SpineMED® decompression system

White Paper

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SpineMED® PROFESSIONAL (S200B/S200C)

SpineMED® EXPRESS (S200E/S200EC)

SpineMED® ULTRA (S200U/S200UC)

Effectively Addressing Back and Neck Pain

Back and neck pain statistics are as painful as the conditions they represent. 85% of North American adults suffer from low back and neck pain at some point in their lives.[1]

Low back pain is especially prevalent. It's the second most common reason to visit a doctor, the fifth most common reason for admission to a hospital, and the third most common indication for surgery.[2] And, as the aging population grows, this number will predictably climb even higher.

While low back and neck pain can typically be managed through traditional treatment options such as physical therapy, chiropractic care, or pain management, discogenic pain can be more intractable. For many patients, addressing the underlying disc pathology is the only answer.

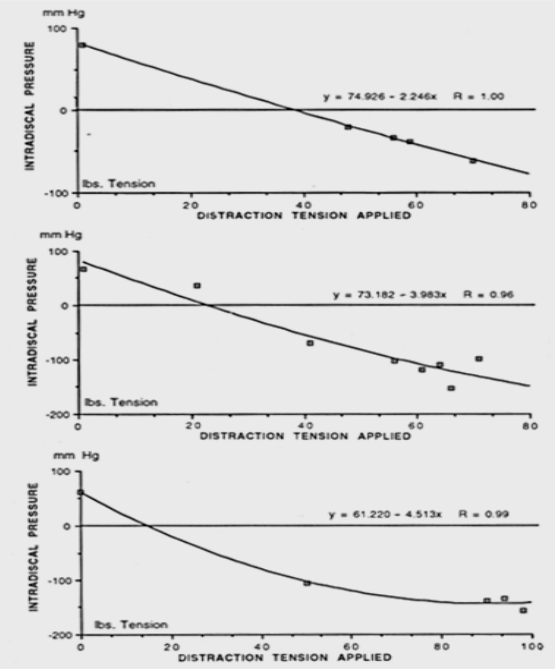
The Beginning and the End of Discogenic Pain

Intervertebral discs are prone to degeneration and injury as they are compressed and twisted through daily activities. As the disc degenerates, the gel-like nucleus loses its hydration, reducing disc height and creating the possibility of facet syndrome and lateral foraminal stenosis. Furthermore, disc degeneration causes the pliable outer coating of the anulus to become brittle and susceptible to cracks and tears that can lead to disc herniations. Bulging or herniated discs often press on spinal nerves, causing severe pain and radiculopathy.

Damaged intervertebral discs seldom heal because they remain under constant pressure, even while a person is at rest. It is widely accepted that the ideal environment to improve disc pathology is to decompress, or reduce the intradiscal pressures of the damaged disc. The goal of reducing intradiscal pressure is to enhance the osmotic diffusion of fluids and nutrients across the endplates into the disc, furthering the body's natural healing abilities.

Additionally, reduction of intradiscal pressures may help draw the nucleus pulposus of a herniated disc back into its center, reducing disc bulge or herniation and thereby relieving pressure on a compressed nerve root—alleviating the problem and the pain.

The Significance of Bypassing Reflexes



It is generally recognized that achieving decompression* depends upon the ability to distract the spine without eliciting reflex muscle contractions or spasms. Many patients, especially those presenting with acute disc pathology, experience a natural guarding reflex under traction. A recent meta-analysis evaluating conventional traction determined that "very few randomized controlled trials reported positive effects on low back pain, and increased pain and intervertebral pressures have been reported after its use."[3]

Additionally, conventional traction has never demonstrated the ability to reduce intradiscal pressures into the negative range. Leading spine researchers, Nachemsom and Anderson, concluded that "when traction is applied so that back muscles contract, then disc pressures will increase."[3]

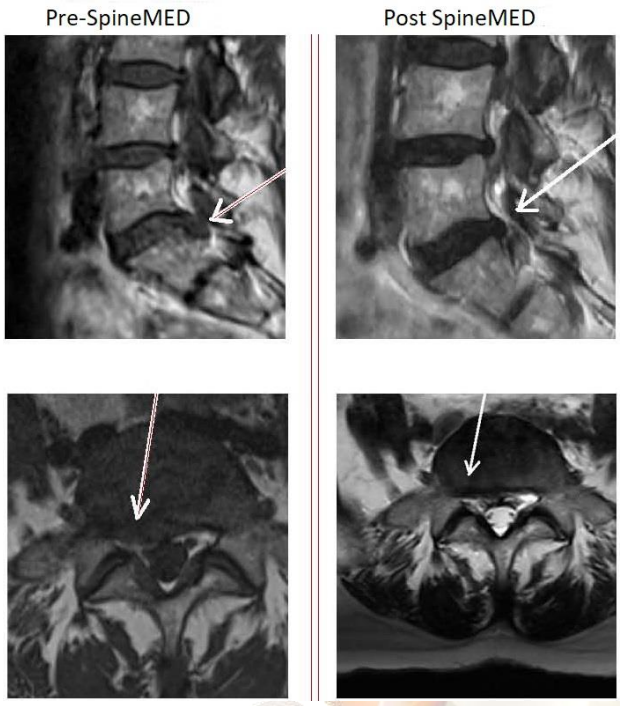
Graphs showing the intradiscal pressures recorded in the L4-5 nucleus pulposus of three patients (Case 3, upper; Case 4, center; and Case 5, lower) with a herniated disc at this level. Pressure is plotted against distraction tension consistent with the range of tension recommended as the therapeutic protocol for the equipment used in this study.

Effects of vertebral axial decompression on intradiscal pressure, GUSTAVO RAMOS, M.D., AND WILLIAM MARTIN, M.D., J Neurosurg 81:350-353, 1994

How SpineMED® Works

SpineMED® is designed to target damaged spinal segments and decompress intervertebral discs in order to promote the body's natural healing abilities.

The Pre- and Post- MRI's of a SpineMED® patient illustrate the dramatic physiological changes to the damaged disc—both a dramatic reduction in disc herniation and an increase in hydration, as observed through T-2 weighted imaging. These objective changes are not random occurrences in the incidence of disc pathology, and suggest the dramatic reduction of intradiscal pressures and subsequent increase in the osmotic diffusion gradient across the disc endplates.



The SpineMED® protocol consists of 20-25 sessions that are 30 minutes each in duration. SpineMED® sessions are typically administered 3-5 times per week over a 4-6 week period. The procedure is performed with the patient fully clothed and has been described as safe and pain-free. In fact, it is not uncommon for patients to fall asleep during the procedure. Each session has a cumulative effect, designed to significantly reduce pain and improve function as patients progress through the SpineMED® program.

For lumbar procedures, the upper torso is captured through the lower margin of the ribcage by a comfortable securing system incorporated into the fixed section of the table. The patented Pelvic Restraints gently rest over the patient's iliac crest to apply the distraction forces directly to the spine through the pelvis. The Pelvic Tilt section will be electronically tilted to rotate the pelvis, so that specific spinal segments can be targeted. With precise computer controlled tension, the specific disc segment is gently distracted.

For cervical procedures, the cervical unit is first electronically tilted to the angle required to target specific segments of the cervical spine through flexion. The patient is then placed on the table with their head positioned in the cervical cradle unit. The patented Cervical Restraints are designed to comfortably capture the base of the patient's skull for direct and controlled distraction.

Post SpineMED® Rehabilitation:

Following a course of SpineMED® sessions, patients in remission should be cautioned to slowly increase their exercise program. If their low back pain has caused them to restrict their activities in the past, their muscle strength may be decreased. In some cases, muscles are smaller (atrophied) and weak as a result of nerve compression. For at least one-month post session, exercises that cause flexion, extension or rotation of the lumbar spine should be commenced in a gradual and cautious manner.

The majority of patients that recover through the SpineMED® procedure generally remain in remission. Some individuals whose lifestyle or work environment exposes them to higher risk factors have found that a maintenance program consisting of occasional sessions may be of benefit. The clinician will determine if this is suitable, and the schedule of these sessions will be decided upon at that time. Generally these sessions are performed at monthly or quarterly intervals. The purpose of the maintenance sessions is to serve as a measure of protection against disabling exacerbation of low back pain syndrome. Patients in this category develop their own rhythm of maintenance visits that keeps them free from problems.

Indications/Contra-indications

Indications

- Pain due to herniated and bulging discs that is longer than four weeks in duration
- Recurrent pain from a failed back surgery that is longer than six months in duration
- Persistent pain from degenerated discs not responding to four weeks of conservative therapy

- Sciatica or peripheral radicular symptoms
- Mechanical low back pain

SpineMED® is designed to help patients with lumbar or cervical disc pathologies and is congruent with other conservative treatment options

Contra-indications

The low force requirements associated with SpineMED® limit the contra-indications significantly.

The primary contra-indications for SpineMED® decompression are:

- Instabilities of the spine, such as recent fractures
- Bilateral pars defects
- Unstable spondylolisthesis (typically grade 2 and above)
- Gross osteoporosis
- Cancers or tumors of the spine
- Surgical hardware fixation in the region of the spine being targeted
- Pregnancy
- Patients under the age of 15

Disc fragmentation, calcification, severe arthritis and any surgical spinal appliances are all relative contra-indications. Post surgical patients are NOT contra-indicated unless they have surgical hardware fixation in the region of the spine being targeted. In fact, failed back surgery patients may respond well to SpineMED®.

It's Easy to Integrate SpineMED® Into Your Practice

The system offers an unattended modality that improves patient flow and should not require additional staff. Additionally, we provide comprehensive training and continuous clinical support to ensure your ongoing success, allowing you to focus on your patients.

The SpineMED® Advantages

SpineMED® offers the most advanced and efficient decompression system in the market. SpineMED® is the ONLY Direct To Spine Decompression System available.

Advanced Computer Controls to Overcome Reflex Contractions

It is commonly recognized that achieving decompression depends upon the ability to distract the spine without eliciting reflex muscle contractions or spasms. SpineMED®'s computer controlled biofeedback response adjusts distractive forces at an astounding rate of 20 milliseconds (the human neurological response is approximately 50 milliseconds), or 50 times per second. Old designs utilizing pelvic harnesses and nylon strap systems simply cannot react and adjust tensions at this incredible speed. While their load sensors and motors are designed to adjust forces in less than a second, the true reaction time is significantly longer as the force is dispersed and absorbed through the traction box, nylon webbing, pulleys, and harness systems. This ability to almost instantly sense and adjust tensions is a key difference that distinguishes SpineMED® Decompression from other devices and conventional traction.

SpineMED® also incorporates built-in Infared Light Therapy in the lumbar section of the System to help relax paravertebral tissues and promote cellular activity to accelerate healing.

Focused Distraction

Zero-in and accurately isolate damaged discs. SpineMED®'s patented pelvic tilt feature places the pellvis into flexion between 0–25 degrees during lumbar sessions to move the focal point of the distraction forces, to target specific spinal segments. While the cervical section positions the head between 0–30 degrees of flexion for cervical sessions to target specific cervical segments. Adjustable patient positioning is designed to accurately move the focal point of distraction, allowing SpineMED® to target specific spinal segments. Older technologies attempt this by raising or lowering the traction box within their tower design.

Lower Force Requirements

Reduce the pressure on your patients. With the elimination of outdated harnesses and the implementation of direct capture of the pelvis with the patented restraints, SpineMED® decompression protocols call for a fraction of the force required with previous devices. For example, the average protocol for a 200lb patient on SpineMED® is 20 to 30lbs of force, compared with over 125 lbs on older devices. SpineMED®'s lower force requirements and Direct to Spine Distraction dramatically increase patient comfort and tolerance while virtually eliminating any risk of exacerbations or other negative side effects. Clinical experience has shown that the frail or geriatric patients are more suitable candidates for the procedure due to the lower forces required with SpineMED®.

Wider Patient Suitability

SpineMED®'s ability to achieve results using lower forces also increases the scope of suitable patients, especially with acute to sub-acute patients, frail patients, and the growing geriatric population. SpineMED®'s pelvic restraints comfortably secure patients of virtually any size (70 to 500 lbs.). The restraints effectively displace adipose tissue to capture the skeletal structure without having to rely on different-sized harnesses for the wide variety of patient structures.

Repeatable Sessions

You'll see the benefits of the SpineMED® design from the moment you prepare your first patient for the procedure. The patented pelvic restraints comfortably secure the patient's pelvis directly; rendering nylon harnesses a thing of the past. This direct capture provides a secure, comfortable, and repeatable setup, eliminating the variability, slippage, and inconvenience of the nylon harnesses found on older systems. Sessions on SpineMED® are virtually 100% repeatable, as the patient is in control of the major positioning and setup of the restraints.

Less Than 2-Minute Setup Time

Save time. Save money. With SpineMED®, it's faster and easier to set patients up. SpineMED®'s pelvic restraints, along with other unique automated technology incorporated in the device, facilitate a patient setup time of less than two minutes, allowing you to see more patients during the same hours, without impacting your current patient flow or requiring additional staff to operate your SpineMED®.

FDA Cleared and Patent Protected

You will also feel very confident with SpineMED®. The FDA has cleared SpineMED® for both Lumbar and Cervical Decompression (510(k) k051013). The SpineMED® has also received Health Canada License #67289 and European Union CE Marking. The system design and key

components are patent protected under US Patent #7201729 and the software systems have been copyrighted.

Smart Design

It's easy to make room for SpineMED®. We've designed the system to fit into existing offices, only requiring a 6 x 9 ½ foot space. Both the console and table have casters for portability, so disassembly is not required to relocate the unit to another room in your office. The modular components are easy to replace and have a solid track record. The built-in battery back up and voltage regulator protect the sensitive electronics of the device and provide power in the event of a power outage. This allows the SpineMED® to be plugged into any standard electrical outlet, without the need or expense of adding a dedicated circuit in your office.

Easy to Operate

You'll be up and running quickly. SpineMED®'s quick and simple patient setup and intuitive controls provide your practice with an unattended modality that can be operated by virtually anyone on staff. Included with your purchase, a certified SpineMED® specialist will provide you with a day of on-site training. You'll learn how to control the proprietary software with easy touch screen menus. The system automatically calculates many of the patient protocols, and you have the power to limit staff access to only those operators with a valid user ID and password, that you assign.

Automated Patient Reporting

Maintain complete record keeping. The SpineMED® system automatically records each session in a permanent electronic patient file, which includes the parameters of the session, the patient's VAS pain score, and any associated SOAP notes or documentation. You can also access a variety of comprehensive reports at the touch of a digital button. You can save the reports as .pdf attachments, e-mail them, or print them through SpineMED®'s built-in printer.

Solid Reliability with Upgradeable Technology

Stay up-to-date with state-of-the art equipment. We use hospital grade components to ensure that the SpineMED® system meets the highest standards of quality to receive Licensing approval from Government Health Authorities worldwide. Extensive computerization with a built in modem allows SpineMED® technicians to "dial" into the system, run diagnostics, check calibrations, and even upload software upgrades over the phone line. This ensures your SpineMED® stays current with the latest industry protocols. The system is backed with the best parts and labor warranty in the industry. Once installed, and calibrated there is no scheduled maintenance required—EVER!

Built-in Audio/Video Entertainment

Make the experience better for your patients. To promote relaxation or provide patient education, SpineMED® includes an adjustable flat panel monitor with a built-in DVD/CD player and includes patient headphones. Patients can watch DVDs, listen to music, or monitor the progress of their session.

Post Purchase Support to Ensure Your Ongoing Success

When we connect and install your SpineMED, we also connect you to our support team. We're here to make sure that SpineMED® is beneficial for both your practice and your patients. As part of the SpineMED® family, we offer continued clinical support, front office

and sales support, as well as access to a suite of marketing tools. We're partners with the same goal—to help your patients.

On-site Office Training

At the end of the day you'll be SpineMED® decompression experts. Installation includes a day of on-site training for the doctors and the staff. We install and calibrate the machine, teach you and your staff how to set up a patient for sessions, and provide detailed instructions on protocols and reporting.

Flexible Patient Financing

Offer more financing options. To increase the acceptance and accessibility of SpineMED®, patients can take advantage of financing packages that eliminate high upfront costs.

About SpineMED®

SpineMED® is the world leader in the modern science of non-surgical spinal decompression. Prior to becoming involved in the design and manufacturing of the SpineMED® System, the principals of SpineMED® owned and partnered with a number of decompression clinics. They also distributed decompression tables from other manufactures to physicians around the world.
Based on their years of clinical experience, and feedback gained from healthcare professionals in the field, the SpineMED® System was designed to overcome the limitations and untoward side-effects found with previous devices. Cumbersome nylon harnesses, outdated tower design, and antiquated traction components have been eliminated and replaced with a patented restraint system, exclusive pelvic tilt mechanism and advanced computer controls.
Quality and innovation are cornerstones of the company's philosophy. We are an ISO13485 and CE certified manufacturer of medical devices, and hold numerous patents on SpineMED®'s unique design and key components. The result is a decompression system built to worldwide hospital standards and whose quality is unmatched in the industry.
SpineMED®'s principal office is located in the interior of British Columbia, Canada.
We are confident that you will find SpineMED® to be the most technologically advanced and clinically effective device available for the conservative care of lumbar and cervical disc pathologies.

To find out more, please call 866-990-4444, email info@spinemed.com, or check out our website at www.spinemed.com.

With SpineMED®, you'll see more patients. And they'll see results.

Endnotes:
1 - "Low back pain: an economic assessment in the United States" . Orthopedic Clinics of North America , Volume 35 , Issue 1 ,
Pages 1 - 5 S . Pai , L . Sundaram.
2 - Bigos S, et al. "Acute Low Back Problems in Adults, Clinical Practice Guideline No. 14". Rockville, MD: U.S. Public Health Service,
U.S. Dept. of Health and Human Services, AHCPR Pub. No. 95-0642, Dec. 1994.
3- #4. Anderson, G., Schultz, A., and Nachemson, A. (1968) "Intervertebral Disc Pressure During Traction". Scand. Journal of Rehabilitation Medicine Suppl. 9. 88-91

*Spinal Decompression, that is, unloading due to non-surgical distraction and positioning.