemoral cartilage loss in elderly patients. Similarly, Iijima et al.¹¹ demonstrated that bilateral pes planus serves as an independent predictor of pain intensity in knee OA. Moreover, insoles with lateral wedge modifications have been shown to reduce the knee adduction moment by altering ankle and tibia alignment during walking.¹² Despite the biomechanical associations observed, the existing evidence concerning the efficacy of footwear interventions, including lateral wedge and arch-support insoles, remains insufficient in elucidating their impact on pain management and functional improvement among individuals afflicted with knee OA.¹³⁻¹⁵

Previous studies have utilized various methods, including the foot posture index or footprint analysis, for assessing foot arch and mid-foot morphology.¹⁶ Despite their widespread utilization, the semiquantitative nature of the foot posture index, which mainly relies on inspection across multiple planes, introduces subjectivity and potential variability in interpretation by practitioners.¹⁷ Similarly, approaches grounded in footprint analysis, such as the Staheli index, may be influenced by various factors, including subcutaneous fat tissue in the foot sole.^{18,19} In contrast, the arch height index (AHI) emerges as a noteworthy anthropometric measure, calculated by dividing foot dorsum height by trimmed foot length, thereby providing a quantitative evaluation of the MLA structure.^{20,21} The AHI method remains unaffected by plantar fat tissue distribution with its proven validity and reliability. Moreover, it enables precise assessment of the MLA stiffness index under diverse load-bearing conditions.²² A healthy MLA should maintain a delicate equilibrium between physiological flexibility during load-bearing and sufficient stiffness during push-off phases throughout the gait cycle.²² The complex relationships between flexibility and height of MLA have been documented in asymptomatic individuals.^{23,24} An excessively mobile MLA has been associated with heightened rotational tibial movement, inducing abnormal moments in the knee joint.^{25,26} Conversely, a stiffer MLA may exacerbate

knee discomfort by impeding adequate shock absorption of the foot during walking.²⁷ The few studies examining the relationship between MLA morphology evaluated by the AHI method and knee pathologies have been conducted in young adults and athletes with patellofemoral pain.²⁸ Nonetheless, a gap in the literature is evident, as no study has specifically investigated MLA stiffness using the AHI method in patients with knee OA. Therefore, this study aimed to explore the impact of MLA height and stiffness, assessed using the AHI method, on knee pain, functionality, disease severity, and knee joint alignment in individuals diagnosed with knee OA.

PATIENTS AND METHODS

This cross-sectional study was conducted in the outpatient clinic of the Gazi University Faculty of Medicine between December 2022 and June 2024. Ninety consecutive patients (75 females, 15 males; mean age: 63.6 ± 9.4 years; range, 50 to 90 years) diagnosed with knee OA according to the American College of Rheumatology criteria were included in the study. A written informed consent was obtained from each patient. The study protocol was approved by the Gazi University Clinical Research Ethics Committee (date: 16.05.2022, no: 2022-367). It is registered in the clinical trials database under the number NCT05656014. The study was conducted in accordance with the principles of the Declaration of Helsinki. The exclusion criteria were as follows: (i) history of lower extremity fracture or surgery, (ii) presence of other rheumatological diseases, (iii) intra-articular knee injections or pain management procedures within the last six months, (iv) neurological disorders affecting the lower extremity, (v) other painful conditions of lower extremity, and (vi) conditions, such as lower extremity edema, that could impede accurate measurement of AHI. All measurements for each patient were conducted on the same visit.

The patients' age, height, weight, and body mass index were recorded. Lower extremity dominance was determined by the ball-kicking test.²⁹ Clinical data related to knee OA

included the duration and severity of knee pain (measured via numeric rating scale [NRS]), scores from the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for pain, joint stiffness, and function, as well as goniometric measurements of knee joint range of motion. Radiological assessments comprised the Kellgren-Lawrence knee OA stage and knee joint alignment, represented by the anatomical and mechanical tibiofemoral angles on standing anteroposterior full-limb radiographs. Knees were categorized by tibiofemoral joint degeneration into minimal-to-mild OA (Kellgren-Lawrence Grades 1 and 2) and moderate-to-severe OA (Kellgren-Lawrence Grades 3 and 4). Radiographic imaging was conducted with the knee in full extension. The foot and lower leg were positioned with the patella oriented anteriorly to ensure optimal centralization of the intercondylar notch, tibial intercondylar eminence, and tibial plafond. The mechanical tibiofemoral angle (TFA) was determined by measuring the angle between the mechanical axes of the tibia (the line between the center of the tibial intercondylar eminence and the midpoint of the tibial plafond) and femur (the line between the center of the femoral head and the midpoint of the intercondylar notch of femur; Figure 1).^{30,31} The anatomical TFA was assessed by measuring the angle from the intersection of the anatomical axis lines drawn on the distal femur and proximal tibia (Figure 1). The anatomical axis of the distal femur was determined by a line drawn between the intercondylar notch and the midpoint on the diaphysis, located 15 cm from the lowest surface of the lateral femoral condyle. Similarly, the anatomical axis of the proximal tibia was defined by a line connecting the center of the tibial intercondylar eminence to the midpoint on the diaphysis, situated 15 cm from the uppermost surface of the lateral tibial plateau. In healthy individuals, the anatomical TFA ranges between 4° and 6°. Typically, the mechanical TFA is approximately 6° lower than the anatomical TFA.³⁰ Lower or negative tibiofemoral angles indicate knee varus.³¹

The evaluation of the MLA structure was conducted utilizing the AHI method, which relies on the measurement of foot length and dorsum height using a sliding caliper

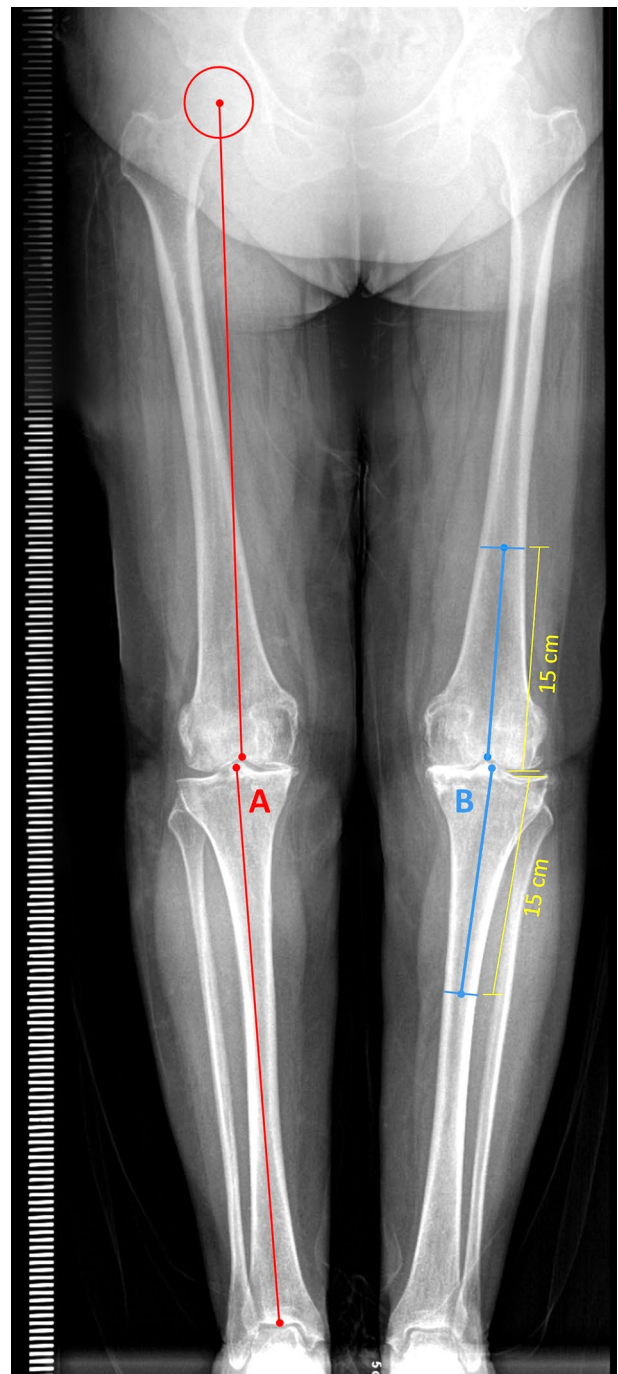


Figure 1. (A) The mechanical tibiofemoral angle representing full limb alignment; (B) the anatomical tibiofemoral angle representing knee varus.

apparatus (Figure 2). The initial step involved the determination of the total foot length, characterized as the distance extending from the heel ball's rearmost point to the toes' foremost point. Subsequently, the truncated foot length

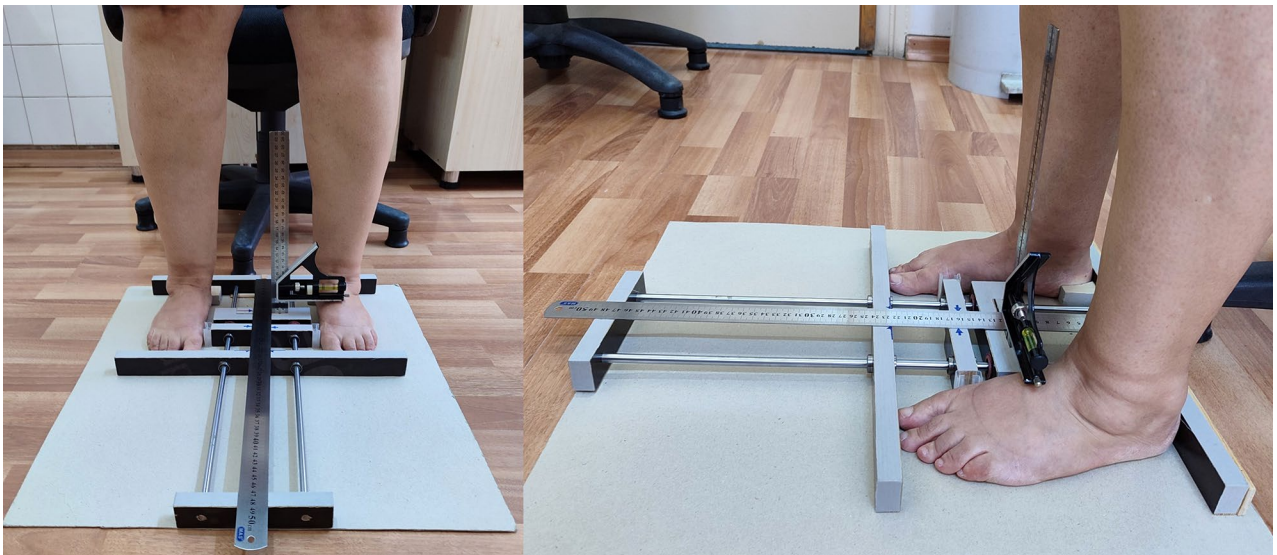


Figure 2. Photographs depict arch height index measurement during bipedal stance.

was ascertained, denoting the distance from the rearmost point of the heel to the medial bulge of the first metatarsophalangeal joint. Foot dorsum height was then quantified as the vertical distance between the ground and the foot dorsum at the midpoint of the total foot length. The AHI was subsequently computed as the quotient of dorsum height to the truncated foot length.²¹

Arch height index measurements were conducted in two distinct weight-bearing positions: sitting and standing. Arch height index during sitting (AHI_{sit}) was assessed with the patient seated on an adjustable chair, with hips and knees flexed at 90° , the back reclined, and both feet resting calmly on the ground. In this position, each foot was assumed to bear approximately 10% of the body weight.³² The AHI measurement in standing position (AHI_{stand}) was conducted during a relaxed, upright bipedal posture, wherein each foot bore an equitable distribution of approximately 50% of the body weight. Consequently, the arch stiffness index (ASI) was calculated using this formula: $ASI = (AHI_{sit} - AHI_{stand}) / (0.4 \times \text{body weight})$. Higher ASI values represented a stiffer MLA structure. Medial longitudinal arch structures were classified into three categories: low arch, normal arch, and high arch, delineated by AHI_{stand} results falling

below 0.31, between 0.31 and 0.37, and above 0.37, respectively.³³

Statistical analysis

It was planned to include at least 82 participants to detect the correlation between knee pain and the AHI, with an effect size of 0.3, 80% power, and a 5% margin of error.

Data were analyzed using IBM SPSS version 27.0 software (IBM Corp., Armonk, NY, USA). Fisher exact test was employed to compare frequencies. Median with interquartile range and mean \pm standard deviation (SD) were used to report ordinal and continuous variables, respectively. Normality was assessed for continuous variables using the Kolmogorov-Smirnov and Shapiro-Wilk tests. The more symptomatic side determined by the WOMAC score was considered when comparing patients. If knee OA symptoms were symmetrical, the dominant lower extremity was analyzed. Comparisons within three MLA groups were performed using the Kruskal-Wallis test with post hoc analysis. Within-patient analyses comparing the more painful or severe OA side with the contralateral side were conducted using paired sample t-tests or the Wilcoxon signed-rank test. Associations between OA parameters and MLA characteristics were analyzed using Pearson and Spearman correlations. Statistical significance was represented by a p-value <0.05 .

RESULTS

The majority of participants had right lower extremity dominance (n=85, 94%). Between-patient analyses included the right knee of 38 patients and the left knee of 52 patients, based on the more symptomatic side. Fifty (%55) patients had moderate-to-severe (Kellgren-Lawrence grade 3 and 4) OA (Table 1). The majority (73%) of patients had normal MLA height. The low MLA rate was relatively low with %11. The AHI_{stand} (0.335 ± 0.03 vs. 0.339 ± 0.02 ; $p=0.629$) and ASI (951 ± 631 vs. 974 ± 350 ; $p=0.297$) were

not different between females and males. Demographic, clinical, and radiological parameters did not differ significantly among the three MLA types, except for the AHI_{stand} values (Table 2).

In within-patient analyses, 85 patients reported a minimum 1-point difference in NRS pain scores between the right and left knee. The AHI_{stand} value was significantly higher on the side with greater knee pain compared to the contralateral side [0.332 ± 0.03 vs. 0.337 ± 0.03 ; $t(84)=2.351$, $p=0.021$]. However, the median ASI values did not differ significantly between

Table 1. Patient characteristics (n=90)

	n	%	Mean±SD
Demographics			
Age (year)			63.6±9.4
Sex			
Females	75	83	
Males	15	17	
Was the included side dominant?			
Yes	39	43	
No	51	57	
Body mass index (kg/m ²)			29.7±4.3
Clinical parameters†			
NRS for pain (mm)			50.3±18
Pain duration (mo)			35.2±48.6
Knee range of motion (degree)			131±12.6
WOMAC scores			
Pain			7.3±3.9
Joint stiffness			2±1.9
Physical function			27.4±15.3
Total			36.7±19.8
Radiographic parameters†			
Kellgren-Lawrence grade			
1	7	8	
2	33	36	
3	25	28	
4	25	28	
Anatomical TF angle			0.7±4.7
Mechanical TF angle			-6±5.6
Medial longitudinal arch characteristics†			
AHI _{stand}			0.335±0.03
Arch stiffness index			955±592

SD: Standard deviation; NRS: Numeric rating scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; TF: Tibiofemoral; AHI: Arch height index; † Data represent the more symptomatic side

Table 2. Comparison of different MLA types regarding OA characteristics

Parameters	Medial longitudinal arch types						p†
	Low arch (n=10)		Normal arch (n=66)		High arch (n=14)		
	Median	IQR	Median	IQR	Median	IQR	
Age (years)	64	60-74	62	55-67	68	57-75	0.144
Body mass index (kg/m ²)	29.1	24.3-32.2	29.6	26.9-32.6	29.4	28.1-34.8	0.677
NRS for pain (mm)	55	30-70	50	40-60	48	30-76	0.728
Pain duration (mo)	24	6-120	12	5-51	8	4-27	0.355
Knee range of motion (degree)	135	120-140	135	125-140	135	120-140	0.930
WOMAC scores							
Pain	8.5	6-12	7	4-9	8	3-11	0.440
Joint stiffness	3	1-5	1.5	0-3	2	1-4	0.151
Physical function	31	21-40	23	16-34	29	13-55	0.385
Total	42	29-55	33	21-44	37	17-72	0.386
K-L grade	3	2-4	3	2-4	2.5	2-4	0.839
Anatomical TF angle	2.3	-4.8-3.3	1.6	-1.8-3.7	1.5	-6.9-3.9	0.890
Mechanical TF angle	-5.75	-13.6 - -2.2	-5	-8 - -2.2	-5.9	-15.6 - -1.4	0.751
AHI _{stand}	0.291	0.270-0.297	0.333	0.318-0.350	0.379	0.371-0.392	<0.001‡
Arch stiffness index	643	508-924	832	643-1107	801	632-1098	0.351

MLA: Medial longitudinal arch; OA: Osteoarthritis; IQR: Interquartile range; NRS: Numeric rating scale; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; K-L: Kellgren-Lawrence; TF: Tibiofemoral; AHI: Arch height index; † Kruskal-Wallis test results; ‡ Post hoc analysis revealed that the AHI_{stand} was different between groups (Low arch < Normal arch < High arch; p<0.05).

Table 3. Comparison of two OA severity groups

	Radiological osteoarthritis severity										p
	Minimal-to-mild (K-L grade 1-2) (n=40)					Moderate-to-severe (K-L grade 3-4) (n=50)					
	n	%	Mean±SD	Median	IQR	n	%	Mean±SD	Median	IQR	
Demographics											
Age (year)			58.6±7.2					67.6±9.1			<0.001†
Sex											0.004‡
Females	28	70				47	94				
Males	12	30				3	6				
Body mass index			28.2±4.2					30.9±4.1			0.002†
Clinical parameters											
NRS for pain (mm)			46.4±16.4					53.4±18.8			0.066†
Pain duration (mo)				7	3-24				24	8-63	<0.001*
Knee ROM				140	135-145				125	117-135	<0.001*
WOMAC scores											
Pain				5	3-8				8.5	6-12	<0.001*
Joint stiffness				1	0-2				2	1-4	<0.001*
Physical function			18.9±9.6					34.2±15.7			<0.001†
Total			25.5±12.2					45.6±20.3			<0.001†
Radiographic parameters											
Anatomical TF angle			3.5±1.9					-1.6±5.1			<0.001†
Mechanical TF angle			-2.6±2.3					-8.8±5.8			<0.001†
MLA characteristics											
AHI _{stand}			0.336±0.03					0.334±0.03	851	665-1128	0.742†
Arch stiffness index				768	607-990						0.229*

OA: Osteoarthritis; K-L: Kellgren-lawrence; IQR: Interquartile range; NRS: Numeric rating scale; ROM: Range of motion; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; TF: Tibiofemoral; MLA: Medial longitudinal arch; AHI: Arch height index; † Student's t-test; ‡ Fisher's exact test; * Mann-Whitney U test.

Table 4. Results of correlation analysis between OA-related parameters and AHI measurements

OA-related parameters	Minimal-to-mild OA (n=40)		Moderate-to-severe OA (n=50)	
	AHI _{stand}	ASI	AHI _{stand}	ASI
NRS for pain	-0.021	-0.452†	0.103	-0.054
Pain duration (mo)	-0.206	-0.292	-0.011	0.013
Knee ROM	-0.127	0.195	-0.251	-0.010
WOMAC-pain	-0.049	0.030	0.055	-0.082
WOMAC-joint stiffness	0.078	-0.052	0.047	-0.176
WOMAC-physical function	-0.017	-0.288	0.225	0.003
WOMAC-total	-0.004	-0.227	0.189	-0.023
Kellgren-Lawrence grade	0.228	0.054	0.109	0.046
Anatomical TF angle	-0.123	0.236	-0.190	-0.311‡
Mechanical TF angle	-0.071	0.019	-0.132	-0.312*

OA: Osteoarthritis; AHI: Arch height index; ASI: Arch stiffness index; NRS: Numeric rating scale; ROM: Range of motion; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; TF: Tibiofemoral; † Spearman's Rho= -0.425; 95% CI: -0.656, -0.121, p=0.006; ‡ Spearman's Rho= -0.311; 95% CI: -0.548, -0.027, p=0.028; * Spearman's Rho= -0.312; 95% CI: -0.549, -0.029, p=0.027.

more painful and less painful extremities [814 (617, 1088) vs. 803 (590, 1089); $Z=-0.379$, $p=0.705$]. Forty patients exhibited asymmetric severity of OA between their knees, as determined by Kellgren-Lawrence grades. The AHI_{stand} was higher in the extremity with more advanced knee OA [0.333 ± 0.03 vs. 0.327 ± 0.03 ; $t(39)=2.533$, $p=0.015$]. However, median ASI values remained comparable between knees with more and less advanced OA [835 (600, 1107) vs. 747 (536, 1111); $Z=-0.753$, $p=0.452$] among knees with asymmetric radiological OA severity.

Due to notable differences in symptoms and radiographic characteristics between minimal-to-mild OA and moderate-to-severe OA (Table 3), correlation analyses were conducted separately within each of these two groups. Spearman correlation analyses showed that ASI was positively correlated with AHI_{stand} ($\rho=0.293$; 95% confidence interval: 0.008, 0.534; $p=0.039$). The anatomical and mechanical TFA were negatively correlated with ASI in the moderate-to-severe OA group. In the minimal-to-mild OA group, ASI was negatively correlated with pain severity. Other correlation analyses revealed no significant results regarding the relationship between MLA and OA features (Table 4).

DISCUSSION

This study highlights several key findings regarding the relationship between MLA characteristics and knee OA. Despite no significant differences in clinical and radiological parameters of OA observed across different MLA types, within-patient comparisons indicated that the foot with higher MLA height was associated with greater knee pain and more advanced OA. Correlation analyses demonstrated that increased MLA stiffness was related to increased knee varus angles, underscoring the biomechanical interplay between MLA structure and knee joint malalignment in advanced OA patients. However, a more flexible arch structure was associated with more intense knee pain in patients with early OA.

The differences in foot posture and MLA structure between individuals with and without knee OA have been widely studied. Studies have reported that patients with knee OA often exhibit a more pronated foot posture compared to healthy controls.^{8,9,34} However, inconsistencies exist in these findings. Some studies have shown no significant difference in navicular height between OA patients and healthy individuals, while others reported lower navicular height in OA patients.^{9,34,35} This study adds to this body of research by revealing a relatively low pes planus

(low MLA) rate of 15% among OA patients and an asymmetry characterized by higher MLA in the extremities with more severe pain and OA grade.

In this study, OA symptoms were not found to be different between MLA groups. However, individuals with asymmetrical knee pain had higher arches in their more painful extremities. The relationship between foot posture, MLA characteristics, and OA symptoms is multifaceted. It has been noted that the risk of knee pain and articular cartilage damage increases with pes planus in elderly people.³⁶ Guler et al.³⁷ investigated the relationship between common foot deformities and pain and functionality in female patients with knee OA. Although there was no significant relationship between foot deformities and VAS scores, WOMAC scores were found to be correlated with the lateral talometatarsal angle and hallux valgus angle. In a study of 95 knee OA patients, Zhang et al.³⁸ found that 78% had pes planus, and these patients experienced more severe knee OA symptoms. On the other hand, Nakazato et al.³⁹ showed that a lower navicular height ratio was associated with the alleviation of knee OA symptoms. Akaltun and Koçyiğit,⁴⁰ in a study in Türkiye, reported that only 10% of OA patients had a pronated foot posture, while a supinated foot posture was associated with more severe pain and higher WOMAC scores. While this heterogeneity in findings may reflect anthropometric variations between populations, it is also important to consider that varying methods were used to evaluate foot posture. The AHI method primarily focuses on the height and rigidity of the MLA in the sagittal plane, without considering foot pronation or rearfoot alignment in the other aspects. However, toe-out walking, foot pronation, and forefoot abduction have been suggested as compensatory mechanisms in patients with painful OA.^{16,41,42} This aligns with previous research showing that a pronated foot posture during walking is linked to lower knee flexion, adduction moment, and medial compartment load.^{43,44} Unlike methods such as gait analysis and the foot posture index, in this study, AHI measurement was conducted in the bipedal stance, in which neutral toe orientation was achieved. This approach may have prevented the patient from using a possible compensatory posture.

Notably, this study is the first to demonstrate the relationship between ASI, knee pain, and lower extremity alignment in knee OA patients. These findings indicate that a stiffer MLA structure is linked to increased knee varus in patients with advanced OA. Increased knee varus, which is associated with a higher knee adduction moment, can exacerbate medial compartment OA.⁴⁵ Conversely, increased MLA flexibility was associated with more severe pain in patients with early OA. These findings align with the report by Levinger et al.,⁹ which observed increased navicular drop in OA patients. A more flexible MLA leads to abnormal patellofemoral and tibiofemoral joint loading through increased tibial internal rotation during stance.²⁵ This may be the biomechanical mechanism underlying the relationship between flexible MLA and knee pain in early OA patients.⁴⁶ However, in the previous literature, knee varus was found to be associated with external tibial rotation in patients with end-stage knee OA.⁴⁷ These findings, suggesting a relationship between a stiffer foot arch and knee varus, may indicate altered foot kinematics via external tibial rotation in advanced knee OA. However, further investigation is required to clarify this issue.

This study has several limitations. First, establishing causal relationships in a cross-sectional study is challenging. Additionally, the parameters were primarily based on static measurement methods, limiting the findings' generalizability to dynamic activities such as walking. The limited number of patients in the low and high arch groups also constrained the ability to employ parametric methods in certain analyses. Lastly, the absence of a healthy control group is a potential limitation. However, given this study's focus on exploring the relationships between MLA structure and clinical parameters of OA, we believe this limitation is not critical.

In conclusion, this study is the first to demonstrate the relationship between ASI, knee pain, and lower extremity alignment in knee OA patients. Although a definitive causal relationship cannot be established, the results suggest that the relationships between arch stiffness and OA-related clinical and biomechanical consequences may differ across OA stages. The asymmetry of MLA height between extremities

in OA patients may guide the planning of interventions without footwear and insoles. These findings support the individual modifications of insoles with arch structure analysis, particularly in people with asymmetric OA symptoms.⁴⁸ Future research should continue to explore the efficacy of various footwear interventions and the potential benefits of addressing MLA characteristics in the treatment of knee OA.

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

Author Contributions: Conceptualization, Investigation, methodology, data analysis: L.K.; Data acquisition, writing-original draft, writing-review & editing: L.K., A.U.K. All authors played a role in the critical revision of the manuscript, approved the final version, and contributed to the study design.

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