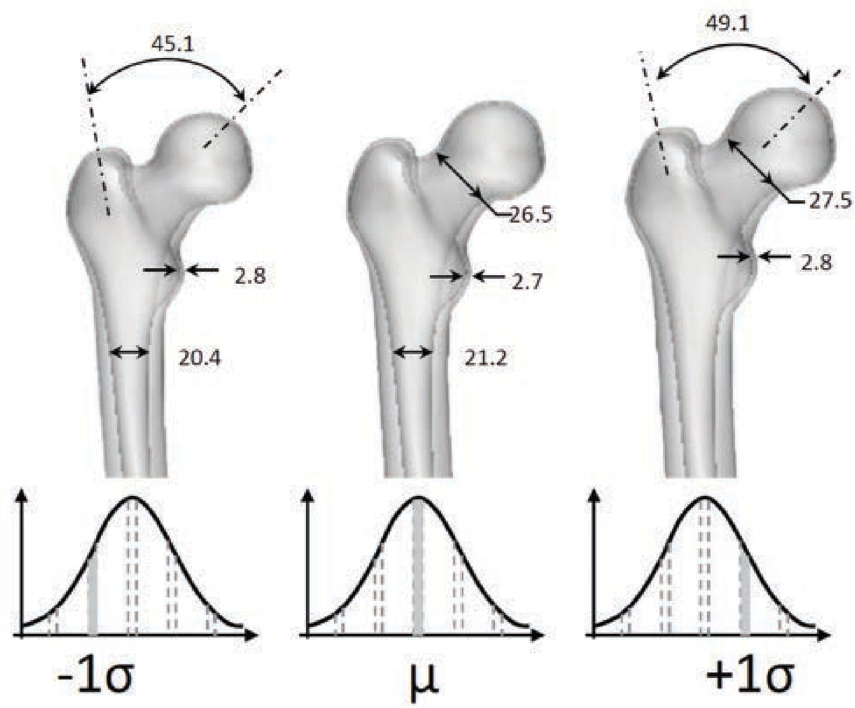
Virtual Population Analysis Improves Orthopedic Implant Design

Sjoerd Kolk and Mike Lawrenchuk • *Contributing Writers*

The orthopedic industry is seeking new methods to drive innovation as greater attention is given to improving patient outcomes and controlling healthcare costs. One method that has been embraced by many companies over the past few years is the use of population analysis based on computed tomography (CT) or magnetic resonance imaging (MRI) to determine new implant shapes and sizes.[1] This technology promises to reduce design iterations, the number of cadaver labs and the risks associated with design errors. Population analysis also can be a powerful argument in convincing regulatory bodies, hospital management and surgeons of the thorough sizing rationale and good performance of a new implant system.

This column examines how the DJO Surgical division of orthopedic device company DJO Global Inc. and medical image processing specialist Materialise N.V. partnered to bring the power of image-based population modeling into the development of DJO's new TaperFill hip stem.

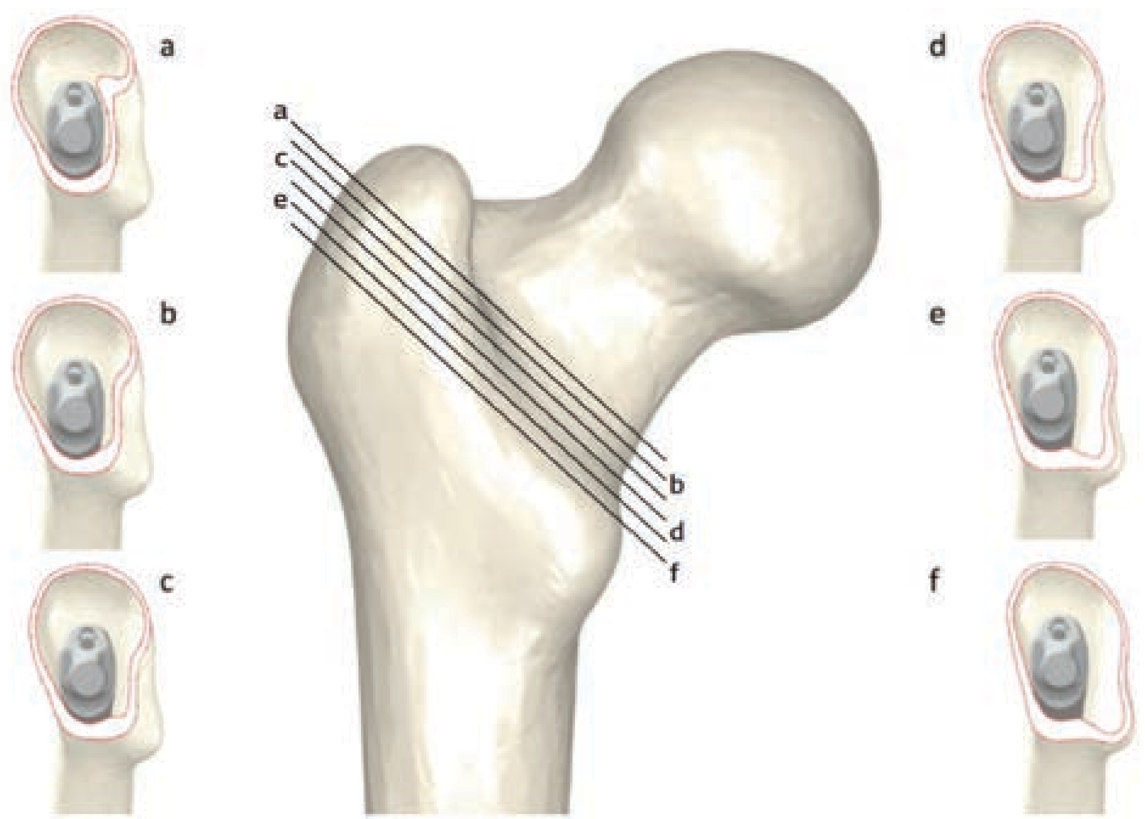


ADaM models represent the sample population of femurs as population-representative discrete geometries. The femur in the middle represents the population average, with the -1 and +1 standard deviation models of the first mode of variation on the left and right, respectively. Image courtesy of DJO.

DJO's TaperFill hip step. Photo courtesy of DJO.

The project goal was to produce a stem optimized for use with the direct anterior (DAA) surgical approach, a relatively new minimally invasive technique designed to spare the critical posterior soft tissue. To accommodate the reduced stem length needed during DAA, the design required the proximal body to be highly congruent with the dense cortical bone, to ensure the initial stability needed to achieve bone ingrowth into the new P-squared coating. Initial attempts to design the required highly congruent proximal body for the TaperFill stem using traditional anatomic information were difficult. Each member of the design team had his or her own expectations of natural femoral anatomy based on their individual experiences and a few plastic representative models. These individual expectations of the femur anatomy could neither be quantified nor shared among the design team, hampering the cooperative engineering of the implant geometry. For instance, it wasn't until physical parts were produced and tried that one promising design had to be discarded due to a potential for over-sizing in smaller bones that could lead to fracturing of the femur during its insertion.

The DJO design team decided to collaborate with Materialise, which de-



Using the model femurs, standardized cross sections were located and then used to design and verify the optimal shape for the TaperFill hip stem proximal body. Image courtesy of DJO.

veloped ADaM technology—an image-based population analysis method.[2] In the project for DJO, Materialise used its expertise in segmentation and statistical population analysis to combine 3-D geometrical bone shapes from a database of male and female femur CT scans into an average 3-D shape of the entire femur. This average shape contains features, trends and population-specific shape information that best represent those of the entire population, thereby forming a good starting point for virtually assessing the fit of an implant design.

Besides the average femur, variation models also were created to reflect the 3-D geometry of typical larger and smaller patients. These variation models are not just larger or smaller versions of the average model; they are able to capture how other aspects (e.g., offset and neck angle) change together with size as well.

"In traditional population analysis, the designer may have to a priori choose a few discrete parameters to measure from the available anatomical data sets, often ignoring a significant amount of the rich geometric data available," said Bryan Kirking, engineer at DJO. "Now that we use the evidence brought by this new technology in our design process, we feel much more confident that we are doing everything we can to optimize implant geometry to the natural anatomy. We are also able to reduce the number of design iterations and cadaver labs, thereby saving the company significant costs."

The team proceeded with virtually fitting their concept design into the femur models, with the aim of better understanding the interaction of bone and implant at key anatomical landmarks. After importing the femur models into their computer-aided design (CAD) software, cross sections were produced at standardized locations and used as input to interactively drive the best implant shape for maximizing congruency and minimizing interference. The results could be directly visualized, quantified and shared among the design team. Moreover, surgeons particularly liked the ability to directly visualize the cut femur as seen during surgery, which helped evaluate insertion and positioning characteristics that previously could only be evaluated at later stages of the design process. Engineers were pleased to be able to use the femur models in the same CAD software already being used to design the implants and the ability to interactively visualize design geometries against the model femurs. The final TaperFill hip stem shares the same medial-lateral tapered profile of DJO's Linear hip stem, which has more than 17 years of clinical success, and also, thanks to ADaM, has an optimized congruency with the

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cortical bone, is easier to insert with a less-invasive anterior approach, and provides feedback to the surgeon for sizing and placement.

"Now that we have experienced the power of this technology first hand, it is like we have a hammer and everything becomes a nail. We have used this technology to improve projects throughout our R&D (research and development) department at DJO," said Kirking.

This illustrates how image-based population modeling can be a powerful tool for understanding and designing for the 3-D anatomy and its variation with size.

"This technology is valuable to any orthopedic company interested in improving patient care through better designs," said Sebastian De Boodt, product manager at Materialise. "By obtaining a much deeper understanding than ever before of the 3-D anatomy and how it varies between patients, engineers are able to come up with designs that are anatomically contoured, allowing them to retain more of the patient's bone, potentially leading to better long-term outcomes. Also, with more people in emerging markets gaining access to good healthcare, it allows to effectively analyze anatomical differences between populations and to adapt new medical devices accordingly, allowing them to be used for a much broader patient population."

Using anatomical evidence in the design also helps companies reduce risks and supports their marketing goals.

"We had situations where a customer discovered design problems right before product launch," said De Boodt. "Using a population study, they were able

DJO's TaperFill hip stem has a congruent proximal body taper optimized using Materialise's femur models. Photo courtesy of DJO.

to quickly pinpoint the problem and perform a redesign, minimizing the cost of a delayed product launch—and more importantly—creating a successful product that satisfied their customer base. The results of the study are now used in a marketing white paper to explain their sizing rationale."

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Editor's note: For more in-depth information on DJO, see the Top Company report in this issue, which begins on page 32.

Mike Lawrenchuk *is a business development manager at Materialise responsible for software and services in the North American orthopedic industry. Mike has nearly 10 years of experience in biomedical applications based on medical image data including patient-specific design, computational modeling, surgical planning, and medical 3-D printing. His recent focus has been on Materialise's Anatomical Data Mining (ADaM) technology and utilizing databases of CT data to statistically model anthropometric trends in bone morphology between populations. Mike is a graduate of the University of Michigan with a B.S.E. and M.S.E. in biomedical engineering.* **Sjoerd Kolk** *is an application engineer at Materialise, as part of a team responsible for the ongoing improvement of Materialise's software and services for the orthopedic industry. He obtained his M.Sc. in biomedical engineering from the University of Twente, the Netherlands, and performed Ph.D. research at the Radboud University Medical Center, the Netherlands. He has authored multiple scientific papers on state-of-the-art image analysis, the biomechanics of the musculoskeletal system, and the functional outcome of orthopedic interventions in the lower limb.*