



Enhancing the radiological classification system from the distal femur to the proximal tibia

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Walldius^[1] developed, in 1951, the first hinge system for primary total knee arthroplasty (TKA), a self-aligning stemmed device capable to achieve a great stability on the frontal plane (varus and valgus deviation), often substituting a deficient collateral ligament apparatus. The hinge system was very attractive due to his simplicity and efficacy; however, this rigid system involved the transfer of torsional forces from the central hinge directly to the stems, generating a high amount of stresses between the bone-cement interface and leading to complications such as fractures and mechanical failures. The introduction of rotating hinge implants in the 1970s^[2] has improved the distribution of the rotational stresses providing better outcomes and reducing associated complications. These changes are represented in survivorship rates and functional knee scores, as reported by Kouk et al.^[3]

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ABSTRACT

Objectives: This study aims to identify anatomical variants of the proximal tibia shaft and to develop a novel classification system for proximal tibia.

Patients and methods: Between October 2019 and April 2020, a total of 200 patients with standard knee anteroposterior radiographs were included in this study. We measured the inner diameter of the tibia 16 cm distally from the tibial plateau and 3 cm distally from the tibial spine. The ratio between these two measurements was applied as the novel index ratio.

Results: A total number of 197 patients (100 males and 97 females) with a median age of 68 years (range, 21 to 89 years) were included in the final analysis. According to the 25th and 75th percentiles, three groups were clustered for each sex. A higher distribution of the type B pattern was found in female and male patients. However, type A with a narrow inner diaphyseal diameter was less common in female patients. The median intra-observer reliability for rater 1 was 0.998. The inter-observer reliability was high (intraclass correlation coefficient: 0.998). There was a moderate correlation between the anteroposterior (AP) diameter and height ($r=0.568$) and a low correlation between the AP diameter and weight ($r=0.376$). The novel index shows no significant correlation between the index ratio and height ($r=0.082$), weight ($r=0.014$) or body mass index ($r=-0.038$).

Conclusion: The novel classification presents three different types of tibia for each sex: type C has a wider inner diaphyseal diameter compared to type A with a narrow inner diaphyseal diameter. Type B has the widest distribution among the subjects.

Keywords: Aseptic loosening, novel classification, novel index, revision arthroplasty, rotating hinge prosthesis, tibia.

In a recent meta-analysis, a rotating hinge knee design demonstrated an overall survival rate of 82% at 10 years with aseptic loosening (AL) being the second cause of failure after infection (17.8%), with an average joint age of 4.06 years.^[4] Our institution data shows a 14-fold higher incidence of AL at the femur compared to the tibial side; at the opposite, its most common localization (whether

femur or tibia) is still debated in the literature.^[5-7] Although the diagnosis can be straightforward and based on simple radiographs in the vast majority of the cases, this occurrence cannot always be predicted or avoided. Once detected, the loosening leads to a mandatory revision, considering that “conservative” approaches have not led to good results.^[8]

A recent article has demonstrated that the inner diaphyseal diameter of the distal femur 20 cm from the articular surface is one of the strongest independent risk factors related to AL following primary TKA using cemented rotating hinge prosthesis.^[9] Similar results have been presented for revision TKA procedures using cemented rotating hinge prosthesis by the same authors.^[10] Subsequently, the novel radiological classification system, also known as Citak Classification, was introduced to the literature.^[5] The Citak Classification divides the distal femur into three groups, where the population with a wider inner diaphyseal diameter is represented by type C with the highest risk for AL of the femoral component.^[9] In the present study, we aimed to identify anatomical variants of the proximal tibia shaft to develop a novel classification system for proximal tibia.

PATIENTS AND METHODS

This single-center, retrospective study was conducted at ENDO-Klinik Hamburg, Department of Orthopedics between October 2019 and April 2020. Initially, a total of 554 patients received radiographs of the knee joint in the outpatient clinic at our institution which were identified using our institutional electronic database. Patients were selected according to the following exclusion criteria: patients <18 years of age, radiographs that were not performed in an external center, patients who underwent previous knee surgical procedure, and scarce visualization of the joint line (e.g., no properly extended knee). Following the exclusion criteria, we randomly enrolled 200 plain radiographs for evaluation. To achieve an “a-priori” demographic balance, we randomly assigned 100 female and 100 male patients, each group with 50 right knees and 50 left knees. Patient charts were reviewed to collect demographic and anthropometric characteristics of all patients. A written informed consent was obtained from each patient. The study protocol was approved by the Local Ethics Committee Institutional Review Board (IRB No: 2021-300061-WF). The study was conducted

in accordance with the principles of the Declaration of Helsinki.

Radiological evaluation

Using standard weight-bearing knee radiographs in anteroposterior (AP) projection, two observers performed an independent and blinded evaluation and measurement, using JiveX-5.2 Mediacad program (VISUS Health IT GmbH Gesundheitscampus-Süd 15-17 44801 Bochum) as a Digital Imaging and Communications in Medicine (DICOM) manager. The following two measurements were performed: initially, the inner diaphyseal diameter of the proximal tibia was quantified at 16 cm from the articular surface on the lateral plateau of the tibia, followed by the measurement of the diameter 3 cm below the medial tibial eminence (Figure 1).

The proximal measurement was arbitrarily placed at 3 cm below the medial tibial eminence to identify a practical parameter for the epiphysis, the distal reference point was placed at 16 cm to locate

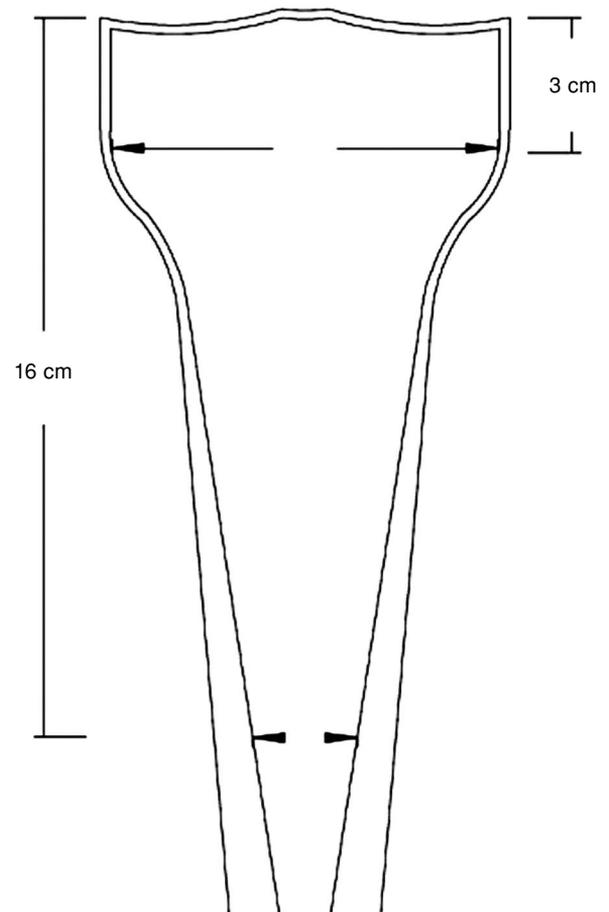


FIGURE 1. Methods of measurement, proximal tibia at 3 cm and tibia shaft at 16 cm from medial spine.

an area some centimeters distal to the majority of the cement restrictors for the cemented tibial stems.

Measurements were conducted twice within a time interval of two weeks. One of the observers was a senior resident in orthopedics and the second observer a physician in training. This study design allowed us to examine whether the reliability of the novel classification system at the tibia was dependent on the experience of the examiner.

Novel classification system

The patients were separated into male and female sex due to morphological differences. Both groups were further divided into three sub-groups according to the distal inner diaphyseal diameter using the 25th and 75th percentile as reference points to identify cut-off values for further classification: A: under percentile 25th, B: between percentile 25th and 75th, and C: over percentile 75th (Table I; Figure 2).

Furthermore, an index ratio was calculated between the inner diaphyseal diameter at 16 cm and the medial tibial eminence diameter at 3 cm to classify male and female patients into three groups with the

same percentile ranges as outlined above (Table II; Figure 3).

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 26.0 software (IBM Corp., Armonk, NY, USA). Continuous data were expressed in median (min-max), while categorical data were expressed in number and frequency. The Mann-Whitney U test was applied for continuous outcomes and revealed normal distribution. The intraclass correlation coefficient (ICC) was utilized to quantify the inter- and intra-observer reliability of all radiographic measurements. The ICC values greater than 0.90 indicate an excellent reliability. The Pearson correlation analysis (linear regression test) was performed to identify a relation between our dependent and independent variables. A *p* value of <0.05 was considered statistically significant.

RESULTS

A total number of 197 patients (100 males and 97 females) with a median age of 68 years (range, 21 to 89 years) were included in the final analysis. Three

TABLE I		
The cut-off values for the inner diaphyseal diameter at 16 cm from the articular surface, from both men and women		
Inner tibial diameter	Sex	
	Male	Female
Group A	<16	<13
Group B	16-20	13-17
Group C	≥20	≥17

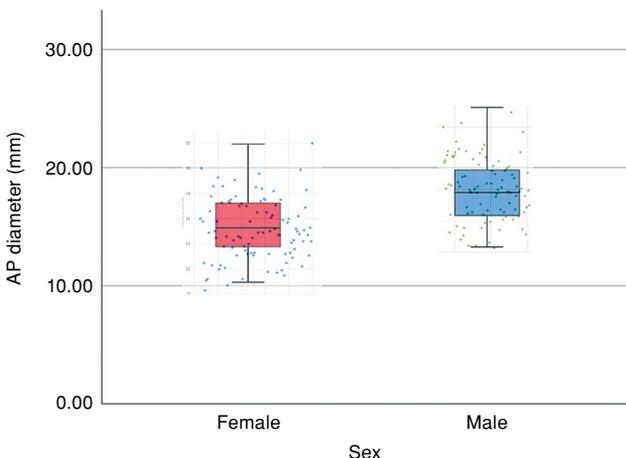


FIGURE 2. Distribution of anteroposterior diameter of the distal femur by sex.

TABLE II		
The index intervals used for classifying patients on each group depending on sex		
Index	Sex	
	Male	Female
Group A	<0.195	<0.191
Group B	0.195-0.234	0.191-0.236
Group C	≥0.234	≥0.236

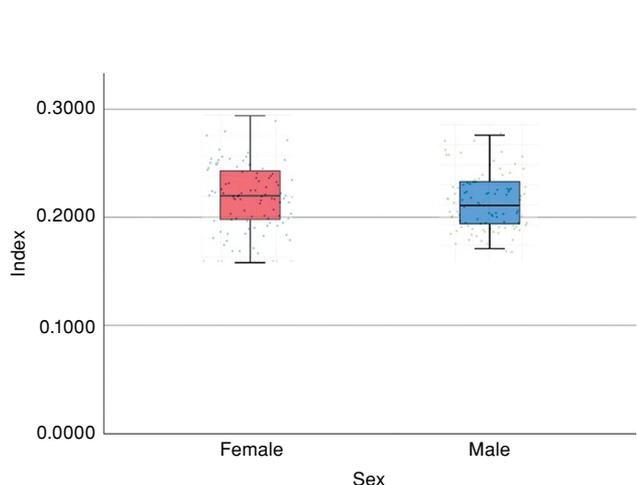


FIGURE 3. Distribution of novel index by sex.

patients were excluded due to the impossibility to measure the inner diaphyseal diameter at 16 cm. There were 47 left knees and 50 right knees in the female group and 50 left knees and 50 right knees in the male group. We identified a moderate correlation

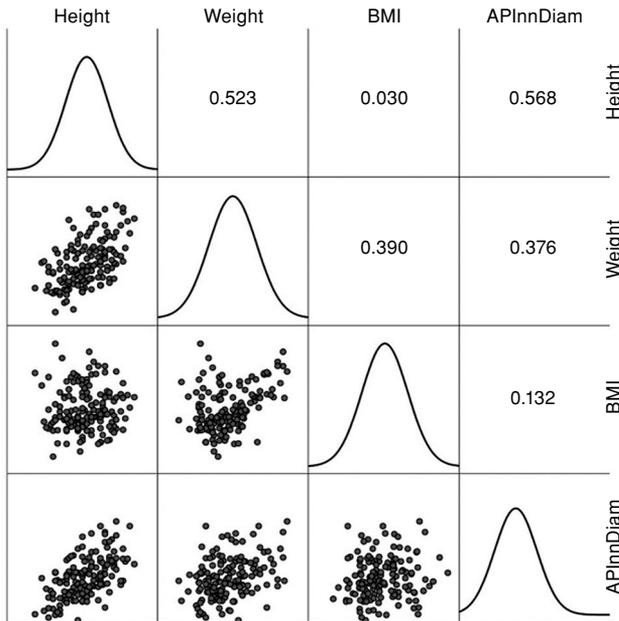


FIGURE 4. Presents the correlation analysis between AP diameter and height, weight, and BMI.
AP: Anteroposterior; BMI: Body mass index; APInnDiam: AP internal diameter.

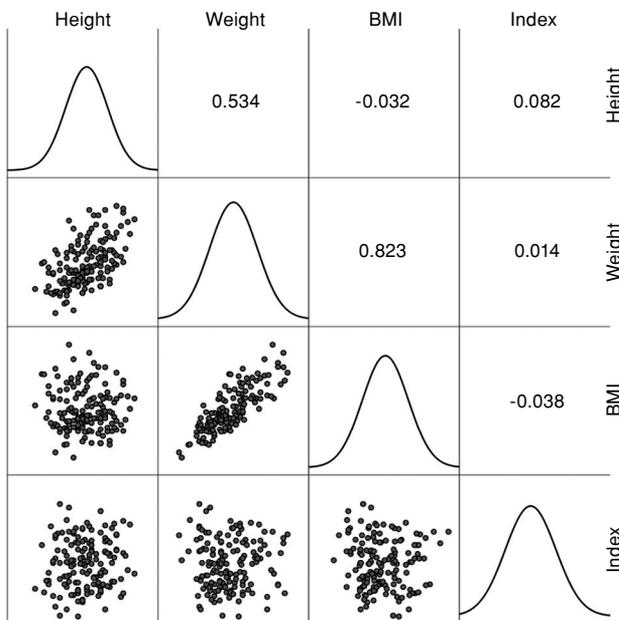


FIGURE 5. Presents the correlation analysis between the novel Index and height, weight and BMI.
BMI: Body mass index.

TABLE III
Patient characteristics by novel classification group

Variables	Male												Female											
	Group A				Group B				Group C				Group A				Group B				Group C			
	n	Median	Range	n	Median	Range	n	Median	Range	n	Median	Range	n	Median	Range	n	Median	Range	n	Median	Range			
Number of patients	25			50			24			17			54			26								
Age (year)	69	22-83		69	44-88		66.5	49-89		67.5	51-88		69	48-90		69	52-84							
Height (cm)	172	164-187		178	163-193		180	168-191		159	149-180		165	152-174		166	154-181							
Weight (kg)	82	71-123		93	65-128		101	70-130		73	63-115		80	50-108		81	58-119							
BMI (kg/m ²)	27.5	21.7-40.2		28.2	22.1-42.4		30.1	22.1-39.2		30.6	24.6-37.6		27.73	18.9-37.7		28	21.8-44.2							
Side																								
Left	13			27			10			7			29			11								
Right	12			23			14			10			25			15								
AP diameter (cm)	15.3	13.3-15.9		17.95	16-19.8		21.6	20-25.1		11.9	10.3-12.9		14.7	13.1-16.9		17.8	17-22							
Novel Index ratio	0.187	0.171-0.215		0.211	0.184-0.265		0.243	0.222-0.276		0.18	0.158-0.232		0.218	0.176-0.284		0.244	0.201-0.280							

BMI: Body mass index; AP: Anteroposterior.

between the AP diameter and height ($r=0.568$) and a low correlation between the AP diameter and weight ($r=0.376$). The results furthermore showed a correlation between the AP diameter and body mass index (BMI) ($r=0.132$), although not statistically significant (Figure 4). Accordingly, there was no statistically significant correlation between the index ratio and height ($r=0.082$) or weight ($r=0.014$) or BMI ($r=-0.038$) (Figure 5).

Radiological findings

According to the 25th and 75th percentile and cut-off values for each sex (Table I; Figure 2), three groups of the anatomical classification of the distal tibia were created. Female patients: type A: <13 mm; type B: 13-17 mm; and type C: ≥ 17 mm. Male patients: type A: <16 mm; type B: 16-20 mm; and type C: ≥ 20 mm.

In conformity to the novel index ratio (inner diameter of the tibial canal 16 cm distal to the knee joint, in relation to the inner diameter of the medullary canal 3 cm distal to the medial tibial eminence in AP knee radiographs), three anatomical classification groups were constructed: female patients: type A: <0.19, type B: 0.19-0.24, type C >0.24; male patients: type A: <0.19, type B: 0.19-0.23, type C: >0.23 (Table II; Figure 3). Significant differences for several AP diameters and the novel index ratio between the three types in male and female patients were observed (Table III).

The median intra-rater agreement was 0.998 (95% confidence interval [CI]: 0.998-0.999) for rater 1 and 0.997 (95% CI: 0.997-0.998) for rater 2. The inter-observer assessment also demonstrated a high ICC of 0.998 (95% CI: 0.998-0.998).

DISCUSSION

Our series of measurements allows to divide the morphology of the proximal tibia into three groups: type A, B and C, having type C the wider inner diaphyseal canal; in addition, significant sex differences were reported. This novel index and classification could be useful in predicting the risk of AL, thus orienting the surgeon toward the choice of a rotating hinge implant. Similar to the Citak classification,^[5] there are other classifications, such as the Dorr classification,^[11] which describe anatomical norm variations of bony structures.

According to cut-off values for each sex, the ratio between the inner diameter of the tibial canal 16 cm distal to the knee joint, in relation to the inner diameter of the medullary canal 3 cm distal to the

medial tibial eminence in AP knee radiographs, led to the development of three anatomical classification groups: female patients: type A: <0.19, type B: 0.19-0.24, type C >0.24; male patients: type A: <0.19, type B: 0.19-0.23, type C: >0.23. Excellent inter- (0.996-0.998) and intra-observer reliability (0.92-0.997) was demonstrated. The femoral index resulting from the Citak classification was shown to be an independent predictor for aseptic femoral loosening of rotating hinge knee prosthesis.^[9] The measurements of the diameter of the internal femoral canal as the basis of the Citak classification were transferred to the tibia in this study; we classified the tibia analogue to the Citak classification of the femur in type A, B and C with quantitative cut-off values for each group and with a similar distribution for each type.

As previously reported, Citak et al.^[5] proposed a new classification for distal femur that may be helpful as preoperative planning for rotating hinge prosthesis. Male and female patients were separate in different groups due to AP diameter found for each group and three types were described. Male type A with AP diameter under 19, type B between 19-24 and type C, 24 or above while female patients were classified as type A below 15, type B between 15 and 20, and type C, 20 or greater values. High inter- and intra-observer reliability indicates the classification to be a useful tool in making decisions on whether a hinged prosthesis is the best choice for a patient considering the risk of (AL). Citak's classification for distal femur has an inter-observer reliability between 0.996-0.998 and an intra-observer reliability between 0.92-0.997 similar to the intra- and inter-observer reliability found in this study of 0.997-0.999 and 0.998 respectively, making it useful as a preoperative tool for patient stratification. In contrast to the femoral novel classification system study, this study showed a moderate correlation between the AP diameter of proximal tibia and height. Although further investigation is needed, a type C with a wider inner diaphyseal diameter of the tibial canal may be helpful to predict AL of the tibial component in TKA tibially, as has been shown femorally.^[5] It is postulated that its combined usage with the classification system for the distal femur may facilitate decision-making processes regarding the implant and patient selection for rotating hinge implants.

Additionally, a novel index was developed, and the distribution of the index ratio values demonstrated a wider range among the female study population, but similar cut-off values for both male and female patients. Ranging from 16%^[12]

to 65%,^[13] AL has shown to be the most important cause of non-septic failures. Moreover, it is well known that an appropriate cementing technique is mandatory; however, it is becoming clear that patient related factors, such as bone stock quality and diaphyseal canal morphology, play an important role in prosthesis fixation and survivorship. The presented high failure rates can be justified by the fact that knee prosthesis with fixed hinge suffers from excessive abnormal stresses, such as tension, compression, and shearing forces. These stresses are transferred from the prosthesis to the bone, applying mostly to the interface.^[7] As suggested by Morgan-Jones et al.,^[14] failure to gain adequate fixation in zone 2 (methaphysis) and 3 (diaphysis) can lead to early failure of a revision implant due to elevated shear stress; The concept of zonal fixation provides a working methodology applicable to both the tibia and the femur when planning revision knee replacement.

Taking this into account, our classification system for proximal tibia offers a new possibility for patient stratification, evaluation and decision-making.^[15] Although no specific studies have been conducted focusing specifically on the tibial component alone, the use of both classification systems may be a better predictor for risk of AL and a tool to choose what is best for patients individually, preventing unwanted outcomes.

This study has the following limitations: First, it has intrinsic limitations related to the retrospective study design. Second, ethnic differences among the study population were not considered, despite the existing proof for sex and race differences in knee morphology as described by Kim et al.^[16] who reported significant differences among sex and races on the tibial medio-lateral and AP dimensions, while Mahfouz et al.^[17] found an evident larger femoral AP diameter, with a smaller aspect ratio comparing Caucasian and East Asian population and a larger aspect ratio of the tibia emerged while comparing Caucasian and African American population. Therefore, the generalizability of the study results is limited and needs further validation in other populations to increase external validity. Third, analyses were carried out on randomly chosen radiographic images already stored in our database that were not adjusted-on-purpose or calibrated; however, all radiographs were performed according to a standardized methodology in our radiology department. The rationale behind that was to create a less controlled and more authentic setting suggesting higher external validity of the novel index. Finally,

the number of included patients may be relatively low and requires further validation in larger multi-center studies to strengthen the level of evidence.

The presented study project should be replicated to further test reliability of the classification, as a predictor for AL in revision cases with different prosthesis designs, as well as its effects on implant survivorship. In addition, future research should investigate the relationship between the novel femur and tibia classification.

In conclusion, AL represents the most frequent non-septic cause of rotating hinge knee prosthesis failure. It is well known that an appropriate fixation is mandatory, particularly in a revision setting where it is difficult to have appropriate bone stock. We believe that our work propose a new classification system to stratify the risk of AL in the tibia.

Declaration of conflicting interests

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