Review Article

Innovations in functional and rehabilitative knee bracing

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Abstract: New knee brace designs are available that have the potential to improve patient outcomes relative to traditional bracing. For the indications of post-knee injury/surgery recovery, conservative management of knee osteoarthritis (OA), total knee arthroplasty (TKA) pre-habilitation, and the treatment of post-surgical extension deficits/flexion contractures, innovative new bracing designs merit review and discussion. The researchers requested information from industry brace manufacturers, and from the information received, have selected those products considered significant improvements over traditional functional brace designs for review in this article. Clinical research supporting the benefits of the innovative products listed in the article have been cited when available. The authors are both Certified Orthotists with over 50 years of combined knee bracing experience.

Keywords: Functional knee bracing; functional rehabilitative knee bracing; posterior cruciate ligament bracing (PCL bracing); anterior cruciate ligament bracing (ACL bracing); osteoarthritis bracing (OA bracing); post-op extension deficit bracing

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The American Academy of Orthopedic Surgeons has traditionally defined four classifications of knee braces: (I) prophylactic: braces which attempt to prevent or reduce the severity of knee injuries in contact sports; (II) functional: braces designed to reduce knee instability and protect and support the knee joint following an injury; (III) rehabilitative: braces that allow protected motion of an injured or surgically repaired knee; and (IV) patellofemoral: braces intended to resist lateral displacement of the patella, maintain patellar alignment and decrease knee pain while worn (1).

With recent innovations in knee bracing, for the purposes of this article, a subclass of functional bracing defined as "functional rehabilitative knee braces" is used. Functional knee braces are defined as braces that support and protect an injured or surgically repaired knee joint. Recent changes in knee brace reimbursement policy has limited functional knee bracing coverage to patients with knee instability as demonstrated by an objective varus/valgus stress test or an anterior/posterior drawer test. Functional rehabilitative knee braces are defined as braces used for patients with an injured or surgically repaired knee joint that have a carry-over rehabilitative effect as a result of repeated brace use resulting in improved unbraced patient functional abilities and reduced knee pain when not wearing the brace. Knee osteoarthritis (OA) braces that have rehabilitative benefits are included in the article as functional rehabilitative knee braces regardless of the fact that the brace also provides functional knee unloading during use.

Innovations in functional knee bracing

The greatest improvement in functional knee bracing is the recent development of dynamic posterior cruciate ligament

(PCL) knee braces that counteract posterior translation of the tibia with an anterior force on the posterior proximal tibia to reduce unwanted forces on the PCL and to lessen the final posterior lag. Unrepaired injury of the PCL can lead to chronic instability and early joint degeneration. Dynamic PCL braces provide a significant new treatment adjunct therapy for the conservative management of PCL injury.

The Ossur Rebound® PCL Knee Brace was the world's first dynamic force (DF) PCL brace launched in 2015. The dynamic PCL knee brace features a dynamic cable tensioning system that increases the anterior drawer force on the posterior proximal tibia reducing the load on the PCL while standing, sitting, squatting, stair descent, etc. The Rebound® PCL brace combines an anterior directed DF on the calf area with an opposing counter force applied on the anterior aspect of the leg. Ossur reports that the Rebound® PCL provides biomechanically stable positioning of the knee and physiological loading of the PCL throughout knee flexion and extension compared to static PCL braces that either do not sufficiently supported the PCL or only provided a static force (SF) to support the PCL, leading to forces that may be too high in knee extension, and providing insufficient support at 90° of knee flexion or both.

Ossur's claims are supported by research performed by LaPrade *et al.* [2015], who conducted research on six adult male patients comparing the forces applied by a DF PCL brace (Ossur Rebound® PCL Knee Brace) (DF) and a SF traditional functional PCL knee brace. Knee forces were measured using a custom pressure mapping technique while patients performed three functional activities; seated unloaded knee flexion, squatting, and during stair descent (2). The Ossur Rebound® Dynamic PCL Knee Brace (DF) was found to apply forces to the posterior proximal tibia that increased with increased flexion angles as well as applying significantly larger force at higher flexion angles. The static brace (SF) did not significantly change in the protective force applied to the posterior proximal tibia during squatting or stair descent. At 45° of knee flexion, the average protective force applied by the dynamic PCL brace was 48.1 N, which was significantly larger than the average force applied by the SF of 25.0 N. The DF was found to more closely replicated the *in situ* loading profile of the native PCL. The superior dynamic protection provided by a DF compared to a SF was believed by the researchers to have the potential result in long-term improved posterior knee laxity following PCL injury (2).

In a clinical study of the Ossur Rebound® PCL Brace, researchers found a reduction in peak patellofemoral joint (PFJ) pressures in PCL deficient knees, especially at high degrees of flexion (3). The PCL resists excessive varus and external rotation forces in the knee and plays a secondary role in resisting posterior translation of the tibia (4). Tension within the PCL during normal movement varies with PCL forces increasing linearly at higher degrees of flexion. Dynamic PCL braces designed to increase anterior force and improve posterior stability at higher degrees of knee flexion to better replicate the natural role of the PCL. Welch *et al.* [2017] reported that simulated tests on cadaver legs using the Ossur Rebound PCL Brace demonstrated a reduction in pressure across all angles tested with no differences in total pressure at greater flexion angles (3).

Most studies on the conservative treatment of injury to the PCL have reported good results in terms of successful PCL healing (5,6). The benefit of a dynamic PCL brace is superior healing with significantly reduced PCL lag post healing. Jacobi *et al.* [2010] reported that use of the Albrecht Jack PCL Brace on 21 patients with grade 1+ and 2+ injury to the PCL who used the Jack PCL Brace for 4 months post injury significantly reducing PCL lag from a mean of 7.1 mm post injury to 2.3 mm after 12 months of use, and 3.2 mm after 24 months. The investigators concluded that the PCL has an intrinsic healing capacity and if the posteriorly translated tibia is reduced to an improved physiological position with the use of a dynamic PCL knee brace, it can heal with less attenuation (7).

The Albrecht Jack Brace features an inbuilt dynamic spring system that applies an anterior force on the proximal tibia to reduce posterior lag of the PCL during brace use. The brace can be loaded into up to 15 positions with each unit increasing the translation force. At a setting of 12 units, the brace applies an anterior force of up to 6 to 7 kg; the posterior force is maintained throughout the range of movement from 0° to 90° of knee flexion (7).

Two additional new brace designs by Medi and Guardian Brace provide a dynamic protective force on the posterior proximal tibia. The brace design for both products have a dynamic adjustable anterior force component located on the posterior proximal calf, which is believed to be superior to static PCL designs, but different from the Albrecht Jack Brace and Ossur Rebound® PCL Brace in that they do not use a cable or tensioning system that adjusts depending on the angle of the knee joint. The Medi M.4s and the Guardian Rehabilitator allow for adjustable increased anterior tension at the calf providing a superior anterior

force when compared to static PCL knee braces.

The Medi M.4s® PCL Dynamic Knee Brace dynamically holds the tibia in the desired position by actively exerting an anterior force via the adjustable spring-loaded PCL protection pad located on the proximal calf. An adjustable tensioning dial on the PCL protection pad can be adjusted to individual comfort and the desired level of PCL protection. A knee brace design with a single setting dynamic anterior force component on the tibia to protect the PCL is intended to prevent posterior drawer of the knee joint during brace use. At the time of this article, no published clinical studies were available for the Medi M.4s® or the Guardian PCL Rehabilitator™.

The Guardian Brace PCL Knee Brace uses a posterior pneumatic air bladder at the calf that provides an anterior DF on the tibia at the proximal calf. Anterior force is dependent on the amount of air used to inflate the posterior air bladder. Braces providing a dynamic protective force on the proximal tibia are assumed to provide superior PCL protection relative to traditional static support PCL knee braces. The Guardian PCL Rehabilitator™ also has a unique extension assist feature that is designed to eliminate a Quadriceps Avoidance Gait and to facilitate quadriceps activation and strengthening during brace use. In clinical studies of the OA Rehabilitator™ Knee Brace on grade III and IV OA patients, the average OA patient had a 54 percent increase in quadriceps strength after 90 days of wearing the brace a minimum of 3 hours a day (8). The mechanism for quadriceps activation and strengthening is the same for both the OA and the PCL Rehabilitator™. Conservative treatment of PCL injury should focus on progressive weight bearing, preventing tibial subluxation, and strengthening of the quadriceps muscles. The Guardian PCL Rehabilitator™ provides the added benefit of strengthening the quadriceps while simultaneously providing pneumatic support of the PCL.

The Rebound® anterior cruciate ligament (ACL) Knee Brace from Ossur is described as the next generation of ACL bracing due to the provision of a dynamic corrective force on the thigh area and opposing counterforces on the anterior aspect of the tibia to reduce stress on the ACL during brace use. The Dynamic Tension System (DTS) is designed to increase the load on the femur as the knee goes from flexion into extension providing an anterior drawer force necessary to decrease the load on the ACL to facilitate ACL healing. The DTS allows for specific load adaptation depending on a patient's individual anatomy and rehabilitative needs. One benefit of a dynamic adjustable ACL support system is that they are believed to provide the added ACL protection for athletes desiring to accelerate rehabilitation for a quicker recovery.

OA rehabilitative knee braces

Clinical studies have evaluated the efficacy of the BioniCare® transcutaneous electrical stimulator and found its use to be an effective treatment for OA related knee OA pain. Mont *et al.* [2006] reported on a long-term trial of patients with knee OA treated with the BioniCare® stimulator (9). They found there was a clear dose-response relationship with patients reporting a significant relief of pain and improvement in function in excess of those reported for NSAIDs, analgesics, and hyaluronans within the first 750 hours of therapy, with even better outcomes for patients who used the devices for 1,750 hours or more. A second study by Hungerford *et al.* [2013] on the combined use of a VQ BioniCare® OActive knee unloader brace simultaneously used with a BioniCare® joint stimulator found that the combined use product provided superior patient outcomes than use of the BioniCare® stimulator by itself. Both the BioniCare® only patients and VQBioniCare® OActive combined product patients both had significantly improved knee pain over time, with the combined patients (brace with stimulator) demonstrating the best outcomes. Both the magnitude of differences and the synergistic effect would indicate there is a real treatment difference in combining the stimulator with the unloading brace. The researchers had three hypotheses to explain the differences. First, the unloading brace may decrease the friction and the subsequent wear of the cartilage with weight-bearing. Second, placing the electrodes inside the brace maintains proper positioning throughout the treatment period. Third, stimulator treatment provides a capacitively coupled exogenous electrical signal similar to the endogenous signal of weight-bearing. When stimulator treatment is used alone, it is delivered with a night wrap while the patient is sleeping, and there is no concomitant endogenous signal created. When stimulator and brace are combined, the exogenous signal combines with the endogenous signal of weight-bearing, and the effect is somehow synergistic (10).

Muscle impairments associated with knee OA are the primary underlying cause of functional limitations. In a meta-analysis of OA research literature relating to muscle impairments on the affected OA leg as well as the unaffected contralateral leg, Alnahdi *et al.* [2012] reported that knee OA subjects had 67% lower quadriceps endurance

and 60% lower extension angular velocity during knee extension in the affected leg compared to healthy controls. The researchers concluded that knee OA cannot solely be considered a disease of the cartilage, and that the clinical management of the disease must also take into account associated muscular impairments. Alnahdi *et al.* [2012] suggested that further research is needed to explore the relationship between quadriceps strength and knee OA initiation and progression, but supported quadriceps strengthening to improve OA patient function (11).

Guardian OA Rehabilitator™ Knee Brace clinical studies found that after wearing a Rehabilitator Knee Brace for a minimum of 3 hours a day for 90 days, patients had increased quadriceps strength of 54% and hamstring strength of 28% while increasing UNBRACED gait speed by 11%, improved timed up and go of 17%, and improved stair climb by 26%. Average reductions of 43% of unbraced knee pain was reported after 90 days of brace wear (12). A gait study by Kapadia *et al.* [2016] reported that after 90 days of Rehabilitator wear a minimum of 3 hours a day, the investigators reported a reduction in unbraced knee impulse at weight bearing of 27 percent (12). The reduction in torque is believed to be due to the improved gait biomechanics, reducing knee cartilage wear and tear and potentially delaying the progression of knee OA. The reduction in weight bearing force on the knee joint makes this technology an excellent adjunct therapy for patients receiving stem cell or Hyaluronic acid injections to delay OA progression.

Rehabilitators™ have four unique features in knee brace design: (I) a semi-rigid, flexible frame with a rotating thigh cuff designed to be more conforming to the shape of the leg as the patient walks in the brace; (II) a pneumatic air bladder system for unloading the varus or valgus knee; (III) a lower profile design (11 or 12 inches long); and (IV) extension assist technology to normalize gait, improve quadriceps firing, and strengthen the weakened OA leg over time. By normalizing unbraced gait biomechanics, the adverse forces responsible for knee wear and tear even when the patient is not wearing the device after 90 days of routine use. After 90 days of brace use, patients using the gait rehabilitating knee brace had 6.2 degrees of improved knee extension in gait as well as an improved loading response at the ankle/foot towards the midline of the foot of 1.7 cm. Clinical research has demonstrated that improper loading at the ankle/foot can neurologically diminish quad excitation. Reduced quad firing, weakened quadriceps strength, and altered gait biomechanics (increased adduction moment and reverse screw home mechanism) are the primary causal factors as to why OA progresses over time. The more significant the gait alterations, the faster the wear and tear on the joint. By normalizing gait, biomechanical forces can be significantly reduced in the knee to slow the progression of knee OA.

Guardian Brace manufactures a Sport Rehabilitator™ Knee Brace that is intended for use for ligament injury or surgery recovery that provides pneumatic medial, lateral, and rotational control of the knee joint and has an extension assist mechanism to eliminate Quadriceps Avoidance Gait to accelerate recovery post injury or surgery. There were no available published completed clinical studies for the Sport Rehabilitator use for ligamentous injury recovery.

Total knee arthroplasty (TKA) pre-habilitation using a rehabilitative knee brace

Clinical research on post TKA patients suggest that six months post operatively, many TKA patient levels of flexor and extensor strength are equivalent to pre-TKA levels (13). This is somewhat surprising considering that with diminished knee pain and increased functional activity post TKA, one would think that six months post TKA the weakened OA leg would be stronger than the pre-TKA leg. A large multicenter investigation of young patients (661 patients, mean age 54 years, age range, 19 to 60) who were 1 to 4 years post TKA revealed that when interviewed by an independent third party about one-third of patients reported residual symptoms and limitations after modern TKA. Approximately 53% of these patients report a limp or difficulty in gait, 54% had difficulty with stairs, and 38% of patients reported difficulty getting in or out of a car (14). The extension assist bands facilitate the normalization of range of motion while increasing quadriceps activation to accelerate leg strengthening post op. There was no clinical study on the use of the Sport Rehabilitator™ for TKA prehabilitation at the time of the article. Use of a Sport Rehabilitator™ 4 to 6 weeks pre-TKA may be used to normalize gait and strengthen the weakened OA leg prior to surgery. Use of the Rehabilitator™ post op may facilitate accelerated recovery and potentially extension deficit free gait and improved patient function long term.

Ambulating double upright extension assist knee brace to reverse post-operative extension deficits/flexion contractures

The traditional bracing regimen for reversing a post-

operative knee extension deficit/flexion contracture in an ambulating patient is to rely on night-time use of a spring-loaded Low Load Prolonged Stretch (LLPS) devices. With significant hamstring and posterior capsule shortening, it is common to have resultant subluxation in the knee joint as a result of the hamstring pulling down on the tibia relative to the femur. The combination of knee subluxation and weak quads can make reversing the final 5 to 8 degrees of tissue shortening very difficult to achieve clinically with a spring-loaded brace alone, as a LLPS brace does not provide any quadriceps strengthening.

The Guardian Sport EXT Rehabilitator™ (EXT for EXTension deficit), is an 18-inch long double upright knee brace with adjustable extension assist of up to 10 inch-pounds of extension assisted stretch with every step. The brace employs four air bladders to facilitate a "glide" stretch with each step to reduce joint knee subluxation during stretch: (I) an inflatable air bladder at the thigh to create a downwards lever on the femur; (II) an air bladder at the calf to apply an anterior force on the tibia; and (III) air bladders on each side of the knee joint. The air bladders when inflated are intended to reduce knee subluxation to recreate active "glide" stretches while ambulating in the brace. It is estimated that when active, the average person will take 1,000 steps per hour. By encouraging brace use and increased walking distance each day, a patient who walks in the brace 3 hours a day for 30 days will receive approximately 250,000 to 300,000 active "glide" stretch steps in a month. Patients are experiencing ROM gains of approximately 10 degrees 6 to 8 weeks, including the last 5 to 10 degrees. In addition to the active extension stretch, the brace is believed to increase quadriceps activation with each step and to normalize post-surgical gait eliminating the potential of a chronic Quadriceps Avoidance Gait. Sport EXT Rehabilitator™ adjunct therapy is the only contracture therapy that simultaneously lengthens the hamstrings and posterior structures while strengthening the quadriceps.

Summary

New innovative technologies in dynamic functional knee brace designs can assist in improving patient outcomes by providing superior protection of the knee joint after injury or surgery with the use of dynamic mechanisms adding superior protective forces relative to more traditional static functional knee braces. Dynamic PCL braces have demonstrated improved patient outcomes with dynamic brace use as a part of a conservative plan for PCL healing. New rehabilitative OA functional knee bracing that provides a rehabilitative muscle strengthening therapy during brace use has shown promise for reducing pain and improving function for OA patients and for accelerated rehabilitation with the potential for improved long-term patient functional outcomes. New ambulating extension deficit/flexion contracture rehabilitative functional bracing offers an alternative to night-time LLPS contracture bracing to reverse postoperative extension deficits/flexion contractures. The economic health benefit of the use of functional rehabilitative bracing technologies that can improve patient outcomes post knee injury/surgery or for the conservative management of knee OA can be considerable. These innovative products are excellent adjunct therapies for patients participating in physical therapy to accelerate recovery and to improve overall treatment outcomes.

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None.

Footnote

Conflicts of Interest: J Kenney, BOCO is an employee of Guardian Brace, manufacturer of the Rehabilitator line of knee braces. J Kenney is also a minority owner of Guardian Brace, and therefore has a financial interest in the company. The Guardian Brace Rehabilitator Knee Braces are discussed in the paper. J Hewlett has no conflicts of interest to declare.

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