Gait Using Pneumatic Brace for End-Stage Knee Osteoarthritis

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Abstract

More than 20 million individuals in the United States are affected by knee osteoarthritis (OA), which can lead to altered biomechanics and excessive joint loading. The use of an unloader pneumatic brace with extension assist has been proposed as a nonoperative treatment modality that may improve gait mechanics and correct knee malalignment. We assessed the following parameters in patients who have knee OA treated with and without a brace: (1) changes in temporospatial 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 midstance 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 nonoperative treatment regimen as the matching cohort for a 3-month period. They underwent evaluation of gait parameters using a three-dimensional gait analysis system at their initial appointment and at 3 months follow-up. All the testing, pre- and postbracing were performed without wearing the brace to examine for retained effects. Treatment with the brace led to significant improvements versus standard treatment in various gait parameters. Patients in the brace group had improvements in walking speed, knee extension at heel strike, total range of motion, knee joint forces, and rate of knee flexion from midstance to terminal stance when compared with the matching cohort. Knee OA patients who used a pneumatic unloader brace for 3 months for at least 3 hours per day had significant improvements various gait parameters when compared with a standard nonoperative therapy 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.

Keywords
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Knee osteoarthritis (OA) affects more than 20 million individuals in the United States.[1] Although it is mostly seen in the elderly population, the recent obesity epidemic has resulted in OA being prevalent in younger individuals, which is expected to double the prevalence in the next decade.[2] One of the purported mechanisms for knee OA progression in these patients is altered joint biomechanics and excessive loading.[3] This ultimately leads to knee pain, reduced activity, and a reduction in the quality of life, which can lead to long-term disability.[4] These patients often progress to end-stage degenerative joint disease and require knee arthroplasty procedures. With the rising number of patients who are affected by knee OA, the number of these procedures performed each year in the United States is expected to increase sevenfold from 500,000 to 3.8 million by the year 2030.[5]

These altered joint biomechanics modify knee joint loading of the tibial and femoral articular cartilage such that the joint is unable to accommodate these forces, which may lead to accelerated OA.[3] Furthermore, characteristic gait changes observed in these knee OA patients include decreased walking speed, increased knee adduction moments, increased knee flexion at heel strike, and decreased peak flexion angles.[6] Although there are various nonoperative methods of treatment to ameliorate pain and improve function,[7–10] there is a current lack of effective long-term protective treatment of these altered gait mechanics. The use of a brace, which has the potential to reduce externally applied knee adduction moments, may be effective in delaying disease progression by also altering gait mechanics.[11–13] Studies have shown that the use of custom-made, adjustable, knee braces can improve gait speed, reduce joint compartment loading of the knee, and improve varus angulation.[4,13,14]

Currently, there is limited data evaluating the clinical efficacy and carry-over impact of unloader braces. In addition, all of the prior gait studies testing efficacy have been performed with the brace in place on the knee. We therefore set out to evaluate a novel pneumatic brace in an attempt to elucidate its effects on gait parameters in patients who have late-stage knee OA when the brace was not worn. We evaluated the following parameters between two cohorts (knee brace vs. standard of care only) for the following parameters: (1) changes in temporospatial 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 from midstance to toe-off.

Methods

This was a 2:1 prospective, randomized, single-center, single-blinded study of 36 patients (24 brace and 12 standard of care) who had radiographic evidence Kellgren–Lawrence grades 3 to 4 knee OA (definitive joint space narrowing, osteophyte development, and cystic and/or sclerotic changes). This is a specific gait-study update to a previously published study utilizing the same bracing device.[6] Before initiation of the study, appropriate Institutional Review Board approval was obtained.

Patients were randomized to receive either a pneumatic brace or a standard of care knee OA including physical therapy (PT). All brace patients were fitted with an OA Rehabilitator brace (Guardian Brace. Pinellas Park, FL). The brace combines the three elements: pneumatic joint unloading, active swing assist, and construction made of a proprietary flexible and elastically deformable material. All patients were instructed to wear the device for a minimum of 3 hours per day when active and ambulating. Patients were allowed to use the brace while performing physical activities such as stair climbing, using an elliptical or regular bike. In addition, to verify compliance with the device, patients were requested to keep a daily log about brace application and duration of use. See Appendix 1 for detailed information about the brace. Patients randomized to the PT cohort underwent 6 weeks of PT two to three times a week focused on isotonic and isometric strengthening, joint mobility, stretching, and mobility exercises as well as gait training. In addition, the PT cohort also received pain-relieving modalities in therapy such as moist heat and/or ultrasound at a standard dose of 1.5 to 1.7 W/cm^2.

The brace cohort consisted of 24 patients (10 men and 14 women) who had a mean age of 59 years (range, 45–79 years). The standard of care plus PT cohort consisted of 12 patients (5 men and 7 women) who had a mean age of 54 years (range, 41–69 years). There were no statistical differences between the two groups in terms of age, gender, or Kellgren–Lawrence OA stage. In the brace group, of the 24 patients, 14 patients had genu varus ($<$ 5 degrees), 2 patients were within 2 degrees of normal, and 8 patients had a mild valgus alignment ($<$ 5 degrees). In the PT cohort, 8 patients had mild varus alignment ($<$ 5 degrees), one patient was within 2 degrees of neutral, and 2 patients had mild valgus alignment ($<$ 5 degrees).

All patients had an initial gait study, which was repeated 3 months later. Of those patients in the bracing cohort, they underwent both gait evaluation without the brace to evaluate if there was any effect on joint biomechanics once the brace was removed. See Appendix 2 for further information on the gait laboratory and evaluations performed.

Postprocessing data analysis was performed using OrthoTrak software (Motion Analysis Corporation, Santa Rosa, CA), and parameters analyzed included walking velocity, knee extension at heel strike, total knee arc of flexion, foot placement, and knee adduction moment and impulse.

Knee adduction moments are instantaneous values expressed in newton-meter (N-m) and measured at loading response in knee flexion. Adduction impulses are summations of all forces during the stance phase and are expressed in newton-meter-second (N-m-s). Measurements of adduction impulses give a more accurate evaluation joint loading throughout the stance phase instead of measuring adduction moments at loading response knee flexion, which represents loading measured just for that instance. We analyzed adduction/abduction impulse data separately for varus and valgus patients. This was done to consider variation in the moments and impulses in both of these deformities. Patients who had varus and normal knee alignment had ground reaction force vectors located medial to the knee joint center. This leads to increased loads on the medial side and lesser compressive loads on the lateral side. Even with slight valgus (2–5 degrees) this remains true, but as the valgus deformity increases, the ground reaction force vector becomes more lateral to the joint center and an adduction moment changes to an abduction moment.

We evaluated dynamic stiffness in both patient groups as well as the rate and acceleration of unloading of the knee joint. Dynamic stiffness is defined as the change in knee flexion moment over the knee flexion angle, expressed as N-m/degree. This is measured in the weight acceptance phase of the loading response portion of the knee flexion curve. It gives an idea of knee joint resistance or stiffness to flexion in the weight acceptance phase (loading response 3–15% of the gait cycle). Slope is the overall rate of change from maximal extension at midstance to knee flexion at toe-off. Slope or rate is expressed as degrees/second. A higher slope shows a quicker transition from midstance to toe-off. Curvature or acceleration is the rate of change in slope, which defines how quickly the slope changes. It shows how quickly knee flexion occurs from a maximally extended position at midstance to knee flexion at toe-off. This determines how much the knee will flex in the swing phase of the gait cycle.

All patients were monitored for adverse events during the study period related to the use of the device. Specific complications monitored included increased pain, local skin reactions (local skin irritation or breakdown due to wear of the device), or any abnormal event due to improper use or malfunction of the device. No severe adverse reactions were found with the use of wearing the device (i.e., ulcerations); however, some patients complained of minor skin irritation ($n = 3$), which was self-limited and concluded within a day or 2 of usage.

Data were recorded on an Excel spreadsheet (Microsoft Corporation, Redmond, WA) and statistical analysis was conducted using a SigmaStat version 3.0 (Systat Inc, San Jose, CA). Pre- and posttreatment variables were evaluated using the Student *t*-test to compare pre- and postoperative continuous data scores between the two cohorts, as well as between visits within their respective cohorts. In addition, we performed a sample size analysis of power using Statistical Solutions LLC software to validate adequacy of our sample size for statistical significance at less than 0.05. All of the significant changes in the study were verified using sample size calculation and were found to have adequate power. When sample sizes were not adequate we noted that in the "Results" section.

Results

The brace cohort had significant improvements in temperospatial parameters of gait including walking speed (see ►**Table 1**). The walking speed increased from 89.2 (range, 51–128 cm/second) to 98.5 cm/second (range, 54–157 cm/second; $p = 0.0027$) when compared with the matching cohort, which improved less from 92.5 (range, 57–123 cm/second) to 95.5 cm/second (range, 58–107 cm/second; $p = 0.47$). There were also significant improvements in knee extension at heel strike from 11 degrees of flexion (range, 2.8–22) to only 4 degrees of flexion (range, − 1.5 to 12.7) ($p = 0.006$), whereas the matching cohort decreased from 7 (range, 0.7–14) to 8 degrees (range, 3–15; $p = 0.78$). The total range of motion improved significantly more in the bracing cohort, 41 (range, 9–56) to 45 degrees (range, 10–65; $p = 0.006$) and 46 (range, 37–52) to 47 degrees (range, 31–55; $p = 0.9$). Loading response knee flexion improved a mean of 9 degrees (range, − 4 to 21) in study patients ($p = 0.07$) and in the matching group, mean change in loading response knee flexion was 3 degrees (− 6 to 12). This change in the matching group was not significant ($p = 0.78$).

Table 1 Gait statistics

	Brace	Control
Prespeed	89.16 (51–128)	92.5 (57–123)
Postspeed	98.5 (54–157)	95.5 (58–107)
Significance	$p = 0.0027$	$p = 0.47$
Knee extension at heel strike		
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	$p = 0.006$	$p = 0.78$
Total ROM	**Brace**	**Control**
Pre-ROM	41 (9–56)	46 (37–52)
Post-ROM	44.9 (10–65)	47 (31–55)
Significance	$p = 0.006$	$p = 0.9$

Abbreviation: ROM, range of motion.

The adduction impulse in bracing cohort who had varus knee alignment ($n = 16$) showed a reduction from a mean of 23.3 (range, 6.5–45.3 N-m-s) to 17.1 N-m-s (range, 6.1–25.0 N-m-s) after brace use ($p = 0.05$). In this group, 15 of 16 patients had a reduction in adduction impulse (reduced medial compressive load). As compared with that in the matching standard of care group of eight patients with varus deformity mean preadduction impulse was 18 N-m-s (range, 8–38.7 N-m-s) and changed to a mean of 14.7 N-m-s (range, 16–22 N-m-s). The change in adduction impulse in the control group was not significant ($p = 0.48$). Patients who had valgus deformities in the brace cohort ($n = 8$) had mean pretreatment abduction/adduction impulses of 2.86 N-m-s (range, − 1.87 to 8.81 N-m-s), and after brace use, a mean abduction/adduction impulse of 0.49 N-m-s (range, − 13.1 to 9.4 N-m-s) ($p = 0.49$). Though the reduction in mean values for the valgus group was not statistically significant, an excess of 120 patients in a 2:1 matched comparison would have been required to evaluate if brace wear would have changed impulse. In the matching group, the changes also were not significant though we only had three valgus patients in this group (see ►**Table 2**). Patients with valgus in the brace group had a pretreatment mean abduction/adduction impulse of 9.8 N-m-s (range, 2.8–19.1 N-m-s); however, after brace use for 90 days, this changed to a mean of 11.5 N-m-s (range, − 2.4 to

Table 2 Knee joint moments and impulse: brace versus control groups

Varus patients	Knee joint forces (patients with knee varus)	Prebrace	Postbrace	Significance
	Adduction impulse (N-m-s)			
Brace		23.3 (6.5–45.3)	17.1 (6.1–25)	**0.05**
Control		18 (8–38.7)	14.7 (16–22)	0.48
	Max. adduction moment N-m × bw			
Brace		43.5 (15.7–61)	38.5 (23–48.1)	0.16
Control		38.9(17.6–91)	38.5 (13.4–61)	0.78
Valgus patients	**Knee joint forces (patients with knee valgus)**	**Prebrace**	**Postbrace**	**Significance**
	Adduction/abduction impulse (N-m-s)			
Brace		2.86 (– 1.87 to 8.81)	0.49 (– 13 to 9.4)	**0.49**
Control		2.2 (1.8–3.87)	2.47 (1.6–4.2)	0.71
	Max. adduction/abduction moment N-m × bw			
Brace		9.8 (2.8–19.1)	11.5 (– 2.4 to 20.3))	0.59
Control		11.9(19–31.3)	8.5 (5.5–16.1)	0.45

Abbreviation: bw, body weight.
Note: Bold values indicate significantly reduced medial compressive forces in the knee, as mentioned in the results section.

20.3 N-m-s) ($p = 0.59$). The change in impulse in the valgus group after 90 days of brace use was not significant; however, our sample size analysis showed that we needed in excess of 160 patients to evaluate change with statistical significance.

The maximum adduction moment measured at the loading response knee flexion in patients with varus alignment in the brace cohort showed a trend toward improvement from 43.5 (range, 15.7–61 N-m) to 38.5 N-m (range, 23–48.1 N-m; $p = 0.16$); however, this was not significant ($p = 0.16$)). As compared with that there was no change in the control group from pre- to 90 days in the adduction moment ($p = 0.45$).

Patients in the brace cohort demonstrated a dynamic stiffness of 0.048 N-m/degrees (range, 0.007–0.082 N-m/degrees) prebrace and 0.050 N-m/degrees (range, 0.009–0.12 N-m/degrees) postbrace. In the matching cohort, the mean pretreatment dynamic stiffness was 0.032 N-m/degrees (range, 0.01–0.081 N-m/degrees) and posttreatment stiffness was 0.022 N-m/degrees (range, 0.01–0.052 N-m/degrees). The change in dynamic stiffness in both the study and matching cohort was not statistically significant ($p = 0.49$, 0.36). Unlike dynamic stiffness, we found that in the bracing cohort both the rate of change and acceleration of knee flexion from maximal extension at midstance to knee flexion at toe-off was significant. The mean rate of change in angle prebrace in the bracing cohort was 94.3 degrees/second (range, 52.6–156.6 degrees/second), and in postbrace, the rate significantly changed to 112.3 degrees/second (range, 57.6–202.3 degrees/second) ($p = 0.003$). In the matched cohort, the pretreatment mean rate was 86.1 degrees/second (range, 16.3–121.1 degrees/second) and posttreatment rate was 85.6 degrees/second (range, 12.9–125.1 degrees/second) ($p = 0.07$) (►**Fig. 1**).

We also found that change in pre- to postacceleration of knee flexion through knee flexion from maximal extension at midstance to knee flexion at toe-off was significantly improved in the study group and no change in the control group was seen. The mean acceleration prebrace in the study group was 559.8 degrees/second (range, 257.4–982.7 degrees/second), and postbrace use this significantly improved to mean of 662.8 degrees/second (range, 380.1 to 1011.9 degrees/second) ($p = 0.006$). The mean acceleration in the matching standard of care cohort pretreatment was 518.6 degrees/second (range, 60.5–1008.1 degrees/second) and in posttreatment, the mean acceleration was 516.6 degrees/second (range, 53.5–878.6 degrees/second; $p = 0.095$) (►**Fig. 2**).

Discussion

The altered biomechanics of knee OA can be difficult to treat with nonoperative methods. Given the increasing population of patients who may suffer from OA in the coming decade, there is a need for further effective nonoperative treatment modalities, such as bracing devices, for these patients.[1,2] The purpose of this study therefore was to evaluate the effects on gait parameters the efficacy of a pneumatic unloader brace with extension-assist bands in patients who have late-stage knee OA. The 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, as well as ease in knee flexion range of motion as shown by improved rate of knee flexion from midstance to toe-off.

The current literature has mixed outcomes results concerning the efficacy of the braces for the treatment of knee OA. There are even fewer studies, which specifically assess

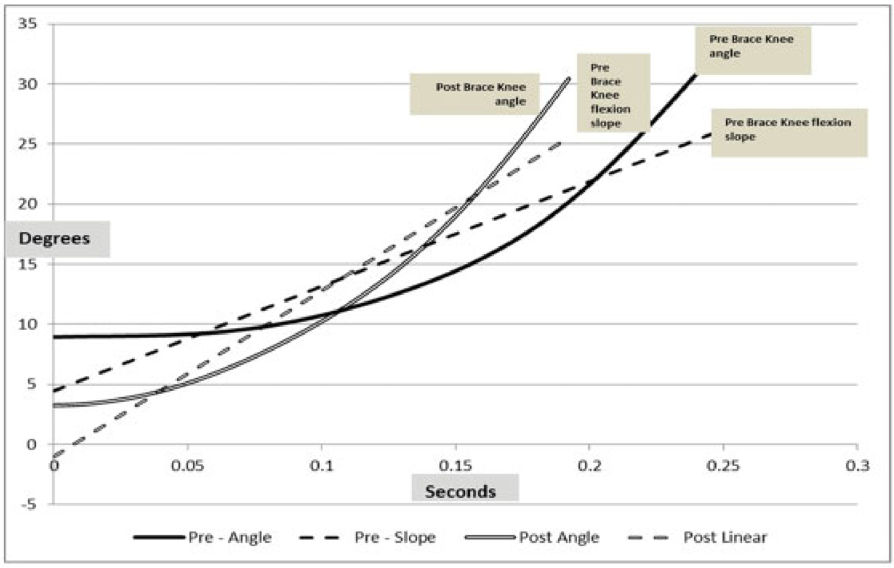

Fig. 1. Mean rates of change in knee flexion angles.

gait changes in patients using these devices as well as any retained benefits. Johnson et al[6] studied 20 osteoarthritic knee patients and demonstrated that the patients who used an unloader brace use ($n = 10$) significantly improved walking speed, total range of motion, knee angle at heel strike, and knee adduction moment when compared with a nonbraced cohort. The mean improvement in knee adduction moment was 48% (range, 16–76% of original peak moment).

In addition, it has been postulated that wearing the brace may enhance proprioception and result in a reduction in pain. A 20-patient study by Birmingham et al[15] evaluated the effects of a functional knee bracing for varus gonarthrosis on measures of proprioception and postural control. The authors demonstrated that proprioception was significantly improved following application of the brace (mean difference = 0.7 degrees; $p = 0.01$); however, postural control values did not reach significant differences during the stable surface test (mean difference = 2.6 cm; $p = 0.72$) or the foam surface test (mean difference = 0.9 cm; $p = 0.54$) with the use of the brace.

Similarly, a preliminary prospective cohort study of 18 patients by Della Croce et al[13] demonstrated results similar to the present report. They found that an unloading brace led to an improved correction of the peak external knee adduction moments observed in patients who have medial compartment knee OA. There was a 7.6% decrease in the net peak

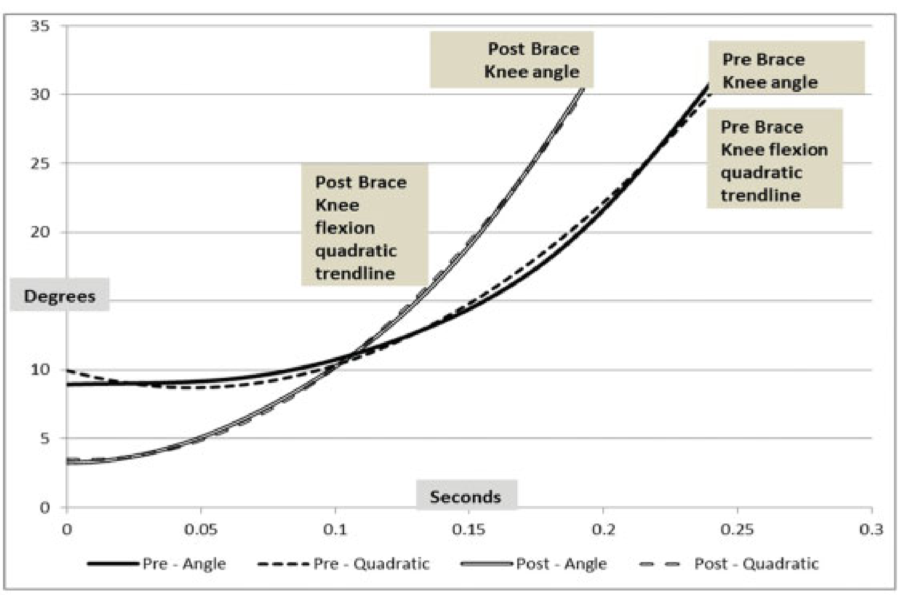

Fig. 2. Quadratic acceleration of knee flexion.

external knee adduction moment for patients who wore the brace compared with those who did not. Similar to the brace design in our study, this device also had an air bladder, which when inflated to 7 psi led to a 26% reduction in net peak external knee adduction moment. In contrast to the study by Della Croce et al, the gait analysis in our study was conducted while the brace was not worn. We believe that this better demonstrates the lasting and retained effects of knee strengthening and gait retraining facilitated by use of this novel brace.

There were several limitations of this study. It was conducted on a small number of patients; however, this is the largest study to the best of our knowledge on this device. The number of patients enrolled was limited due to the extensive gait testing that was required. Typically, these tests are not performed on patients who are undergoing treatment for OA and therefore can increase the length of visit by up to 3 hours. However, the number of patients was sufficiently large to provide statistically significant results in many of the observed metrics. In addition, although these results are encouraging at 3 months, it will be useful to repeat these outcomes at future time points to evaluate longer term improvements in pain scores and patient functionality, which is planned. A more definitive outcome of whether or not a treatment has successfully improved the clinical nature of OA would be if it could either (1) delay or (2) prevent the need for total knee arthroplasty. However, that was not the scope of the present study and this will be evaluated and reported later as these patients are being followed longitudinally.

Knee OA patients who used an unloader pneumatic brace with extension assist bands demonstrated statistical improvements in various gait parameters such as speed, range of motion, knee extension at heel strike, force and rate of change of flexion, and acceleration. In addition to these improvements, the even load distribution achieved with the use of this brace on the knee might delay the progression of OA, as well as the need for surgery. The authors believe that the high compliance found was due to the ease of use, which makes it capable of being incorporated into all nonoperative treatment algorithms for knee OA. These patients will continue to be followed to report on longer term outcomes, to see if these improvements are maintained after discontinued brace usage.

References

1 Dillon CF, Rasch EK, Gu Q, Hirsch R. Prevalence of knee osteoarthritis in the United States: arthritis data from the Third National Health and Nutrition Examination Survey 1991-94. J Rheumatol 2006;33(11):2271–2279

2 Losina E, Walensky RP, Reichmann WM, et al. Impact of obesity and knee osteoarthritis on morbidity and mortality in older Americans. Ann Intern Med 2011;154(4):217–226

3 Favre J, Erhart-Hledik JC, Andriacchi TP. Age-related differences in sagittal-plane knee function at heel-strike of walking are increased in osteoarthritic patients. Osteoarthritis Cartilage 2014; 22(3):464–471

4 Arazpour M, Hutchins SW, Bani MA, Curran S, Aksenov A. The influence of a bespoke unloader knee brace on gait in medial compartment osteoarthritis: a pilot study. Prosthet Orthot Int 2014;38(5):379–386

5 Lehil MS, Bozic KJ. Trends in total hip arthroplasty implant utilization in the United States. J Arthroplasty 2014;29(10):1915–1918

6 Johnson AJ, Starr R, Kapadia BH, Bhave A, Mont MA. Gait and clinical improvements with a novel knee brace for knee OA. J Knee Surg 2013;26(3):173–178

7 Hrnack SA, Barber FA. Managing the pain of knee osteoarthritis. Phys Sportsmed 2014;42(3):63–70

8 Roque V, Agre M, Barroso J, Brito I. Managing knee ostheoarthritis: efficacy of hyaluronic acid injections. Acta Reumatol Port 2013; 38(3):154–161

9 Rosneck J, Higuera CA, Tadross N, Krebs V, Barsoum WK. Managing knee osteoarthritis before and after arthroplasty. Cleve Clin J Med 2007;74(9):663–671

10 Hanypsiak BT, Shaffer BS. Nonoperative treatment of unicompartmental arthritis of the knee. Orthop Clin North Am 2005;36(4): 401–411

11 Maleki M, Arazpour M, Joghtaei M, Hutchins SW, Aboutorabi A, Pouyan A. The effect of knee orthoses on gait parameters in medial knee compartment osteoarthritis: a literature review. (epub ahead of print) Prosthet Orthot Int 2014;pii: 0309364614547411

12 Lamberg EM, Streb R, Werner M, Kremenic I, Penna J. The 2- and 8-week effects of decompressive brace use in people with medial compartment knee osteoarthritis. (epub ahead of print) Prosthet Orthot Int 2015;pii: doi: 0309364615589537

13 Della Croce U, Crapanzano F, Li L, et al. A preliminary assessment of a novel pneumatic unloading knee brace on the gait mechanics of patients with knee osteoarthritis. PM R 2013;5(10):816–824

14 Moyer RF, Birmingham TB, Bryant DM, Giffin JR, Marriott KA, Leitch KM. Biomechanical effects of valgus knee bracing: a systematic review and meta-analysis. Osteoarthritis Cartilage 2015; 23(2):178–188

15 Birmingham TB, Kramer JF, Kirkley A, Inglis JT, Spaulding SJ, Vandervoort AA. Knee bracing for medial compartment osteoarthritis: effects on proprioception and postural control. Rheumatology (Oxford) 2001;40(3):285–289