A biomechanical assessment of disc pressures in the lumbosacral spine in response to external unloading forces

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Abstract

BACKGROUND CONTEXT: Axial back pain affects a large percentage of the population. Often aggravated by weight-bearing activity, these patients frequently have associated degenerative or post-traumatic lumbar disc disease. Aquatherapy is frequently used to transition patients from less activity limited by pain to greater activity by reducing weight-bearing load of the lumbar spine. Development of a means to permit patients similar spinal unloading while active during normal daily living would have the potential to promote similar effects.

PURPOSE: The purpose of this study is to measure internal disc pressure at L4/L5 in response to forces exerted by an external vest. The study hypothesis anticipated an unloading of the lumbar spine during upright posture, as measured by intradiscal pressure at the L4/L5 disc, correlating with external forces provided to the trunk by the device.

STUDY DESIGN: A controlled experimental study of spine biomechanical loading was undertaken using isolated cadaver torsos obtained from an approved tissue source. Ages ranged at death with a mean of 65±6 years.

METHODS: The distractive force created by inflating a set of pneumatic lifters within vests for treatment of low back pain were calibrated in a materials testing machine. Effects of inflation on the disc pressures within the lumbar spine then were tested. A microscopic pressure sensor (Samba, Gothenburg, Sweden) was placed into the nucleus of the L4/L5 disc of six isolated cadaver torsos (1 female, 5 male) using a 15-gauge spinal needle under direct fluoroscopic visualization. The pressure sensor was 0.42 mm in diameter, and had a calibrated response range of 0–7500 mm Hg. A pneumatically actuated lumbar vest was fit snugly to the torso. Each torso was supported in an upright, weight-bearing position for testing. The vest was inflated while the internal disc pressure was monitored and recorded. The data were analyzed to test for correlation between the amount of external unloading force provided by the vest and the intradiscal pressure measured in vitro.

RESULTS: Application of external loads between the pelvis and ribcage by the vest demonstrated a maximum mean reduction of internal disc pressure at L4/L5 of 25% when the vest was inflated to a level producing approximately 400 N of effective load. The reduction in disc pressure was significantly different compared with baseline (upright, weight-bearing disc pressure without the vest) for all distraction settings (p<.01) except for the very lowest setting which was significant only at p=.025.

CONCLUSIONS: Spinal unloading with an externally applied vest with adequate surface interface is effective in reducing intradiscal pressures. Ambulatory reduction of pressure would permit beneficial reduction of loads and permit patients with weight-bearing intolerance a better quality of life.

Keywords: Biomechanics; Disc pressure; Spine unloading; Rehabilitation
Introduction

Axial back pain with underlying degenerative lumbar disc disease affects a large percentage of the population. It encompasses a myriad of pathologic features including degenerative change, annular tears, nucleus pulposus protrusion, and internal disc derangement. With progressive age and pathologic change, the discs can deform to a greater degree and are less able to provide stability and the appropriate distribution of the loads. Tears may develop within the annulus. Efforts by the body to heal these defects can result in neurovascular invasion of the disc material, making the disc nociceptive under weight-bearing conditions.

The disc is a composite structure, with the nucleus serving to minimize vertebral end plate stress concentration and the annulus acting as a restraining ligament. Magnetic resonance imaging findings show dehydration of the nucleus pulposus in the majority of people over the age of 40 and in discs that have undergone significant trauma. These changes affect the behavior of the intervertebral disc and its response to loading by altering the hydrophilic [1–3] and viscoelastic properties [1,4]. The hydrostatic properties in the nucleus pulposus and integrity of the annulus fibrosis together are necessary for normal attenuation and transmission of spinal loads [5–9] during activity. Both the subchondral bone of the vertebral end plates and the fibers of the annulus fibrosus are innervated and may be a source of pain [2,10]. A microinstability environment may be created [11] that promotes increased discal strain under loading even from normal activity.

The threshold where disc changes become clinically painful is unknown. Disc degeneration is a continuum that begins with biochemical changes progressing to significant morphologic changes and instability. Pain may present at any point along this continuum [12]. A progressive loss of disc space by 1–3 mm [13] may result in overloading of the facet joints and a decrease in foraminal cross-sectional area [14,15] that may compromise the neural elements. It is known that degenerative lumbar discs alter load transmission and the loading of both the annulus fibrosus and the subchondral bone of the vertebral end plates [16]. Effects of excessive force transmission and microinstability acting on the annulus fibrosus may be transmitted through the sinu-vertebral nerves and potentially be a cause of pain [2,5,6,12].

Intradiscal pressure is related to the biomechanical integrity of the disc. An unloaded healthy spine demonstrates a baseline pressure or prestress arising from the disc hygroscopic properties, the elastic ligamentous and muscular tensions that provide a resting compression [17]. The landmark work of Nachemson, subsequently confirmed by others [18–22], shows that normal intradiscal pressure will vary as much as 40% from changes in position and posture alone.

In summary, disc damage is an acquired defect that limits its ability to resist loading effects from normal activities of daily living and accelerates degenerative change. The hydrostatic pressures fall, and the annulus is subjected to higher concentration of stresses that may lead to further injury. It has been suggested that mechanical loading of a disrupted annulus may sensitize the surrounding nociceptors that are further irritated by inflammatory chemical mediators from exposure to migrating nuclear material [23]. The purpose of this study was to test whether forces applied externally to the trunk and directed to unload the spine would result in measurable and predictable decreases in intradiscal pressure.

Materials and methods

The pneumatic vest (Fig. 1) consists of a pair of semirigid, adjustable bands custom fit to the individual torso to which it is to be applied. The bands anchor the vest to the torso by compression, being drawn tight by a rack and pinion gear mechanism. Minimum distance between the upper band, positioned about the lower thorax, and the lower band at the upper pelvis is maintained by vertical pneumatic struts. Unloading of the spine is attempted by sequential inflating of the anterior and the posterior strut pairs. Inflation is controlled by monitoring a graduated manometer gauge (arbitrary scale range 1–10) attached to a hand-held pump. Once

Fig. 1. Side view of a patient fitted with the pneumatic vest showing the parasagittal positions of two of the lifters. Inflation is achieved by anterior or posterior pairs being activated simultaneously by a hand-held, detachable pump mechanism.
inflated, the pump is detached and stored. The inflated vest shunts a portion of the upper torso weight from the thorax to the pelvis, bypassing the lumbar spine.

A study of vest inflation effect was conducted in two phases. In the first phase, the relationship between vest inflation was calibrated by monitoring the axial force developed by the lifters. In the second phase, vests were fit to cadaver torsos instrumented with intradiscal pressure sensors to evaluate passive unloading of the disc.

**Vest calibration**

Two standard vests (Orthotrac vers. III; Orthofix, Inc., McKinney, TX) were tested. The devices were constrained between horizontal plates as fixators within an MTS testing system (MTS Alliance RT/10, Eden Prairie, MN) (Fig. 2). The upper plate was connected in series to a uniaxial load cell by a universal joint that allowed the tracking of the total vertical forces produced by vest inflation. A simulation of the patient torso was produced by a shaped foam insert placed within the vest cavity. Free sliding was permitted between the vest bands and the foam so that friction resistance was negligible.

The initial test configuration used a small (6 N) preload on each vest in the uninflated position within the MTS machine. Inflation was accomplished with the standard hand pump in steps to maximum levels for four repetitions. Maximum pressure within the pneumatic struts was defined by any sign of gas release from a built-in safety pressure relief valve. Front lifters were inflated followed by the rear lifters. Total force acting on the MTS plates and generated by the pneumatic lifters within the vest was monitored at each unit gradation of the manometer to extrapolate a linear calibration.

**In vitro disc pressure tests**

Six fresh human cadaveric torsos, ranging in age from 50 to 70 at the time of death (Table 1), were obtained and kept frozen at −20°C before testing. Each cadaveric torso was thawed for 24 hours before testing, and tissue hydration was maintained by sealing the isolated torso in a plastic sheet. All cadaveric tissue used was free from metastatic disease, thus eliminating potential adverse effects on the bone and soft tissue.

Using a fluoroscopically assisted percutaneous surgical approach, spinal needles (15-gauge, 6 inches long) were placed into the nucleus of the L4/L5 intervertebral discs. A microscopic pressure sensor (Samba, Göteborg, Sweden) was then passed through the needle as a cannula until it reached the nucleus. At this point, the needle was withdrawn from the disc space, leaving the transducer in place to record intradiscal pressure load. The Samba transducer was calibrated in air at room temperature before each test insertion. The Orthotrac pneumatic vest was anchored to the torso by tightening of the upper and lower compression hoops. The vest was inflated stepwise as in Phase I while the internal disc pressure was monitored and recorded using a strain and voltage data acquisition system (Micromeasurements Group Inc., Malvern, PA). Disc pressures were measured over a series of three sets of inflations for each torso.

**Results**

The age distribution and cause of death for each torso used in this study are listed in Table 1. All deaths were attributable to nonmusculoskeletal and nontraumatic factors.

**Calibration**

Vest calibration was based on four sets of inflation in unit steps based on manometer recordings. MTS mean force readings with standard deviations at each step are listed in Table 2. The relationship of total axial force to manometer reading proved to be sigmoidal with an initial toe region.

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**Table 1**

<table>
<thead>
<tr>
<th>Specimen</th>
<th>Sex</th>
<th>Age</th>
<th>COD</th>
</tr>
</thead>
<tbody>
<tr>
<td>43103</td>
<td>M</td>
<td>70</td>
<td>Respiratory arrest</td>
</tr>
<tr>
<td>43133</td>
<td>M</td>
<td>67</td>
<td>Alzheimer’s</td>
</tr>
<tr>
<td>43138</td>
<td>M</td>
<td>70</td>
<td>Renal failure</td>
</tr>
<tr>
<td>43186</td>
<td>M</td>
<td>55</td>
<td>Cardiogenic shock</td>
</tr>
<tr>
<td>43276</td>
<td>M</td>
<td>65</td>
<td>Myocardial infarction</td>
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<tr>
<td>53100619</td>
<td>M</td>
<td>64</td>
<td>Heart failure</td>
</tr>
</tbody>
</table>

COD=cause of death.
Table 2
Mean and standard deviation of vest calibration loads for the four trials on each vest

<table>
<thead>
<tr>
<th>Pump reading</th>
<th>Load (N)</th>
<th>SD</th>
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<tbody>
<tr>
<td>2</td>
<td>26.5</td>
<td>10.9</td>
</tr>
<tr>
<td>3</td>
<td>139.6</td>
<td>12.9</td>
</tr>
<tr>
<td>4</td>
<td>274.6</td>
<td>23.0</td>
</tr>
<tr>
<td>5</td>
<td>394.8</td>
<td>16.7</td>
</tr>
<tr>
<td>6</td>
<td>549.7</td>
<td>47.4</td>
</tr>
<tr>
<td>Max</td>
<td>601.0</td>
<td>60.0</td>
</tr>
</tbody>
</table>

Table 2

and a final plateau, a characteristic typical for forces developed by a pressure vessel like that of the pneumatic lifters. The intermediate region is approximately linear with maximum developed force acting on the MTS machine of 601 N (±60 N). Vest internal pressure required to reach maximum force loads measured by the MTS was 79 N/cm². Figure 3 demonstrates the precision of inflation across the functional range of the vest. A regression analysis of the manometer gauge versus load shows an r value of .997.

In vitro cadaver testing

Technical factors resulted in compromise of the integrity of transducer insertion at the L4/L5 disc space in one of the torso specimens requiring reinsertion in the L5/S1 disc for that specimen (specimen 43138). As a result, data are available for five L4/L5 intradiscal pressure measurements and one L5/S1. Because the assumptions of biomechanical modeling predict insignificant differences in intradiscal pressures between the two levels as a result of compressive loading in comparison to the total loads measured, all data were pooled for analysis.

Disc pressure measurements were obtained during stepwise inflation of the vest as described earlier. The vest was inflated up to its maximum allowable pressure. The mean and standard deviation of disc pressures (mm Hg) across the central linear region of vest function (Fig. 4) for all six specimens at each manometer setting are shown in Table 3. The response of intradiscal pressure to axial unloading at the vest interface with the torso is given in Fig. 3. Data fit a nonlinear curve (R² = .9998) with mean peak reduction of disc pressures of 25%.

Discussion

The pneumatic vest decreased intradiscal pressures in cadaveric human intervertebral discs as measured by a transducer placed within the nucleus material. At the peak unloading, a 25% reduction was observed and occurred near the maximum inflation of the vest. As shown in Fig. 3, the axial decompression effect decreased slightly from peak values as the vest inflation continued. This is attributed to loss of friction purchase on the torso and subsequent sliding of the retaining bands used to anchor the vest by compression.

Axial and mechanical low back pain are still poorly understood. Classic intradiscal pressure studies in normal discs show high pressures with weight-bearing activities, including sitting, standing, and bending [10,17–22]. The sitting position increased the pressure in the nucleus pulposus approximately 40% when compared with standing [10,17–19]. There remains some disagreement in the evidence as to whether sitting or standing postures are the most stressful for the disc [2,20,22] which may reflect advances in measurement technology development.

Degenerated discs show a more unpredictable loading behavior, both between specimens and for different trials of single specimens [21]. Some of that variability is accounted for by the loss of disc height and transfer of normal weight bearing on to the facet articulations. The remainder may reflect the variable severity of degenerative change that cannot be readily determined by imaging methods alone.

Mechanical back pain is the most common type of back pain. The cascade is thought to begin with mechanical overload of the disc and/or posterior elements which can sensitize
the pain-sensitive nerves, which may then be further irritated by released chemical mediators. This cascade is supported by experimental evidence from rabbit models of disc degeneration [14], for example, produced either by direct mechanical injury to the disc or injection of chymopapain. Similarly, Panjabi et al. provide evidence of a succession of secondary changes in facet joints after disc injury [9]. Instability of the posterior spinal joints likewise increases loading and intradiscal pressure [24]. These observations form the rationale for surgical interventions imposing instrumented posterior fusion to decrease intradiscal pressure within the spanned level [25]. Bradford and colleagues [12] have shown proteoglycan alterations and some reconstitution of the intervertebral disc after enzymatic digestion of the nucleus. This leads to a postulation that controlling instability in the spine may decrease the histological and inflammatory cascade causing mechanical low back pain and impart a fibrous stiffening to the disc.

Present nonoperative treatment for central axis and mechanical back pain consists of anti-inflammatory medications, physical therapy, traction, strengthening, activity modification, and static support or compression bracing. The application of lumbosacral-type braces is thought to assist patients with low back pain by the unloading of the spine through increased abdominal pressure or by limiting the range of motion. Decreasing weight bearing, as with aquatherapy, has been used to transition patients from less activity limited by pain to greater activity [26]. Based on the results of the present study, the Orthotrac pneumatic vest may offer significant advantages in efforts to unload the spine and reactivate patients limited by pain from weight bearing. At the same time, use of an ambulatory device like the vest would avoid the pitfalls of patient reliance on special equipment and pools or scheduled clinic times. Because of its low profile when fitted to the torso, it would seem to empower normal activity without posing restrictions on standing, sitting, or bending tasks while unloading the lumbar spine. Use in clinical situations can be expected to facilitate increasing patient function and comfort. The role of reducing intradiscal pressure in limiting further deterioration or in any potential intradiscal fibrous stiffening needs to be investigated.

To our knowledge, there is no other literature that demonstrates biomechanical unloading of the disc and spine with use of a nonoperative modality. Recent clinical research has demonstrated the effect that unloading therapy can have on both function and pain. Early results from a randomized controlled study comparing the Orthotrac pneumatic vest to a typical lumbar brace measured statistically significant reduction in leg and back pain as well as improvements in activities of daily living. These clinical results are consistent with the expectations of effects from the kind of spinal unloading observed biomechanically in the present report [27,28].

As a cadaver study simulating weight-bearing loads on the spine in patients, there are limitations in the direct applicability of the results. The data are reported as percent drop in intradiscal pressure from upright posture of the torso without the head. The additional mass of the head or any other load being lifted could reduce the efficiency of unloading effect proportionate to their additional load on the spine. Similarly, this study does not consider the effects of trunk muscle action and can only reflect changes in passive loads transmitted through the spine. No information is available to say whether muscle behavior is altered by the use of the vest in clinical applications. If muscle activity were to increase, then it would reduce the efficiency of unloading by competitive compression of the disc. If muscle action is reduced then, efficiency may not be significantly influenced. Additionally, looking at muscle behavior in clinical settings should be a part of future work.

Table 3
Mean disc pressures (mm Hg) and standard deviations averaged across all six specimens for each pump reading

<table>
<thead>
<tr>
<th>Manometer</th>
<th>Intradiscal pressure mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>1490.5</td>
<td>674.8</td>
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<tr>
<td>3</td>
<td>1313.8</td>
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<td>4</td>
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<tr>
<td>5</td>
<td>1143.6</td>
<td>541.2</td>
</tr>
<tr>
<td>6</td>
<td>1248.2</td>
<td>507.8</td>
</tr>
</tbody>
</table>

Conclusion

The Orthotrac pneumatic vest is an effective device for unloading the spine consistent with beneficial effects in patients reported elsewhere in the literature. It lowered intradiscal pressures at the lumbosacral junction by 25% of torso weight. The use of an ambulatory vest, such as studied here, may permit any beneficial effects of unloading to be applied while in upright weight-bearing activities.
References