

## CLINICAL OVERVIEW

### Gait Using Pneumatic Brace for End-Stage Knee Osteoarthritis

Full Study appeared in *The Journal of Knee Surgery*. 2016: Vol 29(3), pp 218 -223. Bhaveen H. Kapadia, MD, Jeffrey Jai Cherian, MD, Roland Starr, MS, Morad Chughtai, MD, Michael Mont, MD, Steven F. Harwin, MD, Anil Bhawe, PT.

The use of an unloader pneumatic brace with extension assist has been proven as a non-operative treatment modality that improves gait mechanics and corrects knee malalignment. We assessed the following parameters in patients who have knee OA treated with and without a brace: (1) changes in temporo-spatial parameters in gait; (2) knee range of motion, knee extension at heel strike and foot placement; (3) knee joint moments and impulse; and (4) changes in dynamic stiffness and rate of change of knee flexion during mid-stance to terminal stance. This 2:1 prospective, randomized, single-blinded trial evaluated 36 patients (24 brace and 12 matching). OA knee patients were randomized to receive either a pneumatic unloader brace or a standard non-operative treatment regimen. They underwent evaluation of gait parameters using a three-dimensional gait analysis system at their initial appointment and at 3 month follow-up. All the testing, pre- and post bracing were performed without wearing the brace to examine for retained biomechanical effects.



Patients in the braced group had improvements in walking speed, knee extension at heel strike, total range of motion, knee joint forces, and rate of knee flexion from mid-stance to terminal stance when compared with the matching cohort. Braced patients demonstrated gait-modifying affects when not wearing the brace. These results are encouraging and suggest that this device represents a promising treatment modality for knee OA that may improve gait, knee pain, and strength in knee OA patients.

#### Subjects

- 36 patients who had Kellgren-Lawrence grades 3-4 knee osteoarthritis were prospectively and randomly enrolled.
- Study (brace) cohort consisted of 24 patients with a mean age of 59 years old; 14 varus, 8 valgus, and 2 within 2° of normal.
- Matched cohort (standard of care plus 6 weeks of PT) consisted of 12 patients with a mean age of 54 years old; 8 varus, 2 valgus, and 1 within 2° of normal.

#### Materials and Methods

- Braced patients were instructed to wear an OA Rehabilitator™ brace (Guardian Brace) for a minimum of three hours a day when ambulating, and were allowed to use while performing activity such as stairs, elliptical training, or riding a bike.
- Matched cohort patients underwent 6 weeks of PT two or three times a week focused on isotonic and isometric strengthening, joint mobility, stretching, and mobility exercises as well as gait training.
- All patients had an initial gait study, which was repeated 3 months later. Brace cohort patients underwent both gait evaluations without the brace to evaluate if there was any affect on joint biomechanics once the brace was removed.
- Parameters analyzed included walking velocity, knee extension at heel strike, total knee arc of flexion, foot placement, and knee adduction moment and impulse.

#### Results

- The brace cohort has significant improvements in temperospatial parameters of gait including walking speed when compared to the matching cohort as well as improvements in knee extension at heel strike and total range of motion.
- Loading response knee flexion improved a mean of 9 degrees.
- Adduction impulse in bracing cohort who had varus knee alignment showed a reduction after brace use.

#### Discussion

- Brace use for up to 3 hours per day resulted in improved walking speed, knee extension, total arc of knee range of motion as well as reduction in abnormal compressive loading.
- Improved load distribution achieved with brace use can delay the progression of knee OA as well as the need for surgery. This will have significant economic impact on management of OA Knee.

	Brace	Control
Pre-speed	89.16 (51-128)	92.5 (57-123)
Post-speed	98.5 (54-157)	95.5 (58-107)
Significance	P= 0.0027	p = 0.47
<b>Knee extension at heel strike</b>		
Pre	11.1 (2.8-22)	7.4 (0.7-13.8)
Post	4.4 (-1.5 to 12.7)	7.7 (3.2-15.2)
Significance	p = 0.006	p = 0.78
<b>Total ROM</b>	<b>Brace</b>	<b>Control</b>
Pre-ROM	41 (9-56)	46 (37-52)
Post-ROM	44.9 (10-65)	47 (31-55)
Significance	p = 0.006	p = 0.9



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# 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.  
J Cherian, A Bhav, B Kapadia, R Starr, M McElroy, M Mont.

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.

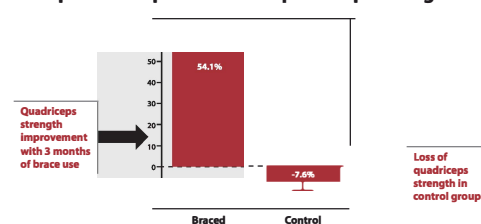
### Results

- 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.

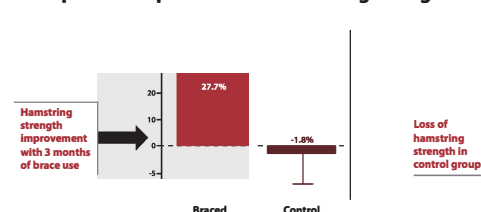
### Discussion

- 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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