Journal of Rehabilitation and Assistive
Technologies Engineering
Volume 3: 1–10
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DOI: 10.1177/2055668316670534
jrt.sagepub.com

A novel distractive and mobility-enabling lumbar spinal orthosis

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Abstract

Purpose: Lumbar spinal orthoses are often used as non-surgical treatment and serve to support the spine and alleviate low back pain. More recently, dynamic orthoses claiming to decompress the spine have been introduced. A previously developed prototype of dynamic mobility orthosis (DMO1) was designed that provided a distractive load across the lumbar spine but required higher sagittal bending moments and was unable to maintain spinal off-loading throughout extended ranges of movement. The objective was to design a new orthosis (DMO2) that reduced bending moment buildup and sustained spinal off-loading throughout daily living ranges of flexion and extension movement.

Methods: A mechanical analog upper torso model and programmable robotic testing platform were used to design features of DMO2: a mobility-enabling component and a distractive force component. Test conditions for DMO2 were 300 *N* of applied vertical torso load over a range of 25° flexion to 10° extension. Loads carried by the brace were determined throughout flexion and extension ranges. Applied moments to the upper torso model and transferred moments to the spine were measured. The difference in applied and transferred moments represented brace moment effects.

Results: The DMO2 prototype improved spinal off-loading capacity from 172 *N* to 290 *N* at end-range flexion and from 247 *N* to 293 *N* at end range extension compared to the original DMO1 prototype. End-range applied moments (flexion-DMO1: 32.4 Nm/DMO2: 21.7 Nm; extension-DMO1: 15.0 Nm/DMO2: 10.9 Nm) and brace moments (flexion-DMO1: 18.6 Nm/DMO2: 6.6 Nm; extension-DMO1: 15.0 Nm/DMO2: 4.4 Nm) were also reduced.

Conclusions: A novel dynamic spinal orthosis was designed that maintained spinal off-loading throughout extended ranges of flexion and extension movement without buildup of adverse bending moments.

Keywords

Lumbar spinal orthosis, low back pain, biomechanical testing, back brace

Date received: 1 March 2016; accepted: 28 August 2016

Introduction

Low back pain (LBP) affects 60% to 90% of individuals at some point in their life.[1] As many as 5.4 million Americans are disabled annually as a result of LBP.[2,3] Back-related problems remain the most expensive cause of work-related disability in terms of worker's compensation and medical expenses.[4–6] Unfortunately, LBP affects not only the elderly; it is the most common cause of disability for those under 45 years of age.[7] The Spine Patient Outcomes Research Trial (SPORT) was designed to improve clinical decision making for surgical treatment of LBP problems. SPORT reported that approximately 70% of spinal diseases that caused LBP were mechanical in nature and included intervertebral disc herniation, spinal stenosis, and degenerative spondylolisthesis.[8] Deyo and Weinstein reported similar findings for causative pathologies of LBP with 97% having a mechanical basis.[6] Although surgery is sometimes required in severe cases, conservative treatment options like physical therapy and medication are available for those suffering from mechanical LBP. Other conservative LBP treatment methods seek to provide a distractive load to the lumbar spine to produce spinal decompression such as water therapy or use of

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a decompressive lumbar spinal orthosis (LSO).[9–12] Clinical studies have suggested that with adequate frequency and duration of treatment, therapeutic exercises that decompress the spine and allow movement, such as water therapy, can be beneficial in the treatment of LBP.[9–11]

LSOs have also been used to treat other spinal diseases for which the role of the brace is to replace the lost mechanical function brought on by the disease and provide varying amounts and combinations of immobilization, support-stabilization, or spinal decompression.[13,14] More recently, dynamic LSOs have been developed to provide relief from pinched nerves or disc or spinal cord compression.[12,15] These devices claim to axially decompress the spine but lack clinical or experimental evidence to support their efficacy. Although many different orthoses exist for treating lower back problems, we are not aware of any that provide the benefits of therapeutic exercise or enable independent living and return to active work. Such a device would well serve individuals suffering from disc degeneration, recovering from an injury, limited by weakness, and the elderly with several degenerative conditions.

The initial goal of this work was to design a back orthosis that offered spinal decompression while enabling some mobility to allow the user to engage in many daily living activities. A first prototype of a distractive mobility-enabling orthosis (DMO1)[16] was designed and tested under simulated biomechanical conditions that determined the amount of spinal off-loading provided by the orthosis during vertical upright stance, initiation of flexion or extension, and over-extended ranges of flexion and extension representative of many daily living activities.[17] The DMO1 was further tested against an existing decompressive stabilizing brace and demonstrated comparable spinal off-loading capacity, but was unable to sustain the spinal off-loading during extended ranges of flexion or extension and became more difficult to bend in at extended ranges of flexion and extension.[18]

The objective of this work was to overcome the design limitations of the original DMO1 prototype by sustaining spinal off-loading throughout extended ranges of flexion and extension with minimal buildup of the sagittal bending moment. Collectively, the new design was referred to as DMO2 and was biomechanically tested under physiological daily living load and movement conditions.

Methods

Distractive mobility-enabling orthosis

The original DMO1 prototype is shown in Figure 1(a) and had two unique design features: a distractive force component (DFC) and a mobility-enabling component (MEC). Each component was placed on the left and right lateral sides of the orthosis. The DFC consisted of a cable pulley system and a flexible graphite rod that was anchored to the pelvic belt as shown in Figure 1(b). The cable pulley system attached to the lower part of the torso glove and to a free-floating coaster. Once the pulley system was engaged, tension on the cable caused the cable pulley system to pull the coaster against the flexible rod. As the flexible rod deflected under the coaster's load, the base of the torso glove was pulled up to engage the torso. A band was placed between the vertically oriented rods to control its structural bending property, acting much like a mid-support of a vertical column carrying a buckling load. The MEC, which can be seen in Figure 1(c), consisted of the flexible graphite rod and the free-floating coaster that was tethered to the torso glove. With the pulley system engaged, the coaster was unconstrained and allowed to roll freely along the curved portion of the rod allowing flexion and extension of the torso glove relative to the pelvic belt.

The design goal for the modified orthosis, DMO2, was to overcome the limitations of the original DMO1 prototype by sustaining spinal off-loading throughout extended ranges of flexion and extension with minimal buildup of the sagittal bending moment. Unlike the original DMO1 design in which the function of the DFC and MEC components were coupled together, the modified design of DMO2, shown in Figure 2, had the two components function independently of each other. The DFC consisted of a modified cable pulley system, a flexible graphite rod, a rod clamp, and a non-deformable ring (see Figure 2(a)). The ends of the graphite rod were anchored to the pelvic belt similar to the original orthotic design, and the upper section of the non-deformable ring attached to the torso glove by the use of tie rod ends. The top portion of the modified cable pulley system was rigidly fastened to the rod via a rod clamp and the lower part was connected to the base of the non-deformable ring. When the modified cable pulley system was engaged, the rod clamp was pulled downward against the rod and deflected under the load. With the rods anchored at the pelvic belt, an upward force was applied to the torso glove through the non-deformable ring. A band similar to that used in the DMO1 design was placed between the rods to control its flexural bending property. The non-deformable ring was translationally constrained by vertical guides and allowed to travel freely when the modified cable pulley system was engaged (Figure 2(b)). The MEC consisted of three tie rod ends fastened to an interface plate and the non-deformable ring (Figure 3). The interface plate attached to a mounting plate on the torso glove. The tie rod ends were guided by the non-deformable ring to provide flexion and extension.

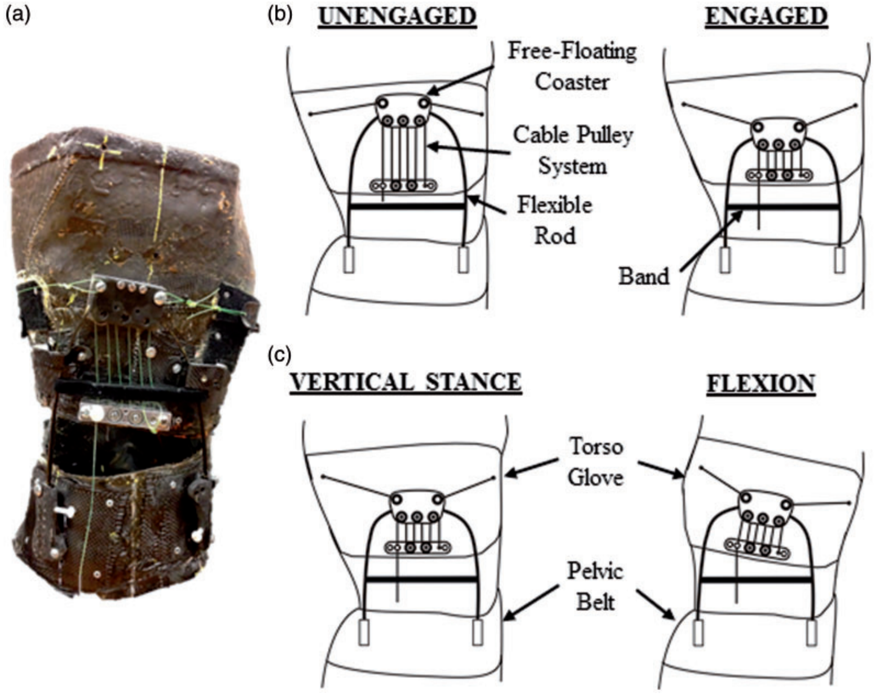

Figure 1. Original DMO1 prototype. (a) Photograph of prototype, (b) the DMO1 distractive force component, and (c) the DMO1 mobility-enabling component. DMO1: previously developed prototype of dynamic mobility orthosis.

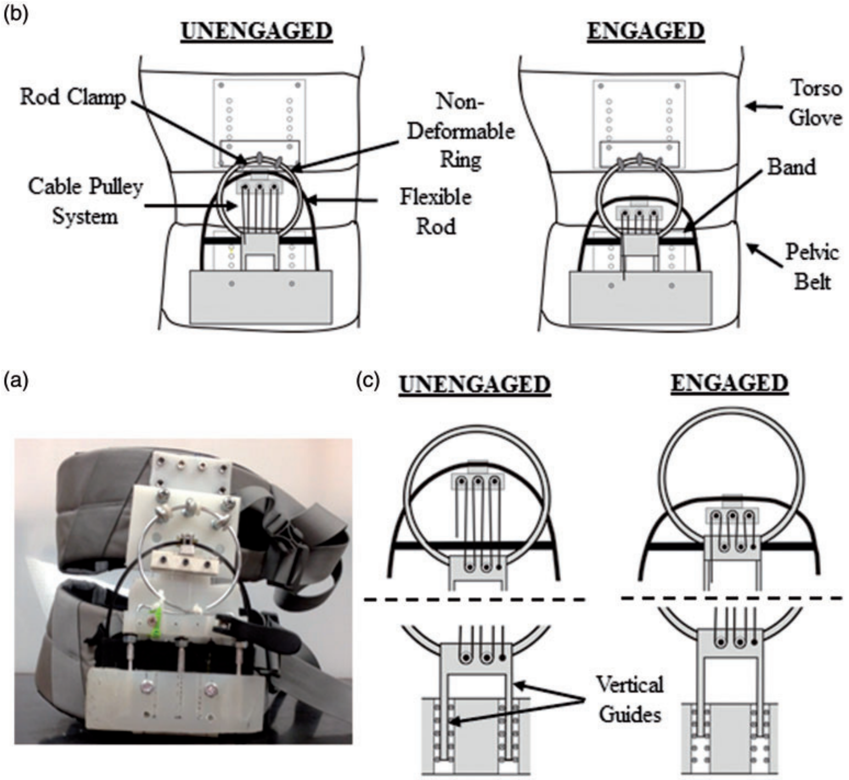

Figure 2. Modified DMO2 prototype. (a) Photograph of prototype, and (b) interaction between the cable pulley system, rod and non-deformable ring during engagement and un-engagement. As the rod deflects, a distractive force is applied across the spine, (c) and the ring was permitted to move vertically in the engaged state. DMO2: new dynamic mobility orthosis.

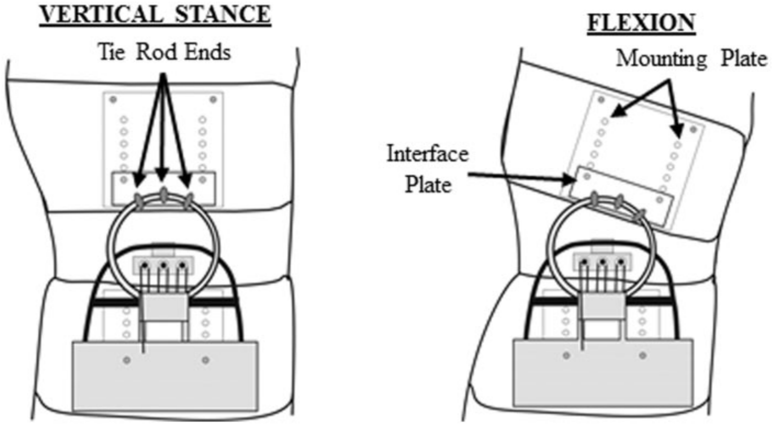

Figure 3. Operation of the mobility-enabling component on DMO2.
DMO2: new dynamic mobility orthosis.

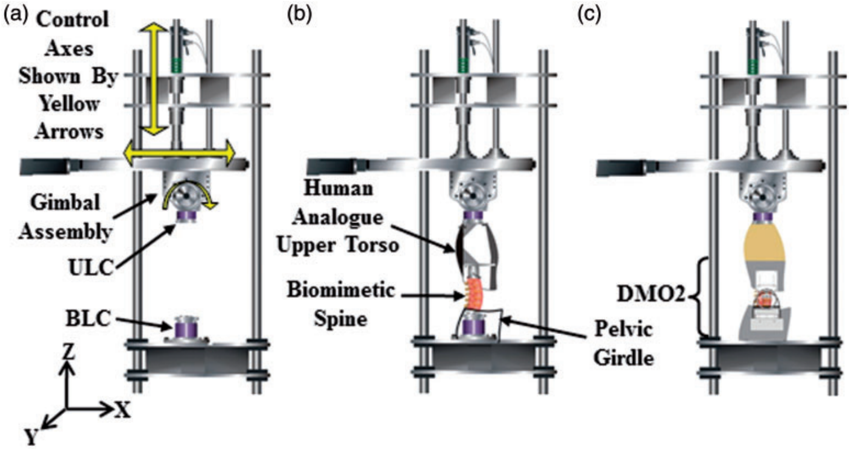

Figure 4. Advanced testing assembly. (a) RTP with programmable axes, (b) human upper torso analog model, biomimetic spine, and pelvic girdle components mounted in the RTP, and (c) placement of DMO2 on the torso analog model mounted in the RTP.
RTP: robotic testing platform; DMO2: new dynamic mobility orthosis.

Robotic testing platform (RTP) and mechanical analog upper torso model

A multi-axis RTP[19] was used that provided four programmable degrees of freedom having a positional resolution of 2 µm in x, 0.31 µm in z, and 0.0002 degrees about y (see Figure 4(a)). The RTP had a six-axis load cell mounted to the upper gimbal assembly and another load cell mounted to the lower base plate. The upper load cell (ULC), which measured applied forces and moments, had a maximum axial force of 445 N and a resolution of 0.2 N. The base load cell (BLC) had a maximum axial force of 4445 N and a resolution of 0.73 N.

An upper torso, biomimetic lumbar spine, and pelvic girdle assembly (the combination of which is referred to as the human mechanical analog) was designed to emulate the physical and structural properties of a male human adult torso. The biomimetic lumbar spine consisted of individual spinal components having shape and size comparable to the human lumbar motion segments. The L1–L5 vertebral bodies were cast in rubber molds made from harvested human spines. The individual discs were fabricated based on characteristics from the literature[20] and provided the anterior and posterior heights for each disc. The material for each disc was 30 durometer urethane (74-30D urethane from US Composites, West Palm Beach, FL). The full L1–L5 lumbar assembly was coated with 30 durometer urethane. The final flexural rotational stiffness over 10° of flexion was 0.66 Nm/degree, which approximated cadaveric test data.[21]

A life-size male mannequin was cut and substantially reinforced internally with carbon fiber and

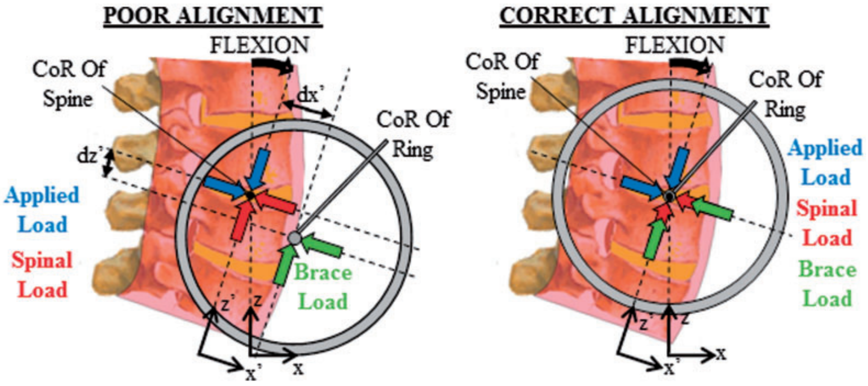

Figure 5. Proper placement of DMO2 on the body. The effort required to move was minimized by aligning the center of the ring close to the center of rotation of the lumbar spine. DMO2: new dynamic mobility orthosis.

epoxy resin to provide an upper torso frame and separate pelvic girdle assembly for engaging a worn orthosis as it was tested. Multiple layers of a textured material (Kobalt Zerust drawer liner, Zerust Corrosion Products, Twinsburg, OH) were placed around the external surface of the upper torso component that simulated the texture and orthosis-engagement properties of human tissue. The material had a hardness of approximately 30 Durometer Shore A at its thickest section of the weave pattern. Each layer was impregnated and externally coated with a thin coating of 30 Durometer Shore A urethane. The biomimetic spine was mounted superiorly to the upper torso frame and inferiorly to the BLC (see Figure 4(b)). The BLC was surrounded by, but not in contact with, the pelvic girdle assembly. The pelvic girdle assembly was provided to mount to and engage the lower portion of an orthosis to be tested and was anchored to the base plate of the RTP.

DMO2 was placed on the mechanical analog upper torso model that was mounted in the RTP and collectively used to design unique features of the proposed dynamic orthosis (Figure 4(c)). The location of the non-deformable ring on DMO2 was adjustable with the goal of aligning the center of the ring close to the center of rotation (CoR) of the lumbar spine (see Figure 5). If the center of the ring was not aligned properly with the CoR of the lumbar spine, the distractive force from the DFC created loads off-axis to the CoR of the spine (dx' and dz') that contributed additional bending moments about the spine. By correctly aligning the center of the ring close to the CoR of the lumbar spine, minimal additional bending moment was required to move. Correct alignment of the center of the ring with the CoR of the lumbar spine ensured that DMO2 and the lumbar spine were working together during extended ranges of flexion and extension.

Testing protocol and force analysis

The test conditions for the DMO2 prototype were similar to that used in the original evaluation of DMO1: an upper torso load of 300 N in upright stance, initiation of flexion and extension, and extended ranges of 25° flexion and 10° extension.[16,18] The 300 N value simulated the upper body (above the abdomen) weight of a person whose approximate total body weight was 750 N based on the anthropometric data that the upper body comprised approximately 40% of total body weight.[22] In the end, the loads applied to the spine and orthosis consisted of a bending moment and the upper body weight force components. To apply these loading conditions, the RTP was first programmed to establish the kinematic path of the lumbar spine alone under pure moment loading by introducing an incremental rotation to the spine and the reducing the off-axis forces by minimizing the distance ($\Delta x'$ and $\Delta z'$) between the initial prescribed CoR and true CoR of the lumbar spine (see Figure 6). Once the location for a pure moment loading condition was established at every 0.5° incremental rotation, the force components of the upper body weight could be applied along the new rotational axes until the end rotation limit was reached to simulate the loading conditions of a bending moment plus upper body weight forces. Data from the modified kinematic path of the robot were also used to determine the CoR of the biomimetic lumbar spine by adapting the CoR equations from Crisco.[23] Note that these CoR values of the lumbar spine were used above to align the center of the non-deformable ring on DMO2 with the CoR of the lumbar spine. The modified orthosis was then mounted on the testing platform, aligned with the spine, and the advanced testing protocol was rerun to simulate the testing conditions above.

The primary outcomes for this study were spinal offloading (brace load) and bending moment (brace effect)

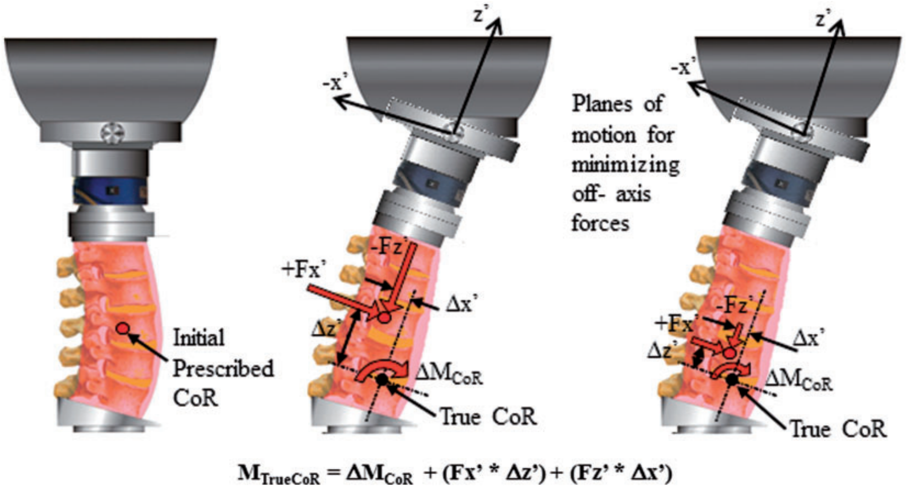

Figure 6. The RTP was programmed to reduce the off-axis force contribution to the lumbar spine at each incremental rotation by minimizing the distance between the initial prescribed CoR and the true CoR of the lumbar spine. RTP: robotic testing platform; CoR: center of rotation.

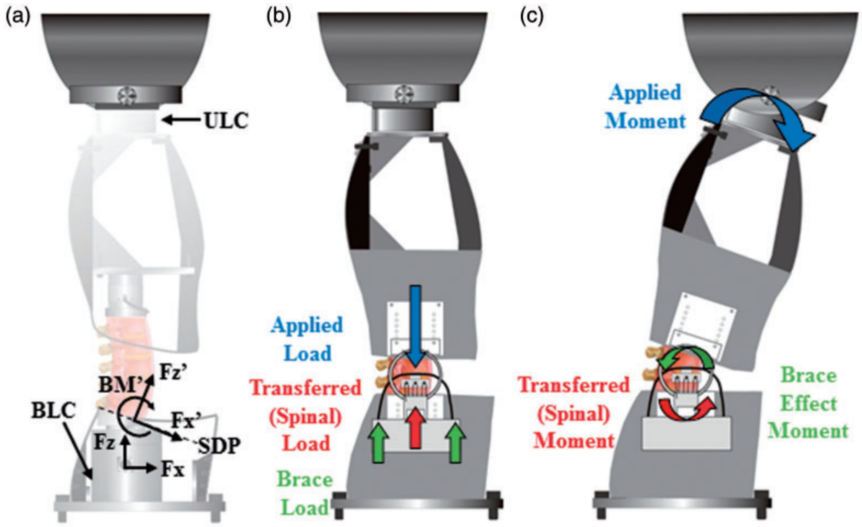

Figure 7. Force analysis of the DMO2 prototype in the RTP. (a) Forces were transformed to the sacral disc plane, (b) the brace load was calculated as the difference in the measured applied load and the transferred load, and (c) the brace effect was calculated as the difference in the measured applied moment and the transferred moment. DMO2: new dynamic mobility orthosis; RTP: robotic testing platform.

of DMO2 at upright stance and during flexion and extension ranges. Applied loads to the torso-orthosis assembly by the RTP were measured at the ULC and the loads transferred through the lumbar spine were measured at the BLC. The ULC and BLC forces and bending moments were transformed to the sacral disc plane (SDP) and compared in flexion and extension (Figure 7(a)). The difference in the applied load and the transferred load represented the brace load carried by DMO2 (Figure 7(b)). The difference in the applied moment and the transferred moment represented the brace effect moment caused by DMO2 (Figure 7(c)).

Results

Spinal off-loading analysis

The off-loading capacity of the modified (DMO2) and original (DMO1) prototypes is shown in Figure 8 for the 300 N upper body weight loading condition in the upright stance configuration and through extended ranges of 25° flexion and 10° extension. The percentage of the applied load carried by each orthosis is given in Table 1 along with the loads carried by the orthoses and the load transferred through the lumbar spine. The load values for DMO1 were determined in a

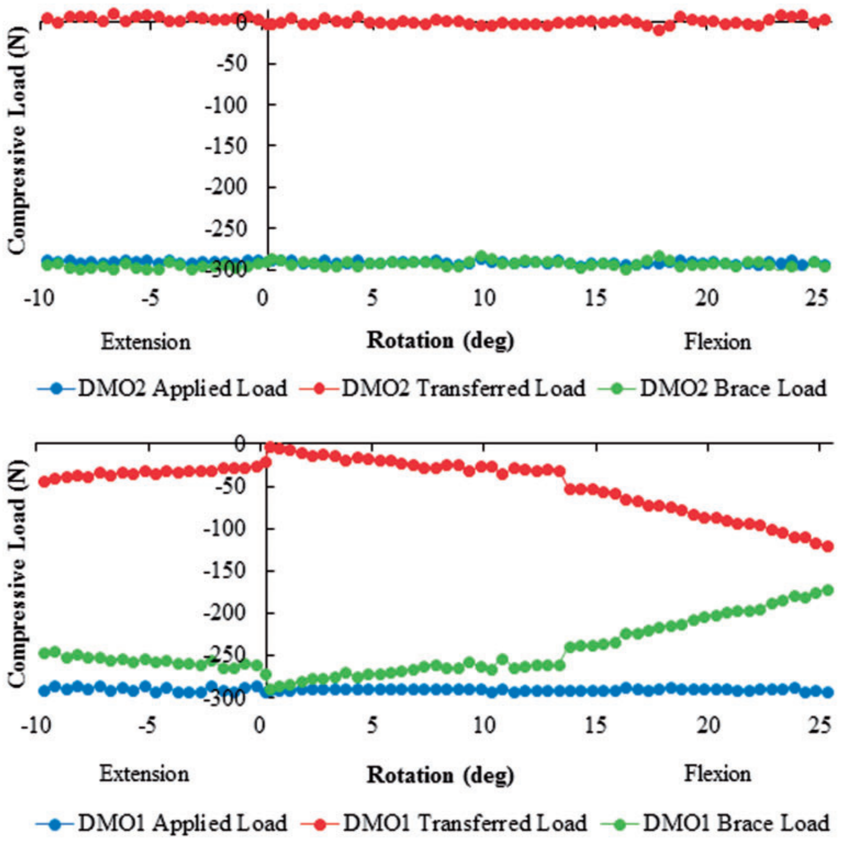

Figure 8. Spinal off-loading of DMO2 (top) compared to DMO1 (bottom). DMO2: new dynamic mobility orthosis; DMO1: previously developed prototype of dynamic mobility orthosis.

Table 1. Comparison of DMO1 and DMO2 compressive load values at upright stance and at end ranges of motion.

Degrees of rotation	Applied load (*N*)[a]	Transferred load (*N*)[a]	Brace load (*N*)[a]	Brace load as a percentage of applied load[a] (%)
At 10° extension	290/288	43/–5	247/293	85/102
At 0°	300/288	0/6	300/282	100/98
At 25° flexion	291/293	119/3	172/290	59/99

[a] DMO1/DMO2. DMO1: previously developed prototype of dynamic mobility orthosis; DMO2: new dynamic mobility orthosis.

previous study under similar test conditions.[14] At end-range flexion, DMO2 supported almost all the applied load (i.e. 99%) compared with 59% for DMO1. At the end-range extension, all the applied load was supported by DMO2 and the spine was placed under slight traction (102%) compared to 85% support for DMO1.

Bending moment analysis

The sagittal bending moment versus angular displacement response of the modified (DMO2) and original (DMO1) prototypes is shown in Figure 9 for the 300 *N* upper body weight loading condition in the upright stance configuration and through extended ranges of 25° flexion and 10° extension. End-range moment values for both DMO1 and DMO2 are listed in Table 2. The applied moment required to reach 25° flexion was 21.7 Nm for DMO2 and 32.4 Nm for DMO1. A similar reduction in the bending moment was required to reach 10° extension by DMO2 (10.9 Nm) compared to DMO1 (15.0 Nm). The moment buildup to movement of each orthosis, referred to as the brace effect, is also listed in Table 2.

At end-range flexion, only 6.6 Nm of sagittal moment was required for DMO2 compared to 18.6 Nm for DMO1. At end-range extension, the brace effect of DMO2 was 4.4 Nm compared with 15.0 Nm for DMO1. The moment buildup for DMO2

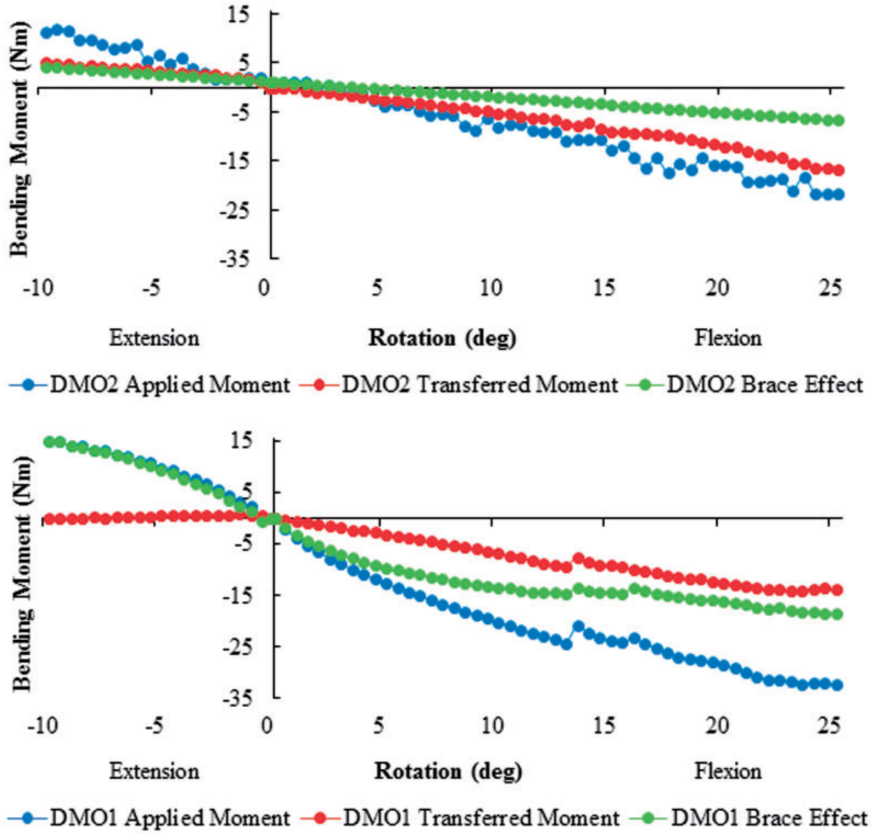

Figure 9. Resistance to bending of DMO2 (top) compared with DMO1 (bottom).
DMO2: new dynamic mobility orthosis; DMO1: previously developed prototype of dynamic mobility orthosis.

Table 2. Comparison of DMO1 and DMO2 bending moment values at upright stance and at end ranges of motion.

Degrees of rotation	Applied moment (Nm)[a]	Transferred moment (Nm)[a]	Brace effect (Nm)[a]	Brace effect as a percentage of applied moment[a] (%)
At 10° extension	15/10.9	0/6.5	15/4.4	100/40
At 25° flexion	32.4/21.7	13.8/15.1	18.6/6.6	57/30

[a] DMO1/DMO2. DMO1: previously developed prototype of dynamic mobility orthosis; DMO2: new dynamic mobility orthosis.

was 27% less than that of DMO1 (i.e. 30% compared with 57%) at end-range flexion and 60% less at end extension (40% for DMO2: 40% compared to 100% for DMO1).

Discussion

Advanced testing assembly

A novel testing assembly was developed that consisted of a custom mechanical analog torso model integrated into a RTF having advanced testing capabilities.[19] The testing assembly has previously been used to evaluate the loading mechanics of existing back orthoses[18] and was used in this study to carry out the design of a novel dynamic spinal orthosis having the unique design goal of providing spinal off-loading while enabling mobility, features currently not available in existing back braces on the market. Aspects of the testing protocol were selected to simulate load and movement conditions associated with many daily living activities.[17]

Limitations of study

As with most biomechanical studies, there were limitations with this research. The testing protocol simulated the force components of the gravitational torso loading mechanics but not the corresponding in vivo spinal bending moment. The resultant bending moment was a function of the biomimetic spine's structural properties that were designed to emulate a normal healthy person. Changes to the structural properties of the biomimetic spine would be needed to emulate the effects of select lumbar disease conditions, e.g. lower Durometer material could be used to model an injured/degenerative disc. Another limitation of the testing protocol was that motion was limited to the sagittal plane only. Future work will expand the capacity of the testing assembly to include lateral bending and axial rotation. Finally, the physical size of the testing platform limited the extended range of motion test to 25° of flexion and 10° of extension. Despite this limitation, this range was more than adequate to simulate the movement conditions of many daily living activities. In the end the testing assembly was successful at demonstrating the spinal off-loading capabilities of the prototype orthoses as well as the required effort to move in the orthoses.

Findings

Minimal clinical or scientific evidence exists that supports the design rationale of dynamic LSO, in particular the efficacy of back braces claiming to off-load the lumbar spine. Further, from the perspective of at least one health insurance company, the Orthotrac thoracic lumbosacral orthosis was not considered to have demonstrated itself as a medically necessary device because of a shortage of peer-reviewed, placebo-controlled trials.[24] More basic science and clinical studies are needed to support the claims of these dynamic spinal orthoses. The goal of this work was to address this shortcoming by designing and biomechanically evaluating novel prototypes of a dynamic LSO that provided spinal off-loading while enabling mobility.

Two prototype models were built and tested. Although the original DMO1 prototype demonstrated some spinal off-loading capabilities, some of the simulated vertical torso weight was transferred to the spine as flexion or extension increased. However, this outcome was not observed with the revised DMO2 model. Spinal loads were completely supported by the orthosis during upright stance and continued throughout extended ranges of flexion and extension. Another positive outcome of the dynamic orthosis was the ability to allow flexion and extension movement to occur with minimal bending moment buildup. The DMO1 prototype required 32.4 Nm of moment to reach 25° flexion compared with 21.7 Nm for the DMO2 prototype. Similarly, the DMO1 prototype required 15 Nm of moment to reach 10° extension compared with 10.9 Nm for the DMO2 prototype.

In the original DMO1 prototype a flexible rod was used to create a distractive force across the lumbar spine. However, the same rod was used as a guide to allow flexion and extension motion. Because of the uncontrolled deformation of the rod under the distractive force, the MEC of DMO1 allowed only limited unconstrained movement until the components began to bind, which affected both the off-loading capacity and the orthosis' resistance to bending, i.e. increased brace (moment) effect. By redesigning the components so the flexible rod was used only for its distractive force capabilities and adding a non-deformable ring that had a fixed rotational axis that could be aligned to the spine's native rotational axis to provide optimal guided motion, a spinal orthosis was redesigned that met the goals of off-loading the lumbar spine while enabling motion without buildup of any excessive bending moments.

Future research design plans for the distractive mobility-enabling orthosis are to expand the orthosis' range of movement to include lateral bending and coupled axial rotation. Also, a clinical trial will be undertaken on patients with mechanical LBP to prove the efficacy of this novel LSO in collaboration with a local physiatrist and physical therapist. An essential outcome of this clinical trial will be to address the short-term and long-term effects on LBP through the use of this dynamic orthosis. Those suffering from degenerative disc disease with associated LBP may greatly benefit from the DMO2 prototype. These patients usually start with dehydration in the nucleus of the disc that affects the disc's ability to properly respond to loading. Over time, overloading of the disc can cause irritation to local pain-sensitive nerves.[15] In order to reduce pain for these patients, the stability of the disc must be controlled and irritation of pain-sensitive nerves must be minimized. It is believed that the distractive load applied across the lumbar spine by DMO2 would directly decrease the load acting on the diseased disc(s) and reduce the associated pain.

The combination of providing distraction across the lumbar spine with the ability to undergo controlled movement with minimal resistance could result in improved core stability and development of motor control to improve coordination of postural muscles. The possible increased lumbar disc height while wearing DMO2 could further lessen the effects of pain and could result in a temporary increase in lumbar disc height. Lastly, the DMO2 is unique in that it can provide spinal off-loading while still allowing the user to perform normal daily living activities unlike previously mentioned proven conservative treatment options such as water therapy.

Conclusions

The combination of the mechanical analog of a life-size human upper torso and an advanced testing protocol served as a design tool to redesign a novel lumbar spinal orthosis that provided distractive forces across the lumbar spine and required minimal effort for movement. This testing assembly can also serve as the foundation for the development of new testing methods for classifying and ranking spinal orthoses.

Acknowledgments

The authors would like to acknowledge John Simmons for his contribution on the design of DMO1 and for the development of the testing protocol. Also, the authors would like to thank Daniel Wido for assistance with programming the RTP. US Patent Application Serial No. 14/209,925 received 7 July 2014, entitled Lifting Distraction Back Support Device.

Declaration of Conflicting Interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the BioRobotics Laboratory in the Department of Orthopaedic Surgery and Biomedical Engineering at The University of Tennessee Health Science Center in Memphis, TN, USA.

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