



Effectiveness of Valgus Offloading Knee Braces in the Treatment of Medial Compartment Knee Osteoarthritis: A Systematic Review

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Context: Knee osteoarthritis affects 9.3 million adults over age 45 years in the United States. There is significant disability associated with this condition. Given the potential complications and the significant cost to the health care system with the dramatic increase in total knee arthroplasties performed for this condition, assessment of the efficacy of nonoperative modalities, such as offloading knee braces, is essential as part of optimizing nonoperative treatment for this condition.

Objective: To determine the effectiveness of valgus offloader braces in improving clinical outcomes for patients with medial compartment knee osteoarthritis.

Data Sources: Three databases (PubMed, MEDLINE, and EMBASE) were searched from database inception through July 28, 2017.

Study Selection: Studies reporting outcomes of valgus offloader knee braces in the treatment of medial compartment knee osteoarthritis were included.

Study Design: Systematic review.

Level of Evidence: Level 4.

Data Extraction: Data pertaining to demographics, descriptive statistics, and clinical outcomes were extracted from the included studies. The methodological quality of included studies was evaluated.

Results: A total of 31 studies were included, with a total of 619 patients. The majority of studies reported improved pain outcomes using valgus offloader braces. However, variable results were reported as to whether valgus offloader braces significantly improved functional outcomes and stiffness. Offloader bracing was more effective at reducing pain when compared with neutral braces or neoprene sleeves.

Conclusion: Valgus offloader bracing is an effective treatment for improving pain secondary to medial compartment knee osteoarthritis. The literature remains unclear on the effectiveness of valgus offloader braces with regard to functional outcomes and stiffness. Larger prospective randomized trials with consistent outcome assessment tools and consideration of patient compliance would be beneficial to more accurately determine treatment effects of valgus offloader bracing.

Keywords: osteoarthritis; knee; valgus; brace

Knee osteoarthritis (OA) is a degenerative condition affecting 9.3 million adults aged 45 years or older in the United States.³⁸ Approximately 10% of individuals older than 55 years suffer from knee OA, 25% of whom are severely disabled,⁴⁶ and OA will become the fourth-leading cause of

disability globally by the year 2020.⁵⁷ As the population continues to age, the incidence of knee OA will continue to increase, placing significant burden on an already strained health care system.⁴⁰ Currently, it is estimated that 10% of direct lifetime medical costs are attributable to knee OA in the United States.³⁸

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The most common definitive management for knee OA is total knee arthroplasty (TKA). However, this treatment is generally reserved for those with severe OA due to the invasiveness of the procedure, cost, and risk for complications.^{36,43} National Hospital Discharge Survey and Medicare data have shown a dramatic increase in TKA rates of 161.5% from 1991 to 2010.³⁷ This increase is projected to continue at a startling rate of 673% by 2030.³⁷ Even more concerning is that the proportion of those cases performed in patients younger than 65 years is projected to increase from the current 41% to 55%.²⁸ Though having high implant survival rates,⁹ TKA is not always advisable, particularly in the younger patient. TKA in the young, active patient can be undesirable due to a 2- to 3-fold increased risk for revision surgery.^{10,55} A cross-sectional study of 1703 primary total knee replacements confirmed that almost 1 in 5 (19%) patients were not satisfied with the outcome—particularly those younger than 70 years.⁴

This finding highlights the importance of nonoperative treatment modalities to reduce pain and improve function in patients with knee OA, allowing for delay or avoidance of TKA. Commonly used modalities include nonsteroidal anti-inflammatory drugs (NSAIDs), intra-articular injections, activity modification, physical therapy, and knee bracing.

Offloader knee bracing aims to correct alignment of the structurally misaligned knee and to address pain associated with pseudolaxity related to the arthritic knee. Knee malalignment can alter gait mechanics and weight distribution within the knee, leading to joint space narrowing and degradation of articular cartilage.³⁴ During the midstance phase of gait, the center of mass is positioned medial to the center of the knee joint, resulting in the medial compartment of the knee carrying 2.2 times more loading than the lateral compartment. For this reason, medial compartment OA and varus malalignment are significantly more common than lateral compartment OA.^{1,24} The asymmetric load distribution is due to the external knee adduction moment (EKAM), and EKAM can be used as an indirect measure of medial joint loading.⁵⁹ Biomechanical studies have demonstrated the ability of valgus offloader bracing to reduce EKAM by up to 7%, thereby reducing undesirable loading on the medial compartment.²⁵

Despite its theoretical benefits, offloader bracing is used much less frequently than other conservative treatment options that involve higher risks, such as NSAIDs and intra-articular joint injections.⁶ This may be related to the limited evidence in the literature supporting its effectiveness. The American Academy of Orthopaedic Surgeons (AAOS) published guideline recommendations in 2010 regarding treatment of knee OA using medial compartment offloader bracing. The recommendation was inconclusive because of a lack of conclusive evidence supporting its use.⁵⁰ This was based on numerous moderate- to high-quality studies in which conclusions on clinical improvement were unclear.^{8,27,56} Therefore, this study aimed to clarify the effectiveness of valgus knee offloader braces for the treatment of medial compartment OA through an updated systematic review of the literature.

METHODS

Search Strategy

Three online databases (PubMed, EMBASE, MEDLINE) were searched by 2 independent reviewers in duplicate for relevant articles from database inception to July 28, 2017. Search terms such as *unloader*, *valgus*, *varus*, *osteoarthritis*, and *arthrosis* were used (see Table A1 in the Appendix, available in the online version of this article). A hand search of references of included studies and abstracts from recent orthopaedic conferences as well as Google Scholar was performed for inclusion of any additional studies.

Study Screening

All titles, abstracts, and full texts were screened in duplicate by 2 independent reviewers. Any disagreements at the title and abstract stages were dismissed and articles were moved forward to the next round of screening to ensure relevant articles were not missed. Disagreements at the full-text stage were discussed among the 2 reviewers. When consensus could not be reached, the input of a third senior reviewer was used to determine the final eligibility of the article.

Assessment of Study Eligibility

Inclusion and exclusion criteria of this systematic review were determined a priori. Inclusion criteria were (1) all levels of evidence, (2) male and female patients, (3) studies of any language, (4) studies on humans, (5) studies reporting on the use of valgus offloading bracing for the treatment of medial compartment OA, and (6) at least 1 clinical outcome reported. Exclusion criteria were (1) any study combining the use of knee offloading braces with surgical treatment, (2) severe lateral or tricompartmental knee OA, and (3) studies using the same patient population as another study already included to prevent duplication. In such instances, the study with the larger patient population was included. If the studies had the same number of participants but presented different outcomes, however, then both were included. Additional exclusion criteria consisted of nonhuman and biomechanical studies.

Quality Assessment

Quality assessment was performed independently and in duplicate for all studies included in this systematic review. The Methodological Index for Non-Randomized Studies (MINORS) appraisal tool was used to assess nonrandomized studies,⁵³ and the Checklist to Evaluate a Report of a Nonpharmacological Trial (Clear NPT) was used for the quality assessment of randomized studies.⁵

With regard to the MINORS appraisal tool, a score of 0, 1, or 2 is given for each of the 12 items on the MINORS checklist, with a maximum score of 16 or 24 given for noncomparative and comparative scores, respectively. Methodologic quality was categorized a priori as follows: 0 to 6, very low quality of evidence; 7 to 10, low quality of evidence; 10 to 14, fair quality of evidence; and >16, good quality of evidence for nonrandomized studies.

The Clear NPT is a validated checklist that is used to assess 10 key elements of the methodology of randomized studies. Studies that met less than 5 of the Clear NPT criteria were considered low quality, between 5 and 7 criteria were of moderate quality, and meeting more than 7 criteria was indicative of a high-quality study.

Data Abstraction and Statistical Analysis

Two independent reviewers abstracted relevant data from included studies into a Microsoft Excel spreadsheet (version 2007; Microsoft). Demographic data abstracted included author, study location and design, and year of publication. Descriptive statistics such as age, sex, sample size, percentage male, level of evidence, and outcome data pertaining to unloader braces and control groups were also abstracted. Specifically, clinical outcomes were abstracted, including pain, function, stiffness, and ability to perform activities of daily living (ADLs). Descriptive statistics such as means, ranges, and measures of variance (eg, standard deviations, 95% CI) are presented where applicable. A kappa (κ) statistic was used to evaluate interreviewer agreement at all screening stages. Agreement was categorized as per the guidelines of Landis and Koch³¹ as follows: 0.81 to 0.99, almost perfect agreement; 0.61 to 0.80, substantial agreement; 0.41 to 0.60, moderate agreement; 0.21 to 0.40, fair agreement; and 0.20 or less, slight agreement.³¹ Revman Review Manager (version 5.3; The Cochrane Collaboration) was used to calculate the descriptive statistics.

RESULTS

Study Identification

The initial search yielded 1114 studies, of which 31 full-text articles met the inclusion criteria (Figure 1). The characteristics of all included studies can be found in Table 1. There was substantial agreement between reviewers at the title ($\kappa = 0.64$; 95% CI, 0.58-0.70) and abstract ($\kappa = 0.78$; 95% CI, 0.70-0.86) screening stages, and almost perfect agreement at the full-text screening stage ($\kappa = 0.95$; 95% CI, 0.89-1.00).

Study Characteristics

All included studies were conducted between 1993 and 2017, 20 of which were published since 2007.^{2,11,12,16-18,20,22,23,25,29,30,32,33,39,44,45,48,51,52} A total of 619 participants received a valgus unloader brace for the management of medial knee OA. The mean sample size of the included studies was 22 patients (range, 7-46 patients). Of these patients, 54.0% were male, with a mean age of 58.1 ± 5.7 years and mean follow-up of 4.3 ± 4.3 months. At final follow-up, 549 patients (92.2%) were available.

Study Quality

A total of 18 nonrandomized and 13 randomized studies were included in this review. The majority of included studies were of level 2 evidence ($n = 14$) (Table 1).^{2,7,11,13,16,18,19,21,22,25,33,44,49,51} There were 3 studies of level 1 evidence,^{27,39,45} 7 studies of level

3 evidence,^{12,14,17,26,47,48,52} and 5 studies of level 4 evidence.^{20,23,29,30,32} The mean MINORS score was 12.3 ± 1.9 , which indicates fair quality of evidence for nonrandomized studies. The mean Clear NPT score was 4.8 ± 1.5 , which indicates low quality of evidence for randomized studies.

Outcomes

A summary of clinical outcomes is available in the Appendix and Table 2. A summary of comparative outcomes are also available in the Appendix as well as Table 3.

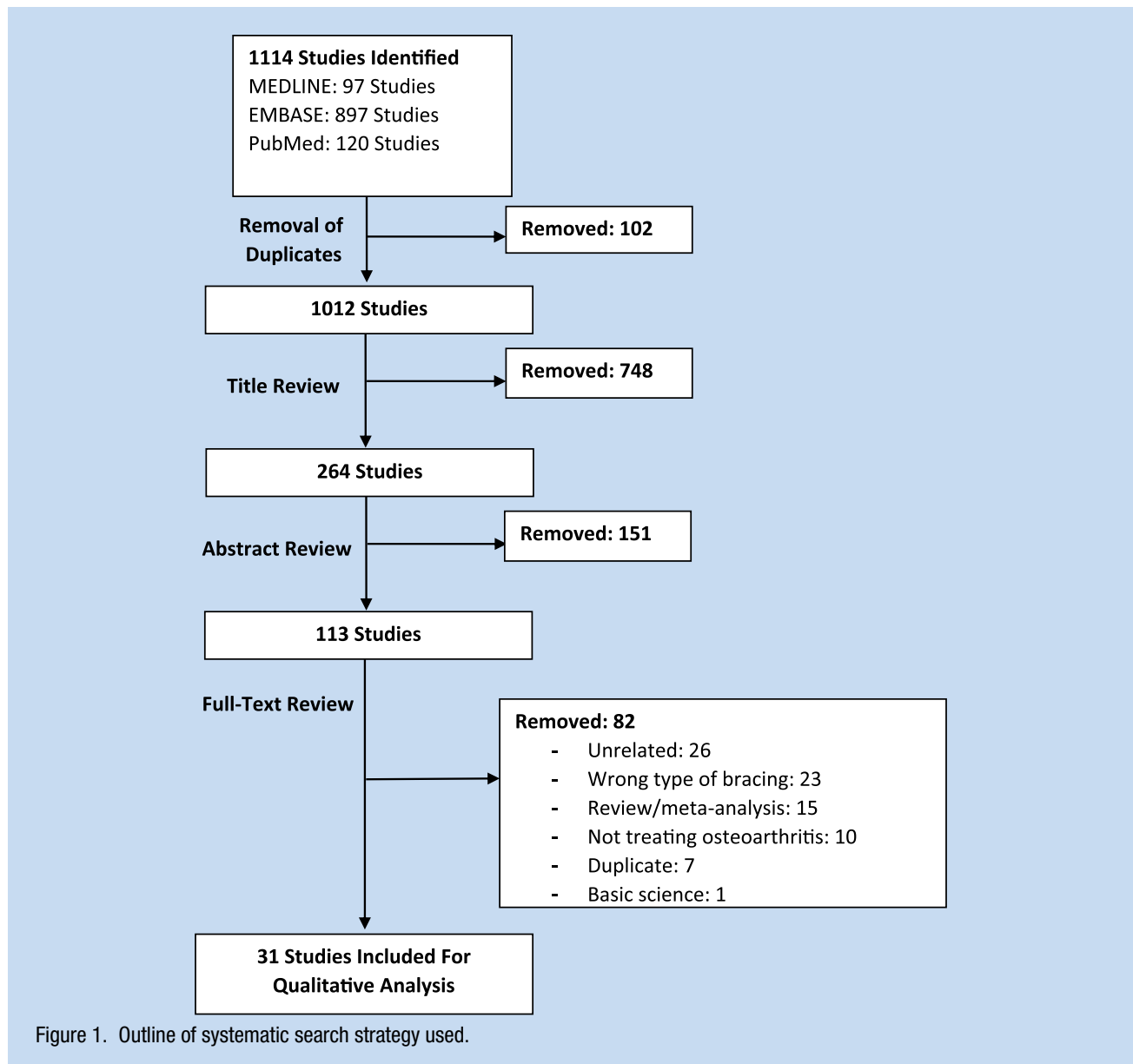
DISCUSSION

The majority of available literature supports the use of valgus offloader braces as effective in improving pain caused by medial compartment knee OA. The literature reported heterogeneous results with respect to improvement in function, stiffness, and ADL. Additionally, we found bracing to be more effective at reducing pain than standard treatment, neutral braces, and the use of neoprene sleeves.

Although, the literature reported relatively equivocal outcomes for non-pain-related outcomes, pain is generally considered one of the most important outcomes to patients and is often the most debilitating symptom driving the need for treatment.^{41,46} Knee pain is frequently cited as the main determinant of self-reported physical functioning.⁴² With regard to function and ADLs, valgus offloader bracing was found to be effective in improving aggregate outcomes such as the 6-minute walk test and the 30-second stair climb test. Effects on stiffness with valgus offloader bracing were equivocal with heterogeneous results between studies. In theory, improvements in pain could lead to increased activity, which could subsequently allow for reductions in stiffness. Conversely, bracing may cause the patient to become hesitant when using the affected knee, as patients often consider the braced knee injured and favor the unaffected knee.¹⁵ This could explain the limited improvements in stiffness found in the literature.

Interestingly, no significant difference was identified between valgus offloader bracing and lateral-wedged insoles for walking distance or pain scores; however, only 4 studies examined this comparison.^{16,25,39,56} Although there is very limited evidence comparing the effectiveness of valgus offloader braces with treatments such as NSAIDs and intra-articular injections, valgus offloader braces have the known advantage of having reduced adverse effects. NSAIDs, for example, can have interactions with antihypertensive and antiplatelet medications as well as contributing to gastrointestinal ulceration.⁶⁰ Additionally, intra-articular corticosteroid injections have a theoretical risk of joint infection.³

The primary disadvantage with knee offloader braces as a treatment modality is poor patient compliance. Squyer et al⁵⁴ found a compliance of 28% 1 year and 25% 2 years after being prescribed an offloader brace. The authors of this study were not able to identify any patient or radiographic factor (eg, sex, age, body mass index, arthritis severity) that predicted the



discontinuation of unloader brace use. A major complaint by patients is discomfort when wearing the brace.^{25,59} Their use has been reported as less than 4 hours per day on average, and the poor rate of compliance is primarily due to poor fit and esthetic aspects of the brace.^{8,54} Many of the included studies in this review did not examine or report compliance, and therefore, the overall effect of offloader braces in the compliant patient may be underestimated. Lateral-wedge insoles are less cumbersome than knee braces and have been shown to have greater levels of acceptance by patients.²⁵ This, in combination with the comparable effects on clinical outcomes compared with valgus offloader braces, supports the need for further research of lateral-wedge insoles as a potential nonoperative treatment modality for knee OA.

The AAOS second edition guidelines for treating knee OA were inconclusive regarding the use of medial compartment offloader bracing.⁴⁹ These guidelines were developed based on findings from 3 randomized control trials, all of which were included in this study.^{8,27,56} This comprehensive review finds low-quality evidence to support the use of offloader knee braces in improving pain and functional outcome scores.

Strengths

The main strength of this systematic review is the rigorous methodology used. The expansive search strategy and inclusion criteria employed ensured that we encompassed as much of the relevant literature as possible. Reviewer bias was also minimized through the use of a systematic approach by 2 independent

Table 1. Characteristics of included studies

Study	Year	Study Design	Level of Evidence	Total Sample Size, N	Sample Size Knee Unloader, n	Sample Size Control, n	% Male	Knee Unloader	
								Age, y, Mean (Range)	BMI, kg/m ² , Mean (Range)
Arzpour et al ²	2014	Randomized cross-over	2	7	7	NA	28.6	62.4 (60-64)	26.94 (25.64-28.24)
Brower et al ⁷	1999	Randomized controlled trial	2	15	11	13	NA	NA	NA
Della Croce et al ¹¹	2013	Randomized cross-over	2	14	14	NA	57.1	68 (59-77)	NA
Dessery et al ¹²	2014	Randomized cross-over	3	24	24	NA	41.7	57.2 (48.6-65.8)	31.6 (26.4-36.8)
Draganich et al ¹³	2006	Randomized cross-over	2	10	10	10	NA	50.8 (45.4-56.2)	34.1 (29.2-39)
Draper et al ¹⁴	2000	Prospective cohort	3	30	30	NA	60	56.2 (35-70)	NA
Duivenvoorden et al ¹⁶	2015	Randomized controlled trial	2	91	46	NA	5	54	30
Fantini Pagani et al ¹⁷	2013	Prospective cohort	3	12	12	NA	41.67	56.0 (51.4-60.6)	27.3 (23.2-31.4)
Fu et al ¹⁸	2015	Prospective cohort	2	10	10	10	40	56 (51-65)	NA
Gaasbeek et al ¹⁹	2007	Prospective cohort	2	15	15	NA	80	NA	NA
Haladik et al ²⁰	2014	Prospective cohort	4	10	10	NA	90	59.5 (52.2-66.8)	NA
Horlick and Loomer ²¹	1993	Randomized double cross-over	2	39	19	20	78.9	46 (34-69)	NA
Hunter et al ²²	2012	Randomized cross-over	2	80	40	40	37.5	63 (62.2-73.8)	32.7 (24.3-41.1)
Hurley et al ²³	2012	Prospective cohort	4	24	24	NA	83.33	57.8 (49.7-65.9)	31.8 (26.6-37)
Jones et al ²⁵	2013	Randomized cross-over	2	28	28	NA	57.14	66.3	29
Katsuragawa et al ²⁶	1999	Prospective cohort	3	14	14	NA	21.4	69 (57-80)	NA
Kirkley et al ²⁷	1999	Randomized controlled trial	1	110	41	69	68.3	59.5	NA
Lamberg et al ²⁹	2015	Case Series	4	15	15	NA	NA	55	35
Lamberg et al ³⁰	2016	Case series	4	21	15	NA	80	55 (39-70)	35 (24-49)
Laroche et al ³²	2014	Prospective cohort	4	20	20	NA	25	64.2 (54-74.4)	27.2 (21.8-32.6)

(continued)

Table 1. (continued)

Study	Year	Study Design	Level of Evidence	Total Sample Size, N	Sample Size Knee Unloader, n	Sample Size Control, n	Knee Unloader		
							% Male	Age, y, Mean (Range)	BMI, kg/m ² , Mean (Range)
Larsen et al ³³	2013	Prospective cohort	2	23	23	23	65.2	63.7 (53.4-74)	30.22 (25.58-34.86)
Moyer et al ³⁹	2017	Randomized cross-over	1	35	35	NA	62.8	55 (49.2-60.8)	30.0 (24.1-35.9)
Ormetti et al ⁴⁴	2015	Prospective cohort	2	20	20	NA	20	64.2 (54-74.4)	27.2 (21.8-32.6)
Ostrander et al ⁴⁵	2016	Randomized controlled trial	1	50	26	24	50	63.1 (56.8-69.4)	29.8 (25.3-34.3)
Pollo et al ⁴⁷	2002	Prospective cohort	3	11	11	11	90.91	53.2 (43.3-63)	25.9
Ramsey ⁴⁸	2007	Prospective cohort	3	16	16	16	NA	54.9 (46.1-63.7)	31.1 (26.9-35.3)
Richards ⁴⁹	2005	Cross-over	2	12	12	12	58.3	60.2 (50-75)	35
Sattari and Ashraf ⁵¹	2011	Randomized controlled trial	2	60	20	20	37	48 (35-65)	NA
Schmalz et al ⁵²	2010	Prospective cohort	3	16	16	0	50	56	35

BMI, body mass index; NA, not available.

Table 2. Summary of clinical outcomes after valgus bracing

Authors (Year)	Description of Brace	Baseline Clinical Outcomes	Final Clinical Outcomes	P Value/Significant Improvement
Arazpour et al (2014) ²	Custom unloader orthosis	Gait velocity (m/s): 0.90 ± 0.020 Step length (m): 0.53 ± 0.038 Cadence (steps/min): 102 ± 8 Knee ROM (deg): 44 ± 1.86	Gait velocity (m/s): 0.95 ± 0.022 Step length (m): 0.56 ± 0.048 Cadence (steps/min): 10.0 ± 7 Knee ROM (deg): 39 ± 1.61	Gait velocity: <i>P</i> = 0.001 Step length: <i>P</i> = 0.001 Cadence: <i>P</i> = 0.504 Knee ROM: <i>P</i> = 0.002
Brower et al (1999) ⁷	Generation II Unloader Select valgus knee brace			Time to ascend stairs: <i>P</i> = 0.0008 Time to descend stairs: <i>P</i> < 0.0001 Pain on stairs: <i>P</i> < 0.0001 Time and pain to walk 50 feet comfortably: <i>P</i> < 0.0001 Pain: (<i>P</i> = 0.0015)
Della Croce et al (2013) ¹¹	Unloading knee brace (OA Lit; DJO Global, Vista, CA) (1) Uninflated, (2) 7 psi	Gait velocity (m/s): Uninflated: 1.17 ± 0.11 7 psi: 1.15 ± 0.13 VAS (0-100): Uninflated: 14.7 ± 11.1 7 psi: 18.7 ± 19.2	Compared with control group	Compared with control group
Desseny et al (2014) ¹²	(1) Valgus brace using a three-point bending force mechanism (VP3 brace) (2) Unloader brace with valgus and external rotation functions (VER brace) Orthoconcept Inc, Laval, Quebec, Canada	Pain (20 cm VAS): V3P brace: 25.3 (17.0) VER brace: 24.1 (17.1) Gait velocity (m/s): V3P brace: 1.39 (0.19) VER brace: 1.37 (0.18)	Mean difference pain (20 cm VAS): V3P brace: -8.9 (-14.6 to -2.2) VER brace: -7.9 (-12.7 to -3.2) Gait velocity (m/s): V3P brace: -0.02 (-0.03 to 0) VER brace: 0 (-0.2 to -0.1)	Pain: V3P brace: <i>P</i> < 0.01 VER brace: <i>P</i> < 0.01 Gait velocity: V3P brace: <i>P</i> = 0.03 VER brace: <i>P</i> = 0.5
Draganich et al (2006) ¹³	(1) Patient-adjustable brace (OAdjuster; DJO, Vista, California) (2) Custom patient-adjustable brace (Adjustable OA Defiance; DJO)	Gait velocity (m/s): 1.20 ± 0.15 WOMAC Pain (0 to 500 mm) 197 Stiffness (max 200 mm) 91 Function (max 1700 mm) 664	Self-selected gait velocity (m/s): OAdjuster: 1.12 ± 0.14 Adjustable OA Defiance: 1.11 ± 0.10 Gait velocity – walking speed controlled (m/s): OAdjuster: 1.01 ± 0.03 Adjustable OA Defiance: 1.02 ± 0.03 WOMAC Pain (0-500 mm) OAdjuster: 120 Adjustable OA Defiance: 71 Stiffness (max 200 mm) OAdjuster: 63 Adjustable OA Defiance: 36 Function (max 1700 mm) Adjustable OA Defiance: 248	Gait velocity: NS Pain and stiffness: Significantly reduced for both braces (<i>P</i> < 0.05) Comparing both braces: Adjustable OA Defiance reduced stiffness more significantly than OAdjuster (<i>P</i> = 0.030) WOMAC Pain: OAdjuster: <i>P</i> = 0.040; Adjustable OA Defiance: <i>P</i> = 0.07 Stiffness: OAdjuster: <i>P</i> = 0.038 Adjustable OA Defiance: <i>P</i> = 0.008 Function: OAdjuster: no significant difference Adjustable OA Defiance: <i>P</i> = 0.010

(continued)

Table 2. (continued)

Authors (Year)	Description of Brace	Baseline Clinical Outcomes	Final Clinical Outcomes	P Value/Significant Improvement
Draper et al (2000) ¹⁴	GII ADJ Unloader (GII Orthotics Europe)	HSS knee score: 69.9 ± 9.9	HSS knee score: 82.0 ± 10.7	HSS knee score: $P < 0.001$
Duivenvoorden et al (2015) ¹⁶	Valgus knee brace (MOS Genu; Baurfeind AG)	Compared with control group	Compared with control group	Compared with control group
Fantini Pagani et al (2013) ¹⁷	Genu Arthro 28K20/21 (Otto Bock Health Care)	Compared with control group	Compared with control group	Compared with control group
Fu et al (2015) ¹⁸	Valgus unloader knee brace (Ossur hf)	WOMAC: Pain: 54.4 Stiffness: 54.4 ADL: 48.8 Total: 48.1 VAS (1-10): 5.5	WOMAC: Pain: 43.3 Stiffness: 47.9 ADL: 46.1 Total: 43.6 VAS (1-10): 4.7	WOMAC: Pain: $P = 0.02$ Stiffness: $P = 0.15$ ADL: $P = 0.56$ Total: $P = 0.28$ VAS: $P = 0.04$
Gaasbeek et al (2007) ¹⁹	SofTec OA valgus brace (Bauerfeind GmbH)	WOMAC (Symptoms): 50.1 ± 17.6 VAS walking: 6.8 ± 2.5	WOMAC (Symptoms): 63.0 ± 18.4 VAS walking: 4.7 ± 3.0	WOMAC (Symptoms): $P = 0.001$ VAS walking: $P = 0.003$
Haladik et al (2014) ²⁰	Medial compartment unloading brace (OA Adjuster; DonJoy)	WOMAC Pain: 17.2 ± 6.3 (range, 9-24) Function: 40.7 ± 16.8 (range, 19-62) Total: 60.3 ± 23.6 (range, 30.8-88.5)	WOMAC: Pain: 22.5 ± 3.4 (range, 18-26) Function: 50.9 ± 13.3 (range, 24-64) Total: 75.5 ± 17.2 (range, 43.5-93.3)	WOMAC: Pain: $P = 0.01$ Function: $P = 0.01$ Total: $P = 0.01$
Horlick and Loomer (1993) ²¹	Valgus knee brace (Generation II)	VAS Pain (1-10): Medial hinge: 4.14 ± 1.73 Lateral hinge: 3.33 ± 1.92 Functioning time: Medial hinge: 0.92 ± 0.57 Lateral hinge: 1.45 ± 1.58	VAS Pain (1-10): Medial hinge: 2.55 ± 1.26 Lateral hinge: 2.30 ± 2.04 Functioning time: Medial hinge: 0.95 ± 0.67 Lateral hinge: 1.11 ± 1.32	VAS Pain: Medial hinge: $P = 0.017$ Lateral hinge: $P = 0.005$ Functioning time: Medial hinge: NS Lateral hinge: NS
Hunter et al (2012) ²²	DonJoy OAadjuster knee brace (DonJoy Braces)	WOMAC Pain: Realignment to placebo: 9.2 ± 3.4 Placebo to realignment: 9.1 ± 3.4 WOMAC Function: Realignment to placebo: 33.3 ± 11.8 Placebo to realignment: 34.6 ± 10.3	WOMAC Pain mean change: Realignment to placebo: -1.7 ± 3.8 Placebo to realignment: 0.03 ± 3.2 WOMAC Function mean change: Realignment to placebo: -4.6 ± 9.6 Placebo to realignment: -1.6 ± 13.1	WOMAC Pain: $P = 0.064$ WOMAC Function: $P = 0.290$
Hurley et al (2012) ²³	Breg Fusion valgus unloader brace	WOMAC: Pain: 6.2 ± 2.6 Stiffness: 3.3 ± 1.4 Function: 18.5 ± 9.4 SF-36 Physical: 65.3 ± 14.0 Gait velocity (m/s): 1.21 ± 0.17 Stride length (m): 1.39 ± 0.15 Daily step count: 5740 ± 3313	WOMAC: Pain: 4.9 ± 3.3 Stiffness: 2.9 ± 1.8 Function: 15.9 ± 9.8 SF-36 Physical: 66.8 ± 14.3 Gait velocity (m/s): 1.24 ± 0.15 Stride length (m): 1.40 ± 0.14 Daily step count: 5869 ± 4160	WOMAC: Pain: $P = 0.059$ Stiffness: $P = 0.313$ Function: $P = 0.89$ SF-36 Physical: $P = 0.376$ Gait velocity: $P = 0.203$ Stride length: $P = 0.112$ Daily step count: $P = 0.828$

(continued)

Table 2. (continued)

Authors (Year)	Description of Brace	Baseline Clinical Outcomes	Final Clinical Outcomes	P Value/Significant Improvement
Jones et al (2013) ²⁵	Valgus knee brace (DonJoy OAdjuster)	WOMAC: Pain: 50 ± 15.7 Stiffness: 61.5 ± 20.3 Function: 54.2 ± 13.9 VAS (1-10): 6.7 ± 1.8	WOMAC: Pain: 36.8 ± 11.7 Stiffness: 54.2 ± 33.8 Function: 46.7 ± 14.5 VAS (1-10): 5.3 ± 2.1	WOMAC: Pain: P = 0.05 Stiffness: NS Function: P = 0.05 VAS: P = 0.05
Katsuragawa et al (1999) ²⁶	Valgus knee brace Unloader (Generation II Orthotics)	Bone mineral density: 60 ± 8	Bone mineral density: 71 ± 9	Bone mineral density: P = 0.0176
Kirkley et al (1999) ²⁷	Custom Generation II valgus-producing functional knee unloader brace (Generation II Orthotics)		WOMAC: Mean aggregate change score: 229.1 mm Mean change score for pain: 43.2 mm Mean change score for stiffness: 28.6 mm Mean change score for physical function: 157.2 mm MACTAR: 41.6 mm 6-minute walk test (change score): 29.6 m Change score for pain after walking test: 16.3 mm Thirty-second stair-climbing test (change score): 11.03 steps Change score for pain after stair test: 20.4 mm Clinical success: n = 25 (61%)	See Table 3 for comparisons
Lamberg et al (2015) ²⁹	Rebel Reliever (Townsend Design) decompressive knee brace	6-minute walk test: 485 m	6-minute walk test: 558 m	6-minute walk test: P < 0.05 KOOS: Pain: P < 0.001 Symptoms: P < 0.01 ADL: P < 0.001 QoL: P < 0.001
Lamberg et al (2016) ³⁰	Rebel reliever (Townsend Design) decompressive knee brace	Gait velocity (m/s): 1.17 ± 0.20	Gait velocity (m/s): 1.30 ± 0.20	Gait velocity: P < 0.05

(continued)

Table 2. (continued)

Authors (Year)	Description of Brace	Baseline Clinical Outcomes	Final Clinical Outcomes	P Value/Significant Improvement
Laroche et al (2014) ³²	ODRA brace (Distraction and Rotation Orthotic Device)	VAS (1-10): 6.3 ± 1.1 WOMAC: Pain: 54 ± 14 Stiffness: 54 ± 19 Function: 56 ± 13 Gait velocity (m/s): 0.98 ± 0.24 Stride length (m): 1.08 ± 0.2 Cadence (cycles/min): 53.4 ± 6.6 Step width (m): 0.28 ± 0.05	VAS (1-10): 3.0 ± 1.3 WOMAC: Pain: 32 ± 16 Stiffness: 38 ± 13 Function: 32 ± 15 Gait velocity (m/s): 1.08 ± 0.26 Stride length (m): 1.13 ± 0.21 Cadence (cycles/min): 56.4 ± 7.2 Step width (m): 0.28 ± 0.06	VAS: <i>P</i> < 0.01 WOMAC: Pain: <i>P</i> < 0.05 Stiffness: <i>P</i> < 0.05 Function: <i>P</i> < 0.05 Gait velocity: <i>P</i> < 0.05 Stride length: <i>P</i> < 0.05 Cadence: <i>P</i> < 0.05 Step width: NS
Larsen et al (2013) ³³	Custom medial pivot-design valgus brace (Free Stride; VQ orthocare)	LEAS: KL grade 1 or 2: 11.27 ± 3.41 KL grade 3 or 4: 10.00 ± 2.52 KSS KL grade 1 or 2: 33.50 ± 14.15 KL grade 3 or 4: 20.00 ± 8.94 Total knee scores: KL grade 1 or 2: 77.52 ± 16.95 KL grade 3 or 4: 61.13 ± 14.22	LEAS: KL grade 1 or 2: 12.20 ± 2.66 KL grade 3 or 4: 10.10 ± 2.73 KSS KL grade 1 or 2: 38.13 ± 11.32 KL grade 3 or 4: 29.50 ± 15.54 Total knee scores: KL grade 1 or 2: 81.13 ± 11.38 KL grade 3 or 4: 72.68 ± 16.79	LEAS: KL grade 1 or 2: <i>P</i> = 0.033 KL grade 3 or 4: NS KSS KL grade 1 or 2: <i>P</i> = 0.289 KL grade 3 or 4: <i>P</i> = 0.472 Total knee scores: KL grade 1 or 2: <i>P</i> = 0.344 KL grade 3 or 4: <i>P</i> = 0.443
Moyer et al (2017) ³⁹	Custom-fit valgus knee brace (Ossur XT Unloader; Ossur Americas)	Compared with control group (Table 3)	Compared with control group (Table 3)	Compared with control group (Table 3)
Ormetti et al (2015) ⁴⁴	Knee brace with the OdrA system (PROTEOR)	VAS (0-100): Pain: 63.1 ± 12.8 Disease severity: 64.2 ± 16.5 KOOS (0-100): Pain: 42.6 ± 12.5 Symptoms: 54.4 ± 17.3 ADL: 44.5 ± 12.6 SL: 14.5 ± 13.4 QoL: 28.6 ± 17.4 Gait velocity (m/s): 0.98 ± 0.24 Stride length (m): 1.08 ± 0.20 Frequency (cycle/min): 53.4 ± 6.6 Stride width (m): 0.28 ± 0.05	VAS (0-100): Pain: 38.1 ± 17.4 Disease severity: 36.9 ± 15.9 KOOS (0-100): Pain: 54.3 ± 13.2 Symptoms: 60.2 ± 16.2 ADL: 58.5 ± 12.7 SL: 34.0 ± 12.4 QoL: 45.7 ± 16.5 Gait velocity (m/s): 1.08 ± 0.26 Stride length (m): 1.13 ± 0.21 Frequency (cycles/min): 56.4 ± 7.2 Stride width (m): 0.29 ± 0.06	VAS: Pain: <i>P</i> < 0.05 Disease severity: <i>P</i> < 0.05 KOOS: Pain: <i>P</i> < 0.05 Symptoms: <i>P</i> < 0.05 ADL: <i>P</i> < 0.05 SL: <i>P</i> < 0.05 QoL: <i>P</i> < 0.05 Gait velocity: <i>P</i> < 0.05 Stride length: <i>P</i> < 0.05 Frequency: <i>P</i> < 0.05 Stride width: <i>P</i> < 0.05

(continued)

Table 2. (continued)

Authors (Year)	Description of Brace	Baseline Clinical Outcomes	Final Clinical Outcomes	P Value/Significant Improvement
Ostrander et al (2016) ⁴⁵	Medial Unloader brace (Fusion OA; Breg, Inc)	KOOS OIs: Pain: 59.5-66.9 Symptoms: 58.0-66.2 Function in daily living: 64.2-72.6 Function in sport and recreation: 30.1-43.7 Knee-related QoL: 30.8-41.2 Total: 56.2-64.0	Compared with control group (Table 3)	Compared with control group (Table 3)
Pollo et al (2002) ⁴⁷	Custom-manufactured valgus braces (Generation II UnloaderADJ brace; Generation II USA, Inc)	VAS: Pain (mm): 7.9 ± 2.2 Activity level (%): 36 ± 26 Gait velocity (m/s): 1.32 ± 1.0	VAS: Pain (mm): 4.4 ± 2.7 Activity level (%): 61 ± 23 Gait velocity (m/s): 1.28 ± 1.0	VAS: Pain: $P = 0.0012$ Activity level: $P = 0.0010$ Gait velocity (m/s): NS
Ramsey (2007) ⁴⁸	Custom knee braces (Generation II Unloader Select; Generation II USA)	Compared with control group (Table 3)	Compared with control group (Table 3)	Compared with control group (Table 3)
Richards (2005) ⁴⁹	Generation II ADJ Unloader (Gill Orthotics Europe)	VAS: Rest: 4.9 Walking: 8.0 Standing: 6.0 Stairs: 8.5 HSS: 49.3 ± 6.3	VAS: Rest: 2.9 Walking: 5.4 Standing: 4.8 Stairs: 5.9 HSS: 65.7 ± 12.5	VAS: Rest: $P < 0.05$ Walking: $P < 0.05$ Standing: NS Stairs: $P < 0.05$ HSS: $P < 0.05$
Sattari and Ashraf (2011) ⁵¹	Varus correct 3-point knee brace	VAS: 7.5 ± 1.5 Walking distance (km): 1.5 ± 0.48	VAS: 3.1 ± 1.4 Walking distance (km): 2.6 ± 0.52	Severity of pain: $P = 0.020$
Schmalz et al (2010) ⁵²	Genu Arthro knee brace (Otto Bock)	VAS: 6.4 ± 1.7 Gait velocity (m/s): 1.27 Cadence (steps/min): 107 Step length (m): 0.71	VAS: 3.3 ± 1.9 Gait velocity (m/s): 1.36 Cadence (steps/min): 110 Step length (m): 0.73	VAS: $P \leq 0.01$ Gait velocity: $P \leq 0.01$ Cadence: $P \leq 0.01$ Step length: NS
van Raaij et al (2010) ⁵⁶	MOS Genu (Bauerfeind AG)		VAS change score: -1.0 ± 2.2 WOMAC (function) change score: 4.0 ± 18.9	Compared with control group (Table 3)
Yeung et al (2004) ⁵⁸	Generation II Unloader Express Brace	Compared with control group (Table 3)	Compared with control group (Table 3)	Compared with control group (Table 3)

ADL, activities of daily living; HSS, Hospital for Special Surgery; KL, Kellgren and Lawrence; KOOS, Knee injury and Osteoarthritis Outcome Score; KSS, Knee Society Score; LEAS, Lower Extremity Activity Scale; MACTAR, McMaster-Toronto Arthritis Patient Preference Questionnaire; NS, not significant (exact P value not reported); OA, osteoarthritis; QoL, quality of life; ROM, range of motion; SF-36, Short Form-36; SL, sport and leisure activities; VAS, visual analog scale; VER, valgus and external rotation; V3P, valgus brace with 3-point bending force mechanism; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

Table 3. Summary of comparative outcomes between valgus brace and control groups

Authors (Year)	Comparison Group	P Value/Significant Difference
Della Croce et al (2013) ¹¹	Unbraced	Gait velocity: ND VAS: $P = 0.12$
Dessery et al (2014) ¹²	ACL brace	Pain (VAS): $P = 0.41^a$ Gait velocity: $P = 0.54^a$
Duivenvoorden et al (2015) ¹⁶	Lateral-wedged insoles	Improved walking distance: $P = 0.375$
Fantini Pagani et al (2013) ¹⁷	Neutral brace	Perception of comfort during rest or gait: NR Perception of changes in gait: NR Acceptance as treatment option: NR
Jones et al (2013) ²⁵	Lateral-wedged insole	Comfort: $P = 0.001$ in favor of the insole Usage: $P = 0.001$ in favor of the insole Gait velocity: ND WOMAC (pain, stiffness, or function): ND
Kirkley et al (1999) ²⁷	(1) Standard treatment for OA, (2) neoprene sleeve	WOMAC aggregate score: (1) $P < 0.001$ (2) $P = 0.066$ WOMAC pain: (1) $P < 0.001$ (2) $P = 0.045$ WOMAC stiffness: (1) $P < 0.001$ (2) $P = 0.91$ WOMAC physical: (1) $P = 0.001$ (2) $P = 0.081$ MACTAR change score: (1) $P = 0.017$ (2) $P = 0.174$ 6-minute walk test: (1) $P < 0.001$ (2) $P = 0.021$ Thirty-second stair-climbing test: (1) $P < 0.001$ (2) $P = 0.016$
Moyer et al (2017) ³⁹	(1) No orthoses, (2) lateral-wedge insole	Gait velocity during stair ascent and descent: (1) and (2)—ND
Ostrander et al (2016) ⁴⁵	Unbraced	KOOS: Less pain: $P < 0.001$ Fewer arthritis symptoms: $P = 0.007$ Better ability to engage in ADL: $P = 0.008$ Ability to engage in sport and recreation: $P = 0.402$ QoL: $P = 0.718$ VAS: Less pain: $P = 0.21$ Better activity levels: $P = 0.35$ Ability to sleep: $P = 0.117$ NSAID use: $P = 0.138$

(continued)

Table 3. (continued)

Authors (Year)	Comparison Group	P Value/Significant Difference
Ramsey (2007) ⁴⁸	Neutral brace	KOOS: Symptoms: $P = 0.049$ Pain and ADL: ND
Sattari and Ashraf (2011) ⁵¹	Unbraced	Severity of pain (VAS): $P = 0.020$ Walking distance: $P = 0.034$
van Raaij et al (2010) ⁵⁶	Lateral-wedge insole	Pain severity (VAS, 0-10): Difference between groups (95% CI): 0.06 (–1.05 to 0.93) Effect size: 0.03 Function (WOMAC, 0-100): Difference between groups (95% CI): 0.15 (–7.95 to 7.65) Effect size: 0.008
Yeung et al (2004) ⁵⁸	Neutral brace	Minimize the increase in pain: $P = 0.037$ Minimize difficulty in function: $P = 0.032$ Minimize stiffness: $P = 0.021$

ACL, anterior cruciate ligament; ADL, activities of daily living; KOOS, Knee injury and Osteoarthritis Outcome Score; MACTAR, McMaster-Toronto Arthritis Patient Preference Disability Questionnaire; ND, no difference (exact P value not reported); NR, not reported; NSAIDs, nonsteroidal anti-inflammatory drugs; OA, osteoarthritis; QoL, quality of life; VAS, visual analog scale; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

^aDifference between orthoses (ACL brace, unloader brace with valgus and external rotation [VER], and valgus brace with 3-point bending force mechanism [V3P]).

reviewers at all stages of study screening. Furthermore, the agreement for all screening stages was substantial. The level of evidence of included studies was primarily level 2 evidence, thus improving the quality of this systematic review.

Limitations

There were some limitations of this systematic review as well. We were unable to pool data in the form of a meta-analysis because of the heterogeneity of outcome measures and the various comparison groups used in the included studies. In addition, most studies had small sample sizes, with very few having more than 100 patients. There are numerous different recognized scoring systems that can be used for each clinical outcome, and this can also make it difficult to draw direct comparisons between groups. Many studies compared valgus offloader braces with control groups; however, the exact treatment protocol was not always described for the control group. In addition, included studies do not quantify the delay in proceeding with TKA when using offloader braces. In a study by Lee et al,³⁵ 63 patients with unicompartmental knee OA pending TKA were prescribed an offloader brace; 25 patients ultimately did not proceed with TKA as a result of improved symptoms. Quantifying the duration by which offloader braces can delay or avoid TKA would increase utilization by primary care providers and specialists. Finally, compliance was rarely examined within the included studies, which could affect the true treatment effects of braces.

Future studies should encompass compliance as an outcome, as this can help determine the overall cost-effectiveness and generalizability of offloader bracing as a treatment modality. An additional factor that would be useful to examine is the degree of OA present and the effectiveness of the offloading brace at that stage of disease. This would help guide treatment decision-making for patients with various severities of knee OA. Randomized studies with larger sample sizes and constituent methodology/outcome measures should also be conducted to better determine the efficacy of offloader bracing compared with other treatments for knee OA.

CONCLUSION

The majority of literature supports valgus offloader bracing as an effective treatment for improving pain secondary to medial compartment knee OA. The literature remains unclear on the effectiveness of valgus offloader braces at improving function and stiffness. Larger prospective randomized trials with consistent outcome assessment tools and consideration of patient compliance would be beneficial to determine more accurate treatment effects of valgus offloader bracing.

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