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Are Gender-Specific Femoral Implants for Total Knee Arthroplasty Necessary?

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A B S T R A C T

The purpose of this study was to determine the effect of gender on epiphyseal morphology and using this information to determine if an implant product line with a single width provides sufficient bone coverage for the entire population of knees being replaced. Morphology of the distal femoral epiphysis from 420 continuous knees was acquired with a surgical navigation system during primary TKA. A three-dimensional model of the distal femur was generated and used to determine the anterioposterior (AP) and mediolateral (ML) dimensions on 19 different virtual knee sections. Female knees had smaller AP and ML dimensions than male knees. The ML width of the distal femoral epiphysis was associated with femur length, not gender. Measurements derived from surgical navigation confirm that distal femoral epiphysis dimensions are related to femur length only independently of gender.

When designing a total knee arthroplasty (TKA) implant, information on distal femur anatomy is needed to optimize the fit and shape of the implants. The main femur parameters required are the anteroposterior (AP) to mediolateral (ML) ratio, size increments, and orientation of the trochlea. Biometric constants for the distal femoral epiphysis used in anthropology can be interpreted as gender or ethnic markers [1–5]. Many anatomical studies [2,6–11] have shown gender-related differences in the AP to ML ratio. To integrate these male/female differences and achieve optimal anatomical fit, some TKA manufacturers have developed a women-specific product line [12,13]. But these gender-related claims are controversial. Some consider these differences a function of the overall femur morphology [12–19] and morphotype [20] rather than being directly correlated to gender. However, no noticeable differences in the outcome between genders have been found when standard TKA implants are used [21–25]. Short-term comparative series with gender-specific implants have not shown any significant improvements in the results for total joint arthroplasty [26–28] or unicompartmental knee arthroplasty [29], which supports the conclusions of various meta-analyses [30,31].

The purpose of this study was to determine if two implant product lines of different widths had to be created. This was accomplished by measuring and comparing the morphology of the distal femoral epiphysis during TKA using a navigation system. We sought to answer two specific questions: 1) Is the shape of the lower end of the femur different between men and women? 2) Does an implant product line offering only one width provide sufficient bone coverage for the entire population of knees being replaced?

Patients and Methods

From May 2010 to January 2012, morphology data from 420 continuous knees were acquired during primary TKA at seven public and private French hospitals. Knees with greater than 10° valgus or varus were excluded. Data from 376 femurs were analyzed. This represents 90% of the included knees. The sample consisted of 37% men and 63% women, a 0.58 gender ratio. The average age was 69 years (range 52–90), and the BMI ranged from 15.8 to 50.6 with an average of 29.3.

Bone morphology of the distal femoral epiphysis was acquired digitally with a surgical navigation system (Amplivision®, Amplitude, France). The surgeon palpated a series of points on the distal and anterior part of the femur, and along the medial and lateral sides. A computer-generated three-dimensional (3D) model of the distal femur was rendered with this morphology information. The maximum error in the model was 1 mm at the palpated points. The morphology data were anonymized and then used to divide the patient population into seven groups. These seven groups corresponded to the seven AP implant sizes (ranging from 47.7 mm to 63.3 mm) in the Score® (Amplitude, France) product line. The size increment between the anterior and posterior cuts was 2.6 mm. Thus

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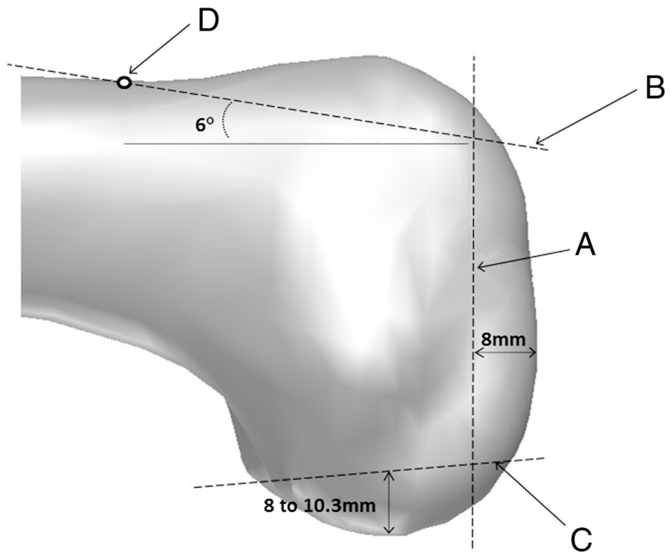

Fig. 1. Sagittal view of the cuts performed on the femur model: (A) distal cut plane, (B) anterior cut plane, (C), posterior cut plane, (D) anterior point.

the seven groups corresponded to the following AP dimensions: G1 (47.7 mm)/G2 (50.3 mm)/G3 (52.9 mm)/G4 (55.5 mm)/G5 (58.1 mm)/G6 (60.7 mm) and G7 (63.3 mm). Three virtual cuts were performed on the 3D bone models: (i) distal cut at 8 mm from the most distal condyle point; (ii) anterior cut at a 6° angle on the anterior cortex; (iii) posterior cut, performed based on an anterior landmark to obtain a posterior resection of 8 to 10.6 mm, which corresponds to the standard increment (2.6 mm) between two sizes (Fig. 1). After the distal femoral epiphysis cuts were made, the mediolateral dimensions were quantified using the same surgical navigation software. The geometry of each epiphysis was described using slices made along the Eckhoff axis [32], which is based on the geometry of the posterior condyles. These slices were made at angles of 0° to 90° in 5° increments. In all, 19 slices from the 3D model were defined and analyzed. This information was used to determine the future medial-lateral position of the implant relative to the edges of the femoral cuts (Fig. 2).

The data were compiled in a spreadsheet (Excel, Microsoft, Redmond, WA) and analyzed with statistical software (SPSS® IBM, Chicago, IL, USA). Student's *t* test was used to compare averages. The chi-square test was used with the nominal (categorical) data. ANOVA was performed to determine the relationship between continuous variables and one or more categorical variables. A Type I error threshold of 5% was used to determine if any of the statistical tests were significant ($P < 0.05$).

Results

Anteroposterior Dimension

The AP dimensions had a Gaussian distribution for both the female and male populations. For women, the highest number of knees was found in G4 (AP = 55.5 mm) and for men in G6 (AP = 60.7 mm). There was a statistically significant difference ($P < 0.05$) difference in the average AP measurement for men and women.

Within an AP size group, the male/female distribution was inhomogeneous. The greatest number of women was in groups G1 to G4 and the greatest number of men in groups G5 to G7 (Fig. 3); this difference was statistically significant ($P < 0.01$). Thus group G4 was representative of female knees (more than 80%) and group G7 of male knees (more than 90%).

Mediolateral Dimension

For each of the 19 slices, the dataset of mediolateral measurements was described by their respective averages and variations. The whole set of biometric data consisted of more than 14,668 measurements. As an example, the ML values for three representative slices at 0°, 40° and 70° are given in Table 1.

The average ML values on the 0° slice (distal femoral cut during TKA) increased with increasing AP size (Fig. 4). The trends were similar in the other slices. For example, in the group with the largest number of knees (G4), the mediolateral width ranged from 63 to 82 mm (Fig. 5). For each slice, the variability in the mediolateral dimension was greater than expected (Fig. 2). On average, female knees quite clearly had smaller AP and ML dimensions than male knees (Fig. 6).

ML/AP Ratio as a Function of Gender and Length

For each knee arthroplasty, femur length was determined using the navigation system to measure the distance between the hip center of rotation (point calculated by the navigation system) and the middle of the notch in the distal femoral epiphysis (point palpated during the surgical navigation).

As the femur length increased, the knee AP dimension increased ($P < 0.001$). On average, the widths of female femurs were smaller than the widths of male femurs (ANOVA $P < 0.0001$). Women also had significantly shorter femurs than men (ANOVA $P < 0.0001$). The ML/

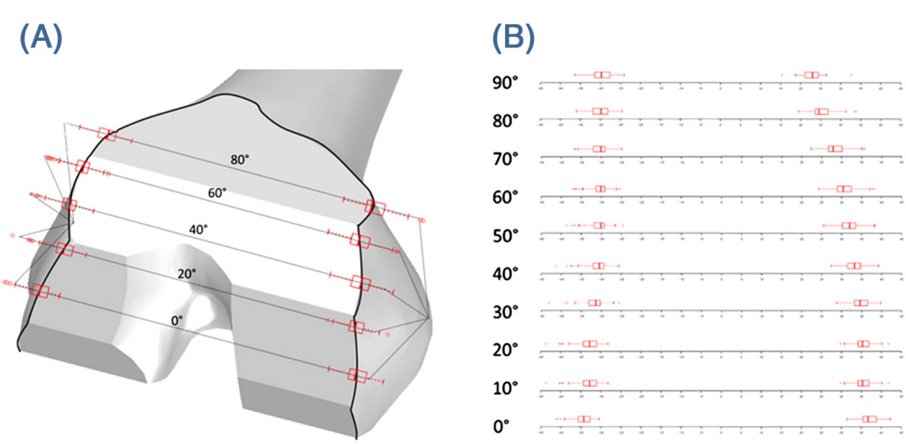

Fig. 2. Range of medial and lateral coordinates: (A) diagram showing five of the slices; (B) values for each slice in Group 4.

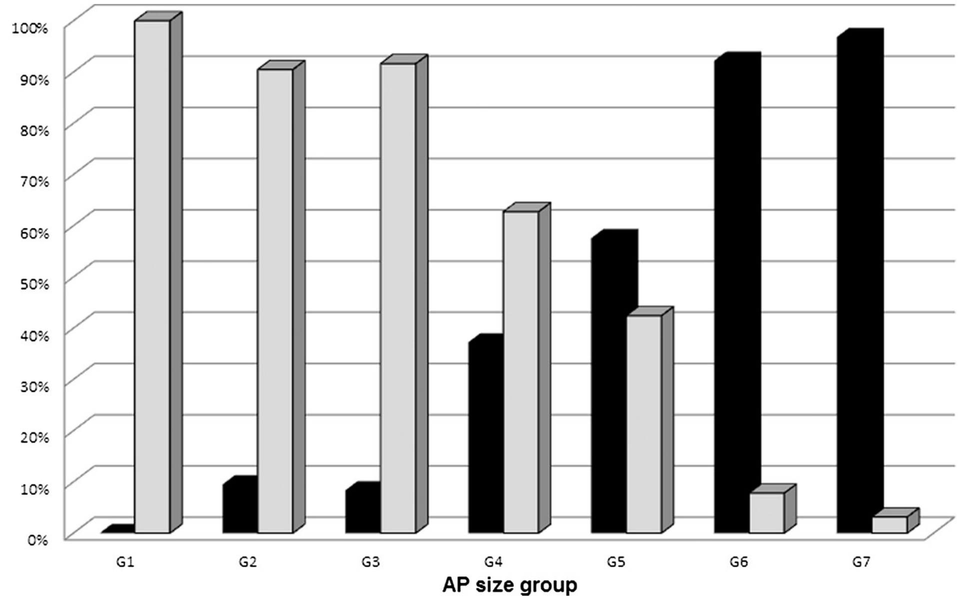

Fig. 3. Distribution in percentage of men (black bars) and women (grey bars) in each AP size group.

Table 1
ML Dimensions for the 0°, 40° and 70° Sections in Each of the Seven Groups.

	Group 1		Group 2		Group 3		Group 4		Group 5		Group 6		Group 7	
	Avg.	σ	Avg.	σ	Avg.	σ	Avg.	σ	Avg.	σ	Avg.	σ	Avg.	σ
ML for 0°	64.9	3.1	66.4	4.4	67.0	3.2	71.3	4.5	71.9	5.4	77.4	3.8	78.2	5.1
ML for 40°	59.1	3.9	61.1	3.5	61.2	3.3	64.4	4.2	66.2	4.7	69.7	3.5	71.3	4.5
ML for 70°	55.8	4.7	57.1	3.6	57.6	4.1	59.2	4.9	61.5	5.3	65.1	3.9	67.5	4.7

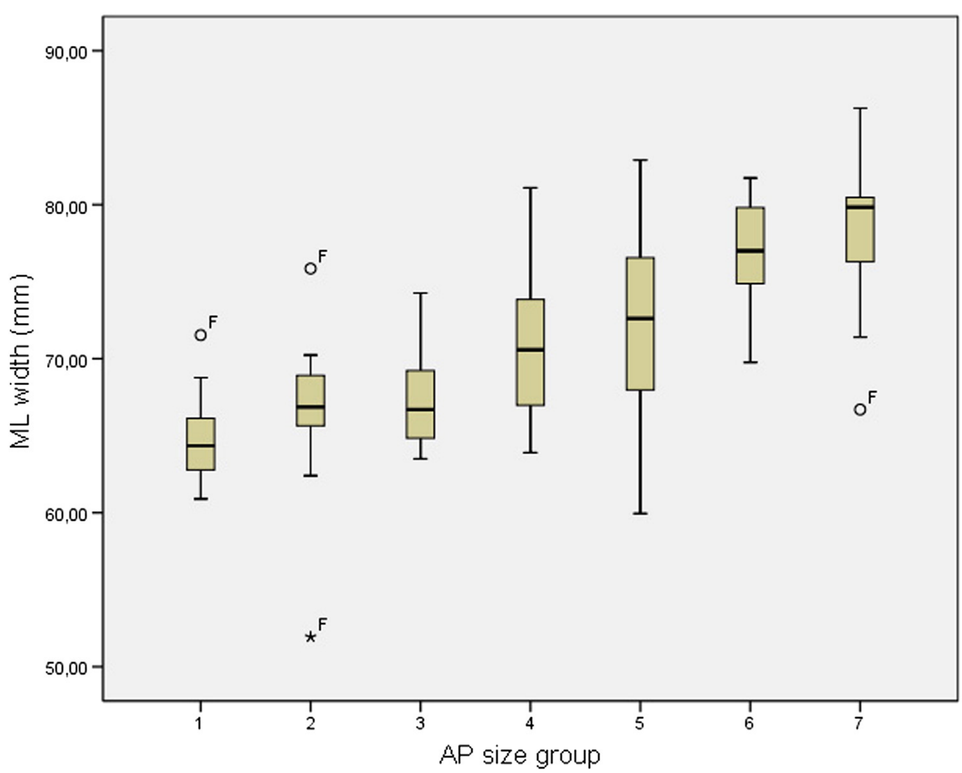

Fig. 4. Boxplots of the ML values by AP group for the 0° slice (distal cut).

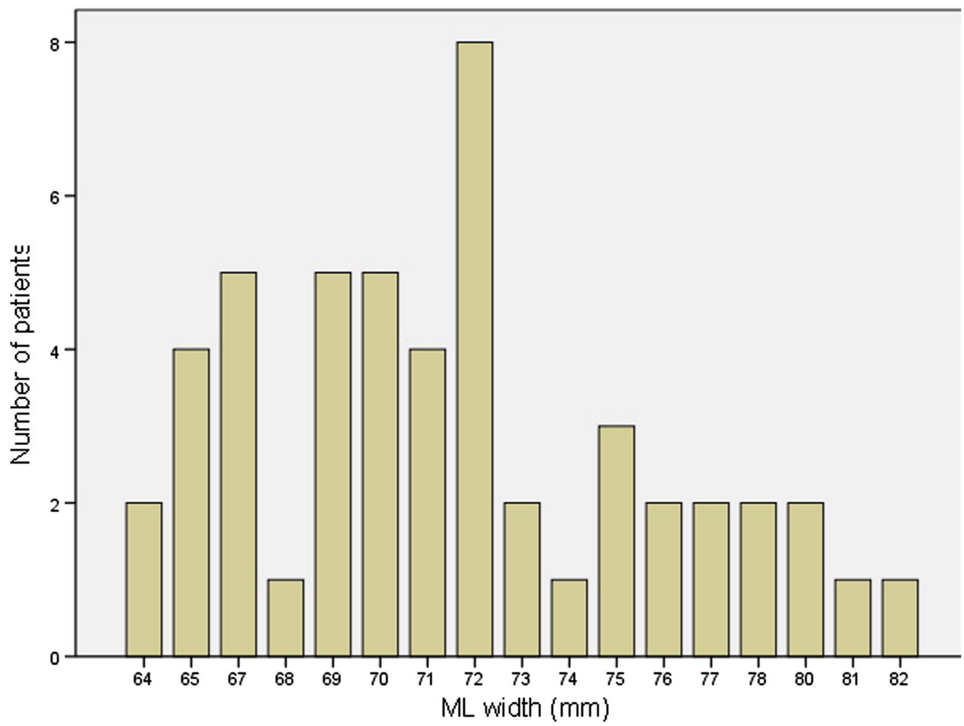

Fig. 5. Distribution of the ML distances for Group 4 on the 0° slice.

AP ratio on the 0° slice was the same for men and women (Fig. 7). On the other hand, the ML dimension of the distal femoral epiphysis was related to femur length, not gender (Fig. 8).

Mediolateral Width of the Implant

For a given AP size, the ML width within each group varied independently of gender (Fig. 4). An implant product line with one ML width was selected for each group by the individual surgeons. In 96% of cases, the implant selected did not result in overhang. This arbitrary choice was a tradeoff between bone coverage and implant overhang. When looking at the chosen implant widths and exposed bone surface by group, it is apparent that going with a single width product line causes the surgeon to accept that the quantity of exposed bone falls within the average (Table 2).

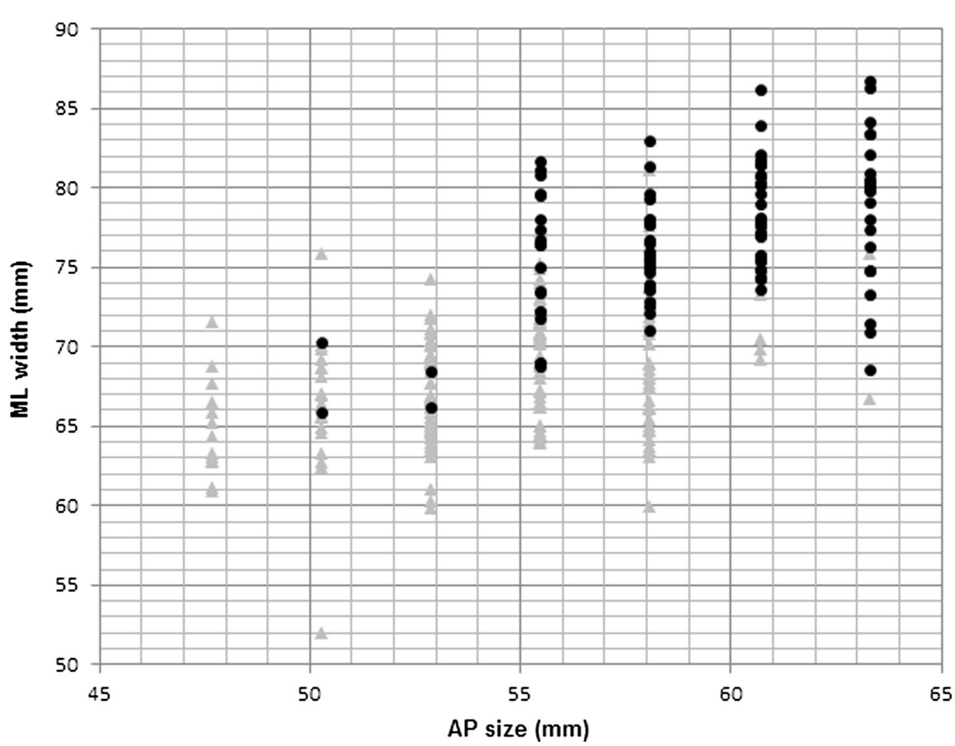

Fig. 6. ML dimensions on the 0° slice for the study population as a function of the AP dimensions and gender. Black circles correspond to male patients and grey triangles to female patients.

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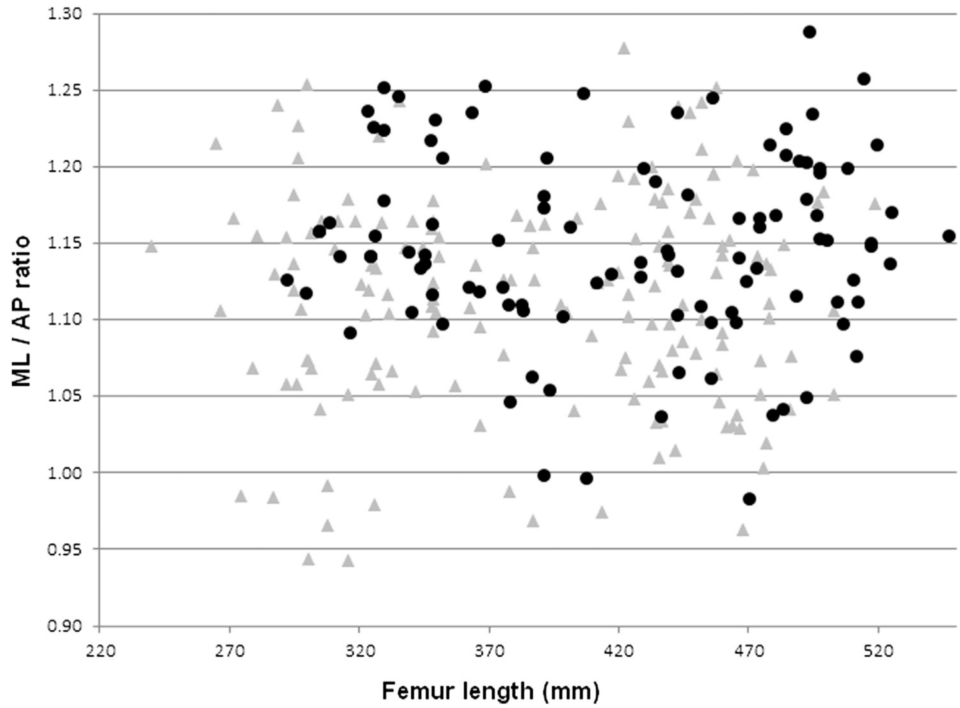

Fig. 7. Individual ML/AP ratio data on the 0° slice shown by gender. Black circles correspond to male patients and grey triangles to female patients.

Discussion

The purpose of this study was to determine the effect of gender on epiphyseal morphology and to use this information to determine if all operated knees could be sufficiently covered using an implant product line having only one mediolateral width. A surgical navigation tool was used to carry out three-dimensional modeling of a large number of arthritic (diseased) knees under operative conditions. The morphology of the distal femoral epiphysis was meticulously analyzed on multiple virtual slices of the knee. This information was used to draw conclusions related to our research questions.

There are limitations to evaluating distal femoral epiphysis biometrics that are acquired with a surgical navigation system. The precision of the acquisition is in the millimeter range, but the lack of intra-observer and inter-observer reproducibility has been highlighted in studies where point and surface capture techniques were used during TKA [33,34]. Most similar studies were based on direct centimeter-level measurements made on cadavers [7,12–15,17–19], intraoperatively during TKA [5,7,8,13], on healthy subjects, or before surgery with CT scan [10–12] or MRI [9,17,19]. Use of intraoperative surgical navigation in the current study is innovative. By using the computer's computational abilities, the AP and ML dimensions of 19 epiphyseal slices in arthritic knees requiring joint arthroplasty could be measured.

The strong points of our study were the ability to precisely define 19 slices of the distal femoral epiphysis and the large number of patients included (376 femurs). This provided us with a statistically robust sample. The morphometric analysis provided an extensive, precise description of the distal femoral epiphysis, unlike most published studies that only used the distal slice (0° slice). Our sample consisted of operated arthritic knees instead of healthy cadaver knees. Use of a surgical navigation system allowed the femur length to be calculated and integrated into the statistical results.

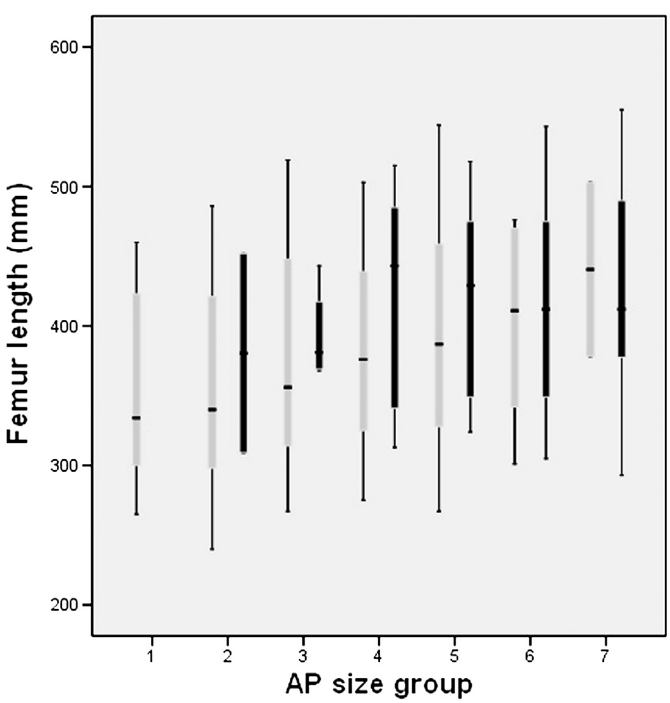

Fig. 8. Femur length by AP size as a function of gender. Black bars correspond to Male patients and grey bars to female patients.

Table 2
Amount of Exposed Bone by AP Size/Group.

Group/size	1	2	3	4	5	6	7
AP	47.7	50.3	52.9	55.5	58.1	60.7	63.3
Population ML (average)	64.9	66.4	67.0	71.3	71.9	77.4	78.8
Population ML (SD)	3.1	4.4	3.2	4.5	5.4	3.8	4.7
Implant ML	58.0	60.1	62.1	64.1	67.2	70.4	73.5
Average exposed bone (mm)	6.9	6.7	5.0	7.2	5.2	7.1	5.8
Maximum exposed bone (mm)	13.5	15.8	12.2	17.5	15.7	15.7	13.2

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Our study clearly showed that gender is only a co-variable and that the AP and ML dimensions of the femoral epiphysis solely depend on femur length. Published studies on the morphological differences between genders provide us with contradictory conclusions. Most highlight the male/female differences on the ML/AP ratio of the femoral epiphysis. For male and female knees having the same AP size, the ML width of the female knee will be less than a male knee of the same AP size [6,8–11,35]. But these studies do not take into account femur length. On the other hand, studies that integrate length data reach the opposite conclusion – there are no gender-related differences in the ML/AP ratio [4,12–15,17–19]. Clinical studies describing TKA results with standard implant designs found that the results were not worse in women because the implants were anatomically inappropriate. They actually appeared to be better in terms of satisfaction [36], survival [36–39], revision rate [24,39], and mobility [37,40].

Matching the coverage of the implant to the bone cut can be problematic. If the implant is too big, the overhang can provoke painful impingement [41] by recreating the obstruction caused by the initial osteophytes and can alter ligament balance [18,42]. Conversely, if the implant is too small and the subchondral bone is partly exposed, more blood loss could occur [18,43] and the risk of developing radiolucent lines related to PE wear increases over time [7,13].

Based on our morphometric data, using group G4 as an example, the variation in the ML width for a given AP size seems significant (about 20 mm, 63–82 mm). One way to address this variation, at least partially, would be to design a gender neutral implant in two widths. Another possibility would be to use all the morphometric data from this study to design an implant as similar as possible to the anatomy of the lower end of the femur, thereby reducing the risk of over-sizing or under-sizing. The authors arbitrarily opted for an ML width that avoids overhang in most cases (96%). By applying this criterion to each slice; they were able, for each AP size, to define the optimal ML width as well as the medial and lateral borders of the distal and anterior portions of the femoral implant (Fig. 2). This means that there is no homothetic increase in the ML width of the femoral implant in relation to the AP size. This morphologically adapted implant offers a good compromise between the risk of a 4% overhang whether distally and anteriorly and the insufficient bone coverage (3.6 mm on average on either side for a Size 4 implant). Table 2 summarizes the maximum and average value of the undercoverage for each size. This solution avoids the redundancy of having two product lines per AP size and eliminates the inherent problems of extra costs and storage.

Using the 3D model derived during surgical navigation, we were able to confirm that distal femoral epiphysis dimensions are related to the femur length only and do not depend on gender. However, there was a large variation in the ML dimension for a given AP size. This requires that a compromise be made when designing knee arthroplasty implants. Based on the morphometric data obtained from this study, we have been able to design a single-width implant product line which seems to address the morphological variations of the distal end of the femur.

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