COVER PAGE for Study Protocol

Title: Using Pressure Detecting Insoles to Reduce Knee Loading

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Study Protocol

This is a randomized, placebo controlled, longitudinal pilot study.

After a telephone prescreening, an in-person visit will be performed to screen for inclusion and exclusion criteria, including a clinical and radiographic assessment, and to identify the index knee (defined as the more painful knee in the case of bilateral knee OA). A total of 40 subjects with symptomatic and radiographic medial knee OA will be enrolled in the study and obtain a standardized flexible shoe ('Mobility shoe', Dr. Comfort Flex-OA). A standing radiograph of the knees will be taken at a screening visit to assess for the existence of knee OA. The 40 subjects will be randomized into two unequal groups: group A will consist of 25 subjects who will train in the mobility shoe with active pressure-based feedback from a pressure-detecting shoe insole (OpenGo, Moticon GmbH, Munich, Germany), and group B will consist of 15 subjects who will train in the same mobility shoe with a deactivated insole.

A total of three study visits will occur at the following time points: baseline, 3 weeks, and 6 weeks. At all three visits, the following outcome variables will be acquired: (1) joint loads using 3D motion analysis of in subjects' gait both in their own shoes and the mobility shoe with inactive insole, and (2) knee symptoms, stiffness, pain, daily function, recreational function, and quality of life using the Knee Injury and Osteoarthritis Outcome Score (KOOS). At the 3 and 6 week visits only, additional data from the insole will provide medial-lateral pressure distribution, total time walking and total steps during walking in the and time spent using shoe and insole.

After enrollment, all subjects will return for the baseline visit within three months. At baseline, subjects in both groups will receive their personal mobility shoe, complete the KOOS, and undergo a baseline motion analysis. Subjects in group A will receive the active OpenGo insoles, in addition to a study-issued Android-based (Android 4.3) smartphone (xperia Z1, Sony, Tokyo) containing a preloaded application (MoticonApp, Moticon Gmbh, Munich, Germany) and without a Subscriber Identity Module (SIM) card (and, therefore, no data or cell phone use), which will provide pressure-based feedback for their index limb, and record the time, steps, and center of pressure (COP) during walking. During this visit, they will receive training by a licensed physical therapist on the use and maintenance of the insole, and they will be given a supply of replacement coin-cell batteries (although it is unlikely that batteries have to be replaced during the 3-week testing interval). The subjects in group A will be asked to train in the combined shoe/insole device for 3x5 min per day, at least 6 days a week for 3 weeks. Subjects in group B will receive the inactive OpenGo insole, which will not provide feedback but will be set in record mode. All subjects will be encouraged to wear the study shoes as their primary form of footwear and for a minimum of 6 hours/day, 6 days/week. They will be given a diary to record the daily time spent wearing the shoe/insole, daily analgesic history, and adverse events. These diaries will be reviewed at the 3 and 6 week study visits. At the 3 week visit, 3D motion analysis will be assessed and the KOOS will be repeated. During this visit, the feedback component in group A's insole will be deactivated but will continue to be recording-capable. From the second visit at week 3 until the third visit at week 6, both groups will

continue to walk with mobility shoe with a recording but otherwise inactive insole. These final 3 weeks will assess for the integration of a new movement pattern in group A. After completing the final KOOS and 3D motion analysis during the third visit, subjects will have completed the study.