

**How To Expand An
Existing Podiatry
Clinic Into A
Successful Podiatric
Pain & Surgical
Rehab Center**

By David Zuckerman D.P.M.

Dear Podiatric Colleague.

I wish to introduce and describe a new approach for the treatment of pain to our patients that present to our offices with both acute and chronic pain. Most of our patients come to our office because something hurts, so I believe that this new podiatric approach to pain treatment should be of interest to both you as podiatrist and your patients in pain.

The Outcome Medical Integrated Peripheral Nerve Block Protocol. Simply stated the protocol combines the use of two widely accepted treatment options for pain into one unique procedure.

So how does Outcome Medical Integrative Nerve Block protocol work?

The first aspect of the procedure is the chemical nerve block or injection. Traditionally, the chemical nerve block employs some form of anesthetic agent, (Lidocaine, Marcaine, Bupivacaine, ect.) usually combined with a corticosteroid for the anti-inflammatory effects. OM protocol modifies this, due to the second part of the protocol, by eliminating the corticosteroids from the injection. We do this primarily for two reasons;

Number 1. The use of the corticosteroid is what dictates the number and frequency with which the injections may be used, as well as having a number of potential negative side effects which can now be avoided. The Outcome Medical protocol utilizes a moderately intensive protocol as defined by Medicare.

Number 2. Outcome Medicals position on the objective of treating any condition which has an inflammatory component is this. It is better to facilitate the inflammatory process to its natural conclusion, than to inhibit the process with very powerful anti-inflammatory drugs like steroids. I know this seems counter-intuitive to accepted practice, but bear with me here, I will explain.

The second aspect of the procedure involves the use of a very sophisticated version of Electrical Stimulation that utilizes the Outcome Medical device. The OM device utilizes, Electronic Signal Treatment (EST) which is an electro-medical treatment that involves the use of computer-modulated electronic signals designed to affect cell behavior. According to Lloyd R. Saberski, MD Yale University at New Haven, in his Foreword in Pain Physician in 2006 states that, "In the end for any therapy to be successful, there has to be a return of homeostasis, a return to a normal regulated state, a return to electrical balance of the cells.

We are all aware of the standard TENS technology which relies on amplitude modulation (AM) of the electric current being delivered to the body. The Outcome Medical Device, which is distributed by Outcome Medical out of Atlanta, GA. has many features that set it apart from any other electrical stimulation device in use today. When treating with electricity its really all about the frequency. Every cell in the body has very specific frequencies of electricity that either stimulate or suppress cell functions. The more frequencies you can produce, the more cells you can communicate with.



Outcome Medical Device

The Outcome Medical device can produce up to 20,000 Hz. Most electrical stimulation devices produce up to 5,000 Hz. The OM device is digital most electrical devices are still analog, though that will eventually change as everything else has, and everyone will go digital. The OM device uses Smart Card technology. All the program information is stored on Smart Cards as apposed to on a chip inside the machine. This provides two benefits; First Benefit: Ease of use. The operation of the OM device, which can be done by any staff member, is very simple. Attach the specialized electrodes to the patient, (more on the electrodes next), select the appropriate card from a list provided with the device, load the card into the slot, start the program, and set the intensity. Second Benefit; Ease of upgrade. If any custom programming is necessary, or a factory upgrade becomes available, it is simply a matter of sending out a



Smart Cards

new set of Smart Cards, not sending the device in for the upgrade. The OM device uses Vasopneumatic, wet sponge, electrodes. The use of these electrodes, which are a billable modality by themselves, increase the conductance of the skin by up to 1000%. Impedance of the skin is reduced by the wet sponge to virtually nothing, allowing the device to be able to produce a measurable physiological response within the body at less than one milliamp of stimulation level. And the device can also produce up to 100 milliamps of treating current! More than enough necessary to deal with even the largest patient! The OM device is attuned to use very specific multi-waveform programs that provide a continually varied, yet randomly generated, digital electrical signal to the body. Most electrical stimulation devices in use today are still analog and can only modulate the amplitude of the signal they were programmed to create (AM). Generating the signals digitally is what allows the fidelity to modulate the frequency (FM) at the same time. This complex electronic signal is manipulated by an on-on-board computer which actually combines or mixes both elements of AM and FM frequency simultaneously.



Typical Electrode Placement

The reason for this complex electrical signaling system changing so often is that the nervous system cannot “learn” or accommodate to the administered signal and that the frequency of the electric signal is so precise, that the cell is better able to interpret the signal. In short, better able to understand and react to the signal.

Sensory or sympathetic nerve blocks have been described years ago by the Legendary Marvin Steinberg, DPM to treat pain and circulatory disease. The use of a local anesthetic to block the posterior tibial nerve creates depolarization of nerve fibers along with hyperemia to the foot.

GREATER, LONGER LASTING patient outcomes appear to be achieved by performing the combination of chemical blocking agents along with the use of Electrical Signal Technology.

Chemical nerve blocks work at the cell level by causing hyperpolarization of the cells at the nociceptive level, while the EST protocol utilizes many different mechanisms of action, from the simple muscle spasm reduction to the much more complex interactions believed to be going on in the dorsal horn region, [Melzack & Wall 1965] to the hormonal changes affected in the brainstem area. [Kreutner, 1987], [Eriksson, Sjolund, 1979], [Cheng, Pomeranz 1979]

The increased production of cAMP is another mechanism of action that is stimulated with the use of the Outcome Medical protocol. Sustained depolarization of the cell stimulates the formation of more mitochondrial bodies within the cell. These mitochondrial bodies produce increased levels of ATP and GTP, these combine to produce cAMP at 3 to 5 times higher than normal levels. cAMP with these increased levels will return the cell to normal cellular activity, which is part of the healing process. OK, this is where the seeming counter-intuitive part comes into play. One of the signaling mechanisms that causes local inflammation is the leakage of arachidonic acid from the damaged cell membranes. If you can facilitate and even accelerate the cell wall repair process with EST 3 to 5 times faster than the cell could under normal circumstances, then you can stop more inflammation from forming, and if you can facilitate all of the metabolic processes necessary to get rid of all the inflammatory agents in the local area, which I believe EST does, via multiple mechanisms of action during each treatment, then you have actually helped stimulate the natural process of inflammation to its normal conclusion, which is supposed to happen naturally, and does in most cases. Maybe counter-intuitive to current practice, but actually helping the cells complete a natural process, to its natural conclusion.

Integrating these blocks, along with a specific EST program has achieved long term pain resolution in many of my tendonopathy, foot and ankle injuries and post-op surgical patients that would normally require more traditional physical therapy.

I have found the need and use of NSAID's, local steroid injections and pain medication use being reduced. As my understanding of this revolutionary technology increases, patient outcomes will improve, and the use of this protocol will increase among my chronic pain patients

The following are only some of the hypothesized mechanisms of Action.

Counter-irritation – The gate control theory explained that repeated by [Melzack & Wall 1965] explains that repeated exogenously-applied electrical signals perceived by the sensory nerve fibers effect pain signal transmission.

Release of Neuropeptides, Stimulation activates the release of pain-suppressing neuro-modulators found in the central nervous system i.e. endorphins, enkephalin, GABA

Nerve Fiber Block- the traveling pain signal is sustained and stopped by cell wall depolarization at the pain site.

Podiatric Case Reports

I have had the opportunity to treat many patients over the past eight months with the Outcome Medical INB Protocol. I would like to briefly discuss a few of my typical cases with you to demonstrate how you, as a podiatrist, can offer this technology which has very few side effects, unlike our present everyday use of NSAID and local steroid injections

CASE # 1. Mrs. X presented to my office with severe pain along the lower half of her left Tibia. There was no history of injury or contributing medical history to account for her pain. She had a dexascan within the past year which was normal. Systemic history was unremarkable and non-contributory. Patient states that this started about one month ago while gardening, which required lots of standing, bending etc. There was severe pain along the anterior crest of the lower leg in the region of the Tibialis Anterior tendon. NV was normal. Medications history non-contributory.

Previous treatment consisted of applications of heat, NSAID, rest, and taping of feet and lower leg. This treatment lasted for one month. There was still no relief. MRI was ordered and confirmed stress fracture of the tibial bone lower leg. There was no displacement or breakage of cortex.

The Outcome Medical INB protocol was initiated for approximately six treatment. After the third treatment, dramatic reduction in pain occurred. VAS scores were reduced to 75% reduction within six treatments over a two week period. Pain resolution was 100% and reached at 30 days.

CASE #2 Patient presented to office with painful 1st MPJ right foot, duration one year. VAS 8/10. . Medical history was non-contributory. Physical examination revealed severe pain with decrease ROM right 1st MPJ. X-ray evaluation revealed decrease joint space narrowing with spurring of the dorsum of the 1st metatarsal head.

Three local steroid injections along with oral depo-medrol, oral medication was prescribed over a 4-6 week period. Power step inserts with padding under the 1st ray were dispensed. Pain relief was temporary and intermittent.

The Outcome Medical INB protocol was discussed with patient due to patient being unable to take time off for surgical correction.

Outcome of the Outcome Medical INB protocol over a 30 day period reduced VAS score to 1 with improvement of ROM. This patient is two months status-post with no return of symptoms to date. Further evaluation will be taking place with periodic re-evaluations over the next year. Here is a case of physical therapy that was kept in your office EST portion of the protocol can be done by trained podiatric assistant.

CASE #3 Patient presented to office with pain, edema, inability to move toe and or wear shoes without pain. Medical history was non-contributory. There was history of trauma/dislocation of midtarsal bones. X-ray revealed normal position of midtarsal bone with multiple screw fixation.

The Outcome Medical INB protocol was explained and administered to patient over a 30 day period. Two treatment session reduced edema and pain with normal movement of toes.

90 days after treatment patient is still able to wear shoes and has dramatic reduction in pain and edema. The Outcome Medical INB protocol is an excellent treatment alternative for the reduction of pain and swelling without the use of any local or systemic use of steroids and or NSAID.

CASE 4. CASE #4 Patient presented to office with chief complaint of ankle pain. She was scheduled for “repair of tendon “of ankle. Patient had been thru extensive physical therapy without any relief. MRI did reveal tear of Extensor Hallux Longus tendon at the level of the ankle. Patient who was nurse revealed that tendon problem was made after repeat MRI studies. Examination revealed excellent ROM of all digits and mpj’s. Strength was 5/5.

The Outcome Medical INB protocol was discussed and offered to patient. Patient obtained complete relief within six treatments and was back to work within 30 days. Note that the original diagnosis may have been in error, however, previous physical therapy had no effect with improved function and or decrease pain or resolution. It wasn’t until The Outcome Medical INB protocol that the patients pain and function returned to normal. The final diagnosis was Capsulitis, tendonitis along with neuritis.

SUMARRY: The Outcome Medical INB protocol has many applications in podiatric and orthopedic medicine. Its use for diabetic neuropathy, pain, edema, wound care, is well documented. The potential for its use in podiatry has just begun. I envision the use of The Outcome Medical INB protocol to be a common treatment option, with podiatrists being the first to open clinics within their office for Diabetic Neuropathy. The Outcome Medical INB protocol can now be integrated into your practice.

My last personal vision for podiatry was 15 years ago when I saw ESWT being used for the treatment of plantar fasciosis as well as with Achilles tendinosis. There is still ESWT treatment in my area of the country. I now would like to offer another treatment option for podiatry where we can again be the leading edge for the proper use of The Outcome Medical INB protocol. Our patients deserve this treatment option so long as there are complications with the use of any local steroid injection or use of systemic NSAID. I respectfully submit to my profession to take a look at this new podiatric treatment option. As always, I am available for discussion or conversation.

Conclusion:

I believe we all will agree that we treat pain in our podiatric medical and surgical practices. The Outcome Medical INB protocol can help you develop and or expand a new specialty. Let’s look at just two treatment areas that we can expand and enhance your practice. The medical treatment of Diabetic neuropathy usually consists of Lyrica, Neurotinin, and or pain medication. Although successful, side effects, as well as addiction are a potential problem. The use of these medications still doesn’t in all cases relieve or control the terrible pain associated with Neuropathy. The potential for practice expansion is endless with the use of The Outcome Medical INB protocol.

How many times do we send out patients for physical therapy of the foot and ankle? This will become something of the past and in some podiatric practices, the jump start to hire that physical therapist that you think you can't afford. I have found that in most cases the Outcome Medical INB protocol can be used to treat most acute and chronic pain, although we must learn to integrate our biomechanical, medical knowledge, with EST treatments. We must always try to determine what the cause of the pain is and integrate, the cause with the treatment.

Future:

Having grown up in podiatry and been involved in ESWT since its inception in the USA. I have learned that we must always look and learn and integrate new technologies and always approach our patients and practices with new ideas and new ways to make our practices grow. It is my belief that The Outcome Medical INB protocol can become an integral part of most podiatric practices. We really are the pain management physicians of the foot and ankle. This protocol is an approach to move in that direction.

Acknowledgement:

I would like to thank the Dixson family, the owners of Outcome Medical. It was their effort and expertise that developed the Protocol that has allowed my patients to be relieved from pain and my practice to grow from satisfied outcomes. In addition, I would like to thank Robert H. Odell MD, PHD for his research, and many publications in the field of Electrical Signal Technology. I am happy to supply anyone interested in reading his many distinguished works. I would also like to open an invitation to anyone who would like to speak with or visit me, and observe how I have integrated The Outcome Medical INB protocol into my practice.

Contact Information: Dr. David Zuckerman
341 S. Evergreen Avenue
Woodbury, NJ 08096
Office: 856-848-3338
Cell: 856-229-2939
Email: footcare@comcast.net