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The association between varus knee deformity and morphological changes in the foot and ankle in patients with end-stage varus knee osteoarthritis

Zhenchao Huang[1], Zian Zhang[1], Wenzhe Wang[1], Fan Chen[1] and Haining Zhang[1*]

Abstract

Background This study aimed to (1) determine the association between varus knee deformity and ipsilateral foot and ankle morphology, and (2) evaluate the relationship between varus knee deformity and foot and ankle pain in patients with end-stage varus knee osteoarthritis (KOA).

Methods A total of 213 patients who underwent primary total knee arthroplasty for end-stage varus KOA were enrolled in this study and divided into a 'severe varus group' ($n=119$) and a 'mild varus group' ($n=94$) based on preoperative knee varus degree. Morphological parameters and pain incidence in the foot and ankle were compared between the two groups. The correlation between knee varus and foot and ankle morphology was analyzed.

Results Significant differences in ankle morphology were observed between the two groups. The deformity magnitudes of the hindfoot valgus ($P<0.001$) and hallux valgus (HVA, $P=0.028$; IMA, $P=0.046$) were significantly higher in the severe varus group. Additionally, the incidences of ankle osteoarthritis (OA) ($P=0.005$) and hallux valgus ($P=0.028$) were higher in the severe varus group. Patients with severe KOA were more likely to experience medial ankle pain ($P=0.023$), hindfoot pain ($P=0.034$), and multiple pain locations ($P=0.015$).

Conclusion Varus knee deformity was associated with morphological changes in the foot and ankle, and the incidence of ankle OA and hallux valgus deformity was significantly higher in patients with severe varus KOA. Patients with severe varus KOA were more prone to medial ankle pain, hindfoot pain, and multiple pain locations, which were associated with corresponding morphological changes.

Keywords Varus knee deformity, Ankle osteoarthritis, Hindfoot, Medial longitudinal arch, Hallux valgus

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Introduction

Knee osteoarthritis (KOA) is a major chronic disease that causes knee pain and disability worldwide [1]. Most previous studies focused solely on local knee malalignment [2]. However, severe KOA can change the alignment of the entire lower extremity and thus influence ankle alignment or even accelerate the progression of ankle osteoarthritis (AOA) [3, 4]. Previous studies showed the relationship between varus KOA and foot deformity [5, 6], nevertheless, those studies were not based on radiographic parameters.

Evidence suggests that knee realignment following total knee arthroplasty (TKA) leads to changes in ankle alignment [7], hindfoot alignment [8], and foot morphology [9]. These findings suggest a biomechanical link between altered coronal knee alignment and altered foot and ankle morphology in patients with varus KOA. However, no study has simultaneously examined the correlation between the knee varus and morphology of the foot (including the hindfoot, midfoot, and forefoot) and ankle in patients with varus KOA based on radiographic parameters. Summarizing these findings is crucial to provide a foundation for the current study.

Patients with varus knee deformities are also more susceptible to concurrent foot and ankle pain [10, 11], and evidence suggests that correcting knee deformity through TKA results in changes in foot and ankle pain [3, 12]. Notably, this evidence suggests that coronal knee alignment is associated with foot and ankle pain. However, the relationship between varus knee deformity and foot and ankle pain has not been fully established.

The aims of this study were to (1) determine the association between varus knee deformity and ipsilateral foot and ankle morphology, and (2) investigate the relationship between varus knee deformity and foot and ankle pain in patients with end-stage varus KOA.

Materials and methods

Patient selection

After obtaining approval from the institutional review board (QYFY WZLL 28765), 213 patients (213 knees) who underwent primary TKA for end-stage varus KOA between December 2020 and November 2023 at the Affiliated Hospital of Qingdao University were retrospectively enrolled in this study based on the following criteria. A flowchart describing the patient selection process is shown in Fig. 1. All patients underwent preoperative radiographic and clinical evaluations of the operated side. The inclusion criterion was primary TKA in patients with end-stage varus KOA. The exclusion criteria were as follows: (1) incomplete preoperative radiographic or clinical data, (2) inflammatory arthritis, and (3) previous surgical history of the ipsilateral lower extremity before TKA.

All enrolled patients were divided into two groups based on the severity of preoperative knee varus deformity. A 10° knee varus (HKA = 170°) before TKA was set as the cutoff value for this study, according to previous studies [8, 13, 14]. Group 1 (n = 119) included patients with severe varus knee deformity (HKA ≤ 170°) preoperatively, defined as the 'severe varus group', whereas group 2 (n = 94) comprised patients with mild varus knee deformity (HKA > 170°) preoperatively, defined as the 'mild

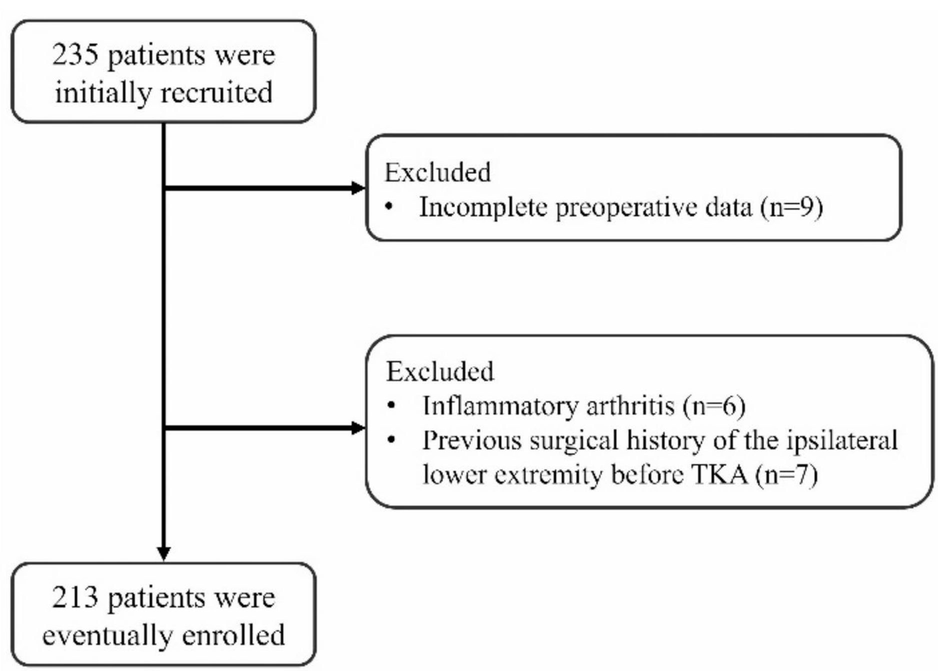

Fig. 1 The study flowchart describing the patient selection process

varus group' [8, 13, 14]. Notably, 1° of knee varus was defined as an HKA of 179° [15].

Radiographic analysis

Preoperative total lower extremity weight-bearing anteroposterior (AP) radiographs, long axial weight-bearing views of the hindfoot, and lateral and AP weight-bearing radiographs of the foot were obtained from all enrolled patients at the time of admission. The patella was forward and the knee was fully extended to avoid measurement errors due to knee rotation when taking preoperative total lower extremity weight-bearing AP radiographs [16]. The long axial weight-bearing view of the hindfoot was obtained as follows [17]: the film cassette was placed flat on the floor, with patients standing on the film cassette and holding their ankle in 10° dorsal flexion, which was verified using a goniometer. The inclination angle of the beam to the floor was set to 45°.

In preoperative total lower extremity weight-bearing AP radiographs, the HKA was defined as the angle between the MA of the femur and the tibia and used to assess the severity of varus knee deformity [18] (Fig. 2). The tibial anterior surface angle (TAS), talar tilt angle (TT), medial tibiotalar joint space (MTJS), and distal medial clear space (DMCS) were used to evaluate morphological changes in the ankle [3, 4, 19]. The TAS was used to evaluate the magnitude of the deformity in the distal tibial plafond. TAS was defined as the medial angle between the distal tibial plafond and the tibial anatomical axis (AA) (Fig. 3A) [4]. TT, MTJS, and DMCS are indicators of cartilage wear (osteoarthritic changes) at the ankle joint, which increase with the progression of AOA. TT was defined as the angle between the distal tibial plafond and upper joint surface of the talus (Fig. 3B) [18]. For TT, the angle of opening to the lateral aspect of the ankle was defined as a positive value. The MTJS and DMCS were used to assess ankle space narrowing. The MTJS was defined as the shortest distance between the medial end of the talar dome and the distal tibial plafond, while the DMCS was defined as the vertical distance from the distal tip of the medial malleolus to the medial articular surface of the talus [3] (Fig. 3C). Furthermore, the radiographic stage of AOA was evaluated based on the modified Takakura ankle osteoarthritis classification system [20] (Table 1).

In the preoperative long axial weight-bearing view of the hindfoot, the hindfoot alignment angle (HA) was used to assess valgus hindfoot deformity [14] (Fig. 4A), and hindfoot valgus was defined as a positive value. In preoperative lateral weight-bearing radiographs of the foot, calcaneal pitch angle (CPA), lateral talus-first metatarsal angle (Meary's angle), lateral talocalcaneal angle (LTCA), and the height of the medial cuneiform (HMC) were used to evaluate the morphology of the medial longitudinal arch (Fig. 4B) [21–25]. In preoperative AP weight-bearing radiographs of the foot, the intermetatarsal angle (IMA), hallux valgus angle (HVA), and hallux interphalangeal angle (HIA) were used to evaluate the severity of the hallux valgus deformity (Fig. 4C) [21, 26, 27]. Notably, hallux valgus was considered present if HVA was >15° [28, 29]. The specific measurement methods for all the preoperative parameters describing foot morphology are shown in Fig. 4A, B, C.

Notably, all preoperative radiographic measurements were performed by the same independent observer who was not involved in the patient treatment.

Clinical analysis

In the orthopaedic ward, the presence and location of preoperative pain around the foot and ankle during walking were assessed and recorded by the same experienced orthopaedic surgeon at the time of admission. Foot and ankle pain was categorized as ankle (medial and lateral), hindfoot, midfoot, forefoot, or multiple pain (pain locations ≥ 2) in this study. Pain was considered present when there was definite focal pain during walking. All the enrolled patients had complete preoperative clinical assessment data.

Statistical analysis

Continuous variables were expressed as mean ± standard deviation (SD), and all data were tested for normality using the Shapiro-Wilk test. An independent samples t-test was used to compare normally distributed variables, whereas the Mann-Whitney U test was used to compare non-normally distributed variables. Categorical variables were expressed as numbers, and the chi-square test or Fisher's exact test was selectively used to compare categorical variables. The Pearson's correlation test (two-sided) was performed to explore the association between varus knee deformity and morphological changes in the foot and ankle. The level of significance was set at $P < 0.05$.

All statistical analyses were performed with IBM SPSS Statistics 26 (IBM Corp, Armonk, NY) software.

Results

Demographic data

There were no significant differences found in age, BMI, affected side, or sex between the two groups (Table 2). All patients cooperated to complete the required preoperative radiographic and clinical evaluations, and no patients were excluded.

Radiographic outcomes

There were significant differences in the ankle joint morphology (TAS, TT, and MTJS) between the severe and mild varus groups (Table 3). The total incidence of AOA

Fig. 2 Measurement method of HKA based on preoperative total lower extremity weight-bearing AP radiograph was shown in Fig. 2. HKA was defined as the angle between mechanical axes of femur and tibia. Notably, HKA = 179° means 1° of knee varus in this study

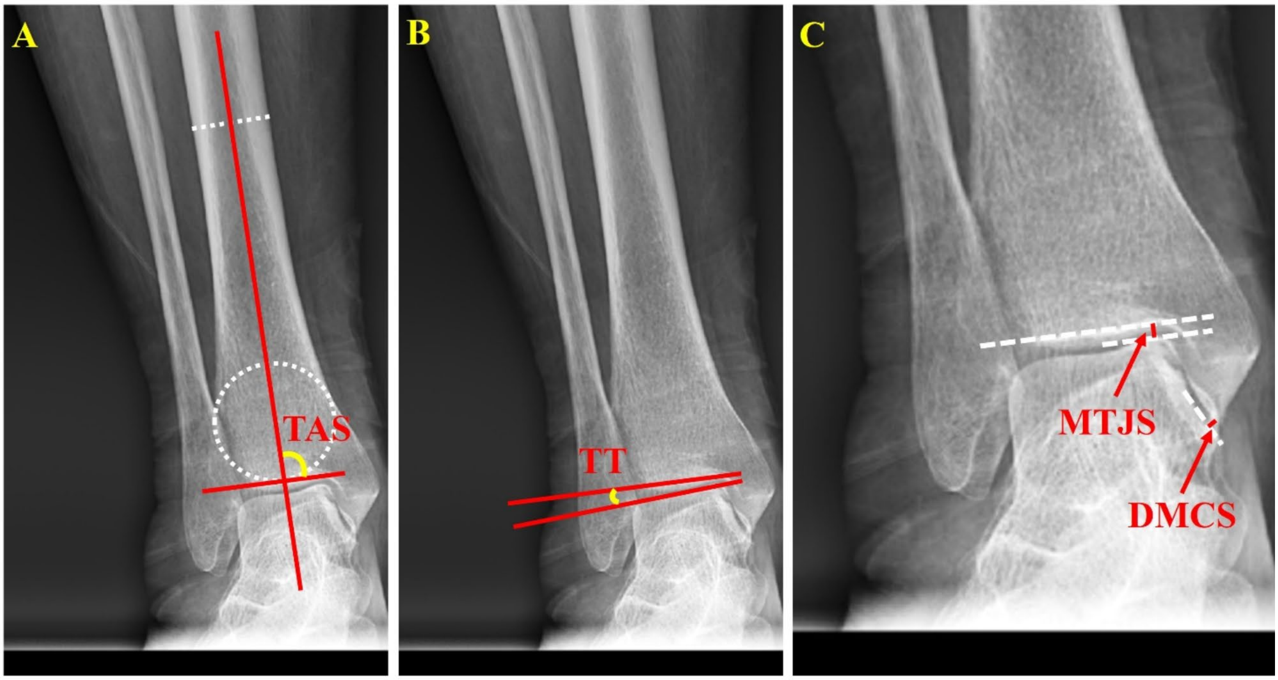

Fig. 3 **A**, **B**, **C** were all partial enlarged images of total lower extremity weight-bearing AP radiograph, showing the measurement methods of several other ankle morphological parameters. **(A)** TAS was defined as the medial angle between distal tibial plafond and the anatomical axis of tibia. **(B)** TT was defined as the angle between distal tibial plafond and the upper joint surface of talus, and the angle opening to the lateral aspect of the ankle as shown in the figure was defined as a positive value. **(C)** MTJS was defined as the shortest distance between the medial end of talar dome and the distal tibial plafond, while DMCS was the vertical distance from the distal tip of medial malleolus to the medial articular surface of talus

Table 1 The modified Takakura ankle OA classification system

Stage	Radiographic characteristics
I	No joint space narrowing, but with early sclerosis and osteophyte formation.
II	Narrowing of the joint space medially.
IIIa	The obliteration of the joint space of medial malleolus.
IIIb	The obliteration extends to the roof of the talar dome.
IV	The obliteration of the whole joint space with complete bone-to-bone contact.

was significantly higher in the severe varus group than in the mild varus group ($P=0.005$), based on the modified Takakura ankle osteoarthritis classification system (Table 3).

In addition, the magnitude of the hindfoot valgus deformity was significantly higher in the severe varus group than in the mild varus group ($p<0.001$) (Table 4). There was no significant difference in the morphology of the medial longitudinal arch between the two groups (Table 4). However, the incidence of hallux valgus was significantly higher in the severe varus group ($p=0.028$) (Table 5). The IMA ($p=0.046$) and HVA ($p=0.028$) were also significantly higher in the severe varus group than in the mild varus group (Table 5).

Pearson's correlation test revealed that the HKA was associated with ankle morphology (TAS, TT, and MTJS), hindfoot alignment (HA), and forefoot morphology (HVA) (Table 6).

Clinical outcomes

Foot and ankle pain in patients with varus KOA was most common in the medial ankle (19.72%), followed by the hindfoot (15.49%) (Table 7). Furthermore, the incidence of medial ankle pain ($P=0.023$) and hindfoot pain ($P=0.034$) was significantly higher in the severe varus group than in the mild varus group, with no difference in midfoot or forefoot pain between the two groups. Notably, patients with severe varus KOA were more prone to multiple pain at foot and ankle ($P=0.015$) (Table 7).

There were significant differences in the ankle joint morphology (TT, MTJS, and DMCS) between the medial ankle pain group and non-medial ankle pain group (Table 8). The HA was significantly higher in the hindfoot pain group than in the non-hindfoot pain group (Table 9).

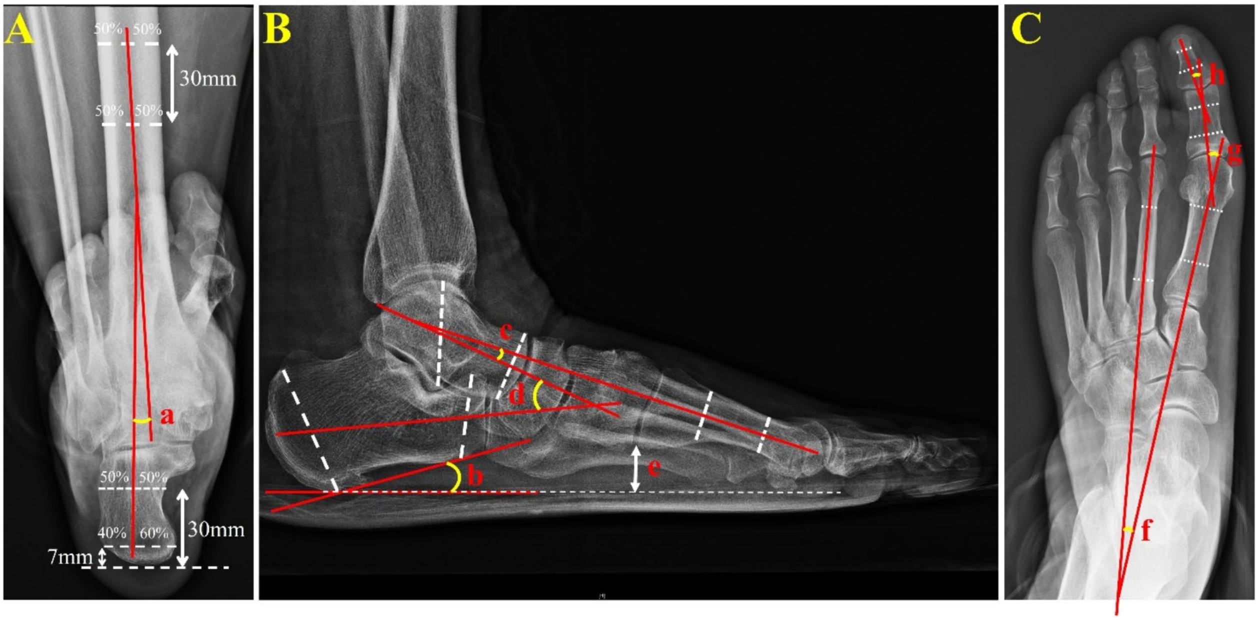

Fig. 4 **(A)** Hindfoot alignment angle (HA) **(a)** was measured on preoperative long axial weight-bearing view of the hindfoot, which was defined as the angle (**a**) between tibial anatomical axis and calcaneal longitudinal axis. The tibial anatomical axis was determined by the extending line through two diaphyseal midpoints (30 mm apart) that bisect the tibial. The calcaneal longitudinal axis was determined by the extending line through two points: one point is the 40% mark of a horizontal line 7 mm above the most distal end of the calcaneus, and the other is the midpoint of a horizontal line 30 mm above the most distal end of the calcaneus. Notably, hindfoot valgus was defined as the positive value. **(B)** Morphological parameters of medial longitudinal arch were measured on preoperative lateral weight-bearing radiograph of foot: **(b)** calcaneal pitch angle (CPA), **(c)** lateral talus-first metatarsal angle (Meary's angle), **(d)** lateral talocalcaneal angle (LTCA), **(e)** height of the medial cuneiform (HMC). **(C)** Morphological parameters of hallux valgus deformity were measured on preoperative AP weight-bearing radiograph of foot: **(f)** intermetatarsal angle (IMA), **(g)** hallux valgus angle (HVA), **(h)** hallux interphalangeal angle (HIA)

Table 2 The comparison of demographic data between the two groups (M ± SD)

	Severe varus group (*n* = 119)	Mild varus group (*n* = 94)	*P*-value
Age (year)	67.2 ± 5.7	67.1 ± 6.4	0.606
BMI (kg/m^2)	27.2 ± 3.7	27.4 ± 3.9	0.698
Side (n)			0.284
Left	72	50	
Right	47	44	
Sex (n)			0.329
Male	39	25	
Female	80	69	

M ± SD, Mean ± Standard deviation; BMI, Body mass index

Table 3 The comparison of ankle morphology and ankle OA incidence between the two groups

	Severe varus group (*n* = 119)	Mild varus group (*n* = 94)	*P*-value
Ankle morphology			
TAS (°)	93.2 ± 2.9	91.9 ± 3.5	0.026
TT (°)	1.3 ± 1.7	0.9 ± 1.4	0.041
MTJS (mm)	2.6 ± 0.7	2.8 ± 0.5	0.003
DMCS (mm)	1.8 ± 0.8	1.9 ± 0.7	0.357
Ankle OA			
Ankle OA (n)	54	25	0.005
Ankle OA grading			
Non-ankle OA (n)	65	69	0.036
I (n)	15	9	
II (n)	23	12	
IIIa (n)	12	4	
IIIb (n)	4	0	
IV (n)	0	0	

TAS, tibial anterior surface angle; TT, talar tilt angle; MTJS, medial tibiotalar joint space; DMCS, distal medial clear space. OA, osteoarthritis

Discussion

The most important finding of this study was that varus knee deformity was associated with morphological changes in the foot and ankle, including the ankle (increased valgus of the distal tibial plafond, decreased medial ankle joint space, and increased incidence of AOA), hindfoot (increased hindfoot valgus), and forefoot (increased hallux valgus). Furthermore, patients with severe knee varus were more prone to medial ankle pain, hindfoot pain, and multiple pain locations than those with mild knee varus. Pain in the medial ankle and hindfoot was associated with corresponding morphological changes.

To date, no consensus has been reached on the relationship between varus knee deformity and ankle

Table 4 The comparison of hindfoot and medial longitudinal arch morphology between the two groups

	Severe varus group (*n* = 119)	Mild varus group (*n* = 94)	*P*-value
Hindfoot morphology			
HA (°)	3.5 ± 4.1	0.7 ± 3.9	< 0.001
Medial longitudinal arch morphology			
CPA (°)	15.9 ± 4.1	17.0 ± 4.3	0.249
Meary's angle (°)	7.7 ± 5.3	6.8 ± 4.9	0.223
LTCA (°)	44.7 ± 4.6	45.4 ± 4.3	0.415
HMC (mm)	15.3 ± 3.7	15.8 ± 4.0	0.462

HA, hindfoot alignment angle; CPA, calcaneal pitch angle; Meary's angle, lateral talus-first metatarsal angle; LTCA, lateral talocalcaneal angle; HMC, height of the medial cuneiform

Table 5 The comparison of the incidence and morphology of hallux valgus between the two groups

	Severe varus group (*n* = 119)	Mild varus group (*n* = 94)	*P*-value
Hallux valgus deformity			
Hallux valgus (n)	57	31	0.028
Hallux valgus morphology			
IMA (°)	10.4 ± 3.1	9.6 ± 3.1	0.046
HVA (°)	16.3 ± 5.7	14.8 ± 5.0	0.028
HIA (°)	9.1 ± 3.7	8.9 ± 3.3	0.575

IMA, intermetatarsal angle; HVA, hallux valgus angle; HIA, hallux interphalangeal angle

Table 6 The correlation of HKA with morphological changes in the foot and ankle

	Correlation coefficient	*P*-value
Ankle morphology		
TAS (°)	-0.15	0.035
TT (°)	-0.18	0.010
MTJS (mm)	0.16	0.017
DMCS (mm)	0.08	0.252
Hindfoot morphology		
HA (°)	-0.28	< 0.001
Medial longitudinal arch morphology		
CPA (°)	0.07	0.293
Meary's angle (°)	-0.06	0.378
LTCA (°)	0.07	0.346
HMC (mm)	0.05	0.481
Hallux valgus morphology		
IMA (°)	-0.10	0.159
HVA (°)	-0.14	0.044
HIA (°)	-0.04	0.523

HKA = 179° means 1° of knee varus in this study

Table 7 The comparison of foot and ankle pain incidence between the two groups

	Severe varus group (*n* = 119)	Mild varus group (*n* = 94)	*P*-value
Pain around the foot and ankle			
Medial ankle pain (n)	30	12	0.023
Lateral ankle pain (n)	5	2	0.399
Hindfoot pain (n)	24	9	0.034
Midfoot pain (n)	10	6	0.579
Forefoot pain (n)	12	6	0.335
Multiple pain (pain locations ≥ 2) (n)	28	10	0.015

Table 8 The relationship between medial ankle pain and ankle morphology

	Medial ankle pain group (*n* = 42)	Non-medial ankle pain group (*n* = 171)	*P*-value
Ankle morphology			
TAS (°)	93.1 ± 3.2	92.5 ± 3.2	0.305
TT (°)	3.1 ± 1.0	0.6 ± 1.3	< 0.001
MTJS (mm)	1.8 ± 0.8	2.9 ± 0.4	< 0.001
DMCS (mm)	0.8 ± 0.7	2.1 ± 0.5	< 0.001

Table 9 The relationship between hindfoot pain and hindfoot morphology

	Hindfoot pain group (*n* = 33)	Non-hindfoot pain group (*n* = 180)	*P*-value
Hindfoot morphology			
HA (°)	4.7 ± 3.6	1.8 ± 4.2	0.001

morphological changes. Gao et al. [30] found that knee malalignment can induce an increased tilt angle of the ankle (TAA). Xie et al. [4] suggested that varus knee deformity was associated with an increased TAS. However, no bulk-sample studies have demonstrated an association between varus knee deformity and ankle alignment. In this study, varus knee deformity was associated with increased TAS, increased TT, and decreased MTJS. This finding suggests that knee varus is associated with increased valgus of the distal tibial plafond and decreased medial ankle joint space. Although the reported incidence of AOA in patients with end-stage KOA ranged from 24.2 to 36.8% [18], these patients notably remained significantly under-aware of AOA [3]. In the present study, the severity and incidence of AOA were significantly higher in patients with severe varus knee deformity. Our findings on ankle alignment and AOA suggest that varus knee deformity may promote AOA progression through morphological changes in the ankle, and further studies are necessary to identify the specific mechanism by which a varus knee deformity causes ankle degeneration.

Hindfoot alignment is not included in the traditional MA of the lower extremity [8]. Although hindfoot alignment and traditional MA of the lower extremities are both important components of lower extremity alignment, no consensus has been reached regarding their association between the two components [8]. In the present study, knee varus was associated with increased hindfoot valgus. This finding suggests the existence of a potential biomechanical link between the knee and hindfoot alignments. Several studies have found that varus knee deformity was correlated with hindfoot valgus [14, 31, 32], which was consistent with the results of our study. However, the mechanism by which knee varus leads to hindfoot valgus is complex, and the mechanisms reported in the abovementioned relevant studies are inconsistent. Further studies are required to address this issue.

Patients with varus KOA are more prone to concomitant foot deformities, particularly a collapsed medial longitudinal arch [33, 34]. However, few studies have analyzed the relationship between knee varus and the medial longitudinal arch morphology. In the present study, both comparison of the parameters between the two groups and results of the Pearson's correlation test showed no association between varus knee deformity and medial longitudinal arch morphology. This finding suggests that although the incidence of collapsed medial longitudinal arch is relatively higher among patients with varus KOA [2, 34], the degree of varus knee deformity is not associated with the foot arch morphology. Ohi et al. [2] also demonstrated that the degree of knee varus was not associated with the navicular height, which supports our findings.

Hallux valgus is another prevalent forefoot deformity in patients with KOA and is characterized by lateral deviation (abduction) of the hallux with a corresponding medial deviation (adduction) of the first metatarsal [35]. In the present study, the incidence and severity of hallux valgus were significantly higher in patients with severe varus KOA. This finding suggested that patients with severe knee varus were more prone to hallux valgus. Ohi et al. [2] suggested that an increased varus knee deformity was associated with an increase in the hallux valgus angle, which was consistent with our findings. However, the mechanism by which knee varus leads to hallux valgus is complex, and no consensus has been reached. Further studies are required to determine the biomechanical link between knee varus and hallux valgus progression.

In patients with end-stage KOA, morphological changes commonly occur in the foot and ankle, which usually indicate arthritis and chronic pain [10]. However, few studies have analyzed the relationship between varus knee deformity and foot and ankle pain. In the present study, we demonstrated for the first time that concomitant foot and ankle pain in patients with varus KOA occurred mostly in the medial ankle (19.72%) and that the incidence of pain in the medial ankle was significantly higher in the severe varus group. Thus, medial ankle pain may be the most common type of foot and ankle pain in patients with KOA, and it was more common in patients with severe knee varus. Furthermore, we found that patients with severe varus KOA were more prone to hindfoot pain and multiple pain locations. However, there were no significant differences in the incidences of lateral ankle, midfoot, and forefoot pain between the two groups. Further studies are required to investigate why knee varus only causes pain in specific regions of the foot and ankle.

In this study, the incidence of pain in the medial ankle and hindfoot was significantly higher in the severe varus group. Additionally, significant morphological differences were observed in the medial ankle and hindfoot between the severe and mild varus group. Therefore, we can speculate that pain in the medial ankle and hindfoot is associated with morphological changes in the corresponding regions. In this study, we analyzed the morphological risk factors for pain and found significantly higher TT, lower MTJS, and lower DMCS in the medial ankle pain group, suggesting that a narrow medial ankle joint space is the cause of medial ankle pain in patients with KOA. We speculate that there are two possible reasons that could lead to a narrowing of the medial ankle space: one is that the lateral collateral ligament may be relaxed, causing an imbalance in muscle strength between the medial and lateral ankle; the other is the degeneration of the medial cartilage, leading to medial AOA. In addition, HA was significantly higher in the hindfoot pain group, suggesting that severe hindfoot valgus is a contributing factor to hindfoot pain. The hindfoot pain described in this study was a diffuse pain located around the hindfoot, which might include the sinus tarsi and subtalar joint. However, no study has yet analyzed the specific mechanisms of medial ankle and hindfoot pain in patients with varus KOA, which should be the focus of future studies.

The present study has several limitations. First, this was a retrospective study, which may affect the reliability of our conclusions. Second, only Asians with end-stage varus KOA were enrolled in this study; thus, the findings may not be generalizable to patients with valgus knee deformity or other races. Third, this study has a fundamental limitation in describing the 3-dimensional morphology of the foot and ankle using 2-dimensional radiographic parameters. Fourth, the pain assessment in this study was based solely on the patient's chief complaint and did not have a relevant score as a basis. Furthermore, a non-precise description of foot and ankle pain was used in this study, which is inadequate for understanding the nature of pain. Finally, this study lacked a control group, which may affect the reliability of our conclusions. Nevertheless, we believe that this study is necessary as a preliminary study for further long-term follow-up studies.

Conclusion

Varus knee deformity was associated with morphological changes in the foot and ankle, and the incidence of AOA and hallux valgus deformity was significantly higher in patients with severe varus KOA. Patients with severe varus KOA were more prone to medial ankle pain, hindfoot pain, and multiple pain locations, which were associated with corresponding morphological changes. This study is necessary as a preliminary study to help understand the relationship between knee varus and foot and ankle morphology and to establish a foundation for the current study.

Author contributions

ZH wrote the paper and edited the manuscript. ZZ collected the data and revised the paper. WW performed all the statistical analysis. FC measured the imaging parameters. HZ designed the whole study and revised the paper. All authors have read and approved the final manuscript.

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Data availability

No datasets were generated or analysed during the current study.

Declarations

Ethical approval and consent to participate

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Institutional Review Board of The Affiliated Hospital of Qingdao University (QYFY WZLL 28765). Written informed consent was obtained from all the enrolled individuals.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

Clinical trial number

Not applicable.

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