Clinical Evaluation of the Dr. Ho 2-in-1 Back Relief Decompression Belt:
Part One: A critical Examination by the Ontario Research Medical Group Director,
Dr. Michel Rice

Part Two: Dr. Chang Han Dong CEO Regulatory Affairs, Quality Engineering
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A Critical Review of Lumbar Orthosis and Its Relevance to Clinical Medicine and

An Interpretive Analysis of the Physiologic Model of

DR-HO’S 2-in-1 Back Relief Decompression Belt.

1 Introduction

The Ontario Research Medical Group (ORM) is an assembly team of physicians and support x-ray technical staff. The author of this paper, Dr. Michel Rice dc is the Director of Clinical Operations. Dr. Eric Saibil, medical radiologist is ORM’s chief radiologist. ORM specializes in the diagnosis of injuries identifiable on x—ray. The types of injuries involve those caused by the sudden deceleration forces on the neck and lower back such as those experienced in motor vehicle accidents. Specifically, we investigate spinal instabilities in the cervical and lumbar spine. ORM is actively involved in research involving the assessment of spinal performance with surgically-ligated specific ligaments.

Our clinical responsibilities involves the assessment of trauma patients for the purpose of writing chronic pain reports, impairment rating reports, catastrophic assessment reports and radiology-based impairment reports.

The connection between ORM and Dr. Ho’s 2-in-1 Back Relief Decompression Belt, hereinafter referred to as the Dr. Ho’s Decompression Belt, involves our choice of recommendation its clinical application for patients with permanent spinal injuries of the stability-type such as full ligament rupture. The Dr. Ho Decompression Belt is therefore recommended for the purpose of improving spine function, reduce suffering and increase stability. This recommendation is based upon our extensive research review, analysis of the belt’s applicable physiologic concepts and from a radiology-based case study. The case study involved testing the Dr. Ho Decompression Belt for its stability capabilities on a patient with severe degenerative disc disease and loss of motion segment integrity in the lumbar spine.

Our preliminary investigation of Dr. Ho’s Decompression belt involved a radiology study on a particular case-study. A patient with degenerative disc disease in the lumbar spine with degenerative instability. We have since approved the Dr. Ho Decompression Belt as it meets with our stabilization requirements for numerous lumbar spine conditions. Specifically, the product fulfills two physiologic principles required for improved lumbar stability: increase IAP (intra-abdominal pressure) in all ranges of motion during motion and in fixed positions.
and reduction of spinal compression (decompression) in all ranges of motion as well as in fixed positions.

The clinical application for this recommendation involves patients who are sedentary, for use during activities of daily living, for increased spine strength and stability during work tasks and to re-enforce and stability age-related overall trunk weakness.

Diagnostic indications involves numerous conditions and injuries such as: acute and chronic sprains and strains, acute and chronic disc injuries (herniation and bulge), permanent instabilities of the ligament-type, congenital deformities such as spina bifida, spondylolysis and listhesis, degenerative arthropathies. The addition of any referral pain patterns such as sciatic irritation or nerve root compression is also to be added to the list of indications. Evidently, any condition that compromises acutely or chronically spinal stability is an indication for the wearing of the Dr.’s Ho Decompression belt.

Below are three physiologic model describing the mechanisms of action of lumbar stability contributed by lumbar support belts. The stability translates to improved lower back function, back pain and radicular pain relief, prevention of further degradation and prevention of recurrences amongst lower back pain chronic sufferers.

An effort is made to explain these models generally and specifically to the Dr. Ho’s 2-in-1 Decompression Back Relief Belt.

2 IAP (Intra-Abdominal Pressure)

The physiologic model working with IAP has been well established in numerous papers that have respectable high impact factors. The action of purely increasing IAP as a stand alone physiologic phenomena is well documented as a spinal stability inducer which directly supports the claims made in Dr. Michael Ho’s clinical report.

Of particular interest is Harman et al.(1989)¹ and Lander et al.(1992)'s² work investigating lumbar belts, stability and repetitive lifting activity. In addition to the stability benefits of increased IAP, they clearly state that lower back musculature firing patterns are unchanged with the wearing of a lumbar spine belt. It is often falsely assumed by health care professionals that the wearing of lumbar spine belts weakens the erector spinae. What ORM thinks to be relevant here is that using Dr. Ho’s Decompression Belt (or any apparatus contributing to increased IAP) allows the patient to increase activity and safely rehabilitate their erector strength in all ranges of motion. The added benefit of using the Dr. Ho Decompression Belt is its portability and practicality factors.

Ivancic et al (2002) have further demonstrated that increased IAP will amplify spinal stability by an approximate 34% with the wearing of the belt. This added stability is considered to be passive (contributory) stability that is added to the patient’s active stability. The passivity addition is most definitely an added benefit extending into the patient’s everyday life.

Of particular interest to ORM is Dr. S. McGill’s discovery that passively increased IAP will reflexly induce lumbar spine extension. This phenomena touches upon the second physiologic principle entitled ‘decompression’ which is discussed below. Worthy to note at this moment is that although the two principles are usually independently discussed, extension is noted to contribute to spinal stability and to decompression effects (see below).

3 I Decompression
Spinal compression has been investigated extensively by Dr. S. McGill extensively. As mentioned above, his publication on the Reassessment of the role of intra-abdominal pressure in spinal compression concludes that raising IAP (Intra Abdominal Pressure) directly reduces spinal compression. This is the result of a natural lumbar extension repositioning which occurs when IAP is increased. This concept should be discussed in more detail in order to clearly explain the added benefit of decompression as provided by Dr. Ho’s Decompression Belt.

Dr. McGill’s work utilized diaphragmatic pressure, induced by passive electric stimulation in order to increase IAP. He did not utilize other Valsalva methods such as abdominal wall contraction or breath holding. The subject, being in a recumbent position, experienced an automatic and uncontrolled natural spinal extension once diaphragmatic stimulation was applied. This is translated to be a pure spinal extension force that is not driven by erectors or abdominal muscular contraction. The extension allows for a direct spinal disc pressure reduction (decompression) as a result of the extension phenomena created by the increased IAP driving force.

More aggressive and invasive clinical trials have been performed to demonstrate that disc decompression is favored in the lumbar extension position. The use of pressure probes inserted into lumbar spine discs were utilized to prove there is least pressure (decompressed spine) when the patient is standing with a full lordotic lumbar curve.

Stokes et al. postulated that abdominal pressure and abdominal wall muscular function had direct correlations with a lumbar spine unloading effect, referred to as ‘spinal unloading

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5 Stokes I, Gardner-Morse M., Henry S. Intra-abdominal pressure and abdominal wall muscular function: Spinal unloading mechanism Clinical Biomechanics 25 (2010); 859-866
or decompressing forces’. A reduction of compression forces were noted to be averaging 20 to 30 percent in varied spinal positions.

The American Academy of Orthopaedic Surgeons states that a flexed spine experiences four times the stress loads which can translate into vertebral body spinal fractures. The extended (decompressed) spine is therefore the more stable and safe spinal position.

Any apparatus assisting with a patients changed position to that of a more extended spine and with the maintenance of this optimally decompressed position is of clinical benefit to the patient.

Of particular clinical interest to ORM is the fact that maximum disc pressure is recorded in the rotated motor segment. This is relevant to the clinical benefit of wearing a belt that will limit ranges of motion that are particularly dangerous on spinal discs such as rotation.

The secondary physiologic benefit of Dr. Ho’s Decompression Belt (decompression) has an extension mechanism built into the belt. This is a phase two, or step two application of the belt. Once the patient applies the outer abdominal tightening (IAP - phase one) to their core, thus increasing the internal abdominal pressure, the second phase, involving the pump further extends the spine.

The action of the pump designed in the innermost layer of the Dr. Ho Decompression Belt expands both superiorly and inferiorly to the limits of a fully extended spine that is specific to the patient’s morphology. The iliac crest and pelvic rim inferiorly and the lower costal margins superiorly are the anatomical landmarks that push and guide the patient into a full extension position. This extension is now maximally expressed, controlled and limited by each patient’s individual morphology and thus optimally decompressed. The end result is a spinal position that is minimally compressed (decompressed) as induced by the decompression pump mechanism of the Dr. Ho Decompression Belt.

4 Clinical Application of a Lumbar Support Belt
ORM’s opinion on the recommendations for lower back pain management are identical to those stated by the International Treatment Guidelines. The Guides uses comparison measures from various countries around the world. Koes et.al. from the Department of General Practice, Erasmus University involves in his statement on management recommendations the use of lower back belts. The International Guidelines consistently encourages patients to become active early and gradually.

Koes et.al. also encourage the involvement of psychosocial input because this facet of life is a risk factor for chronic pain. This etiologic statement is especially important for what we believe applies to most patients afflicted by chronic lower back pain. These two

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recommendations, the wearing of a belt and increase psychosocial input directly relates to the benefits reported by numerous research papers pertaining to subjects’ feelings of both reassurance and protection as well as the improvements in activity level from patients who wear a lumbar spine belt. The type of activity, length of time performing the activity and the intensity of activity are three factors that have been reported to be improved when wearing a lumbar belt.

The NCBI (National Center for Biotechnology Information) further adds that the gradual activation of the patient who suffers chronic low back pain as well as the provision of psychological input must be consistent internationally as a recommendation for the treatment of low back pain. ORM fully endorses this recommendation.

5  | About Decompression Therapeutic Modalities (Motorized Traction)
On the matter of decompression therapy as offered by therapy machines such as the VAX-D unit, there exists a paper review on the subject of non-surgical spinal decompression therapy’s efficacy claims. The author of the paper review, Dr. Dwain Daniel⁷, who we are aware is personally invested on this therapy, discusses his literature review on the matter of existing scientific literature supporting this form of therapy. Conclusions were not favorable as there is only limited evidence available to warrant that routine use of non-surgical spinal decompression. This brings us to the subject of what is considered more efficient as a therapeutic modality. An apparatus that can induce extension (decompression) and allows the patient to wear continuously, as opposed to in-clinic only availability, has more practicality and is therefore more efficient and therapeutic for the patient. The added advantage of mobility in a supported position is far superior than any lying therapeutic modality. Even invasive joint replacement therapies today are mobilized actively as soon as possible.

Albeit a low impact factor rating, Drs. Macario and Pergolizzi⁸ published in The Pain Practice Journal the result of their systematic literature review on the subject of spinal decompression via motorized traction for chronic discogenic low back pain. Their findings also agreed that the motorized traction methods remain to be unproven scientifically, largely based upon a lack of well-designed studies. ORM does not support the use of motorized table for this reason. We are therefore in full support of a portable and practical orthopedic appliance such as a back belt that can decompress (extend) the spine while the is living actively. Dr. Ho’s Decompression Belt meets these physiologic requirements.

6  | Closing Remarks
In closing, our review and opinion on the benefits of the lumbar support belt is fully

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⁷ Daniel D.M. Non-surgical spinal decompression therapy: does the scientific literature support efficacy claims made in the advertising media? Chiropractic & Osteopathy 2007; 15: 7
supportive of their use as a therapeutic modality that encourages patient activity for lumbar conditions ranging from mild sprains and strains to the opposite of the clinical spectrum, post surgical lumbar procedures such as discectomies and fusions. The use of a lumbar belt is also recommended for any patient that has a history of lower back pain and injury. Although not yet supported scientifically, we highly recommend it as a preventative measure for work tasks known to be beyond normalcy for range of motion and spinal stress loads. The belt is also recommended for re-enforcement in patients that are frail or aging. The added physical stability, notwithstanding the psychological boost, will allow for muscular retraining and assist with gravity-based activity that will without doubt re-enforce Wolfe’s Law and its benefit to prevent or even reverse osteoporosis.

The Dr. Ho 2-in-1 Decompression Back Relief Belt involves two physiologic principles that have been shown in this paper to be fully supported by evidence-based medicine. The Dr. Ho Decompression Back-Relief Belt has benefits beyond what is currently available in the market in both the clinical and fitness world – two physiologic concepts that contribute to the stability of the lumbar spine which extends benefits to those wearing it involving a reduction of pain and suffering, preventative recurrent episodes of lower back pain and injuries, protection of further spinal degradation of existing pathology and, our favorite, quantitative and qualitative improvements of physical activity.

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Doctor of Chiropractic  
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ORM does not endorse treatments, procedures, products, or physicians referenced herein.  
This information is provided as an educational service.
1. General Details

Proprietary Device: DR-HO’S 2-in-1 Back Relief Decompression Belt

Manufacturer of the device: Xinbo Electronic Co., LTD

The structure of the device: The DR-HO’S 2-in-1 Back Relief Decompression Belt is constructed with 2 layers. It has an inner inflatable belt with an attached air valve. The inner belt can be inflated by an accompanying hand pump. There is an additional outer supplemental belt with Velcro strap for tightening and closure.

Medical Device Directive 93/42/EEC requires an evaluation of the safety and efficacy of the products to be certified in the course of the conformity assessment process and the demonstration of compliance with the Essential Requirement process and the demonstration of the compliance with the Essential Requirements (Annex I).

This evaluation shall consider and document the validity of the defined intended use of the product. The following evaluation is performed on the basis of Annex 10 of the MDD, section 1.1, as well as MEDDEV-Guideline 2.7.1. -- Clinical Evaluation (12.2009). Chapter 5 of the MEDDEV Guideline describes three different options to perform a risk-benefit evaluation on the basis of:

a) Literature review
b) Clinical trial with the product
c) A combination of both

NB-MED/2.7/Rec1 delineates on when a clinical investigation is needed for CE marking. It is recommended that clinical investigation of a medical device is likely to be required in particular in the following circumstances:

a) Where a completely new device is proposed for the market, whose components, features and / or method of action are previously unknown. or

b) Where an existing device is modified and the modification might significantly affect the
clinical safety and performance. or

c) Where a previously established device is proposed for a new indication. or

d) Where a device incorporates new materials, previously unknown, coming into contact with the human body or existing materials applied in a location not previously exposed to that material, and for which there is no convincing prior clinical experience, or that the device will be used for a significantly longer time.

The medical device under investigation does not meet any of the above criteria for clinical investigation. It is a medical device with the following characteristics:

a) It is a device with three decades of clinical application history

b) The device within the application is intended for the same clinical application as the comparable devices on the market.

c) It is a device made of the same material as other similar products on the market.

Therefore we believe that a literature review is the most appropriate method for the DR-HO’S 2-in-1 Back Relief Decompression Belt product. The results of literature review are summarized in the following pages. Additionally, we provided the clinical evaluation report as objective evidence to support the safety and effectiveness of the product.

Referenced publications are;

- MDD 93/42/EEC Annex X
- NB-MED 2.7/Rec1 Guidance on clinical
- NB-MED 2.7/Rec3 Evaluation of clinical data
- MEDDEV 2.7.1 Evaluation of clinical data

2. Description of the device and its intended application

2.1 Overview

Chronic low back pain (LBP) creates a profound socioeconomic problem in today’s society.

Recent studies support the hypothesis that patients suffering from LBP of mechanical origin try to compensate for their injuries with additional or different muscle recruitment patterns, presumably to increase spinal stability. In healthy individuals, mechanical stability is provided to
the spine by trunk muscles and ligaments. Injuries and chronic mechanical defects in the osteo-ligamentous structures reduce spinal stability. To maintain a normal level of stability, trunk muscles must compensate by altering their normal activation pattern. Some research suggests that wearing both an abdominal belt and raising intra-abdominal pressure (IAP) can each independently, or in combination, increase lumbar spine stability.

Abdominal belts have been shown to help individuals in generating higher IAP levels during load-handling activities. There exists anecdotal evidence that people “feel safer” wearing abdominal belts when exerting themselves. This is especially true for weight lifters and power lifters, who use belts apparently for no obvious benefit other than to increase their IAP during lifting. While a few studies reported marginal improvement in lifting capacity with the use of abdominal belts, the overwhelming evidence suggests that belts have no beneficial effect on muscle strength, fatigue, or low back injury incidence.

The DR-HO’S 2-in-1 Back Relief Belt has two functions:

**First function:** When worn non-inflated, it can help to support the lower back to protect the lower back during activities.

**Second function:** When inflated with air, the belt will increase in height by about 10.0 centimeters or 4 inches. The lower rim of the belt is secured to the upper pelvic crest and the upper rim of the belt is secured against the lower rib cage. When the belt expands in height, it will help to stretch the lower back muscles and also helps to reduce pressure on lumbar spinal discs. The belt works to help relieve lower back pain and radiating hip and leg pain relating to degenerated discs and pinched nerves in the lower back. The effects of the belt translates to a lessened pressure on the spine. This lowered disc / spine pressure has been compared to the effect of hanging upside down. Decompression bed markets also make similar claims of decompression.

**2.2 Marketing history**

The abdominal belt has been used successfully for over 80 years throughout the world. Various
modifications of this device have been developed over the years, such as the inflated abdominal belt. The main manufacturers are Air LOMB Co., Ltd and Disc Disease Solutions, Inc.

3. Intended indication and claims

3.1 Applications

Abdominal belts are intended for use by patients with the following conditions:

3.1.1 Lower back pain attributable to degenerated or herniated disc.
3.1.2 Back strain
3.1.3 Muscle tension
3.1.4 CT scans
3.1.5 Degenerative, herniated or bulging discs
3.1.6 DJD Degenerative Joint Disease
3.1.7 Acute lumbar injuries
3.1.8 Osteoporosis

3.2 Contraindications

3.2.1 Spinal, rib or pelvic fractures
3.2.7 Serious cardiovascular or respiratory diseases
3.2.8 Pregnant women
3.2.9 Children

3.3 Intended use

1. The Dr. Ho 2-in-1 Back Relief Decompression Belt’s deflated state can help support the lower back to protect it during activity.

2. The inflated state of the belt helps relieve lower back pain and radiating hip and leg pain relating to degenerated discs and pinched nerves in the lower back. Essentially this state will have a clinical impact on the disc structure of the spine. The belt is unlike any other support or back pain belt because it provides additional clinical grade extension traction on the lumbar spine and therefore decompression therapy which is a proven technique endorsed by medical professionals and used in both upper and low back pain treatment. As the belt inflates with air,
it expands vertically, gently stretching the lower back. This gentle non-invasive traction helps decompress the spinal discs, stretch and relax tight muscles to relieve lower back pain.

3.4 Potential complications
The DR-HO’S 2-in-1 Back Relief Decompression Belt can increase intra-abdominal pressure (IAP). Some researchers suggest that the level of IAP has a close relationship with the case fatality rate of abdominal compartment syndrome (ACS) and the stomach intestine function recovery time. When increasing the level of IAP, the case fatality rate of ACS patients also increases. It also prolongs the stomach intestine function recovery time. Therefore, patients undergoing abdominal procedures should not use this device.

3.5 Warning and precautions
If any discomfort or pain is experienced during or after using the belt, it could indicate that the back muscles are very tight and the back should slowly and gradually be stretched to allow the tight muscles to relax. If pain persists, a doctor should be consulted before resuming use of the belt.

4. Equivalence comparison and clinical data
4.1 Clinical equivalence
The DR-HO’S 2-in-1 Back Relief Decompression Belt has the same intended use as the Ceinture Lombaire Air LOMB MATERNITY from Air LOMB Co., Ltd. and the DDS 500 - LUMBAR TRACTION from Disc Disease Solutions, Inc. All three are intended to support the back and to stretch the lower back muscles.

4.2 Technical equivalence
Attached is the summary of similarities and differences between the DR-HO’S 2-in-1 Back Relief Decompression Belt, DDS 500 - LUMBAR TRACTION and the Air Lumbar Inflatable belt.
4.3 Equivalence conclusion

As described in the above-mentioned description, the Back Relief Belt consists of major components either taken directly from or based heavily on those of already existing components. These same components, such as used in the DDS 500 - LUMBAR TRACTION device, have been used on the worldwide market since 2006 and have been demonstrated to be safe and effective for their intended use through positive market experience and an extremely low rate of safety related incidents. Additional evidence of this device being safe and effective can be seen from the fact that it has been deemed as such by independent government agencies (US FDA).

<table>
<thead>
<tr>
<th>Product</th>
<th>FDA Clearance</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDS 500 - LUMBAR TRACTION</td>
<td>3005396293</td>
</tr>
</tbody>
</table>

4.4 Database resource

Data for clinical evaluation on the safety and performance of the belt were derived from literature reviews published between 1990 and November 2012. Searches were conducted at the NIH PubMed web site [1] http://www.ncbi.nlm.nih.gov/sites/entrez, using various combinations of search terms (Table 1). The NIH PubMed remains the most popular search engine used to retrieve original studies. [2] When the Pubmed search engine is compared to Google scholar search engine, PubMed appears to be more practical to conduct searches. A total of 7025 articles published between 1990 and the present were found, including 339 review articles. This
report is based mainly on the original papers. Among the review articles, only 15 review articles use “belt” in their article title, and most articles are related to seat belts, and are not related to abdominal belts. Most articles that only marginally relate to lumbar belt were eliminated from the analysis. Additionally, when we searched with “inflatable” and “belt”, only 11 articles were found, and all those articles are related to seat belts and obstetric belts.

4.5 Retrieval protocol

The literature search was performed by Dr. Chang. Dr. Chang has a long history in the manufacturing and distribution of medical devices. Miss Li is the authorized clinical expert for Osmunda Co., Ltd. Consequently both persons have detailed knowledge about the risks associated with the product categories.

The following evaluation is an attempt to summarize common views of the authors:

<table>
<thead>
<tr>
<th>Table 1. Search Terms and Results</th>
<th>All References</th>
<th>Review References</th>
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</thead>
<tbody>
<tr>
<td>1. Abdominal belt</td>
<td>523</td>
<td>44</td>
</tr>
<tr>
<td>2. Back belt</td>
<td>362</td>
<td>19</td>
</tr>
<tr>
<td>3. Traction belt</td>
<td>15</td>
<td>0</td>
</tr>
<tr>
<td>4. Support belt</td>
<td>3034</td>
<td>116</td>
</tr>
<tr>
<td>5. Belt</td>
<td>7181</td>
<td>339</td>
</tr>
<tr>
<td>6. Lumbar belt</td>
<td>202</td>
<td>18</td>
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<tr>
<td>7. Lumbar support belt</td>
<td>53</td>
<td>2</td>
</tr>
<tr>
<td>8. Back pain belt</td>
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<td>9</td>
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<td>9. Waistband</td>
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<td>10. 1,2,3,4,5,6,7,8,9, 1990- present</td>
<td>7205</td>
<td>339</td>
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<td>11. Inflate belt</td>
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<td>12. Inflatable belt</td>
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<td>13. Air belt</td>
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<td>14. Air belt conveyor</td>
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5. Summary of clinical data

Table 1 Criteria list of methodological assessment of controlled clinical trials on the abdominal belt.

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<tr>
<th>Criteria</th>
<th>Score</th>
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<td>Internal validity</td>
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<tr>
<td>A Similarity for relevant baseline characteristics</td>
<td>+</td>
</tr>
<tr>
<td>B Randomization procedure adequate</td>
<td>+</td>
</tr>
<tr>
<td>C Loss to follow up &lt;20%</td>
<td>+</td>
</tr>
<tr>
<td>D Other interventions avoided</td>
<td>+</td>
</tr>
<tr>
<td>E Blinded effect measurement</td>
<td>+</td>
</tr>
<tr>
<td>F Intention to treat analysis</td>
<td>+</td>
</tr>
<tr>
<td>External validity</td>
<td></td>
</tr>
<tr>
<td>G Homogeneity</td>
<td>+</td>
</tr>
<tr>
<td>H Adequate control group</td>
<td>+</td>
</tr>
<tr>
<td>I Outcome measures relevant</td>
<td>+</td>
</tr>
<tr>
<td>J Follow up &gt; 3 months</td>
<td>+</td>
</tr>
<tr>
<td>Precision</td>
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<tr>
<td>K &gt;20 subject in smallest group</td>
<td>+</td>
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Table 2 Methodological quality of crucial clinical trials list

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<th>Authors</th>
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<td>Thoumie P et al, 1998</td>
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<td>Miyamoto K et al., 2008</td>
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<td>Jonai H et al., 1997</td>
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<td>Harman EA et al., 1990</td>
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<td>Granata KP et al., 1997</td>
<td>Lumbar posture and motion</td>
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<td>Kato S et al., 2010</td>
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<tr>
<td>Masaki I et al., 2011</td>
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**Table 3: The list of crucial clinical trials using an abdominal belt**
<table>
<thead>
<tr>
<th>Source</th>
<th>Description</th>
<th>Number</th>
<th>Material</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lander JE et al., 1992</td>
<td>Effectiveness of weight-belts</td>
<td>5</td>
<td>weight-belts</td>
<td>These data suggest that a weight-belt aids in supporting the trunk by increasing IAP, and that any differential effect due to wearing a weight-belt did not occur over eight repetitions.</td>
</tr>
<tr>
<td>McGill SM et al., 1990</td>
<td>Trunk-muscle activity and IAP</td>
<td>6</td>
<td>abdominal belt</td>
<td>The case studies with subjects wearing an ergogenic corset designed for use by industrial manual materials handlers, perceptions of improved trunk stability were reported. However, the muscle activity and IAP results of this study during short duration lifting tasks make it difficult to justify the prescription of abdominal belts to workers.</td>
</tr>
<tr>
<td>Granata KP et al., 1997</td>
<td>Biomechanical assessment</td>
<td>15</td>
<td>lifting belt</td>
<td>These results demonstrate that the biomechanical operation of lifting can be influenced by the type of lifting belts used.</td>
</tr>
<tr>
<td>Lavender SA et al., 1995</td>
<td>Trunk motion</td>
<td>16</td>
<td>belts</td>
<td>These results appear to support the use of lifting belts in asymmetric lifting conditions, but more research is needed to determine.</td>
</tr>
<tr>
<td>McGill SM et al., 1994</td>
<td>Passive stiffness</td>
<td>37</td>
<td>belt wearing</td>
<td>Torsos are stiffer in lateral bending and capable of storing greater elastic energy. Regression equations were formulated to define stiffness and energy stored for input to biomechanical models that examine low back function and for bioengineers designing hardware for stabilization and bracing or investigation of traumatic events such as automobile collision</td>
</tr>
<tr>
<td>Sparto PJ et al., 1998</td>
<td>Effect of lifting belts</td>
<td>13</td>
<td>Wearing belt</td>
<td>The results also demonstrate a need for greater study of the consequences on the risk of injury to the other joints. More laboratory experiments and prospective epidemiological studies are needed before a conclusive recommendation could be made in favor of using the belt as a valid preventive measure.</td>
</tr>
<tr>
<td>Thoumie P et al., 1998</td>
<td>Spine posture and</td>
<td>27</td>
<td>Wearing belt</td>
<td>As changes affecting postural</td>
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</table>
parameters (orthostatic or mean values during continuous recording) depend on subject morphometry, individual parameters should be taken in account when evaluating and using a lumbar support.

<table>
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<tr>
<th>Jacek et al., 1999</th>
<th>Spine stability</th>
<th>10</th>
<th>Wearing belt</th>
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<tbody>
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<td></td>
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<td></td>
<td>The results indicate that both wearing an abdominal belt and raised IAP can each independently, or in combination, increase lumbar spine stability. However, the benefits of the belt must be interpreted with caution in the context of the decreased activation of a few trunk extensor muscles.</td>
</tr>
</tbody>
</table>

6. Data Review

6.1 Performance

Previous studies show that the lumbar support belt has benefits to improve lumbar instability, as follows:

Electrogoniometric and radiographic data from lumbar curve angles and motion changes during flexion/extension of the spine were slightly different but reasonably well correlated ($r = 0.58-0.77$). The lumbar support decreased the mean total range of motion of the lumbar spine during a single flexion/extension movement by 17% and during continuous recording by 22%. The lumbar curve angle in the orthostatic position was reduced by 3 degrees and the mean lumbar curve (assessed by continuous recording) was reduced by 4 degrees (mean for 15 subjects). There were major individual changes in these two parameters and the reduction in lumbar curvature was correlated with the initial ($r = 0.66-0.72$). Electrogoniometer data on lumbar motion is reasonably well correlated with X-ray data. The comparative values registered during flexion/extension tests and continuous recording confirm that a support belt slightly limits global lumbar motion. As changes affecting postural parameters (orthostatic or mean values during continuous recording) depend on subject morphometry, individual parameters should be taken into account when evaluating and using a lumbar support. [3]
6.2 Safety and adverse event reporting

Previous studies have evaluated the safety of industrial back belts. A number of studies demonstrate that the belt has a high safety rating for human subjects. In order to evaluate the safety of the abdominal belt, we use the key word “belt” to search the FDA adverse event database. Only one adverse event was found. It describes that the nurse was lifting a patient off the toilet using the sara nova lift. The mast cap (part) detached from the column, which disabled the lift from holding the patient. The patient fell on the nurse's feet. No physical injuries were reported for the patient or the nurse. The FDA report number is 9617021-1999-00007 and this event in not related to the use or wearing of an abdominal belt.

Additionally, we searched the FDA MAUDE using identical strategies. The FDA MAUDE lists adverse events involving the use of medical devices. The data consists of voluntary reports since June 1993, user facility reports since 1991, distributor reports since 1993, and manufacturer reports since August 1996. We used the term “belt” to search the database and retrieved 169 results. Of the 169 search results, there were 13 results actually related to support belts. The others were not related to support belts. There were no serious adverse events in these 13 event results. Therefore the abdominal belt is considered to be safe for usage by human subjects. The 5 adverse events are described below:

1. 11/21/2004, CONTOUR 5000 UNK UNTRACEABLE
   Event report:
   The employer sent the employee out on a delivery. The employer reported that the wearing of the best was mandatory as safety apparatus for employees. The device collapsed on the employee when he/she lifted two cases of antifreeze that were taped together for shipping. The back support belt failed and consequently became loose on the employee. The employer and the manufacturer failed to warn of impending dangers of such device. The employee suffered an injury to his/her lower back at L3-L4 L4-L5 L5-S1 which was deemed as being permanent. [note** medical device was sold via an industrial safety catalog] The employer was aware that the devise was classified as formal safety equipment. Both the employer and the manufacturer failed to warn of the impending danger of this device. The employer and manufacturer failed to label the device as being medical equipment.

2. 11/24/2008, ABDOMINAL STRAP 4425EAO
Event report: It had been discovered during an internal review that some abdominal belts may contain latex. The product labeling may not adequately explain that the part contains latex. FDA has not received any reports of patient injury attributed to allergic reactions. FDA investigation into the reported occurrence is still ongoing. A follow-up report will be issued when the investigation has been completed.

3. 1/15/2003, AB ENERGIZER UNK
Event report: In 2002, a patient used the “Ab Energizer Belt”, with gel, and sustained a burn to their abdomen. One week after initial incident, consumer used the belt, without the gel, sustained a burn to the abdomen. He/she did not seek medical treatment. The patient self treated with "creams that he/she had in the house". The patient's God-child also used the belt and subsequently sustained a burn. The consumer stated that he/she purchased the device after seeing the product being advertised on television for the purpose of weight loss.

4. 6/4/2009, POSEY DELUXE WALKING BELT 6537DX
Event report: The customer reported that the “teeth” on the gait belt buckle was not holding the strap when the belt was secured. It was reported that the strap became loose when used while lifting a patient. No patient injury was reported.

5. 03/11/2013, TECTRON BACK SUPPORT BELT
Event report: The client purchased the back support belt from a consumer shopping store. The consumer opened the package and an odor emitted from it. It was also reported that a water substance was leaking from it. The customer contacted the seller and the seller agreed to send him another one. The patient received the second back support belt in 2013 and a noticeable odor emitted from it as well. The toxic fumes filled the room, which made the patient nauseous. There is a label warning on the device indicating it can cause cancer, birth defects and reproductive harm. The patient was concerned that the device was toxic.

The MHRA (Medicines and Healthcare Products Regulatory Agency) AE database was also searched. The Medicines and Healthcare Products Regulatory Agency also includes the National Institute for Biological Standards and Control (NIBSC) and the Clinical Practice Research Datalink (CPRD). The MHRA search system showed that there were 33 results for belts but most of the reports were about seat belts or wheelchairs. No results were found corresponding with
abdominal belts.

In consideration of the above-mentioned search results, we can conclude with reasonable certainty that there are no significant adverse events found in human subjects and that the safety on the use of abdominal belt is acceptable for human subjects.

6.3 Prevention of back injury and back pain

The National Institute for Occupational Safety and Health (NIOSH) does not recommend the use of back belts to prevent injuries among workers who have never been injured because of insufficient scientific evidence. Instead, the NIOSH encourages efforts to investigate the association between the use of a back belt and prevention of low back injury.

Many studies on the effect of wearing back belts have been conducted, especially in medical settings, but with equivocal results. These studies were mainly concerned with the effect of back belts on the range of motion (ROM), the muscular activity and the intra-abdominal pressure (IAP). Previous studies investigated the effects of medical orthoses (a lumbosacral corset, a chair back brace, and a molded plastic thoracolumbosacral orthoses) and the restriction of gross body motions. They found that all three orthoses restricted at least some gross body motion to approximately two thirds to one half of the no-orthosis values and concluded that gross body motion restrictions relieved lumbar trunk muscle and spine loads. The same authors also studied the effect of these orthoses on the myoelectric signal levels of the erector spinae and oblique abdominal muscles. None of the orthoses were consistently effective in reducing the measured myoelectric activities; in many cases, the signal levels increased when the orthoses were worn.

According to the Labor Standard Bureau of Japan, accidental back injuries accounted for about 60% of all occupational injuries and diseases in the last decade. The Ministry of Labor issued guidelines to prevent low back injuries in 1994 to address the problem. The use of back belts is recommended for some special working conditions but details on its proper use were not given. This study was planned to evaluate a newly developed back belt and was done at an express package delivery company where the incidence of low back injury was high. The BackTracker was
used to evaluate the effect of the back belt on the range and velocity of torso motion. The results indicated that there were no significant differences in the range of motion (ROM) during flexion/extension, lateral bending, and rotation between with and without the belt. The maximum angular velocity (MAV) of flexion decreased significantly (average decrease: 30 +/- 28.3 degrees/sec) when the back belt was worn. The MAV of extension with belt showed a decreasing tendency though not significant. No notable trends were observed in the MAV during lateral bending and rotation of the subjects while wearing and not wearing the belt. The results also indicated that the back belt affected the torso motion of each subject differently. This study suggested that this back belt could be useful for tasks with high velocity of flexion/extension and that proper instruction on the use of the back belt is needed for each worker.

6.4 The increased intra-abdominal pressure
Abdominal belts have been shown to help individuals in generating higher intra-abdominal pressure (IAP) levels during load-handling activities [6, 7, 8, 9]. Intra-abdominal pressure (IAP) has been widely hypothesized to reduce potentially injurious compressive forces on spinal discs during lifting. To investigate the effects of a standard lifting belt on IAP and lifting mechanics, IAP and vertical ground reaction force (GRF) were monitored by computer using a catheter transducer and force platform while nine subjects aged 28.2 +/- 6.6 yr dead-lifted a barbell both with and without a lifting belt at 90% of maximum. Both IAP and GRF rose sharply from the time force was first exerted on the bar until shortly after it left the floor, after which GRF usually plateaued while IAP either plateaued or declined. IAP rose significantly (P less than 0.05) earlier than without the belt. When the belt was worn, IAP rose significantly earlier than did GRF. Both with and without the belt, IAP ended its initial surge significantly earlier than did GRF. Variables significantly greater with rather than without a belt included peak IAP, area under the IAP vs time curve from start of initial IAP surge to lift-off, peak rate of IAP increase after the end of its initial surge, and average IAP from lift-off to life completion. In contrast, average rate of IAP increased during its initial surge was significantly lower with the belt. Correlations are presented which provide additional information about relationships among the variables. Results suggest that the use of a lifting belt increases IAP which may reduce disc compressive force and improve lifting safety.
6.5 Trunk stiffness or reducing its range of motion

Some studies have reported that subjective feelings of increased support may stem from abdominal belts passively increasing trunk stiffness and/or reducing its range of motion \[10, 11, 12, 13, 14\]. Previous studies demonstrate that biomechanical operation of lifting can be influenced by the type of lifting belts used. \[10\] Lifting belts reduced peak trunk angles, velocities and accelerations in the sagittal, lateral and transverse planes. However, only the elastic belt successfully reduced trunk motions in all three dimensions. The orthotic belt significantly increased the lifting moment associated with a given weight. A minor redistribution in muscle activity was observed when wearing an elastic belt. A statistically significant reduction in spinal load was associated with the elastic belt. However, a great deal of variability between subjects was noted. Some subjects experienced increased spinal load while wearing the elastic lifting belt.

Another study shows that reesthe support belt has benefit in torso motion \[11\]. Results indicated that during lifting, lateral bending and twisting motions were reduced by both the lifting belt and foot motion; the most pronounced effect was observed at 90 degrees of asymmetry. Trunk motions in the sagittal plane during lifting were not affected by the lifting belt. These results appear to support the use of lifting belts in asymmetric lifting conditions, but more research is needed to determine whether the muscles in the torso benefit from the reduced motion or are working harder to overcome this resistance to motion, causing increased internal loads on the spine during asymmetric material-handling tasks.

Moreover, an article also describes the stiffness of the lumbar torso when wearing a belt \[12\]. This work investigated the passive bending properties of the intact human torso about its three principal axes of flexion: extension, lateral bending, and axial rotation. Additionally, the effects of wearing an abdominal belt and holding the breath (full inhalation) on trunk stiffness were investigated. The torsos of 22 males and 15 females were subjected to bending movements while "floating" in a frictionless jig with isolated torso bending measured with a magnetic device.

6.6 The effect of spine stability
There are a few studies focusing on spinal stability when wearing an abdominal belt. Jacek et al demonstrates a novel study showing that wearing an abdominal belt increases spine stability. Ten volunteers were placed in a semi-seated position in a jig that restricted hip motion leaving the upper torso free to move in any direction. The determination of lumbar spine stability was accomplished by measuring the instantaneous trunk stiffness in response to a sudden load release. The quick release method was applied in isometric trunk flexion, extension, and lateral bending. Activity of 12 major trunk muscles was monitored with electromyography and the IAP was measured with an intra-gastric pressure transducer. A two-factor repeated measures design was used (P < 0.05), in which the spine stability was evaluated under combinations of the following two factors: belt or no belt and three levels of IAP (0, 40, and 80% of maximum). The belt and raised IAP increased trunk stiffness in all directions, but the results in extension lacked statistical significance. In flexion, trunk stiffness increased by 21% and 42% due to 40% and 80% IAP levels respectively; in lateral bending, trunk stiffness increased by 16% and 30%. The belt added between 9% and 57% to the trunk stiffness depending on the IAP level and the direction of exertion. In all three directions, the EMG activity of all 12 trunk muscles increased significantly due to the elevated IAP. The belt had no effect on the activity of any of the muscles with the exception of the thoracic erector spine in extension and the lumbar erector spinae in flexion, whose activities decreased. The results indicate that both wearing an abdominal belt and raised IAP can each independently, or in combination increase lumbar spine stability. However, the benefits of the belt must be interpreted with caution in the context of the decreased activation of a few trunk extensor muscles.

6.7 Physical function

Previous studies also demonstrate the physical function of abdominal belts. In the study described below, Hilgen et al. (1991) examined the relative effectiveness of an inflatable-bladder-type (air belt) and an elastic-type back belt to reduce estimated spinal forces during lifting. The objectives of the experiment were to measure various physiological and biomechanical parameters from subjects performing manual lifting tasks, and then use the data to estimate the magnitude of spinal loading during a manual lifting task. Five healthy adult males who were experienced in manual lifting performed a sequence of lifting tasks with and without
the back belt. The tasks consisted of lifting a weighted box from the floor to a shelf at knuckle height at a rate of one lift per minute. The weight of the box ranged from 11.5 to 31.5 kg in 5 kg increments. The physiological and biomechanical measures included three-dimensional kinematic data (position, velocity, and acceleration), force platform data (vertical and shear forces at the feet), and EMG data from surface electrodes placed over the right erector spinae and right external oblique abdominal muscles. Joint moments, spinal forces, and impulses were then computed from the measured data using a quasi-static, four-link, biomechanical model developed by one of the authors. Although the data was poorly presented and the statistical results were inconsistently evaluated (in some cases significance was cited when $P < .25$), the authors reported that: (1) there was very little variability between predicted IAP produced among the three belt-use conditions; (2) the no-belt condition yielded the lowest average predicted muscle, compression, and shear forces during the lift; and, (3) the no-belt condition gave the lowest average muscle and compression forces and impulses and the lowest average shear force and impulse in the final phase of the lift. In spite of the reported results, the authors concluded that abdominal belts were of some benefit to the subjects during lifting. The working group concluded that the study presented little evidence that back belts provided any significant reduction in spinal loading.

6.8 inflatable products clinical studies

6.8.1 Disk Dr. back support belt

There is a clinical study for Disk Dr. back support belt, back traction device. This study was carried out at the Department of Orthopaedic Surgery, College of Medicine, Inje University Seoul Paik Hospital by professors Byungjik Kim and Shinwoo Park and their teams. This study examined the performance and the efficacy of Disk Dr. after use by patients with low back pain. The study has evaluated pain levels, radiographic changes and strength of both flexor and extensor at the lumbar vertebrae by using an isokinetic evaluation device. Participants include 22 patients with acute or chronic lumbago; age ranging from 19 to 58 with average age of 44, 8 patients in the age range of 50 to 59 years, 9 men and 13 women, 9 patients with herniated disc, 9 patients with acute lumbago and 4 patients with chronic lumbago. Firstly, Macnab's criteria were used to examine changes of the pain. Secondly, radiographic imaging was used to analyze side views of
the lumbar and sacral vertebrae, comparing with those photographed before wearing Disk Dr., and thirdly, a Cybex 6000 Trunk Extension Flexion (TEF) Unit was used to measure and analyze the muscular strength of the lumbar flexors and extensors[19].

As a result, approximately 80% of the patients reported three (3) “Excellent” and fifteen (15) “Good” among the total of 22 patients. After the application of Disk Dr, we could confirm the fact that there was physical body softness between the segments of the 4th and 5th lumbar vertebrae and the motion of extensor lasted longer.

6.9.2 Disc Disease Solution (DDS) Waist Belt

The Disc Disease Solution (DDS) conducted a clinical trial in Korea. This study was carried out at the Department of Orthopaedic Surgery, College of Medicine, Inje University Seoul Paik Hospital by Professors Byungjik Kim and Shinwoo Park and their teams. The study examined the performance of the efficacy of DDS after use by patients with low back pain have evaluated pain levels, radiographic changes and strength of both lumbar flexor and extensor muscles by using an isokinetic evaluation device. 22 patients with acute or chronic lumbago; age ranging from 19 to 58 with average age of 44, 8 patients in the age range of 50 to 59 years, 9 men and 13 women, 9 patients with herniated disc, 9 patients with acute lumbago and 4 patients with chronic lumbago.

Firstly, Macnab’s criteria were used to examine changes of the pain. Secondly, radiographic imaging was used to analyze side views of the lumbar and sacral vertebrae, comparing with those Trunk Extension Flexion (TEF) Unit was used to measure and analyze muscular strength of the flexor and the extensor at the lumbar vertebrae. Macnab’s criteria were measured as follows: Excellent is a state without pain, without restriction of movement and which would allow the patient to work normally. Good is a state with occasional pain, but which would allow the subject to work normally. Fair indicates slight progress and Poor reflects no progress. The results show that approximately 80% of patients reported favorable results with 3 subjects reporting “Excellent” relief of pain and 15 reporting “Good” relief of pain (out of 22 patients).
It was shown that approximately 80% of subjects reported either Excellent or Good results after 3 days of using the DDS (3 Excellent, 15 Good out of a total of 22 patients). In the radiographic test and isokinetic evaluation, increase in the anterior curvature of the lumbar vertebrae and increased distraction between the fourth and fifth lumbar vertebrae were found. Also, the mobility of extensor muscles were improved. These results were obtained from both the subjective and objective examination of the patients and leads us to believe that use of DDS can play an important and effective role in the treatment of both acute & chronic low back pain patients. [20]

7. Conclusion of Clinical Evaluation

The aforementioned data shows the detail of the DR-HO’S 2-in-1 Back Relief Decompression Belt product. This data includes general information about the product, the product’s function, structure, application to disease and its intended use. The product has several different applications including the treatment of lower back pain attributable to mechanical or degenerative discs, back strain and muscle tension.

A clinical assessment was performed via critical review of the literature available for abdominal belts with respect to the intended uses of the subject device. Based on this extensive review, we believe that the DR-HO’S 2-in-1 Back Relief Decompression Belt is designed and manufactured in such a way that, when used by trained persons under the conditions and for the purpose intended, the product will not compromise the clinical condition(s) and safety of patients, the safety and health of users, or safety and health of other persons.

These studies and reviews, in conjunction with the product risk analyses, demonstrate that the use of this product by medical professionals does not pose any undue risks to patients with respect to a risk benefit analysis at the physician’s discretion. Moreover, with the adverse event database search in FDA MAUDE and MHRA, EMA, there is no serious adverse event appears in similar products. It demonstrates the safety of this product.
In summary, previous studies demonstrate that products similar to that of the DR-HO’S 2-in-1 Back Relief Decompression Belt have significant effects and benefits on conditions such as lower back pain, improved trunk and lumbar spine stability and back muscle functionality. The effects of back injury prevention amongst subjects who have no history of back injury needs to be further determined as some studies concluded no effects in prevention of back injuries. In conclusion, the aforementioned clinical evidence generated from the existing data demonstrate that the DR-HO’S 2-in-1 Back Relief Decompression Belt has a high performance rating for back conditions indicated and reveals high safety and reasonable risk management for human use.

8. Reference


[18] Masaki Ishida1, Andreas Schuster1, Shinichi Takase, Geraint Morton, Amedeo Chiribiri, Boris Bigalke1, Tobias Schaeffter1, Hajime Sakuma2 and Eike Nagel1Impact of an abdominal belt on breathing patterns and scan efficiency in whole-heart coronary magnetic resonance angiography: comparison between the UK and Japan. Ishida et al. Journal of Cardiovascular
Clinical studies for Disk Dr. back support belt, back traction device.

http://www.orthomedical.co.uk/clinical-studies

Professor Byungjik Kim, Professor Shinwoo Park and their team at the Department of Orthopedic Surgery, College of Medicine at Inje University Seoul Paik Hospital reported positive results after conducting a Clinical Study with the DDS 500.

http://www.discdiseasesolutions.com/clinical.html,