

Key Point Summary of the Diabetes Care Study

Journal: Diabetes Care, January 2004, Volume 27, Number 1, Pages 168-172.

Author(s): David R. Leonard, MC, FACE, M.Hamed Farooqi, MC, FACE, Sara Myers, RN

Study Site(s): Joslin Center for Diabetes at Morton Plant Hospital

of Subjects: 27

Study Design: Prospective, Randomized, Double Blind, Placebo Controlled

Protocol Used: All subjects in the study had chronic pain and/or circulatory deficiency in the extremities. Subjects initially received treatment with active therapy pads on one limb and sham pads on the other limb 3 times per week for 40 minutes each visit for 2 weeks (6 treatments). This was followed by six active treatments of the same duration administered to both limbs during the following 2 weeks.

Pain Endpoint: Numeric Visual Analog Scale from 0 – 10

Results :

Group	VAS Baseline	After 6 MIRE Treatments	After 12 MIRE Treatments	P Value
Group 1 (N=18)	4.2 ± 2.3	3.2 ± 1.9	2.3 ± 1.7	<0.0001
Group 2* (N=9)	4.2 ± 3.9	2.6 ± 2.3	2.0 ± 2.3	NS

* Patients more impaired

Conclusion: The results of the study demonstrate that treatments with near-infrared photo energy delivered in the manner specified in the study protocol resulted in a significant reduction in pain.

Key Point Summary of the Journal of Diabetes and Its Complications Study

Journal: Journal of Diabetes and Its Complications, Volume 20, Issue 2, March-April 2006, Pages 81-87

Author(s): Lawrence B. Harkless, DPM, SalvatoreDeLellis, DPM, Thomas J. Burke, PhD

Study Site(s): Multiple Site

of Subjects: 2239

Study Design: Multiple Site Retrospective Chart Review based on Prospective, Repeated Measures Analysis

Protocol Used: All subjects in the study had chronic pain and/or circulatory deficiency in the extremities. The average treatment protocol was 3 x per week for 30-45 minutes for 5 weeks and included physical therapy interventions such as therapeutic exercise, neuromuscular re-education and/or gait training.

Pain Endpoint: Numeric Visual Analog scale from 0 – 10

Results : **Patients Reporting Significant Pain Pre and Post Treatment**

Pre	Post	# Improved	% Improved
1563	33	1530	98%

Changes in Pain on 11 point VAS

Pre	Post	# Points Improved	P-Value	% Improvement
7.2 ± 2.2	2.4 ± 2.1	4.8 ± 2.4	<0.0001	67%

Conclusion: MIRE treatments are associated with a reduction in pain that had been previously unresponsive to other interventions.

Key Point Summary of the Physical and Occupational Therapy in Geriatrics Study

Journal: Physical and Occupational Therapy in Geriatrics, Vol 24(2): 1-17, 2006

Author(s): Wendy Voker, MSPT, Katrina Corgan, PTA, Ahmed Hassan, MSPT, Mohamed Hassan, MSPT, Vicki Smock, PT, Justin Connor, PT, Shayne Ferguson, PT, GS, WS, MHS, Thomas J. Burke, PhD

Study Site(s): Genesis Medical Center (Davenport, IA), Premier PT (Evergreen Park, IL, Orland Park, IL and Hinsdale, IL), Westside Retirement Village (Indianapolis, IN), Sonoma Valley Hospital (Sonoma, CA), Helmwood Healthcare (Elizabethtown, KY)

of Subjects: 272

Study Design: This was a retrospective Chart Review in 7 facilities and was based on Prospective, Repeated Measures Analysis.

Protocol Used: All subjects in the study had chronic pain and/or circulatory deficiency in the extremities. The therapy intervention included Anodyne Therapy for pain and circulation and physical therapy interventions such as therapeutic exercise, neuromuscular re-education and/or gait training 3 x per week for an average of 6 weeks.

Pain Endpoint: Numeric Visual Analog scale from 0 – 10

Results : **Patient Demographics (Pre-Treatment)**

	Total
Patients	272
Male	135
Female	137
Age ^a	69 ± 12.3
Mean Number of Treatments	18 ± 10.2
Treatment Time (in minutes)	34.2 ± 9.4

Pain Pre and Post Treatment

All Patients (Pain ≥ 4)	(n = 257)
VAS Pre-Treatment	7.7 ± 1.2
VAS Post-Treatment	4.8 ^a ± 2.2
VAS Decreases	2.9 ± 2.2
% Pain Reduction	38%

Pain Pre and Post Treatment

Horrible to Excruciating Pain (VAS 8.5-10)	(n = 37)
VAS Pre-Treatment	9.4 ± 0.5
VAS Post-Treatment	4.8 ^a ± 2.7
VAS Decreases	4.6 ± 2.9
% Pain Reduction	49%

Distressing Pain (VAS 6.5-8)	(n = 189)
VAS Pre-Treatment	7.8 ± 0.4
VAS Post-Treatment	5.0 ^a ± 1.9
VAS Decreases	2.8 ± 1.9
% Pain Reduction	36%

Discomforting Pain (VAS 4-6)	(n = 31)
VAS Pre-Treatment	5.3 ± 0.9
VAS Post-Treatment	3.5 ^a ± 2.5
VAS Decreases	1.8 ± 2.4
% Pain Reduction	34%

Values expressed as mean ± SD; a = All post treatment measures are P<0.0001 vs. Pretreatment

Conclusion: Use of MIRE in combination with manual physical therapy is associated with reduced pain.

Key Point Summary of the Age and Ageing Study

Journal: Age and Ageing, 35; 11-16, 2006.
Author(s): Mark W. Powell, MD, Dale Carnegie, DPM, Tom Burke, Ph.D.
Study Site: Multiple Sites
of Subjects: 252

Study Design: Retrospective Chart Review and Patient Questionnaire

Protocol Used: All subjects in the study had chronic pain and/or circulatory deficiency in the extremities. The initial therapy intervention included Anodyne Therapy for pain and circulation and physical therapy interventions such as therapeutic exercise, neuromuscular re-education and/or gait training. Patients then used an Anodyne Therapy System at home for an average of 8 months after the initial treatment in a clinical setting.

Pain Endpoint: Numeric Visual Analog scale from 0 – 10

Results : **Pain Reduction Based on Average Number of Months Using MIRE**

	1-3	3-6	6-9	9-12	12+
# of Patients	36	33	22	94	67
Ave. Months after MIRE Clinical Treatment	1.2	4.0	6.7	10.1	13.3
Mean Age	75	74	76	76	76
Male/Female	23/14	20/13	9/13	44/50	40/27
% of Patients Reporting Reduction in Pain	94%	80%	91%	85%	91%

Conclusion: The medical records indicated that 220 out of 252 patients (87%, $p < 0.0001$) obtained substantial reduction in pain. When patients have continuing access to MIRE in their homes following clinical treatment, there is a significant reduction in pain.

Key Point Summary of the J Neurol Orthop Med Surg

Journal: J Neurol Orthop Med Surg (1996) 16:242-245

Author(s): T.L. Thomasson, D.D.S.

Study Site: Facial Pain Treatment Centre, Denver, CO

of Subjects: 784

Study Design: Prospective, Repeated Measures Analysis

Protocol Used: Anodyne Therapy was used in clinic for 45 minutes X 3 sessions and at home for 30 minutes daily X 1 week for pain in the facial area, jaw area and/or neck area.

Pain Endpoint: Clinical patients were asked to rate the percent relief of pain. Rating parameters were total relief (100%), excellent relief (>75%), fair relief (50-75%), poor relief (<50%) and no relief (0%). Ratings were taken at each treatment appointment and treatment discontinued if no additional improvement occurred on three successive visits, or if total relief was reported with no recurrence of symptomology or signs. For reporting purposes, lengths of treatment were divided into three categories: 1-3 treatments, 4-6 treatments and 7-12 treatments.

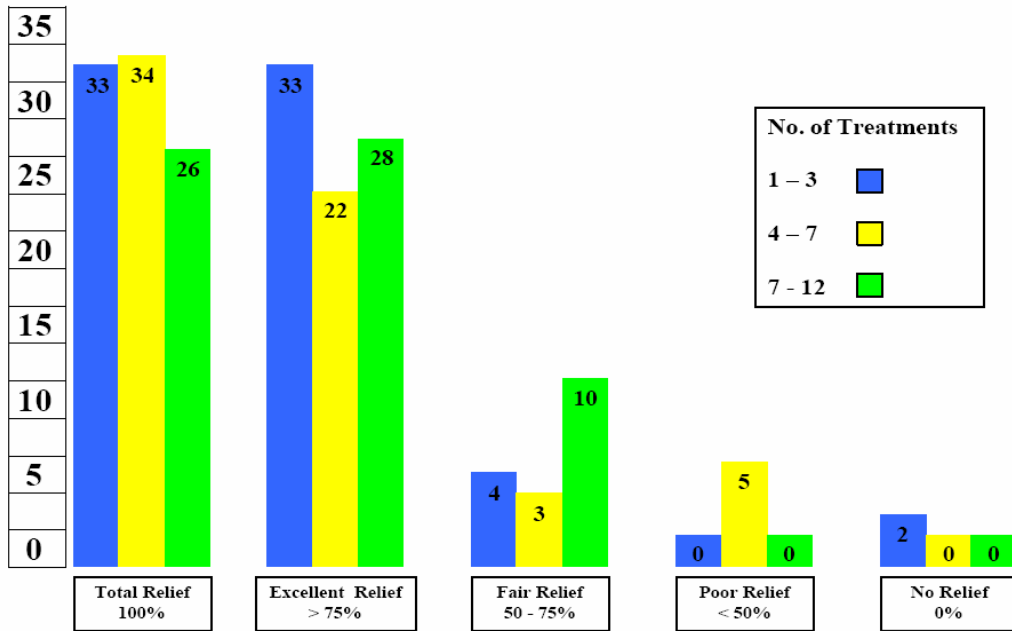
Results: See Graphs next pages

Conclusion: 88.8% of patients reported Excellent to total relief, 9.9% reported fair to poor relief and 1.3% reported no relief. Since nearly all patients treated (91.9%) had a history of some type of previous therapeutic intervention, the results indicate a high rate of successful conservative treatment whether or not the diagnoses were new or subjected to previously applied standard treatment parameters.

No. of Cases

Results of TS/SCS treatment of 200 cases

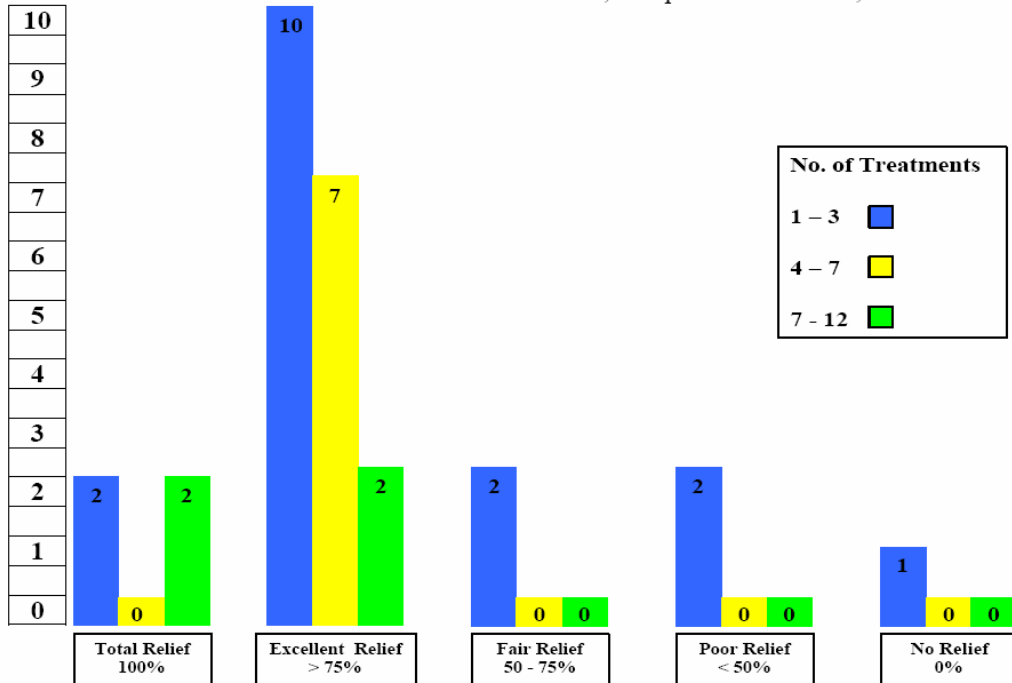
Total excellent relief 88.0%, fair-poor relief 11.0%, no relief 1.0%



No. of Cases

Results of postoperative capsulitis – 28 cases

Total excellent relief 82.1%, fair-poor relief 14.3%, no relief 3.6%

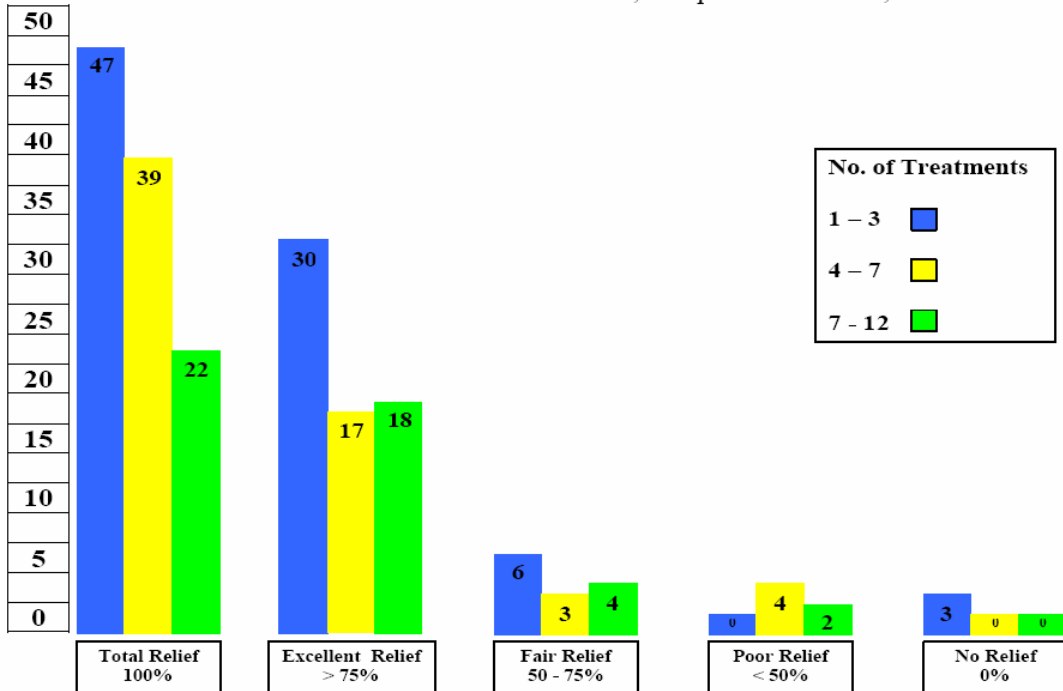


Please see the Instruction Manual for important safety information.

No. of Cases

Results of non-surgical capsulitis – 195 cases

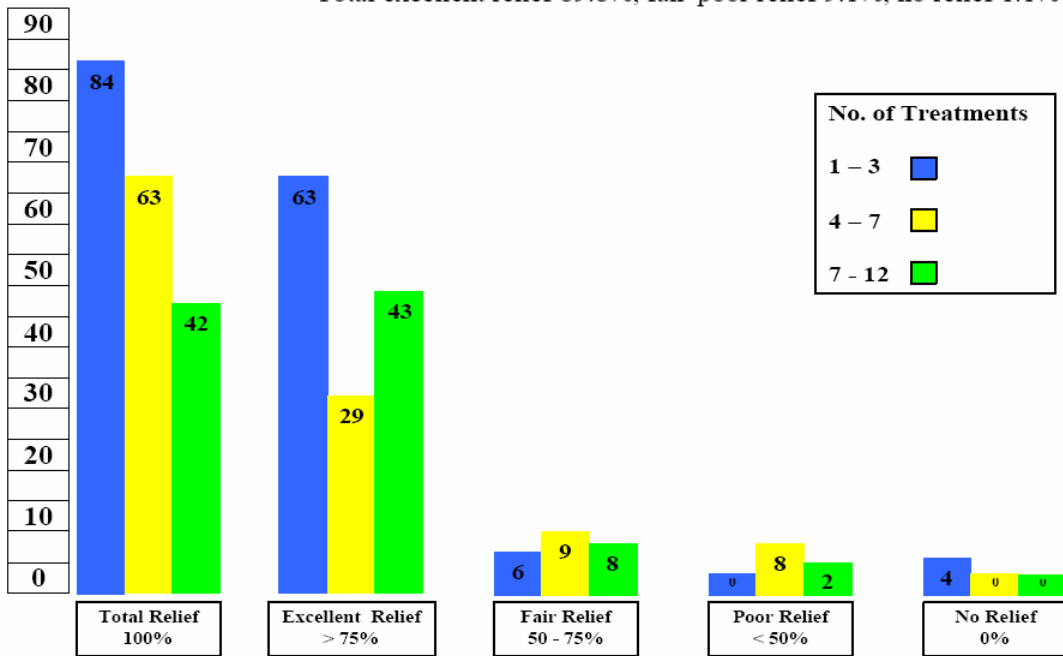
Total excellent relief 88.6%, fair-poor relief 9.8%, no relief 1.6%



No. of Cases

Results of myofascial pain/muscle spasm – 361 cases

Total excellent relief 89.8%, fair-poor relief 9.1%, no relief 1.1%



Please see the Instruction Manual for important safety information.