

Women are Unequally Represented Among Clinical Trial Leadership by Orthopaedic Subspecialty

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INTRODUCTION: Orthopaedic surgery remains one of the least diverse medical specialties. Clinical trial leadership offers a pathway through which orthopaedic surgeons can advance their careers and mentor future generations of trainees. Prior studies have identified the lack of women among principal investigators (PIs) of orthopaedic clinical trials as an obstacle to academic career progression and as a contributor to the underrepresentation of women within academic orthopaedics. This study compares gender representation within clinical trial leadership between subspecialties of orthopaedics. We hypothesized that representation would vary by subspecialty, identifying focus areas for future initiatives to reduce sex disparities within orthopaedics.

METHODS: A retrospective analysis of orthopaedic surgery clinical trials registered on ClinicalTrials.gov from 2007-2025 was performed. Trials were manually reviewed for subspecialty relevance and PI identity. PI sex was determined via genderize.io, a validated application that assigns a predicted gender to user-input names. Trials without orthopaedic surgeons as PIs, those with multiple PIs, or those with low-confidence gender predictions via genderize.io were excluded. Female representation in trial leadership was compared across subspecialties, intervention types, and locations using chi-square tests. Chi-square tests were also performed in a pair-wise fashion to compare the percentage of women-led trials between each subspecialty. Statistical significance was set at $p < 0.05$. A U.S.-specific analysis also assessed prevalence-to-participation ratios (PPRs) to normalize female representation against subspecialty demographics. Participation is defined as the number of PIs of a sex in each subspecialty divided by the total number of PIs in that given subspecialty. Prevalence is defined as the number of academic faculty of that sex in each subspecialty divided by the total number of academic faculty of that specialty. PPR is then participation divided by prevalence. $PPR < 0.800$ was defined as underrepresentation and $PPR > 1.200$ was defined as overrepresentation.

RESULTS: Of 1,257 trials worldwide, 7.8% were led by women. Female PI representation varied significantly by subspecialty ($p < 0.001$) and study intervention ($p < 0.001$, **Figure 1**). Globally, pairwise comparisons revealed that more trials were women-led in pediatric orthopaedics than in hip and knee ($p < 0.001$), foot and ankle ($p < 0.001$), sports medicine ($p < 0.001$), trauma ($p < 0.001$), spine ($p = 0.005$), hand ($p = 0.014$), and shoulder and elbow ($p = 0.003$). When considering only trials based within the U.S., female PI representation varied significantly by trial location ($p = 0.017$), study intervention ($p < 0.001$), and subspecialty ($p < 0.003$, **Figure 2**). Pediatrics had significantly greater female representation than hip and knee ($p < 0.001$), foot and ankle ($p = 0.005$), hand ($p = 0.038$), and sports medicine ($p = 0.005$). Trauma had higher female representation compared to hip and knee ($p = 0.002$), foot and ankle ($p = 0.018$), and sports medicine ($p = 0.026$). Additional significant differences were seen between shoulder and elbow (11.0%) and hip and knee (4.0%) ($p = 0.029$). PPR analysis (**Figure 3**) identified spine as the only subspecialty in which female investigators were over-represented ($PPR = 1.787$). In contrast, women were under-represented in hip and knee ($PPR = 0.635$), foot and ankle ($PPR = 0.177$), trauma ($PPR = 0.623$), pediatrics ($PPR = 0.714$), hand ($PPR = 0.392$), oncology ($PPR = 0.709$), and sports medicine ($PPR = 0.672$). Males were equitably represented among clinical trial leadership in all subspecialties.

DISCUSSION: This is the first study to directly compare the representation of women among clinical trial leadership between subspecialties of orthopaedic surgery. Our results indicate a high level of variation in representation at a global scale and within the U.S., with pediatric orthopaedics generally having a higher proportion of female-led trials than other subspecialties. After adjusting for the demographics of each specialty, women were underrepresented as PIs in hip and knee, foot and ankle, trauma, pediatrics, hand, oncology, and sports medicine. Targeted initiatives, such as through industry partnership programs or research grants, should be made to better support women pursuing research leadership in these fields.

SIGNIFICANCE/CLINICAL RELEVANCE: This analysis identifies orthopaedic subspecialties in which women are underrepresented among clinical trial leaders, with the goal of guiding targeted strategies to support their increased participation.

Subspecialty	Female: n (%)	Male: n (%)	p-value
Subspecialty			<0.001
Hip and Knee	24 (6.1%)	367 (93.9%)	
Foot and Ankle	5 (4.8%)	100 (95.2%)	
Trauma	16 (8.3%)	177 (91.7%)	
Pediatrics	17 (23.6%)	55 (76.4%)	
Spine	8 (8.2%)	89 (91.8%)	
Hand	9 (9.6%)	85 (90.4%)	
Shoulder and Elbow	10 (8.3%)	110 (91.7%)	
Oncology	3 (10.0%)	27 (90.0%)	
Sports	6 (3.9%)	149 (96.1%)	
World Region			0.136
North America	58 (7.1%)	763 (92.9%)	
Europe	32 (10.8%)	264 (89.2%)	
South America	2 (12.5%)	14 (87.5%)	
Asia	6 (5.7%)	99 (94.2%)	
Other	0 (0.0%)	18 (100.0%)	
Study Intervention			<0.001
Behavior	12 (32.4%)	25 (67.6%)	
Biological	0 (0.0%)	1 (100.0%)	
Device	16 (5.2%)	290 (94.8%)	
Drug	17 (7.7%)	203 (92.3%)	
Procedure	20 (5.6%)	335 (94.4%)	
Other	33 (9.8%)	305 (90.2%)	
Study Type			0.127
Interventional	68 (7.1%)	884 (92.9%)	
Observational	30 (9.8%)	275 (90.2%)	

Figure 1. Representation of orthopaedic clinical trials worldwide by subspecialty and other characteristics.

Subspecialty	Female: n (%)	Male: n (%)	p-value
Subspecialty			0.003
Hip and Knee	8 (4.0%)	194 (96.0%)	
Foot and Ankle	1 (1.9%)	51 (98.1%)	
Trauma	13 (14.0%)	80 (86.0%)	
Pediatrics	9 (19.1%)	39 (80.9%)	
Spine	4 (8.0%)	46 (92.0%)	
Hand	5 (6.8%)	69 (93.2%)	
Shoulder and Elbow	8 (11.0%)	65 (89.0%)	
Oncology	2 (10.5%)	17 (89.5%)	
Sports	6 (5.1%)	111 (94.9%)	
US Census Region			0.017
Northeast	20 (13.4%)	129 (86.6%)	
Midwest	13 (5.9%)	206 (94.1%)	
South	11 (5.0%)	208 (95.0%)	
West	12 (8.8%)	125 (91.2%)	
Study Intervention			<0.001
Behavior	10 (34.5%)	19 (65.5%)	
Biological	0 (0.0%)	0 (0.0%)	
Device	10 (5.6%)	170 (94.4%)	
Drug	15 (8.7%)	157 (91.3%)	
Procedure	7 (4.8%)	139 (95.2%)	
Other	14 (7.0%)	186 (93.0%)	
Study Type			0.260
Interventional	40 (7.1%)	524 (92.9%)	
Observational	16 (9.8%)	148 (90.2%)	

Figure 2. Representation of clinical trials in the United States by subspecialty and other characteristics.

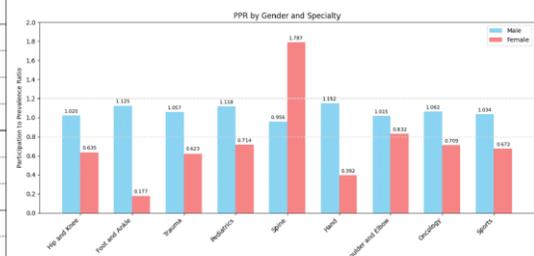


Figure 3. Prevalence-to-participation ratios by gender and subspecialty in the United States. Dashed lines indicate cut-offs for over-representation (1.20) and under-representation (0.80).