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Original article

Sociodemographic differences in anatomical anthropometry in Egyptian wrists: A cross-sectional study in 2021-2022

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Abstract

Background: To restore the structural and functional architecture of the wrist joint, radiographic evaluation is essential. Diversities based on age, race, and gender were noted. The objective of this study was to assess a few wrist radiography characteristics and establish correlations between them and the sociodemographic traits.

Methods: During the years 2021–2022, 238 posteroanterior plain x-ray wrist pictures were gathered and evaluated from the radiology departments of Zagazig University hospitals in Egypt. The following parameters were estimated: ulnar variance, radial height, radial inclination, scaphoid length, lunate length, scapholunate distance, capitate length, carpal height, third metacarpal length, revised carpal height ratio, and scaphoid-capitate ratio. The t-test, ANOVA, Kendall's tau_b correlation, and linear regression were used to conduct the comparisons.

Results: Radial height, inclination, and ulnar variation all showed significant gender differences (p=0.004, 0.013, and 0.002, respectively). The carpal height and carpal height ratio, together with the radial cord, scaphoid, lunate, capitate, and third metacarpal lengths, all demonstrated significant results (p < 0.001). The right side had a greater radial cord, height, and radial inclination than the left; nevertheless, the left side had a substantially longer lunate (P=0.0168, <0.001, 0.049, and <0.001, respectively). Age differences revealed varying levels of significance in the following areas: carpal height, carpal height ratio, ulnar variance, scapholunate space, capitate height, scapho-capitate ratio, and radial cord (p=0.044, 0.011, 0.039, 0.026, 0.048, 0.002 and 0.017, respectively).

Conclusion: When treating wrist problems, variations in wrist characteristics should be given careful consideration. To suggest algorithms that could improve the results of wrist diseases in Egyptians, more research is required.

Keywords: X-ray; Sociodemographic diversities; Ulnar variance; Capitate; Metacarpal; Egypt

Introduction

The human wrist is a complicated joint that is frequently the source of morphological variations. These variations, especially in monozygotic twins, were well documented (1). When it comes to both functional results and potential degenerative changes, radiocarpal articular congruity and plain radiography examination of the wrist are regarded as essential components of wrist care (2). Even though the radiographic anatomy of the wrist has been extensively documented in the literature, radiographic assessment and quantification of the morphological variations in the wrist were crucial in

many clinical circumstances when making decisions (3).
Identification of living human parameters is known as anthropometry, and it is essential for understanding various physical variances in human growth research and clinical therapies (4). A population's age, gender, ethnicity, income, education level, and location are its sociodemographic features. Numerous variables were assessed in the typical wrist and revealed significant variation between racial, age, and gender groups (4). The assessment and association between these factors and additional variables are crucial in orthopedic practice for organizing and carrying out the treatment of carpal pathologies and wrist disorders (5). The precise identification of age and gender in human bones is also highly valuable in forensic medicine and bio-archaeology (6).
The purpose of the current study was to evaluate wrist plain radiography measurements in Egyptian populations and to conduct a morphometrical analysis of the obtained data. Moreover, to clarify the statistical relationships between various indicators and between various sociodemographic categories.

Materials and Methods

A cross-sectional study was carried out to examine the relationships between various wrist x-ray parameters and sociodemographic characteristics. Every wrist plain radiograph reported to the radiology department of Zagazig University hospitals in Egypt between 2021 and 2022 that did not show any skeletal abnormalities in the upper limb was evaluated. The only identifiable information was the wrist's side, gender, and age.
During this time, 241 posteroanterior images of the wrists were taken, and the study included them without regard to anything other than a normal skeleton. Out of these radiographs, 238 were assessed, and three were eliminated because the wrist was positioned incorrectly, masking certain bone features.
The conventional posteroanterior view, taken with the elbow fully extended and the wrist in a neutral forearm posture, was used in the investigation. After transferring the Digital Imaging and Communications in Medicine (DICOM) data to the workstation, every measurement was done digitally. Millimeter measurements were made for the scapholunate joint distance, ulnar variance, radial height, radial inclination, scaphoid length, lunate length, capitate length, carpal height, and third metacarpal length. Additionally, the scapho-capitate ratio, revised carpal height ratio, and carpal height ratio were computed.
The radial cord was formerly defined as the distance between the medial margin of the radial articular surface and the tip of the radial styloid process (4). The distance measured between the tip of the radial styloid process and a line drawn tangential to the distal edge of the ulna and perpendicular to the long axis of the radius is said to be the radial height (1). The angle between two lines—one drawn perpendicular to the long axis of the ulna and the other from the tip of the radial styloid process to the medial margin of the radial articular surface—was defined as the radial inclination (7).
By drawing a line perpendicular to the long axis of radius, intersecting the distal cortical margin of the ulna, and passing through the medial portion of the radial articular surface, the ulnar variance was calculated as the relative distance difference between the radial and ulnar distal articular ends (8). By measuring the scaphoid's long axis, the length of the scaphoid was determined (9). Moreover, lunate length was defined as the separation between the lunate's radial and ulnar poles (7). Furthermore, the scapholunate joint space was measured from the proximal pole of the scaphoid to the radial pole of the lunate (3). The length of the capitate was measured as the separation along the bone's longitudinal axis between its two poles (9).
Both the third metacarpal length and the carpal height were measured along the longitudinal axis of the third metacarpal bone (6) and from the base of the third metacarpal bone to the distal articular surface of the radius in accordance with its long axis (1). The ratio of the carpal height to the third metacarpal length and the ratio of the carpal height to the capitate length, respectively, were used to compute the carpal height ratio and revised carpal height ratio (1). Ultimately, the ratio of the scaphoid to the capitate length was determined to be the scapho-capitate ratio (9). Figure 1 displays the major checkpoints included in the assessments as well as the techniques employed for measuring each parameter.
To ensure the accuracy of the measurements, each parameter was assessed by three separate observers, and the mean value was determined. Excel and the Statistical Package for Social Science (SPSS) version 25 software were used to statistically alter the data. The means ± standard deviation (±SD) were interpreted, and frequencies were computed and shown as percentages. The data were analyzed at a significance level of $P < 0.05$ using the independent t-test, ANOVA, non-parametric Kendall's tau_b correlation, and linear regression techniques.

Results

Two hundred thirty-eight posteroanterior plain radiography images of wrists that have been determined to be normal and free of skeletalabnormalities were used in the investigation. To account for interrater bias, three examiners assessed various radiological parameters, and the mean was computed. Males made up 63.4% of the cases (n = 151), while females made up 36.6% (n = 87). Of the sample of 131 radiographs, 115 were of the right wrist, and 145 were of the left wrist.
The mean ± SD of the cases' ages, which ranged from 20 to 70 years, was 37.72 ± 13.67 years. The cases (20-29, 30-39, 40-49, 50-59, and above 60 years) were categorized into five age groups, with corresponding frequencies of 35%, 25%, 18%, 13%, and 9% (n=83, 60, 43, 31 and 21). Figure 2 displays the specific frequency distribution of the cases.
The measured parameters were compared between males and females using an independent t-test. Significant gender disparities were found in all assessed radiological parameters according to the comparison. However, no significant difference was seen in the scapholunate space, revised carpal height ratio, or scapho-capitate ratio (p values 0.447, 0.465, and 0.523, respectively). Figure 3 illustrates significantly varied parameters across genders.
Males had greater average values for the following parameters: radial cord, radial height, ulnar variance, scaphoid length, lunate length, capitate height, carpal height, 3rd metacarpal length, and carpal height ratio; females had higher average radial inclination. Table 1 displays the means ± SD of all the parameters that take gender into account.
With respect to wrist side, the means of radial height, radial inclination, and radial cord indicated a statistically significant increase on the right side relative to the left (p=0.017, < 0.001, and < 0.001, respectively). On the other hand, the mean lunate length on the left wrist was substantially higher than on the right (p=0.049). There were no notable distinctions between the right and left wrists in the remaining evaluated measurements (Means ± SD are displayed in Table 1).
One-way ANOVA and the post hoc Tukey test were used to compare various age groups in terms of age diversity. The variables that exhibit varying degrees of significant differences include the radial cord, ulnar variance, scapholunate space, capitate height, scapho-capitate ratio, carpal height, and carpal height ratio (Figure 4). Nevertheless, there were no discernible variations in the radial height, scaphoid, lunate, and third metacarpal lengths between the age groups (p=0.15, 0.59, 0.12, and 0.36, respectively). Additionally, there were no discernible variations between the revised carpal height ratio and radial inclination (p= 0.37 and 0.86).
Selective intergroup variability revealed that, in comparison to other age groups, the group population over sixty exhibits notable variances in several indicators. When comparing the population over sixty to the age range of 20–29 years old, there was a substantial drop in the means of carpal height and carpal height ratio (p = 0.009 and 0.04). When comparing the oldest age group (> 60 years) to the age group of 30-39 years old, the following parameters showed a significant decrease: radial cord, ulnar variance, capitate height, carpal height, and carpal height ratio (p=0.025, 0.014, 0.011, 0.001, and 0.014, respectively).
Furthermore, compared to the middle age group (40-49 years old), the same age group (> 60 years old) pursued a significant decline in the means of carpal height (p= 0.042). The means of the scapholunate space and scapho-capitate ratio, however, significantly increased in the older age group's favor (p= 0.03 and 0.032). Furthermore, compared to the younger age group (50-59 years old), there was a significant decrease in the carpal height and carpal height ratio (p= 0.009 and 0.016) in the older age group.
Table 1 displays the Mean ± SD of all the assessed metrics split up across the various age groups. Numerous noteworthy relationships were found via non-parametric Kendall's tau_b correlation between various metrics and sociodemographic traits. The radial cord with capitate and carpal height showed the strongest moderately favorable relationships (r= 0.557 and 0.611). Furthermore, a somewhat favorable connection was seen between radial height and radial inclination, as well as between capitate height and carpal height (r=0.620 and 0.685, respectively). However, there was a moderately negative connection (r=-0.502) between gender and the radial cord. Table 2 displays the entire significant correlation matrix. Additionally, a linear regression analysis was performed to validate the associations between various parameters and sociodemographic attributes. The radial height, ulnar variance, carpal height ratio, third metacarpal length, and radial inclination (β= -0.49, -0.30, -6.09, -2.41, and 1.70, respectively) were all quantified as multiple significant relations with the gender.
Furthermore, there was a significant regression on the wrist's side with respect to the radial height, scapholunate ratio, and radial inclination, with β= -0.45, -0.05, and -3.15, respectively. Significant relationships were also observed between age group and ulnar variance and scapholunate ratio (β = -0.09 and 0.02). Furthermore, numerous noteworthy

relationships between the various observed characteristics were quantified and shown in Table 2.

Table 1. Means ± SD of all parameters considering gender, the wrist side, and age groups

Parameters	Gender		Side of the wrist		Age groups				
	Male	Female	Right	Left	20-29 years	30-39 years	40-49 years	50-59 years	More than 60 years
Radial cord	30.52 ± 2.91	26.67 ± 2.05	29.38 ± 3.40	28.80 ± 2.96	29.08 ± 2.78	29.57 ± 3.51	29.16 ± 3.34	29.60 ± 3.45	27.16 ± 2.86
Radial height	13.96 ± 2.63	12.96 ± 2.42	14.39 ± 2.62	12.63 ± 2.22	13.51 ± 2.42	14.07 ± 2.76	13.43 ± 2.14	13.90 ± 3.14	12.46 ± 2.57
Radial inclination	27.41 ± 5.23	29.24 ± 5.58	29.54 ± 5.22	26.29 ± 5.14	27.92 ± 5.13	28.61 ± 5.33	27.65 ± 4.67	28.48 ± 7.08	27.50 ± 5.80
Ulnar variance	2.39 ± 1.02	2.06 ± 0.58	2.35 ± 0.91	2.17 ± 0.88	2.32 ± 0.99	2.54 ± 0.93	2.14 ± 0.76	2.09 ± 0.79	1.82 ± 0.56
Scaphoid length	20.19 ± 2.73	17.60 ± 2.61	19.25 ± 2.96	19.24 ± 2.96	19.33 ± 2.88	19.55 ± 2.91	18.61 ± 2.79	19.40 ± 3.78	19.09 ± 2.40
Lunate length	15.71 ± 2.04	13.87 ± 1.60	14.80 ± 1.99	15.33 ± 2.18	15.31 ± 1.98	15.04 ± 1.99	15.04 ± 2.20	15.04 ± 2.10	13.93 ± 2.34
Scapholunate space	1.30 ± 0.18	1.28 ± 0.19	1.31 ± 0.19	1.26 ± 0.17	1.27 ± 0.17	1.31 ± 0.20	1.25 ± 0.18	1.29 ± 0.17	1.39 ± 0.19
Capitate height	23.39 ± 2.37	20.59 ± 2.08	22.33 ± 2.69	22.40 ± 2.58	22.48 ± 2.53	22.95 ± 2.89	22.12 ± 2.33	22.31 ± 2.38	20.80 ± 2.78
Carpal height	37.15 ± 3.46	32.87 ± 2.94	35.63 ± 4.03	35.53 ± 3.68	35.63 ± 3.50	36.45 ± 4.19	35.39 ± 3.62	36.10 ± 3.95	32.57 ± 3.45
Scapho-capitate ratio	0.87 ± 0.10	0.86 ± 0.11	0.86 ± 0.10	0.86 ± 0.11	0.86 ± 0.10	0.85 ± 0.09	0.84 ± 0.11	0.87 ± 0.13	0.92 ± 0.07
3rd metacarpal length	66.57 ± 5.67	61.71 ± 4.67	65.24 ± 5.95	64.25 ± 5.61	64.77 ± 5.36	65.64 ± 6.88	64.81 ± 5.32	64.71 ± 5.97	62.59 ± 4.74
Carpal height ratio	55.97 ± 4.83	53.32 ± 3.59	54.65 ± 4.23	55.43 ± 4.98	55.09 ± 4.02	55.63 ± 4.31	54.71 ± 4.93	55.98 ± 6.09	51.98 ± 3.05
Revised carpal height ratio	1.59 ± 0.09	1.60 ± 0.09	1.60 ± 0.07	1.59 ± 0.10	1.59 ± 0.09	1.59 ± 0.07	1.60 ± 0.08	1.62 ± 0.09	1.57 ± 0.10

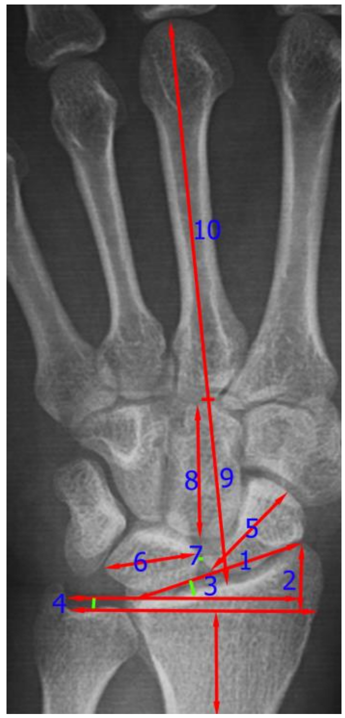

Figure 1. Illustration of the measurement procedure for all parameters. 1. Radial cord, 2. Radial height, 3. Radial inclination, 4. Ulnar variance, 5. Scaphoid length, 6. Lunate length, 7. Scapholunate joint distance, 8. Capitate length, 9. Carpal height, and 10. Third metacarpal length. All parameters were measured in millimeters except radial inclination was presented in degrees.

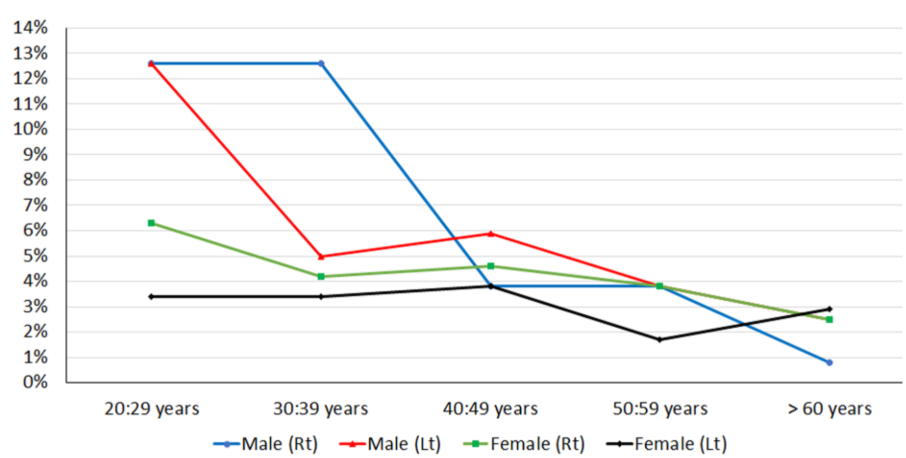

Figure 2. Representation of the sample frequency distribution according to age, gender, and the side of the wrist

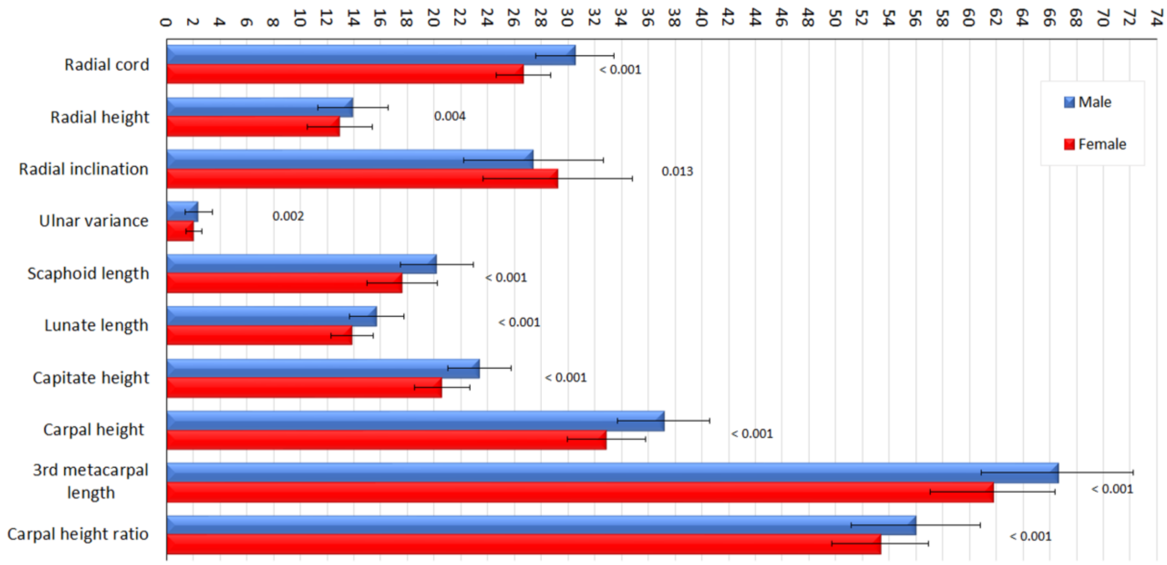

Figure 3. Graphical representation of the parameters that showed significant differences between males and females and their p-value elaborated by independent t-test. Values are presented as Mean ± SD

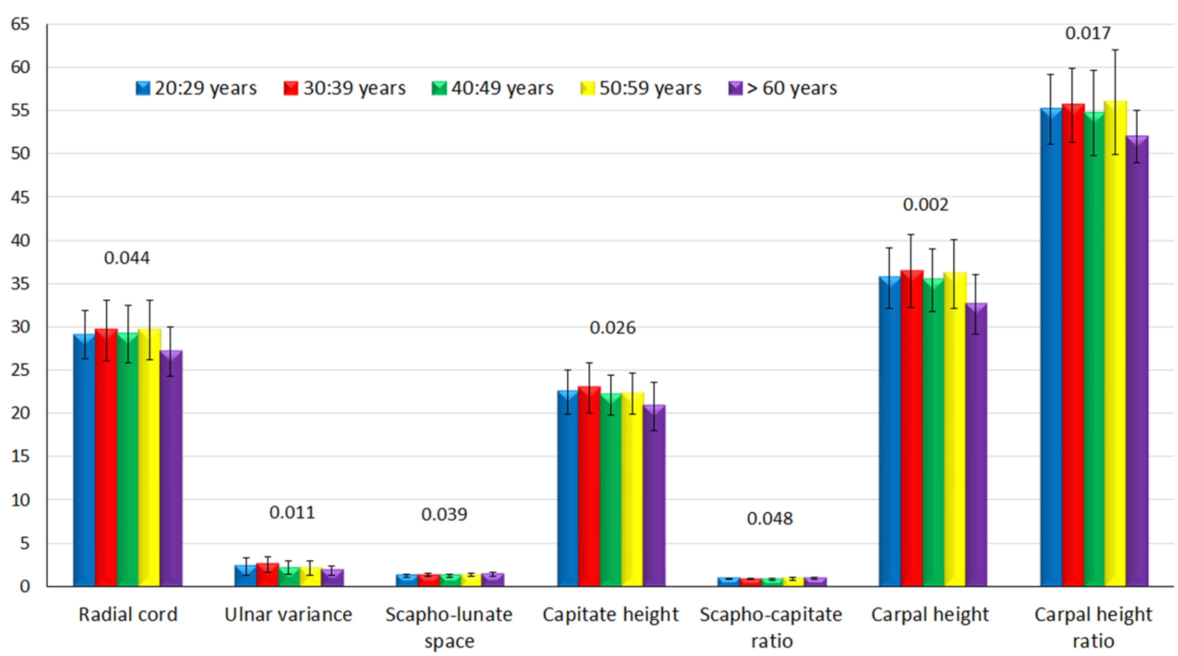

Figure 4. Illustrative diagram of the parameters that showed significant differences between different age groups and their p-value analyzed by AVOVA test. Values are presented as Mean ± SD

Table 2. Significant relations (correlation and regression) between different study parameters. Data are presented in each cell as **r/p** above and **β/p** below

Parameters	**Gender**	**Radial cord**	**Radial height**	**Radial inclination**	**Ulnar variance**	**Scaphoid length**	**Lunate length**	**Scapholunate space**	**Capitate height**	**Scapho-capitate ratio**	**Carpal height**	**3rd metacarpal length**	**Carpal height ratio**	**Revised carpal height ratio**
Gender			-0.169 0.001 -0.486 0.0004	0.112 0.035 1.700 0.0174	-0.128 0.016 -0.3020 0.030	-0.354 < 0.001 - -	-0.354 < 0.001 - -		-0.424 < 0.001 - -		- - -0.455 < 0.001	-0.352 < 0.001 -6.0085 < 0.001	-0.228 < 0.001 -2.413 < 0.001	
Side of the wrist			-0.253 < 0.001 -0.4450 0.0001	-0.234 < 0.001 -3.149 < 0.001			0.114 0.032 - -	- - 0.0190 0.0393						
Age group	0.179 0.002 - -				- -0.0850 0.048		-0.121 0.012 - -	- - 0.0190 0.0441	-0.100 0.039 - -		- - -0.101 < 0.001		-0.130 0.32 - -	
Radial cord	-0.502 < 0.001 - -		0.260 < 0.001 - -	-0.119 0.006 - -	0.091 0.036 - -	0.429 < 0.001 - -	0.438 < 0.001 - -		0.557 < 0.001 - -		- - 0.611 < 0.001	0.457 < 0.001 - -	0.251 < 0.001 - -	
Radial height		- - 1.7931 < 0.001		0.620 < 0.001 - -	0.161 < 0.001 - -	0.119 0.006 - -	0.099 0.023 - -		0.200 < 0.001 - -	- - 0.006 0.011	- - 0.288 < 0.001	0.266 < 0.001 - -		

Radial inclination		- - -0.7921 < 0.001	- - 0.4000 < 0.001		- - 0.0360 0.001	- - -0.0110 0.0410	- - -0.0633 < 0.001			- - -0.0024 0.0130				
Ulnar variance				0.115 0.008 - -				-0.098 0.024 - -		- - 0.032 < 0.001	- - 0.089 0.040	0.122 0.005 - -		0.090 0.039 - -
Scaphoid length				-0.136 0.002 - -			0.356 < 0.001 - -	0.376 < 0.001 - -	0.437 < 0.001 - -	- - 0.016 < 0.001	- - 0.481 < 0.001	0.367 < 0.001 - -	0.210 < 0.001 - -	
Lunate length				-0.149 0.001 - -		- - 1.2333 < 0.001		-0.269 < 0.001 - -	0.435 < 0.001 - -	- - 0.186 < 0.001	- - 0.491 < 0.001	0.316 < 0.001 - -	0.251 < 0.001 - -	
Scapholunate space						- - 14.5698 < 0.001	- - -5.2988 < 0.001							
Capitate height		- - 0.6022 0.0175		-0.049 0.030 - -		- - -0.3776 0.0340			- - 0.6357 < 0.001		- - 0.685 < 0.001		0.342 < 0.001 - -	-0.257 < 0.001 - -

Scapho-capitate ratio				-0.086 0.047 - -		0.456 < 0.001 - -		0.474 < 0.001 - -	-0.108 0.013 - -			0.417 < 0.001 - -		0.263 < 0.001 - -
Carpal height		- - -0.4930 0.0200								- - -0.0137 < 0.001			0.448 < 0.001 - -	
3rd metacarpal length					- - 0.2200 0.048	- - 0.1586 0.0030				- - -0.0041 < 0.001	- - 0.547 < 0.001	0.430 < 0.001 - -	-0.122 0.005 - -	
Carpal height ratio				-0.093 0.033 - -		- - 0.1784 0.0050				- - -0.0043 < 0.001	- - 0.641 < 0.001	- - -0.417 < 0.001		0.089 0.041 - -
Revised carpal height ratio		- - 8.0561 0.0243				- - -5.0210 0.0450			- - -14.002 < 0.001	- - 0.4558 < 0.001			- - 11.970 0.0002	

Discussion

238 normal wrist plain radiographs were used in the current cross-sectional investigation to evaluate the various relationships between x-ray parameters and the sociodemographic characteristics. When treating wrist joint injuries, it is important to consider the radiographic architecture of the distal radius (10). The radial cord was measured in this study, and the results indicated a considerable increase in males compared to females and in the right wrist compared to the left wrist across various age groups. Furthermore, an important correlation was established between the radial inclination, revised carpal height ratio, capitate height, carpal height, and radial height.

Prior research evaluating the radial cord in the Egyptian and Turkish populations found no variations in side or age, but rather substantial gender-dependent differences (1,4). Additionally, there was no discernible difference found between the radiocarpal joint's left and right radial articular surfaces. Nonetheless, the right radial articular surface was found to be wider than the left in 41% of instances (11).

Following Yalçın and Polat (1), the radial height was measured; the findings indicated a significant difference with gender and wrist side, but no variation with age. Similar findings with notable differences were observed in recent articles (5,10) when gender or gender and wrist side were examined. On the other hand, no statistically significant differences were found in Turkish populations according to gender or wrist side (1).

One of the most important factors to take into account while reducing distal radius fractures is the radial inclination (12). In the current population, there were no variations in radial inclination with age, however females had a considerably larger inclination on the right side than the left. However, in a different sample of the Egyptian population, significant relationships were estimated with respect to age and gender (4).

Furthermore, substantial relationships based on wrist side and gender were found in the Indian population (5). According to reports, there is no discernible relationship between the radial inclination and age, gender, or wrist side (13, 14). Additionally, a substantial relationship with gender was revealed by a Pakistani study (10). A retrospective investigation conducted on the Chinese population, however, found no evidence of a significant correlation with age, gender, or wrist side (14).

The pathophysiology of various wrist illnesses is greatly influenced by the wrist's load distribution, which is mostly determined by ulnar variance (15). The ulnar variance assessment showed that males had a significantly higher rise than females, with no difference on the wrist side. It also revealed notable variations throughout age groups. This is consistent with earlier research showing a correlation between gender and age-related declines in ulnar variance (4,13).

Furthermore, ulnar variance shown a significantly higher increase in males than in girls, according to ur Rehman and colleagues (10). Furthermore, a prior study found that females had a much higher ulnar variance than males did, and that there was a significant difference based on the side that did not change with age (16). Sharma et al. (17) confirmed that although there were age-related differences, females exhibited a larger ulnar variance than males. Furthermore, Gunalan observed that gender and wrist side have a substantial impact on ulnar variance (5). Nonetheless, a number of authors claimed that the ulnar variance did not alter based on gender or age (1,14,18).

The primary location for force distribution via the wrist and appropriate hand movements is the radiocarpal articulation (19). Additionally, calculating the carpal height reveals how much carpal collapse there is (20). This led to the performance of multiple carpal measurements in this investigation. The individuals' age, gender, and side were assessed, and the lengths of their scaphoid, lunate, and capitate as well as their overall carpal height were correlated.

While there were substantial gender differences in all of these parameters, only the lunate length showed a significant increase in the left hand, and the capitate length varied considerably between age groups. There was shown to be a significant relationship between the lunate and scaphoid lengths and the wrist's side (7). The lengths of the scaphoid, lunate, and capitate in Mastrangelo and colleagues' anatomical analysis showed substantial gender-related variances.

But there were no distinctions seen between the left and right wrists (21). Prior research revealed notable variations in carpal and capitate height by gender. But the only meaningful relationship found in carpal height is with age (4). Although carpal height is larger in men than in women, another study found no discernible variations in carpal height among ages, sides, or genders (14). Males had significantly greater carpal height and capitate length than females, with no difference in age or wrist side (1).

Wrist pain is thought to be frequently caused by scapholunate dissociation (3). Furthermore, in scaphoid reconstruction, it is essential to estimate the scaphoid length without measuring the contralateral scaphoid (9). This study also evaluated scapholunate space and scapho-capitate ratio. There was no variation in them based on gender or wrist side, however there were notable changes between age groups. Gender, age, and wrist side did not significantly correlate with either the scapholunate space or the scapho-capitate ratio (1,9,14).

The carpal height ratio was computed and a correlation with sociodemographic factors was assessed based on the third metacarpal length. Males significantly outperformed females in both parameters. Other than that, there were no alterations found in relation to the wrist's side. Furthermore, the carpal height ratio was the only one to alter considerably with age. These findings corroborated the recently released information (6) showing a significant difference in the length of the third metacarpal between males and girls.

Furthermore, only the length of the third metacarpal grew considerably in males compared to females, but the carpal height ratio and third metacarpal length differed significantly between age groups (4). However, in the Turkish population, no discernible variations were found for the two parameters (1). Lastly, the carpal height was divided by the length of the capitate to determine the updated carpal height ratio.

The revised carpal height ratio did not significantly alter based on gender, age, or wrist side, despite the two parameters exhibiting strong relationships with age and gender. Given that the study was conducted on Egyptian citizens, this is consistent with other reports (4). Nonetheless, there was no discernible variation in the revised carpal height ratio between genders and age groups in the Turkish population research (1).

Conclusion

We may infer that the wrist is among the most complex articulations in the human body, exhibiting significant morphological variability within and between individuals. For the diagnosis, prognosis, and treatment of numerous wrist conditions, radiographic measures of the wrist are essential. When making decisions, one should consider variations based on age, gender, side, and population. To develop approximate methods about these divergences, numerous investigations involving correlations from other aspects and in other populations are required. This may also help doctors create implants with greater precision and improve patient outcomes following therapy for wrist diseases.

Data availability

The author will provide access to the data upon request.

Conflict of interest

The author states that he has no competing interests.

Acknowledgment

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Ethics approval

The University of Bisha's College of Medicine's local research ethics committee (UBCOM-RELOC) criteria were adhered to, according to the study's author. These rules said that since the study did not directly involve human individuals or their data, ethical approval was not required.

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