BIOEN 520 | ME 527: Musculoskeletal Biomechanics

Winter 2016

Final Project Assignment

All students are required to complete a written final project (research proposal) which will be due at the time of the scheduled final exam date (Tuesday, March 15, 2014). This assignment is being given in lieu of a final examination and is designed to challenge the student to apply the concepts and tools discussed in class towards addressing a real-world musculoskeletal problem. Students are expected to work independently and submit individual reports.

For the final project, each student may choose between two possible topics: 1) A new bioresorbable interference screw for ACL reconstruction, and 2) the effect of diabetes mellitus on the structural properties of the plantar soft tissue. These topics are described below. The objective is to develop a research proposal addressing one of these topics using the proposal format outlined on page three of the assignment.

Topic 1

Description:

A start-up medical device company that is working to develop a new screw for ACL (anterior cruciate ligament) reconstruction has just hired you to lead a research team to establish the feasibility and efficacy of this new product. You and your team have been tasked with testing and evaluating a prototype interference screw that can be 3D printed using a novel bioresorbable material. The screw is designed to mechanically hold a tendon graft in place during the initial weeks following the reconstructive surgery, and will then slowly begin to dissolve once the graft has incorporated. The advantages of using a resorbable material for the screw (over existing metal screws) is that the screw is radiolucent (allowing better visualization of graft incorporation on x-ray), and that the screw will eventually "melt away" reducing the need for removal in the event of infection or migration. Previous studies on resorbable screws have shown promising results (Myers, 2008; Shen, 2010).

As the only engineer with biomechanics experience on the product development team, your responsibility is to develop a biomechanical research study including the experimental test protocols and performance metrics to evaluate the prototype screw. Although the development team is enamored by being able to 3D print implants using their "cool" new bioresorbable material, you are concerned that the screw must also serve it's mechanical role which is to ensure the graft is held firmly in place while it heals (which takes many weeks) while allowing patients to rehab immediately after surgery to retain joint mobility and minimize other post-surgical complications.

References:

1. Myers P, Logan M, Stokes A, Boyd K, Watts M (2008). "Bioabsorbable Versus Titanium Interference Screws With Hamstring Autograft in Anterior Cruciate Ligament Reconstruction: A Prospective Randomized Trial With 2-Year Follow-up." Arthropscopy 24(7): 817-823.
2. Shen C, Jiang SD, Jiang LS, Dai LY, (2010). "Bioabsorbable Versus Metallic Interference Screw Fixation in Anterior Cruciate Ligament Reconstruction: A Meta-Analysis of Randomized Controlled Trials." Arthropscopy 26(5): 705-713.

Topic 2

Description:

Diabetes, and the subsequent complication of lower limb ulcers leading to potential amputation, remains an important health care problem in United States, even with declining amputation rates among veterans (Tseng et al., 2011) and the general population (Belatti and Phisitkul, 2013; Li et al., 2012). To develop more effective prevention and treatment strategies, it is highly desirable to better understand the complex and multi-factorial pathomechanics of ulcer formation, which has aspects related to autonomic and peripheral neuropathy, poor circulation and aberrant mechanical tissue loading (Sumpio, 2000). Many groups have studied the mechanical properties of diabetic plantar soft tissue, often with ultrasound devices on living subjects; it has been well documented that these properties can be affected by diabetes, although this finding is not universal. Using cadaveric testing, Dr. Ledoux's group's work has demonstrated that diabetes increases plantar soft tissue modulus (i.e., a material property) (Pai and Ledoux, 2010). However, the effect of diabetes on the structural properties is less understood. Hence, this topic centers on the development of a research proposal that would biomechanically investigate the effect of diabetes mellitus on the structural properties of the plantar soft tissue.

References:

1. Belatti DA, Phisitkul P (2013). "Declines in Lower Extremity Amputation in the US Medicare Population, 2000-2010." Foot Ankle Int 34(7): 923-31.

2. Li Y, Burrows NR, Gregg EW, Albright A, Geiss LS (2012). "Declining rates of hospitalization for nontraumatic lower-extremity amputation in the diabetic population aged 40 years or older: U.S., 1988-2008." Diabetes Care 35(2): 273-277.

3. Pai S, Ledoux WR (2010). "The compressive mechanical properties of diabetic and non-diabetic plantar soft tissue." J Biomech 43(9): 1754-1760.

4. Sumpio BE (2000). "Foot ulcers." N Engl J Med 343(11): 787-793.

5. Tseng CL, Rajan M, Miller DR, Lafrance JP, Pogach L (2011). "Trends in initial lower extremity amputation rates among Veterans Health Administration health care System users from 2000 to 2004." Diabetes Care 34(5): 1157-1163.

Final Project Proposal Format:

The final project proposal is limited to 3500 words (not including references) and should be 1-1/2 or double-spaced (line spacing); use 11- or 12-point font; have 1" margins; and should be organized to include the following sections (subsections may also be used).

TITLE PAGE (...not in page limit)

ABSTRACT (max 150 words)

INTRODUCTION

Briefly describe the problem or question and why it is important (i.e., relevance and significance). Clearly identify the research question(s) and/or hypothesis(es) that you'll be answering/testing, and discuss the anatomical, biological and clinical framework of your topic.

BACKGROUND

Provide a complete but succinct literature review of previous research on this topic. Do not simply regurgitate results from papers, but rather, synthesize their findings and present them such that the current "state-of-the-art" is easily appreciated. (Include pertinent references.)

RESEARCH PLAN

Begin this section by summarizing what you believe are the shortcomings in our current knowledge of this topic. Then, develop a research plan (including study design) that will address the project objectives. Include a pilot study that would provide some preliminary data in support of your hypothesis(es) and for a power analyses. Next, expand your proposal to include a detailed methodological approach for asking and answering the research questions. Include your selection of suitable tools, instrumentation, research model(s), and techniques (loading/sampling rates, test environment, etc.) that you would propose to perform the study, and reference any previous studies that have used specialized techniques you may wish to adopt. Also describe how you would analyze your data, what metrics you would evaluate, and any statistical methods you would employ.

DISCUSSION

Provide a rationale for choosing the research approach, methods, and metrics utilized in your proposal and discuss how you would interpret and compare your results with previous studies. Also discuss potential problems that might be encountered with your selected methods along with possible "work-arounds." Conclude with the likely outcomes from your proposed work and the potential significance and relevance of your findings.

REFERENCES

References and reference citations should conform to the style of the Journal of Biomechanics *(http://www.jbiomech.com/content/authorinfo)*.