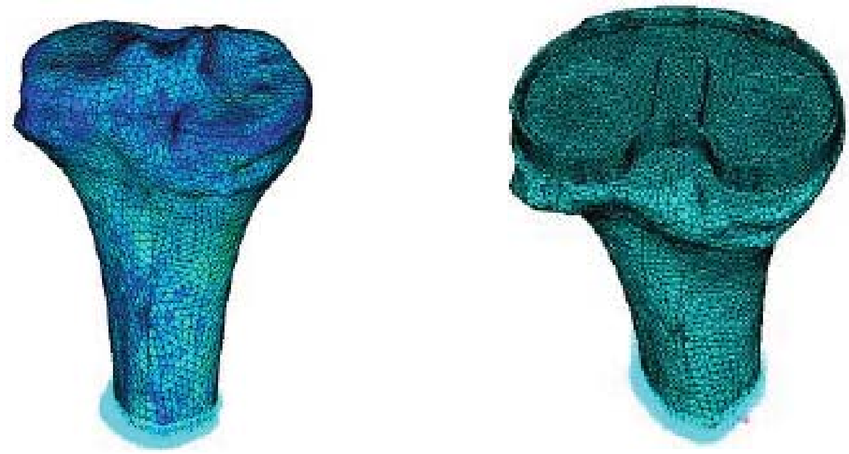
CAE ASSOCIATES
ENGINEERING ADVANTAGE

Case Study

Stryker® Triathlon™ Knee System



Pre-operative (Intact) proximal tibia FE Model with mapped bone properties (Left) and Reconstructed (Post-operative) proximal tibia FE model (Right)

Bone Remodeling Predictions using ANSYS

Bone remodeling is a natural, lifelong process in which old bone is absorbed and replenished by new bone. Ultimately, the long term density of bone is strongly influenced by the level of mechanical stimulus it receives. When the loads transmitted through bone are reduced over time, the bone responds with a gradual decrease in density. For example, astronauts who spend significant time in the weightless conditions of space are prone to experience a loss in bone density due to the reduction in mechanical stimulus. As a result, NASA has designed specialty exercise equipment to help counter this effect. On the contrary, an increase in mechanical stimulus offers the potential of bone apposition (i.e.; an increase in bone density). Professional weight lifters are typical of individuals with evidence of above average bone densities.

In the case of total knee and hip replacements, introduction of the prosthesis has the potential to alter load paths. For total knee replacement (TKR) procedures (see Figure, above), the surgeon removes the damaged articular cartilage and nearby, adjoining bone from the joint. The remaining, underlying bone is subsequently resurfaced or “capped” with prosthetic components which are typically manufactured out of metal, ceramic, and/or polyethylene.

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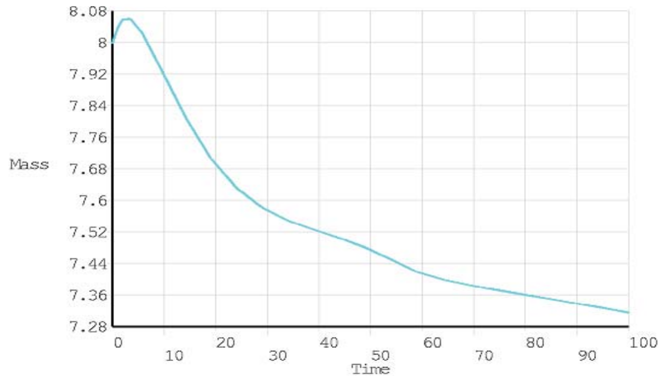
1579 Straits Turnpike, Suite 2B / Middlebury, CT 06762 / P 203.758.2914 / F 203.758.2965



Plot of bone mass as a function of time predicted by the Bone Remodeling Algorithm

Bone Remodeling Predictions using ANSYS / *Continued*

Stryker® Total Hip Replacement System

In the case of a traditional hip replacement (see Figure, left), a long metal stem is inserted down the shaft of the proximal femur, while the acetabulum is resurfaced.

The replacement of the pre-operative, adjoining bone at the joint with prosthetic components (which are typically stiffer than the cartilage and bone combination they replace) results in the potential of load path changes within the underlying bone. When prosthetic devices are designed, the potential for the underlying bone (which surrounds and supports the prosthesis) to be "stress shielded" by the prosthesis should be considered. Inordinate levels of stress shielding may, over time, result in a reduction of bone density, loss of fixation, and eventual loosening of the device.

Stryker Orthopaedics, a global leader in the development, manufacture and sale of orthopaedic products and services, sought to develop customized finite element simulations to evaluate long term, bone-implant interaction by characterizing bone density changes in hip and knee replacement recipients over a period of years. Pre-operative bone shape and quality data are obtained from patient CT (computed tomography) and DEXA (dual energy x-ray absorptiometry) scans as "initial conditions". Designs to be evaluated can be existing designs or, more importantly, design concepts.

CAE Associates incorporated a bone remodeling algorithm into ANSYS via the USERMAT material model user-subroutine. This bone remodeling algorithm is a material law that characterizes how bone density changes over time as a result of load path changes between the pre-operative and post-operative stress/strain state in the bone. Bone remodeling is a slow progressing phenomenon with a typical time step in the order of weeks. This nonlinear, iterative approach uses a

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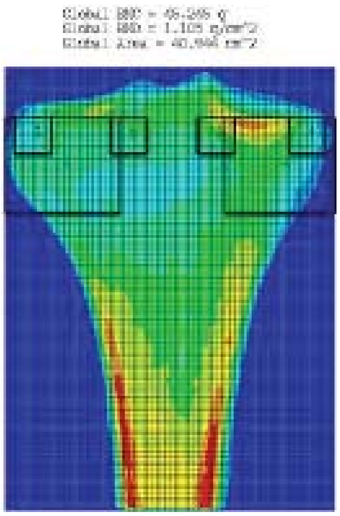
remodeling signal based on the strain energy density to predict changes in bone density as a function of position and time.



"Virtual DEXA scan" in A/P view using Bone Remodeling Algorithm analytical result predictions

The output data generated by the bone remodeling analysis procedure include 3D bone FE model result plots of the bone density at time, t, as well as the incremental density change between time steps. The ability to perform "virtual DEXA" plots was also developed by CAE Associates to facilitate direct bone density comparisons to clinical data, which are typically presented in this form. Examples of the models and results are shown in Figures 3-5. Preliminary results obtained from this approach compare favorably with published data.

CAE Associates worked closely with Walter Schmidt, Principal Research Engineer in the Modeling & Simulation, Reconstructive Technologies Group at Stryker Orthopaedics R&D to develop the finite element-based bone remodeling simulation system. Mr. Schmidt describes the contributions of CAE Associates as follows:

"CAE Associates welcomed the opportunity to provide consulting services in biomechanics-based scientific research, which many consider to be a novel and unique application of FEA. The development of a bone remodeling algorithm, which operates on mechanical stimulus changes between two, independently analyzed, finite element models (i.e.; a pre-operatively loaded bone and a post-operatively loaded one), represented a significant challenge.

"CAE Associates integrated the ability to readily adjust bone loss rates, bone gain rates, and dead zone (i.e.; non-reactive) limits to facilitate our clinical validation efforts. CAE Associates was extremely responsive to our continuous requests for software enhancements as user feedback was supplied. Stryker has found a valuable and reliable resource in CAE Associates' experts for our customized software development needs."

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