Changes in Gait and Function for Patients Receiving Synvisc® Injections for Osteoarthritis of the Knee.

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Introduction

Osteoarthritis (OA) of the knee is one of the major causes of pain and physical disability in older adults. Acetaminophen and Non-Steroidal Anti-Inflammatories (NSAIDs) are generally used as first-line treatment, but there are adverse reactions of these medications and they do not slow disease progression. Viscosupplementation using an intra-articular hyaluronic acid (Hylan G-F 20; Synvisc®) has been shown to be safe and effective in treating OA of the knee, resulting in significant pain relief and minimal adverse reactions.

Statement of Clinical Significance

Osteoarthritis of the knee is an active disease process involving destruction of cartilage, subchondral bone thickening, and new bone formation.[9] Prevalence of primary OA increases nonlinearly with age after 50 years, and it is estimated that 25%-30% of persons aged 45-64 years and 85% of individuals older than 65 years of age have radiographically detectable arthritis.[3] Osteoarthritis of the knee is one of the major causes of pain and physical disability in older adults.[4]

Objective

The objective of this study is to document changes in gait and function after Synvisc® injections for patients with osteoarthritis of the knee using the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), SF-36, and temporal-spatial gait parameters.

Methodology

The study utilized a one group repeated measures design. Subjects for this study were recruited from the Rothman Institute and Jefferson Family Medicine practice at Thomas Jefferson University. Subjects were included based on patient history, physical examination, and radiographic findings consistent with unilateral or bilateral osteoarthritis. Exclusion criteria included inability to walk 10 meters without an assistive device, presence of a lower extremity prosthesis, or if Synvisc® was contraindicated. Subjects received a series of three Synvisc® injections over a three-week period.

Temporal and spatial gait parameters were evaluated using the GAITRite® system. This system employs an electronic walkway, with dimensions of 460 x 90 x 0.6 cm (L x W x H). The mat contains six sensor arrays that are encapsulated in a roll-up portable carpet. The active measurement area is 61cm wide and 366 cm long. The sensors are arrange in a 48 x 288 grid pattern and are placed 1.27 cm on center. The system records the location of activated sensors and time of activation/deactivation.[5] The raw data are transferred to a Windows® based personal computer and processed to identify footfall patterns and to calculate temporal-spatial parameters. The GAITRite® system has been shown to be a valid and reliable tool for measuring selected gait components: spatial parameters (step and stride lengths), temporal parameters (step time), and derived measures of rate in a healthy subject walking at different speeds and various degrees of step symmetry.[8]

Function was evaluated using the SF-36 assessment of Health Related Quality of Life, and the WOMAC, a commonly used OA-specific health status measure. The WOMAC is a self-

administered questionnaire designed specifically to evaluate patients with OA of the hip or knee. It contains 24 questions that assess pain, stiffness, and physical function using a five-point Likert scale.[2] The WOMAC has been shown to be a reliable, valid, and responsive outcome measure designed specifically to evaluate patients with OA of the hip or knee.[1] The SF-36 is a patient completed survey including 36 multiple choice questions that assess eight categories: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health.[10] The SF-36 has also been shown to be a reliable and valid outcome measure in clinical trials to assess general health status of individuals with arthritis.[6,7]

Gait parameters were measured prior to the 1st, 2nd, and 3rd injections, and at the Week 8 follow up. Prior to the 1st and 3rd injections and at the Week 8 follow up, subjects completed the WOMAC and SF-36 questionnaires.

Results

This study is ongoing. At the time of submission, complete data sets had been collected for 9 subjects. Differences were found for both the stiffness and function categories of the WOMAC between Weeks 1 and 3 ($p = .003$, $p = .014$ respectively). There were, however, no differences in WOMAC pain scores, the SF-36 Physical Composite Score, the SF-36 Mental Composite Score, or gait parameters. Further analysis of the data, with 5 additional subjects that have only completed the injection series, showed differences in WOMAC pain scores between Weeks 1 and 3 ($p = .014$).

Discussion

We project a completed enrollment of 30 subjects in the following six months. With this preliminary analysis, we have seen a decrease in knee stiffness and improved physical function between Weeks 1 and 3, with no carryover to Week 8. If this result is confirmed by the completed study, it may indicate that follow-up Synvisc® series must be administered more frequently than is now common. Currently, patients are advised to repeat the Synvisc® series every six months; however, our study indicates that improvements in pain and function are lost after two months. We also noted an increase in knee stiffness between Weeks 3 and 8. This may be due to increased activity in the subjects, due to decreased pain. Further study in this area is warranted.

References

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