

study using an electrostimulation unit alone.

[0067] The figures are not intended to be exhaustive or to limit the invention to the precise form disclosed. It should be understood that the invention can be practiced with modification and alteration, and that the invention be limited only by the claims and the equivalents thereof.

DETAILED DESCRIPTION OF THE EMBODIMENTS OF THE INVENTION

[0068] Referring now to the drawings in detail, wherein like reference characters refer to like elements, there is shown in FIG. 1 a knee brace 10 according to the present invention. The invention will be described with reference to a knee brace; however, it will be understood that the invention is also applicable to other orthotic devices such as an ankle, back, arm, shoulder, or wrist brace, and other devices for relieving pain in any body portion of the user. Although this invention will be described by way of example and with reference to preferred embodiments thereof, it is to be understood that modifications or improvements may be made thereto without departing from the scope or spirit of the invention. It should be noted that various changes and modifications to the presently preferred embodiments described herein will be apparent to those skilled in the art. Such changes and modifications may be made without departing from the spirit and scope of the present invention and without diminishing its attendant advantages. It is, therefore, intended that such changes and modifications be included within the present invention.

[0069] Referring to FIG. 1, a knee brace 10 is shown having a biomechanical support comprising two substantially rigid arms, 13 and 16, which are joined together by a hinge assembly 19. Connected to the rigid arms are upper and lower structures 22 and 25, respectively which, together with straps 28 and 31 are used to form a primary engagement with the user's leg above and below the knee 34. This engagement can be augmented by further straps 37 and 40. The hinge assembly 19 has a predetermined range of movement corresponding to the desired range of flexion/extension of the knee of the user. The upper and lower support structures 22, 25 are generally referred to as cuffs.

[0070] The upper cuff 22 is adapted to be secured to the user's thigh (femur) and the lower cuff 25 is adapted to be secured to the lower leg or calf (tibia). In this way the hinge assembly 19 is placed adjacent the axis of the user's knee joint, thereby allowing the knee brace 10 to substantially mimic the bending of the user's knee as the user goes about his or her otherwise normal activities. In the preferred embodiments, upper and lower cuffs 22, 25 comprise adaptive support structures that are constructed from a semi-rigid material such as a thermoplastic elastomer or a thermoplastic rubber.

[0071] Furthermore, the preferred embodiments may include a rigid material 43 that is integrally molded into upper and lower structures 22, 25, or is alternatively fixedly attached to the structures. Rigid material 43 has a greater rigidity than the semi-rigid material from which upper and lower structures 22, 25 are molded, and is preferably malleable. In the preferred

CLAIMS

1. A system for treating arthritis, comprising:

- a) at least one joint stabilizing assembly for providing relief from arthritis;
- b) at least one signal transmission element engagement member operatively connected to said at least one joint stabilizing assembly for connecting a signal transmission element;
- c) at least one signal transmission element supported by said at least one signal transmission element engagement member; and,
- d) an electrostimulation unit, electrically connected to said at least one signal transmission element, for producing at least one signal for improving the overall function of an arthritic joint,

wherein said electrostimulation unit is directed to be used in conjunction with said at least one joint stabilizing assembly for greater than 150 hours of treatment, and wherein said at least one signal is a modality specifically intended to provide arthritic joint stimulation, and

wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate nerves,

wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate muscle, and

wherein said at least one signal comprises a Transcutaneous Electrical Stimulator for Arthritis (TESA) signal.

2. The system of Claim 1, wherein the Arthritis (TESA) signal has a nominal frequency of 100Hz, said electrostimulation unit produces at least one signal which performs at least one of the following functions:

- a) Increase DNA synthesis;
- b) Increase chondrocyte proliferation;
- c) Generate hyaline cartilage;
- d) Accelerate differentiation of progenitor cells to mature chondrocytes;
- e) Increase proteoglycan synthesis;
- f) Increase glycosaminoglycan synthesis;
- g) Increase transforming growth factor beta (TGFB);
- h) Activate genes responsible for the production of proteoglycans and Type II collagen;
- i) Suppress production of IL-1, Tumor necrosis factor, prostaglandins (PGE2), and matrix metalloproteinases including MMP1, MMP3, MMP13;

- j) Inhibit Mitogen-activated protein kinases (MAPKs);
 - k) Inhibit of interferon, IL-9, and IL-6;
 - l) Down regulate IL-15.
3. The system of Claim 1, wherein said at least one joint stabilizing assembly is adapted to treat the foot, ankle, knee, hip, wrist, hand, elbow, spine, pelvis, or shoulder joints.
 4. The system of Claim 1, wherein said electrostimulation unit is adapted to treat the foot, ankle, knee, hip, wrist, hand, elbow, spine, pelvis, or shoulder joints.
 5. The system of Claim 1, wherein said at least one joint stabilizing assembly comprises an osteoarthritis brace being constructed as a rigid support to the joint and surrounding anatomy.
 6. The system of Claim 1, wherein said at least one joint stabilizing assembly is constructed as a non-rigid support to the joint and surrounding anatomy.
 7. The system of Claim 1, wherein said electrostimulation unit generates different signals of varying duty cycles, or no signal at all, for portions of the treatment.
 8. The system of Claim 1, wherein said electrostimulation unit provides for custom programming based on the patient's needs, conditions, or attributes.
 9. The system of Claim 1, further comprising a dynamic signal modulation system operatively associated with said at least one joint stabilizing assembly and said electrostimulation unit for varying the signal dynamically, based on the joint's instantaneous position.
 10. The system of Claim 1, wherein said at least one joint stabilizing assembly comprises adhesive tape used to support the anatomy and treat arthritis, said at least one signal transmission element being integrally constructed as part of said adhesive tape, such that a synergistic and convenient effect is achieved for the user, said adhesive tape providing mechanical support/treatment, and said signal transmission element providing stimulation treatment to the joint.
 11. The system of Claim 10, wherein said adhesive tape is provided in roll form, sheet form, or at least one pre-cut shape.

12. The system of Claim 10, wherein said adhesive tape is formed of elastic material.

~~13. A method for treating arthritis, comprising the steps of:~~

- ~~a) providing a joint stabilizing assembly of a type comprising adhesive tape integrally constructed with a signal transmission element to promote range of motion and support of the anatomy, while also providing electrotherapy to said anatomy;~~
 - ~~b) choosing the best positioning of at least one electrical contact point on the anatomy to facilitate the optimal amount of electrotherapy signal flow through the affected anatomy;~~
 - ~~c) wrapping the affected anatomy with said selected adhesive tape;~~
 - ~~d) providing said electrotherapy signal flow selected from signals configured to improve the overall function of an arthritic joint with a modality specifically intended to provide arthritic joint stimulation, and~~
- ~~wherein said electrotherapy signal flow improves the overall function of an arthritic joint with a modality not intended to stimulate nerves,~~
- ~~wherein said electrotherapy signal flow improves the overall function of an arthritic joint with a modality not intended to stimulate muscle, and~~
- ~~wherein said at least one signal comprises a Transcutaneous Electrical Stimulator for Arthritis (TESA) signal.~~

~~14. A method for treating arthritis, comprising:~~

- ~~a) providing at least one joint stabilizing assembly for providing relief from arthritis;~~
- ~~b) providing at least one signal transmission element engagement member operatively connected to said at least one joint stabilizing assembly for connecting a signal transmission element;~~
- ~~c) providing at least one signal transmission element supported by said at least one signal transmission element engagement member;~~
- ~~d) providing an electrostimulation unit, electrically connected to said at least one signal transmission element, for producing at least one signal for improving the overall function of an arthritic joint; and,~~
- ~~e) directing the utilization of said electrostimulation unit in conjunction with said joint stabilizing assembly for greater than 150 hours of treatment, and wherein said at least one signal is a modality specifically intended to provide arthritic joint stimulation, and~~

~~wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate nerves,
wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate muscle, and
wherein said at least one signal comprises a Transcutaneous Electrical Stimulator for Arthritis (TESA) signal.~~

~~15. The method of Claim 14, wherein said electrostimulation unit produces at least one signal which performs at least one of the following functions:~~

- ~~a) Increase DNA synthesis;~~
- ~~b) Increase chondrocyte proliferation;~~
- ~~c) Generate hyaline cartilage;~~
- ~~d) Accelerate differentiation of progenitor cells to mature chondrocytes;~~
- ~~e) Increase proteoglycan synthesis;~~
- ~~f) Increase glycosaminoglycan synthesis;~~
- ~~g) Increase transforming growth factor beta (TGFB);~~
- ~~h) Activate genes responsible for the production of proteoglycans and Type II collagen;~~
- ~~i) Suppress production of IL-1, Tumor necrosis factor, prostaglandins (PGE2), and matrix metalloproteinases including MMP1, MMP3, MMP13;~~
- ~~j) Inhibit Mitogen-activated protein kinases (MAPKs);~~
- ~~k) Inhibit of interferon, IL-9, and IL-6;~~
- ~~l) Down regulate IL-15.~~

~~16. The method of Claim 14, wherein said joint stabilizing assembly is adapted to treat the foot, ankle, knee, hip, wrist, hand, elbow, spine, pelvis, or shoulder joints.~~

~~17. The method of Claim 14, wherein said electrostimulation unit is adapted to treat the foot, ankle, knee, hip, wrist, hand, elbow, spine, pelvis, or shoulder joints.~~

~~18. The method of Claim 14, wherein said electrostimulation unit generates different signals of varying duty cycles, or no signal at all, for portions of the treatment.~~

~~19-13.~~ An orthotic device system optimized for improving the function of an arthritic joint comprising:

- a) a joint stabilizing assembly optimized for improving arthritic joint function;
- b) at least one signal transmission element contacting a user;

- c) at least one signal transmission element engagement member for supporting said signal transmission element; and
- d) an electrostimulation unit electrically connected to said signal transmission element for producing at least one signal optimized for improving the function of an arthritic joint;

wherein said electrostimulation unit is directed to be used in conjunction with said joint stabilizing assembly for greater than 150 hours of treatment, and wherein said at least one signal is a modality specifically intended to provide arthritic joint stimulation, and

wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate nerves,

wherein said at least one signal for improving the overall function of an arthritic joint is a modality not intended to stimulate muscle, and

wherein said at least one signal comprises a Transcutaneous Electrical Stimulator for Arthritis (TESA) signal.

20-14. The system of claim 19-13 wherein said electrostimulation unit is integrally manufactured into the joint stabilizing assembly.

21-15. The system of claim 19-13 wherein said electrostimulation unit is detachable from said joint stabilizing assembly.

22-16. The system of claim 19-13 wherein said electrostimulation unit is interchangeable based on the user's treatment needs.

23-17. The system of claim 19-13 wherein said joint stabilizing assembly includes a thigh cuff that is interchangeable based on the user's treatment needs.

24-18. The system of claim 19-13, wherein attachment of said electrostimulation unit to said joint stabilizing assembly automatically establishes electrical contact with said signal transmission element.

25-19. The system of claim 19-13, wherein said electrostimulation unit is attached to said joint stabilizing assembly by means of a releasable securing mechanism.

26-20. The system of claim 25-19, wherein said releasable securing mechanism comprises a snap-fit mechanism.

27.21.____ The system of claim ~~25~~19, wherein said releasable securing mechanism comprises a hook and loop fastening system.

~~28.22.~~____ The system of Claim 1, wherein said joint stabilizing assembly includes a receptacle configured to receive said electrostimulation unit, wherein the receptacle is integral with said joint stabilizing assembly.