Gait Modifications and Cutaneous Stimulation

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Study Protocol and Statistical Analysis Plan

Purpose. The purpose of this study is to quantify differences in joint mechanics between different types of walking in healthy individuals and individuals with knee pathology. We will determine how modifying gait through feedback and/or cutaneous stimulation changes joint loading. Such modifications may be simple, low cost solutions to treat knee pathology.

Scientific Rationale. Neuromuscular dysfunction such as decreased quadriceps muscle strength and voluntary activation has been demonstrated in patients with osteoarthritis and with other joint pathologies including ligament injuries and meniscectomy (Childs et al. 2004, Lewek et al. 2004). Physical therapy, braces, elastic wraps, and taping have been commonly used to treat many types of these musculoskeletal conditions. For example, rehabilitative programs including quadriceps strengthening have been shown to reduce pain and disability in subjects with knee osteoarthritis. Quadriceps strengthening, however, may require complex clinic-based regimens or machinery not readily available to patients, and can have poor adherence rates. Further, despite aggressive rehabilitation programs directed at improving quadriceps function following ACL injury and reconstruction, a condition leading to accelerated joint degeneration, a universally accepted effective treatment approach to reverse this muscle weakness has yet to be identified. The quadriceps weakness following ACL injury has been shown to be related to the potential for re-injury and development of knee OA (Becker et al. 2004, Bodor 2001, Lewek et al. 2002). Thus, while available interventions have achieved some clinical success, it is often the case that the results are not sustained due to limitations associated with compliance in using the therapy or continuing to the wear a particular intervention.

Knee injuries and disease cause substantial pain and disability, and their high prevalence necessitate simple interventions. Clinical guidelines for management of knee OA and associated joint injuries emphasize the importance of non-pharmacological conservative strategies. Gait modification through cutaneous stimulation offers a low cost alternative to rehabilitation programs and current treatments to address deficient muscle activation in knee OA and conditions related to development of the disease.

This study will address the gap in current research, and will evaluate gait modifications that include cutaneous stimulation (e.g. vibratory, tactile), in both healthy individuals and patients with knee pathology.

Focus. This study aims to examine the differences in joint mechanics between different types of walking in healthy individuals and individuals with knee pathology. We will determine how modifying gait through feedback and/or cutaneous stimulation changes joint loading.

Anticipated Impact. Knee injuries and disease cause substantial pain and disability, and their high prevalence necessitate simple interventions. Clinical guidelines for management of knee OA and associated joint injuries emphasize the importance of non-pharmacological conservative strategies. Gait modification through cutaneous stimulation may offer a low cost alternative to rehabilitation programs and current treatments to address deficient muscle activation in knee OA and conditions related to development of the disease. This study will address the gap in current research and will evaluate gait modifications which may help decrease disability from knee joint pathologies.

Methods. We plan to recruit up to 90 individuals at Stanford and the VA Palo Alto. The participants will be individuals with knee pain or pathology and healthy volunteers with no known knee pain or pathology. Participants to be recruited will be 18 years or older. Both males and females will be recruited. Individuals below the age of 18 years old are excluded as they may not have yet reached skeletal maturity.

Departmental clinicians will identify potential subjects with joint pathology meeting the inclusion and exclusion criteria. Departmental clinicians will notify potential subjects about the study and ask permission to have a clinical coordinator contact him/her with more information. If permission is granted, study staff will follow-up in person at the clinic or by phone to arrange for informed consent. Asymptomatic subjects will be recruited by responding to flyers advertising the study. Subjects with joint pathology may also be recruited by responding to flyers advertising the study or by referral from their clinician.

Following informed consent, information about the subject's health history will be collected. The information to be collected includes: age, gender, weight, height, medical and joint-health history. Pregnant subjects will be excluded from the study.

On the testing day, each subject may be asked to walk at a variety of speeds. Subjects will also be asked to walk while receiving external feedback/stimulation. Outdoor testing may occur in a selected outdoor location that is also safe and unobstructed. Feedback and stimulation (for example: audio, video, tactile, vibratory) may be provided to improve gait modification and

muscle activation abilities. Subjects may be asked to respond to feedback/stimulation, but not required to respond. There is little to no risk to the subjects beyond the normal risks associated with walking.

Kinematic and kinetic gait measurements: A motion capture system consisting of infrared cameras and small reflective balls (markers) attached to the subjects using small double sided stickers and force platforms embedded in the floor will be used estimate subjects kinematics and kinetics during gait following the point cluster method protocol and standard inverse kinetics calculations. Pressure sensors may also be used to provide a 2 dimensional map of the pressure distribution in the stance phase of gait. EMG may be used to provide information on muscle activation. Additionally, inertial sensors may be placed on the bodies of the subjects to measure their kinematics. The markers and sensors will be placed on the bodies so that they do not impede the subject's movements in any way. Moreover, these elements do not impart excessive force. Ideally, the subject will forget that they are wearing the system.

Subjects may also be asked to complete questionnaires regarding pain, function, and physical activity. Subjects may be asked to return for a repeated testing session.

Statistical Analysis Plan. Normality of data will be checked using Shapiro-Wilks tests. Within-test differences in joint loading parameter (peak knee flexion moment) between experimental conditions and walking speeds will be analyzed using paired Student’s t-tests or non-parametric alternative if non-normally distributed.