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Editorial

The Need for Advanced Orthopaedic Device Design: Considering Race and Ethnicity

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Introduction

Orthopaedic patient populations within the United States and all over the world are growing at a rate higher than ever before. This growth is attributed to an increase in the number of elderly individuals as well as increased orthopedic injuries to people of all ages. It is projected that the orthopaedics device industry will pass $32 billion by 2015. This tremendous need has created a renewed interest by industry, clinicians, and researchers in more clinically and cost effective solutions [1]. One way to address problems associated with poor device function, is to widen design considerations for orthopaedic devices to account for race and/or ethnicity.

Orthopaedic devices have undergone numerous design changes over time. While the orthopaedic device industry has tried to develop devices that fit large percentages of the patient population, it is understood that this is approach ineffective. Only recently have these same devices, and even some treatments, been designed specifically for women and children. Previous attempts to consider the needs of devices for women and children meant taking equipment designed around the biomechanics of Caucasian men, and proportionally shrinking the device to a size that was believed to fit women and/or children. While this is a step in a positive direction, these specialized designs showed limited to no consideration for anatomical differences between races. Such considerations would greatly benefit the orthopaedic device design. It is natural to ask, why would such considerations improve device design? Firstly, orthopaedic device performance is heavily dependent upon the devices' interaction with the surrounding environment (*i.e.* bone, cartilage, tendons, and ligaments). The environment (often bone), is a complex living system which responds to load, nutrition, and can vary based on a person's sex and race/ethnicity. Bone density is a primary example of the differences found between races. Research confirms that Blacks have a higher bone mineral density when compared to Whites, and the gradual loss of density over time is significantly less for Black women compared to White women [2]. The benefits of such differences have been well explored with regard to Osteoporosis, but little else. Bone mineral density is a material property of bone, the surrounding environment of orthopaedic devices. Therefore, it can be hypothesized that orthopaedic devices which do not account for such differences in density, will lack maximum efficacy, or worse, be detrimental to the patient. Though, there is scientific evidence of other anatomical differences in the skeletal systems of Black and Caucasians [3] little is done to incorporate these differences into device designs. Research on anatomical and physiological differences between races, has a dark history. Ill-posed studies were used to justify subjugation of people. However, current technology and research methods provide a robust way, to ethically explore anatomical differences, if any.

The marketplace is taking these differences into consideration with regard to device design. One, internationally recognized orthopaedics company found significant differences in the skeletal size in various regions of China. In understanding these differences, this company has released designs implants that account for size differences. While there is a clear business case for this company's decision, it is also exciting to note detectable differences in anatomy and physiology within one race/ethnicity; however questions remain, where is the research related to anatomical and physiological differences across races and ethnicities? Where are the much needed advancements for devices designed specifically for women and children?

Critics may argue that such consideration of race are illogical due to the amount of variation within one group other anecdotal evidence suggests no such differences exist. It may also be argued that accounting for size differences, also accounts for changes stemming from race/ethnicity, or that the most effective way to address the different design needs according to race/ethnicity is to accelerate the development of patient specific orthopaedic devices. While many device providers are moving in the direction of personalization, there are still significant hindrances, including limitations in manufacturing and lack of evidence regarding patient specific device superiority.

In conclusion, research, and clinical communities must drive innovations for orthopaedic devices that account for physiological differences seen between races. This work should begin with special attention given to research that explores the biomechanical factors specific to a race or ethnicity, and the impact of these factors. Even if such research concludes that anatomical factors associated with race/ethnicity have a negligible impact on orthopaedic device performance, the field of biomechanics will benefit from this new knowledge by eliminating potentially confounding factors that impact device design. If, however, it is determined that the previously described factors are dependent upon race, such findings open up new avenues for exploration. These and other questions discussed in this editorial could not have come at a more appropriate time as numerous studies have cited the significant increase in the number of Black patients opting for total joint replacement surgeries. The changing demographics of orthopaedic patients highlight the need to consider anatomic and physiological differences in the design, surgical, and post-surgical plans.

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