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Bracing and Orthoses: A Review of Efficacy and Mechanical Effects for Tibiofemoral Osteoarthritis

Neil A. Segal, MD, MS, CSCS

Abstract: The knee is the weight-bearing joint most commonly affected by osteoarthritis. Bracing of the knee or the foot can be a useful nonoperative and nonpharmacologic treatment for persons with osteoarthritis that predominantly involves either the medial or lateral tibiofemoral compartment. The aim of wedged insoles and realigning knee braces is to reduce articular contact stress in the more involved tibiofemoral compartment. There is evidence that even knee sleeves that do not have an effect on alignment may confer symptomatic relief and enhance joint position sense. This review summarizes the current state of knowledge regarding the degree to which bracing at the knee or foot can effectively correct tibiofemoral malalignment, improve knee joint pain, and enhance physical function, and provides clinical recommendations for prescription of these devices to optimize effectiveness.

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INTRODUCTION

Osteoarthritis (OA) is a leading cause of disability in older adults. All structures involved with the joint are affected, including not only the loss of hyaline cartilage but also subchondral bone attrition and remodeling, meniscal degeneration, ligamentous laxity, fat pad extrusion, and impairments of neuromuscular control. The overall effect of these changes is to alter the distribution of loads over the articular surface [1]. This process contributes to a cycle by which aberrant loading leads to further worsening of the disease. Once loads are inappropriately distributed, erosion of the articular cartilage results in malalignment, which interferes with the ability of ligaments to restrict joint motion to preserve physiological load distribution. Focal overload of the articular surface accelerates disease progression. In this context, pain inhibition and alteration of the line of action of muscles can reduce their ability to protect the joint. Although OA affects numerous joints, this review of biomechanical therapies will focus on tibiofemoral knee OA, which has been studied to a greater extent than other joints. Adverse loading of the articular surface almost certainly plays an important role in the development of OA, which can occur because of abnormal biomechanics acting on normal cartilage and bone or because of normal biomechanics acting on abnormal cartilage and bone. Either of these, in the context of impaired capacity to heal (eg, older age, inflammation, insufficient muscle strength, excessive body weight, or joint injury) can lead to OA.

Approximately 25% of persons older than age 55 years experience episodes of persistent knee pain [2]. The medial compartment is by far the most frequently affected. The reason for the preponderance of medial involvement is that, during the mid-stance phase of gait, approximately 70%-80% of the joint load passes through the medial compartment because the center of the mass is located medial to the knee joint center [3]. Malalignment may further skew this distribution. The relative load on the medial compared with the lateral compartment is estimated by the external knee adduction moment (EKAM), which is the torque pulling the knee into varus. For patients with unicompartmental tibiofemoral OA, there is evidence that realigning therapies could potentially confer a disease-modifying effect [4,5]. However, there are mixed results regarding the effectiveness of various therapies for realigning the knee, altering adverse loading, improving symptoms and physical function, and modifying the course of OA.

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The medial and lateral compartments of the tibiofemoral joint accept body weight from the femur onto the tibia while allowing a small degree of axial rotation. The passive stabilizers are the cruciate ligaments, collateral ligaments, and menisci. The principal active stabilizers are the quadriceps, hamstrings, and gastrocnemius muscles, although additional muscles also contribute. It, therefore, is not surprising that injury to the passive stabilizers and weakness of the active stabilizers have been identified as risk factors for incident symptomatic and progressive knee OA [6-8]. Current bracing for alleviation of tibiofemoral OA is directed at realignment of the joint but may have nonspecific effects on the active stabilizers. Immobilizer or "rest" braces are not good long-term solutions for a chronic disease such as knee OA, because they may result in weakening of the "natural brace" for the knee joint, ie, the muscle brace. Therefore, this review will be confined to use of dynamic bracing of the knee and foot, which allows joint movement.

MALALIGNMENT

Malalignment of the mechanical axis of the lower limb (the angle formed by joining the hip, knee, and ankle joint centers) is a risk factor for progression of radiographic joint-space narrowing [4], cartilage loss on magnetic resonance imaging (MRI) [9-11], and decline of physical function [4]. After multivariate adjustment, bilateral lower limb malalignment of more than 5° (either varus or valgus) has been associated with a greater degree of physical functional decline in comparison with less than 5° of malalignment [4]. Although the focus of much research has been on tibiofemoral OA, malalignment may also contribute to development of patellofemoral OA [12]. Therefore, there is a theoretical rationale for using bracing to reduce malalignment of the knees in individuals with or at risk for OA to reduce contact stress, pain, and functional limitations, and possibly to slow disease progression.

One biomechanical approach to unicompartamental tibiofemoral OA is to reduce loading and to improve symptoms by redistributing the load to the relatively unaffected compartment. The principal functions of bracing are to maintain alignment of a joint, to stabilize a joint, to reduce articular contact stress, and to reduce adverse muscle contraction. The following sections will review the current state of knowledge regarding the degree to which bracing at the knee or foot can effectively reduce joint pain and possibly correct malalignment. Of note, bracing may also improve periarticular sensorimotor function in patients with tibiofemoral OA and, therefore, may have effects that are unrelated to anatomical joint realignment.

ORTHOTIC OPTIONS FOR KNEE OA

Laterally Wedged Insoles

The Osteoarthritis Research Society International [13] and the American College of Rheumatology [14] recommend the

use of laterally wedged insoles for medial compartment knee OA. The goal of these foot orthoses is to increase foot pronation and to shift the center of pressure of the foot laterally to shorten the moment arm between the ground reaction force and the knee joint center, thereby reducing medial compartment loading. Off-the-shelf laterally wedged insoles are available from a variety of vendors and can also be formed in the office or incorporated into custom-molded insoles with additional features. The wedged portion may be heel length or one-half, two-thirds, or full length, with varying heights of 6-12 mm. Due to the variability in length, height, material properties, and concurrent kinetic chain impairments, research findings may not be extrapolated to different wedged insoles or patient populations.

There have been mixed results regarding whether wedged insoles may be effective for knee realignment or symptomatic relief. Inserted laterally wedged insoles do not appear to correct the femorotibial or hip-knee-ankle angles [15-18]. However, static measurements do not correlate well with dynamic alignment of the lower limb (eg, EKAM). Several studies of full-length wedged insoles have reported a reduction in the EKAM in healthy adults [19] and in patients with mild or moderate medial compartment OA immediately, and at 1-3 months after initiation of use [16,20,21]. However, heel wedges and two-thirds length laterally wedged insoles have not demonstrated a consistent reduction in the EKAM. In addition, wedged insoles have not consistently relieved pain [22-24].

Reasons for these inconsistent results have not been fully elucidated but may relate to disease severity [20], insole length [25], or patient characteristics. For example, Keating et al [26] reported that some patients with knee OA who had an excessive subtalar joint valgus angle received no analgesic or physical functional benefit from use of a laterally wedged insole. In addition, Kakahana et al [27] demonstrated that, in contrast to older adults without knee OA, a laterally wedged insole did not consistently reduce the EKAM in those with knee OA, and even increased the EKAM in some [28]. Most recently, Kutzner et al [29] reported that, in a group of subjects with instrumented knee implants, the use of wedged shoes or wedged insoles did not provide a consistent reduction in medial compartment loading. However, there were significant between-subject differences in response due to a portion of the effect of the wedges being lost at the ankle joint [29]. These studies suggested that there are mechanical limitations of lateral wedges for treatment of knee OA but that full-length wedged insoles may have a more consistently positive biomechanical effect.

The lack of consistency in both reduction in EKAM and relief of pain also may relate to averaging results of responders and nonresponders, reduced response with a longer duration of use, use in patients with more than unicompartamental involvement, or inappropriate patient selection. One interesting finding is that, in comparison with neutral in-

soles, laterally wedged insoles have been shown to reduce use of oral analgesics in patients with medial knee OA at 6 months and 2 years, despite a lack of improvement in self-reported pain and physical function [22,30].

Considering the evidence that compartmental loading predicts progression of anatomical worsening, in the context of the reduction in loading of the affected compartment in some patients who use wedged insoles, there is a need to assess whether use of wedged insoles also might reduce the rate of knee OA progression. Clinical trials of 1-2 years' duration have not demonstrated disease modification in participants who wore laterally wedged insoles [22,31]. It is possible that the duration of these studies was insufficient to allow detection of an effect on OA progression, because a minimum of 2 years may be necessary to detect progression of cartilage loss. It is also possible that, because patients had pre-existing moderate knee OA, wedged insoles may not have had as great an effect as they may have in individuals with early knee OA [32].

A systematic review of the efficacy and safety of wedged insoles published by the National Institute of Health and Clinical Excellence of the United Kingdom in 2008 concluded that wedged insoles provided no significant benefit for knee pain severity, stiffness, function, and disability, and patients' global assessment of functioning. However, this review did recognize the significant reduction in the use of analgesics [22].

In addition to assessing the potential benefits, some studies have characterized potential contributors to adverse outcomes. Properties of the laterally wedged insole, such as material (eg, rubber, cork, foam,), length, tilt angle, and the addition of strapping can influence both the beneficial effects as well as the adverse effects [21,25,33,34]. There appears to be a dose-response with a higher tilt angle that results in greater realignment but also more adverse events. In 1 study that compared 5° and 10° laterally wedged insoles with comparable thickness neutral insoles, the 5° wedge reduced the peak EKAM by approximately 6% and the 10° wedge by approximately 8% [21]. The investigators noted that the 10° wedge was less well tolerated due to pain. Similar findings were reported by another investigator, who compared 8-, 12-, and 16-mm-thick compressible wedged insoles, with more than 40% of the subjects reporting worsening symptoms with the 16-mm-thick wedged insole [35]. The lateral wedge used in that study was augmented with an ankle strap, which has been reported to lead to more adverse effects compared with laterally wedged insoles without strapping [15]. In addition to the increased symptoms of popliteal pain, low back pain, and plantar foot pain with the use of strapping, it is unclear whether knee pain or the Lequesne score significantly differed when comparing strapped and non-strapped wedged insoles at 2-year follow-up [36].

In summary, there is evidence that laterally wedged insoles may reduce the relative load on the medial compart-

ment and symptoms in at least some patients with mild or moderate medial compartment knee OA. However, there is insufficient evidence to guide clinicians regarding which patients are most likely to benefit. Decisions regarding their use must balance the potential positive effects with the potential adverse effects. Use of thicker wedges or the addition of strapping may be more likely to lead to adverse outcomes.

Accommodative Bracing: Flexible Knee Sleeves

Knee sleeves provide warmth and mild compression, and are made from cotton elastic or from neoprene, nylon, or other synthetic fibers, so even patients with allergies may find a knee sleeve that is tolerable. Some sleeves have a patellar cutout, an open popliteal fossa, a patellar reinforcement with C- or J-shaped cushions with or without buttress straps, and/or built-in lateral stays to increase stiffness. Although there is no appreciable effect on joint alignment or stability, knee sleeves have demonstrated effectiveness in improving OA symptoms [37,38]. This effect of simple neoprene sleeves has been superior to the use of analgesic medications even at a 6-month follow-up but not as great as that compared with the use of a corrective knee brace (see Corrective Bracing: Rigid Realignment Braces section) [38]. Based on current knowledge, knee sleeves may be most helpful in treating early knee OA, even when tri-compartmental.

The mechanism for alleviation of symptoms does not appear to be due to a warming effect. Heat-retaining sleeves in a 4-week study did not demonstrate greater relief of pain, stiffness, or physical disability in comparison with standard sleeves [39]. One study with a crossover design revealed improved static and dynamic balance with the use of an accommodative neoprene sleeve [40], which led to supposition that knee sleeves may provide analgesia through enhancing joint proprioception. However, the mechanism of action of knee sleeves remains incompletely understood.

Corrective Bracing: Rigid Realignment Braces

For treating knee OA that is moderate or severe but that does not involve both the medial and lateral compartments, there is evidence that corrective braces are more effective than knee sleeves. Sagittal-plane braces have been modified for patients with knee OA by angling the hinge in the frontal plane to create a valgus or varus force, with the goal of reducing loading and symptoms of unicompartmental knee OA. Certain variants also permit the insertion of an adjustable patellar sleeve to induce medial or lateral traction on the patella by using Velcro straps (Velcro USA Inc., Manchester, NH) and cushions around the patella. Such braces can be helpful in alleviating symptoms of both tibiofemoral and patellofemoral OA by reducing loading in the more affected compartment,

by improving stability of a knee with ligamentous laxity, and by enhancing proprioception.

There are numerous models of realigning knee OA braces. In general, the degree of correction is adjusted by either single or double upright hinges, dynamic force straps, or adjustment of the femoral condyle pads. Some braces use muscle power to direct a force against the medial or lateral knee during terminal extension, which relieves pain even in the context of moderate-to-severe OA. Some models have restraint systems and buckles to enable suspension of the brace on limbs that may not tolerate a rigid brace or enable patients with reduced grip strength to adjust the straps. Other models incorporate an extension stop to prevent painful full extension. In addition, gel pads can dissipate load over a larger area to improve comfort over the femoral condyles.

More recent designs have incorporated lightweight materials, a single upright hinge placed opposite the involved knee compartment, or an air bladder that adjusts the angle of the hinge (Figure 1). Single-upright braces have less effect on stabilization of the knee joint but have a lower profile. The lower profile contours and breathable fabric have improved airflow and aesthetic appearance, which allows patients to

wear these braces under their clothing. Some fabrics are designed to stretch in the superior-inferior dimension, but not circumferentially, which enhances fit. These advances have improved tolerance and compliance in comparison with prior brace models and should be considered in the orthotic prescription.

Biomechanics of Knee Realignment Braces

Studies of the effects of corrective braces have focused on either the alteration of pathomechanics known to be associated with knee OA or on the alleviation of pain and mobility limitations. Because one of the cardinal signs of knee OA is joint-space narrowing, and progression has been associated with aberrant loading, biomechanical studies have assessed improvement in joint-space width as well as the effectiveness of braces for redistributing loads within the knee joint. In 1 study of a single-upright valgus realignment brace, fluoroscopic assessment of the knee joint during gait demonstrated an average increase in medial condylar separation of 1.2 mm and a tibiofemoral coronal angle change of approximately 2.2° at initial contact [41]. This magnitude of change was achieved with



Figure 1. Realigning braces for patients with knee osteoarthritis induce a valgus or varus torque on the knee, with the aim of reducing contact stress in the involved medial or lateral knee joint compartment, respectively. Four main brace designs for right knee medial compartment osteoarthritis are depicted, from the most to the least bulky (left to right). The availability of a variety of brace types enables appropriate fit with an individual patient's needs, thereby enhancing compliance. Some cloth sleeve designs incorporate an inflatable air bladder to induce realignment. © Journal of Musculoskeletal Medicine 2012 JMM88020

a valgus brace setting of 4°. In that study, 12 of 15 patients assessed reported reduced pain at this setting. In a separate study, the reduction in medial compartment load with valgus bracing was estimated to be 11%-15% at the 4° setting (depending on the strap tension) and 17% at the 8° setting [42].

These results clarified that adjustment of the hinge in the frontal plane had a greater effect on the medial compartment load than increasing the strap tension, although both are necessary for optimal efficacy of the brace. The subjects who did not achieve an increase in joint-space width were those for whom obesity interfered with appropriate fitting of the brace. In addition to direct evidence of correction of the affected compartment width and angulation, indirect evidence of load modification was detected in another study in which the ratio of lateral to medial bone mineral density was increased with the use of the valgus brace for 3 months, which indicates a shift in load from the medial to the lateral tibial plateau [43].

As described above, the EKAM is affected by the mechanical alignment of the lower limb as well as by the ground reaction force. With more varus alignment, the greater distance between the knee joint center and the ground reaction force vector increases the EKAM. Results of several studies have demonstrated a reduction in the EKAM of more than 10% with use of a valgus knee brace [44,45]. Pollo et al [42] evaluated the unloading moment by using braces instrumented with strain gauges. These findings demonstrated that valgus bracing could reduce the EKAM by as much as 20% [42]. However, there have been no reports of the effect of realignment knee braces on progression of anatomical worsening of knee OA.

Symptomatic Effect of Knee Realignment Braces

Although there may not be evidence for disease modification, results of several clinical trials that used realignment braces have shown pain reduction in patients with unicompartmental knee OA [38,46]. In a study by Brouwer et al [46], use of a valgus brace for medial knee OA or a varus brace for lateral knee OA reduced knee pain at a 12-month follow-up in the group that wore the brace. The subgroup with medial knee OA, particularly those individuals younger than age 60 years, appeared to have a better therapeutic response. Kirkley et al [38] conducted a prospective, parallel group, randomized controlled trial that compared (a) medical treatment alone, (b) a neoprene knee sleeve, and (c) a realignment brace for patients with unicompartmental tibiofemoral OA. At 6-month follow-up, total Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) score, WOMAC pain subscore, and pain during a 6-minute walk testing were significantly better in the brace group than in the neoprene sleeve group, and in the neoprene sleeve group in comparison with the medical treatment only group [38].

Because the use of realignment braces has resulted in greater reduction in pain and mobility limitations than use of nonsupportive sleeves, it may be a combination of stabilization and re-angulation of the joint that confers these benefits. A study that compared the effects of a brace set in neutral versus valgus revealed that the neutral setting improved confidence and gait function as well as correcting joint load distribution [47]. However, the valgus setting reduced pain as well. These findings suggest that the improvement in pain with valgus bracing is due to a mechanical effect, because a neutral hinged brace did not reduce pain.

The improvement in pain and physical function with corrective bracing may work through mechanisms other than simply altering joint loading. For example, the use of a valgus knee brace may also improve the ability to reproduce joint position, one component of proprioception [48]. Although Birmingham et al [48] demonstrated that a 4° valgus knee brace did not have an effect on postural control, a 12-month study by Matsuno et al [49] did reveal improvement in postural control. In addition to limb re-alignment reducing contact stress in the more affected compartment and potentially enhancing proprioception, bracing may also increase mechanical stability of a knee with incompetent ligaments, improve perception of knee stability, or improve pain and function through nonspecific effects.

In summary, realignment braces have benefits beyond those of knee sleeves or neutral knee braces. Both sleeves and realignment braces appear to exert effects through proprioceptive facilitation in addition to other mechanisms. In some clinical centers, symptomatic relief and functional improvement during walking have been so great with valgus realignment knee bracing that performance of high tibial osteotomies was discontinued at those institutions (Kelly Krohn, MD, written communication, November 2011).

SUMMARY AND TREATMENT RECOMMENDATIONS

OA is a chronic disease and a primary cause of disability in older adults. The knee is the most common weight-bearing joint affected by OA. Among other therapeutic options, braces and insoles are likely underused, possibly due to a lack of knowledge of providers or to poor response or poor compliance in subgroups of patients, particularly in those patients concerned with the aesthetic impact of the use of these devices. Knee sleeves are a simple and inexpensive intervention that may effectively reduce knee pain. They also are simple for patients to use and quick for providers to recommend. However, sleeves do not enhance joint stability, and realigning knee braces confer greater benefits and reduce compressive loading of the more affected joint compartment. In addition, realignment braces may also confer improved proprioception and quadriceps strength [49]. These potential advantages need to be weighed against the greater costs,

reduced comfort, and possibility for adverse effects [50]. Although custom-fit braces can be expensive, when effective, the cost is offset by reduced costs of pharmacologic and surgical therapies. Contraindications to bracing include flexion contracture of more than 10°, peripheral vascular disease, or intractable contact dermatitis. Patients who spend the majority of their time sitting or standing may be better served by a foot orthosis rather than a knee brace.

A less expensive and possibly more comfortable option, wearing a laterally wedged insole, may reduce the EKAM in some patients, but may not consistently improve knee pain or physical function. Although there is inconsistent evidence of efficacy of laterally wedged insoles, this therapy is inexpensive and may benefit some patients. Patient tolerance is affected by both the degree of angulation and the quality of education regarding what to expect when starting to wear the insole. Angulation of the weight-bearing surface and the associated lateral movement of the center of pressure alters foot and ankle biomechanics and can be unpleasant for some patients. Evaluation of this option is efficient, because patients who do not benefit in the first 1 to 2 weeks rarely attain benefit [26,34].

The ideal patient for biomechanical therapies is very similar to the patient for whom a high tibial osteotomy or possibly a unicompartmental knee arthroplasty might be considered. The patient should be motivated to use a non-pharmacologic nonsurgical treatment; in addition, the ideal patient will be physically active, not severely obese, younger, have unicompartmental symptomatic tibiofemoral OA, and, most importantly, have malalignment that is reducible by valgus or varus stress maneuvers on physical examination. Finally, laterally wedged insoles may be more beneficial in patients who have early to mild, rather than moderate, knee OA.

Bracing at the knee and foot is a reasonable option for patients who can tolerate wearing the device and who aim to reduce pain and swelling or to delay knee surgery. Patients with mild OA may only require a brace during high-impact activities, whereas those with more severe knee OA may need to wear a brace during all weight-bearing activities. Each wedged insole and knee brace has unique properties that influence both efficacy and tolerance by subgroups of patients. Because of these differences, the results of clinical trials with particular braces or insoles may not be generalizable to expected results for other braces or insoles. Providers should be aware of features that will enhance patient clinical outcomes and compliance.

Addendum: Clinical Pearls

- Pearls for prescribing a wedged insole:
 - For varus knee OA, starting with a laterally wedged insole is most reasonable.

- A wedged insole that is full length may be more effective than a shorter length insole.
- Depending on the material, a 6°-8° wedge may optimally balance efficacy and patient tolerance.
- Pearls for prescribing a realignment knee brace:
 - Realignment bracing should be considered for adjunctive treatment of patients with tibiofemoral OA with biomechanical knee pain or a sense of instability.
 - The practitioner should have a few sample braces in the clinic to allow patients to see them. If the patients do not indicate that they are comfortable with the idea of wearing a brace, then they are unlikely to wear one.
 - Low-profile braces may be better tolerated by patients with a concern about the appearance, whereas a double-upright design may be more appropriate for patients with incompetent ligaments.
 - The appearance of the brace (bulkiness, style), the ease of donning, patient education in proper donning and adjustment of the brace, as well as fit and comfort can influence compliance with use of the brace and should be considered in prescription.
 - The brace should be donned slightly superior to the desired position, because of settling with use.
 - Sufficient calf bulk is needed to suspend the brace, and the superior calf strap is the most important one to tighten to maintain brace position.
 - For braces with a diagonal strap for inducing the frontal plane angle correction, tightening this strap while the patient is seated, with the knee flexed to approximately 90°, results in greater correction after standing.
 - For patients with bilateral varus knee OA, bracing should be considered for the more symptomatic knee. In rare circumstances, bilateral bracing can be prescribed if indicated.
 - Patients who are obese, whose legs are difficult to fit with an off-the-shelf brace, or who have not benefitted from laterally wedged insoles may require custom-fit braces.
 - Adequate studies are lacking; but, for treatment of lateral tibiofemoral OA, either a medial wedge or a neutral foot orthosis is reasonable and can be augmented with a varus knee brace.
 - If combining use of a foot orthosis and a valgus knee brace, a neutral position is preferable for the foot orthosis.

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