Magnetically-Assisted Medial Unloading Knee Brace

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Clinical Problem

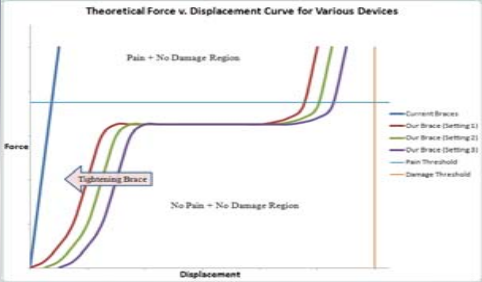
With obesity becoming an increasingly common occurrence in the United States, bow-legged syndrome has also become an increasing problem. The bow-legged configuration of many patients causes degenerative osteoarthritis (OA) within the knee joint due to an uneven loading on the chondials of the knee . This can lead to an early need for total knee replacement. However, total knee replacement is not a feasible option for everyone including patients who are either young, obese, or still in the early stages of degenerative osteoarthritis. With the current technologies for total knee replacement having average lifetimes of 10-15 years, younger patients would be forced to have numerous replacement surgeries within their lifetimes. In fact, most surgeons will not perform total joint replacement for patients under the age of 60. With obesity being a contra-indicator for surgery, overweight patients also become poor candidates for total knee replacement. These conditions have resulted in the advent of medial unloading knee braces (OA knee braces) which correct the angulations of the knee in order to redistribute the load on the chondials of the knee to relieve pain. Finally, the OA knee brace serves as a preventative measure for those patients who are still in the early stages of degenerative osteoarthritis.

However, these braces are required to offer a variety of unloading forces in order to comfortably accommodate the range of activities the patient undergoes. Currently, one of the biggest challenges with such braces is patient compliance. Keys to compliance include comfort and weight of the brace, and the ability to continue with normal activities while wearing it. The current technologies in the market provide support, at the expense of comfort in high-loading activities. For example, the force required to unload the knee during times of inactivity is much less than walking or running. Therefore, a brace calibrated to support the knee comfortably during low-load activities becomes painful to wear during more aggressive routines.

Current medial unloading OA knee braces provide a single, highly asymptotic unloading profile (Force v. Displacement Curve below). A small displacement is met with a large force, resulting in rigid support. When the patient is participating in an activity which would see a high displacement, such as running, they are met with a large lateral force on the joint. This rigid reaction results in a painful scenario, leaving the patient with high levels of discomfort. This makes the patient unlikely to wear the brace during these high displacement activities, when they need the support the most.

Solution

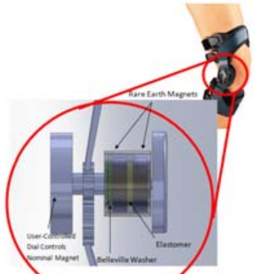
An ideal force profile would be an initial fairly rigid response to a small displacement to provide effective support for low-impact activities; however, in more aggressive routines, the brace would provide a constant force below the pain threshold (Force v. Displacement Curve below). By allowing some additional displacement, the brace is able to provide a supportive, yet unpainful force. Magnetic Ventures has developed a novel unloading system which can provide this desired force response and be seamlessly integrated within the current standard unloading braces.



Magnetic Ventures has designed a novel unloading piston technology that can be easily incorporated into the current standard medial unloading braces. This piston is comprised of a nonlinear spring in series with a custom-designed Belleville washer.

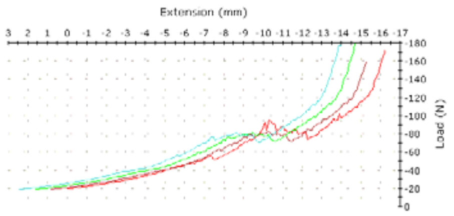
The nonlinear portion of the piston, as shown below, is composed of an elastomer in-between two neodymium rare earth cylindrical magnets. However, the elastomer is an optional component and maybe removed later in the design process.

When these two systems are put into series with each other, one is able to provide the cushioning effect of a nonlinear spring and at the same time "buffer" a particular load to produce a force plateau which holds the supporting force below the pain threshold of the patient.



Proof of Concept & Data

In order to demonstrate the novelty of our technology, preliminary piston prototypes were built and their force profiles were characterized with an Instron device.



As we can see, when 3 belleville washers are assembled in series with two repulsive magnets within a cylinder piston encasing, we are able to generate cushioning force, followed by a force plateau. When the compression reaches a certain limit, the force begins to asymptote as we see the strength of the neodymium magnets.

By altering various parameters including:

- Magnet thickness/diameter
- Belleville washer height, inner diameter, outer diameter, tapering, and curvature factors

We are able to optimize the force displacement curve to provide the optimal plateau level and force-ramping.

In conducting many tests and varying the use of different magnet-belleville washer combinations, the following important observations were noted:

- Ridges in force-displacement curve are due to frictional forces encountered during compression of piston.
- In order to optimize plateau characteristics, an even number of belleville washers is required.
- Plateau load cannot be adjusted within single piston; however, ramping slope can be adjusted by increasing initial compressive strain.

The Inventor

- **John-William Sidhom (BSE '11)**
  - Premedical/Biomedical Engineering undergraduate at the University of Michigan
  - Receiving Minor in Entrepreneurship and Mathematics
  - Chief Executive Officer, Magnetic Ventures
  - Inventor on MAAJ patent
  - 2 years of experience with CAD
  - Experience with finite element analysis (COMSOL) and numerical methods
  - Research experience in Neural Tissue Engineering (NJIT) & Biomechanics Department (UMICH).

Scientific Advisory Board

- **Aileen Huang-Saad, PhD**
  - Principal Investigator on NCIIA Grant
  - Biomedical professor at the University of Michigan
- **Steve Goldstein, PhD**
  - The Henry Ruppenthal Family Professor of Orthopedic Surgery and Bioengineering
  - Associate Chair of Orthopedic Research at the University of Michigan
  - Met with the team over the past 14 months and has served as an invaluable mentor in developing the technology.
- **James Ashton-Miller, PhD**
  - Director of the Biomechanics Research Lab at the University of Michigan
  - Research professor of Mechanical Engineering.
- **David Blaha, MD**
  - Professor of Orthopedic Surgery
  - Met with the team several times over the past year and has extended his enthusiasm about the project.

Timeline of Magnetic Ventures' Future

September – October, 2010
- Complete Prototype with ZDR, a biomedical engineering design and development firm.

November – December, 2010
- Patient testing to gain insight into the patient experience

January, 2011
- Attempt to sell technology to large knee brace manufacturer