

tion. A flexible, fabric sheath (not illustrated) may also be worn between the brace and the skin to reduce chaffing and help stabilize the brace.

[0032] The thigh and tibial cuffs and tensioning structures of the exemplary brace **20** utilize flexible, fabric-like bindings to bind the bracing element **22** to the soft tissue of the limb. The bindings of the exemplary brace typically include a short length of a hook material on one side of the binding proximate to at least one end of the binding. A complementary eye material is attached to another portion of the binding. The binding is wrapped around the limb and the end of the binding is doubled over the eye material to secure the end of the binding as required. While the cuffs and tensioning structures of the exemplary brace **20** include formed cuff bases and fabric bindings with hook and eye fastening elements, other attaching elements and methods, such as elastic sleeves and straps with buckles, may be used to constrain an orthotic brace and a limb.

[0033] The major factor limiting the ability of an external device, such as the orthotic brace **20**, to control a joint is deflection of the soft tissue to which the brace is bound by its attaching cuffs and tensioning structures. The skin, fatty tissue, and muscles, particularly when flaccid, are easily rolled around the limb. In addition, the soft tissue translates longitudinally on the limb in response to the application of force. This is partly due to the thickening and thinning of the muscles as they flex to operate the joint. Further, soft tissue compresses in response to pressure from the brace cuffs and bindings. In addition, the dimensions of the limb change substantially as the muscles flex to operate the joint causing the tension exerted at the cuffs and tensioning structures to increase and decrease as the joint is flexed. The effects of soft tissue deflection vary with body type, muscle tone, and limb element position during movement. Maximizing the cuff and strap areas bearing on the soft tissue and increasing the separation of the attaching elements reduce the pressure acting on the soft tissue and improve joint control, but limb size limits the dimensions of the brace and soft tissue movement cannot be eliminated. Simply tightening the bindings of a brace does not eliminate the effects of soft tissue compression, translation, and rotation, and the binding tension is limited by user comfort and adverse effects on circulation.

[0034] Lateral force can be applied to the joint by increasing the tension in the straps of the tensioning structures. As the joint is pulled toward or permitted to move away from the bracing element, the load on the joint can be shifted from one side of the joint to the other. Such compartmental loading of a joint may be desired as part of a treatment regime or to protect a specific element of the joint structure. For example, as the knee is pulled toward bracing element **22**, by increasing the tension in the binding of the lower thigh tensioning structure **32** and the upper tibial tensioning structure **36**, the portion of the load on the knee that is borne by the side of the joint opposite the bracing element is increased and the portion of the load on the side of the joint nearest the bracing element is reduced. Conversely, the load on the side of the joint opposite the bracing element can be reduced or unloaded and the loading of the side of the joint adjacent to the bracing element increased or loaded by reducing tension in the bindings of the tensioning structures and permitting the joint to move away from the bracing element.

[0035] The effect or result of changing the tension in the bindings of the tensioning structures is to apply leverage to the proximal and distal portions of the respective limb elements and to displace the joint laterally relative to the hinged bracing element **22**. The resultant compartmental loading is determined by the force exerted by the tensioning structures and by the relative profiles of bracing element and the surface of the limb against which the bracing element bears. Since the profile of the surface of the limb varies between users, bracing elements are often purposefully and semi-permanently deformed in a direction substantially normal to the limb to provide a custom profile that will properly load the joint when force is applied by the tensioning structures. However, semipermanent deformation of the brace cannot accommodate the changing shape of the muscles as the joint is flexed and may cause undesirable loading of the joint during certain portions of the joint's range of motion. Further, altering the shape or deflection characteristics of the bracing element in response to a dynamic condition, such as a blow to the side of the leg, particularly when the tibia and femur are in a vulnerable alignment, may provide added protection for the joint.

[0036] Orthotic braces are also used to assist or resist flexion or extension of the joint as part of physical therapy or strength augmentation, particularly during joint rehabilitation. Typically, such a brace includes a spring or similar device to assist or resist the flexing of the hinged bracing element. These devices can often be adjusted to vary the general level of resistance or assistance exerted on the levers of the brace, but the force-joint displacement characteristics are generally a function of the design of the force exerting element and not readily adjustable to permit the force to be varied at specific points in the joint's articulation so that the relationship of force and articulation can be tailored to a treatment regimen.

[0037] The present inventor concluded that the performance of an orthotic brace could be improved if the characteristics of the brace could be adjusted dynamically to optimize the attachment of the brace to the joint, optimize the shape of the bracing element, and vary the resistance or assistance to joint articulation in response to changes in the limb or events effecting the limb or to accomplish a particular function or treatment regimen. The preferred materials for use in such a brace include, for example, piezoelectrics, electroactive polymers, or a combination thereof.

[0038] One of the many features of the present invention is the use of active, dynamic materials to assist in achieving the desired effect. The result is likewise unique in that the one of the goals is to actively reduce injury or rehabilitate a previous injury. Previously existing devices espousing the same goal, generally achieved their ends by physically limiting the joint's movements in a range of motion, instead of permitting generally normal movement up to a point, but then counteracting injury causing extremes in joint motion.

[0039] Dynamic materials include but are not limited to electroactive polymers and piezoelectric compounds. Unlike a traditional electric motor, these materials deform to do work directly, creating stress and strain within the material itself, and affecting the surrounding environment via application of the stress and/or strain. This is a conceptual shift given that the material itself does some work, as opposed to necessitating merely a mechanical linkage to a traditional