

# CLINICAL OVERVIEW

## STRENGTH AND FUNCTIONAL IMPROVEMENT USING PNEUMATIC BRACE WITH EXTENSION ASSIST FOR END-STAGE KNEE OSTEOARTHRITIS: A PROSPECTIVE, RANDOMIZED TRIAL

Full study appeared in *The Journal of Arthroplasty*. 2015: Vol 30, Issue 5, 747-753.  
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Pneumatic unloader bracing with active extension assists and neuromuscular retraining properties have been proposed as a non-operative modality that may delay the need for knee surgery by reducing pain, increasing muscle strength, and improving function. This prospective, randomized trial evaluated 52 patients who had late stage knee osteoarthritis for changes in: (1) muscle strength; (2) objective functional improvements; (3) subjective functional improvements; (4) pain; (5) quality of life; and (6) conversion to total knee arthroplasty (TKA) compared to standard of care treatment. Patient outcomes were evaluated at a minimum of 3 months. Braced patients demonstrated significant improvements in muscle strength, several functional tests, and patient reported outcomes when compared to the matched cohort. These results are encouraging and suggest that this device may represent a promising alternative to standard treatment methods for knee osteoarthritis.



### Subjects

- 59 patients who had Kellgren-Lawrence grades 3-4 knee osteoarthritis were prospectively and randomly enrolled.
- Final study (brace) cohort consisted of 26 patients with mean age of 59 years.
- Final matched (standard of care) cohort consisted of 26 patients with a mean age of 54 years.

### Materials and Methods

- Patients in both groups were instructed in a self-directed exercise program and were allowed to continue taking previously prescribed NSAIDs.
- Bracing patients were instructed to wear an OA Rehabilitator™ brace (Guardian Brace, Pinellas Park, Florida) for 6 weeks, for a minimum of three hours / day when ambulating, and were allowed to use while performing activity such as stairs, elliptical training, or riding a bike.
- Matched cohort patients were offered treatment of corticosteroid injections (12 patients accepted) and physical therapy (9 patients accepted) three times per week for 6 weeks.
- Objective functional improvements were measured using a timed up and go (TUG), timed stair-climb, two minute walk, repeated chair rise, single limb step, and isokinetic quadriceps and hamstrings muscle strength tests.
- Subjective functional improvements were measured using the lower extremity functional scale (LEFS) and the new Knee Society Functional and Objective Scores (KSS).
- Pain was evaluated using a visual analog scale (VAS).
- All testing was performed without the brace to examine the retained effects of the rehabilitating knee brace.

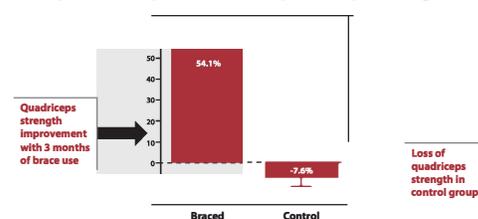
### Results

- Bracing patients showed a mean improvement of 54% in quadriceps and 27.7% in hamstrings strength; matching patients lost a mean of 8% quadriceps and 1.8% hamstrings strength.
- Bracing patients showed statistically significant improvement compared to matched patients for TUG, stair climbing and 2 minute walk tests.
- Mean LEFS scores improved 8.3 points in brace patients, and decreased 3.5 points in matched patients.
- Mean KSS objective scores improved 10.7 points in brace patients, and 5 points in matched patients.
- Mean VAS scores decreased 1.9 points in brace patients, and increased .1 point in matched patients.
- Two bracing patients versus 5 matched cohort patients elected to undergo TKA during the study period.

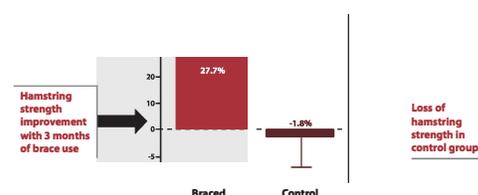
### Discussion

- Use of the OA Rehabilitator™ brace with dynamic extension assist resulted in significant improvements in quadriceps (54%) and hamstring (28%) strength, several functional tests, and patient reported outcomes when compared to a matched cohort.
- The OA Rehabilitator™ brace was easy to use, had good patient compliance, resulted in adjuvant pain relief, and led to functional improvements in patients with end-stage knee osteoarthritis.
- Authors believe OA Rehabilitator™ brace treatment can be incorporated into all non-operative treatment algorithms for knee osteoarthritis (Kellgren Lawrence Grade 1 through 4).

**Braced vs. control patients  
percent improvement in quadriceps strength**



**Braced vs. control patients  
percent improvement in hamstring strength**



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