Clinical and gait outcomes of novel pneumatic knee brace with extension assist

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Introduction

Osteoarthritis of the knee is a debilitating disease that results in decreased function and marked pain in an estimated 3.8% of the population in the United States, and costs over $5,000 per person annually for pain management. Currently, it is estimated that there are over 10 million people affected by this disease in the United States. Several studies have described the efficacy of knee brace for pain relief in knee osteoarthritis, however, the 2013 American Academy of Orthopaedic Surgeon evidence base guidelines for the treatment of knee osteoarthritis reported that there is currently limited level 1 evidence supports or refutes the use of unloader bracing in uni-compartmental knee OA. Due to this limited number of level 1 trial evaluating the clinical efficacy and impact of these braces for the treatment of knee osteoarthritis in the United States. Therefore, we evaluated this novel brace in an attempt to elucidate its effects on patients who have late stage knee osteoarthritis (Kellgren Lawrence grade 3 and 4) and tested all patients without the brace at a minimum of 3 months of usage. Specifically, we assessed: (1) changes in isokinetic muscle strength; (2) objective functional improvements; (3) subjective functional improvements; (4) quality of life measures; (5) patients pain perceptions; and (6) conversion to total knee arthroplasty and several gait parameters using a 3 dimensional gait laboratory.

Methods

This was a prospective, randomized, single center, single blinded, and IRB approved study of patients who had Kellgren-Lawrence grades 3 to 4 osteoarthritis, comparing pneumatic brace to standard non-operative therapy. Patient inclusion criteria were as follows: were between the ages of 18 and 80 years of age, uni-compartmental osteoarthritis in medial or lateral compartment, able to comply with study requirements, and no history of corticosteroid injection in the last 3 months. We prospective, randomized 59 patients (29 study, 30 control) who had Kellgren-Lawrence grades 3 to 4 osteoarthritis to receive either the pneumatic brace or standard non-operative therapy.

Results

- Treatment with the brace resulted in significant (P= 0.0045) improvements in mean quadriceps muscle strength.
- In comparison, the matching control cohort had a significant loss of quadriceps muscle strength.
- Patients who used the unloader pneumatic brace demonstrated statistical improvements in functional parameter tested: they had improvements, timed up and go tests, timed stair climbs, repeated chair rise tests, and 2-minute walk tests, as well as greater improvements in new Knee Society objective scores, higher LEFS scores, and decreased pain on the visual analog scale when compared to the matching group (P= 0.05 to 0.006).
- In addition patients in brace group showed significant improvement in speed, knee extension at heel strike , impulse and rate of flexion at the knee after using the pneumatic bracer for 90 days (p= 0.043).

Conclusions

This treatment using novel pneumatic bracing can be incorporated into all non-operative treatment algorithms for knee osteoarthritis (Kellgren Lawrence Grade 1 though 4). Additionally, the patients in this study will be followed in a long-term longitudinal manner in order to determine if any functional improvements from this therapy may lead to a decrease in knee arthroplasty procedures performed.

Conclusion significant changes

- Gait retraining effects retained with out the brace
- Reduced VAS pain scores
- Quad and hams strengthening
- Improved foot position
- Reduced rate of TKA in brace group
- Improvement in objective functional tests
- Improvement in subjective scores