#2045 - Experimental Study / Free Papers

3D Spatiotemporal Parameters Of Gait In Individuals With Osteoarthritis Of The Knee Submitted To Treatment With Intra-Articular Viscosupplementation: A Prospective Double-Blinded Randomized Controlled Trial.

General Topics / Biomechanics

Leonardo Metsavaht[1], Gustavo Leporace[1], Bernardo Crespo[1], Raphael Serra Cruz[1], Gabriel Zeitoune [1], Marcelo Motta[2], Felipe Gonzalez[2], Marcelo Kubota[3], Marcus Luzo[3]

1. Instituto Brasil de Tecnologias da Saude, Rio De Janeiro, Brazil
2. Hospital da Força Aérea do Galeão, Rio De Janeiro, Brazil
3. DOT - EPM - Universidade Federal de São Paulo, São Paulo, Brazil

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Background
The results obtained from systematic reviews and meta-analysis remain controversial about the effects of substances used for viscosupplementation of the osteoarthritic knee (KOA). The subjective methods frequently used for measurement of outcomes with small sample sizes may be important factors regarding reliability of analysis.

Objectives
To run a prospective double-blind randomized controlled trial to compare one single-dose knee joint infiltration of a viscosupplementation substance with a sham group through 3D spatiotemporal gait parameters of individuals with KOA prior to treatment, as well as after 1, 6 and 12 weeks (W1, W6, W12) after the infiltration.

Study Design & Methods
44 individuals with symptomatic KOA were randomly allocated into two groups of 22, immediately before the procedure, either to receive an ultrasound guided intra-articular infiltration of 4 ml of an active compound (AG) composed of hyaluronic acid 80 mg and sorbitol 160 mg (Synolis VA®, Aptíssen, Switzerland) or an ultrasound guided sham (SG) intra-articular infiltration of 4 ml of saline solution. Inclusion criteria were patients in the institution waiting list for a Total Knee Arthroplasty (TKA), Kellgren-Lawrence (KL) classified as III or IV, age of 60 or older, any gender, BMI and race. Non-inclusion of patients with KOA related to trauma, infection, neurologic impairments or unable to stand and walk 10 m without assistance. Kinematic data of gait were collected by a 3D motion analysis system (VICON, Oxford Metrics, UK), with mathematical models already used in previous studies at baseline (BL) one week before and 12 weeks after the initial intervention. Recruitment and KL classification were performed by 2 orthopedic surgeons (OS). The patients, the attending crew for collection, processing and interpretation of data were blinded. The intervention OS, or their crew, did not have any contact with patients before study was complete. Two blinded OS were 24 h accessible for patients in case of any intercurrence. All randomized patients were included in the study by the intention-to-treat principle and missing data was inputed in the statistical analysis as the "last observation carried forward". Data before and after intervention was compared using a two-way mixed-effect model Anova, with a significance level of 0,05. The post-hoc test (Turkey) was used to identify the differences between the two groups. Dependent variables were gait velocity, step cadence,

initial double leg stance time (%), single leg stance time (%), terminal double leg stance time (%), step length and stride length. The Anova factors were TIME (before vs after intervention) and GROUP (AG vs SG).

Results
Both groups similarly decreased initial double leg stance time ($p < 0.01$), and increased single leg stance time ($p < 0.01$), step length ($p < 0.01$) and stride length ($p < 0.05$) after 12 weeks of the injection. There were no differences in gait velocity, cadence and terminal double leg stance time.

Conclusions
The viscossuplementation group (AG) and the sham group (SG) showed similar improvement in spatiotemporal gait parameters after intervention, probably indicating a placebo effect on both groups or spatiotemporal parameters may not be a sensitive tool for such analysis.