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Definition of normal, neutral, deviant and aberrant coronal knee alignment for total knee arthroplasty

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Abstract

Purpose: One of the most pertinent questions in total knee arthroplasty (TKA) is: what could be considered normal coronal alignment? This study aims to define normal, neutral, deviant and aberrant coronal alignment using large data from a computed tomography (CT)-scan database and previously published phenotypes.

Methods: Coronal alignment parameters from 11,191 knee osteoarthritis (OA) patients were measured based on three dimensional reconstructed CT data using a validated planning software. Based on these measurements, patients' coronal alignment was phenotyped according to the functional knee phenotype concept. These phenotypes represent an alignment variation of the overall hip knee ankle angle (HKA), femoral mechanical angle (FMA) and tibial mechanical angle (TMA). Each phenotype is defined by a specific mean and covers a range of ±1.5° from this mean. Coronal alignment is classified as normal, neutral, deviant and aberrant based on distribution frequency. Mean values and distribution among the phenotypes are presented and compared between two populations (OA patients in this study and non-OA patients from a previously published study).

Results: The arithmetic HKA (aHKA), combined normalised data of FMA and TMA, showed that 36.0% of knees were neutral within ±1 SD from the mean in both angles, 44.3% had either a TMA or a FMA within ±1–2 SD (normally aligned), 15.3% of the patients were deviant within ±2–3 SD and only 4.4% of them had an aberrant alignment (±3–4 SD in 3.4% and >4 SD in 1.0% of the patients respectively). However, combining the normalised data of HKA, FMA and TMA, 15.4% of patients were neutral in all three angles, 39.7% were at least normal, 27.7% had at least one deviant angle and 17.2% had at least one aberrant angle. For HKA, the males exhibited 1° varus and females were neutral. For FMA, the females exhibited 0.7° more valgus in mean than males and grew 1.8° per category (males grew 2.1° per category). For TMA, the males exhibited 1.3° more varus than females and

ABBREVIATIONS: CT, computerised tomography; FMA, femoral mechanical angle, lateral distal femoral angle; HKA, hip knee ankle angle; OA, osteoarthritis; SD, standard deviation; TKA, total knee arthroplasty; TMA, tibial mechanical angle, medial proximal tibial angle.

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both grew 2.3° and 2.4° (females) per category. Normal coronal alignment was 179.2° ± 2.8–5.6° (males) and 180.5 > ± 2.8–5.6° (females) for HKA, 93.1 > ± 2.1–4.2° (males) and 93.8 > ± 1.8–3.6° (females) for FMA and 86.7 > ± 2.3–4.6° (males) and 88 > ± 2.4–4.8° (females) for TMA. This means HKA 6.4 varus or 4.8° valgus (males) or 5.1° varus to 6.1° valgus was considered normal. For FMA HKA 1.1 varus or 7.3° valgus (males) or 0.2° valgus to 7.4° valgus was considered normal. For TMA HKA 7.9 varus or 1.3° valgus (males) or 6.8° varus to 2.8° valgus was considered normal. Aberrant coronal alignment started from 179.2° ± 8.4° (males) and 180.5 > ± 8.4° (females) for HKA, 93.1 > ± 6.3° (males) 93.8 > ± 5.4° (females) for FMA and 86.7 > ± 6.9° (males) and 88 > ± 7.2° (females) for TMA. This means HKA > 9.2° varus or 7.6° valgus (males) or 7.9° varus to 8.9° valgus was considered aberrant.

Conclusion: Definitions of neutrality, normality, deviance as well as aberrance for coronal alignment in TKA were proposed in this study according to their distribution frequencies. This can be seen as an important first step towards a safe transition from the conventional one-size-fits-all to a more personalised coronal alignment target. There should be further definitions combining bony alignment, joint surfaces' morphology, soft tissue laxities and joint kinematics.

Level of Evidence: III.

KEYWORDS

coronal alignment, distal femoral angle, knee phenotypes, normality, proximal tibial angle, total knee arthroplasty

INTRODUCTION

Personalised medicine has arrived in total knee arthroplasty (TKA) [1, 2]. Personalised alignment methods such as kinematic alignment, functional alignment and customised patient specific TKA are intensively debated at meetings and in the current literature [3–11]. Fostered by the knee phenotype concept and the findings of several large database studies, there has been considerable discussion about what we consider as normal, abnormal and pathological alignment [3, 4, 12–15]. Most of the discussion has been focused on coronal alignment, but these questions also need to be applied to sagittal and rotational alignment [12–15]. The pertinent questions around alignment are as follows: Where does deformity begin? To which degree is deformity acceptable or correctable? Which deformity should not be restored and corrected instead?

Over the last decades, the gold standard 'mechanical alignment', a 'one size fits all' alignment technique aiming for neutral femoral and tibial mechanical axes and off the shelf implants were used. With more personalised strategies, knee surgeons have moved away from one systematic standard to new standards in alignment [16, 17]. However, individual normality has still not been defined. Furthermore, it is unclear what to do with knees outside a certain range, which can be seen as pathological alignment. Where should we put the threshold for a pathological condition? In general, a condition should be considered pathological when it contributes to the disease process. Scientifically, normality, when a criterion is normally distributed and follows the Gaussian curve, can be objectively defined using mean, standard deviation and confidence intervals. This concept of normality can help establish a functional safe zone for TKA representing the best compromise between anatomy, function and longevity. Coronal alignment values within the normal range should be restored. Abnormal values should be adjusted to fit into the safe zone. More extreme outliers (pathological) should be corrected into the safe zone [18–20].

One of the most pertinent questions of coronal alignment in TKA is: What is considered normal, abnormal or pathological coronal alignment? This study aims to define neutral, normal, deviant or aberrant coronal alignment, according to their distribution frequencies, using large data from a lower limb CT-scan database and previously published phenotypes.

MATERIALS AND METHODS

A cross-sectional, observational study was conducted comparing knee osteoarthritis (OA) patients to non-OA Caucasian patients from a previously published cohort [14, 15]. For the knee OA population, a manufacturer's CT database (Medacta) was used. All CT scans in the database were retrospectively assessed and included if patients were between 40 and 90 years at the time of imaging and showed no signs of previous fractures, osteotomies or rheumatoid arthritis. Patients were also excluded if a significant bone loss was seen or patients had a an extension deficit >15°. A total of 11,991 patients were included (6247 right and 5744 left knees). The male-to-female ratio was 4972 (41.5%): 7019 (58.5%) and the overall mean age±standard deviation (SD) was 68.7 ± 8.9 years (range 40–90 years).

The control group (non-OA) contained a total of 301 knees from 160 patients (192 [64%] males and 109 [36%] females). The mean age ± SD was 30.1 ± 6.7 years (range 16–44 years). All non-OA patients received a CT scan and the main reasons for the CT scan were osteochondrosis dissecans, sports injuries, patella pathology and pain without diagnosis.

Due to the retrospective nature of the study representing a data analysis of anonymised data only, approval of a local ethical committee was not necessary. All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

Alignment measurement

The following parameters were measured and then further reported: the hip knee ankle angle (HKA), femoral mechanical angle (FMA) and tibial mechanical angle (TMA). The detailed description of all measurements is illustrated in Figures 1 and 2. All angles were measured medially for FMA and TMA to maintain consistency. The angle at 90° or 180° represents the neutral alignment, a value above 90° or 180° represents a valgus alignment, and below 90° or 180° a varus alignment of the femur and tibia, respectively. All measurements were performed by trained engineers of the company with serval years of experience in this field. For CE marking, the accuracy of measurements including inter- and intra-observer reliability has been reported as excellent, having measurement variability within 1° [14, 15].

Definition of knee phenotypes

All these phenotypes consist of a phenotype specific mean value (HKA, FMA or TMA value) and cover a range of ±1.5° from this mean (e.g., 180° ± 1.5). The phenotype specific mean values represent 3° increments of the angle starting from the rounded overall mean value of the angle (HKA: 180°; FMA: 93°; TMA: 87°). The nomenclature of the phenotypes is organised as following:

The first part (NEU, VAR and VAL) defines the direction of alignment. The second subscripted part (HKA, FMA and TMA) states the measured angle. The last part (0°, 3° and 6°) shows the mean deviation of the phenotype from the mean value.

Ethical approval was obtained from ethical committee Nordwestschweiz EKNZ 2021-00046.

Statistical analysis

Descriptive statistics such as means, standard deviations, medians, range and percentages were presented. The distribution of all measured values was presented in a matrix highlighting the zones defined by mean ± 1 SD, mean ± 2 SD, mean ± 3 SD, mean ± 4 SD

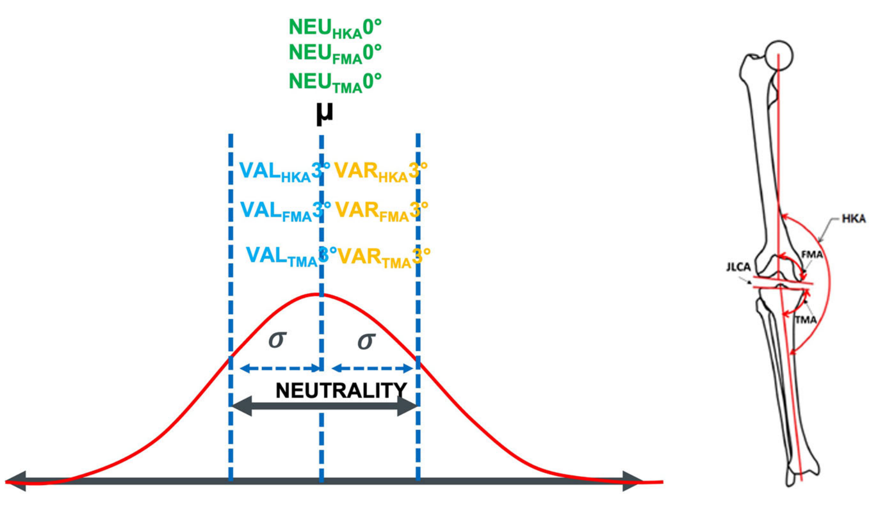

FIGURE 1 Left: Definition of neutrality for the hip-knee-ankle axis (HKA). Right: The coronal alignment measurements including HKA, femoral mechanical angle (FMA) and tibial mechanical angle (TMA).

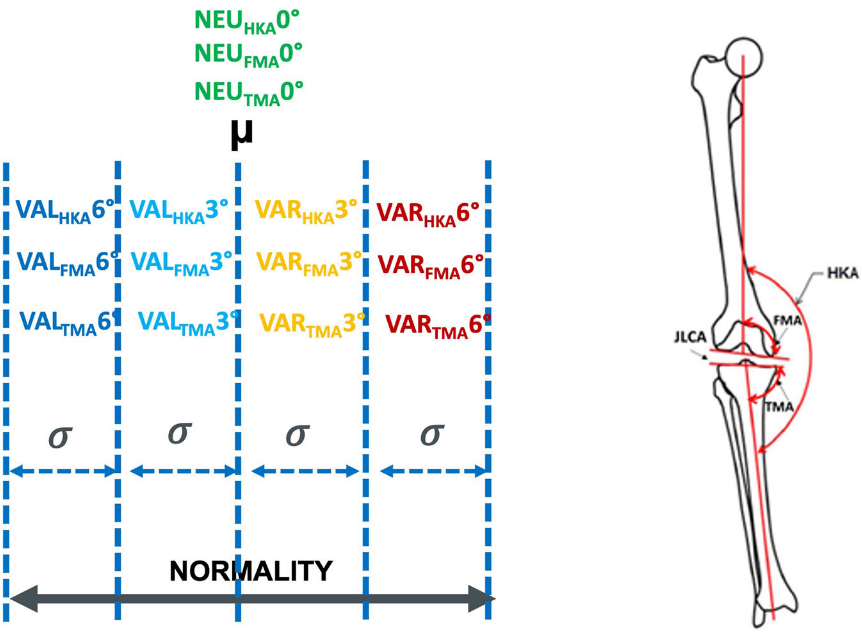

FIGURE 2 Left: Definition of normality for the hip knee ankle (HKA) axis. Right: The coronal alignment measurements including HKA, femoral mechanical angle (FMA), tibial mechanical angle (TMA).

and mean ± 5 SD and these all values was analysed for the case group (Figures 1–3). The absolute values of all measurements were calculated, and the percentages of knees within these zones were presented. For the normalisation of the data, the previously published sample of non-OA patients was included in analysis as the control group [14, 15]. Mean and standard deviation of HKA, FMA, and TMA of this non-OA population were calculated separately for male and female patients, group differences were tested using t-tests for independent samples, and these distributions of the non-OA-population were the basis for the definitions of deviations of the OA population. The alignment measured values were categorised as: mean ± 1 SD (neutra, mean ± 2 SD normal), mean ± 2–3 SD (deviant) and from mean ± 3–5 SD aberrant). The statistical level of significance was set at $p < 0.05$. All calculations were performed by a professional statistician using SPSS software version 26.

RESULTS

Table 1 shows the mean ± SD and ranges of basic alignment parameters found in male and female patients in the non-OA population (control group) and the OA population. According to HKA alignment, 98 (32.6%) of non-OA knees were varus aligned, 122 (40.5%) were neutrally aligned (within ± 1.5°) and 81 (26.9%) were valgus aligned. For the OA group, 7908 (65.9%) were varus aligned, 1867 (15.6%) were neutrally aligned and 2261 (18.5%) were valgus aligned with a mean alignment deviation of −4.0° in males and −2.4° for females. The FMA and TMA showed a high correlation with the HKA ($r = 0.66$ and 0.63 respectively, $p < 0.001$), but only a low correlation with each other ($r = 0.11$, $p < 0.001$).

Coronal knee alignment in OA-population, based on SD

Figures 3–5 show the distribution of HKA, FMA and TMA of the non-OA and OA populations by gender and the percentage of patients in the different groups.

Hip knee ankle angle

The normalisation of HKA data showed that 27.7% of the patients were neutral within ±1 SD from the mean (males 29.0%. females 26.9%), 32.6% werenormal within a deviation of ±1–2 SD from the mean (60.3% in total), 24.1% were deviant within ±2–3 SD and 15.5% were aberrant with > ± 3 SD.

FMA

The normalisation of FMA data showed that 56.1% of the patients were neutral within ±1 SD of the mean, 31.0% were normal within ±1–2 SD (87.1% in total), 10.1% were deviant within ±2–3 SD and 2.8% of them were aberrant with > ± 3 SD.

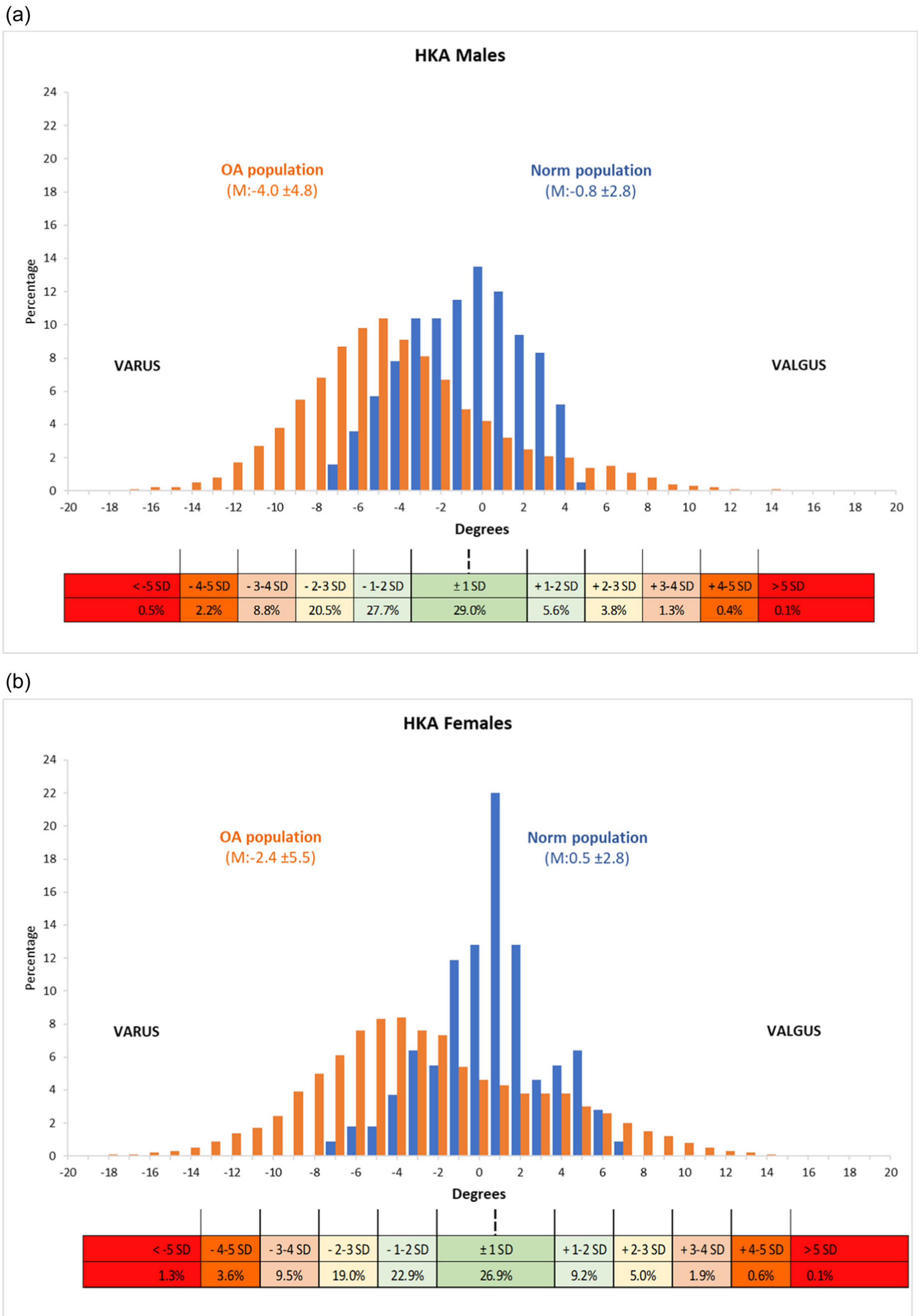

FIGURE 3 Distribution of hip knee ankle (HKA) between OA and non-OA population in males (a) and females (b).

TABLE 1 Comparison of all alignment parameters in OA and non-OA population.

Gender		HKA Control	HKA OA	HKA p	FMA Control	FMA OA	FMA p	TMA Control	TMA OA	TMA p
Males	N	192	4972	<0.001	192	4972	<0.001	192	4972	n.s.
	Mean	−0.8	−4.0		93.1	92.3		86.7	86.7	
	SD	2.8	4.8		2.12	2.4		2.3	2.7	
	Min.	−0.6	−31.8		87.9	77.0		81.3	75.5	
	Median	−7.4	−4.6		93.2	92.3		86.8	86.6	
	Max.	4.9	18.1		100.0	103.5		94.6	103.4	
Females	N	109	7019	<0.001	109	7019	0.001	109	7019	<0.001
	Mean	0.5	−2.4		93.83	93.3		88.01	87.0	
	SD	2.8	5.5		1.75	2.5		2.37	2.7	
	Min.	−7.1	−24.2		90.1	83.3		82.3	61.6	
	Median	0.6	−3.1		93.7	93.3		88.2	86.9	
	Max.	7.1	24.5		98.1	104.2		94.0	103.0	
M vs. F	p	<0.001	<0.001		0.003	<0.001		<0.001	<0.001	

Abbreviations: FMA, femoral mechanical angle; HKA, hip-knee-ankle angle; TMA, tibial mechanical angle.

TMA

The normalisation of TMA data showed that 63.0% of the patients were neutral within ±1 SD of the mean, 28.6% were normal within ±1–2 SD (91.6% in total), 6.6% were deviant within ±2–3 SD, and 2.8% of the patients were aberrant with > ±3 SD.

Combined data

The combined normalised data of FMA and TMA showed that 36.0% of knees had neutral alignment within ±1 SD in both angles, 44.3% had either TMA or FMA within ±1–2 SD (normally aligned), 15.3% of the patients were deviant within ±2–3 SD and only 4.4% of them had an aberrant alignment (±3–4 SD in 3.4% and >4 SD in 1.0% of the patients respectively) as presented in Table 2. However, combining the normalised data of HKA, FMA and TMA, 15.4% of patients were neutral in all three angles, 39.7% were at least normal, 27.7% had at least one deviant angle and 17.2% had at least one aberrant angle.

Coronal knee alignment in OA-population, based on phenotype

Hip knee ankle angle

The normalisation of HKA data with the previously published functional knee phenotype concept [21] showed that the most common phenotype was $VAR_{HKA}6°$ (172.5°–175.5°) which represented 24.8% of the patients, followed by $VAR_{HKA}3°$ (23. 6%, 177° ± 1.5), NEU_{HKA} (13.5%, 180 ± 1.5), $VAR_{HKA}9°$ (13.3%, 171° ± 1.5) and only 9.4% of them had $VAL_{HKA}3°$ (183 ± 1.5).

Femoral mechanical angle

The normalisation of FMA data showed that most common phenotype was NEU_{FMA} (91.5°–94.5°) which represented 46.4% of the patients, followed by $VAR_{FMA}3°$ (24.9%, 90° ± 1.5) and $VAL_{FMA}3°$ in 22.3% (96° ± 1.5).

TMA

Similarly, TMA data showed that most common phenotype was NEU_{FMA} (85.5°–88.5° with mean TMA = 87° ± 1.5) which represented 46.8% of the patients, followed by $VAR_{TMA}3°$ in 25.6% (84° ± 1.5) and $VAL_{TMA}3°$ (19.5%, 90° ± 1.5). The distribution of phenotypes among male and female in total population are presented in Table 3.

Combined data

The combined data of FMA and TMA for phenotypes is shown in Figures 6 and 7. The resulting coronal alignment values are presented in the categories of

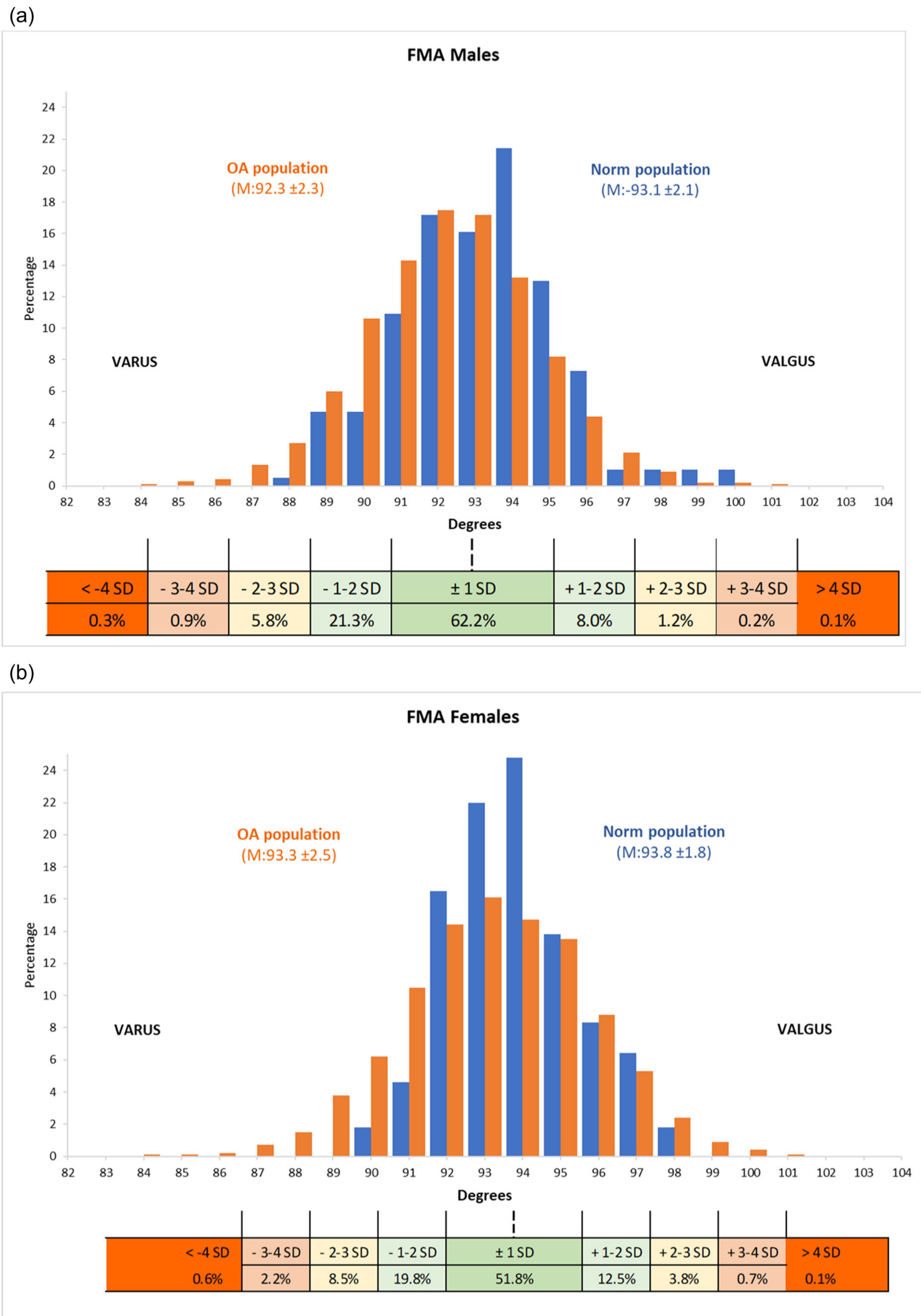

FIGURE 4 Distribution of femoral mechanical angle (FMA) between OA and non-OA population in males (a) and females (b).

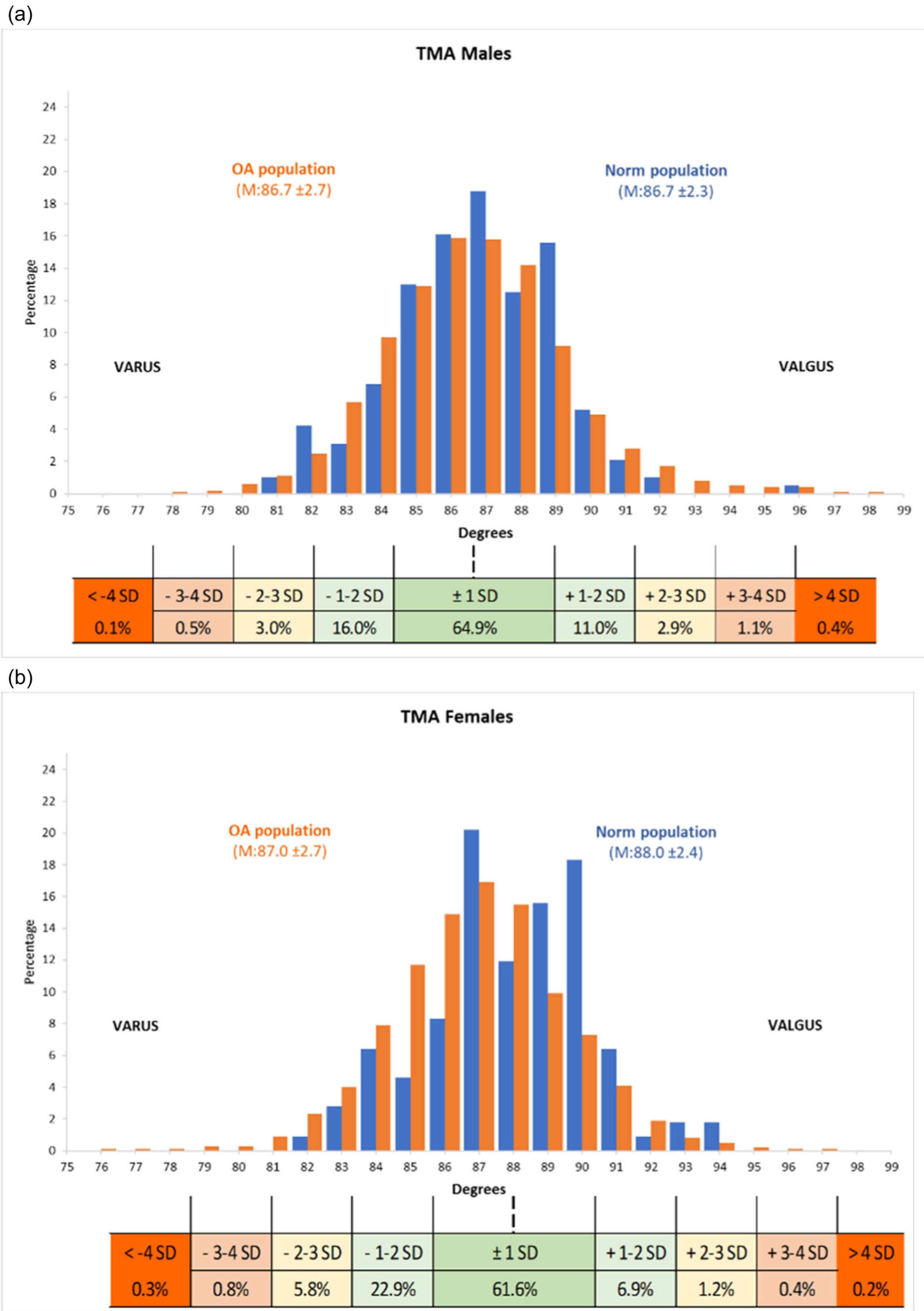

FIGURE 5 Distribution of tibial mechanical angle (TMA) between OA and non-OA population in males (a) and females (b).

TABLE 2 Comparison of TMA and FMA in OA population, based on SD.

FMA		TMA < −4 SD	−3 to 4 SD	−2 to 3 SD	−1 to 2 SD	+/−1 SD	+1 to 2 SD	+2 to 3 SD	+3 to 4 SD	>4 SD	Total
< −4 SD	*N*	0	0	4	19	24	3	2	4	1	57
	%	0.00%	0.00%	0.03%	0.16%	0.20%	0.03%	0.02%	0.03%	0.01%	0.48%
−3 to 4 SD	*N*	4	3	22	56	98	13	1	2	1	200
	%	0.03%	0.03%	0.18%	0.47%	0.82%	0.11%	0.01%	0.02%	0.01%	1.67%
−2 to 3 SD	*N*	8	13	66	195	523	50	16	10	2	883
	%	0.07%	0.11%	0.55%	1.63%	4.36%	0.42%	0.13%	0.08%	0.02%	7.36%
−1 to 2 SD	*N*	5	21	122	540	1525	179	31	18	6	2447
	%	0.04%	0.18%	1.02%	4.50%	12.72%	1.49%	0.26%	0.15%	0.05%	20.41%
+/−1 SD	*N*	6	38	294	1313	4321	589	117	37	16	6731
	%	0.05%	0.32%	2.45%	10.95%	36.04%	4.91%	0.98%	0.31%	0.13%	56.13%
+ 1 to 2 SD	*N*	2	3	42	221	822	135	37	8	5	1275
	%	0.02%	0.03%	0.35%	1.84%	6.86%	1.13%	0.31%	0.07%	0.04%	10.63%
+ 2 to 3 SD	*N*	0	0	8	44	201	52	17	2	2	326
	%	0.00%	0.00%	0.07%	0.37%	1.68%	0.43%	0.14%	0.02%	0.02%	2.72%
+ 3 to 4 SD	*N*	1	0	2	10	32	9	4	0	1	59
	%	0.01%	0.00%	0.02%	0.08%	0.27%	0.08%	0.03%	0.00%	0.01%	0.49%
>4 SD	*N*	0	0	0	3	6	3	1	0	0	13
	%	0.00%	0.00%	0.00%	0.03%	0.05%	0.03%	0.01%	0.00%	0.00%	0.11%
Total	*N*	26	78	560	2401	7552	1033	226	81	34	11991
	%	0.22%	0.65%	4.67%	20.02%	62.98%	8.61%	1.88%	0.68%	0.28%	100.00%
		+/−1 SD		36.04%							
		+/−2 SD		44.40%							
		+/−3 SD		15.15%							
		+/−4 SD		3.39%							
		> +/−4 SD		1.02%							

Note: The color codes the normality, neutrality, aberrance and deviance for all values.

Abbreviations: FMA, femoral mechanical angle; TMA, tibial mechanical angle.

neutrality, normality, deviance and aberrance in Table 4.

Coronal alignment values categorised to neutrality, normality, deviance and aberrance on the basis of non-OA-knees

For HKA, the males exhibited 1° varus and females were neutral. For FMA, the females exhibited 0.7° more valgus in mean than males and grew 1.8° per category (males grew 2.1° per category). For TMA, the males exhibited 1.3° more varus than females and both grew 2.3° and 2.4° (females) per category. Aberrant coronal alignment started from 179.2° ± 8.4° (males) and 180.5° > ± 8.4° (females) for HKA, 93.1° > ± 6.3° (males) 93.8° > ± 5.4° (females) for FMA and 86.7° > ± 6.9° (males) and 88° > ± 7.2° (females) for TMA. This means HKA > 9.2° varus or 7.6° valgus (males) or 7.9° varus to 8.9° valgus was considered aberrant.

Figure 7 shows the normality, neutrality, deviance and aberrance in terms of TMA and FMA based on knee phenotypes and SD. Figures 8, 9 and 10 highlight the clinical consequence of such a normality-based categorisation.

TABLE 3 Distribution of HKA, FMA and TMA values in OA population, based on phenotypes.

			Gender		
			Male (*N* = 4972)	Female (*N* = 7019)	Total (*N* = 11991)
HKA	<−16.5	*N*	11	22	33
		%	0.2%	0.3%	0.3%
	−16.5 to −13.5	*N*	38	71	109
		%	0.8%	1.0%	0.9%
	−13.5 to −10.5	*N*	262	282	544
		%	5.3%	4.0%	4.5%
	−10.5 to −7.5	*N*	801	794	1595
		%	16.1%	11.3%	13.3%
	−7.5 to −4.5	*N*	1436	1538	2974
		%	28.9%	21.9%	24.8%
	−4.5 to −1.5	*N*	1186	1639	2825
		%	23.9%	23.4%	23.6%
	−1.5 to 1.5	*N*	615	1001	1616
		%	12.4%	14.3%	13.5%
	1.5 to 4.5	*N*	325	802	1127
		%	6.5%	11.4%	9.4%
	4.5 to 7.5	*N*	203	534	737
		%	4.1%	7.6%	6.1%
	7.5 to 10.5	*N*	72	247	319
		%	1.4%	3.5%	2.7%
	>10.5	*N*	23	89	112
		%	0.5%	1.3%	0.9%
FMA	<85.5	*N*	28	18	46
		%	0.6%	0.3%	0.4%
	85.5 to 88.5	*N*	221	167	388
		%	4.4%	2.4%	3.2%
	88.5 to 91.5	*N*	1538	1443	2981
		%	30.9%	20.6%	24.9%
	91.5 to 94.5	*N*	2382	3181	5563
		%	47.9%	45.3%	46.4%
	94.5 to 97.5	*N*	734	1935	2669
		%	14.8%	27.6%	22.3%
	97.5 to 100.5	*N*	62	265	327
		%	1.2%	3.8%	2.7%
	>100.5	*N*	7	10	17
		%	0.1%	0.1%	0.1%
TMA	<79.5	*N*	19	38	57
		%	0.4%	0.5%	0.5%
	79.5 to 82.5	*N*	213	239	452
		%	4.3%	3.4%	3.8%
	82.5 to 85.5	*N*	1409	1658	3067
		%	28.3%	23.6%	25.6%
	85.5 to 88.5	*N*	2289	3320	5609
		%	46.0%	47.3%	46.8%
	88.5 to 91.5	*N*	841	1493	2334
		%	16.9%	21.3%	19.5%
	91.5 to 94.5	*N*	148	223	371
		%	3.0%	3.2%	3.1%
	>94.5	*N*	53	48	101
		%	1.1%	0.7%	0.8%

Abbreviations: FMA, femoral mechanical angle; HKA, hip knee ankle angle; TMA, tibial mechanical angle.

DISCUSSION

The most important finding of the present study using a large database are that lower limb coronal alignment distribution according to its frequency of occurrence is presented and categorised in normality, neutrality, deviance and aberrance. The combined (HKA, TMA, FMA) normalised data of coronal alignment showed that only 15.4% of knees were within 1 SD in all three angles (neutral), 39.7% had at least one angle within ±1–2 SD (normal), 27.7% had at least one angle within ±2–3 SD (deviant), and 17.2% had at least one angle > ± 3 SD. This information is crucial for every knee surgeon, as the pertinent question of the optimal coronal alignment target for each individual patient's knee has still not been answered sufficiently. It is important to know more about native knee/limb anatomy. Understanding the diversity of the anatomy will fasten the correlation between native anatomy and outcomes. The reality is that implant alignment target will also depend on bone quality, joint stability, life expectancy, activity level, BMI and other factors. Furthermore, AI will help to define individual target based on multiple parameters [22].

The understanding of static alignment has evolved and become more profound over the last years. The consequence is an ongoing shift away from systematic

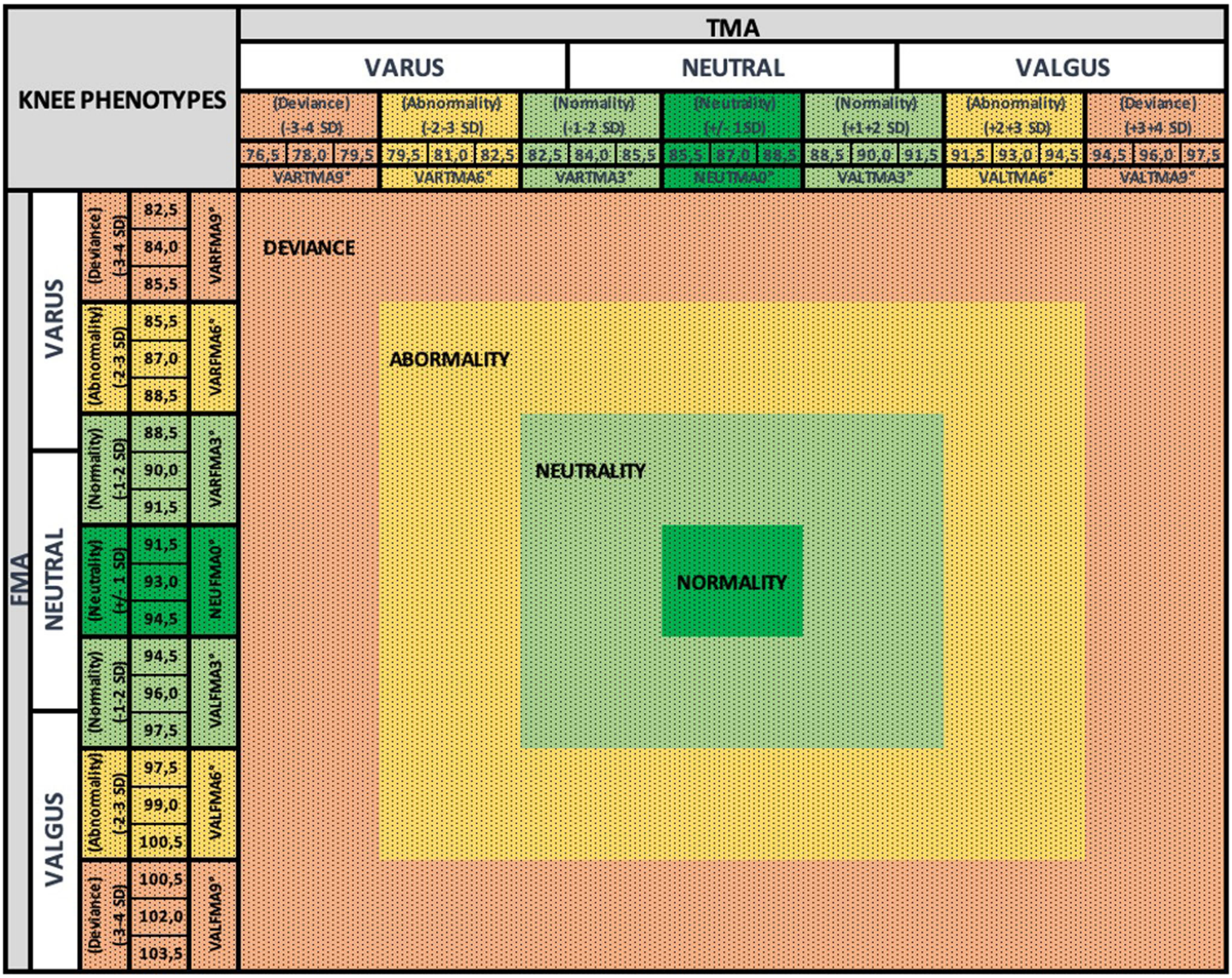

FIGURE 6 Normality, neutrality, abnormality, deviance and aberrance in terms of tibial mechanical angle (TMA) and femoral mechanical angle (FMA).

mechanical alignment to more personalised alignment targets. There are by now numerous different alignment techniques and targets with standard off the shelf or customised implants [5–10, 23, 24]. The evidence about their impact is evolving, but still longer-term comparative data is pending [6]. The discussion focuses on the question how far personalisation could go, potentially improving functional outcome without an increase of complications such as early loosening. Which native alignment should be restored, and which should be corrected?

Following the 'safe zone' concept, pre-arthritic coronal knee alignment representing neutrality or normality can be restored after TKA while outlier coronal knee alignments should be adjusted towards neutrality [19, 25]. In a similar study, Almaawi, Vendittoli et al. evaluated 4884 knee CT scans from a database of patients undergoing TKA with patient-specific instrumentation [18]. A joint surface orientation of >5° was found in 19% of the tibias and 17% of the femurs. HKA > 5° in 19% (10% in valgus and 9% in varus); and 3% had extreme anatomy with an HKA of >10°. Based on anatomy distribution, Vendittoli proposed surgical boundaries of restricted KA [20]. This present study provides evidence on alignment by analysing a large CT database. One can consider the results presented as a validation of the previously introduced safe zone concept [19, 25]. This approach is not based on outcome data yet, but it allows for deeper insight into normality values of the patients treated. Combining the previously presented functional phenotype concept with the normalised data presented in this study can be used to identify the safe zones as well as target zones for personalised alignment techniques [13–15, 26–28]. If one considers values within mean ± 2SDs as "normal", mean ± 3 SDs as "deviant" and

KNEE PHENOTYPES		TMA: VARUS (Deviance) (-3-4 SD) 76,5 78,0 79,5 VARTMA9°	VARUS (Abnormality) (-2-3 SD) 79,5 81,0 82,5 VARTMA6°	NEUTRAL (Normality) (-1-2 SD) 82,5 84,0 85,5 VARTMA3°	NEUTRAL (Neutrality) (+/- 1SD) 85,5 87,0 88,5 NEUTMA0°	NEUTRAL (Normality) (+1+2 SD) 88,5 90,0 91,5 VALTMA3°	VALGUS (Abnormality) (+2+3 SD) 91,5 93,0 94,5 VALTMA6°	VALGUS (Deviance) (+3+4 SD) 94,5 96,0 97,5 VALTMA9°	Total
FMA: VARUS	(Deviance) (-3-4 SD) 82,5 84,0 85,5 VARFMA9°	0 (0,00%)	3 (0,00%)	10 (0,10%)	11 (0,10%)	7 (0,10%)	3 (0,00%)	4 (0,00%)	38 (0,30%)
VARUS	(Abnormality) (-2-3 SD) 85,5 87,0 88,5 VARFMA6°	5 (0,00%)	18 (0,20%)	98 (0,80%)	128 (1,10%)	71 (0,60%)	7 (0,10%)	7 (0,10%)	328 (2,70%)
NEUTRAL	(Normality) (-1-2 SD) 88,5 90,0 91,5 VARFMA3°	17 (0,10%)	100 (0,80%)	675 (5,60%)	1205 (10,00%)	513 (4,30%)	76 (0,60%)	29 (0,20%)	2615 (21,80%)
NEUTRAL	(Neutrality) (+/- 1 SD) 91,5 93,0 94,5 NEUFMA0°	20 (0,20%)	167 (1,40%)	1334 (11,10%)	2720 (22,70%)	1169 (9,70%)	169 (1,40%)	37 (0,30%)	5616 (46,80%)
NEUTRAL	(Normality) (+1-2 SD) 94,5 96,0 97,5 VALFMA3°	9 (0,10%)	61 (0,50%)	592 (4,90%)	1336 (11,10%)	790 (6,60%)	148 (1,20%)	29 (0,20%)	2965 (24,70%)
VALGUS	(Abnormality) (+2-3 SD) 97,5 99,0 100,5 VALFMA6°	0 (0,00%)	9 (0,10%)	58 (0,50%)	165 (1,40%)	126 (1,10%)	40 (0,30%)	7 (0,10%)	405 (3,40%)
VALGUS	(Deviance) (+3-4 SD) 100,5 102,0 103,5 VALFMA9°	1 (0,00%)	0 (0,00%)	2 (0,00%)	13 (0,10%)	6 (0,10%)	2 (0,00%)	0 (0,00%)	24 (0,20%)
Total		52 (0,40%)	358 (3,00%)	2763 (23,00%)	5578 (46,50%)	2682 (22,40%)	445 (3,70%)	113 (0,90%)	11991 (100,00 %)

FIGURE 7 Normality, neutrality, abnormality, deviance and aberrance in terms of tibial mechanical angle (TMA) and femoral mechanical angle (FMA) based on knee phenotypes and SD.

TABLE 4 Coronal alignment values categorised to neutrality, normality, deviance and aberrance on the basis of non-OA-knees.

		Varus				Valgus			
Coronal alignment	SD	Aberrant (< −3 SD)	Deviant (−2 to 3 SD)	Normal (−1 to 2 SD)	Neutral (+/− 1 SD)		Normal (+1 to 2 SD)	Deviant (+2 to 3 SD)	Aberrant (> +3 SD)
M - HKA	2.78	<170.8	170.8–173.6	173.6–176.4	176.4–179.1	179.1–181.9	181.9–184.7	184.7–187.5	>187.5
F - HKA	2.82	<172.0	172.0–174.8	174.8–177.7	177.7–180.5	180.5–183.3	183.3–186.1	186.1–188.9	>188.9
M - FMA	2.12	<86.7	86.7–88.8	88.8–91.0	91.0–93.1	93.1–95.2	95.2–97.3	97.3–99.4	>99.4
F - FMA	1.75	<88.5	88.5–90.3	90.3–92.0	92.0–93.8	93.8–95.5	95.5–97.3	97.3–99.0	>99.0
M - TMA	2.27	<79.9	79.9–82.1	82.1–84.4	84.4–86.7	86.7–89.0	89.0–91.2	91.2–93.5	>93.5
F - TMA	2.37	<80.9	80.9–83.2	83.2–85.6	85.6–88.0	88.0–90.3	90.3–92.7	92.7–95.1	>95.1

Abbreviations: F-FMA, female-femoral mechanical angle; F-HKA, female- hip-knee-ankle angle; F-TMA, Female-tibial mechanical angle; M-FMA, male-femoral mechanical angle; M-HKA, male- hip-knee-ankle angle; M-TMA, male-tibial mechanical angle.

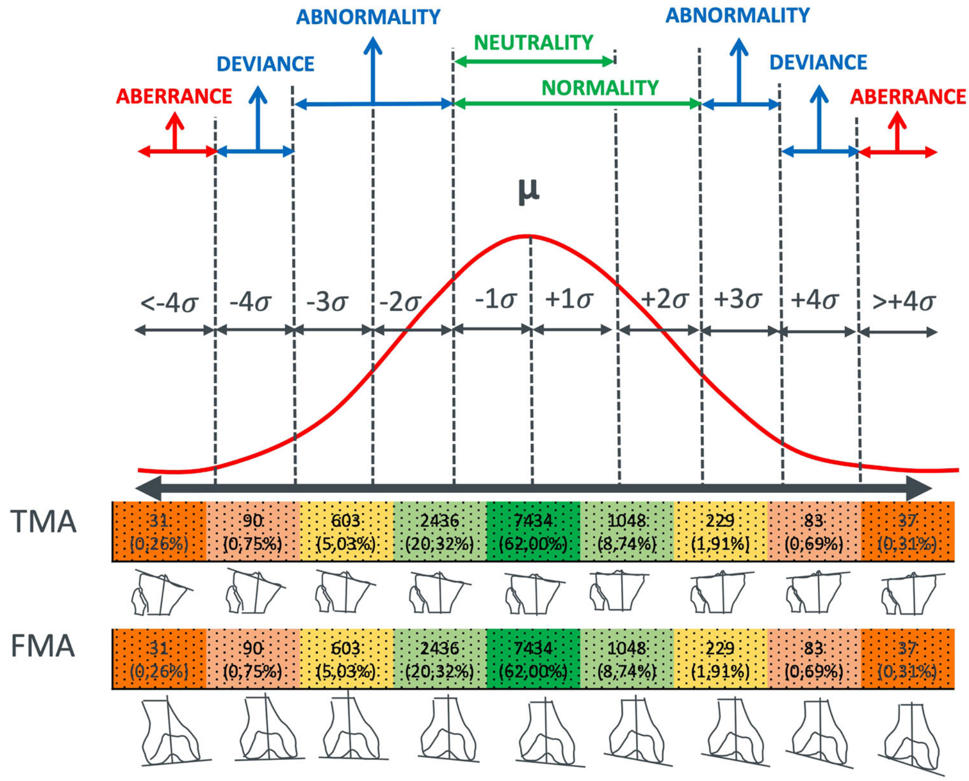

FIGURE 8 Showing the distribution of hip knee ankle (HKA) angle and defining neutrality, normality, abnormality, deviance and aberrance on the basis of standard deviation (SD).

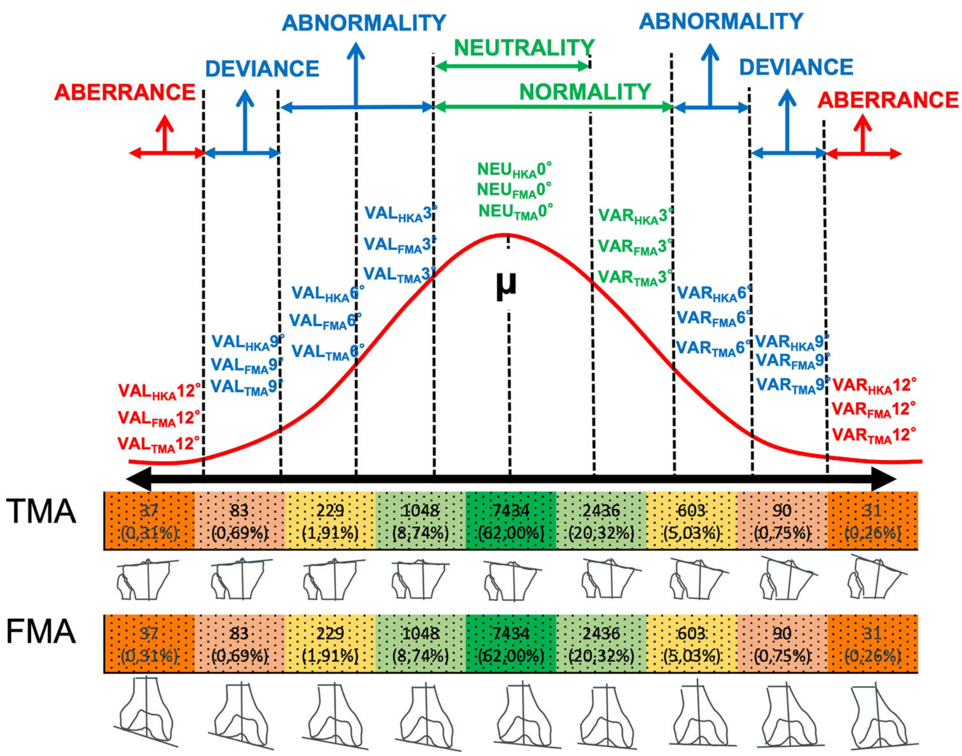

FIGURE 9 Showing the distribution of hip knee ankle (HKA) angle and defining neutrality, normality, abnormality, deviance and aberrance on the basis of standard deviation (SD) and knee phenotypes.

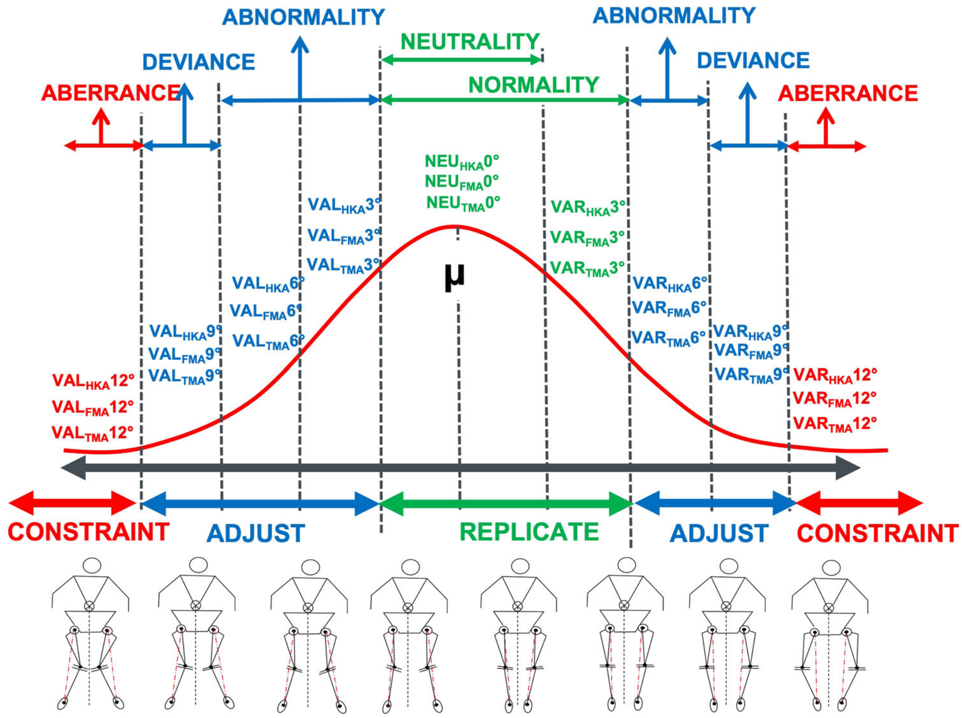

FIGURE 10 Highlighting the clinical consequences of the of the categorisation on the basis of standard deviation (SD) and knee phenotypes.

larger than this as "aberrant", then the coronal alignment was neutral in 22.7% cases, 63.3% were within normality, 12.1% were deviant, and only 1.8% were aberrant. As a clinical consequence in 86% of knees, the knee phenotype should be restored. In 12%, the coronal knee phenotype should be adjusted towards normality. Approximately 2% of knees showed a pathological coronal alignment and should probably not be used as a target for personalised alignment targets. However, this group might be underrepresented in the database investigated, as more severe alignment deviations might not be done with standard patient specific instrumentation (PSI) TKA.

For HKA, the males exhibited 1° varus and females were neutral. For FMA, the females exhibited 0.7° more valgus in mean than males and grew 1.8° per category (males grew 2.1° per category). For TMA, the males exhibited 1.3° more varus than females and both grew 2.3° and 2.4° (females) per category. Aberrant coronal alignment started from 179.2° ± 8.4° (males) and 180.5° > ± 8.4° (females) for HKA, 93.1° > ± 6.3° (males) 93.8° > ± 5.4° (females) for FMA and 86.7° > ± 6.9° (males) and 88° > ± 7.2° (females) for TMA. This means HKA > 9.2° varus or 7.6° valgus (males) or 7.9° varus to 8.9° valgus was considered aberrant.

The bony coronal alignment mainly represents the static coronal alignment only, meaning that even within the normality of bony alignment, abnormality of joint laxity might exist. Hence, the normality values for bony alignment as defined here need to be combined with the normality values for joint laxity as well as normality values for sagittal and axial knee anatomy, and knee kinematics. Until now, only a few authors reported laxity values for individual phenotypes [21, 29, 30]. However, it is crucial to understand how much soft tissue release and balancing is necessary depending from the bony resection and the individual knee phenotype [21, 29–31]. Bony alignment is just one part of the static coronal knee alignment. The other part is the wear of the cartilage and natural joint play or laxity, which have a major influence on the resulting alignment. One needs to differentiate the pure forms of constitutional alignment, which is mainly determined by bony anatomy from OA alignment, which is characterised by wear of the cartilage leading to a further change of preexisting coronal alignment. A fact which is clear when considering that HKA is a surrogate of the bony and ligament phenotypes. This definition of coronal alignment is an important first step towards a safe transition from the conventional one-size-fits-all to a more personalised coronal alignment target.

A considerable number of limitations need to be acknowledged. Firstly, this study used a large medtech CT database of patients who underwent a PSI TKA.

There is a possibility of selection bias due to the fact that some surgeons might use a specific TKA prosthesis, constraint or enabling technology in a select group of patients. However, the size of the database and number of patients included help reduce selection bias. Secondly, this database included mainly Caucasian patients, hence the findings are only valid for this group. Thirdly, the absolute and relative representation of patients with abnormal and pathological coronal alignment values might be underrepresented, as many surgeons might choose a higher constraint for such severe deformities. Nevertheless, this would only have a marginal influence on the definition of neutral, normal, abnormal and pathological coronal alignment. Fourth, dynamic alignment could not be assessed, and there are patients who have a varus or neutral coronal alignment under static conditions, which can shift to coronal valgus alignment under dynamic conditions [32]. Fifthly, patients with severe bone loss were not included in this database.

For the first time coronal knee alignment was classified in normal, neutral, aberrant and deviant. Based on these findings limits of constraints and surgical alignment targets for personalised alignment in TKA are identified.

CONCLUSION

Definitions of neutrality, normality, deviance as well as aberrance for coronal alignment in TKA were proposed in this study according to their distribution frequencies. This can be seen as an important first step towards a safe transition from the conventional one-size-fits-all to a more personalised coronal alignment target. For HKA, the males exhibited 1° varus and females were neutral. For FMA, the females exhibited 0.7° more valgus in mean than males and grew 1.8° per category (males grew 2.1° per category). For TMA, the males exhibited 1.3° more varus than females and both grew 2.3° and 2.4°(females) per category. Aberrant coronal alignment started from 179.2° ± 8.4° (males) and 180.5° > ± 8.4° (females) for HKA, 93.1° > ± 6.3° (males) 93.8° > ± 5.4° (females) for FMA and 86.7° > ± 6.9° (males) and 88° > ± 7.2° (females) for TMA. This means HKA > 9.2° varus or 7.6° valgus (males) or 7.9° varus to 8.9° valgus was considered aberrant and should not be restored. There should be further definitions combining bony alignment, joint surfaces' morphology, soft tissue laxities and joint kinematics.

AUTHOR CONTRIBUTIONS

All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Michael T. Hirschmann, Zainab Aqeel Khan and Manuel P. Sava. The first draft of the manuscript was written by Michael T. Hirschmann and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors have no relevant financial or non-financial interests to disclose.

ETHICS STATEMENT

Due to the retrospective nature of the study representing a data analysis of anonymised data only, approval of a local ethical committee was not necessary. All procedures were performed in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards.

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