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USING ACTIVITIES OF DAILY LIVING TO EVALUATE THE DESIGN AND PLACEMENT OF A PROXIMAL RADIUS FRACTURE FIXATION DEVICE

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INTRODUCTION

The return of a patient to activities of daily living following a surgical intervention (i.e. joint replacement, rigid fixation, etc.) involving an implantable device is often used as one component to measure the success of the surgery [1]. The longevity of the implant subject to the forces imposed when performing those normal daily activities is another. As people are living longer and continuing to maintain active lifestyles, the paradigm of everyday activities that are used to evaluate implant longevity must also evolve. Although physiological boundary conditions during pre-clinical implant evaluations have been used for simulating the life span of a new device, only a small number of everyday activities used for deriving those forces have been widely characterized. The purpose of this paper is to demonstrate how musculoskeletal simulation can be used for providing the boundary conditions of a finite element model used to evaluate the design space of an implant subject to specific activities of daily living (Figure 1).

Physical testing and computer simulations of new implantable devices have utilized estimated physiological loading conditions to better understand the development of known failure modes prior to in vivo clinical trials [2,3]. Cristofolini et al. [2] proposed a method for incorporating loading profiles of several normal activities (i.e. ingress/egress, sit-to-stand, etc.), used in a physical test rig, to evaluate the failure associated with the fixation of cemented hip implant stems. It is unknown whether such procedures have been incorporated early in the design process of new devices (for evaluating material selection, geometry, etc.) or used more traditionally as a pass/fail test to evaluate whether a particular design satisfies a minimum criterion. It is believed the latter scenario is the more prevalent use of data pertaining to activities of daily living.

The design of a proximal radius fracture fixation device is characterized here to demonstrate the integration of musculoskeletal simulation and finite element modeling. The everyday activity of a wheel chair push exertion is used as input for evaluating the maximum stress and fatigue life of the parametrically defined implant design.

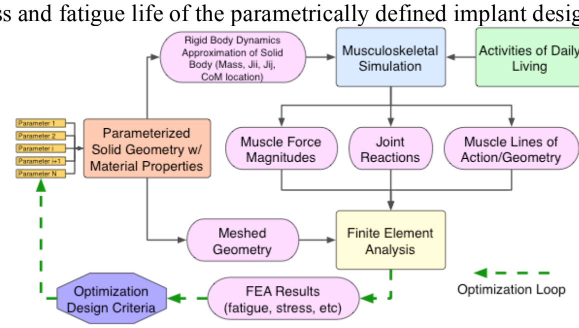


Figure 1. Information flow for implant design evaluation. Optimization loop depicts how design criteria (i.e. fatigue life) can be optimized for parametrically defined geometry.

METHODS

The AnyBody Modeling System (Aalborg, Denmark) was used to simulate the musculoskeletal loading (Figure 2) of a subject performing a forward wheelchair propulsion (AnyBody Repository 7.0). The outputs of the inverse dynamics musculoskeletal simulation were used as inputs to a finite element model of the fracture fixation implant (attached to the proximal portion of a simulated fractured radius). Specifically, the musculoskeletal simulation output included the muscle attachment (and wrapped surface contact) points, the corresponding muscle force magnitudes, and the joint reaction forces over time.

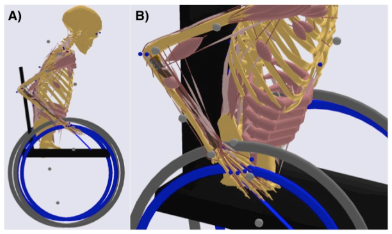
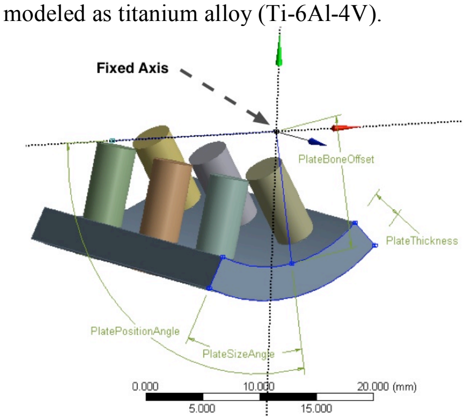


Figure 2. Musculoskeletal simulation used to define the boundary conditions of the finite element model at t=0.20 s.

The geometry of an implant was parameterized and the three parameters of plate thickness, angular plate size, and angular plate position, were varied over the ranges presented in Figure 3. A 100° angular plate position is defined to be located on the proximal lateral side of the radius. An increase in the angular position corresponds to a counterclockwise rotation of the plate about an axis defined by looking down the radius shaft from the proximal toward the distal end. The implant was modeled as titanium alloy (Ti-6Al-4V).



Parameter Ranges	Minimum	Maximum
PlatePositionAngle (degrees):	10	170
PlateThickness (mm):	2	4
PlateSizeAngle (degrees):	35	45

Figure 3. Implant geometry parameterization and associated range limits used for each parameter

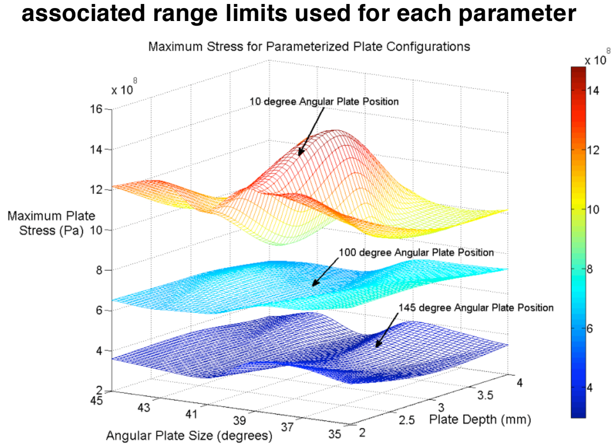


Figure 4. Iso-curves of the maximum stress for three angular plate positions (10, 100, and 145 degree) over all the sampled plate depth and angular plate size parameters.

RESULTS

Three geometrical parameters of the fixed plate (plate thickness, angular size, and position) were varied and the resulting design space was evaluated. The implant position had the strongest influence on the maximum stress and fatigue life of the plate. The angular implant plate size and thickness had a strong influence at certain implant positions, but accounted for significantly less of the overall variation for both the maximum stress (Figure 4) and fatigue life.

DISCUSSION

The analysis presented here illustrates a method for utilizing activities of daily living to understand the design space of a parametrically varied fixed plate implant geometry. A full factorial analysis was conducted over the geometry parameter space (Figure 3) subject to the muscle loads derived from a musculoskeletal simulation of a wheel chair exertion. From an engineering perspective, the position of the fixed plate with respect to the radius bone was the most critical component for maximizing implant longevity (due to high-cycle fatigue) and minimizing the maximum equivalent stress on the plate.

One limitation of this work is that the musculoskeletal simulation requires an input motion to calculate the muscle forces used in the finite element model. The implication of using such an input is that the effect of the implant on the motion pattern is not taken into account. To the knowledge of the authors, there currently exist no motion simulation technology robust enough to replicate realistic human motion for even a small number of possible activities of daily living. Until such technologies become available, utilizing actual motions is the next best alternative. A primary assumption with utilizing recorded motions for evaluating implantable medical devices is that the design of the device is intended to replicate (or not significantly change) the function of the un-perturbed system (i.e. with no medical device). The practicality of this assumption is supported by Jahromi [4], who found a positive correlation between a patient's perception of how 'normal' a knee replacement felt and the outcome criteria of a return to exercise and activities of daily living. Patients whose knee replacements felt 'normal' were more likely to return to work and activities of daily living suggesting that one goal in the design of such devices should be to mimic the normal behavior of the joint or complex.

The use of everyday activities to evaluate the fatigue life of an implantable device in a pre-clinical environment is not new [3]. However, the widespread use of physiological loading conditions to optimize the design of a particular implant (as proposed in Figure 1) for enduring everyday activities has been underutilized. In addition, the incorporation of a larger number of activities of daily living, similar to that proposed for hip replacements [2], in analyses similar to those presented here can be used to develop more robust designs prior to clinical trials, further reducing the risk to potential patients.

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