

Extracorporeal shock wave therapy for musculoskeletal conditions

Clinical Expert

Michael W. Chang, MD, PhD

Medical Director, Physical Medicine Institute Bellevue, Washington

MA - Health Technolog	gy Assessment	The state of the s
Applicant Name	Michael Chang, MD, PhD	
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# Business Investments of More Than \$1,000

(Do not list the amount of the investment or include individual items held in a mutual fund or blind trust, a time or demand deposit in a financial institution, shares in a credit union, or the cash surrender value of life insurance.)

If you or a member of your household had a personal, beneficial interest or investment in a business during the immediate preceding calendar year of more than \$1,000, list the following:

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I certify that I have read and understand this Conflict of Interest Form and the information I have provided is true and correct as of this date.

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# **CURRICULUM VITAE**

Michael W. Chang, MD, PhD Medical Director Physical Medicine Institute

Physical Medicine/Rehabilitation
Neuromuscular/Electrodiagnostic Medicine
Image-Guided Acoustic Research/Treatment
12340 NE 8th St, #101 Tel: (425) 603-1988
Bellevue. WA 98005 Fax: (425) 451-2696

E-mail: <u>mwc@uw.edu</u>

# **PRIVATE PRACTICE** - Physical Medicine Institute, Bellevue, WA, 8/1/08 - present

# **FACULTY POSITIONS** - University of Washington, Seattle, WA (8/1/92 - retired on 8/1/08)

Assistant Professor, Department of Rehabilitation Medicine, School of Medicine, 8/92 - 6/99

Graduate Faculty, Graduate School, 10/92 - 8/08

Affiliate Faculty, Biomechanics Pathway, Department of Bioengineering, 12/95 – 8/08

Adjunct Assistant Professor, Department of Chemical Engineering, College of Engineering, 7/93 - 6/99

Adjunct Associate Professor, Department of Chemical Engineering, College of Engineering, 7/99 - 12/01

Associate Professor, Department of Rehabilitation Medicine, School of Medicine, 7/99 – 8/08

Adjunct Associate Professor, Department of Mechanical Engineering, College of Engineering, 12/03 – 8/08

# HOSPITAL POSITIONS – University of Washington Medical Center & Harborview Medical Center, Seattle, WA (8/1/92 - retired on 8/1/08)

Attending Physician, Neuromuscular & Electrodiagnostic Medicine Clinic, University of Washington Medical Center, 8/92-7/08

Attending Neurophysiologist, UW Intra-Operative Neuro-monitoring Service, University of Washington & Harborview Medical Centers, 1/93 – 7/08

Attending Physician, Rehabilitation Medicine Inpatient Service, University of Washington Medical Center, 8/92 - 7/08

PM&R Consult Attending Physician, University of Washington Medical Center, 7/96 - 7/08

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Attending Physician, Musculo-Skeletal Medicine Clinic, University of Washington Medical Center, 7/96 – 7/08

Consult Attending Physician, Multi-disciplinary Pain Center, University of Washington Medical Center, 10/92 - 3/96

Attending Physician, Brain Injury Rehabilitation Clinic, University of Washington Medical Center, 1/94 - 7/96

Attending Physician, Rehabilitation Medicine Clinic, Harborview Medical Center, 7/96 - 2/97

Attending Physician, Neuromuscular & Electrodiagnostic Medicine Clinic, Harborview Medical Center, 3/03 – 7/08

# **SEATTLE MEDICAL AND REHABILITATION CENTER** – An Affiliated Facility with University of Washington (3/97 – 3/08)

Medical Director/Chief Rehabilitation Consultant, Seattle Medical and Rehabilitation Center, 555 16th Ave, Seattle, WA 98122, Tel: (206) 324-8200, Fax: (206) 324-0780

# **EDUCATION**

BS	1974	Chemistry, National Tsing Hua University, Taiwan, ROC
PhD	1981	Chemical Engineering, University of Washington, Seattle, WA
MD	1988	University of Texas Medical Branch, Galveston, TX

#### **POSTGRADUATE TRAINING**

Internship	1988 - 89	Internal Medicine, Baylor College of Medicine, Houston, TX
Residency	1989 - 92	Physical Medicine and Rehabilitation, Multi-Campus Rehabilitation Medicine Residency Program, University of California Los Angeles, CA

### **BOARD CERTIFICATIONS & RECERTIFICATIONS**

Fellow, American Board of Physical Medicine and Rehabilitation, 1993 – 2003

Fellow, American Board of Neuromuscular & Electrodiagnostic Medicine, 1995 – 2005

Certified Medical Director (CMD), American Medical Directors Certification Program, 2002 – 2008

# LICENSURE TO PRACTICE MEDICINE

Washington 1992 - present

California 1989 - present Texas 1988 - 1996

## PROFESSIONAL EXPERIENCES

Lieutenant, National Service, Army Artillery, Taiwan, ROC, 1974 - 76

Research Engineer, Shell Development Company, a subsidiary of Shell Oil Company, Houston, TX, 1981 – 85

#### NATIONAL PEER REVIEW/ADVISORY BOARD

Member of Advisory Board for Center of Excellence in Limb Loss Prevention and Prosthetic Engineering, Veterans Affairs Puget Sound Health Care System, Seattle, WA, 2002 - present.

Member of Review Panel for Biomedical Engineering and Research to Aid Persons with Disabilities, National Science Foundation, Arlington, VA, January 13 - 14, 2004

Member of Review Panel for Biomedical Engineering and Research to Aid Persons with Disabilities, National Science Foundation, Arlington, VA, January 27 - 28, 2005

Member of Review Panel for Theory, Modeling and Simulation NER Panel, National Science Foundation, Arlington, VA, March 4, 2005

Member of Review Panel for Biomedical Engineering, National Science Foundation, Arlington, VA, December 11 - 12, 2006

Member of Review Panel for Biomedical Engineering, National Science Foundation, Arlington, VA, May 10 - 11, 2007

#### INDUSTRIAL ADVISORY BOARD

SanuWave Inc, an electrohydraulic shockwave device manufacturing company, Alpharetta, GA

#### **GRANTS (FUNDED)**

"A Comparison of Magnetic Resonance Spectroscopy with Electrodiagnostic Techniques in Determining the Prognosis of Vegetative State in the Subacute Traumatically Brain Injured Patient", NIH sponsored CNS Trauma Program Project, Dept. of Neurosurgery, University of Washington. \$20,000, 5% time commitment. Role: Co-Principal Investigator, 5/1993 - 5/1994

"Predicting Laryngeal Penetration on Dysphagic Patients Using a Computational Fluid Dynamics Model: Development and Testing of the Model", funded by the Whitaker Foundation, Biomedical Engineering Research Grants Program. \$179,983, 18% time commitment. Role: Principal Investigator, 9/1994 - 6/1998

"Collaboration of Upper Limb Pain in Spinal Cord Injury", funded by NIDRR. \$492,501.00, 15% FTE. Role: Center Director for the Research Site at University of Washington, 12/1/01 - 11/30/07

"Physical Mechanisms of Shock Wave Therapy in Orthopaedics", funded by NIH for RO1. 5% FTE. Role: Consultant (key personnel), 8/1/07 - 7/31/11

"Video Oximetry Imaging for Assessment of Wound Healing", funded by Small Grants Translational Research Projects, Institute of Translational Health Sciences, University of Washington. Role: Co-Investigator, 9/1/08 – 8/31/09

# PROFESSIONAL ORGANIZATIONS

The International Society for Medical Shockwave Treatment (ISMST)

American Institute of Ultrasound in Medicine (AIUM)

North American Vascular Biology Organization (NAVBO)

American Academy of Physical Medicine and Rehabilitation (AAPMR)

American Association of Neuromuscular & Electrodiagnostic Medicine (AANEM)

Washington State Medical Association (WSMA)

King County Medical Society (KCMS)

Board of Directors, Chinese Nursing Home Society, Seattle, WA, 2/22/94 - 12/31/96

Board of Directors, Kin On Community Health Care/Kin On Health Care Center, Seattle, WA, 1/1/00 - 12/31/02

#### **HONORS**

Foreign Exchange Scholarship, University of Washington, Seattle, WA, 1977 - 79

Vice President, Student Association, University of Washington, Seattle, WA, 1979 - 80

TAU BETA PI Engineering Honor Society, University of Washington, Seattle, WA, 1977 - 81

Shell Achievement Recognition Award, Shell Development Co, Houston, TX, 1985

First Place in Clinical-Related Research Studies, Biomechanical Characteristics of the Radio-Carpal Joint. Medical Student Research Training Program sponsored by National Institutes of Health, University of Texas Medical Branch, Galveston, TX, 1986

Chief Resident, Physical Medicine and Rehabilitation Multi-Campus Rehab Medicine Residency Program, University of California Los Angeles, CA, 1991 - 92

Poster Award Winner, Sixth Annual Dysphagia Research Society Meeting, Toronto, Canada. The Effect of Bolus Viscosity on Pharyngeal Phase of Swallowing - A Study Using Computational Fluid Dynamics, 1997

# **EDITORIAL ACTIVITIES**

Annals of Biomedical Engineering
Ad Hoc Editorial Reviewer, 1998 - present

Journal of Biomechanics Ad Hoc Editorial Reviewer, 1999 - present

Muscle and Nerve
Ad Hoc Editorial Reviewer, 2000 - present

VA Journal of Rehabilitation Research and Development Ad Hoc Editorial Reviewer, 2004 - present

American Journal of Rehabilitation Medicine Ad Hoc Editorial Reviewer, 2006 - present

Critical Care Medicine Ad Hoc Editorial Reviewer, 2008 - present

Journal of Orthopaedic Research Ad Hoc Editorial Reviewer, 2008 - present

Journal of Rheumatology
Ad Hoc Editorial Reviewer, 2009 – present

The American Journal of Sports Medicine
Ad Hoc Editorial Reviewer, 2013 – present

American Journal of Physical Medicine & Rehabilitation Ad Hoc Editorial Reviewer, 2014 – present

### **PRESENTATIONS: National and International**

Chang MW, Finlayson BA, Sleicher CA. Heat Transfer in Flow Past Cylinders with Variable Viscosity. 2nd National Symposium on Numerical Methods in Heat Transfer, College Park, MD, September 1981.

Chang MW, Finlayson BA, Sleicher CA. Heat Transfer in Flow Past Cylinders with Variable Fluid Properties. Annual Convention, American Institute of Chemical Engineering, New Orleans, LA, November 1981.

Tencer AF, Viegas SF, *Chang MW*, Hicks C, O'Meara C. **Biomechanical Characteristics of the Radio-Carpal Joint.** 33rd Annual Meeting, Orthopaedic Research Society, San Francisco, CA, January 19 - 22, 1987.

*Chang MW*, Viegas SF, Tencer AF. **Biomechanical Characteristics of the Radio-Carpal Joint.** 28th Annual National Student Research Forum, Galveston, TX, April 22 - 24, 1987.

Tencer AF, Viegas SF, Cantrell J, *Chang MW*, Clegg P, Hicks C, O'Meara C, Williamson J. Contact Pressure Characteristics of the Radio-Carpal Joint with Ligamentous Instability. 34th Annual Meeting, Orthopaedic Research Society, Atlanta, GA, February 1 - 4, 1988.

Viegas SF, Tencer AF, Cantrell J, *Chang MW*, Clegg P, Hicks C, O'Meara C, Williamson J. **Load Transfer Characteristics of the Wrist (Normal and Perilunate Instability).** 55th Annual Meeting, American Academy of Orthopaedic Surgeons, Atlanta, GA, February 4 - 9, 1988.

*Chang MW*, Bonebakker A, Mehta A, Nikas V. **Neuralgic Amyotrophy in a Paraplegic.** Oral Presentation, 52nd Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Phoenix, AZ, October 21 - 26, 1990.

Chang MW, Oldendorf WH, Strouse J. Composition and Relaxation of Proton Magnetization in Beef Femur Compact Bone. Submitted for Int Conf on Innovative Medicine and Related Technologies '92, San Francisco, CA, November 1 - 4, 1992.

Chang MW, Scremin AME. Myogenic Knee Contracture from Acute Pelvic Venous Thrombosis. Poster Presentation, 54th Annual Assembly of American Academy of Physical Medicine and Rehabilitation, San Francisco, CA, November 13 - 17, 1992.

*Chang MW.* **Magnetic Resonance Imaging in Traumatic Brain Injury.** Oral Presentation, 54th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, San Francisco, CA, November 13 - 17, 1992.

Chang MW, Sun J. Initialization of the Oral Anticoagulant Warfarin Dosages Utilizing Computer Modeling. Poster Presentation, 56th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Anaheim, CA, October 8 - 12, 1994.

*Chang MW*, Rosendall B, Finlayson B, Yorkston K, Miller R. **Mathematical Modeling Of Pharyngeal Bolus Transport**. 3rd Annual Meeting, Dysphagia Research Society, McLean, VA, October 13-14, 1994.

Chang MW, Oldendorf WH, Strouse J. Composition and Relaxation of Proton Magnetization in Beef Femur Compact Bone. Progress in Electromagnetics Research Symposium 95, Seattle, WA, July 24 - 28, 1995.

Bell KR, *Chang, MW,* Richards T. **Proton Magnetic Resonance Spectroscopy to Evaluate Outcome in Traumatic Brain Injury**. Oral presentation, 57th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Orlando, FL, November 16 - 20, 1995.

Brecht SJ, *Chang MW*, Price R, Lehmann J. **Decreased Balance Performance in Cowboy Boots Compared with Tennis Shoes**. Poster presentation, 57th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Orlando, FL, November 16 - 20, 1995.

*Chang MW*, Rosendall B, Finlayson B. **Finite Element Analysis of Pharyngeal Bolus Transport.** Poster presentation, 57th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Orlando, FL, November 16 - 20, 1995.

Finlayson BA, Rosendall BM, *Chang MW*. **Finite Element Modeling of the Pharyngeal Phase of Swallowing**. Invited speaker at the Department of Chemical Engineering, Oklahoma State University, April 11, 1996.

Chang MW, Higashi L. Optimizing Cushion to Prevent Pressure Sores Using a Finite Element Method. Poster presentation, 58th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Chicago, IL, October 10-13, 1996.

*Chang MW.* **Mathematical Modeling of Pharyngeal Bolus Transport**. Invited speaker at the National Taiwan University Hospital, Taipei, Taiwan, R.O.C., March 20, 1997.

*Chang MW.* **Mathematical Modeling of Pharyngeal Bolus Transport**. Invited speaker at the Chang Gung Memorial Hospital, Linko, Taiwan, R.O.C., March 19, 1997.

Chang MW, Rosendall BM, Finlayson BA, Lin E, Hwang J-N. Predicting Laryngeal Penetration Using a Computational Fluid Dynamics Model. Poster Presentation, The Whitaker Foundation Biomedical Engineering Research Conference, Snowbird, UT, July 11-13, 1997.

Chang MW, Rosendall BM, Finlayson BA. Mathematical Modeling of Pharyngeal Bolus Transport. Oral presentation at the 8th World Congress of the International Rehabilitation Medicine Association (IRMA VIII), Kyoto, Japan, August 31 - September 4, 1997.

Chang MW, Lin E, Hwang J-N. **3-D Contour Tracking of Pharyngeal Bolus Movement**Using a Knowledge-Based Snake Search Algorithm. Poster presentation at the Sixth Annual Dysphagia Research Society Meeting, Toronto, Ontario, Canada, October 16 - 17, 1997.

Chang MW, Rosendall BM, Finlayson BA. The Effect of Bolus Viscosity on Pharyngeal Phase of Swallowing - A Study Using Computational Fluid Dynamics. Recipient of the *Poster Award* at the Sixth Annual Dysphagia Research Society Meeting, Toronto, Ontario, Canada, October 16 - 17, 1997.

Rosendall BM, Finlayson BA, *Chang MW*. **Finite Element Model of the Pharyngeal Phase of Swallowing: Effects of Viscosity**. Oral presentation at the Tenth International Conference on Finite Element in Fluids, Tucson, AZ, January 5 - 8, 1998.

Lin E, Hwang J-N, *Chang MW*. **Boundary Conditions of Pharyngeal Bolus Modeling by Neural Network Inversion**. Presented at the 1998 IEEE Signal Processing Society Workshop on Neural Networks for Signal Processing, Cambridge, England, August 31 - September 3, 1998.

*Chang MW*, Higashi L, Wen-Shiang Chen. **A Static Heel-Cushion Contact Model for Prevention of Pressure Sores**. Presented at the 60th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Seattle, WA, November 5 - 8, 1998.

*Chang MW*, Lin E, Rosendall BM, Finlayson BA. **Determination of Bolus Consistency for Safe Oral Feeding: A Study Using a 3-D Fluid Mechanics Model**. Presented at the 60th Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Seattle, WA, November 5 - 8, 1998.

Chen W-S, Higashi L, *Chang, MW*. Characteristics of the Internal Tissue Stress: A Study Using a Heel Contact Model. Presented at the 61st Annual Assembly, American Academy of Physical Medicine and Rehabilitation, Washington, D.C., November 11 - 14, 1999.

Chen W-S, Higashi L, *Chang, MW*. A Study of Internal Tissue Stress Using a Heel Contact Model. Presented at the MSC Software Corporation and University of Minnesota 2001 Simulation in Biomedical Engineering Conference, Minneapolis, MN, September 7, 2001.

*Chang MW.* **Biomedical Simulation in Clinical Medicine.** Presented at the MSC Software Corporation and University of Minnesota 2001 Simulation in Biomedical Engineering Conference, Minneapolis, MN, September 7, 2001.

Chang MW. Common Biomechanical Complications in Spinal Cord Injury Rehabilitation. Invited Speaker at the Biomedical Aspects of Spinal Cord Injury. Peter Wall Institute for Advanced Studies, University of British Columbia, Vancouver, B.C. Canada. September 26 - 27, 2003.

Chang MW, Sun J, Rosendall BM, Lin E, Higashi L, Chen W-S, Luo Y, Hwang J-N, Finlayson BA, **Mathematical Modeling in Clinical Medicine.** Presented at Symposium on Digital Biology: the Emerging Paradigm. NIH Biomedical Information Science and Technology Initiative Consortium (BISTIC), National Institutes of Health, Bethesda, MD, November 6 - 7, 2003.

Chang MW. Mathematical Modeling Helps to Improve Patient Care. Presented at Biomedical Informatics for Clinical Decision Support: A Vision for the 21th Century. NIH Bioengineering Consortium (BECON) and Biomedical Information Science and Technology Initiative Consortium (BISTIC), National Institutes of Health, Bethesda, MD, June 21 - 22, 2004.

Chang MW. Physical and Biological Responses to Shock Wave Therapy: Potential for Multiple Clinical Applications. Visiting Professor Lecture at Dept of Orthopaedic Surgery, Chang Gung Memorial Hospital, Kaohsiung, Taiwan, R.O.C., November 14, 2006.

*Chang MW.* **Management of Swallowing Disorders.** Visiting Professor Lecture at Dept of Physical Medicine and Rehabilitation, Chang Gung Memorial Hospital, Kaohsiung, Taiwan, R.O.C., November 14, 2006.

*Chang MW*. **Biomedical Modeling in Clinical Medicine.** Visiting Professor Grand Round Series, Surgical Division, Chang Gung Memorial Hospital, Kaohsiung, Taiwan, R.O.C., November 15, 2006.

Chang MW. Physical and Biological Responses to Shock Wave Therapy: Potential for Multiple Clinical Applications. Visiting Professor Lecture at Dept of Orthopaedic Surgery, Chang Gung Memorial Hospital, Chia-I, Taiwan, R.O.C., November 16, 2006.

*Chang MW.* Physical and Biological Responses to Shock Wave Therapy: Potential for Multiple Clinical Applications. Visiting Professor Lecture at Dept of Orthopaedic Surgery, Chang Gung Memorial Hospital, Linko, Taiwan, R.O.C., November 17, 2006.

*Chang MW.* **Understanding ESWT Applications to Various Tissues**. SanuWave Advisory Board Meeting, Alpharetta, GA, April 2, 2007.

Chang MW. Physical & Biological Responses to Shockwaves: Potential for Various Clinical Treatments. Visiting Professor Lecture at Dept of Physical Medicine & Rehabilitation, National Taiwan University Hospital, Taipei, Taiwan, R.O.C., April 11, 2007.

*Chang MW.* **Modeling of Shockwave Treatment**. Visiting Professor Lecture at Dept of Orthopaedic Surgery, Chang Gung Memorial Hospital, Kaohsiung, Taiwan, R.O.C., April 12, 2007.

Chang MW. Modeling of an Electrohydraulic Shockwave Device – Implications for Optimal Device Operation. 10th International Congress of International Society for Medical Shockwave Treatment (ISMST), Toronto, CA, June 7, 2007.

*Chang MW*, Truong A, Santosa D, Vaezy S. Cavitation Fields Induced by Shockwave Propagation in Polyacrylamide Gel and Exo-vivo Porcine Tissue. 10th International Congress of International Society for Medical Shockwave Treatment (ISMST), Toronto, CA, June 7, 2007.

Seals K, Wise M, *Chang MW*. **ESWT and Bacteria: A Critical Review**. 10th International Congress of International Society for Medical Shockwave Treatment (ISMST), Toronto, CA, June 8, 2007.

Wise M, Seals K, *Chang MW*. Extracorporeal Shockwave Therapy and Its Effect on The Nervous System: A Critical Review of Current Literature. 10th International Congress of International Society for Medical Shockwave Treatment (ISMST), Toronto, CA, June 9, 2007.

Chang MW, Oda A, Osathanon T, Giachelli G. **Treatment of Heterotopic Ossifications Using Shockwave: An In Vitro Study**. 11th International Congress of International Society for Medical Shockwave Treatment (ISMST), Antibes, France, June 6, 2008.

*Chang MW*, Oda A, Osathanon T, Giachelli G. **Treating Heterotopic Ossifications with Shockwaves**. Invited Speaker, Annual Meeting of Acoustic Society of America (ASA), Portland, Oregon, May 20, 2009.

Matula T, Paun M, *Chang MW*. **Monitoring for Cavitation During Shock Wave Treatment for Ankle Pain**. 10th International Symposium on Therapeutic Ultrasound 2010, Tokyo, Japan, June 9-12, 2010.

*Chang MW*, Paun M, Matula T. **Monitoring for Cavitation During Shock Wave Therapy**. 13th International Congress of the International Society for Medical Shockwave Treatment (ISMST), Chicago, IL, USA, June 24-26, 2010.

Chang MW, Matula T. Shockwave Therapy for Mature Heterotopic Ossifications – A Case Report. 13th International Congress of the International Society for Medical Shockwave Treatment (ISMST), Chicago, IL, USA, June 24-26, 2010.

Chang MW, Matula T. Neurophysiological Monitoring During Shockwave Therapy for Elbow Heterotopic Ossifications. 13th International Congress of the International Society for Medical Shockwave Treatment (ISMST), Chicago, IL, USA, June 24-26, 2010.

Seals K, Bryers J, *Chang MW*. **Mathematical Modeling of Shockwave Therapy for Osteomyelitis.** 13th International Congress of the International Society for Medical Shockwave Treatment (ISMST), Chicago, IL, USA, June 24-26, 2010.

*Chang MW.* Physical and Biological Responses to Shockwave Therapy: Potential for Multiple Clinical Applications. Visiting Industrial Lecture, Storz Medical AG, Tagerwilen, Switzerland, June 6, 2011.

Chang MW. Potential Roles of Cavitation in Tissue Angiogenesis - Observations from Direct Cavitation Monitoring during Shockwave Therapy. 14th International Congress of the International Society for Medical Shockwave Treatment (ISMST), Kiel, Germany, June 9-11, 2011.

*Chang MW.* **Invited Moderator**. Asia Pacific Summit in Shockwave Medicine, Kaohsiung, Taiwan, October 2-4, 2015.

#### PRESENTATIONS: Local

Chang MW. Equations of State to Calculate Reservoir Fluid Properties for Miscible Flooding. Reservoir Engineering Research Conference, Shell Development Co, Houston, TX, August 9, 1984.

*Chang MW.* **MRI in Adult Brain Injury.** Neurological Sciences Grand Rounds, Rancho Los Amigos Medical Center, September 13, 1991.

Shin DY, Stone LR, Shen J, *Chang MW*. Chemical Neurolysis in the Management of Cerebral Spasticity. Demonstration in Educational Courses of the American Academy of Neurology in the Neurological Rehabilitation of Traumatic Brain Injury Patients. Daniel Freeman Memorial Hospital and Rancho Los Amigos Medical Center, October 14-18, 1991.

*Chang MW.* **Magnetic Resonance in Brain Injury Rehabilitation.** Oral presentation at the 54th Annual Meeting, North Pacific Society for Neurology, Neurosurgery and Psychiatry, Blaine, WA, March 17-20, 1993.

*Chang MW.* Predicting Laryngeal Penetration on Dysphagic Patients Using Finite Element Analysis. Friday Research Meetings, Harborview Injury Prevention and Research Center, Harborview Medical Center, Seattle, WA, September 17, 1993.

*Chang MW.* **Computerized Dose Modeling of Warfarin.** 1993 Anticoagulation Clinic Traineeship, Department of Pharmacy, University of Washington Medical Center, Seattle, WA, October 12, 1993.

Chang MW. Composition and Relaxation of Proton Magnetization in Beef Femur Compact Bone. Biomechanics Seminar Series, Center for Bioengineering, University of Washington, Seattle, WA, March 1, 1994.

*Chang MW*, Sun J. **Initialization of the Oral Anticoagulant Warfarin Dosages Utilizing Computer Modeling.** 9th Annual Justus F. Lehmann Symposium and 31st Annual Clinical Meeting of the Northwest Association of Physical Medicine and Rehabilitation, Seattle, WA, May 18-21, 1994.

Chang MW, Scremin AME. Myogenic Knee Contracture from Acute Pelvic Venous Thrombosis. 9th Annual Justus F. Lehmann Symposium and 31st Annual Clinical Meeting of the Northwest Association of Physical Medicine and Rehabilitation, Seattle, WA, May 18-21, 1994.

*Chang MW.* **Fluid Mechanics of Pharyngeal Bolus Transport.** Speech Pathology Conference, Harborview Medical Center, Seattle, WA, May 26, 1994.

Chang MW. Mathematical Modeling: How Is It Done and How Can It Be Used to Address Clinical Questions? Rehabilitation Research Development Seminar, University of Washington, Seattle, WA, November 21, 1994.

*Chang MW.* **Mathematical Modeling in Clinical Medicine**. Biomechanics Seminar Series, Center for Bioengineering, University of Washington, Seattle, WA, December 6, 1994.

*Chang MW.* **Mathematical Modeling of Pharyngeal Bolus Transport.** Gastroenterology Grand Rounds, University of Washington, Seattle, WA, March 3, 1995.

Rosendall BM, Finlayson BA, *Chang MW*. **Mathematical Modeling of Normal Pharyngeal Swallowing**. Oral presentation at the 10th Annual Justus F. Lehmann Symposium and 32nd Annual Clinical Meeting of the Northwest Association of Physical Medicine and Rehabilitation. University of Washington, June 2, 1995.

Brecht SJ, *Chang MW*, Price R, Lehmann J. **Decreased Balance Performance in Cowboy Boots Compared with Tennis Shoes**. Poster presentation at the 10th Annual Justus F. Lehmann Symposium and 32nd Annual Clinical Meeting of the Northwest Association of Physical Medicine and Rehabilitation. University of Washington, June 2, 1995.

*Chang MW.* **Decreased Balance Performance in Cowboy Boots Compared with Tennis Shoes**. Biomechanics Seminar Series, Center for Bioengineering, University of Washington, Seattle, WA, November 7, 1995.

*Chang MW.* **Management of Motor Disorders and Contractures**. The 17th University of Washington Review Course in Physical Medicine and Rehabilitation. Seattle, WA, March 16-23, 1996.

Rosendall BM, Finlayson BA, *Chang MW*. **Mathematical Modeling of Pharyngeal Phase of Swallowing**. Dysphagia Study Group Meeting, University of Washington Medical Center, Seattle, WA, May 23, 1996.

*Chang MW.* **Mathematical Modeling of Pharyngeal Bolus Transport.** Rehabilitation Research Seminar, University of Washington, Seattle, WA, September 23, 1996.

Chang MW. Mathematical Modeling of Pharyngeal Bolus Transport - First Generation Model. Biomechanics Seminar Series, Center for Bioengineering, University of Washington, Seattle, WA, May 6, 1997.

Chang MW. Current and Future Research in Pharyngeal Phase of Swallowing at the Mathematical Modeling Laboratory. Retreat for the UWMC Swallowing Center, University of Washington, Seattle, WA, June 12, 1997.

*Chang MW.* **Pharyngeal Structure and Function**. Gastroenterology Grand Rounds, University of Washington, Seattle, WA, October 3, 1997.

*Chang MW.* **Neuromuscular Junction Studies and Disorders: Single-Fiber EMG**. Rehab 596, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, February 12, 1998, February 11, 1999.

*Chang MW.* **Myoneural Junction Studies and Disorders**. Rehab 596 Course, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, February 11, 1999.

*Chang MW.* **Approach to NMJ Disease**. Presented at the 18th annual Review Course in Physical Medicine and Rehabilitation, University of Washington, Seattle, WA, March 20 - 28, 1999.

*Chang MW*, Lin E. **Determination of Bolus Consisency for Safe Oral Feeding**. Poster presentation at the 14th Annual Justus F. Lehmann Symposium, Seattle, WA, June 4, 1999.

*Chang MW*, Chen W.-S. A Static Heel-Cushion Contact Model to Study Internal Tissue Stresses. Poster presentation at the 14th Annual Justus F. Lehmann Symposium, Seattle, WA, June 4, 1999.

*Chang MW.* Effective Utilization of Videofluorographic Study for the Management of **Dysphagia**. Lecture at the Rehab Radiology Conference, January 24, 2000.

*Chang MW.* **Radiculopathies**. Lecture in Rehab 596 – Electromyography and Clinical Neurophysiology, February 28, 2000.

*Chang MW.* **Electrodiagnosis for Neuromuscular Junction Diseases**. Rehab 596 Course, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, April 17, 2000.

*Chang MW.* Contracture Management, Phenol Neurolysis. Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Summer 1998, Summer 1999, Summer 2000.

*Chang MW.* **Botulinum Toxin Injection** (demo). Presented at the Rehab 592 Course, University of Washington, Seattle, WA, Summer 1998, Summer 1999, Summer 2000.

*Chang MW.* **Orthotic Evaluation: Human Motion Analysis**. Presented at the Rehab 592 Course, University of Washington, Seattle, WA, Summer 1998, Summer 1999, Summer 2000.

*Chang, MW.* **Human Motion Analysis**. Musculoskeletal Conference, University of Washington, Seattle, WA, March 5, 2001.

*Chang, MW.* **Human Motion Analysis: Gait Evaluation**. 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 20, 2001.

*Chang, MW.* **Therapeutic Footwear/Foot Orthoses**. 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 20, 2001.

*Chang, MW.* **Myoneural Junction Studies**. 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 24, 2001.

*Chang, MW.* **EDX for NMJ Diseases**. EMG Conference, University of Washington, Seattle, WA, April 16, 200 and November 19, 2001.

*Chang MW.* **Mathematical Modeling in Clinical Medicine**. Oral presentation at the 16th Annual Justus F. Lehmann Symposium, Seattle, WA, June 1, 2001.

*Chang MW.* **Principles of Orthotic Use in Rehabilitation**. Presented at the Resident Orientation, Dept of Rehabilitation Medicine, July 9, 2001.

*Chang MW.* **Principles of Orthotics: Introduction, Course Outline/Assignment**. Presented at the Rehab 592 Course, University of Washington, Seattle, WA. Summer 1998, Summer 1999, Summer 2000, Summer 2001.

*Chang, MW.* **Human Motion Analysis: Gait Evaluation**. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Summer 2001. Seattle, WA, Summer 2001.

*Chang MW.* Contracture Management: Phenol/Botox, Surgery. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Summer 2001.

*Chang MW*. **Tissue Biomechanics**. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Summer 2001.

*Chang MW.* **Shoe/Foot Orthoses**. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Summer 2001.

*Chang MW.* **Myoneural Junction Studies**. Rehab 596 Course, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, March 11, 2002.

Sell J, Price R, *Chang MW*. Characteristics of Wheelchair Propulsion on A Two-Roller Treadmill System. Poster Presentation, MSRTP, University of Washington, Seattle, WA. September 19, 2002.

*Chang MW.* **Collaborative Upper Limb Pain**. Presented at the meeting of researchers and Consumer Advisory Board of the Northwest Regional Spinal Cord Injury System. University of Washington, Department of Rehabilitation Medicine, March 13, 2003.

*Chang MW.* **Swallowing Dysfunction and Strok**e. Presented at the 20th University of Washington Review Course in Physical Medicine and Rehabilitation. March 15, 2003.

*Chang MW*. **Gait Analysis and Lower Limb Orthoses**. Presented at the 20th University of Washington Review Course in Physical Medicine and Rehabilitation. March 18, 2003.

*Chang MW.* **Electrodiagnosis of Neuromuscular Junction Disorders**. Rehab 596 Course, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, August 18, 2003.

*Chang MW.* **Physical Medicine and Rehabilitation.** Multidisciplinary Medical Specialty Presentation. Presented at the Events for Senior Day Sponsored by Asian Senior Concern Foundation, Bellevue, WA, September 6, 2003.

*Chang MW.* Engineering in Clinical Medicine. Biomechanics Seminar Series, Mechanical Engineering, University of Washington, Seattle, WA, October 9, 2003.

Chang MW, Fallon W. Principles and Applications of Extracorporeal Shock Wave Treatment in Musculoskeletal Medicine. Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2003.

*Chang MW.* **Principles of Orthotics and Human Motion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2003.

*Chang MW.* **Wheelchair Propulsion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2003.

*Chang MW.* **Gait Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2003.

*Chang MW.* Lower Limb Orthoses/Orthotic Prescription. Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2003.

*Chang MW*, Fallon W. **Principles and Applications of Extracorporeal Shock Wave Treatment in Musculoskeletal Medicine.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2004.

*Chang MW.* **Principles of Orthotics and Human Motion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2004.

*Chang MW.* **Wheelchair Propulsion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2004.

*Chang MW.* **Gait Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2004.

*Chang MW.* Lower Limb Orthoses/Orthotic Prescription. Presented at the Rehab 592 Course. University of Washington, Seattle, WA, Winter 2004.

*Chang MW.* **Human Motion Analysis - Gait Evaluation**. 21st University of Washington Review Course in Physical Medicine and Rehabilitation, March 22, 2004.

*Chang MW.* **Lower Limb Orthoses**. 21st University of Washington Review Course in Physical Medicine and Rehabilitation, March 22, 2004.

*Chang MW*. **Swallowing Dysfunction and Strok**e. 21st University of Washington Review Course in Physical Medicine and Rehabilitation. March 26, 2004.

*Chang MW.* **Neuromuscular Junction Studies**. Rehab 596 Course, Electromyography and Clinical Neurophysiology, University of Washington, Seattle, WA, August 23, 2004.

Chang MW. **ESWT in Musculoskeletal Medicine - Potential and Limitations.** Minisymposium on Extracorporeal Shock Wave Treatment (ESWT) in Musculoskeletal Medicine, Applied Physics Laboratory, University of Washington, Seattle, WA, September 22, 2004.

Chang MW, Fallon W. Principles and Applications of Extracorporeal Shock Wave Treatment in Musculoskeletal Medicine. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Winter 2005.

*Chang MW.* **Principles of Orthotics and Human Motion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Winter 2005.

*Chang MW.* **Wheelchair Propulsion Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Winter 2005.

*Chang MW.* **Gait Analysis.** Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Winter 2005.

*Chang MW.* Lower Limb Orthoses/Orthotic Prescription. Presented at the Rehab 592 Course. University of Washington, Seattle, WA. Winter 2005.

*Chang MW.* **Human Motion Analysis - Gait Evaluation**. 22nd University of Washington Review Course in Physical Medicine and Rehabilitation, April 4, 2005.

*Chang MW.* **Lower Limb Orthoses**. 22nd University of Washington Review Course in Physical Medicine and Rehabilitation, April 4, 2005.

*Chang MW.* **EDX Techniques and Neuromuscular Junction Diseases**. 22nd University of Washington Review Course in Physical Medicine and Rehabilitation. April 6, 2005.

*Chang MW.* Common Problems and Treatments for Back Pain. Presented at the Asian Senior Concerns Foundation, Seattle, WA, August 27, 2005.

*Chang MW.* **ESWT in Medicine.** Biomechanics Seminar Series, Mechanical Engineering, University of Washington, Seattle, WA, December 8, 2005.

Chang MW. From Basic Science to Patient Care: A Vision for ESWT Research and Clinical Care at University of Washington. Presented at the ESWT Group Meeting, University of Washington, December 13, 2005.

Chang MW. Principles and Clinical Applications of ESWT: Future Opportunities and Challenges. Presented at the Mini Symposium on Extracorporeal Shock Wave Treatment (ESWT): Angiogenesis, Micro-Vascular Remodeling and Wound Healing, University of Washington, February 2, 2006.

*Chang MW.* Case Presentations and Discussion. Presented at the Mini Symposium on Extracorporeal Shock Wave Treatment (ESWT): Angiogenesis, Micro-Vascular Remodeling and Wound Healing, University of Washington, February 2, 2006.

*Chang MW.* **Image-Guided ESWT in Medicine.** Bioengineering 599L, Image-Guided Therapy, University of Washington, Seattle, WA, February 28, 2006.

Chang MW. Shock Wave Therapy in Calcified Tissue – Potential Clinical Cases. Presented at Round Table Discussion, University of Washington, Seattle, WA, March 20, 2006.

*Chang MW.* **Human Motion Analysis - Gait Evaluation**. 23rd University of Washington Review Course in Physical Medicine and Rehabilitation, April 3, 2006.

*Chang MW.* **Lower Limb Orthoses**. 23rd University of Washington Review Course in Physical Medicine and Rehabilitation, April 3, 2006.

Wise M, Seals K, Adams J, *Chang MW*, Extracorporeal Shockwave Therapy and Its Effect on the Nervous System. Platform oral presentation at the University of Washington Undergraduate Research Symposium, Seattle, WA. May 8, 2006.

Wise M, Seals K, *Chang MW*, Extracorporeal Shockwave Therapy and Its Effect on the Nervous System. Poster presentation at the 21st Annual Justus F. Lehmann Symposium, Seattle, WA. May 12, 2006.

Price R, Ashwell ZR, Chang MW. Upper Limb Joint Power and its Distribution in Wheelchair Users with Spinal Cord Injury: Comfortable Self-Selected Speed vs. Acceleration Trials. Poster presentation at the 21st Annual Justus F. Lehmann Symposium, Seattle, WA. May 12, 2006.

Ashwell ZR, *Chang MW*, Price R. **Potential for Impingement of the Subacromial Space During Wheelchair Propulsion**. Poster presentation at the 21st Annual Justus F. Lehmann Symposium, Seattle, WA. May 12, 2006.

Santosa D, Truong A, Vaezy S, *Chang MW*. Physics of Cavitation in Polyacrylimide Gel and Exo-vivo Porcine Muscle Tissue. Poster presentation at the CREE Program Research Symposium, Bioengineering, University of Washington, August 17, 2006

*Chang MW.* **ESWT in Clinical Medicine.** Rheumatology Grand Round, Division of Rheumatology, Department of Medicine, University of Washington, Seattle, WA, Oct 24, 2006.

Truong A, Santosa D, Vaezy S, *Chang MW*. Evaluation of Shockwave Propagation in Polyacrylimide Gel and Porcine Tissue. Poster presentation at the MSRTP Research Symposium, School of Medicine, University of Washington, October 26, 2006

Chang MW. Physical and Biological Responses to Shockwaves: Potential for Multiple Clinical Applications. Biomechanics Seminar Series, Mechanical Engineering, University of Washington, Seattle, WA, December 7, 2006.

*Chang MW.* Physical and Biological Responses to Shock Waves: Potential for Various Clinical Treatments. Mini-Symposium for Extracorporeal Shock Wave Treatment (ESWT), University of Washington, Seattle, WA, January 29, 2007.

*Chang MW.* Principles of Shock Waves and Multiple Clinical Potential in Medicine. Invited Speaker, Asian Senior Concerns Foundation, Seattle, WA, March 10, 2007.

*Chang MW.* **Human Motion Analysis - Gait Evaluation**. 24th University of Washington Review Course in Physical Medicine and Rehabilitation, March 26, 2007.

*Chang MW.* **Lower Limb Orthoses**. 24th University of Washington Review Course in Physical Medicine and Rehabilitation, March 26, 2007.

Chang MW. Physical and Biological Mechanisms of Shockwaves Therapy: highlights from 10th ISMST meeting, Toronto. EMG Conference, Dept of Rehab Medicine, University of Washington, Seattle, WA, June 18, 2007.

*Chang MW.* Physical and Biological Mechanisms to Shock Wave Therapy: Potential for Multiple Clinical Applications. Mini-Symposium for Shock Wave Research, University of Washington, Seattle, WA, July 9, 2007.

*Chang MW.* **Development of Personalized Shockwave Treatments**. Biomechanics Seminar Series, Mechanical Engineering, University of Washington, Seattle, WA, November 15, 2007.

Chang MW. Physical and Biological Responses to Shock Waves: Potential for Multiple Clinical Applications. Mini-Symposium for Extracorporeal Shock Wave Treatment (ESWT), University of Washington, Seattle, WA, March 5, 2008.

*Chang MW.* **Modeling of Electrohydraulic Shockwave Propagation.** Mini-Symposium for Extracorporeal Shock Wave Treatment (ESWT), University of Washington, Seattle, WA, March 5, 2008.

*Chang MW.* Cavitation Fields Induced by Shockwaves. Mini-Symposium for Extracorporeal Shock Wave Treatment (ESWT), University of Washington, Seattle, WA, March 5, 2008.

Chang MW. Physical and Biological Responses to Shock Waves: Potential for New Clinical Treatments. Visiting Professor Lecture, SonoSite Inc., April 24, 2008.

Chang MW. Physical and Biological Responses to Shock Waves: Potential for Multiple Clinical Applications. Visiting Industrial Lecture, Philips Health Care, February 17, 2009.

Chang MW. Physical and Biological Responses to Shockwave Therapy: Potential for Variety of Clinical Applications. Visiting Lecture, Boeing Applied Physics Laboratory, March 10, 2010.

Chang MW. Extracorporeal Shockwave Therapy, Clinical Applications & Mathematical Modeling: Future Research Needed. Workshop in ESWT, Osteoporosis & Bone Modeling, Applied Math Department, University of Washington, Seattle, WA, October 10, 2011.

# **UNIVERSITY OF WASHINGTON: SCHOOL OF MEDICINE: Committees and Courses:**

Member, Intradepartmental Scientific Review Committee, Department of Rehabilitation Medicine, University of Washington, 1994 - 2008

Member, Medical Students Research Training Program Committee, School of Medicine, University of Washington, 1995 - 2008

Member, Undergraduate Prosthetics - Orthotics Committee, School of Medicine, University of Washington, 1995 - 2008

Coordinator, Rehabilitation Research Seminar, Department of Rehabilitation Medicine, University of Washington, 1996 - 2001.

Member, Sub-acute Rehabilitation Medicine Committee, Department of Rehabilitation Medicine, University of Washington, 1997 - 2008

Course Director, Rehab Medicine 592, Principles of Orthotic Use in Rehabilitation, Department of Rehabilitation Medicine, University of Washington, 1997 - 2002

Member, Operating Committee for Human Motion Analysis Laboratory, and Chair of Upgrade Committee, Department of Rehabilitation Medicine, University of Washington, 1997 - 2002

Co-Chairperson, Len Higashi's Master Thesis Supervisory Committee (Mechanical Engineering); (with Professor Colin Daly), 1995 - 96

Co-Chairperson, Brigette Rosendall's PhD Dissertation Supervisory Committee (Chemical Engineering); (with Professor Bruce Finlayson), 1994 - 96

Graduate Faculty Representative, Paul Carlson's PhD Dissertation Supervisory Committee (Bioengineering), 1996 - 99, Thesis Advisor: Professor Paul Yager, Department of Bioengineering.

Member, Eugene Lin's PhD Dissertation Supervisory Committee (Electrical Engineering); 1997 - 11/1999, Thesis Advisor: Professor Jenq-Neng Hwang

Graduate Faculty Representative, Geoffrey Raynak's PhD Dissertation Supervisory Committee (Orthopaedics and Bioengineering), 1998 - 2002, Thesis Advisor: Professor Randy Ching

Member, Chimba Mkandawire's PhD Dissertation Supervisory Committee (Orthopaedics and Bioengineering), 1998 - 2003, Thesis Advisor: Professor Randy Ching

Member, Supervisory Committee, Daniel Richard Einstein (Bioengineering/Mechanical Engineering), 2000 - 2003, Thesis Advisor: Professor Per Reinhall

Member, Advisory Committee, Medical Rehabilitation Research Training Program, 2001 - 2008.

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Coordinator, Electrodiagnostic Medicine Conferences, Department of Rehabilitation Medicine, University of Washington, 2001 - 2008.

Module Chair. Gait and Orthotics. 19th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 20, 2001.

Graduate Faculty Representative, Vesna Zderic's PhD Dissertation Supervisory Committee (Bioengineering), 2002 - 2004.

Ad Hoc Reviewer, Royalty Research Grant, University of Washington, 2002.

Course Director, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, 2002 – 2008.

Module Chair. Gait and Orthotics. 20th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 18, 2003.

Instructor for UW Medical School Gross Anatomy Lab and Living Anatomy Session, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter 2004.

Chair, Master Degree Supervisory Committee, Zach Ashwell (Mechanical Engineering), 2003 - 2006.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, 2003

Instructor in Gross Anatomy Lab and Living Anatomy Session, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter 2005.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, 2004

Module Chair. Gait and Orthotics. 21st University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 22, 2004.

Graduate Faculty Representative, Kevin M. Krudys' PhD Dissertation Supervisory Committee (Bioengineering), 2004 - 2007.

Graduate Faculty Representative, Jessica L. Foley's PhD Dissertation Supervisory Committee (Bioengineering), 2004 - 2007.

Chair, Mini-symposium on Extracorporeal Shock Wave Treatment (ESWT) in Musculoskeletal Medicine, Applied Physics Laboratory, University of Washington, Seattle, WA, September 22, 2004.

Instructor in Gross Anatomy Lab, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter 2005.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, 2005.

Module Chair. Gait and Orthotics. 22nd University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, April 4, 2005.

Co-Chair, ME 495, Senior Capstone Design, Department of Mechanical Engineering, University of Washington, Summer & Fall, 2005.

Chair, Master Degree Supervisory Committee, Zach Ashwell, Department of Mechanical Engineering, University of Washington, 2005.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, 2006.

Committee Member, Medical Student Research Training Program (MSRTP) Committee, University of Washington, Seattle, WA, Winter 2006.

Instructor for UW Medical School Gross Anatomy Lab, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2006.

Chair, Mini-symposium on Extracorporeal Shock Wave Treatment (ESWT): Angiogenesis, Micro-Vascular Remodeling and Wound Healing, University of Washington, February 2, 2006.

Co-Chair, ME 495, Senior Capstone Design, Department of Mechanical Engineering, University of Washington, 2006.

Module Chair, Gait and Orthotics. 23rd University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, April 3, 2006.

Graduate Faculty Representative, Wen-Bo Luo's PhD Dissertation Supervisory Committee (Bioengineering), 2005 - 2007.

Member, Michael Dahl's PhD Dissertation Supervisory Committee (Mechanical Engineering), 2005 - 2008.

Member, Shannon Kroeker's PhD Dissertation Supervisory Committee (Mechanical Engineering), 2006 - present.

Chair, Special Presentations and Round Table Discussion: Shock Wave Therapy in Calcified Tissue, University of Washington, March 20, 2006.

Instructor for UW Medical School Gross Anatomy Lab, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2007.

Chair, Mini-Symposium for Extracorporeal Shock Wave Therapy (ESWT): Reversal of Soft Tissue Calcifications, Orthopaedic Applications and Bactericidal Effects, University of Washington, January 29, 2007.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, Winter Quarter, 2007.

Module Chair, Gait and Orthotics. 24th University of Washington Review Course in Physical Medicine and Rehabilitation, Seattle, WA, March 26, 2007.

Chair, Rehab Medicine 592, Principles of Physical Medicine: Biophysics/Biomechanics, Orthotics and Assistive Technology, Department of Rehabilitation Medicine, University of Washington, Winter Quarter, 2008.

Instructor for UW Medical School Gross Anatomy Lab, Musculoskeletal Core Course, HuBio 553, School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2008.

Chair, Mini-Symposium for Extracorporeal Shock Wave Treatment (ESWT), University of Washington, March 8, 2008.

Member, Thanaphum Osathanon's PhD Dissertation Supervisory Committee (Oral Biology, Dental School), 2008.

Member, Review Panel for Mary Gates Venture Proposal, Mary Gates Endowment, University of Washington, 2008.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2009.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2010.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2011.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2012.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2013.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2014.

Instructor for UW Medical School Gross Anatomy Lab, HuBio 553, Musculoskeletal System. School of Medicine, University of Washington, Seattle, WA, Winter Quarter, 2015.

Instructor for UW Medical School, HFF Sessions, Block 2: Invaders & Defenders, Introduction to Joint, Knee Dissection. School of Medicine, University of Washington, Seattle, WA, Fall Quarter, November 23, 2015.

#### UNIVERSITY OF WASHINGTON - THESIS, RESEARCH STUDENT SUPERVISION:

Supervisor for Joannie Sun (Medical Student), Summer 1993, Medical Student Research Training Program (MSRTP)/ISMS. "Prediction of the Oral Anticoagulant Warfarin Dosages Utilizing Computer Modeling"; supported through R&T grant from the NCMRR.

Supervisor for Garrett Marshall (Medical Student), Summer 1994, Medical Student Research Training Program (MSRTP)/ISMS. "Optimization of Cushion Design to Prevent Pressure Sores"; supported through R&T grant from the NCMRR.

Supervisor for Stephen Brecht (Medical Student), Summer 1994, Medical Student Research Training Program (MSRTP)/ISMS. "Balance Analysis of Western Boot Design Versus Conventional Footwear Measured on a Motion Spec Balance Platform"; supported through R&T grant from the NCMRR.

Supervisor for Malcolm Murdoch (PM & R resident), 1994-95, Master's Thesis Advisor. "Central Pontine Myelinolysis in Liver Transplant Patients".

Supervisor for Tristan Seitz (Medical Student), Summer 1995, Medical Student Research Training Program (MSRTP)/ISMS. "Effect of Bolus Variables on the Pharyngeal Phase of Swallowing"; supported through the NCMRR.

Supervisor for Amy Huang (Mechanical Engineering), Fall 1996, Undergraduate Research Training Program - "Digitization of Barium Videofluorography".

Supervisor for Arthur J. Greenwood (Chemistry), 1996 - 97, Undergraduate Research Training Program - "Treatment of Spasticity with Botulinum Toxin".

Supervisor for Len Higashi (Mechanical Engineering); Co-Chairperson (with Professor Colin Daly) of the Master's Thesis Supervisory Committee, 1995 - 96. "**Soft Tissue Modeling for Heel Cushion Design Optimization**".

Supervisor for Brigette Rosendall (Chemical Engineering); Co-Chairperson (with Professor Bruce Finlayson) of the PhD Supervisory Committee, 1994 - 96. "Mathematical Modeling of Pharyngeal Phase of Swallowing"; supported through the Biomedical Engineering Research Grant of the Whitaker Foundation.

Supervisor for David Pommer (Medical Student). Summer 1997, Medical Student Research Training Program (MSRTP)/ISMS. "**Design of Cushion to Prevent Pressure Sores**"; supported through R&T grant from the NCMRR.

Supervisor for Eugene Lin (Electrical Engineering); (with Professor Jenq-Neng Hwang). "3-D Contour Tracking of Pharyngeal Bolus Movement Using a Knowledge-Based Snake Search Algorithm", 1997 - 98; "Three Dimensional Modeling of Pharyngeal Bolus Movement", 1998; PhD Dissertation Committee, partially supported through the Biomedical Engineering Research Grant of the Whitaker Foundation.

Supervisor for Wen-Shiang Chen (Bioengineering). "Soft Tissue Biomechanics: An in-vivo Measurement Technique and Mathematical Modeling", Biomechanics Pathway, 1998.

Member, Supervisory Committee, Geoff Raynak (Bioengineering). "Cervical Spine Injury Potential Resulting from Sagittal Plane Inertial Loading", 1998.

Member, Supervisory and PhD Thesis Reading Committee, Chimbaugona Mkandawire (Bioengineering). "Biomedical Comparison of Hindfoot Ligaments in Normal Foot, Flatfoot and Reconstructed Flatfoot", 1999.

Member, Supervisory Committee, Daniel Richard Einstein (Bioengineering), "Modeling of Cardiac Valves", Summer 2000.

Supervisor for Eric Smith (Medical Student). Medical Student Research Training Program (MSRTP)/ISMS. "Prediction of Metabolic Energy During Performance of the Barbell Bench Press Using 3-Dimensional Computerized Human Motion Analysis", supported through R&T grant from the NCMRR, Summer 2000.

Graduate representative member, PhD Supervisory Committee, Vesna Zderic (Bioengineering), "Ultrasound-Enhanced Drug Delivery". 2002 - 2004.

Supervisor for Justin Sell (Medical Student). Medical Student Research Training Program (MSRTP)/ISMS. "Characteristics of Wheelchair Propulsion on A Two-Roller Treadmill System", supported through R&T grant from the NCMRR, Summer 2002.

Member, Supervisory and PhD Thesis Reading Committee, Daniel Richard Einstein (Bioengineering/Mechanical Engineering). "Nonlinear Acoustic Analysis of the Mitral Valve", 2002 - 2003.

Graduate Faculty Representative, Kevin M. Krudys' PhD Dissertation Supervisory Committee (Bioengineering), "Use of Population Approaches in the Assessment of Insulin Sensitivity and beta-Cell Function". 2004 – March 3, 2006.

Graduate Faculty Representative, Jessica L. Foley's PhD Dissertation Supervisory Committee (Bioengineering), "Image-guided High Intensity Focused Ultrasound (HIFU) Neurolysis of Peripheral Nerves to Treat Spasticity and Pain". 2004 - present.

Faculty adviser for PM&R residents: Dr. Keith Hardy (PGY 2), Dr. Jyoti Sharma (PGY 4).

Graduate Faculty Representative, Wen-Bo Luo's PhD Dissertation Supervisory Committee (Bioengineering), "Image-guided HIFU Neurolysis of Peripheral Nerves to Treat Spasticity and Pain". 2005 - present.

Chair, Master Degree Supervisory Committee, Zach Ashwell (Mechanical Engineering), "Biomechanics of Wheelchair Propulsion". 2003 - 2005.

Supervisor for Kevin Seals (Undergraduate Pre-Med Student), Undergraduate Research Program, University of Washington, "Literature Review of Biological Responses to Extracorporeal Shock Wave Treatment (ESWT)", Fall 2005, Winter/Spring 2006.

Supervisor for Karl Hamavand, Matthew Kuffel, Neil Golke, ME 495 Senior Capstone Design, "A Customized CPM Device for Isolated Hip & Knee Range of Motion Exercise", Department of Mechanical Engineering, University of Washington, Summer/Fall 2005 & Winter/Spring 2006.

Medical Consultant, PhD Dissertation for Juan Tu (PhC, Bioenegineering, Advisor: Dr. Tom Matula), University of Washington, Summer/Fall 2005 & Winter/Spring 2006.

Medical Consultant, PhD Dissertation for Kirsten Fagnan (PhC, Applied Mathematics, Advisor: Dr. Randall LeVeque), University of Washington, Fall 2005, Winter/Spring 2006.

Supervisor for Dr. Greg Phillips (PM&R Resident). "Characteristics of Wheelchair Propulsion among Subjects with Significant Upper Limb Pain", Winter/Spring/Summer 2006.

Supervisor for Kevin Seals, Morgan Wise, Jesse Adams (Undergraduate Pre-Med Students), Rehab 499, Undergraduate Research Program, University of Washington, "Literature Review of Biological Responses to Extracorporeal Shock Wave Treatment (ESWT)", Spring, Summer 2006.

Supervisor for Anh Truong (Medical Student). Medical Student Research Training Program (MSRTP)/ISMS. "Angiogenesis and Micro-vascular Remodeling Induced by Extracorporeal Shock Wave Treatment and Implications on Wound Healing", School of Medicine, University of Washington, Summer 2006.

Supervisor for Daniel Santosa (Chemical Engineering Student). Clinical Research Experience for Engineer (CREE). "Physics of Cavitation in Polyacrylimide Gel and Exo-vivo Porcine Muscle Tissue." Department of Bioengineering, University of Washington, Summer 2006.

Supervisor for Erika Korinke (Undergraduate Pre-Med Student), Rehab 499, Undergraduate Research Program, University of Washington, "Literature Review of Biological Responses in Calcified Tissues to Extracorporeal Shock Wave Treatment (ESWT)", Spring, 2007

Supervisor for Adrienne Oda (Bioengineering Student). Clinical Research Experience for Engineer (CREE). "Reversal of Soft Tissue Calcifications Using Shock Wave Treatment" Department of Bioengineering, University of Washington, Summer 2007.

Supervisor for Aaron Flanagan (Medical Student). Rehab 499, Medical Student Research Credit, "Characteristics of Wheelchair Propulsion among Subjects with Spinal Cord Injury", School of Medicine, University of Washington, Summer & Fall 2007, Winter 2008.

Supervisor for Morgan Wise (Physiology Student). Mary Gates Scholar. "Extracorporeal Shock Wave Therapy and Biofilms: Bacteriacidal Potential", University of Washington, Fall & Winter, 2007, Spring 2008.

Supervisor jointly with Professor James Bryers for Kevin Seals (Bioengineering & Pre-Med Student). Clinical Research Experience for Engineer (CREE). "Extracorporeal Shock Wave Treatment and Biofilms: Bacteriacidal Potential" Department of Bioengineering, University of Washington, Summer 2008.

Supervisor jointly with Professor James Bryers for Kevin Seals (Bioengineering & Pre-Med Student). Senior Capstone Project. "Extracorporeal Shock Wave Treatment to Disrupt Bacterial Biofilms" Department of Bioengineering, University of Washington, Fall 2008 through Spring 2009.

#### **BIBLIOGRAPHY**

# **Refereed Publications**

*Chang MW*, Finlayson BA. On the Proper Boundary Conditions for the Thermal Entry Problem. Int J Numerical Method in Engineering 15:935-942, 1980.

Chang MW and Finlayson BA. Heat Transfer in Flow Past Cylinders at Re<150. Part I. Calculations for Constant Fluid Properties. Numerical Heat Transfer 12:179-195, 1987.

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Viegas SF, Tencer AF, Cantrell J, *Chang MW*, Clegg P, Hicks C, O'Meara C, Williamson J. **Load Transfer Characteristics of the Wrist. Part I. The Normal Joint**, pp 971-978; J Hand Surgery 12A(6), November 1987.

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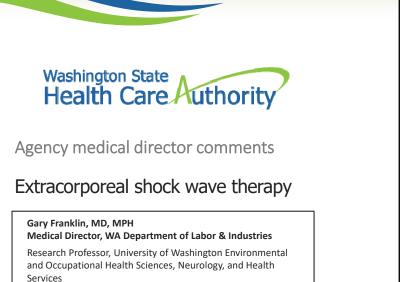
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Washington State Health Care Authority

#### Background

March 17, 2017

- The shockwaves are abrupt and high amplitude pulses of mechanical energy generated by an electromagnetic coil or a spark in water
- In 1980, extracorporeal shockwaves were used clinically to break up urinary stones (lithotripsy)
- In the early 1990s, effect of treatment for calcific tendinopathy of the shoulder by focused ESWT were first published
- Shortly thereafter, studies were published evaluating the effect of ESWT on lateral epicondylitis, Achilles tendonitis, and plantar fasciitis



#### Background, cont.

- In October of 2000, the FDA approved OssaTron device (HealthTronics, Marietta, GA) for chronic plantar fasciitis and in 2003 for chronic lateral epicondylitis of the elbow.
- Proposed therapeutic mechanism the effects from direct forces and cavitation from indirect forces cause trabecular microfractures or interstitial gaps and hematoma formation, as well as focal cell death, which then stimulate new tissue formation. (Coombs et al 2000; Ogden 2001; Church 1989; Delius 1995; Dellian 1993; Steinback 1992 and 1993)
- Though the therapeutic mechanism of ESWT for MSK disorders is not fully understood, the application of ESWT is expanding.

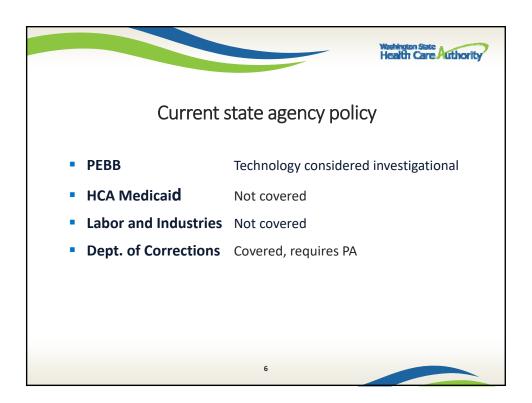
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#### Background, cont.

- Many published studies 72 RCTs included in the evidence report
- Is the evidence strong enough to support ESWT being an effective, safe and cost-effective treatment alternative for certain soft tissue disorders?
- Scope: Patients with tendinopathy or tendinitis, plantar fasciitis, heel spurs, subacromial shoulder pain, or osteoarthritis

# Agency medical director concerns Safety = High Efficacy = High Cost = Medium/High





#### Agency utilization and cost

No data since non-covered

7



#### Key questions

- 1. What is the evidence of the short- and long-term efficacy and effectiveness of ESWT compared with standard alternative treatment options, sham, or no treatment?
- 2. What is the evidence regarding short- and long-term harms and complications of ESWT compared with standard alternative treatment options, sham, or no treatment?
- 3. Is there evidence of differential efficacy, effectiveness, or safety of ESWT compared with standard alternative treatment options, sham, or no treatment? Include consideration of age, sex, race, ethnicity, socioeconomic status, payer, and worker's compensation?
- 4. What is the evidence of cost-effectiveness of ESWT compared with standard alternative treatment options or no treatment?



#### Methodological issues in current effectiveness base for ESWT

- Tremendous heterogeneity in application of ESWT: e.g., low vs. high energy, few standards
- Lack of dosing precision: e.g., frequency and duration of pulses varies
- Local anesthetic often used b/c of intervention caused pain
- May be difficult to define focus of maximal tenderness (e.g., tendon)
- Great variety of comparators and outcome metrics What is the most relevant outcome for function for each condition?
- Consistent difference in outcomes for proportions v.s., mean change in scores

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# PF: ESWT vs placebo: FDA study (2000) - 12 week outcomes -

Outcome	ESWT	Placebo	Significance
Patient VAS	3.48	4.18	50% better
50% better & VAS ≤ 4	59.7%	48.3%	0.08
Distance without pain	1.72	1.88	0.49
No/ rare pain meds	69.7%	72.2%	0.41

"Majority of treatment effect observed in blinded evaluator's assessment of heel pain"



#### Plantar fasciitis: Active control studies

 Pain and function outcomes the same or worse for ESWT compared to steroid injections, PT stretching, NSAIDS

1:



#### Ibrahim study (2010): Radial ESWT for plantar fasciitis

- Miraculous results Second sentence of *Results* section:
  - "RSWT had a profound and lasting impact on the mean VAS and RM scores of the patients"
- Nothing happened in the controls??



#### Lateral epicondylitis

 Grip strength may be the most important functional outcome - NS across 4 studies (Fig 24)

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#### Safety

- Four cases fascial tear or tendon rupture
- EG: Gerdesmeyer et al, JAMA, 2003. Chronic calcific tendonitis of rotator cuff.
  - 36/48 receiving high energy ESWT had moderate to severe pain; 8/16 reporting severe pain required IV analgesics
  - 36/48 in high energy group and 32/48 in low energy group with petechiae, bleeding, hematoma, or erythema



#### Cost-effectiveness of EWST

No evidence

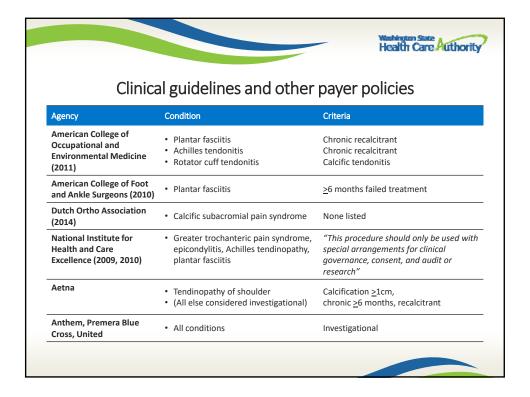
Costs from one podiatry center: \$900 - \$3,000, depending on number of sessions, geographic location, and severity of condition

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#### National coverage decision (NCD)

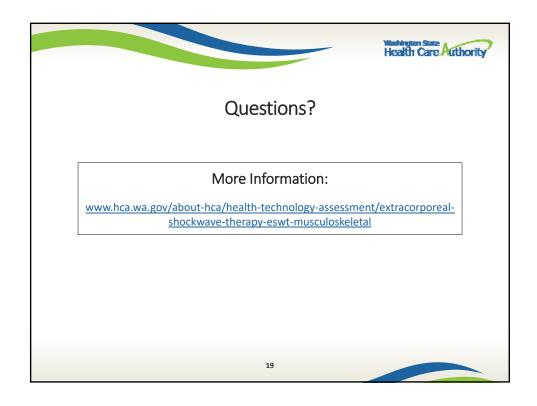
 The CMS does not have a national coverage determination on ESWT.





#### Agency medical director recommendation

 Extracorporeal shock wave therapy is not a covered benefit.





#### Order of scheduled presentations:

#### **Extracorporeal shock wave therapy**

	Name
1	
2	
3	
4	
5	
6	

No requests to provide public comment on this technology review were received.

# Extracorporeal Shock Wave Therapy

March 17, 2017

#### Prepared by:

Erika Brodt, BS Joseph Dettori, PhD

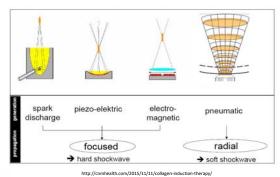




Image source: http://www.chinesport.com/DB_files/sottofam/800_338/web_banner_ondeurto3.jpg

#### Background

- Extracorporeal Shock Waves are pressure waves
- Two categories, Focused and Radial
  - Focused pressure field converges at selected tissue depth
  - <u>Radial</u> pressure highest at skin surfaces and diverges as it penetrates deeper



spectrumresearch

#### Mechanism

Not fully understood - 3 main theories

- 1. Pain relief via hyperstimulation by acting on substance P, CGRP expression, neurovascular sprouting.
- 2. Mechanotransduction affecting the cytoskeleton, increasing protein synthesis, promoting angiogenesis, and stimulating healing through release of TGF-b1 and IGF-1.
- 3. Disorganization and disintegration of calcification in tendons



3

#### **Conditions Receiving ESWT**

- Plantar fasciitis
- Tendinopathies
  - Lateral epicondyle tendinopathy
  - Achilles tendinopathy
  - Patellar tendinopathy
  - Rotator cuff tendinopathy
- Osteoarthritis
  - Knee

**FDA** approval





Image source: http://www.clker.com/cliparts/c/a/f/2/5/O/runner-hi.png

#### **ESWT Procedure**

#### Lack of standardization for:

- Focused vs. Radial
- Energy dosages (0.06-0.64 mJ/mm²)
  - **❖** Low: <1.2
  - **❖** Medium: 1.2-2.0
  - **❖** High: >2.0
- Number of impulses (1000-6000)
- Frequency of application (1-5 times over days to weeks)
- Use of local anesthesia
- Direction of application (site of pathology vs. site of maximal tenderness)









#### **Key Questions**

- Short-and long-term efficacy compared with alternative treatment options, sham or no treatment
- Short- and long-term harms and complications compared with alternative treatment options, sham or no treatment
- 3. Differential efficacy, effectiveness, or safety compared with alternative treatment options, sham or no treatment (age, sex, race, ethnicity, socioeconomic status, payer, and worker's comp)
- 4. Cost-effectiveness compared with alternative treatment options



#### **Inclusion Criteria**

#### Population:

- Patients with musculoskeletal tendinopathies, plantar fasciitis and osteoarthritis
- (excluded: kidney stones, fracture, non- or delayed union, wounds, dental conditions)

#### • Intervention:

- Focused or Radial ESWT
- (excluded: ESWT in conjunction with other procedures such as surgery)

#### Comparators:

- Alternative treatment(s), sham, or no treatment
- (excluded: comparisons of different characteristics of ESWT such as Focused vs. Radial, high vs. low energy)



7

#### **Inclusion Criteria**

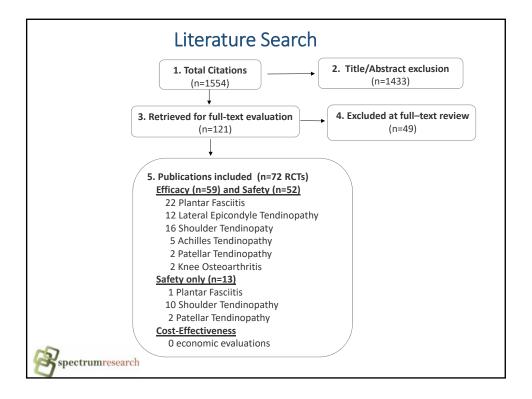
#### **Primary outcomes:**

- Physical Function
  - ✓ Proportion of patients achieving ≥50% improvement
  - ✓ Mean improvement
- Pain
  - ✓ Proportion of patients achieving ≥50% improvement
  - ✓ Mean improvement (MCID: 1.5 on 0-10 scale)
- Composite Outcome
  - ✓ Proportion of patients achieving ≥50% improvement in pain and function
- Adverse events or complications

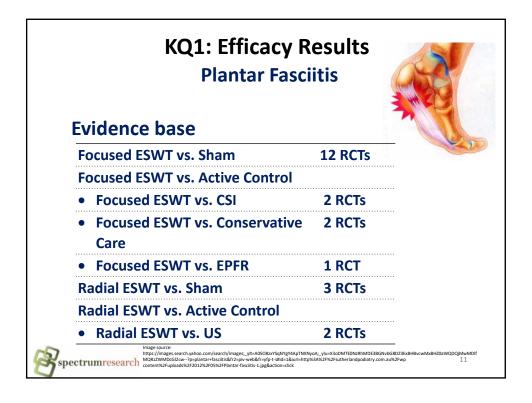
#### Follow-up definitions:

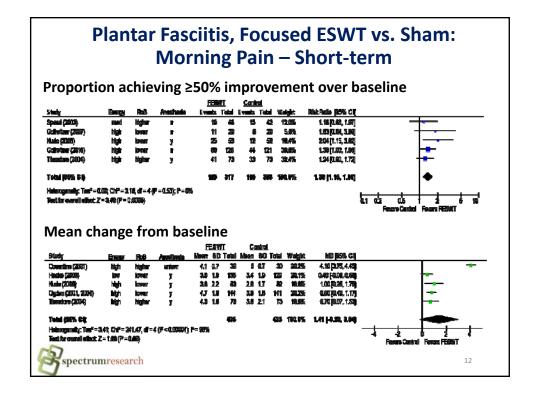
Short-term: ≤3 months Intermediate-term: >3 to <12 months Long-term: ≥12 months

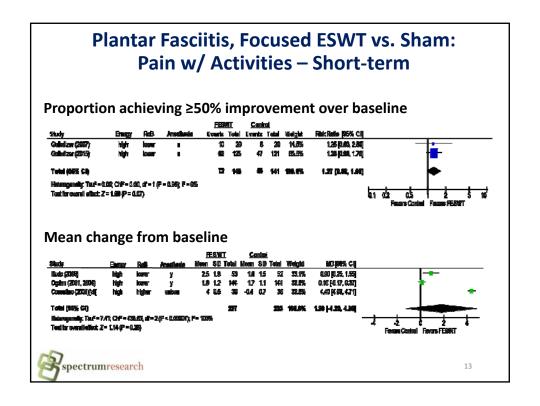




#### Overall strength of evidence (GRADE) **Quality rating** Interpretation High High confidence that the evidence reflects the true effect. Moderate Moderate confidence in the effect estimate; the true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different. Confidence in the effect estimate is limited; the true effect Low may be substantially different from the estimate of the effect. Very little confidence in the effect estimate; the true effect Insufficient is likely to be substantially different from the estimate of the effect. spectrumresearch 10

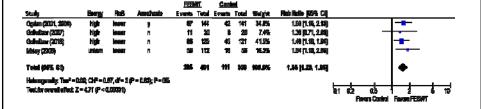




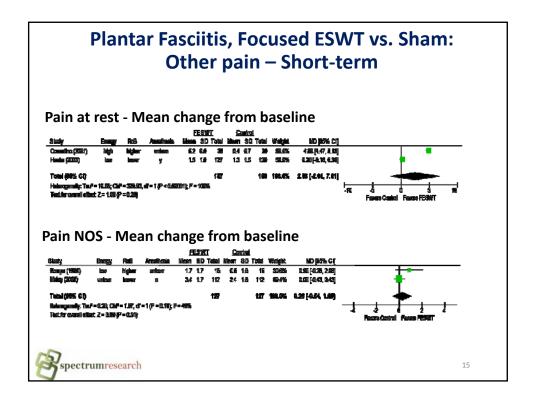


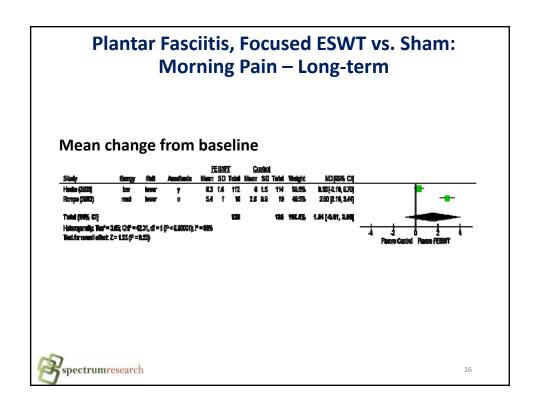
#### Plantar Fasciitis, Focused ESWT vs. Sham: Composite Pain Success – Short-term

Proportion meeting all criteria on a composite of pain outcomes









## Plantar Fasciitis, Focused ESWT vs. Sham: Function

#### **AOFAS Ankle-Hindfoot Scale**

#### Short term: 1 RCT (n=105)

No difference between groups in success or mean change from baseline



#### Intermediate- and Long-term: 1 RCT (n=45)

Statistically and clinically greater improvement in mean change from baseline with FESWT vs. sham at both timepoints:

- MD 17.8 (95% CI 11.3, 24.3)
- MD 12.0 (95% CI 6.3, 17.7)



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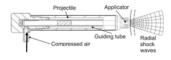
# Plantar Fasciitis Focused ESWT vs. Active Control

	Outcome	F/U	RCTs	Results
vs. CSI	Pain in AM	Short-term	1	Favors CSI
				MD -2.16 (-3.14, -1.18)
		Long-term	1	No diff
	Composite pain	Short-term	1	No diff
	Pain NOS	Short-term	1	No diff
vs. "Conservative	Pain in AM	Short-term	1	No diff
care"		Intermediate	1	No diff
	Pain NOS	Short-term	2	No diff
		Intermediate	2	No diff
	Pain at rest	Short-term	1	No diff
		Intermediate	1	No diff
	Function	Short-term	1	No diff
		Intermediate	1	No diff
vs. EPFR	Pain in AM	Short-term	1	No diff
		Long-term	1	No diff
	Function	Short-term	1	No diff
		Long-term	1	No diff

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spectrumresearch

# Plantar Fasciitis, Radial ESWT vs. Sham: Pain, Short-term



	RCTs	Radial			
Outcome		<b>ESWT</b>	Sham	RR (95% CI)	P-value
Pain in AM success	1	60.8%	48.3%	1.26 (1.00, 1.59)	.051
Pain with activity success	1	60.0%	40.7%	1.48 (1.14, 1.91)	<.001
Composite pain success	1	61.0%	42.2%	1.44 (1.12, 1.86)	<.001
Pain NOS success	1	96.0%	0%	not calculable	<.001

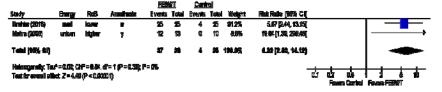


Image source - http://www.slideshare.net/pripper/swiss-dolorclast-applications-for-podiatr

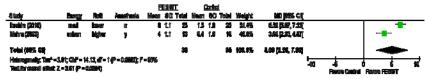
19

# Plantar Fasciitis, Radial ESWT vs. Sham: Pain, Intermediate-term

#### Proportion w/ pain NOS success



#### Mean change from baseline, pain NOS





# Plantar Fasciitis Radial ESWT vs. Active Control

#### Vs. Ultrasound

Outcome	F/U	RCTs	Results
Pain in AM success	Short-term	1	No diff
	Long-term	1	No diff
Pain walking success	Short-term	1	No diff
	Long-term	1	No diff
Pain in NOS scores	Short-term	1	Favors RESWT
			MD 2.40 (2.35, 2.45)
	Intermediate	1	Favors RESWT
			MD 4.10 (3.98, 4.22)



2

# **KQ1: Efficacy Results Lateral Epicondyle Tendinopathy**

#### **Evidence base**

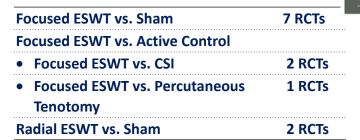
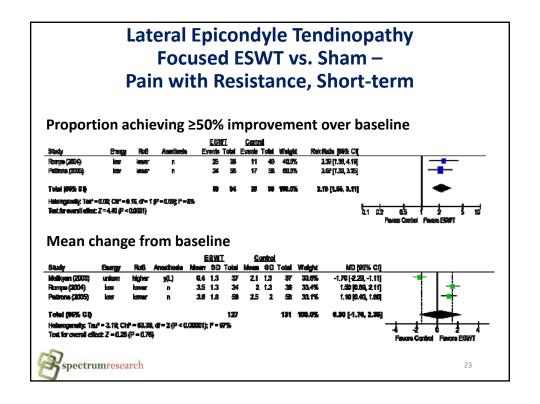
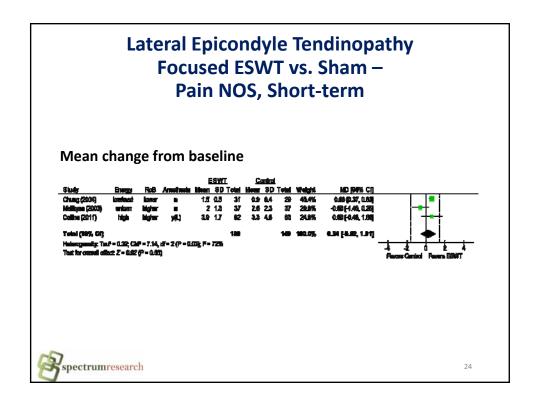




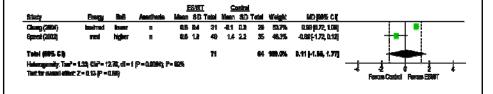
Image source: http://www.rheumatologynetwork.com/sites/default/files/rm/1532862.pn





# Lateral Epicondyle Tendinopathy Focused ESWT vs. Sham – Night Pain, Short-term

#### Mean change from baseline





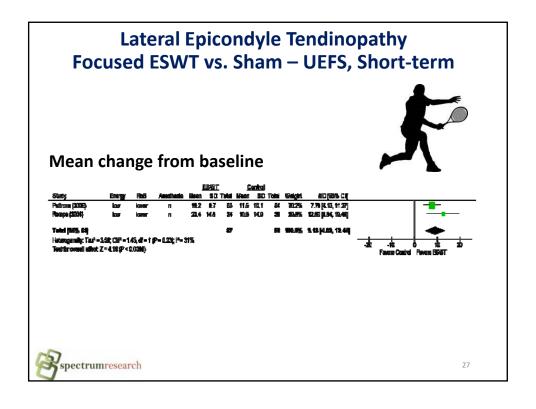
25

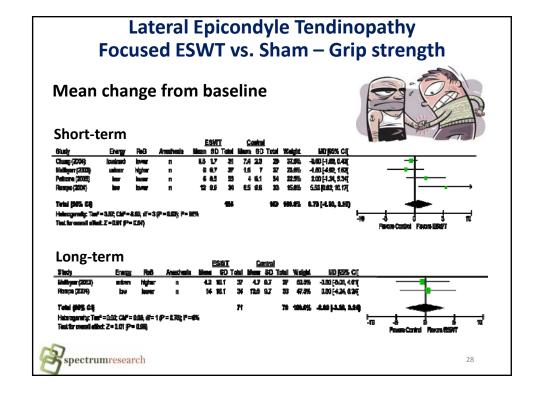
#### Lateral Epicondyle Tendinopathy Focused ESWT vs. Sham – Pain with Resistance, Long-term

#### Mean change from baseline









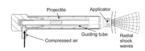
# Lateral Epicondyle Tendinopathy Focused ESWT vs. Active Control

	Outcome	F/U	RCTs	Results
Vs. CSI	Pain NOS	Short-term	1	Favors CSI
	Pain w/ resistance	Short-term	1	No diff
		Intermediate	1	Favors FESWT
		Long-term	1	Favors FESWT
	<b>Function UEFS</b>	Short-term	1	No diff
		Intermediate	1	Favors FESWT
		Long-term	1	Favors FESWT
Vs. Percutaneous	Pain w/ resistance	Short-term	1	No diff
Tenotomy		Long-term	1	No diff



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# Lateral Epicondyle Tendinopathy Radial ESWT vs. Sham



#### Short-term mean change from baseline

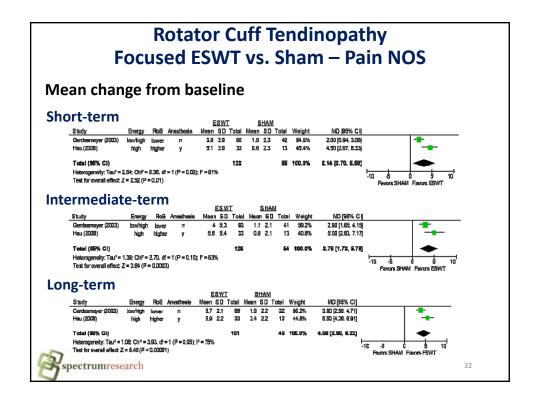
Outcome	RCTs	MD (95% CI)	P-value
Pain at rest	1	0.1 (-1.41, 1.61)	NS
Pain with activity	1	1.2 (-0.33, 2.73)	NS
PRTEE function	1	4.8 (-2.75, 12.35)	NS

#### Intermediate-term mean change from baseline

Outcome	RCTs	RR (95% CI)	P-value
Pain success (≥3 pt improvement)	1	8.5 (1.3, 56.1)	<.05



Shoulder Tendino	patny	
Evidence base		
Rotator Cuff Tendinopathy		
FESWT vs. Sham	7 RCTs	
FESWT vs. Active Control		
<ul> <li>FESWT vs. US-guided needling + CSI</li> </ul>	1 RCT	10
FESWT vs. TENS	1 RCT	
RESWT vs. Sham	1 RCT	
RESWT vs. Active Control		
RESWT vs. UGPL	1 RCT	
Adhesive Capsulitis		
FESWT vs. Sham	1 RCT	
FESWT vs. Active Control		
FESWT vs. Oral Steroid Therapy	1 RCT	
RESWT vs. Sham	1 RCT	
Subacromial Shoulder Pain		
RESWT vs. Sham	1 RCT	
Bicipital Tenosynovitis		
RESWT vs. Sham	1 RCT	



# Rotator Cuff Tendinopathy Focused ESWT vs. Sham, Other Pain

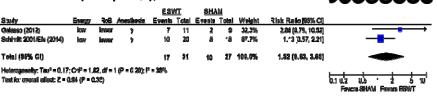
Outcome	F/U	RCTs	Results
Pain at night, success	Short-term	1	No diff
Pain at night, scores	Short-term	1	No diff
	Intermediate-term	1	No diff
Pain at rest, scores	Short-term	1	No diff
	Long-term	1	No diff
Pain w/ activity, scores	Short-term	1	No diff
	Long-term	1	No diff



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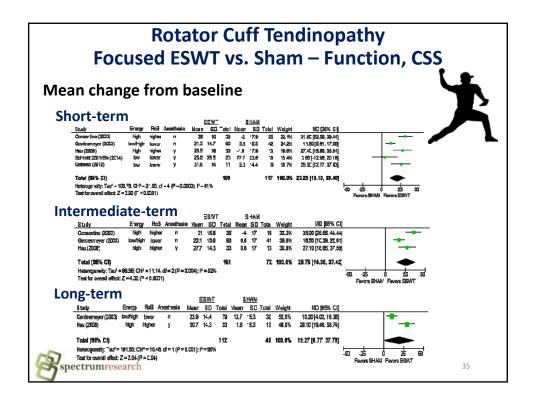
## Rotator Cuff Tendinopathy Focused ESWT vs. Sham – Function Success

#### CSS Success (≥30 pt. ↑), Short-term



	Focused				
Outcome	F/U	RCTs	ESWT	Sham	RR (95% CI)
≥30% ↑ in CSS	Short	1	58%	21%	2.70 (1.47, 4.94)
	Intermediate	1	61%	17%	3.94 (1.97, 7.86)
	Long	1	67%	22%	3.07 (1.57, 6.01)
≥50% ↑ in SPADI	Short	1	35%	45%	0.78 (0.44, 1.39)





# Rotator Cuff Tendinopathy Focused ESWT vs. Active Control

Vs. US-guided needling + CSI 1 RCT (n=54), lower RoB

Outcome	F/U	Results
Pain NOS	Short-term	No diff
	Intermediate-term	No diff
	Long-term	Favors CSI
		MD -2.4 (95% CI NC)
ASES, SST	Short-term	No diff
	Intermediate-term	No diff
	Long-term	Favors CSI
		MDs -24.1, -8.3 (95 Cls NC)



# Rotator Cuff Tendinopathy Radial ESWT

	Outcome	F/U	Results
Vs. Sham	Pain NOS	Short-term	No diff
1 RCT (n=77)		Intermediate	No diff
Higher RoB	CSS, SST	Short-term	No diff
		Intermediate	No diff
Vs. Active Control:	Pain success	Long-term	Favors UGPL
UGPL	<b>Pain NOS scores</b>	Short-term	Favors UGPL
1 RCT (n=201)		Intermediate	Favors UGPL
Higher RoB		Long-term	Favors UGPL



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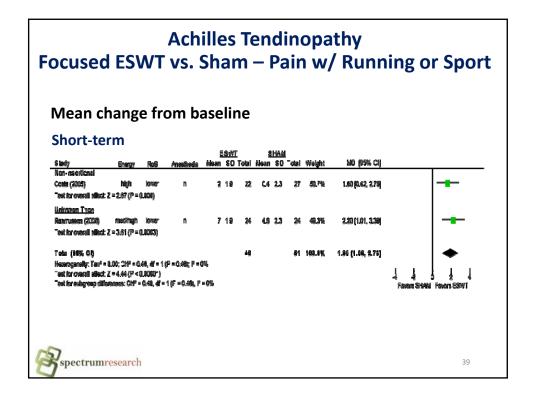
# KQ1: Results Efficacy and Effectiveness Achilles Tendinopathy

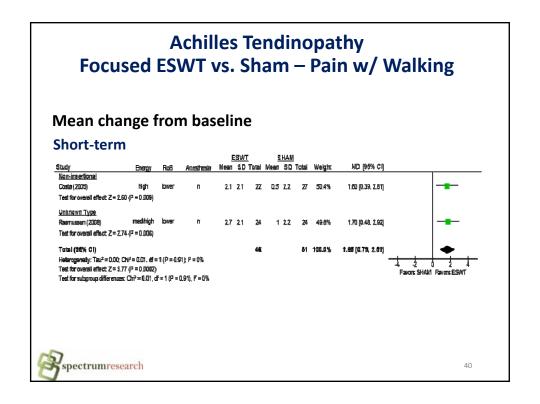
#### **Evidence base**

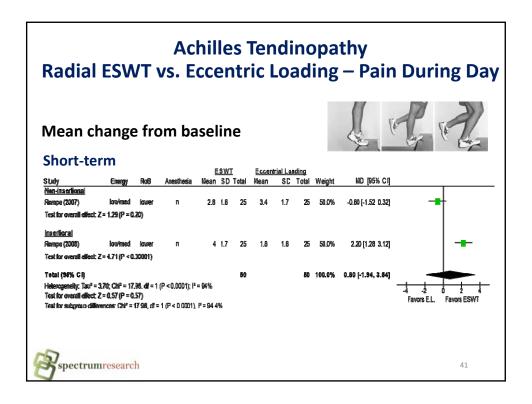
FESWT vs. Sham	2 RCTs
RESWT vs. Active Control	
RESWT vs. Eccentric Ex	2 RCT
• RESWT + Eccentric Ex vs. Eccentric Ex alone	1 RCT
RESWT vs. no treatment	1 RCT



http://www.elitepodiatry.com/achilles-tendinopathy/







# **KQ1: Results Efficacy Patellar Tendinopathy**

#### **Evidence base**

2 small RCTs (both higher RoB)



	Outcome	F/U	Results	Effect (95% CI)
Focused ESWT vs.	Pain NOS	Short-term	Favors FESWT	NC
<b>SHAM</b> (1 RCT, n=20)	VISA-P	Short-term	Favors FESWT	NC
Focused ESWT vs.	Pain composite	Long-term	Favors FESWT	RR 1.8 (1.2, 2.7)
Conservative care	Pain w/ stairs	Long-term	Favors FESWT	MD 4.8 (4.2, 5.3)
(1 RCT, n=50)	VISA-P	Long-term	Favors FESWT	MD 47.6 (44.0, 51.2)



Image source: http://www.shockwavetherapy.education/index.php/tutorials/knee/patella-tendinopathy

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#### **KQ1: Results Efficacy Osteoarthritis of the Knee**

#### **Evidence base**

2 small RCTs (1 higher and 1 lower RoB)



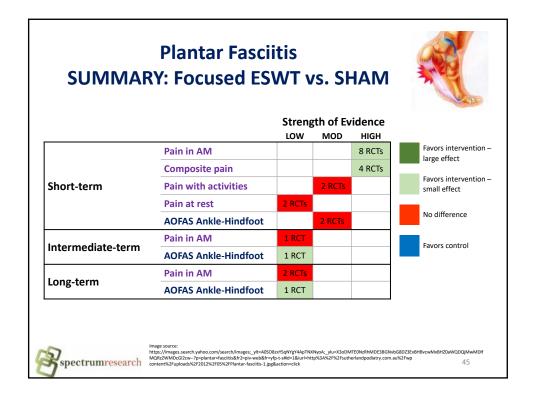
	Outcome	F/U	Results	MD (95% CI)
Focused ESWT +	Pain NOS	Short-term	Short-term Favors FESWT	
IMS vs. IMS alone		Intermediate	Favors FESWT	2.1 (1.8, 2.4)
Focused ESWT +	Pain NOS	Short-term Favors FESWT		0.7 (0.4, 1.1)
IMS vs. US + IMS		Intermediate	Favors FESWT	0.9 (0.6, 1.2)
Radial ESWT vs.	Pain walking	Short-term	Favors RESWT	2.6 (2.2, 3.0)
SHAM	WOMAC	Short-term	Favors RESWT	10.6 (5.4, 15.8)
	Lequesne index	Short-term	Favors RESWT	2.1 (0.9, 3.4)

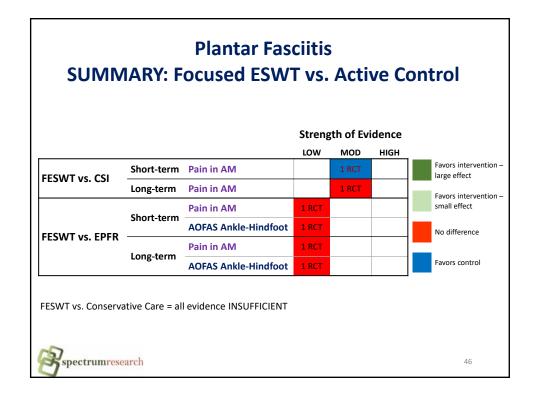


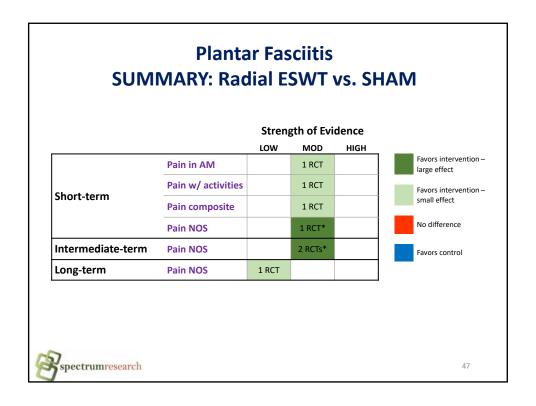
 $Image \ source - http://www.physio-pro.com/2013/12/06/osteoarthritis-of-the-knee-hip-and-shoulder/ \\$ 

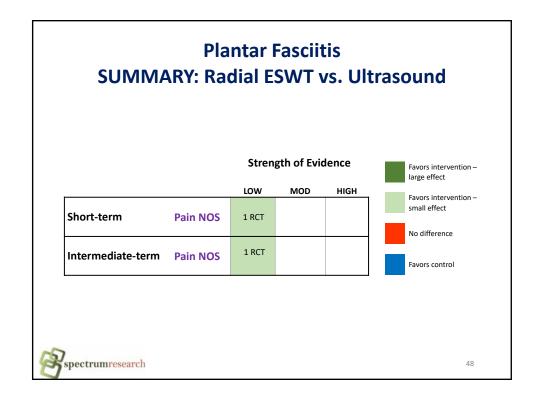
## **KQ1: Efficacy Summary**

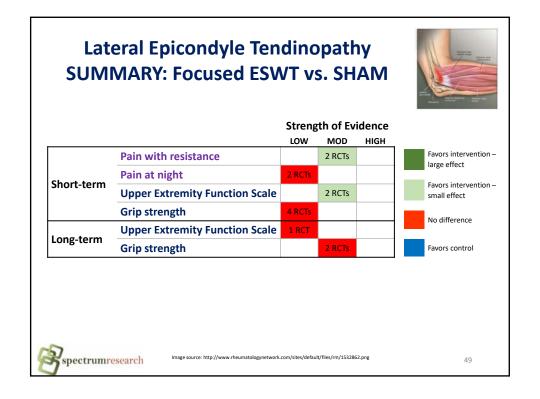












## Lateral Epicondyle Tendinopathy SUMMARY: Focused ESWT vs. Active Control

#### All evidence INSUFFICIENT:

#### FESWT vs. CSI (1 RCT, n=73)

- Pain NOS (short-term)
- Pain w/ resistance, UEFS (short-, intermediate, and long-term)

#### FESWT vs. Percutaneous Tenotomy (1 RCT, n=56)

- Pain w/ resistance (short- and long-term)
- No evidence for function or intermediate-term follow-up



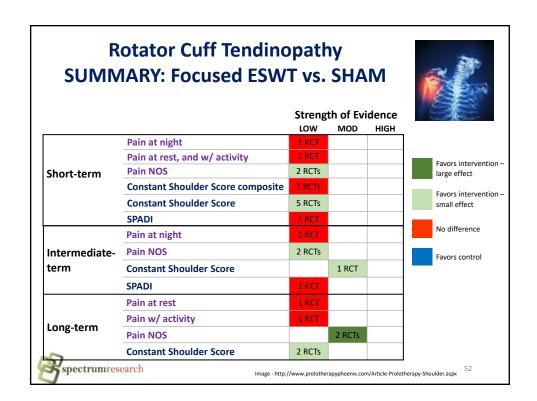
## Lateral Epicondyle Tendinopathy SUMMARY: Radial ESWT vs. SHAM

All evidence **INSUFFICIENT** in the short term:

- Pain at rest, pain w/ activity, PRTEE (1 RCT, n=45)
- Pain NOS (1 RCT, n=24)

No evidence for intermediate- or long-term follow-up





#### **Rotator Cuff Tendinopathy SUMMARY: Focused ESWT vs. Active Control** Ultrasound-guided needling + CSI Strength of Evidence LOW MOD Favors intervention -**Pain NOS** large effect **Short-term ASES** score 1 RCT Favors intervention small effect 1 RCT **Simple Shoulder Test** Pain NOS 1 RCT No difference Intermediate-term **ASES** score 1 RCT Favors control Simple Shoulder Test 1 RCT **Pain NOS** 1 RCT **ASES** score 1 RCT Long-term **Simple Shoulder Test** 1 RCT spectrumresearch

## Rotator Cuff Tendinopathy SUMMARY: Radial ESWT

#### All evidence was INSUFFICIENT

vs. SHAM (1 RCT, n=77) in the short- and intermediate-term:

- Pain NOS
- · Constant Shoulder Score
- Simple Shoulder Test

No evidence over the long-term

vs. UGPL (1 RCT, n=201) in the short-, intermediate, and long-term:

- Pain NOS
- · No evidence for function



#### **Subacromial Shoulder Pain SUMMARY: Radial ESWT vs. Supervised Exercise** Strength of Evidence LOW MOD HIGH Favors intervention – Pain at rest 1 RCT large effect Short-term Pain w/ activity 1 RCT Favors intervention – SPADI 1 RCT Pain at rest 1 RCT No difference Intermediate-term Pain w/ activity 1 RCT 1 RCT **SPADI** Favors control Pain at rest 1 RCT Pain w/ activity 1 RCT Long-term SPADI spectrumresearch

## Adhesive Capsulitis of the Shoulder SUMMARY: Focused ESWT

All evidence was **INSUFFICIENT** 

vs. SHAM (1 RCT, n=36) in the short- and intermediate-term:

- SPADI pain
- SPADI function

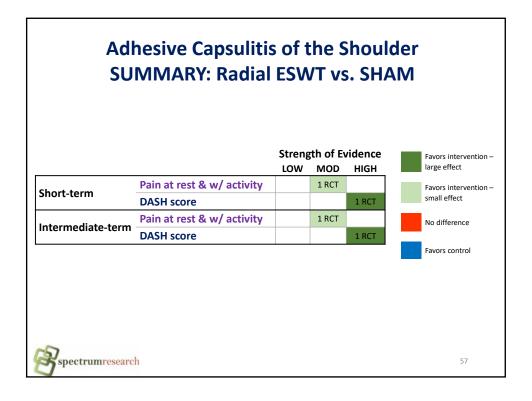
No evidence over the long-term

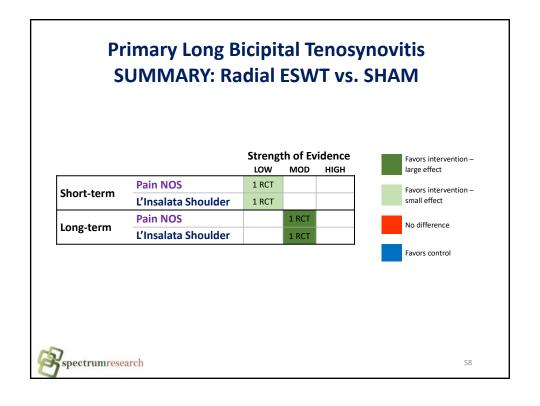
vs. Oral Steroids (1 RCT, n=34) in the short-term:

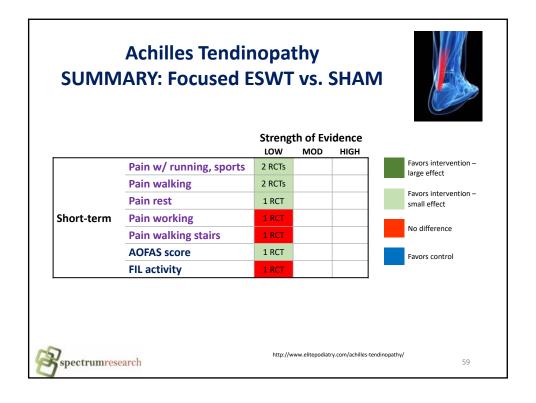
- Constant Shoulder Score
- · Oxford Shoulder Score
- · No evidence for pain

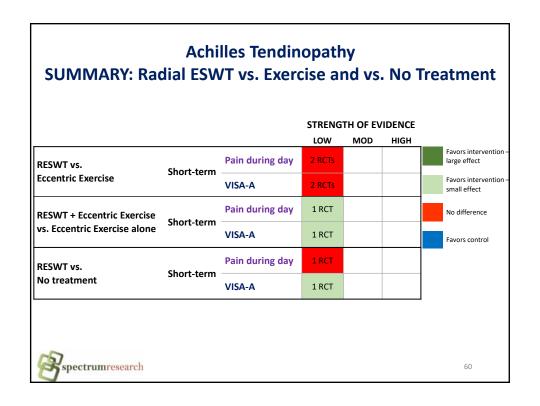
No evidence over the intermediate- or long-term

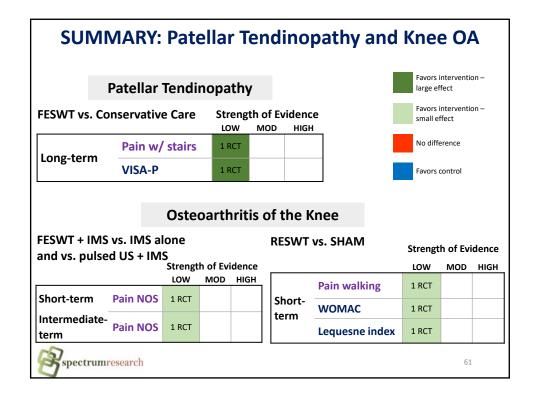














### **Serious or Potentially Serious Adverse Events**

	RCT	ESWT n/N	Control n/N	ESWT % (95% CI)	Control % (95% CI)
Total	n=65	17/3197	5/2283	0.53% (0.33%, 0.86%)	0.22% (0.08%, 0.53%)
Focused ESWT	n=47	16/2419	5/1558	0.66% (0.40%, 1.1%)	0.32% (0.11%, 0.77%)
Radial ESWT	n=18	1/778	0/725	0.13 (0.0%, 0.80%)	0.0% (0.0%, 0.48%)

- **Acute bursitis subacromialis** (FESWT; 2000, 0.23 or 0.42): 7.5% (6/80)
  - · 1 RCT, shoulder tendinopathy
- ➤ Allergy/reaction to anesthetic (FESWT vs. sham): 2.2% (5/227) vs. 2.2% (5/226)
  - 2 RCTs, elbow tendinopathy
- Fascia tear (FESWT [1500, 0.22] vs. sham): 1.5% (2/130) vs. 0% (0/130)
  - 1 RCT, plantar fasciitis
- > Tendon rupture (FESWT [1500, 0.20] vs. sham); 9.0% (2/22) vs. 0% (0/27)
  - 1 RCT, Achilles tendinopathy; 1 case report
- Death
  - FESWT vs. sham (1 RCT, elbow): 0.75% (1/134) vs. 0% (0/136)
  - RESWT vs. exercise (1 RCT, shoulder): 2.2% (1/46) vs. 0% (0/48)



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#### **Nonserious Adverse Events**

Non-serious adverse events occurred frequently and were primarily expected following ESWT but were reported inconsistently, the most common of which included:

- Pain/discomfort during treatment: 5% to 100%
- Transient reddening of the skin: 0% to 100%
- Local erythematous changes (i.e., petechaie, bleeding, hematoma or bruising): 0% to 100%
- Local swelling: 1% to 27%
- Mild/transient neurological symptoms (i.e., myalgia, dysesthesia, hypesthesia, paresthesia): 0% to 7%



### **KQ3: Differential Efficacy (No Safety)**

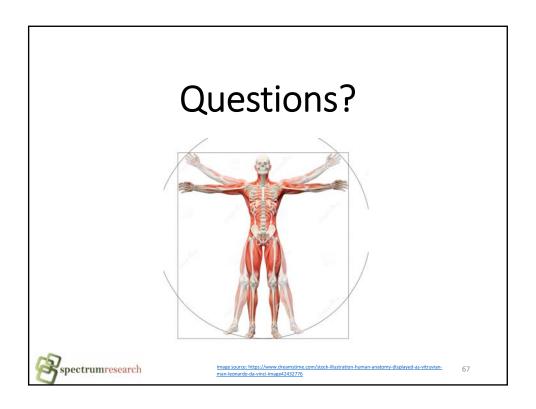
Exposure	RCTs	Conclusion	
Plantar Fasciitis: Fo	ocused E	SWT vs. Sham	
• Sex	1 RCT	Conclusion: No modifying effect (LOW)	
• Age	N=168		
<ul> <li>Body weight</li> </ul>			
Rotator Cuff Tendi	nopathy	: Focused ESWT vs. Sham	
• Energy Intensity	2 RCTs	Conclusion: FESWT better than sham with hig	
High vs. Low	N=252	but not low intensity SW (LOW)	
Lateral Epicondyle	Tendino	pathy: Focused ESWT vs. Sham	
• Symptom	1 RCT	Conclusion: Insufficient strength of evidence	
duration	N=60	precludes firm conclusions	
Achilles Tendinopa	thy: Foc	used ESWT vs. Sham	
• Sex	1 RCT	Conclusion: Insufficient strength of evidence	
	N=48	precludes firm conclusions	
Rotator Cuff Tendinopathy: Radial ESWT vs. Sham			
• Calcium	1 RCT	Conclusion: Insufficient strength of evidence	
formation	N=75	precludes firm conclusions	

### **Cost Effectiveness**

No formal economic evaluations were identified

- > Cost of ESWT ranges from \$900 to \$3000
- ➤ High energy costs more than low energy





# HTCC Coverage and Reimbursement Determination Analytic Tool

HTA's goal is to achieve *better health care outcomes* for enrollees and beneficiaries of state programs by paying for proven health *technologies that work*.

To find best outcomes and value for the state and the patient, the HTA program focuses on three questions:

- 1. Is it safe?
- 2. Is it effective?
- 3. Does it provide value (improve health outcome)?

The principles HTCC uses to review evidence and make determinations are:

#### Principle One: Determinations are evidence-based

HTCC requires scientific evidence that a health technology is safe, effective and cost-effective¹ as expressed by the following standards²:

- Persons will experience better health outcomes than if the health technology was not covered and that the benefits outweigh the harms.
- The HTCC emphasizes evidence that directly links the technology with health outcomes. Indirect evidence may be sufficient if it supports the principal links in the analytic framework.
- Although the HTCC acknowledges that subjective judgments do enter into the evaluation of evidence and the weighing of benefits and harms, its recommendations are not based largely on opinion.
- The HTCC is explicit about the scientific evidence relied upon for its determinations.

#### Principle Two: Determinations result in health benefit

The outcomes critical to HTCC in making coverage and reimbursement determinations are health benefits and harms³:

- In considering potential benefits, the HTCC focuses on absolute reductions in the risk of outcomes that people can feel or care about.
- In considering potential harms, the HTCC examines harms of all types, including physical, psychological, and non-medical harms that may occur sooner or later as a result of the use of the technology.
- Where possible, the HTCC considers the feasibility of future widespread implementation of the technology in making recommendations.

¹ Based on Legislative mandate: See RCW 70.14.100(2).

² The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

³ The principles and standards are based on USPSTF Principles at: http://www.ahrq.gov/clinic/ajpmsuppl/harris3.htm

- The HTCC generally takes a population perspective in weighing the magnitude of benefits against the magnitude of harms. In some situations, it may make a determination for a technology with a large potential benefit for a small proportion of the population.
- In assessing net benefits, the HTCC subjectively estimates the indicated population's value for each benefit and harm. When the HTCC judges that the balance of benefits and harms is likely to vary substantially within the population, coverage or reimbursement determinations may be more selective based on the variation.
- The HTCC considers the economic costs of the health technology in making determinations, but costs are the lowest priority.

#### Using evidence as the basis for a coverage decision

Arrive at the coverage decision by identifying for Safety, Effectiveness, and Cost whether (1) evidence is available, (2) the confidence in the evidence, and (3) applicability to decision.

#### 1. Availability of Evidence:

Committee members identify the factors, often referred to as outcomes of interest, that are at issue around safety, effectiveness, and cost. Those deemed key factors are ones that impact the question of whether the particular technology improves health outcomes. Committee members then identify whether and what evidence is available related to each of the key factors.

#### 2. Sufficiency of the Evidence:

Committee members discuss and assess the evidence available and its relevance to the key factors by discussion of the type, quality, and relevance of the evidence⁴ using characteristics such as:

- Type of evidence as reported in the technology assessment or other evidence presented to committee (randomized trials, observational studies, case series, expert opinion);
- The amount of evidence (sparse to many number of evidence or events or individuals studied);
- Consistency of evidence (results vary or largely similar);
- Recency (timeliness of information);
- Directness of evidence (link between technology and outcome);
- Relevance of evidence (applicability to agency program and clients);
- Bias (likelihood of conflict of interest or lack of safeguards).

⁴ Based on GRADE recommendation: <a href="http://www.gradeworkinggroup.org/FAQ/index.htm">http://www.gradeworkinggroup.org/FAQ/index.htm</a>.

Sufficiency or insufficiency of the evidence is a judgment of each clinical committee member and correlates closely to the GRADE confidence decision.

Not Confident	Confident
Appreciable uncertainty exists. Further information is needed or further information is likely to change confidence.	Very certain of evidentiary support. Further information is unlikely to change confidence

#### 3. Factors for Consideration - Importance

At the end of discussion a vote is taken on whether sufficient evidence exists regarding the technology's safety, effectiveness, and cost. The committee must weigh the degree of importance that each particular key factor and the evidence that supports it has to the policy and coverage decision. Valuing the level of importance is factor or outcome specific but most often include, for areas of safety, effectiveness, and cost:

- Risk of event occurring;
- The degree of harm associated with risk;
- The number of risks; the burden of the condition;
- Burden untreated or treated with alternatives;
- The importance of the outcome (e.g. treatment prevents death vs. relief of symptom);
- The degree of effect (e.g. relief of all, none, or some symptom, duration, etc.);
- Value variation based on patient preference.

#### **Clinical Committee Findings and Decisions**

#### **Efficacy Considerations**

- What is the evidence that use of the technology results in more beneficial, important health outcomes? Consider:
  - Direct outcome or surrogate measure
  - Short term or long term effect
  - Magnitude of effect
  - Impact on pain, functional restoration, quality of life
  - Disease management
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to no treatment or placebo treatment?
- What is the evidence confirming that use of the technology results in a more beneficial outcome, compared to alternative treatment?
- What is the evidence of the magnitude of the benefit or the incremental value?
- Does the scientific evidence confirm that use of the technology can effectively replace other technologies or is this additive?

- For diagnostic tests, what is the evidence of a diagnostic tests' accuracy?
  - Does the use of the technology more accurately identify both those with the condition being evaluated and those without the condition being evaluated?
- Does the use of the technology result in better sensitivity and better specificity?
- Is there a tradeoff in sensitivity and specificity that on balance the diagnostic technology is thought to be more accurate than current diagnostic testing?
- Does use of the test change treatment choices?

#### Safety

- What is the evidence of the effect of using the technology on significant morbidity?
  - Frequent adverse effect on health, but unlikely to result in lasting harm or be lifethreatening, or;
  - Adverse effect on health that can result in lasting harm or can be life-threatening?
- Other morbidity concerns?
- Short term or direct complication versus long term complications?
- What is the evidence of using the technology on mortality does it result in fewer adverse non-fatal outcomes?

#### **Cost Impact**

 Do the cost analyses show that use of the new technology will result in costs that are greater, equivalent or lower than management without use of the technology?

#### Overall

- What is the evidence about alternatives and comparisons to the alternatives?
- Does scientific evidence confirm that use of the technology results in better health outcomes than management without use of the technology?

#### **Next Step: Cover or No Cover**

If not covered, or covered unconditionally, the Chair will instruct staff to write a proposed findings and decision document for review and final adoption at the following meeting.

#### **Next Step: Cover with Conditions**

If covered with conditions, the Committee will continue discussion.

- 1) Does the committee have enough information to identify conditions or criteria?
  - Refer to evidence identification document and discussion.
  - Chair will facilitate discussion, and if enough members agree, conditions and/or criteria will be identified and listed.
  - Chair will instruct staff to write a proposed findings and decision document for review and final adoption at next meeting.

- 2) If not enough or appropriate information, then Chair will facilitate a discussion on the following:
  - What are the known conditions/criteria and evidence state
  - What issues need to be addressed and evidence state

The chair will delegate investigation and return to group based on information and issues identified. Information known but not available or assembled can be gathered by staff; additional clinical questions may need further research by evidence center or may need ad hoc advisory group; information on agency utilization, similar coverage decisions may need agency or other health plan input; information on current practice in community or beneficiary preference may need further public input. Delegation should include specific instructions on the task, assignment or issue; include a time frame; provide direction on membership or input if a group is to be convened.

#### **Clinical Committee Evidence Votes**

#### **First Voting Question**

The HTCC has reviewed and considered the technology assessment and information provided by the administrator, reports and/or testimony from an advisory group, and submissions or comments from the public. The committee has given greatest weight to the evidence it determined, based on objective factors, to be the most valid and reliable.

**Discussion Document:** What are the key factors and health outcomes and what evidence is there? (Applies to the population in the PICO for this review)

Safety Outcomes	Importance of Outcome	Safety Evidence / Confidence in Evidence
Adverse events		
Anesthesia reaction		
Fascia tear		
Tendon rupture		
Death		
Other complications		

Efficacy – Effectiveness Outcomes	Importance of Outcome	Efficacy / Effectiveness Evidence
Functional improvement		
Pain improvement		
Pain/function composite improvement		
Morning pain		
Night pain		
Pain with activities		

Efficacy – Effectiveness Outcomes	Importance of Outcome	Efficacy / Effectiveness Evidence
Pain with resistance		
Grip strength		

Cost Outcomes	Importance of Outcome	Cost Evidence
Cost-effectiveness		
Direct cost		

Special Population / Considerations Outcomes	Importance of Outcome	Special Populations/ Considerations Evidence
Age		
Gender		
Other		
Body weight		
Energy intensity		
Symptom duration		
Calcium formation		

**For Safety:** Is there sufficient evidence that the technology is safe for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

**For Efficacy/Effectiveness:** Is there sufficient evidence that the technology has a meaningful impact on patients and patient care?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

**For Cost Outcomes/Cost-Effectiveness:** Is there sufficient evidence that the technology is cost-effective for the indications considered?

Unproven (no)	Less (yes)	Equivalent (yes)	More in some (yes)	More in all

#### **Discussion**

Based on the evidence vote, the committee may be ready to take a vote on coverage or further discussion may be warranted to understand the differences of opinions or to discuss the implications of the vote on a final coverage decision.

- Evidence is insufficient to make a conclusion about whether the health technology is safe, efficacious, and cost-effective;
- Evidence is sufficient to conclude that the health technology is unsafe, ineffectual, or not cost-effective
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for all indicated conditions;
- Evidence is sufficient to conclude that the health technology is safe, efficacious, and cost-effective for some conditions or in some situations

A straw vote may be taken to determine whether, and in what area, further discussion is necessary.

#### **Second Vote**

Based on the evidence a	about the technologies' safety,	efficacy, and cost-effectiveness, it is
Not Covered	Covered Unconditionally _	Covered Under Certain Conditions

#### **Discussion Item**

Is the determination consistent with identified Medicare decisions and expert guidelines, and if not, what evidence is relied upon.

#### **Next Step: Proposed Findings and Decision and Public Comment**

At the next public meeting the committee will review the proposed findings and decision and consider any public comments as appropriate prior to a vote for final adoption of the determination.

- 1) Based on public comment was evidence overlooked in the process that should be considered?
- 2) Does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

#### **Next Step: Final Determination**

Following review of the proposed findings and decision document and public comments:

#### **Final Vote**

Does the committee approve the Findings and Decisions document with any changes noted in discussion?

If yes, the process is concluded.

If no, or an unclear (i.e., tie) outcome Chair will lead discussion to determine next steps.

### **Medicare Coverage and Guidelines**

[From page 89 of the final evidence report]

#### **Centers for Medicare Service (CMS)**

There is currently no National Coverage Determination for ESWT for any conditions published from the Centers for Medicare and Medicaid Services. A single Local Coverage Determination applicable to South Carolina, Virginia, West Virginia, and North Carolina has been published and considers ESWT to be investigational in the treatment of musculoskeletal conditions.

#### **Guidelines**

Table 2. Summary of Clinical Guidelines [from page 71 of final evidence report]

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
American College of Occupational and Environmental Medicine (ACOEM)	NR	ESWT is strongly recommended for calcific rotator cuff tendinitis.	Strongly recommended (A)*
Occupational medicine practice guidelines (2011)			
Shoulder Disorders ⁹⁹			
American College of	NR	ESWT is not recommended for acute, sub-	Insufficient- Not
Occupational and		acute, or post-operative Achilles	Recommended
Environmental Medicine (ACOEM)		Tendinopathy.	(Consensus-based) (I)*
		ESWT is recommended as an adjunct to	
Occupational medicine practice guidelines (2011)		eccentric exercise for chronic, recalcitrant Achilles Tendinopathy.	Recommended (C)*
Ankle and Foot Disorders ⁹⁶		ESWT is recommended for chronic plantar fasciitis in select patients with chronic recalcitrant conditions.	Insufficient- Recommended (Consensus-based) (I)*

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
American College of Occupational and Environmental Medicine (ACOEM)	NR	ESWT is not recommended for acute, subacute, or chronic lateral epicondylalgia.	Strongly Not Recommended (A)*
Occupational medicine practice guidelines (2012)			
Elbow Disorders ⁹⁷			
American College of Occupational and Environmental Medicine (ACOEM)	NR	The ACOEM has no recommendation on ESWT for patellar tendinosis.	Insufficient- No Recommendation (Consensus-based) (I)*
Knee Disorders ⁹⁸			
Colorado Division of Workers' Compensation Shoulder Injury Medical Treatment Guidelines (2015) ³⁹	105 studies, type NR	<ul> <li>Indications for use of ESWT include:</li> <li>Patients with calcific tendinitis who have not achieved functional goals after 2-3 months of active therapy</li> <li>Calcium deposits must be Type I, homogenous calcification with well-defined borders, or Type II, heterogeneous with sharp borders or homogeneous with no defined border</li> </ul>	NR
Dutch Orthopedic Association  Guideline for the Diagnosis and Treatment of Subacromial Pain Syndrome: A multidisciplinary review by the Dutch Orthopedic Association (2014) ⁶¹	NR	<ul> <li>ESWT is recommended for the treatment of chronic tendinosis calcarea.</li> <li>Use of high-energy ESWT can be considered for proven subacromial calcium deposits.</li> <li>ESWT is not recommended for treatment in the acute phase, and in absence of tendinosis or bursitis calcarea.</li> <li>ESWT (all forms) is no more effective than placebo or other treatments in reducing pain or in improving shoulder function of patients without calcium deposition in the tendons</li> </ul>	Level 1†
American Academy of Family Practice  Common Overuse Tendon Problems: Review and Recommendation for	1 animal study, 1 RCT	The following "clinical recommendation" was provided:  Extracorporeal shock wave therapy appears to be a safe, noninvasive, effective but expensive means of pain relief for a number of chronic tendinopathies.	Grade B‡ Recommendation
Treatment (2005) ²⁵⁰ American College of Foot	<u>Plantar</u>	CONT is no common and of facilities that the start to the	Grade B§
and Ankle Surgeons  The Diagnosis and	Heel Pain 30 studies, type NR	ESWT is recommended for the treatment of chronic plantar heel pain, but only after receiving at least six months of other treatments (e.g., home physical therapy,	Recommendation
Treatment of Heel Pain: A			

Guideline	Evidence Base	Recommendation	Rating/ Strength of Recommendation
Clinical Practice Guideline (2010) ²³¹	Achilles Conditions 4 studies, type NR	corticosteroid injections, night splits, etc.).  ESWT is recommended for the treatment of Achilles enthesopathy and Tendinopathy	
			Grade B§ Recommendation

ESWT: Extracorporeal shockwave therapy; NR: not reported; RCT: Randomized Controlled Trial

*American College of Occupational and Environmental Medicine Strength of Recommendations:

Strongly Recommended (A): The intervention is strongly recommended for appropriate patients. The intervention improves important health and functional outcomes based on high quality evidence, and the Evidence-Based Practice Panel (EBPP) concludes that benefits substantially outweigh harms and costs.

Moderately Recommended (B): The intervention is recommended for appropriate patients. The intervention improves important health and functional outcomes based on intermediate quality evidence that benefits substantially outweigh harms and costs.

Recommended (C): The intervention is recommended for appropriate patients. There is limited evidence that the intervention may improve important health and functional benefits.

Insufficient- Recommended (Consensus-based) (I): The intervention is recommended for appropriate patients and has nominal costs and essentially no potential for harm. The EBPP feels that the intervention constitutes best medical practice to acquire or provide information in order to best diagnose and treat a health condition and restore function in an expeditious manner. The EBPP believes based on the body of evidence, first principles, or collective experience that patients are best served by these practices, although the evidence is insufficient for an evidence-based recommendation.

Insufficient- No Recommendation (Consensus-based) (I): The evidence is insufficient to recommend for or against routinely providing the intervention. The EBPP makes no recommendation, Evidence that the intervention is effective is lacking, of poor quality, or conflicting and the balance of benefits, harms, and costs cannot be determined.

Insufficient- Not Recommended (Consensus-based) (I): The evidence is insufficient for an evidence-based recommendation. The intervention is not recommended for appropriate patients because of high costs or high potential for harm to the patient.

Not Recommended (C): Recommendation against routinely providing the intervention. The EBPP found at least intermediate evidence that harms and costs exceed benefits based on limited evidence.

Moderately Not Recommended (B): Recommendation against routinely providing the intervention to eligible patients. The EBPP found at least intermediate evidence that the intervention is ineffective, or that harms or costs outweigh benefits.

Strongly Not Recommended (A): Strong recommendation against providing the intervention to eligible patients. The EBPP found high quality evidence that the intervention is ineffective, or that harms or costs outweigh benefits.

† Dutch Orthopedic Association Strength of Recommendations:

Level 1: For therapeutic intervention studies: high-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: A1-level study or at least 2 independently conducted A-2 level studies.

Level 2: For therapeutic intervention studies: moderate-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one A2-level study or at least 2 independently conducted B-level studies.

Level 3: For therapeutic intervention studies: low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one B-level study or at least 2 independently conducted C-level studies.

Level 4: For therapeutic intervention studies: very low-quality studies. For diagnostic accuracy research or prognosis, etiology or side effects: one C-level study.

‡ American Academy of Family Practice (AAFP) Strength of Recommendation Taxonomy (SORT):

A: Consistent, good-quality, patient-oriented evidence

B: Inconsistent or limited-quality, patient-oriented evidence

C: Consensus, disease- oriented evidence, usual practice, expert opinion, or case series.

§American College of Foot and Ankle Surgeons Grades of Recommendations:

Grade A: Treatment options are supported by strong evidence (consistent with Level I or II studies).

Grade B: Treatment options are supported by fair evidence (consistent with Level III or IV studies).

Grade C: Treatment options are supported by either conflicting or (Level IV studies).

Grade I: Insufficient evidence to make a recommendation.