Supplement to Chiropractic Economics

# The INDUSTRY COMPENDIUM of CHIROPRACTIC RESEARCH

VOL. 56 NO. 18

#### chiropractic economics



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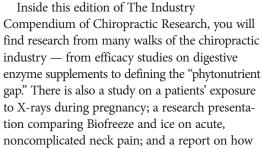
# See a need, fill a need

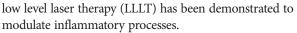
The need for research will always have to be filled

HAT A CONCEPT. The principle of "see a need, fill a need" can drive the creation of many a successful business — and business venture. This can be especially true when it is based on feedback from you and experts in your industry.

When we conduct our surveys, one question we ask is, "What topics would you like to read more about?" The overwhelming majority answer "research" almost every time. And

with each edition of The Industry Compendium of Chiropractic Research, we find there is an ever-growing need and desire for more research.





While research comes in many forms and from many sources, the intent is for you to take what is presented and put it forth in your practice to better your life and the lives of your patients.

In presenting you with this edition of The Industry Compendium of Chiropractic Research, we also hope you can utilize what is presented to enhance the services you provide to all who come through your practice door — no matter who they may be.

While some things are easier to deliver than others, research was one wish we could grant you. You asked for research, and we give you research.

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Wendy Bautista, Editor

## chiropractic economics

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### Update on research and development at Standard Process Inc.

NNOVATION CAN COME FROM A EUREKA! MOMENT OR THROUGH COLLABORATION AND THE EXCHANGE OF IDEAS BETWEEN SCIENTISTS. While shouting "Eureka!" and running down the hall may be cinematic, the real life experience can be years of painstaking research and documentation, followed by more years of the same. Why do scientists do it? Because it's fun. And teasing knowledge out of complexity to increase the body of knowledge that ultimately contributes to health is both rewarding and downright interesting.

To inch the line of knowledge forward, scientists collaborate and share their findings through meetings and publications. To this end, the Discovery Science group within Research and Development at Standard Process has presented their most recent findings in two papers accepted by peer-review journals, and attended one of the premier scientific meetings — Experimental Biology.

## **Experimental biology posters**

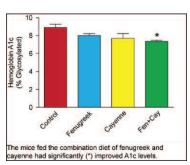
# Combination of fenugreek and cayenne improves glucose handling of a type 2 diabetic mouse model

Paul Hanlon<sup>1</sup>, Bruce Eshelman<sup>2</sup>, William Harriman<sup>2</sup>, and David Barnes<sup>1</sup>

<sup>1</sup>Research & Development, Standard Process Inc.

<sup>2</sup>Dept of Biological Sciences, University of Wisconsin-Whitewater

Fenugreek and cayenne contain bioactive phytochemicals that have both been shown to affect glucose handling.



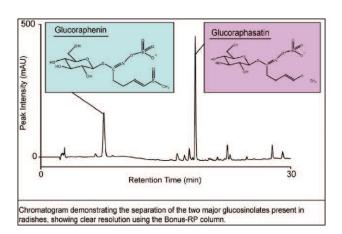
Diabetic mice fed diets containing either fenugreek or cayenne alone did not have significant improvement in comparison with control. However, after four weeks the mice fed the combination of fenugreek and

cayenne demonstrated significantly improved fasting glucose and glycosylated hemoglobin A1c levels, two markers of glucose control.

## Improved prep-scale isolation of glucosinolates from cruciferous vegetables using a novel stationary phase

Chris Scholl, David Barnes, and Paul Hanlon Research & Development, Standard Process Inc.

Phytochemicals known as isothiocyanates (ITCs) have been extensively studied because of links to induction of



detoxification enzymes and reduction in the risk of cancer. ITCs are not present in raw vegetables, but instead are stored in vegetables as another type of phytochemical — glucosinolates (GLS).

When vegetables are ground or chewed the GLS are converted through an enzymatic process into the highly active ITCs. GLS are present in high concentrations in cruciferous vegetables such as broccoli, kale, Brussels sprouts, and radishes; each of these different vegetables tends to have a unique mixture of glucosinolates.

Glucosinolates are measured through chromatography — a method of chemical separation that allows the individual phytochemicals to be identified. The interest in GLS metabolites calls for a fast and efficient prep scale isolation method — a way to separate bioactive compounds on a large scale. Glucoraphasatin is the most common GLS in radishes. The Bonus-RP column significantly improved resolution of glucoraphasatin and glucoraphenin, as well as other GLSs present in broccoli and other cruciferous vegetables. This technique gives us another tool to help us understand the role that individual phytochemicals play in the context of the complex mixture of phytochemicals present in cruciferous vegetables.

# Water soluble extracts from multiple mushroom varieties inhibit activation of Jurkat cells (immortalized T Lymphocytes)

Brandon Metzger, Melissa Robbins, David Barnes, and Paul Hanlon

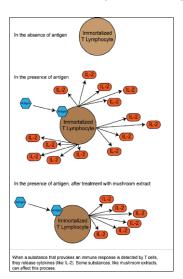
Research & Development, Standard Process Inc.

The human immune system is complex. When the body comes across a substance that provokes an immune response (an antigen), proteins, called cytokines, are released by different types of T cells and regulate the actions of the immune system. T lymphocytes have the ability to recognize and kill

other cells, and thus contribute to immune responses.

Some substances can influence cytokine expression by T lymphocytes. Many mushroom varieties have traditionally been used for the modulation of immune function.

The extracts from six varieties of mushrooms were evaluated for their ability to reduce T lymphocyte activation:



- Coriolus versicolor (turkey tail)
- ► Hericium erinaceus (bearded tooth)
- Ganoderma lucidum (reishi)
- Grifola frondosa (maitake)
- Lentinula edodes (shiitake)
- ► Cordyceps sinensis

The cells were treated with different doses of mushroom extract, and the concentration of interleukin 2 (IL-2) secreted by the cells was

measured after 24 hours. IL-2 is a cytokine that is produced by T cells in response to an immune challenge. This cytokine encourages the activation of T and B cells; and enhances Natural Killer cell activity.

This study found that the hot water extracts from all mushroom varieties reduced IL-2 concentrations in a dose-dependent manner, and that extracts from cordyceps and maitake were the most potent.

### Papers accepted for publication

Accepted by the Journal of Herbs, Spices, and Medicinal Plants: Longitudinal expression of antioxidant phytochemicals in buckwheat (Fagopyrum esculentum Moench)

Brandon Metzger, Melissa Williams, and David Barnes Research & Development, Standard Process Inc.

Buckwheat is a commercial source of rutin and numerous

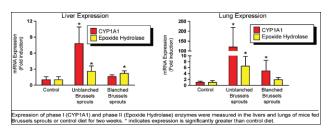


other antioxidant phytochemicals. Rutin levels are known to be the highest during the flowering stage of crop growth, but it is unknown if this is the optimal harvest time for other antioxidant phytochemicals. A longitudinal study of buckwheat was performed in the spring of 2007 to characterize the expression of antioxidant phytochemicals and total antioxidant capacity from vegetative growth through seed development using several different fields and planting cycles. While the optimal harvest time for individual compounds varied, when phytochemical composition and yield were both considered, four to five weeks after sowing was found to be the optimal time to harvest.

# Accepted by the Journal of Food Science: Induction of detoxification enzymes by feeding unblanched Brussels sprouts containing active myrosinase to mice for two weeks

Melissa Robbins¹, Johanna Hauder², Veronika Somoza³, Bruce D. Eshelman⁴, David Barnes¹, and Paul Hanlon¹¹Research and Development, Standard Process Inc. | ²German Research Center for Food Chemistry | ³Research Platform Molecular Food Science, University of Vienna | ⁴University of Wisconsin-Whitewater, Dept of Biological Sciences

In cruciferous vegetables, myrosinase metabolizes the relatively inactive glucosinolates into isothiocyanates and other products which have the ability to increase detoxification enzyme expression. Thus, maintaining myrosinase activity during food preparation may be critical to receiving the maximum benefit of consumption of Brussels sprouts or other cruciferous vegetables.



To test the importance of maintaining myrosinase activity for maximizing bioactivity, experimental diets containing 20 percent unblanched (active myrosinase) or 20 percent blanched (inactivated myrosinase) freeze-dried Brussels sprouts and a nutrient-matched control diet were evaluated for their ability to induce detoxification enzymes in mice.

Exposure to Brussels sprouts with active myrosinase (unblanched Brussels sprouts) resulted in greater induction of both phase I and phase II detoxification enzymes in the liver and the lungs of mice, which correlated with plasma sulforaphane (an isothiocyanate) concentrations.

Understanding the impact of processing on biological activity is critical in terms of retaining (or improving) product quality.

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This research was provided by Standard Process. 800-558-8740 • www.standardprocess.com

### Low level laser therapy: the power and penetration myth

Ryan Maloney, PhD

HE UNDERSTANDING OF HOW THE HUMAN BODY FUNCTIONS IN CONJUNCTION WITH LOW LEVEL LASER THERAPY (LLLT, 3LT, cold laser) is an advancing paradigm in modern wellness approaches. These transformative changes are encouraging a clearer understanding of the mechanism of how each new invention affects each system.

3LT is not excluded from the advancing medical technology that requires continual scientific evidence of the mechanism before we can thoroughly comprehend the magnitude of the neurological and physiological changes taking place. Nevertheless, 3LT is one of the few devices that have published, peer-reviewed double blinded controlled studies dating back more than 20 years and many "clinicians and researchers are unaware of the extensive research that has been done in field of biophysics, bionics, photobiology and quantum biology during the past 80 years"1 that aid in clarity of the mechanism of laser applications.

The first milestone made in the United States for 3LT was a FDA approval in 2002. With this approval came a new classification of therapeutic devices, referred to as NHN,2 which is a category for nonheating modalities for adjunctive use in pain therapy commonly known as biostimulation, which we will address later. The first market clearance (510k approval) was issued for the treatment of neck and shoulder pain. Since this accomplishment, the FDA has issued 510(k) clearances in the NHN category for the treatment of carpal tunnel and post surgical pain based on clinical data and cellular/molecular research.

Unfortunately, other laser companies have not adhered to such standards of their therapeutic devices and have filed what is referred to as "substantial equivalence" against a laser previously granted market clearance by acceptable completion of clinical trial data. A "substantial equivalence" submission to the FDA is authored by the company or a representative of the company that is intending to obtain market clearance without conducting clinical trials.

The substantial equivalence document shows the device attempting to obtain market clearance being compared against a device that already has been awarded market clearance by comparison of features and components. The company submitting a substantial equivalence document, using the features and components comparison as a catalyst, then authors a narrative explaining why the device they are vying for fits in the same category of therapeutic applications of the laser or laser(s) being compared to.

Laser classification is a regulated feature of a laser device and is a component of comparison in a substantial equivalence submission.

As recently quoted in Tunér and Hodes's article "Confounders and magicians,"3 classification of laser devices are determined by "the possible risk for eye injuries and has nothing to do with the efficiency in treatment ... The classification is not only a question of output power; it has to do with wavelength, divergence of the beam, emission area, pulsing, etc." The FDA approval process is extremely complex; this brief explanation is simply a highlight of the proceedings of receiving a laser approval and also to show that the considerations of the approval are independent of the advertising and marketing that follow.

The most recent flux of laser advertising has led to a great deal of confusion pertaining to the field. Much of this confusion about the use of therapeutic lasers stems from attempting to look at laser effects from a Newtonian mechanistic perspective that has now been supplanted by nonlinear dynamics and quantum physics. Oftentimes, we assume things natural from current knowledge to fit within a paradigm of healing. If this was the only approach, new and innovative applications would never be developed.

The latest trend in the development and what is commonly mistaken for proper applications of low level laser therapy, are the influx in approvals for topical heating devices (ILY).4 These devices have an associated low level laser component, with the removal of the collecting lens from a high powered laser, but are not low level lasers. The problem is that when you remove the collecting lens out of configuration it ceases to be a focused laser. This in essence is now just a concentrated heat lamp, which gleans to the understanding of why market clearance was so easily obtainable.

By far one the most difficult concepts of laser is the energy density or fluency, this component is what in large part relates to a nonlinear approach to understanding the applications. In the market place, it is the focal point of sales in the approach that depth of penetration is somehow related to this component.

Let's look at common myths in laser therapy pertaining to power and how it correlates to penetration. Several articles have claimed, in this publication and other journals, that you need

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### Effects of Biofreeze vs. ice on acute, noncomplicated neck pain

Barton Bishop, DPT; Jay Greenstein, DC, CCSP; Bob Topp, PhD, RN

BART BISHOP, DPT, OF SPORT AND SPINE REHAB IN ROCKVILLE, MD., COMPARED BIOFREEZE TOPICAL ANALGESIC AND ICE APPLICATION to patients with bilateral neck pain. Bishop stated, "We've used both ice and Biofreeze on our neck patients, but never had any evidence to support using one versus the other."

He found that both modalities reduced pain significantly, but patients preferred the Biofreeze application 8-to-1 compared to ice. The Biofreeze treatment lasted longer in nine out of 10 patients, with twice as much pain reduction compared to ice.

"Now that we know how effective Biofreeze is, we are going to continue including it as a standard treatment for neck pain patients and start investigating its effectiveness in other patient populations. We also think that using Biofreeze can help improve patient compliance and retention as so many more of them felt comfortable with the treatment."

Bishop presented his findings at the TRAC 2009 meeting in Cancun, Mexico.

**Methods:** Fifty-one males and females between the ages of 19 and 65 (37 +/-11.2 years) with bilateral nonradicular, acute neck pain (myalgia) were given both ice and the topical analgesic Biofreeze on each side of the neck. The patients had no history of surgery in the neck nor had they received a cortisone injection in the neck in the last year.

The study was randomized so that

the ice was on the left side of the neck and Biofreeze Pain Reliever was on the right side or vice versa. Thus, both sides of the neck had one cryotherapy modality. The patients were asked to rate their pain on a zero-to-10 visual analog scale (VAS) for each side of the neck both before and immediately following the 10-minute treatment.

In addition, the patients were asked to answer two questions about which modality they would use in the future for pain control and the level of comfort of each modality during its application on a five-point scale (1 = very unlikely or very uncomfortable and 5 = very likely or very comfortable).

Finally, the patients were asked the following day to pick whether they preferred ice or Biofreeze and to pick which modality had a longer lasting effect. **Results:** Overall, when asked to rate the comfort and preference, patients preferred Biofreeze 8-to-1 (p=0.000). The average score on the five-point Likert scale was 4.20 for Biofreeze and 2.57 for ice.

In addition, nine out of 10 subjects reported that Biofreeze lasted longer (p=0.000). Further, the average score on the five-point Likert scale was 4.47 to 2.63 for Biofreeze and ice, respectively. For actual levels of pain change, the average pretreatment VAS score went from 6.24 to 3.65 for Biofreeze and from 6.31 to 5.00 for ice.

A paired t-test demonstrated that both ice and Biofreeze had a signifi-

cant reduction on pain levels (p = 0.000); however, there was nearly two times the reduction of pain on the Biofreeze side.

**Conclusions:** Both ice and Biofreeze significantly decreased pain levels; however, Biofreeze decreased pain nearly two times as much as ice.

In addition, it was rated as substantially more comfortable, patients preferred it, and it lasted longer nine out of 10 times. This is the first study to evaluate solely the immediate effects of two different cyrotherapy methods and as such it is not unexpected that the results of this study would differ slightly from other published studies evaluating menthol products.

Conservative care specialists are often looking for methods to improve patient satisfaction and compliance and with the results significantly favoring Biofreeze this is recommended as the primary method of cryotherapy application on the first visit.

Future considerations: More studies are needed to determine whether this short-term effect can be extrapolated to long-term improvement in outcomes, improved patient satisfaction and improved patient compliance. 

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# The effect of applied spinal manipulation force vector on resultant vertebral accelerations: an in vivo animal model

Christopher J. Colloca, DC1; Victor Kosmopoulos, PhD2; Robert Gunzburg, MD, PhD3; Robert J. Moore, PhD4

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#### Abstract

**Introduction:** In the performance of spinal manipulative therapy (SMT) and/or chiropractic adjustment it is theorized that the application of force should be in a specific angle to maximize efficiency of the therapeutic intervention. Recent research in an in situ porcine model found that SMT force vectors that were perpendicular to the spine maximized vertebral accelerations as opposed to directing forces vectored at 30 degrees cephalad or caudal.

The purpose of the current study was to determine the effect of varying SMT applied angle on vertebral accelerations in an in vivo ovine model.

**Methods:** Twelve healthy, young Merino sheep (mean 24 kilograms, s/d/ 3 kilograms) were examined using a protocol approved by the Institutional Animal Ethics Committee of the Institute for Medical and Veterinary Science in Adelaide, Australia. Prior to testing, anesthesia was induced with an intravenous injection of 1 gram thiopentone and was maintained after endotracheal intubation by 2.5 percent halothane.

Throughout testing the animals were ventilated and the respiration rate was linked to the tidal volume keeping the monitored C02 between 40 to 60 mmHg.

To quantify the dynamic, vibration response of the spine 10-g piezoelectric, tri-axial accelerometers were attached to intraosseous pins rigidly fixed to the L2 and L4 spinous processes under fluoroscopic guidance (Figure 1). The X-, Y- and Z-axes of the accelerometers were oriented with respect to the medial-lateral (ML), dorsoventral (DV), and cranial-caudal or axial (AX) axes of the vertebrae. Only AX acceleration responses are reported herein.

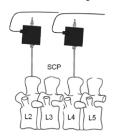


Figure 1. High frequency tri-axial accelerometers were rigidly attached to stainless steel pins inserted into the L2 and L4 spinous processes to quantify the vertebral accelerations during the chiropractic thrusts.

SMT was applied to the L3 spinous process using a handheld Impulse Adjusting Instrument equipped with an impedance head (load cell and accelerometer). In each trial, 13 SMTs (~200 N peak force) were applied over 2.5 seconds (~6 Hz) at input force vectors of 90 degrees (z-axis), 60 degrees (cephalad), and 120 degrees (caudal) in a randomly determined order (Figure 2). A protractor held over the right sided transverse processes was used to determine the input SMT force vectors.



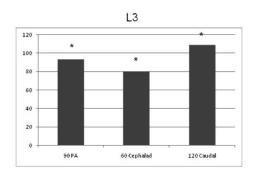




**Figure 2.** Three input force vectors were examined (A) 60 degrees (cephalad), (B) 90 degrees (posteroanterior), and (C) 120 degrees (caudal) to investigate the effect of chiropractic line of drive on spinal motion responses.

Three trials were conducted for each applied force vector in each animal using repeated measures design. During the SMTs, vertebral accelerations at L2 and L4 were recorded at a sampling frequency of 5000 Hz using a 16-bit data acquisition system. Peak-peak acceleration responses at L2, L4, and L2-L4 were computed for each trial. A one-way analysis of variance (ANOVA) compared the mean acceleration responses between the three applied force vectors. Statistical significance was p<.05.

**Results:** Significantly increased peak-to-peak accelerations were observed for caudal (120 degree) vectored thrusts at the segmental contact point (L3) (Figure 3).



**Figure 3.** L3 vertebral accelerations (m/s2) for 90 degree PA, 60 degree cephalad, and 120 degree caudal vectored SMTs (\*p<.01).

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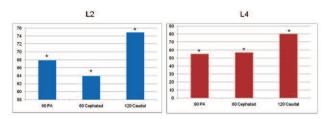
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#### **RESEARCH**COMPENDIUM

A significant increase in mean L2, L4, and L2-L4 vertebral accelerations were also observed for all SMTs directed at 120 degrees (p<.01). For SMTs directed at a cephalad force vector (60 degrees), mean L2 vertebral accelerations were significantly greater than L4 vertebral accelerations (p<.01), and conversely, for caudally directed thrusts (120 degrees) L4 vertebral accelerations were significantly greater than accelerations observed at L2 (p<.01). SMTs applied perpendicularly to the spine at 90 degrees caused larger vertebral accelerations at L2 compared to SMTs directed cephalad (60 degrees), however, L4 accelerations were significantly greater for SMTs directed cephalad compared to those delivered at 90 degrees (p<.01) (Figure 4).



**Figure 4.** L2 and L4 adjacent segment vertebral accelerations (m/s2) for 90 degree PA, 60 degree cephalad, and 120 degree caudal vectored SMTs (\*p<.01).

**Conclusions:** The applied force vector at which SMT is delivered has a significant effect upon the segmental contact point and adjacent segment vertebral accelerations. Enhancing vertebral motions by selecting an appropriate force vector is an important biomechanical consideration for clinicians whom are attempting to improve intersegmental mobility during spinal manipulative treatments.

**Discussion:** Chiropractic technique classes throughout the world's chiropractic colleges emphasize the importance of doctor line of drive. In the current study, we examined this issue using a validated gold-standard technique for quantify-

ing vertebral motions.

We hypothesized, that superior vectored thrusts (cephalad) would result in larger magnitude vertebral accelerations when compared to those thrusts delivered straight PA as we have previously observed in humans. However, the facet angulations of the ovine spine (figure 5) may have had an influence in our findings that 120 degree (caudal) directed thrusts produced the largest magnitude vertebral accelerations.

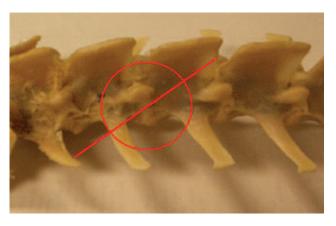


Figure 5. Facet angulation of the ovine spine.

Because improving or restoring spinal mobility is a fundamental goal of spinal manipulation and chiropractic adjustments, research into techniques best suited to maximize vertebral motions are of interest to clinicians and form the basis for this and future work.

\*This study was presented, in part, at the 2009 European Chiropractors' Union Convention, Alghero, Sardinia, Italy, May 21-23, 2009.

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This research was provided by Neuromechanical Innovations. 888-294-4750 • www.neuromechanical.com



### Foot Levelers' Stabilizers improve pedal alignment

Kuhn DR, Shibley NJ, Austin WM, Yochum TR

#### **Abstract**

**Objective:** To determine whether any positive change in the alignment of the bones of the feet occur with the use of Foot Levelers custom-made flexible orthotics, cast by weight bearing, in individuals having flexible pes planus. **Methods:** Anteroposterior and lateral radiographs were obtained with and

without orthotics in place. The anteroposterior and lateral talocalcaneal angles and the lateral pitch of both the left and right foot were assessed.

**Results:** The radiographic measurements indicated statistically significant improvements in weight-bearing foot alignment with the use of Foot Levelers orthotics.

**Discussion:** Biomechanical faults in the pedal foundation can adversely affect any of the joints and structures of the foot/ankle complex, lower extremities, pelvis, and spine.

**Conclusion:** This study supports the use of Foot Levelers custom-made flexible orthotics for the improvement of pedal structural alignment. 

•

### Foot Levelers' Stabilizers decrease Q-angle

Kuhn DR, Yochum TR, Cherry AR, Rodgers SS, Nosco DL

#### Abstract

**Objective:** To evaluate the effects of full-length, custom-made flexible orthotics (Spinal Pelvic Stabilizers) on quadriceps angle (Q-angle) in volunteers with bilateral foot hyperpronation.

**Methods:** Forty chiropractic student volunteers were selected. Inclusion criteria were asymptomatic, male, evidence of bilateral hyperpronation, and no history of ankle surgery. Custom-made,

flexible orthotics were produced. Subjects' Q-angles were measured before and after orthotic insertion. **Results:** Orthotic insertion demonstrated reduced Q-angle, in the direction of correction, in 39/40 test subjects. **Discussion:** Research suggests that the hyperpronated foot is an etiologic factor in many lower extremity complaints, including foot, knee, hip, and low back pain. Literature indicates that custom-

made, flexible orthotics can stabilize the pes planus foot and restore optimal degree of pronation. Reduced pronation decreases the amount of tibial and femoral internal rotation, with subsequent Q-angle reduction.

**Conclusion:** Full-length, flexible orthotics significantly improve the Qangle in hyperpronating male patients and offer the possibility of long-term benefits.

### Foot Levelers' Navicular Drop measurements accurate

Kuhn, DR, Bennett N, Carpenter J, Eldridge A, Nosco DL

**Objective:** To determine the validity of Brody's Navicular Drop Test (NDT), recorded using Foot Levelers' Postural Stability Indicator (PSI) card, by correlating the change in the vertical height of the navicular bone in weightbearing and nonweightbearing positions.

**Methods:** Fifty-two volunteer subjects had their navicular positions documented using the PSI card system. Those values were then compared to "the more accurate values produced by radiography." **Results:** Of the 52 subjects measured radiographically, three showed an

increase in navicular height, three demonstrated no change, and 46 demonstrated a decrease in height from nonweightbearing to weightbearing positioning.

**Discussion:** Proper identification and application of orthotic intervention in patients with pes planus could prevent injury and improve performance within the kinetic chain of the spine and pelvis. In 1997, Foot Levelers announced the creation of the PSI, a simple, calibrated card to help chiropractors identify their patients' risk

factor for pronation.

**Conclusion:** The report determined that the ability of the NDT to reflect navicular position accurately was verified by comparison to the currently accepted procedure, X-ray analysis. Foot Levelers' PSI card is a simple, reliable test for navicular position. •

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#### RESEARCHCOMPENDIUM

# Gastric stable emulsions provide increased bioavailability of long chain $\omega$ -3 fatty acids

T Seternes<sup>1</sup>, IJ Haug<sup>2</sup>, D Zeiss<sup>3</sup>, LB Sagmo<sup>3</sup>, IC Olsen<sup>4</sup>, KI Draget<sup>2</sup>

#### **Objective**

The present study comprises the design of, as well as the effect of, pre-emulsification of  $\omega$ -3 fatty acids on the bioavailability of docosahexaenoic acid and eicosapentaenoic acid.

In vitro studies have shown that long-term steric stabilization of an o/w-emulsion is obtained by arresting the oil droplets in a gelatin continuous gel matrix. The emulsion was also stable upon dissolution of the gel matrix at physiological conditions in vitro and is hence referred to as a gastric stable emulsion (GSE).

#### **Procedure**

In the bioavailability study, healthy young students were recruited and presented two different single-dose treatments of fish oil containing 5 grams of ω-3 fatty acids; one group receiving the

fatty acids in traditional soft gel capsules, whereas the other group received the fatty acids using the GSE technology.

Time resolved (two to 26 hours) blood plasma analysis after intake of this single dose  $\omega$ -3 fatty acids revealed significantly increased AUC0-26h and Cmax of EPA (45 percent and 100 percent, respectively) and EPA + DHA (43 percent and 106 percent, respectively) when administered as GSE compared to traditional soft gel capsules.

#### Results

In vitro results indicated that the fish oil presented in soft gel capsules may not have been as effectively emulsified in the stomach compared to fish oil in a GSE formulation, which in turn would have led to a reduced conversion rate (per unit time) of the pancreatic lipases.

#### **Conclusion**

The overall conclusion hence becomes that  $\omega$ -3 fatty acids, such as docosahexaenoic acid and eicosapentaenoic acid, will exhibit improved bioavailability and absorption in blood plasma by being pre-emulsified into an acid stable emulsion prior to oral ingestion.  $\bigcirc$ 

#### REFERENCES

<sup>1</sup>Ayanda AS, TROMSØ, Norway

<sup>2</sup>Department of Biotechnology, Norwegian University of Science and Technology, Trondheim, Norway

<sup>3</sup>Faculty of Health Sciences, Nord-Trøndelag University College, Namsos, Norway, Namsos, Norway

<sup>4</sup>Smerud Medical Research International AS, Oslo, Norway

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### The influence of lactic acid bacteria (OM-X) on bone structure

Masayuki Kawakami, Naohiko Araki, Koji Inokihara, and Takashi Matsubara of the College of Liberal Arts and Science, Kurashiki University of Science and the Arts; Lichiroh Ohhira of the Research Institution of Okayama Life Science; and Hideto Iwasaki of Sanyo Gakuen University

#### **Abstract**

We studied the effect of taking a lactic acid bacteria product (OM-X) on the bone structure. The subjects are 157 males and females, ages from 20 to 70 years. The bone density and bone mineral content measurements were taken on the radial and ulna on upper arm of the opposite side of each subject's handedness. The main results are as follows:

1. For both men and women, the bone mineral content showed higher in the groups taking OM-X than the groups without OM-X (p<0.05). In comparison with others their age, the groups older than 40 had lower bone mineral content than the groups younger than 40 (p<0.05).

2. For both men and women, the bone density in the groups taking OM-X was higher than in the groups without OM-X (p<0.05). In comparison with their age, groups older than 40 had lower bone density than the groups younger than 40 (p<0.05).

In conclusion, it appears that lactic acid bacteria OM-X promotes the bone health. We assume it affects enterobacteria in the intestine, improving absorption.

#### Introduction

For many years of history, eating traditional fermented foods with lactic acid bacteria produced intestine balancing benefits to humans.<sup>3,14,29</sup> These traditionally successful foods still exist in modern civilization, along with various kinds of additional foods that may or may not be healthier.<sup>11,12</sup> Recent changes in dietary habits could affect human biological function in many ways, including the increased risk of malignant tumor and other disorders

in tissue metabolism.30,33

An example is the decline of immunity and resistance to infection.<sup>22,33</sup> Also, for young people in their growth stage, changes in diet may give rise to changes to physical function.<sup>2,18</sup> While the growth rate on young people is increased by the improvement of diet and other changes in environment, full development of a healthy body may be compromised.<sup>23</sup> Specifically, regarding bone structure, physical growth and bone structure may not be matched, causing various bone problems.

This can be seen not only in young people, but also in children. There is certainly an increased risk of bone fracture in the everyday life of people of advanced age. The issue discussed in this article is the connection of bone problems to lactic acid bacteria in the gut and its effect on people of all ages. 16,17,21,22 We aim to bring attention to the fact that lactic acid bacteria in the gut affect, this aspect of our biological functioning.

We are all aware that the food we eat is first digested in the stomach and small intestine before being absorbed. However, in addition to the activity of the body's digestive processes, enterobacterial activity is involved. This introduces the possibility that imbalances in the bacterial environment of the intestine can cause a decline in nutrient absorption.

The food processing technology that modern culture has brought to our lives also brings to our body several food additives and chemicals preservatives that affect basic the machinery of life.<sup>28,29</sup> Food additives influence enterobacteria as well, and have a tendency to suppress or inhibit enterobacterial activity in digestion and

absorption.<sup>26,28,33</sup> We have previously reported that intake of lactic acid bacteria increases the volume of hemoglobin in red corpuscles.<sup>11</sup> Many researchers have reported other influences of lactic acid bacteria on human function.<sup>7,8</sup>

In this study, we focused on the effect of lactic acid bacteria supplementation on bone health and the possible connection to osteoporosis, that substantial failure of bone structure that is often related to poor lifestyle choices. Osteoporosis affects not only athletes and post-menopausal women but also in rare instances even young people.<sup>32,33</sup> With this in mind, we designed an experiment to find the influences on bone structure of supplementing with lactic acid bacteria. We found that the degree of the influence differs by age and sex.

The strain of lactic acid bacteria we used in this experiment is referred to as OM-X, a vegetable fermented substance containing relatively low amount of lipid. We used an encapsulated form since lactic acid bacteria are susceptible to destruction by stomach acid. The complete ingredient list of OM-X is shown at the end of the references along with the U.S. commercial source.

#### Methods

**A. Subjects.** The subjects were 157 males and females. There were 77 males who took no lactic acid bacteria (age years  $26.2 \pm 6.8$ , referred to as group A) and 27 males took lactic acid

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# The first quantitative evidence proving the efficacy of supplemental enzymes

National Enzyme Company, Forsyth, Mo.; TNO Nutrition and Food Research, Zeist, Netherlands

**Background:** The underlying premise for taking a digestive enzyme supplement is the capacity for better nutrient absorption through enhanced digestion. National Enzyme Company has been advocating this application for more than 70 years.

Throughout these years, we have collected a plethora of anecdotal and qualitative information backing the use of digestive enzymes. While we were convinced of the efficacy of fungal digestive enzymes, we have been lacking the quantitative information that would prove the same under disinterested scientific scrutiny.

To achieve this goal, we embarked on a collaborative effort with TNO of the Netherlands to prove the efficacy of supplemental, fungal digestive enzymes for the digestion of food and absorption of nutrients.

The Netherlands Organisation for Applied Scientific Research TNO (TNO Nutrition and Food Research) based in Zeist, Netherlands, is a reputable scientific organization whose mission is to be a link of knowledge between fundamental research and its applications to food, drugs, and agrochemicals. To quantify the efficacy of supplemental enzymes, TNO proposed a series of experiments using a computer controlled dynamic gastrointestinal model (TIM).

TIM is a unique patented technology, developed by TNO, which simulates the conditions of the human stomach and the small intestine. Using this technology, we accurately replicated the dynamic environment of the human stomach and the small intestine when food is being digested and absorbed. The stellar feature of this

system is that it allowed for sampling at various times during the digestive process, which enabled us to gather information in real time about the extent of digestion and absorption of food under various conditions.

The protocols for TIM have been validated. The various studies that have been performed using TIM are well documented in literature.

The first step in this project was the formulation of a digestive enzyme blend that was generic, yet also effective. To this end, NEC formulators created a blend of fungal digestive enzymes that is the basis of all our digestive enzyme products.

In other words, we chose a basic blend of proteases, carbohydrases, and lipases. This blend was tested under two sets of conditions to observe digestibility and absorption of nutrients. The two conditions were perfect human digestion and impaired human digestion.

The TIM system was fed a meal (standard FDA type) with and without NEC digestive enzymes. The extent of digestion was monitored by sampling nutrients (glucose and nitrogen) at various times and at different points in the GI tract.

Study protocol and test conditions: The study was performed in TNO's dynamic, multicompartmental system of the stomach and small intestine (TIM). The model simulated very closely the successive dynamic conditions in the stomach and small intestine of healthy human adults with normal gastric and intestinal secretions and of human adults with impaired digestion due to lower levels of gastric and intestinal secretions.

In other words, a perfect digestive

system and an extremely impaired digestive system were chosen as test conditions. The two extremes were tested because the digestive capabilities of most humans fall somewhere in between. For each TIM run, 170 grams of the standardized FDA-type of test meal (proteins, carbohydrates, and fats) were mixed with 100 milliliters drinking water and 70 milliliters artificial saliva.

Four different types of TIM experiments were performed in duplicate with this meal as follows:

- (a) Meal without the digestive enzyme blend under perfect digestive conditions,
- (b) Meal with addition of digestive enzyme blend under perfect digestive conditions,
- (c) Meal without the digestive enzyme blend less than 70 percent reduced gastric and intestinal secretion (impaired digestion), and
- (d) Meal with addition of digestive enzyme blend less than 70 percent reduced gastric and intestinal secretion (impaired digestion).

The secretion products of the human digestive system consisting of gastric juice with enzymes, pancreatin, bile, and bicarbonate were added to the system at the appropriate times.

The pH was monitored and maintained at physiological conditions and peristalsis was mechanically simulated. The gastric emptying and intestinal passage time were mimicked as per human conditions.

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# Applying Nutrigenomics to help reduce pain and cartilage degradation while enhancing mobility

Mark Kaye, DC, director of clinical services, Metagenics Inc.

#### Introduction

Nutrigenomic research has yielded the discovery of phytocompounds derived from Humulus lupulus (hops) and berberine with a high degree of predicted safety that may help reduce overexpression of specific matrix metalloproteinases (MMPs) associated with degenerative joint pathologies. MMPs play a key role in the breakdown of collagens that compose the tendons, ligaments, cartilage, and other tissues collectively called the extracellular matrix (ECM).1-17 These novel phytocompounds have been shown to selectively inhibit inflammatory mediators that foster greater production of specific MMPs that lead to cartilage and collagen degradation.

#### **Collagen degradation**

The ECM is the mesh-like extracellular milieu that distinguishes animal tissue and provides support and anchorage for cells. This dynamic structure — composed of collagen, elastin, chondrocytes, osteoblasts, and more — allows for the body's ability to adapt to gross structural and physiological stressors, such as mechanical loading. The ECM also plays a key role in regulating intercellular communication, and is responsible for the circulation of nutrients and the removal of cellular waste products. 12

ECM proteins are regulated by a family of more than 20 zinc-binding MMPs that are further subdivided into groups (e.g., gelatenases, collagenases, stromelysins).<sup>11-13,16-18</sup> MMPs are key in the normal turnover activities in ECM components — and are also networked to inflammatory and immune processes.<sup>11,13,15,18,19</sup> In lower concentration, MMPs are beneficial to normal growth, tissue repair, and

reproduction. <sup>11-13,15,17,18</sup> But in higher concentration, MMPs have been implicated in numerous degenerative pathologies. <sup>10-15,20-21</sup> Elevated MMP expression has also been associated with tendon pathologies (acute tendon injuries, tendonitis, torn rotator cuffs), degenerative discs, and sites of repeated injury or mechanical strain. <sup>22-26</sup>

MMP-13, sometimes referred to as collagenase-3, exhibits high activity against type II collagen, the primary collagen found in cartilage, and has been expressed in pathologies associated with excessive ECM degradation. 12,13,15,17,27 (MMP-13 also degrades types I, III, IV, X, and XIV collagen, along with aggrecan core protein.)12,13 MMP-13 also plays a role in activation of MMP-2 (gelatinase-A) and MMP-9 (gelatinase-B), which can degrade basement membrane components and are thought to play an important role in final collagen degradation following MMP-13-mediated damage. 13,15,18

MMPs are produced by structural cells (fibroblasts, endothelial/epithelial cells) and inflammatory cells (macrophages, lymphocytes, neutrophils, eosinophils). <sup>15</sup> The following mediators are pivotal in the regulation of MMP production, expression, and activity:

- Proinflammatory cytokines, such as tumor necrosis factor-a (TNF-α), interleukin-6 (IL-6), oncostatin M (OSM), and interleukin-1β (IL-1β).<sup>12,18,19,27-31</sup>
- ►Oxidative stress and reactive oxygen species (ROS), such as hydrogen peroxide.<sup>7,9,15,16,32-33</sup>
- Transcription factors, such as nuclear factor-κB (NF-κB), activator protein-1 (AP-1), and runt-related transcription factor 2 (RUNX-2).<sup>15,18,19,27,30-31,34-35</sup>
- ► Mitogen-transducing signal proteins,

- including protein kinase C (PKC).<sup>15,16,18,31</sup>
- ▶ Protein kinase B (PKB/Akt) and protein kinase A (PKA).¹8
- ► Mitogen-activated protein kinase (MAPK) pathways, including p38 MAPK, the Jun kinase pathway (JNK), and the extracellular signal-regulated kinases 1 and 2 pathway (ERK 1/2).<sup>13,15,16,18,27,34-35</sup>
- ▶ Phosphatidylinositol 3-kinase signaling pathway (PI3K/Akt). 18,19,29
- ►Poly (ADP-ribose) polymerase (PARP).<sup>36-38</sup>
- ► Cyclooxygenase-2 (COX-2) and prostaglandins (PGE2). 18,34
- ► Elevated homocysteine. 16,32,39

Additionally, MMPs are capable of inducing expression of other MMPs (e.g., MMP-13 can activate MMP-2 and vice versa) and have the ability to produce or modulate precursors to proinflammatory cytokines and transcription factors, thereby contributing to inflammation and further MMP expression.17 Inhibition of signaling pathways, transcription factors, and associated cytokines has therefore been suggested in a growing amount of scientific evidence as a therapeutic approach to conditions associated with MMP overexpression. 6-8,10-13,17-18,21,23-25,29-30,37-38,40-42

#### Natural agents for downregulating MMP enzymes

The following nutrients and derivatives have been shown to support inhibition of collagen-damaging expression of MMPs:

THIAA. In an extensive screen for kinase activity at the MetaProteomics LLC Nutrigenomics Research Center — the proteomics research facility of Metagenics Inc. — THIAA (tetrahydro isoalpha acids derived from hops),

favorably modulated PKC beta and gamma, two important kinases involved in cell inflammatory processes.<sup>1</sup>

Berberine. This plant alkaloid has a long history of use in Ayurvedic and traditional Chinese medicine, as well as in a variety of applications in modern clinical use.  $^{3,5-9,43-44}$  Berberine has been shown to down-regulate the activity of MMP-1 (which also acts against type II collagen and activates MMP-2) and MMP-9, as well as modulating the expression or activity associated with ROS, IL-1 $\beta$ , IL-6, NF- $\kappa$ B, AP-1, TNF- $\alpha$ , and kinase pathways.  $^{4-9}$ 

Selenium. This essential trace element provides defense against ROS and inflammation, and has also been shown to reduce MMP-2 and MMP-9 expression through modulation of ROS and NF- $\kappa$ B, as well as through possible interference with the p38 MAPK pathway. <sup>44-46</sup>

Zinc. Zinc supplementation may be effective in reducing spontaneous cytokine release and inflammatory activity, as well as support rather than suppress immune response. <sup>47-48</sup> In a recent study, an increase in circulating zinc (among subjects who started with low or borderline-normal levels) favorably modulated IL-6 and monocyte chemotactic protein-1 activity (MCP-1, a marker associated with inflammation), as well as natural killer cell activity. <sup>48</sup>

Biotin. Status of this vitamin may play a role in inflammatory disease. A deficiency in biotin has been suggested to up-regulate TNF- $\alpha$  production.<sup>49</sup> One clinical study suggests that biotin supplementation modulates IL-1 $\beta$  and IL-2 expression.<sup>50</sup>

Niacinamide. Niacinamide has been shown to modulate expression of PARP [Poly (ADP-ribose) polymerase, a protein involved in DNA repair and cellular apoptosis] with a corresponding decrease in activity of transcription factors and cytokines.  $^{36-38}$  An in vitro study demonstrated the effectiveness of niacinamide in inhibiting IL- $1\beta$ -induced cartilage degeneration.  $^{51}$ 

Folic acid and vitamins B6 and B12. Folic acid, alone or in combination with vitamins B6 and B12, has been shown to reduce elevated homocysteine levels, associated with inflammatory conditions and the disturbance of collagen synthesis. 15-16,39,41,52-54 In a sixweek clinical trial with folic acid supplementation, subjects whose elevated homocysteine levels normalized also had a significant reduction in MMP-9 levels. 41 Some evidence suggests that homocysteine triggers the ERK 1/2 pathway that regulates MMP-9 expression. 16

#### **Nutrigenomic and clinical research**

Cell studies conducted by MetaProteomics LLC indicated that a combination formula containing a 1:1 ratio of THIAA to berberine plus biotin, folic acid, niacinamide, selenium, zinc, and vitamins B6 and B12 may support the ECM by reducing TNF-α- and IL-1β-induced expression of MMP-13, one of the main MMPs found in cartilage.<sup>2</sup>

Additionally, the Functional Medicine Research Center — the clinical research arm of Metagenics — measured the efficacy of this combination formula in a small, open-label, case study series that was conducted with offsite practitioners who were asked to select subjects with specific clinical and examination history:

- ▶ Patients, for whom bodywork had only been of brief help, previously requiring repeated adjustments
- Patients with active inflammatory challenges, including chronic and acute pain states
- ▶ Patients with poor tissue integrity secondary to chronicity of symptoms, fibrosis (fibromyalgia), and hypothyroidism

Subjects (n=12) took two tablets of the THIAA/berberine formula one hour before bodywork, and then one to two tablets as needed three times daily up to 10 tablets per day. Questionnaires were administered at baseline prior to bodywork and administration of formula, and at specific time points: immediately after bodywork and then one hour, six hours, 24 hours, and seven days afterward. Subjects were asked to score the severity of their pain and lack of flexibility using Likert psychometric scales of one to 10. On the pain scale, a score of 10 represented the highest level of pain. On the flexibility scale, a score of one represented the least level of flexibility.

Pain scores over the course of seven days were dramatically decreased (range: two to four) relative to the baseline median score of seven. The median improvement in pain averaged 71 percent immediately after treatment and 70 percent for 24 hours after bodywork and formula administration. The median flexibility score of three at baseline improved immediately after treatment to a score of seven, and was maintained at nearly that level 24 hours later. One week later, the median score for pain remained at a 43 percent reduction from initial score, suggesting lasting benefits from the combination of bodywork and the continuation of nutritional supplementation.

Overall tolerance of the product was good. Two subjects noted some gastrointestinal (GI) discomfort after taking the product on an empty stomach, which was addressed by taking the tablets with food. One subject had more persistent GI discomfort, including a presumed episode of gastrointestinal reflux disease.

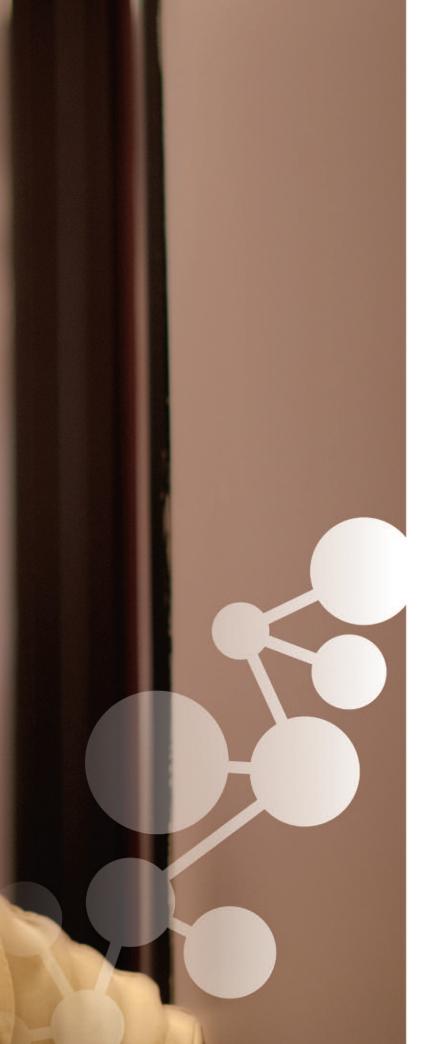
#### **Conclusion**

The collective results from cell line testing and clinical observations suggest that the combination THIAA/berberine formula may offer nutritional support to help modulate cartilage-damaging MMP expression

To see this research in its entirety, visit www.ChiroEco.com/ccr4metagenics.

This research was provided by Metagenics Inc. 800-692-9400 • www.metagenics.com







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### Biocommunication — improving patient compliance and clinical outcomes

#### Case study

Rachel is in her late 20s and has been divorced for five years (no children). Her marriage of three years failed as the result of her ex-husband becoming addicted to pornography and his subsequent perverted sexual pursuits.

Although she's lived with chronic constipation her entire life, Rachel's health would be considered good until she learned of her husband's infidelity. Within days of this discovery her health began to fail. Her first symptom was a debilitating migraine headache that landed her in the hospital for several days. Within two months, her migraines were followed by cardiac arrhythmia and a racing pulse, the cause of which was determined to be Graves' disease. She was prescribed medications appropriate to each condition.

After a few years she concluded that the medicinal cocktail she was consuming every day was creating its own set of problems and not completely solving the problems they were intended to address. Most days she felt she was running on raw willpower.

About a year ago, she decided to stop taking her prescribed medication and upon doing so immediately felt healthier. She still maintains the lifestyle choices she has learned over the years, and during those times of the month when her headaches get worse she takes the edge off with a few 800 milligram doses of ibuprofen.

She still grieves over the failure of her marriage, and even though she has a boyfriend who'd like to get married, she's hesitant to do it again.

This is part of Rachel's health history. She came to the clinic looking for better answers and resolution to problems she doesn't want to carry the rest of her life.

Successful practice involves:

- 1. Identifying the problem correctly,
- 2. Designing and implementing a treatment plan that can deliver the desired outcome, and
- 3. Communicating enough understanding to the patient to get them to follow through. Without patient compliance the best plan is doomed to failure.

Identifying the problem requires information. We gather this with health histories, X-rays, physical exams, blood tests, etc. With training and experience we learn to connect the dots and create "the patient's story." But some patients present with such complexity that the dots are hard to identify, let alone connect, leaving the story incomplete.

#### **Biocommunication**

Biocommunication is a computerized technique that helps you identify and connect the dots by essentially allowing the body to "have a conversation with a computer." The computer has in it a library of binary signatures for items that may have clinical significance. In a process called a biosurvey, the computer sequentially sends a predetermined number of these signatures to the body and records the body's responses. Each binary signature is unique, so each response carries its own value. It's like the body's filling out a survey, thus the name biosurvey.

Biocommunication is not a diagnostic process; it doesn't identify or treat disease. What it does provide is a determination called biological preference. Each response is scored as a positive or a negative. A positive response is considered a biological preference and a negative response a biological aversion. The computer can read the intensity of each response, so the body's responses can be ranked. This ranking allows you to attach a priority, making it easier to know what

you should pay attention to.

The biosurvey process is fast and noninvasive, so a substantial amount of data can be processed in a short period of time. The objective is to make better decisions faster; helping you choose the best diagnostic procedures and the therapies most likely to get results.

In December 2007, a pilot study using biocommunication technology was conducted in Beijing, China at Hospital 301. On the campus of 301 is situated a completely modern, eightstory diagnostic center. The normal procedure at this diagnostic center is to keep each patient overnight and during a two-day period complete a battery of diagnostic tests. At the conclusion of the testing period a report of findings is compiled together with the opinions of the attending physicians.

During a one-week period, a biosurvey was run on a large number of patients at the diagnostic center. At the end of the week, the results of those biosurveys, along with the lab results and reports of finding for each patient was given to John Diamond, MD, in Reno, Nev. for analysis.

Diamond was trained as a pathologist and had several years experience in his own private complementary and alternative medical practice, so he was well acquainted with the data given to him.

His analysis showed an 85-percent correlation between the biocommunication data, the biosurveys, and the diagnostic reports. His findings were analyzed further by a physicist William Tiller, PhD, and Zeng Qiang, MD, the director of the diagnostic center at Hospital 301. These three then authored an article reporting their

To see this research in its entirety, visit www.ChiroEco.com/ccr4zyto.

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### America's phytonutrient report: women's health

**Executive summary:** Most Americans have intakes of fruit and vegetables that fall below minimum recommended intakes. Consequently, most Americans may be falling short in key nutrients found in fruit and vegetables, including phytonutrients.

Based on data presented in America's Phytonutrient Report: Quantifying the Gap, on average, eight out of 10 American adults (76 percent) have a "phytonutrient gap."

As stated in that previously released report, the "phytonutrient gap" is defined as the percentage of the adult population with phytonutrient intakes less than the median intake by adults who meet government guidelines for recommended daily intakes of fruits and vegetables ("meeters"). In other words, the "gap" represents the shortfall of phytonutrient intakes based on a typical level of phytonutrient intake consistent with a diet that is considered to have a prudent amount of fruits and vegetables.

More specifically, a strong majority of Americans are falling short in virtually every color category of phytonutrients:

- ▶69 percent fall short in green (includes EGCG, isothiocyanates, lutein/zeaxanthin, and isoflavones)
- ▶74 percent fall short in red (includes lycopene and ellagic acid)
- ▶83 percent fall short in white (includes allicin and quercetin)
- ▶76 percent fall short in purple/blue (includes anthocyanidins and resveratrol)

▶80 percent fall short in yellow/orange (includes alpha-carotene, beta-carotene, hesperitin, and beta-cryptoxanthin)

The present extension report, titled America's Phytonutrient Report: Women's Health by Color explores patterns of phytonutrient intakes among adult women in different age groups, with particular attention to a category of phytonutrients called carotenoids, which are concentrated in fruits and vegetables, and have been shown to be beneficial to several women's health outcomes.

The carotenoids of interest for this report fall into three of the color categories as follows:

- ▶Green lutein/zeaxanthin
- ▶Red lycopene
- ►Yellow/orange alpha-carotene, betacarotene and beta-cryptoxanthin

For the purposes of these analyses, women have been grouped into "older women" (45 years and older) and "younger women" (19 to 44 years old).

Key findings based on energyadjusted data include:

- Dolder women have total carotenoid intakes 20 percent greater than those of younger women, suggesting a more pronounced "carotenoid gap" or shortfall among younger women.
- Calorie for calorie, older women consume 50 percent more beta-carotene, 40 percent more of both lutein/zeaxanthin and alphacarotene, and 10 percent more beta-cryptoxanthin.
- Calorie for calorie, older and younger

- women consume comparable amounts of lycopene.
- Average carotenoid intakes are driven largely by the consumption of a small number of common foods, which are not always the most concentrated source of a given carotenoid.
- Cooked pumpkin is a concentrated source of alphacarotene, beta-carotene, and beta-cryptoxanthin, but accounts for no more than 3 percent of the intake of any of these carotenoids.
- Spinach is the most common food source of lutein/zeaxanthin among American women, while kale accounts for no more than 3 percent of intake. However, kale offers triple the lutein/zeaxanthin compared to an equivalent serving of spinach.

Overall, consuming a wide variety of the most phytonutrient-rich whole fruits and vegetables is the primary dietary goal.

Given the shortfall of carotenoid intakes, it is prudent for women of all ages to focus on increasing both the quantity and quality of carotenoid-rich foods.

Beyond this, a natural plant-based dietary supplement is an option for those women wishing to address their "phytonutrient gap" as well as their "carotenoid gap."

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# In vivo effects of low level laser therapy on inducible nitric oxide synthase

Yumi Moriyama, DDS<sup>1</sup>; Jacqueline Nguyen<sup>1</sup>; Margarete Akens, PhD<sup>1,2</sup>; Eduardo H. Moriyama, PhD<sup>1</sup>; and Lothar Lilge, PhD<sup>1,3</sup>

<sup>1</sup>Ontario Cancer Institute, Princess Margaret Hospital, Toronto, Ontario, Canada; <sup>2</sup>Sunnybrook and Women's College Health Sciences Centre, Toronto, Ontario, Canada; <sup>3</sup>Department of Medical Biophysics, University of Toronto, Ontario, Canada

Background and objectives: Low level laser therapy (LLLT) has been demonstrated to modulate inflammatory processes with evidence suggesting that treatment protocol, such as wavelength, total energy, and number of treatments determine the clinical efficacy.

In this study, the effects of LLLT mediated by different wavelengths and continuous versus pulsed delivery mode were quantified in a transgenic murine model with the luciferase gene under control of the inducible nitric oxide synthase (iNOS) expression.

#### Study design/material and methods:

LLLT modulated iNOS gene expressed in the acute Zymosan-induced inflammation model is quantified using transgenic mice (FVB/N-Tg(iNOS-luc)). Here, an energy density of 5 J/cm2 at either 635, 660, 690, and 905nm in continuous wave mode and at 905 nm for short pulse delivery were evaluated.

Age of the animals was determined as additionally modulating the inflammatory response and the LLLT efficacy for some treatment protocols.

**Results:** Animals younger than 15 weeks showed mostly a reduction of

iNOS expression, while older animals showed increased iNOS expression for some LLLT protocols. Intensity and time course of inducible nitric oxide expression was found to not only depend on wavelength but also on the mode of delivery, continuous versus pulsed irradiation.

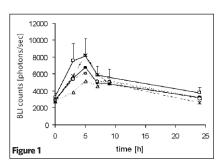
**Discussion:** Pulsed delivery of 905 nm radiation showed higher signal in both age groups. LLLT mediated by 690 nm significantly reduced the BLI signal compared to control groups for both age groups, indicating an effect on iNOS expression.

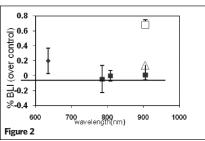
Mitochondria and the rough endoplasmic reticulum both have high relative amounts of lipid membrane shown to absorb NIR light and their size and possibility of lipid as being the main absorber makes both organelles potential target structures for selective photothermolysis mediated LLLT; wherein, the mechanism is possible due to change in the membranes integrity over time periods less than a few microseconds but long enough to permit ions or proteins to cross them.

Additionally, for the pulsed light model, the bioluminescence intensity (BLI) signal peaked at a later time (four to six hours after) compared to other groups (figure 1).

Furthermore, a 700-percent increase in nitric oxide production over control was observed when using 905 nm pulsed delivery (figure 2).

Of additional clinical importance is





the efficacy of the 905 nm NIR light as it experiences a lower attenuation compared to 635 nm red light and, hence, is better suited for the treatment of large tissue volumes such as knee joints affected by osteoarthritis.

**Conclusion:** LLLT exhibits different effects in induced inflammatory process according to different wavelengths and wave mode. Upregulation of iNOS gene following 905nm pulsed wave suggests a different mechanism in activating the inflammatory pathway response when compared to the continuous wave.

## For more research, visit www.ChiroEco.com/ccr4theralase.

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### Survey results show high satisfaction rate for Stabilizers

Duarte MA, Cambron JA

#### **Abstract**

**Objective:** The purpose of this study was to survey the reasons for foot orthotic use and the resultant level of satisfaction within a chiropractic outpatient clinic.

**Methods:** Subjects were randomly sampled from a list of patients who previously purchased Foot Levelers orthotics (Spinal Pelvic Stabilizers) at a chiropractic teaching clinic.

A three-page, IRB-approved survey was either mailed or personally presented to each selected subject. The survey's questions included the subject's chief complaint when initially presenting to the clinic, the reason orthotics were recommended, and the subject's

overall satisfaction with their orthotics. **Results:** The rate of return on the 100 questionnaires was 100 percent. The majority of patients receiving orthotics initially presented to the clinic with a chief complaint of either foot pain, low back pain, or knee pain. The majority of subjects (79 percent) were satisfied with their Stabilizers, and 73 percent would recommend orthotics to a friend. **Discussion:** This study represents the first survey of foot orthotic use and satisfaction of use in a chiropractic setting. The majority of disorders treated by orthotics in this setting were biomechanically related. The main disorders described were flat feet and knee pain, which have consistently been described

as indications for treatment with orthotics. Also, the majority of subjects surveyed were satisfied with the use of orthotics, similar to previous studies.

Patient satisfaction and willingness to refer indicates that chiropractic physicians might better help their patients resolve painful conditions related to biomechanical deficits by prescribing custom-made orthotics as indicated.

**Conclusion:** In a random sample of chiropractic patients who utilized foot orthotics, the majority of subjects indicated that they wore orthotics for knee pain and flat feet and they were satisfied with foot orthotics for their symptoms.  $\bigcirc$ 

### Low leg pain improves with Foot Levelers' Stabilizers

Austin WM

#### **Abstract**

**Objective:** To discuss treatment protocols for a recreational middle-distance runner who suffered from anterior shin splints complicated by an underlying posterior tibial tendinitis, who was unable to train to his full capacities, and who turned to chiropractic care when standard medical protocols proved ineffective.

**Methods:** A multifaceted treatment approach was used. Foot Levelers' custom-made, flexible orthotics — to support the skeletal alignment in a more appropriate range for weightbearing posture — provided increased heel-strike shock absorption and enhanced afferent-motor response.

Manipulation of the navicular, cuboid, and metatarsal heads was administered. Ice massages were recommended, and evertors and invertors were strengthened with low-tech resistive exercises.

**Results:** After three weeks of care, the patient was able to resume running at a moderate pace and distance (two to three miles every other day) and after six weeks, he was running 40 miles per week without pain and was released from care.

**Discussion:** It is not unusual for the chiropractor, especially the sportsminded practitioner, to be consulted for the vague pain and nonspecific symptoms accompanying the gradual onset of a stress reaction to the soft tissues and/or bone.

These conditions can be effectively managed if identification is early and an appropriate treatment program is followed. Ultra-lightweight, flexible orthotics can play a major role in preventing many overuse injuries in runners and joggers.

**Conclusion:** When assessing overuse injuries, it is imperative to look for intrinsic as well as extrinsic factors. Addressing one without the other in the treatment regime may lead to unsatisfactory or only short-term results.

However, correcting or supporting the faulty biomechanics often makes the difference in providing long-term relief of symptoms and return to activities of daily living, including intense athletic training programs. •

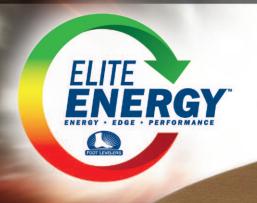
For more research, visit www.ChiroEco.com/ccr4footlevelers.

This research was provided by Foot Levelers.

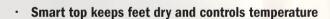
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# **Your patients' exposure to X-rays during pregnancy**

Steven Gould, DC, DACBR

Steven Gould, DC, DACBR, wrote this article on behalf of NCMIC. NCMIC was founded in 1946 for the express purpose of providing the chiropractic profession with malpractice coverage. Today, NCMIC covers more than 38,000 DCs, and its strength is summarized by the motto, "We Take Care of Our Own." Gould is a board certified chiropractic radiologist who became a diplomate of the American Chiropractic Board of Radiology (DACBR) in 1993. He has a full-time radiology and clinical/patient practice where he performs interpretations of plain film radiographs and MRIs for referring chiropractors. Gould holds memberships in the American Chiropractic College of Radiology and the American Chiropractic Association (ACA). He was president of the ACA's Council of Diagnostic Imaging and is currently their secretary/treasurer.

S A CHIROPRACTIC RADIOLOGIST, I OFTEN TALK TO DOCTORS OF CHIROPRACTIC WHO HAVE QUESTIONS ABOUT THEIR EXAM FINDINGS. Recently, I heard from a doctor who was concerned about a two-view lumbar X-ray that revealed a fetus.

The 16-year-old patient had been experiencing low back pain and had denied pregnancy on several occasions: on the X-ray consent form, during the history and upon being questioned by the chiropractic radiologic technologist. The patient's mother also was unaware of the teenager's condition.

The doctor was concerned about the radiation exposure to the fetus, as well as his malpractice liability. Though the question of the doctor's liability would be best be answered by his malpractice carrier, the effects of radiation on the fetus would depend on:

▶The settings of the X-ray machine

compared to the patient's size, and

The type of X-ray unit and filmscreen (or digital detector) combination used.

What the research says: In general, it appears that the risk to a fetus during X-ray is fairly low. The National Commission on Radiation Protection (NCRP) states the risks to pregnancy from 5,000 mRad of exposure are negligible. Therefore, a two-view lumbar X-ray, which would expose a patient's body to about 200 to 400 mRad, would not likely injure the fetus. Even so, it is not advisable to radiograph pregnant patients, unless there are life-threatening injuries or emergent conditions.

In "real-world" terms, an article in the Journal of the American Chiropractic Association by Dr. Joseph Howe and Dr. Terry Yochum stated that it would take nearly 45 X-rays done in a short period of time to cause irreparable damage to the fetus.

The Department of Health and Human Services and Center for Disease Control and Prevention has a fact sheet (www.bt.cdc.gov/radiation/pdf/prenatal.pdf) that addresses fetal exposure to radiation. This fact sheet indicates that even a rough equivalent of 500 chest radiographs at one time would increase the lifetime cancer risk by about 2 percent over the natural incidence rate of 40 percent to 50 percent.

Avoiding X-ray exposure during pregnancy: Many people find it hard to believe that a woman wouldn't know she was pregnant. However, there are instances of repeated pregnancy tests showing negative results, despite the woman being pregnant. In addition, there are multiple cases of women who

were unaware they were pregnant until going into labor.

One simple procedure to protect patients and their unborn babies is the "10-Day Rule." This means only X-raying females who are within the first 10 days of their menstrual cycles. Days one through 10 of the menstrual period are the least likely time for pregnancy in the female cycle, with ovulation taking place on approximately day 14 of the cycle. It is important to include a notation of the last menstrual period date on the intake and X-ray consent forms of any female of childbearing age and/or with an active menstrual cycle.

Most chiropractic patients are not emergent cases and radiographic evaluation can be postponed until the next menstrual period begins. Putting the 10-day rule into place in your practice can reduce the potential for exposing a pregnant patient to radiography and can aid in evaluation of patients with unknown, underlying gynecologic conditions.

If the patient does not have a menstrual cycle in the normal time frame, it could be that a pregnancy exists. Or, there may be an undiagnosed pathology, such as ovarian or uterine disease, endometriosis, amenorrhea, or other hormonal abnormalities from multiple causes. In any event, the patient may require a referral to a gynecologic/obstetric specialist, and you will have provided them with a valuable healthcare service.

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## RESEARCHCOMPENDIUM

# Stabilizers help with prolonged standing problems

Zhang J, Zhou J

#### Abstract

**Objective:** To determine the effect of chiropractic care and orthotics on reducing discomfort in individuals who spend long hours standing during working hours.

**Methods:** The subjects filled out a patient information sheet and prescreening foot pain questionnaire.

The chiropractic treatment was performed using the Activator technique. In-home exercise was prescribed to the subject receiving orthotics and chiropractic care. Foot and Ankle Outcome Score (FAOS) was used for the specific region survey. FAOS was developed to assess the patients' opinion about a variety of foot- and ankle-related problems.

FAOS consists of five subscales: pain, other symptoms, activities in daily living (ADL), function in sport and recreation, and foot- and ankle-related quality of life (QOL).

The study used a computerized scan offered by Foot Levelers Inc. to record and analyze the foot data. Based on the data collected, the need for orthotics (Spinal Pelvic Stabilizers) was determined and the data were sent to Foot Levelers for creating the orthotics.

**Results:** Two cases, one from experimental and one from control groups, are reported. The experimental case was a 56-year-old female who presented with complaints of both feet pain, right dorsal foot numbness, and right hip pain after long standing at work.

After chiropractic and orthotics, the preorthotic and postorthotic foot pain questionnaire from the beginning of the study to the end of the second week showed improvement of the pain score from 50 to 83, the symptom score from 75 to 82, the ADL score from 52 to 94, the score of function in sports and recreational activities from 50 to 95, and the QOL score from 44 to 56.

The control case was a 42-year-old male research assistant who presented with a chief complaint of bilateral heel pain after prolonged standing or walking. The subject also complained of lower back pain and knee pain once or twice a month.

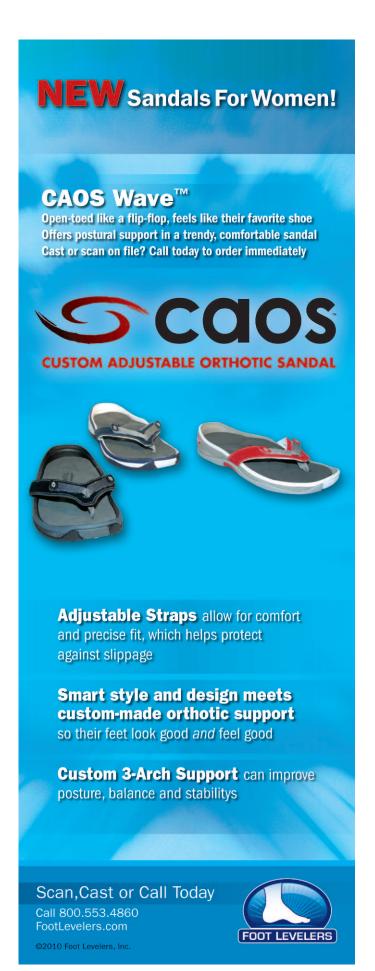
Without chiropractic care and orthotics, the preorthotic and postorthotic foot pain questionnaire from the beginning of the study to the third week revealed no significant changes in all items.

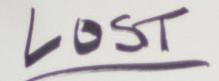
**Discussion:** These case studies were directed to the evaluation of the effectiveness of chiropractic care and orthotics on

To see this research in its entirety, visit www.ChiroEco.com/ccr4footlevelers.

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# The prevalence of suboptimal vitamin D status in a randomly selected cohort of Colorado firefighters

Gerard Guillory, MD, and Michael Mutzel, MSc

**Abstract:** Vitamin D insufficiency has been associated with increased risk of CVD, various cancers, autoimmune disease and type 2 diabetes.

Despite adequate sun exposure, individuals inhabiting metropolitan areas display a high prevalence of vitamin D insufficiency as determined by serum levels of 25(OH) vitamin D less than 32 ng/mL.

The purpose of this study was to:

- 1. Assess the serum levels of 25(OH) vitamin D and prevalence of vitamin D deficiency in a cohort of 20 firefighters that work and reside in the Denver metropolitan region and
- 2. Perform follow-up lab work after eight weeks supplementation with a microemulsified liquid vitamin D-3 preparation.

The initial baseline blood levels of 25(OH) vitamin D were assessed and the study subjects were advised to take 4,000 IU/daily (two drops) of the vitamin D3 preparation for eight weeks.

After the eight-week supplemental period, serum levels were retested to establish the percent increase in the 25(OH) vitamin D blood levels. The average initial 25(OH) vitamin D blood level and eight-week post-test blood levels was 27.02 ng/mL and 54.01 ng/mL, respectively.

Pretest, 75 percent of the study subjects were defined as deficient (less than 32 ng/mL) and only 25 percent were deficient after eight weeks of supplementation with the liquid emulsified vitamin D-3. The average percent increase in serum 25(OH) vitamin D levels was 106 percent.

Conclusion: Suboptimal vitamin D status is prevalent in Denver firefighters and eight weeks of 4,000 IU/daily supplementation with a micro-emulsified liquid vitamin D-3 preparation

increased blood levels on average 106 percent.

#### Introduction

Vitamin D deficiency is a serious medical condition that has been associated with an increased risk of developing cardiovascular disease, type 2 diabetes, hypertension, various cancers, and autoimmune diseases.

Vitamin D insufficiency occurs at epidemic levels in many industrialized countries, where exposure to sunlight tends to be limited and diets tend not to include sufficient amounts of foods naturally rich in vitamin D. During 2009, Gerard Guillory, MD, tested more than 1,200 of his patients and found that roughly 90 percent had sub-optimal vitamin D levels, as determined by serum 25(OH) vitamin D levels less than 32 ng/mL.

Guillory achieved great success in treating this with Bio D Mulsion, a microemulsified preparation made by Biotics Research Corporation. The purpose of this study was to:

- 1. Increase public and physician awareness of the scope and seriousness of vitamin D deficiency and
- 2. Assess the effectiveness of the microemulsified vitamin D preparation.

Several preparations have been recommended to patients by physicians for the treatment of vitamin D insufficiency. The availability of vitamin D preparations ranges from high potency tablets, capsules, to liquid forms. Vitamin D is a fat soluble hormone and thus requires biliary secretions to properly saponify the fats for proper intestinal absorption.

To maximize the efficacy and bioavailability of fat soluble nutrients, enhanced delivery methods have been developed. One such method is an oil in water micro-emulsification, a closely held process that enables a fat soluble (water-insoluble) vitamin to be placed into a uniformly micrometer sized, fat soluble particle that is dispersible in water and capable of intestinal transport independent of bile acid-saponification.

The aim was to ascertain how efficacious two drops, yielding 4,000 IU of micro-emulsified vitamin D-3 would be in raising low serum levels of 25(OH) vitamin D in a group of 20 firefighters residing in the Denver metropolitan area.

### **Materials and methods**

Twenty full-time firefighters of the Aurora Fire Department were selected on a volunteer basis to participate in an eight-week study during the winter/spring months of 2009.

The 20 subjects were advised to stop consuming multivitamins, cod liver oil, and other supplements containing vitamin D upon initiation of the study. The subjects filled out a medical symptom questionnaire aimed to assess subjective indications of mood, energy level, and digestive complaints.

All subjects had blood drawn (at the Care Group, PC, office of Gerard Guillory MD in Aurora, Colo.) and serum levels of 25- hydroxyvitamin D (25(OH) vitamin D tested through Laboratory Corporation of America (Lab. Corp) via an assay developed by DiaSorin.

The subjects were advised to take 4,000 IU/day (two drops) daily of the liquid emulsified preparation produced by Biotics Research Corporation. After

To see this research in its entirety, visit www.ChiroEco.com/ccr4biotics.

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(Howitz KT. et al. 2003 Nature 425, 191-196; Borra MT, et al. 2005 280(17):17187-17195.)

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## **RESEARCH**COMPENDIUM

# How important is technique? Supporting 'Tailored-Individualized-Input'

Kenneth V. Vinton, DC

Kenneth V. Vinton, DC, is a 1989 graduate of Palmer College of Chiropractic with research honors. He is a seminar instructor and consultant, and maintains a private practice in Grove City, Pa. Over the past 15 years Vinton has worked extensively with neurofeedback and biofeedback instrumentation while documenting the psycho-physiological effects of adjusting.

### Commentary

The graph demonstrates that adjusting instruments can elicit substantial brainwave responses.

The graph also illustrates that different methods of application, i.e., variable forms of afferent input, can play a significant role in the outcome. Different technique approaches apply different qualities of mechanoreceptor input, which in turn, elicit different brain wave responses.

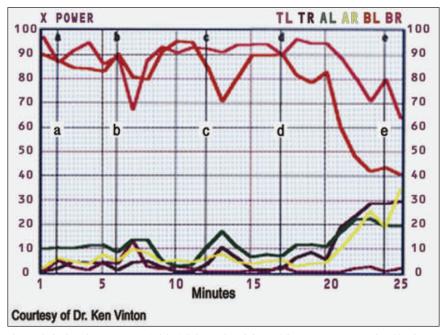
All manual and instrument-assisted adjustments "talk to the brain." Different patients require different amounts of input (e.g., time and force combinations) in order to produce effective, long-lasting changes.

One of the most important skills a practitioner can develop is the ability to tailor the intensity of applied forces to meet the needs of individual patients, i.e., Tailored-Individualized-Input/Neural-Afferent-Threshold-Ology. Adjusting instruments enable a practitioner to produce various types of mechanoreceptor input that can be difficult or impossible to produce by hands only.

#### **Brain wave activity**

One adjustment can be a band-aid; another adjustment has the potential to be life changing. Take for example the graph shown, which displays the brainwave activity of a subject who was adjusted several times over a 25-minute time period.

- ▶"a-b" = the subject rested.
- ▶At "b", the subject was adjusted by a practitioner using an



The graph displays the percentage of alpha (A), beta (B), and theta (T) brainwave activity produced by the subject's right (R) and left (L) hemispheres.

ArthroStim adjusting instrument. The subject was adjusted a second time near the end of the "b-c" time period. Both adjustments produced transitory changes in brainwave activity. (Note: transitory brainwave responses to the second adjustment continued into the "c-d" time period.)

- ▶"c-d" = the subject rested.
- At "d", the patient was adjusted a third time by using the ArthroStim instrument and a different technique approach. This adjustment produced substantial, sustained changes in brainwave activity, i.e., a reduction in beta activity and a rise in deeper, healing, alpha and theta activity.

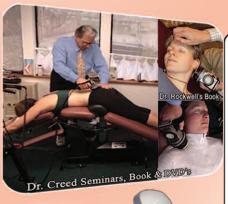
The subject was adjusted using the ArthroStim instrument by IMPAC Inc. The Bio-Integrator instrument was used to monitor EEG changes.  $\bigcirc$ 

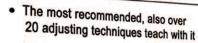
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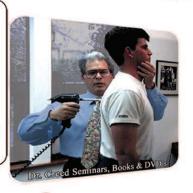


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# WebExercises: an advanced rehab and revenue tool

David, Cruz, BS, DC, CSCS

David Cruz, BS, DC, CSCS, is president and founder of WebExercises and practices full time in Marin County, Calif.

OULDN'T YOU LIKE TO HAVE YOUR PATIENTS ACTUALLY DO THE EXERCISES YOU PRESCRIBE AND GET COMPENSATED FOR IT? Now you can with WebExercises, the unique exercise prescription program.

The value of patient participation with exercise prescription can not be underestimated given the fact that millions of Americans suffer from chronic illnesses, which can be prevented or improved with regular physical activity.

According to the online journal, Preventing Chronic Disease, sedentary patients cost an average of \$1,500 per year more in related healthcare cost when compared to active patients.

Chiropractors are trained to recommend therapeutic and rehabilitative exercises, therefore are the best suited to prescribe exercises for patients recovering from a specific injury or suffering from chronic illness.

WebExercises enables you to become a rehab and exercise expert by giving the ability to quickly and easily create concise and personalized patient exercise prescription, selecting from more than 1,000 clinically accepted exercises and stretches for all parts of the body. Instruction sheets can be printed with your clinic's name and logo or delivered by e-mail viewable from any computer or Apple iPhone.

WebExercises will complement your care by delivering video demonstration of exercises prescribed specific to your patient's condition. All exercises employ low-tech equipment designed to be performed at home. Billing code guidelines are also available for third-party reimbursement.

Regardless of the technique you practice, you will find that WebExercises can be a great addition to your clinic.

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Medical Director, Partners in Integrative
Medicine, New York, NY



"Most of my patients who take
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- Donald Dennis, M.D., F.A.C.S., Medical
Director, Atlanta Center for ENT, Atlanta, GA



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- Juan Remos, M.D., M.B.A., Wellness

Director, The Miami Institute, Miami, FL

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Those 50 or older are at greater risk of osteoporosis, but there are steps that can help reduce that risk.\*\*

2004, the U.S. Surgeon General rocked the medical community. MAmerica's top doctor at the time, Richard H. Carmona, M.D., released the 2004 Bone Health Report, which warned that if we don't change our lifestyle habits by 2020, half of American citizens older than 50 years of age would be at risk of osteoporosis or low bone mass.

We tend to think of bone health as it relates to the elderly, but bone health—and more appropriately bone mineral loss—should be a concern at all ages of life. So, if you are over 30, the age that is associated with end of the "bone growth" stage of life and the onset of normal agerelated bone mineral loss, then the Surgeon General's report should be particularly alarming to you. Thankfully, Dr. Carmona and his team of medical experts laid out a three-part plan to address the alarming trends described in this report.

The plan includes improved diet, exercise and health literacy. Particular attention was paid to calcium and vitamin D. The FDA concurs—evidenced by its approved health claim—that adequate calcium and vitamin D intake, when combined with physical activity and a healthful diet, may reduce the risk of osteoporosis later in life.

Of course, many people looking to boost their bone health choose to supplement their diets. It is in this area that one of the most common myths associated with bone health is found.

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# Bone Loss IS A BIG DEAL

No one plans on bone loss, so it's best to stop it before it starts

Healthy adults—especially women over 40—can expect to experience normal bone loss. Adults lose approximately between .5 percent and 1 percent of their bone mineral density every year. While that doesn't sound like much, years of losing a seemingly small percentage of bone mineral density adds up, and if left unchecked, osteoporosis can occur.

Currently, osteoporosis leads to 1.5 million fractures per year, mostly in the hip, spine and wrist, according to the National Institutes of Health. The condition afflicts more than 44 million Americans—68 percent of them older women. For women, bone loss accelerates during and after menopause to about 5 percent for five to seven years, and then returns to 1-2 percent per year.

Simply put, women could lose a significant percent of their bone mass during their menopausal years alone. Additionally, one in three women past the age of 50 will suffer a vertebral fracture because her bones are brittle. Shrinking height is also a revealing sign of osteoporosis.

# The Calcium Myth

If you want healthy bones, all you need is calcium, right? That is the sum total of many people's knowledge of bone health nutrition. Thousands of manufacturers of calcium supplements would happily have you believe that first statement. That alone should make you wary. When thousands of companies profit from a single widely-held belief, it's probably time to question that belief.

Here is the truth. No calcium supplement, taken in the absence of other vitamins and minerals and without proper diet and exercise, has ever been proven in clinical studies to help you strengthen bones. The best that can be said is that calcium supplementation helps slow down or stop bone loss. H While slowing bone loss is a great goal, it's a far cry from making them stronger and healthier by increasing bone mineral density.

As you will learn, there are several factors that go into actually building bone mineral density or growing bone. The source of your calcium is a key factor. Did you know that most calcium supplements are ground-up rocks or oyster shells? Of equal importance to the source of calcium are a host of other vitamins, minerals and trace elements that help calcium achieve its ultimate goal in the body.

# The Grow Bone System<sup>†</sup>

There is good news on the horizon, however, for the millions of women and men looking to support healthy, strong bones. Garden of Life is proud to introduce their new Vitamin Code Grow Bone System with RAW Calcium and Growth Factor S.

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# Confidence = Money Back Offer

\* Certain restrictions apply. For complete details, see www.growbone.com.

Far from "just another calcium supplement" intended to reduce the risk of osteoporosis<sup>††</sup>, the Grow Bone System is intended to stimulate bone growth, increase bone strength and bone mineral density.<sup>†</sup>

The RAW Calcium in the Grow Bone system is a patented form of marine algae known as *algas calcareas.sp*, which is sustainably harvested by hand off the pristine shores of remote South America. It is picked up in knee-deep ocean waters, rinsed in fresh water, dried in the sun, and then milled at low temperatures into a powder. This is the only raw, organic plant form of calcium that Garden of Life has ever found.

Sun-drenched and teeming with life, our bodies thrive on the nutrition that plants provide. The same will never be said of rocks.

Additionally, and of particular importance for bone health<sup>†</sup>, when you take a plant-form calcium supplement, you're getting far more than just calcium.

The consumption of bone-building co-factor minerals such as magnesium, silica, boron, vanadium and strontium have all been linked to healthy bones.† And all of them are naturally occurring in the RAW Calcium *algas calcareas.sp*.

In addition to the raw, plant-formed calcium, Vitamin Code RAW Calcium also contains

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# DOUBLE YOUR MONEY BACK OFFER\*

To take the Grow Bone Challenge, you'll need to get a baseline DEXA scan to assess your starting bone mineral density. Then you can start consuming Vitamin Code RAW Calcium along with Vitamin Code Growth Factor S daily, as directed, for a minimum of six consecutive months. Upon completion of the six-month protocol, you'll need to have a second DEXA scan done to measure your results from the Grow Bone Challenge.

If your bones are not healthier, stronger and denser after at least 180 consecutive days as evidenced by a full-body DEXA scan, Garden of Life will refund not one month, not two, but *double* all six months of your Grow Bone System purchase plus your out-of-pocket costs for both DEXA scans. We want you to feel the confidence we have in this system. We make you this amazing offer because we're assured of the Grow Bone System's ability to build bone density.†

\*Certain restrictions apply. For complete details, visit www.GrowBone.com.

† These statements have not been evaluated by the Food and Drug Administration.
This product is not intended to diagnose, treat, cure or prevent any disease.

This product is for normal age-related bone loss. It is not intended to treat Osteopenia or Osteoporosis.

a host of other raw vitamins and minerals as well as live probiotics and enzymes. Raw Vitamin  $D_3$ , an important bone-building vitamin, is included in the amount of 1,600IU per serving, Vitamin  $D_3$  is vital to bone health and acts as a hormone to increase the absorption of calcium by up to 80%. Emerging research has also shown that vitamin  $K_2$  has important bone-health implications by ensuring that calcium gets to the bones where it belongs and not in the arteries, where calcium doesn't belong, One thing you may want to note where vitamin  $K_2$  is concerned is that there are two forms generally available in most supplements: MK-4 and MK-7. Vitamin Code RAW Calcium uses the MK-7 form,

which is absorbed faster than MK-4.

The second formula in the Grow

Bone System is Vitamin Code

Growth Factor S, which is a
combination of strontium, a
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and probiotics, enzymes
and raw organic fruits and
vegetables.†

Clinical trials conducted on strontium found it most effective at 680 mg per day—the same amount contained in Growth Factor S.

It has been 5 years since the Surgeon General's warning about the state of bone health in our nation. Isn't it time we started taking it seriously? If you want the best for your body, try Vitamin Code Grow Bone System—the ultimate support for stronger, healthier bones.†

Take the Grow Bone Challenge and be sure to also eat a diet rich in calcium and vitamin D, and chances are that by 2020, no matter what your age, you'll be more likely to have strong, healthy bones.



\*\* Adequate calcium and vitamin D as part of a healthful diet, along with physical activity, may reduce the risk of osteoporosis later in life.

# **Outcomes-based contracting**

# The value-based approach for optimal health with chiropractic services

Cyndy Nayer, MA; Bruce Sherman, MD, FCCP, FACOEM; Jack Mahoney, MD, MPH

Published by The Center for Health Value Innovation (CHVI).

The Center acknowledges the Foundation for Chiropractic Progress which supported the Innovators' Summit in May 2010 that led to the development of this landmark report.

#### **Executive Summary**

As the country experiences innovation and adoption in health reform, the opportunity arises to expand the continuum of care services in order to apply the right mix of resources for each individual.

Chiropractic intervention is one area in which new analysis may define the placement in the care continuum. This will be especially important in the transformational years of patient-centered care with low numbers of primary care physicians to serve as medical home quarterbacks.

Care that causes early engagement of both the patient and clinician coupled with shared accountability for the outcome is the most desirable of relationships. Chiropractic may be able to support and enhance this relationship.

There are many in America who experience reduction in disability and pain through chiropractic services. There are also many health plan products that can be purchased to fortify the resolution of low-back and neck pain, contributors to one of the highest-cost conditions in the nation, musculoskeletal pain and injury.

Yet there are many who argue that chiropractic is not a mainstream therapy, uses too many imaging and longterm resources, and is unclear on the application of guidelines for assessment and treatment.

In 2009, Niteesh Choudhry, MD, PhD, and Arnold Milstein, MD, MPH, conducted an analysis of the cost-effectiveness of chiropractic for neck and back pain. They concluded that there is reasonable data to show chiropractic could be an effective and cost-efficient

service for relief of pain and reduction in disability.

The Center for Health Value Innovation (CHVI) views this discussion as an opportunity to showcase the decision process for the potential health value of chiropractic. If the value to the purchaser or plan sponsor can be demonstrated in a scalable, replicable format, then the choice to use chiropractic or other medical intervention can be applied across a variety of instances.

If there is no population approach, and it is an individual decision with few guidelines, then its value is not so easily determined and should not be broadly applied. Or, if there is some level of systematic approach but there are missing elements, these should be enumerated and steps should be taken to close the gaps so that systematic, population-based approaches can simplify the choice and insertion points for the service.

This manuscript explains the application of the Choudhry/Milstein findings and creates a decision process for choosing chiropractic services as part of the benefit plan for improving health value. The chiropractic services must be part of the total Health Value Supply Chain, so care is coordinated within a patient-centered medical home, and the patient is an active participant in his or her health improvement.

When the population's health is aligned with the payer's business strategy, engagement in appropriate health services is enhanced, absenteeism and avoidable expense are reduced, and improved access and care coordination reduces friction. Using an outcomesbased framework for the potential metrics and alignment of incentives, a

plan is considered for improving the total health and economic outcomes of the population and the organizations. In this paper, payer and employer are grouped into the category plan sponsor.

This paper is the result of the Innovators' Summit on Chiropractic Services, held in Orlando, Fla., May 1, 2010.

An invited group of center directors and advisors along with Choudhry and representatives from the Foundation for Chiropractic Progress (F4CP) attended. We wish to thank the foundation for its support of the summit and the work of the center as we seek innovation that speeds health and economic improvement, and as we guide decisions through educational efforts that expand the horizon of health value.

The Center for Health Value Innovation thanks the following attendees and contributors to the Innovators' Summit: Ford Brewer, MD; Laura Carabello; Niteesh Choudhry, MD, PhD; Gerry Clum, DC; Steven Delaronde; Peter Hayes; Jerry Reeves, MD; and Mark Zeigler, DC.

We would also like to extend our appreciation to William Dorney, DC, for his insights regarding the development of this paper.

#### **Overview**

The continued rise in healthcare costs, amplified with the new efforts of healthcare reform, have prompted plan sponsors to think differently about approaches to health benefits management.

It is now evident that in order to effectively mitigate long-term healthcare cost trend, plan sponsors must focus on behavior change: higher

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## RESEARCHCOMPENDIUM

engagement and more accountability for health outcomes. This focus on improved engagement and accountability is supported by plan designs that not only cause the consumer to change his or her behaviors, but also for the plan sponsor and the service providers to improve their accountability for better outcomes.

This shared accountability is fundamental to sustainable health improvement. [NOTE: for the purposes of this paper, plan sponsors and employers will represent the payers who design benefits and purchase services that improve health, hence we will use the term plan sponsor throughout this paper.]

A value-based benefit design is a plan design that uses insurance and incentives to cause the desired behavior change. The design focuses on improved, sustainable outcomes over the long-term. It incorporates an understanding that some healthcare offerings create more value, or health and economic dividends, than others.

For example: Compliance with chronic condition care yields a higher value for plan sponsors than treatment of toenail fungus.

For these high value services, plan sponsors incorporate "levers," or nudges, to incentivize their use, most often through reduced out-of-pocket beneficiary costs.

Alternatively, for lower value services, a financial disincentive may be incorporated in the form of a higher co-pay or co-insurance. In this way, levers can be used to influence beneficiary behavior toward use of desired, higher value health services for improved health and economic outcomes.

Similarly, levers can be applied across service providers to encourage higher quality and more efficient services, such as increasing reimbursement to the clinician who adopts an electronic medical record or expands his/her services to include care coordination, pharmacy education, and more.

Organizations that have incorporated a value-based approach into their health benefits design generally follow a similar path.

Initially, the focus is on current risk and waste reduction, with implementation of disincentives for low-value services and incentives for compliance with prevention and wellness guidelines as well as treatment of chronic conditions. As these health plans and plan sponsors become more comfortable with the strategy, additional value-based considerations are incorporated, focusing on future risk reduction, including incen-

# To see this research in its entirety, visit www.ChiroEco.com/ccr4chvi.

This research was provided by The Center for Health Value Innovation. www.vbhealth.org



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## RESEARCHCOMPENDIUM

# Spine rehabilitation — curve restoration

Calvin Hargis, DC, DABCO

Calvin Hargis, DC, DABCO, is a 1980 magna cum laude graduate of Palmer College of Chiropractic. He received his board certification in chiropractic orthopedics from New York Chiropractic College in 1995. He has maintained an active practice in Warwick, N.Y., for the past 30 years. He is a patented inventor with several braces on the market.

ERVICAL SPINE TRAUMA IS A MAJOR CAUSE OF SOFT TISSUE DAMAGE AND MUSCULAR WEAKNESS. Cervical curve reversal is one of the leading causes of patient symptoms and degenerative spinal changes. Both conditions can be effectively treated with the Curve Restorer from Hill Laboratories.

Forward head displacement requires the muscles of the neck and upper back to contract harder overloading the cervical spine, increasing spinal compression and leading to disc and joint deterioration. C spine trauma alters and weakens myofacial dynamics. A host of patient symptoms ensue: neck pain, headaches, TMJ, radiculopathy, myofacial syndromes, upper back pain, fatigue, occipital neuralgia, balance issues, and emotional stress to name a few.

Having practiced since 1980, I have tried a number of devices that claimed to rehabilitate the cervical spine and to restore cervical lordosis. I have found none to be effective. Some indicate curve improvement when they are in place but make no permanent correction when removed from the patient. None seem to effectively rehab both the anterior and posterior cervical musculature.

In 2003 I began to consider how a device would need to be constructed to achieve both objectives. What would be the mechanics and engineering principals needed? Obviously, one would need to first stretch the reversed cervical curve forward and then, at the same time, be able to work the major muscles of the neck and upper back to rehab and hold the correction.

It also seemed obvious this would take time. I realized it was not the vertebrae that would be resistant to change but the soft tissue of the discs, joints, ligaments, and muscles. These structures would have to be stretched and strengthened over time to allow either rehabilitation, spinal correction, or both.

I envisioned a light handheld device with an elastic strap that would contact the mid-rearward neck at C4-5 and draw forward the reversed cervical spine as the user pulled the device into position. At that point, with the neck better oriented toward or at a lordotic position, resistance exercises would be performed. Loops engaging the rearward base of the skull and upper shoulder would provide a contact point

for this resistance if they were levered to a spring steel coil. Coil placement would be critical.

Mechanically, the resistance needed to be directed from the center of a healthy lordotic spine, (the center of maximal cervical work, stress and motion).

Partnering with Hill Laboratories, we developed a working prototype and began clinical trials in 2003. We have continued to refine the device and monitor patient progress over the intervening years.

The improvements we are seeing in patient cervical curve restoration are impressive! Using comparative lateral cervical spine X-rays on a quarterly basis, we have validated our patient's consistent progress.



### Impressive results

Working with many patients over the past few years, we have seen dramatic permanent restoration of cervical curvatures. With daily use of the Curve Restorer, the typical patient is achieving curve correction in six to 12 months.

A typical case is that of Cory Demala. Demala, an attractive young woman in her 20s was an active horse trainer and riding instructor. Like many riders she had taken a number of falls in her time. This may have accounted for her cervical curve reversal that was measured at a negative or kyphotic eleven degrees. Unfortunately, she carried her head forward of her body's center in an unbalanced position, producing much more work on the muscles of the neck and upper back.

As a result, she was plagued by chronic neck and upper back pain and occasional headaches. Her riding suffered as well, since she was off balance in the saddle. Due to her curve reversal the inclination of her head was rotated downward causing her far vision to be focused below the horizon. This made judging distances and jumps difficult. Demala began daily Curve Restorer exercises in July 2003 along with weekly adjustments. In November 2003, we did a comparative lateral C spine X-ray. For the follow-up X-ray she was standing, as do all our patients, in a relaxed erect position without any external aid or device that would alter the cervical curve.

The second lateral X-ray demonstrated that Demala had progressed from a negative 11 degrees of spinal curve to a positive 4 degrees. An improvement of 15 degrees in four months!

Five months later in April 2004, a third X-ray demonstrated a 30 degree, smooth and very perfect appearing lordotic cervical curve. Her symptoms of pain and headache were greatly reduced.

Not only had we eliminated her complaints, but I had made lasting changes to her spine that would have farreaching benefits in terms of reducing the degenerative changes that ongoing curve reversal would have produced.

Since I had several months during treatment to educate my patient as to the importance of spinal hygiene, I developed a patient bond that continues to bring her and her referrals to my office for spinal care!

### **Curve Restorer mechanics and exercise protocol**

The Curve Restorer is comfortable and easy to use. Grasping two handles, the user positions the unit's elastic strap to the rearward mid-neck and pulls forward to position the rearward curves to the skull base and shoulder.

At this point, approximately 4 to 5 pounds of forward pull and elastic band pressure is exerted on the mid-cervical spine. When positioned in this fashion, and as the patient maintains forward pull on the handles, a series of exercises is performed.

The first exercise is that of a slow extension, a momentary pause while fully extended and then a slow return to the starting position. I recommend the patient count 1,000, 2,000, 3,000, 4,000, hold on 5,0000, and slowly release to the same count. Ten extensions should be performed.

Follow this with 10 retractions. The retraction exercise is performed from the same staring position at which time the patient slowly draws the head into the torso while continuing to look forward. Care should be taken that the patient does not raise their shoulders. (Retractions are akin to a turtle pulling its head into its shell and an instructional DVD comes with each unit.) Following the 10 retractions, a second set of 10 extensions and 10 retractions is performed.

Prior to the exercises, I advise that the patient use a

small rolled-up towel placed beneath the neck while lying supine for approximately five minutes. The diameter of the towel should be no more than 2 to 3 inches. This pre-stretch ensures a more compliant and flexible spine going into the exercise routine.

#### **Cautions and considerations**

The exercises needed to restore cervical curvature are somewhat strenuous, and like any exercise routine, need to be implemented slowly. I would suggest that acute or severe cervical pain be treated and diminished before beginning.

Since the exercises are taxing to the muscles, muscle injury or strain needs to resolve somewhat prior to the start of this protocol. Advanced degenerative changes of the cervical spine may present a contraindication for curve restoration as excessive disc degeneration or joint arthrosis may make changes difficult or impossible.

However, in my clinical experience working with a number of patients, I have found the protocol successful in most patients including many with degenerative changes.

As with any treatment, good judgment should be exercised. Should symptoms flare, the regimen should be discontinued until it can be determined that the patient has sufficient healing or capacity for the exercises. Good doctorpatient contact and dialog is essential.

Lastly, as the exercises are new to the patient, the doctor should not only instruct the patient in performing the exercises correctly, but should subsequently monitor the patient in performing their exercises during the beginning days of their routine.

#### **Practice considerations**

The unit is usually priced to the patient at \$200 or more and comes with a complete set of billing codes for the insurance company, both for dispensation of the unit and as an inoffice rehabilitational therapy.

Treatment results are best accomplished by weekly cervical spine adjustments and comparative lateral C spine X-rays will be needed for periodic monitoring of patient progress. Periodic review of exercises or in-office exercise routines can be billed under the therapeutic exercise code provided in the included DVD.

#### For more research, visit www.ChiroEco.com/ccr4hilllabs.

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