

Summary of Prospective Peripheral Neuropathy Studies of 220 Limbs Showing Restoration of Protective Sensation^[1] through Treatment with Monochromatic Infrared Photo Energy

Study 1 - Kochman, Carnegie, Burke

Study Summary: 98 lower limbs in 49 subjects received twelve Anodyne treatments with four therapy pads on each lower limb. 84 of the lower limbs exhibited loss of protective sensation (LOPS)¹ due to diabetic peripheral neuropathy (DPN).

Results: All limbs exhibited protective sensation to the Semmes Weinstein 5.07 monofilament (SWM) at the conclusion of the final treatment. With 5.07 being a 10-gram monofilament, mean SWM sensitivity increased from 5.49 to 4.26 in Type 1 diabetic patients and 5.44 to 4.45 in Type 2 diabetic patients ($p < 0.0001$). Published in March 2002 in the peer-reviewed Journal of the American Podiatric Medical Association.

Study 2 - Joseph D. Barta, D.P.M., Florida Foot Care Associates, Spring Hill, FL

Study Summary: This was a controlled study of 15 lower extremities with LOPS¹ in eight patients. Twelve Anodyne treatments (two therapy pads per foot) were administered to the active limbs and none to control limbs. Control limbs were later crossed over and received twelve active treatments.

Results: All actively treated limbs increased sensation to SWM at no less than one site, while there was no improvement in the control group until they crossed over to active treatment. 11 of 15 limbs obtained protective sensation (detection of 10 gram monofilament at a minimum of two of three tested sites.)

Study 3 - Salvatore L. DeLellis, D.P.M., P.A., Tarpon Springs, FL

Study Summary: 19 lower extremities in ten patients exhibiting loss of protective sensation received ten treatments with two therapy pads per foot.

Results: All limbs improved by at least one measured site and 18/19 limbs obtained protective sensation.

Study 4 - Dale C. Carnegie, DPM, Chief of Podiatric Services, Department of Orthopedics, Denver Health Medical Center, Denver, CO

Study Summary: This was a double blind, placebo controlled study of 16 limbs with LOPS in eight patients. Both limbs received a single, 45-minute Anodyne treatment with four therapy pads. One limb was treated with functional diode arrays while the opposite limb was treated with inactivated (placebo) arrays.

Results: All actively treated limbs obtained protective sensation. The mean improvement in the number of sensate sites was 0.3 of 5 tested sites for placebo versus 3.6 of 5 for active ($p = 0.0008$ using the paired/paired T-test). The more rigorous method of Random effects with repeated measures analysis also demonstrated statistical significance ($p = 0.0009$).

Study 5 - Stuart M. Goldman, D.P.M. - Diplomat, American Board of Podiatric Surgery; Fellow, American College of Foot and Ankle Surgeons, Boca Raton, FL

Study Summary: Eighteen lower extremities with LOPS in nine patients received twelve Anodyne treatments with two therapy pads per limb. Patients were reexamined at 12 to 24 weeks after final Anodyne treatment.

Results: All of the actively treated limbs ($n=18$) obtained improvement in sensation to SWM 5.07 (mean increase in number of sites detected was 3.0). At follow-up evaluation, 16 of 18 lower limbs exhibited decreased sensitivity to the SWM (mean reduction 2.3 sites) with 4 limbs returning to pretreatment levels.

Study 6 - Alan Kochman, MS, PT – Aurora Medical Center, Aurora, CO

Study Summary: 76 lower limbs exhibiting LOPS in 38 subjects received twelve Anodyne treatments with two therapy pads per limb. Subjects had prior history of falls and impaired balance and gait.

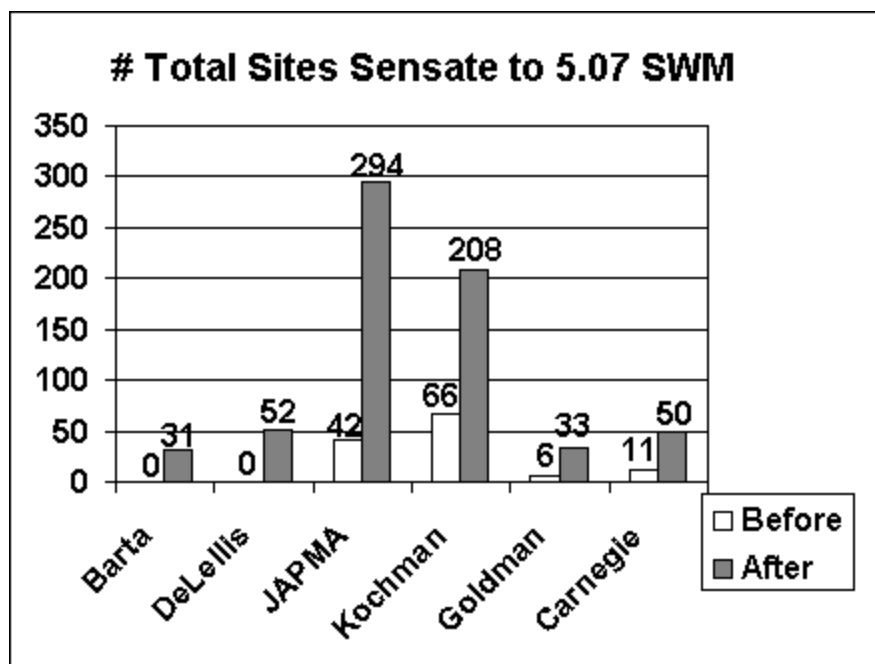
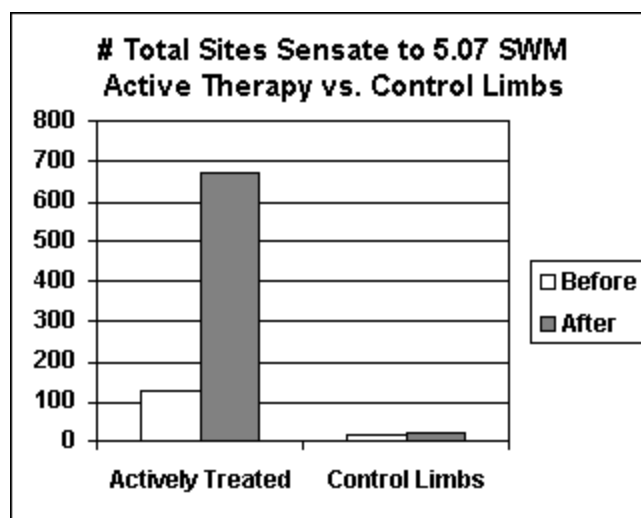
Results: All limbs exhibited protective sensation to the SWM 5.07 monofilament at the conclusion of the final treatment with a mean SWM sensitivity improvement of 1.8 sites per patient. Every patient also exhibited improved balance and gait as measured on the Tinetti scale (mean 10 point gain or 93%).

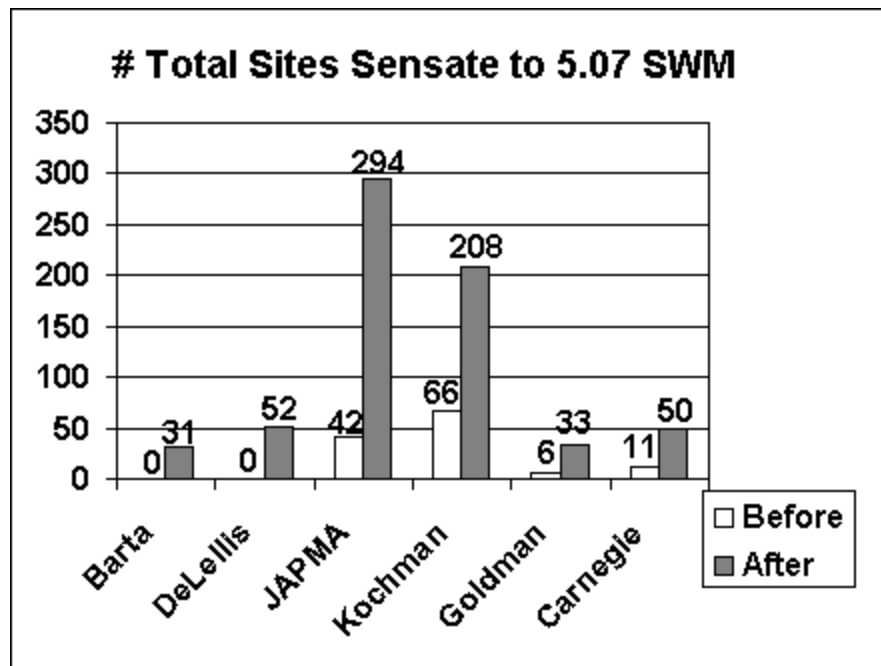
Reported falls decreased from 98 in a 3-month period preceding treatment to only 4 in the 3 months after treatment.

Data Summary of Improved Sensation as Measured by 5.07 (10 gram) Monofilament Before and After Anodyne Therapy Treatments

Study	Type	Ave # Tx	Time per Tx	# Limbs with LOPS	# Limbs with LOPS After Treatment
JAPMA	Clinical Setting	12	30 mins	84	0
Kochman	Clinical Setting	12.7	30 mins	76	0
Goldman	Clinical Setting	12	30 mins	18	1a
DeLellis	Clinical Setting	10	30 mins	19	1a
Barta	Controlled with Crossover	12	30 mins	15	4 a
Carnegie	Double blind placebo controlled	1	45 mins	8	0
Total				220	6 a

a These limbs were sensate at 0 sites before treatment and were only sensate at 1 site of 3 after treatment.





[1] Loss of protective sensation (LOPS) is insensitivity at a minimum of 2 sites on the foot to a 5.07 Semmes Weinstein Monofilament (SWM) as defined in the CMS (Medicare) Decision Memorandum (10/17/01).