Short-term Effect of SpineMED Decompression System for Lumbar Disc Herniation

Sun Jingtai[1] Hou Ximin[1] Li Xiunan[2] Piao Xing[2] Ji Gaoying[1]

1. Spine Department, Qingdao Air Force Aviation Medicine Appraising and Training Center, Qingdao 266071
2. Pain Control Department, Yanhe Clinic , Yanji City, Jilin Province, 133000

Abstract: ***Objective***: to explore the mechanism and effect of the non-surgical SpineMED decompression system for lumbar disc herniation . ***Method***: We used the SpineMED decompression system manufactured by the Universal Pain Technology Canada. The operation consisted of a series of two force phases per cycle, which consisted of a 60 second “Maximum Tension” distraction phase (high force), and a 30 second “Minimum Tension” relaxation phase (low force) for an approximate period of 30 minutes. For the high force, the distractive tension was calculated as Body weight X 1/4 – 4.5 KG. For the low force, the distraction tension was set as High force tension X 1/2 + 3.5 KG.. The pain was evaluated by Visual Analogue Scales (VAS) and MacNa method. ***Result***: 118 patients were followed up for 1 year and 7 months. Compared with before the treatment, the VAS score decreased an average of 8.2 ±1.1, being significantly decreased （$P<0.05$）after the treatment. The rate of excellent and good was 93% and no complication was observed.

Conclusion: For lumbar disc herniation, decompression has the advantages of safe, non-invasive, effective and complication free. It can be the first choice for patients with initial onset. Strictly controlled indication selection is the key to ensure the treatment effect.

Keywords: disc herniation, decompression, indications

Lumbar disc herniation is a common disease. Non surgical treatment is the preferred method for both doctors and patients. The traditional lumbar traction method can effectively pull back the protrusion and relieve the symptoms by reducing the intervertibral disc pressure. However the treatment effects varied greatly due to different devices or equipment used. Recurrence is considered as one important disadvantage [1]. Researchers all over the world have been studying and exploring the mechanical action and therapeutic mechanism of traction and updating the treatment devices. From August 2010 to April 2012 we had used SpineMED DECOMPRESSION SYSTEM THERAPY, which is a new patented device developed by Universal Pain Technology Canada, to treat 118 patients with lumbar disc herniation and observed satisfying short-term therapeutic effect.

1. Clinical Data

1.1 General materials

118 patients (62 male, 56 female) aged 18 to 82 years old (mean 53.6 years old) were included in this study. Among them 66 patients had low back pain with unilateral or bilateral leg pain and numbness; 52 patients had simple low back pain. CT or MRI examination showed 26 lumbar disc protrusion and 92 lumbar disc herniation. They were classified as 20 cases central stenosis, 25 cases central-lateral stenosis, 45 cases lateral stenosis, 1 extreme-lateral stenosis and 1 free type. 44 cases involved single segment, 58 cases double segments, 10 cases three segments and 6 cases complicated with Ⅰ° vertebral spondylolisthesis. 48 cases accompanied by joint degeneration and spinal canal stenosis to various degrees. The shortest history was 8 days and the longest 30 years.

1.2 Treatment

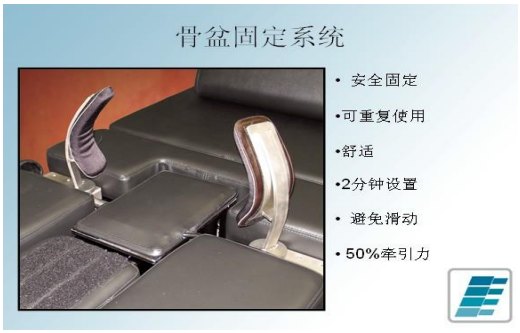
The lesion site and herniation type were confirmed based on the radiological imaging data obtained in recent three months. The pain intensity was evaluated by Visual Analogue Scales (VAS). Non Steroidal Anti-inflammatories and Calcium Gluconate were given to the patients 2 days prior to the first procedure to alleviate muscle spasm.

The starting distractive force to be used for the patient was calculated according to the body weight. The operation consisted of a series of two force phases per cycle, which consisted of a 60 second “Maximum Tension” distraction phase (high force), and a 30 second “Minimum

Tension" relaxation phase (low force) for an approximate period of 30 minutes. For the high force, the distractive tension was calculated as Body weight X 1/4 – 4.5 KG. For the low force, the distraction tension was set as High force tension X 1/2 + 3.5 KG. The decompression started from a beginning force of zero KG and slowly built up to the maximum force. The "Progressive Times" was preset at 5 cycles (7 minutes and 30 seconds). The maximum and minimum phases in the cycles repeated through the session of 30 minutes, and at the end of the session, force was gradually diminished to zero KG over the "Regressive Times" period, which was preset at 2 cycles (3 minutes). The procedure was administered daily, for 6 days each week. Initially if there was no obvious treatment effect and discomfort for 3 days, 2KG was added to the distraction force. Gradual increase of distraction forces were based on patient response to distraction plus the general guideline of 2 KG/ session. Maximum distraction tensions of 1/4 body weight + 11KG was applicable to all patients. The maximum distractive tensions should never exceed 45Kg, which was the calculations for a 136 Kg patient. Each treatment procedure consisted of 18 to 26 sessions. 5-10 sessions could be added after the procedure if the treatment effect was not satisfying.

Session procedures: After 20 minutes' low back Infrared heating, the patient was helped to lying on his/her back on the Table so that his/her iliac crests were immediately below the position of the pelvic horns.

Position the upper restraint harness around the patient so that it was immediately below, and captured the lower margin of the ribcage. Assist the patient to bend his/her knees, and insert the knee bolster to the correct height for his/her leg length to help relax the lumbar muscles. (Picture 1, a,b.)



Picture 1 a .Decompression **b**.Pelvic fixing and tilting angle adjusting system

Settings for variable pelvic angles to target specific spinal segments were programmable. Enter the lesion segment into the treatment system computer, the tilting angle of the pelvis were adjusted automatically as followings: L5～S1　0; L5～S1, L4～L5　5°; L4～5　10°; L4～L5, L3～4　15°; L3～4　20°. After inflating the lumbar sac and turning on the InfraRed heat application, start the decompression treatment which was automatically stopped after 30 minutes. Remove the external harness and move to physical therapy bed for 10 minutes' Cryotherapy and 15 minutes' Interference current therapy.

Precautions after the Procedure: rest for 1-2 hours immediately after the treatment; don't bend or twist the spine in four hours; pay

attention to the sitting and lying positions; don't lifting heavy objects; don't wear high-heel shoes; don't do heavy exercises and don't walk more than 2 kilometers. Back muscle exercises in supine or prone position are permitted within a time limit of 20 minutes. In this study, 1 patient had 14 sessions and other 117 patients had 20-29 (mean 22) treatment sessions.

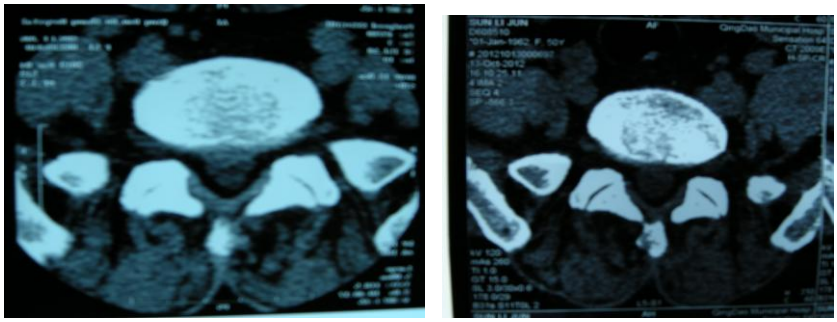
1.3 Statistical analysis:

Data were expressed as mean ± standard deviation (± S). SPSS10.0 software was used for comparing the VAS before and after the treatment. T test was used and $P < 0.05$ was regarded as statistically significant.

2. Results

The 118 cases were followed up for an average period of 1 year and 7 months. VAS and MacNa were used for treatment effect evaluation. Pain intensity scored from 0 to 10 points, while 0 indicates no pain and 10 severe pains. The evaluations were recorded by the same physician. The score was 8.9±1.2 before the treatment and 1.7±1.1 after the treatment, with an average decrease of 7.2. The difference was statistically significant （$P<0.05$）. For functional evaluation （MacNa）: **Excellence**: Pain free, movement free, resume normal life and work; **Good**: symptoms almost disappear, occasionally pain, can engage in general labour. **OK**: Improved symptoms and signs, activity partially restricted, analgesics needed occasionally. **Bad**: mild improvement of symptoms and signs, still

radicular pain. In this study, the Excellent and Good rate was 93% with 78 cases Excellence, 32 Good, 6 OK and 2 Bad. After the treatment, 40 patients (21 male and 19 female) experienced increased body height of 0.5 to 3.5 cm. The average height was 1.689 cm before treatment and 1.711 after treatment, with an average increase of 2.02 cm. Typical case: Sun Lijun, female, 51 years old, with L5/S1 herniation, started the treatment from April 4, 2012 and had had 26 sessions. The follow-up in Jan. 14 2013 showed that her pain disappeared; she returned to work and her height increased 2 cm. CT scan showed retraction of herniated disc (Picture 2, a. b.).



Picture 2 **a** Before Treatment **b.** 8 month follow-up retraction of disc

3. Discussion

In the treatment of disc herniation, for patients of initial onset or mild symptoms with short history, non-surgery treatment is the first choice. When the non-surgery treatment is not effective, traditionally surgery is the last option. Patients are unwilling to accept the traumatic surgery due to its great risks. In recent years, minimally invasive surgery has been

widely used [2], such as percutaneous lumbar discectomy, percutaneous laser disc decompression, ozone dissolution of nuclear and other radio-frequency ablation nucleoplasty. All these methods make the protrusion retracted by reducing the volume of nucleus pulposus and subsequently reducing intradiscal pressure. Sun Ronghua, etc. [3] regarded it as an indirect decompression. Limited treatment effect and disc tissue trauma are main shortcomings.

In this study we use the SpineMed Decompression System, which was shown by a research in the University of Texas to be able to reduce the intradiscal pressure from the usual 100 ~ 300mm/Hg to negative 150mm/Hg, a vacuum decompression status. This function and the increased tension of the posterior longitudinal ligament have helped the retraction of the bulging and prominent nucleus. As the disc has no direct vascular supply for oxygen, it obtains nutrition by diffusion penetration through fibrous cartilage plates (70%) and the annulus (30%). Decreased intradiscal pressure can enhance the osmotic diffusion of fluids and nutrients across the endplates into the disc, favoring annulus repair and reducing the relapse rate.

The advantages of SpineMed we found include: 1. It is commonly recognized that achieving decompression depends upon the ability to distract the spine without eliciting reflex muscle contractions or spasms. SpineMED monitors tension applied to the patient every 2.5 milliseconds

and can make adjustments every 20 milliseconds. This ability to almost instantly sense and adjust tensions is a key difference that distinguishes SpineMED Decompression from other devices and conventional traction. Adjuncts to the Procedure, The Non-Steroidal Anti-Inflammatory Drugs (NSAID) taken before and during the treatment, Calcium Supplements, and 25 to 35 mm depth of infrared radiant heat can help relaxing the back muscles and accelerating the blood circulation. The above adjuncts can effectively decrease the intradiscal pressure with a lower traction force. 2. It is a simplified, comfortable and efficient method of stabilizing the patient during decompression. The pelvic restraints produce a very replicable and consistent hip capture overcoming the easy to loose and slip shortcomings of the traditional pelvic girdle traction. 3. SpineMED's patented pelvic tilt feature is designed to adjust patient positioning to accurately isolate and decompress specific spinal segments. With increased specificity and a more efficient capture, SpineMED is engineered to achieve optimum decompression. Decompression is carried out with the infrared thermal radiation, thus increase the volume of the spinal canal, intervertebral foramen and lateral recess and reduce the pressure of nerve roots. The warm effect can help eliminate the root edema and aseptic inflammation and significantly alleviate symptoms[4~5]. It's significantly effective for patients with combined spinal canal and lateral recess stenosis.

In our study, no complications or relapses were observed after the treatment. The increased body height experienced by the 40 patients may be explained by the correction of the lumbar deformation of varying degrees caused by disc herniation. Further studies are required for investigating whether the increased height is related to widened intervertebral space due to increased water content in the discs.

Authors' experience: A strictly controlled indication is the key to improve the efficacy. In our study the best indication is discogenic back pain, such as herniated, bulging and degenerative discs. The contraindications include extreme lateral prominent, extrusion type, free type and extreme lateral type with ruptured annulus, disc herniastion with calcification, stenosis caused by spinal bone and yellow ligament hypertrophy, and Ⅱ ° lumbar spondylolisthesis or greater. The decompression treatment is safe and effective. It can help the repair and regeneration of the anulus as well as treat and delay the disc degeneration. Our study followed up for a comparatively short period, the long term effect needs further studies and explorations.

Jan 28 2013, Qingdao

Reference

1. Lu Yulai, Lumbar disc herniation [M](Second edition),Beijing, People's Army Medical Publishing House, 2008.8:271～279.

2. 2. Kvarstein G,Mawe L,Indahl A,et al.A randomized double-blind controlled trial of intra - annular radiofrequency thermal disc therapy - a 12 - month follow - up[J].pain,2009,3:279 - 286.

3. Sun Ronghua, Yang Weiquan, Liu Yulong, Percutaneous radiofrequency thermocoagulation target therapy for lumbar disc herniation, an observational study of 530 cases, Chinese Journal of Orthopaedic Surgery, 2011,19.1612 ~ 1614.

4. Zhou Bingwen, Back pain, Beijing, People's Health Publishing House, 2005.11: 189-190.

5.Azulay N,Forgerit M,Alava EG,et al.A novel radiofrequency ther-mocoagulation method for treatment of lower back pain:thermal con-duction after instillation of saline solution into the nucleuspulposus - preliminary results[J].Acta Radiol,2008,8:934 - 939.

First author: Sun Jingtai (1963 -), male, Qingdao, vice chief physician. Research direction: non-surgical treatment of bone and joint diseases.

Tel: 13808992087

E-mail: www.jzjy789 @ 163.com