

The effect of 3.5 % menthol gel on knee pain and functioning among patients with knee osteoarthritis.

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Purpose: The purpose of this clinical trial is to compare the knee pain, and functioning of knee osteoarthritis patients under two different treatment conditions consisting of 3.5 % menthol gel and an inert placebo ointment.

Background: Osteoarthritis (OA) is one of the most common chronic health problems, affecting over 27 million Americans (Helmick et al., 2008), with Murphy et al., (Murphy et al., 2008) estimating that approximately half of adults will develop symptomatic knee OA by age 85. Characteristics of knee OA include a reduced ability to complete functional tasks, decreases in knee strength, decreased knee range of motion (ROM) and joint pain. (Creamer, 2004) Knee OA pain is commonly managed pharmacologically with NSAIDs, analgesics and narcotics in an attempt to preserve knee ROM, strength and ability to complete functional tasks. Protracted oral pharmacological management of knee OA is associated with significant side effects resulting in gastrointestinal, renal, and neurological dysfunction.

Topical applications containing menthol have long been applied to OA-affected knees to relieve pain and improve functioning. Limited empirical support indicates that the mechanism of action of menthol gel may be as a counter-irritant or an anti-inflammatory agent by inhibiting blood flow to the targeted region. To date no study has attempted to establish the treatment efficacy of a 3.5 % menthol gel on reducing pain and improving functioning among among knee OApaitents.

Methodology: A convenience sample of 20 individuals previously diagnosed with unilateral osteoarthritis of the knee were recruited from email solicitations to faculty and staff at a small university. Inclusion criteria will be age 40 years or older, ≥ 2 OA of the knee (Kellgren-Lawrence scale), consuming daily scheduled dosages of NSAIDs and able to

complete a simple battery of functional tasks. Exclusion criteria comprise exercise testing exclusion criteria outlined by the ACSM (2010), inability to travel to the testing site and/or the inability to read and write English at an eighth grade level. If subjects do not appear to meet any of the exclusion criteria during a telephone screening they were scheduled for two separate visits to the Bellarmine University Physical Therapy clinic, with each of these visits separated by approximately one week. hours. During the initial visit subjects provided informed consent prior to any data collection. Participants underwent the same data collection protocol at each visits which included performance of five functional tasks and an a self-report of knee pain while performing each task. The functional tasks included a 6-minute walk (6MW), the timed get up and go (TUG), 30-second timed chair stand (TCS) and the time required to ascend (StairUp) and descend (StairDown) a flight of ### stairs. Subjects reported their level of knee pain immediately following performance of each of the functional tasks using a 100mm visual analog scale anchored with 0 = "No Pain" and 100 = "Worst Pain Possible." These assessments of pain, and functioning were assessed twice at each subject visit; upon arrival at the facility without any intervention and again during the same visit after random application of 3ml of 3.5 % menthol ointment (BioFreeze) or 3ml of an inert water-soluable gel (KY-jelly).

Results: Univariate repeated measures (paired t-tests) compared the subjects functioning and pain to determine changes under the treatment conditions ($\alpha < .05$). These analyses indicate that following application of the menthol gel the subject performed significantly better in the 6MW and the TCS. While under the placebo condition the sample improved only on the TCS at a rate of approximately 2/3 of the improvement under the menthol condition. The analysis also indicated the menthol intervention resulted in significant reductions in pain during the TCS, StairUp and StairDown tasks. The placebo condition resulted in a significant decline in StairUp pain at a rate of 2/3 of that realized under the menthol condition.

Conclusion: These preliminary findings appear to support the efficacy of a 3.5% menthol gel to improve functioning and reduce pain among knee OA patients