Washington State Health Care Authority

January 31, 2025 Meeting Materials
Health Technology Clinical Committee

Vertebroplasty, kyphoplasty, and sacroplasty (VKS)

Contents

- ☐ VKS HTCC clinical expert information
- ☐ Agency Medical Director presentation
- ☐ Scheduled public comments presenters and presentations
- ☐ VKS evidence presentation
- ☐ HTCC decision aid
- ☐ VKS final key questions

Health Technology Clinical Committee Application for Membership

Washington State Health Care Authority

1 Contact information

First name: Sohail

Middle initial: K

Last name: Mirza

Address:

Phone number:

Best method, time to reach you: After 5pm eastern time

Email:

Today's date: 10/15/2024

2 Personal information (optional)

Gender:

- [x] Male
- [ ] Female
- [ ] X/non-binary[1]

Pronouns (select all that apply)

- [ ] She/her
- [x] He/him
- [ ] They/them
- [ ] Other (subj./obj.):

Race or Ethnicity

- [ ] American Indian or Alaska Native
- [x] Asian or Pacific Islander American
- [ ] Black/ African American
- [ ] Latino, Hispanic, Spanish
- [ ] White/ Caucasian
- [ ] Other:

3 Professional training

Education (list degrees): MD, MPH, BS

Health care practitioner licenses: Virginia, Washington, Californiua, Colorado

Professional affiliations: NASS, AAOS, AOA, CSRS

Board certifications, formal training, or other designations: ABOS

Current position (title and employer): Professor, Thayer School of Engineering at Dartmouth College, Hanover, NH

Current practice type and years in practice: Spine surgeon 24 years

Total years as an active practitioner: 24

Location of practice (city): Fairfax, VA

1 *Non-binary (X) is an umbrella term used to describe those who do not identify as exclusively male or female. This includes but is not limited to people who identify as genderqueer, gender fluid, agender, or bigender.*

4 Experience

Provide a brief explanation (up to 150 words each) addressing the following:

1) Why you would like to serve on the clinical committee;

Experienced spine surgeon and researcher.

2) The value of informing health policy decisions with scientific evidence, including any examples incorporating new evidence into your practice;

Health plocy should be supported by scientifically robust clinical evidence.

3) How your training and experience will inform your role on the committee

Academic experience at U Washington (1996 to 2008) and Dartmoulth College (2008 to present).

4) Treating populations that may be underrepresented in clinical trials: women, children, elderly, or people with diverse ethnic and racial backgrounds, including recipients of Medicaid or other social safety net programs?

The population served by my clinical practice in Fairfax, VA, is diverse. I also serve uninsured patients.

5 Ability to serve

Are you able to participate in all-day meetings, an estimated six times per year? ✔ Yes ☐ No

Are you willing to commit to the responsibilities of a committee member, including:

- Attending meetings prepared for the topics of the day;
- Actively participating in discussions;
- Making decisions based on the evidence presented and the public interest1? ✔ Yes ☐ No

Could you, or any relative, benefit financially from the decisions made by the HTCC? ☐ Yes ✔ No

6 References

Provide three professional references:

1.

First name: Keith
Last name: Paulsen
Relationship: Colleage
Title: Professor
Contact email:
Phone number:

2.

First name: Steven
Last name: Hughes
Relationship: Colleage
Title: Spine surgeon
Contact email:
Phone number:

3.

First name: Jeffrey
Last name: Jarvik
Relationship: Colleague
Title: Professor
Contact email:
Phone number:

For your application to be reviewed, please include:

✔ Completed application ✔ curriculum vitae ☐ **conflict of interest disclosure**

Download this form and send the completed version to **shtap@hca.wa.gov**

OR mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

1 *Detailed in Washington Administrative Code (WAC) and committee bylaws*

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.

Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name: Sohail

Middle initial: K

Last name: Mirza

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.

B. Employment including work as an independent contractor, consultant, whether written or unwritten.

C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.

D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.

E. Participating on a company's proprietary governing boards.

F. Participating in a speakers bureau.

G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
C, D	CEO, PEER Techonologies PLLC	$0.00	✓ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Yes, I have published papers and editorials on vertebroplasty/kyphoplasty.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

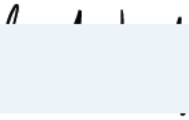
Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature 

Date 10/16/24

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

Sohail K. Mirza (Curriculum Vitae)

Personal Information

[redacted]

Education

2002-2005	MPH	University of Washington *School of Public Health and Community Medicine, Seattle, Washington*
1985-1989	MD	University of Colorado *School of Medicine, Denver, Colorado*
1982-1985	BA	Colorado College *Major: Physics* *Colorado Springs, Colorado*
2008-2009		*(classes only) Executive Leadership Series for Dartmouth-Hitchcock* *Tuck School of Business at Dartmouth, Hanover, New Hampshire*
2004		*(certificate) AOA-Kellogg Leadership Series Module 1* *Northwestern University, Kellogg School of Management,* *American Orthopaedic Association, Chicago, Illinois*
2005-2006		*(certificate) Leadership Scholars Program* *University of Washington, School of Medicine, Seattle, Washington*

Training

1994-1995	Fellowship in Spinal Surgery Harvard Medical School, Boston, Massachusetts *Beth Israel Hospital* *Children's Hospital Boston*
1990-1994	Residency in Orthopedic Surgery University of Washington, Seattle, Washington *University of Washington Medical Center* *Harborview Medical Center* *Seattle Children's Hospital* *Veteran's Affairs Puget Sound Healthcare System* *Virginia Mason Medical Center*
1989-1990	Internship in General Surgery University of Washington, Seattle, Washington *University of Washington Medical Center* *Harborview Medical Center* *Seattle Children's Hospital* *Veteran's Affairs Puget Sound Healthcare System*

Certification

2017 Re-certification	American Board of Orthopaedic Surgery
2007 Re-certification	American Board of Orthopaedic Surgery
1997 Part II (oral)	American Board of Orthopaedic Surgery
1995 Part I (92nd percentile)	American Board of Orthopaedic Surgery
1990 Part III (94th percentile)	National Board of Medical Examiners
1988 Part II (99th percentile)	National Board of Medical Examiners
1987 Part I (99th percentile)	National Board of Medical Examiners

Licensure

Washington (active)	Issued July 28, 1993	Number: 025209
Massachusetts (inactive)	Issued April 13, 1994	Number: 79228
California (active)	Issued June 15, 1994	Number: 79154
Colorado (active)	Issued August 17, 1995	Number: 34710
New Hampshire (active)	Issued December 3,2008	Number: 14258
Virginia (active)	Issued August 23, 2016	Number: 0101261117

Academic Appointments

2018- present	Professor, Thayer School of Engineering Co-Director, The Center for Surgical Innovation *Dartmouth College, Hanover, New Hampshire*
2013-2018	Medical Director, The Center for Surgical Innovation Geisel School of Medicine and Thayer School of Engineering *Dartmouth College, Hanover, New Hampshire*
2010-2016	Chair, Department of Orthopaedics Geisel School of Medicine at Dartmouth *Dartmouth College, Hanover, New Hampshire*
2008-2010	Vice Chair, Department of Orthopaedics Geisel School of Medicine at Dartmouth *Dartmouth College, Hanover, New Hampshire*
2009-2018	Professor of Orthopaedics Geisel School of Medicine at Dartmouth *Dartmouth College, Hanover, New Hampshire*
2008-2009	Visiting Professor Dartmouth Medical School *Dartmouth College, Hanover, New Hampshire*
2009-2018	Professor, The Dartmouth Institute *Dartmouth College, Hanover, New Hampshire*
2005-2008	Surgical Dynamics Endowed Chair for Spine Outcomes Research *Department of Orthopaedics and Sports Medicine* *School of Medicine, University of Washington, Seattle, Washington*
2006-2008	Professor of Orthopaedics and Sports Medicine *Department of Orthopaedics and Sports Medicine* *School of Medicine, University of Washington, Seattle, Washington*

2006-2008	Professor of Neurological Surgery *Department of Neurological Surgery* *School of Medicine, University of Washington, Seattle, Washington*
2005-2008	Director of Spine Education *Department of Orthopaedics and Sports Medicine* *School of Medicine, University of Washington, Seattle, Washington*
2001-2006	Associate Professor of Orthopaedics and Sports Medicine *Department of Orthopaedics and Sports Medicine* *School of Medicine, University of Washington, Seattle, Washington*
2001-2006	Associate Professor of Neurological Surgery *Department of Neurological Surgery* *School of Medicine, University of Washington, Seattle, Washington*
1997-2001	Assistant Professor of Neurological Surgery *Department of Neurological Surgery* *School of Medicine, University of Washington, Seattle, Washington*
1996-2008	Director, Spine Trauma and Outcomes Research *Harborview Medical Center, Seattle, Washington*
1995-2001	Assistant Professor of Orthopaedics and Sports Medicine *Department of Orthopaedics and Sports Medicine* *School of Medicine, University of Washington, Seattle, Washington*

Hospital Appointments

2017-Present	Active Staff INOVA Fairfax Medical Center *Fairfax, Virginia*
2017-Present	Active Staff INOVA Fair Oaks Hospital *Fairfax, Virginia*
2008-2017	Attending Surgeon Dartmouth-Hitchcock Medical Center *Lebanon, New Hampshire*
2002-2008	Attending Surgeon Seattle Cancer Care Alliance *University of Washington, Seattle, Washington*
1995-2008	Attending Surgeon Harborview Medical Center *University of Washington, Seattle, Washington*
1995-2008	Attending Surgeon University of Washington Medical Center *University of Washington, Seattle, Washington*

1995-2008	Attending Surgeon Children's Hospital and Medical Center *University of Washington, Seattle, Washington*
1995-2008	Attending Surgeon Veteran's Affairs Puget Sound Health Care System *University of Washington, Seattle, Washington*
1999-2003	Chief, Section of Spine Surgery Veteran's Affairs Puget Sound Health Care System *University of Washington, Seattle, Washington*

Awards and Honors

2018	North American Spine Society Leon Wiltse Clinical and Research Leadership Award
2014	American Academy of Orthopaedic Surgeons Kappa Delta Clinical Research Award
2003	American Orthopaedic Association American-British Canadian Fellowship *Great Britain, Australia and New Zealand*
1997	American Orthopaedic Association North American Traveling Fellowship *15 academic institutions in United States and Canada*
2003	Induction into the American Orthopaedic Association
2003	Clinical Service Excellence Award Harborview Medical Center *University of Washington, Seattle Washington*
1999	Research Award Cervical Spine Research Society Award *Measuring cervical spine instability by neural space occlusion*
1994	Daniel E. Hogan Spine Fellowship Beth Israel Hospital *Harvard Medical School, Boston, Massachusetts*
1994	Laurnen Award for Spine Research University of Washington *Seattle, Washington*
1991	Orthopaedic Resident Service Excellence Award Harborview Medical Center *University of Washington, Seattle Washington*
1989	Honors in Medicine University of Colorado *School of Medicine, Denver, Colorado*

1988 Alpha Omega Alpha
University of Colorado
School of Medicine, Denver, Colorado

1986 Robert C. Lewis Award for Biochemistry
University of Colorado
School of Medicine, Denver, Colorado

1986 Carbon Gillespie Award for Surgical Anatomy
University of Colorado
School of Medicine, Denver, Colorado

1985 Phi Beta Kappa
The Colorado College
Colorado Springs, Colorado

1985 Magna Cum Laude, Physics
The Colorado College
Colorado Springs, Colorado

1982 Scholarship in Chemistry
The Colorado College
Colorado Springs, Colorado

1982 Honors at Admission
The Colorado College
Colorado Springs, Colorado

1982 Regents Scholarship
University of Colorado
Boulder, Colorado

Professional Societies

1997-Present	Member	American Academy of Orthopaedic Surgeons
1989-Present	Member	American Medical Association
2001-Present	Member	Orthopedic Research Society
2001-Present	Member	Cervical Spine Research Society
2003-Present	Member	American Orthopedic Association
2006-Present	Member	North American Spine Society
1988-present	Member	Alpha Omega Alpha
1985-present	Member	Phi Beta Kappa
1994-2008	Member	Washington State Orthopaedic Association
2004-2005	Member	AO Spine North America
1994-2008	Member	Washington State Medical Association
1995-2008	Member	Puget Sound Spine Interest Group
1993-2008	Member	Western Orthopaedic Association
1997-2001	Member	American Association for the Advancement of Science
1997-1999	Member	International Society for Computer Aided Surgery

National Committees

2007-present	Member Cochrane Collaboration Back Review Group Advisory Board
2006-2007	Member Puget Sound Health Alliance Committee on Back Pain
2005-2007	Chair North American Traveling Fellowship Committee, American Orthopaedics Association (AOA)
2004-2005	Member North American Traveling Fellowship Committee (NATF)
2004-2005	Member Committee for Scientific Abstract Review North American Spine Society (NASS)
2005-2006	Member Task Force for Policy for Financial Disclosure North American Spine Society (NASS)
2004-2007	Member Continuing Medical Education North American Spine Society (NASS)
2004-2006	Member Task Force on Perioperative Blindness Advisory American Society of Anesthesiologists (ASA)
2004-2005	Member North American Fellowship Committee American Orthopaedics Association (AOA)
2005-2007	Member Committee on Fellowships American Orthopaedics Association (AOA)
2003-2006	Member Research Development Committee American Academy of Orthopedic Surgeons (AAOS)
2002-2005	Member Research Committee Cervical Spine Research Society (CSRS)
1997-1999	Member Think First, Board of Directors

(12) Institutional Committees

2008-2016	DHMC	Board of Governors
2008-2016	DHMC	Compliance Committee

2008-2016	DHMC	Clinical Chairs Committee
2009-2016	DHMC	Senior Leadership Group
2009-2016	DHMC	Inpatient Coverage Committee
2009-2016	DHMC	Ongoing Professional Practice Evaluation (OPPE) Committee
2008-2016	DHMC	Dean's Academic Board
2008-2015	DHMC	OR Advisory Committee
2012-2013	DHMC	Chair, Search Committee for Chair of Radiology
2009-2010	DHMC	Search Committee for Chief Operations Officer
2010-2014	DHMC	Chair, Advance Surgery Center Work Group
2009-2014	DHMC	Population Health/Clinical Transformation Work Group
2010-2010	DHMC	Hematology-Oncology Internal Review Board
2009-2010	DHMC	Search Committee for Chief Operations Officer
2008-2013	DHMC	Information Systems Steering Committee
2008-2013	DHMC	Continuing Medical Education Advisory Committee (CMEAC)
2007-2008	UW	Committee for Continuous Professionalism Improvement
2004-2007	UW	Faculty Council on Academic Affairs
2003-2004	UW	Appointments and Promotions Council
2000-2004	UW	Imaging Council
2000-2001	UW	Appointments and Promotions Council
1998-2001	UW	Faculty Council on Research
1998-2002	UW	Medical Quality Assurance Committee
1998-2002	UW	Clinical Advisory Committee
1998-2000	UW	Faculty Senate
1995-2007	UW	Resident Selection Committee

Grants

Pending

NIH/NIBIB SBIR Phase II
Smart Cavity Creator for Lumbar Interbody Fusion
Mirza, Sohail (PI) *$1,750,000 direct cost*

Funded

NIH/NIBIB T32
Training in Surgical Innovation 06/01/2017 – 05/31/2023
06/01/2023 -- 05/31/2028
Co-PI: Paulsen; Mirza *$1,079,000 direct cost*

NIH/NIDA SBIR Phase I
Nanoparticle Probes to Objectively Measure Pain following Back Surgery
Mirza, Sohail (PI) *$150,000 direct cost*

NIH/NIBIB SBIR Phase I
Smart Cavity Creator for Lumbar Interbody Fusion
Mirza, Sohail (PI) *$150,000 direct cost*

NIH/NIBIB R01
12/1/2017 to 11/30/2022
Image based registration and intraoperative updating for guiding spine surgery
Mirza, Sohail and Paulsen, Keith (Dual PIs) *$250,000/yr direct cost x 4y*
Goal: to develop and validate stereovision surgical guidance for spine surgery.

NIH/NIA SBIR Phase 1
12/1/2017 to 5/30/2018
GreenCare Interactive Guide for Knee Replacement Surgery
Mirza, Sohail (PI) *$150,000/yr direct cost x 1y*
Goal: to develop and commercialize an interactive guide for sharing of patient-reported outcomes.

R21 EB021456-02 (Weaver) 07/01/2016 - 06/30/2018
KL2TR001088 *$150,000/yr direct cost x 2y*
NIH/NCATS
Novel Technology for Early Identification of Surgical Infections
Weaver, John (PI)
The goal of this project is to develop novel nanoparticle technology for monitoring local inflammation over time to identify surgical site infections early.

T32EB021966 06/01/2017 – 05/31/2022
NIH/NIBIB *$88,752/yr direct cost x5y*
Training in Surgical Innovation
Paulsen, Keith (PI)
The main goal is to train predoctoral students in Surgical Innovation.

NIH/NCRR C06 RR 030432
Advanced Surgical Center for Translational Research at Dartmouth
Colacchio, Thomas (PI) *$9.5M*
Medical Director: S. Mirza
Scientific Director: K. Paulsen
Infrastructure grant to build a surgical suite with intra-operative CT and MR imaging capability and integrated image processing and image guidance.

T32AR049710, NIH/NIAMS
The Dartmouth Orthopaedics Clinician/Researcher Training Program (DOC/RTP)
Lurie, Jon (PI)
05/01/14-04/30/19
The Orthopaedic Residency Program, in association with The Dartmouth Institute for Health Policy and Clinical Practice (TDI), has created a unique opportunity for orthopedic residents to spend a fellowship year earning a Master's degree in health services and leadership. Program goals are to educate our residents through a core set of courses to increase their knowledge and develop skills in clinical research methods, evaluating impact of healthcare policy, and critical evaluation of published literature. I serve as a core faculty member for this training program.
Role: Co-Investigator

P60AR062799 , NIH/MIAMS
Multidisciplinary Clinical Research Center in Musculoskeletal Diseases
Tosteson, Anna (PI)
09/01/12-08/31/17
The main objective of the MCRC is to improve health for individuals with musculoskeletal disease. By expanding a unique national research program in musculoskeletal diseases, this grant trains new researchers and provides high-quality resources for research projects addressing health care in those who have broken a bone, decision-making about back surgery, and the safety of new medical devices. I serve as the principal investigator on one project and co-investigator on another project.

Role: Co-Investigator

RC1 AG036268, NIH/NIA
Variation in the Safety of Back Pain-Related Surgery
Mirza, Sohail (PI)
09/30/09-08/31/11 $978,000
The goal of this project was to characterize variations in complications associated with surgery for intervertebral disc herniation for the purpose of understanding safety of these procedures.
Role: PI

National Institute of Health/NIAMS: Complications of Surgery for Spinal Stenosis: A Clinical Prediction Rule
9/16/2008 – 7/31/2011: $258,767
Principal Investigator: Richard A. Deyo, MD, MPH
Investigator: Sohail K. Mirza

National Institute of Health Patient-Oriented Research Career Development Award
"Safety of Lumbar Fusion Surgery for Chronic Back Pain"
7/1/02-7/31/07: $626,265
Prinicipal Investigator: Sohail K. Mirza, MD

NIAMS Multidisciplinary Clinical Research Center
2/15/02 – 7/31/08: $5,211,115
Principal Investigator: Richard A. Deyo, MD, MPH
Principal Investigator for Project 2 "Cohort Study of Oucomes for Discogenic Back Pain": Sohail K. Mirza

Northwest Regional Spinal Cord Injury System
7/1/01 – 6/30/06
Principal Investigator for program: Diana D. Cardenas, MD
Principal Investigator for Project 3 "Neurological recovery following spinal cord injury": Sohail K. Mirza

Orthopaedic Research and Education Foundation
"Neural Instability of the Cervical Spine"
7/1/99 – 6/30/01: $98,000
Principal Investigator: Sohail K. Mirza, MD

Royalty Research Fund
"Vertebral Strength Following Percutaneous Vertebroplasty"
8/1/99 – 7/31/00: $29,000
Principal Investigator: Sohail K. Mirza, MD

Cervical Spine Research Society
"Cervical Spine Instability as Measured by Neural Space Occlusion"
12/5/99 – 6/30/99: $28,000
Principal Investigator: Sohail K. Mirza, MD

Genetics Institute

"Efficacy of rh-BMP-2 /cancellous allograft in comparison to iliac crest autograft in treatment of tibial fracture defects"
6/1/00 – 5/31/02: $82,000
Principal Investigator: Sohail K. Mirza, MD

Epidemiology Research and Information Center, Veterans Affairs HSR&D

"Influence of coexisting medical conditions on health related quality of life measurement"
10/1/98 – 4/30/99: $23,000
Principal Investigator: Sohail K. Mirza, MD

Genetics Institute

"Safety and efficacy of rh-BMP-2 in open tibia fractures"
10/1/97 – 4/30/99: $78,000
Principal Investigator: Sohail K. Mirza, MD

Hansen Chair for Traumatology Research, Harborview Medical Center

"Measuring spine instability by neural space volume changes: A pilot study"
10/1/98 – 7/30/99: $16,000
Principal Investigator: Sohail K. Mirza, MD

Daniel E. Hogan Research Fund, Harvard Medical School

"Percutaneous lumbar interbody fusion: A safety and biomechanical evaluation"
10/1/94 – 7/15/95: $5,000
Principal Investigator: Sohail K. Mirza, MD

Centers for Disease Control

National Center for Injury Prevention and Control
"Low speed cervical whiplash injury"
9/1/96 -8/31/99: $480,000
Principal Investigator: Allan F. Tencer, PhD
Co-Principal Investigator: Sohail K. Mirza, MD

Centers for Disease Control

National Center for Injury Prevention and Control
"A practical method for the reduction of cervical spine whiplash injury in rear-end motor vehicle accidents"
9/1/99 – 8/31/01: $460,000
Principal Investigator: Allan F. Tencer, PhD
Co-Principal Investigator: Sohail K. Mirza, MD

National Highway Traffic Safety Administration

"Neck Mechanics and Injury Tolerance as a Function of Developmental Age"
9/20/99 – 9/19/04: $750,000
Principal Investigator: Randal P. Ching, PhD
Investigator: Sohail K. Mirza, MD

National Highway Traffic Safety Administration
"Age-Dependent Properties of the Spine"
4/1/99 – 3/31/01: $300,000
Principal Investigator: Randal P. Ching, PhD
Investigator: Sohail K. Mirza, MD

Harborview Injury Prevention Center
"Prospective Inception Cohort Study on the Evolution and Prognostic Significance of Physical Examination Findings and Expectancy in Whiplash Injury"
12/1/99 – 11/30/01: $65,000
Principal Investigator: Arthur A. Rodriquez, MD, MS.
Investigator: Sohail K. Mirza, MD

Patents

U.S. Patent No. 15/470,819 Issued 2/14/2024
"Interactive healthcare system for managing back or neck pain"
Inventor: Sohail K. Mirza, MD

U.S. Patent No. 16/779,556 Issued 4/4/2023
"System and method to measure pain levels of patients following surgery"
Inventors: Sohail K. Mirza, John B. Weaver

Application Serial No. 62/313,651 Issued 2022
"Smart Cavity Creator Drill"
Inventors: Sohail Mirza, MD; Keith Paulsen, PhD; Ryan Halter PhD

U.S. Patent No. 9597043B1 Issued March 21, 2017
"System and Method for Supporting a Patient for Imagery During Surgery"
Inventors: Sohail Mirza, MD; Keith Paulsen, PhD; Atthar Mirza

U.S. Patent No. 6,358,251 Issued March 19, 2002
"*Method and apparatus for forming a cavity in soft tissue or bone"*
Inventor: Sohail K. Mirza, MD

U.S. Patent No. 5,928,239 Issued July 27, 1999
"Percutaneous surgical cavitation device and method"
Inventor: Sohail K. Mirza, MD

Teaching Experience

Graduate Students

2017 to 2020	Alicia Everitt	PhD, Bioengineering
2016 to 2019	Prajan Divakar	PhD, Bioengineering
2015 to 2018	Fioleda Prifti	PhD, Bioengineering
2011 to 2013	Ben Keeney	PhD, Health Services
2007 to 2010	Brook I. Martin	PhD, Health Services
2005 to 2007	Ken F. Linnau	MS Health Services
2003 to 2005	Sham M-Juratli	MPH, Health Services
1998 to 2002	David J. Nuckley	PhD, Bioengineering
1997 to 2002	Jarrod W. Carter	PhD, Bioengineering
1996 to 2001	Geoff C. Raynak	PhD, Bioengineering

Spine Fellows

2007-2008	Anthony Russo, MD	Orthopedics
2007-2008	Paul Kraemer, MD	Orthopedics
2007-2008	Delmore Morsette, MD	Neurosurgery
2006-2007	Joshua Patt, MD	Orthopedics
2006-2007	Troy Caron, MD	Orthopedics
2005-2006	Jason Thompson, MD	Orthopedics
2004-2005	Rick Bransford, MD	Orthopedics
2003-2004	Tim McHenry, MD	Orthopedics
2002-2003	Diana Wiseman, MD	Neurosurgery
2002-2003	Michael Binette, MD	Orthopedics
2001-2002	Greg Wiggins, MD	Neurosurgery
2000-2001	Julie York, MD	Neurosurgery
1999-2000	Allain Girouard, MD	Orthopedics
1999-1999	Anthony Avellino, MD	Neurosurgery
1999-1999	James Schuster, MD	Neurosurgery
1998-1999	John Borkowski, MD	Orthopedics
1998-1998	Andrew Dailey, MD	Neurosurgery

Resident Researchers

2014-2015	Matthew DeWolf MD	Orthopedics
2010-2014	Wale Adeniran MD	Orthopedics
2005-2006	Thomas Manning, MD	Neurosurgery
2005-2006	Melvin Wahl, MD	Orthopedics
2005-2006	John Lesher, MD	Rehabilitation Medicine
2005-2005	Catherine Heike, MD	Pediatrics
2005-2005	Jyoti Sharma, MD	Rehabilitation Medicine
2003-2005	Alex Mohit, MD	Neurosurgery
2000-2001	Brett Quigley, MD	Orthopedics
1999-2000	Saadi, Ghatan, MD	Neurosurgery
1998-1999	Fritz Lomoshitz, MD	Radiology

Medical Students

2017 to 2018	George Wang	Geisel School of Medicine at Dartmouth
2016 to 2017	Karissa LeClair	Geisel School of Medicine at Dartmouth
2016 to 2017	Soham Rege	Geisel School of Medicine at Dartmouth
2011 to 2013	Derek Jones	Geisel School of Medicine at Dartmouth
2011 to 2012	Mitch Wyffels	Geisel School of Medicine at Dartmouth
2010 to 2011	Justin Kim	Geisel School of Medicine at Dartmouth

Undergraduate Students

2018 to now	Maxwell Durtschi	Dartmouth College
2014 to 2015	Ailin Song	Thayer School of Engineering at Dartmouth
2014 to 2015	Edrei Z. F. Chua	Thayer School of Engineering at Dartmouth
2014 to 2015	Jonathan Huang	Thayer School of Engineering at Dartmouth
2014 to 2015	Kathleen Li	Thayer School of Engineering at Dartmouth
2014 to 2015	Shu Chen Sung	Thayer School of Engineering at Dartmouth
2011 to 2013	Rajiv Raghavan	Thayer School of Engineering at Dartmouth
2011 to 2011	Jaya Batra	Thayer School of Engineering at Dartmouth

2011 to 2012	Nathan Friendly	Thayer School of Engineering at Dartmouth
2011 to 2012	Vipul Kakkad	Thayer School of Engineering at Dartmouth

Courses Chaired

2001 – 2004 Orthopedic Core Curriculum, Spine Section
Organized 6 sessions/year, presented 1 session

1999 – 2000 Orthopedic Core Curriculum, Spine Section
Organized 10 lectures, presented 4 lectures

October 1999 UW OR Personnel Spine Skill Course
Organized 5 lectures and 4 workshops

1998 – 1999 Orthopedic Core Curriculum, Spine Section
Organized 10 lectures, presented 7 lectures, Conducted review session

September 1998 UW OR Personnel Spine Skill Courses
Organized 5 lectures and 4 workshops

1997 – 1998 Orthopedic Core Curriculum, Spine Section
Organized 10 lectures, presented 6 lectures, Conducted review session

1996 – 1997 Orthopedic Core Curriculum, Spine Section
Organized 10 lectures, presented 8 lectures, Conducted review session

1995 – 1996 Orthopedic Core Curriculum, Spine Section
Organized 10 lectures, presented 5 lectures

Courses Taught

Oct 2007 North American Spine Society: Advances in Motion Technology, Austin, TX
(1 presentation)

Oct 2007 Spine Forum: Lumbar Degenerative Disease (Synthes), Seattle, WA
(1 presentation)

Mar 2006 North American Spine Society Spring Break, San Diego, CA
(3 lectures)

Oct 2005 Harvard Medical School Symposium on Therapeutic Motion Technology
Boston, MA
(1 Lecture)

Oct 2005 Daniel E. Hogan Fellows meeting
Boston, MA
(invited to give 1 lecture)

Oct 2005 Harvard Medical School Orthopedics Core Curriculum
Boston, MA
(invited to give 1 lecture)

Oct 2005	Breast Cancer CME Update (invited to give 1 presentation), Seattle, WA
Sep 2005	Symposium on Low Back Pain *(1 Lecture),* Seattle, WA
May 2005	University of Washington Rehabilitation Lecture *(1 Lecture)*
May 2005	University of Washington Spine Conference *(1 Lecture)*
April 2005	University of Washington Spine Conference *(1 Lecture)*
Aug 2004	University of Washington Spine Grand rounds *(1 Lecture)*
May 2004	University of Washington Spine Conference *(2 Lectures)*
Sep 2003	Symposium on the Aging Spine *(1 lecture),* Seattle, WA
Sep 2003	Northwest Regional Spinal Cord Injury Update *(1 lecture),* Seattle, WA
Aug 2003	University of Washington Didactic Trauma Teaching Session (1 Lecture)
Aug 2003	University of Washington Neuroradiology Conference (2 Lectures)
Aug 2003	University of Washington Spine Grand Rounds (1 Lecture)
July 2003	University of Washington Neurology M&M (1 Lecture)
May 2003	University of Washington Spine Conference (1 Lecture)
April 2003	University of Washington Spine Conference (1 Lecture)
Feb 2003	University of Washington Spine Conference (3 Lectures)
Nov 2002	University of Washington Didactic Trauma Teaching Session (1 Lecture)
Nov 2002	University of Washington Spine Conference (1 Lecture)
Oct 2002	University of Washington Spine Conference (1 Lecture)
July 2002	Harborview Medical Center Advanced Clinical Research Symposium (1 Lecture)
July 2002	University of Washington Spine Conference (1 Lecture)
June 2002	University of Washington Spine Conference (1 Lecture)
March 2002	University of Washington Rehabilitation Medicine Lecture (1 Lecture)
May 2002	Controversies and New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, Seattle, 2002. (2 labs)
April 2002	University of Washington Spine Conference (1 lecture)

March 2002	University of Washington Rehabilitation Medicine Research Seminar (Guest Lecturer)
Feb 2002	University of Washington Spine Conference (2 lectures)
Feb 2000	Washington State Society of X-ray Technologists Symposium, Bellevue, WA (2 lectures)
Feb 2000	Primary Care Orthopedics (4 lectures)
Dec 1999	Howard H. Steel Conference on Pediatric Spinal Cord Injury Rancho Mirage, California (1 lecture, 2 discussion groups)
Nov 1999	AO Advanced Techniques in Spine Surgery, Bermuda (2 lectures, 1 session moderator and 3 surgical technique demonstrations)
Nov 1999	AO Basic Spine Course, Bermuda (1 lecture, 1 session moderator and 2 surgical technique demonstrations)
Aug 1999	Rehab 592 Orthotics (1 lecture)
July 1999	Orthopedic Trauma Association Regional Trauma Update (1 lecture)
July 1999	Nursing Operating Room Clerkship (1 lecture)
May 1999	Rehabilitation Medicine, Medical Sciences (1 lecture)
March 1999	Principles of Biomechanics (Graduate student course, 1 lecture)
Jan1999	The Spine Center: A contemporary update on disorders of the spine. Whistler, BC, Canada. (1 lecture, 3 discussion groups and 3 surgical technique demonstrations)
Aug 1998	Rehab 592 Orthotics (1 lecture)
Nov 1998	AO/ASIF Spine Course Tacoma, Washington (1 lecture, 2 lab demonstrations)
July 1998	Nursing Operating Room Clerkship (1 lecture)
May 1998	Rehabilitation Medicine, Medical Sciences (1 lecture)
March 1998	Trauma Radiology (1 lecture)
Jan 1998	The Spine Center: A contemporary update on disorders of the spine. Whistler, BC, Canada. (2 lectures, 1 discussion groups, 4 surgical technique demonstrations)
Sep 1997	The Spine: Current Concepts and Techniques Palm Beach, Florida. (1 lecture, 2 workshops)
Aug 1997	Rehab 592 Orthotics (1 lecture)

July 1997	Nursing Operating Room Clerkship (1 lecture)
May 1997	Rehabilitation medicine, Medical Sciences (1 lecture)
March 1997	AO/ASIF Advanced Techniques in Spine Surgery Banff, Canada. (5 lectures, 4 discussion groups, 4 surgical technique workshops)
Nov 1996	AO/ASIF Basic and Advanced Course for OR Personnel. Seattle, Washington. (2 surgical technique workshops)
Oct 1996	Low Back Pain and Sciatica in the Era of Managed Care Harvard Medical School, Boston, Massachusetts (1 lecture, 1 group session)
July 1996	Orthopedic Trauma Update, University of Washington, Seattle, Washington (1 lecture, 2 discussion groups)
March 1996	Low Back Pain Symposium: AHCPR Guidelines, Controversies. University of Washington, Seattle, Washington (1 lecture)
Nov 1995	Orthopedic Trauma Update, University of Washington, Yakima and Spokane, Washington (4 lectures)

Workshops Taught

July 1999	AO Basic Spine Techniques Workshop (Organized and supervised 4 surgical skills exercises)
July 1998	AO Basic Spine Techniques Workshop (Organized and supervised 4 surgical skills exercises)
June 1998	New resident orientation and orthopedic skills workshop (1 lecture and 1 surgical skills session)
July 1997	AO Basic Spine Techniques Workshop (Organized and supervised 4 surgical skills exercises)
June 1997	New resident orientation and orthopedic skills workshop (1 lecture and 1 surgical skills session)
June 1996	New resident orientation and orthopedic skills workshop (1 lecture and 1 surgical skills session)

Peer-Reviewed Publications

1. Martin B1, Mirza SK, Spina N, Spiker WR, Lawrence B, Brodke DS. Trends in Lumbar Fusion Procedure Rates and Associated Hospital Costs for Degenerative Spinal Diseases in the United States, 2004-2015.Spine (Phila Pa 1976). 2018 Aug 2. doi: 10.1097/BRS.0000000000002822. [Epub ahead of print]

2. Martin BI, Lurie JD, Farrokhi FR, McGuire KJ, Mirza SK. Early effects of Medicare's Bundled

Payment for Care Improvement (BPCI) program for lumbar fusion. Spine (Phila Pa 1976). 2018 May 15;43(10):705-711. doi: 10.1097/BRS.0000000000002404. PMID: 28885288

3. Tapp SJ, Martin BI, Tosteson TD, Lurie JD, Weinstein MC, Deyo RA, Mirza SK, Tosteson ANA. Understanding the value of minimally invasive procedures for the treatment of lumbar spinal stenosis: the case of interspinous spacer devices. Spine J. 2017 Aug 25. pii: S1529-9430(17)30944-0. doi: 10.1016/j.spinee.2017.08.246. [Epub ahead of print] PMID: 28847740

4. Lollis SS, Fan X, Evans L, Olson JD, Paulsen KD, Roberts DW, Mirza SK, Ji S. Use of Stereovision for Intraoperative Coregistration of a Spinal Surgical Field: A Human Feasibility Study. Neurosurgery. 2017 Jun 27. doi: 10.1093/ons/opx132. [Epub ahead of print] PMID: 28658939

5. Patel NK, Moses RA, Martin BI, Lurie JD, Mirza SK. Validation of Using Claims Data to Measure Safety of Lumbar Fusion Surgery. Spine (Phila Pa 1976). 2017 May 1;42(9):682-691. doi: 10.1097/BRS.0000000000001879. PMID: 27557452

6. Beachler DC, Yanik EL, Martin BI, Pfeiffer RM, Mirza SK, Deyo RA, Engels EA. Bone Morphogenetic Protein Use and Cancer Risk Among Patients Undergoing Lumbar Arthrodesis: A Case-Cohort Study Using the SEER-Medicare Database. J Bone Joint Surg Am. 2016 Jul 6;98(13):1064-72. doi: 10.2106/JBJS.15.01106. PMID: 27385679 Free PMC Article

7. Deyo RA, Mirza SK. CLINICAL PRACTICE. Herniated Lumbar Intervertebral Disk. N Engl J Med. 2016 May 5;374(18):1763-72. doi: 10.1056/NEJMcp1512658. Review. No abstract available. PMID: 27144851

8. Pearson AM, Martin BI, Lindsey M, Mirza SK. C2 Vertebral Fractures in the Medicare Population: Incidence, Outcomes, and Costs. J Bone Joint Surg Am. 2016 Mar 16;98(6):449-56. doi: 10.2106/JBJS.O.00468. PMID: 26984912

9. Mirza SK. Surgery and physical therapy likely yield similar outcomes in spinal stenosis. Evid Based Med. 2016 Feb;21(1):31. doi: 10.1136/ebmed-2015-110220. Epub 2016 Jan 4. No abstract available. PMID: 26729775

10. Martin BI, Deyo RA, Lurie JD, Carey TS, Tosteson AN, Mirza SK. Effects of a Commercial Insurance Policy Restriction on Lumbar Fusion in North Carolina and the Implications for National Adoption. Spine (Phila Pa 1976). 2016 Jun;41(11):647-55. doi: 10.1097/BRS.0000000000001390. PMID: 26679877 Free PMC

11. Ji S, Fan X, Paulsen KD, Roberts DW, Mirza SK, Lollis SS. Intraoperative CT as a registration benchmark for intervertebral motion compensation in image-guided open spinal surgery. Int J Comput Assist Radiol Surg. 2015 Dec;10(12):2009-20. doi: 10.1007/s11548-015-1255-5. Epub 2015 Jul 21. PMID: 26194485

12. Ji S, Fan X, Paulsen KD, Roberts DW, Mirza SK, Lollis SS. Patient Registration Using Intraoperative Stereovision in Image-guided Open Spinal Surgery. IEEE Trans Biomed Eng. 2015 Sep;62(9):2177-86. doi: 10.1109/TBME.2015.2415731. Epub 2015 Mar 26. PubMed PMID: 25826802; PubMed Central PMCID: PMC4545737.

13. Martin BI, Lurie JD, Tosteson AN, Deyo RA, Farrokhi FR, Mirza SK. Use of bone morphogenetic protein among patients undergoing fusion for degenerative diagnoses in the

United States, 2002 to 2012. Spine J. 2015 Apr 1;15(4):692-9. doi: 10.1016/j.spinee.2014.12.010. Epub 2014 Dec 15. PubMed PMID: 25523380; PubMed Central PMCID: PMC4375057.

14. Desai A, Ball PA, Bekelis K, Lurie J, Mirza SK, Tosteson TD, Weinstein JN. SPORT: Does incidental durotomy affect longterm outcomes in cases of spinal stenosis? Neurosurgery. 2015 Mar;76 Suppl 1:S57-63; discussion S63. doi: 10.1227/01.neu.0000462078.58454.f4. PubMed PMID: 25692369; PubMed Central PMCID: PMC4517439.

15. Weinstein JN, Tosteson AN, Tosteson TD, Lurie JD, Abdu WA, Mirza SK, Zhao W, Morgan TS, Nelson EC. The SPORT value compass: do the extra costs of undergoing spine surgery produce better health benefits? Med Care. 2014 Dec;52(12):1055-63. doi: 10.1097/MLR.0000000000000250. Erratum in: Med Care. 2015 Apr;53(4):386. PubMed PMID: 25334052; PubMed Central PMCID: PMC4504199.

16. Martin BI, Franklin GM, Deyo RA, Wickizer TM, Lurie JD, Mirza SK. How do coverage policies influence practice patterns, safety, and cost of initial lumbar fusion surgery? A population-based comparison of workers' compensation systems. Spine J. 2014 Jul 1;14(7):1237-46. doi: 10.1016/j.spinee.2013.08.018. Epub 2013 Nov 7. PubMed PMID: 24210578; PubMed Central PMCID: PMC4013264.

17. Martin BI, Lurie JD, Tosteson AN, Deyo RA, Tosteson TD, Weinstein JN, Mirza SK. Indications for spine surgery: validation of an administrative coding algorithm to classify degenerative diagnoses. Spine (Phila Pa 1976). 2014 Apr 20;39(9):769-79. doi: 10.1097/BRS.0000000000000275. PubMed PMID: 24525995; PubMed Central PMCID: PMC4018409.

18. Mirza SK, Martin BI, Goodkin R, Hart RA, Anderson PA. Developing a toolkit for comparing safety in spine surgery. Instr Course Lect. 2014;63:271-86. PubMed PMID: 24720313.

19. Mirza SK, Deyo RA, Heagerty PJ, Turner JA, Martin BI, Comstock BA. One-year outcomes of surgical versus nonsurgical treatments for discogenic back pain: a community-based prospective cohort study. Spine J. 2013 Nov;13(11):1421-33. doi: 10.1016/j.spinee.2013.05.047. Epub 2013 Jul 23. PubMed PMID: 23890947.

20. Deyo RA, Martin BI, Ching A, Tosteson AN, Jarvik JG, Kreuter W, Mirza SK. Interspinous spacers compared with decompression or fusion for lumbar stenosis: complications and repeat operations in the Medicare population. Spine (Phila Pa 1976). 2013 May 1;38(10):865-72. doi: 10.1097/BRS.0b013e31828631b8. PubMed PMID: 23324936; PubMed Central PMCID: PMC3855445.

21. Desai A, Bekelis K, Ball PA, Lurie J, Mirza SK, Tosteson TD, Zhao W, Weinstein JN. Variation in outcomes across centers after surgery for lumbar stenosis and degenerative spondylolisthesis in the spine patient outcomes research trial. Spine (Phila Pa 1976). 2013 Apr 15;38(8):678-91. doi: 10.1097/BRS.0b013e318278e571. PubMed PMID: 23080425; PubMed Central PMCID: PMC4031041.

22. Martin BI, Mirza SK, Franklin GM, Lurie JD, MacKenzie TA, Deyo RA. Hospital and surgeon variation in complications and repeat surgery following incident lumbar fusion for common degenerative diagnoses. Health Serv Res. 2013 Feb;48(1):1-25. doi: 10.1111/j.1475-6773.2012.01434.x. Epub 2012 Jun 20. PubMed PMID: 22716168; PubMed Central PMCID: PMC3465627.

23. Desai A, Bekelis K, Ball PA, Lurie J, Mirza SK, Tosteson TD, Zhao W, Weinstein JN. Spine patient outcomes research trial: do outcomes vary across centers for surgery for lumbar disc herniation? Neurosurgery. 2012 Oct;71(4):833-42. PubMed PMID: 22791040; PubMed Central PMCID: PMC4011394.

24. Karandikar M, Mirza SK, Song K, Yang T, Krengel WF 3rd, Spratt KF, Avellino AM. Complex pediatric cervical spine surgery using smaller nonspinal screws and plates and intraoperative computed tomography. J Neurosurg Pediatr. 2012 Jun;9(6):594-601. doi: 10.3171/2012.2.PEDS11329. PubMed PMID: 22656248.

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27. Cizik AM, Lee MJ, Martin BI, Bransford RJ, Bellabarba C, Chapman JR, Mirza SK. Using the spine surgical invasiveness index to identify risk of surgical site infection: a multivariate analysis. J Bone Joint Surg Am. 2012 Feb 15;94(4):335-42. doi: 10.2106/JBJS.J.01084. PubMed PMID: 22336972; PubMed Central PMCID: PMC3273877.

28. Deyo RA, Ching A, Matsen L, Martin BI, Kreuter W, Jarvik JG, Angier H, Mirza SK. Use of bone morphogenetic proteins in spinal fusion surgery for older adults with lumbar stenosis: trends, complications, repeat surgery, and charges. Spine (Phila Pa 1976). 2012 Feb 1;37(3):222-30. doi: 10.1097/BRS.0b013e31821bfa3a. PubMed PMID: 21494195; PubMed Central PMCID: PMC3167951.

29. Martin BI, Mirza SK, Flum DR, Wickizer TM, Heagerty PJ, Lenkoski AF, Deyo RA. Repeat surgery after lumbar decompression for herniated disc: the quality implications of hospital and surgeon variation. Spine J. 2012 Feb;12(2):89-97. doi: 10.1016/j.spinee.2011.11.010. Epub 2011 Dec 21. PubMed PMID: 22193055; PubMed Central PMCID: PMC3299929.

30. Pearson A, Lurie J, Tosteson T, Zhao W, Abdu W, Mirza S, Weinstein J. Who should have surgery for an intervertebral disc herniation? Comparative effectiveness evidence from the spine patient outcomes research trial. Spine (Phila Pa 1976). 2012 Jan 15;37(2):140-9. doi: 10.1097/BRS.0b013e3182276b2b. PubMed PMID: 21681140; PubMed Central PMCID: PMC3472961.

31. Zhu Y, Wu JJ, Weis MA, Mirza SK, Eyre DR. Type IX collagen neo-deposition in degenerative discs of surgical patients whether genotyped plus or minus for COL9 risk alleles. Spine (Phila Pa 1976). 2011 Nov 15;36(24):2031-8. doi: 10.1097/BRS.0b013e3181ffdd61. PubMed PMID: 21311409; PubMed Central PMCID: PMC3137765.

32. Deyo RA, Martin BI, Kreuter W, Jarvik JG, Angier H, Mirza SK. Revision surgery following operations for lumbar stenosis. J Bone Joint Surg Am. 2011 Nov 2;93(21):1979-86. doi: 10.2106/JBJS.J.01292. PubMed PMID: 22048092; PubMed Central PMCID: PMC3490709.

33. Deyo RA, Mirza SK, Martin BI. Error in trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. JAMA. 2011 Sep 14;306(10):1088. doi: 10.1001/jama.2011.1300. PubMed PMID: 21917578.

34. Desai A, Ball PA, Bekelis K, Lurie J, Mirza SK, Tosteson TD, Weinstein JN. SPORT: does incidental durotomy affect long-term outcomes in cases of spinal stenosis? Neurosurgery. 2011 Jul;69(1):38-44; discussion 44. doi: 10.1227/NEU.0b013e3182134171. PubMed PMID: 21358354; PubMed Central PMCID: PMC4517460.

35. Mirza SK. Folly of FDA-approval studies for bone morphogenetic protein. Spine J. 2011 Jun;11(6):495-9. doi: 10.1016/j.spinee.2011.05.009. PubMed PMID: 21729798.

36. Desai A, Ball PA, Bekelis K, Lurie JD, Mirza SK, Tosteson TD, Weinstein JN. Outcomes after incidental durotomy during first-time lumbar discectomy. J Neurosurg Spine. 2011 May;14(5):647-53. doi: 10.3171/2011.1.SPINE10426. Epub 2011 Mar 4. PubMed PMID: 21375385; PubMed Central PMCID: PMC4517441.

37. Cooper Z, Gross JA, Lacey JM, Traven N, Mirza SK, Arbabi S. Identifying survivors with traumatic craniocervical dissociation: a retrospective study. J Surg Res. 2010 May 1;160(1):3-8. doi: 10.1016/j.jss.2009.04.004. Epub 2009 May 13. PubMed PMID: 19765722.

38. Deyo RA, Mirza SK, Martin BI, Kreuter W, Goodman DC, Jarvik JG. Trends, major medical complications, and charges associated with surgery for lumbar spinal stenosis in older adults. JAMA. 2010 Apr 7;303(13):1259-65. doi: 10.1001/jama.2010.338. PubMed PMID: 20371784; PubMed Central PMCID: PMC2885954.

39. Wilson MA, Cooke DL, Ghodke B, Mirza SK. Retrospective analysis of preoperative embolization of spinal tumors. AJNR Am J Neuroradiol. 2010 Apr;31(4):656-60. doi: 10.3174/ajnr.A1899. Epub 2009 Nov 26. PubMed PMID: 19942697.

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41. Martin BI, Turner JA, Mirza SK, Lee MJ, Comstock BA, Deyo RA. Trends in health care expenditures, utilization, and health status among US adults with spine problems, 1997-2006. Spine (Phila Pa 1976). 2009 Sep 1;34(19):2077-84. doi: 10.1097/BRS.0b013e3181b1fad1. PubMed PMID: 19675510.

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43. Mirza SK. Deconstructing Pieces: Risks of Subgroup Reporting for Regulatory Clinical Trials. Commentary & Perspective on "Outcome of Lumbar Arthrodesis in Patients Sixty-five Years of Age or Older" by Steven D. Glassman, MD, et al. The Journal of bone and joint surgery. American volume. 2009 April; 94(4):783-790.Edit Citation Edit citation

44. Juratli SM, Mirza SK, Fulton-Kehoe D, Wickizer TM, Franklin GM. Mortality after lumbar fusion surgery. Spine (Phila Pa 1976). 2009 Apr 1;34(7):740-7. doi: 10.1097/BRS.0b013e31819b2176. PubMed PMID: 19282796.

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following lumbar spine surgery and the influence of spinal fusion procedures. Spine (Phila Pa 1976). 2007 Feb 1;32(3):382-7. PubMed PMID: 17268274.

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2. **Mirza** SK: Measuring the Safety of Spine Surgery. Interurban Orthopaedic Society Annual Meeting. Durham, North Carolina. October 2004.
3. **Mirza** SK: Justification and methodology for measuring end results. Annual Meeting of the Orthopaedic Guild. Seattle, Washington. September 2000.
4. **Mirza** SK: Management of cervical spine injuries: Timing of reduction and surgery. Montreal Orthopedic Association / Canadian Orthopaedic Association. Orlord, Canada. March 1999.
5. **Mirza** SK: Assessment of instability: Risk of neurologic injury with cervical spine lesions. Montreal Orthopaedic Association / Canadian Orthopaedic Association. Orlord, Canada. March 1999.
6. **Mirza** SK: Risk of neurologic deterioration with early reduction and surgery in cervical spine injuries. Singapore Orthopaedic Association / ASEAN Orthopaedic Association. Singapore. October 1998.

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National

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2. Mirza SK: Statistics 101 -- A Guide for the Perplexed. North American Spine Society Annual Spring Break Meeting, San Diego. March 9, 2006 (available at http://www.spine.org/springbreak06_presentations.cfm)
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7. **Mirza** SK: Conflicts of Interest for Orthopedics Research. White Symposium, Harvard Medical School, Boston, Massachusetts, October 19, 2005.
8. **Mirza** SK: Surgery for Chronic Back Pain: Artificial Disk Replacement. American College of Sports Medicine Annual Meeting, Nashville, Tennessee, June 2 – 4, 2005.
9. **Mirza** SK: Measuring the Quality of Care in Spine Surgery. Anesthesia Grand Rounds. Seattle. June 2005.
10. **Mirza** SK: Moderator: General Care Aspects of the Elderly. Synthes The Aging Spine Symposium, Seattle, Washington, September 25, 2004.
11. **Mirza** SK: Vertebroplasty and Kyphoplasty. Synthes The Aging Spine Symposium, Seattle, Washington, September 25, 2004.
12. **Mirza** SK: The Perspective on Low Back Pain: What Do We Know Now? Synthes Controversies & New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, University of Washington, Seattle, Washington, May 18, 2002.
13. **Mirza** SK: Moderator: Neoplastic and Infectious Disorders. Synthes Controversies & New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, University of Washington, Seattle, Washington, May 18, 2002.
14. **Mirza** SK: Lab: Sawbones: Deformity Correction USS, Click-X, Click-X Reduction Set. Synthes Controversies & New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, University of Washington, Seattle, Washington, May 18, 2002.
15. **Mirza** SK: Lecture: Vertebroplasty: Helpful or Sham? Synthes Controversies & New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, University of Washington, Seattle, Washington, May 18, 2002.
16. **Mirza** SK: Question and Answer: Outlook on Spine Reconstruction. Synthes Controversies & New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, University of Washington, Seattle, Washington, May 18, 2002.
17. **Mirza** SK: Percutaneous Vertebroplasty: History Indications, Techniques, and Complications. Synthes Annual Spine Meeting. Tucson, Arizona, November 17-20, 2001.
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32. **Mirza** SK, Chapman JR, Newell DW et al: Posterior cervical lateral mass fixation with a rigid locking implant. The 26th Annual Meeting of the Cervical Spine Research Society. 105-106, Atlanta, GA, 1998.
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49. **Mirza** SK: Classification of Scoliosis, AOA Resident Conference. 1994
50. **Mirza** SK: Stabilizing Properties of the Halo Apparatus, Cervical Spine Research Society. New York City, NY, 1993.
51. **Mirza** SK, Moquin R, Anderson PA, Steinmann J, Tencer AF, Varnau D: Stabilizing properties of the halo vest. The 21st Annual meeting of the Cervical Spine Research Society. 51-53, New York City, NY, 1993.

Regional and Local

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2. Cervical Spine Case Studies, Thoracolumbar Trauma Case Studies, Degenerative Lumbar Spine, Tumors, Infection Case Studies, "Evaluation of the Back Pain Patient" . AO ASIF Spine Course, Portland, OR, November 2003.
3. Spine fractures and dislocations. Rehabilitation Medicine Medical Science Course, University of Washington, 2002.
4. The perspective on low back pain: What do we know? Controversies and New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, Seattle, 2002.
5. Neoplastic and infections disorders. Controversies and New Techniques in the Reconstruction of the

Thoraco-Lumbar Spine, Seattle, 2002.

6. Reconstruction options: high or low tech? Controversies and New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, Seattle, 2002.
7. Vertebroplasty: helpful or sham? Controversies and New Techniques in the Reconstruction of the Thoraco-Lumbar Spine, Seattle, 2002.
8. Emergent Management of Spinal Injuries. Orthopedic resident conference, 2002.
9. Spinal Orthoses, Rehabilitation Orthotics course, 1999.
10. Principles of spinal surgery. Surgical nursing clerkship, 1999.
11. Low Back Pain: Evaluation and Management. Orthopedic resident conference. 1999.
12. Spinal Stenosis. Orthopedic resident conference. 1999.
13. Cervical Myelopathy. Orthopedic resident conference. 1999.
14. Spinal Orthoses, Rehabilitation Orthotics course, 1999.
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24. Critical Musculoskeletal Trauma Issues, Spokane Surgical Society, Coeur d'Alene, Idaho, 1997.
25. Information Systems and Outcome Assessment, Spokane Surgical Society, Coeur d'Alene, Idaho, 1997.
26. Introduction to Internal Fixation and AO Workshop, Orthopedic Resident Workshop, 1997.
27. Hardware: Type, Function and What Needs to be Known for Preoperative Planning, Trauma Radiology Program, 1997.
28. Spinal Orthoses, Rehab Orthotics Course, 1997.
29. AHCPR Guidelines for Low Back Pain: A Surgeon's Perspective, Seattle, 1996.
30. Pathophysiology of lumbar spinal stenosis, Rehabilitation Medicine Resident Conference, 1996.
31. Surgical approaches to the cervical spine, Orthopedic Resident Anatomy Laboratory, 1996.
32. Surgical approaches to the thoracolumbar spine, Orthopedic Resident Anatomy Laboratory, 1996.
33. Emergency room evaluation of spinal injuries, Orthopedic Student Conference, 1996.
34. Evaluation and management of low back pain, Orthopedic and Rehabilitation Medicine Resident Orientation, 1996.
35. Reliability of history and examination in evaluation of low back pain and sciatica, Harborview Orthopedic Conference, 1996.
36. Evaluation of cervical radiographs, Orthopedic Student Conference, 1996.
37. Mechanism of thoracolumbar fractures, Harborview Junior Resident Conference, 1996.
38. Low Back Pain AHCPR Guidelines, Seattle, 1996.
39. AO Basic and Advanced Course, Seattle, 1996.
40. Cervical spine management in rheumatoid arthritis, University of Washington Orthopedic Grand Rounds, 1995.
41. Occipitocervical injuries, Orthopedic Resident Conference, 1995.
42. Injuries of the lower cervical spine, Orthopedic Resident Conference, 1995.
43. Acute management of spinal cord injuries, Orthopedic Resident Conference, 1995.
44. Classification of thoracolumbar injuries, Orthopedic Resident Conference, 1995.
45. Management of thoracolumbar fractures, Orthopedic Resident Conference, 1995.
46. Decision making in lumbar disc herniation, Rehabilitation Medicine Resident Conference, 1995.
47. Trauma Update: Cervical Spinal Injuries, Yakima, 1995.
48. Trauma-Update: Emergent Management of Spinal Cord Injury, Yakima, 1995.

49. Decision-Making in Thoracolumbar Injuries, Yakima, 1995.
50. Trauma Update: Cervical Spinal Injuries, Spokane, 1995.
51. Trauma-Update: Emergent Management of Spinal Cord Injury, Spokane, 1995.
52. Decision-Making in Thoracolumbar Injuries, Spokane, 1995.Limitations of the halo apparatus in immobilizing the cervical spine, Resident Research Days, 1994.
53. Three-dimensional mathematical modeling of the subtalar joint, Resident Research days, 1993.
54. Spinal Instrumentation, Spinal Cord Injury Update, Seattle, 1993.
55. What is the optimal size of femoral head in total hip arthroplasty? Orthopedic Resident Conference, 1992.
56. Diabetic peripheral neuropathy, University of Washington Orthopedic Grand Rounds, 1992.
57. Heterotopic ossification in total hip arthroplasty, Orthopedic Resident Conference, 1991.
58. Electromagnetic stimulation of bone healing, University of Washington Orthopedic Grand Rounds, 1991.
59. Use of drains in elective orthopedic surgical procedures, University of Washington Orthopedic Grand Rounds, 1990.

Scientific Exhibits

1. Wiggins GC, **Mirza** SK, York JE, Bellabarba C, Kuntz C, Chapman JR, Shaffrey CI: Thoracic vertebral body screw placement using fluoroscopic, FluoroNav, and Stealth Station guidance: A cadaveric study. Scoliosis Research Society. Cleveland, OH, 2001.
2. Nuckley DJ, Carter JA, Eck M, **Mirza** SK, Ching RP: Age-related changes in compressive strength of vertebrae. The 46th Annual Meeting of the Orthopedic Research Society. Orlando, FL, 2000.
3. Tencer AF, **Mirza** SK, Martin D, Schafer G, Sackett R, Goodwin V: The effect of pre-impact head position on head/neck kinematics in rear impact automobile collisions: relationship to cervical spine whiplash. The 27th Annual Meeting of the Cervical Spine Research Society, pp. 261-62, Seattle, WA, 1999.
4. Tencer AF, **Mirza** SK: Estimating the flexion load acting on the cervical spine during "whiplash" resulting from a rear-end automobile accident. The 27th Annual Meeting of the Cervical Spine Research Society, Seattle, WA, 1999.
5. Raynak GC, Nuckley DJ, **Mirza** SK, Tencer AF, Ching RP: Neuroforaminal space stenosis associated with sub-injury cervical spine position. Transactions of the 44th Annual Meeting of the Orthopedic Research Society, New Orleans, LA, 1998.
6. **Mirza** SK, Chapman JR, Grady MS, Tencer AF, Boatright C, White AA: Assessment of instability in lower cervical spine injuries. The 24th Annual Meeting of the Cervical Spine Research Society, Palm Beach, FL, 1996.

Media Coverage

In Image-Guided Operating Suites, Surgeons See Real-Time MRI, CT Scans
Imaging during surgery reduces risk, gives more visual cues from inside in the body. The Wall Street Journal, February 16, 2015, by Laura Landro.
http://www.wsj.com/articles/in-image-guided-operating-suites-surgeons-see-real-time-mri-ct-scans-1424122291

Using Real-Time Data For Real-Life Healthcare Choices. Forbes, February 18, 2015, by Derek Klobucher.
http://www.forbes.com/sites/sap/2015/02/18/using-real-time-data-for-real-life-healthcare-choices-video/

Bad to the bone: A medical horror story. Fortune, September 18, 2012 by Mina Kimes.
http://fortune.com/2012/09/18/bad-to-the-bone-a-medical-horror-story/

How Tiger Woods Won the Back Surgery Lottery. New York Times, May 15, 2019, by Gina Kolata. https://www.nytimes.com/2019/05/15/sports/how-tiger-woods-pga-back-surgery.html

Washington State Health Care Authority

Agency medical director comments

Vertebroplasty, Kyphoplasty, and Sacroplasty

Azadeh Farokhi, MD, MPH, MOH
Associate Medical Director
Department of Labor and Industries

January 31, 2025

Background

- Vertebral Compression Fractures (VCFs) are a significant health burden
  - Over 700,000 VCFs occur annually in the US as a result of osteoporotic disease
  - 66,000 physician office visits
  - 45,000 - 70,000 hospitalizations each year
- Risk of fracture increases with age
  - Worldwide, there are approximately 9 million fractures per year as a result of osteoporosis
  - One in 3 females and 1 in 5 males over the age of 50 will have an osteoporotic fracture
- Considerable pain, loss of function, and decreased quality of life

Treatment of VCFs

- Conservative Management
  - Opioids/analgesics, Bracing, Physical Therapy, Nerve Root Blocks
- Percutaneous Vertebral/Sacral Augmentation
  - Minimally invasive spinal augmentation procedure using polymethylmethacrylate (PMMA) to treat spinal pain caused by fractures in the vertebrae/sacrum
  - Cementoplasty techniques are thought to relieve pain by stabilizing the fractured bone(s)

Percutaneous Vertebral/Sacral Augmentation

- Vertebroplasty
  - Involves injection of bone cement directly into a partially collapsed vertebral body under CT or fluoroscopic guidance
- Kyphoplasty
  - Is a modification of vertebroplasty that expands the partially collapsed vertebral body with an expansion device (e.g., inflatable balloon) before the injection of bone cement
- Sacroplasty
  - Extension of vertebroplasty, involving the injection of bone cement into the sacrum to repair sacral insufficiency fractures

2010 HTCC Review – Vertebroplasty, Kyphoplasty, and Sacroplasty

- Vertebroplasty, Kyphoplasty, and Sacroplasty (VKS)
  - VKS is not a covered benefit.
  - Final Findings & Decision VKS 2011 (wa.gov)
- Update literature review
  - 2016, 2017, 2020
- Substantial new evidence available for this update
  - 32 RCTs

Number and Coverage Topic

20101210A – Vertebroplasty, Kyphoplasty and Sacroplasty

HTCC Coverage Determination

Vertebroplasty, Kyphoplasty and Sacroplasty are **not a covered benefit**.

HTCC Reimbursement Determination

- **Limitations of Coverage**
  - N/A
- **Non-Covered Indicators**
  - Vertebroplasty, Kyphoplasty and Sacroplasty are not covered benefits

Agency Medical Director Group Concerns

Vertebroplasty, Kyphoplasty and Sacroplasty | Washington State Health Care Authority

AMDG Concerns – Initial Review

Safety = Medium

Efficacy = Medium

Cost = Medium

AMDG Concerns – Current Review

Safety = High

Efficacy = High

Cost = Medium

Washington State Health Care Authority

Current State Agency Policies

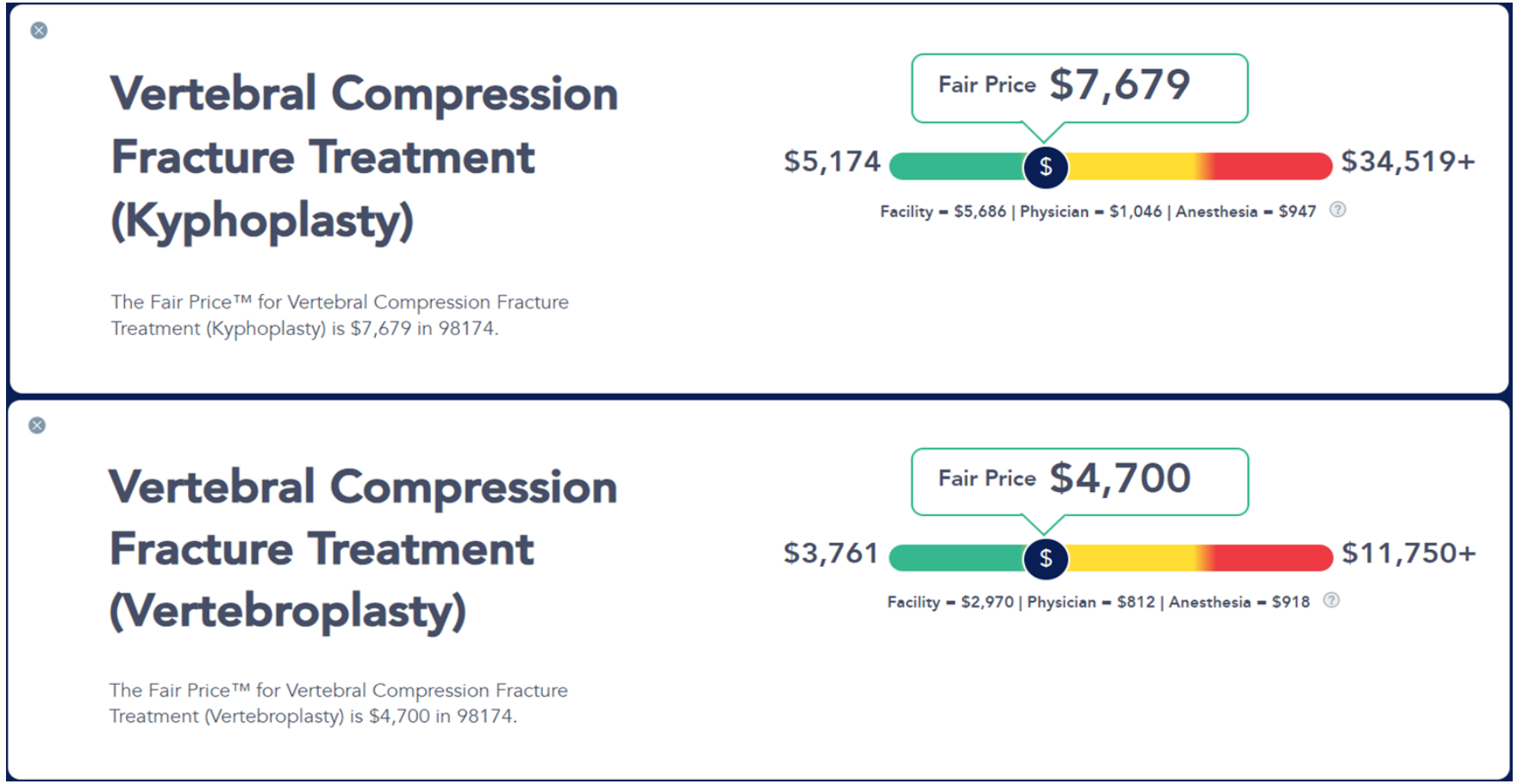
- Vertebroplasty, Kyphoplasty, Sacroplasty

Agency	Policy
UNIFORM MEDICAL PLAN (UMP)	Not Covered
MEDICAID	Not Covered
LABOR AND INDUSTRIES	Not Covered

Combined Utilization and Cost: VKS

- Due to low volume of claims, cost and utilization data would not be meaningful, therefore this data is not reported

Kyphoplasty/Vertebroplasty Cost Estimates (Healthcare Bluebook)



https://www.healthcarebluebook.com/explore-home/

Washington State Health Care Authority

Effectiveness: Vertebroplasty vs. Usual Care for OVCF

Effect/Improvement favors VP unless otherwise indicated

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (<4 on 0-10 VAS)	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
Pain Response (Complete relief)	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
VAS/NRS pain scores (0-10)	Large, 3 RCTs, N=343 (SOE: Moderate)	Moderate, 4 RCTs, N=432 (SOE: Low)†	Large, 3 RCTs, N=398 (SOE: Low)	Moderate, 5 RCTs, N=569 (SOE: Moderate)	Similar, 4 RCTs, N=523 (SOE: Low)	Moderate, 5 RCTs, N=567 (SOE: Low)
Function scores‡	No evidence	Small, 4 RCTs, N=432 (SOE: Low)	Small, 3 RCTs, N=398 (SOE: Moderate)	Small, 4 RCTs, N=440 (SOE: Moderate)	Small, 3 RCTs, N=398 (SOE: Moderate)	Small, 4 RCTs, N=436 (SOE: Moderate)

Effectiveness: Vertebroplasty vs. Sham for OVCF

Effect/Improvement favors VP unless otherwise indicated

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (≥30% improvement from baseline)	Large likelihood, 1 RCT, N=113 (SOE: Low)	Similar likelihood, 2 RCTs, N=186 (SOE: Moderate)	Moderate likelihood, 3 RCTs, N=313 (SOE: Moderate)	Small likelihood, 2 RCTs, N=176 (SOE: Moderate)	Small likelihood, 2 RCTs, N=171 (SOE: Moderate)	Small likelihood, 3 RCTs, N=339 (SOE: Moderate)
VAS pain scores (0-10)	Similar, 4 RCTs, N=500 (SOE: Low)	Similar, 6 RCTs, N=616 (SOE: Moderate)	Small, 6 RCTs, N=616 (SOE: High)	Small, 6 RCTs, N=605 (SOE: High)	Small, 5 RCTs, N=550 (SOE: High)	Similar, 5 RCTs, N=478 (SOE: Low)
RDQ function scores (0-24)	Similar, 2 RCTs, N=244 (SOE: Low)	Similar, 5 RCTs, N=531 (SOE: Low)	Small, 5 RCTs, N=566 (SOE: Moderate)	Similar, 5 RCTs, N=557 (SOE: Low)	Small, 5 RCTs, N=548 (SOE: Low)	Similar, 4 RCTs, N=432 (SOE: Low)

A Good Quality Sham-Controlled RCT

RESEARCH

Vertebroplasty versus sham procedure for painful acute osteoporotic vertebral compression fractures (VERTOS IV): randomised sham controlled clinical trial

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Additional material is published online only. To view please visit the journal online.

Cite this as: *BMJ* 2018;360:k1551
http://dx.doi.org/10.1136/bmj.k1551

Accepted: 19 March 2018

ABSTRACT

OBJECTIVE
To assess whether percutaneous vertebroplasty results in more pain relief than a sham procedure in patients with acute osteoporotic compression fractures of the vertebral body.

DESIGN
Randomised, double blind, sham controlled clinical trial.

SETTING
Four community hospitals in the Netherlands, 2011-15.

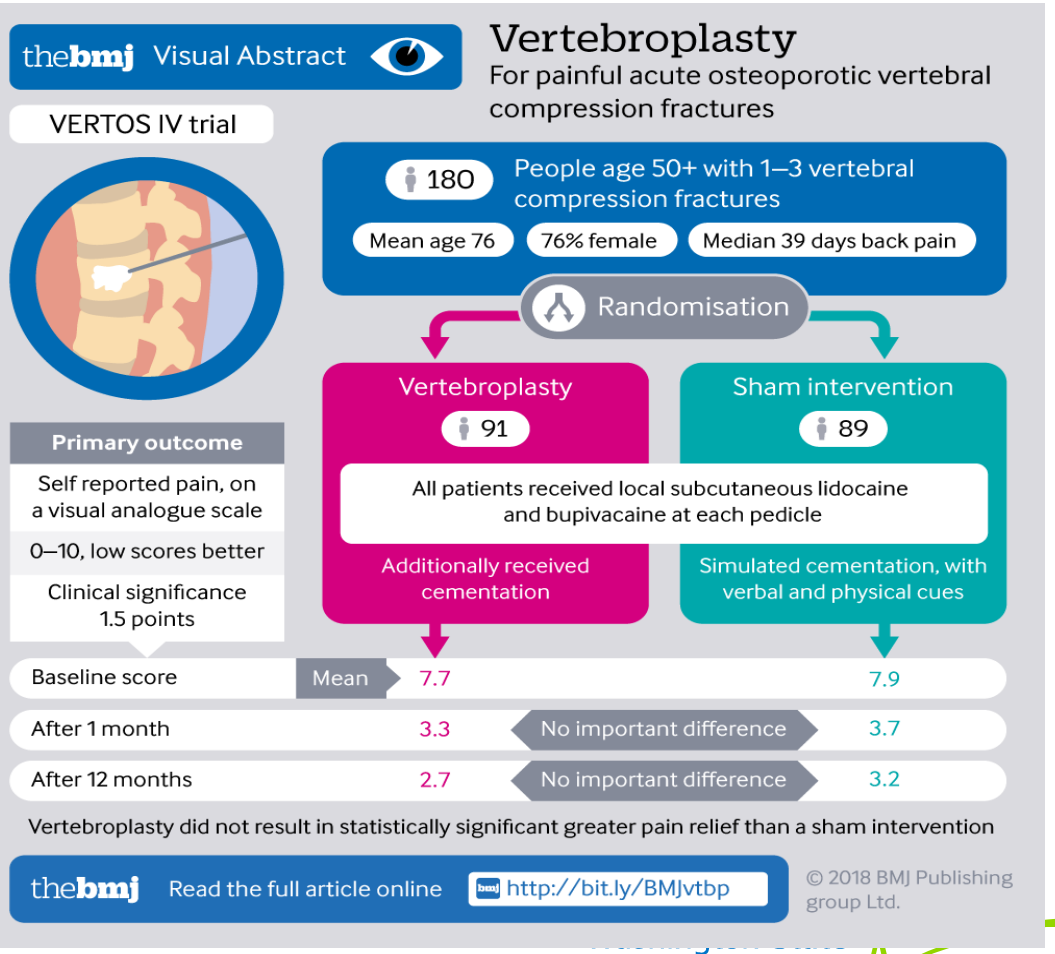
PARTICIPANTS
180 participants requiring treatment for acute osteoporotic vertebral compression fractures were randomised to either vertebroplasty (n=91) or a sham procedure (n=89).

INTERVENTIONS
Participants received local subcutaneous lidocaine (lignocaine) and bupivacaine at each pedicle. The vertebroplasty group also received cementation, which was simulated in the sham procedure group.

MAIN OUTCOME MEASURES
Main outcome measure was mean reduction in visual analogue scale (VAS) scores at one day, one week, and one, three, six, and 12 months, compared with baseline. The mean difference in VAS scores between groups was 0.20 (95% confidence interval −0.53 to 0.94) at baseline, −0.43 (−1.17 to 0.31) at one day, −0.11 (−0.85 to 0.63) at one week, 0.41 (−0.33 to 1.15) at one month, 0.21 (−0.54 to 0.96) at three months, 0.39 (−0.37 to 1.15) at six months, and 0.45 (−0.37 to 1.24) at 12 months. These changes in VAS scores did not, however, differ statistically significantly between the groups during 12 months' follow-up. The results for secondary outcomes were not statistically significant. Use of analgesics (non-opioids, weak opioids, strong opioids) decreased statistically significantly in both groups at all time points, with no statistically significant differences between groups. Two adverse events occurred in the vertebroplasty group: one respiratory insufficiency and one vasovagal reaction.

CONCLUSIONS
Percutaneous vertebroplasty did not result in statistically significantly greater pain relief than a sham procedure during 12 months' follow-up among patients with acute osteoporotic vertebral compression fractures.

TRIAL REGISTRATION
ClinicalTrials.gov NCT01200277.



Health Care Authority

Effectiveness: Vertebroplasty vs. Medial Branch Nerve or Facet Blocks for OVCF

Effect/Improvement favors VP unless otherwise indicated

Outcomes	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
VAS/NRS pain scores (0-10)	Moderate, 1 RCT, N=206 (SOE: Low)	Moderate, 2 RCTs, N=233 (SOE: Low)	Similar, 2 RCTs, N=230 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)*	Similar, 1 RCT, N=206 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low
RDQ function scores (0-24)	Moderate, 1 RCT, N=206 (SOE: Low)	Large, 1 RCT, N=206 (SOE: Low)*	Similar, 2 RCTs, N=230 (SOE: Low)	Similar, 2 RCTs, N=227 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)

Effectiveness: Kyphoplasty vs. Usual Care for OVCF

Effect/Improvement favors KP unless otherwise indicated

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
VAS/NRS pain scores (0-10)	INSUFFICIENT	Large, 1 RCT, N=300 (SOE: Low)†	Moderate, 1 RCT, N=300 (SOE: Low)†	Moderate, 2 RCTs, N=380 (SOE: Low)	Moderate, 1 RCT, N=300 (SOE: Low)†	*12, 24 months* Small, 1 RCT, N=300 (SOE: Low)
Function scores‡	INSUFFICIENT	INSUFFICIENT	Moderate, 1 RCT, N=300 (SOE: Low)†	Moderate, 1 RCT, N=300 (SOE: Low)†	Small, 1 RCT, N=300 (SOE: Low)	*12 months* Small, 1 RCT, N=300 (SOE: Low) *24 months* Similar, 1 RCT, N=300 (SOE: Low)

Effectiveness: Vertebroplasty vs. Kyphoplasty for OVCF

Effect/Improvement favors VP unless otherwise indicated

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (total effective rate)†	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
VAS/NRS pain scores (0-10)	Similar, 3 RCTs, N=313 (SOE: Moderate)	INSUFFICIENT	Similar, 2 RCTs, N=460 (SOE: Low)‡	Similar, 2 RCTs, N=419 (SOE: Low)‡	Similar, 3 RCTs, N=248 (SOE: Low)	*12-24 months*: Similar, 5 RCTs (N=673) (SOE: Low) *60 months*: INSUFFICIENT
Function scores§	Similar, 1 RCT, N=106 (SOE: Low)	No evidence	INSUFFICIENT	Similar, 2 RCTs, N=399 (SOE: Low)‡	Similar, 3 RCTs, N=238 (SOE: Moderate)	*12 months*: Similar, 5 RCTs (N=643) (SOE: Low) *24 months*: INSUFFICIENT

Evidence Considerations: Osteoporotic VCF

- Vertebroplasty
  - vs. Usual Care – some effect
  - vs. Sham – no difference
  - vs. Medial branch nerve or facet blocks – no difference
  - Secondary Outcomes
    - Opioid Use
      - Proportion of patients using strong opioids and weaker opioids was similar between patients receiving VP and those receiving sham treatment
      - VP was associated with a large increase in the likelihood of using major opioids at 12 months compared with usual care
- Kyphoplasty
  - vs. Usual Care – some effect
  - vs. Vertebroplasty – no difference
  - No studies to compare with sham

Evidence Considerations: Fractures Due to Tumors or Malignancy

- Kyphoplasty vs. Usual Care
  - Limited evidence
  - 1 RCT showed large improvement in pain and function with KP versus UC in patients with pathological fracture due to malignancy
  - High cross-over rate after 1 month
- Vertebroplasty vs. Kyphoplasty
  - Sparse and insufficient evidence due to high risk of bias, unknown consistency and imprecision for these studies

Safety Considerations – Vertebroplasty/Kyphoplasty

- Harms were variably defined and inconsistently reported
- Risk of mortality, new vertebral fractures, SAE were similar
- Cement leakage is very common
  - Following VP, range across RCTs of 40% to 91% of treated levels
  - Damage to the intervertebral disc, paravertebral soft tissue, and the spinal cord
  - Cardiac and pulmonary cement embolization
- Case Study
  - Cement pulmonary embolism - 3 years after vertebroplasty
  - Unknown long term effect

Cement Leakage Following Vertebroplasty in RCTs of VP versus Sham

Table 16. Cement leakage following vertebroplasty reported in RCTs of VP versus Sham

Author, year Quality	Mean PMMA volume (ml)	Cement leakage % (n/N)	Comments
Carli, 2023 Fair	1.4 ml	70% of treated levels (n=72 treated)	Detected on CT; Symptomatology NR
Firanescu, 2018 Good	5.1 ml	91.3% (105/115) of treated levels; Leakage type/location, % treated levels • Type 1 = disc above treated level (20%) • Type 2 = disc under treated level (15%) • Type 3 = perivertebral tissue (10%) • Type 4 = perivertebral veins (39%) • Type 5 = pulmonary (7%) • Type 6 = spinal canal (8%)	Any perceptible on post-procedural CT; recorded even very small cement traces outside the target vertebra. All leaks reported as asymptomatic
Hansen, 2019 Fair	2 to 4 ml	None observed (number of treated levels NR)	No further detail; Symptomatology NR
Buchbinder, 2009 and Staples 2015 Good	3 ml	36.8% (14/38) of patients 40.0% (18/45) of treated levels	Authors report as minimal; based on postprocedural images; Symptomatology NR

NR = not reported; PMMA = polymethylmethacrylate; RCT = randomized controlled trial.

Efficacy and Safety: Sacroplasty for Sacral Insufficiency Fractures (SIF)/Malignancy

- Evidence base evaluating the effectiveness and safety of sacroplasty remains sparse and insufficient due to high risk of bias, unknown consistency and imprecision for these studies

Cost-Effectiveness

- 6 full economic studies relevant to populations with OVCF and 1 relevant to cancer-related VCF
  - Only two U.S. based studies (both industry funded)
  - Relied in part on Medicare Claims data for mortality
    - Limitations: selection bias, inability to control confounding, missing data, etc.
    - Causal inference for mortality benefit is not possible
- In general, most economic studies suggest that vertebral augmentation may be cost effective

Selected Other Payers' Policies - VKS

Payer	Policy	Note
CMS	No NCD identified	
BCBS NC 5/2024	BCBSNC will provide coverage for percutaneous vertebroplasty, balloon kyphoplasty, or mechanical vertebral augmentation using an FDA cleared device when it is determined to be medically necessary and when the medical criteria and guidelines shown below are met.	Percutaneous sacroplasty and spineoplasty are considered investigational for all applications
Cigna 6/2024	Percutaneous vertebroplasty or percutaneous kyphoplasty is considered medically necessary when imaging (e.g., x-ray, MRI, bone scan) demonstrates recent (i.e., < 3 months) vertebral compression fracture (e.g., progressive collapse on x-ray, edema on MRI) that correlates with the patient's clinical signs and symptoms, and ANY of the following criteria is met:	Percutaneous sacroplasty is considered experimental, investigational, or unproven for ALL indications.
United Healthcare 2023	Medically Necessary: Percutaneous vertebroplasty and kyphoplasty for pain causing functional/physical impairment in cervical, thoracic, or lumbar vertebrae within 4 months of onset, unresponsive to optimal medical therapy for: - Osteoporotic VCF, Steroid-induced vertebral fracture, Osteolytic metastatic disease, Multiple myeloma, Aggressive vertebral hemangioma, Unstable fractures due to osteonecrosis (e.g., Kummel disease)	
Aetna 2023	Medically Necessary: Percutaneous vertebroplasty or kyphoplasty for persistent, debilitating pain in cervical, thoracic, or lumbar vertebrae due to: Primary malignant bone or marrow neoplasm; Osteoporotic or Steroid-Induced Fractures	Not Covered: Sacroplasty for osteoporotic sacral insufficiency fractures and other indications due to insufficient evidence
Premera Blue Cross 7/2024	Medically Necessary: Symptomatic osteoporotic vertebral fractures that have failed to respond to conservative treatment (e.g., analgesics, physical therapy, and rest) for at least 6 weeks; Or Symptomatic osteoporotic vertebral fractures that happened less than 6 weeks ago and have led to hospitalization or persist at a level that prevents ambulation; Or Severe pain due to osteolytic lesions of the spine related to multiple myeloma or metastatic malignancies	Percutaneous sacroplasty is considered investigational for all indications

Selected Guidelines on Use of VKS

Clinical Guidelines	Recommendations
American Academy of Orthopaedic Surgeons (2023)	Vertebroplasty: Not recommended for osteoporotic spinal compression fractures without neurological impairment (Strength of recommendation: Strong); Kyphoplasty: Option for osteoporotic spinal fractures; benefits in pain and function up to 6 months (Strength of recommendation: Limited)
American College of Rheumatology (ACR) (2022)	Vertebroplasty: Recommended for osteoporotic compression fractures with spinal deformity, worsening symptoms, or pulmonary dysfunction; no active management for asymptomatic VCFs without pain or activity restriction.
North American Spine Society (NASS), 2023	NASS recommends vertebral augmentation for vertebral body fractures due to osteoporosis, avascular necrosis, or neoplasm with severe pain unresponsive to conservative treatment, impaired daily activities, and confirmed acute fracture on imaging. No specific tools or products recommended; not applicable to traumatic fractures or primary vertebral tumors.
American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE), 2020	Vertebroplasty and Kyphoplasty are not recommended as first-line treatments for vertebral fractures due to unclear pain relief benefits and potential increased risk of adjacent vertebral fractures (Grade A, BEL 1; downgraded).
American Association of Neurological Surgeons (AANS), 2023	Candidates for Vertebroplasty or Kyphoplasty include patients with osteoporotic VCFs (present >2 weeks, moderate to severe pain, unresponsive to conservative therapy), painful metastases or multiple myelomas, painful vertebral hemangiomas, vertebral osteonecrosis, and for reinforcement of a weak vertebral body before surgical stabilization. Contraindications: Vertebroplasty or Kyphoplasty should not be performed in patients with fully healed or conservatively managed VCFs, VCFs older than one year, vertebral body collapse >80-90%, non-osteoporotic spinal curvature, spinal stenosis or herniated discs unrelated to VCF, untreated coagulopathy, osteomyelitis, discitis, or significant spinal canal compromise from bone fragments or tumors.
National Institute for Health and Care Excellence (NICE) (United Kingdom), 2013	Vertebroplasty/Kyphoplasty recommended for severe, ongoing pain from recent vertebral fractures unresponsive to pain management, and in cases of vertebral metastases without spinal cord compression or instability, following specialist agreement. Guidance last reviewed in 2014.

AMDG Recommendation

- Vertebroplasty, Kyphoplasty, and Sacroplasty are not a covered benefit for the treatment of vertebral compression fractures/sacral insufficiency fractures secondary to osteoporosis or tumors/malignancy

Questions?

Azadeh Farokhi, MD, MPH
faza235@lni.wa.gov

Washington State Health Care Authority

Washington State Health Care Authority

Vertebroplasty, kyphoplasty, and sacroplasty

Order of scheduled presentations:

	Name
1	Douglas Beall, MD – Society of Interventional Radiology
2	Emily Panteli – Medtronic, Stryker, and Merit Medical
3	Daniel Kreiner, MD
4	Neal Shonnard, MD
5	Ray Jensen, MD – Department of Interventional Radiology, University of Washington

Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

Instructions

This conflict of interest (COI) form must be completed by an applicant for appointment to the state of Washington Health Technology Clinical Committee (HTCC) or clinical expert serving in a temporary capacity on the HTCC, as well as appointment to any of its subcommittees or work groups.
Those wishing to provide public comment at HTCC meetings are also requested to complete this COI form, but are not required to do so.

Instructions specific to HTCC applicants

As stewards of public funds, the practicing clinicians who serve (or apply to serve) on the Committee strive to uphold the highest standards of transparency and impartiality. Identifying financial, professional, and other interests contributes to the effective management of perceived, potential, and/or real conflicts of interest/bias that could affect Committee determinations (WAC 182-55). Management of potential conflicts of interest on specific topics are addressed in committee bylaws.

1 Applicant information

First name: Douglas

Middle initial:

Last name: Beall

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.

Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B.	Medtronic, Merit Medical, Johnson & Johnson, I		✓ Self	Family
C	Artio, Sophiris, Eleven Biotherapeutics, Flow Fo		✓ Self	Family
D	Medtronic, Medical Metrics, Avanos, Relievant, B		✓ Self	Family
E	Medtronic, ReGelTec, Nanofuse, Talosix, Spinal		✓ Self	Family
F.	Stryker, Medtronic, Boston Scientific, Merit, Ava		✓ Self	Family
G	Stryker, Medtronic, Boston Scientific, Merit, Ava		✓ Self	Family
			Self	Family

3 Other interests

Please respond to the following questions. Disclose all interests that may apply to health technology assessment (HTA) topics covered in upcoming meetings.

Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Yes, many scientific articles.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

Yes, medical society guidelines.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

To sign this request, do not use the "Fill & Sign" function; instead, simply click in the signature field to add your signature.

Signature

Date

10-15-2024

Download this form and send the completed version to shtap@hca.wa.gov.

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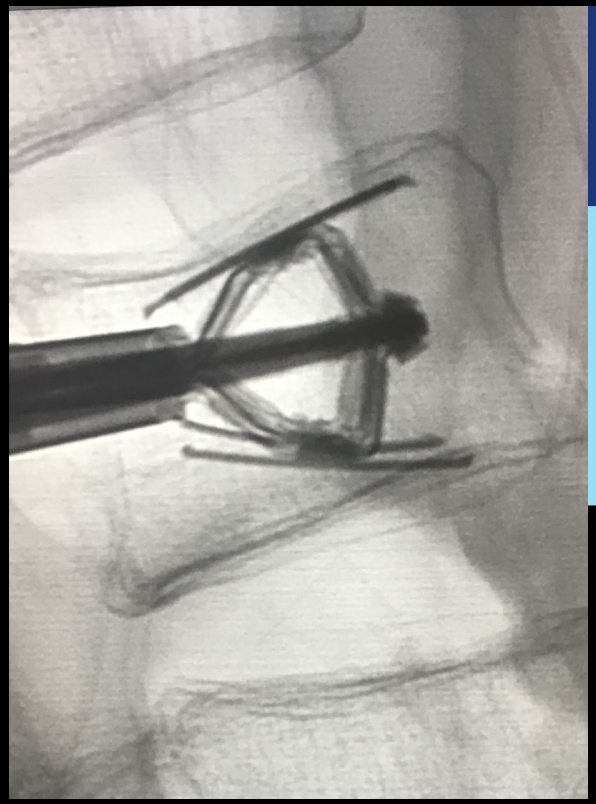
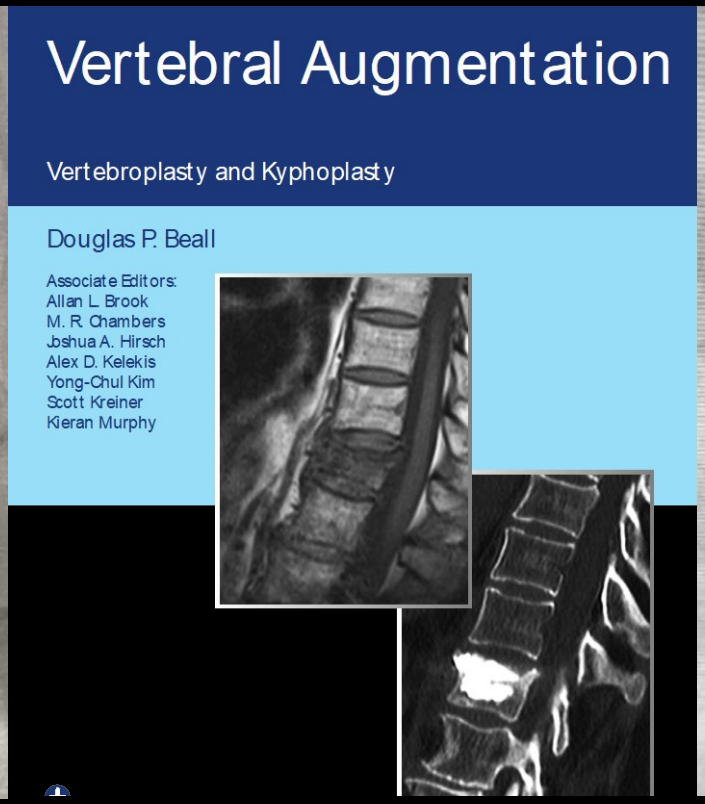
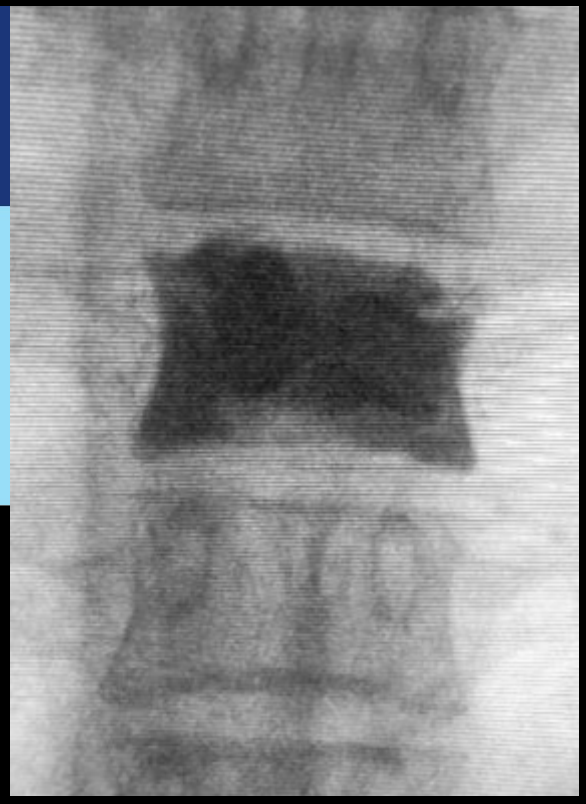
Treating Vertebral Compression Fractures: Data for Non-Surgical Mgt & Vertebral Augmentation







Douglas P. Beall, M.D.

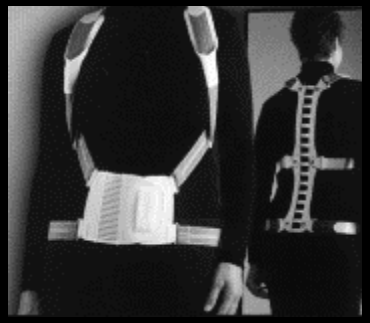
NSM vs **NSM** – RCTs bracing

- Bracing:
  - No brace / soft brace / rigid brace for 12 weeks
    → **No difference** in pain reduction[1]
  - No brace or brace for 8 weeks for acute (<72 h) fractures → **No difference** in pain reduction[2]

1. Kim HJ et al. J Bone Joint Surg Am 2014;96:1959-66; 2. Bailey CS et al. J Neurosurg Spine 2009;11:295-300

Efficacy of NSM – meta-analyses

- Non-surgical management[1]:
  - 5 studies
  - **Low-quality evidence** on benefits of opioids, NSAIDs, or spinal orthoses
  - Conclusion: **There is insufficient data to recommend the optimal conservative management for osteoporotic vertebral fractures.**



1. Rzewuska M et al. Eur Spine J 2015;24:702-14;

Kyphoplasty vs Vertebroplasty: Meta-Analysis of Vertebral Aug vs NSM

- 27 prospective multi-arm studies* with ≥ 20 pts
  - VAS ↓: BKP 5.07, VP 4.55, NSM 2.17
  - BKP sig better than VP in QOL improvement
- Hoyt et al. Level I & II studies (2020)
  - BKP sig better pain reduction comp to PVP & NSM

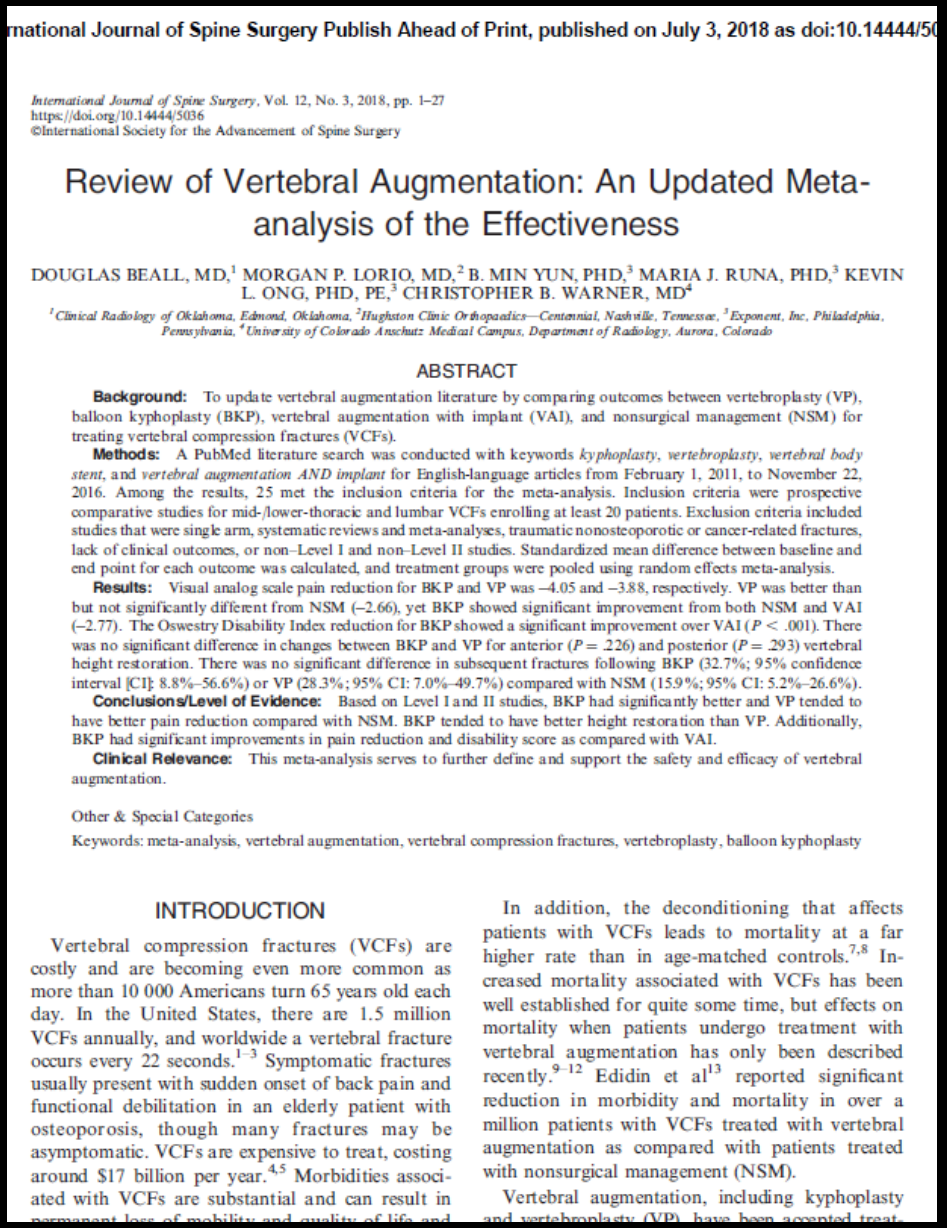
*Papanastassiou ID, Phillips FM, Meirhaeghe JV, et al. Comparing effects of kyphoplasty, vertebroplasty, and nonsurgical management in a systematic review of randomized and non-randomized controlled studies.

**Hoyt D, Urits I, Orhuru V, et al. Current concepts in the management of vertebral compression fractures. Curr Pain Headache Rep. 2020; 20:24(5).

Pain Reduction & Height Restoration

Conclusions:

- Based on Level I and II studies, BKP had significantly better pain reduction than NSM
- BKP tended to have better height restoration than VP



rnational Journal of Spine Surgery Publish Ahead of Print, published on July 3, 2018 as doi:10.14444/50

International Journal of Spine Surgery, Vol. 12, No. 3, 2018, pp. 1–27
https://doi.org/10.14444/5036

Review of Vertebral Augmentation: An Updated Meta-analysis of the Effectiveness

DOUGLAS BEALL, MD,[1] MORGAN P. LORIO, MD,[2] B. MIN YUN, PHD,[3] MARIA J. RUNA, PHD,[3] KEVIN L. ONG, PHD, PE,[3] CHRISTOPHER B. WARNER, MD[4]

[1]*Clinical Radiology of Oklahoma, Edmond, Oklahoma,* [2]*Hughston Clinic Orthopaedics—Centennial, Nashville, Tennessee,* [3]*Exponent, Inc, Philadelphia, Pennsylvania,* [4]*University of Colorado Anschutz Medical Campus, Department of Radiology, Aurora, Colorado*

ABSTRACT

Background: To update vertebral augmentation literature by comparing outcomes between vertebroplasty (VP), balloon kyphoplasty (BKP), vertebral augmentation with implant (VAI), and nonsurgical management (NSM) for treating vertebral compression fractures (VCFs).

Methods: A PubMed literature search was conducted with keywords *kyphoplasty*, *vertebroplasty*, *vertebral body stent*, and *vertebral augmentation AND implant* for English-language articles from February 1, 2011, to November 22, 2016. Among the results, 25 met the inclusion criteria for the meta-analysis. Inclusion criteria were prospective comparative studies for mid-/lower-thoracic and lumbar VCFs enrolling at least 20 patients. Exclusion criteria included studies that were single arm, systematic reviews and meta-analyses, traumatic nonosteoporotic or cancer-related fractures, lack of clinical outcomes, or non–Level I and non–Level II studies. Standardized mean difference between baseline and end point for each outcome was calculated, and treatment groups were pooled using random effects meta-analysis.

Results: Visual analog scale pain reduction for BKP and VP was –4.05 and –3.88, respectively. VP was better than but not significantly different from NSM (–2.66), yet BKP showed significant improvement from both NSM and VAI (–2.77). The Oswestry Disability Index reduction for BKP showed a significant improvement over VAI ($P < .001$). There was no significant difference in changes between BKP and VP for anterior ($P = .226$) and posterior ($P = .293$) vertebral height restoration. There was no significant difference in subsequent fractures following BKP (32.7%; 95% confidence interval [CI]: 8.8%–56.6%) or VP (28.3%; 95% CI: 7.0%–49.7%) compared with NSM (15.9%; 95% CI: 5.2%–26.6%).

Conclusions/Level of Evidence: Based on Level I and II studies, BKP had significantly better and VP tended to have better pain reduction compared with NSM. BKP tended to have better height restoration than VP. Additionally, BKP had significant improvements in pain reduction and disability score as compared with VAI.

Clinical Relevance: This meta-analysis serves to further define and support the safety and efficacy of vertebral augmentation.

Other & Special Categories

Keywords: meta-analysis, vertebral augmentation, vertebral compression fractures, vertebroplasty, balloon kyphoplasty

INTRODUCTION

Vertebral compression fractures (VCFs) are costly and are becoming even more common as more than 10 000 Americans turn 65 years old each day. In the United States, there are 1.5 million VCFs annually, and worldwide a vertebral fracture occurs every 22 seconds.[1–3] Symptomatic fractures usually present with sudden onset of back pain and functional debilitation in an elderly patient with osteoporosis, though many fractures may be asymptomatic. VCFs are expensive to treat, costing around $17 billion per year.[4,5] Morbidities associated with VCFs are substantial and can result in

In addition, the deconditioning that affects patients with VCFs leads to mortality at a far higher rate than in age-matched controls.[7,8] Increased mortality associated with VCFs has been well established for quite some time, but effects on mortality when patients undergo treatment with vertebral augmentation has only been described recently.[9–12] Edidin et al[13] reported significant reduction in morbidity and mortality in over a million patients with VCFs treated with vertebral augmentation as compared with patients treated with nonsurgical management (NSM).

Vertebral augmentation, including kyphoplasty

Meta-Analyses of Vertebral Aug

- According to Papanastassiou et al., as of Feb 1, 2011 there are 1,587 articles in the English language
- This included 27 Level I and Level II studies

Eur Spine J
DOI 10.1007/s00586-012-2314-z

REVIEW ARTICLE

Comparing effects of kyphoplasty, vertebroplasty, and non-surgical management in a systematic review of randomized and non-randomized controlled studies

Ioannis D. Papanastassiou · Frank M. Phillips · Jan Van Meirhaeghe · James R. Berenson · Gunnar B. J. Andersson · Gary Chang · Brent J. Small · Kamran Aghayev · Frank D. Vrionis

Received: 20 August 2011 / Revised: 16 November 2011 / Accepted: 9 April 2012
© Springer-Verlag 2012

Abstract *Purpose* To determine if differences in safety or efficacy exist between balloon kyphoplasty (BKP), vertebroplasty (VP) and non-surgical management (NSM) for the treatment of osteoporotic vertebral compression fractures (VCFs). *Methods* As of February 1, 2011, a PubMed search (key words: kyphoplasty, vertebroplasty) resulted in 1,587 articles out of which 27 met basic selection criteria (prospective multiple-arm studies with cohorts of ≥20 patients).

This systematic review adheres to preferred reporting items for systematic reviews and meta-analyses (PRISMA) guidelines. *Results* Pain reduction in both BKP (−5.07/10 points, $P < 0.01$) and VP (−4.55/10, $P < 0.01$) was superior to that for NSM (−2.17/10), while no difference was found between BKP/VP ($P = 0.35$). Subsequent fractures occurred more frequently in the NSM group (22 %) compared with VP (11 %, $P = 0.04$) and BKP (11 %, $P = 0.01$). BKP retained greater kyphosis reduction than VP (4.8° vs. 1.7°, $P < 0.01$). Quality of life (QOL) improvement showed superiority of BKP over VP ($P = 0.04$), along with a trend for disability improvement ($P = 0.08$). Cement extravasation was less frequent in the BKP ($P = 0.01$). Surgical intervention within the first 7 weeks yielded greater pain reduction than VCFs treated later. *Conclusions* BKP/VP provided greater pain relief and fewer subsequent fractures than NSM in osteoporotic VCFs. BKP is marginally favored over VP in disability improvement, and significantly favored in QOL improvement. BKP had a lower risk of cement extravasation and resulted in greater kyphosis correction. Despite this analysis being restricted to Level I and II studies, significant heterogeneity suggests that the current literature is delivering inconsistent messages and further trials are needed to delineate confounding variables.

Keywords Vertebral compression fractures · Osteoporotic · Balloon kyphoplasty · Vertebroplasty · Systematic review

Abbreviations
VCF(s) Vertebral compression fracture(s)
BKP Balloon kyphoplasty

Published online: 29 April 2012

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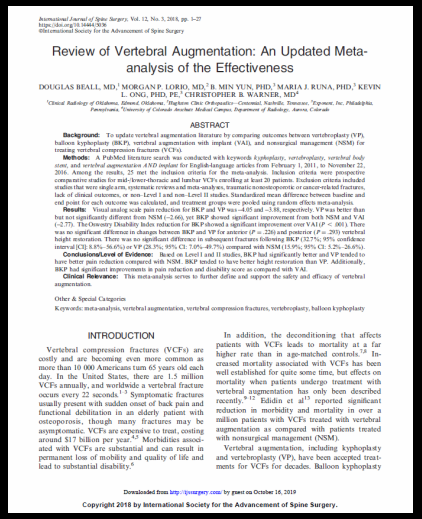
- This included 25 Level I and Level II studies



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In addition, the deconditioning that affects patients with VCFs leads to mortality at a far higher rate than in age-matched controls.[7,8] Increased mortality associated with VCFs has been well established for quite some time, but effects on mortality when patients undergo treatment with vertebral augmentation has only been described recently.[9,12] Edidin et al[12] reported significant reduction in morbidity and mortality in over a million patients with VCFs treated with vertebral augmentation as compared with patients treated with nonsurgical management (NSM).

Vertebral augmentation, including kyphoplasty and vertebroplasty (VP), have been accepted treatments for VCFs for decades. Balloon kyphoplasty

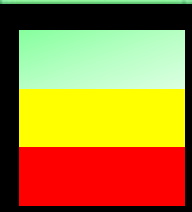
- ~250 manuscripts per yr re: Vertebral Augmentation
- 52 Level I & II studies

Papanastassiou ID, Phillips FM, Meirhaeghe JV, et al. Comparing effects of kyphoplasty, vertebroplasty, and nonsurgical management in a systematic review of randomized and non randomized controlled studies. Eur Spine J DOI 10.1007/s00586-012-2314-z

Beall DP, Lorio MP, Yun M, Runa MJ, Ong KL, Warner CB. Review of Vertebral Augmentation: An Updated Meta-analysis of the Effectiveness. *Int J Spine Surg*, July 3, 2018. Retrieved from http://ijssurgery.com/content/early/2018/07/02/5036

Vert Aug Literature Analysis – 52 Level I & II Studies

Authors	Conclusions
Boonen et al	BKP has improved QOL, pain relief, disability improvement, patient satisfaction for 2y over NSM. Overall better performance of BKP over 1 y, but patients improve around 2-y mark for NSM. BKP has improved disability (RMDQ) and activity days at 12 mo but not at 24 mo.
Borgstrom et al	BKP improves QOL, pain, disability compared to NSM over 2 y. Pain relief shown to have most contribution to QOL measures/scales.
Chen et al	PVP was found to be associated with greater pain relief and improved functional outcomes at 1 y compared with CT.
Clark et. al., Lancet 2016	Vertebroplasty was shown to reduce pain from osteoporotic spinal fractures of less than 6 wk when compared with a true placebo control.
Dohm et al	BKP and VP have SS less pain, disability, QOL, but not SS between groups. Both have similar AE profiles. Kyphoplasty had fewer cement leakages, a trend of longer fracture-free survival.
Dong et al	VP and BKP both improve pain scores, kyphotic angle, and vertebral height restoration.
Endres and Badura	Determined that the type of cement augmentation system used for primary osteoporosis patients does not matter. Overall, the vertebroplasty technique may be considered the surgical procedure of choice.



Vert Aug More Effective – Green
Sham equivalent to VP – Yellow
Sham More Effective than Vert Aug – Red – No Studies

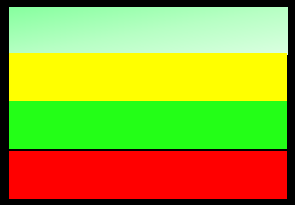
Authors	Conclusions
Farrokhi et al	Compared with patients who received OMT, patients who received PV had statistically significant improvements in QOL for 36 mo,VAS for 6 mo.
Folman and Shabat	SK system is technically superior in reconstructing the collapse and repair of the local kyphotic deformity, but this advantage is not manifest in the main index of procedure success—namely, pain relief. Both systems have a high level of safety.
Fritzell et al	Study could not demonstrate cost-effectiveness of BKP over control.
Korovessis et al	Supports KIVA implant as a reliable alternative technique to BKP for treating fresh (3 mo) osteoporotic fractures. The better radiological reduction of posttraumatic kyphosis associated with KIVA may at least theoretically influence the medium- and long-term results (less back pain, less frequent adjacent segment fractures).
Kroon et al	Found no beneficial effects of vertebroplasty over a sham procedure at 12 or 24 mo among patients with painful osteoporotic vertebral Fractures
Lee et al	When patients have no risk factors, conservative treatment for an initial 3 wk will be helpful in the treatment of acute OVCFs. However, if the patient failed conservative treatment, kyphoplasty also resulted in excellent results at 1 y after trauma.
Li et al	Both BKP and VP improved disability and pain scores, but BKP offered better spinal deformity correction and resulted in less cement leakage than VP.
Liu et al	BKP and VP have SS less pain, kyphotic angle, greater vertebral heights. No SS difference between BKP and VP for VAS pain scores after 5 y.

Authors	Conclusions
Movrin	Correction of the vertebral morphology and prevention of further deterioration achieved with BKP probably has a positive effect on the spinal biomechanics and thus reduces the incidence of subsequent fracture.
Nakano et al	Vertebroplasty using CPC following cavity formation of VB provided better clinical and radiological results than conservative treatment for osteoporotic burst fracture in patients without neural deficit.
Otten et al	Kiva is superior to BKP with pain VAS scores. Disability improvement was similar across Kiva and BKP. Both groups had vertebral height restoration and same risk of cement extravasation. Kiva operation time is shorter
Staples et al	VP in placebo-controlled studies has failed to provide superior pain relief or functional benefit compared with placebo, but the study did not observe an increase in subsequent fracture risk beyond that experienced by those with vertebral fractures.
Tutton et al	Kiva should be seriously considered to reduce pain, decrease disability, and improve quality of life in patients with painful VCFs. The Kiva system is noninferior to BKP in its ability to safely relieve pain and improve function in the treatment of osteoporotic VCFs.
Van Meirhaeghe	Compared with NSM, BKP rapidly reduces pain and improves function, disability, and QOL during the course of 2 y and the reduction in pain. EQ-5D QOL, patient satisfaction, and kyphotic angulation remain statistically significant at all time points.

Authors	Conclusions
Wang et al42	HVCV has a lower cement leakage rate. HVCV is recommended for the treatment of OVCFs. BKP is more effective in vertebral height restoration.
Werner et al15	No beneficial effect of vertebral body stenting over balloon kyphoplasty with regard to kyphotic correction, cement leakage.
Yang et al43	Vertebroplasty-BF: Bone cement distribution was more physiological. Lumped distribution was avoided. Sufficient bone cement injection was possible without increasing the rate of bone cement leakage. It can be considered as a compatible option for the osteoporotic compression fracture and has the advantages of both conventional vertebroplasty and kyphoplasty.
Yokohama et al44	The vertebral height restoration and kyphotic changes that were achieved after surgery largely depended on the preoperative vertebral mobility in not only the patients treated by VP but also those treated by BKP. The use of the balloon in BKP contributed little to the resolution of the vertebral deformities following surgery.

Sham Trial Summaries

Buchbinder et al.; Spine J 2010	No difference between VP and SHAM up to 6 months
Kallmes et al.; N Engl J Med 2009	No difference between VP and SHAM up to 1 month
Clark et. al., Lancet 2016	VP is superior to placebo for pain reduction in pts w/ OVCF's of < 6 wks in duration. No single measure which was in favour of placebo.
Hansson, et. al. Global Spine J 2016	Stat sig higher VAS-score in SHAM pts, both groups improved sig in all clinical parameters.
Firanescu et. al,	PercVP did not result in stat sig > pain relief than sham during 12 mos f/u in pts with acute OVCFs



Vert Aug More Effective – Green
Sham equivalent to VP – Yellow
VP More Effective than Sham – Bright Green
Sham/Bracing/Anything More Effective than Vert Aug – Red – No Studies

VCF treatment options
Vertebroplasty vs Sham Studies

Vertebroplasty vs sham	N-value	Follow-up	Key findings
Kallmes et al.* (NEJM 2009)[28]	**131** VP (n=68) Control (n=63)	**30 days**	• **Improvements in pain and pain-related disability** associated with osteoporotic VCFs in patients treated with vertebroplasty were **similar to the improvements in a control group**. VP ⟷ Sham
Buchbinder et al.* (NEJM 2009)[29]	**78** VP (n=38) Control (n=40)	**6 Months**	• **No beneficial effect of vertebroplasty as compared with sham procedure** in patient with painful osteoporotic vertebral fractures, at 1 week or at 1, 3, or 6 months after treatment. VP ⟷ Sham
Clark et al.* (Lancet 2016)[30]	**120** VP (n=61) Control (n=59)	**12 Months**	• **Vertebroplasty is superior to placebo for pain reduction** in **acute OVCFs of less than 6 wks in duration** VP > Sham
Hansen et al.* (Integrative J of Ortho and Traumatology 2016)[31]	**46** VP (n=22) Control (n=24)	**3 Months**	• **Vertebroplasty is statistically superior to sham for pain reduction** in **acute OVCFs** VP > Sham
Lohle et al.* (*12th Annual European Vertebral and Osteoarticular Interventional Therapeutics*. Paris, France, 2020)[32]	**80** VP (n=40) Control (n=49)	**12 Months**	• **Vertebroplasty is superior to sham in regard to pain reduction (VAS) and quality of life (Qualeffo)** in **chronic VCFs of > 3 months in duration** VP > Sham

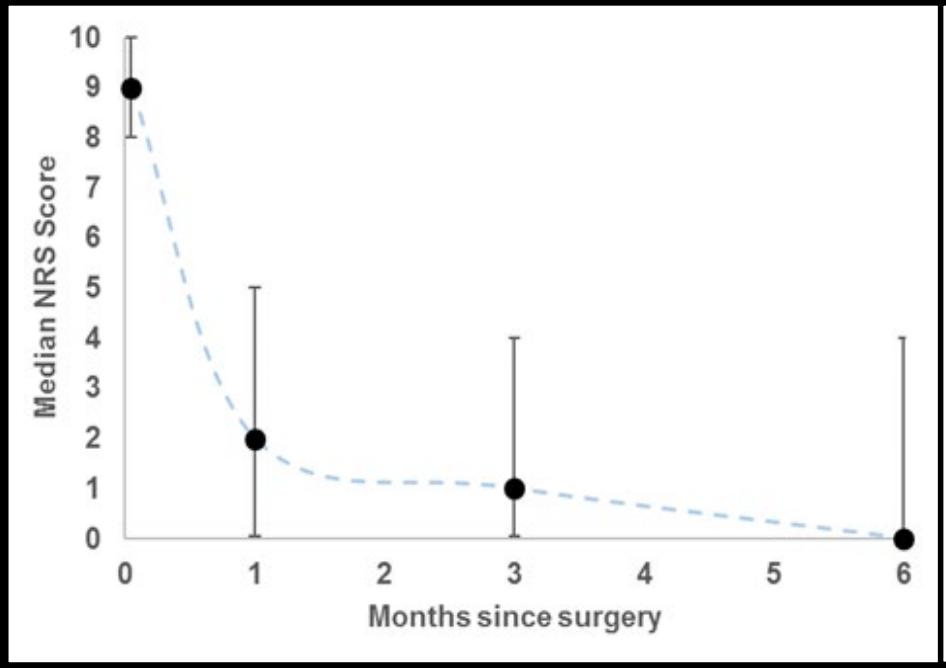
The US Vertebral Augmentation Registry: Findings from the World's Largest Registry of Vertebroplasty & Kyphoplasty.

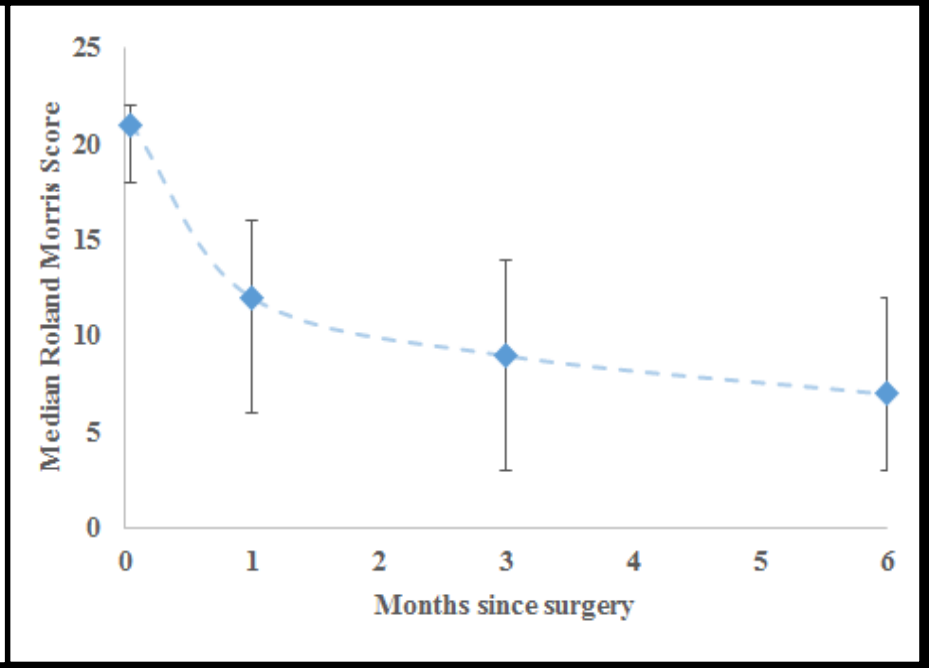
- Prospective enrollment @ 10 sites
- 1096 Total Pts
- 6 month data available for 732 pts
- Painful, acute/subacute, VCF's
- 1° Endpoints: NRS back pain, RMDQ
- 2° endpoints: AE's, cement extrav, hospital readmission

Patient Demographics and Baseline Characteristics

Characteristics		N (%)
N		732
Age, mean (SD)		78.1 (10.5)
Female		529 (72.3%)
Steroids use	No	275 (37.6%)
	Yes	91 (12.4%)
Smoking History	Current Smoker	45 (6.1%)
	Former Smoker	143 (19.5%)
Failure of conservative medical management for back pain	No	114 (15.6%)
	Yes	616 (84.2%)
Received non-operative treatment	No	23 (3.1%)
	Yes	530 (72.4%)
Procedure Technique	Balloon Kyphoplasty	419 (76.9%)
	Vertebroplasty	75 (13.8%)
	missing	187 (25.5%)

Finding of the US Vert Aug Registry: **Results**





Mean VAS Reduction from 8.7 to 2

Median VAS Reduction from 9 to 0 at 6 mos

Roland Morris decrease from 21 to 7 at 6 mos

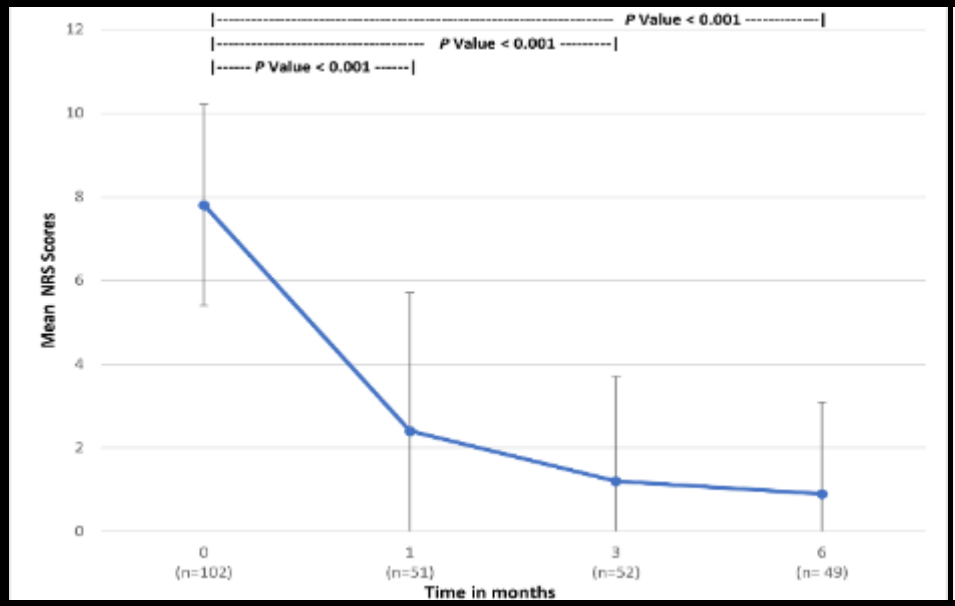
The US Sacroplasty Registry: Findings from an Interim Analysis of the First 102 Patients

- Prospective enrollment @ 10 sites
- 102 Total Pts
- 6 month data for 102 pts
- Painful, acute/subacute/chronic SIFs
- 1° Endpoints: NRS back pain, RMDQ
- 2° endpoints: AE's, cement extrav, hosp readmission, neurolotic deficits, & death

Patient Demographics and Baseline Characteristics

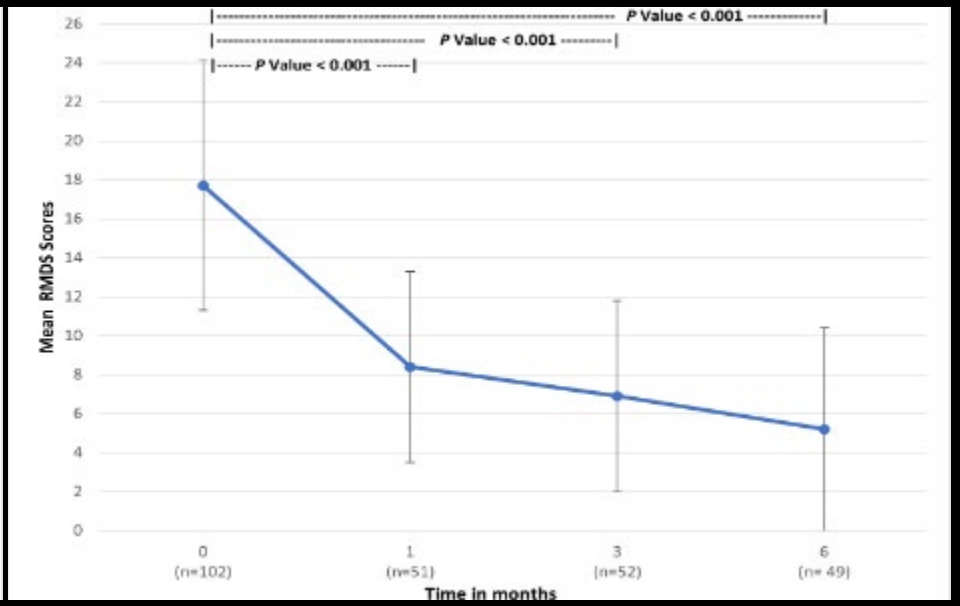
Characteristics		N (%)
N		102
Age, mean (SD)		74.1 (10.1)
Female		70 (68.6%)
Steroids use	Yes	15 (14.7%)
Smoking History	Current Smoker	17 (16.7%)
	Former Smoker	34 (33.3%)
Failure of NSM	No	6 (5.9)
	Yes	95 (93.1)
Length of NSM prior to surgery, n (%)	< 1 Month	36 (35.3)
	Betw 1 & 4 Month	43 (42.2)
	> 4 Months	16 (15.7)
Imaging Guidance Used	CT	36 (35.3)
	Fluoroscopy	59 (57.8)
	CT & Fluoro	6 (5.9)

Finding of the US Vert Aug Registry: Median VAS & RMDQ Scores



Mean NRS Reduction from 7.8 to 0.9 at 6 mos

Median NRS Reduction from 9 to a 0 at 6 mos



Mean RMDQ Reduction from 17.7 to 5.2 at 6 mos

Median RMDQ Reduction from 19.5 to a 4 at 6 mos

EVOLVE: Eval of QOL, Pain & ADL's for BKP in the Tx of Medicare Pts w/ OVCF's: **Methods**

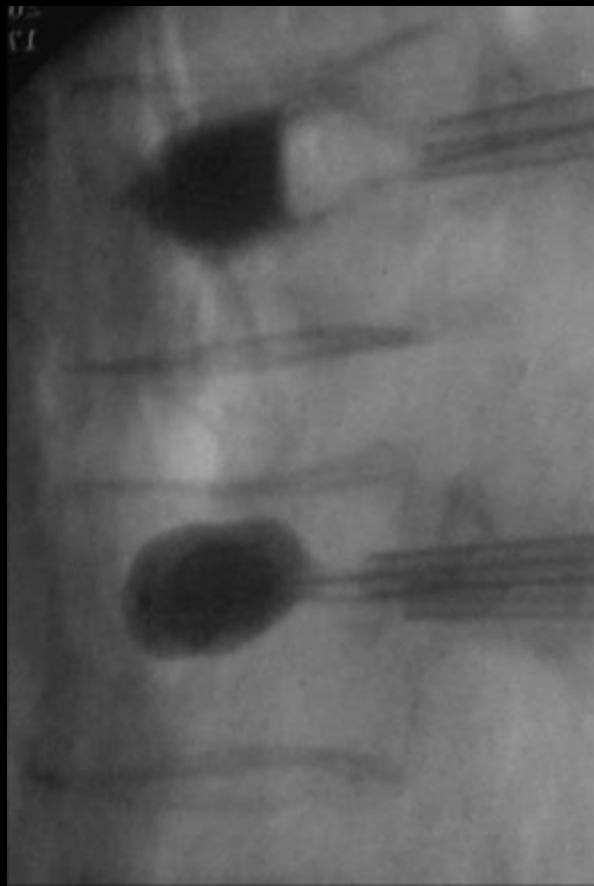
- Prospective enrollment @ 24 sites
- 354 Medicare eligible Pts
- 350 pts underwent BKP
- Painful, acute/subacute, VCF's
- 4 Co-Primary Endpoints: NRS back pain, ODI, SF-36v2 PCS & EQ-5D @ 3 mos
- Data collected @ baseline, 1, 3, 6 & 12 mos

Patient Demographics and Baseline Characteristics

Variable		BKP (n=354)
Age, mean (range)		78.9 (51-100)
Female, n (%)		276 (78.0)
BMI, mean (range)		26.1 (12.6-43.7)
Caucasian, n (%)		333 (94.1)
Smoking, n (%)	Never	195 (55.1)
	Former	131 (37.0)
	Current	28 (7.9)
Working prior to VCF, n (%)		36 (10.2)
Working after VCF, n (%)		18 (5.1)
Estimated fracture age, mean (SD)		34.7 (27.8)
Etiology of VCF, n (%)	1º Osteoporosis	316 (89.3)
	2º Osteoporosis	30 (8.5)
	Cancer	8 (2.3)
Subjects with any Prior Fracture, n (%)	Yes	130 (36.7)
	No	224 (63.3)

EVOLVE: Eval of QOL, Pain & ADL's for BKP in Tx of Medicare Pts w/ OVCF's: **Discussion**

- EVOLVE Showed stat sig differences in ALL PRIMARY ENDPOINTS at ALL TIME POINTS
  - 4 Co-Primary Endpoints: NRS back pain, ODI, SF-36v2 PCS & EQ-5D @ 3 mos
  - 2° End Pts: Amb status, Ltd Activity & Bedrest Days, Barthel Ind, Med Usage, VBA & Vert Height Δ, Cement Extrav; New VCF's, AE's
  - NRS: 8.7 to 2.7 (↓6.0) & ODI 63.4 to 27.1 (↓36.3)

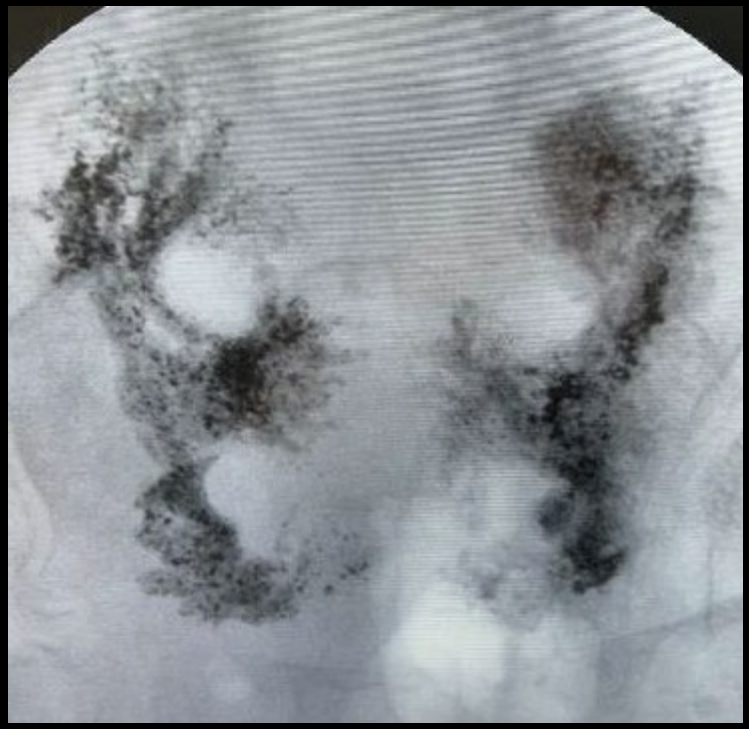


Mean Pain Reduction Scores: Real World/Post Market Compared w/ RCTs

- Sacroplasty Registry – 6.9 pts
- Kyphoplasty: EVOLVE Trial – 6.0 pts
- US Vert Aug Registry – 6.7 pts

Vs

- INVEST – 3.5 pts
- Buchbinder – 2.6 pts
- FREE Trial – 3.5 pts



Health Technology Clinical Committee Conflict of Interest Disclosure

Washington State Health Care Authority

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1 Applicant information

First name: Emily

Middle initial: A

Last name: Panteli

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
Indicate the source and date of the financial interest. For each chosen category, include date and if your activities are ongoing.
Indicate the recipient. Family: spouse, domestic partner, child, stepchild, parent, sibling (his/her spouse or domestic partner) currently living in your home.

Financial interest categories

Use these categories to indicate the nature of the financial interest:

A. Payment from parties with a financial or political interest in the outcome of work as part of your appointment or activity.
B. Employment including work as an independent contractor, consultant, whether written or unwritten.
C. Ownership or owning stock (stock, options, warrants) or holding debt or other significant proprietary interests or investments in any third party that could be affected.
D. Receiving a proprietary research grant or receiving patents, royalties, or licensing fees.
E. Participating on a company's proprietary governing boards.
F. Participating in a speakers bureau.
G. Receiving honoraria.

Please list your financial interests on the next page. Attach additional sheets if necessary.

Financial interest disclosures

Category (A-G)	Source of income and date	Amount	Recipient	
B	Employee of Stryker since November 2023 to pres	Salary (app	✔ Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Yes - coauthored paper currently being submitted for publication on topic of vertebral osteonecrosis and vertebral augmentation devices.

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

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Signature

Date

21 Oct 2024

Download this form and send the completed version to **shtap@hca.wa.gov**.

Or mail to:
Health Technology Assessment Program
Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

WASHINGTON STATE HEALTHCARE AUTHORITY

TIMELY & EQUITABLE ACCESS TO VERTEBRAL AUGMENTATION PROCEDURES

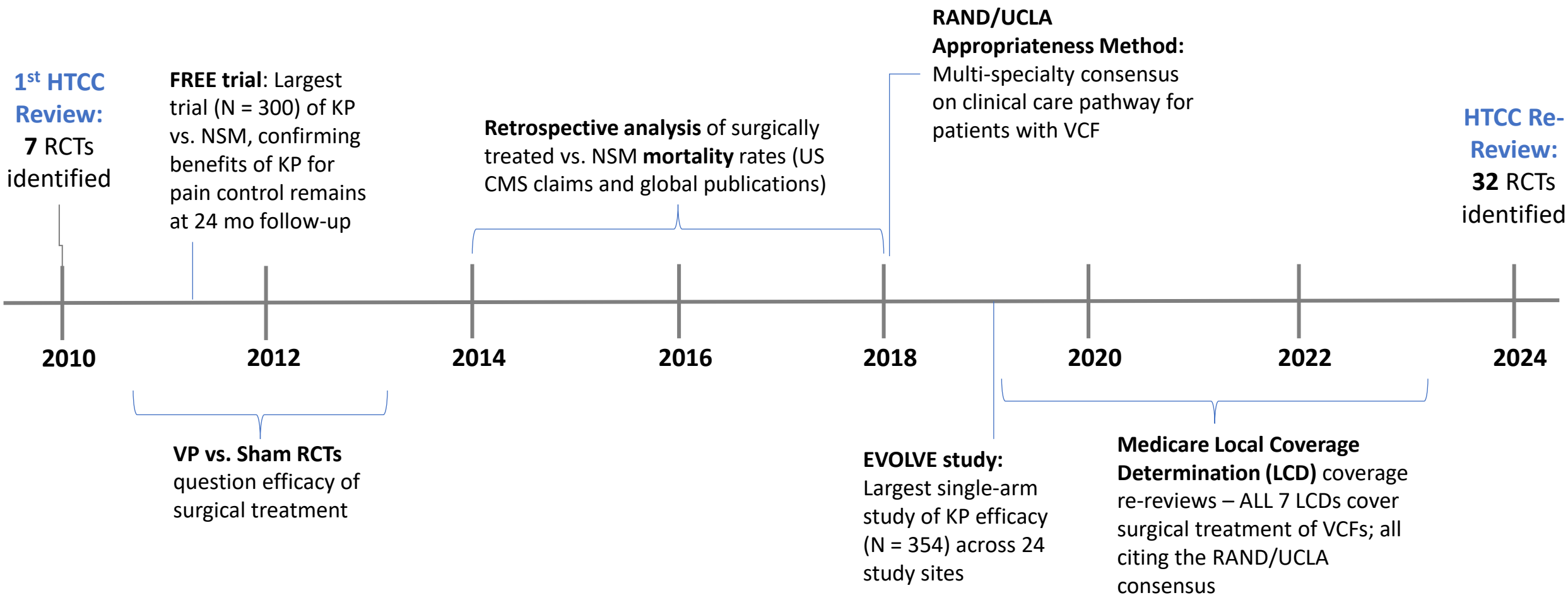
Public Meeting Comments
15 November 2024

Dr. Emily A. Panteli, *MB, BCh, BAO, MCh.*
Clinical Evaluation Specialist, Medical Affairs, Interventional Spine, Stryker Instruments
on Behalf of Manufacturers of VCF Technologies

Medtronic MERITMEDICAL stryker

EVIDENCE FOR TREATMENT OF VERTEBRAL COMPRESSION FRACTURES (VCF)

Since HTCC's first review – substantial additional evidence pointing to the efficacy and safety of surgical intervention over non-surgical management (NSM)



VCF Procedures are Broadly Covered by Medicare and Commercial Payers

Patients in WA state remain outliers with no access to surgical intervention.

Medicare Administrative Contractor (MAC)	Local Coverage Determination	Conditions Covered	Latest Update
CGS	L38201	Osteoporotic fractures Osteolytic vertebral metastatic disease or myeloma involving a vertebral body.	10/05/2023
FSCO	L34976	Osteoporotic fractures Osteolytic vertebral metastatic disease or myeloma involving a vertebral body	07/11/2021
NGS	L33569	Osteoporotic fractures Coverage will remain available for medically necessary procedures for other conditions not included in this LCD.	12/01/2020
Noridian	L34228 and L34106	Osteoporotic fractures Coverage will remain available for medically necessary procedures for other conditions not included in this LCD.	01/10/2021
Novitas	L35130	Osteoporotic fractures Osteolytic vertebral metastatic disease or myeloma involving a vertebral body	07/11/2021
Palmetto	L38737	Osteoporotic fractures Osteolytic vertebral metastatic disease or myeloma involving a vertebral body	07/20/2023
WPS	L38213	Osteoporotic fractures Osteolytic vertebral metastatic disease or myeloma involving a vertebral body	08/01/2024

HTCC COVERAGE RECOMMENDATIONS

Enable Timely & Equitable Access to Surgical Treatment of VCFs

- Clinical evidence is sufficient in support of a coverage decision for the treatment of osteoporotic VCFs.
- Treatment of malignant VCFs is imperative given the severe pain and quality of life implications of delayed/non-treatment.
- Sacroplasty evidence is evolving.

KEY MANUFACTURING CONTACTS

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1 Applicant information

First name: Daniel

Middle initial:

Last name: Kreiner

Phone number:

Email:

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.
List amounts totaling $1,000 or more from a single source.
Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.
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			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

3 Other interests

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

Chapter Author and Associate Editor of Vertebral Augmentation by Beall, Thieme Publishing, New York, NY

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

I have been involved an a Vertebral Augmentation Guideline being developed by the International Pain and Spine Intervention Society and am a co-author on vertebral augmentation AUCs published by the North American Spine Society. I am also currently the President of the North American Spine Society

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

Potentially. I am currently the President of the North American Spine Society that has published Coverage Policy Recommendations on Vertebral Augmentation, a non-coverage determination may conflict with policies we promote

4 Signature

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Signature

Date

1/16/2025

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Washington State Health Care Authority
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Olympia, WA 98504-2712

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1 Applicant information

First name: Neal

Middle initial: H

Last name: Shonnard MD

Phone number: 253-219-5228

Email: neal.shonnard@gmail.com

2 Financial interests

Disclose your financial interests and relationships occurring over the last twenty-four months.

List amounts totaling $1,000 or more from a single source.

Indicate the category of financial interest/relationship by referring to the disclosure categories below. Select the letter corresponding to your financial interest(s). You may indicate multiple categories.

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Financial interest disclosures

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	None		Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family
			Self	Family

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Have you authored, coauthored, or publicly provided an opinion, editorial, or publication related to any meeting topic? Topic(s):

JAMA Surgery Mar. 7, 2018: Development and Validation Prediction Model for Pain & Function Outcomes After Spine Surgery
Pain Physician 2020: Appropriate Management Vertebral Compression Fractured Vertebral Compression Fracture Registry

Are you involved in formulating policy positions or clinical guidelines related to any meeting topic? Topic(s):

No, however, LNI asked me to speak to the HTA in 2009 regarding cervical disc replacement for injured workers (highway patrolman). Subsequently, cervical disc replacement became a covered treatment.

Could a coverage determination based on a Committee topic conflict with policies you have promoted or are obliged to follow? Topic(s):

No

4 Signature

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Signature

Neal Shommarka

Date

10/22/24

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Or mail to:
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Washington State Health Care Authority
P.O. Box 42712
Olympia, WA 98504-2712

SUCCESSFUL COLLABORATION

VKS HTA Meeting
Jan 31, 2025

Neal Shonnard MD

SUCCESSFUL COLLABORATION LOOKS LIKE

PREDICTIVE OUTCOMES

*JAMA Surg*2018;153(7):634642.
doi:10.1001/jamasurg.2018.0072

Original Investigation

FREE

July 2018

Development and Validation of a Prediction Model for Pain and Functional Outcomes After Lumbar Spine Surgery

Sara Khor, MASc[1]; Danielle Lavallee, PharmD, PhD[1]; Amy M. Cizik, PhD, MPH[2]; Carlo Bellabarba, MD[2]; Jens R. Chapman, MD[3]; Christopher R. Howe, MD[4]; Dawei Lu, MD[5]; A. Alex Mohit, MD[6]; Rod J. Oskouian, MD[3]; Jeffrey R. Roh, MD, MBA[3]; Neal Shonnard, MD[7]; Armagan Dagal, MD[8]; David R. Flum, MD, MPH[1,9]

» Author Affiliations | Article Information

JAMA Surg. 2018;153(7):634-642. doi:10.1001/jamasurg.2018.0072

Editorial Comment

Related Articles

Key Points

Question Which patients are most likely to have improvement in function, back pain, and leg pain after lumbar fusion surgery?

Findings Using statewide prospective data from 15 hospitals and 1965 adult surgical candidates, 3 prediction tools were generated to predict the likelihood of improvements in function, back pain, and leg pain after lumbar fusion surgery. The predictive ability and calibration of these predictive tools were confirmed in a validation cohort.

Meaning These predictive tools could be incorporated into decision-making activities in the clinic and may be helpful in managing expectations for patients considering lumbar fusion surgeries.

SUCCESSFUL COLLABORATION LOOKS LIKE

REAL WORLD DATA

TALOSIX VCF REGISTRY

- Reliable Safety – 0.5% AE (cement leak 24%)
- Reliable Treatment Outcomes – Pain 6.5, RMDQ 11.5
- Reliable Data – Real World

Pain Physician 2020; 23:E343-E351 • ISSN 2150-1149

Management Pathway

Appropriate Management of Vertebral Fragility Fractures: Development of a Pathway Based on a Vertebral Compression Fracture Registry

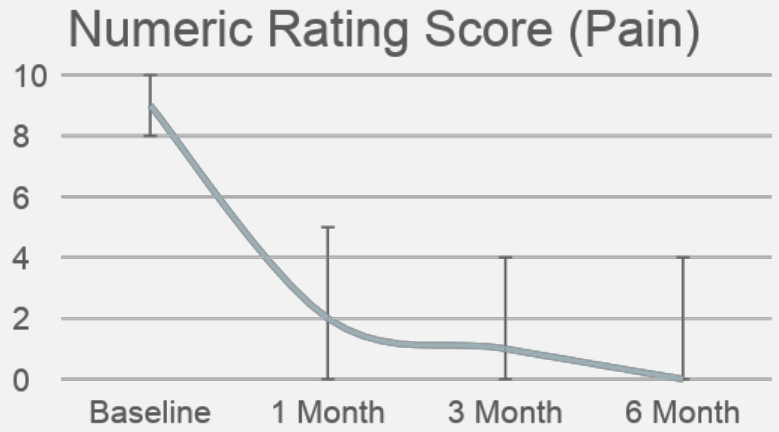
Neal H. Shonnard, MD[1], Sigurd Berven, MD[2], Paul A. Anderson, MD[3], Evert Verschuyl, MD[4], Justine Norwitz, MD[5], Nell Shonnard, BS[5], Sara Khor, MASc[6], Derrick D. Wagoner, DO[7], Edward S. Yoon, MD[8], and Douglas P. Beall, MD[9]

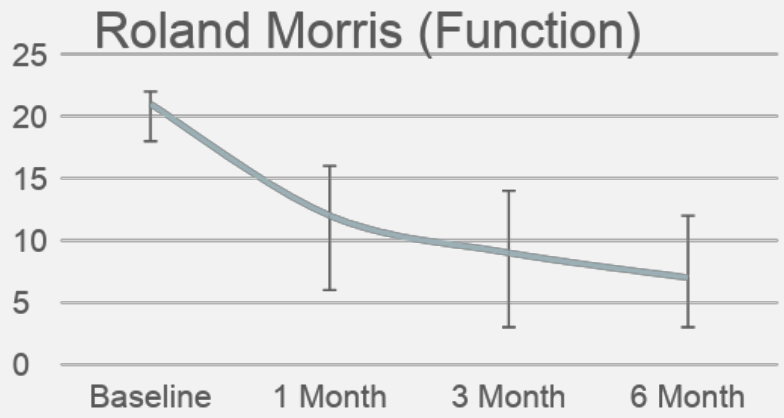
SUCCESSFUL COLLABORATION LOOKS LIKE

REAL WORLD DATA

REAL WORLD OUTCOMES

- What Really Works? Clinical Data Registries Find the Answer
- Registry Outcomes of Cement Augmentation for Osteoporotic Vertebral Compression Fractures





Vertebral Compression Fracture Registry. Pain Physician 2020; 23:E343-E351.

REGISTRY ROAD MAP

HETEROGENEITY

TALOSIX VCF REGISTRY
HETEROGENEITY OF TREATMENTS

Procedure Characteristics			
Procedure Technique Used (choose all that apply)			
Balloon Kyphoplasty (BKP) ○ Yes ○ No *If yes, indicate manufacturer:* Confidence ○ Yes ○ No Stryker ○ Yes ○ No Merit/ Dfine ○ Yes ○ No Synthes ○ Yes ○ No Globus ○ Yes ○ No Medtronic/ Kyphon ○ Yes ○ No IZI ○ Yes ○ No Osseon ○ Yes ○ No Other (specify): _____ ○ Yes ○ No None ○ Yes ○ No	**Cavity Creation** ○ Yes ○ No *If yes, indicate manufacturer:* Confidence ○ Yes ○ No Stryker ○ Yes ○ No Merit/ Dfine ○ Yes ○ No Synthes ○ Yes ○ No Globus ○ Yes ○ No Medtronic/ Kyphon ○ Yes ○ No IZI ○ Yes ○ No Osseon ○ Yes ○ No Other (specify): _____ ○ Yes ○ No None ○ Yes ○ No	**Vertebroplasty (VP)** ○ Yes ○ No *If yes, indicate manufacturer:* Confidence ○ Yes ○ No Stryker ○ Yes ○ No Merit/ Dfine ○ Yes ○ No Synthes ○ Yes ○ No Globus ○ Yes ○ No Medtronic/ Kyphon ○ Yes ○ No IZI ○ Yes ○ No Osseon ○ Yes ○ No Other (specify): _____ ○ Yes ○ No None ○ Yes ○ No	**Other** ○ Yes ○ No *If yes, please specify:* _____ *If yes, indicate manufacturer:* Confidence ○ Yes ○ No Stryker ○ Yes ○ No Merit/ Dfine ○ Yes ○ No Synthes ○ Yes ○ No Globus ○ Yes ○ No Medtronic/ Kyphon ○ Yes ○ No IZI ○ Yes ○ No Osseon ○ Yes ○ No Other (specify): _____ ○ Yes ○ No None ○ Yes ○ No

SUCCESSFUL COLLABORATION LESSONS

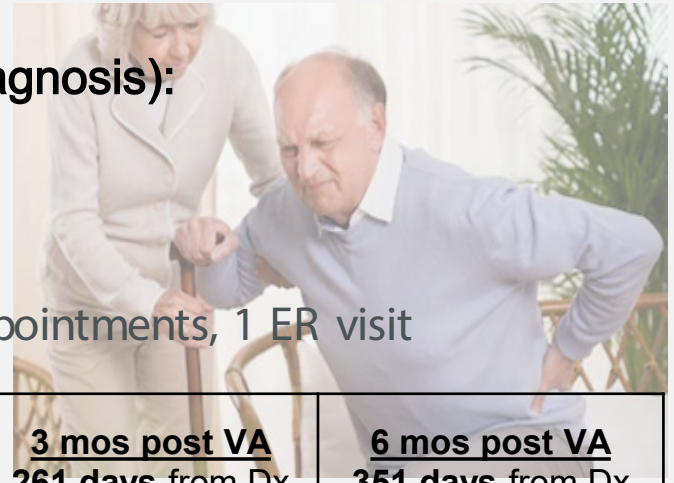
PROMOTE PATIENT'S INTERESTS

Prompt Care (VA 2 Days from diagnosis):

Positive impact on quality of life

- Cost $6,420
- 1 clinical appointment, 3 imaging appointments

	Pre-op VA **2 days from Dx**	**3 mos post VA** **92 days from Dx**	**6 mos post VA** **182 days from Dx**
Disability (Roland Morris)	20	1	3
Pain (NRS)	8	1	1



Delayed Care (VA 171 Days from diagnosis):

Negative impact on quality of life

- Cost $19,590
- 16 clinic appointments, 8 imaging appointments, 1 ER visit

	Pre-op VA **171 days from Dx**	**3 mos post VA** **261 days** from Dx	**6 mos post VA** **351 days** from Dx
Disability (Roland Morris)	20	5	9
Pain (NRS)	8	1	3

Shonnard, N et al. Pain Physician 2020; 23:E343-E351.Data on file, courtesy of Talosix

SUCCESSFUL COLLABORATION LESSONS

PAYER'S INTERESTS

Early Care (1 Day)

- Cost $6,420
- Only 3 imaging appointments

Positive impact on quality of life.

- Roland Morris: 20 (Baseline), 1 (Three Months), 3 (Six Months)
- NRS: 8 (Baseline), 1 (Three months), 1 (Six months)

Delayed Care (171 Days)

- Cost $19,590
- 16 clinic appointments, 8 imaging appointments, 1 ER visit

Negative impact on quality of life.

- Roland Morris: 20 (Baseline), 5 (Three Months), 9 (Six Months)
- NRS: 8 (Baseline), 1 (Three months), 3 (Six months)

PAYER COST OF DELAYED TREATMENT

PAYER'S INTERESTS

PAIN MEDICINE CASE REPORTS

ISSN 2768-5152

Volume 8, Number 7, pp.

TIME TO TREATMENT VERSUS HEALTH CARE UTILIZATION IN COMPRESSION FRACTURES TREATED WITH VERTEBRAL AUGMENTATION: THE VERTEBRAL AUGMENTATION CARE PATHWAYS CASE SERIES

Emanuel Narcis Husu, MD[1,2], Edward S. Yoon, MD[3], Neal H. Shonnard, MD[4], Justine Norwitz, MD[5], Nell Shonnard, BS[5], and Douglas P. Beall, MD[6]

Background: There is little data on the economics of the timing of percutaneous vertebral augmentation (PVA) for vertebral compression fractures (VCFs).

Case Report: The purpose of this case series is to compare health care utilization (HCU) costs vs the time to treatment (TTT) of the VCF. The BenchMarket Medical VCF Registry (now Talosix) was utilized. Patients receiving acute or intermediate treatment had the greatest pain and function improvement and the lowest HCU costs. Patients receiving delayed treatment had the least improvement and the highest (3-fold) HCU costs. Any TTT delay resulted in higher HCU costs and diminished benefits. The most beneficial PVA outcome and lowest HCU costs were recorded in patients whose PVA was expedited and performed within 3 months from injury.

THANK YOU

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1 Applicant information

First name: Ray

Middle initial:

Last name: Jensen

Phone number:

Email:

2 Financial interests

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No

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No

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4 Signature

I have read the Conflict of Interest Disclosure form. I understand the purpose of the form and agree to the application of the information to determine conflicts of interest. The information provided is true and complete as of the date the form was signed. If circumstances change, I am responsible for notifying HTA program staff in order to amend this disclosure. I will complete this form annually by July 1st of each year of committee membership (*applies to HTCC committee only*).

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Vascular & Interventional Radiology

UW Medicine

Mortality

ORIGINAL RESEARCH • EVIDENCE-BASED PRACTICE

Radiology

Mortality Outcomes of Vertebral Augmentation (Vertebroplasty and/or Balloon Kyphoplasty) for Osteoporotic Vertebral Compression Fractures: A Systematic Review and Meta-Analysis

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J.A.H. supported by a grant from the Harvey L. Neiman Health Policy Institute.

Conflicts of interest are listed at the end of this article.

See also the editorial by Jennings in this issue.

Radiology 2020; 295:96–103 • https://doi.org/10.1148/radiol.2020191294 • Content codes: MK IR

Background: Osteoporotic vertebral compression fractures (OVCFs) are prevalent, with associated morbidity and mortality. Vertebral augmentation (VA), defined as either vertebroplasty and/or balloon kyphoplasty (BKP), is a minimally invasive surgical treatment to reduce pain and further collapse and/or renew vertebral body height by introducing bone cement into fractured vertebrae. Nonsurgical management (NSM) for OVCF carries inherent risks.

Purpose: To summarize the literature and perform a meta-analysis on the mortality outcomes of patients with OVCF treated with VA compared with those in patients treated with NSM.

Materials and Methods: A single researcher performed a systematic literature review using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses, or PRISMA, guidelines. Online scientific databases were searched in April 2018 for English-language publications. Included studies investigated mortality in patients with OVCF with VA as the primary intervention and NSM as the comparator. A meta-analysis was performed for studies that reported hazard ratios (HRs) and 95% confidence intervals (CIs). HR was used as a summary statistic and was random-effect-models tested. The χ^2 test was used to study heterogeneity between trials, and the I^2 statistic was calculated to estimate variation across studies.

Results: Of the 16 included studies, eight reported mortality benefits in VA, seven reported no mortality difference, and one reported mixed results. Seven studies were included in a meta-analysis examining findings in more than 2 million patients with OVCF (VA = 382 070, NSM = 1 707 874). The pooled HR comparing VA to NSM was 0.78 (95% CI: 0.66, 0.92; $P = .003$), with mortality benefits across 2- and 5-year periods (HR = 0.70, 95% CI: 0.69, 0.71, $P < .001$; and HR = 0.79, 95% CI: 0.62, 0.9999, $P = .05$; respectively). Balloon kyphoplasty provided mortality benefits over vertebroplasty, with HRs of 0.77 (95% CI: 0.77, 0.78; $P < .001$) and 0.87 (95% CI: 0.87, 0.88; $P < .001$), respectively.

Conclusion: In a meta-analysis of more than 2 million patients, those with osteoporotic vertebral compression fractures who underwent vertebral augmentation were 22% less likely to die at up to 10 years after treatment than those who received nonsurgical treatment.

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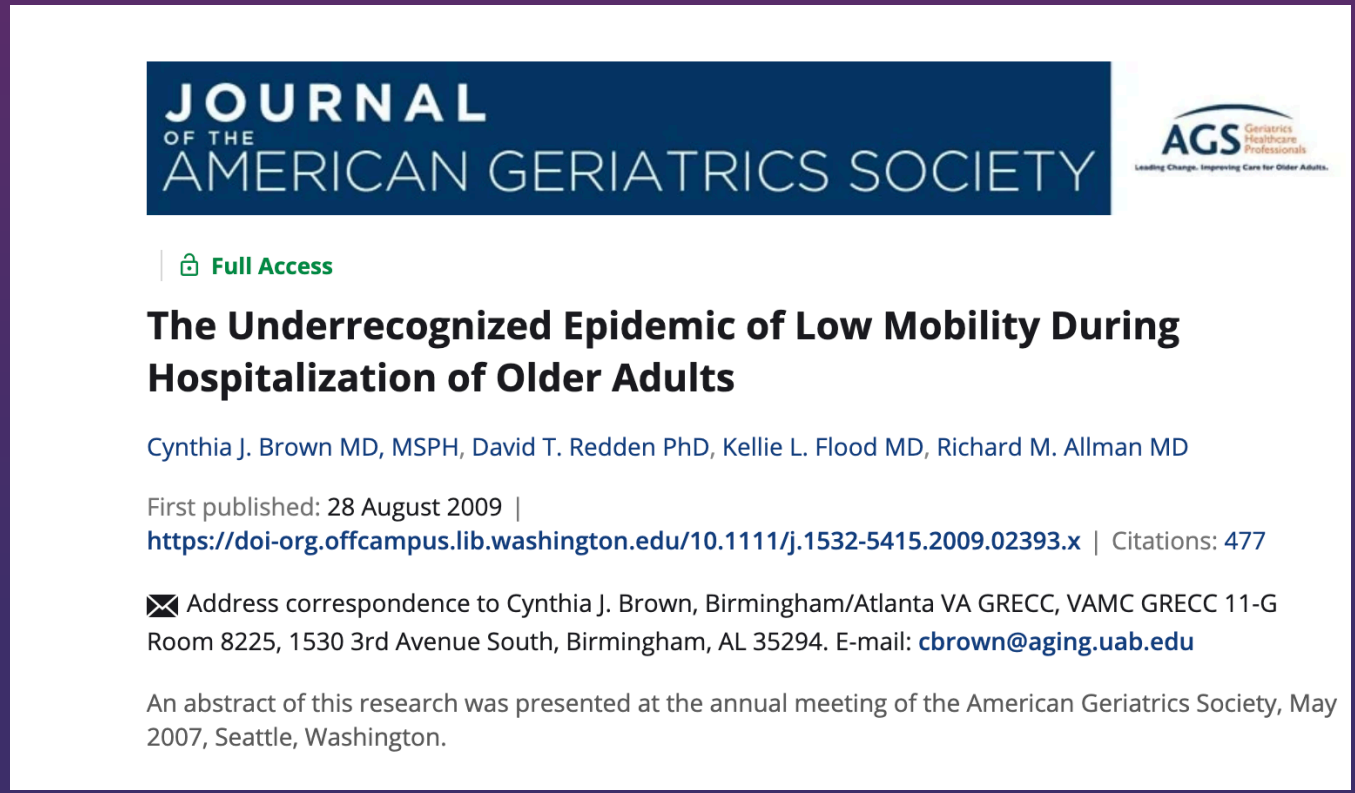
Effects of conservative care

VCF associated with:

- Prolonged bedrest & limited mobility
  - In healthy older adults, 10 days of bed rest results in a substantial loss of lower extremity strength, power, and aerobic capacity
- Decrease in cardiac function
- Decreased respiratory function
- Loss of muscle mass
  - Bedrest causes catabolic crisis



JOURNAL OF THE AMERICAN GERIATRICS SOCIETY

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The Underrecognized Epidemic of Low Mobility During Hospitalization of Older Adults

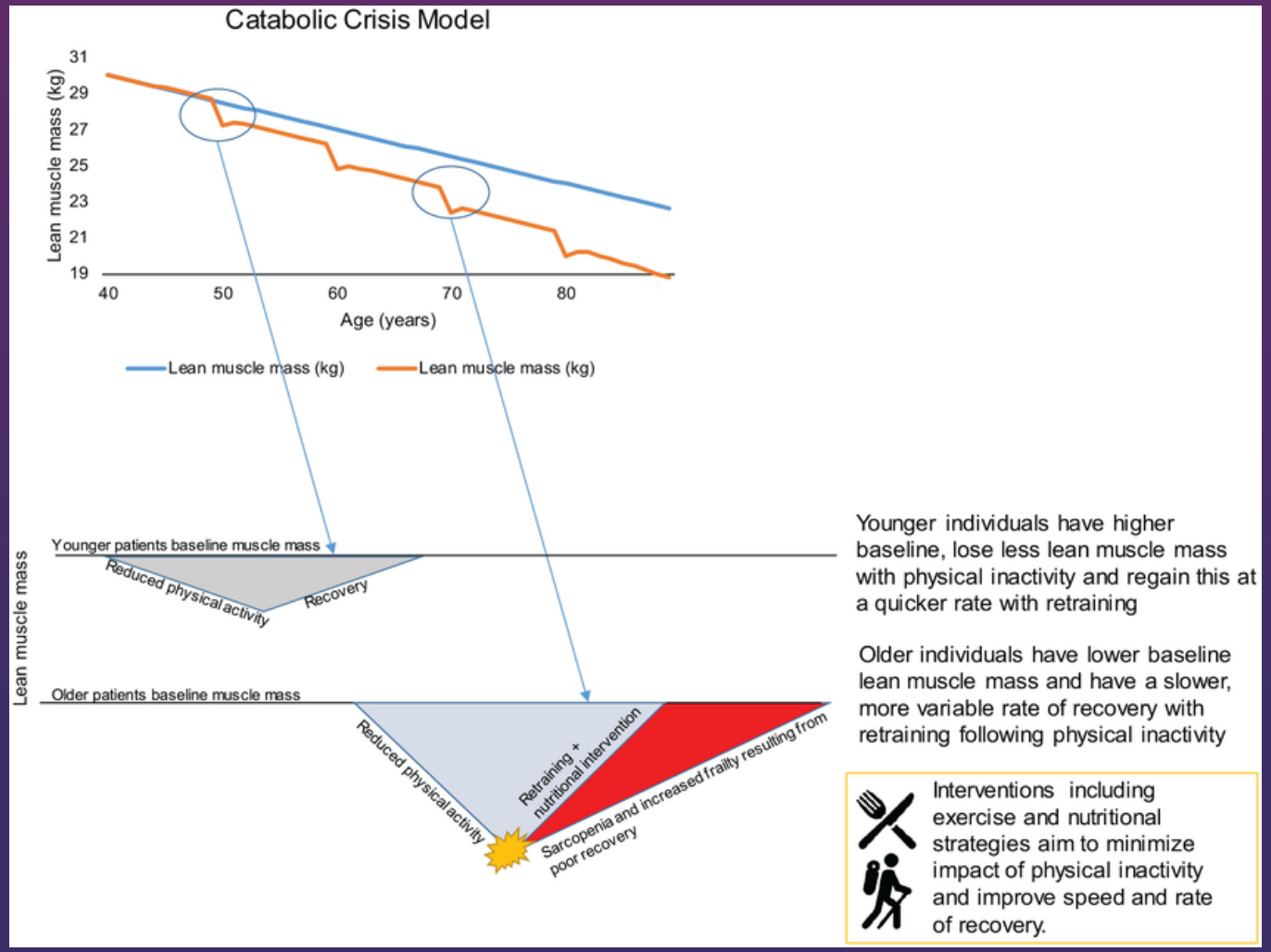
Cynthia J. Brown MD, MSPH, David T. Redden PhD, Kellie L. Flood MD, Richard M. Allman MD

First published: 28 August 2009 |
https://doi-org.offcampus.lib.washington.edu/10.1111/j.1532-5415.2009.02393.x | Citations: 477

Address correspondence to Cynthia J. Brown, Birmingham/Atlanta VA GRECC, VAMC GRECC 11-G Room 8225, 1530 3rd Avenue South, Birmingham, AL 35294. E-mail: cbrown@aging.uab.edu

An abstract of this research was presented at the annual meeting of the American Geriatrics Society, May 2007, Seattle, Washington.

Effects of injury



A Plea

- Vertebroplasty and Kyphoplasty Covered by Medicare, Cigna, Regence
- Washington State HCA is the only provider in the region that denies coverage for these services
- On behalf of the patients under your care, I urge you to reconsider your stance

Vertebroplasty, Kyphoplasty, and Sacroplasty: Re-review

Presentation to
Washington State Health Care Authority
Health Technology Clinical Committee

Andrea C. Skelly, PhD, MPH
Erika D. Brodt, BS

January 31, 2025

Report prepared by:
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2010 Report

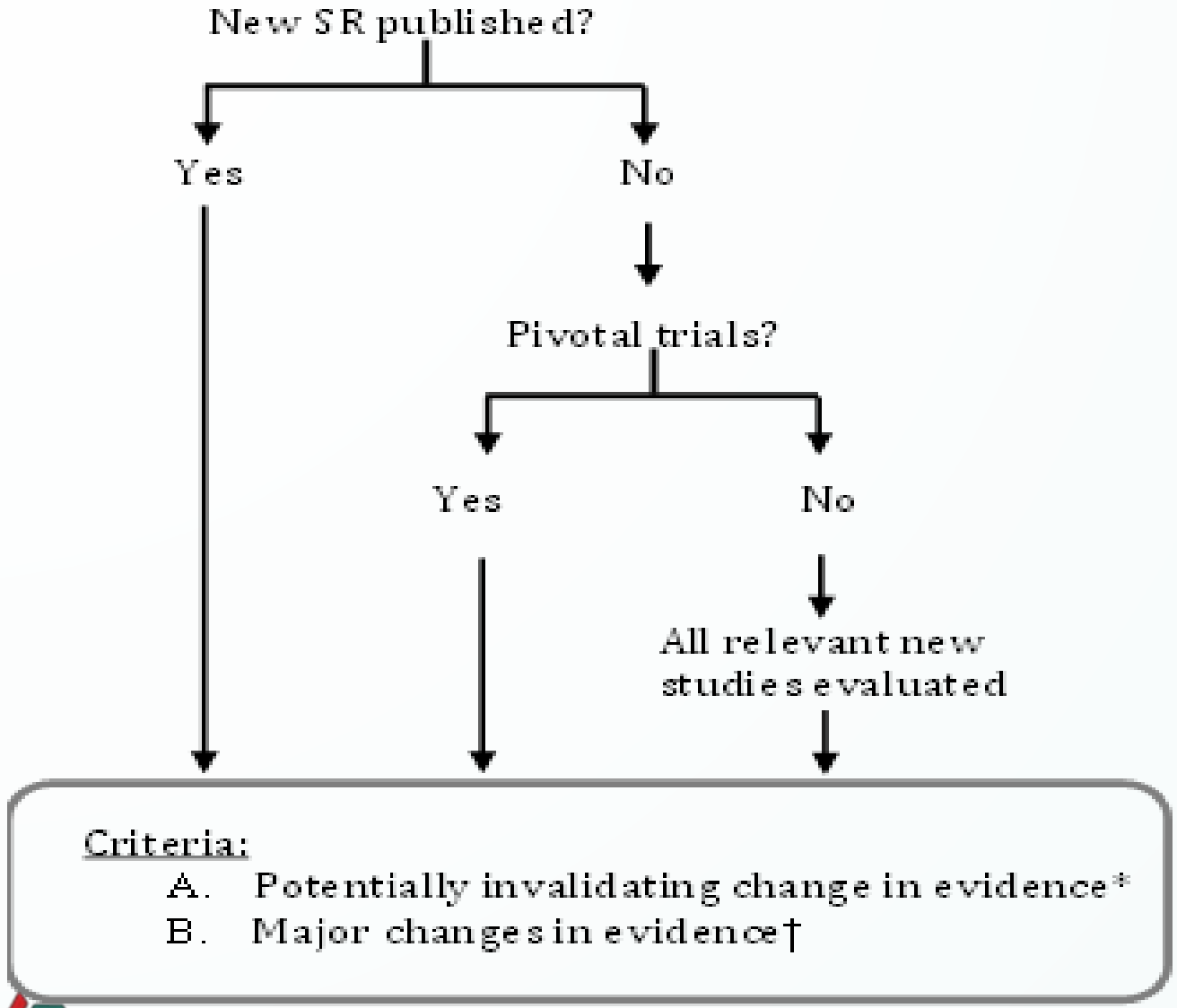
- Evidence base: 7 RCTs (2 VP vs. Sham, 3 VP vs. UC, 1 KP vs. UC, 1 VP vs. KP) across 7 publications, 9 prospective NRSIs (2 VP vs. UC, 1 KP vs. UC, 6 VP vs. KP), 11 retrospective NRSIs (3 VP vs. UC, 2 KP vs. UC, 6 VP vs. KP), 1 SR and 5 case series for sacroplasty

- Conclusions:

  - **Effectiveness**
    - VP is no more effective than sham for pain or function.
    - VP is better than UC for pain and function, though benefits decrease over time; short-term gains are seen in VP patients.
    - KP is more effective than UC for pain and function up to a year, with longer-term KP effects on pain and some function outcomes.
    - Both VP and KP improve pain, but no significant difference between them.
    - Sacroplasty trials are limited; 1 SR shows sacroplasty improves pain across case reports and case series, with further improvements in function and patient satisfaction, though data is inconsistent.

  - **Safety**
    - Fracture rates for VP, KP, and UC were similar (<10%) and data too limited for conclusions; asymptomatic cement leakage is common (up to 87%). Comparative studies suggest leakage is more likely with VP (9-87%) than KP (0-49%); symptomatic leakage is rare. Procedure-related events (0.4-3.8%) and mortality (0.6-2.3%) are rare. Complications in sacroplasty are rare (<1%).

Overview of Signal Update Methods, Decision Making



Signals for update

*A-1. Opposing findings

A-2. Substantial harm

A-3. Superior new treatment

†B-1. Important changes in effectiveness short of "opposing findings"

B-2. Clinically important expansion of treatment

B-3. Clinically important caveat

B-4. Opposing findings from discordant meta-analysis or nonpivotal trial

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Overview of Signal Updates Performed 2016, 2020

- **Methodology:** Evidence from new high-quality SR(s), new pivotal, high-quality trial(s) that may change conclusions of prior HTA on efficacy and/or safety.
- Signal Update (2020) Overview; New RCTs (7 in 2010 vs. 24 in 2020) and SRs
  - **KQ 1 (Efficacy):** No changes to previous conclusions regarding VP or KP.
    - Exception: change in statistical significance of pain response favoring VP vs. Sham (osteoporotic VCF).
    - Potential impact on SOE noted for some outcomes/comparisons.
    - No new evidence for sacroplasty.
  - **KQ 2 (Safety):** No changes to conclusions; inconsistent evidence on mortality from SRs noted; section could be updated.
  - **KQ3 (Differential impact**): No new evidence.
  - **KQ4 (Cost-effectiveness):** Section could be updated, new data; doesn't signal need for update.
- Relevant primary studies are carried forward, incorporated into re-review.

Re-Review Rationale and Topic Refinement

- **Rationale**: Additional evidence and technical advances related to use of vertebroplasty, kyphoplasty, and sacroplasty, including newly FDA approved devices.
- **Topic Refinement**:
  - Public comment to topic nomination and draft key questions/scope were reviewed, considered, and discussed with HTAP as was input from clinical experts prior to finalization of KQs and PICOTS scope. Public comment to draft report was reviewed and considered for final report. All suggested citations were evaluated against the final PICOTS for possible inclusion.
- **Clinical input** on specific clinical questions obtained throughout report development; internal clinical and methods review, clinical peer review of the draft report.

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Background

Vertebral Compression Fractures (VCFs)

- **Osteoporotic fractures – common with osteoporosis**
  - ≥1 million VCFs annually with highest prevalence seen in post-menopausal women.
  - Vertebral collapse results in pain, function loss, decreased QOL; bone pieces may compress the spinal cord and nerves.
  - Pain may resolve in 4-6 weeks; some may develop chronic back pain; VCF may take 6-12 weeks to heal.
  - Greater risk of morbidity and mortality; patients usually have medical comorbidities.
- **VCFs due to metastatic bone disease**
  - Incidence varies depending on cancer diagnosis, but ranges from 2% to 28%.
  - Additional risk of VCF in patients following radiotherapy.
- **Treatment**
  - Initially, nonoperative management is done: Bracing, rest, medication, supplements.
  - Augmentation usually considered for symptomatic VCF refractory to nonoperative management.
  - Surgical procedures more involved; require general anesthesia and are usually reserved for patients with instability or neurologic compromise; bone quality may impact success.

Vertebroplasty, Kyphoplasty, and Sacroplasty

- Minimally invasive spinal augmentation procedures that use bone cement (usually polymethyl methacrylate [PMMA]) to treat VCFs:
  - **Vertebroplasty:** Bone cement is injected directly into fractured/collapsed vertebra.
  - **Kyphoplasty:** Inflatable balloon (or other mechanical device) is first inserted into the vertebra to create a cavity and restore vertebral height prior to injecting cement.
  - **Sacroplasty:** Bone cement is injected into the sacrum to repair sacral insufficiency fractures.
- IV sedation or general anesthesia; procedure done with imaging guidance (fluoroscopy).
- Goal is to reduce/relieve pain, improve mobility, and prevent further vertebral collapse.
- Newer FDA approved mechanical devices/implants to restore to restore vertebral height (e.g., SpineJack System, Kiva System, OsseoFix System).

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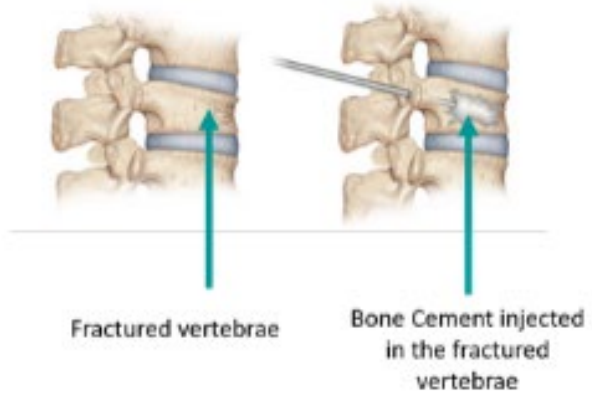
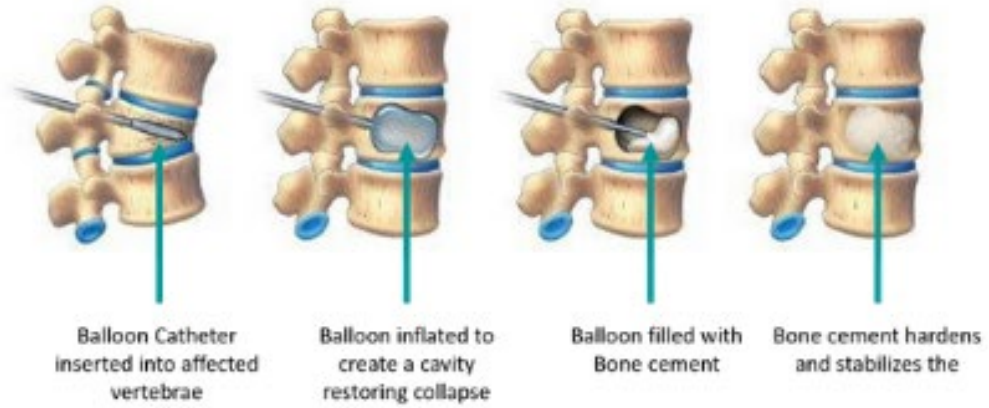
Vertebroplasty, Kyphoplasty, and Sacroplasty (cont.)



Vertebroplasty



Kyphoplasty

Image from: https://spineandsportsclinic.in/vertebroplasty-kyphoplasty-treatment/

Sacroplasty

Long-axis approach

Short-axis approach

Image from: https://providers.strykerivs.com/procedures-and-conditions/sacroplasty

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Indications and Contraindications

- **Most Common Indications**
  - Painful vertebral compression fractures (VCFs) caused by osteoporosis, malignancy or other conditions (e.g., osteonecrosis, nonunion, cystic degeneration, severe kyphosis, Kümmell Disease) that are refractory to conservative treatment.

- **Contraindications**
  - Asymptomatic fractures; clinical improvement during non-surgical care; history of osteomyelitis or spinal infection; allergy to bone fillers, bone cement, or opacification agents; uncorrected coagulopathy; systemic infection; fracture that breaches the posterior vertebral wall; fractures due to high-energy trauma.

- **Relative Contraindications**:
  - Loss of vertebral body height ≥75%; damaged pedicles and facets; and tumors invading the spinal canal.

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Possible Complications

- **Common complications:** Post-procedure pain, vasovagal reactions.
- **Cement leakage:** Is common, usually clinically insignificant and asymptomatic. Leak into adjacent veins may cause pulmonary embolus (<1%) or through fracture clefts may cause nerve or cord impingement (~1-2%).
- **New vertebral fractures/Refracture**: May be associated with VA, may be due to underlying osteoporosis.
- **Procedural trauma:** Bleeding, pneumothorax, epidural hematoma, infection, hyperalgesia, PMMA allergy.
- **Severe adverse events**: May include mortality, deterioration in health, pulmonary complications, deep vein thrombosis, cardiac complications; these are rare.

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Questions and Scope

Key Questions

When used in adult patients with spinal pain due to vertebral fracture:

1. What is the evidence of short and long-term **effectiveness** of vertebroplasty, kyphoplasty or sacroplasty?
2. What is the evidence of the **safety** of vertebroplasty, kyphoplasty or sacroplasty?
3. What is the evidence that of vertebroplasty, kyphoplasty or sacroplasty has **differential efficacy or safety** issues in sub-populations of interest?
4. What is the evidence of **cost-effectiveness** of vertebroplasty, kyphoplasty or sacroplasty?

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PICO Scope: Inclusion Criteria

- **Population**
  - Patients with spinal pain due to **vertebral fracture** secondary to osteoporosis or malignancy
- **Intervention**
  - Vertebroplasty, kyphoplasty, or sacroplasty
- **Comparator**
  - Sham procedure or placebo
  - Conservative care, conventional care
  - Other minimally invasive procedures (e.g., face joint block, nerve block)
  - Surgical procedures
  - Vertebroplasty versus kyphoplasty
- **Outcomes**
  - **Primary**: Functional outcomes, pain relief, harms/complications (***SOE on these only***)
  - **Secondary**: Quality of life, measures of disability, opioid use, return to work/return to normal activity.
  - **Economic**: Cost-effectiveness (e.g., cost per improved outcome), cost-utility (e.g., cost per quality adjusted life year (QALY), incremental cost effectiveness ratio (ICER) outcome)

PICO Scope: Inclusion Criteria (cont.)

- **Study Design**
  - Key Questions 1: Comparative clinical studies with a focus on studies with least potential for bias (RCTs); NRSI with concurrent controls that control for confounding will be considered if RCT evidence is not available for KQ 1.
  - Key Question 2: safety, RCTs, NRSI with ≥250 patients that are specifically designed to evaluate safety that control for confounding will be considered; case series will be considered if adequate information is not available from comparative NRSIs and RCTs or for rare or long-term adverse events; systematic reviews may be considered for safety.
  - Key Question 3: RCTs only.
  - Key Question 4: Formal economic studies (i.e., cost-effectiveness, cost-utility, cost-minimization, and cost-benefit studies).
- **Publication**
  - Studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports, published HTAs; KQ 4 full/formal economic studies published after those in the prior HTA.

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Methods

Systematic Review Process

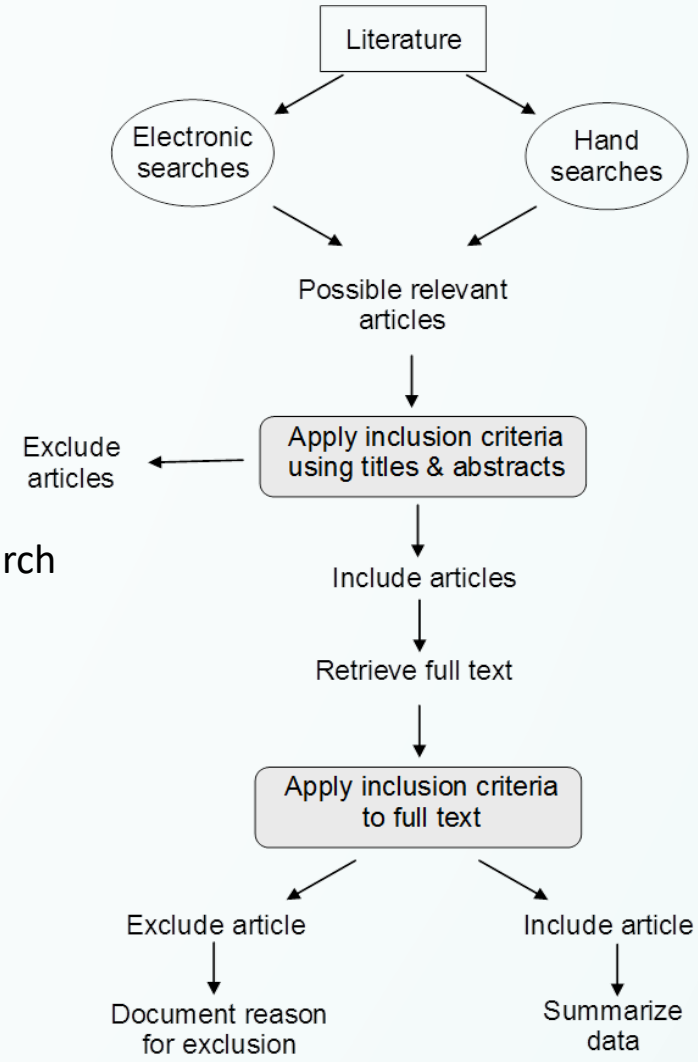
Methodological Standards:
AHRQ, IOM/NASEM, Cochrane

Topic Refinement
- Key question development
- Scope (inclusion/exclusion)
  - Population
  - Intervention
  - Comparators
  - Outcomes
  - Timing
  - Studies
  - Setting
- Preliminary Search

Finalization/Work Plan

Role of Clinical Experts

Formal, Structured Search



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Quality (Risk of Bias) Assessment

Predefined criteria used to assess individual studies based on study design and methods (AHRQ, Cochrane); independent, dual assessment

Rating	Description and Criteria
Good	• **Low risk of bias; study results generally considered valid** • Employed valid methods for selection, inclusion, and allocation of patients to treatment; report similar baseline characteristics/key risk factors for testing groups being compared; clearly describe attrition and have low attrition; use appropriate means for preventing bias (e.g., blinded outcomes assessment); and use appropriate analytic methods (e.g., intention-to-treat analysis); full reporting on pre-specified outcomes. • For studies of testing, pre-specification of thresholds for a positive test,
Fair	• **Study is susceptible to some bias but not enough to necessarily invalidate results** • May not meet all criteria for good quality, but no flaw is likely to cause major bias; the study may be missing information making it difficult to assess limitations and potential problems • **This category is broad; studies with this rating will vary in strengths and weaknesses; some fair-quality studies are likely to be valid, while others may be only possibly valid**
Poor	• **Significant flaws that imply biases of various kinds that may invalidate results; the study contains "fatal flaws" in design, analysis or reporting; large amounts of missing information; discrepancies in reporting or serious problems with intervention or test delivery** • Study results are at least as likely to reflect flaws in the study design or execution as the true difference between the compared interventions • **Considered to be less reliable than higher quality studies when synthesizing the evidence, particularly if discrepancies between studies are present**

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Individual Studies: Risk of Bias –Appendix E

Study Methods Criteria (areas for possible downgrade)
RCTs • Random sequence generation • Statement of allocation concealment • Intent-to-treat analysis • Blinding (patients, providers, assessors) • Groups comparable at baseline • Complete follow-up of >80% • <10% difference in follow-up between groups • Reported specified outcomes

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Individual Studies: Risk of Bias

Study Methods Criteria (areas for potential downgrade)
Nonrandomized Studies of Intervention (Observational) • Patient sampling (random, consecutive) from the same underlying population • Groups comparable at baseline on key prognostic factors • Blind, independent assessment of outcomes/analysis • Follow-up of >80% • <10% difference in follow-up between groups • Prespecified outcomes • Accurate measurement methods • Follow-up duration reasonable for investigated events • Controlling for possible confounding   • Multivariate analysis, matching (including propensity) *case series are considered at high risk of bias

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Strength of Evidence (SoE)- is not the same thing as study risk of bias

SoE for overall body of evidence for primary outcomes was assessed based on:

- **Risk of bias**: the extent to which the individual included studies protect against bias
  - Appropriate randomization
  - Allocation concealment
  - Intention to treat analysis
  - Blind assessment of outcomes
  - Adequate follow-up (≥80%) and <10% follow-up difference between groups
  - Controlling for confounding
- **Consistency**: degree to which estimates across studies of a specific outcome are similar in terms of range and variability.
- **Directness**: whether the evidence is directly related to patient health outcomes. NOTE: None were considered indirect.
- **Precision**: level of certainty surrounding the effect estimates.
- **Publication/report bias**: selective reporting or publishing.

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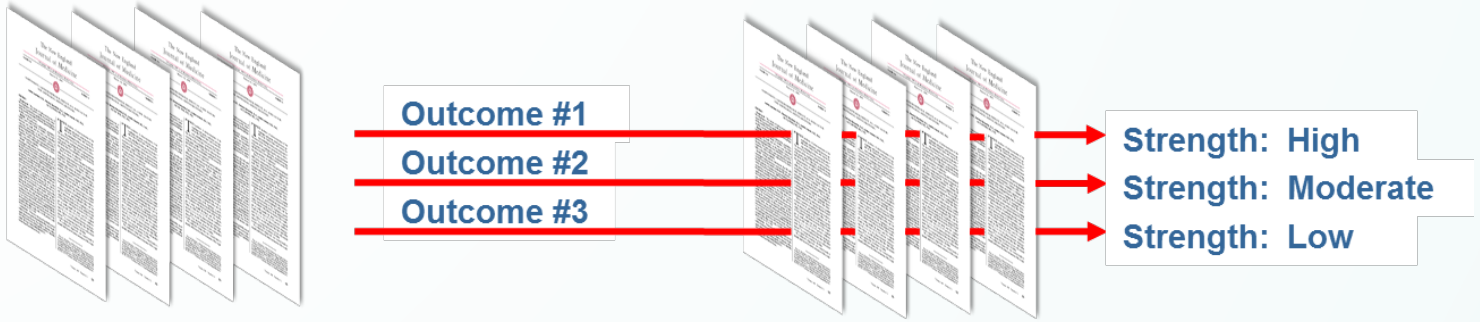
Systematic Review Process

Studies meeting eligibility criteria
- Efficacy: RCTs
- Harms: RCTs, observational studies
- Economic studies (SOE not done)

Risk of Bias Appraisal (Study)
Good, Fair, or Poor
Synthesis/analysis

Overall Strength of Evidence Determination (GRADE/AHRQ)



Strength of Evidence Ratings	
High	Very confident that effect is true.
Moderate	Moderately confident.
Low	Limited confidence.
Insufficient	No evidence or no confidence in effect.

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Magnitude of Effects (Appendix Q)

Slight/Small	Moderate	Large/Substantial
Pain		
5–10 points on a 0-to 100-point VAS or the equivalent 0.5–1.0 points on a 0-to 10-point numerical rating scale or the equivalent	>10–20 points on a 0-to 100-point VAS or the equivalent >1–2 points on a 0-to 10-point numerical rating scale or the equivalent	>20 points on a 0-to 100-point VAS or the equivalent >2 points on a 0-to 10-point numerical rating scale or the equivalent
Function		
5–10 points on the ODI 1-2 points on the RDQ	>10–20 points on the ODI >2-5 points on the RDQ	>20 points on the ODI >5 points on the RDQ
Pain or function		
0.2 to 0.5 SMD 1.2 to 1.4 RR/OR	>0.5 to 0.8 SMD 1.5 to 1.9 RR/OR	>0.8 SMD ≥2.0 RR/OR

Based on mean between-group differences for continuous scores

Small effects may be below published thresholds for clinically meaningful effects. However, for some patients, a small improvement in pain or function may be important.

Effects below the threshold for small were categorized as no effect.

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RESULTS

Primary Evidence Base: RCTs

	Number of RCTs included	
	2010 HTA	New or updated in 2024 Report
VP vs. Sham	2 RCTs	6 RCTs
VP vs. UC	3 RCTs	9 RCTs
KP vs. Sham	0	0
KP vs. UC (OP/Malignancy)	1 RCT/0	5 RCTs/1 RCT
VP vs. KP	1 RCT	9 RCTs
VP vs. Nerve/Facet Block	0	2 RCTs
KP vs. Other Surgical Intervention	0	1 RCT
Sacroplasty	0	0
TOTAL	**7 RCTs**	**32 RCTs**

KP = kyphoplasty; OP = osteoporosis; UC = usual care; VP = vertebroplasty

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Overview of Evidence

- Focus on “best evidence”
- Quality of Studies
- Heterogeneity
  - Included populations
  - Procedures
  - Comparators
- Across RCTs, adverse events were variably and sparsely reported; Serious adverse events were variably defined and trials report that most were not procedure related.

KQ 1: Effectiveness Overview

Vertebroplasty (osteoporosis)

May improve pain and function, inconsistencies across comparators, times

- VP vs. Sham and vs. UC
  - Inconsistent associations over time with VP vs. sham than with VP vs. UC.
  - Smaller ESs for pain with VP vs. Sham than with VP vs. UC; ESs small for function for both.
- VP vs. blocks: improved pain at early times only.
- VP vs. KP: Similar pain and function improvement.

Kyphoplasty

May improve pain and function vs. UC

- Osteoporosis: KP improved pain and function vs. UC.
- Malignancy: KP improved pain and function versus UC between <2 weeks and ≤1 month.

Sacroplasty

Evidence for remains sparse, insufficient.

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KQ 2: Safety Overview: RCTs

Vertebroplasty

Osteoporotic VCF

- Similar risk for VP vs. sham, VP vs. UC and VP vs. KP:
  - Mortality
  - New fractures
- Cement leakage common with VP; few studies reported symptomatic leakage.
- VP and KP: similar risk for symptomatic cement leakage.

Kyphoplasty

Osteoporotic VCF

- Similar risk for KP vs. UC
  - Mortality, AEs (any, serious)
  - New fractures

Malignancy: Sparse evidence KP vs. UC

- Similar risk
  - Mortality, SAEs
  - New symptomatic fracture (1 month)
- New symptomatic fracture greater with KP >1 to ≤12 months
- Symptomatic cement leak was rare

Sacroplasty

No RCTs, Evidence insufficient

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KQ 3. Differential effectiveness or safety

Analyses are limited. Confidence in findings is very low.

VP vs. Sham or UC

- No apparent modification of treatment effect for pain or function based on
  - Sex, prior fracture (1 RCT).
  - Fracture age or pain duration (RCT subgroup analysis; stratified analysis of RCTs).

- No modification (stratified analyses of RCTs) by
  - PMMA volume.
  - Study enrollment requirement – MRI findings of bone marrow edema.

VP vs. KP

- No impact of sex, age, preoperative pain scores or preoperative RDQ scores on pain. No data provided.

KQ 4. Cost Effectiveness

Osteoporotic VCF:

- 2 U.S. studies: VA was cost-effective vs. non-operative management; cost-effectiveness was sensitive to varying the degree of assumed mortality differences.
- A comprehensive CUA (UK National Institute for Health Research) noted that cost-effectiveness of VP and KP was influenced by mortality assumptions based on administrative data and comparisons based on blinded trials or unblinded trials.

Malignant VCF:

- VP and KP may be cost-effective vs. nonsurgical management (Canada CUA).

Fractures Due to Osteoporosis
Effectiveness
Safety

Osteoporotic Fractures
KQ 1. Effectiveness

Vertebroplasty
Kyphoplasty

Vertebroplasty versus Sham

- 6 RCTs (11 publications), N=641
- Demographics: 75 years old, 75% female
- Pain duration: ≤9 weeks (4 RCTs), 18 weeks and 26 weeks in other 2 RCTs
- Evidence of bone marrow edema required in 3 RCTs
- Intervention: Single level most common (60% to 87%) in 4 RCTs reporting, mean PMMA volume 1.4mL to 7mL
- Sham: verbal/physical cues consistent with PMMA injection, PMMA preparation to create odor, local anesthetic injection (periosteal, 4 RCTs; vertebral body, 1 RCT; subcutaneous, 1 RCT)
- Quality: 4 good, 2 fair

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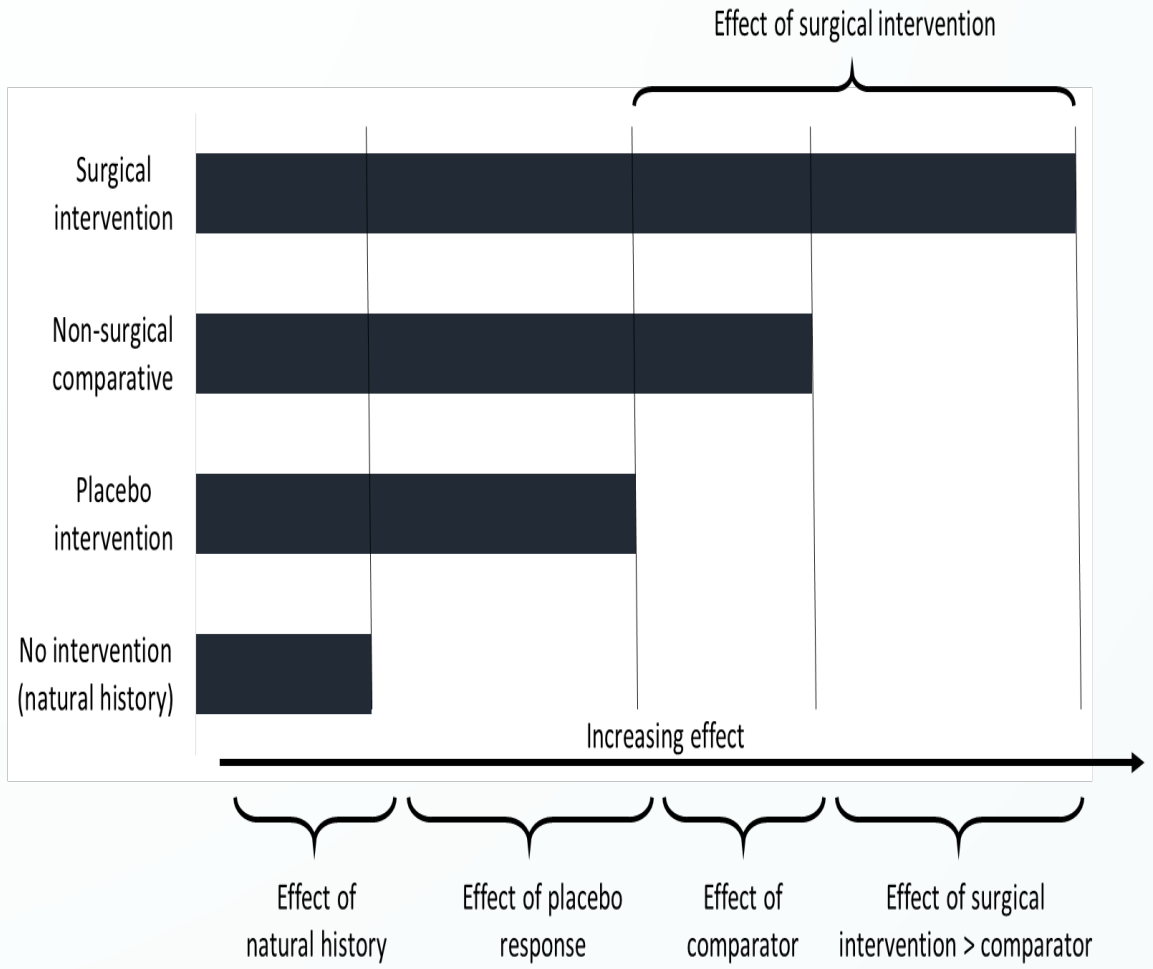
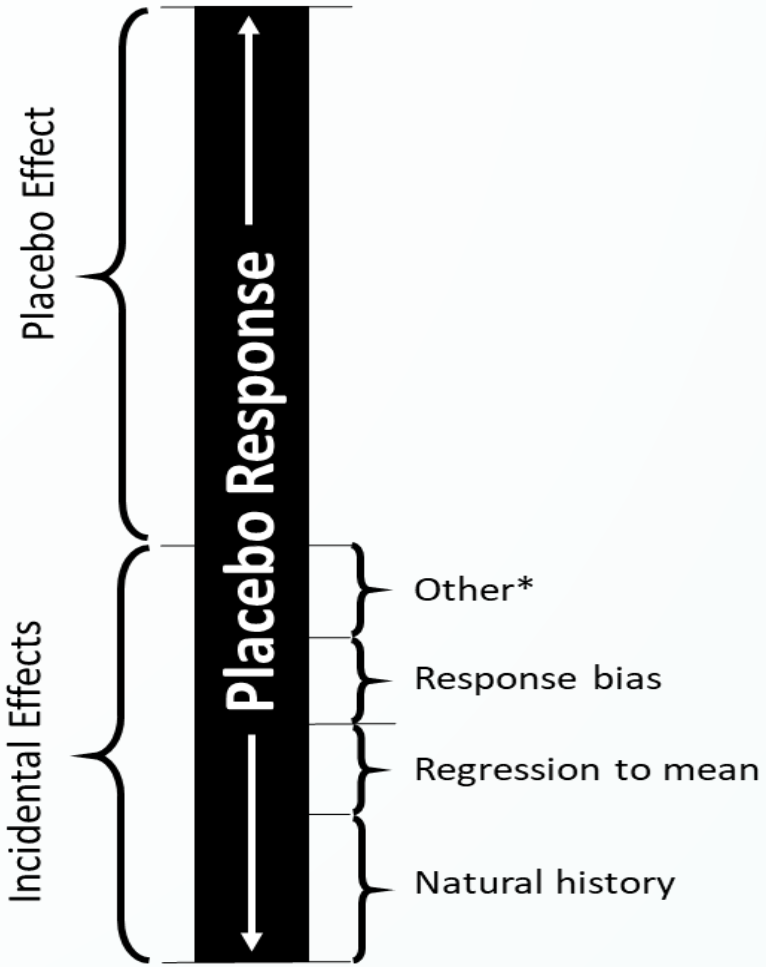
Conceptual contribution of effects following an intervention



- Treatment response is more than the effect of a given treatment: culture, presentation and ceremony around the treatment and expectation of provider and patient impact outcome.
- The placebo response heightens the significance of having a comparative group to evaluate treatment effectiveness; case series should rarely be interpreted as supporting treatment effectiveness.

Dettori, JR, et. al. Global Spine Journal Vol. 9(6) 680-683

Placebo Response



*such as diet, exercise, sleep, stress, support structure, physical or psychological treatment

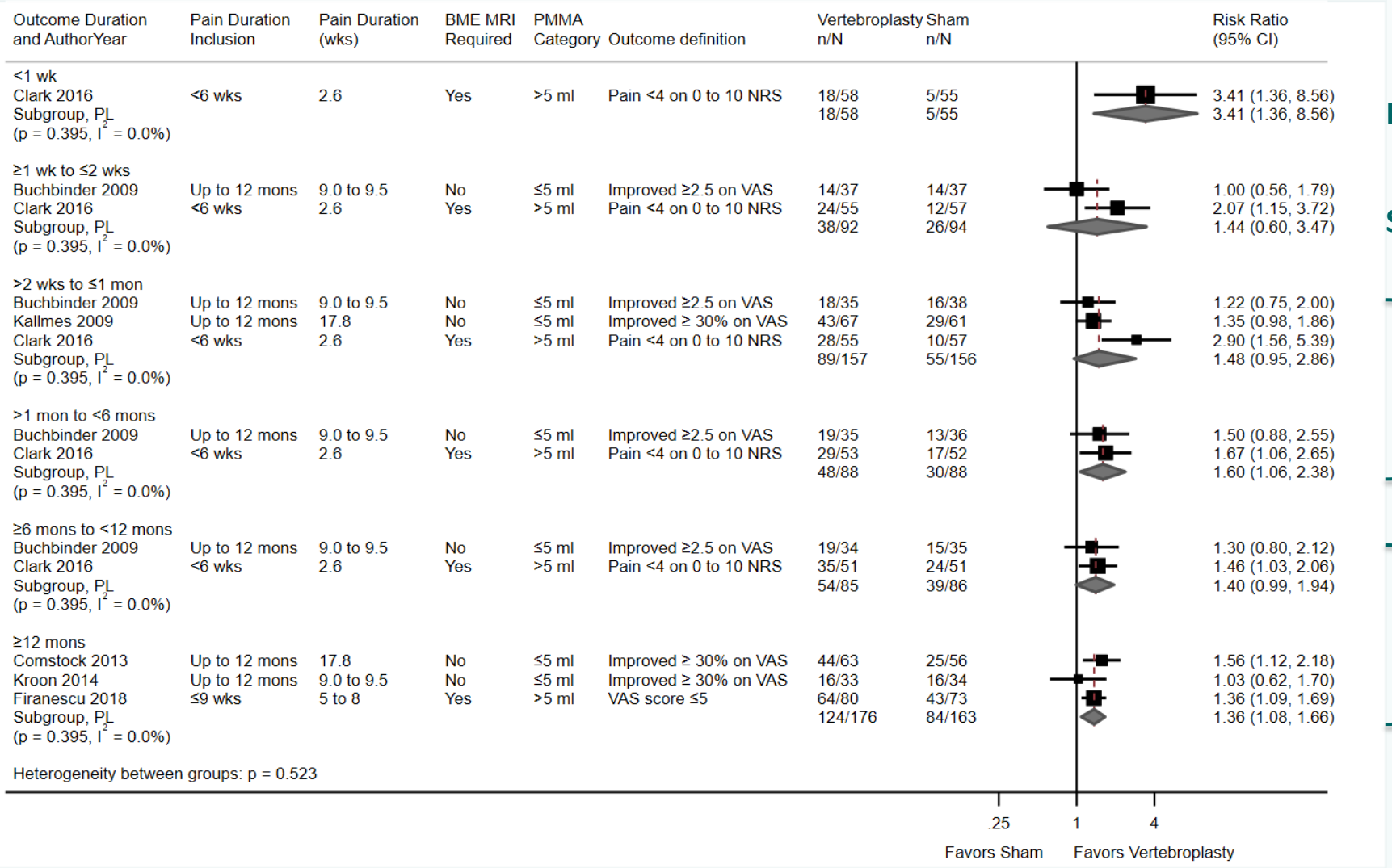
- Total response attributable to placebo (or sham) administration.
- Includes proportion of response that would be likely to occur even without treatment (i.e., incidental effects).
- Placebo effect is the proportion of improvement (or worsening) that remains after controlling for incidental effects.

Aggregate Analytics

Dettori, JR, et. al. Global Spine Journal Vol. 9(6) 680-683

Osteoporosis - VP versus Sham:
Pain Response (≥30% VAS pain reduction from baseline, 0-10 scale)

- VP associated with a **greater likelihood** of achieving pain response at most time points (except ≥1 to ≤2 weeks).



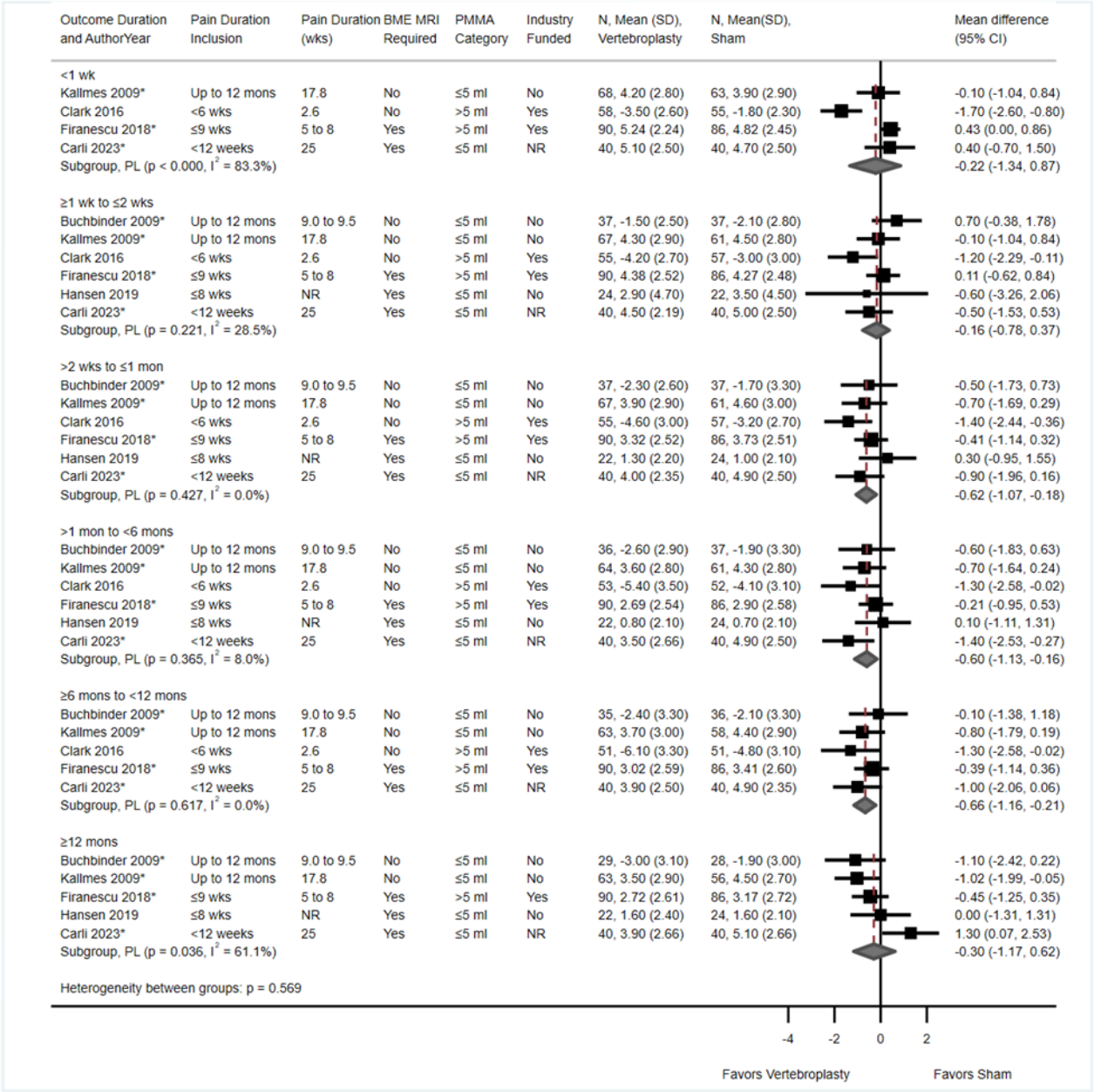
Large likelihood, Low SOE

Similar likelihood, Moderate SOE

Moderate likelihood, Moderate SOE

Small likelihood, Moderate SOE

Osteoporosis – VP versus Sham: Pain scores (VAS or NRS pain, 0-10 scale)



Similar improvement, Low SOE

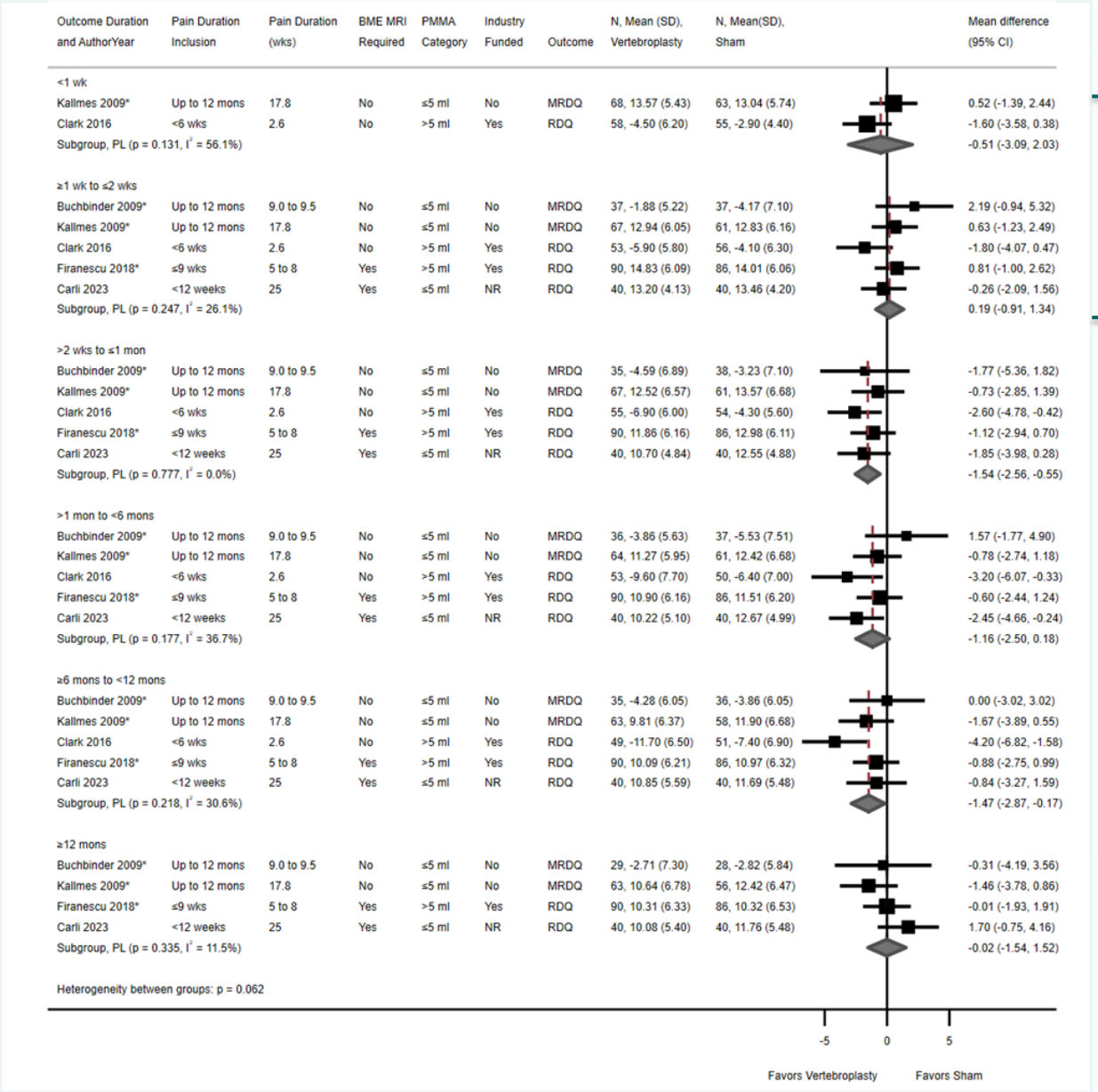
Similar improvement, Moderate SOE

Small improvement, High SOE

Similar improvement, Low SOE

- **Similar** pain improvement at earliest and latest time frames.
- VP associated with **small** improvement in pain at more intermediate follow-up times.

Osteoporosis - VP versus sham: Function (RDQ, 0-24 scale)



Outcome Duration and AuthorYear	Pain Duration Inclusion	Pain Duration (wks)	BME MRI Required	PMMA Category	Industry Funded	Outcome	N, Mean (SD), Vertebroplasty	N, Mean(SD), Sham	Mean difference (95% CI)
<1 wk									
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	68, 13.57 (5.43)	63, 13.04 (5.74)	0.52 (-1.39, 2.44)
Clark 2016	<6 wks	2.6	No	>5 ml	Yes	RDQ	58, -4.50 (6.20)	55, -2.90 (4.40)	-1.60 (-3.58, 0.38)
Subgroup, PL (p = 0.131, I^2 = 56.1%)									-0.51 (-3.09, 2.03)
≥1 wk to ≤2 wks									
Buchbinder 2009*	Up to 12 mons	9.0 to 9.5	No	≤5 ml	No	MRDQ	37, -1.88 (5.22)	37, -4.17 (7.10)	2.19 (-0.94, 5.32)
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	67, 12.94 (6.05)	61, 12.83 (6.16)	0.63 (-1.23, 2.49)
Clark 2016	<6 wks	2.6	No	>5 ml	Yes	RDQ	53, -5.90 (5.80)	56, -4.10 (6.30)	-1.80 (-4.07, 0.47)
Firanescu 2018*	≤9 wks	5 to 8	Yes	>5 ml	Yes	RDQ	90, 14.83 (6.09)	86, 14.01 (6.06)	0.81 (-1.00, 2.62)
Carli 2023	<12 weeks	25	Yes	≤5 ml	NR	RDQ	40, 13.20 (4.13)	40, 13.46 (4.20)	-0.26 (-2.09, 1.56)
Subgroup, PL (p = 0.247, I^2 = 26.1%)									0.19 (-0.91, 1.34)
>2 wks to ≤1 mon									
Buchbinder 2009*	Up to 12 mons	9.0 to 9.5	No	≤5 ml	No	MRDQ	35, -4.59 (6.89)	38, -3.23 (7.10)	-1.77 (-5.36, 1.82)
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	67, 12.52 (6.57)	61, 13.57 (6.68)	-0.73 (-2.85, 1.39)
Clark 2016	<6 wks	2.6	No	>5 ml	Yes	RDQ	55, -6.90 (6.00)	54, -4.30 (5.60)	-2.60 (-4.78, -0.42)
Firanescu 2018*	≤9 wks	5 to 8	Yes	>5 ml	Yes	RDQ	90, 11.86 (6.16)	86, 12.98 (6.11)	-1.12 (-2.94, 0.70)
Carli 2023	<12 weeks	25	Yes	≤5 ml	NR	RDQ	40, 10.70 (4.84)	40, 12.55 (4.88)	-1.85 (-3.98, 0.28)
Subgroup, PL (p = 0.777, I^2 = 0.0%)									-1.54 (-2.56, -0.55)
>1 mon to <6 mons									
Buchbinder 2009*	Up to 12 mons	9.0 to 9.5	No	≤5 ml	No	MRDQ	36, -3.86 (5.63)	37, -5.53 (7.51)	1.57 (-1.77, 4.90)
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	64, 11.27 (5.95)	61, 12.42 (6.68)	-0.78 (-2.74, 1.18)
Clark 2016	<6 wks	2.6	No	>5 ml	Yes	RDQ	53, -9.60 (7.70)	50, -6.40 (7.00)	-3.20 (-6.07, -0.33)
Firanescu 2018*	≤9 wks	5 to 8	Yes	>5 ml	Yes	RDQ	90, 10.90 (6.16)	86, 11.51 (6.20)	-0.60 (-2.44, 1.24)
Carli 2023	<12 weeks	25	Yes	≤5 ml	NR	RDQ	40, 10.22 (5.10)	40, 12.67 (4.99)	-2.45 (-4.66, -0.24)
Subgroup, PL (p = 0.177, I^2 = 36.7%)									-1.16 (-2.50, 0.18)
≥6 mons to <12 mons									
Buchbinder 2009*	Up to 12 mons	9.0 to 9.5	No	≤5 ml	No	MRDQ	35, -4.28 (6.05)	36, -3.86 (6.05)	0.00 (-3.02, 3.02)
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	63, 9.81 (6.37)	58, 11.90 (6.68)	-1.67 (-3.89, 0.55)
Clark 2016	<6 wks	2.6	No	>5 ml	Yes	RDQ	49, -11.70 (6.50)	51, -7.40 (6.90)	-4.20 (-6.82, -1.58)
Firanescu 2018*	≤9 wks	5 to 8	Yes	>5 ml	Yes	RDQ	90, 10.09 (6.21)	86, 10.97 (6.32)	-0.88 (-2.75, 0.99)
Carli 2023	<12 weeks	25	Yes	≤5 ml	NR	RDQ	40, 10.85 (5.59)	40, 11.69 (5.48)	-0.84 (-3.27, 1.59)
Subgroup, PL (p = 0.218, I^2 = 30.6%)									-1.47 (-2.87, -0.17)
≥12 mons									
Buchbinder 2009*	Up to 12 mons	9.0 to 9.5	No	≤5 ml	No	MRDQ	29, -2.71 (7.30)	28, -2.82 (5.84)	-0.31 (-4.19, 3.56)
Kallmes 2009*	Up to 12 mons	17.8	No	≤5 ml	No	MRDQ	63, 10.64 (6.78)	56, 12.42 (6.47)	-1.46 (-3.78, 0.86)
Firanescu 2018*	≤9 wks	5 to 8	Yes	>5 ml	Yes	RDQ	90, 10.31 (6.33)	86, 10.32 (6.53)	-0.01 (-1.93, 1.91)
Carli 2023	<12 weeks	25	Yes	≤5 ml	NR	RDQ	40, 10.08 (5.40)	40, 11.76 (5.48)	1.70 (-0.75, 4.16)
Subgroup, PL (p = 0.335, I^2 = 11.5%)									-0.02 (-1.54, 1.52)
Heterogeneity between groups: p = 0.062									

Similar improvement, Low SOE

Small improvement, Moderate SOE

Similar improvement, Low SOE

Small improvement, Low SOE

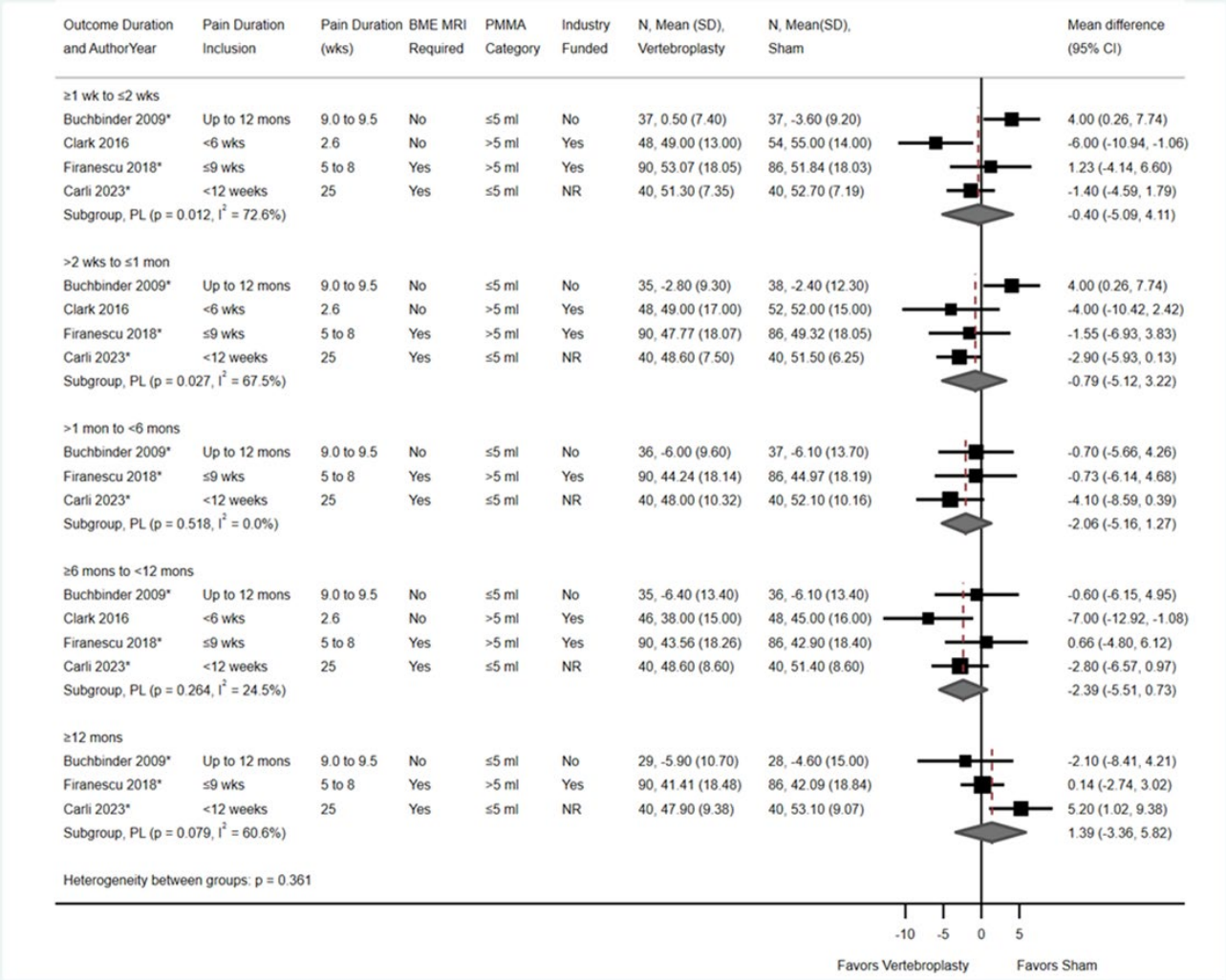
Similar improvement, Low SOE

- VP associated with **small** improvements in function at two time points: >2 weeks to ≤1 month, and at ≥6 to <12 months.
- Scores between groups **similar** at other times.

Osteoporosis - VP vs. sham:
SECONDARY OUTCOMES (no SOE)

➢ **Similar quality of life scores and opioid use at all time points.**

Quality of Life (QUALEFFO scores, 0-100)



Opioid use

4 RCTs, N=411, at latest follow-up (1-12 mos.):

- **Strong opioids**: 32.2% vs. 29.0%, RR 1.13 (95% CI 0.82 to 1.50), I^2=0%.
- **Weak opioids**: 25.2% vs. 22.5%, RR 1.14 (95% CI 0.75 to 1.61), I^2=0%.

Osteoporosis - Vertebroplasty vs. Usual Care

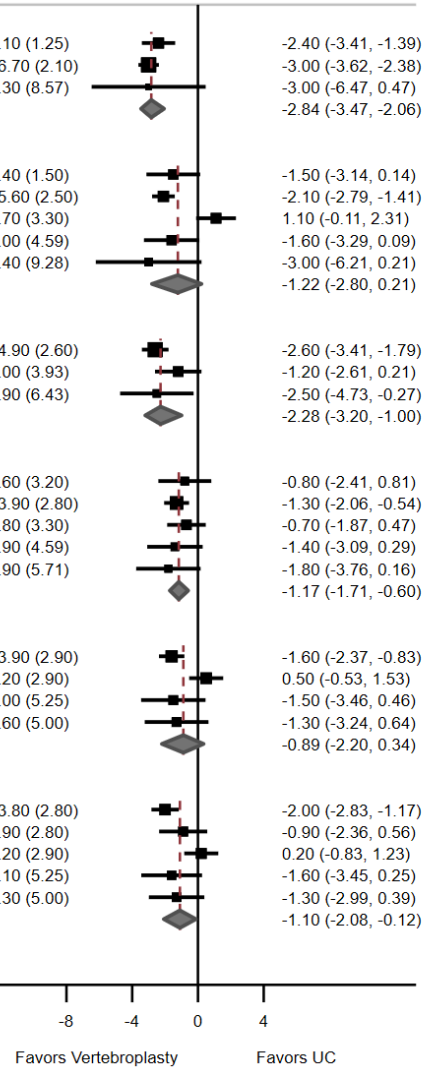
- 9 RCTs (12 publications), N=1,334 (range, 34 to 400)
- Demographics: Mean age range 66 to 80 years, 65% to 100% female
- Pain duration: ≤4 weeks (4 RCTs), ≥12 weeks (4 RCTs), not reported (1 RCT)
- Evidence of bone marrow edema required in 7 RCTs
- Intervention: Mean 1 to 2.5 levels treated, mean PMMA volume 3.2mL to 4.5mL
- Quality: 5 fair, 4 poor

Aggregate Analytics

Osteoporosis - VP vs. UC: Pain scores (VAS or NRS, 0-10 scale)

- VP associated with large or moderate pain improvement for most time points (except ≥6 to <12 months).

Outcome Duration and AuthorYear	Pain Duration Inclusion	Pain Duration (wks)	BME MRI Required	PMMA Category	Industry Funded	N, Mean (SD), Vertebroplasty	N, Mean (SD), UC	Mean difference (95% CI)
<1 wk								
Voormolen 2007	6 wks - 5 mons	11.7	Yes	≤5 ml	NR	18, 4.70 (1.75)	16, 7.10 (1.25)	-2.40 (-3.41, -1.39)
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 3.70 (2.40)	101, 6.70 (2.10)	-3.00 (-3.62, -2.38)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 4.30 (9.73)	51, 7.30 (8.57)	-3.00 (-6.47, 0.47)
Subgroup, PL (p = 0.611, I^2 = 0.0%)								-2.84 (-3.47, -2.06)
≥1 wk to ≤2 wks								
Voormolen 2007	6 wks - 5 mons	11.7	Yes	≤5 ml	NR	18, 4.90 (2.50)	16, 6.40 (1.50)	-1.50 (-3.14, 0.14)
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 3.50 (2.50)	101, 5.60 (2.50)	-2.10 (-2.79, -1.41)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 5.80 (3.60)	61, 4.70 (3.30)	1.10 (-0.11, 2.31)
Chen 2014	≥3 mons	30.4	Yes	≤5 ml	No	46, 3.40 (3.39)	43, 5.00 (4.59)	-1.60 (-3.29, 0.09)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 3.40 (7.48)	51, 6.40 (9.28)	-3.00 (-6.21, 0.21)
Subgroup, PL (p < 0.000, I^2 = 81.3%)								-1.22 (-2.80, 0.21)
>2 wks to ≤1 mon								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 2.50 (2.50)	101, 4.90 (2.60)	-2.60 (-3.41, -1.79)
Chen 2014	≥3 mons	30.4	Yes	≤5 ml	No	46, 2.80 (2.71)	43, 4.00 (3.93)	-1.20 (-2.61, 0.21)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 2.40 (5.24)	51, 4.90 (6.43)	-2.50 (-4.73, -0.27)
Subgroup, PL (p = 0.237, I^2 = 30.5%)								-2.28 (-3.20, -1.00)
>1 mon to <6 mons								
Rousing 2009	≤8 wks	1.1	No	NR	No	23, 1.80 (2.30)	23, 2.60 (3.20)	-0.80 (-2.41, 0.81)
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 2.60 (2.70)	101, 3.90 (2.80)	-1.30 (-2.06, -0.54)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 4.10 (3.40)	61, 4.80 (3.30)	-0.70 (-1.87, 0.47)
Chen 2014	≥3 mons	30.4	Yes	≤5 ml	No	46, 2.50 (3.39)	43, 3.90 (4.59)	-1.40 (-3.09, 0.29)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 2.10 (4.49)	51, 3.90 (5.71)	-1.80 (-3.76, 0.16)
Subgroup, PL (p = 0.844, I^2 = 0.0%)								-1.17 (-1.71, -0.60)
≥6 mons to <12 mons								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 2.30 (2.70)	101, 3.90 (2.90)	-1.60 (-2.37, -0.83)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 4.70 (3.00)	61, 4.20 (2.90)	0.50 (-0.53, 1.53)
Chen 2014	≥3 mons	30.4	Yes	≤5 ml	No	46, 2.50 (4.07)	43, 4.00 (5.25)	-1.50 (-3.46, 0.46)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 2.30 (5.24)	51, 3.60 (5.00)	-1.30 (-3.24, 0.64)
Subgroup, PL (p = 0.014, I^2 = 71.9%)								-0.89 (-2.20, 0.34)
≥12 mons								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 2.20 (2.70)	101, 3.80 (2.80)	-2.00 (-2.83, -1.17)
Rousing 2010	≤8 wks	1.1	No	NR	No	22, 2.00 (2.10)	22, 2.90 (2.80)	-0.90 (-2.36, 0.56)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 4.40 (3.00)	61, 4.20 (2.90)	0.20 (-0.83, 1.23)
Chen 2014	≥3 mons	30.4	Yes	≤5 ml	No	46, 2.50 (3.39)	43, 4.10 (5.25)	-1.60 (-3.45, 0.25)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 2.00 (3.74)	51, 3.30 (5.00)	-1.30 (-2.99, 0.39)
Subgroup, PL (p = 0.027, I^2 = 63.4%)								-1.10 (-2.08, -0.12)
Heterogeneity between groups: p = 0.000								



Large improvement, Moderate SOE

Moderate improvement, Low SOE [excluding outlier]

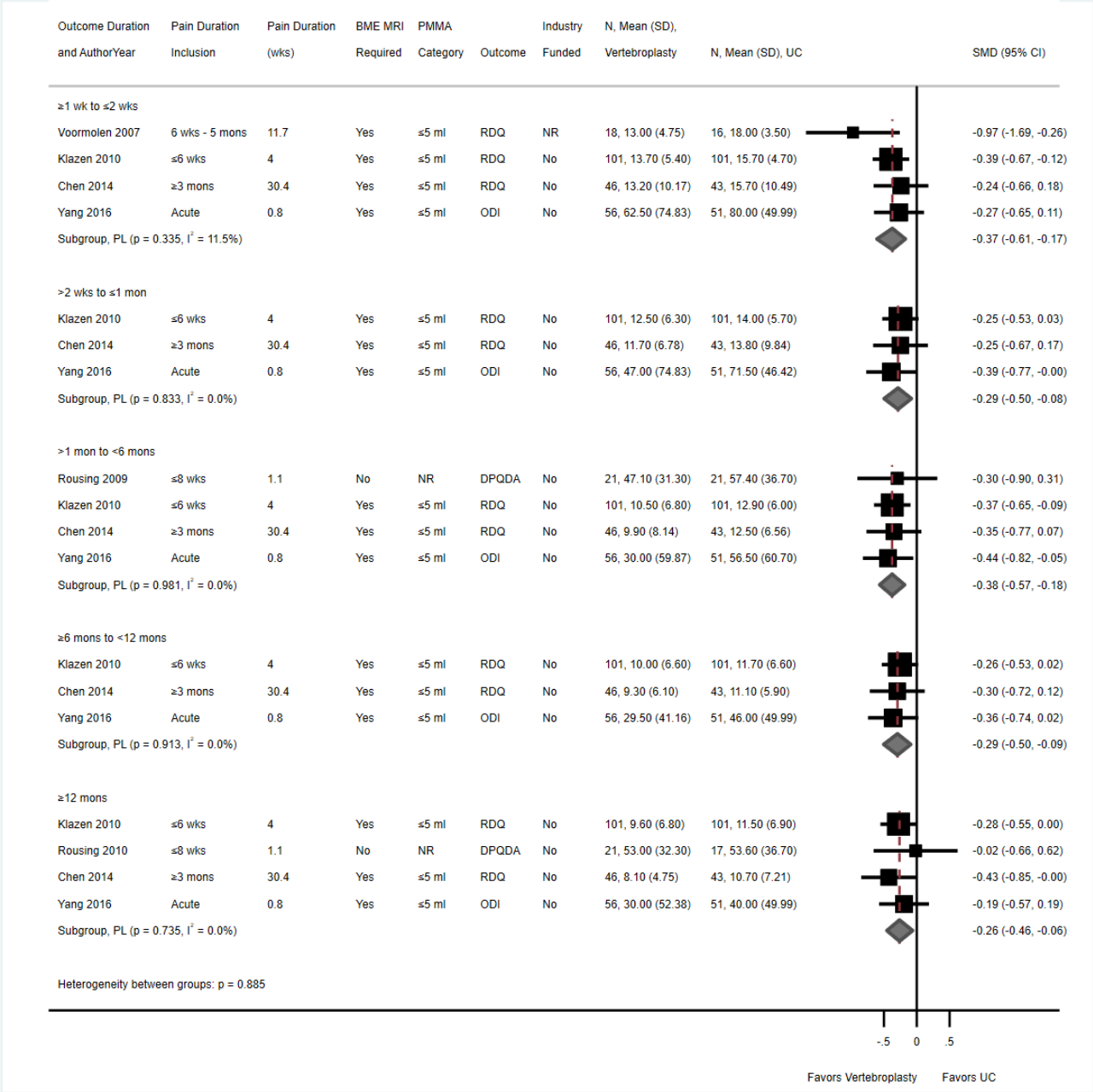
Large improvement, Low SOE

Moderate improvement, Moderate SOE

Similar improvement, Low SOE

Moderate improvement, Low SOE

Osteoporosis - VP vs. UC: Function scores

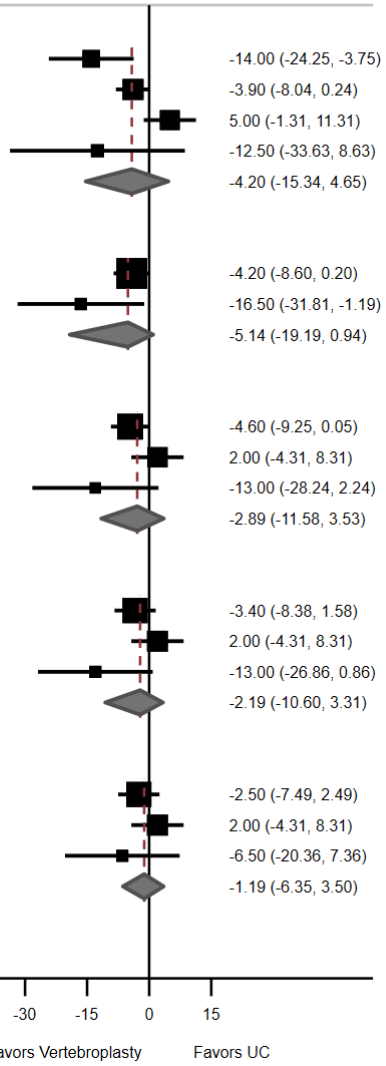


- VP associated with a **small** improvement in function at all timepoints.
- SOE **Moderate** at all timepoints except the earliest (≥1 to ≤2 weeks, SOE Low).

Osteoporosis - VP vs. UC: SECONDARY OUTCOMES (no SOE)

Quality of Life: QUALEFFO scores (0-100 scale)

Outcome Duration and AuthorYear	Pain Duration Inclusion	Pain Duration (wks)	BME MRI Required	PMMA Category	Industry Funded	N, Mean (SD), Vertebroplasty	N, Mean (SD), UC	Mean difference (95% CI)
≥1 wk to ≤2 wks								
Voormolen 2007	6 wks - 5 mons	11.7	Yes	≤5 ml	NR	18, 53.00 (12.75)	16, 67.00 (12.00)	-14.00 (-24.25, -3.75)
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 45.60 (14.50)	101, 49.50 (15.50)	-3.90 (-8.04, 0.24)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 62.00 (18.00)	61, 57.00 (18.00)	5.00 (-1.31, 11.31)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 65.00 (48.64)	51, 77.50 (61.42)	-12.50 (-33.63, 8.63)
Subgroup, PL ($p = 0.009$, $I^2 = 74.0\%$)								-4.20 (-15.34, 4.65)
>2 wks to ≤1 mon								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 42.90 (15.80)	101, 47.10 (16.10)	-4.20 (-8.60, 0.20)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 49.50 (44.90)	51, 66.00 (35.71)	-16.50 (-31.81, -1.19)
Subgroup, PL ($p = 0.130$, $I^2 = 56.3\%$)								-5.14 (-19.19, 0.94)
>1 mon to <6 mons								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 39.60 (17.10)	101, 44.20 (16.60)	-4.60 (-9.25, 0.05)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 57.00 (18.00)	61, 55.00 (18.00)	2.00 (-4.31, 8.31)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 43.00 (41.16)	51, 56.00 (39.28)	-13.00 (-28.24, 2.24)
Subgroup, PL ($p = 0.105$, $I^2 = 55.7\%$)								-2.89 (-11.58, 3.53)
≥6 mons to <12 mons								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 38.90 (17.80)	101, 42.30 (18.30)	-3.40 (-8.38, 1.58)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 54.00 (18.00)	61, 52.00 (18.00)	2.00 (-4.31, 8.31)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 40.00 (37.42)	51, 53.00 (35.71)	-13.00 (-26.86, 0.86)
Subgroup, PL ($p = 0.119$, $I^2 = 53.0\%$)								-2.19 (-10.60, 3.31)
≥12 mons								
Klazen 2010	≤6 wks	4	Yes	≤5 ml	No	101, 39.70 (18.30)	101, 42.20 (17.90)	-2.50 (-7.49, 2.49)
Blasco 2012	Up to 12 mons	20.4	Yes	NR	No	64, 54.00 (18.00)	61, 52.00 (18.00)	2.00 (-4.31, 8.31)
Yang 2016	Acute	0.8	Yes	≤5 ml	No	56, 42.50 (37.42)	51, 49.00 (35.71)	-6.50 (-20.36, 7.36)
Subgroup, PL ($p = 0.405$, $I^2 = 0.0\%$)								-1.19 (-6.35, 3.50)
Heterogeneity between groups: $p = 0.714$								



Opioid use

1 RCTs, N=125, follow-up 2 weeks and 2, 6, 12 months:

- **Major opioids**: similar likelihood at all timepoints except 12 months: N=83, 36.6% vs. 16.7%, RR 2.20 (95% CI 1.00 to 4.82).
- **Minor opioids**: similar likelihood at all timepoints.

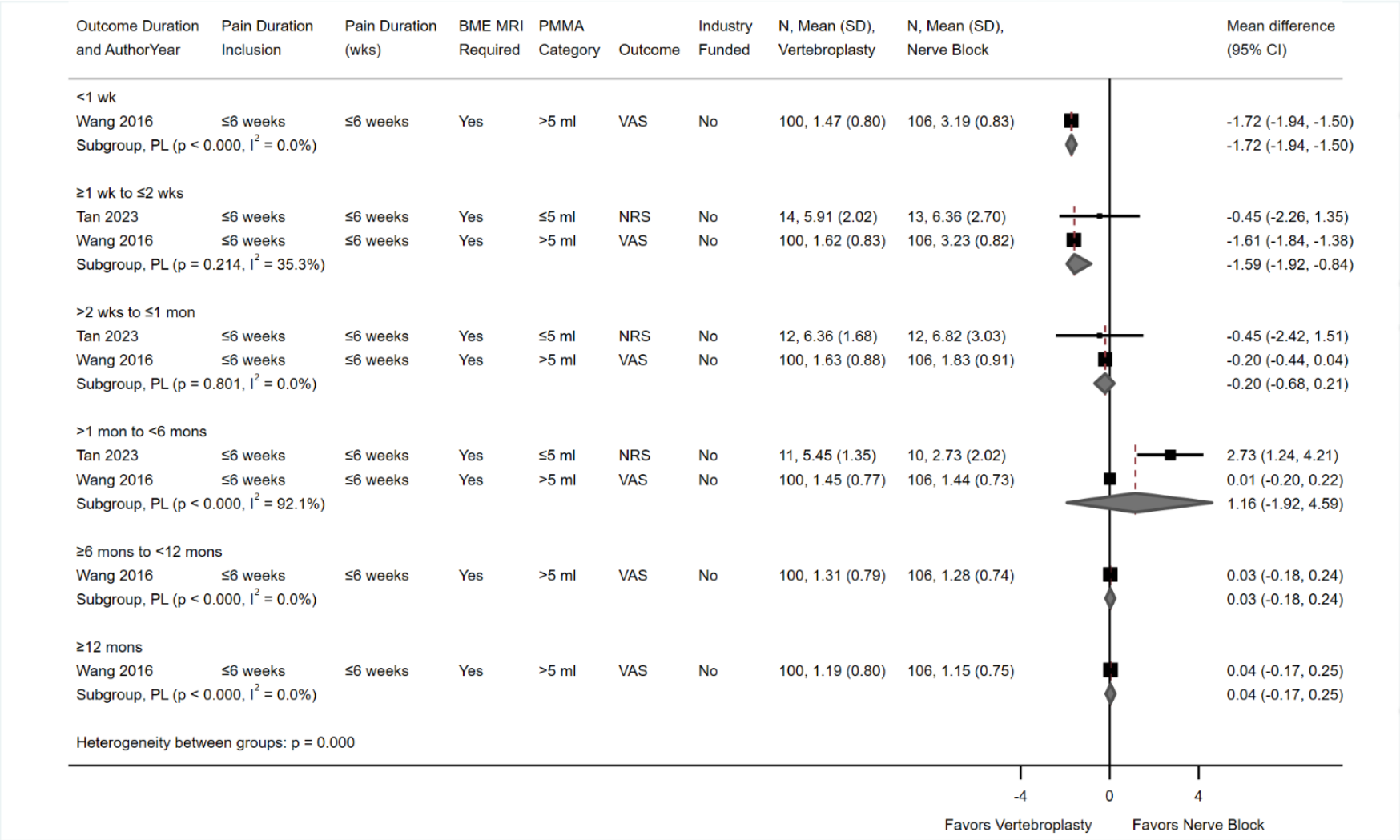
Osteoporosis - Vertebroplasty versus Nerve Block

- 2 RCTs (N=247, range 30 to 217), 1 NRSI (N=164)
- Demographics: Mean age 63 to 82 years, 26% (NRSI) to 83% female
- Pain duration (RCTs): >6 to 8 weeks
- Evidence of bone marrow edema required in both RCTs
- Intervention (RCTs): levels NR in RCTs, 1 level (NRSI); mean PMMA volume 3mL to 10mL
- Quality: 2 fair, 1 poor

Aggregate Analytics

Osteoporosis - VP versus Nerve/Facet Block: Pain score (VAS or NRS, 0-10 scale)

- VP was associated with moderate pain improvement at earliest time frames (<1 week, ≥1 to ≤2 weeks) but at later times pain was similar between groups.

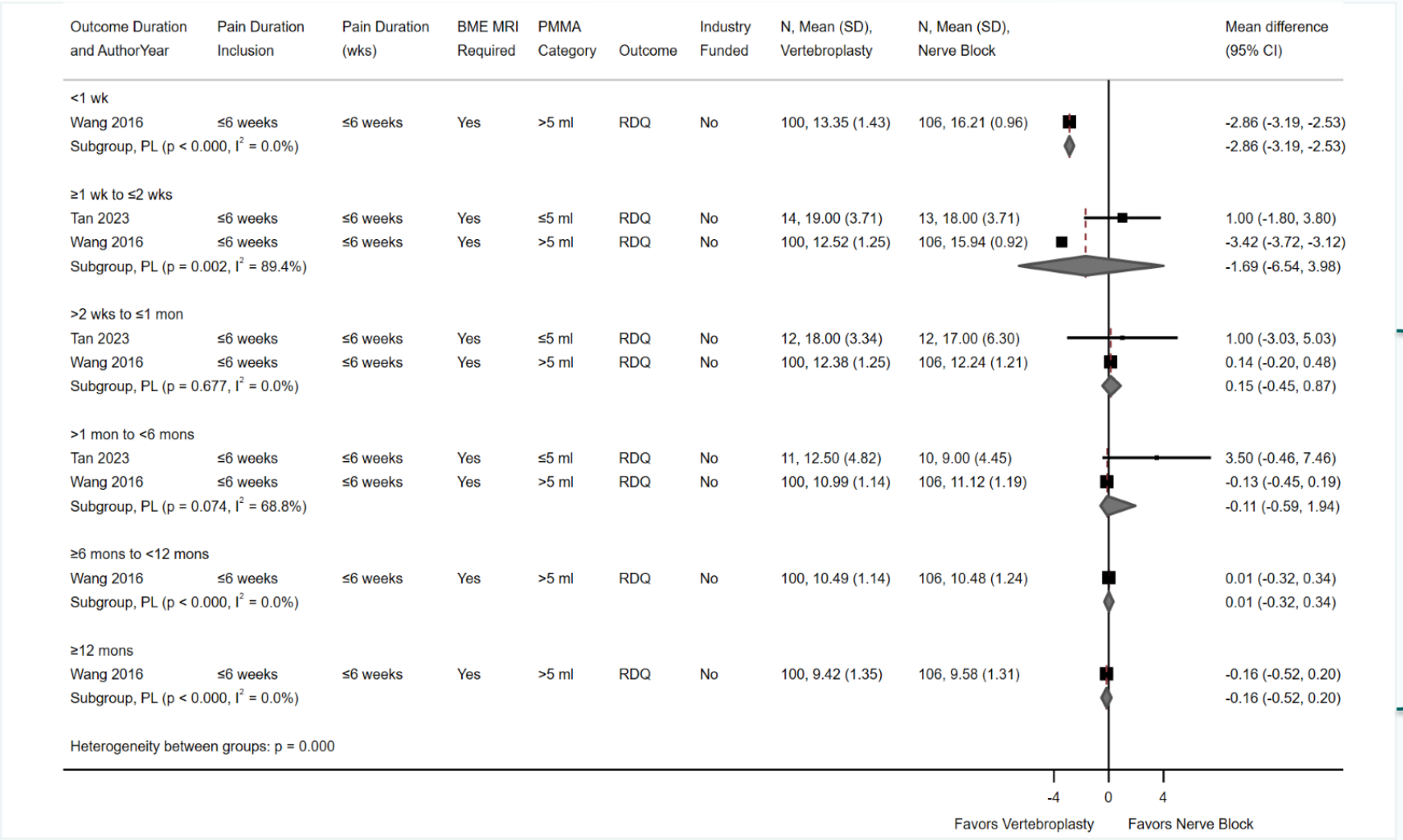


Moderate improvement, Low SOE

Similar improvement, Low SOE
Based on larger, fair-quality trial

Osteoporosis - VP vs. Nerve Block: Function Scores (RDQ, 0-24)

- VP was associated with moderate and large improvement in function at earliest time frames (<1 week, ≥1 to ≤2 weeks) but at later times function was similar between groups.



Moderate improvement, Low SOE

Large improvement, Low SOE
[based on large, fair-quality trial]

Similar improvement, Low SOE

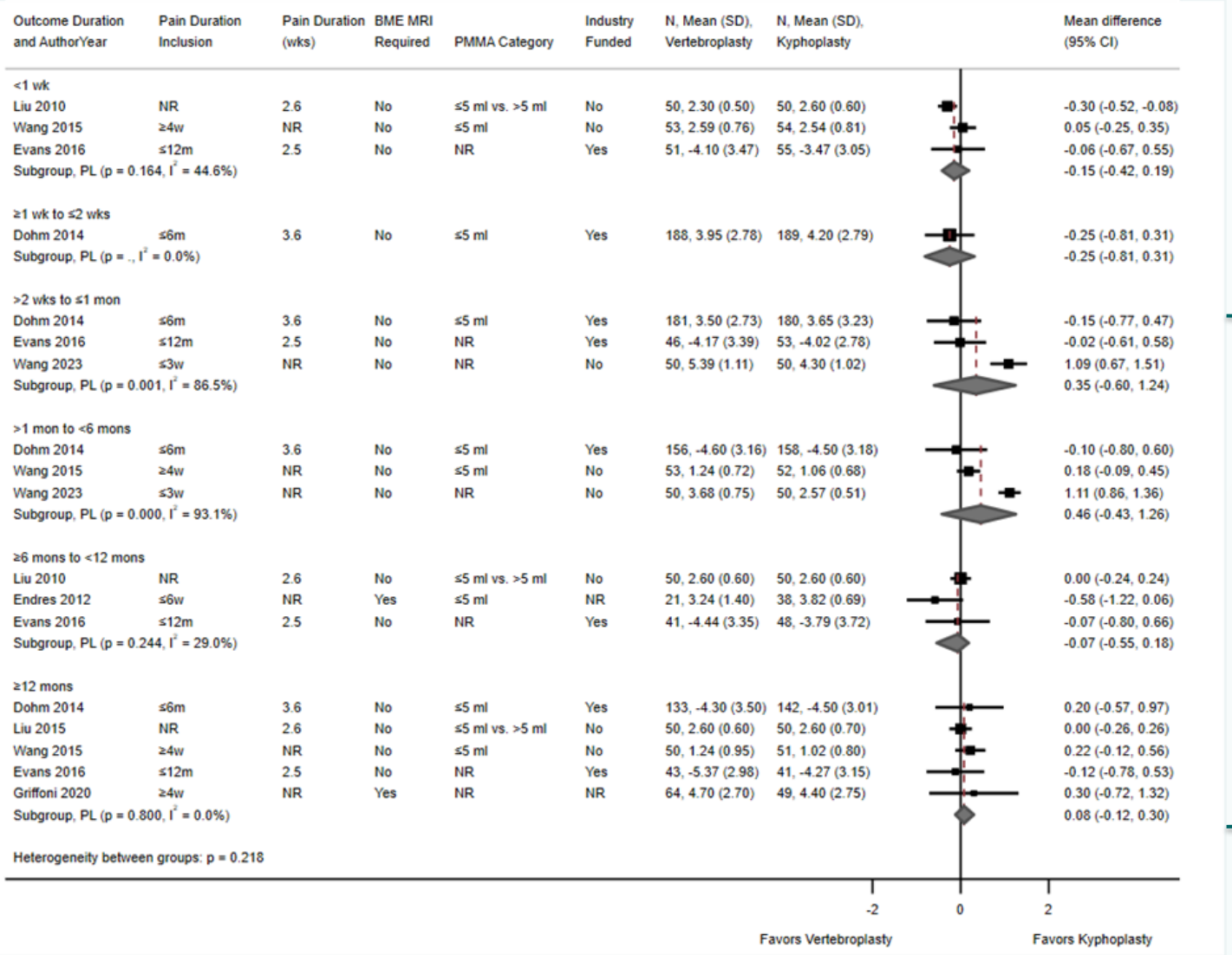
Osteoporosis - Vertebroplasty versus Kyphoplasty

- 10 RCTs (11 publications), N=1,337 (range, 66 to 404)
- Demographics: Mean age range 42 to 82 years, 44% to 100% female
- Pain duration: ≤6 weeks (6 RCTs), ≥4 weeks (2 RCTs), not reported (2 RCTs)
- Evidence of bone marrow edema required in 2 RCTs
- Intervention: Mean 1 to 3 levels treated, mean PMMA volume 3.1mL to 4.9mL (VP) vs. 3.8mL to 5.6mL (KP)
- Quality: 3 fair, 7 poor

Aggregate Analytics

Osteoporosis - VP vs. KP: Pain scores (VAS or NRS, 0-10 scale)

- Pain improvement was similar for VP and KP at all time frames for which there was sufficient evidence to assess this.



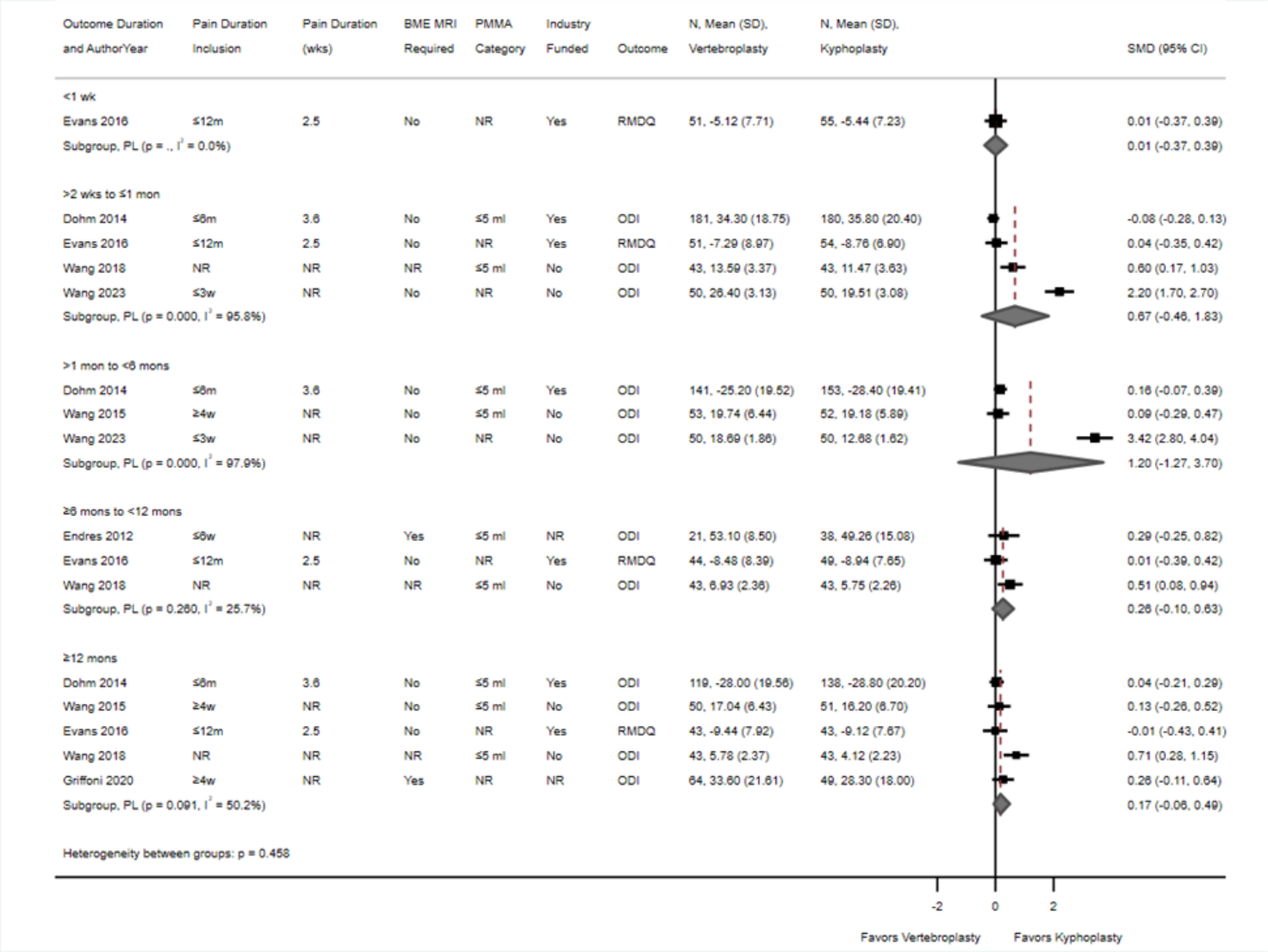
Similar improvement, Moderate SOE

Insufficient SOE [1 poor-quality trial]

Similar improvement, Low SOE
[excluding potential outlier trial at >2 weeks to ≤1 month and >1 to <6 months]

Osteoporosis - VP vs. KP: Function scores

- Function improvement was similar for VP and KP at all time frames for which there was sufficient evidence to assess this.



Similar improvement, Low SOE

Insufficient SOE

Similar improvement, Low SOE
[excluding potential outlier trial]

Similar improvement, Moderate SOE

Similar improvement, Low SOE

Osteoporosis - VP vs. KP: SECONDARY OUTCOMES (no SOE)

- Quality of Life
  - Similar improvement across various time points:
    - EQ-5D scores: 3 RCTs
    - SF-36 PCS scores: 2 RCTs
    - SF-36 MCS scores: 1 RCT
- Opioid Use
  - Similar likelihood at 6 and 24 months in 1 RCT

Aggregate Analytics

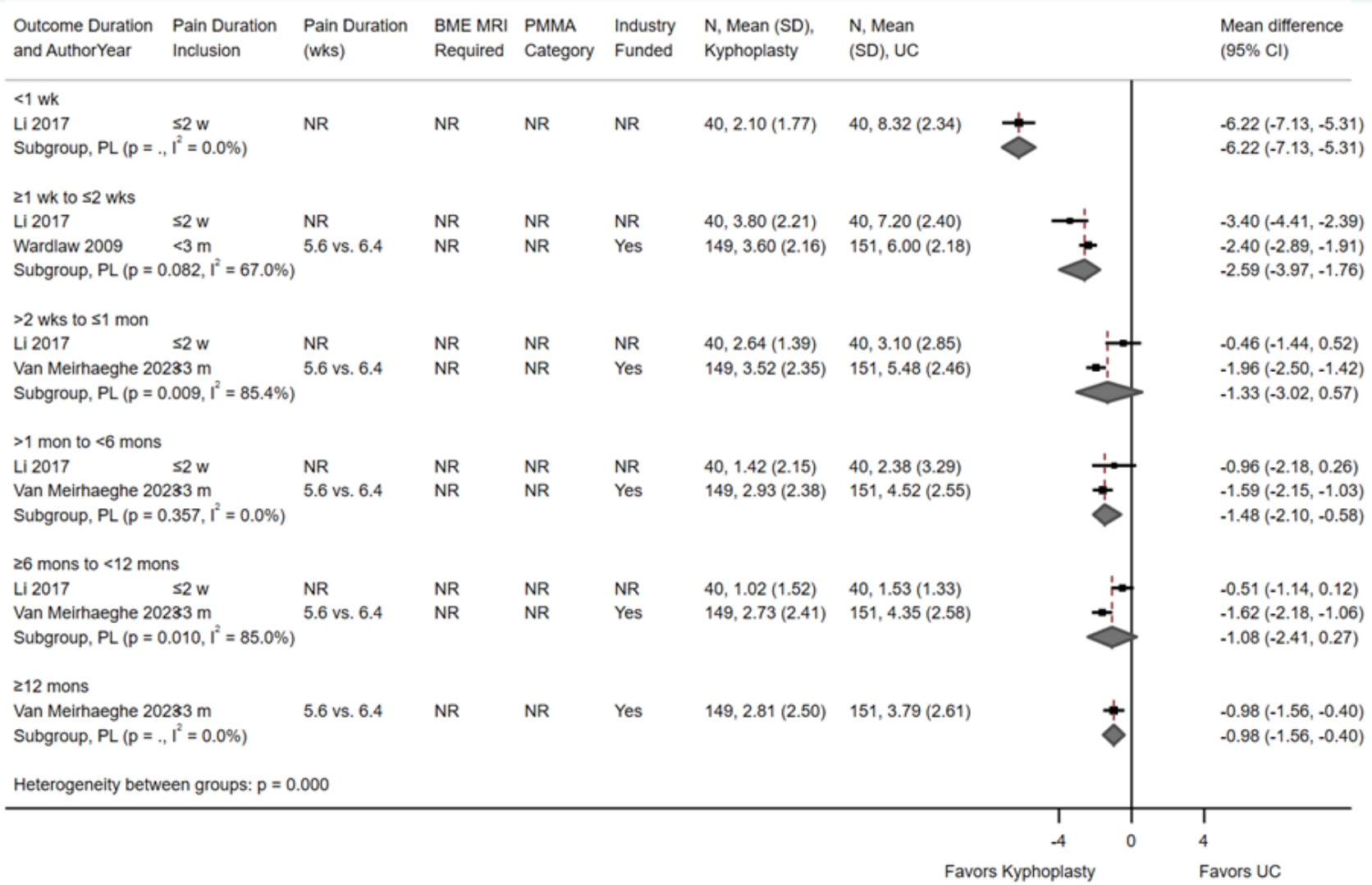
Osteoporosis - Kyphoplasty versus Usual Care

- 4 RCTs (6 publications), N=696 (range, 30 to 800)
- Demographics: Mean age range 66 to 74 years, 30% to 70% female
- Pain duration: <3 weeks (1 RCT), not reported in 3 RCTs
- Evidence of bone marrow edema required in 1 RCT
- Intervention: Mean 1.4 levels treated (1 RCT), 1 to 3 levels treated (1 RCT), number of levels treated not reported in 2 RCTs; mean PMMA volume not reported
- Quality: 1 fair, 3 poor

Aggregate Analytics

Osteoporosis - KP versus UC: Pain Scores (VAS 0-10 scale)

- KP (vs. UC) was associated with substantial pain improvement at ≥1 to ≤2 weeks which diminished to moderate improvement between >2 weeks to <12 months and to small improvement by ≥ 12 months.
- Results primarily from a single large, fair-quality RCT (FREE trial).



Insufficient SOE
[one, poor-quality trial]

Large improvement, Low SOE
[based on the large, fair-quality trial]

Moderate improvement, Low SOE
[based on the large, fair-quality trial]

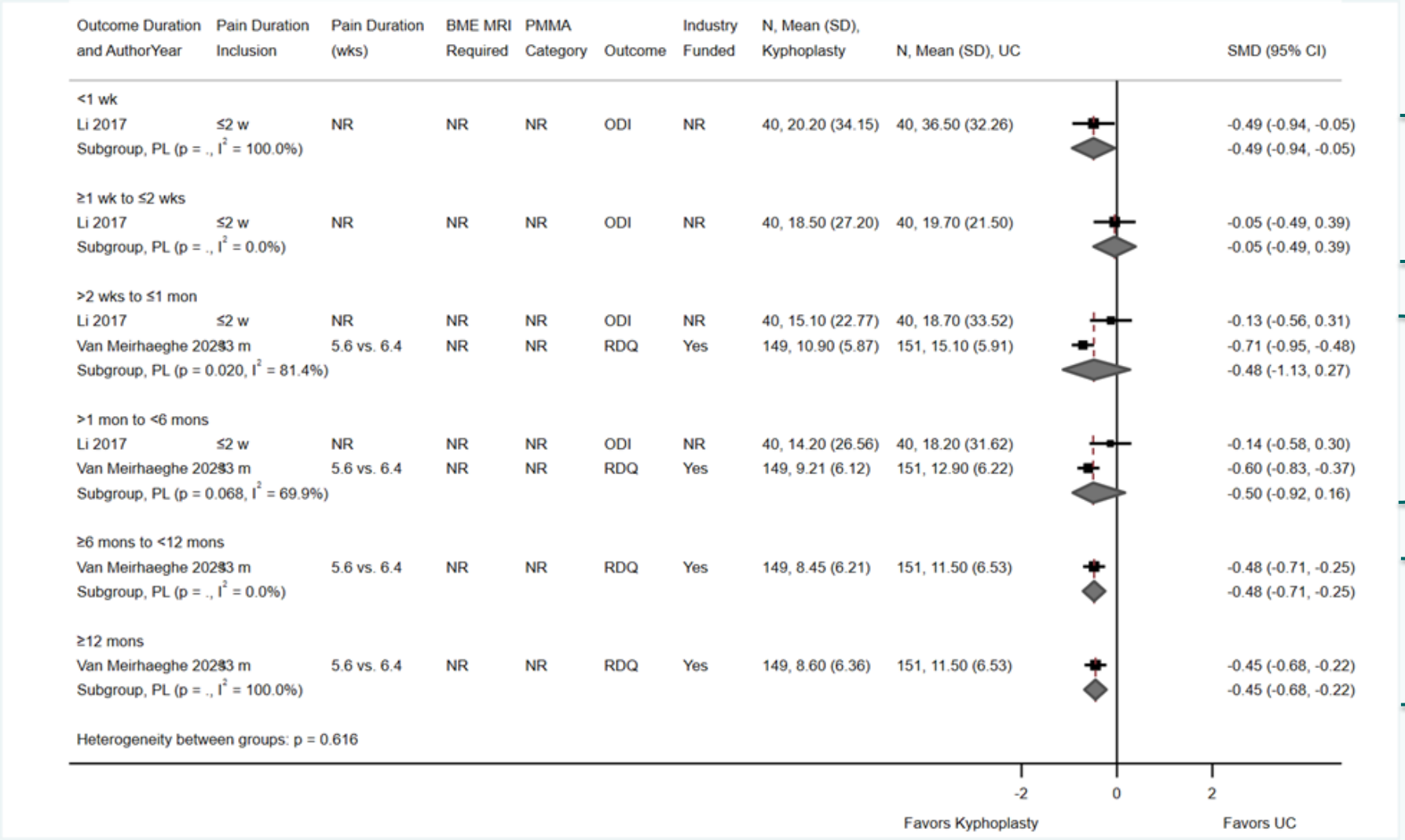
Moderate improvement, Low SOE

Moderate improvement, Low SOE
[based on the large, fair-quality trial]

Small improvement, Low SOE

Osteoporosis - KP versus UC: Function Scores

- KP associated with moderate functional improvement at two intermediate time frames (>2 weeks to ≤1 month, >1 to <6 months), and a small improvement seen for times ≥6 to 12 months. Function was similar vs. UC at 24 months (data not shown).



Insufficient SOE
[one, poor-quality trial]

Moderate improvement, Low SOE
[based on the large, fair-quality trial]

Small improvement, Low SOE

Osteoporosis - KP vs. UC:
SECONDARY OUTCOMES (no SOE) from the FREE trial

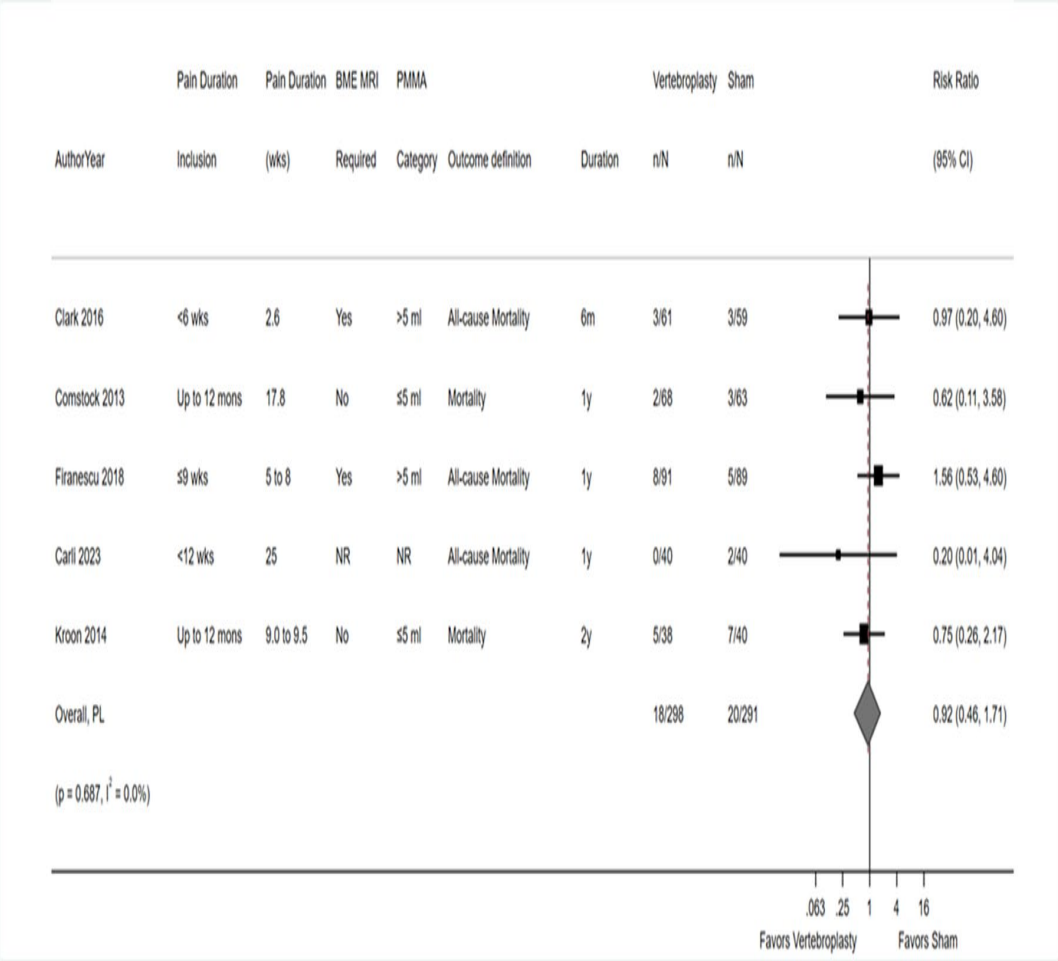
- **Quality of Life**
  - KP associated with small to moderate improvement vs. UC up to 6 months depending on measure (EQ-5D or SF-36 PCS); 12–24-month results less consistent
- **Opioid Use**
  - KP associated with moderate increase in likelihood of less opioid (any) use at 6 months vs. UC (30% vs. 43%, RR 0.69, 95% CI 0.49 to 0.98), but similar at 12 and 24 months; strong opioid use similar.

Aggregate Analytics

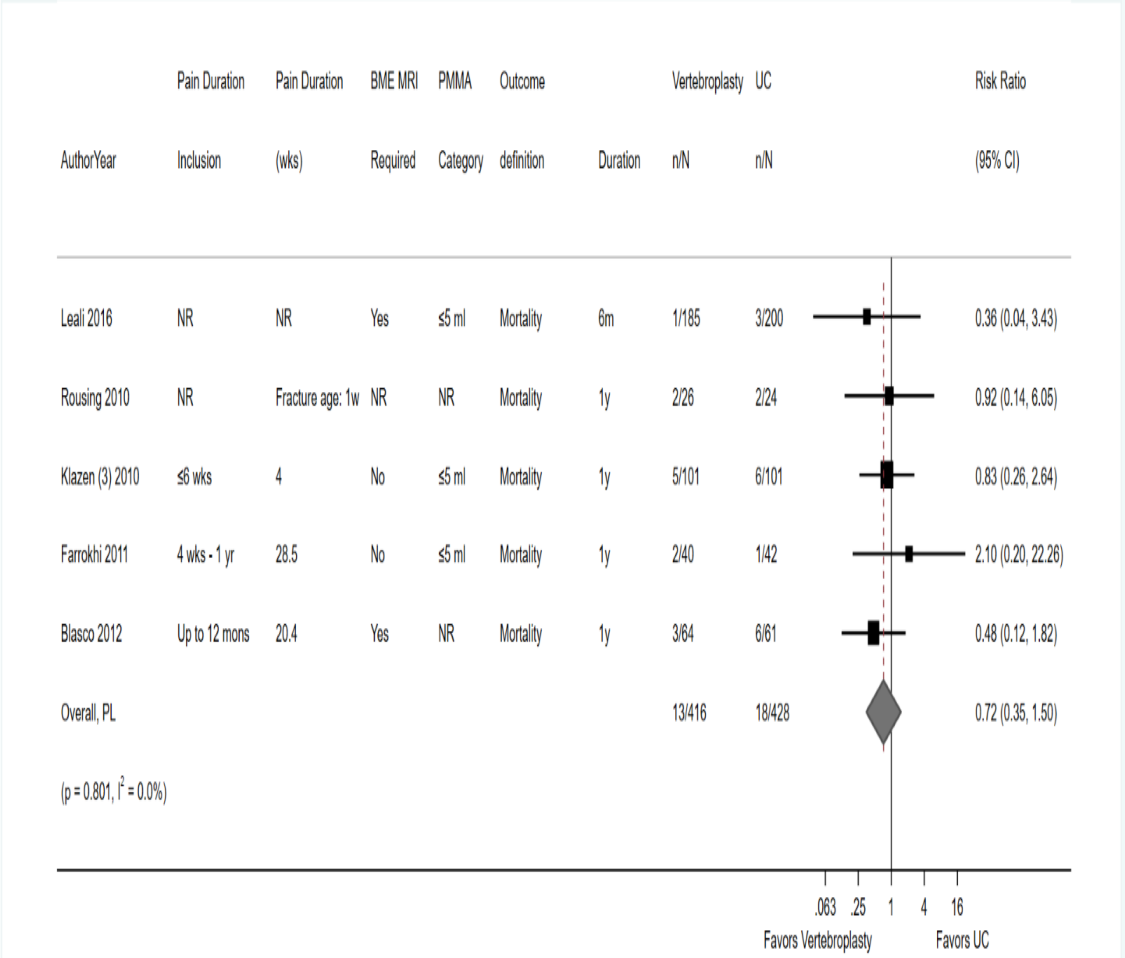
Osteoporotic Fractures
KQ 2. Safety
Vertebroplasty
Kyphoplasty

KQ 2. Safety: Vertebroplasty – Mortality – RCTs (Osteoporosis)
SOE Moderate: Similar Risk for VP vs. Sham, VP vs. UC

VP vs. Sham



VP vs. UC

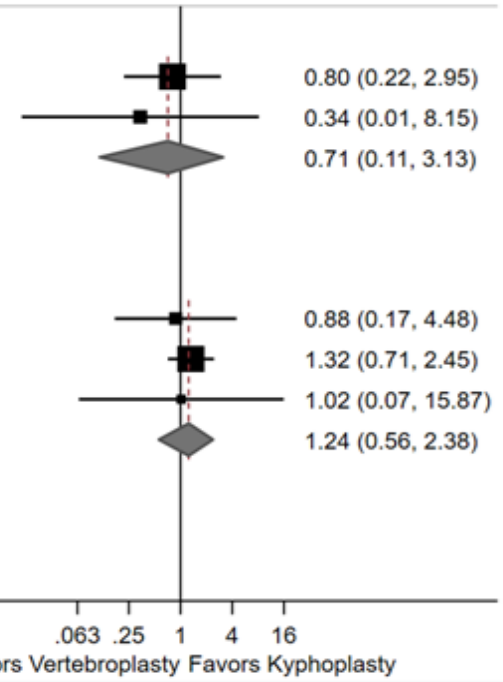


Notes: RCTs may be underpowered; ESs from RCTs and administrative data studies are reasonably consistent. RCT results are NS, but ROB for admin data is high; causality cannot be inferred from administrative data

KQ 2. Safety: Vertebroplasty – Mortality – RCTs (Osteoporosis)

VP vs. KP – Similar risk, SOE Low; Trials underpowered

Outcome Duration and AuthorYear	Pain Duration Inclusion	Pain Duration (wks)	BME MRI Required	PMMA Category	Outcome definition	Vertebroplasty n/N	Kyphoplasty n/N	Risk Ratio (95% CI)
>1 mon to <6 mons								
Dohm 2014	<6 mons	NR	No	≤5 ml	Mortality	4/190	5/191	0.80 (0.22, 2.95)
Wang 2015	≥4 wks	NR	No	≤5 ml	Mortality	0/53	1/54	0.34 (0.01, 8.15)
Subgroup, PL (p = 0.623, I^2 = 0.0%)						4/243	6/245	0.71 (0.11, 3.13)
≥12 mons								
Vogl 2013	≤6 wks	NR	No	≤5 ml	Mortality	2/28	4/49	0.88 (0.17, 4.48)
Dohm 2014	<6 mons	NR	No	≤5 ml	Mortality	21/190	16/191	1.32 (0.71, 2.45)
Wang 2015	≥4 wks	NR	No	≤5 ml	Mortality	1/53	1/54	1.02 (0.07, 15.87)
Subgroup, PL (p = 0.890, I^2 = 0.0%)						24/271	21/294	1.24 (0.56, 2.38)
Heterogeneity between groups: p = 0.410								



VP vs. nerve or facet block: Mortality NR (RCT or NRSI)

Mortality: Summary across administrative data studies (vertebroplasty or kyphoplasty): SOE Insufficient

30-Day mortality:

An association between vertebral augmentation (VA) and 30-day mortality was not consistently seen

- 1 study (20% random sample of Medicare Data) reported risks for VA vs. nonoperative treatment of 0.3% (31/9017) vs. 0.6% (51/9017), Adj OR 0.61 (95% CI 0.39-0.95).
- 1 NIS study - mortality risks for KP vs. nonoperative: 0.3% vs. 1.6%, adjusted OR 0.52, p=0.003 (CI NR).
- 2 studies (ACS-NSQIP, overlap in data) reported VA type was not an independent risk factor for mortality.

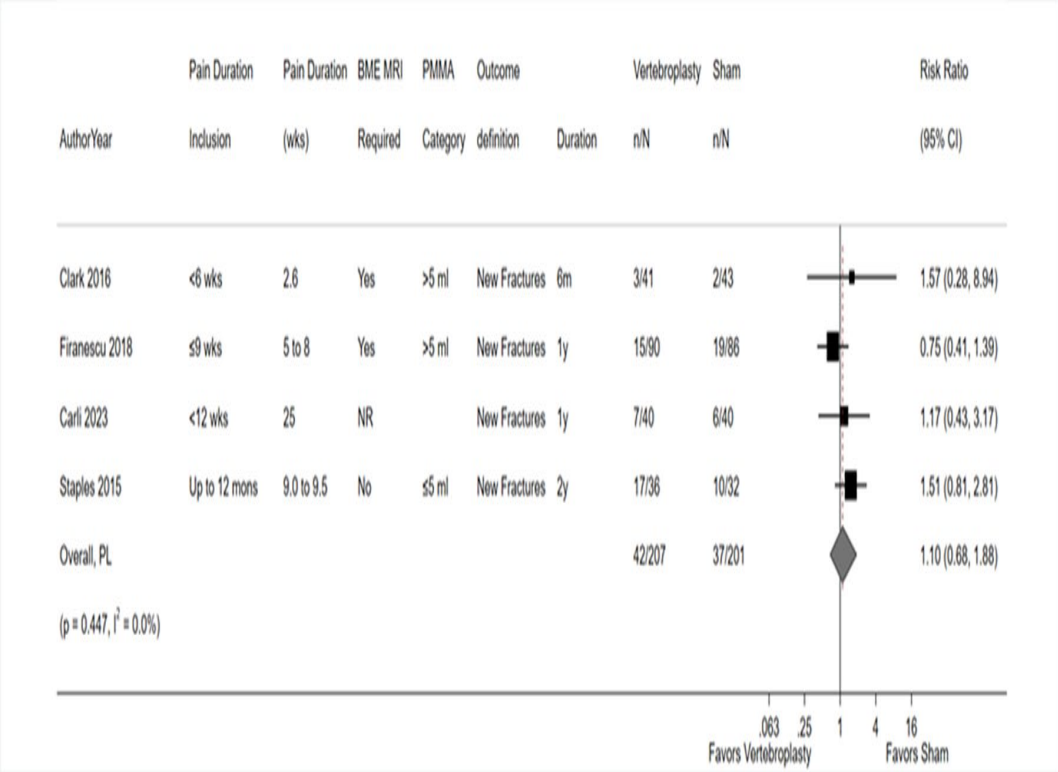
Longer term mortality:

An association between VA and mortality was not consistently seen

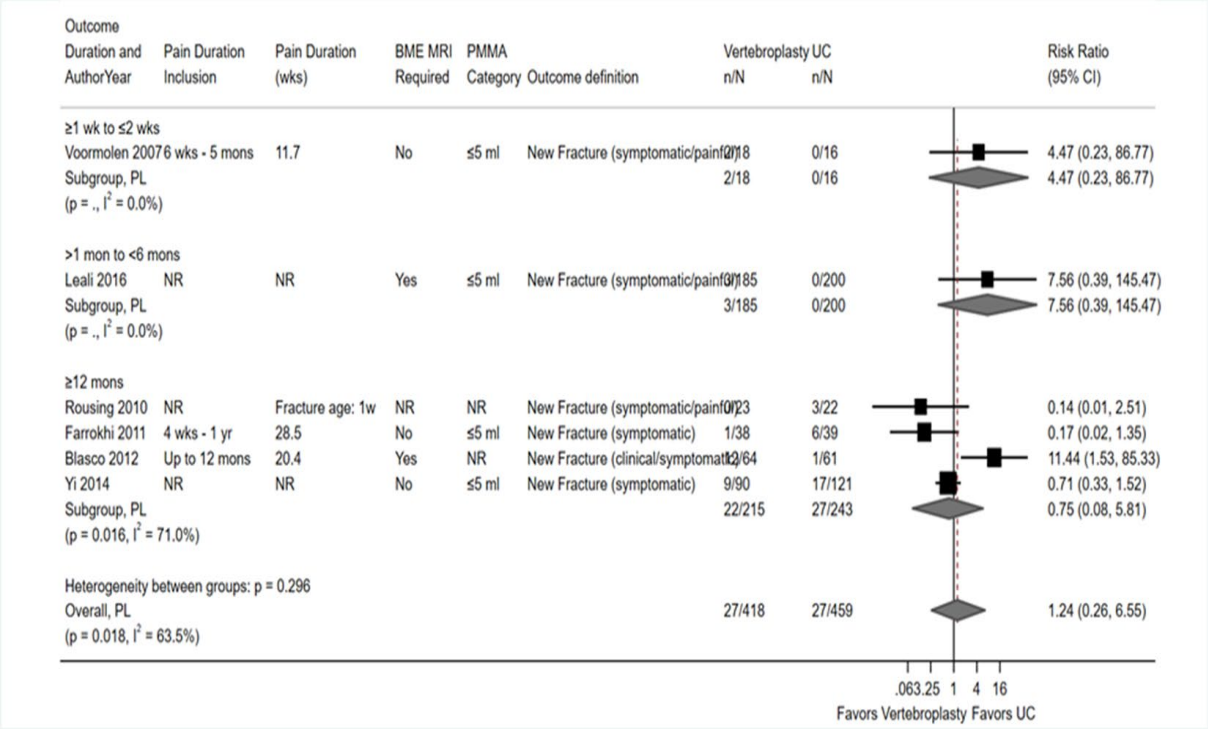
- 2 studies (industry funded; Medicare data, overlapping sample frames) report that vertebral augmentation was associated with slightly lower mortality risk compared with nonoperative care {Ong, Edidin 2015}.
  - (These studies also reported lower mortality with KP vs. VP)
- 3rd study (nonindustry funded) using 20% random sample of Medicare data reported no association {McCollough}.
- 1 small hospital-based study: no difference in mortality between VA and no treatment {Levy}.
- 2 studies (Taiwan, overlapping data) and 1 (Germany) reported lower mortality with VA vs. nonoperative care.

KQ 2. Safety: Vertebroplasty – New Fractures – RCTs (Osteoporosis)
Similar Risk for VP vs. Sham, VP vs. UC

VP vs. Sham – cumulative; SOE: Moderate



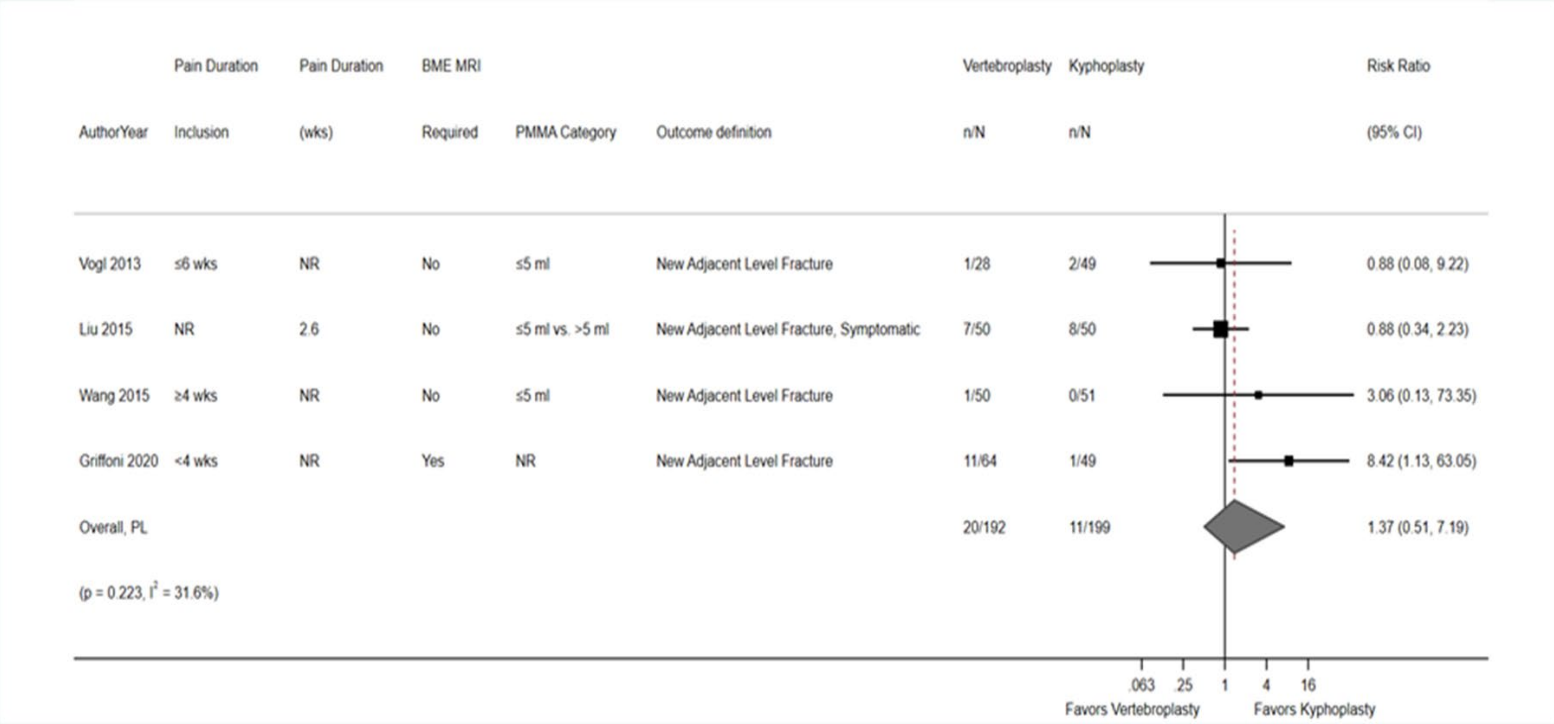
VP vs. UC – New *symptomatic* by time; SOE: Low



Notes: VP vs. UC, cumulative risk of *any* new fracture similar between groups at all times.
VP vs. Sham: 1 RCT (N=34) reported new *symptomatic* fractures: 40% vs. 31%, RR 0.84 (95% CI 0.38 to 1.84); SOE Low.

KQ 2. Safety: Vertebroplasty – New Fractures – RCTs (Osteoporosis)
Similar Risk for VP vs. KP and VP vs. facet block

VP vs. KP: Any new fracture (SOE Low)



VP vs. KP: similar risk for

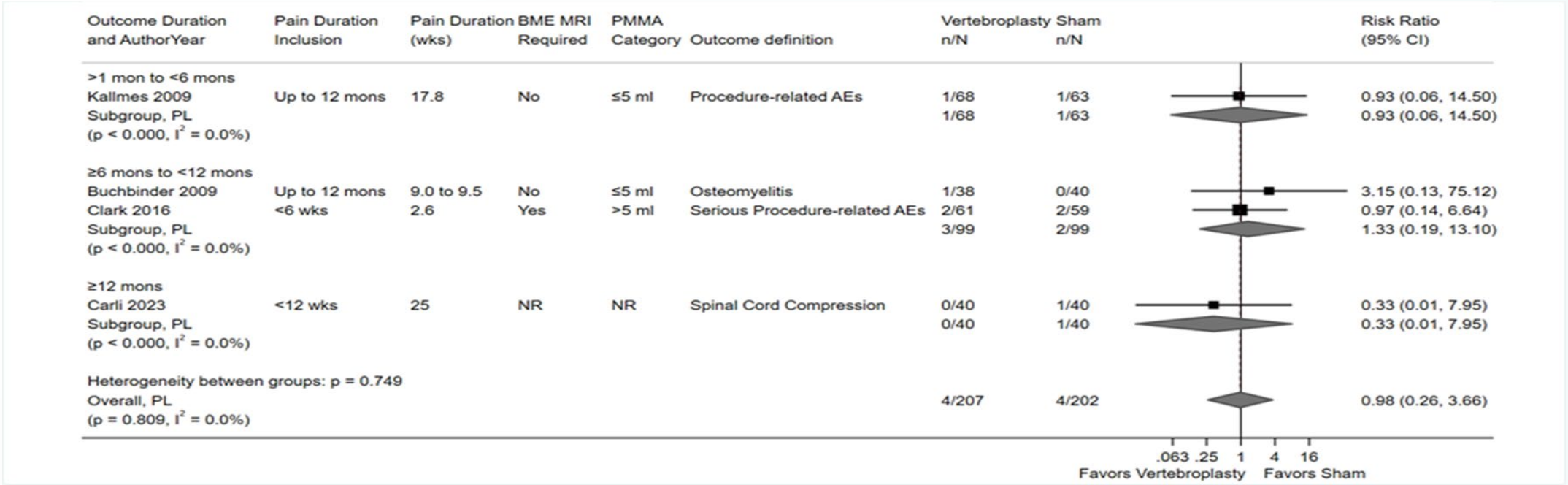
- New adjacent level fracture (SOE Low).
- New symptomatic fracture (SOE Insufficient).

VP vs. facet block:

Similar risk any new VCF (1 RCT): 13% vs. 10.4%, RR 1.25 (95% CI 0.59 to 2.67); SOE Low.

KQ 2. Safety: Vertebroplasty – Serious AEs – RCTs (Osteoporosis)
Similar Risks for VP vs. Sham, VP vs. UC

VP vs. Sham – (SOE Low)



VP vs. UC – (SOE Low)

- SAEs (unspecified): none occurred (2 RCTs, N=261).
- DVT/thrombophlebitis: 3.6% vs. 7.8%, RR 0.46 (95% CI 0.09 to 2.38) (1 RCT, N=107).
- Reoperation: 10.0% (9/90) vs. 9.1% (11/121), RR 1.10 (95% CI 0.48 to 2.54) (1 RCT, N=211); range, 2.5% to 11.1% across VP arms (3 RCTs, n range 18 to 90); cause: symptomatic new fractures or cement leak causing LE pain.

Notes: RCT evidence is sparse. Trials may be underpowered to detect rare events; estimates are imprecise. Treatment-related SAEs were poorly reported, were not considered to be procedure related.

KQ 2. Safety: Vertebroplasty Cement Leakage from RCTs (Osteoporosis): VP vs. Sham, VP vs. UC and VP vs. KP

Any cement leakage is common with VP (no data for KP); symptomatic cement leakage appears to be rare for both VP and KP and occurs with similar frequency

VP vs. Sham	3 RCTs (N=232 treated levels) Carli 2023, Firanescu 2018, Buchbinder 2009	**Symptomatology not reported** Range, **40% to 91%** of treated levels (3 RCTs). A fourth RCT (n=55 levels): none were observed (Hansen 2019)	⊕⊕⊕◯ **MODERATE SOE** (Inconsistency, imprecision)
VP vs. UC	7 RCTs (n=varies) Blasco 2012, Chen 2014, Farrokhi 2011, Klazen 2010, Rousing, 2009/2010, Yang, 2016, Yi, 2014	**Symptomatic cement leakage:** Range, **0% to 1%,** 7 RCTs (range of levels, n=63 to 140 across 6 RCTs; NR by 1 RCT); one symptomatic leakage reported in 1 RCT (1%, 1/100 levels) **Asymptomatic cement leakage** Range, **13.0% to 72.4%**, 5 RCTs (range of levels, n=65 to 140); Range, **49.3 % to 72.4%**, 3 fair-quality RCTs (range of levels, n=69 to 140); 2 RCTs (63 levels; 90 patients [levels NR]): all fractures asymptomatic, data not clear/NR	⊕⊕⊕◯ **MODERATE SOE** (ROB, imprecision)
VP vs. KP	5 RCTs (N=800) Dohm 2014, Endres 2012, Vogl 2013, Wang 2015, Yi 2024	**Symptomatic Cement Leakage:** **VP: range, 0% to 1.1%; KP: range, 0% to 1.9%** 3 RCTs (N=312) reported no events in either group 1 RCT: 1.1% (2/190) vs. 0.5% (1/191), RR 2.01 (0.18 to 21.99) 1 RCT: 0% (0/53) vs. 1.9% (1/54), p=0.68; required discectomy and fusion **Symptomatic embolism:** 1 RCT (Dohm 2014): **0.5% (1/190) vs. 0.5% (1/191)**; RR 1.01 (0.06 to 15.96) Dohm 2014 **Asymptomatic embolism:** 1 RCT (Wang): **0% (0/50) vs. 2.0% (1/51)**	⊕⊕◯◯ **LOW SOE** (ROB, Imprecision)

KQ 2. Safety: Vertebroplasty – Other adverse events - RCTs (Osteoporosis): VP vs. KP

Evidence was insufficient for the following:

- Serious Adverse Events
- Refracture or worsening index level fracture
- Procedure or device related SAEs (not further defined)
- Reoperation for any new or repeat fracture

KQ 2. Safety: Kyphoplasty vs. UC (Osteoporosis)

Similar risk of AEs; SOE Low (RoB, inconsistent/consistency unknown, imprecision)

Outcome	Studies	KP vs. Usual Care Effect estimate (95% CI) Conclusion
Mortality	1 RCT (N=300) Wardlaw 2009, Boonen 2011	24 months: 8.1% (12/149) vs. 7.2% (11/151); RR 1.11 (0.50 to 2.43)
SAEs (any)	2 RCTs (N=500) Wardlaw 2009, Boonen 2011, Van Meirhaeghe 2013; Yi 2014	Fair quality trial, 30 days: 16.1% (24/149) vs. 11.2% (17/151), RR 1.43 (0.80 to 2.55) 24 months: 49.7% (74/149) vs. 48.3% (73/151), RR 1.02 (0.82 to 1.29) Poor-quality trial, mean 49 months: 0% (0/79) vs. 0% (0/121)
Treatment-related SAEs†	1 RCT (N=300) Boonen 2011, Van Meirhaeghe 2013	30 days: 1.3% (2/149) vs. 0.7% (1/151), RR 2.03 (0.19 to 22.12) 12 and 24 months, KP arm only: 1.3% (2/149) and 2.0% (3/149)
Withdrawals due to AEs	1 RCT (N=300) Wardlaw 2009, Boonen 2011	0.6% (1/149) vs. 0.6% (1/151), RR 1.01 (0.06 to 16.05)
New clinical/symptomatic vertebral fractures	2 RCTs (N=500) Boonen 2011, Van Meirhaeghe 2013, Yi 2014	Fair-quality trial, 24 months: 17.4% (26/149) vs. 11.3% (17/151), RR 1.55 (0.88 to 2.74) Poor-quality trial: 49 months: 6.3% (5/79) vs. 14.0% (17/121), RR 0.45 (0.17 to 1.17)
New radiographic vertebral fracture	1 RCT (N=300) Boonen 2011, Van Meirhaeghe 2013	Any new fracture: 47.5% (56/118) vs. 44.1% (45/102), RR 1.08 (0.81 to 1.44) New index level fractures: 4.2% (5/118) vs. 10.8% (11/102), RR 0.39 (0.14 to 1.09) New adjacent level fractures: 23.7% (28/118) vs. 16.7% (17/102), RR 1.42 (0.83 to 2.45)
Reoperation (for new symptomatic fractures)	1 RCT (N=300) Wardlaw 2009, Boonen 2011	8.1% (12/149) vs. 4.0% (6/151), RR 2.03 (0.78 to 5.26)

Fractures Due to Malignancy

Malignancy – Kyphoplasty vs. Usual Care

- 1 RCT (CAFE trial), N=134, fair-quality
- 22 sites across U.S., Canada, Europe and Australia; funded by industry
- Mean age 64 years, 58% female, median fracture age 3.4 months
- Number of fractures: 3 (31%), 2 (29%), 1 (39%)
- Primary cancer: myeloma (38%), breast (22%) and other (26%; colon, ovarian, esophageal, and bladder cancer); considered stable (38%), progressive (36%), in remission (8%)
- Most common previous treatments: chemotherapy/hormonal therapy (67%), surgery (51%), steroids (35%), radiation (21%)
- High cross over rate after 1 month (59%)

Aggregate Analytics

Malignancy – Kyphoplasty vs. Usual Care:
KQ 1: Summary of efficacy results from the CAFE Trial (Berenson, 2011)

- KP associated with large improvements/likelihoods of improvement across all pain and function outcomes at 1 month (except KPS score ≥70 which was moderate).
- Outcomes past 1 month not reported due to high crossover rate from UC to KP (59%).

Outcome at 1 month	N	KP vs. UC Effective Size (95% CI)	SOE
Primary Outcomes			
Pain: NRS scores (0-10; worse)	114	MD -3.50 (-4.37 to -2.63)	**LOW** Single, fair-quality trial
Function: RDQ scores (0-24; worse)	113	MD -8.9 (-9.49 to -8.31)	
Function: KPS (0-100; better)	112	MD 14.5 (12.83 to 16.17)	
Function: Responders, RDQ (≥2 points)	113	81% vs. 28%, RR 2.89 (1.82 to 4.58)	
Function: Responders, KPS (≥10 points)	112	65% vs. 27%, RR 2.45 (1.49 to 4.04)	
Function: Proportion with KPS score ≥70 (ability to care for oneself)	112	75% vs. 39%, RR 1.92 (1.32 to 2.81)	
Secondary Outcomes			
SF-36 PCS (0-100; better)	105	MD 8.0 (7.18 to 8.82)	*No SOE*
SF-36 MCS (0-100; better)	105	MD 10.0 (8.74 to 11.26)	

Malignancy – Kyphoplasty vs. Usual Care:
KQ 2: Summary of safety results from the CAFE Trial (Berenson, 2011)

Outcome*	Followup	Analysis group	KP % (n/N)	Usual Care % (n/N)	RR (95% CI)	Conclusions *All LOW SOE*
Mortality*	1 month	As randomized	2.8% (2/70)	1.5% (1/64)	1.82 (0.17 to 19.69)	Similar risk
	≥1 month and ≤12 months	As randomized	30.0% (21/70)	19.2% (5/26)	1.56 (0.66 to 3.71)	KP tended to have higher risk; NS
		As treated (after crossover)	25.0% (27/108)	19.2% (5/26)	1.30 (0.55 to 3.05)	
Any Serious AEs†	1 month	As randomized	NR	NR	NR	-----
	≥1 month and ≤12 months	As randomized	52.8% (37/70)	30.7% (8/26)	1.72 (0.93 to 3.19)	KP tended to have higher risk; NS
		As treated (after crossover)	50.9% (55/108)	30.7% (8/26)	1.66 (0.90 to 3.03)	
Symptomatic Fracture	1 month	As randomized	2.8% (2/70)	4.7% (3/64)	0.61 (0.11 to 3.53)	Similar risk
	≥1 month and ≤12 months	As randomized	12.8% (9/70)	0% (0/26)‡	NC, p=0.056	Occurred in KP patients only (long term)
		As treated (after crossover)	16.7% (18/108)	0% (0/26)	NC, p=0.026	
Cement Leakage	1 month	As randomized	1.4% (1/70)	NA	NC	Appears to be rare
Any AEs§	1 month	As randomized	37.1% (26/70)	29.7% (19/64)	1.25 (0.77 to 2.03)	Similar risk

Malignancy - Vertebroplasty versus Kyphoplasty
SOE INSUFFICIENT

- 3 retrospective, comparative NRSIs (N=410; range, 34 to 342), 1 SR of case-series (VP and KP, n=3,426), 4 case series (2 VP, 2 KP, n range 44 to 92) not include in SR
  - **Pain**: Similar improvement in pain (% responders and 0-10 VAS scores) for VP vs. KP from comparative NRSIs; both VP and KP significantly improved pain compared with baseline in case series.
  - **Other outcomes from case series**: Significant improvement (versus baseline) in ODI/KPS function scores, SF-36 quality of life scores, and opioid use (reduction) for both VP and KP.
  - **Safety**: Overall, incidence of AEs was low and occurred with similar frequency between VP vs. KP (comparative NRSIs); substantial range in frequency of most harms across case series, though SAEs and symptomatic cement leakage were rare.

Aggregate Analytics

Sacral Insufficiency Fractures

Sacral Insufficiency Fractures – Sacroplasty
SOE INSUFFICIENT

4 poor-quality comparative NRSI (1 prospective, 3 retrospective) (N range, 27 to 244); 1 SR of case series (N=861, n range 6 to 243), 1 prospective registry study (N=102)

- **Pain and Function, results varied by comparator:**
  - Sacroplasty associated with significantly *greater* improvement vs. UC (3 studies), significantly *less* improvement vs. percutaneous teriparatide injections (1 study), and *similar,* but more rapid*,* improvement vs. surgery/screw fixation (1 study); statistically significant improvement from baseline in the SR and registry studies.
- **Safety**:
  - Decreased risk of mortality with sacroplasty vs. usual care, similar risk vs. surgery; SAEs, symptomatic cement leakage, new fracture rare.

Aggregate Analytics

KQ3: Differential Effectiveness and Safety

Differential Effectiveness and Safety (KQ3)
Osteoporotic Fractures

Analysis of factors that may modify treat effects is limited by study sample sizes and small numbers of trial, particularly for evaluation of fracture age and duration of symptoms. Trials reporting interaction and an AHRQ review reporting stratified analyses across RCTs are included.

Confidence in findings is very low, estimates are imprecise

VP vs. Sham or UC

- There does not appear to be modification of treatment effect for pain or function based on
  - Sex, prior fracture (1 RCT).
  - Fracture age or pain duration (Included RCT subgroup analysis; stratified analysis of RCTs).
- Based on stratified analyses of RCTs, no modification seen by
  - PMMA volume.
  - MRI findings of bone marrow edema – study enrollment requirement.

VP vs. KP

- No appreciable differences in the magnitude of pain reduction form subgroup analysis on sex, age, preoperative pain scores or preoperative RDQ scores. No data or p-values for interaction provided.

KQ 4: Cost Effectiveness

KQ 4. Cost Effectiveness

- One CUA in patients with malignant VCF: VP and KP may be cost-effective vs. nonsurgical management.
- A comprehensive CUA (UK National Institute for Health Research) noted that cost-effectiveness of VP and KP was influenced by:
    - Assumptions about differential mortality for augmentation vs. UC based on administrative data; causal inference regarding mortality is not possible from administrative data.
    - Comparisons based on blinded trials.
- Two U.S. studies reported that was cost-effective versus non-operative management, however cost-effectiveness was sensitive to varying the degree of assumed mortality differences; Medicare claims data models used for mortality.

SUMMARY

Summary of effectiveness and safety evidence for vertebroplasty versus sham in patients with *osteoporotic* vertebral compression fractures (KQs 1 and 2)

Effect/Improvement favors VP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (≥30% improvement from baseline)	Large likelihood, 1 RCT, N=113 (SOE: Low)	Similar likelihood, 2 RCTs, N=186 (SOE: Moderate)	Moderate likelihood, 3 RCTs, N=313 (SOE: Moderate)	Moderate likelihood, 2 RCTs, N=176 (SOE: Moderate)	Small likelihood, 2 RCTs, N=171 (SOE: Moderate)	Small likelihood, 3 RCTs, N=339 (SOE: Moderate)
VAS pain scores (0-10)	Similar, 4 RCTs, N=500 (SOE: Low)	Similar, 6 RCTs, N=616 (SOE: Moderate)	Small, 6 RCTs, N=616 (SOE: High)	Small, 6 RCTs, N=605 (SOE: High)	Small, 5 RCTs, N=550 (SOE: High)	Similar, 5 RCTs, N=478 (SOE: Low)
RDQ function scores (0-24)	Similar, 2 RCTs, N=244 (SOE: Low)	Similar, 5 RCTs, N=531 (SOE: Low)	Small, 5 RCTs, N=566 (SOE: Moderate)	Similar, 5 RCTs, N=557 (SOE: Low)	Small, 5 RCTs, N=548 (SOE: Low)	Similar, 4 RCTs, N=432 (SOE: Low)
Mortality	Similar, 5 RCTs, N=589, at last follow-up (12-24 months) (SOE: Moderate)					
Any new vertebral fracture	Similar, 4 RCTs, N=408, at last follow-up (6-24 months) (SOE: Moderate)					
Any new symptomatic fracture with bone edema	Similar, 1 RCT, N=34, 12 months (SOE: Low)					
Any SAE	Similar, 4 RCTs, N=409, at last follow-up (3-12 months) (SOE: Low)					
Cement leakage, any	Common after VP, 3 RCTs, N=232 levels, any time (SOE: Moderate)					

Summary of effectiveness and safety evidence for vertebroplasty versus usual care in patients with *osteoporotic* vertebral compression fractures (KQs 1 and 2)

Effect/Improvement favors VP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (<4 on 0-10 VAS)	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
Pain Response (Complete relief)	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
VAS/NRS pain scores (0-10)	Large, 3 RCTs, N=343 (SOE: Moderate)	Moderate, 4 RCTs, N=432 (SOE: Low)†	Large, 3 RCTs, N=398 (SOE: Low)	Moderate, 5 RCTs, N=569 (SOE: Moderate)	Similar, 4 RCTs, N=523 (SOE: Low)	Moderate, 5 RCTs, N=567 (SOE: Low)
Function scores‡	No evidence	Small, 4 RCTs, N=432 (SOE: Low)	Small, 3 RCTs, N=398 (SOE: Moderate)	Small, 4 RCTs, N=440 (SOE: Moderate)	Small, 3 RCTs, N=398 (SOE: Moderate)	Small, 4 RCTs, N=436 (SOE: Moderate)
Mortality	Similar, 6 RCTs, N=844, at last follow-up (6-12 months) (SOE: Moderate)					
Any new vertebral fracture	Similar, 9 RCTs, N=830, at last follow-up (2 weeks to 49 months) (SOE: Low)					
Any new symptomatic vertebral fracture	Similar, 6 RCTs, N=877, at last follow-up (2 weeks to 12 months) (SOE: Low)					
SAEs	Similar, 4 RCTs, N=408, any time (SOE: Low)					
Reoperation	Similar, 1 RCT, N=211, any time (SOE: Low)					
Cement leak, symptomatic	Rare with VP, 7 RCTs, N=661 levels, any time (SOE: Moderate)					
Cement leak, asymptomatic	Common with VP, 7 RCTs, N=661 levels, any time (SOE: Moderate)					

Summary of effectiveness and safety evidence for vertebroplasty versus kyphoplasty in patients with *osteoporotic* vertebral compression fractures (KQs 1 and 2)

Effect/Improvement favors VP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
Pain Response (total effective rate)†	No evidence	No evidence	No evidence	No evidence	No evidence	INSUFFICIENT
VAS/NRS pain scores (0-10)	Similar, 3 RCTs, N=313 (SOE: Moderate)	INSUFFICIENT	Similar, 2 RCTs, N=460 (SOE: Low)‡	Similar, 2 RCTs, N=419 (SOE: Low)‡	Similar, 3 RCTs, N=248 (SOE: Low)	*12-24 months*: Similar, 5 RCTs (N=673) (SOE: Low) *60 months*: INSUFFICIENT
Function scores§	Similar, 1 RCT, N=106 (SOE: Low)	No evidence	INSUFFICIENT	Similar, 2 RCTs, N=399 (SOE: Low)‡	Similar, 3 RCTs, N=238 (SOE: Moderate)	*12 months*: Similar, 5 RCTs (N=643) (SOE: Low) *24 months*: INSUFFICIENT
Mortality	Similar, 4 RCTs, N=631, at latest follow-up (12-24 months) (SOE: Low)					
Any new vertebral fracture	Similar, 6 RCTs, N=781, at latest follow-up (12-49 months) (SOE: Low)					
Cement leak, symptomatic	Similar and rare, 5 RCTs, N=800, any time (SOE: Low)					
Cement embolism, any	Similar and rare, 2 RCTs, N=381, any time (SOE: Low)					
Any new symptomatic vertebral fracture	INSUFFICIENT					
Refracture or worsening at index level	INSUFFICIENT					
SAEs, any and procedure or device related	INSUFFICIENT					
Reoperation for new fracture	INSUFFICIENT					

Summary of effectiveness and safety evidence for vertebroplasty versus medial branch nerve or facet blocks in patients with *osteoporotic* vertebral compression fractures (KQs 1 and 2)

Effect/Improvement favors VP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
VAS/NRS pain scores (0-10)	Moderate, 1 RCT, N=206 (SOE: Low)	Moderate, 2 RCTs, N=233 (SOE: Low)	Similar, 2 RCTs, N=230 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)*	Similar, 1 RCT, N=206 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)
RDQ function scores (0-24)	Moderate, 1 RCT, N=206 (SOE: Low)	Large, 1 RCT, N=206 (SOE: Low)*	Similar, 2 RCTs, N=230 (SOE: Low)	Similar, 2 RCTs, N=227 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)	Similar, 1 RCT, N=206 (SOE: Low)
New vertebral fractures	Similar, 1 RCT, N=206, 12 months (SOE: Low)					
Cement leak, asymptomatic	INSUFFICIENT					

Aggregate Analytics

Summary of effectiveness and safety evidence for kyphoplasty versus usual care in patients with *osteoporotic* vertebral compression fractures (KQs 1 and 2)

Effect/Improvement favors KP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to <6 months	≥6 to <12 months	≥12 months
VAS/NRS pain scores (0-10)	INSUFFICIENT	Large, 1 RCT, N=300 (SOE: Low)†	Moderate, 1 RCT, N=300 (SOE: Low)†	Moderate, 2 RCTs, N=380 (SOE: Low)	Moderate, 1 RCT, N=300 (SOE: Low)†	*12, 24 months* Small, 1 RCT, N=300 (SOE: Low)
Function scores‡	INSUFFICIENT	INSUFFICIENT	Moderate, 1 RCT, N=300 (SOE: Low)†	Moderate, 1 RCT, N=300 (SOE: Low)†	Small, 1 RCT, N=300 (SOE: Low)	*12 months* Small, 1 RCT, N=300 (SOE: Low) *24 months* Similar, 1 RCT, N=300 (SOE: Low)
Mortality	Similar, 1 RCT, N=300, 24 months (SOE: Low)					
Any SAE	Similar, 2 RCTs, N=500, at last follow-up (24-49 months) (SOE: Low)					
Treatment-related SAEs	Similar, 1 RCT, N=300, 30 days (SOE: Low)					
Withdrawals due to AEs	Similar, 1 RCT, N=300, 24 months (SOE: Low)					
New vertebral fracture	Similar, 1 RCT, N=300, 24 months (SOE: Low)					
New symptomatic vertebral fracture	Similar, 2 RCTs, N=500, at last follow-up (24-49 months) (SOE: Low)					
Cement leak, symptomatic	Not uncommon, 2 RCTs, N=228 KP, at last follow-up (24-49 months) (SOE: Low)					
Reoperation for new symptomatic fracture	Similar, 1 RCT, N=300, 24 months (SOE: Low)					

Summary of effectiveness and safety evidence for kyphoplasty versus usual care in patients with vertebral compression fractures due to *tumors or malignancy* (KQs 1 and 2)

Effect/Improvement favors KP unless otherwise indicated

SOE	High	Moderate	Low

Outcomes*	<1 week	≥1 to ≤2 weeks	>2 weeks to ≤1 month	>1 to ≥12 months
VAS/NRS pain scores (0-10)	No evidence	Large, 1 RCT, N=117 (SOE: Low)	Large, 1 RCT, N=114 (SOE: Low)	No evidence*
Function Responders (≥2.5-point improvement on RDQ)	No evidence	No evidence	Large, 1 RCT, N=113 (SOE: Low)	No evidence*
Function Responders (≥5-point improvement on KPS)	No evidence	No evidence	Large, 1 RCT, N=112 (SOE: Low)	No evidence*
Function Responders (KPS score ≥70)	No evidence	No evidence	Moderate, 1 RCT, N=112 (SOE: Low)	No evidence*
RDQ function scores (0-24)	No evidence	No evidence	Large, 1 RCT, N=113 (SOE: Low)	No evidence*
KPS function scores (0-100)	No evidence	No evidence	Large, 1 RCT, N=112 (SOE: Low)	No evidence*
Mortality	Similar, 1 RCT, N=134, 1 month (SOE: Low) Similar, 1 RCT, N=96, >1 to ≤12 months, ITT (SOE: Low)			
SAEs	Similar, 1 RCT, N=134, 1 month (SOE: Low) Similar, 1 RCT, N=96, >1 to ≤12 months, ITT (SOE: Low)			
New symptomatic fracture	Similar, 1 RCT, N=134, 1 month (SOE: Low) Risk greater with KP, 1 RCT, N=96, >1 to ≤12 months, ITT (SOE: Low)			
Cement leak, symptomatic	Rare, 1 RCT, N=70 in KP, 1 month (SOE: Low)			

Summary of effectiveness and safety evidence for vertebroplasty versus kyphoplasty in patients with vertebral compression fractures due to *tumors or malignancy* (KQs 1 and 2)

The evidence base – 3 retrospective comparative NRSIs (2 from the prior report, 1 newly identified) – remains sparse and insufficient.

- Pain response and pain improvement for VP and KP were similar.
- Adverse events were sparsely reported. No neurological or pulmonary complications or new fractures were observed; one death was reported. (Detail of adverse events from case series are found in the full report.)

Aggregate Analytics

Summary of effectiveness and safety evidence for sacroplasty versus usual care, teriparatide injections and surgery in patients with *sacral insufficiency fracture* (KQs 1 and 2)

The evidence base – 4 poor-quality comparative NRSI (1 prospective, 3 retrospective) – remains sparse and insufficient.

- *Versus Usual Care*: Sacroplasty conferred greater improvement in pain scores across most timepoints (3 studies) and function scores at all timepoints (2 studies). Mortality was less common following sacroplasty (1 study).
- *Versus Percutaneous Teriparatide Injections*: Sacroplasty associated with significantly less improvement in function scores (1 study).
- *Versus Screw Fixation (with cement augmentation):* Patients in both groups experienced significant improvement in pain and function (1 study). Data were not well reported. Mortality was similar for the two groups.

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Summary of Differential Effectiveness and Safety (KQ3) - Osteoporotic Fractures

Confidence in findings is very low

Evidence is limited and estimates are imprecise.

VP vs. Sham or UC

- No modification of treatment effect for pain or function based on
  - Sex, prior fracture (1 RCT).
  - Fracture age or pain duration (Included RCT subgroup analysis; stratified analysis of RCTs).
- No modification seen by
  - PMMA volume.
  - MRI findings of bone marrow edema – study enrollment requirement.

VP vs. KP

- No differences in the magnitude of pain reduction from subgroup analysis on sex, age, preoperative pain scores or preoperative RDQ scores. No data provided.

Summary of Cost Effectiveness (KQ 4)

- VP and KP may be cost-effective vs. nonsurgical management in malignant fractures.
- VA was cost-effective versus non-operative management in 2 U.S. studies; however, cost-effectiveness was sensitive to assumed mortality differences; Medicare claims data models were used for mortality.
- Cost-effectiveness of VP and KP may influenced by:
  - Assumptions about differential mortality for augmentation vs. UC.
  - Comparisons based on blinded trials vs. comparisons with unblinded trials.

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Considerations

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Considerations

The body of RCT evidence is substantially larger for this update versus the 2010 HTA

- Additional RCTs for VP vs. sham and UC, VP vs. KP and KP vs. UC.
- No evidence for KP vs. Sham.
- Evidence for malignant fractures and sacroplasty remains sparse/poor.

There is substantial heterogeneity across trials of vertebroplasty

- Patient selection (e.g., pain duration, severity).
- Procedure protocols (e.g., PMMA volume).
- Comparators: UC note well defined/variable; Variation in sham procedures.
- AEs were variably defined and inconsistently reported.

Differences in observation of an association and effect sizes: VP vs. Sham and VP vs. UC; Reasons are unclear

- Impact of potential placebo, other non-specific effects due to lack of blinding is unclear.
- Potential for some sham procedures to provide a “therapeutic” effect is unclear.
- Impacts of pain duration/pain severity and timing of treatment are unclear.

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Considerations

- Adverse events: RCTs may be underpowered to detect rare events.
- Evidence is insufficient to firm draw conclusions regarding modification of treatment by factors such as pain duration/fracture age, PMMA volume and others due to the small numbers of trials evaluating subgroups, lack of statistical power for the trials and imprecise estimates available from stratified analyses at the study level.

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Questions?

Appendix Slides: AEs from NRSI Osteoporosis

KQ 2. Safety: Adverse Events from Database Studies Osteoporosis – VP vs. UC SOE: Insufficient

Serious adverse events:

- **Pulmonary embolism** (3 studies): Adjusted HR at 4 years: 1.07 (1 study); Propensity adjusted risk vs. UC 3% higher at 1 year, 7% higher at 2 years, 6% higher at 5, 8, and 10 years (1 study); 1 study reported only prevalence (not significant)
- **Deep vein thrombosis** (2 studies): Adjusted HR at 4 years: 1.03 (1 study); Propensity adjusted risk vs. UC 5% higher at 1 year, 3% higher at 2 years, 0% higher at 5, 8, and 10 years (1 study)
- **Cardiac complications** (2 studies): Adjusted HR at 4 years: 0.96 (1 study); Propensity adjusted risk vs. UC 20% lower at 1 year, 13% lower at 2 years, 9% lower at 5 years, 7% lower at 8 and 10 years (1 study)
- **Pulmonary/respiratory complications** (2 studies): Adjusted HR at 4 years: 1.07 (1 study); Propensity adjusted risk vs. UC 1% higher at 1 and 2 years, no difference at 5, 8, and 10 years (1 study)
- **Respiratory failure** (1 study): Adjusted HR 0.68
- **Infection (2 studies**): Adjusted HR at 4 years: 1.00 (1 study); Propensity adjusted risk vs. UC 6% lower at 1 year, 1% lower at 2, 5, 8, and 10 years (1 study); An additional study reports only prevalence of osteomyelitis or infection
- **New fracture (**1 study): Prevalence only, results not significant
- Reoperation (1 study): Adjusted HR 11.1 for subsequent augmentation or fusion

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Osteoporosis – Mixed Vertebroplasty/Kyphoplasty: Adverse Events Other than Mortality from Comparative Database and Comparative Nonrandomized Studies
SOE: Insufficient

Adverse Event	Database	Study Database search dates	N	Finding and conclusion
SAE				
Specific SAEs	NIS	Purvis, 2018 (2002-2011)	VP/KP: 11,116 UC: 46,962	Post-op, all p=NR Stroke: 0.1% (11/11116) vs. 0% (0/46962) MI: 0.6% (67/11116) vs. 0.8% (376/46962) PE: 0.2% (22/11116) vs. 0.3% (141/46962) Shock: 0.2% (22/11116) vs. 0.2% (94/46962)
Any SAE	NIS	Purvis, 2018 (2002-2011)	VP/KP: 11,116 UC: 46,962	Post-op 8.1% (900/11116) vs. 8.7% (4086/46962), Adj. OR 0.95 (95% CI 0.87–1.03)
	Medicare	McCullough, 2013* (2002-2006, 20% random sample)	VP/KP: 9,017 UC: 9,017 propensity- score matched	30 days 9.5% (860/9017) vs. 10.5% (947/9017), Adj. OR 0.90 (95% CI 0.81-0.99) 1 year 29.8% (2691/9017) vs. 30.0% (2709/9017), Adj. HR 1.00 (95% CI 0.94-1.06)
Recurrent Fracture	NA	Levy 2012† (NA)	VP/KP: 57 UC: 27	17.5% (10/57) vs. 25.9% (7/27), unadjusted RR 0.68 (0.29 to 1.58); p=NS in adjusted analyses
Mixed VP/KP vs. Operative Treatment				
SAEs	NIS	Purvis, 2018 (2002-2011)	VP/KP: 11,116 Open Surgery: 1,487	Post-op Stroke: 0.1% (11/11116) vs. 0.3% (4/1487), p<0.001 MI: 0.6% (67/11116) vs. 2.2% (33/1487), p<0.001 PE: 0.2% (22/11116) vs. 1.2% (18/1487), p<0.001 Shock: 0.2% (22/11116) vs. 1.0% (15/1487), p<0.001 Any SAE: 8.1% (900/11116) vs. 16.3% (242/1487); Adj. OR 0.48 (95% CI 0.41-0.56)

Osteoporosis – Mixed Vertebroplasty/Kyphoplasty: Adverse Events Other than Mortality from Single Arm Studies: SOE Insufficient

Adverse Event	Follow Up	Study	% (n/N)
Mortality			
Any	1 month	Choo, 2018	2.0% (49/2433)
	1 month	Kim, 2022*	2.1% (40/1932)
SAE			
Any	1 month	Choo, 2018	5.8% (140/2433)
	1 month	Kim, 2022	4.9% (95/1932)
	NR	Wang, 2014	0% (0/358)
Thromboembolic events			
Any thromboembolic event	1 month	Choo, 2018	1.0% (24/2433)
PE	1 month	Kim, 2022	0.7% (13/1932)
DVT	1 month	Kim, 2022	0.7% (14/1932)
Cardiac events			
Cardiac arrest	1 month	Kim, 2022	0.2% (4/1932)
MI	1 month	Kim, 2022	0.1% (1/1932)
CVA events			
Stroke	1 month	Choo, 2018	0.1% (3/2433)
CVA with neurologic deficit	1 month	Kim, 2022	0.1% (1/1932)
Infection			
Deep infection	1 month	Kim, 2022	0% (0/1932)
Septic complication	1 month	Choo, 2018	0.8% (20/2433)
Sepsis	1 month	Kim, 2022	0.5% (9/1932)
Septic shock	1 month	Kim, 2022	0.2% (4/1932)
Bleeding			
Bleeding requiring transfusion	1 month	Choo, 2018	0.7% (16/2433)

Adverse Event	Follow Up	Study	% (n/N)
Pulmonary Cement Embolism			
Asymptomatic PCE	Median 412 days	Sun, 2023	17.2% (64/373)
	Perioperative	Venmans, 2008	3.7% (11/299)
New Fracture			
Any fracture	Mean 31 months	Wang, 2014	12.6% (45/358)
Adjacent level, symptomatic fracture	6 months	Wang, 2014	3.1% (11/358)
	Mean 31 months	Wang, 2014	7.3% (26/358)
Cement Leakage			
Any symptomatic leakage requiring intervention	Mean 31 months	Wang, 2014	0% (0/358)
Any leakage	Mean 31 months	Wang, 2014	40.8% (146/358)
	NR	Zhang, 2020	32.5% (96/295 levels)
Spinal canal leakage	NR	Zhang, 2020	2.7% (8/295 levels)
Reoperation			
Any	1 month	Choo, 2018	3.6% (88/2433)
	1 month	Kim, 2022*	3.2% (61/1932)
Repeat VP/KP for symptomatic adjacent level fracture	Mean 31 months	Wang, 2014	7.3% (26/358)
Any AE			
	1 month	Kim, 2022	8.6% (166/1932)

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-effective[1] as expressed by the following standards[2]:

- 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 harms[3]:

- 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.

Based on Legislative mandate: RCW 70.14.100(2).

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 evidence[4] 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).

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

[4] Based on GRADE recommendation: http://www.gradeworkinggroup.org/FAQ/index.htm

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 life-threatening, 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
Mortality		
New fractures		
Serious AEs		
Cement leakage		
Reoperation		

Efficacy – effectiveness outcomes	Importance of outcome	Efficacy / Effectiveness evidence
Pain response		
Pain score		
Function score		

Cost outcomes	Importance of outcome	Cost evidence
Cost		
Cost-effectiveness		

Special population / Considerations outcomes	Importance of outcome	Special populations/ Considerations evidence
Age		
Sex		
Comorbidity		
Adolescents		
Pregnant individuals		

For safety:

Is there sufficient evidence that the technology is safe for the indications considered?

No relevant studies	Low Risk Safe	Moderate Risk	High Risk Unsafe
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For efficacy/ effectiveness:

Is there sufficient evidence that the technology has a meaningful impact on patients and patient care compared to the evidence-based alternative(s)?

No relevant studies	Less Less effective	Equivocal	More More effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

For cost outcomes/ cost-effectiveness:

Is there an accepted scale for cost effectiveness for treatments for this disease? If so, how does this treatment compare with evidence-based alternatives?

No relevant studies	Less Less cost effective	Equivocal	More

			More cost effective at least in some
	Confidence: Low Medium High	Confidence: Low Medium High	Confidence: Low Medium High

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 about the technologies' safety, efficacy, and cost-effectiveness, it is:

Not covered	Covered unconditionally	Covered with conditions

Discussion item

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

Medicare Coverage

[see page 54 of final report]

No National Coverage Determination identified.

Clinical Practice Guidelines
[see pages 12 – 19 of final report]

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
American Academy of Orthopaedic Surgeons (AAOS), 2010 (McGuire, 2011), updated 2023	5 RCTs: -2 RCTs of grade level I (i.e., defined as reliable) -3 RCTs of grade level II (i.e., defined as moderately reliable) Inconclusive evidence comparing the procedure with conservative care and vertebroplasty	**Vertebroplasty:** Not recommended for osteoporotic spinal compression fractures without neurological impairment.	Strong
		Kyphoplasty: Option for osteoporotic spinal fractures; benefits in pain and function up to 6 months.	Limited
		Calcitonin: Suggested for acute fractures (0-5 days) for 4 weeks.	Moderate
		Ibandronate/Strontium Ranelate: Options to prevent additional symptomatic fractures.	Limited
		L2 Nerve Root Block: Option for acute L3/L4 fractures with neurological intactness.	Limited
		Bed Rest/Alternative Medicine/Analgesics: Options for managing osteoporotic spinal fractures.	Inconclusive
		Bracing: Option for osteoporotic spinal fractures with correlating symptoms.	Inconclusive
		Exercise Program: Supervised or unsupervised for managing osteoporotic spinal fractures.	Inconclusive
		Electrical Stimulation: Option for managing osteoporotic spinal fractures with correlating symptoms.	Inconclusive
American College of Radiology (ACR), 2022	ACR Appropriateness Criteria® Management of Vertebral Compression Fractures: Variants 1 to 9 https://acsearch.acr.org/list	**Vertebroplasty:** Recommended for osteoporotic compression fractures with spinal deformity, worsening symptoms, or pulmonary dysfunction; no active management for asymptomatic VCFs without pain or activity restriction.	NR
		MRI Evaluation: Suggested before vertebral augmentation in patients with malignancy history or atypical features; helps differentiate recent from chronic fractures.	NR
American College of Radiology (ACR),	NR	Vertebral augmentation is recognized as safe and established by ACR, ASN, ASSR, SIR, and SNIS, with guidelines for patient selection and procedure. Indications include	NR

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
American Society of Neuroradiology (ASNR), Society of Neurointerventional Surgery (SNIS), American Society of Spine Radiology (ASSR), and the Society of Interventional Radiology (SIR), 2017 (updated 2022)		symptomatic osteoporotic fractures, insufficiency fractures unresponsive to therapy, weakened vertebrae from osteoporosis or neoplasia, symptomatic microfractures, benign painful lesions, progressive fractures, and severe kyphosis. Not recommended for prophylactic use against future fractures.	
American Society of Interventional and Therapeutic Neuroradiology, Society of Interventional Radiology, American Association of Neurological Surgeons/Congress of Neurological Surgeons, and the American Society of Spine Radiology, 2007	NR	In 2007, a position statement affirmed that percutaneous vertebral augmentation (vertebroplasty and kyphoplasty) is safe, effective, and durable for symptomatic osteoporotic and neoplastic fractures, recommended when traditional therapy fails to relieve pain or significantly impacts the patient's lifestyle.	NR
International Society for the Advancement of Spine Surgery (ISASS), 2019	NR	The 2019 policy statement (Lamlice et al.) deems vertebral augmentation eligible for patients with severe pain-related functional limitations, history of VCFs, physical exam consistent with VCFs, and confirmed fracture by imaging. Contraindications include blood-borne infection, surgical site infection, or osteomyelitis. ISASS 2019 supports vertebral augmentation (preferably kyphoplasty) as safe, effective, and beneficial over conservative management, emphasizing early treatment to reduce mortality and morbidity.	NR
North American Spine Society (NASS), 2023	Studies, RCTs (Chandra et al. (2014), NICE's key	**Coverage Recommendations (March 2023):** NASS recommends vertebral augmentation for vertebral body fractures due to osteoporosis, avascular necrosis, or neoplasm with severe pain unresponsive to conservative treatment, impaired	NR

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
	conclusions, meta-analyses, RCTs, retrospective multicenter studies, prospective cohort studies, SRs, VAPOUR study)	daily activities, and confirmed acute fracture on imaging. No specific tools or products recommended; not applicable to traumatic fractures or primary vertebral tumors.	
		Absolute Contraindications: Vertebral augmentation is contraindicated for chronic fractures without active imaging evidence, active systemic or local infection, and during pregnancy.	NR
		Relative Contraindications: Caution is advised in cases of allergy to fill material, coagulopathy, spinal instability, myelopathy, neurologic deficit, or neural impingement.	NR
National Institute for Health and Care Excellence (NICE) (United Kingdom), 2013	Technology appraisal guidance 9 RCTs, 5 open-label trials Risk assessment, diagnosis, and management (CG75)	**Vertebroplasty/Kyphoplasty (NICE 2013 & 2008):** Recommended for severe, ongoing pain from recent vertebral fractures unresponsive to pain management, and in cases of vertebral metastases without spinal cord compression or instability, following specialist agreement. Guidance last reviewed in 2014, next review in 5 years.	NR
American Academy of Family Physicians (AAFP), 2016	NR	**AAFP 2016 Recommendations:** Offer conservative therapy for vertebral compression fractures. Consider percutaneous vertebral augmentation if nonsurgical care fails to relieve pain or if pain significantly impacts quality of life. Evaluate patients for osteoporosis and initiate preventive therapy if needed.	NR
American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) (Camacho et al., 2016; Updated 2020)	NR	**Recommendation:** Vertebroplasty and kyphoplasty are not recommended as first-line treatments for vertebral fractures due to unclear pain relief benefits and potential increased risk of adjacent vertebral fractures (Grade A, BEL 1; downgraded).	NR
American Association of Neurological Surgeons (AANS)	NR	**AANS 2023 Guideline:** Candidates for vertebroplasty or kyphoplasty include patients with osteoporotic VCFs (present >2 weeks, moderate to severe pain, unresponsive to conservative therapy), painful metastases or multiple myelomas, painful vertebral hemangiomas, vertebral osteonecrosis, and for reinforcement of a weak vertebral body before surgical stabilization.	NR

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
		AANS 2023 Contraindications: Vertebroplasty or kyphoplasty should not be performed in patients with fully healed or conservatively managed VCFs, VCFs older than one year, vertebral body collapse >80-90%, non-osteoporotic spinal curvature, spinal stenosis or herniated discs unrelated to VCF, untreated coagulopathy, osteomyelitis, discitis, or significant spinal canal compromise from bone fragments or tumors.	NR
Society of Interventional Radiology (SIR), American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS), American College of Radiology (ACR), American Society of Neuroradiology (ASNR), American Society of Spine Radiology (ASSR), Canadian Interventional Radiology Association (CIRA), and Society of NeuroInterventional Surgery (SNIS), 2014	NR	**2014 Consensus Statement:** Vertebroplasty and kyphoplasty are considered safe, effective, and durable for symptomatic osteoporotic and neoplastic fractures when non-operative therapy fails to relieve pain or significantly affects quality of life. No current indication exists for prophylactic use to prevent future fractures; recommendations may evolve with future research.	NR
Society of NeuroInterventional Surgery (SNIS), 2014	SR (details unclear)	**2014 SNIS Report:** Kyphoplasty is superior to conservative therapy in reducing pain, disability, and improving quality of life in cancer patients with vertebral fractures (Class IIA, Level B). Vertebroplasty and kyphoplasty are reasonable options for severe, refractory back pain from cancer or osteoporotic vertebral fractures (Class IIA, Level B).	NR
German Society for Orthopaedics and Trauma (DGOU), 2018	Review of literature and case series (i.e., 707 clinical cases	**Management of Osteoporotic Vertebral Fractures:** Conservative management is recommended for OF type 1 and 2 fractures (and those scoring <6 on the OF scale). Vertebral augmentation with instrumentation is indicated for OF type 3, 4, and 5	

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
	from 16 hospitals were evaluated)	fractures. Consider intraoperative complications of cement augmentation, including neurological injuries, cement leakage, embolization, vertebral body perforation, hematoma, pneumothorax, and contrast fluid incompatibilities.	
WFNS Spine Committee, 2022	Literature search (2010 to 2021) (i.e., RCTs, prospective non-randomized studies, retrospective studies, SRs)	**Cement Augmentation for Osteoporotic Compression Fractures:** - Conflicting studies on efficacy; meta-analyses are inconclusive regarding pain reduction. - Insufficient evidence to determine optimal timing for vertebral augmentation. - No significant difference between unilateral and bilateral approaches in pain control, quality of life, or mobilization. - Complications: cement leakage common in vertebroplasty; progressive vertebral height loss, adjacent fractures, and cardiac issues more frequent in kyphoplasty. **Recommendation:** Further high-quality, well-designed randomized controlled studies are needed to establish the role of vertebral augmentation in osteoporotic compression fractures.	NR
American Society of Anesthesiologist (ASA), American Society of Regional Anesthesia and Pain Medicine (ASRA), 2010	RCTs (number unclear)	**Consensus:** Consultants, ASA members, and ASRA members strongly agree that minimally invasive spinal procedures should be performed for pain related to vertebral compression fractures.	NR
Society of Interventional Radiology (SIR), 2014	NR	**2014 SIR Guideline:** Vertebral augmentation is recommended for compression fractures unresponsive to medical therapy, including cases where patients are nonambulatory due to pain, unable to tolerate physical therapy despite analgesics, or experience unacceptable side effects (e.g., sedation, confusion, constipation) from necessary pain medication.	NR
American Society of Pain and Neuroscience (ASPN), 2021	NR	**Recommendation:** Vertebral augmentation is strongly recommended for symptomatic vertebral compression fractures from spinal metastases (Level 1-A). However, ASPN notes limited data on the superiority of vertebroplasty versus kyphoplasty in treating malignant fractures.	NR
International Myeloma Working Group (IMWG), 2013	NR	**Guideline Summary:** Vertebroplasty and kyphoplasty are effective for pain relief and functional improvement in neoplastic spinal fractures, but the role of vertebroplasty in myeloma patients remains unclear due to a lack of randomized trials. Two	NR

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
		randomized studies showed no benefit of vertebroplasty over conservative therapy for osteoporotic fractures.	
Cardiovascular and Interventional Radiological Society of Europe (CIRSE), 2017	NR	**Vertebroplasty Indications:** Painful osteoporotic VCFs, benign bone tumors, malignant osteolysis, osteonecrosis, vertebrae plana, acute/chronic fractures, or for reinforcement before surgery. **Absolute Contraindications:** Asymptomatic/improving VCFs, unstable fractures, infections, severe coagulopathy, or allergies to materials. Not for prophylaxis in osteoporosis. **Relative Contraindications:** Radicular pain, tumor extension, posterior column fractures, sclerotic metastasis, or multiple metastases. **Percutaneous Kyphoplasty Indications:** Best for acute traumatic VCFs with kyphosis; similar indications to VP. **Recommendation:** CIRSE does not find strong evidence for preferring KP over VP in routine cases. KP may be preferred when height restoration is crucial, e.g., acute kyphotic fractures in younger patients.	NR
RAND/UCLA Appropriateness Method Clinical Care Pathway, multispecialty Expert Panel, 2018	12-member expert panel from key disciplines (orthopedic and neurosurgeons, interventional neuro radiologists, and pain specialists)	**Included patients**: Patients presenting to an Emergency Department or outpatient clinic (any specialty) with moderate to severe back pain (VAS ≥5) as the primary or secondary complaint. **Excluded patients**: Patients with back pain following a high-velocity trauma, those with suspected malignant (non-fragility) compression fracture, and children (≤18 years). 1. **Key signs and symptoms for the suspicion of VFF**: Severe limitation in mobility/activities of daily living, pain diminishes or is resolved with rest, recent history of minimal/low-velocity trauma, pain is activity or movement related, osteoporosis or osteopenia, previous VFF, chronic use of corticosteroids, tenderness to palpation/percussion over posterior spinous processes, pain exacerbates by change of position, and midline back pain. 2. **Diagnostic evaluation of patients suspected of VFF**:	NR

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
		- If conventional radiography is used in patients suspected of VFF, standing anterior-posterior and lateral radiographs are highly recommended (75% agreement) - In patients with moderate symptoms (VAS 5-6) and a low probability of VFF, a conservative treatment regimen without further imaging is usually the most appropriate strategy (92% agreement) - In patients with severe symptoms (VAS ≥7) and a low probability of VFF, advanced imaging is indicated (92% agreement) - All patients with an intermediate to high probability of VFF, with or without supportive evidence from conventional radiography, should be referred for advanced imaging (100% agreement) - For patients with an intermediate to high probability of VFF, with or without supportive evidence from conventional radiography, MRI is the preferred advanced imaging technique (100% agreement) - If MRI is unavailable or if the patient has a contraindication for MRI, CT scan, and nuclear bone scan are the best alternatives (100% agreement) - If a treatment decision on vertebral augmentation needs to be taken, advanced imaging had to be repeated if the previous one was done more than 30 days ago (67% agreement) 3. **Appropriateness criteria for VP versus non-surgical management**: Advanced imaging findings (strongly in favor of vertebral augmentation if positive) and evolution of symptoms (vertebral augmentation more appropriate if symptoms had worsened). Outcomes in relation to duration of pain have similar appropriateness for ≥1 week. In other variables, vertebral augmentation is still more appropriate for more unfavorable conditions. Logistic regression analysis implied that the impact of various conditions on appropriateness is cumulative; the appropriateness of vertebral augmentation increases with the number and relative weight of unfavorable conditions. 4. **Contraindications for VP**: Absolute contraindications: active infection at surgical site, untreated blood-borne infection, Osteomyelitis (usually a strong contraindication), pregnancy (usually contraindicated). Relative contraindications: allergy to fill material, coagulopathy, spinal instability, myelopathy from the fracture, neurologic deficit, neural impingement. - Fracture repulsion/canal compromise is generally not a contraindication.	

Guideline	Evidence Base	Recommendation/Consensus	TRUST Score Strength of Recommendation
		5. **Follow-up treatment of VFF**: 1. After either vertebral augmentation or conservative treatment, a follow-up visit should be planned at 2-4 weeks; 2. In patients with a satisfactory result of vertebral augmentation at first follow-up, there is generally no need for further post-operative monitoring. Follow-up for management of the underlying pathology does not need to be managed by the proceduralist; 3. All patients presenting with VFF should be referred for evaluation of bone mineral density and osteoporosis education for subsequent treatment as indicated; 4. All patients with VFF should be instructed to take part in an osteoporosis prevention/treatment program; 5. If symptoms are not resolved at follow-up, repeat imaging (preferably MRI) is mandatory; 6. If the pain is not resolved after vertebral augmentation, repeat augmentation (at the same level) may be considered, but does require a careful diagnostic evaluation to identify any other sources of pain.	

AANS = American Association of Neurological Surgeons; ACR = American College of Radiology; ASA = American Society of Anesthesiologists; ASNR = American Society of Neuroradiology; ASRA = American Society of Regional Anesthesia and Pain Medicine; ASSR = American Society of Spine Radiology; BEL = Best Evidence Level; CIRA = Canadian Interventional Radiology Association; CIRSE = Cardiovascular and Interventional Radiological Society of Europe; CNS = Congress of Neurological Surgeons; IMWG = International Myeloma Working Group; KP = kyphoplasty; VFF = vertebral fragility fractures; VP = vertebroplasty.

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 unclear (i.e., tie), outcome chair will lead discussion to determine next steps.

Washington State Health Care Authority

Final key questions

Vertebroplasty, kyphoplasty, or sacroplasty

May 14, 2024

Background

Vertebral compression fractures (VCFs) and sacral insufficiency fractures (SIF) often result in considerable pain, loss of function, and decreased quality of life. Patients with osteopenic vertebral or sacral fractures are at greater risk of morbidity and mortality, yet operative intervention (e.g., fusion with instrumentation) may be problematic in this elderly population, making less invasive methods more attractive. VCFs can also occur due to metastatic bone disease leading to disability and morbidity and again, operative interventions may not be feasible.

Vertebroplasty, kyphoplasty and sacroplasty are minimally invasive surgical procedures used to treat spinal pain believed to be caused by fractures in the vertebra or sacrum. These are all cementoplasty (augmentation) techniques intended to stabilize the fractured bone(s), but the mechanism of pain relief is not clear. Osteoporosis, vertebral metastasis and multiple myeloma are the most frequently reported indications for these procedures. Cementoplasty may reduce pain and improve stability of the bone.

Vertebroplasty involves injection of bone cement into a partially collapsed vertebral body under computed tomography (CT) or fluoroscopic guidance. Kyphoplasty is a modification of vertebroplasty that expands the partially collapsed vertebral body with an inflatable balloon or other mechanical device before the injection of bone cement. Sacroplasty is an extension of vertebroplasty, involving the injection of bone cement into the sacrum to repair sacral insufficiency fractures. These surgical procedures are less invasive than other spinal surgical procedures, but more invasive than conservative medical therapy. Vertebroplasty, kyphoplasty and sacroplasty are surgical procedures and are not subject to FDA approval, however materials and devices used as part of these procedures are subject to FDA approval.

Topic Background

A Health Technology Assessment titled: Vertebroplasty, Kyphoplasty, Sacroplasty, was published on November 5, 2010, by the Health Care Authority. New evidence has been published subsequent to the 2010 review and additional devices have been FDA approved. The scope for the rereview will be essentially the same as the original review with regard to key questions to be addressed and PICOTs inclusion and exclusion. It will reflect clarification of the inclusion/exclusion scope based on clinical expert input as clinical practice has evolved since 2010. The final scope for the rereview is consistent with the scope of the prior report.

As noted, the PICOTS for the rereview reflects clarification of the inclusion/exclusion scope based on clinical expert input as clinical practice has evolved since 2010. It also reflects consideration of public comments received to the posting of the draft key questions. The assessment update will be restricted to devices approved by the FDA for management of the FDA-approved conditions as described in PICOTS (Table 1).

Objectives

The aim of this report is to systematically review, critically appraise, analyze and synthesize research evidence evaluating the effectiveness and safety of vertebroplasty, kyphoplasty and sacroplasty for primary treatment of vertebral or sacral fracture due to osteoporosis or tumor/malignancy compared with placebo/sham, no treatment, surgery or common conventional treatment options to reflect evidence published subsequent to the 2010 report. Vertebroplasty and kyphoplasty will be compared with each other. The differential effectiveness and safety of these therapies for subpopulations will be evaluated, as will the cost effectiveness.

Draft Key Questions and Scope

Key Questions (KQ)
When used in patients with spinal pain due to vertebral fracture:

Key Question 1:
What is the evidence of effectiveness of vertebroplasty, kyphoplasty or sacroplasty, including consideration of short-term and long-term outcomes?

Key Question 2:
What is the evidence of the safety of vertebroplasty, kyphoplasty or sacroplasty? Including consideration of:

a. Adverse events type and frequency (mortality, major morbidity, other)
b. Revision/re-operation rates

Key Question 3:
What is the evidence that vertebroplasty, kyphoplasty or sacroplasty has differential efficacy or safety issues in sub populations? Including consideration of:

a. Gender
b. Age
c. Psychological or psychosocial co-morbidities
d. Diagnosis or time elapsed from fracture
e. Other patient characteristics or evidence-based patient selection criteria
f. Provider type, setting or other provider characteristics
g. Payer/beneficiary type: including worker's compensation, Medicaid, state employees

Key Question 4:
What is the evidence of cost-effectiveness of vertebroplasty, kyphoplasty and sacroplasty?

Table 1. Draft PICOTS Scope: Summary of inclusion and exclusion criteria

Study Component	Inclusion	Exclusion
Participants	Patients with spinal pain due to ***vertebral fracture*** secondary to • Osteoporosis • Malignancy Subgroups, special populations: • Gender	• Fractures due to high energy trauma

	• Age • Psychological or psychosocial co-morbidities • Diagnosis or time elapsed from fracture • Other patient characteristics or evidence-based patient selection criteria • Provider type, setting or other provider characteristics • Payer/beneficiary type: including worker's compensation, Medicaid, state employees	
Intervention	• Vertebroplasty • Kyphoplasty • Sacroplasty	• Cements, devices that are not FDA approved unless being studied in a Phase III trial • Spineoplasty graft consisting of mesh filled with bone chips instead of the traditional cement • Percutaneous cement discoplasty (PCD) - intervertebral disc is filled with percutaneously injected acrylic cement; may be used as prep or with vertebroplasty • Studies of exercise/rehab post augmentation • Stentoplasty, vertebral body stenting, • Vesselplasty
Comparators	• Sham procedure or placebo • Conservative care, conventional care • Other minimally invasive procedures (e.g., facet joint block, nerve block) • Surgical procedures • Vertebroplasty vs. kyphoplasty	• Comparisons of different cement types • Comparisons of surgical approaches or techniques • Comparison of different vertebroplasty techniques with each other or different forms of kyphoplasty with each other • Use of vertebroplasty, kyphoplasty or sacroplasty as an adjunct to other procedures (e.g., ablation) • Augmentation combined with zoledronic acid (ZOL) versus augmentation alone • Types of imaging guidance, other guidance, e.g., Robotic assisted vs. fluoroscopy • Stentoplasty/vertebral body stenting, • Vesselplasty
Outcomes	**Primary outcomes** • Functional outcomes (e.g., ODI) • Pain relief • Harms/Complications (e.g., procedure related, leakage, new fracture, medical complications, mortality, revision/re-operation) **Secondary outcomes**	• Measures that are not validated • Intermediate outcomes measures (e.g., radiographic measures of disc height)

	• Quality of life • Measures of disability (e.g., work lost) • Opioid use • Return to work/return to normal activity	
Studies	• **Key Question 1**: Comparative clinical studies with a focus on studies with least potential for bias (RCTs); NRSI with concurrent controls that control for confounding will be considered if RCT evidence is not available for KQ 1. • **Key Question 2**, safety, RCTs, NRSI with ≥250 patients that are specifically designed to evaluate safety that control for confounding will be considered; case series will be considered if adequate information is not available from comparative NRSIs and RCTs or for rare or long-term adverse events; systematic reviews may be considered for safety • **Key Question 3:** RCTs only • **Key Question 4:** Full formal economic studies	• Case reports • Case series, single arm studies, pre-post studies with fewer than 5 patients (for sacroplasty) • NRSIs for effectiveness or benefit for osteoporotic fractures (KQ1) • NRSI that do not control for confounding (exception for sacroplasty)
Publication	• Full-length studies published in English in peer reviewed journals, published HTAs or publicly available FDA reports • Full formal economic analyses (e.g., cost-utility studies) published in English in HTAs or in a peer-reviewed journal published after those represented in previous HTAs	• Abstracts, editorials, letters • Duplicate publications of the same study which do not report on different outcomes • Single reports from multicenter trials • Studies reporting on the technical aspects of these procedures • White papers • Narrative reviews • Articles identified as preliminary reports when results are published in later versions • Incomplete economic evaluations such as costing studies

FDA = Food and Drug Administration; HTA = Health Technology Assessment; ODI = Oswestry Disability Index; NRSI = Nonrandomized studies of interventions; RCT = Randomized Control Trial;