Effects of Reparel™ Knee Sleeve on Knee Osteoarthritis

Study Protocol & Statistical Analysis Plan

NCT04743921

April 4th, 2022

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Objectives:

Osteoarthritis (OA) is one of the most prevalent musculoskeletal ailments worldwide. Numerous conservative therapies exist, but evidence for such treatments remains conflicting. Recently, there has been growing interest surrounding bioactive sleeves for managing knee arthritis. However, the literature on their efficacy for relieving pain and improving function in the setting of knee OA is limited. Therefore, we sought to investigate the effect of a bioactive sleeve on patient reported outcome measures (PROMs) in a small cohort of OA patients.

Methods:

Patient Recruitment and Inclusion

Following institutional review board approval and registration with ClinicalTrials.gov, the authors will prospectively follow a series of patients at an outpatient orthopaedic sports medicine clinic between February and July 2021. Patients who opt for non-operative management of knee OA will be informed and consented for the study. Patients will be included if they have radiographic evidence of knee OA, no previous surgery on the symptomatic knee, no corticosteroid knee injection within 3 months of the study, and agree to abstain from a knee injection during the 3 month study period. Patients will be excluded if diagnosed with bilateral symptomatic knee OA, had previously undergone knee surgery, were grossly unstable on physical examination, or had a history of knee malignancy. Patients will be instructed to wear the sleeve (Reparel, Chico, CA) as long as tolerated throughout the day and to refrain from modifying usual activities and diet.

Patient Assessment

Participants will be asked to complete the following patient reported outcome measures (PROM): the University of California, Los Angeles Activity Score(UCLA),[11] which measures current activity level; the Lysholm Score(LKS),[12] which measures joint stability and function; the Oxford Knee Score (OKS),[13] which measures knee related health status; the Knee Injury and Osteoarthritis Outcome Score (KOOS),[14] which assesses difficulties with physical activity; the Single Assessment Numeric Evaluation (SANE),[15] which assesses perceived functional level; and the Visual Analog Scale (VAS),[16] which assesses perceived pain level. These surveys will be administered at the initial visit and subsequently over the phone at 2 weeks, 6 weeks, and 3 months later. Patients will also be asked about average daily sleeve usage, product satisfaction, and complaints/issues.

Osteoarthritis Severity Assessment

OA severity will be defined by clinical radiographic imaging using the Kellgren-Lawrence (KL) classification system at the baseline clinical visit.[17] The radiographs will be read and graded by a sports medicine fellowship trained orthopedic surgeon.

Statistical Analysis

Statistical analysis will be performed using SPSS (IBM SPSS Statistics for Macintosh, Version 27.0. Armonk, NY: IBM Corp). Mann-Whitney test will be used to compare baseline demographics between male and female patients. Wilcoxon Signed-Rank test will be used to compare baseline PROMs and hours of sleeve use with those at 2 week, 6 week, and 3 month time points. Kruskal Wallis test will be performed to evaluate differences in PROs between the four time points. When analyzing PROs between

time points within groups with differing population counts, only patient scores that are available between groups will be analyzed. Significance will be set to an alpha of 0.05.