

THESIS

**Design and Evaluation of a Novel Back Supporting Device for
Manual Lifting Tasks**



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Acronyms

AB	Abdominal belt
cNSLBP	Chronic non-specific low back pain
EO	External oblique
ES	Erector spinae
IAP	Intra-abdominal pressure
IO	Internal oblique
IVD	Intervertebral discs
IVR	Intervertebral rotation
LBP	Low back pain
LD	Latissimus dorsi
MF	Multifidus
RA	Rectus abdominus
ROM	Range of motion
TLF	Thoracolumbar fascia
TrA	Transversus abdominus
Trap	Trapezius muscle

Abstract

Low back disorders, including low back pain (LBP), are a highly prevalent musculoskeletal conditions that impose a significant burden on individuals, industries, and governments. A substantial portion of the population experiences limitations in daily activities due to back pain, with mechanical issues such as spinal instability being widely recognized as a major contributing factor.

Recent research has focused on the development of exoskeletons to assist with lifting tasks. However, these technologies are often cumbersome, complex to operate, and not easily accessible to the general workforce. Furthermore, their effectiveness in improving wearer stability is limited. Consequently, this dissertation aims to investigate the effectiveness of passive methods, specifically through the increase in intra-abdominal pressure (IAP) and the support provided by paraspinal muscles and the thoracolumbar fascia (TLF), in enhancing spine stability. The major focus of this research was to develop and evaluate a novel passive back support device that facilitates the generation of IAP during trunk flexion. To achieve this, an accurate and representative model of the spine was first developed to assess the factors contributing to spine stability when wearing an abdominal belt (AB). Next, a novel back support device was designed, developed, and evaluated using a unique mechanism to selectively improve stability. The specific objectives of this study were (1) to investigate the impact of wearing an AB on IAP and spine stability using numerical simulations, and (2) to develop and evaluate the effectiveness of the novel back support device in improving spine stability during functional tasks.

The results of objective 1 indicate that the use of an AB improves trunk bending stiffness, primarily within the lumbar spine, by generating IAP. Wearing an AB may also reduce stress on the intervertebral discs by decreasing tensile stress within the multifidus and TLF. However, the study revealed a substantial increase in transverse stress in part of the TLF spinal attachments associated with the change in IAP, which could have clinical significance in terms of LBP. The spine model developed in this study was validated through *in silico* and *in vivo* comparative tests, demonstrating its accuracy and effectiveness in representing spine physiology within the defined scope of validation.

Preliminary results from objective 2 reveal that the novel back support device increases both IAP and segmental stability during various functional tasks, for both healthy and LBP groups. This suggests that the novel device enhances stability during lifting tasks, thereby reducing loading on spinal tissues, improving the wearer's confidence in lifting, and potentially facilitating the reintegration of workers with LBP.

This dissertation contributes to the understanding of passive assistive technologies for improving spine stability, specifically through the generation of IAP and by mimicking the support provided by paraspinal muscles and the TLF. These findings have implications for improving the management and treatment of low back disorders, with potential benefits for individuals, industries, and society as a whole.

Résumé

Les pathologies lombaires, y compris la lombalgie, sont des troubles musculo-squelettiques très répandus qui représentent un fardeau important pour les individus, les industries et les gouvernements. Une grande partie de la population souffre de limitations dans ses activités quotidiennes en raison de douleurs lombaires, et les problèmes mécaniques tels que l'instabilité de la colonne vertébrale sont largement reconnus comme un facteur contributif majeur.

Les travaux de recherche récents se concentrent sur le développement d'exosquelettes permettant de faciliter les tâches de levage. Cependant, ces technologies sont souvent encombrantes, complexes à utiliser et peu abordables pour grand public. De plus, leur efficacité à améliorer la stabilité de l'utilisateur est limitée. Par conséquent, cette thèse vise à étudier l'efficacité des méthodes passives, notamment par l'augmentation de la pression intra-abdominale (PIA) et le soutien fourni par les muscles spinaux et le fascia thoracolombaire (FTL), pour améliorer la stabilité de la colonne vertébrale. L'objectif principal de cette recherche était de développer et d'évaluer un nouveau dispositif passif de soutien lombaire qui facilite la génération de PIA lors de flexions du tronc. Pour ce faire, un modèle par éléments finis détaillé et représentatif de la colonne vertébrale a d'abord été développé afin d'évaluer les facteurs contribuant à la stabilité de la colonne vertébrale lors du port d'une ceinture abdominale. Ensuite, un nouveau dispositif de soutien lombaire reposant sur un mécanisme unique d'amélioration sélective de la stabilité a été conçu, développé et évalué. Les objectifs spécifiques de cette étude étaient (1) d'étudier l'impact du port d'une ceinture abdominale sur la PIA et la stabilité de la colonne vertébrale à l'aide de simulations numériques, et (2) de développer et d'évaluer l'efficacité du nouveau dispositif de soutien lombaire pour améliorer la stabilité de la colonne vertébrale lors de tâches de levage.

Les résultats du premier objectif indiquent que l'utilisation d'une orthèse améliore la rigidité en flexion du tronc, principalement au niveau de la région lombaire, grâce à la génération de PIA. Le port d'une ceinture abdominale permet également de réduire les pressions exercées sur les disques intervertébraux en diminuant les tensions dans le muscle multifide et le FTL. Cependant, l'étude a révélé une augmentation substantielle de la contrainte transversale dans une section des attaches vertébrales du FTL associée à l'augmentation de la PIA, ce qui pourrait être cliniquement significatif en termes de douleurs lombaires. Le modèle numérique de tronc développé dans le cadre de cette thèse a été validé par des tests comparatifs *in silico* et *in vivo*, démontrant sa fiabilité

et son exactitude dans la représentation de la physiologie de la colonne vertébrale dans le cadre défini par la validation.

Les résultats préliminaires du second objectif indiquent que le nouveau dispositif de soutien lombaire augmente à la fois la PIA et la stabilité locale pour diverses tâches fonctionnelles à la fois pour le groupe en bonne santé et celui souffrant de lombalgie. Cela suggère que le nouveau dispositif améliore la stabilité pendant les tâches de levage, réduisant ainsi la charge sur les tissus entourant la colonne vertébrale, améliorant la confiance du porteur dans ses capacités de levage et facilitant possiblement la réintégration des travailleurs souffrant de lombalgie.

Cette thèse contribue à mieux comprendre les technologies d'assistance au levage passive destinées à améliorer la stabilité de la colonne vertébrale, en particulier par la génération de PIA et en imitant le soutien fourni par les muscles spinaux et le FTL. Ces résultats ont des implications pour l'amélioration de la gestion et du traitement des troubles lombaires, avec des avantages potentiels pour les individus, les industries et la société dans son ensemble.

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I am deeply grateful for the invaluable support and guidance I have received throughout my research journey. Foremost, I would like to extend my sincere appreciation to my research supervisor, Dr. Mark Driscoll, whose leadership and academic acumen have been instrumental in shaping the success of this project. His insightful research project proposals have led to the formation of a diverse and highly dedicated research team, who collaboratively explore cutting-edge technologies in our field. Dr. Driscoll's expertise in the field of spine biomechanics and his insightful discussions on various topics have not only propelled this research forward but have also fostered an inspiring and enjoyable work environment.

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Author's Contribution

I, Emeric Bernier, certify that I am the primary author of all the manuscripts and chapters included within this dissertation. The dissertation is organized in a manuscript-based style. The first manuscript is currently under review by the editorial board of the Journal of Biomechanics and the second manuscript has yet to be submitted for publication, pending the analysis of electromyography (EMG) data and the completion of statistical analysis to ensure robust and comprehensive reporting of the results. This dissertation contributes to the literature's understanding of AB mechanisms and provides an alternative to existing assistive technologies, which could lead to more effective treatment options for individuals with LBP.

The author contributed to the definition of market/customer needs and requirements, the concept design, the construction, modelling, validation and analysis of a finite element model of the trunk for a first proof of concept, the writing of the clinical study proposal, the realization of the *in vivo* experiment, the data collection and analysis, as well as the writing of the two manuscripts.

1. Thesis Introduction

In most workplaces, workers are required to perform repetitive, and prolonged tasks, such as bending, lifting, or sitting, which have been opined to participate in the development of low back pain (LBP) [1]. When heavy loads are involved, lifting aids, such as hoist, trolleys, or lifts are often used to assist the worker. However, in many situations these lifting aids are not suitable because they are bulky, heavy and cannot perform complex tasks. Additionally, mechanical lifting aids are slower than human lifting, which leads workers to prioritize efficiency by lifting heavy loads without assistance. In other scenarios, such as office work, workers are required to sit at their desks for prolonged periods of time, often without the recommended ergonomic configuration suggested by occupational therapists. Back injuries from occupational activities are typically the result of accumulated damage caused by repetitive sub-failure loads or continuous stress over time, rather than a single event [2]. Repetitive loading and constant stress may cause the viscoelastic tissue to slowly deform and creep, resulting in loss of strength, and reduction in failure tolerance eventually leading to microfailure and local instability [3]. Sustained loading applied to the posterior passive tissues may also cause damage to the disc annulus (disc herniation) [4, 5]. Studies also suggest that tissue damage can change the biomechanics of the spine and affect nociceptors (pain sensory receptors) to further stimulation [6]. Therefore, people with a history of LBP may exhibit motor control deficits, delayed muscle response, loss of spine range of motion (ROM), and increased muscle fatigue [7, 8]. Consequently, anatomical changes, lower muscle endurance, lack of balance, increased sensitivity, and reduced spine stability can be observed in such individuals [7, 9-11].

Moreover LBP is described by the World Health Organization as one of the health problems that causes the most disability in a lifetime [12], such that an estimated 540 million people worldwide will be affected at some point in their lives by LBP [13]. In some individuals, the pain persists and worsens to the point of significantly limiting their daily activities. The time away from work is most often temporary, but it may last several months or even years, making it a major and costly cause of absenteeism among workers. In Quebec, the most frequent injury site is the back (24.9%), which results in annual costs of \$672 million [14]. In the United States, the total annual cost associated with LBP care is estimated to be between \$40 and \$50 billion annually [15].

The prevalence of LBP in industrialized countries may be associated with the complexity and multifactorial characteristics of the pathological mechanism [13]. In as high as 85% of lumbar disorder cases, the etiology is not defined, that is to say there is no definitive pathoanatomical diagnosis and no medical cause can explain the origin of the pain [16]. Clinical examinations or medical imaging tests prove to be of little use and a pain diagnosis of non-specific origin is most often made [17, 18]. Discrepancies in current diagnostic practices and limitations in the diagnostic technology are at the root of poor diagnosis and unsatisfactory low back care. Healthcare practitioners have developed a variety of ergonomic intervention strategies to lower the risk of injury. Their objective is to reduce loading on the spine whether through redesign of the work and the workstation, better training of workers, or the use of lifting aids. Corsets are one of the earliest lifting aids worn on the body. They are most often worn tightly over the abdomen, which generates pressure inside the abdominal cavity, also known as intra-abdominal pressure (IAP). However, the effectiveness of spinal corsets cannot be determined based on the current literature [19]. The primary objective of this dissertation is to design and evaluate the usability and performance of a novel back supporting device for manual lifting tasks. This will be accomplished via two specific objectives:

Objective 1:

Investigate the effects of wearing an abdominal belt (AB) on IAP and spine stability numerically.

Objective 2:

Develop and evaluate the effectiveness of a novel back supporting device that increases spine stability during functional tasks, building on the knowledge acquired in Objective 1.

To investigate the effects of IAP on spine stability, two finite element models (FEMs) were developed leveraging previously validated work from within the Musculoskeletal Biomechanics Research Lab at McGill [20]. The first model represented a healthy subject, while an identical second model including an AB was developed. Using the results from this study, a novel back support device was developed, and its effectiveness was evaluated in a prospective cross-sectional study that measured parameters to identify changes in spine stability. The hypothesis is that increasing stability of the spine may help in preventing injury for those with a history of LBP.

The following flow chart describes the stepwise approach to the objectives of this dissertation:

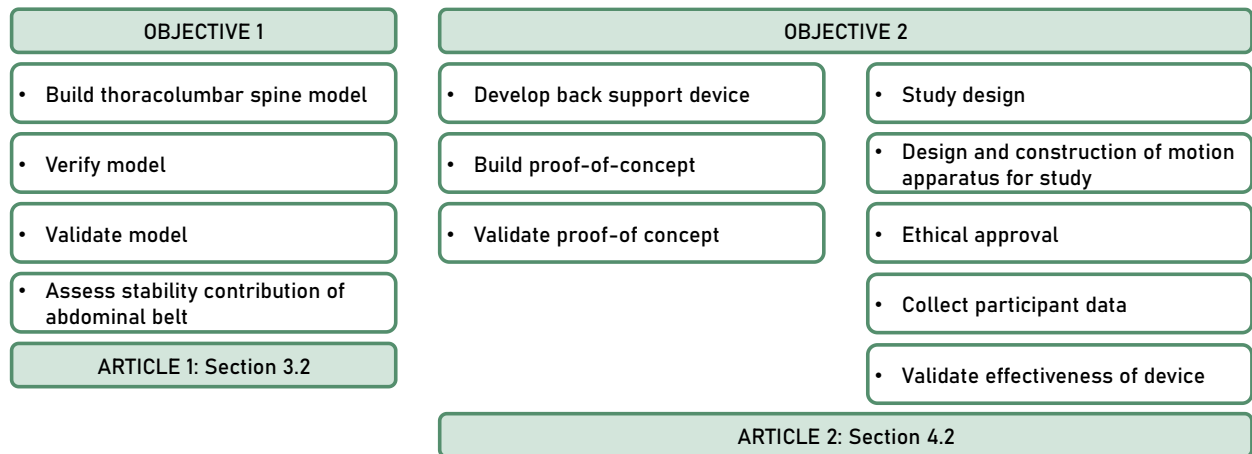


Figure 1.1.1: Thesis flowchart and research steps.

2. Literature Review

2.1 Functional Anatomy of the Trunk

2.1.1 Anatomical Planes

Anatomical terminology commonly utilizes the anatomical planes and axes to designate various body sections. The three primary anatomical planes are: transverse, coronal (or frontal), and sagittal. Additional terminology is also used to express the position and motion of body parts with respect to one another, such as medial (towards the midline of the body), lateral (away from the midline of the body), proximal (towards a reference point), distal (away from a reference point), superior (above), inferior (below), anterior (towards the front), and posterior (towards the back).

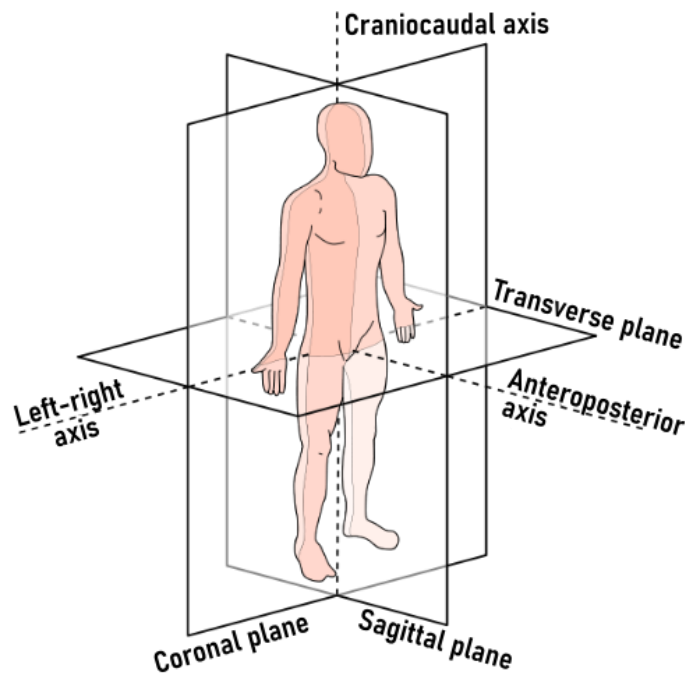


Figure 2.1.1: Anatomical planes and axes (accessed February 13th, 2023. [Online]. Available: https://commons.wikimedia.org/wiki/File:Anatomical_Planes-en.svg).

2.1.2 Structure of the Spine

The spinal column generally consists of 33 vertebrae divided in five anatomic regions: seven cervical (C1-C7), 12 thoracic (T1-T12), five lumbar (L1-L5), five sacral (S1-S5), and four coccygeal bones [21]. Vertebrae share a common structure consisting of a disc-shaped vertebral body and a vertebral arch. The arch comprises two pedicles, two laminae, and seven processes, including spinous, transverse, and articular processes. The lamina provides support and protection

for the posterior side of the spinal cord. The spinous process extends posteriorly from the vertebra, while the transverse processes protrude laterally from the junction of the lamina and the pedicle on either side of the vertebra, serving as attachment points for muscles and ligaments that mobilize and stabilize the spine. Articular processes project upward and downward from the vertebral arch of each vertebra serving as contact surfaces between adjacent vertebrae, facilitating movement and supporting the weight of the body.

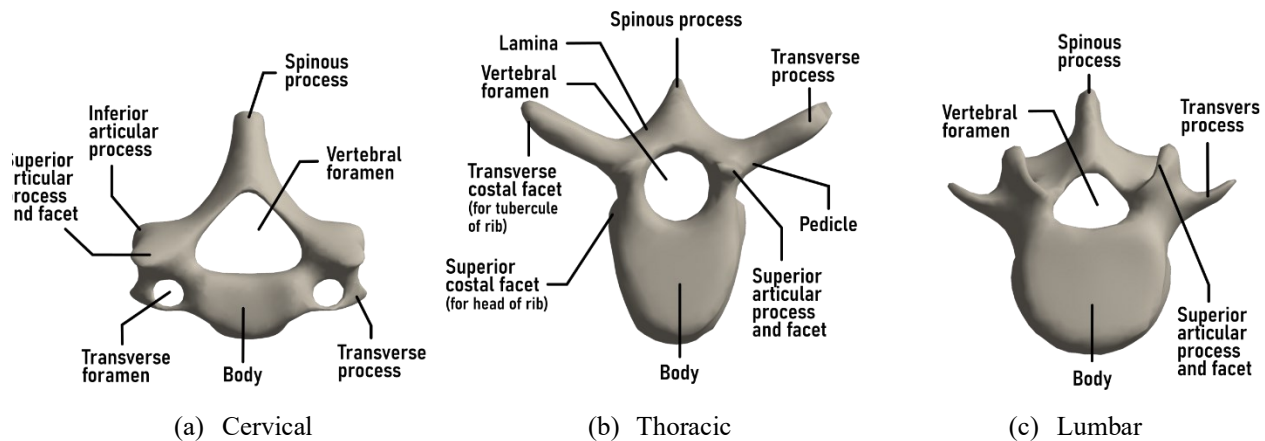


Figure 2.1.2: Characteristics of cervical (a), thoracic (b), and lumbar (c) vertebrae.

Vertebrae are separated at each level by intervertebral discs (IVDs). The discs are made up of the central nucleus pulposus, the peripheral annulus fibrosis, and the endplate of the disc. The nucleus pulposus, a gel-like substance with high water content, can be represented as a quasi-incompressible fluid. The annulus fibrosis is made up of collagen fibers in concentric laminated bands that help resist rotational, tensile, and shear stresses. To protect the IVDs, vertebral endplates act as an intermediary layer between the vertebrae and the discs. The endplates are strong but porous, allowing blood and nutrients to flow from capillaries in the bone to cells in the discs. The structure of the disc is viscoelastic, allowing it to deform according to the loading rate. This property provides flexibility to the spinal column and acts as a shock absorber in the spine. IVDs undergo age-related degenerative changes making them less resilient and stiffer, which contributes to some of the most common causes of impairment and disability in older people.

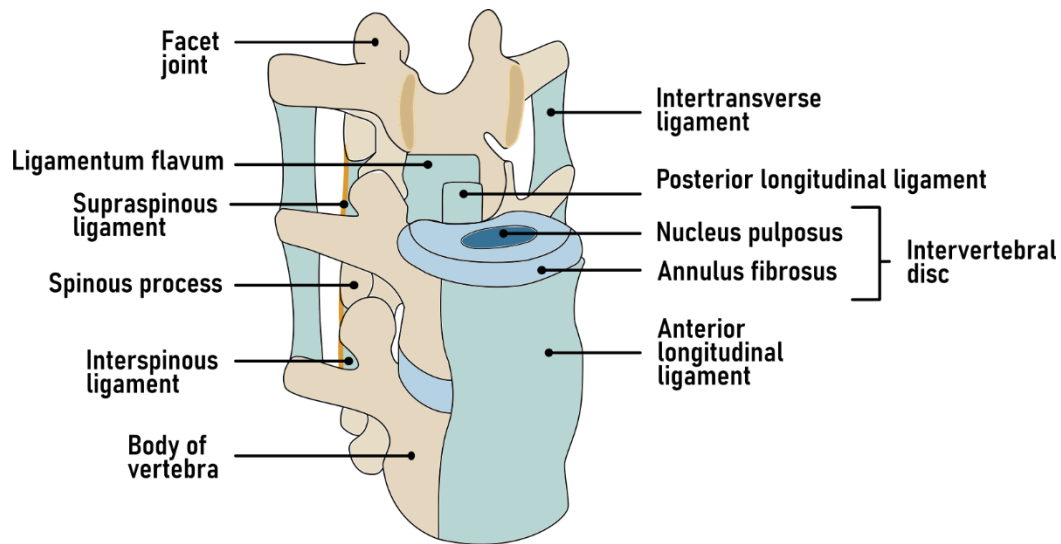


Figure 2.1.3: Major spinal ligaments and structure of intervertebral discs composed of the nucleus pulposus surrounded by the annulus fibrosis.

The spine stabilizing system comprises three distinct subsystems: active, passive, and neural [22]. Muscle activation controls the active subsystem, which may create compressive pressures on the spine via tendon attachments and pressure buildup inside trunk cavities. In addition to the previously described vertebrae and IVDs, the passive system comprises ligaments, tendons, fascia, and passive muscle contribution. The anterior and posterior longitudinal ligaments are crucial in maintaining the stability and preventing injury of the spine by limiting hyperflexion and hyperextension [23]. The elastic ligamentum flavum, which connects adjacent vertebrae, stores energy during movement, reducing the spinal load and potential injury [23]. Lastly, the neural system is made up of the central nervous system (CNS) and nerve roots, which are in charge of monitoring sensory information and activating subsystems to provide stability.

The primary curvatures in the adult spine are kyphosis in the thoracic and sacral regions, and lordosis in the cervical and lumbar regions. The four normal curves occur in the sagittal plane, while no curve is observed in the frontal plane of a healthy spine. The cervical and lumbar lordosis become more prominent during early childhood due to the gravitational forces created by the weight of the head and upright posture [24].

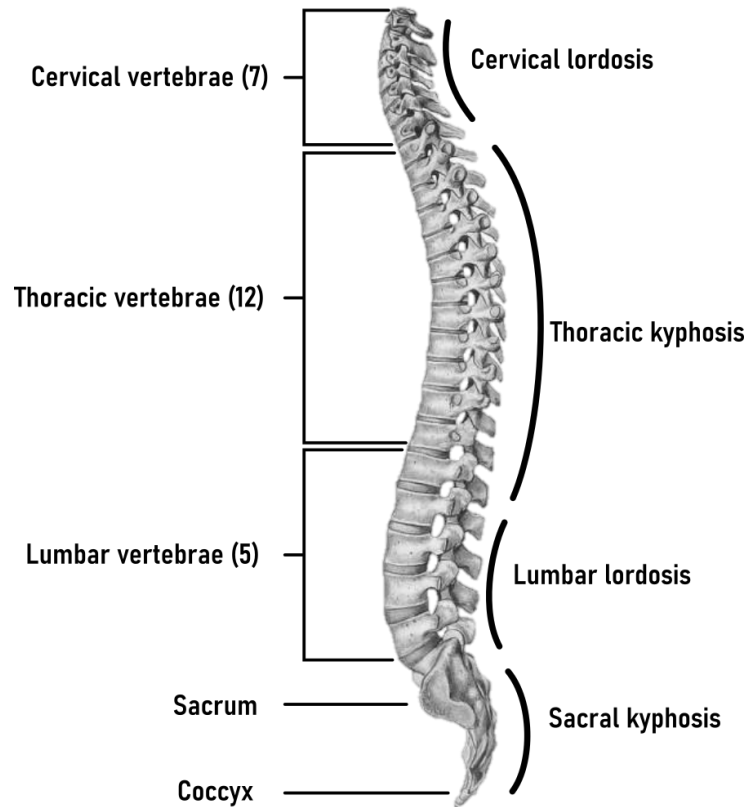


Figure 2.1.4: Vertebrae and corresponding spinal curvatures: cervical, thoracic, lumbar, sacrum, and coccyx (accessed March 3rd, 2023. [Online]. Available: https://commons.wikimedia.org/wiki/File:Spinal_column_curvature_es.svg).

The structural and physiological changes that occur in the IVDs and vertebrae over a lifetime vary for each individual. The variations can be amplified in particular by congenital malformations, aging of the spine, traumatic injuries, neurological disorders, imbalances of the paraspinal muscles, or the formation of osteophytes [25]. Osteophytes, which are bony growths that develop on the spine or around joints, are a natural response to joint instability caused by arthritis. They form as a way to alleviate stress on the affected joint, which can otherwise lead to spinal imbalances and other pathological conditions. Since the spine is flexible in nature, there is a significant ability to compensate for abnormalities or deformities.

2.1.3 Function of the Spine

The human endoskeleton functions to provide stability to the spinal column, internal support to the soft tissues and organs, protection for the spinal cord and associated nerve roots, and controlled movement to the trunk, head, and limbs. The physiological curvatures increase the flexibility and elasticity of the spine, allowing it to absorb shocks more effectively. The forces on

the spine emerge from the force of gravity, the ground reaction forces, and the forces produced by muscular contractions. The spongy cancellous, or trabecular, structure of mature adult bone is arranged in columns, forming a three-dimensional latticework that offers robust mechanical support along lines of stress, while minimizing the vertebrae's weight. Due to the load-bearing function of the spine, the vertebral bodies increase in size from the cervical to the lumbar region. Load is transferred to the lower limbs via the pelvic bone.

2.1.4 Abdomen

The human abdomen is a cavity that houses vital organs of the digestive, urinary, endocrine, exocrine, circulatory, and parts of the reproductive system [26]. It is located anterior to the spine and extends from the diaphragm superiorly and the pelvic brim inferiorly, as shown in Figure 2.1.5. The spine is a rigid boundary while the abdominal cavity is continuous with the pelvic cavity [27]. The anterior wall of the abdomen has multiple layers, most notably the skin, external obliques (EOs), internal obliques (IOs), transversus abdominis (TrA), and the peritoneum. The peritoneum is a continuous membrane divided into visceral and parietal layers lining the organs and cavity wall, respectively. This results in the formation of the peritoneal cavity, which is filled with extracellular fluid to lubricate the surfaces and reduce friction. The abdominal cavity comprises the peritoneal cavity and all organs within the abdomen. The abdominal cavity is regarded as having a closed volume of incompressible fluid with uniform pressure, defined as IAP [28]. The abdominal wall and diaphragm's flexibility allows for changes in the volume enclosed in the abdominal compartment, resulting in pressure variations during functional activity. The activation of the abdominal muscles leads to a typical range of IAP between 1 and 16 mmHg [29], which may increase up to 150 mmHg during demanding physical activities [30].

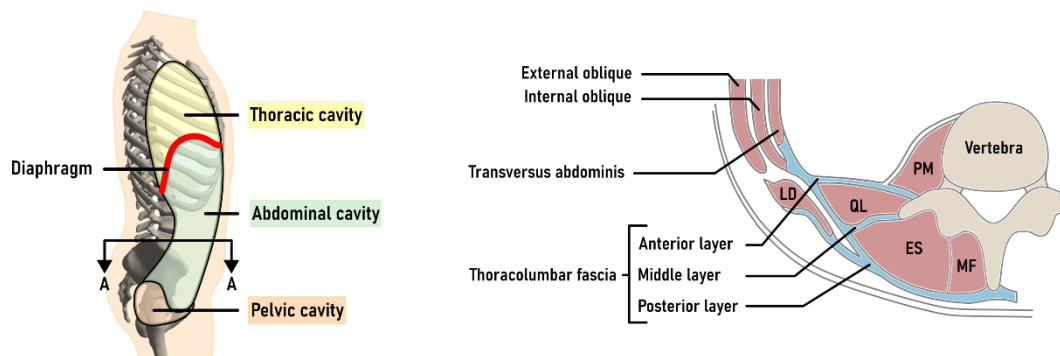


Figure 2.1.5: Location of the abdomen with upper and lower bound along with cross-section of the abdomen showing the layers of the thoracolumbar fascia and connections to neighbouring tissues. LD: latissimus dorsi, QL: quadratus lumborum, PM: psoas major, ES: erector spinae, MF: multifidus.

As the volume inside the abdomen changes, the shape of its cavity also changes in the transverse plane [31]. Between 0 and 12 mmHg, the abdominal wall expands in the anteroposterior direction while contracting in the left-right direction, causing the cavity to transition from an elliptical to a nearly circular shape [31]. However, in patients with obesity, this shape change may not occur [32]. When the IAP exceeds 15 mmHg, the rectus abdominis (RA) muscles start stretching until reaching the elastic limit of the abdominal wall (typically around an IAP of 25 mmHg), at which point IAP increases exponentially [33].

2.1.5 Spinal Muscles

Muscles of the spine are essential structures of the back. These muscles can be divided into three groups: superficial, intermediate, and intrinsic. The superficial muscles, which include the splenius cervicis and splenius capitis, are responsible for the movement of the shoulders and neck. The intermediate back muscles are mostly responsible for the movement of the thoracic cage. These muscles are divided into three groups of longitudinal muscles that span the length of the spine on both sides: iliocostalis, longissimus, and spinalis, which form a column known as the erector spinae (ES). These muscles generally have a similar function, which is to extend and laterally flex the spine. Each of these muscle groups consists of three subdivisions, which corresponds to the anatomic region of the spine to which they insert: lumborum, thoracis, cervicis, and capitis. The longissimus thoracis muscle, which appears between the iliocostalis and spinalis muscles, is the longest and thickest muscle in this group. Its primary function is to maintain the erect posture of the thoracic and lumbar regions, and to laterally flex the spine. Located underneath the ES, the deep intrinsic muscles are a group of short muscles that insert into the transverse and spinous processes of the spine. There are three major muscles in this group: semispinalis, multifidus (MF), and rotatores. The MF muscles have a distinct anatomical structure in which they fill the groove between the transverse and spinous processes of the vertebrae, providing additional support to the spine. Due to their insertion onto all the vertebrae except the atlas, the MF muscles are capable of extending, rotating, and laterally flexing the spine. Another important deep muscle group is the intertransversarii muscles, which span between the adjacent transverse processes, stabilizing adjacent vertebrae during spinal movements. The deep muscles are essential in articulating the spine and contributing to proprioception, which ultimately aids in balancing and stabilizing the spine.

Other significant muscles include the psoas major, which is one of the strongest muscles in the lower back, serving as a hip flexor while simultaneously providing support for upper body straightening, and the trapezius (Trap) and latissimus dorsi (LD), which may activate to set the thoracolumbar fascia (TLF) in tension [34, 35].

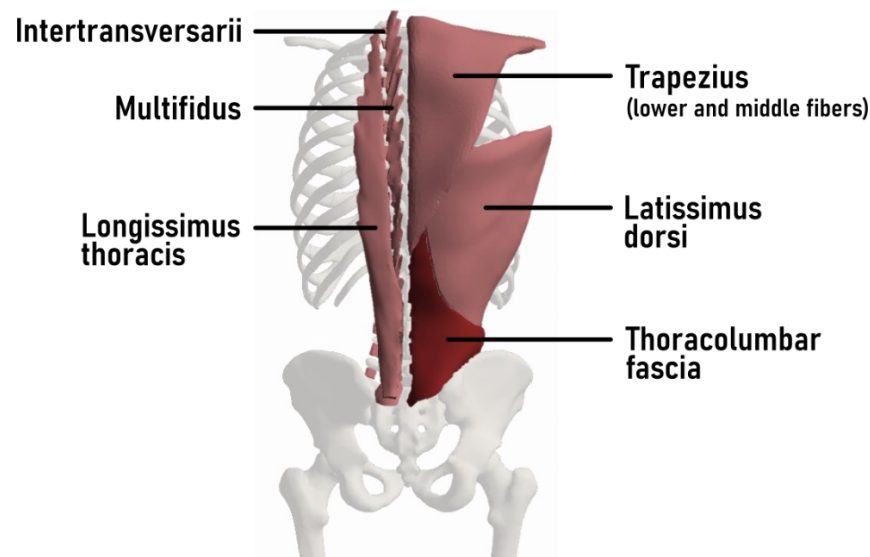


Figure 2.1.6: Major paraspinal soft tissues

2.1.6 Thoracolumbar Fascia

The TLF which extends from the thoracic spine to the sacrum, is a significant structure that plays an important role in transferring forces between the spine, pelvis, and lower limbs [36]. In the lumbar spine, the TLF is a strong sheet of dense connective tissue divided into three distinct layers. The posterior layer attaches to the lumbar spinous processes, interspinous ligaments, and sacrum, and connects the LD to the gluteus maximus vertically (see Figure 2.1.5). The anterior and middle layers surround the quadratus lumborum muscle.

As the three layers come together laterally, they attach to the TrA. Barker et al. noticed a substantial increase in the thickness of the middle TLF at the sites of attachment of the transverse processes, suggesting the involvement of TrA in lumbar segmental control [37]. In the thoracic spine, the TLF forms a thin sheet covering the ES muscle. As a result, when the MF or ES contracts, the TLF undergoes a longitudinal increase in tension, which may result in load transfer to surrounding tissues [36, 38]. Barker and Briggs have found superior extensions of the fascia, suggesting transmission of tension to numerous additional tissues, such as the Trap [39]. Under tension, the TLF may increase segmental stiffness and reduce muscle activation by generating

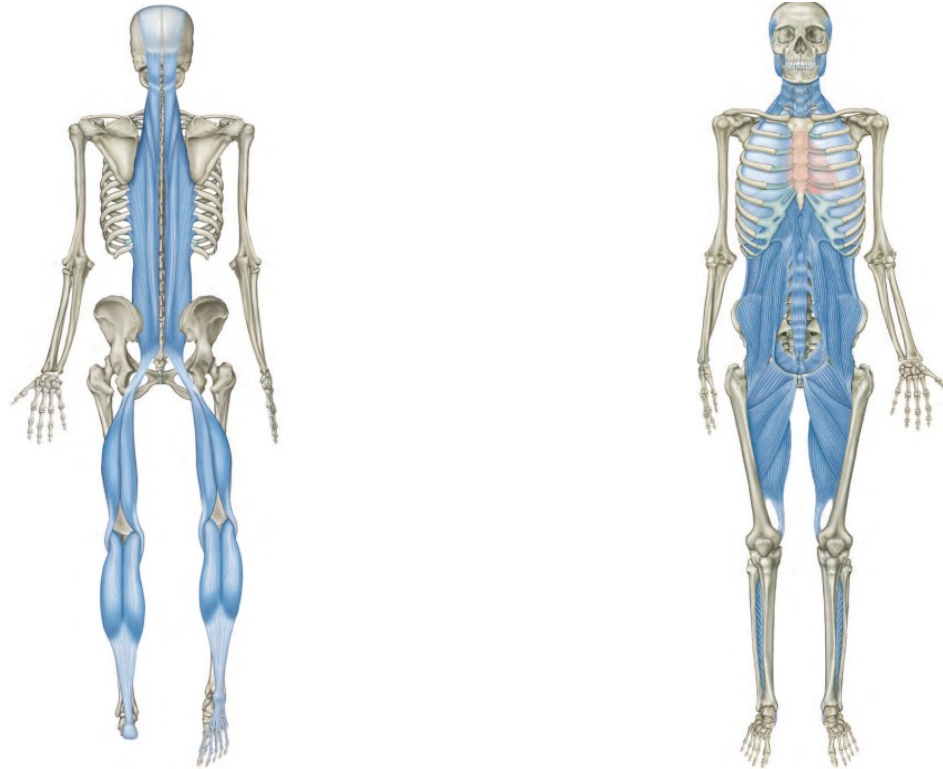
tensional forces posterior to the spinous processes, and by acting as a spring-like energy storage system [40].

Traditionally viewed as passive, the TLF is believed to act as a sensory organ through proprioceptive and nociceptive innervation, adding to the musculoskeletal system's feedback control [41]. However, Schleip et al.'s correlation between myofibroblast density and contractile response in fascia suggests the TLF has an active role in musculoskeletal dynamics, but further investigations are necessary [42].

2.1.7 Myofascial Meridians Lines

A theoretical framework explored by Myers discusses the complexity and interdependence of the human body's musculoskeletal system in what is referred to as the myofascial meridian lines. Myers proposes that the body's fascial network, composed of the muscles, ligaments, tendons, and fascia, forms a series of continuous, interconnected pathways, or meridians, that influence movement, posture, and overall structural integrity. These myofascial meridians differ from traditional anatomical models that focus on individual muscles or discrete systems. Instead, Myers emphasizes the fascial connections that span multiple regions and link various muscle groups and joints.

Several myofascial meridians play important roles in stabilizing the spine, but the Superficial Back Line (SBL) and the Deep Front Line (DFL) are the most significant. The SBL runs along the posterior part of the body, including structures such as the plantar fascia, calves, hamstrings, ES, and nuchal ligament. It plays a crucial role in maintaining an upright posture and distributing tensile forces during activities such as walking and running. The DFL is an anterior meridian line that extends from the toe flexors to the deep cervical flexors, through the tibialis anterior, adductors, hip flexors, and abdominal muscles. The DFL contributes to core stability, gait coordination, and spinal alignment. Dysfunction or deficiency along the SBL or DFL can compromise the stability of the spine and affect overall movement.



(a) Posterior view of the Superficial Back Line

(b) Anterior view of the Deep Front Line

Figure 2.1.7: Myofascial meridian lines of the (a) Superficial Back Line, and (b) Deep Front Line (reprinted from [43]).

2.2 Spine Stability and Instability

2.2.1 Definitions

The spine is a complex system that requires the input and collaboration of multiple structures to maintain the posture and movements of the human body. Maintaining a stable spine is critical for efficiently transferring forces between the upper and lower limbs, generating active forces in the trunk, preserving the spine's long-term biomechanical health, and minimizing energy expenditure during muscular activity. The literature explored numerous biomechanical and clinical definitions of spine stability, but no widely recognized definition has been established. According to White and Panjabi, spine stability refers to the spine's ability to maintain its displacement patterns when subjected to physiological loads, as to not damage or irritate the spinal nerve roots and to prevent major deformity or pain caused by structural changes [23]. Similarly, the American Academy of Orthopedic Surgeons defined spine stability as the vertebrae's ability to maintain cohesiveness and preserve normal displacements during physiological movements [44].

Spine instability, the opposite of spine stability, is hypothesized as a potential mechanism explaining LBP symptoms and disability [45]. Such a diagnosis is non-specific and confirms the pathomechanism's complexity. Similar to spine stability, there is no universally accepted definition for spine instability. Pope and Panjabi described spine instability as a loss of stiffness, resulting in atypical and increased motion within the segments [46]. In 1985, Louis built from Denis' three-column theory to separate stability in axial and transverse. According to this theory, a "loss of stability is a pathological process which can lead to displacement of vertebrae beyond their normal physiological limits" and is caused by the dysfunction of one of the columns [47, 48].

All the definitions of stability and instability refer to a change in spinal movements beyond the physiological limits which are associated with back and/or nerve root pain. This is consistent with the concept of engineering stability in structures, which refers to the tendency of a structure to return to its original equilibrium position following a disturbance [49, 50]. In Figure 2.2.1, the four cones are in equilibrium. If perturbed slightly, cone A will move away from its equilibrium position (unstable equilibrium), cone B will return to its original equilibrium position (stable equilibrium), and cone C will find a new equilibrium position after being displaced (neutral equilibrium).

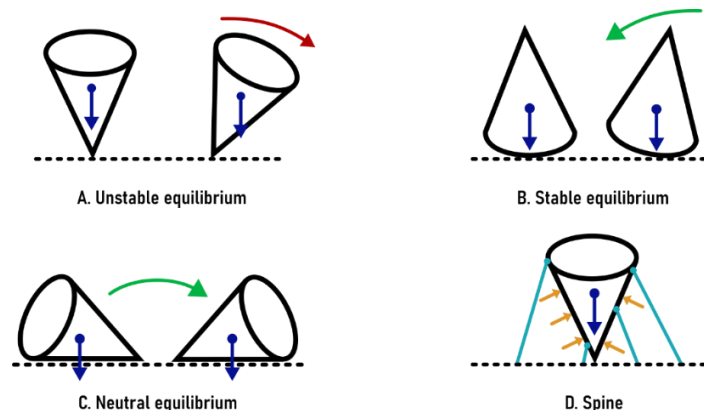


Figure 2.2.1: Equilibrium of a cone. If perturbed slightly, cone A will move away from its equilibrium position (unstable equilibrium), cone B will return to its original equilibrium position (stable equilibrium), cone C will find a new equilibrium position after being displaced (neutral equilibrium), and cone D will attempt to return to its original equilibrium position using the passive, active and control subsystems (cyan and yellow lines/arrows). The blue arrows represent the line of action of the weight of the cone passing through the center of gravity.

The spine is inherently unstable, similar to cone A. Following a perturbation, it requires the involvement of the passive, active and control subsystems to maintain its equilibrium position and maintain movements within physiological limits (cone D). In clinical settings, the comprehensive analysis of global spine stability poses challenges due to the need for sophisticated biomechanical

assessment tools, such as motion capture systems. Accessible alternatives, such as assessing individual soft tissue stiffness, muscle activity, and segmental radiography imaging (see Figure 2.2.2), provide cost-effective solutions for assessing local spine stability. However, the normal physiological limits continue to be debated because of the considerable overlap between movement patterns of healthy and LBP individuals. It poses a challenge in establishing standardized references and meaningful correlations between clinical and radiological findings.

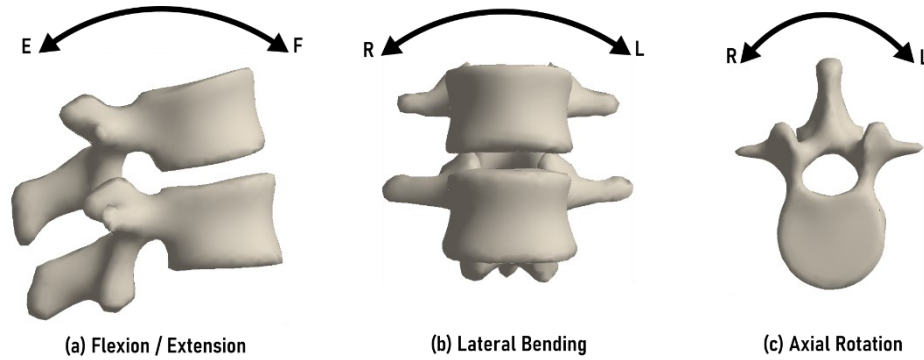


Figure 2.2.2: Segmental rotation of the vertebrae in the (a) sagittal, (b) coronal, and (c) transverse planes.

2.2.2 *Passive Subsystem*

In the passive subsystem, the bones, IVDs, and ligaments play a crucial role in providing intrinsic structural support and controlling the maximal ROM. Each passive structure has a distinct anatomical location and arrangement, contributing to stability during specific movements and loading conditions. However, due to repeated mechanical stresses, these structures are susceptible to degeneration, which may impair functionality, create pain, or result in dysfunction [51].

The load-bearing capacity of vertebrae depends on their size, shape, and trabecular bone density. The trabecular bone's column arrangement provides robust mechanical support along the lines of stress, primarily in the vertical direction for receiving and transmitting vertical loads, as well as horizontally connecting the transverse processes. People with osteoporosis have a weakened (thinner) trabecular network, which results in reduced vertebral load-bearing capacity and a higher risk of stability loss. Articular processes and facet joints of the vertebrae also control the direction and amplitude of movement and load distribution. Typically, the facet joints bear a relatively small proportion of the load. However, in cases of hyperlordosis, prolonged loading, or poor posture, the load on the facet joints may increase significantly and asymmetrically [52].

Asymmetric loading of the facet joints increases the risk of instability and premature degeneration of the facets and IVDs [53]. Biomechanics of the thoracic spine also play an important role in spine stability. The thoracic cage spans the entire thoracic spine and *ex vivo* studies have shown that, along with its cartilage and strong ligaments, it contributes considerably to the overall stiffness and stability of the spine [54].

The IVD is a unique structure that can withstand both tensile and compressive forces, enabling complex spine movements, including compression, distraction, flexion, extension, lateral bending, and axial rotation. Its nucleus pulposus transmits low axial loads to adjacent vertebrae, while the stiffer annulus fibrosis bears higher loads. The IVD effectively serves as a shock absorber, distributing mechanical stresses during motion. Bending movements generate the greatest tensile and compressive loads, resulting in bulging and stretching, while axial rotation generates torsional shear forces and can lead to annular delamination. Degeneration causes hydrostatic and osmotic pressures to fluctuate, resulting in higher shear stresses that can lead to fissures, delamination, and structural fatigue. Ultimately, these disturbances can prevent the IVD from performing its role as a spine stabilizer.

In the cone analogy (Figure 2.2.1.D), the cyan lines represent the passive contribution of ligaments, fascia, muscles, and ligaments acting as a guy wire system to stabilize the spine. The major ligaments contributing to spine stability are the anterior longitudinal ligament covering the ventral section of the vertebrae, the posterior longitudinal ligament covering the dorsal cortex of the vertebra, the ligamentum flavum connecting the laminae of the vertebrae, the intertransverse ligaments connecting the transverse processes and the interspinous and supraspinous ligaments connecting the dorsal section of the spinous processes. The stabilizing action of ligaments, fascia, muscles, and tendons depends on their mechanical properties, but also on the length of the lever arm by which they act.

2.2.3 Active Subsystem

A healthy spine should be able to withstand large compressive loads, produced during daily tasks, up to about 1500 N [55]. However, the ligamentous lumbar spine on its own will buckle or become mechanically unstable under compressive loads of approximately 90 newtons [56]. In order to preserve an upright posture and remain stable during movements, a normal person must then benefit from the stabilizing effect of the active subsystem.

The active subsystem mostly controls the early ROM where there is little resistance to movement due to the laxity of the capsules, ligaments, and tendons. Degeneration or traumatic injury to any soft tissue of the spine leads to an increase in ROM, which results in increased demands on the muscles to maintain stability [22].

Muscles may be divided into superficial (RA) and deep (psoas) flexors, as well as superficial (latissimus dorsi, Trap, ES) and deep (intertransverse, interspinous, multifidus, rotatores) extensors. The superficial muscles are long and act at a greater moment arm, which makes them the primary generators of force and movement. The deep muscles articulate the spine and contribute to proprioception, which helps balance and stabilize the spine. The obliques and the TrA muscles are primarily flexors and rotators of the lumbar spine, but they also tension the TLF and generate IAP (Figure 2.1.5). By establishing connections between the thoracic and lumbar vertebrae and surrounding muscles, including the Trap, gluteal, and LD muscles, the TLF enables load transfer and acts as a key structure to stabilize the spine [57-61]. Moreover, the TLF envelops multiple paraspinal muscle compartments and possesses a long lever arm as it attaches posteriorly to the spinous processes (see Figure 2.1.5). This anatomical arrangement leads to increased tension within the TLF when these muscles contract [36, 38]. However, the involvement of the TLF in LBP has been reported in the literature. LBP patients have been observed to exhibit a stiffer TLF, suggesting an increased ability to bear load and potentially shielding surrounding tissues from normal engagement [62, 63]. In addition, the TLF of LBP patients tends to be thicker and exhibits reduced shear strain, indicative of reduced mobility between the dense layers of connective tissue [64].

The primary mechanism of action of IAP is believed to be internal stabilization by exerting a balanced force against the abdominal wall and the anterior spine (see yellow arrows in Figure 2.2.1.D) [65, 66]. These forces, combined with the increased stiffness of the abdominal muscles, create a rigid cylinder which provides structural support to the spine [67]. Increased IAP also facilitates co-contraction of the deep muscles, primarily TrA and multifidus, thereby increasing segmental trunk stiffness and reducing the risk of excessive movements [68, 69]. Furthermore, IAP is thought to generate an extensor moment acting on the pelvis and diaphragm, which may reduce back muscle activation and, consequently, alleviate pressure on the discs [70]. The overall contribution and impact of IAP are dependent on the activity performed and the posture [58].

Together, the TLF and the IAP can reduce imbalances in postural asymmetry and improve spine stability.

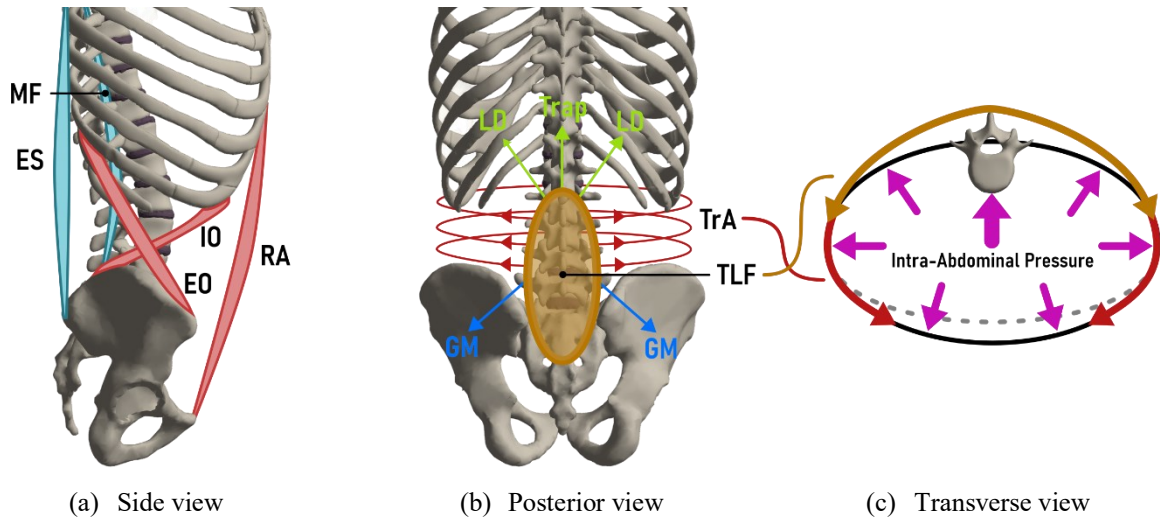


Figure 2.2.3: Segmental trunk stiffness increase through back and abdominal muscle co-contraction and thoracolumbar fascia attachment. RA: rectus abdominus, ES: erector spinae, EO: external oblique, IO: internal oblique, MF: multifidus, TLF: thoracolumbar fascia, TrA: transversus abdominus, GM: gluteus muscle, LD: latissimus dorsi, Trap : trapezius.

2.2.4 Control Subsystem

Mechanoreceptors located within all joints, muscles, and ligaments relay proprioceptive information about loads, movements, and posture to the CNS, which orchestrates an appropriate and coordinated feedback muscle response. This system is responsible for accomplishing complex tasks with constantly changing requirements. At any point in time, the amplitude of muscle recruitment must be computed and optimized to maintain proper posture and ensure the least amount of energy is consumed to accomplish the task. Several physiological cost functions have been proposed to describe how energy optimization occurs to achieve a minimum target level of stability. Intervertebral forces, muscles forces or total muscle and joint forces may be minimized, or spinal displacements may be optimized by minimizing local (or global) spinal displacements [71-75]. The spine is inherently unstable, and a combination of these strategies is essential to prevent buckling instability and maintain dynamic stability.

In LBP patients, there is evidence that suggests a disturbance in the control mechanism. These patients have impaired lumbar proprioception [76, 77], poor postural control [78, 79], and delayed muscle response [80]. The resulting symptoms are repositioning errors, altered muscle activation patterns and resulting kinematics, and altered paraspinal muscle spindle afference and sensory input processing by the CNS [81-83]. In an effort to protect their lower back, these patients may

adapt by modifying their trunk motor control [84, 85]. To protect themselves against large tissue strain and high muscle forces, LBP patients may use a tight control or loose control strategy, respectively (Figure 2.2.4). However, a tight control may lead to high compressive loading on the spine and sustained muscle activity, whereas a loose control may lead to excessive tissue strain. A deficient motor control mechanism may increase the risk of instability and the susceptibility to injury or re-injury.

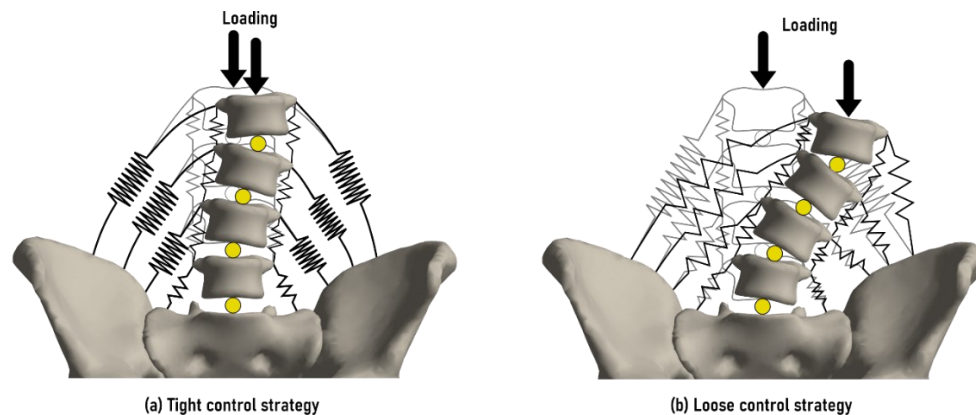


Figure 2.2.4: (a) tight and (b) loose control strategies adopted by LBP patients to protect themselves against injury.

2.3 Low Back Pain

2.3.1 Definition

LBP is generally defined as pain, muscular tension, stiffness, or discomfort, localized below the costal margin and above the inferior gluteal folds, with or without radiating symptoms to the leg(s) [86]. LBP is not a diagnosis, but rather a symptom that is caused by either intrinsic or extrinsic factors which may or may not be associated with identifiable structural abnormalities. LBP is also considered a disability because it affects the ability to perform certain normal activities. It can be classified as acute (lasting less than 6 weeks), subacute (lasting 6 to 12 weeks), chronic (lasting more than 12 weeks), and recurrent (return of symptoms after recovering from an episode) [87].

2.3.2 Sources of Low Back Pain

LBP can originate from a number of anatomical structures, such as bones, IVDs, joints, ligaments, muscles, neural structures, and blood vessels. Because it involves both psychological and physiological components, LBP can be attributed to a specific cause such as an osteoporotic fracture, neoplasm, or infection in only approximately 5-15% of cases. In the remaining 85-95%

of cases, there is no identifiable cause, and the condition is classified as non-specific, making its evaluation complex [88]. Certain occupational factors also represent a risk factor for LBP. The point prevalence of LBP is approximately 40% in manual workers who perform bending and twisting tasks, but only 18.3% in sedentary male workers [89].

2.3.3 Injury Mechanics

LBP can be attributed to a variety of intrinsic and extrinsic factors, including lumbar moments, tensile forces, compressive forces, shear forces, torsional forces, spinal curvature, soft tissue properties and psychological variables. To understand the fundamentals of LBP, it is important to be familiar with these parameters and their combinations in order to examine the failure modes.

2.3.3.1 Lumbar Moments

During lifting tasks, flexion occurs primarily at the hip joint and lumbar spine. To counteract the dynamic moments of the trunk, an extension moment must be generated in the opposite direction (see Figure 2.3.1). The hip flexors, including the gluteal and hamstring muscles, contribute to this moment by rotating the hips backwards, but the ES muscles contribute the most to this extension moment. However, a good proportion of the force required can be attributed to other mechanisms [60]. First, other trunk muscles, such as the MF, RA, and EO, help stabilize the spine during movement, reducing the amount of counterbalancing moment required (see Figure 2.2.3a), [68, 69]. Also, other structures play an important role in the moment generation, such as the TLF, which distributes loads to the surrounding tissues (see Figure 2.2.3b) [58, 59], IAP, which generates an extension moment through the activation of the abdominal muscles (see Figure 2.2.3c) [70], and ligaments combined with IVDs [90]. Failure can occur because of sudden impact [91], repetitive loading [92, 93], or sustained static loading [94, 95].

Repetitive loading can cause considerable fatigue of the ES muscles and thus significantly increase the moment acting on the lumbar spine [92]. Increase in peak lumbar flexion during prolonged or repetitive tasks may also increase the occurrence of viscoelastic creep which can reduce the tolerance to failure of the fascial tissues that act as elastic springs during movement [96, 97]. Tissue creep is more frequent and develops more rapidly in people who already have stiffer posterior tissues [98, 99]. Tissue creep is also known to reduce lumbar stiffness, impair motor control, delay muscle response, and increase muscle fatigue [7, 8, 99]. The progressive increase in creep/laxity in the viscoelastic tissues during cyclic work and the impaired neuromuscular

activation leave the spine unstable and vulnerable to injury [96]. The increased exposure to injury may result in a compensatory motor control to restore spine stability, which can increase muscle activation and consequently loading on the spine. Creep also produces an inflammatory process which may increase muscle spasms, specifically under high-loading scenario, which further increases the risk for LBP injury [96].

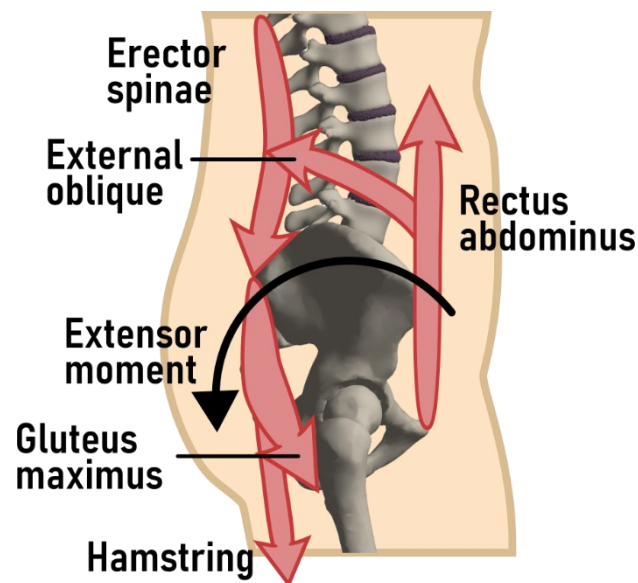


Figure 2.3.1: Lumbar moments to counteract the dynamic moments of the trunk during bending or lifting tasks.

2.3.3.2 Compressive Forces

The spine and its surrounding tissues are subjected to various ranges of compressive forces. The compressive strength of the L4/L5 and L5/S1 joints is generally assessed due to the higher mechanical loads on the lumbar spine [100]. A wide range of acceptable compressive forces endured before failure of the discs or the endplates has been proposed in the literature. The United States National Institute for Occupational Safety & Health proposed that for any individual the maximum compressive force may go from 3400 N to 6400 N [101]. Compressive forces on the spine result from body weight but mainly the tensile forces generated in the back and abdominal muscles, which stabilize and move the trunk. The amount of lumbar compression is influenced by many factors, such as muscle activity, which varies with posture and speed of movement, load amount, lever arm, and trunk kinematics.

2.3.3.3 Shear Forces

Shear strength of the lumbar vertebrae is reported to be between 1,000 N and 5,000 N [102, 103]. According to McGill, in the upright posture, the lumbar muscles are capable of generating

posterior shear forces of up to 650 N [104]. However, anterior shear forces of around 1,600 N can be generated in lifting tasks with large lumbar flexion angle (i.e., stoop lifts) [105]. While a shear force limit of 1,000 N for one-time loading on the lumbar vertebrae is recommended for occasional lifters, this recommended limit goes down to 700 N for workers performing over 100 lifting cycles per day [106]. According to Norman, the risk of back pain increases in workers exposed to repetitive shear forces exceeding 500 N [107] because repetitive loading can result in increased antero-posterior shear forces due to altered movement and muscle recruitment [93]. Soft tissues, such as muscles, tendons, ligaments, and discs are primarily designed to withstand compressive and tensile forces acting along their length. Their geometry and composition make them less resistant to shear forces, which involve sliding or deformation of layers within the tissue. Unlike cartilage or joint structures which are specifically adapted for shear resistance, these soft tissues lack the structural elements needed to effectively counteract shear stress, which can lead to injury or damage. Therefore, strategies aimed at reducing the magnitude of shear forces may be effective in mitigating the risks associated with LBP.

2.3.3.4 Torsional Forces

Torsional forces applied to the spine and its surrounding tissues have been identified as important risk factors for LBP [108]. When combined with forward flexion or lateral bending, the probability of injury increases substantially, especially when maintained over a prolonged period of time [109-111]. Twisting the spine on its craniocaudal axis generates compressive forces on the facet joints, which typically bear only a small fraction of the compressive load during symmetric exertions [112]. Torsional injuries can result from disc annulus rupture, posterior ligament injury, and facet joint injury [113]. Such injuries can result in stretching and/or impingement of nerve roots, which may trigger painful symptoms.

2.3.3.5 Lumbar Curvature

The literature presents conflicting evidence regarding lumbar curvature for lifting tasks and its impact on lifting and injury mechanisms. However, most recent studies show that lifting with a flat or slightly rounded back (squat lifting posture) is safer than with a purely rounded back (stooped lifting posture) [114-116]. In the squatting position, the lordosis of the lumbar spine is maintained, which activates the ES muscle of the spine. In a stooped lift, stability relies on passive support from the posterior ligaments and the TLF. Although muscle activation may increase the

compressive and shear forces on the spine, muscles are large and can adapt to generate significant forces which, ligaments and fascial tissue can't [117]. They can also counteract anterior shear forces caused by upper body weight during lifting [118]. Shirazi-Adl et al. reported that large flexion angles are associated with increased disc pressure, annulus fiber strain, and ligament and facet forces [115, 119]. They also suggest that a squat lifting posture reduces the stabilizing sagittal moments, requiring smaller muscle forces which would in turn reduce compressive loading on the spine. Therefore, relying on muscle rather than passive soft tissue can help prevent back injuries during lifting by preventing anterior shear and reducing tension on the ES muscles and passive soft tissues.

2.3.3.6 Soft Tissue Properties

The role of soft tissue mechanical properties is crucial in the initiation and development of LBP. Changes in anatomy, caused by factors such as aging, lifestyle (sedentary, heavy manual tasks, etc.) or history of LBP, can lead to uneven weakening of trunk muscles, resulting in asymmetric atrophy [120, 121]. This in turn may trigger a compensatory mechanism to stabilize the spine, which places a greater load on other soft tissues and induces changes in their mechanical properties and functionality [62, 63]. These property changes can disturb joint motion, trigger abnormal muscle activations, and reduce the ROM of the lumbar spine, thus compromising the individual's ability to balance and lift [122]. Therefore, individuals with unbalanced mechanical properties have increased instability and are therefore more susceptible to injury.

2.3.3.7 Psychosocial Factor

Worker satisfaction, stress, anxiety, mood, and depression are associated with a higher risk of back injury, although the relationships and pain mechanisms of these factors are often unclear [123-125]. Workplace factors influencing job dissatisfaction, including monotonous tasks, poor work relations, lack of social support, physical job demands, stress, and perceived ability have been identified as important risk factors for LBP [126, 127]. Cognitive factors experienced by people with LBP, such as attitude, passive coping, and fear avoidance are also often related to the development and maintenance of pain and disability [128]. Psychosocial factors are also believed to contribute significantly to the transition from acute to chronic LBP [128]. Therefore, understanding and addressing these psychosocial factors are crucial for effective prevention and management strategies for spine-related injuries.

2.4 Low Back pain Treatment Options

2.4.1 *Clinical Perspective*

Clinicians play an important role in the treatment and prevention of LBP, focusing on relieving pain symptoms, restoring normal function, minimizing work absences, and educating patients on good practices. However, the non-specific nature of most LBP cases makes it challenging to accurately identify the underlying causes for the prescription of appropriate treatment. Currently, methods to measure LBP rely on clinician experience and the use of questionnaires, such as the Oswestry scale and Roland-Morris scores [129]. To minimize the need for treatment, clinicians employ diagnostic methods, such as a comprehensive assessment of the patient's history, environment, habits, lifestyle, and working conditions, using structured questions. Next, clinicians perform a physical examination to locate the source of the pain before establishing a treatment plan. Treatment modalities may involve drug therapy (e.g., nonsteroidal anti-inflammatory drugs, opioids, muscle relaxants, analgesics), therapeutic injections (e.g., trigger-point injections, selective joint injections, epidural steroid injections), physical treatments (e.g., core strengthening, stretching and flexibility exercises, traction), alternative treatments (acupuncture, electrical nerve stimulation, laser therapy, shock wave therapy), or, in some cases, invasive surgical procedures.

2.4.2 *Manual Therapy*

According to guidelines established by the American College of Physicians, manual therapy is the primary clinical recommendation for noninvasive treatments of LBP. [130]. This therapeutic approach involves the movement or manipulation of various body parts to alleviate pain, reduce stress, anxiety, and depression, and promote overall well-being. Examples of manual therapy techniques include chiropractic and osteopathic treatments, physical therapy, and massage therapy. Chiropractic treatment focuses on mobilization of the spine, while osteopathic treatment involves manipulation, stretching and movement of muscles and joints to relieve pain and improve functionality. Some recent evidence is compelling, but not enough to alter clinical procedures [131]. Fascial palpation is another manual therapy technique used to treat low back injuries. It involves myofascial release therapy, which aims to break down adhesions in the TLF, thereby facilitating blood flow and promoting oxygen and nutrient absorption in areas affected by muscle and fascial dysfunction [87]. Fascial palpation is believed to stimulate fascial mechanoreceptors which may trigger changes in muscle tone, fluid hydration, and regulate the

impaired neuromotor control of lumbar muscles [132]. Kinesio-taping is a widely practiced technique, although there is little significant clinical data supporting its benefits in patients with chronic LBP. Recent studies have indicated that kinesio-taping does not provide significant pain relief but may improve proprioception by stimulating skin mechanoreceptors [133]. Manual therapy techniques, when combined with proper exercise, can be beneficial in the treatment of LBP as they provide immediate pain relief, allowing patients to perform exercises with greater proficiency [134].

2.4.3 Assistive Technologies

Technologies that aim to reduce pain and improve function for people with LBP generally involve two components: removing the stressor that create or exacerbate damage and enhancing activities that build healthy supportive tissues [122]. Clinical interventions typically focus on increasing spine stability prior to trunk efforts to mitigate potential damage caused by delayed in muscle response and poor motor control in LBP patients [78, 80]. Two commonly recommend interventions are active co-contraction of the abdominal and back muscles and passive use of an assistive wearable device [135, 136]. To improve trunk muscles co-contraction, strength and stabilization exercises involving isometric contractions are prescribed. On the other hand, several assistive wearable devices exist to passively stabilize the spine. Since the objective of these devices is to assist an individual with a pathology, namely LBP, they are called spinal orthoses (and for the purpose of this discussion, cervical spinal orthoses are neglected). They are generally classified based on clinical assessment, function, or manufacturing parameters (materials, construction). They generally come in two different forms: soft and rigid orthoses. Additionally, soft orthoses have different naming conventions based on their function.

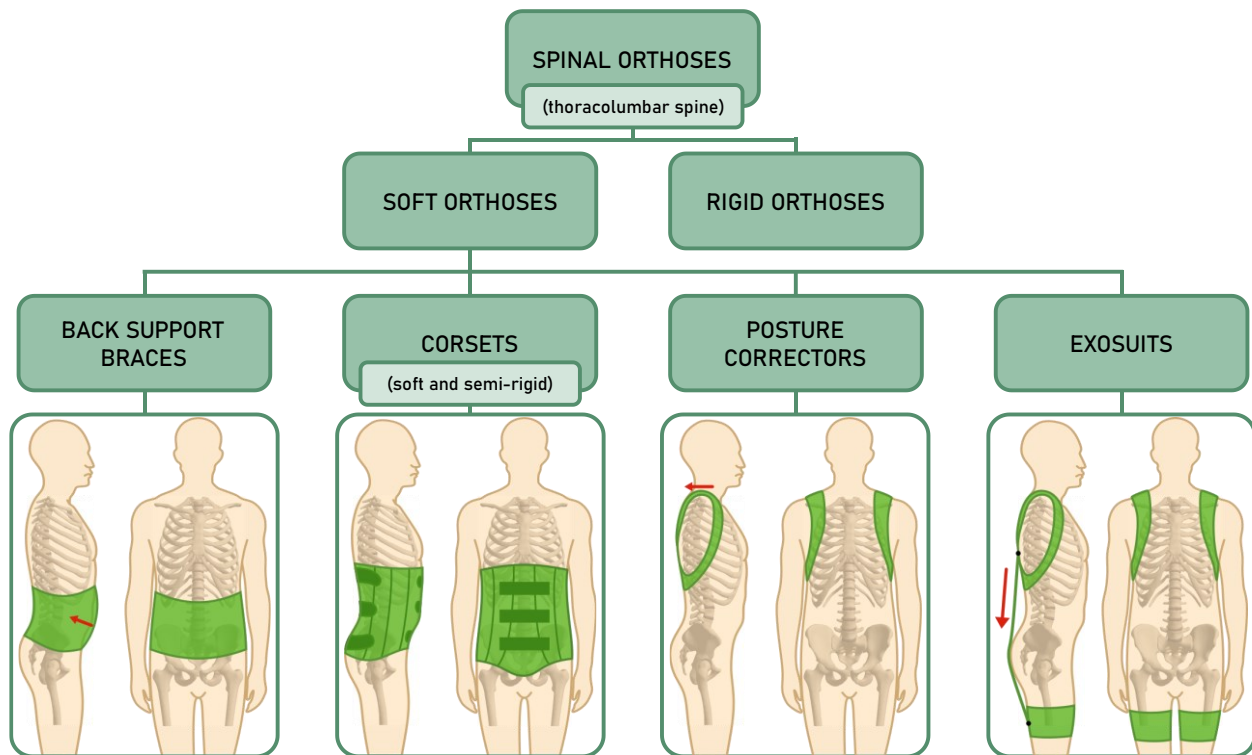


Figure 2.4.1: Classification of spinal orthoses according to their construction and function.

2.4.3.1 Rigid Orthoses

Rigid corsets are primarily used to treat curvature disorders of the spine (e.g., lordosis, scoliosis, kyphosis) or during post-operative healing. Rigid immobilization is typically accomplished using a custom fabricated ‘body jacket’ constructed from plastic with a soft foam lining. Metal or plastic rigid stays (permanent or removable) may be incorporated into the foam for additional restriction of motion if desired [137]. Rigid corsets generally require greater compliance as they must be worn for long hours and for several weeks or months. Rigid orthoses generally provide better results than soft orthoses because of their ability to increase trunk stiffness and limit ROM. However, they generally have different functions and target different injuries.

2.4.3.2 Back Support Braces

Back support braces, such as ABs, lumbar belts, and binders, are commonly used to treat acute, chronic, or recurrent pain in the lumbar region. These braces are composed of soft, flexible, materials, such as cotton, nylon, and polyurethane fibers. Polyurethane fibers like Spandex or Lycra, famous for their elastic properties, are commonly used to provide stretch, comfort, and functional performance to garments and accessories [138]. Several hypotheses have been proposed to explain the potential mechanisms through which back support braces may be effective in

relieving symptoms of LBP: increased IAP [139, 140], trunk stiffening [141], limited ROM [139], improved proprioception [77, 79], and reduction of spinal compressive loads [142].

Despite the absence of scientific consensus on their efficacy, back support braces continue to be used in the prevention and post-injury treatment of LBP, as well as in manual handling tasks. The most commonly cited mechanism of action for back support braces involves the application of pressure on the abdomen, resulting in an increase of IAP, which has been shown to enhance static and dynamic spine stability and stiffness [70, 140].

Another debated mechanism of action involves the generation of a trunk extensor moment through the IAP mechanism. Some studies suggest that increased IAP reduces activation of the back muscle [143, 144], subsequently decreasing spinal compressive forces [145-148]. However, the scientific literature presents inconsistent findings regarding the relationship between IAP and the activity of ES muscles [149-151]. Therefore, evidence suggests that back support braces may not effectively reduce compressive loading on the spine [150, 152], although very few studies have explored this aspect *in vivo* due to the invasive nature of the procedure.

Braces are believed to stabilize the spine by making it stiffer, even during neutral trunk posture, thereby slightly reducing trunk muscle activity [153, 154]. This not only helps maintain posture [69] but also provides a stable core for other motions of the body, such as bending, lifting, or twisting, while preventing muscle fatigue [155, 156]. Back support braces have the advantage of increasing IAP and stiffness without the additional antagonistic coactivation of the abdominal and ES muscles, which can reduce strain on these tissues and surrounding structures [140, 152]. However, the overall contribution and impact of IAP depends on the specific activity performed and the posture of the person during the activity [58]. The IAP mechanism appears more supportive in tasks that require trunk extensor moment such as lifting or jumping. In addition, the increased stiffness may assist in reducing muscle spasms by allowing the spinal muscles to relax [85].

Back support braces can also limit excessive motion and velocity by minimally constraining certain movements and acting as a kinesthetic reminder to voluntarily restrict movement as opposed to exerting three-point pressure control as in rigid orthoses [157]. This reduction in trunk motion and velocity may decrease the net muscle moment exerted on the L5/S1 joint and mitigate the impact of large joint angles on the trunk structures [139]. The biomechanical effect of wearing a brace is not only beneficial at the end ROM, but also during early movement such as in trunk

flexion [158]. The early restriction of spine movement offers benefits not only to workers who frequently perform maximal trunk flexion such as construction workers or movers, but also to those who perform small trunk flexion tasks such as white-collar workers. Although the reduction in trunk muscle activation is minimal, prolonged use of braces may alleviate pain symptoms associated with lumbar spine loading [159].

Another hypothesis regarding the mechanism of action of back support braces is that they enhance proprioception, thereby improving the perception of stability [160, 161]. By exerting compressive forces on the skin, braces are thought to stimulate cutaneous mechanoreceptors that provide the CNS with additional sensory information regarding body position. As a result, wearers are more aware of their position in space and may reconsider placing their trunk in harmful positions. Studies by McNair and Heine [160] and Newcomer, et al. [161] have demonstrated improved somatosensory information received by the CNS, resulting in fewer trunk repositioning errors. However, recent studies have challenged this hypothesis, suggesting that wearing a brace does not necessarily improve proprioception [162]. The opposing hypothesis suggests that the constant tactile pressure from the brace may lead to decreased stimulation of the cutaneous mechanoreceptors, which may deteriorate lumbar proprioception.

The combined biomechanical and psychological benefits reported by patients wearing back support braces often serve as motivation for their use [163, 164]. The biomechanical effect is expressed as a reduction in net external lumbar moment [165], a reduction in maximum flexion, and a reduction in the velocity and acceleration of movements [157]. There is also evidence that wearing a brace stiffens the trunk [157, 166], making it more robust to perturbations [153]. The psychological impact can help restore confidence in the back, reduce fear of movement and facilitate a progressive return to normal activities [158]. The presence of a brace can also serve as a reminder to use proper lifting techniques [161]. Soft orthoses, such as back support braces, have higher compliance rates compared to rigid orthoses, although the reported compliance remains below 50% [163, 164, 167]. On the other hand, their efficacy and safety are still being investigated [165]. Some also argue that back support braces give wearers a false sense of security, tempting them to lift heavier loads or perform more repetitions while the spinal load remains the same [122]. Increased pressure and heat in the lumbar region, causing sweating, has also been reported as sources of discomfort [168]. Furthermore, increased IAP has been associated with

increased blood pressure and reduced venous return, which can have adverse effects on neighboring organs and is a predisposing factor to other disorders [146, 169].

2.4.3.3 Corsets

Soft and semi-rigid corsets are commonly used in the management of recurrent pain and the treatment of spinal instability and injury. They offer potential benefits for people with a variety of spinal conditions, including strains, sprains, traumas (e.g., fractures), disc problems (e.g., herniated discs, degenerative disc disorder), structural problems (e.g., spinal stenosis), and arthritis (e.g., osteoarthritis, spondylitis) [170]. Semi-rigid corsets tend to perform better compared to their flexible counterparts due to their ability to enhance trunk stiffness and restrict ROM more effectively [141, 142]. In most cases, corsets are pre-fabricated and custom fit to the patient's specific needs. The incorporation of rigid metal or plastic stays in the front, back, or sides of the corset helps to enhance stability and restrict motion.

Taller corsets extending from the pelvis to the ribcage generally contribute to increased spinal stiffness [157]. Lumbo-sacral corsets are primarily used to address spinal pathologies ranging approximately from the first lumbar vertebra (L1) to the fourth or fifth lumbar vertebra (L4-5) [137]. Meanwhile, thoraco-lumbo-sacral corsets are designed to treat spinal pathologies ranging from approximately the sixth thoracic vertebra (T6) to the third or fourth lumbar vertebra (L3-4) [137]. In some cases, a support reaching the shoulders can be incorporated to allow control of the fourth and fifth thoracic vertebrae (T4-5), while the inclusion of a cervical extension is recommended for more comprehensive control above the sixth thoracic vertebra (T6) [137].

The mechanisms through which corsets achieve their therapeutic effects include three-point pressure control, indirect load transfer through IAP increase, correction of spinal alignment, and sensory feedback in the form of kinesthetic reminders [171]. The specific design characteristics of the corset, such as its rigidity, determine the range of spinal motions that is restricted [135]. Therefore, the selection of a rigid or more flexible corset is contingent on the degree of required spinal motion restriction. For example, a geriatric patient with an unstable spinal fracture requires a rigid corset to effectively restrict motion of the affected spinal segment. Conversely, the management of a stable compression fracture allows for greater flexibility in selecting a lightweight and less restrictive device, without compromising patient safety [172].

The use of corsets to support the spine, correct its anatomical alignment or facilitate body movement is an important therapeutic consideration in rehabilitation. It is essential to involve the patient and strike a balance between maximum effectiveness and patient compliance. Attention should also be paid to possible adverse effects of the orthosis on the skin and subcutaneous connective tissue of the wearer [173].

2.4.3.4 Posture Correctors

Posture correctors are devices used to promote proper posture and relieve LBP, stress, and muscle fatigue. They are currently not indicated for any acute or chronic pain or to treat any condition. These devices are designed to move the shoulder girdle in the correct position and encourage the wearer to adjust their back, neck, and shoulders to maintain good posture. They are predominantly used by individuals with prolonged sitting jobs, however limited research exists regarding their effectiveness. By promoting good posture, they are believed to assist in maintaining a more neutral spine, increasing shear support, and minimizing the risk of ligament damage. In addition, short-term evaluations have shown that posture correctors may have cognitive and behavioural effects on adults. First, by serving as a kinesthetic reminder for maintaining proper posture, and then by considerably adjusting angles in the back, hips, and knees (during sitting posture) [174], and shoulders (during standing posture) [175]. However, there is no clear relationship between muscle activity and improved posture from posture corrective braces [175].

2.4.3.5 Exosuits and Exercise Garments

Exosuits, also called soft wearable exoskeletons, and exercise garments aim to enhance performance and reduce back muscle fatigue [176-178]. Unlike rigid exoskeletons, exosuits are textile garments that offer a lightweight, conformal, and unobtrusive solution of interfacing with the body. To ensure synergistic interactions with the wearer, these wearable garments must attach securely to the body, transmit assistive torques, and allow unrestricted joint movement, while approximating the body's natural biomechanics. Exosuits can passively generate assistive forces through wearer's natural movement using springs or spring-like mechanisms or actively using powered force-generating mechanisms [179]. Pneumatic actuators and cable driven actuators are some that have been shown to have a positive effect on mobility [180, 181]. An advantage of exosuits is that they minimize the distal mass of mounted actuation and transmission systems,

enhancing comfort and usability. Integrated sensors, such as gyroscopes, pressure sensors, and inertial measurement units, facilitate control and evaluation of the wearer's movement.

Back exosuits primarily assist human movement by generating an extensor moment that acts in parallel to muscles and tendons while mimicking their function. Although comprehensive studies evaluating their efficacy are limited, preliminary research suggests that exosuits can reduce muscle activity and metabolic cost during walking [182]. During lifting tasks, both muscle activity and muscle fatigue have been reported to decrease using an exosuit [183-185], however, there is no evidence of a reduction in metabolic cost [186, 187]. Exosuits have applications in occupational tasks, military, and sports activities to augment the capabilities of healthy individuals, as well as in the rehabilitation of patients suffering from muscle weakness or neurological disorders [188]. However, a common concern is that these devices do not directly enhance spine stability, can give a false sense of confidence and transfer mechanical loads to surrounding soft tissues, potentially increasing the risk of injury when lifting heavy loads [189]. In addition, exosuits exert compressive and shear forces on various soft-tissue regions of the wearer, which can lead to pressure damage [187, 188].

2.4.3.6 Conclusion

The use of spinal orthoses in the treatment of LBP or for occupational lifters has both advantages and disadvantages, depending on the type of orthosis used. In general, wearing a spinal orthosis can be beneficial for individuals performing prolonged or repetitive tasks that may lead to tissue creep and lumbar posture problems. It can also assist movement and increase trunk stiffness in workers with a history of LBP [158].

However, rigid spinal orthoses that restrict rather than assist movement may create a habit of restricted motion, preventing improvements in the wearer's condition. In addition, the frequent unidentified origin of pain often leads practitioners to administer non-specific orthotic treatments, which generally do not yield consistent results [19]. Therefore, a thorough assessment of pain-inducing movements, postures and loads, as well as an analysis of routine and habits, are crucial for the appropriate prescription of spinal orthoses [122, 167].

2.5 Finite Element Models

2.5.1 Models of the Spine

Finite element models (FEMs) have emerged as powerful tools in the field of spine research, offering unique advantages for validating medical devices and testing their performance and behaviour. Unlike real-world experiments, FEMs enable the evaluation of early concept ideas and can simulate complex geometries found in human structures. With the ability to customize and add precision to specific areas, FEMs allow researchers to assess how critical factors impact the entire structure and identify potential failure points. These *in silico* studies facilitate the calculation of clinical indices such as spinal alignment, intra-discal pressure, and vertebral rotation, providing valuable insights into spinal biomechanics. Additionally, FEMs can estimate forces and pressures applied to soft tissues in minutes, which are typically challenging to measure *vivo* studies. New FEMs now attempt to incorporate patient-specific information, enabling the extraction of results tailored to individual morphology and material properties, further enhancing their clinical relevance.

Numerous FEMs of the spine have been explored in the literature, each with distinct characteristics. While most models focus solely on vertebral bodies and IVDs, they still provide valuable insights into spinal loadings. A highly cited study by Dreischarf, et al. [190] provides an example of comparing eight different lumbar spine FEMs. These models incorporated variations in muscle and tendon representations, vertebrae geometries, and cartilage effects. Despite not accounting for fascia, tendons, or IAP effects, the study demonstrated good agreement with *in vivo* biomechanical parameters such as facet joint forces, spinal displacements, and IVD pressure, thus confirming the reliability of their assumptions.

Recognizing the importance of IAP in spine stability, recent studies attempt to incorporate IAP effect in FEMs. Some models consider IAP as vector forces acting on surrounding tissues but fail to account for the actual inflation of the diaphragm and abdomen, resulting in overestimation of IAP values [191]. Others explore IAP by modelling it as an incompressible fluid within a closed cavity, using either non-linear anisotropic viscoelastic [192] or linear/transverse isotropic material laws [20, 193]. Given the important relationship between IAP and abdominal compression, the present study aims to integrate a representative abdominal cavity with physiological boundaries and connections to surrounding tissues. Incorporating the TLF into spine models has also gained

attention due to its role in load transfer and support to surrounding tissues. Recent models have adopted reconstructed representative geometries, attaching to anatomical landmarks such as the spinous processes and EO muscles [57]. These advancements provide a more accurate representation of the TLF's load-bearing capabilities, emphasizing its importance in stability-based FEMs.

While numerous studies have investigated the effectiveness of rigid spinal orthoses designs using computer models of the musculoskeletal spine [194-197], research concentrating on soft orthoses, notably ABs, has been comparatively limited. These studies have provided valuable insights into the immediate effects of restoring spinal alignment prior to going through extensive orthosis therapy. However, to the author's knowledge, no prior attempt has been made to assess the performance of ABs using a FEM that accurately represents the geometry of the torso. The current study fills this research gap by integrating ABs into the model, enabling researchers to explore their impact on spine stability and contribute to a comprehensive understanding of orthotic design and its clinical implications.

2.5.2 Verification and Validation

Both verification and validation are fundamental steps in establishing confidence in FEMs used in spine analysis. Verification ensures the accuracy and correctness of the FEM algorithm implementation through code verification and mesh convergence analysis [198]. It verifies the mathematical model's accurate solution and data error tolerances [199]. On the other hand, validation assesses the model's accuracy and reliability by comparing its predictions to experimental results, such as *ex vivo*, *in vitro*, or *in vivo* data related to spinal behaviour [200]. Sensitivity analyses are then performed to evaluate the impact of varying input parameters on the FEM's predictions. This process ensures the model's appropriateness and robustness in representing real-world spine biomechanics within a predefined context of use. The credibility and reliability of computational models are crucial for decision-making, as emphasized in the document "V&V 40: Assessing Credibility of Computational Modelling through Verification and Validation" [201]. Following these steps ensures trustworthy and meaningful FEM analysis results, supporting device design, performance evaluation, and spinal intervention safety. The next two papers are designed to describe the validity and potential benefits of wearing a novel back support device developed by the author in the Musculoskeletal Biomechanics Research Lab.

3. Numerical investigation of intra-abdominal pressure and spinal load-sharing upon the application of an abdominal belt

3.1 Framework of Article 1

The study explored herein investigates the underlying mechanisms contributing to changes in trunk stiffness and stability when using abdominal belts (ABs) during flexion tasks. The prevalence of LBP among workers involved in lifting tasks highlights the potential benefits of ABs as wearable assistive devices to alleviate lumbar muscle fatigue. However, the precise mechanisms through which ABs achieve their effects remain not fully understood. To address this knowledge gap, two finite element models (FEMs) of the human torso musculoskeletal system were developed, one with an AB and another without, and subjected to a simulated flexion movement to examine intervertebral rotations (IVRs), intra-abdominal pressure (IAP), and intervertebral disc (IVD) pressure. By gaining insight into how ABs influence trunk stiffness and stability, this study aims to contribute to the development of a more effective back support device for preventing LBP during manual lifting tasks and reducing muscular demands during rehabilitation or in the early stages of work after a back injury. The novel back support devices being developed throughout this dissertation seeks to leverage IAP to stabilize the spine during flexion movements, thereby offering similar benefits than ABs but without the continuous compressive stresses on the abdomen. The present study marks the initial step towards validating this novel back support device discussed in Article 2.

The present article explores the first objective of numerically investigating the effects of wearing an AB on IAP and spine stability, thereby providing answers to the two hypotheses, with a specific focus on ABs. The manuscript has been submitted for publication in the Journal of Biomechanics and is currently being reviewed after minor edits requested. The paper was also presented at the “*4th International Workshop on Spinal Loading and Deformation*” in Berlin, Germany on July 6th, 2023.

3.2 Article 1: Numerical investigation of intra-abdominal pressure and spinal load-sharing upon the application of an abdominal belt

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Abstract

Chronic low back pain patients may experience spinal instability. Abdominal belts (ABs) have been shown to improve spine stability, trunk stiffness, and resiliency to spinal perturbations. However, research on the contributing mechanisms is inconclusive. ABs may increase intra-abdominal pressure (IAP) and reduce paraspinal soft tissue contribution to spine stability without increasing spinal compressive loads. A finite element model (FEM) of the spine inclusive of the T1-S1 vertebrae, intervertebral discs (IVDs), ribcage, pelvis, soft tissues, and abdominal cavity, without active muscle forces was developed. An identical FEM with an AB was developed. Both FEMs underwent trunk flexion. Following validation, the models' intervertebral rotation (IVR), IAP, IVD pressure, and tensile stress in the multifidus (MF), erector spinae (ES), and thoracolumbar fascia (TLF) were compared. The inclusion of an AB resulted in a 3.8 kPa IAP increase, but a decreased average soft tissue tensile stress of 0.28 kPa. The TLF withstood the majority of tension being transferred across the paraspinal soft tissues (>70%). The average IVR in the AB model decreased by 10%, with the lumbar spine experiencing the largest reduction. The lumbar IVDs of the AB model likewise showed a 31% reduction in average IVD pressure. Using an AB improved trunk bending stiffness, primarily in the lumbar spine. Wearing an AB had minimal effect on reducing tensile stress in the ES. The skewed stress distribution towards the TLF suggests its large contribution to spine stability and the potential advantage in unloading the structure when wearing an AB, measured herein at 8%.

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3.2.1 Introduction

Low back pain (LBP) is recognized as one of the leading causes of work limitations and poor physical health, which has serious socio-economic repercussions [1, 2]. An estimated 540 million people worldwide will be affected at some point in their lives by LBP [3]. This pain is often the result of prolonged and repetitive lifting tasks that lead to low back muscle fatigue, discomfort and decreased muscle strength [4]. Impaired mobility within the lumbar region may increase the bending moment exerted on the spine during lifting tasks, elevating the risk of damage to the intervertebral discs (IVDs) and ligaments [5]. Wearable assistive devices, such as abdominal belts (ABs), have been proposed to reduce lumbar muscle fatigue during bending or lifting [6]. However, the underlying mechanisms contributing to these changes are not fully understood [7].

One potential mechanism for the action of ABs in the prevention or reduction of LBP is an increase in lumbar stability [8], which refers to the ability of the spine to maintain its displacement patterns under physiological loads [9]. Inadequate trunk stiffness, a surrogate measure of stability, may increase the risk of pain and tissue injury in the lower back [10]. Intervertebral rotations (IVRs) may indicate resistance to perturbations and the resulting change in trunk stiffness or stability. ABs have been shown to increase trunk stiffness and enhance spine stability reducing the burden on paraspinal soft tissues which function to maintain stability [11]. However, studies have reported conflicting results regarding the efficiency of different ABs [12, 13].

Finite element models (FEMs) representative of the human lumbar musculoskeletal system can provide insight into the underlying mechanisms of spinal disorders [14]. Recent advancements in computational power have enabled the development of increasingly intricate and anatomically realistic models of the spine that consider the effects of intra-abdominal pressure (IAP) [15]. A significant advantage of FEMs is the ability to analyze the use of ABs on the mechanical behaviour of the spine and aid in the design of effective interventions to reduce the burden of LBP. Inclusion of IAP within FEMs is of particular importance as it has been shown that the pressure within the abdominal cavity plays a crucial role in lumbar stability [16]. By restricting the outward expansion of the abdomen, ABs may increase IAP and aid the trunk extensor moment. In turn, IAP may reduce the contribution of paraspinal muscles to spine stability without increasing spinal compressive loads [17, 18]. In the transverse plane, IAP and intramuscular pressure was also shown to buttress the spine and convey supportive forces through the TLF [19, 20]. However, the

mechanisms through which ABs stabilize the spine are still unknown. Thus, the purpose of this study is to investigate the underlying mechanisms contributing to the changes in trunk stiffness, or stability, upon the application of an AB through the comparison of two musculoskeletal FEMs, one with and one without the assistance of an AB.

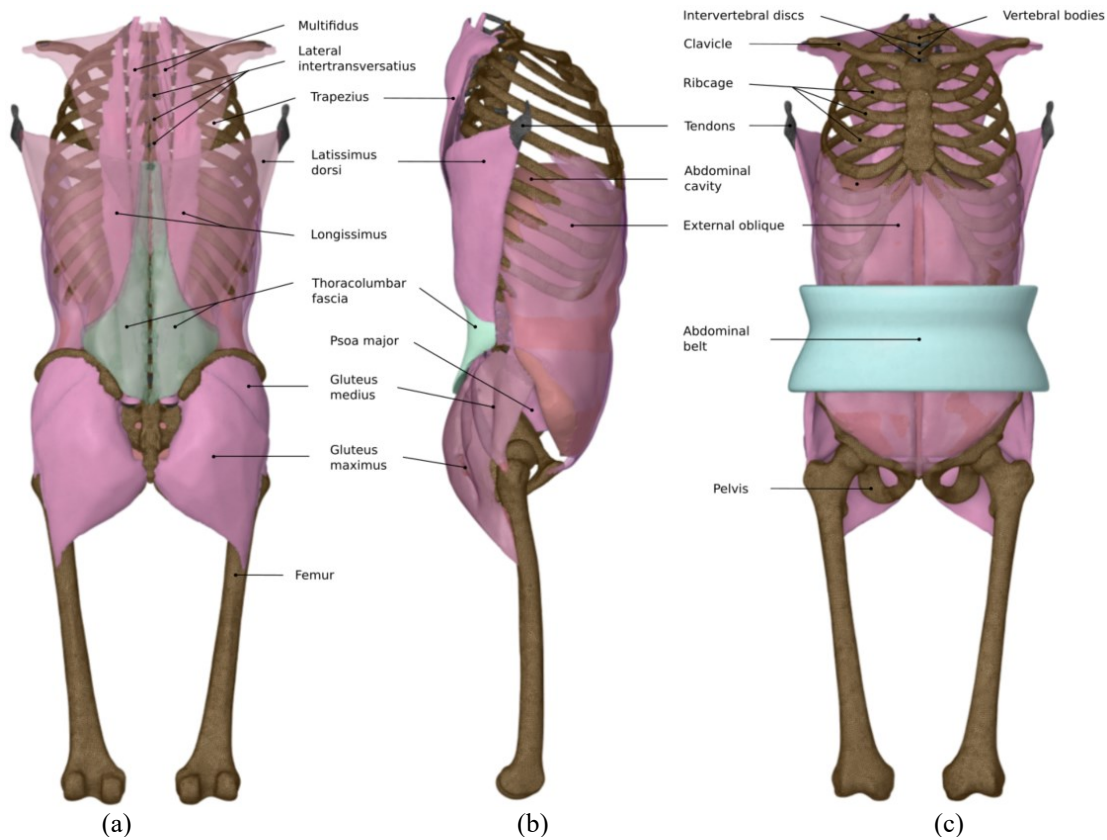


Figure 3.2.1. Finite element model of the spine including the vertebral bodies, ribcage, pelvis, and femurs modelled as surface bodies, and the intervertebral discs, major thoracolumbar soft tissues, abdominal cavity, and abdominal belt modelled as volumetric deformable bodies in: (a) posterior; (b) lateral; (c) anterior views.

3.2.2 Methods

To investigate the effects of IAP on spine stability, two finite element models (FEMs) were developed leveraging previously validated work [21]. The first model represented a healthy subject, while an identical, second model including an AB was developed. The model geometry representing tissues was obtained from a database of stereo lithography files constructed from a 3D MRI-scanned human male (Body-Parts3D/Anatomography) [22]. These files were imported into ANSYS, a finite element analysis software (v2022, ANSYS, USA), to create an exhaustive model of the musculoskeletal spine inclusive of 17 vertebrae (12 thoracic and five lumbar), 16 IVDs, bones, soft tissues contributing to spine stability, and a simplified abdominal cavity (Figure 3.2.1).

3.2.2.1 Model Construction

The vertebrae, ribs, pelvis, and femurs were modelled as surface bodies. The thickness of these anatomical structures' cortical layers was assigned from available literature. The IVDs and major thoracolumbar soft tissues, including the multifidus (MF), erector spinae (ES) (represented by the longissimus), psoas major, lateral intertransversarii, latissimus dorsi (LD), thoracolumbar fascia (TLF), external oblique (EO), trapezius (Trap), and all corresponding tendons, were modelled as volumetric deformable bodies. The soft tissues selected for inclusion in the models were chosen for their contribution to spine stability. In addition, IAP was modelled as an incompressible fluid within a pressurized cavity bounded by the remaining abdominal muscles (i.e., IO, TrA and RA), the diaphragm, and the upper plane of the pelvic cavity. A second model was developed and included the same tissues, but with an AB. The geometry of the AB was shaped to conform to the gluteus medius and maximus, TLF and LD posteriorly, and the EO anteriorly. The AB was bounded superiorly by the bottom of the last true rib and inferiorly by the top region of the sacrum. Bonded contacts were applied between the AB and body surfaces in alternating vertical bands to restrict sliding at these interfaces, while accommodating the small shearing effect observed in thin subjects during flexion exercises, based on relevant literature findings [23]. The AB was loaded horizontally posteriorly to create tightening forces and generate pressure on the abdomen. The experimental elastic properties of a common elastomeric fibre, polyurethane, were attributed to the AB-assisted model. No other differences existed between the developed FEMs. The material properties of the various anatomical structures were taken from the literature assuming linear elastic and isotropic properties (Table 3.1).

3.2.2.2 Model Loading and Boundary Conditions

To simulate the physiological motion of the spine, the base of the psoas major muscles, the sacrum, and the pelvis were designated as fixed supports. To simulate arm movement in flexion, the superior distal tendons of the LD were displaced anteriorly. A 1 kPa abdominal pressure was introduced to simulate the static standing condition prior to flexion [24]. A follower load, wherein the resultant vector of muscle and gravity forces produced a single internal force vector acting tangentially to spinal curvature through each vertebral body centroid [25], was placed on the model. The magnitude of the follower load was based on the cumulative body weight load applied at every vertebral level as described by Schultz, et al. [24] and muscle contributions as described by Nachemson [26], with respect to the degree of trunk flexion.

$$FL_{i,flexion} = F_{intrinsic} + 2.1 \cdot W_i + 3.6 \cdot W_i \cdot \sin(\alpha)$$

Where i refers to the specific vertebral level, $F_{intrinsic}$ to the intrinsic force from the supine position applied on the first thoracic vertebra, and the constants to the percentage of body weight loading. The calculations are based on a 90 kg, average-weight American male [27]. To reproduce realistic loading conditions experienced by spinal tissues during physiological motion, as well as to compare to literature data, 30-degree lumbar flexion was imposed on the unassisted model through moments on every vertebra. The moments were applied to simulate IVRs at every level extracted from the literature, and IVRs were measured. The same moments were then applied on the AB-assisted model as a comparative analysis. The soft tissues responded passively to loading, as no external loading was imposed on them. Inter-tissue connections were bonded to prevent slipping and separation, and frictionless contacts were considered at the interface between soft tissues to prevent the generation of frictional stresses.

Table 3.1. Material properties of the components present in both finite element models. Note: thickness is only provided for tissues which are modelled as surface bodies and the abdominal wall.

Anatomical Structures	Young's Modulus (MPa)		Poisson's Ratio	Thickness (mm)
Abdominal wall	0.0425	[28]	0.499	9.7 [15]
Abdominal belt	3	[29]	0.499	-
External oblique	0.14	[30]	0.499	-
Femur	10,500	[31]	0.3	3 [32]
Intervertebral discs	8	[33]	0.499	-
Intertransversarii	0.037	[34]	0.499	-
Latissimus dorsi	0.037	[34]	0.499	-
Erector spinae	0.042	[35]	0.499	-
Multifidus	0.091	[35]	0.499	-
Pelvis	17,000	[36]	0.3	1 [36]
Psoas major	0.055	[37]	0.499	-
Ribcage	7,440	[38]	0.3	1.4 [39]
Tendons	200	[40]	0.499	-
Thoracolumbar fascia	0.61	[41]	0.499	-
Trapezius	0.081	[42]	0.499	-
Vertebral bodies	17,400	[43]	0.3	T1-T4: 0.54 T5-T8: 0.63 T9-T12: 0.66 L1-L5: 0.69 [44]

MPa = megapascal, mm = millimeter

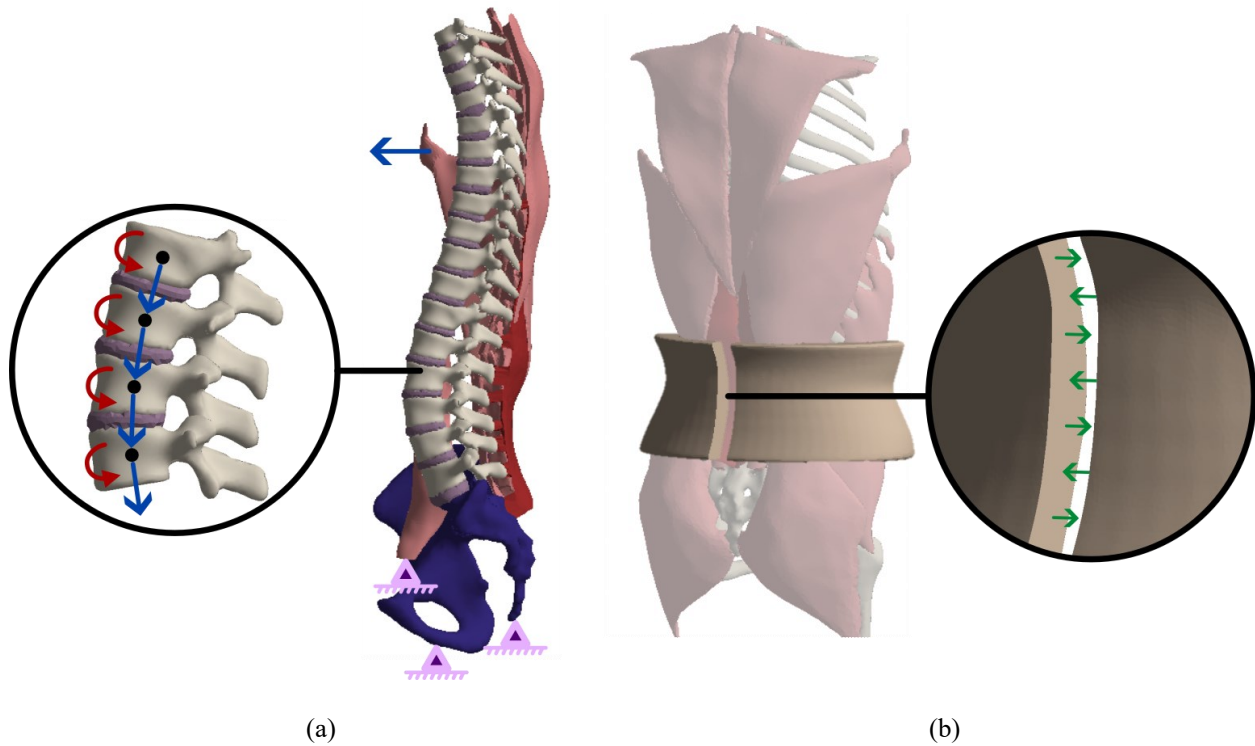


Figure 3.2.2. Loading scenario applied on: (a) the thoracolumbar spine of the unassisted and AB-assisted FEMs to simulate 30-degree flexion; (b) the abdominal belt to generate tightening forces. The red and blue arrows represent moments and follower loads applied to the vertebrae, respectively. The green arrows represent tightening forces applied on the abdominal belt. The pink triangles indicate a fixed boundary condition.

3.2.2.3 Measurements and Model Validation

IVRs were calculated for every segment using the superior-posterior and inferior-posterior vertebral corners. The location of these points was recorded at the baseline (0-degree flexion) and after flexion. Posterior tangents were intersected to calculate the relative rotation angles of adjacent vertebrae, as depicted in Figure 3.2.3 [45]. The average normal stress recorded at the surface of the discs was used to derive IVD pressure values and approximate the pressure within the IVDs, which has been shown to generate similar results as modelling bi-phasic discs when working in the linear behaviour range of material laws [46]. Lastly, the average normal stress in the longitudinal direction (+Z) was calculated for the TLF, ES, MF, Trap, and LD, and in the transverse direction (+X) for the TLF, while ignoring compressive stresses. Model validation was obtained by comparison of IVR, IAP and IVD pressure values to available published data for the unassisted model. The selected studies were chosen based on their relevance in simulating conditions similar to those in the present study.



Figure 3.2.3. Segmental posterior tangent method using the superior-posterior and inferior-posterior vertebral corners (red squares) to calculate intervertebral rotation between baseline and flexion.

3.2.2.4 Sensitivity Analyses

To ensure the model accurately represented the physical behaviour of the system and its outcomes were robust to variations in input data, sensitivity analyses were conducted. First, the mesh size was decreased from 3 mm to 1 mm. In a second test, hexahedral and quadrilateral mesh elements replaced the tetrahedral and triangular elements. Lastly, the material properties of various components including vertebrae, tendons, IVDs, TLF, ES, MF, Trap, LD, EO, and abdominal wall were adjusted above and below the average values reported in the consulted literature.

3.2.3 Results

3.2.3.1 Model Validation

The validity of the unassisted FEM's IVR, IAP and IVD pressures at 30-degree lumbar flexion was confirmed by comparison against available literature. The IVRs recorded in the thoracic spine were validated against the mean IVRs obtained from an *ex vivo* experiment [47] (Figure 3.2.4a). The lumbar spine IVRs were validated against the mean IVR of an *in vivo* study where patients executed 30-degree lumbar flexion [48] (Figure 3.2.4b). The mean IVR recorded in the unassisted FEM varied at most from *ex vivo* values by 0.83 degrees at the T1-T4 segment and 1.13 degrees at L1-L2 compared to *in vivo* patient data. All recorded IVR fell within the validated range for 30-degree lumbar flexion. Recorded IAP values were validated using data from an *in vivo* study that measured mean pressures in subjects performing various tasks [24] (Figure 3.2.5). The study revealed that the largest variation of 0.3kPa was recorded in 30-degree lumbar flexion. Likewise, models' IVD pressures of the thoracic vertebrae showed little variability when compared to the

mean IVD pressures measured in subjects performing a standing 30-degree lumbar flexion for T6-T7 to T10-T11 [49], and when compared at T4-T5 to an *ex vivo* experiment [50] (Figure 3.2.6a). For the lumbar vertebrae, validation of the IVD pressure was obtained through comparison to the mean value of multiple *in silico* models likewise undergoing 30-degree lumbar flexion [14] (Figure 3.2.6b). Additional validation was also obtained through the comparison of L3-L4 [24] and L4-L5 [51] to *in vivo* studies, for which there was little variation in IVD pressure during forward bending (Figure 3.2.6). The unassisted model was found to differ at most from *in vivo* measurements by 0.11 MPa at the T8-T12 segment and 0.04 MPa at the L3-L4 disc. Finally, all IVD pressures measured in the lumbar spine were confirmed to be within the validated range of Dreischarf, et al. [14] *in silico* analysis.

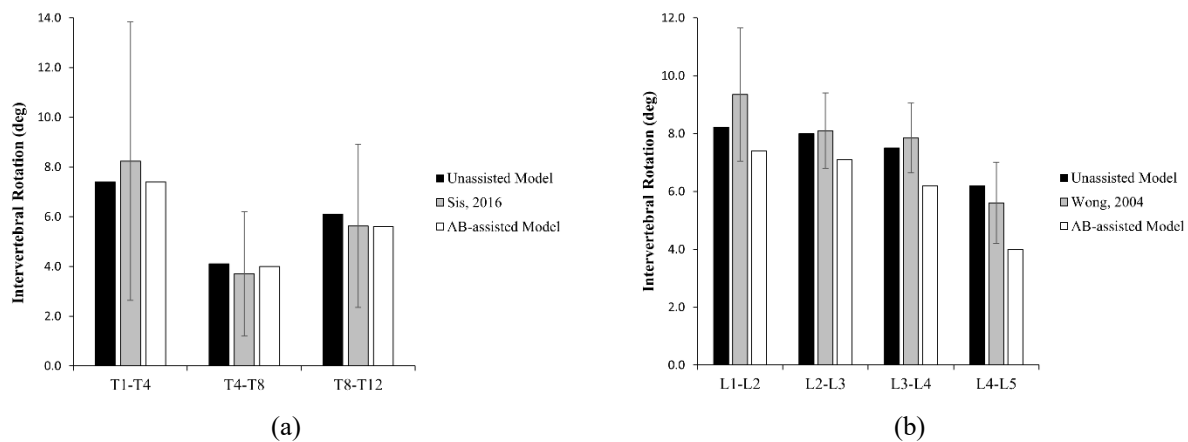


Figure 3.2.4. Comparison of intervertebral rotation (IVR) in the finite element models excluding (“unassisted”) and including (“AB-assisted”) an abdominal belt to literature for: (a) the thoracic vertebrae from T1-T12; (b) the lumbar vertebrae from L1-L5 [47, 48].

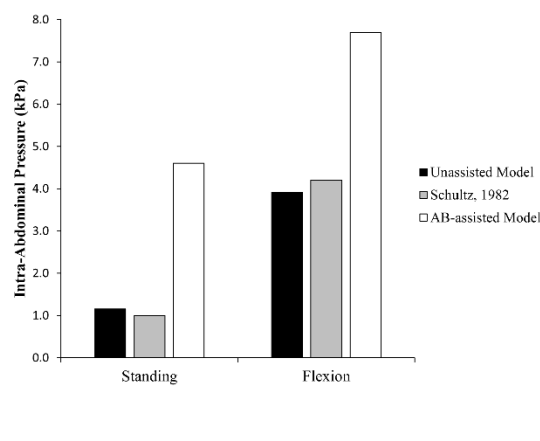


Figure 3.2.5. Comparison of intra-abdominal pressure (IAP) in the finite element models excluding (“unassisted”) and including (“AB-assisted”) an abdominal belt to literature [24].

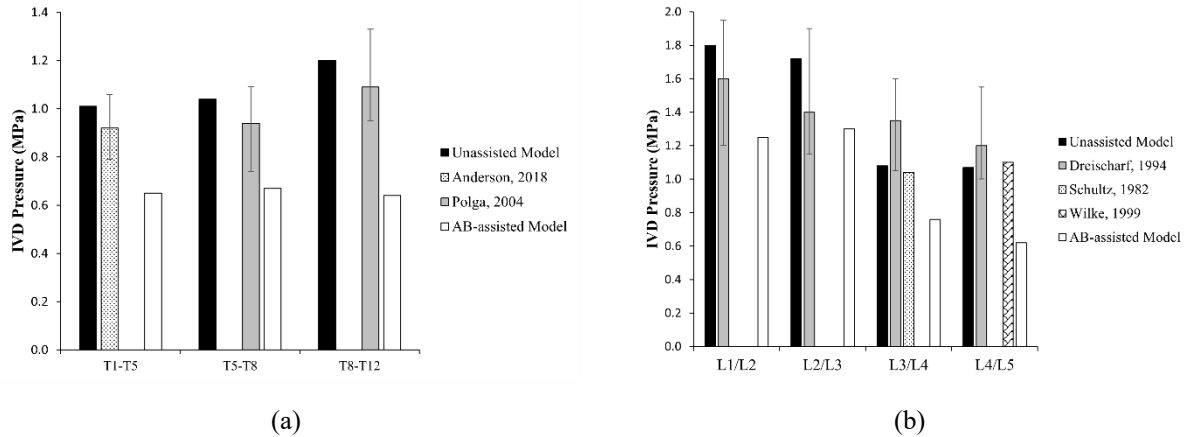


Figure 3.2.6. Comparison of intervertebral disc (IVD) pressure in the finite element models excluding (“unassisted”) and including (“AB-assisted”) an abdominal belt to literature for: (a) thoracic IVDs from T1-T12; (b) lumbar IVDs from L1-S1 [14, 24, 49-51]

3.2.3.2 Model Comparison Results

Results demonstrate that there were no significant differences in thoracic spine IVR, while the AB-assisted FEM showed a considerable decrease in IVR in the lumbar spine. Specifically, as compared to the unassisted FEM, the reduction was 3% in the thoracic spine and 14% in the lumbar spine. The difference in IVR between the two models got increasingly pronounced as the vertebral level neared the fulcrum, or the pelvis. The difference at the L1-L2 segment was 10%, whereas the difference at the L4-L5 segment was 19%. The AB-assisted FEM reported a significant increase in IAP from 3.92 kPa to 7.69 kPa (96%) in flexion when compared to its unassisted equivalent. The AB-assisted model also revealed considerable reductions in IVD pressure compared to the unassisted model at each IVD level, ranging from 0.42 MPa (24%) at L2-L3 to 0.56 MPa (47%) on average for the T8-T12 segment. The average IVD pressure change was 0.43 MPa (40%) in the thoracic spine and 0.44 MPa (31%) in the lumbar spine. The AB-assisted FEM showed a decrease in soft tissue tensile stress in the longitudinal direction when subjected to the same loading conditions as the unassisted model, as detailed in Table 3.2. Specifically, the soft tissues of the AB-assisted FEM had an average decrease in tensile stress of 0.3 kPa (7%) compared to the unassisted FEM, with the greatest difference being 10% (0.3 kPa) within the MF. In the ES and Trap muscles, average tensile stress remained relatively constant between the two models, only decreasing by 23.2 Pa (3%) and 5.8 Pa (1%) respectively. The LD showed an increase in stress in the AB-assisted FEM by 0.1 kPa (9%) compared to the unassisted FEM. The TLF experienced the largest change in normal stress in the longitudinal direction between the two models, with a

decrease of 1.1 kPa (8%) in the AB-assisted FEM as compared to the unassisted model. The TLF carried the most load among paraspinal soft tissue in both models, accounting for 74% in the unassisted FEM and 73% in the AB-assisted FEM.

Table 3.2. Average measured normal stress (in kPa) in the longitudinal direction (+Z) for the targeted soft tissues and recorded intra-abdominal pressure within the unassisted and AB-assisted finite element models.

	Unassisted FEM (kPa)	Assisted FEM (kPa)	Difference (%)
Total average tension	3.89	3.61	- 7%
Thoracolumbar fascia	14.40	13.27	- 8%
Erector spinae	0.78	0.76	- 3%
Multifidus	2.75	2.46	- 10%
Trapezius	0.68	0.68	-1%
Latissimus dorsi	0.82	0.90	+ 9%
IAP	3.92	7.69	+ 96%

kPa = kilopascal

In the transverse plane, the AB-assisted model showed a decrease in tensile stress in the TLF where the AB was applied, as compared to the unassisted model (see Figure 3.2.7). In the section just above, from the spinous process attachments of T10 to L2, the stress increased significantly by an average of 217%, while tensile stress decreased in the uppermost section of the TLF.

3.2.3.3 Sensitivity Analysis

To evaluate the accuracy and robustness of the model, a sensitivity analysis was conducted. The analysis involved changing the mesh size from 3 mm to 1 mm, resulting in a maximum difference of 4%. Modification of mesh elements from tetrahedral and triangular to hexahedral and quadrilateral produced a maximum difference of 3%. Varying the modulus of elasticity within the range of healthy material properties for tendons, IVDs, TLF and paraspinal and abdominal muscles led to a maximum difference of 13%. Overall, the sensitivity analysis demonstrated that the model was robust and accurate in accounting for variations in mesh size, mesh elements, and material properties.

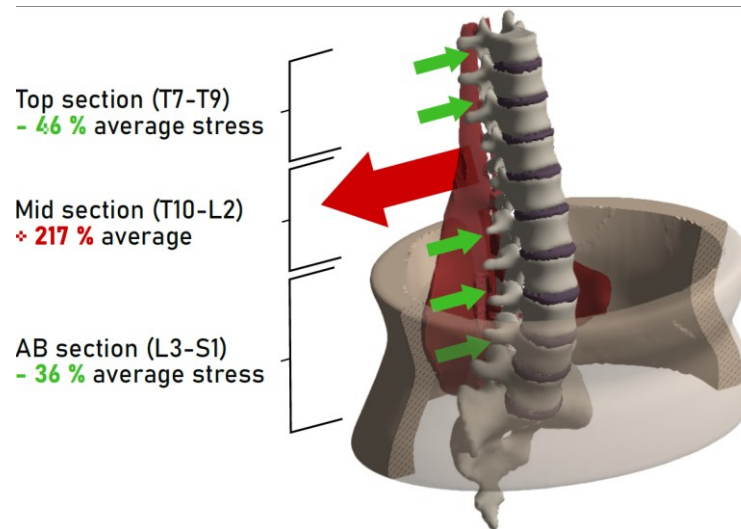


Figure 3.2.7. Comparison of tensile stress in TLF, in the transverse plane (+X), between unassisted and AB-assisted models. Red arrow pointing left indicates an increase in tensile stress, and green arrows pointing right indicate a decrease in tensile stress.

3.2.4 Discussion

The objective of this study was to investigate the mechanisms contributing to the changes in trunk stiffness, or stability, upon the application of an abdominal belt (AB). To achieve this, two FEMs were developed, one with and one without an AB, and validated against previous studies. Advancements in computational biomechanics have allowed for more accurate FEM representations of the human torso and its biomechanical behaviour. However, most FEMs are constructed based on approximated geometries and previous trunk FEMs often did not incorporate paraspinal and abdominal tissues, ignoring the muscles' passive contributions to spine stability [14, 52]. To address this, the newly developed FEMs for use within this study incorporate anatomically representative geometries and include major tissues of the musculoskeletal spine contributing to spine stability like the EO, ES, MF, and TLF. The presence of the TLF is especially important since current research indicates its key role in load transfer in the lower back [19, 20, 53-55]. Furthermore, the FEM includes an anatomically accurate abdominal cavity, making it unique in assessing the potential role of ABs in enhancing spine stability. Few FEMs provide insight into the effects of IAP generation, and those that include an abdominal cavity do not include as many tissues as adopted herein [21, 56]. Validation of the unassisted FEM in reflecting the physiological motion of the human torso was achieved through comparison to available literature. Comparison demonstrated good agreement between the unassisted FEM and *in vivo* and *ex vivo*

data for IVRs, indicating that the model is a reliable representation of the human torso under the simulated loading conditions. The IAP values predicted by the unassisted FEM were consistent with those reported in the literature, with only minor differences observed for the functional task described herein (<7%). The unassisted FEM's IVD pressure values were also in agreement with those reported in previous studies for the thoracic and lumbar segments. Furthermore, the influence of bonded contacts between the AB and body surfaces on model's results was minimal (<6%).

Sensitivity analyses were carried out in the current study to evaluate the model's sensitivity to mesh type, size, and change in the modulus of elasticity in order to assess the accuracy of the numerical results retrieved. The mesh sensitivity tests revealed that variations in mesh type and size had minimal effect on the model's outcomes. The tests conducted on material properties revealed that variations in the modulus of elasticity of soft tissues did not significantly affect the model's results. These findings suggest that the models developed in this study may be considered robust.

The results of the current study suggest that ABs may contribute to increasing IAP and reduce IVRs, more particularly in the lumbar spine. This finding is consistent with previous research, which has shown that ABs can increase trunk stiffness by increasing IAP [13]. The analysis of the results revealed that IAP increased considerably for the assisted FEM relative to the unassisted model (+ 96%). The assisted model also improved lumbar stiffness by reducing the average IVR by 14% in the lumbar spine. Excluding pelvic rotation from the study is considered to be reasonable given the imposed trunk forward flexion, thus simplifying the simulation while maintaining clinical applicability.

The study also suggests that IAP aids in trunk extension, which in turn may reduce the contribution of paraspinal muscles leading to a reduction in IVD compressive loads. The results are consistent with some studies that have reported small decrease in paraspinal muscle activation (4% of maximal voluntary contraction within the ES) when wearing an AB during sagittal symmetric exertions [57]. However, the available literature provides conflicting evidence regarding the impact of wearing an AB on the contribution of paraspinal muscles in terms of a decrease in myoelectric activity [13, 58]. Although the incorporation of active muscles in the current model could potentially affect the pressure on the IVDs, the differences identified between the unassisted and AB-assisted models underline the significant contribution of wearing an AB.

Despite small variations in IVR between the unassisted and AB-assisted models in the thoracic spine, there was a considerable decrease in IVD pressure in this region. This finding may be associated with higher lumbar bending stiffness, which results in less trunk flexion in the AB-assisted model. As a result, shear stress on the IVDs may decrease, as may pressure on the disc surfaces. The analysis of the results revealed that the TLF was taking the majority of the load being transmitted throughout the paraspinal soft tissues (>70%) for the loading conditions simulating flexion. The uneven stress distribution towards the TLF reveals a large demand on this structure to stabilize the spine while in flexion. A decrease in TLF normal stress in the longitudinal direction (1.1 kPa, or 8%) is also observed in the assisted model relative to the unassisted model indicating that the increase in IAP contributes to reducing load sharing within this tissue. The assisted FEM also yielded a decrease in normal stress in the longitudinal direction within the MF (0.3 kPa, or 10%). Furthermore, the study's results revealed that the AB had no significant effect on load sharing within the other paraspinal muscles. These findings suggest that the underlying mechanism of the AB is directed mainly towards the TLF and MF. As these tissues are significant contributors to spine stability, a reduction in loading may help alleviate symptoms of LBP [53, 59]. In the transverse plane, the direct support provided by the AB resulted in a decrease in tensile stress in the TLF where the AB was applied. As a compensatory mechanism, the section above experienced a significant stress increase to overcome the stress decrease observed in the AB section. This increase in stress may indicate the continued involvement of the TLF in stabilizing the spine despite the direct support provided by the AB. Lastly, the increase in tensile stress observed in the uppermost section of the TLF suggests that the overall reduction in spine flexion, facilitated by the AB, may have resulted in a reduced demand for stability on this section of the TLF.

3.2.4.1 Limitations

Simplifying assumptions are often made in FEMs to optimize computational efficiency without compromising accuracy. One of the key assumptions made in the FEMs developed in this study is the homogeneity and linearity of material properties, whereas human tissues are inhomogeneous, viscoelastic, and anisotropic. While FEMs can incorporate complex material properties, these models can be computationally expensive. As such, previous clinical studies were consulted to obtain the material properties used in this study (Table 3.1). This study focuses on a quasi-static analysis, specifically static conditions and static stability within the linear behaviour range of the material laws adopted, as detailed in El Bojairami et al. (2020). Therefore, there is no imperative

need to incorporate more comprehensive material laws for this particular investigation. As a result, although simplifications have been made by assuming linear, elastic and isotropic anatomical structures, the models developed herein provide a tool for preliminary clinical evaluation and rapid assessment of medical device designs. Nonetheless, the authors acknowledge that modelling the nucleus pulposus and annulus fibrosus with nonlinear properties would have provided a more comprehensive perspective on stress distribution across the discs. As a result, although simplifications have been made by assuming linear, elastic and isotropic anatomical structures, the models developed herein provide a tool for preliminary clinical evaluation and rapid assessment of medical device designs. Despite bones being composed of cortical and cancellous bone cells, these tissues were modelled as hollow cortical shell structures in this study. Simplifying bone geometry and material properties had little influence on the models' outcomes according to sensitivity analyses. Moreover, although the material properties of specific tendons and intertransversarii muscles were not available in the literature, sensitivity analyses indicated that variation in moduli had little influence on the models' outcomes. Given that soft tissue properties and behaviour may vary widely between individuals, both models in this study used identical material properties, boundary conditions, and loading conditions to address this problem. An important limitation of this study is the exclusion of active muscle forces, which may potentially result in an underestimation of the generated IAP for conditions investigated herein, and an overestimation of the IAP increase when incorporating the AB. Due to the complexity of the model, the present study used boundary and loading conditions derived from validated *in silico* studies. To simulate individual vertebral rotation during a 30° lumbar flexion, a moment was applied to every vertebra. The validation of IVRs, IAP, and IVD pressure throughout the thoracolumbar spine confirm the accuracy of the results, despite the new approach for simulating flexion. Further investigation is needed to evaluate the stabilizing effect of the belt on the spine during various exertions and movement tasks and the resulting effects on trunk stiffness, and spinal load sharing. Overall, the current study provides valuable insights into the mechanisms of ABs, and it may inform the development of more effective treatment options for individuals with LBP.

3.2.5 Conclusion

The study aimed to investigate the underlying mechanisms contributing to changes in trunk stiffness or stability when wearing an AB. Using two novel FEMs, the effect of an AB on IVRs,

IAP, IVD pressure, and load distribution among paraspinal soft tissues was determined. In accordance with literature, this study confirmed the role of ABs in raising IAP, reducing IVR, and thereby improving spine stiffness. The findings indicate that wearing an AB leads to a decrease in longitudinal tensile stress within the MF and TLF compared to not wearing any support, resulting in an unloading of the IVDs. The application of an AB decreased transverse tensile stress in the TLF where it was applied, leading to a compensatory stress increase in the section above, indicating continued TLF involvement in spine stabilization. These results provide evidence of improved stability without the increase in compressive stress on the IVDs.

3.2.6 Acknowledgements

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3.2.7 Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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4. Feasibility of a novel back support device to improve spine stability and muscular activity during trunk flexion: a prospective cross-sectional study with healthy controls and low back pain subjects.

4.1 Framework of Article 2

The findings of Article 1 revealed that wearing an AB enhances spine stiffness and stability by acting through the IAP mechanism, resulting in reduced load distribution in spinal soft tissues and decreased compressive stress on the intervertebral discs. Based on these findings, the present study seeks to explore the feasibility of a novel back support device specifically designed to enhance spine stability and reduce muscular activity during trunk flexion movements. Unlike existing ABs that exert constant pressure on the abdomen and conventional exosuits that reduce back muscle activity without effectively enhancing spine stability, the proposed back support device addresses these limitations by generating abdominal compression strictly during flexion movements. This distinctive feature has the potential to selectively improve lumbar stability through the IAP mechanism.

Building on the numerical analysis presented in Article 1, the subsequent study evaluated lumbar ROM, IAP magnitudes, and muscle activity in a cohort of 36 participants (comprising 18 individuals with LBP and 18 healthy individuals). By enhancing lumbar spine stability without increasing muscle coactivation, this novel device has the potential to facilitate the reintegration of physical activities for workers affected by LBP. Ethical approval for the study was successfully obtained from the Research Ethics Board of the McGill University Health Centre prior to its commencement.

Specifically, the present article centers on the secondary objective of developing and evaluating the effectiveness of a novel back supporting device that increases spine stability during lifting tasks. It aims to address the two hypotheses proposed in this dissertation, with a specific focus on the novel device. The present study represents a proof concept, and further iterations of the device will be developed based on the insights gained from this investigation. The manuscript has yet to be submitted for publication (pending the analysis of electromyography (EMG) data and the completion of statistical analysis to ensure robust and comprehensive reporting of the results).

4.2 Article 2: Feasibility of a novel back support device to improve spine stability and muscular activity during trunk flexion: a prospective cross-sectional study with healthy controls and low back pain subjects.

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4.2.1 Abstract

Low back pain (LBP) is a widespread condition with significant global implications, being the leading cause of disability worldwide. Despite efforts to diagnose LBP, over 80% of cases are classified as non-specific, making it challenging to offer customized treatments. Manual lifting, a common occupational task, is associated with LBP, particularly due to the stresses imposed on the lumbar spine during such activities. Existing assistive technologies like abdominal belts and exoskeletons have limitations in managing LBP effectively and safely. This paper presents a novel back support device designed to generate abdominal compression during flexion activities, potentially enhancing lumbar stability through increased intra-abdominal pressure (IAP). The study involved 18 participants with chronic non-specific low back pain (cNSLBP) and 18 age- and gender-matched healthy controls. Results indicated that the back support device significantly increased IAP in both groups during various functional tasks. Healthy participants experienced greater IAP increase during active trunk flexion, while cNSLBP participants benefited more during tasks requiring precision or intensity. The device effectively reduced lumbar ROM during trunk flexion in both groups, with minor changes observed at the lumbosacral junction in the cNSLBP group. The back support device improved lumbar spine stability without increasing muscle coactivation, potentially facilitating the reintegration of physical activities for workers with cNSLBP. The study's limitations include the exclusion of overweight participants and the use of mathematical approximations for IAP measurement. Despite these limitations, the results suggest promising benefits in managing LBP and warrant further investigation into the device's long-term impact.

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4.2.2 Introduction

Low back pain (LBP) is a prevalent and growing issue with profound global implications. It is the leading cause of disability worldwide, and the number of people affected by LBP is increasing as the global population grows and ages [1]. Despite thorough evaluation, over 80% of LBP cases are diagnosed as non-specific, where the exact underlying pathology remains unidentified [2]. The causes of non-specific LBP are multifactorial and may originate from structures other than the lumbar spine. Non-specific LBP symptoms may be influenced by various factors such as posture, activity, and cumulative spinal loading over prolonged duration [3]. The absence of a definitive diagnosis makes it difficult to offer specific treatment and management options to people suffering from this condition. Failure to treat or inadequate treatment of patients with LBP can have substantial and long-term consequences on many aspects of daily life, such as employment, social activities, and self-care [4-7]. The resulting medical expenses and job absenteeism represent a significant economic burden in many regions of the world and pose enormous challenges for individuals, families, communities, businesses, and governments alike [8, 9].

Manual lifting, a common occupational task, has consistently been associated with the initiation and maintenance of disabilities related to LBP, posing a significant concern for workers performing physically demanding tasks. Lifting and holding weights away from the body can subject the lumbar spine to significant compressive stresses, resulting in changes in soft tissue properties and muscle fatigue within the lumbar soft tissue [10]. Moreover, individuals with LBP have been shown to exhibit increased lumbar stiffness, which is believed to be the result of different muscle activation strategies aimed at improving lumbar stability [11, 12]. These alterations in lumbar stiffness may have implications on soft tissue mechanical properties and contribute to the maintenance of LBP [13].

Spine instability is often cited as the most common etiology of LBP symptoms [14]. Tissue strain and damage can occur as a result of poor spine stability, increasing the likelihood of developing LBP. As a result, including spine stability into preventive and treatment measures is critical for reducing the global burden of this condition.

Assistive technologies like abdominal belts (ABs) and exoskeletons have been proposed for managing LBP during lifting tasks, but their efficacy and safety are still being investigated [15, 16]. For instance, ABs, which enhance intra-abdominal pressure (IAP) without requiring

additional muscle contractions, have been shown to improve spine support and stability [17]. However, the constant elevation of IAP that accompanies the use of ABs is believed to be associated with increased blood pressure and reduced venous return, which may have adverse effects on nearby organs and potentially serve as predisposing factors for other disorders [18, 19]. Then, exoskeletons aim to assist human mobility in labour-intensive activities and lower the risk of muscle and joint damage. While they can simplify tasks by relieving strain on spine tissues, their bulky and heavy design may result in low compliance and limited effectiveness [20]. Prolonged use of these devices may also lead to muscle weakening and discomfort from continuous pressure. Therefore, there is a need for innovative approaches to address the limitations of existing assistive technologies and provide effective solutions for managing LBP, specifically in the context of manual lifting tasks among physically active workers.

In this paper, we propose a novel back support device which leverages back flexion to generate abdominal compression, raising IAP specifically during flexion activities. We will present the design considerations and preliminary findings of a novel back support device, highlighting its possible benefits in improving lumbar stability through IAP in those with LBP and healthy controls. We will also discuss how the proposed back support device may contribute to the reduction of elevated asymmetric levels of trunk muscle activation reported in subjects with LBP during standing and trunk flexion tasks [12].

4.2.3 Methods

4.2.3.1 Participants

The study is a prospective cross-sectional study involving 18 participants with chronic non-specific low back pain (cNSLBP) (age range, 18-65 years) and 18 age- and gender-matched healthy control participants. Patients were recruited continuously until the desired sample size was achieved. The healthy participants were recruited via McGill University channels (email, social media posts, etc.), whereas the participants of the cNSLBP group were recruited from a database made available from the Quebec Back Pain Consortium. Study participants were included in the cNSLBP group if they had a history of recurrent cNSLBP for at least 3 months and has resulted in pain and/or limitations in at least half of the days in the past 6 months, as diagnosed by a physician. All participants had a normal BMI (18.5–24.9 kg/m²), rated their pain as less than 3 on a 10-point scale (0 being no pain and 10 the worst pain), and were able to stand and walk without assistance.

The exclusion criteria for both groups were: lack of consent to participate in the study, recent spinal or lower-body injury, recent spinal surgery, presence of spinal abnormalities, diagnosed hearing or vision defects, diagnosed neurological, cardiovascular, rheumatologic, or orthopaedic disorders, balance disorders, uncontrolled diabetes or blood pressure, birth defects, scoliosis, cancer, and pregnancy. Participants using non-prescribed medications or substances affecting balance or muscle function were excluded. Participants with inflammation, reddening, or scars at the testing sites were also excluded. Study participants were included in the control group if they had no significant history of LBP requiring medical intervention or limitations in their daily activities in the past 12 months. The approval of the Research Ethics Board of the McGill University Health Centre to conduct this study was obtained. Participants' characteristics are shown in Table 4.1. No between group differences were detected for age, height, mass, or body mass index.

4.2.3.2 Prototype design and functions

A novel back support device was designed and fabricated. The design of this back support device aimed to overcome the limitations of current assistive technologies by addressing issues related to aesthetics, weight, size, and cost. The concept was designed to provide both assistive trunk extensor support and improve spine stability. It combines the features of a back/abdominal braces and an exosuits by redistributing external load from the lumbar joints to the abdomen, pelvis, and lower body during flexion tasks (see Figure 4.2.1). The back support device consists of textile-based sections connected by elastic and semi-rigid elements (orange components in Figure 4.2.1a), resembling human muscle and fascia architecture facilitating energy storage and release to support and assist the trunk during lifting and lowering phases. The upper section (green), the lower section (cyan), and the abdominal compression unit (purple) are connected via a rhombus scissor mechanism in the lumbar region which converts tension from hip and spine rotation into compressive forces on the abdomen.

4.2.3.3 Procedure—passive movements

All participants underwent two separate protocols. To ensure standardized tasks, participants were asked not to perform strenuous exercise within 12 hours of the data collection, including their mode of transport to the session. Furthermore, they were asked to abstain from consuming energy drinks 24 hours before the session, alcohol, or more than one cup of coffee within 12 hours before the session, and food within 2 hours before the session.

The first protocol assessed muscle activation, intervertebral motion, and IAP in passive movements. Participants were positioned in a custom-built motion apparatus, with their sacrum immobilized and their hands on a swivel arm (Figure 4.2.1b). Participants were instructed to flex their trunk forward ($+60^\circ$). The maximum ROM of the trunk was restricted by a mechanical stop on the motion apparatus. The participants guided their own motion and held at the end ROM for three seconds before returning to the upright standing posture. The participants repeated all tasks wearing the back support device securely fitted to their trunk and thighs.

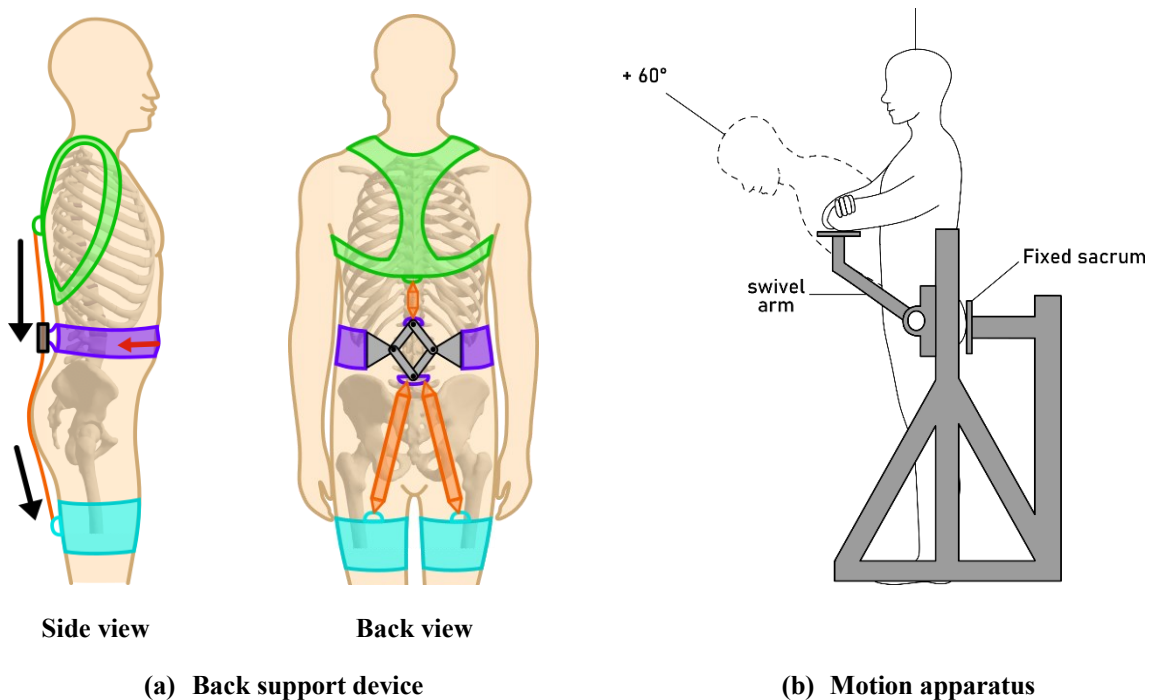


Figure 4.2.1 (a) Novel back support device investigated in this study and (b) custom-built motion apparatus for movements in the sagittal plane with restriction at the level of the sacrum.

To ensure familiarization and to remove potential learning effects, each participant completed two practice trials and two recorded trials for each test condition. The order of the tasks was randomized. Compliance to the instructions was monitored visually by the investigators.

Muscle activation was captured using five pairs of bipolar surface electromyographic (sEMG) electrodes (model SX230 1000) located on longissimus thoracis, iliocostalis thoracis, multifidus, gluteus maximus and the external obliques, with a Biometrics Ltd Datalog System (MWX8; VA, USA; sampling rate: 1200 Hz; bandwidth: 20–500 Hz).

IAP was captured using the lab-developed CorePro device (Musculoskeletal Biomechanics Research Lab, McGill University, Canada), which is a non-invasive technology validated *in vivo* to measure soft tissue elasticity. The device uses suction against the skin to induce a displacement in abdominal tissue from which IAP is calculated [21].

The fluoroscopic images were collected with a C-arm of a dual fluoroscopic imaging system (GE Miniview 6800). Four fluoroscopic images were collected for each of the two tasks (flexion, flexion with the back support device). For each condition, the first image was collected at the initiation of the movement (erect standing position) and the second image was collected at the completion of the movement (see Figure 4.2.2). The images were collected in two repeated movements to capture the lumbar spine from L2-S1. The first repetition captured the L4/L5 and L5/S1 lumbar levels while the second captured the L2/L3 and L3/L4 lumbar levels. The radiation exposure rate was 20-160 μA at an intensity of 40-80 kV, and a time of 5-10 seconds/image (movement and three-second static hold at the end ROM). Therefore, for the three tasks there was a maximum total radiation exposure of 12.8 mA.s ($160 \mu\text{A} \times 10 \text{ seconds/image} \times 4 \text{ images/condition} \times 2 \text{ tasks}$).



Figure 4.2.2. Passive movement protocol illustrating the flexion task under investigation.

4.2.3.4 Procedure—functional movements

The second protocol evaluated muscle activation and IAP but now in functional movements. Participants performed three tasks: standing flexion, picking, and lifting. To remove potential learning effects and to standardize the tasks between participants, video instructions were

presented to every participant for every condition and each participant completed two practice trials and two recorded trials for each task. For the flexion task, participants were instructed to bend forward as low as possible from an upright standing posture. They were asked not to bend the knees and hold at the end ROM for three seconds before returning to the upright standing posture. The picking task consisted of picking up a sponge from the ground, with their right hand. The distance between the sponge and the feet were normalized at 15 cm and centered between the feet. The lifting task was performed with both hands and again, normalized 15 cm away from the feet and centered. For every task, compliance to the instructions was monitored visually by the investigators. The participants repeated all tasks wearing the back support device securely fitted to their trunk and thighs.

Table 4.1. Characteristics of the recruited participants.

	Healthy group				cNSLBP group				p-value	
	Male		Female		Male		Female		Group	Sex
	(n = 9)		(n = 9)		(n = 9)		(n = 9)			
	Mean	(SD)	Mean	(SD)	Mean	(SD)	Mean	(SD)		
Age	30	8	31	7	48	10	44	10	0.39	0.42
Height	1.82	0.046	1.6	0.0	1.8	0.1	1.6	0.1	0.63	0.02
Mass (kg)	71.8	8.7	58.9	6.6	67.2	5.1	59.6	9.9	0.64	0.01
BMI	21.8	2.1	22.2	1.7	21.0	1.8	22.4	1.2	0.69	0.29

The p-values ≤ 0.05 are identified in bold characters.

BMI: Body mass index.

4.2.4 Results

4.2.4.1 Intra-abdominal pressure

Both healthy participants and those with cNSLBP experienced an increase in IAP after wearing the back support device. IAP variations were consistent across all functional tasks. Wearing the device contributed to increasing IAP more significantly in the healthy participants for active trunk flexion movements, whereas picking and lifting activities showed the opposite pattern. In the passive trunk flexion task, the cNSLBP participants benefited from using the device more

substantially than the healthy cohort, where the effect on IAP was negligible, only increasing by 2%. *Statistical analysis has yet to be performed on this set of data.*

4.2.4.2 Intervertebral motion

When the back support device was used, there was a noticeable decrease in motion between the lumbar vertebral segments, with an average reduction of $31 \pm 4\%$ for both healthy participants and those with cNSLBP. With the exception of the L5/S1 level in the cNSLBP group, this decrease in ROM was consistently seen at all levels. The cNSLBP participants exhibited minor changes at the lumbosacral junction (L5/S1) while using the back support device, exhibiting a 0.5% decrease. *Statistical analysis has yet to be performed on this set of data.*

4.2.4.3 Muscle activity

This section of data is currently being analyzed. No data can be presented at the moment.

4.2.5 Discussion

The primary objective of this study was to investigate the effect of the novel back support device on trunk and gluteal muscles, as well as lumbar stiffness. The study also sought to determine whether those cNSLBP responded differently to the back support device than did healthy controls.

The recorded increase in IAP for both groups when wearing the back support device suggests its potential role in enhancing lumbar stiffness and spine stability without the need for corresponding antagonistic muscle activation. It appears that healthy participants may not require the device's support during passive trunk flexion, as evidenced by a negligible 2% increase in IAP, while the cNSLBP group benefited considerably with a 26% increase in IAP. Nevertheless, healthy participants did receive benefits from the device during functional movements. Furthermore, the cNSLBP participants appear to receive greater assistance from the device during tasks requiring precision (picking) or intensity (lifting) compared to healthy participants. This could be attributed to the cNSLBP group's greater demand for stability while executing more complex tasks. cNSLBP participants also appeared to reduce their degree of trunk flexion during the active flexion task with the device, possibly to maintain the perceived sense of security provided by improved stability, thereby explaining the smaller variation in IAP.

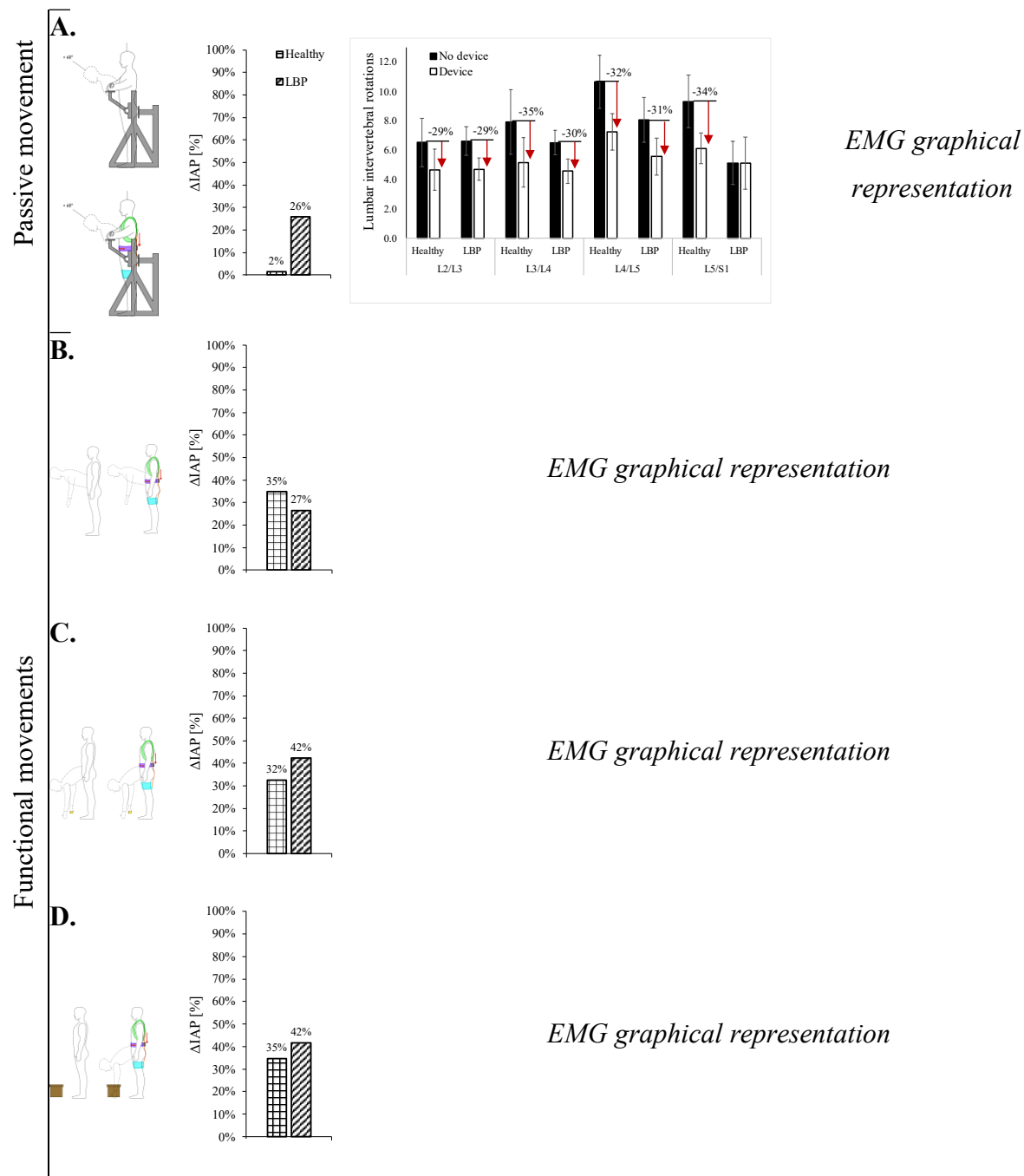


Figure 4.2.3. Biomechanical analysis during passive and functional movement protocols. Effect of wearing the novel back support device during (A) passive trunk flexion, (B) active trunk flexion, (C) picking light object task, and (D) lifting task.

Our study findings indicate that the back support device effectively reduces lumbar ROM in participants with cNSLBP (as in healthy controls), during tasks involving trunk flexion, regardless of constraints on knee and hip flexion. The reduction in lumbar flexion appears more important in healthy participants, possibly suggesting that cNSLBP participants have adapted their trunk motor control to prevent excessive tissue strain and protect their lower back [22, 23]. The negligible

difference in ROM among cNSLBP participants at the L5/S1 level when wearing the device may also reflect their existing stiff protective mechanism for the lumbosacral joint. The overall decrease in lumbar ROM is important as it may provide a protective effect against various mechanisms of injury, during a variety of work tasks. Moreover, literature suggests that soft tissues can take up to 3 months to heal properly, although injured workers return to work earlier [24]. The back support device may aid in reducing muscular demands during rehabilitation or in the early weeks of work after a back injury. Adjusting the device's elastic band stiffness throughout rehabilitation could gradually reduce muscle activity and abdominal compression, allowing injured tissues to heal while promoting strength in healthy tissues. However, clinical trials are needed to validate this approach on injured workers.

The device represents a promising method to increase lumbar stiffness, and as a result, spine stability, without the associated increase in muscle coactivation documented by Cholewicki, et al. [17], which is known to increase the compression load on the spine. From a disability prevention perspective, these effects could help workers with cNSLBP to gradually reintegrate physical work activities, while from a prevention standpoint, it may help maintain these activities at the workplace, contributing to overall better back health management.

4.2.5.1 Limitations

One important consideration is that the use of the back support device is its individual suitability. The pressure provided by the device can vary significantly, and excessive pressure may lead to discomfort or potential harm. To ensure comfort and safety, the pressure was individually tailored for each participant in the present study, rather than applying a uniform pressure as seen in previous studies [25]. Although all participants had the same stiffness in the elastic elements and abdominal compression unit for the study, the required reduction in muscle activity is specific to an individual's size and geometry. This individual variability may have amplified or reduced the effects in some participants since more or less muscular force would be required to achieve the same amount of work.

This study is part of a larger investigation, and participants may have experienced fatigue towards the end of the session when wearing the back support device, which could potentially influence the results. However, this potential fatigue affected all participants equally, ensuring the comparative analysis remains relevant and valid. Furthermore, this study is cross-sectional, which

means that the results are extracted from a single point in time. To fully comprehend the long-term impact of using the device, further longitudinal studies would be required. The use of a fluoroscopic imaging system with a small opening constrained the recruitment of participants to those within healthy BMI ranges. As a result, individuals who may have been overweight or experienced weight changes, which are closely associated with LBP [26], were excluded. This exclusion could potentially impact the severity of LBP among the recruited participants. Additionally, the imaging system's limited resolution might have affected the precision of the extracted vertebral motions. However, the statistical analysis demonstrated good inter-rater reliability (inter-rater reliability = 0.86) proving the credibility of the results despite the imaging limitations. The CorePro device used for measuring IAP applies mathematical equations derived from the Hencky solution, which relies on pressure and deformation measurements. These measurements, in turn, depend on the properties and geometries of the soft tissues under analysis. Consequently, the IAP measurement obtained is an approximation rather than an exact value. However, to minimize the impact of this approximation, the elasticity and circumference of the abdominal wall were directly taken from each participant.

Due to the partial coverage of the electrodes by the back support device, there may be some artifact in the measured myoelectric activities of the back and abdominal muscle. *Analysis of EMG data is warranted to estimate the effects of electrode compression.*

4.2.6 Conclusions

The back support device shows promise in managing chronic non-specific low back pain (LBP) during manual lifting tasks. By increasing intra-abdominal pressure and reducing ROM during trunk flexion movements, the device improves lumbar stability without any increase in muscle coactivation and the associated compressive load on the spine. While further validation is needed, the device offers potential benefits in addressing the global burden of and enhancing workplace health management.

4.2.7 Acknowledgements

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4.2.8 Declaration of Competing Interest

The authors of the manuscript, “Feasibility of a novel back support device to improve spine stability and muscular activity during trunk flexion: a prospective cross-sectional study with healthy controls and low back pain subjects” declare that they have no conflict of interest.

4.2.9 References

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4.3 Additional Work: Development of the Novel Back Support Device

4.3.1 *Design and Functionality of Novel Back Support Device*

Back support braces are wearable assistive devices designed to passively assist individuals by increasing IAP and potentially enhancing spine stability. However, they do not provide an additional extensor force vector to unload back soft tissues. They also maintain a continuous buildup of IAP due to their inherent tightness. In contrast, wearable soft exoskeletons, or exosuits, offer an additional force vector to facilitate lifting tasks, but do not directly improve spine stability. Therefore, current technologies are deficient in simultaneously providing an assistive trunk extensor moment and improving spine stability. The novel back support device can be thought of as a combination of a back brace and an exosuit, as it redistributes part of the external load on the upper body from the lumbar joints to the abdomen, the pelvis and then the lower body during flexion tasks. This redistribution generates the desired extension moment while directly increasing IAP to improve spine stability.

The back support device proposed in this work comprises three textile-based sections, connected by elastic and semi-rigid elements, as shown in Figure 4.2.1 (a), (b), and (c). The figure visually represents the upper body unit (green), the abdominal compression unit (purple), the lower body unit (cyan), the Tensile-to-Compression Converter (black), and the elastic and semi-rigid elements (orange). The Tensile-to-Compression Converter is a mechanically advantageous system that converts tension generated from hip and spine rotation in the sagittal plane into compressive forces, or radial stress, applied to the wearers' abdomen. In the interests of conciseness, the traction-compression converter is shown as a "black box" in the figure, as further information on the multiple actuation mechanisms is given in Section 4.3.3.4 and 4.3.3.5.

The novel back support device is modelled on the concept of human muscles, tendons, ligaments and fascia architecture via elastic and semi-rigid elements that can be viewed as external soft tissues that store energy and support the trunk tissues in the lowering phase, and then release the energy and generate additional power in the lifting phase (Figure 4.3.2). This simple passive actuation mechanism consists of elastic bands whose elasticity factor is adjusted to provide the necessary resistance. These elements are arranged longitudinally to resemble the myofascial meridian lines discussed in section 2.1.7, which convey forces and moments from the spine to the

shoulders, hips, and knees. The elements run adjacent to the Front and Back Functional Lines which represented by red bands in Figure 4.3.2 (a), (b), (c). The external functional lines of the back support device start from the superior end of the lower Trap and run down the LD, the TLF, and the sacral fascia posteriorly, crossing the midline at approximately the level of the L5/S1 joint to the lower fibers of the gluteus maximus on the opposite side. The lower fibers of gluteus maximus then extend down the posterolateral edge of the femur. Anteriorly, the line extends from the superior end of the lower Trap to the pectoralis major and deeper the serratus anterior, crossing the midline at the level of the xiphoid process to reach the middle of the ribcage (approximately the 6th rib) laterally. The elements also descend along the Spiral Line represented by the blue bands in Figure 4.3.2 (a) (b), (c). The Spiral Line circles the body in two opposing helices that envelop the ribcage to then cross anteriorly at the level of the navel down to the hips, passing through the IOs. Finally, the superficial back line connects the lower neck to the knees, descending vertically alongside the ES muscles and the TLF, then diverging laterally via the sacrotuberous ligament and the hamstrings (yellow bands in Figure 4.3.2 (a) (b), (c)).

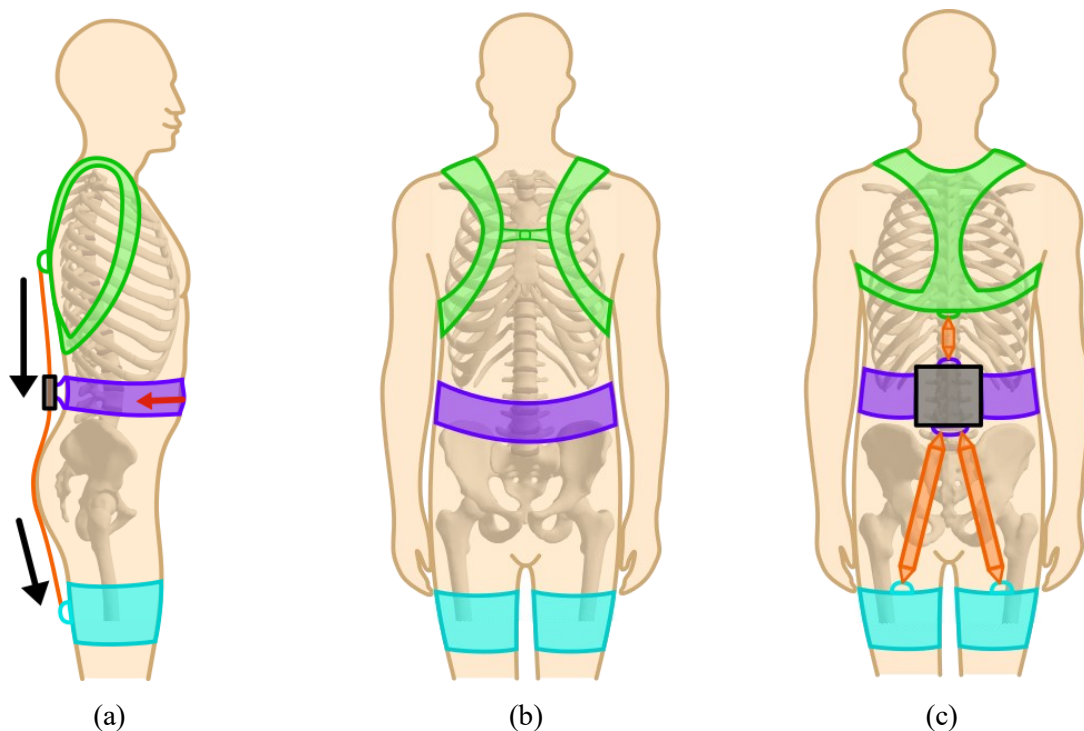


Figure 4.3.1: Layout of the novel back support device in (a) side, (b) front and (c) back perspectives. The upper body unit is represented in green, the abdominal compression unit in purple, the lower body unit in cyan, the Tensile-to-Compression Converter in black, and the elastic and semi-rigid elements in orange.

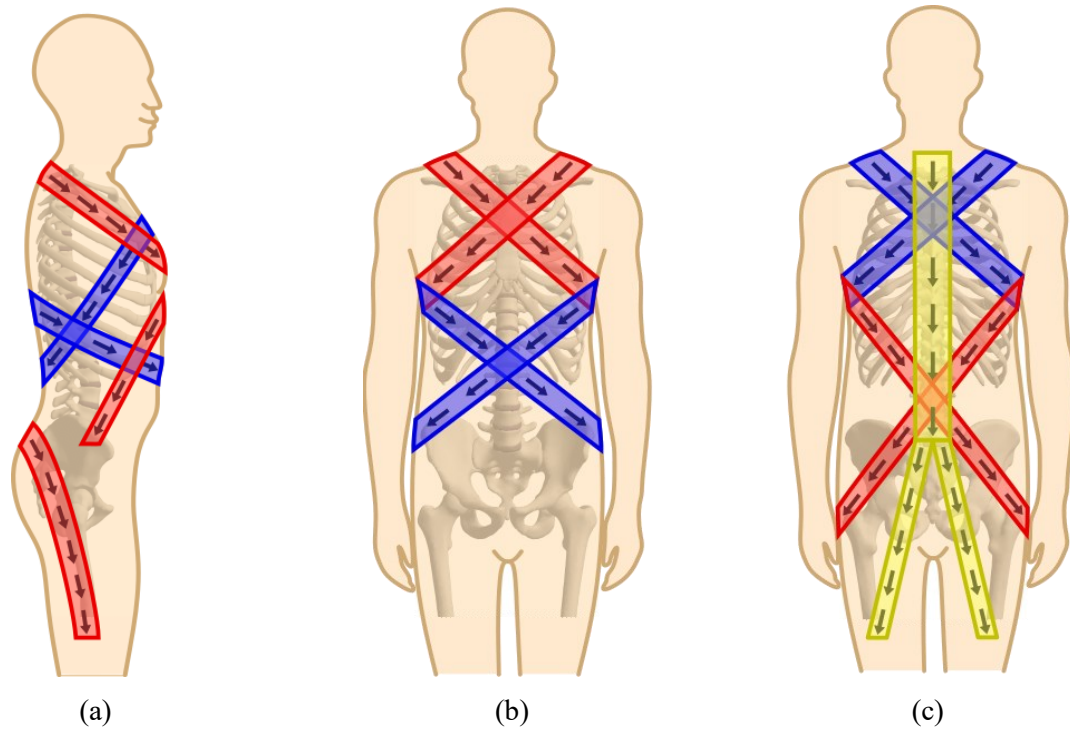


Figure 4.3.2: Layout of the myofascial meridian lines in (a) side, (b) front and (c) back perspectives. The red bands correspond to the back and front functional lines, the blue bands to the spiral line and the yellow bands to the superficial back line.

Before validating the concept *in silico* or in a clinical trial, a mechanical analysis of the design is required to understand the impact of the new back support device on the human body during lifting tasks, in particular L4/L5 compression and shear forces, IAP generation and muscle forces assistance. The following section describes the biomechanics of the back support device using a static 2D model and experimental data to determine the design factors that influence the forces transferred to the abdomen, shoulders, hips, and knees, as well as posterior soft tissues unloading.

4.3.2 Design Criteria

Existing evidence suggests that reducing compressive and shear forces on the spine can potentially mitigate the risks associated with LBP and disability [107]. Reducing forces and moments could also facilitate the rehabilitation of injured workers who fear reinjuring their back [202] or who require a long recover [203]. The most important design criteria for the novel back support device are efficiency and safety in the workplace, and improved static and dynamic stability of the spine.

Efficiency encompasses subjective factors such as comfort speed and accuracy when performing tasks. Nevertheless, certain efficiency parameters can be quantified, such as the

increase in IAP and the decrease in extension moment required. As IAP is known to play an essential role in stabilizing the spine and generating an extensor moment [204], the main objective was to design a passive actuation mechanism that increases IAP during lifting tasks. The elastic and semi-rigid elements were designed to tension the abdominal compression unit while storing energy as the back extends during flexion tasks. This meant ensuring that these elements possessed elastic properties for energy storage while still providing adequate assistance and activating the Tensile-to-Compression Converter. Therefore, the stiffness coefficient of these elements may be adjusted for specific groups of individuals to avoid excessive demands on muscles to stretch them.

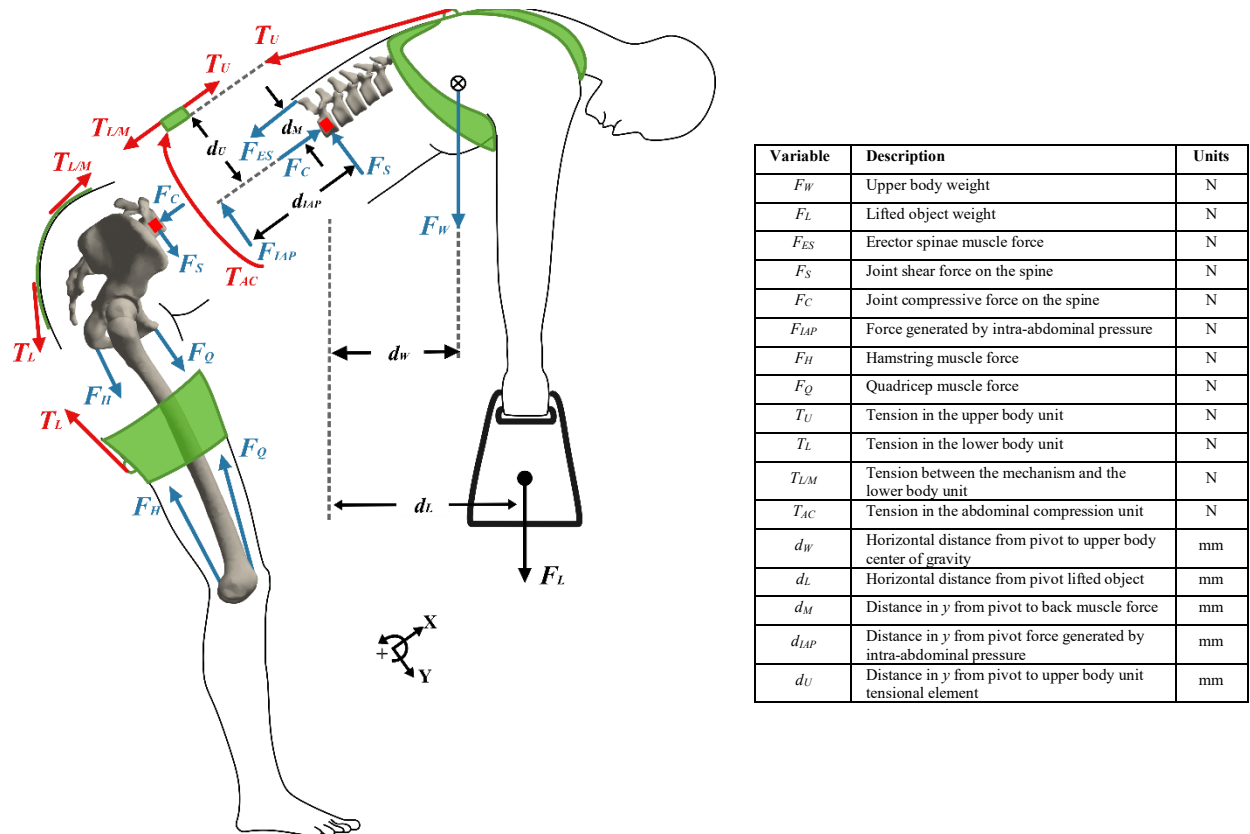


Figure 4.3.3: Free body diagram of the novel back support device. Blue arrows represent physiological body forces and red arrows represent device forces.

Other design considerations aim to maintain an acceptable level of force distribution over the shoulders, thighs, lower back, and pelvis to allow workers to perform bending tasks comfortably while minimizing excessive stresses on these regions. In a study by Stevenson et al. (2004), backpacks that subjected the shoulders to a pressure of 35 kPa caused subjective discomfort, while 90% of wearers reported discomfort with an average pressure exceeding 20 kPa during a 6 km

walk [205]. In the same study, an external pressure limit of 105 kPa was recommended for the lumbar region.

In addition, anchor points and structural positioning of components must be configured to ensure unrestricted mobility and avoid the risk of interference with workplace equipment. Finally, the design of the back support device must be lightweight, conform to the wearer's body, easy to use, breathable, comfortable, affordable, durable, and aesthetically pleasing.

4.3.3 Mathematical Concept

4.3.3.1 Intra-Abdominal Pressure

The most important design factor affecting the back support device's geometry is the generation of hoop stress to subsequently increase IAP. Assuming the Tensile-to-Compression Converter acts at a 1:1 ratio and the abdominal cavity is a cylinder, the tensile forces (T_{AC}) generated in the mechanism are converted to IAP and axial stress following the stress relationships for thin-walled cylinders:

$$T_{AC} \approx \sigma_{hoop} = \frac{IAP \cdot R}{t_{exo}} \quad (4.1)$$

$$\sigma_{axial} = \frac{IAP \cdot R}{2t_{exo}} \quad (4.2)$$

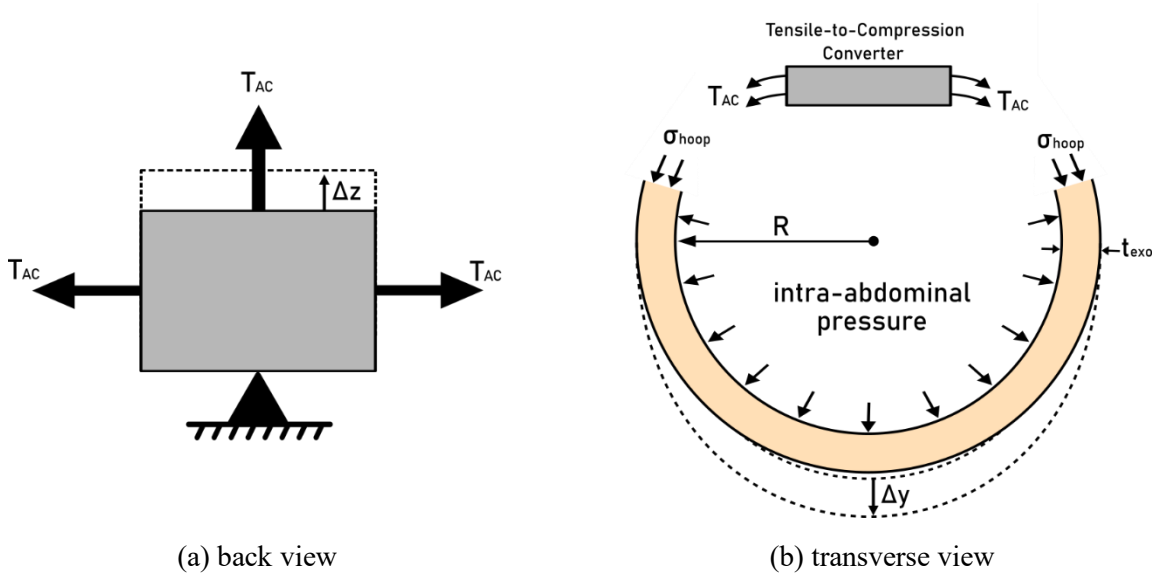


Figure 4.3.4: Mechanism of action of the Tensile-to-Compression Converter.

According to Hooke's law, tension in the elements (T_{AC}) is linearly proportional to stiffness (K) multiplied by the length change (Δz). As a result, equation (4.1) can be rewritten to establish a relationship between IAP and the change in length of the elastic or semi-rigid elements:

$$IAP = \frac{K \cdot \Delta z \cdot t_{AC}}{R} \quad (4.3)$$

Still according to Hooke's law, the tensile stress in the abdominal compression unit (σ_{hoop}) is linearly proportional to its fractional extension ($\Delta y/L_o$), multiplied by the modulus of elasticity (E). Therefore equation (4.1) and (4.3) can be combined to find a relationship between the elastic and semi-rigid elements and the abdominal compression unit:

$$\begin{aligned} \frac{K \cdot \Delta z \cdot t_{exo}}{R} &= \frac{E \cdot \Delta y / L_o \cdot t_{AC}}{R} \\ K \cdot \Delta z &= \frac{E \cdot \Delta y}{L_o} \end{aligned} \quad (4.4)$$

Consequently, the material of the elastic and semi-rigid elements must be stiffer to ensure that deformation occurs first in the abdominal compression unit at the start of the lifting task. Experimental testing revealed the following data for the Tensile-to-Compression Converter:

1. Displacement of the uppermost section at a 30-degree flexion:
 - 5th percentile female: 2.33 cm
 - 95th percentile male: 3.75 cm
2. Support in the longitudinal direction:
 - 5th percentile female: 70 N
 - 95th percentile male: 150 N

Based on these empirical findings, the spring constants for the elastic and semi-rigid elements were determined using Hooke's law:

- 5th percentile female: 3000 N.m
- 95th percentile male: 4000 N.m

Considering the transfer of displacement to abdominal compression and accounting for the softness of the abdominal region, half of the support is assumed to determine the spring constants for the abdominal compression unit:

- 5th percentile female: 750 N.m
- 95th percentile male: 1000 N.m

To determine the potential increase in IAP at 30-degree flexion, equation (3) is used, taking into account the approximate thickness of the abdominal compression unit as 2.5 cm. Additionally, abdominal circumference values for the 5th percentile female and 95th percentile male have been reported at 55.3 cm and 101.3 cm, respectively [206].

- 5th percentile female: 37 mmHg
- 95th percentile male: 43 mmHg

4.3.3.2 Extensor Moment

The geometry of the back support device is influenced by the generation of an extensor moment, which is an important design factor. El Bojairami and Driscoll (2021) found that IAP plays an important role in maintaining static equilibrium, providing around 25% stability when supporting structures (muscles, ligaments and fascia) are not present [60].

However, other structures are instrumental in generating stability during lifting tasks. In the same study, El Bojairami and Driscoll determined that the TLF contributes around 75% to stability by dissipating and absorbing excessive loads, while the paraspinal muscles (ES, MF, and LD) contribute around 53% to stability. The ES muscles are responsible for generating most of the force required to lift loads [90, 114], acting at a lever arm of around 0.05 m at the L4/L5 level [90, 203].

The distance between the skin surface and the center of the L4/L5 joint was estimated at around 0.10 m. Considering the combined thickness of the Tensile-to-Compression Converter and its distance from the skin (approx. 3 cm), the lever arm of the elastic and semi-rigid elements is estimated at 0.13 m.

Appendix A.1 details the loading scenario for the new back support device, specifically for a static lifting task in a 60-degree stoop position with a weight of 15 kg in hands. The exercise considers both a 5th percentile female and a 95th percentile male to estimate the range of anthropometric measurements and loading conditions that vary between individuals. The data specific to each scenario was extracted from the NASA Anthropometry and Biomechanics database [206], Plagenhoef, et al. [207], Abdulla and Fahad [208], and Johnson [209].

4.3.3.3 Effect of Wearing the Back Support Device

The results obtained from the biomechanical model detailed in Appendix A.1 reveal that wearing the back support device significantly increases IAP, which is believed to improve spine stability. The contribution of IAP to the spine extensor moment also significantly reduces tension in the back soft tissues by more than 24% and hip extensor muscles by over 18%. As a result of these biomechanical load changes, there is a substantial reduction in compressive forces exerted on the L4/L5 disc, amounting to over 25%. Furthermore, the support provided to the trunk and hip extensor muscles, along with the improved stability, is believed to have a secondary, although minor, unloading effect on other lower-body joints such as the knees and ankles. Despite these benefits, a slight increase in shear forces on the vertebral discs, reaching up to 8% at L4/L5, has been observed.

The findings for both the 5th percentile female and the 95th percentile male show consistent trends, although with varying degrees of soft tissue tensile load reductions in proportion to the increase in IAP. The 5th percentile female, in particular, experiences more substantial reductions in soft tissue tensile loads, relative to the increase in IAP, potentially owing to the choice of the elastic elements, which can be tailored to individual needs and morphologies. By assisting soft tissues (muscles, ligaments, and fascia) and joints, the back support device may have considerable benefits for physical performance enhancement, fatigue reduction, and injury risk mitigation during physically demanding tasks. It may also offer a promising solution for individuals with mobility impairments seeking to regain functional capacity. These results therefore warrant further investigation and could pave the way for better interventions for repetitive or heavy lifting tasks.

4.3.3.4 Rhombus Mechanism

The Tension-to-Compression Converter mechanism presented in this section is a rhombus linkage system. This system is mechanically simple while effectively enabling the generation of a mechanical advantage through the adjustment of the lengths and angles of its constituent rigid bodies. Consequently, this design is compact, cost-effective, and easily maintainable. Specifically, it comprises four rigid-body linkages assembled in a diamond configuration.



Figure 4.3.5: Passive back support device according to an embodiment of the invention featuring a rhombus as mechanical advantage system in (a) front, (b) back, and (c) side view.

In this context, the fixed reference point resides at the position of the lowest pin, while the highest pin remains free to slide in the cranio-caudal direction. Both lateral points are fixed to the abdominal compression unit, facilitating its constriction when the individual bends forward, as visually depicted in Figure 4.3.6.

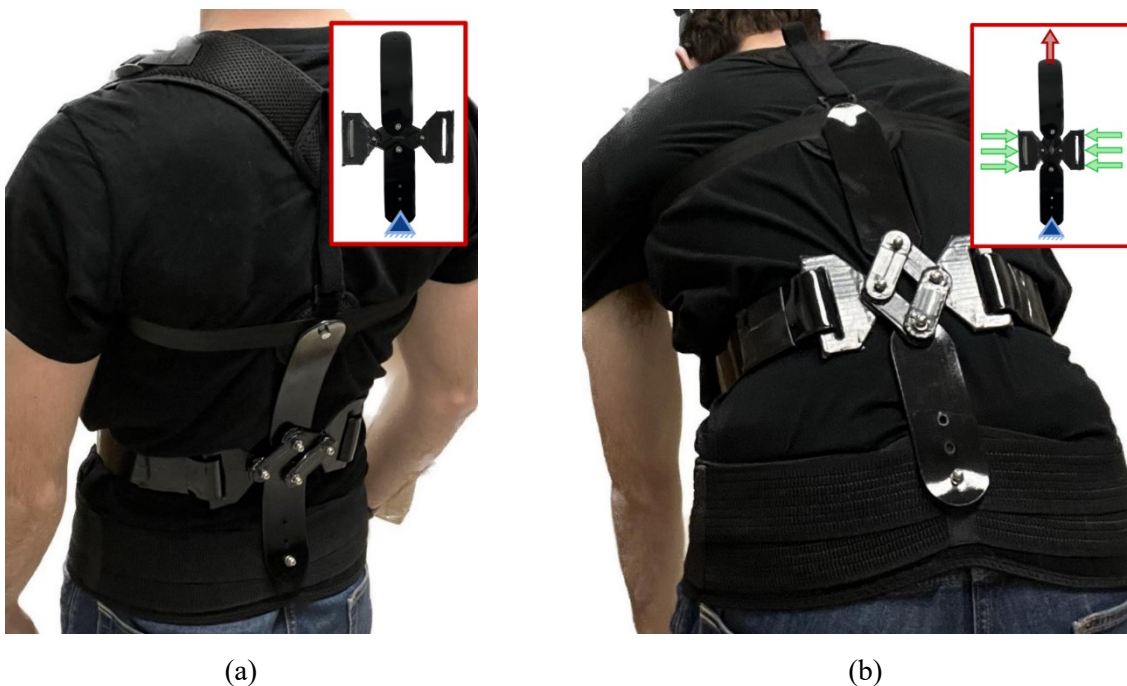


Figure 4.3.6: Load on each joint of the mechanical advantage system according to one embodiment of the invention featuring a rhombus (a) before and (b) after actuation.

The sizing and configuration of the rhombus mechanism are driven by the mechanical advantage arising from the conversion of tension forces within the elastic and semi-rigid elements to compression forces exerted upon the abdominal compression unit. From the free body diagram (Figure 4.3.7), the relationship between vertical forces and horizontal forces can be extracted.

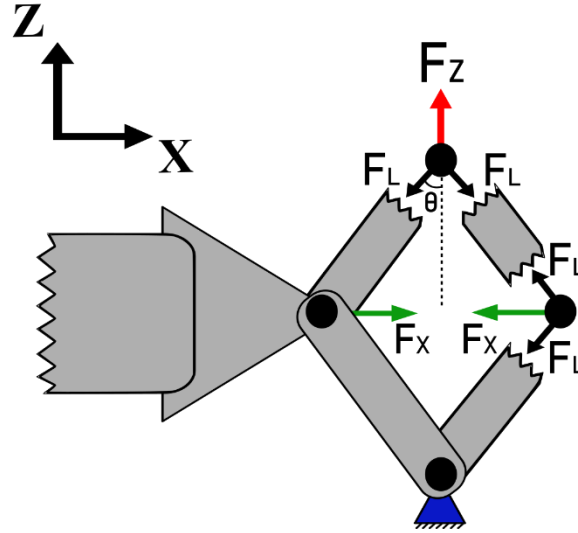


Figure 4.3.7: Free-body diagram of the rhombus linkage mechanism illustrating the transfer of forces. The red arrow represents the forces generated from extension of the back during flexion, the green arrows represent the forces transferred to the abdominal compression unit, and the blue triangle represents the fixed boundary condition.

$$F_z = 2 \cdot F_L \cdot \cos \theta \quad (4.5)$$

$$F_x = 2 \cdot F_L \cdot \sin \theta \quad (4.6)$$

$$\Rightarrow F_x / F_z = \tan \theta \quad (4.7)$$

Therefore, linkages of equal lengths orientated at a minimum 45-degree angle produce a mechanical advantage exceeding twofold, effectively amplifying the applied force intended to compress the abdominal unit. According to equation (1), this advantage suggests a potential increase in IAP of up to 42% for the 5th percentile female model and 31% for the 95th percentile male, solely owing to the influence of the mechanism.

4.3.3.5 Other Tension-to-Compression Mechanisms

This section introduces alternative mechanisms capable of providing a mechanical advantage by facilitating the transition from flexion to abdominal compression. One such mechanism is a system of pressurized inflatable cells (Figure 4.3.8) where compression is generated by inflating air (or other fluids) cells. The lengthening of the cells leads to a reduction in their horizontal

dimension, leading to compression. A pulley and cables system (Figure 4.3.9) can also generate compression on the abdomen from the separation of the middle pins which forces the lateral pins to move closer to one another. However, within the scope of this project, the rhombus mechanism alone was fabricated and tested.

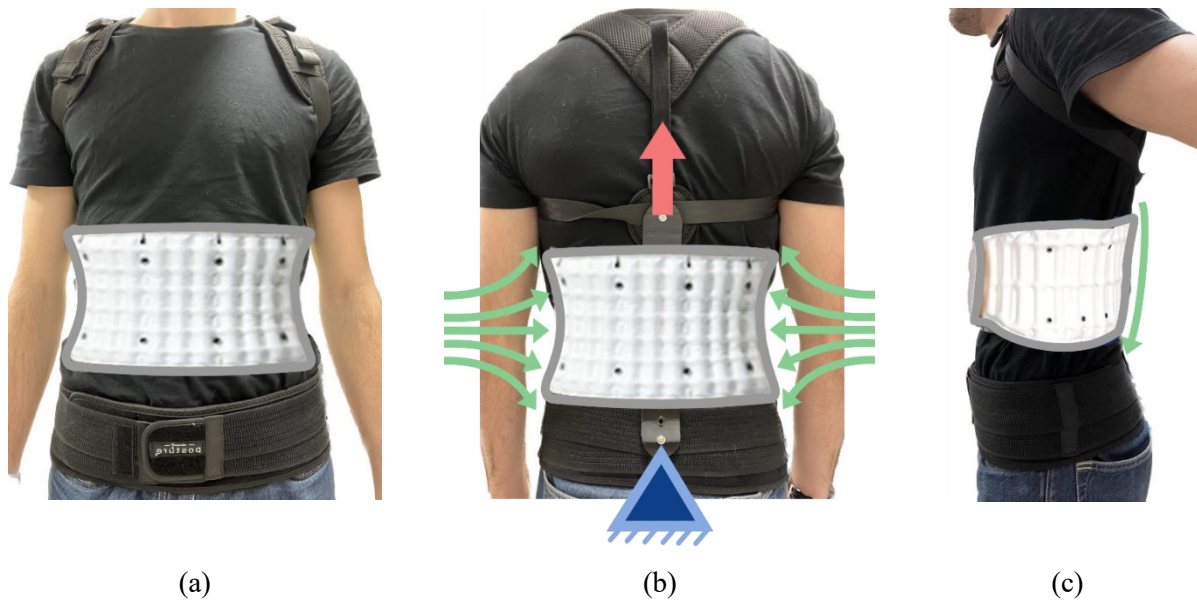


Figure 4.3.8: Passive back support device according to an embodiment of the invention featuring pressurized inflatable cells as mechanical advantage system in (a) front, (b) back, and (c) side view.

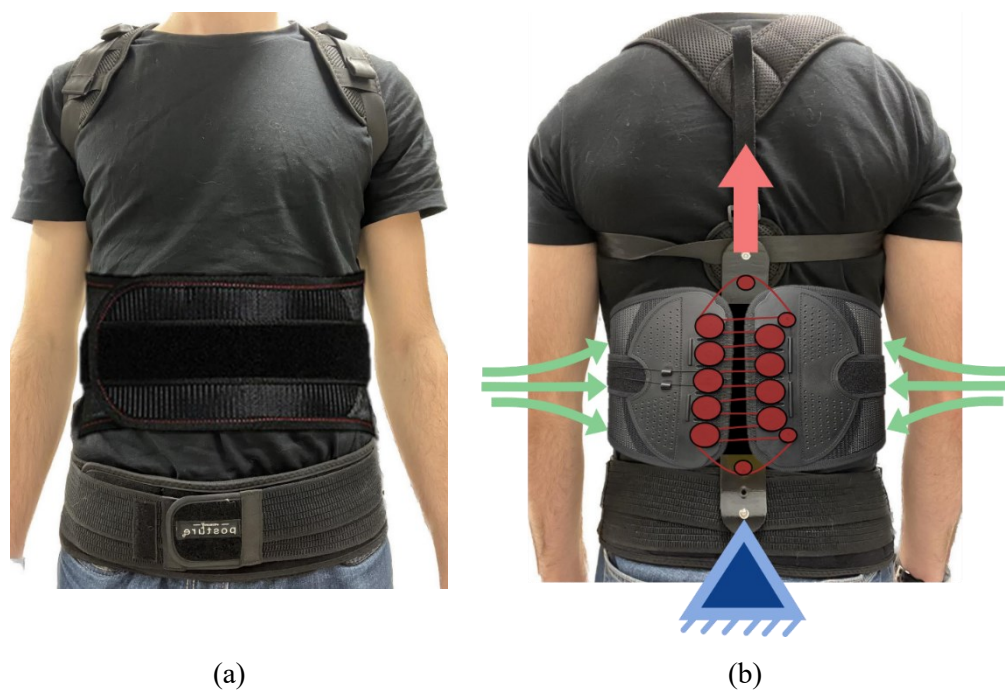


Figure 4.3.9: Passive back support devices according to an embodiment of the invention featuring pulleys and cables as a mechanical advantage system in (a) front and (b) back view.

4.3.4 Conclusion

The novel back supporting device is designed achieve two primary objectives: (1) increase pressure on the abdomen and, consequently, IAP during functional tasks, and (2) serve as a kinesthetic reminder to lift properly. As previously mentioned, IAP is believed to play a key role in spine stability, whereas spine instability, being a common cause of LBP, underscores the significance of bolstering IAP. Therefore, increasing IAP in functional tasks has the potential to alleviate LBP symptoms and mitigate the risk of its onset.

Moreover, the device exerts pressure around the abdomen and shoulders with increasing intensity as the back extends further, which is associated with an increased risk of injury. This mechanism effectively serves as a kinesthetic reminder to maintain an upright posture while executing lifting tasks. The elastic and semi-rigid elastic elements further have the effect of reducing trunk and, by extension, lower body soft tissues strain and joint velocities/accelerations during lifting activities. Simultaneously, it forces symmetrical lifting techniques, encouraging the wearer to maintain balanced movements. By preventing asymmetric increases in trunk velocity/acceleration and minimizing and simultaneous lateral bending and twisting on the spine during dynamic motions, the device increases the spine's resilience and protects it from potential harm [108].

5. General Discussion

The central theme of this dissertation revolves around the development of an innovative back support device aimed at enhancing spine stability. However, as highlighted in the literature review, the concept of spine stability is a subject of debate within the scientific community. Nonetheless, it is believed to play a crucial role in enabling the spine to perform its essential functions within normal ROM without inciting mechanically-induced pain. Despite its significance, there is limited information on the mechanism and quantification of spine stability, making it a controversial parameter. The literature review underscores that the loss of stability is associated with the development of spinal conditions, such as LBP. Therefore, there is a significant interest in further exploring and understanding this concept, as it could lead to improved treatments and solutions for spinal conditions. Numerical models are seen by the author as valuable tools to aid in comprehending this concept, as they offer cost effectiveness, ethical benefits, reproducibility, and detailed insights into internal processes. They allow the investigation of a wide range of scenarios without involving human subjects. The concept can then be further validated in a clinical setting using a diverse range of participants, including those with or without stability deficiencies. Consequently, this study quantified the impact of wearing an assistive device using both numerical models and clinical evaluations.

Using finite element analysis, the first article of this dissertation demonstrates that spine stability is influenced by the coordination of various trunk soft tissues, including paraspinal and abdominal muscles, as well as structural soft tissues like spinal ligaments and the TLF, and the IAP mechanism. The development of a biomechanical model of the trunk was a challenging but fundamental aspect of this dissertation.

Several factors were considered during the generation of the model. Notably, by representing the human anatomy more accurately using volumetric muscles and including the TLF. The inclusion of the TLF itself is interesting due to the possible pain relationship associated with the load allocation bias of this structure [59], even while wearing an AB as demonstrated in Article 1. The complexity of the model, comprising hundreds of components, required careful decision-making to ensure its eventual applicability in a clinical setting, where it could assist clinicians in determining the need for corrective actions and simulating interventions.

For computational efficiency and practicality, the model was constructed with conforming meshes to join the spine structures [20]. This is based on the assumption that tissues interact with the spine with minimal separation or sliding under normal physiological conditions [210]. In FEM, a common significant assumption is the adoption of linear elastic material laws. While this might be seen as a limitation considering the typically inhomogeneous, viscoelastic, and anisotropic nature of spinal tissues, it serves the purpose of the study presented in article 1. This study focuses on a quasi-static analysis, specifically static conditions and static stability within the linear behaviour range of the material laws adopted. Therefore, there is no imperative need to incorporate more comprehensive material laws for this particular investigation. Although it may appear counter-intuitive, the essence of FEM lies in finding appropriate compromises that align with the study objectives without drastically affecting the underlying theoretical framework. This pragmatic approach is not uncommon in the literature, where many studies resort to linear material properties whenever the ROM remains statically constrained within the linear behaviour of the material [60,63,211]. Then, to establish the connection between the AB and body surfaces, bonded contacts were strategically applied in alternating vertical strips. This decision was based on relevant findings from existing literature, which indicates that waist belts on slim physiques generally experience minimal shear and vertical pressure during flexion exercises [212]. The body composition of the subject modelled being slim, the incorporation of alternating bands was a pragmatic approach to account for subtle shear effects and allow a certain level of sliding without compromising the computational efficiency of the model. This assumption has a small impact on the model's result, more specifically a 6% peak difference in IVD pressure at the L1-L2 level when comparing all the results of the study for two scenarios: bonded contacts applied as alternating stripes and frictional contacts for a 30-deg flexion movement. Moreover, analytical models used in spine biomechanics often adopt an osteoligamentous form and employ follower loads to approximate compressive forces experienced by the vertebral column during normal movements. This approach is based on previous studies [213], which showed applied compressive forces stiffen the segmental response of the spine in flexion, revealing a potential mechanism through which muscles stabilize the spine *in vivo*.

With these models, it becomes possible to exclude volumetric skeletal muscles, while still considering the contributions of local muscles to spine stability during physiological loading [214-215]. However, the exclusion of volumetric muscles prevents the investigation of the passive

effects of soft tissues on spine biomechanics and stability. In this study, the developed FEMs incorporated spinal tissue geometries along with the follower load to effectively capture both active and passive contributions of the musculoskeletal system.

The calculations in the study are based on prior research which provided insights into the cumulative body weight load applied to each vertebral level [216], and muscle contributions [217]. The cumulative body loading was determined by distributing the weight of the head and arms onto the first thoracic vertebra, while the weight of the trunk was distributed among the remaining vertebrae of the thoracolumbar spine above the third lumbar level. The muscle contribution involved applying the intrinsic force from the supine position to the first thoracic vertebra, along with the load on the specific disc.

$$FL_{i,flexion} = F_{int} + 2.1 \cdot W_i + 3.6 \cdot W_i \cdot \sin(\alpha) \quad (5.1)$$

Where i refers to the specific vertebral level, F_{int} to the intrinsic force from the supine position applied on the first thoracic vertebra, and the constants to the percentage of body weight loading.

Again, the main focus of this dissertation is to develop a novel back support device that overcomes the limitations of existing back support braces and by emphasizing the improvement of spine stability. Therefore, the design and evaluation of the new concept becomes pivotal steps. The device is specially designed to offer two advantages simultaneously: providing a moment of trunk extension assistance while improving spine stability during lifting tasks. The hypothesis underlying the concept of this device revolves around the idea that, through the strategic redistribution of external load, it can effectively shift the burden from the lumbar joints to the abdomen and lower body. In doing so, the device may generate the extension moment required for lifting tasks, while increasing IAP to enhance spine stability. This dual mechanism is considered by the author to be the key to an effective and comprehensive solution for improving back support during physically demanding activities.

Chapter 2 introduced the various tissues contributing to spine stability and the deficits experienced by individuals with LBP that necessitate assistive devices. It also presents the problem statement, emphasizing the limitations of current technologies in providing both trunk extensor assistance and spine stability. The chapter proposes a novel back support device that combines the features of a back brace and an exosuit. It highlights the significance of reducing compressive and

shear forces on the spine to mitigate LBP-related risks. Chapter 2 also outlines the design and functionality of the proposed back support device, incorporating a Tensile-to-Compression Converter that converts tension generated from hip and spine rotation into compressive forces applied to the wearer's abdomen. The design criteria emphasize efficiency, safety, improved static and dynamic stability, unrestricted mobility, compatibility with workplace equipment, lightweight, comfort, affordability, durability, and aesthetics. A mathematical concept to determine the magnitude of IAP generation and extensor moment provided by the back support device is also introduced, focusing on a rhombus mechanism to convert back flexion into abdominal compression. Chapter 3 presents numerical results indicating that compression of the abdomen during flexion movements improves static stability of the spine, leading to a reduction in the forces generated in the spinal tissues and an associated decrease in spinal compressive forces. Chapter 4 then presents experimental evidence indicating that wearing the back support device increases IAP and improves spine stability, regardless of the condition of the wearer (healthy or LBP).

5.1 Future Directions

Data from the clinical study provide valuable insights into the improvements needed to make the existing prototype effective and meet user expectations. Qualitative data on device performance collected using the “Quebec User Evaluation of Satisfaction with Assistive Technology” questionnaire are summarized below (see Appendix 2 for sample questionnaire).

Table 5.1. Quebec User Evaluation of Satisfaction with Assistive Technology questionnaire filled out by every participant of the clinical study after their participation.

Criteria	Satisfaction (/5)
Dimensions	3.6
Weight	2.8
Ease in adjusting	4.5
Safe and secure	4.8
Durability	4.2
Easy to use	4.2
Comfortable	3.9
Effective	4.1

Overall, participants' ratings of the device were promising. Key parameters such as adjustability, safety, durability, ease of use and effectiveness were all rated above 4 out of a possible 5. Dimension, weight, and comfort were rated lower by participants, but these parameters can be improved easily. This lower rating may be explained by the fact that there was a single device for a variety of body shapes and sizes, and that materials were not carefully selected to optimize weight, but rather to confirm the concept. Therefore, the device needs further development to satisfy user satisfaction and optimize efficiency. Moreover, a longitudinal study would be beneficial to understand the long-term impact of using the device on performance and wearer's condition.

To date, there has been no single finite element spine model analysis on a representative spine physiology, inclusive of primary spine tissues and inclusive of an AB. The development of the model permitted to lay foundations for an equilibrium spine stability comparative analysis, simulating the action of a stabilizing assistive device, namely an AB. To date, there has been no assistive device developed that assist both the trunk extensor moment and enhances stability through the generation of IAP. Hence, this dissertation makes significant contributions to the field of assistive devices and opens avenues for further research and validation of the novel back support device, as disseminated by the two scientific journal articles presented herein.

6. Conclusion and Recommendations

In conclusion, a new assistive device was designed and validated to improve trunk stiffness and stability during occupational bending and lifting tasks. This is the first device to simultaneously improve trunk stiffness/stability while providing an external trunk extensor moment. It is also the first device to selectively improve stability during tasks that actually require it. All the original contributions improve the understanding of assistive device mechanisms, particularly with regard to intra-abdominal pressure (IAP). The conclusions for each of the initial objectives are presented below:

Objective 1: Investigate the effects of wearing an AB on IAP and spine stability numerically.

Article 1 found that wearing an AB significantly increased IAP by 96% during flexion movements and reduced vertebral motions in the sagittal plane by 14% in the lumbar spine. The AB also decreased tensile stress in the multifidus and thoraco-lumbar fascia, reducing disc pressure by 24% to 47% at different levels. However, the study revealed a substantial increase in stress in part of the TLF spinal attachments associated with the change in IAP. This could have clinical significance in terms of LBP, as the TLF has been shown to be innervated, although further research is required to better describe this mechanism. These results suggest that ABs can improve spine stability, which could provide relief from LBP.

Objective 2: Develop and evaluate the effectiveness of a novel back support device that increases spine stability during functional tasks.

Article 2 revealed that the developed back support device significantly increased IAP in both healthy and LBP groups during various functional tasks. The device reduced the amplitude of lumbar movement on average by $31 \pm 4\%$. Muscle coactivation did not increase while wearing the device, which could facilitate the reintegration of workers with LBP.

The studies set out in this thesis provide substantial evidence that increasing IAP during movements that require a higher level of stability can reduce the risk of injury by unloading the spine and surrounding tissues. The rhombus mechanism has also been shown to enable efficient conversion from tension to compression, as well as providing a kinesthetic reminder to maintain correct lifting posture. Consequently, the device offers potential benefits in terms of improving physical performance, mitigating the risk of injury and enhancing functional capacity. The author believes that the device offers a comprehensive solution for people at risk of LBP or in need of lifting assistance, regardless of their injury status.

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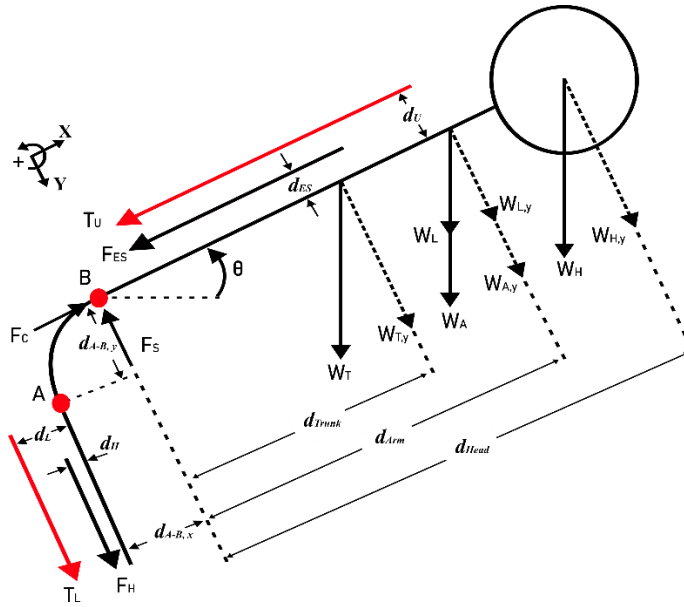
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A. Appendix

A.1 2D Mathematical Model

A simple 2D model was developed to estimate the contribution of back soft tissues, namely the ES and the TLF, as well as IAP to spine stability and the resulting spinal compression and shear forces at the L4/L5 joint during a static stooped lifting task (60-degree flexion). The potential unloading effect of wearing a back support device was also examined.



Variable	Description	Units
Θ	Angle between trunk and horizontal	deg
W_H	Head weight	N
$W_{H,y}$	$W_H \cos \Theta$	N
W_A	Arm weight	N
$W_{A,y}$	$W_A \cos \Theta$	N
W_T	Trunk weight	N
$W_{T,y}$	$W_T \cos \Theta$	N
W_L	Lifted object weight	N
$W_{L,y}$	$W_L \cos \Theta$	N
F_{ES}	Erector spinae muscle force	N
F_S	Joint shear force on the spine	N
F_C	Joint compressive force on the spine	N
F_H	Hamstring muscle force	N
T_U	Tension in the upper body unit	N
T_L	Tension in the lower body unit	N
d_{Head}	Distance in y from pivot B to head	mm
d_{Arm}	Distance in y from pivot B to arms	mm
d_{Trunk}	Distance in y from pivot B to trunk	mm
$d_{A-B,x}$	Distance in x from pivot A to pivot B	mm
$d_{A-B,y}$	Distance in y from pivot A to pivot B	mm
d_{ES}	Distance in y from pivot to erector spinae	mm
d_U	Distance in y from pivot B to upper body unit	mm
d_H	Distance in x from pivot A to hamstring	mm
d_L	Distance in x from pivot A to lower body unit	mm

Figure 5.1.1. 2D static free body diagram illustrating the loads on the human body when performing a stoop lift. Pivot point A corresponds to the coccyx and pivot B to the L4/L5 joint.

The model was analyzed in two different scenarios: for a 5th percentile female and a 95th percentile male. The objective was to get an overall idea of the range of forces acting on any potential back support device wearer, since there is a wide range of anthropometric dimensions and loading conditions that vary from one individual to another. This information will be helpful in defining the required assistance for different groups of individuals.

Effect of Back Support Device on Back Soft Tissues

Without the Back Support Device

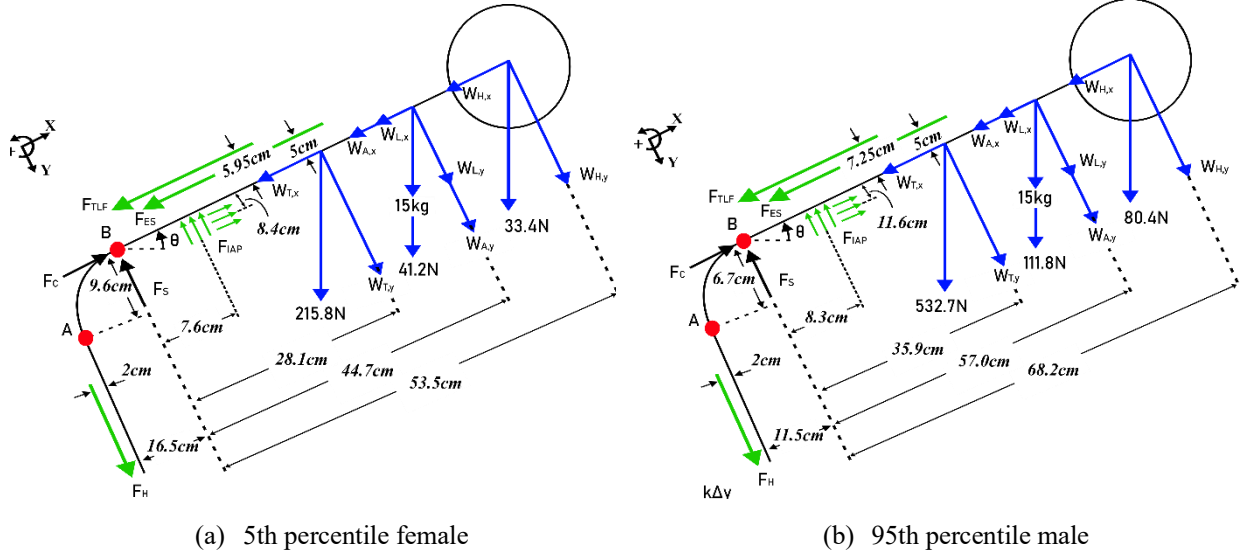


Figure 5.1.2. 2D static free body diagram illustrating the loads on (a) a 5th percentile female and (b) a 95th percentile male for a static stoop lift with a 15 kg weight in arms extended. Blue arrows represent body weight forces and external forces, and green arrows represent physiological body forces. Data from [206-209].

The required extensor moment generated by the ES muscles, the TLF, the hamstring muscles and IAP to stabilize the spine can be determined arithmetically by examining the equilibrium equations for the static forces acting around point B (L4/L5 joint) in the model of Figure A.1.2 (a) and (b). The relationship between all these structures towards static spine stability explored by El Bojairami and Driscoll [60] is also considered (equation A.4). There are six unknowns: F_H , F_{TLF} , F_{ES} , F_{IAP} , F_C , and F_S .

$$\Sigma M_{external, B} = W_{T,y} \cdot d_{Trunk} + (W_{A,y} + W_{L,y}) \cdot d_{Arm} + W_{H,y} \cdot d_{Head} \quad (A.1)$$

$$\Sigma F_x: F_C + F_{IAP,x} - F_{TLF} - F_{ES} - W_{T,x} - W_{A,x} - W_{L,x} - W_{H,x} = 0 \quad (A.2)$$

$$\Sigma F_y: F_H + W_{T,y} + W_{A,y} + W_{L,y} + W_{H,y} - F_S - F_{IAP,y} = 0 \quad (A.3)$$

$$F_{TLF} = (0.46 \cdot \Sigma M_B) / d_{TLF}, \quad F_{ES} = (0.32 \cdot \Sigma M_B) / d_{ES}, \quad (A.4)$$

$$F_{IAP} = (0.15 \cdot \Sigma M_B) / d_{IAP}, \quad F_H = (0.07 \cdot \Sigma M_B) / (d_H + d_{A-B,x})$$

Solving equations A.1 – A.4 simultaneously using the data from Figure A.1.2 (a) for a 5th percentile female and (b) for a 95th percentile male yields the following results:

Table A.1.1: Results of the forces generated in the biomechanical model without any assistance for a 5th percentile female and a 95th percentile male

Parameter	5 th percentile female [N]	95 th percentile male [N]
F_H	53	176
F_{TLF}	1081	2155
F_{ES}	895	2174
F_{IAP}	194	392
F_C	2024	4424
F_S	332	733

With the Back Support Device

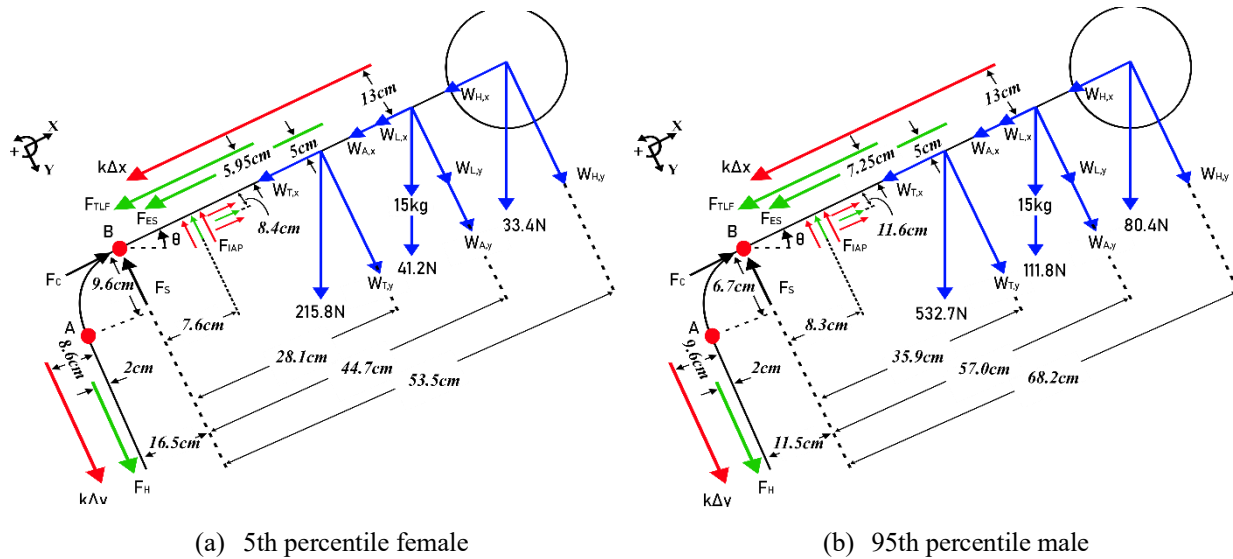


Figure 5.1.3. 2D static free body diagram illustrating the loads on (a) a 5th percentile female and (b) a 95th percentile male for a static stoop lift with a 15 kg weight in arms extended while wearing the novel exosuit. Blue arrows represent body weight forces and external forces, green arrows represent physiological body forces, and red arrows represent exosuit forces. Data from [206-209].

With the back support device on, the required extensor moment generated by the ES muscles and the TLF to stabilize the spine is hypothesized to be smaller using the same static force equilibrium equations that act about point B (L4/L5 joint) in the model of Figure A.1.2 (a) and (b). Again, there are six unknowns: F_H , F_{TLF} , F_{ES} , F_{IAP} , F_C , and F_S .

$$\Sigma M_{external, B} = W_{T,y} \cdot d_{Trunk} + (W_{A,y} + W_{L,y}) \cdot d_{Arm} + W_{H,y} \cdot d_{Head} - T_L \cdot (d_L + d_{A-B,x}) - T_U \cdot d_U \quad (A.5)$$

$$\Sigma F_x: F_C + F_{IAP,x} - F_{TLF} - F_{ES} - W_{T,x} - W_{A,x} - W_{L,x} - W_{H,x} - T_U = 0 \quad (A.6)$$

$$\Sigma F_y: F_H + W_{T,y} + W_{A,y} + W_{L,y} + W_{H,y} + T_L - F_S - F_{IAP,y} = 0 \quad (A.7)$$

$$F_{TLF} = (0.46 \cdot \Sigma M_B) / d_{TLF}, \quad F_{ES} = (0.32 \cdot \Sigma M_B) d_{ES}, \quad (A.8)$$

$$F_{IAP} = (0.15 \cdot \Sigma M_B) / d_{IAP}, \quad F_H = (0.07 \cdot \Sigma M_B) / (d_H + d_{A-B,x})$$

The tension generated in the upper body unit (T_U) and in the lower body unit (T_L) is estimated at 70 N for the 5th percentile female and 150 N for the 95th percentile male, using Hooke's law and the information in Section 4.3.3. The subsequent increase in force resulting from the elevated IAP caused by the back support device's faction can be determined using the surface area of the abdomen in the sagittal plane [206]. The additional force contribution from IAP is thus 260 N for the 5th percentile female and 582 N for the 95th percentile male which represents on average a 2.5-fold increase in the contribution of IAP towards spine stability.

Solving equations A.5 – A.8 simultaneously using the data from Figure A.1.3 (a) for a 5th percentile female and (b) for a 95th percentile male yields the following results:

Table A.1.2: Results of the forces generated in the biomechanical model with the back support device on for a 5th percentile female and a 95th percentile male.

Parameter	5 th percentile female		95 th percentile male	
	[N]	% difference	[N]	% difference
F _H	41	- 22%	143	- 18%
F _{TLF}	778	- 28%	1628	- 24%
F _{ES}	627	- 30 %	1599	- 26 %
F _{IAP}	259	+ 33%	549	+ 40%
F _C	1467	- 28%	3336	- 25%
F _S	357	+ 8%	772	+ 5%

A.2 Evaluation of Prototype Questionnaire

Quebec User Evaluation of Satisfaction with assistive Technology

QUEST (Version 2.0)

Technology device: _____

User name: _____

Date of assessment: _____

The purpose of the QUEST questionnaire is to evaluate how satisfied you are with your assistive device and the related services you experienced. The questionnaire consists of 12 satisfaction items.

- For each of the 12 items, rate your satisfaction with your assistive device and the related services you experienced by using the following scale of 1 to 5.

1	2	3	4	5
not satisfied at all	not very satisfied	more or less satisfied	quite satisfied	very satisfied

- Please circle or mark the **one number** that best describes your degree of satisfaction with each of the 12 items.
- Do **not** leave any question unanswered.
- For any item that you were not "very satisfied", please comment in the section *comments*.

Thank you for completing the QUEST questionnaire.

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1	2	3	4	5
not satisfied at all	not very satisfied	more or less satisfied	quite satisfied	very satisfied
ASSISTIVE DEVICE				
<i>How satisfied are you with,</i>				
1. the dimensions (size, height, length, width) of your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
2. the weight of your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
3. the ease in adjusting (fixing, fastening) the parts of your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
4. how safe and secure your assistive device is?				
<i>Comments:</i>				
1	2	3	4	5
5. the durability (endurance, resistance to wear) of your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
6. how easy it is to use your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
7. how comfortable your assistive device is?				
<i>Comments:</i>				
1	2	3	4	5
8. how effective your assistive device is (the degree to which your device meets your needs)?				
<i>Comments:</i>				
1	2	3	4	5

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1	2	3	4	5
not satisfied at all	not very satisfied	more or less satisfied	quite satisfied	very satisfied
SERVICES				
<i>How satisfied are you with,</i>				
9. the service delivery program (procedures, length of time) in which you obtained your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
10. the repairs and servicing (maintenance) provided for your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
11. the quality of the professional services (information, attention) you received for using your assistive device?				
<i>Comments:</i>				
1	2	3	4	5
12. the follow-up services (continuing support services) received for your assistive device?				
<i>Comments:</i>				
1	2	3	4	5

- Below is the list of the same 12 satisfaction items. PLEASE SELECT THE **THREE ITEMS** that you consider to be the **most important** to you. Please put an X in the 3 boxes of your choice.

- | | |
|---|---|
| ☐ 1. Dimensions | ☐ 7. Comfort |
| ☐ 2. Weight | ☐ 8. Effectiveness |
| ☐ 3. Adjustments | ☐ 9. Service delivery |
| ☐ 4. Safety | ☐ 10. Repairs/servicing |
| ☐ 5. Durability | ☐ 11. Professional service |
| ☐ 6. Easy to use | ☐ 12. Follow-up services |

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QUEST Scoring Sheet

This page is for scoring the answers to your questions.
DO NOT WRITE ON THIS PAGE.

- Number of non-valid responses
- Device subscale score
For items 1 to 8, add the ratings of the valid responses and divide this sum by the number of valid items in this scale.
- Services subscale score
For items 9 to 12, add the ratings of the valid responses and divide this sum by the number of valid items in this scale.
- Total QUEST score
For items 1 to 12, add the ratings of the valid responses and divide this sum by the number of valid items.
- The 3 most important satisfaction items

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