

Multidisciplinary Analgesia/PT Approach to Treating Peripheral Neuropathy

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Peripheral neuropathy is a degenerative peripheral nerve condition marked by muscle weakness and atrophy, pain, and numbness. It may affect motor, sensory, or vasomotor nerve fibers, and can lead to disability, foot ulcers and amputations, and injurious falls. Those falls result from a combination of

- **Loss of proprioception**, compounded by age-related deterioration of vestibular function
- **Loss of muscle tone and response, leading to compensated gait and stance** induced by pain and loss of sensorimotor feedback
- **Settings when patients lose visual input**, e.g. going to the bathroom at night.

Although most commonly recognized as a complication of Type 2 diabetes, the vast majority of those who suffer from peripheral neuropathy do not have diabetes.

Therapy for peripheral neuropathy today focuses mainly on a spectrum of drugs that, to varying degrees, relieve the chronic pain associated with the condition in some patients, but don't alter the course of the disease, and in some cases, present side effects that can increase the risk of falls.

As a result of pain, numbness and the compensatory stance and gait they encourage, peripheral neuropathy patients face a high risk of falling that might be ameliorated only by rigorous physical therapy. However, the success of physical therapy in treating peripheral neuropathy has been checkered. A Medline search reveals no randomized clinical trials to evaluate the role of physical therapy in this condition, although many articles on the disorder make references to exercises, stretching and splinting as possible PT maneuvers to reduce pain or strengthen muscles.

This document reviews current perspectives of peripheral neuropathy, and its clinical and economic impact.

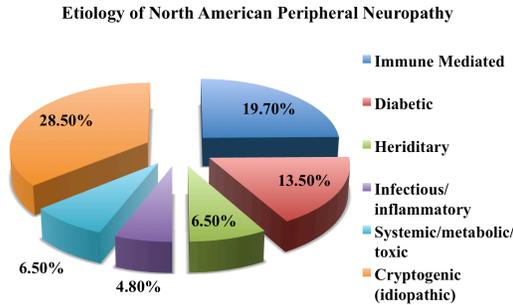
- It presents a new multidisciplinary protocol combining anesthetics, electroanalgesia, and balance-focused physical therapy, combining a clinic-based Biodex Balance System with home Thera-Tube exercises.
 - Preliminary experience across several hundred patients with diverse diagnosed and idiopathic neuropathies suggests this protocol may relieve pain, improve balance, and enable patients to again ambulate confidently in the community.
 - Virtually all NBO's protocol experience was generated in patients who had failed multiple

attempts at conventional pharmaceutical and physical therapy. Some entered the NBO protocol because they were facing amputation due to repeated infection and inadequate peripheral circulation.

- Pre/post testing with the Balance System conclusively documents results never reported with any prior pharmaceutical, anesthesiology or physical therapy alone – specifically,
 - Reduction or elimination of neuropathic pain
 - Improved proprioception as a result of restored sensation
 - Demonstration of significantly normalized response to balance challenges similar to those they will encounter in the community
- The NBO protocol opens the possibility of collaboration between physical therapy and physicians – specifically, anesthesiologists in pain centers and neurologists – to combine these different modalities, to offer relief to millions of Americans often suffering a decade or more from neuropathies of different etiology, but with the common characteristics of extremity numbness, pain, and the vulnerability to injurious falls.

Prevalence of peripheral neuropathy

The prevalence of peripheral neuropathy has been reported in the general population to range from 2.4 to 8.0% with a higher prevalence in the elderly.¹



Pasnoor M et al North America and South America (NA-SA) neuropathy project. Int J Neurosci. 2013 Apr 17.

- The Neuropathy Association estimates that 20 million Americans suffer from this condition.
- A 1999 survey found that 8-9% of Medicare recipients have peripheral neuropathy as their primary or secondary diagnosis. The annual cost to Medicare exceeds \$3.5 billion.²
- Most disturbing for America's insurance companies – peripheral neuropathy, once incorrectly considered a characteristic of “normal aging” – is increasing most sharply as a primary discharge diagnosis in individuals with diabetes under 45 years of age.³

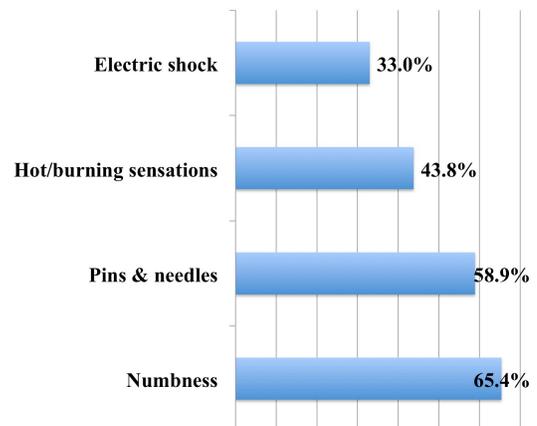
Symptoms. The symptoms of peripheral neuropathy vary by involved neurological systems. Those of large fiber neuropathy include numbness, tingling, weakness and loss of deep reflexes. By contrast, symptoms of small fiber neuropathy include the most physically and emotionally distressing pain.



This neuropathy patient did not feel the first ulcers on the bottom of her foot until it was too late. Extreme infection had set in and antibiotics were ineffective. Parts of the bone in her foot were removed and replaced with steel plates and the top portion of her second toe had to be amputated.

In a 2011 reported study⁴ of 399 Midwestern patients with diabetes, 46.4% reported symptoms of painful peripheral neuropathy, with 27.6% reporting a duration of more than five years. Common characteristics of nerve pain included numbness (65.4%), pins and needles (58.9%), hot and burning sensations (43.8%), and electric shock (33.0%). The percentage of patients who reported moderate to severe pain (pain score 4 or higher) over a 1-week period was 64.4%, with 41.1% experiencing it throughout the day. For reporting pain, 23% had been treated, while 30% received no treatment; only 48% were satisfied with their current treatment regimen.

399 Midwestern Peripheral Neuropathy Patients: Reported Pain Sensations



Autonomic dysfunction can also present in peripheral neuropathy, manifesting as orthostatic hypotension, urinary bladder incontinence, sexual dysfunction in both men and women, gastroparesis, sweating abnormalities, sluggish pupil reaction and exercise intolerance.⁵

Anatomy. Photomicrographs show that the destruction of nerves is truly “peripheral,” so that the more distal tissues are the most affected - most significantly, the hands and feet. Loss of sensation in the feet explains how patients with diabetic neuropathy become vulnerable to unappreciated injuries and foot ulcers that can lead to osteomyelitis and amputation.

Etiologies. Peripheral neuropathy is a common complication of Type 2 diabetes. According to the ADA, 18.8 million people in US have Type 2 diabetes. Community based studies report the prevalence of painful diabetic polyneuropathy as around 16-26%,⁶ and in one study 80% of the patients had moderate or severe pain.⁷ But among North American patients, Type 2 diabetes is the etiology of only about 13% of the condition.⁸ Other causes include

- Alcoholism, and nutritional deficiencies (e.g. thiamine, B12)

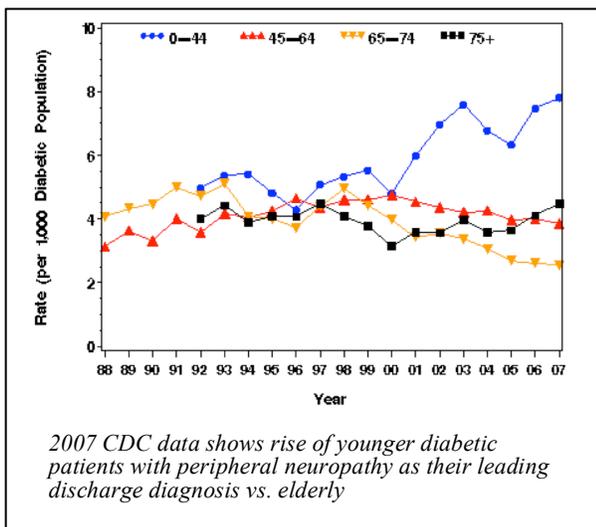
- Infections (e.g. HIV, Lyme disease)
- Malignancies (e.g. bronchogenic carcinoma, renal cell carcinoma, lymphoma, multiple myeloma)
- Autoimmune diseases (e.g. systemic lupus erythematosus, Sjogren syndrome, rheumatoid arthritis)
- Hereditary neuropathies (e.g. hereditary sensory neuropathy types I, II, III, and IV, Krabbe disease, Charcot-Marie-Tooth disease)
- Pharmaceuticals (especially chemotherapy)

Chemotherapy. Chemotherapy is also an important cause of peripheral neuropathy. The incidence of peripheral neuropathy with chemotherapy is high (50 – 71% with taxanes, 74% with oxaliplatin) – and more than 500,000 patients are treated with taxane class annually.⁹ The neurotoxicity of taxanes is believed to result from their upregulation of matrix metalloproteinases (MMPs), with a resulting sequence of nerve damage, pain.

Oxaliplatin-induced neuropathy is also a challenge. In the MOSAIC¹⁰ trial: 44% of patients had grade 2 or grade 3 neurotoxicity at the end of treatment, 6% one year after therapy, and 4% after 18 months.¹¹ In a EU trial, 26% with grade 3 neurotoxicity had persistent symptoms at 28 months,¹² and in an Australian prospective study,¹³ 79% of patients had persistent neuropathy, with 12% reporting Grade 3 neuropathy at 29 months following cessation of therapy.

However, in clinical practice, after excluding diabetes and other readily diagnosed conditions, up to 70% of diagnosed peripheral neuropathy may be functionally idiopathic.

Treatment. Today, the range of therapies available for peripheral neuropathy is limited, and offers limited efficacy. The most popular pharmacologic option for



the painful variant is Lyrica® (pregabalin), which costs about \$400/month and offers only a 50%

reduction in pain for half of treated patients. Pregabalin also carries a side effect profile impacting almost a third of patients – including dizziness that accounted for 42% of patients terminating use of the drug.¹⁴

Cost of complications. One of the driving forces for relieving the pain and numbness of peripheral neuropathy is the cost of complications suffered by patients.¹⁵

Due to a combination of limited sensitivity to injury and infection, 6% of those with Type 2 diabetes will develop foot ulcers.

- Yearly costs of ulcers not infected: \$9,256
- Yearly costs of ulcers with cellulitis: \$24,544
- Yearly cost of ulcers that become osteomyelitis: \$45,552

As a result of complications resulting from peripheral neuropathy, about 70,000 patients/year undergo amputation – the immediate costs of which are considerable:

- Toe: \$22,702
- Foot: \$42,673
- Leg: \$51,280

Prevalence in elderly mistakenly believed “normal”

Loss of sensation in the feet and legs is so common among the elderly that many patients and their clinicians consider it a part of normal aging.¹⁶ And in fact, a chain of Michigan and Florida neuropathy-focused clinics serves mainly older patient with the painful variant of the condition

A study that demonstrated the prevalence in seniors was conducted by the University of Oklahoma of 795 noninstitutionalized individuals 65+ recruited from practices of Oklahoma family physicians via completed questionnaires. The study logged sociodemographic, medical conditions, and symptoms (numbness, pain, balance/gait issues) common to individuals with peripheral neuropathy - and their physicians tested their ankle reflexes, position sense, and vibratory/fine-touch sensitivity, and evaluated their balance and gait with the Tinetti balance test and a 50 foot timed walk.

The study detected peripheral neuropathy in 26% of those 65-74 and 54% of those 85+ - despite the fact that only 40% reported a disease known to cause peripheral neuropathy. Predictors of deficits included increasing age and body mass, low income, and history of military service, Type 2 diabetes and vitamin B12 deficiency.

Despite the prevalence in the elderly, demographically, the face of peripheral neuropathy

today is a 30-50 year old undiagnosed male with loss of sensation in feet, resulting in large part by the explosion in U.S. middle-aged obesity and Type 2 diabetes.

Between 1988 and 2007, peripheral neuropathy among diabetic individuals under the age of 45 decisively passed those 45-64 years of age, or 75 years and older. In fact, while the peripheral neuropathy as a primary diagnosis at discharge was unchanged for people aged 45-64 years, for those less than 45 years old were ~1.7 times higher than for people aged 75 years or older (7.8 vs. 4.5 per 1,000 diabetic population).¹⁷

Peripheral neuropathy explains many falls in the elderly. Peripheral neuropathy challenges both balance and gait, due to pain and/or parasthesia, and compensation. Because of peripheral neuropathy, affected individuals have little or no proprioception, and depend in daylight on their vision and vestibular function to ambulate. As a result, the most common fall for peripheral neuropathy sufferers occurs when they get up in dark to go to the bathroom.

At NBO Medical, patients report that falls and fear of falling are close behind pain and numbness as motivation for seeking care.

However, elderly individuals with peripheral neuropathy are of high interest to insurers because their common comorbidities accentuate the consequences of adverse events relating to neuropathy-induced falls:

- 65% with peripheral neuropathy suffered at least one fall/year, and 30% suffered a fall-related injury in small 1-year study¹⁸
- A study to isolate peripheral neuropathy as causing falls proved it is an independent risk factor, not associated with meds, vision or cardiac status¹⁹
- Faster walking speeds increase local instability among people with peripheral neuropathy²⁰

A University of Michigan study, in which patients w/EMG-documented peripheral neuropathy patients were studied versus age/medically matched EMG-normals, documents fall risk in peripheral neuropathy patients

- After 1 year, 55% of peripheral neuropathy patients suffered one or more falls, vs. 10% of normals
- Peripheral neuropathy subjects who fell demonstrated significantly worse vibratory sense at the ankle and finger ($p < .05$), and significantly decreased unipedal stance time (3.1 sec vs. 9.1 sec, $p < .05$) than the peripheral neuropathy subjects who did not fall
- Careful analysis of fallers: No medication or other

condition but peripheral neuropathy explained falls

Falls are expensive, whether patients seriously injured or not. Recurrent, uninjured fallers used additional \$12,000/yr. in health care resources vs. non-fallers²¹ By comparison, subjects who experienced 1 or more injurious falls/year,

- Increased home health utilization 7-fold
- Increased hospitalization costs 3-fold
- Increased ED costs 4-fold
- Generated incremental Medicare claims of \$19,440 annually

Current therapy for peripheral neuropathy

Much of how medicine treat peripheral neuropathy today follows the recommendations of a landmark study, "Evidence-Based Guideline: *Treatment of Painful Diabetic Neuropathy*," published in the May 2011 issue of *Neurology*.²² Collaborating in the development of the guideline development were the American Academy of Neurology, the American Association of Neuromuscular and Electrodiagnostic Medicine, and the American Academy of Physical Medicine and Rehabilitation.

The guidelines presented in that paper were based on a rigorous evaluation of all peer-reviewed literature on the treatment of painful peripheral neuropathy between the years of 1960 and August 2008. Their conclusions were based on Class I "definitive randomized clinical trials and consensus of expert medical opinion. The objective of their effort was to set forth currently accepted standard of care (ASOC) for peripheral neuropathy.

The collective effort attempted to answer the question: Can drugs reduce pain, and improve both function and quality of life? The team studied different drug classes - specifically, anticonvulsants,



Lyrica® (pregabalin) is the leading drug for treating painful peripheral neuropathy, with 2012 sales of more than \$4 billion. And yet, its package insert claims that randomized clinical trials showed only 50% of patients obtained a 50% decrease in pain, accompanied by a 30% incidence of side effects.

antidepressants, opioids, capsaicin, isosorbide dinitrate spray, clonidine and pentoxifylline. In addition, the group evaluated one Class I study that reported percutaneous electrical nerve stimulation reduced pain by 42% vs. sham treatment, and improved sleep.

“Probably effective” drugs. The study group concluded that 12 different drugs were “probably effective” to some degree in managing the pain of peripheral neuropathy. However, only two medications are approved specifically for the treatment of diabetic peripheral neuropathic pain: pregabalin (Lyrica[®]) and duloxetine (Cymbalta[®]). And only pregabalin was found to be consistently effective in treating peripheral neuropathy in patients with diabetes.

However, that determination of pregabalin effectiveness must be measured against the findings of two FDA-reviewed randomized, prospective clinical trials. In one, 50% of patients reported a 50% reduction in neuropathic pain. In a second, 40% reported their pain reduced by 50%. Despite its defined efficacy in providing measurable relief to a large subset of patients, pregabalin proved only modestly better than placebo in improving sleep among peripheral neuropathy patients.

The benefits of pregabalin must be considered along with the side effects presented in its package insert. Pregabalin causes 23% of patients to report dizziness and 13% to complain of somnolence at the most effective dose (300 mg/day). Therefore, half the patients taking pregabalin must balance a 50% chance of reducing pain and discomfort by 50% with at least a 30% chance of experiencing significant side effects. Conversely, 50% will not reduce their pain/discomfort by 50%, but will still have a greater than 30% chance of experiencing side effects.

Due to the cost of pregabalin (typically, \$400-500/month), many managed care companies require step therapy with other drugs in similar classes but without the formal indication for peripheral neuropathy - specifically, tricyclic antidepressants (e.g., amitriptyline or nortriptyline [Pamelor[®]]) or the off patent anticonvulsants (e.g., gabapentin

(Neurontin[®]). None of these have efficacy equal to that of pregabalin - for example, in clinical trials gabapentin was barely superior to placebo. Most present side effects as least as onerous as those of pregabalin.

NBO: Combined peripheral injection nerve blocks, Electroanalgesia (EA) and balance-focused PT

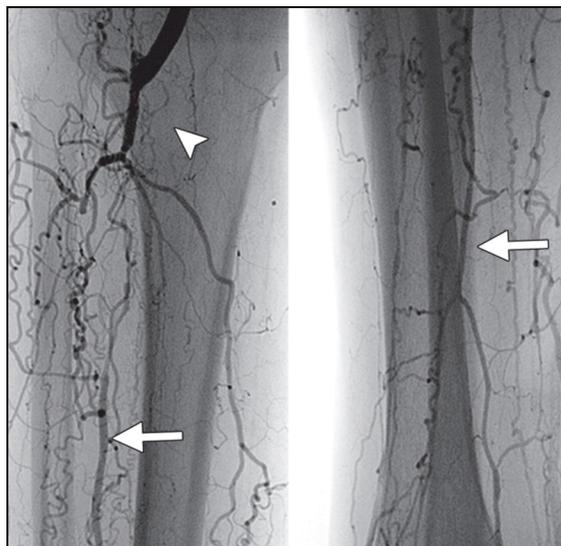
In recent years, a treatment modality has been used by physicians for peripheral neuropathy and has been shown both in basic science and clinical studies²⁷ to not only diminish the sensation of neuropathic pain, but also to facilitate the reversal of the damage caused by the disease state itself. To this treatment modality, NBO has added a balance-focused physical therapy program to enhance patient ambulation and reduce risk of falls.

NeuroMed Electroanalgesic Delivery System

with the NeuroSanos software version 5/1.0 is a FDA approved medical device that has cleared clinical indication of use to: 1) Stimulate peripheral nerves for the purpose of providing pain relief. 2) Increasing local blood circulation. 3) Management and symptomatic relief of chronic (Long-term) **INTRACTABLE PAIN.**

This treatment modality, often termed as “Electroanalgesia” (EA) therapy, utilizes the application of low frequency (<2,000 Hz) and medium frequency (2,000 – 100,000 Hz) combined with local anesthetic peripheral nerve blocks to achieve a variety of therapeutic actions including analgesia, reduction of edema and inflammation, and facilitation of metabolism in the neuropathic extremity.

Electroanalgesia (EA) is accomplished by placing large 5” X 8” electrodes over the treatment area. The strength of EA treatment is to reduce the ability of the affected nerves to transmit pain signals and, at the same time, promote healing by means of the depolarization effects on the nerve cells.



Baseline angiograms of proximal (left, antero-posterior projection) and distal (right, lateral projection) vessels in the leg of a diabetic patient with advanced peripheral vascular disease. It shows complete occlusion of the anterior and posterior tibial arteries and proximal occlusion of the peroneal artery, the middle and distal segments of which are patent (arrows). A femoropopliteal bypass (arrowhead) also is depicted. (Courtesy of Enrico Brocco, MD, Policlinico Abano Terme, Abano Terme, Italy.) [reference/contact at <http://radiographics.rsna.org/content/31/6/1623.full>

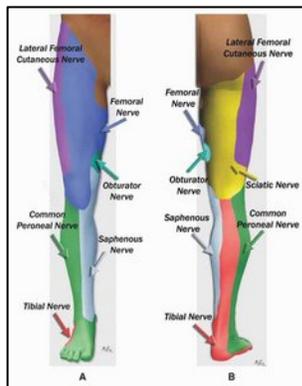
This medical device uses specific pre-programmed software algorithms to bioelectrically trigger different desired physiological mechanisms of actions from frequencies starting at .1 Hz - .5 Hz (for stimulation) then changing throughout the treatment to include a 5,000 Hz frequency. This technology also uses a High Definition frequency generator (HDfg)TM that can produce much higher frequencies, (8,300 Hz). EA technology is continually using a specific 1) carrier frequency, 2) and physician is changing the intensity (dosage) of the current to precisely match parameters delivered at the appropriate time.

When a peripheral nerve is exposed to a local anesthetic, then electrical impulses are interrupted via blockage of voltage-gated sodium channels, inhibiting both afferent signals from and efferent signals to the tissues innervated by the nerve. The afferent blockade results in a decrease in pain perception distal to the site of the blockade, which in turn facilitates regional muscle relaxation and increased circulation. The efferent blockade results in an inhibition of regional sympathetic tone causing vasodilatation that further augments local circulation. These effects complement the physiologic effects of the EA treatment.

To date, the local anesthetic blocks employed with EA treatment have involved relatively distal sites of injection (ankle and wrist blocks). As such, the benefit of the addition of a chemical block to the EA treatment would be logically limited to the anatomy immediately surrounding and distal to the injection sites.

Rationale for proximal nerve block

The argument for employing proximal nerve blocks with EA treatment is based on the fact that although clinical and electrodiagnostic (NCS/EMG, quantitative sensory testing, autonomic studies) testing most often will reveal the presence of a peripheral neuropathy²³, they do not always identify the specific site or extent of damage in the axon. Therefore, the more proximal the treatment (placement of local anesthetic and electrodes) in the affected limb(s), the



Potential sites of peripheral nerve blocks (Landmarks for Peripheral Nerve Blocks: Upper and Lower Extremities, Lippincott Williams Wilkins ISBN: 0781787521 | edition 2007 |

greater the chance of successfully treating the nerve damage caused by the neuropathic disorder.

Traditionally, proximal nerve blocks (such as femoral, sciatic and brachial plexus) have been employed in the surgical setting for the purpose of attaining intraoperative anesthesia and postsurgical analgesia. Because these blocks involve the use of relatively large volumes of local anesthetic to achieve the desired results, they carry a significant risk of systemic toxicity (via inadvertent intravascular injection or deposition of local anesthetic in highly vascular areas) and therefore are performed almost exclusively by anesthesiologists. High levels of success are achieved in these techniques with the use of ultrasound and/or nerve stimulators to assist in verifying needle position before injection, therefore minimizing not only the risk of systemic toxicity but also of nerve damage from intraneural injection.

With EA treatment, block only A-δ and C fibers

When employed in the setting of EA treatment, the purpose of performing the nerve blocks changes. Instead of attempting to attain blockade of all nerve fibers (profound anesthesia/analgesia), the goal is rather to block only the small myelinated (A-δ) and unmyelinated (C) fibers that carry pain and autonomic signals, while sparing the larger (A-α, A-β, A-γ) fibers responsible for proprioception and motor signals.

Performing the same technique as placement of traditional nerve blocks, but utilizing a fraction of the local anesthetic dose, accomplishes the desired effect. The degree to which each nerve fiber type is affected by local anesthetic is affected by several factors, including fiber diameter, degree of myelination, location in the nerve bundle, and firing rates.²⁴ The first modality to disappear is normally pain, followed by loss of sensation of cold, warmth, touch, deep pressure and, finally, loss of motor function.

To this end, proximal blocks are performed using a maximum of 7.5mg of bupivacaine (3cc of 0.25%) per block site. At this dose, the therapeutic goals of pain reduction and sympathetic blockade may be achieved easily. The possibility of creating a clinically significant motor blockade will be remote, yet provide a wide margin of safety in relation to toxicity risk. Even when performed for bilateral lower extremity EA treatment (bilateral femoral and sciatic blocks), the total amount of bupivacaine injected will be 30mg, one seventh of the toxic level of 3cc/kg in the average 70kg adult.

Pioneer published study. Cernak and colleagues tested bupivacaine combined with electrical stimulation in a 101-patient prospective study.²⁵

In the Cernak study, patients received a total of 12 electroanalgesia treatments, given three times per week for four weeks. The treatment duration was 25 minutes applied to either one or both feet, depending

on where the neuropathy was present.

During the first and third (Monday and Friday) treatment of each week, injections of 0.25% bupivacaine were performed using a 27-gauge needle. Injection sites were determined by the peripheral distribution of neuropathic pain. Up to four nerves were blocked in the same visit, including the sural, superficial peroneal, deep peroneal, saphenous, and posterior tibial. At the end of the study, 80% of patients reported a 70-99% improvement in peripheral neuropathy pain.

Shortcomings of EA Treatment without PT. While EA treatment alone will alleviate pain and may improve some degree of proprioception, it alone does little to reverse fall-predisposing “compensated” stance and gait acquired by peripheral neuropathy patients over the often months or years of pretreatment pain – and it is those “compensation” habits that predispose falling. As a result of compensation, their fast-response muscles are atrophied, and their ankle strength gone. They walk and climb stairs with a tentative small-step gait.

It was a desire to address not only the pain of peripheral neuropathy, but also, to reduce the risk of falling, that led NBO to develop its combination EA treatment/PT protocol.

Opening the window to PT. As long as neuropathy patients have severe pain, physical therapists that attempt to treat them face significant hurdles. In most cases, patients struggle through clinic sessions under the urging of the PT, the absence of which discourages intensive home exercises.

NBO clinicians have determined that, while Electroanalgesia and bupivacaine do not provide long term relief of neuropathic pain, the combination, after several twice-weekly visits, relieves pain sufficiently for most patients to begin a systematic clinic and home physical therapy protocol that

- Enhances analgesia-encouraged perfusion
- Begins the slow process of recovering proprioception, muscle strengthening and fast-fiber response times
- Offers the chance to regain a confident gait, reduced risk of falling – and escape from the unremitting pain that induces compensation.

That summarizes the perceived mechanisms of the NBO protocol, and may explain its ability to provide persistent benefits not seen with conventional pharmacologic and PT-only regimens.

NBO’s EA Treatment-synergistic physical therapy protocol

How NBO’s detailed evaluation, patient education and technology-supported PT reverses stance/gait issues that put peripheral neuropathy patients at risk of falls

Poor balance is a major risk for patients with peripheral neuropathy, which puts them at high risk of falls, whether their neuropathy is manifest by pain or numbness.

Because of peripheral neuropathy, they have little or no proprioception, and depend in daylight on their vision and vestibular function to ambulate. As a result, falls and fear of falling are close behind pain and numbness as reasons why peripheral neuropathy patients seek treatment.

Misperceptions about PT role. The potential role of PT in treating the peripheral neuropathy patient isn’t always well understood by either prescribing physicians or their patients.

As a result, patients with long-standing peripheral neuropathy typically come with a history of prior, unfavorable PT experience – usually prescribed for (or interpreted by the patient as) an attempt at pain management. They complain that PT didn’t relieve their numbness, burning and falls. That prior experience can negatively impact their participation in, and compliance with, a more focused PT component of a combined Electroanalgesia/PT program. The value of education is setting expectation for a difficult, painful condition like this cannot be overstated

Therefore, the PT’s first mission is to help the patient connect those falls and functional issues with the objective of physical therapy for peripheral neuropathy within the EA Treatment/PT protocol.

Failure to properly set those expectations and to demonstrate their targeted objectives may at least partially explain the limited PT success in this patient group.

First PT, then EA treatment. The precise implementation of NBO’s EA treatment/PT protocol



The Biodes Balance System is a computerized instrument that measures a patient’s static and dynamic vestibular balance and proprioception. It enables objective, graphic demonstration of the vulnerability of patients to a fall vs. age-matched normal, and provides a series of assessment challenges, presents patient performance in real time on a large heads-up computer screen. It stores that performance for retrieval, progress assessment and printout for medical records.

is guided by evaluation of an NBO physician who first screens the patient into the program. If the patient is suffering from profound neuropathic pain, PT sessions won't begin until the effects of the EA treatment therapy are sufficiently established to enable meaningful patient participation.

However, upon achieving that level of pain relief, patients come to the clinic two to three visits a week for a 60-90 minute PT session, followed by their EA treatment injections and Electroanalgesia. Physical therapy precedes the medical treatment, because peripheral nerve blocks and Electroanalgesia cause short-term attenuation of proprioception.

Bupivacaine is injected next to peripheral nerves associated with neuropathy symptoms, followed by electrostim utilizing low frequency (<2KHz) to stimulate, and medium frequency (2-100KHz) to increase blood flow and decrease inflammation.

PT history. While obviously part of any PT's first encounter with a patient, a careful history is especially important in preparing a course of therapy for a neuropathy patient. Such a history can disclose falls and frightening near-falls when they get up to go to the bathroom in the middle of the night. Discussion of going up and down stairs – even simple tasks like backing up after taking dishes out of a kitchen cabinet or food from a refrigerator – even walking across their lawn – can disclose how poorly they react to everyday challenges.

Review of those challenges opens up essential discussions beyond the patient's neuropathic pain or numbness. It provides the opportunity to explain how the human vestibular system, vision system and somatosensory system all normally combine to keep us safe –and how loss of the somatosensory system in peripheral neuropathy puts them in danger when they can't see clearly, or must maneuver on stairs, on grass, or uneven sidewalks.

An important part of setting PT expectations at NBO is explaining that, while reduction of pain is the objective of anesthesiology and neurology, the role of physical therapy is to enhance safe patient function.

But whether a patient is insured by private or public insurance, both physicians and PTs face additional challenges today:

- *Objectively document the need for therapy* before initiation
- *Objectively demonstrate the progress of the therapy* as it progresses
- *Objectively demonstrate the potential benefit of continuing that therapy* beyond the fixed limits often imposed, based on payer experience with less successful subjective therapies

A key tool in objectively assessing, treating and documenting the progress of our combined electroanalgesia and PT therapy is the Biodex Balance System SD.

Assessment. The NBO protocol begins with a

functional assessment worksheet of 20 questions that roughly resembles the G2 Functional Status section of the MDS 3.0 form used to assess patients entering a skilled nursing facility. NBO questions have a 0 to 10 rating scale on percentage of deficit in each functional category, from getting up from a chair, getting in and out of a car, going to the bathroom (actually negotiating onto the toilet and getting back up), working in their kitchen, putting on their clothes.

We fill out the form based on their responses at the initiation of our therapy, and every four weeks while they are in treatment. During those re-evaluations, we don't let them see how they scored themselves on prior questioning because we don't want them to be biased by what they had reported from four weeks earlier. Then we'll do it again at discharge. It gives us very concrete numbers specifically related their perceived

Patient Experience: Chemotherapy, Post-Trauma Peripheral Neuropathy

Sandra: In 2000 I underwent surgery and then chemo for breast cancer. Evidently my liver didn't like it and my pancreas failed, and I became a full-fledged diabetic, totally out of control.

I started having a lot of numbness in my feet. I had pain shooting out of my toes. I couldn't stand anything to touch them. But within 30 days of starting therapy, the pains stopped. I now have total feeling in my feet and between my toes. The back pain that had caused me to go for steroid treatments went away.

Because I could walk, in two weeks, my weight went from 216 to 192. My blood sugar is under control. Before treatment for my neuropathy, I was on 200 units of insulin twice a day. Now I am taking only 50 to 80 units a day.

Gail: My neuropathy stemmed from serious injuries to left leg in an automobile accident in 2004. After graft surgery, I had constant burning. Then I had the numbness start in my toes. I would wake up in the middle of the night with shooting pains up the back of my leg. My surgeon offered me a procedure that would leave my leg totally numb. I said no, even though it meant bearing the pain of constant burning from my knee to my ankle. I couldn't walk. I couldn't sleep. Those pains in the middle of the night, when they wake you up, they are horrible.

I heard about the program here, and my life has totally improved. I got a bicycle for Christmas last year and after coming here for treatments I was able to ride it. I go to the Y four times a week and do exercises in the pool. I have recommended probably a dozen people to NBO, and they all had really good results from the treatments here.

changes in functional ability.

A key part of our initial assessment is determining the duration, degree and progression of their numbness or pain. We have patients who've been living in dysfunction for 20 years. Many no longer appreciate what they've lost, and how that connects to their disease – and they must understand that, so they appreciate our therapy goals.

One way to explain their challenge, and where we want to take them, is a “box” visualization. I explain that each of us is capable of different movements in space, and how well we perform those movements determines the size of our personal “box.”

I have a box, and it's a pretty normal sized box. But gymnasts and football players live in really big boxes. If I tried to live in their box, I would end up in a hospital, because their boxes are huge.

I watched you walk in here today, and I could see you today are in a small box. You walk like you don't know where your feet are. And that small box makes you vulnerable to falls. The objective of our therapy is to help you push out the walls of your box, so you're able to do more and more, safer and safer. As a result you're going to have a better quality of life.

To break their compensated stance and gait, it's important that they understand how that stance and gait endangers them. They need to understand how their small steps and wide stance puts them at risk, because that's contrary to what they believe or even may have been told. We watch them walk and climb stairs, and explain how their compensation puts torsion on their knees, hips and back. Then they develop ankle problems, knee problems, back problems. We can prevent other problems from occurring by improving their walking patterns.

We explain that our objective is to get them confident enough to lengthen and quicken their stride, because they know where their feet are, thus decreasing their chances of falling.

Explaining somatosensory. The key loss in peripheral neuropathy is somatosensory feedback, and so it's critical that even our elderly patients

fully understand the focus of our therapy on its recovery.

You don't have feeling coming up through your feet right now. But you should have feeling coming up through your feet. That feedback is important, because it sends critical information to your brain via your spinal cord so you can improve your reaction time. If you don't have that feedback, you're more likely to fall, less likely to function, and you're going to live in a smaller and smaller box.

Visual system. Many peripheral neuropathy patients must rely on their eyes to compensate for the fact that they don't have somatosensory feedback. The Biodex Balance System provides a test and rehab protocol that enables us to demonstrate, quantify and benchmark their degree of both their somatosensory limits and visual system dependence.

Gait analysis. Gait is a key part of the NBO evaluation, because peripheral neuropathy patients so significantly modify their gait, either to minimize pain or adopt what they believe is a safer stance and gait.

Many neuropathy patients of all ages are afraid to take long steps – afraid to move out of their “box”

NBO also performs the Berg, Tinetti and ABC tests. In our experience, only the ABC properly evaluates fall risk at all. Patients can score a 48 out of 56 on the Berg, but are still a high fall risk. For that reason, the “gold standard” we use to evaluate, rehabilitate and document progress is the Biodex Balance System SD.

Testing on the Biodex Balance System

The Biodex Balance System is a computerized instrument that measures a patient's static and dynamic vestibular balance and proprioception. It

Enables objective, graphic

Patient Experience: 15 years of Lyme's Disease Neuropathy

Nicholas: Prior to my disability, I was a clinical psychologist for the Federal government, counseling both rescue personnel and families in trauma settings like school shootings and plane accidents. I often would spend time in areas contaminated by chemicals and heavy metals, and finally, Lyme's disease. My nerve conduction from the knees down was zero. From the knees down, I was totally numb. I went 15 years feeling like I was walking on broken Coke bottles every day of my life. I could not roll over in bed. The pain was just unbelievable.

I was seeing eight different doctors every quarter that had no treatments to relieve me. My charges to Blue Cross Blue Shield were running over \$200,000 a year. I was taking Topomax, Neurontin, Mobic, Celexa, Darvon and generic Provigil, was costing Blue Cross \$24,000 a year. In addition, I was using 100 microgram fentanyl patches to control my pain, and over 15 years, probably 50 steroid injections in my back. My feet were purple and red. I was at risk of amputation.

Within eight months of initiating treatment at NBO, all the swelling has gone down in my feet. I lost 20 pounds and my average blood sugar has gone down 20 points. I can go up and down stairs now without a cane, without even using the handrail. I can get our granddaughter out of her crib and carry her the whole length of the house, which is about 70 feet. I can crawl on the floor and do things with her. I can drive a car again. I'm off almost all my medications.

I've had no Lyme's flares, which often put me in the hospital. I even planted bulbs in the garden last fall after just three months of treatment.

demonstration of the vulnerability of patients to a fall vs. age-matched normal.

Provides a series of assessment challenges, presents patient performance in real time on a large heads-up computer screen

Stores that performance for retrieval, progress assessment and printout for medical records.

Provides objective assessment clinics today must demonstrate to payers.

This Balance System provides valid, reliable, and repeatable measures of bilateral and unilateral balance on stable and unstable surfaces, and documents each patient's neuromuscular control in a safe environment. During static and dynamic exercise testing and training, this system provides visual feedback of patients' ability to control their center of gravity. It also provides visual feedback of patients' ability to control their limits of stability.

Each of the six NBO clinics is equipped with a Balance System, which precisely identifies and quantifies each patient's specific vulnerable quadrants, and then exercises them on those quadrants, to regain strength and fast muscle fiber response necessary to fight falls. The Balance System targets the somatosensory sensory and neuromuscular control aspect of balance, and helps to restore effective motor skills by retraining new neural pathways.

But equally important, the Balance System gives the patient an instant graphic demonstration of their deficiencies and risks. They quickly grasp what we're doing and why. And they can see from session to session where they're improving, and where, at home, they must work harder.

CTSIB. The principal screening test on the Biodex Balance System is the CTSIB – “Clinical Test of Sensory Integration of Balance.” The CTSIB is the calibrated and computerized equivalent of a Romberg test, which is based on the premise that a person requires at least two of the three senses to monitor and adjust for changes in body position.

On the Balance System, we evaluate a patient with their eyes open, on a static position, to get a baseline. The somatosensory, vestibular, and visual systems are all functioning at the maximum for that patient at that given time.

- With the Balance System platform locked in the static mode, we ask them to close their eyes and hold that position, to evaluate their sway index. Excessive sway with loss of visual feedback indicates a high risk of falling when dependent on their vestibular and somatosensory systems.
- In the third CTSIB test, we place a dense foam rubber pad on the Balance System platform, and test their stability with their eyes open. That tests their balance with just vestibular and visual

systems operating – the foam dulls somatosensory feedback.

- In the final CTSIB test, the patient stands on foam with their eyes closed, relying almost totally on their vestibular system.

That series of tests – especially the fourth – effectively challenges patients in the real-world situation where they get out of bed at night, and step onto a soft carpeted surface in the dark. They are already somatosensorily compromised because of the neuropathy and they can't see very well.

Most peripheral neuropathy patients can't complete the test – we have to be ready to catch them. However, the CTSIB gives the therapist an excellent picture of the patient's status. The printouts give the patient an understanding of both their weaknesses and where the PT will work with them.

And equally important in today's payer-driven world, the Balance System printouts objectively document the patient's qualification for NBO's EA treatment/PT intervention.

Limits of Stability test. The Balance System's “Limits of Stability” test provides a very detailed assessment of each patient's directional fall risks. It can show if, for example, a patient biases anterior to the left, anterior to the right, straight anterior, posterior to the right or to the left. It reveals their comfort zone, and where they “can't go” – usually, either posterior left or right.

Focused biasing to a specific direction – for example, anterior right – means they've developing abnormal, compensatory neural “pathways of comfort.” If challenged in other directions by environment, they're going to fall.

The limits of stability test results show the patient precisely where they're at risk. It graphically shows them why our therapy will focus on developing both their comfort in those vulnerable directions, and their speed of reaction to challenges there. We explain to them,

If you're not moving to every quadrant, you're not developing strength/learning. When you hit a challenge that forces you to that unfamiliar quadrant, you'll likely fall.

By repeatedly challenging patients in those directions within the safety of the Balance System, we can develop their ankle and leg strength, and fast muscle fiber response – two factors most affected by compensated stance and gait resulting from prolonged periods of peripheral neuropathy.

Each patient gets a minimum of one hour of one-on-one PT prior to medical treatment. Each session typically begins on the Balance System, where we assess progress since the prior EA treatment and PT session. Then, using foam pad from the Balance System, we stand them in a corner for support, and do

“eyes-open/eyes-closed” exercises, followed by seated strengthening of quads and hamstrings.

Then, we work on overcoming situations that challenge them in the home or in the community – e.g. getting up in the middle of night. Within 4-5 EA treatment/PT sessions, clear evidence of benefit is common.

Home exercises. Like all good PT programs, NBO therapy only begins in clinic. To be successful, it must be sustained in the period after their injections and electrostim, at home.

We prescribe a series of Thera-Tube exercises for their feet, because most “don’t know where feet are.” We ask them to do a series of repetitive dorsiflexion, plantar flexion, inversion and eversion exercises while watching their feet; then, to repeat them while not watching their feet. With repetition, that has three major benefits:

- It reinforces the visual/somatosensory neural pathways we attempt to build in the clinic with the Biodex Balance System – and thus, helps to restore the foot position awareness diminished by peripheral neuropathy.
- It strengthens all the muscles their ankles and lower legs, to help them work more effectively on the Balance System, where we focus on gaining both control and fast response to balance challenges
- It improves circulation and enhances neuron recovery in their extremities

In addition to home foot-ankle exercises, we also give them a series of home hip rotation/strengthening exercises with the Thera-Tube. Most older patients need to exercise their rotators to protect against falls overground. We teach them how to anchor a Thera-Tube to a heavy table or post, and how to kick against it into flexion, abduction, extension adduction, and internal/external rotation

Finally, both at home and on the Balance System, we give them a series of single-leg stance home exercises to reinforce those we give them on the clinic Balance System, which logs their session-to-session improvement

NBO education, high-tech PT pays off. While NBO spends much of its therapy sessions educating patients, they payoff is that patients fully embrace the program, comply, rarely miss sessions or drop out – and “graduating” with greater mobility and freedom from pain, promote the clinics to their friends and neighbors.

Case histories from NBO CTSIB/Limits of Stability Tests

“CAROLE” 77-year-old woman with a one-year history of numbness in both feet and hands.

Patient reports difficulty in walking, especially on uneven ground. Because of unstable balance, she is unable to perform regular home chores. She ambulates at home by “cruising” between fixed objects. She reports several recent falls. She complains of severe foot and back pain, and difficulty sleeping.

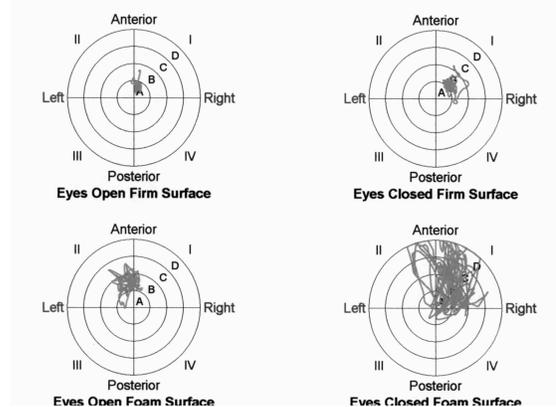
ICD-9 DIAGNOSIS:

- 781.2: Abnormality of gait
- 781.3: Lack of coordination
- 780.4: Dizziness and giddiness
- 729.5: Pain in limb

COMORBIDITIES: Abnormal (low) BMI, chronic low blood pressure

TREATMENTS: Patient received 14 PT treatments and 18 EA treatments

DECEMBER 20, 2012: Carole’s clinical test of sensory integration of balance (CTSIB) study shows that with her eyes closed on a firm surface, she demonstrates significant bias to the anterior right quadrant. She demonstrates an anterior bias with her eyes open on a foam surface. But with her eyes closed on foam, with neither visual nor somatosensory feedback, she demonstrates very poor vestibular feedback. This is a very typical example of a peripheral neuropathy patient who is at a high risk of falling.

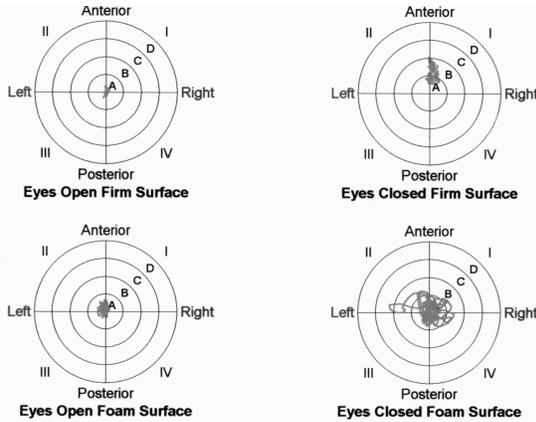


Her Limits of Stability test on the same date illustrated decreased level of objective coordination and meandering toward targets. Overall score = 30 out of >65

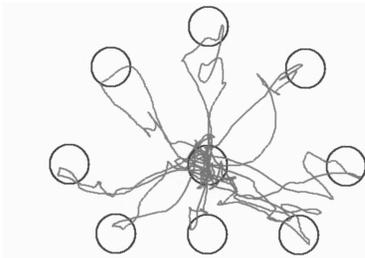


BIODEX CLINICAL PROTOCOL

FEBRUARY 12, 2013 (DISCHARGE). *A repeat CTSIB study demonstrates anterior bias with eyes closed on a firm surface, her performance on foam with her eyes closed illustrates extraordinary improvement, well within normal.*



Likewise, a Limits of Stability study on the same day showed significant improvement in all quadrants: Limits of Stability Test Results: No bias; overall score = 53 out of >65



At discharge, patient improved in walking on uneven and soft surfaces, reports no problem with performance of regular household duties such as laundry, cooking, walking dogs, going shopping. She claims the pains in her feet and back are gone, and that she sleeps through the night.

Both the repeat CTSIB and limits of stability tests show this patient has very significantly improved proprioception as a result of the NBO protocol. Note her very purposeful, controlled movements in the repeat LOS study. She has much greater control, strength and response capabilities, and thus, may be at sharply reduced fall risk, as well as pain free.

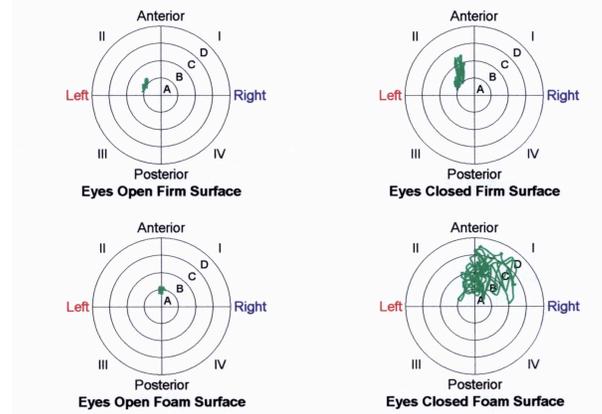
“KAY” 68 year old woman with peripheral neuropathy, Type 2 diabetes

Patient reports severe balance problem, does not feel her feet, “walks like on rocks.” Cannot make a sharp turn because afraid falling (reports history of several falls in last year). Walk only short distances due to pain in both legs/ feet, very difficult to walk on uneven surfaces. Unable to perform regular housewife tasks because of unstable balance.

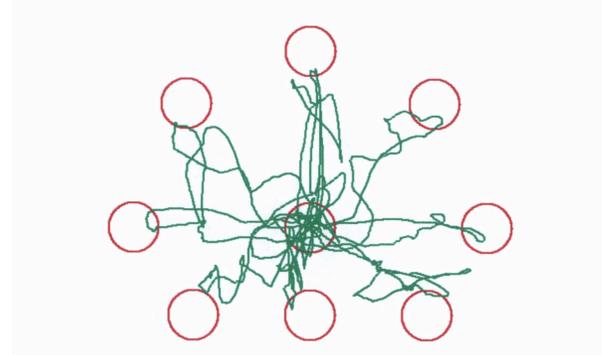
COMORBIDITIES: Abnormal (low) BMI, chronic LBP

Patient received __ PT treatments and __ EA treatments

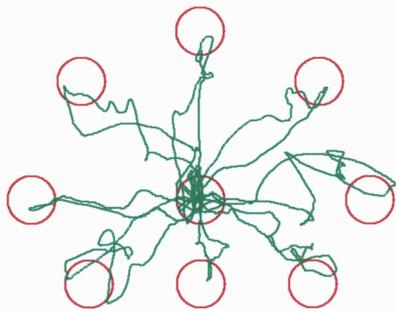
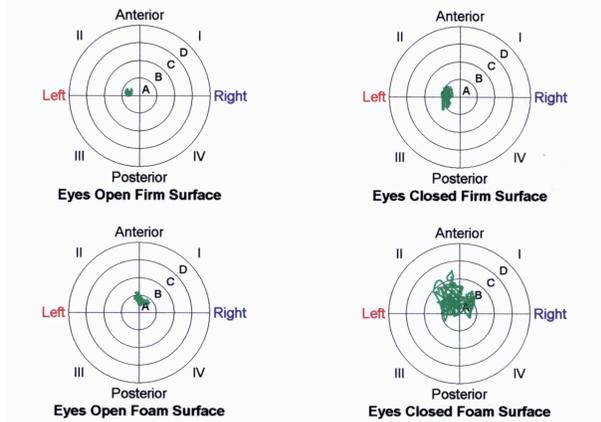
NOVEMBER 15, 2012: *Patient’s CTSIB shows bias toward anterior left quadrant on firm surface, anterior bias in foam, especially with eyes closed.*



Patient’s limits of stability study showed decreased level of objective coordination and meandering toward targets



DECEMBER 11, 2012: In less than a month, patient shows improvement in all quadrants, especially with eyes closed on foam. The study suggests that, in addition to improved vestibular Shows speed of muscle response and enhanced proprioceptive feedback.



Upon discharge on _____, patient reported ability to walk pain free, no falls, and no fear of falling. She is able to perform housework without restrictions.

Like the prior patient Carole, “Kay” displays evidence of greatly improved proprioception, control and stability that cannot be explained simply by vestibular training. Note how purposefully she followed the random target challenge of the LOS test – she is now able to sense her feet and apply that enhanced proprioception to avoid falls. No pharmaceutical therapy to date has demonstrated such enhanced proprioception.

Case histories from NBO Sway Index Tests

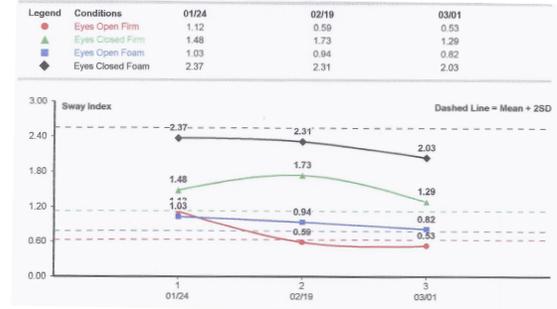
“DOLORES” 54 yo woman with postop peripheral neuropathy

Patient complains of a history of progressive neuropathy (pain/numbness in feet and difficulty walking – decreased activity increased weight gain. Difficulty going up/down stairs and ADLs. Reports recurrent falls in ordinarily “safe” environments (e.g. getting down from chiropractor’s treatment table, standing in her living room). Onset of symptoms followed bilateral knee surgery 7 months prior to self-referral to NBO.

COMORBIDITIES: HTN, obesity

Patient had received 14 EA treatments and 9 PT sessions as of report date 4/16/2013

GRAPH OF SWAY INDEX CHANGES 1/24/2013-3/01/2013



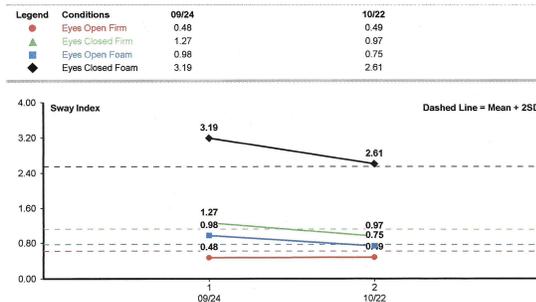
Patient reports significant improvement in standing activities (meal prep, house work and stairs, walking level/uneven surfaces), no falls. Self-reports balance improvement from 3/10 to 8/10.

“WILLIAM” 67 yo man with idiopathic peripheral neuropathy

Patient complains of a history of progressive pain and numbness in his toes and feet, difficulty walking.

Comorbidities: (NBO- please fill in)

GRAPH OF SWAY INDEX CHANGES 9/24/2012-10/22/2012



Patient reports significant resolution of pain, improvement in balance

Conclusion: Promising approach to treating both pain and fall risk

While traditional pain-focused medications can relieve at least some of the discomfort resulting from peripheral neuropathy, that relief may actually encourage patients to re-engage in activities despite compensated, uncorrected gait and stance habits that increase a patient’s fall risk.

The NBO protocol for treating peripheral neuropathy demonstrates the potential to treat the pain, numbness, disability and fall risk associated with peripheral neuropathy of many etiologies, as well as idiopathic peripheral neuropathy.

Unlike common pharmaceutical therapy, the multi-modality approach offers several advantages beyond simple analgesia. The NBO protocol

- Capitalizes on two important mechanisms of local injected and electro-analgesia – relief of pain and improvement of local circulation
- Augments circulatory enhancement encouraged by local/electro-analgesia with aggressive home and clinic exercises that improves blood flow to affected extremities
- Exploits the pain-relieved period following local analgesia for balance-supportive home and clinic exercises that would be difficult or impossible without EA treatment
- Applies high-technology static and dynamic balance training with the Biodex Balance System, which
 - Identifies the precise balance axes which most challenge each patient and represent his/her greatest fall risk

A Patient Experience: Lost Years, Insurer Cost of Untreated Neuropathy

All my life, I’ve been a pretty active guy – I’d hunt, fish, garden. About 15 years ago, suddenly, as I am walking back on grass to my deer blind with my bow and arrow, I’m having trouble. Pretty soon, I’m stumbling. I started worrying about things like MS and Lou Gehrig’s disease.

I went to a neurologist, then a neurological surgeon, then and a rheumatologist. They said it might be because of the statin I was taking for cholesterol. I quit it but I still couldn’t walk right.

When I went to the neurologist, I thought he was touching me with his finger. On the way to the parking lot, my wife told me he was poking needles into my legs. I didn’t know. I had no feeling. I tried physical therapy but that didn’t seem to do it.

Then, in 2007, I had an infection in the bottom part of my foot. I should have been in excruciating pain but I had absolutely no feeling from the hips down.

This infection went into the bone of the first toe, and they had to remove it. I should have been in excruciating pain but I felt nothing. I could have lost my leg. Then I saw a story on TV about an NBO patient who sounded like me, and one day, after therapy, he said he walked out without remembering his cane.

So I started therapy at NBO. When I started, before they gave me the injections, they used to warn me, “poke.” But I felt nothing. Now I’ve got the feeling totally back now, both upper and lower legs. When they poke me, I feel it. What does it feel like? I get a little emotional when I talk about this. To feel your feet inside your sock, inside your shoes, is incredible.

Last week, I am sitting there and I say, “Sandy, something is wrong with my legs.” She asks, “What is it?” I got up and walked around. They were working like they were supposed to. Perfectly normal. It lasted probably five or six hours. I was walking around, crying. I’m a guy who doesn’t cry. But now I cry because I know I’m getting better.

We were sitting in a huge restaurant out in Perry the other day. I was having a salad. I thought a big chunk of salad fell down on my leg. Then I looked down. It was just a little bitty piece of lettuce. But I felt it.

I think of how much I lost because I didn’t get this therapy sooner, and what it cost Blue Cross Blue Shield. I can’t remember if the amputation cost them \$19,000 or \$29,000, because it cost me just \$200. But that’s not counting the surgeon. That’s not counting the home nurse. That’s not counting the two weeks on IV at home on antibiotics and all the check-ups afterwards. It had to approach \$50,000.

- Validates the patient’s fall risk and need for therapy
- Provides a wide range of exercises that increase both the muscle strengthening and fast-fiber response enhancement necessary to overground balance challenge

- Provides visual and tactile feedback to the patient, aiding their ability to follow therapist
- Demonstrates to both patient and payer the progress of the patient from high fall risk toward the goal of normative data collected from age-matched normals

The NBO protocol demonstrates how physicians and physical therapists can productively collaborate to address the challenge and risks inherent in peripheral neuropathy.

Biographies of authors

Paul N. DeWeese, MD is chief executive officer and founder of NBO Medical, a network of neuropathy-focused clinics in Michigan and Florida. He trained at the Wayne State University School of Medicine, and is board certified in internal medicine. He has more than 25 years of experience in emergency medicine, where he first began to fully appreciate the burden of peripheral neuropathy, and inspired his search for improved therapy. He serves as an assistant professor of medicine at Michigan State University College of Human Medicine, and is a board member of the Nyaka AIDS Orphan School in Uganda, Africa. He served two terms as a State Representative in the Michigan House of Representatives for the 67th District of Michigan.

Steven Woodring, DO is medical director of NBO Medical of Florida, LLC, and a Diplomate of the American College of Anesthesiology. Dr. Woodring received his doctor of osteopathy degree from A.T. Still University (ATSU), Mesa, AZ, the founding institution of osteopathic healthcare. He served a traditional medical internship at Ohio University College of Osteopathic Medicine, Athens, OH, and completed an anesthesiology residency at Case Western Reserve University School of Medicine. He continues his practice of general anesthesiology as a member of Mobile Anesthesiologists of Florida, LLC, which provides anesthesia and recovery services to ambulatory surgical centers. He also serves Anesthesia and Pain Consultants of Southwest FL, which provide general anesthesia services at Gulf Coast Medical Center Hospital and several ASCs.

Jeffrey Carter, PT, MBA is a consulting physical therapist to NBO Medical, and designed the physical therapy component of that group's neuropathy therapy program. He has been a licensed physical therapist for 28 years since graduating from the University of Medicine and Dentistry of New Jersey and Kean University, Union, NJ. He received his MBA from Grand Valley State University, Allendale, MI. Mr. Carter brings to NBO Medical a diverse background in acute care settings, rehabilitation centers, sports medicine, and in general orthopedic private practices. He is certified with the International Academy of Orthopedic Manual Medicine, and specializes in the special needs of the aging population, utilizing his training focus in balance and ambulation-recovery techniques.

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