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 and as the population continues to live longer, coupled with the growing obesity epidemic, this number is expected to nearly double in the next decade. In light of the cost of managing these patients, and estimations that the incidence of Total Knee Arthroplasty (TKA) will increase from 488,000 to 3.75 million by the year 2030, this represents a tremendous potential economic burden on the healthcare system.

Several studies have described the efficacy of knee brace for pain relief in knee osteoarthritis, however, the evidence based guidelines for the treatment of knee osteoarthritis report that there is currently limited level 1 evidence supports or refutes the use of knee bracing including un-loader bracing in knee OA.

There are limited number of level 1 trial evaluating the clinical efficacy and impact of knee braces for the treatment of knee osteoarthritis with long term follow up. Therefore, we evaluated this novel brace in an attempt to elucidate its effects on patients who have late stage knee osteoarthritis (Kellegren Lawrence grade 3 and 4). In addition we followed these patients with minimum 1 year follow up to see how many less injections and pain medications were used by patients in the brace group as well as the rate of conversion to TKA surgery.

Specifically, we assessed: (1) changes in isokinetic muscle strength at 60 deg/sec (2) objective functional improvements; (3) subjective functional improvements; (4) quality of life measures; (5) patients pain perceptions; and (6) gait parameters using a 3 dimensional gait laboratory.

All of the functional and gait testing was performed without the brace pre and post to evaluate carryover effects of the brace

Clinical 1-2 year follow up: 1) Incidence of injections 2) Use of pain medications, 3) Conversion to Total Knee Arthroplasty

Brace Technology: Unique feature of the Novel brace include 1) Pneumatic bladders for unloading, custom fitting and anti-migration 2) Extension assist bands for promoting extension during terminal stance and eccentric loading in early stance 3) Lightweight design with easy snap on snap off removal 4) Swivel thigh cuff for ease of sitting and stair ascent and descent. 5) Dynamic conformability: allows for ease of functional movements.

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

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**Results obtained due to**

- Minimum 3 hrs use per day for 90 days
- 3000 to 4000 reps per day
- Improved knee extension
- Better quad recruitment
- Neural retraining
- Improved foot position
- Compliance monitoring daily log of use

**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

**Conclusions of clinical follow up for 1-2 years The Novel strengthening OA Rehabilitator™ Knee Brace use resulted in**

1) Less number of patients undergoing TKA surgery in brace group as compared to control group ( 18% vs. 36 %)
2) Time to TKA was longer in the Brace group
3) Incidence of joint injections in the brace group was significantly lower as compared to control group.