Preliminary Findings

RESOLVING CHRONIC LOW BACK PAIN: THE FOOT CONNECTION

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Abstract. *This study (i) statistically links untreated forefoot varum deficits to intractable low back pain, and (ii) correlates long-term effectiveness of back therapy to control of hyperpronation patterns. In a random study of 208 chronic low back pain sufferers, 202 were diagnosed with forefoot varum deficits greater than 16 mm. All 208 participants were fitted with postural control orthotics. Subjective profiles were taken one year post-therapy: Ninety-six percent (202/208) reported an ongoing attenuation in low back pain as long as the orthoses were worn.*

Descriptors. *bio-implosion, forefoot varum, hyperpronation, low back pain, orthoses, overbite*

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INTRODUCTION

Low back pain is one of the most common complaints seen by health care providers. Usually, the back pain is not related to a specific injury. Rather, the back pain develops insidiously, progressing from mild in early life to debilitating in later life. Many low back pain sufferers are treated by a number of health care providers. However, in most cases, when therapy ends, back pain returns.

The findings of the present, preliminary study argue that forefoot varum (sometimes referred to as forefoot supinatus) is a leading cause of mechanical low back pain. The prevalence of forefoot varum has been described (1) and related to musculoskeletal pain (2,3). Biomechanically, forefoot varum forces the foot's medial column to roll inward, downward, and forward (hyperpronate). This displaces the body's line of gravity forward and orchestrates the forward pelvic rotation (*Figure 1*). The engineer expresses this concept: "Where the foundation goes, so goes the rest of the building." Pelvic repositioning is prodromal to low back pain. Pregnant women entering their third trimester are classic examples of patients with evolving low back symptoms associated with malpositioning of the pelvis. In these cases, the weight and position of the fetus rotates the innominates forward, producing the sacral-iliac strain and associated low back pain. Postpartum, the pelvis repositions itself, and the low back symptoms subside.

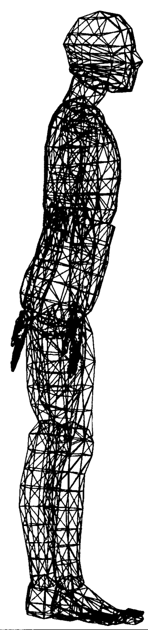

Figure 1. Sagittal view of a postural imploder. This unstable postural model is generated by a pattern of hyperpronation, left STJ > right STJ (see Photograph 2): hands pronated. Innominates rotated forward and outward (pelvic tilt), left > right. Scapulas protracted. Thoracic cage rotated counterclockwise (right arm anteriorly displaced relative to the left arm). Cranium thrusted forward.

Stable alignment. Good posture is dependent upon stability within the subtalar joint. In a relaxed standing position, the

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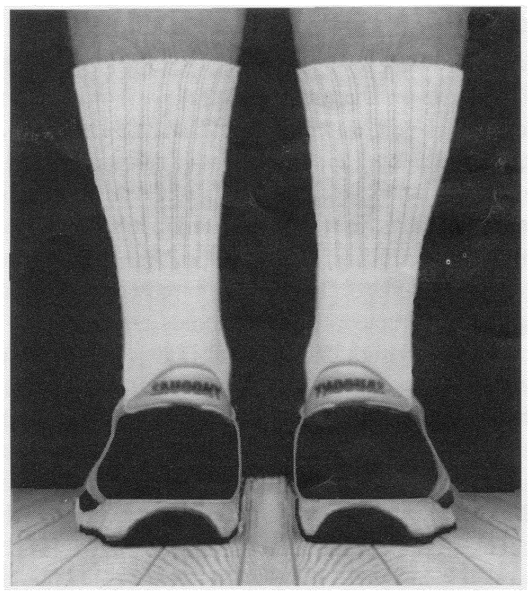
subtalar joint is congruous, neither pronated or supinated (*Photograph 1*). The body's line of gravity transects the foot through the subtalar articulation. In walking, the subtalar joint pronates/supinates 6-8 degrees around its anatomical neutral position (*i.e.* subtalar joint does not hyperpronate). This functional axis maintains upward joint congruity within (*i*) the sacral iliac joints (stable pelvis), (*ii*) the gleno humeral articulation and, (*iii*) the cervical spine (head remains centered over the cervical spine, not thrusted forward with the associated orthodontic problems) (*Figure 2*).



Photograph 1. Neutral subtalar joint. Posterior view of leg and foot. The subtalar joint (STJ) is neither hyperpronated nor supinated. Note even wear patterns in shoes.

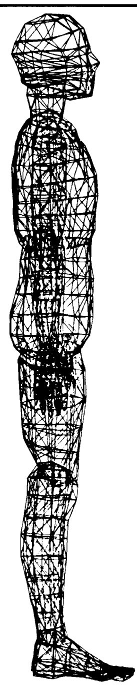
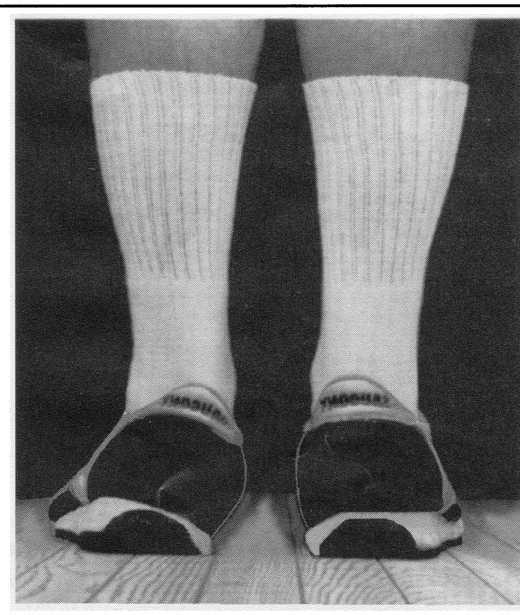


Figure 2. Sagittal view of a vertical posture. This stable postural model is generated by a neutral subtalar joint (see photograph 1). Hands neutral position, thumbs pointing forward. Neutral position of sacral iliac joints (level pelvis). Retracted scapulas (straight shoulders). No thoracic cage torsion (both arms lie on the frontal plane). Head centered over cervical spine.

This neutral model is the classic concept of "perfect" posture. The shoulders, pelvis, and ankle joints are level side-to-side. The student of kinetics would describe the body's center of gravity as being in the anatomically correct position; or, more eloquently, as being at equilibrium. Visually, the patient stands perfectly straight. Dynamically, the "perfect" anatomical model has a smooth, quiet, walking pattern. There is no excessive motion, no ungainly, asymmetrical lurges. At heel contact, the 6-8 degrees of normal pronation act as a torque transducer, isolating the generated reactive forces to the subtalar joint (4-6). The same straight lines observed in quiet stance are maintained while walking.

Hyperpronator. In contrast to good postural mechanics, poor postural mechanics is ungainly, uneven, asymmetrical. Visually, there is some degree of inward rotation of both feet (*Photograph 2*). This inward collapse of the feet affects all the weight-bearing joints. The knees may come closer together, the low back appears swayed, and the head and shoulders shift forward. It is common to hear that the patient is diagnosed with a leg length discrepancy or muscular tightness. As these patients walk, they appear to limp. They walk heavy-footed. The shoulders and arms have a more limited motion and appear tight. With each step, these patients are putting gravitational stress through their entire musculoskeletal structure.



Photograph 2. Hyperpronated subtalar joint. Posterior view of leg and foot. Note the functional hyperpronation pattern left > right (as seen in patient AMR).

Postural control orthoses verse arch supports. Currently, arch supports are the most frequently prescribed orthoses and are effective during the early stance phase. However, in the presence of forefoot varum, the effectiveness of these devices diminishes as the forefoot is loaded. To address this issue, a new generation of orthoses (Postural Control Orthotics™ or PCO) have been introduced. The keystone in the PCO design is the extended application of force under the entire first metatarsal bone (*Figure 3*). The lateral extension of force ends at the medial margin of the second metatarsal (*Figure 4*). This makes the postural control orthotic proficient in eliminating mid-to-late stance phase hyperpronation without jamming the lateral compartment of the foot. With this extended control, dysfunctional postural mechanics can be addressed more effectively.

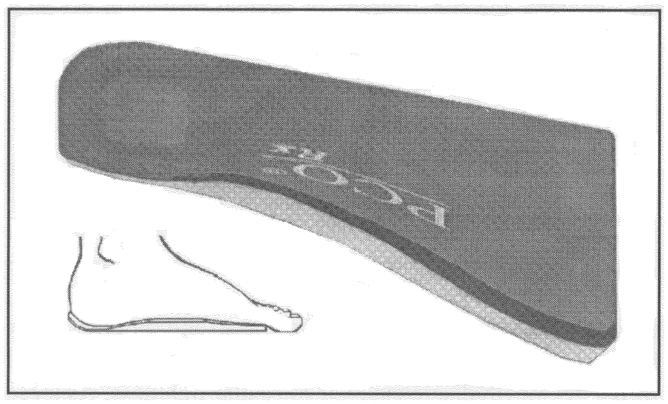


Figure 3. Medial (inner arch) view of PCO. The unique design extends the vertical height to the head of the first metatarsal. This elongated force model is essential in controlling mid to late stance hyperpronation.

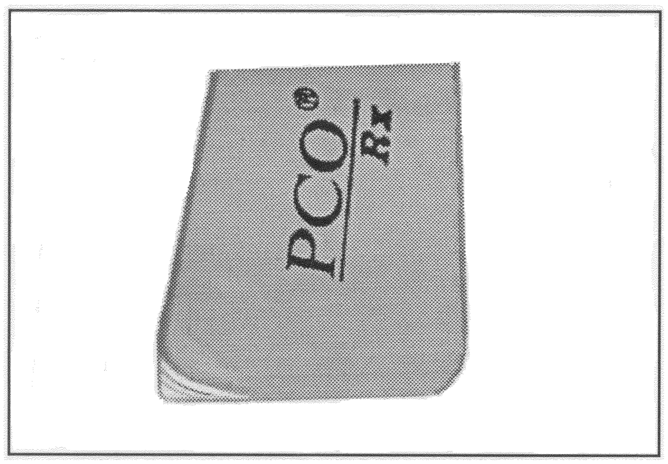


Figure 4. Front view of PCO. Vertical support does not extend past the medial margin of the second metatarsal bone. Since Forefoot Varum only involves the medial column of the foot, any prescriptive force under the second metatarsal diaphysis could cause jamming as the forefoot leads in mid to late stance phase of gait.

CASE STUDY

Chronic mechanical low back pain. AR is a 56 year old female, 5'6", 150 pounds. Her chief complaint is a chronic sharp-to-dull ache across her low back. On occasion, this pain will radiate down her thighs as a burning ache—left side more frequently than right side—but rarely does this burning reach her ankle or foot.

Subjective symptoms increase with certain activities involving concurrent bending-twisting motion or maintaining one position for a period of time (*e.g.*, standing at the sink washing dishes). Onset is insidious and not related to any specific injury. Over a span of approximately 25 years, the back pain became more persistent and more intense. She had been treated by neurologists, orthopedists, and chiropractic physicians. X-rays and MRI are negative for stenosis; however traction bars are noted at L4/L5 and diagnosed as spondylosis. Disclosed in the patient's history are (*i*) foot and leg tiredness, (*ii*) right ankle instability, (*iii*) episodic knee pain (left > right), (*iv*) shoulder tightness, and (*v*) daily headaches (right > left).

Examination. The examination was performed with the patient standing in an anatomical neutral position. The anterior scalenes (right > left) and sternocleidomastoides (left > right) are tender to palpation. Side bent head rotation is limited (right > left). Temporal mandibular joints click during excursion. The mandible tracks right (open mouth) to left (closed mouth). Open mouth position is restricted, less than 2 finger widths. Pterygoids are tender to touch. The bite is retrognathic. The scapulas are protracted. The rhomboids are tender to touch (right > left). Palpation of the sacral-iliac joints elicit subjective 1+ sensitivity right, 3+ sensitivity left (0-5 scale). Iliotibial band tenderness is bilateral, 1+ right, 3+ left. Tightness is noted in the quadratus laborum (left > right). Hamstrings and triceps surae are tight. Standing, the inner longitudinal arch is slightly depressed. There is no midtarsal bulging, the talonavicular alignment is intact. However, the inner arch prolapses (left > right), as the knees flex. Prone, the left leg appears 30 mm longer than the right leg. Supine, both legs are the same length. Straight leg test is negative for sciatica. The foot is cavus off weight-bearing.

Measurements. Forefoot varum is measured at 21 mm right, 20 mm left (gauged standing on Biovector™). Neutral position casts demonstrate a forefoot varum pattern, 14 degrees right, 11 degrees left. The first metatarsal is plantarflexed (right > left). Tibial varum is 2 mm right, 0 mm left. Ankle joint dorsiflexion is greater than 15 degrees bilaterally. Active range of motion of the first metatarsal-phalangeal articulation, off weight-bearing, is greater than 20 degrees bilaterally. First metatarsal-phalangeal extension, on weight-bearing, is 15 degrees right, 12 degrees left.

Gait evaluation (visual analysis). The calcaneus is vertical at heel contact, bilaterally. The right foot is more abducted than the left. At midstance, hyperpronation is observed through the subtalar joint (left > right). A forward-outward rotation of both innominates is noted (left > right). Both hands are pronated. Arm swing is restricted (right > left). The upper trunk is rotated counterclockwise, seen as a scapular protraction pattern (right > left). The head is thrusted forward and side-bent left. The mandible is retrognathic with a Class II bite.

Treatment Day 1. Postural control orthotics are fitted with a forefoot vertical height (extrinsic post) of 12 mm right, 10 mm left. The patient initially feels lightheaded and nauseous. The patient feels pressure along the distal medial margin of the PCO. A slow break-in period is stressed, increasing/decreasing wear-time one hour per day as tolerance permits.

Week 2. AR is able to wear the PCOs full-time, forgetting the PCOs are in her shoes (referred to as transparency). The following postural reactions are noted: Day 2, increase low back aching (left > right); Day 5, increase mid-back pain associated with standing or bending; Days 4-8, increase tiredness in both legs and feet. All postural reactions are subsiding by Day 11. Day 12, the low back is improved. AR is able to do more before her back starts to ache.

Week 10. For the first time in years, the patient is able to wash dishes at the sink without back discomfort. Foot and leg fatigue has disappeared. The orthotics are transparent, *i.e.*, comfortable to wear. Her husband comments, "She doesn't seem to limp as much when she wears her orthotics."

Week 17. Low back pain is slowly increasing in frequency and severity over the past 12-14 days. The orthotic transparency index is diminishing. AR states, "I can't wear my orthotics now without my toes falling asleep." Posturally, changes are noted as the patient states, "I'm slouching more." Forefoot measurements are retaken and record as 23 mm right, 22 mm left. Forefoot hyperpronation is visually increased from the last gait evaluation. Using Temporary Elevation in Medial Posts (TEMPs), vertical lift is increased 6 mm right, 4 mm left. The orthotics now measure right 0/18, left 0/14.

Week 18. Low back pain and digital paresis are gone. Orthotics are transparent. Patient is standing more upright. AR is recalibrated and fitted with a second pair of PCOs (right 0/18, left 0/14).

Week 32. Patient is able to do daily home activities with little or no low back pain. She is unable to recall her last episode of low back pain. Her knees are asymptomatic even with increased activity. Surprising to AR, her neck and shoulder symptoms are attenuating. "I can't remember when I had my last headache." Once again, she feels as if she is standing and sitting straighter.

Week 45. Stiffness in the shoulders and neck is reoccurring. The patient repines that the orthotics are making her worse. "I have headaches now, almost daily. I never use to have headaches before I wore orthotics." However, the headaches no longer radiate from the back of the neck. Instead, they emanate from the right temporal mandibular joint to the right orbital. The orthotics irritate her feet. "My left foot feels bruised by mid-morning. I have to take them out of my shoes for a while to get rid of that dull-to-sharp foot ache." Her postural implosion is increasing; however, her low back remains asymptomatic. Without orthotics, the patient's hyperpronation pattern has changed dramatically. The rearfoot hyperpronates at heel contact and the talonavicular joint collapses at midstance. The forefoot hyperpronation pattern is unchanged Forefoot varum measurements record as 24 mm right, 22 mm left. TEMPs are applied and the patient is recalibrated for her third pair of PCOs.Subjective distortion of pain symptoms is a common occurrence associated with PCO therapy. For example, AR complains of a new symptom (daily headaches) due solely to orthotic therapy. She has forgotten that daily headaches were one of her initial presenting complaints. This is a survival mechanism most chronic pain sufferers acquire. They learn to bury or forget their pain in order to make it through the day. A continuously upgraded symptomatic profile prevents the clinician from being misled by this "selective memory syndrome."

Week 47. AR is fitted with PCOs: 0/22 right, 0/19 left. Her headache immediately subside, then returns when she removes the PCOs (third pair). Gait analysis demonstrates a nearly vertical calcaneus at heel contact and midstance, with a dramatic scapula retraction and leveling of the innominates.

Week 49. AR is uncomfortable wearing the new PCOs. Her symptoms include (*i*) constant aching across the shoulder blades, (*ii*) aching in both shoulders with radiating pain into the left arm and jaw, and (*iii*) foot irritation. The patient complains that the balls of her feet ache (left > right) by early noon. AR is referred to a physical therapist for anterior chain release therapy.

Week 50 (PT). AR is evaluated in physical therapy with a diagnosis of bilateral forefoot varum (right > left). She has a prescription to release articular and soft tissue restrictions in her musculoskeletal system. AR's observed "slouched" standing posture is typical of patients with chronic pain complaints. Standing and walking on her postural control orthotics, the following observations are recorded: (*i*) a mild head forward position with upper cervical extension, (*ii*) a mandibular retraction with Class II overbite, (*iii*) a mild scapular protraction, (*iv*) an internal shoulder rotation (right > left) in the transverse plane, (*v*) a mildly exaggerated upper thoracic kyphosis with trunk rotation to the left, and (*vi*) a mild hyper-lordotic lumbar curve. Without the PCOs, the upper body is significantly more forward and inward (bio-imploded). No significant structural deviations are noted in the patient's lower body except for mild subtalar/forefoot hyperpronation (left > right}. Without the postural control orthotics, the feet are dramatically more collapsed.

Active knee flexion in a standing position produces a mild genu valgum (left > right) as the patinet's weight shifts forward. Active knee flexion without the PCOs produces a severe genu valgum (*i.e.*, medial margins of the knees touch) as the weight comes forward over the foot. Mobility evaluation (patient standing) demonstrates a mild A/PROM deficit in mandibular protraction, upper cervical flexion, cervical rotation/side bending (right > left), and thoracic extension. Limitations in rib excursion is noted with attempted diaphragmatic breathing. The patient easily moves into an imploded posture (trunk flexion, scapular protraction, internal shoulder rotation, and head forward with upper cervical extension); however, she finds it very difficult to move into an "exploded" posture past her anatomical neutral position.

Articular/soft tissue assessment demonstrates varying levels of irritation throughout the patient's trunk and cervical spine. Focal articular irritability is isolated to the upper cervical (C0-C3) mid-thoracic facets (right > left), acromio-clavicular and sterno-clavicular joints (right > left), and left temporal mandibular joint. Soft tissue palpation demonstrates pathophysiologic changes over the dorsal/ventral aspects of the cervical, trunk, and pelvic zones. Muscular elements in the anterior zones demonstrate a functionally-shortened resting length. Muscular elements in the posterior zones demonstrate a functionally-lengthened resting length. Muscular trigger points are palpated throughout the dorsal/ventral aspects of the involved upper trunk, cervical, and cranio-mandibular zones. A greater predominance of trigger points are found in the posterior chain muscular elements. Myofascial and connective tissue tightness is noted throughout the dorsal/ventral aspects of the trunk and cervical spine. Dural meningeal assessment demonstrates a reduced amplitude of cranio-sacral motion and torsional strain patterns in the pelvis/cranio-mandibular zones.

In order for orthotic therapy to be successful, musculoskeletal compliance must occur. This allows the bony framework to shift as the PCO forces are applied. Intrinsic factors which limit this compliance also limit the body's ability to tolerate PCO therapy. These factors include (*i*) reactive muscular changes, (*ii*) soft tissue fibrosis, (*iii*) bony and /or articular restrictions, (*iv*) congenital anomalies, (*v*) nutritional deficits, and (*vi*) certain musculoskeletal and neuromuscular disease states.

AR demonstrates an adaptive shortening of muscular and connective tissue elements over the anterior zones of her trunk, shoulder girdle, and cervical spine. These emerge as the primary source of musculoskeletal resistance in reestablishing an upright posture. PCO therapy is essentially a battle of opposing forces being waged throughout the body (*i.e.*, downward postural collapse versus upward orthotic support). These antagonistic forces generate muscular strain patterns which can act as barriers to any further postural corrections. It is this mechanism that stages AR's protracted upper body "pain storm" and inability to tolerate her PCOs.

The goal of the physical therapist is to increase the musculoskeletal compliance. This facilitates the posterior shift in the body's line of gravity and allows the orthoses to work more effectively. Treatment encompasses myofascial release (initially using spray/stretch as described by Travell and, later, the more effective cold laser), articular mobilization, and cranial-sacral techniques to reduce torsional strain patterns in the patient's dural meningeal system. A home stretching/ strengthening protocol is utilized to augment the musculoskeletal responses.

Week 54 (PT). After four weeks of physical therapy intervention, AR reports a moderate reduction of her previously focal foot pain. A substantial reduction in the patient's cranio-mandibular and thoracic symptomatology is noted. She is able to tolerate a gradual build-up in the intensity of her daily home spinal stabilization exercises without experiencing musculoskeletal flare-ups.

Week 58 (PT). AR reports full-time utilization of her PCOs without foot irritation. The patient notes a near complete reduction of her previous cranio-mandibular and cervical/ thoracic symptomatology. She is now executing normal activities of daily living (ADL) without musculoskeletal discomfort. AR is instructed to continue her daily home program until active PCO therapy is concluded. A discharge notice is sent to the attending podiatrist providing a summary of the patient's updated musculoskeletal state and response to physical therapy.

Week 60. All upper body symptoms have subsided, and, for the first time in AR's adult life, strenuous housework and child care is performed pain-free. Her orthotics are transparent, and she is visibly standing more erect.

Week 84. The patient states her low back pain is 90% improved; feet, legs, and knees 95% improved; neck, shoulder, and headaches 80% improved. A final set of forefoot measurements are taken and recorded as 24 mm right, 22 mm left.

DATA COLLECTION

Over a span of five years (1990-94), 208 chronic low back pain patients participated in a study at the Bellevue Foot and Ankle Center. They were randomly selected from a pool of chronic low back pain sufferers and, prior to this study, treated with various modalities including nonsteroidal anit-inflammatory drugs (NSAIDs), massage therapy, injections, and, in some cases, surgery. Subjective outcomes were reported as less than anticipated and, in many cases, very disappointing. All of the paticipants were committed to diminishing their disability and to improving their quality of life. Subsequent gait evaluations demonstrated that 202 of the 208 participants were hyperpronators. All were fitted with postural control orthotics. One year after therapy, questionnaires were sent to each of the 208 patients (*see page 89*). The participants were asked to evaluate the percentage of low back improvement since wearing PCOs. Of 208 respondents, 139 reported an improvement of 70% or greater, 31 reported an improvement of 50-60%, 24 reported an improvement of 10-40%, and 6 reported no improvement or an increase in their low back pain.

STATISTICAL EVALUATION

Biovector measurements, taken at the conclusion of therapy, provided the final data for this study. Means and standard deviations were calculated for both feet. The mean vertical height and standard deviation for the right and left foot was 23.9 mm/2.7 mm, 21.8 mm/ 2.7 mm respectively. Using the formula

$$Vd = VHR - VHL$$

the frequency of vertical discrepancy was tabulated. Low back

Bellevue Foot and Ankle Center

A Sports Medicine Facility

Orthotic Questionnaire

Chief complaint or reason for seeking care ______________________________

____

How were you referred to the Bellevue Foot & Ankle Center (Physician/Friends or Relatives/Yellow Pages/Other) ________

____

Have you had (Check where appropriate)

Surgery or Orthopedic Care	☐
Osteopathic Manipulation	☐
TMJ Work	☐
Chiropractic Care	☐
Physical Therapy	☐

In Box A, Check your location of Symptoms

	A	B
Neck		
Back		
Knee		
Legs		
Ankle		
Feet		

In Box B, Estimate your percentage of Improvement since wearing Orthotics

Have you had prior experience with orthotics? ______________ (Yes/No)

If Yes: Type (Hard/Soft/Leather/Plastic/AD/PCO) ______________________

Dispensed by : Physician_______ Physical Therapist________ Other_________

Are you pleased with the results since wearing *our* Orthotics (Yes/No) ____________

What Percentage of time are you wearing your Orthotics (Circle where appropriate)

80-100%
60- 80%
40- 60%
<40%

What suggestions do you have to improve our care of service ______________________________

____

____

Date

C #

pain (LBP), initially reported predominantly on the left side, correlated to Vd ranges = 0 to +4 with a mean of 2.54 ± 1.01. LBP initially reported predominantly on the right side correlated to Vd ranges = -3 to 0 with a mean of -1.14 ± 0.77. LBP initially reported as centered correlated to Vd ranges = -2 to +2 with a mean of 0.33 ± 1.07. Frequency curves demonstrate a negative skew with left sided pain, a positive skew with right sided pain, and a bell-shape curve with centered pain.

The Vd computations parallel the visual gait analysis. Remembering that function mirrors structure, a higher VHR (and higher Vd), produces an hyperpronation pattern (left > right). This drives the left innominate further forward and the associated left-sided back pain. Conversely, a higher VHL (and lower Vd), produces an hyperpronation pattern (right > left). This drives the right innominate further forward and the associated right-sided back pain.

The presence of forefoot varum deficits is statistically correlated to the presence of LBP. The null hypothesis was *individuals without forefoot varum deficits are equally likely to have low back pain as individuals with forefoot varum deficits.* The chi square test was applied and that the null hypothesis was rejected with a 99.9% level of confidence that forefoot varum deficits greater than 16 mm are correlated to LBP. The sample size for FFV< 11 mm is too small to extrapolate any meaningful correlation.

The observed and expected frequencies of orthotic effectiveness associated with vertical deficits greater than 16 mm and less than 11 mm were calculated. The chi square test for FFV > 16mm = 5.98 E − 34. This asserts, with a 99.9% level of confidence, that postural control orthotic therapy is effective with vertical deficits greater than 16 mm. The sample size for FFV< 11 mm is too small to make any meaningful correlation.

DISCUSSION

How postural control orthoses work is better understood by evaluating the force mechanics of standing and walking. Due to the earth's gravitational field, foot instability affects the entire body. A vertical deficit forces the ball of the foot to roll inward, downward, and forward until the forefoot reaches the ground. The body's line of gravity shifts to the inside of the foot which, in turn, forces the innominates downward and outward. The lumbar spine is carried with this pelvic rotation, producing a lumbar lordosis and a compensatory thoracic kyphosis (hunched shoulders). As the scapulas protract, the neck loses its normal curvature, and the head is thrust forward (orthodontic Class II overbite). This phenomenon of gravity-induced skeletal collapse is termed *bio-implosion* (3).

The use of vertical force (posting) under the entire medial column of the foot to control forefoot varum, is based on Newtonian mechanics. With judicious posting, reactive ground forces through the foot are augmented to reduce subtalar and sacral iliac joint incongruity. That is, wedging the medial column and, retroactively, the subtalar joint, reduces the forward rotation of the pelvis, much as stabilizing the foundation of a building, stabilizes the entire superstructure. By maximizing joint surface fit within the pelvis and low back, articular compressive forces are dissipated over a larger surface area. Articular cap regeneration and reduction in low back pain is the end result.

AR personifies the classic textbook description of chronic pain syndrome. Historically, proactive factors (*e.g.*, musculolskeletal deconditioning, reduced neuromuscular coordination, pyscho-social factors) are implicated as the etiology of patients' unrelenting symptoms. Often ignored is the correlation between forefoot varum and the ensuing reactive skeletal collapse. This reactive model explains the biomechanical strain patterns found throughout the various body segments. That is, muscles reactively conform to the spatial orientation of the bony framework. Adaptive shortening occurs in the imploders; adaptive lengthening occurs in the exploders.

Forefoot varum, in terms of vertical deficits, has been recorded previously. Over 1000 profiles were collected as of December 1994 and a preliminary diagnostic profile has been suggested as follows:

- Under 10 mm of forefoot vertical deficit, PCO therapy is not recommended.
- Between 11 mm - 19 mm of vertical deficit, PCO therapy is recommended if (*i*) an intractable injury to a weight bearing joint has occurred, or (*ii*) patellar femoral stress syndrome is diagnosed (3).
- Over 20 mm of vertical deficit, PCO therapy is highly recommended initiating therapy ideally before age 12.

SUMMARY

The data show that (*i*) chronic low back pain correlate with forefoot varum and (*ii*) postural control orthotics are effective in resolving chronic low back pain syndrome. The case mean study presented has shown that the use of postural control orthoses (sometimes referred to as postural control devices) improve foundational stability and abridge the associated musculoskeletal symptoms. This preliminary study is an attempt to share the investigators' observations. Responses are welcome.

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