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Current state of unloading braces for knee osteoarthritis

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Abstract
Purpose Unicompartmental knee osteoarthritis (OA) is often treated with the prescription of an unloading knee brace to decrease pain and stiffness. Braces have been shown to improve the quality of life by applying an external moment to offset increased compressive tibiofemoral contact loads, but evidence regarding mechanical efficacy at the joint is controversial. Thus, the purpose of this study was to review the current state of unloading braces on knee mechanics, clinical impact, and long-term disease progression.
Methods A literature search was performed through the PubMed MEDLINE database for the search terms "osteoarthritis," "knee," "brace," and derivatives of the keyword "unload." Articles published since January 1, 1980 were reviewed for their relevance. Evidence for the effectiveness of unloading braces for disease management both biomechanically and clinically was considered.
Results While significant research has been done to show improvement in OA symptoms with the use of an unloading brace, current literature suggests a debate regarding the effectiveness of these braces for biomechanical change. Clinical findings reveal overall improvements in parameters such as pain, instability, and quality of life.
Conclusion Although clinical evidence supports brace use to improve pain and functional ability, current biomechanical evidence suggests that unloading of the affected knee compartment does not significantly hinder disease progression.
Level of evidence III.

Keywords Brace · Unload · Knee · Osteoarthritis

Introduction

Due to the high prevalence of knee osteoarthritis (OA) and the knee's weight-bearing role in activities of daily living [36, 39, 52], minimizing pain and increasing function in those with this disease has become particular concern [79]. Disease progression stems from altering force application on articular cartilage that has adapted to native biomechanical cyclic loading patterns over time, resulting in a mechanical heterogeneity across the knee joint contact surfaces [13, 20, 29]. Altered tibiofemoral kinematics and resulting contact mechanics due to injuries such as ligament tears [13, 16] or traumas can result in loading patterns shifted to areas poorly suited for such stresses, causing cartilage degeneration to occur in an isolated area [6, 19, 29, 65].

Although OA is incurable, unicompartmental knee OA has been treated with braces designed to unload the degenerating joint compartment in the osteoarthritic patient in an overall effort to maintain general physical health [32, 55, 66, 79]. The unloading theory of knee bracing is implemented by applying an external force to the joint that distracts the stress from the affected compartment of the tibial plateau [35]. Clinicians have prescribed the use of such braces as an alternative or precursor to surgery with improving patient clinical outcomes and quality of life [79].

While the theory itself has shown success in cadavers [8] and such unloading bracing of unicompartmental knee OA is commonly prescribed, the in vivo biomechanical efficacy

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with habitual loading remains unclear [68]. Although clinical evidence shows improved quality of life and pain scores [11, 63], there is a lack of support that unloading mechanically prolongs disease progression. Past reviews on bracing and clinical outcomes [6, 9, 14, 35, 45, 63, 64, 68, 69, 78] have discussed the overall efficacy as a measure of patient satisfaction, description of available treatment methods, or how to improve clinical guidelines without a focus on the underlying mechanics. Thus, the purpose of this review was to critically assess the current research on biomechanical effects and clinical evidence of unloading braces for knee joint unicompartmental OA, revealing future directions and improvements for minimized long-term disease progression.

Materials and methods

Literature search and selection strategy

To evaluate the current findings on unloading brace efficacy for unicompartmental knee OA, a literature search was performed through the PubMed MEDLINE database for the combinations of the search terms "osteoarthritis," "knee," "brace," and derivatives of the keyword "unload." All articles, including reviews and original studies, were limited to those pertaining to humans and those written in the English language since January 1, 1980. Those not previously published in peer-reviewed scientific journals, except those published online as "Epub ahead of print," were excluded. However, no restrictions were placed on the definition or degree of OA in patients. Other exclusion and inclusion criteria are listed in detail in Fig. 1.

The initial search using any combination of the aforementioned search terms resulted in 156,755 relevant journal articles. Narrowing the search to more a constraining combination, guaranteeing the presence of both "brace" and "unload," resulted in 37 results. Remaining articles were subsequently reviewed more critically for their pertinence to therapeutic unloading of the knee joint for optimal OA treatment. Seventeen articles were removed for various reasons as described in Fig. 1. Reference sections of the remaining articles, particularly relevant past reviews

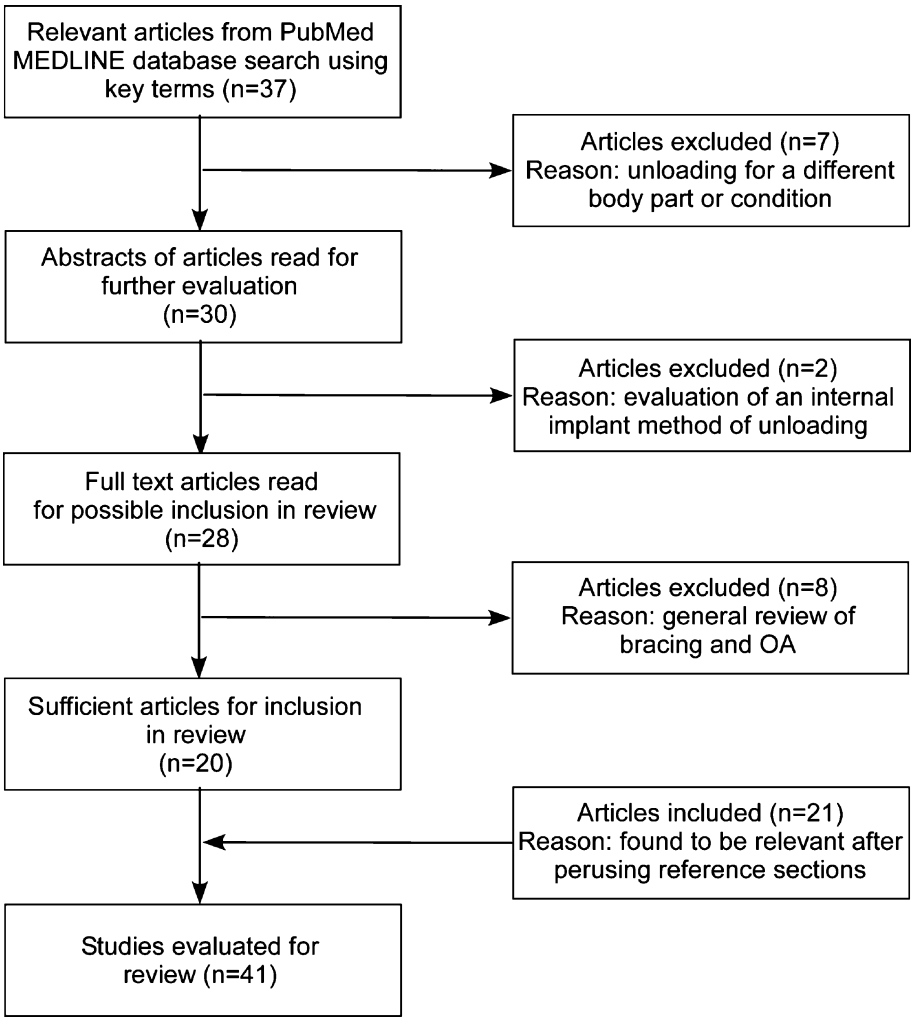

Fig. 1 A flowchart displaying the process of article selection with the number of studies identified, excluded, and included along with reasons for exclusion or inclusion

on similar areas of research ($n = 5$), were then perused for additional sources not included in the PubMed search. Searching the references of related articles resulted in the addition of 21 peer-reviewed articles (Fig. 1).

Data extraction

This review focused on assessing the biomechanical and clinical application of unloading knee bracing for the treatment for unicompartmental OA of the knee joint. Thus, studies were accepted for inclusion in the review based on the ability to critically evaluate the effectiveness of bracing in either or both categories (Fig. 2). Studies were primarily reviewed for current evidence for or against the recommendation for the use of OA unloading braces as a conservative treatment option along with the recent history of unicompartmental unloading. Additionally, gaps in the literature as well as where unloading bracing may be improved upon in the future were discussed based on the findings.

Results

History of unloading bracing for the treatment for OA

Unloading braces, termed as such if it is functionally designed to promote a valgus or varus alignment for those with medial or lateral OA, respectively, have been a focus in modern treatment techniques for OA with the rates of knee replacements increasing in both the elderly and those between the ages of 45 and 64 [48]. The Osteoarthritis Research Society International's (OARSI) guidelines for managing knee OA state a recommendation score of 76 % for the use of unloading braces in reducing pain and improving stability [83], and it has been further shown that the use of such braces can delay the need for surgery [55, 65]. However, the Cochrane Review has stated there is a limited amount of evidence on the effectiveness of brace treatment [12]. Despite this debate, the prescription of unloading braces has reportedly increased over the years with positive clinical outcomes [68]. Although recommendations based on clinical findings are high, patients with OA are often not informed of this option, with only 11 % of a group of 326 questioned patients told about a bracing option in 2004 [54]. In 2009, it was reported that 23 % of physicians and 9 % of rheumatologists prescribe unloading braces regularly with 32–51 % of physicians and 26–58 % of rheumatologists rarely or never prescribing them [6].

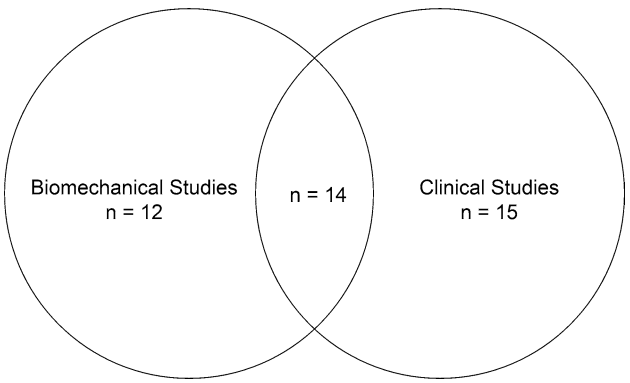

Fig. 2 Venn diagram depicting the distribution of studies ($n = 41$) evaluated in the present review for unloading bracing evidence

Biomechanical characteristics of OA

It has been shown that the most influential cause of medial knee OA is greater adduction moment due to malalignment in a bowlegged or varus position [4, 26, 44, 74] with lateral knee OA often caused by a valgus alignment [30, 74]. This altered alignment is detrimental to patients as it displaces the load to the medial compartment of the knee, leading to a greater external moment at the joint and eventually resulting in failure of the articular cartilage and narrowing of the joint space [3, 14, 74]. Numerous reports have shown the clear relationship between the resulting external adduction moments, shown in medial OA, from malalignment and disease progression [14, 38, 42, 44, 74]. Researchers have previously reported that an increase in 4–6° of varus alignment can increase medial compartment loading by 70–90 % during weight-bearing [76]. Further, as low as a 20 % increase in the peak adduction moment will increase the risk of OA progression [76]. The coupling of both varus deformity, currently existing or caused by external factors such as obesity [59, 72], and increased medial compartmental loading has been associated with a fourfold increase in the odds of disease advancement [74].

Knee OA is also exacerbated or caused by kinematics favoring unnatural loads on the tibia [19]. Altered kinematics can occur due to a number of factors including malalignment, changes in knee laxity, ligament injury, or anatomical trauma in the knee or surrounding joints [13, 16, 53, 73]. Any sudden change in a joint will change its natural biomechanics along with those in the same joint chain. Changes in kinematics, such as greater abduction or rotation throughout daily activities, can thus cause increased loads in poorly suited areas of cartilage, similar to the presence of malalignment alone. It has been shown retrospectively that individuals with medial compartment knee OA have greater peak tibiofemoral rotation, decreased tibial posterior translation, and decreased range of motion, resulting in exacerbated adduction moments at the joint [4, 19, 61, 78]. The significant correlation between varus and valgus alignment with compartmental knee OA [42, 74] along with exacerbating kinematics [19] leads to the creation of

treatment interventions with the goal of combating these mechanical variations.

Biomechanical evaluation of unloading bracing for OA

Based on the biomechanical characteristics of individuals with medial compartment OA, unloading braces should primarily aim to combat the compressive forces on the knee joint cartilage, as this is the direct cause of disease [74]. Thus, the ideal measure for determining whether unloading braces are successful in prolonging and assisting directly to the treatment for OA is to directly measure the contact forces in vivo [1]. Anderson et al. [1] were able to arthroscopically insert pressure sensors in the knee joint space of eleven patients with medial knee OA for the evaluation of force changes with brace use. However, no significant differences in pressure were found. The researchers concluded that although measure of joint contact forces in vivo is feasible, the sensors used likely moved with knee flexion, limiting conclusions [1]. Further, Pollo et al. [65] attempted to measure internal medial compartment loading using a model of external and internal forces affecting the knee joint. Despite many assumptions in this model, researchers found a significantly reduced medial compartment compressive load with brace use [65]. Other attempts at directly measuring medial internal loads have been made with a recent publication of a case series [51] of three patients who had undergone total knee arthroplasty and were subsequently implanted with an instrumented tibial tray that sent strain changes to an external receiver. Although limited by number of subjects and using postsurgical patients, shifting of medial loads on the tibial plateau was shown, which varied depending on the type of activity [51].

Due to the complications and difficultly in measuring direct contact patterns in vivo, many studies aim to measure the amount of joint space using radiographs and other images, which is less intrusive although not as direct as measuring joint contact patterns. Researchers have observed differing results with such methods [22, 37, 50, 60]. Particularly, Haladik et al. [37] found using dynamic biplane radiographs on ten patients that joint space was not affected by brace wear. Further, researchers found with the same images and model-based tracking that joint contact centers also did not change [37]. However, another group has found significant increases in joint space in the affected compartment with the use of unloading with no changes in those who were obese [21, 50], and others have found significance in joint space deviations in some brace brands but not others using video fluoroscopy [22, 60]. Another indirect measure of load displacement was performed by Katsuragawa et al. [47], who measured bone mineral density across the tibial plateau after the use of a valgus unloading brace for three months. Researchers reported a greater increase in bone mineral density in the lateral tibial condyle relative to the medial, suggesting a successful shift in force following brace wear.

Easily measured in vivo, typically using motion capture analysis along with ground force plates, knee adduction moments themselves can be indirect measures of changes in compressive loading [27, 65]. Current studies performed have shown significant decreases in knee adduction moment throughout daily activities such as walking and stair stepping [27, 28, 33, 41, 46, 55, 65, 67, 71, 77, 82]. Particularly, Johnson et al. [46] found in a level II prospective study that after 3 months of bracing, intervention peak adduction moment during normal gait was decreased by 48 %. However, some researchers have found no significant changes in tibiofemoral joint angles conducive to joint moments. Particularly, Haladik et al. [37] found no differences using a more accurate biplane image tracking approach.

Further, Ramsey et al. [67] found in a level II study that whether medial unloading braces were successful in reducing the adduction moment about the knee depended on the degree of which malalignment and instability was corrected based on the brace fit. Researchers concluded that although adduction angle did not change significantly whether the brace was set in a neutral alignment or valgus unloading alignment, the adduction excursion was affected, with a significantly decreased excursion in the valgus alignment relative to baseline and neutral conditions with excursion decreased from baseline to a lesser degree in the neutral alignment condition [67]. Similar results have been shown in a prospective cohort study on 18 individuals wearing an unloading brace with pneumatic technology, increasing external load by inflating instrumented air bladders as opposed to tightening load-displacing straps [18]. Della Croce et al. [18] observed a greater decrease in adduction moment following the inflation of the air bladders to 7 pounds per square inch (psi; lb/in^2) relative to walking in the brace uninflated and a larger difference existed relative to wearing no brace.

Some researchers have shown braces to shift the mechanical center axis off of the medial compartment with diminished varus angles [2, 17, 31, 46, 50, 57], while some have not seen significant changes [5, 37]. Particularly, Arazpour et al. [2] found an improved angle of 6 degrees in standing radiographs of individuals. In a therapeutic level II study, Draganich et al. [24] reported a significantly reduced varus alignment in those who wore a custom unloading brace, but found no significant difference in malalignment correction in the same individuals when wearing an off-the-shelf unloading brace [24]. The custom brace significantly reduced adductor moment relative to baseline with no brace as well as relative to wearing the off-the-shelf brace, showing increased improvements with the custom brace.

Further, other researchers have found that variances exist even if all braces tested are off the shelf [51].

However, deleterious kinematics can occur without the presence of malalignment. Orishimo et al. [62] observed the kinematic changes in normally aligned individuals in response to unloading of the joint for medial compartment OA. In this level II prospective study, researchers observed the effect of an off-the-shelf unloading brace at varying degrees of tension on 12 healthy subjects. Results showed increasingly decreased adduction moment with increasing external load with similar findings by other researchers [27].

Clinical evaluation of unloading bracing for OA

Notably, researchers have shown a clinical improvement due to unloading brace wear over other treatment options [49]. Kirkley et al. [49] performed a prospective randomized clinical trial that was comprised of three groups: a control group, a neoprene-sleeve group, and an unloading brace group. Each group, including the control group, was treated with standard medical management comprised of overall education on the disease, methods of coping, and how to maintain flexibility. They were further instructed to use acetaminophen and anti-inflammatory drugs as needed. After a six-month follow-up, patients in the unloading brace group showed improved stiffness, quality of life, and pain with both treatment types relative to control, although the unloading brace group displayed greater amounts of improvement [49]. Further, researchers found a significant decrease in the medication use with the prescription of a custom unloading brace compared to the use of a neoprene sleeve and obtaining no treatment.

Overall findings support an overwhelming improvement in pain in patients prescribed an unloading brace [5, 11, 23, 25, 27, 31, 33, 40, 41, 46, 49, 55, 57, 65, 70]. One study was found to show no significant improvement in quality of life with brace wear despite decreased medication use [12]. Specifically, Matsuno et al. [57] reported that 95 % of a group of individuals wearing a custom unloading brace for medial knee OA showed improved pain scores with walking. Similar results have been found in off-the-shelf braces as shown by a comparable walking study by Johnson et al. [46] Here, nine out of ten patients showed improved pain scores with 3 months of brace use. Also, with 3 months of wear, Draper et al.'s [25] work supports a decrease in pain using gait analysis. Pain improvements have also been reported with shorter lengths of brace use with Pollo et al. [65] among others [55] showing the quality-of-life benefits after only 2 weeks of wear. In addition to pain improvements alone, it has been shown that willingly performing daily activities had increased [31, 55] as well as a diminished need for oral pain medications [5, 12, 49].

Similarly, researchers have observed improvements in knee function [15, 17, 23, 25, 27, 33, 46, 55, 57, 70]. In addition to pain scores improved with walking in the previously mentioned study by Johnson et al. [46], researchers observed an improvement in various functional measures including walking speed and total range of motion [27, 33, 46, 77]. Further, improvements in muscle strength [6, 43, 57], proprioception [7], stability [56], and postural control [57] have been described. However, some studies have shown an improvement in pain without an improvement in daily function [41], including no change in postural control [7], range of motion [33], and gait parameters such as walking speed and stride length [43, 51, 65].

Various factors may contribute to differing results. One study in particular, by Draganich et al. [24], addressed possible alterations in quality of life and functional outcomes depending on whether the brace prescribed was custom-made or off the shelf. Clinically, researchers found that all parameters of pain, stiffness, and function were significantly improved with both the custom and off-the-shelf brace. However, the custom brace was further improved from the off-the-shelf option, giving additional benefits to those users [24]. Ramsey et al. [67] additionally found no difference in pain scores and quality of life in individuals wearing an OA brace in a neutral alignment relative to an unloading position with 4 degrees of alignment correction, suggesting that improvements in pain are correlated with the stability of the brace due to fit, not change in alignment. This was similarly found by Pollo et al. [65] in that significant changes in brace valgus moment existed when the brace correction was increased to 8 degrees or strap tension was increased.

Discussion

The most important finding of this review is that bracing with the purpose of displacing compressive loads from an affected knee joint compartment has positive clinical outcomes regarding pain and in most cases functionality and quality of life. There is a wide debate surrounding the mechanical function of unloading braces in increasing joint space, distracting compressive loads to the opposing compartment, and decreasing resulting knee moments [6, 67]. Although numerous studies show decreased adduction moments with bracing in individuals with medial compartmental disease using motion capture analysis, other parameters remain unchanged or reveal ambiguous data [1, 37]. Despite the strong association of knee moments with OA progression, these moments do not directly cause OA alone. Malalignment along with joint space narrowing is the crucial factor, with a lack of biomechanical evidence showing a significant change following bracing.

Despite the overall support for brace use clinically, the group of patients benefitting the most from brace wear has not been determined. Positive outcomes may depend on the patient's maintenance of treatment duration and consistency. A low likelihood of continued brace use after 1 year with a survival rate of 25 % after the second year has been reported in 2013 [75] with similar findings in past years [34]. The same results have been found with patient follow-ups at various time points, with discontinued use commonly due to discomfort from the high forces imparted on the knee, skin irritation, and poor brace fit [5, 41, 56, 75, 80]. Data on true continued use of unloading braces are limited due to the various prescriptions by clinicians, as some individuals need the brace to reduce their pain in activities of daily living such as walking and ascending stairs while some only need pain relief during recreational sports [31].

It is also notable that brace wear varies by the individual. Typically, braces are only worn when the patient experiences symptoms, which makes it difficult to compare current studies [31, 43, 75]. In fact, some patients only have OA pain when performing recreational or competitive athletics and thus wear the brace only during this time. These individuals would likely remove the brace when pain is not limiting their activity, leaving time periods where there is no brace use and weight-bearing stresses are not distracted. Thus, currently published biomechanical studies supporting the use of the brace are not always relevant. Braces are currently used to help patients reduce symptoms of OA not to specifically reduce weight-bearing stresses in the joint. Thus, patients whose OA has progressed to a degree where a brace is needed in order to maintain function throughout daily life are more likely to show correlations between brace dosage and functional biomechanical outcomes [43].

Based on this review, it was particularly notable that the research involving patients diagnosed with lateral compartment OA was lacking. Medial compartmental disease is more common with rates of 29 and 8 % of medial and lateral compartment OA, respectively, in a group of 5,202 individuals in 2012 [81]. This is likely due to the mechanical promotion of weight displacement on the medial tibial plateau with a greater contact surface and common varus alignment [51, 78]. For instance, it is estimated that 60–80 % of weight-bearing loads during walking is distributed to the medial compartment of the knee [6]. Different mechanisms of load displacement may warrant research specialized for those using braces to correct a valgus posture.

It was also noted that in the literature, there are currently few studies evaluating the effect on surrounding joints [3, 10, 58, 77]. Just as osteoarthritis can develop following alterations in kinematics [13, 19], the correction of these mechanics localized to the knee can have global consequences [77]. For instance, Toriyama et al. [77] found significant changes in the affected knee joint as well as at the ipsilateral hip and contralateral hip and knee. Further, it should be considered what effect a medial compartmental unloading brace, for instance, has on the lateral compartment of the knee [47]. Although assisting in the management of medial knee OA, a brace designed to shift the weight-bearing load could exacerbate the stresses on the opposing compartment with possible deleterious effects in the long-term despite short-term quality of life and pain improvements [47].

Conclusion

While significant research has been done to show improvement in OA symptoms with the use of an unloading brace, current literature suggests a debate regarding the effectiveness of these braces for biomechanical change. Medial compartment compressive loads, successfully decreased by unloading in cadaver studies [8], may not be directly affected by adduction moment alone in vivo, leading to a need to address more parameters such as joint space in improved brace technologies [62]. Other parameters affecting compressive stresses may be resolved by various fit and alignment, which stems the debate regarding the lack of or the presence of long-term mechanical efficacy. The feasibility of directly measuring in vivo compressive loads has been shown [1, 51, 65], leading to the future direction of research regarding OA isolated to the knee joint. It is these data along with controlled and maintained doses that will afford a resolution of unloading brace efficacy both biomechanically and clinically.

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