

5 Summary of Studies

Healy is a medical device for the treatment of pain in chronic pain, fibromyalgia, skeletal pain and migraine, as well as for the supportive treatment of mental illnesses such as depression, anxiety and related sleep disorders. All other applications of Healy are not recognized by conventional medicine due to lack of evidence in the sense of conventional medicine.

The studies for the indications mentioned here were not carried out with Healy, but the parameters used with Healy are based on the studies mentioned.

5.1 “Pain Treatment” Study Report

Pain, Myalgia, Fibromyalgia

Chronic:

Stephen I. Zimmerman, R. P. T., Fred N. Lerner; Biofeedback and electromedicine: Reduce the cycle of pain-spasm-pain in low-back patients; American Journal of Electromedicine; 1989 Jun, S. 108- 120

Jerry T. Holubec; Cumulative Response from Cranial Electrotherapy Stimulation (CES) for Chronic Pain; Practical Pain Management; 2009 Nov-Dec (n=525)

Acute:

Rockstroh G., Schleicher W., Krummenauer F.; The advantage during a stationary follow-up-treatment applying microcurrents on patients after implantation of a knee totalendoprosthesis - a prospective randomised clinical case study; Rehabilitation 2010, 49: p. 173-179

Daniel L. Kirsch; Cranial Electrotherapy Stimulation in the Treatment of Fibromyalgia; Practical Pain Management, Electromedicine; Sept. 2006; S. 60-64

A. S. Lichtbroun, M. M. Raicer, R. B. Smith; The treatment of fibromyalgia with cranial electrotherapy stimulation; Journal of clinical rheumatology; 2001 Apr; 7(2): S. 72-8; discussion 78

Postoperative:

T. M. Sarhan; Doghem; Effect of microcurrent skin patch on the epidural fentanyl requirements for post operative pain relief of total hip arthroplasty; Middle East Journal of Anesthesiology; 2009; S. 411-415

Back Pain

Joseph S. H. A. Koopman, Dorien H. Vrinten M. D., Albert J. M. van Wijck; Efficacy of microcurrent therapy in the treatment of chronic nonspecific back pain: a pilot study; Lippincott Williams & Wilkins; 2009

Muscle Pain

D. Curtis; S. Fallows; M. Morris; C. McMakin; The efficacy of Frequency Specific Microcurrent therapy on delayed onset muscle soreness; Journal of bodyworkand movement therapies; 2010 Juli; Elsevier

TMJ Pain

Degenerative disease of the temporomandibular joint:

L. E. Bertolucci, T. Grey; Clinical comparative study of microcurrent electrical stimulation to mid-laser and placebo treatment in degenerative joint disease of the temporomandibular joint; Cranio: the journal of craniomandibular practice, 1995 Apr; 13(2): S. 116- 120

Headache, Migraine

Tension headache:

Seymour Solomon, Arthur Elkind, Fred Freitag, R. Michael Gallagher, Kenneth Moore, Bernard Swerdlow, Stanley Malkin; Safety and Effectiveness of Cranial Electrotherapy in the Treatment of Tension Headache; Headache-The Journal of Head and Face pain; July 1989, Vol. 29, Nr. 7, S. 445- 450

D. L. Kirsch; Electromedical Treatment of Headaches; Practical pain management, Electromedicine; 2006 Nov/Dec, S. 58-65

Migraine:

P. Brotman; Transcranial Electrotherapy, Low-intensity transcranial electrostimulation improves the efficacy of thermal biofeedback and quieting re-ex training in the treatment of classical migraine headache; American Journal of Electromedicine; 1989 Sep, S. 120-123

5.2 Studies and Case Reports – Psyche

Depression

Marshall F. Gilula; Daniel L. Kirsch; Cranial Electrotherapy Stimulation Review: A Safer Alternative to Psychopharmaceuticals in the Treatment of Depression; Journal of Neurotherapy; 2005, Vol. 9(2), S. 7-26; The Haworth Press

Anxiety States

Ray B. Smith; Frank N. Shiromoto; The Use of Cranial Electrotherapy Stimulation to Block Fear Perception in Phobic Patients; Life Balance International, Current Therapeutic Research; 1992, Vol. 51, Nr. 2, S. 249-254

Stress

Ronald R. Mellen et al.; Cranial Electrotherapy Stimulation (CES) and the Reduction of Stress Symptom in a Sheriff's Jail Security and Petrol Officer Population: A Pilot Study; American Jails, 2008 Nov/Dez, 22, 5, Docstoc, S. 32

Aggression

A. Childs; Cranial electrotherapy stimulation reduces aggression in a violent retarded population: a preliminary report; The Journal of Neuropsychiatry and clinical Neurosciences; 2005 Herbst; 17(4): S. 548-51

Insomnia

Marshall F. Gilula; Daniel L. Kirsch; Cranial electro therapy (CES) in the Treatment of Insomnia: A Review and Meta-analysis; Journal of Neurotherapy; 2005, Vol. 9(2), S. 7-26; the Haworth Press

Lack of Concentration

S. Southworth; The family institute and Associates; A study of the effects of CES on attention and concentration; Integrative physiological and behavioural science; Jan-Mar 1999, Vol. 34, No. 1, S. 43-53

Withdrawal from Smoking

William S. Eidelmann; Control of cigarette cravings with cranial electrotherapy stimulation; Townsend letter; 2009, June

5.3 Studies and Case Reports – Infections

Shingles

C. McMakin; Non-pharmacologic treatment of shingles; Mai 2010; Practical Pain Management; S. 24-29

5.4 Studies and Case Reports – Neurology

Tinnitus

C. H. Chouard, B. Meyer, D. Maridat; Transcutaneous electrotherapy for severe tinnitus; Acts Otolaryngol; 1981; 91: S. 415-22

M. Engelberg, W. Bauer; Transcutaneous electrical stimulation for tinnitus; Laryngoscope 1985; 95: S. 1167-72

Ronald L. Steenerson, Gave W. Cronin; Treatment of tinnitus with electrical stimulation; Otolaryngology - Head and Neck Surgery; 1999 Nov; Vol. 121, S. 1-4

Parkinson

Pain in Parkinson:

H. D. Rintala; G. Tan; P. Willson; S. Bryant Mon; E. C. H. Lail; Feasibility of Using Cranial Electrotherapy Stimulation for Pain in Persons with Parkinson Disease; Research Article, SAGE-Hindawi access to research, Parkinson's Disease 2010 Vol., 2010 Article ID 569154 S. 1-8

Neuritis

Neuropathic pain:

Soler, H. Kumru, R. Pelayo, J. Vidal, J. M. Tormos, F. Fregni, X. Navarro, A. Pascual-Leone; Effectiveness of transcranial direct current stimulation and visual illusion on neuropathic pain in spinal cord injury; Brain: A Journal of Neurology; 2010 Sep, 133(9): S. 2565-77. Epub 2010 Aug 4

Multiple Sclerosis

Ray B. Smith; The use of cranial electrotherapy stimulation in the treatment of multiple sclerosis; The original internist, Sep 2002, Vol. 9, Nr. 3, S. 25-28

5.5 Studies and Case Reports – Skin

Psoriasis

A. Philipp; G. K. Wolf; B. Rzany; H. Dertinger; E. G. Jung; Interferential current is effective in palmar psoriasis: an open prospective trial; European Journal of Dermatology; 2000, 10: 195-8

5.6 Studies and Case Reports – Injuries, Wound Treatment

Wound Treatment, Burns

M. O. Ullah; A study to detect the efficacy of microcurrent therapy on pressure ulcers; Proceedings of Pakistan Academy of Sciences; 2007; 44(4): S. 281-287

S. Young; S. Hampton; M. Tadej; Study to evaluate the effect of low-intensity pulsed electrical currents on levels of oedema in chronic non-healing wounds; Journal of wound care; 2011 Aug, Vol. 20, Nr. 8, S. 368-373

Edema

S. Young; S. Hampton, BSc; M. Tadej; Study to evaluate the effect of low-intensity pulsed electrical currents on levels of oedema in chronic non-healing wounds; Journal of wound care; 2011 Aug, Vol. 20, Nr. 8, S. 368-373

5.7 Studies and Case Reports – Cardio-Vascular Diseases

Hypertension

A. Vlasov, A. Safronov, V. Vladimirsky, A. Vladimirskaia, M. Umnikova; Efficiency of dynamic electroneurostimulation in patients with arterial hypertension; Ural state Medical Academy, Yekaterinburg, Russia; 2006; S. 1-2

V. I. Podzolkov; T. S. Mlnikova; I. A. Suvorova; L. I. Churganova; S. P. Starovoitova; Cranial electrostimulation - a new nondrug method of treating the initial stage of hypertension 1992; Terapeuticheskii Arkhiv; 64(1): S. 24-27

5.8 Studies and Case Reports – Internal Medicine

Diabetes Mellitus, Hypertension, Chronic Wounds

Bok Y. Lee, Noori AL-Waili, Dean Stubbs, Keith Wendell, Glenn Butler, Thia AL-Waili, Ali AL-Waili; 2010; Ultra-low microcurrent in the management of diabetes mellitus, hypertension and chronic wounds: Report of twelve cases and discussion of mechanism of action; International Journal of medical sciences; 7(1): S. 29-35

5.9 Studies and Conventional Medicine

About the Studies and Case Collections Mentioned

Perhaps you are wondering about the notes on some pages. These are a legal requirement. They are meant to protect consumers from misleading or suggestive advertising statements (which they are unable to verify due to lack of specialist knowledge) or statements making explicit promises or suggesting a specific outcome. Among other things, this includes mentions of studies, indications or particularly treatment successes.

All this is why we provide the respective notes for the sources mentioned. Many studies, case collections and investigations exist and are mentioned here. These are also the basis for the medical product approval of Healy and define its intended use; they do not all comply, however, with the gold standard defined by conventional medicine. We therefore would like to explain briefly where exactly the differences lie in the study evaluations.

The Gold Standard

For the indications mentioned in these studies, there are many studies, case collections and individual case reports that suggest possible effectiveness of a treatment. Among others, these studies also include placebo-controlled, randomized, double-blind studies. What distinguishes these from the generally recognized evidence in respect to conventional medicine? Conventional medicine is based upon the so-called gold standard, which requires at least two studies on a specific topic to exist in addition to the above criteria (placebo-controlled, randomized, double-blind study), no studies making statements to the contrary being available and specialist literature to recognize and mention the effectiveness of the studies.

It is important to us for you to understand that there are many serious studies in the application areas mentioned which just do not comply with the standards just mentioned. In conventional medicine as well, some treatments are often applied that are based on simpler study designs not conforming to the gold standard. It is our wish that conventional and integrative medicine shall complement each other positively.