Current Evidence and Clinical Applications of Therapeutic Knee Braces

ABSTRACT


Braces are commonly used for the management of musculoskeletal injuries. With improvements in design and application, the knee brace has gained recognition by many as a treatment and prevention modality. However, there exist many different categories of knee braces, leading to confusion among many end users. The theoretical basis of the mechanism of action of the unloader, prophylactic, patellofemoral, and functional knee braces are explained in this review. This article also provides an update on the various knee braces in terms of the clinical efficacy and appropriate prescription recommendations.

Key Words: Knee Brace, Unloader, Prophylactic, Patellofemoral, Functional

The knee is one of the more common sites for injuries. The wide and varied methods of treatment and prevention of knee injuries include the use of knee braces. The general purpose of the knee brace is to support, align, or immobilize the knee. Its role extends to prevention or correction of deformity, thus improving function and possibly slowing disease progression. The knee brace has gained recognition by many as a treatment and prevention modality with improvements in design and application. Particularly in the sporting context, the use of knee braces by high-profile athletes has heightened awareness. Knee braces are divided into several categories: (i) the unloader knee brace (used in osteoarthritis [OA] of the knee to provide pain relief and improve function), (ii) the prophylactic knee brace (used to protect the healthy knee from injuries during athletic activities), (iii) the patellofemoral knee brace (used for anterior knee pain), and (iv) the functional knee brace (used to provide stability for the unstable knee in ligament injury, such as a torn anterior cruciate ligament [ACL] or post-ACL reconstruction). Because there are many different categories of knee braces, confusion exists among players, coaches, parents, patients, and physicians regarding their use. The objectives of this paper are to review the various types of knee braces and their respective mechanisms of action, and to summarize the current evidence regarding their clinical efficacy.
More than 20 million people in the United States have OA. The disease’s chronic course and high costs for intervention comprise a considerable societal burden. Trauma and other inflammatory conditions have been implicated in the pathogenesis of OA. In sports, the development of OA has been linked to injuries of the ACL, the posterior cruciate ligament (PCL), the meniscus, and the articular cartilage. OA involves destruction of hyaline cartilage attributable to repeated mechanical friction in any of the three articular compartments of the knee. The compartments are divided into the medial, lateral, and patellofemoral compartments. The medial compartment is usually first affected as greater compressive and rotational forces are transmitted through the medial compartment, where the medial femoral condyle is larger and longer than the lateral condyle. Medial-compartment OA is often associated with varus knee alignment, shifting the mechanical axis and load bearing more through the medial compartment, contributing to the progression of the disease. Given that alignment has an important role in the disease process, interventions are aimed at correcting alignment and, thus, reducing stress in the affected compartment. The purpose of the unloader knee brace is to “unload” the affected compartment by altering alignment.

Mechanism of Action of the Unloader Knee Brace

The medial unloader knee brace was designed to apply a valgus moment about the knee for medial-compartment OA. Conversely, the lateral unloader allows for application of varus moments for lateral-compartment OA. The brace is made of hinge components, which create an angulation that induces a bending moment at the hinge. This produces a valgus or varus alignment greater than that of the lower-limb alignment. The hinge components are secured with a series of straps that produce a three-point-contact bending system. The valgus brace produces medially directed force to the lateral aspect of the knee joint and laterally directed forces to the medial aspects proximally and distally from the joint, as illustrated in Figure 1. There is, thus, a resultant valgus moment produced about the knee.

Clinical Efficacy of the Unloader Knee Brace

Most clinical research evaluating the efficacy of the unloader knee brace has been carried out on medial-compartment OA because of its higher prevalence. Many of the studies have measured effectiveness through the magnitude of improvements in pain, function, and quality of life. Hewett and coworkers have evaluated the effectiveness of valgus bracing on symptoms and functional gait patterns in patients with OA knees and found significant improvements in pain parameters but not in dynamic gait parameters. This prospective study, however, includes a broad range in baseline characteristics and demographics in a small cohort of subjects. It has attempted to use more objective measures to estimate improvement, but the only improvements noted in the study have been subjective in nature. The Cochrane library published a critical review of a study by Kirkley and colleagues, who report a prospective randomized control trial that compared valgus knee bracing vs. a neoprene sleeve vs. controls. The valgus brace (Generation II Orthotics, Richmond, British Columbia, Canada) used in this study was custom made with a valgus angulation of 4 degrees. Quality of life was measured with the Western Ontario and McMaster University Osteoarthritis Index and the McMaster–Toronto Arthritis Patient Preference Disability Questionnaire. Functional status was measured by performance on 6-min walking and 30-sec stair-climbing tests. The researchers found significant improvements in patients in the brace and sleeve groups compared with controls, as well as a significant difference between those in the brace and sleeve groups with regard to pain after functional tests. They conclude that valgus bracing was better than the use of a neoprene sleeve, which was better than no support with regard to improv-
ing pain, stiffness, and function. The authors were able to adequately overcome difficulties with randomization and, to a lesser extent, blinding. However, the evaluation period was 6 mos in the study; this is relatively short, considering that OA is a chronic condition. The long-term benefits of application of the unloader brace for OA still need to be assessed. The fact that the treatment groups had different baseline characteristics adds to the methodological problems of the study. On the basis of this study, the Cochrane recommendation concludes that “there was only limited evidence for the effectiveness of bracing in the treatment of medial-compartment knee OA.”

Because increased knee adduction moment during gait is associated with OA, biomechanical parameters are generally thought of as useful markers of objective efficacy. Linderfeld and coworkers have shown the effects of the custom unloader brace on gait by decreasing adduction moment about the knee. Mean adduction moment was 10% greater without the brace than with the brace. Improvements in pain and function resulted from decreased biomechanical knee loading through the medial compartment. This study nicely demonstrates the biomechanical improvements with brace use in reducing adduction moments. Matsumo and coworkers evaluated the effects of the Generation II OA brace (Generation II USA Inc., Bothell, WA) for 12 mos in patients with moderate to severe medial OA of the knee, in terms of pain relief and mechanical improvement. The researchers found significant improvements in the Japan Orthopedic Association’s knee scoring system (which evaluates pain on walking and stair climbing) and in isokinetic quadriceps strength. The authors theorize that the improvements may be attributable to increased knee stability through decreased center of gravity, increased quadriceps strength, and decreased femorotibial angle. However, the study had no control group for comparison, raising into question the strength of the findings. In a prospective cohort study, Pollo and coworkers quantify the valgus moment produced by custom Generation II valgus braces and reduction of medial-compartment loads, using three-dimensional gait analyses. Compartment loads were extrapolated using gait analysis and brace-moment data. Pollo and coworkers found that varus moment about the knee was reduced by an average of 13%, and medial-compartment load at the knee was reduced by an average of 11%.

Effect of Proprioception

Proprioception is the perception of limb position in space and involves sensory inputs from muscle, skin, and joint structures. The OA disease process has been associated with deficits in various aspects of neuromuscular function, including proprioception and other sensory–motor functions. Increased proprioception, as a neuromuscular component, may be the underlying mechanism for improvements with brace use. If so, one wonders whether a sleeve should suffice. In 2001, Birmingham and coworkers set out to investigate the mechanical effects of valgus-directed thrust of the Generation II unloader knee brace on proprioception and posture control in subjects with OA. In this study, proprioception was assessed with the subjects seated, using an isokinetic dynamometer to quantify the subjects’ ability to reproduce target knee-joint angles. Postural control was assessed with a force platform using single-leg standing balance on a stable surface and, subsequently, on foam, to quantify deviation from the center of pressure. Small improvements were seen in proprioception (0.7 degrees) but not in postural control. However, the quality of the study was compromised by the lack of a control group for comparison of effects.

Recommendations for the Use of the Unloader Knee Brace

There are situations in which patients with knee OA may be unsuitable for arthroplasty because of medical or other conditions that compromise the patient’s ability to withstand anesthesia or surgery. The medial unloader knee brace is designed to create a valgus moment about the knee to counteract the varus moments in knees with medial-compartment OA. The above-cited clinical studies have shown some improvements in pain symptoms and function with the use of the unloader brace. The biomechanical data from these studies demonstrate a reduction in adduction moments in varus knees with brace use. From the existing evidence, it seems that the unloader knee brace may provide reductions in pain when it is properly fitted in selected patients with OA of the knee.

(II) PROPHYLACTIC KNEE BRACES

Prophylactic braces are designed to protect the knee from valgus stress injuries; they are generally used in sports with a high risk of collision, such as football. Because knee injuries frequently occur in football, and because the medial collateral ligament (MCL) is a frequently injured ligament, attention is focused on ways of decreasing its incidence. Players that seem most at risk are the offensive and defensive linemen, linebackers, and tight ends (who, additionally, are the most common users of the prophylactic brace).
Mechanism of Action of the Prophylactic Knee Brace

There are two basic constructs of the prophylactic knee brace: a single lateral upright with single-axis, dual-axis, or polycentric hinges, and braces with bilateral uprights and polycentric hinges.19 The design of the construct is intended to protect the MCL during valgus knee stresses and, secondarily, to support the cruciate ligaments during rotational stress. The sequence of a valgus injury begins with application of force to the lateral joint line, leading to immediate tension in the MCL, the ACL, and then the PCL with increasing valgus.20,21

Clinical Efficacy of the Prophylactic Knee Brace

The prophylactic knee brace’s efficacy in preventing ligament injury with routine use has been of continued controversy. A few studies have supported the belief that prophylactic knee braces decrease the incidence and severity of MCL injuries with routine use. Biomechanical studies have shown that the prophylactic knee brace can add 20–30% greater resistance to a lateral blow to the knee (one that potentially could cause medial-joint-line opening).22 At West Point, Sitler and colleagues23 conducted a study of 1396 cadets to assess the prophylactic knee brace’s effectiveness in reducing the incidence and severity of knee injuries in football players. A significantly higher rate of injury was found in the control group (3.4 injuries per 1000 exposures) compared with the braced group (1.5 injuries per 1000 exposures). The study reveals that brace use was associated with a reduction in the number of MCL injuries, but not in the severity of injury. In a descriptive study of 987 Big Ten Conference football players, Albright and colleagues24 compare the injury rates in players of the same position and in the same playing conditions, with or without the use of prophylactic knee braces. A nonsignificant but consistent reduction in MCL injuries was found for braced players in every position and string during practice. Reduced injury rates also have been found for linemen and the linebacker/tight-end group during games, but not in the skilled position group. These two epidemiologic studies suggest a trend in the clinical effectiveness of the prophylactic knee brace.

Effect of the Prophylactic Knee Brace on Performance

The use of prophylactic knee braces has been associated with decrease in performance, especially in athletes involved in speed and agility. Important factors that contribute to this decrease in performance are the weight, restrictive straps, and fit of the brace. The effect of weight of the brace on athletic performance was shown by increased energy consumption measured by various parameters such as heart rate, oxygen consumption, and blood lactate levels.25,26 The restrictive straps were associated with increased intramuscular pressure, which was related to premature muscular fatigue from reduced blood flow to the muscles.27–29 The fit of the brace was an important factor, because migration and slipping of the brace during athletic activity affected speed and agility.30 Views on the effect of prophylactic-brace use on strength are conflicting. Houston and colleagues26 report a 12–30% reduction in maximal torque output during isokinetic knee extension in braced subjects. This reduction was more evident at higher angular velocities. Sforzo and coworkers31 found that peak torque performance was negatively influenced by brace wear in their cohort of female athletes, but not in their male athletes. On the other hand, Veldhuizen and colleagues32 did not find any significant drop in peak torque of knee flexion and extension.

Potential Adverse Effects of the Prophylactic Knee Brace

Other studies question the effectiveness of the brace and report its potentially adverse effects. Grace and coworkers33 studied the effects of using single- and double-hinged prophylactic knee braces compared with matched controls in 580 high school football players. The authors noticed that knee injuries were significantly more frequent in athletes who wore single-hinged braces than in matched controls. There was no significant difference in the number of knee injuries in athletes who wore double-hinged braces compared with their matched controls. Of note, significantly more injuries of the foot and ankle were reported in the athletes who wore braces. The National College Athletic Association study by Teitz and coworkers34 sought to evaluate the efficacy of the prophylactic brace in reducing the severity and frequency of knee injuries in collegiate football players. The study reveals significantly more injuries in athletes who wore braces. No difference in the severity of injuries was found in the braced and control groups.

Recommendations for Use of Prophylactic Knee Braces

The American Academy of Orthopaedic Surgery and the American Academy of Pediatrics conclude in their position statement that “prophylactic braces lack sufficient evidence of efficacy in reducing the incidence or severity of ligamentous knee injuries.”35 Furthermore, it has been shown that these braces may slow the athlete down and inhibit performance. Evidence on the efficacy of the pro-
phylactic brace has been conflicting, and therefore, routine use of the prophylactic knee brace is currently not recommended.

(III) PATELLOFEMORAL BRACES

Patellofemoral pain syndrome is one of the most common disorders of the knee, and it affects athletes and nonathletes alike. Females experience anterior knee pain more often than males, with incidence rates of 10% in young female athletes and 7% in young male athletes. Patellofemoral pain accounts for 33% of all knee injuries in female athletes and 18% of all knee injuries in male athletes. Three main mechanisms have been identified for developing patellofemoral pain: articular cartilage damage from direct trauma, overuse repetitive microtrauma, and abnormal patellar tracking (which results in increased strain on the peri-patellar soft tissues and/or increased patellofemoral joint stress). The patellofemoral brace is designed to resist lateral displacement of the patella, and to maintain patellar alignment. It is usually made of elastic material such as neoprene, and it may include straps or buttresses that help to stabilize the patella.

Mechanism of Action of the Patellofemoral Brace

The mechanism of action by which the patellofemoral knee brace alleviates knee pain remains unclear; however, the theories of how it works are shown in Table 1.

The patellofemoral knee brace is said to improve pain by altering patellar alignment or tracking. Shellock and coworkers have examined the effects of the patellofemoral brace (OnTrack Patellofemoral Knee Brace System, OrthoRx, Inc, San Diego, CA) in influencing patella alignment using kinematic magnetic resonance imaging with the limb in open-chain active movement and against resistance. The majority of patients were found to have improved centralization of the patella or a decrease in patellar displacement after application of the brace. However, Muhle and coworkers, using kinematic magnetic resonance imaging, analyzed patellar tracking patterns with open-chain knee movements with regard to patellar tilt angle, bisect offset, and lateral patellar displacement, and found no statistically significant differences with the patellar realignment brace (Genutrain P3, Bauerfeind USA, Kennesaw, GA).

Powers and colleagues have proposed that a change of patellofemoral position may be an alternate mechanism in which contact is shifted from sensitive to less irritated areas. The researchers made measurements using kinematic magnetic resonance imaging through a range of 0–45 degrees of open-chain knee flexion in subjects with lateral patella subluxation. They found that there were no significant changes in medial/lateral patellar displacement and medial/lateral patellar tilt. A small but significant change in depth of the trochlear groove was found, indicating a change in patellar position within the trochlea. Another study by Powers and colleagues examined the influence of patellofemoral brace (On-Track; Don Joy, Vista, CA) on patellar alignment and patellofemoral-joint-contact area. Patellofemoral mechanics were assessed using the more physiologic closed-chained knee exercises. The authors found that decreases in pain were associated with changes in the patellofemoral contact area, without sizable changes in patellar alignment, with the use of patellofemoral brace. Because stress is proportional to force and inversely proportional to the surface area it acts on, increases in patellofemoral contact area could serve to distribute forces over a greater surface area and, theoretically, decrease stress to the patellofemoral articular surface.

Still another proposed mechanism is through unloading of the knee-extensor mechanism. Earl and coworkers studied the effect of knee bracing (Protonics brace, Empi, St. Paul, MN) at moderate or high resistance during the lateral step-down exercise and found that there was less quadriceps activity in patients in the braced group compared with those in a control group. Aside from the above mechanisms, other proposed mechanisms have been suggested, such as through improvements of temperature, circulation, or proprioception.

Recently, Powers and colleagues examined the effects of bracing in patients with patellofemoral pain with functional activities such as walking, stair ascent, and stair descent. An average decrease in pain of 56% was found with use of the On-Track Patellar Tracking brace (On-Track; Don Joy, Vista, CA). Peak stress during walking was significantly reduced, and this was associated with improvements in joint-contact area. This was not so for stair ascent and descent, where improvement in contact area was balanced with greater knee-extensor muscle moments and joint-reaction forces.

<table>
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<th>TABLE 1 Proposed mechanisms of action of patellofemoral brace</th>
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<td>1. Improved patellar tracking</td>
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<td>2. Dissipated lateral patellar forces</td>
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<td>3. Increased patellofemoral contact area</td>
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<td>4. Changed patella positioning</td>
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<td>5. Unloads the extensor mechanism</td>
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<td>6. Increased temperature, neurosensory feedback, and circulation</td>
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<td>7. Psychological: improved confidence</td>
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Clinical Efficacy of the Patellofemoral Brace

Outcome in the treatment of patellofemoral pain syndrome using the patellofemoral brace (Special FX Knee Brace; Generation II Orthotics, Inc, Richmond, BC) was assessed recently by Lun and colleagues. Treatments in this prospective study were randomized into home exercise program alone, patellar bracing, home exercise program and patellar bracing, and home exercise program with knee sleeve. The clinical outcome of all treatment groups resulted in no significant differences in improvements in knee pain and function. This implies that patellar bracing can be used for patellofemoral pain syndrome but that it is not a superior treatment option compared with other strategies. Timm and coworkers randomly divided 100 subjects into control and braced groups to assess the effects of bracing on patellofemoral pain, position, and function. Significant improvements were found in patellofemoral congruence (using the merchant view on radiographs), in function (using the Kujala patellofemoral score), and in pain (using the visual analog scale). However, the merchant view is a static measure that may not reflect true physiologic conditions. In a prospective randomized study, Miller and colleagues investigated the efficacy of the Palumbo Dynamic Patellar Brace (DynOrthotics, Vienna, VA) in treating a homogeneous group of military subjects with anterior knee pain. Change of symptoms was compared with the different treatment groups (bracing, knee strap, and no bracing). The subjects were treated with physical therapy and antiinflammatory medications and were evaluated 6–8 weeks later. No significant differences were found between treatment groups.

Investigating its effect of the patellofemoral brace (On-Track System, dj Orthopedics) in preventing anterior knee-pain syndrome, Van Tiggelen and coworkers conducted a prospective randomized controlled trial of 167 military recruits undergoing a 6-wk basic military training program. Significantly fewer subjects in the braced group developed anterior knee pain than in the control group. All the studies mentioned did not stratify the different subgroups of patellofemoral pain such as patellar subluxation, maltracking, or pain from other biomechanical causes. As such, the lack of homogeneity of the subjects creates an inherent difficulty in evaluating the efficacy of the patellofemoral brace.

Recommendations for Use of the Patellofemoral Knee Brace

The effectiveness of the patellofemoral knee brace lacks consensus, because conflicts on the true mechanism of action remain. Multiple contributory factors such as patellofemoral biomechanics, temperature, proprioception, and neuromuscular factors may play a role in its effectiveness. Further research is, therefore, needed to elucidate the exact mechanism of action. There likely is a subgroup of patients with patellofemoral pain who are likely to benefit from the brace, such as those with obvious patellofemoral maltracking or subluxations. Future research in the efficacy of brace use on specific subgroups is needed. As technology continues to improve, it is possible that certain braces might prove more effective than others; thus, further studies that directly compare the different models of the patellofemoral braces on the market are needed.

(IV) FUNCTIONAL KNEE BRACE

The functional knee brace is designed to provide support for an unstable knee from ACL injury. It is commonly used to protect the ACL graft after ACL reconstructive surgery, and it also may be used for collateral ligament injury. The brace may be presized or custom fit, and it typically incorporates the use of double-hinged uprights with range-of-motion stops and straps with fitted shells or cuffs. The construct is intended to restore normal motion and kinematics in ACL-deficient knees by reducing anterior translation of the tibia in relation to the femur.

Mechanism of Action of the Functional Knee Brace

Beynnon and coworkers investigated the effect of functional bracing on the ACL by arthroscopic implantation of a transducer on the ligament to measure its strain behavior. Significant increase in ligament strain was detected in the unbraced knee when injury loads were applied to non–weight-bearing and weight-bearing knees. Bracing significantly reduced the strain values for anterior-directed loading and internal–external torque of the tibia. Similarly, Fleming and coworkers affirm that the brace reduced strain in anterior-posterior shear loading and in internal torque of the tibia. The authors further found that it did not reduce strain values when the knee was subjected to external torques or varus–valgus moments in non–weight-bearing and weight-bearing conditions.

Clinical Efficacy of the Functional Knee Brace in ACL-Deficient Knees and After ACL Reconstruction

Biomechanical studies by Wojtys and coworkers of ACL-deficient knees have shown decreased anterior tibia translation in braced knees under low loads, which was similar to daily activities. Beynnon and colleagues had concerns of anteroposte-
rior shear when compressive loads were applied. Significant reduction of anteroposterior laxity was found during non-weight bearing and weight bearing, but not in transition between the two. Recently, Swirtun and coworkers\textsuperscript{57} evaluated the effect of functional bracing on acute ACL injuries and found that most of their subjects who used the brace reported significant benefits, with 95% reporting improved knee stability. However, most of the clinical outcome scores used in this prospective randomized study were subjective measures.

Improvements in the surgical technique and accelerated rehabilitation programs have led to more predictable results in the treatment of ACL injuries.\textsuperscript{54,59} The need for postoperative functional bracing and for consensus involving the duration of the bracing in many rehabilitation protocols comes into question. Harilainen and colleagues\textsuperscript{60} have compared the effects of functional bracing after ACL reconstruction against not bracing postoperatively. No significant difference in functional outcome, degree of stability, or isokinetic muscle torque was detected at 1 and 2 yrs postoperatively between the two groups. In a similar study, Risberg and coworkers\textsuperscript{61} found no significant differences in knee-joint laxity, range of motion, muscle strength, functional knee tests, or pain. Patients in the braced group had significantly increased thigh atrophy compared with those in the nonbraced group at 3 mos. However, patients in this group recorded significantly improved knee function with the Cincinnati knee score compared with those in the nonbraced group at the 3-mo follow-up. Muellner and coworkers\textsuperscript{62} evaluated the effects of functional bracing compared with bandaging after ACL reconstruction and found no differences between the two groups in terms of strength and stability. Free range of motion was achieved significantly earlier in the bandaged group. The sensorimotor performance of the knee after ACL reconstruction has been studied by Wu and coworkers,\textsuperscript{63} who found that bracing improved proprioception. The study involved comparison between the functional knee brace, placebo knee brace, and no brace after ACL reconstruction. Similar improvements in proprioception were found in the brace and placebo brace groups, suggesting that the apparent improvement was not attributable to the mechanical restraining action of the functional brace. Recently, in a study of young military servicemen, McDevitt and coworkers\textsuperscript{64} found no significant difference in clinical outcome in braced and unbraced groups after ACL reconstruction.

**Recommendations for Use of the Functional Knee Brace**

It has been shown that functional bracing may be effective in controlling anteroposterior translation in ACL-deficient knees under low loading conditions, but it may not be effective under high loading conditions that occur during athletic activities. The danger is when ACL-deficient patients are led to have a false sense of security by the use of the brace, especially when normal knee stability is not restored under higher loading conditions. Subjective improvements in knee stability and function are frequently reported, but objective evidence has yet to prove its effectiveness. The effectiveness of the functional brace in ACL-deficient knees depends heavily on appropriate rehabilitation programs. The decision to use functional knee braces after ACL reconstruction depends greatly on the surgical outcome in terms of stability and the patient’s physiologic factors. Given the generally predictable results and high success rates of ACL reconstruction techniques, the evidence does not support the use of a functional knee brace after successful ACL reconstruction.

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