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ACTIVITIES OF DAILY LIVING AND IMPLANT DESIGN: EVALUATION OF A FEMORAL FRACTURE FIXED PLATE IMPLANT DURING BICYCLE PEDALING

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INTRODUCTION

The process of using activities of daily living to evaluate the performance of implantable devices under physiological loading conditions has been researched [1,2,3,4]. In particular, long-term stability of hip-implants, as related to fatigue, have been evaluated using normal walking [1,2,4], sit to stand [1], stair climbing [2,4], and combinations of everyday activities [3]. Current methods that utilize estimated physiological loading conditions are traditionally used as pass/fail tests to identify whether a particular design performs to a set of minimum specifications for long-term use. Such tests are also traditionally limited to a small number of physiologically representative loading conditions (i.e. walking, stair climbing, sit-to-stand).

The limited number of activities used as physiological loading conditions in pre-clinical design evaluations suggests there exists a scarcity of data related to everyday activities. Due to such contributing factors, it is believed that everyday activities are underutilized in the design phase for evaluating new implant geometries, materials, and configurations. This is supported with the perception that only a failure to pass a minimum criteria associated with a physiological loading condition traditionally results in a design change, and not fully incorporated as a component to a robust design process that seeks to maximize the life cycle of an implant subject to the same loading profile.

The purpose of this paper is to present a methodology for incorporating musculoskeletal simulation as a tool for providing physiologically representative boundary conditions in the design of new implants. The thickness of a distal femoral fracture fixation plate is varied and evaluated under the physiological loading condition of a pedaling (cycling) exertion.

MATERIALS AND METHODS

Data were recorded from an experienced cyclist on a raised bicycle fixture (Figure 1). A bicycle fit specialist adjusted the bike to match the anthropometry of the female rider. Reflective markers were placed on the outside of the thigh, knee, and ankle and used as reference locations for tracking the motion. The participant was asked to cycle at a comfortable speed and the average observed cadence of 62 rpm was used as input in the musculoskeletal model.

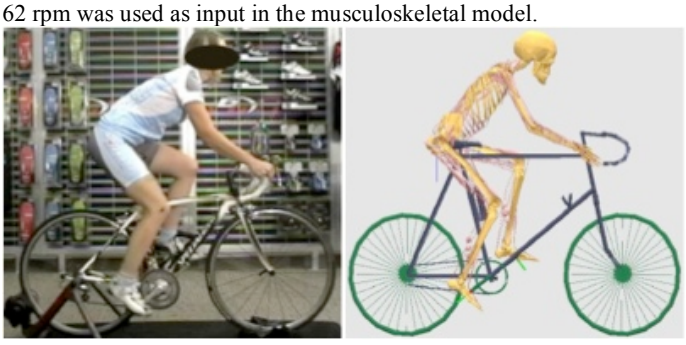

Figure 1. Participant in cycling fixture and corresponding scaled musculoskeletal model (the bicycle frame is un-scaled and used only for visualization purposes).

The AnyBody Modeling System (Aalborg, Denmark) was used to simulate the musculoskeletal loading of the cyclist. The outputs of the inverse dynamics musculoskeletal simulation were used as inputs to a finite element model of a fracture fixation implant (attached to the distal lateral portion of a simulated fractured femur). 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. Three fixed plate

implants of unique thicknesses (3.25 mm , 4.00 mm, and 4.75 mm) were created in ANSYS to be representative of a distal lateral femoral locking plate commercially available for femoral fracture fixation (Figure 2). The finite element model of the femur and the 4.75 mm thick fixation device consisted of 45,439 elements with 166,994 nodes. The implant was modeled as titanium alloy (Ti-6Al-4V).

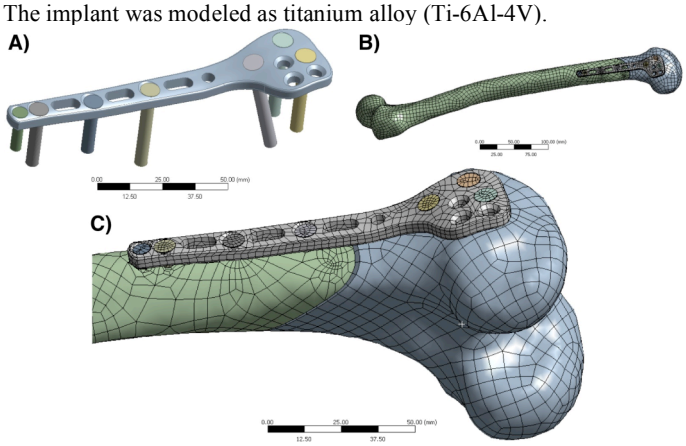

Figure 2. A) Fixed plate implant (4.75 mm thick) with screws, B-C) Femur bone and attached implant mesh.

RESULTS

The three implant designs were evaluated using the following failure conditions: 1) deformation resulting in contact between separate bone segments, 2) stresses in the plate beyond the material (Ti-6Al-4V) yield strength, and 3) a minimum fatigue life below 5 million cycles. The failure conditions were analyzed over the full cycling cadence and the results from a characteristic time step (97% of the cadence with a right knee flexion of 112°) are presented. None of the plate configurations, subject to the pedaling loading, violated the deformation failure criteria. As expected, none of the von-Mises stresses (Figure 3) in any of the tested implant designs exceeded the yield point of the material (930 MPa). However, only the 4.75mm thick implant plate achieved the desired fatigue life of 5 million cycles, with a predicted fatigue life of 14.7 million cycles. The 4.00mm and 3.25mm thick plate designs failed at 335,000 and 178,000 cycles, respectively.

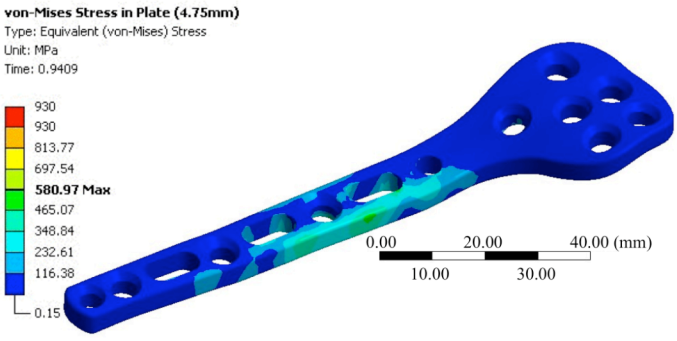

Figure 3. Von-Mises stresses for the 4.75 mm thick implant at 97% of the cadence (t = 0.9704).

DISCUSSION

The analysis depicted here focused on one implant variable (plate thickness) and a single physiological loading condition (cycling). A conventional approach, with respect to the integration of activities of daily living, was depicted (i.e. 3 plate thicknesses for a single activity were evaluated) to illustrate how current musculoskeletal simulation technology can be integrated with device evaluation. However, the primary impact of the technology and processes illustrated here lies in the capability of extracting boundary loading conditions and applying those to finite element model analyses through computer simulation, which can subsequently be automated. Such a unified methodology suggests there exists the potential for incorporating multiple tests and activities of daily living in the design process to optimize a particular implant subject to selected criteria, in contrast to testing and accepting a design simply to meet minimum requirements.

One potential limitation of the methodology presented is in the validity of the musculoskeletal simulation results in providing accurate loading conditions derived for an everyday activity (defined as pedaling here). Simulation of the musculoskeletal system is an emerging field and a comprehensive validation for any musculoskeletal simulation package has yet to be accomplished. Comparisons between simulation results of select movements (i.e. walking, wheel chair propulsion) and collected data have been performed with the AnyBody modeling system resulting in validation for the muscle recruitment algorithm for those specific tasks. Additional research, development, and validation of such simulation software associated with musculoskeletal modeling in general is necessary for the procedure described here to be applied to novel activities of daily living not well previously studied.

The use of activities of daily living (modeled with musculoskeletal simulation) as input criteria for implant design has not been widely utilized. The process described here is a generalizable approach for evaluating and understanding how the forces from everyday, recreational, and/or exercise activities are balanced by an implant. Although, a fixed plate implant is evaluated here, the methodology is equally translatable to joint replacement design (i.e. total hip replacement, TKR, etc.). With the capacity to depict and assess physiological loading conditions during pre-clinical developments through in-silico testing, there exists the potential that the design of implantable devices can be optimized for select performance criteria. Such analysis could be used to determine the effects of critical design factors including the effect of screw selection on the structural integrity of the plate (and bone), the fatigue life cycle during realistic operating conditions, and the locations of high stress concentrations. Examples of this type of integrated procedure will yield more robust medical implants (improving longevity), better tested devices prior to clinical trials (reducing potential patient risk), and potentially designs optimized for particular populations and/or exercise activities.

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