

Academic Delphi Panel Results on the Use of Bone Marrow Concentrate (BMC) to Treat Pain or Orthopedic Disease:

The following are the consensus recommendations of this Delphi panel:

- **Use of a Treatment Registry**-It is desirable that patients who receive BMC for an orthopedic indication should be entered into a formal treatment registry that uses validated outcome tools and collects complications data at set time points.
- **Use of Candidacy Grades**-Each patient receiving BMC for an orthopedic indication should be provided a documented candidacy grade based on the best available medical evidence (if available).
- **Expanded Informed Consent**-Informed consent should include simple language that the use of the BMC for an orthopedic indication is not standard of care and is investigational and as such, it may pose unknown risks.
- **Publication of Research**-If the BMC is used in a medical indication where a controlled trial doesn't yet exist, then the data generated by that use should be submitted for publication in the peer-reviewed literature by the individual or group using that orthobiologic.
- **Advertising**-Any advertising to the general public about BMC for an orthopedic indication must be grounded in the basic science or known clinical science.
- **Use of an IRB**-If BMC is used for an indication where animal models show promise, but this is a first in human use, an institutional review board should review and approve.
- **Use of Mid-levels**-Prior to the establishment of level 1 evidence for that medical indication, BMC for an orthopedic indication should only be used by licensed physicians or a by a physician-supervised mid-level and not in office settings where direct physician supervision is absent.
- **Imaging Guidance**-Image guidance or direct visualization should be used to deliver BMC to the target joint or tissue (i.e. ultrasound imaging, fluoroscopy, or arthroscopy/open surgery as appropriate).
- **Level of Evidence Required for Clinical Use**-At least a comparison trial should exist prior to the use of BMC for an orthopedic indications. Meaning, the panel members did not believe that a randomized controlled trial is required before use of BMC.

Details: The panel was convened with 25 members with a five-member steering committee who participated in 4 rounds of consensus questionnaires. A five-point Likert scale from Strongly Agree to Strongly Disagree was used for each question. The anonymized aggregate results of each round were shared with the group prior to voting in the next round in accordance with the Delphi process (1). Consensus was defined as 80% agreement of the statements indicating either “Strongly Agree” or “Agree” as defined by Putnam et. al. (2)

The following physicians participated in the Delphi panel:

Sairam Atluri, MD, FIPP

Board Certified in Anesthesia and Interventional Pain Management

Editorial Board of the journal "Pain Physician"
Fellow of Interventional Pain Practice

Tariq M. Awan, D.O.

Assistant Professor Department of Orthopaedic Surgery
University of Michigan
Board-certified American Board of Family Medicine
Certificate of Added Qualification (CAQ) Sports Medicine

Douglas P. Beall, M.D.

Board Certified, The American Board of Radiology
Board Certified as a Fellow of Interventional Pain Practice by the World Institute of Pain
Fellow of the Society of Interventional Radiology
Diplomate of the Academy of Integrative Pain Management
Chief of Services Clinical Radiology of Oklahoma
Summit Medical Center and the Oklahoma Spine Hospital, Oklahoma City, OK, USA

Don Buford, MD, RMSK

Board Certified, The American Board of Orthopedic Surgery
Registered Musculoskeletal Sonography (RMSK), Alliance for Physician Certification and Advancement (APCA)
Director, The Texas Orthobiologic Institute
Director, The Sports Medicine Clinic of North Texas

Thomas K. Bond, M.D., M.S., CAQSM

Sports Medicine / Regenerative Medicine
The Regenerative Medicine Institute of Louisiana
Director, TotalCare Health & Wellness Medical
Director, Vitality Medical Center of Baton Rouge
Past-President & Board Member, American Academy of Orthopedic Medicine (AAOM)
Physician, Regenexx Physician Network

Robert Bowers, DO, PhD, CAQSM

Board Certified, American Board of Physical Medicine and Rehabilitation
Assistant Professor of Orthopaedics
Assistant Professor of Rehabilitation Medicine
Emory University School of Medicine
Emory Sports Medicine Center

James P. Bradley, MD

Clinical Professor of Orthopaedic Surgery University of Pittsburgh School of Medicine
Head Orthopedic Surgeon of the Pittsburgh Steelers

President of The American Orthopaedic Society for Sports Medicine

Aaron K. Calodney, MD

American Board of Interventional Pain Physicians

Fellow of Interventional Pain Practice

Fellow of the American Society of Anesthesiologists

Director of Clinical Research, Precision Spine Care

Associate Clinical Professor of Anesthesiology, Louisiana State University Health Science Center,
Shreveport, Louisiana

Christopher J. Centeno, M.D.

Board Certified in Pain Management

Medical Director Centeno-Schultz Clinic

Founder of the Interventional Orthopedics Foundation

Director of the CSC Interventional Orthopedics Fellowship

Rahul Desai, M.D.

Board Certified in Radiology

Fellowship Trained in MSK Radiology

Present, Restore PDX

E. Jeffrey Donner, MD

Dual Board Certified in Orthopedic and Spinal Surgery

Staff Physician, University of Colorado Health

Jason L. Drago, MD

Professor and Vice Chairman

Endowed Chair of Regenerative Medicine

University of Colorado

Head Team Physician Denver Nuggets

Team Physician Denver Broncos

Director, UCHealth Steadman Hawkins Center

Michael J. DePalma, MD

President, Medical Director

Director, Interventional Spine Care Fellowship

Virginia iSpine Physicians, PC

President, Director of Research

Virginia Spine Research Institute, Inc

Gregory E. Lutz, MD

Founder & Medical Director

Regenerative SportsCare Institute, NY, NY
Regenerative SportsCare Foundation
Physiatrist-in-Chief Emeritus
Hospital for Special Surgery
Professor of Clinical Rehabilitation Medicine
Weill Cornell Medical College

Gerard A. Malanga, MD

Clinical Professor, Dept. of Physical Medicine and Rehabilitation
Rutgers School of Medicine- NJ Medical School
Founder and Partner, NJ Regenerative Institute
President, Interventional Orthopedic Foundation
NFL Pain Management consultant
NY Jets football

Ken Mautner, MD, CAQSM, RMSK

Associate Professor Department of PM&R and Orthopedics at Emory University
Director of Primary Care Sports Medicine
Fellowship Director, Sports Medicine Fellowship

Rudolph Mason, MD, RMSK, CAQSM, Dip Sports Med (IOC)

Board Certified, American Board of Family Medicine
Registered Musculoskeletal Sonography (RMSK),
Alliance for Physician Certification and Advancement (APCA)
Assistant Professor of Orthopaedics
Assistant Professor of Family Medicine
Emory University School of Medicine
Emory Sports Medicine Center
Editorial Board Biologic Orthopedics Journal

Grant M. Pagdin, MD, FCFP

Fellow of the College of Family Physicians of Canada
Fellowship in Stem Cell Therapy (ABAARM)
Principal Investigator, Innovate Clinical Trials
Clinical Instructor, University of British Columbia

Roger Kruse, MD, FAAFP, FACSM

Director of Sports Medicine Fellowship, University of Toledo College of Medicine
Head Team Physician, University of Toledo
Clinical Assistant Professor, University of Toledo, College of Medicine and Science
Clinical Assistant Professor, Michigan State University, College of Medicine
NCAA Committee of Competitive Safeguard and Medical Aspects of Sports

Fellow, American Academy of Family Practice
Fellow, American College of Sports Medicine
Head Drug Crew Chief for Track and Field, Atlanta Olympics
Head Team Physician, Winter US Olympic Team, 1998 Nagano, Japan
Team Physician US Figure Skating

Rowan V. Paul, M.D.

Clinical Assistant Professor, Dartmouth Geisel SOM
Primary Care Sports Medicine Site Director, Stanford University SOM
Clinical Instructor, California Pacific Medical Center
Partner, California Pacific Orthopaedics and Sports Medicine
Diplomat, American Academy of Family Physicians
Teaching Faculties: The Orthobiologic Institute (TOBI), Regenerative Medicine Training Institute (RMTI), Boston BioLife, Global Regenerative Congress.

Christopher J. Rogers, MD RMSK

Founder, San Diego Orthobiologics Medical Group, Inc
Medical Director, Personalized Stem Cells, Inc
Board Certified, American Academy of Physical Medicine and Rehabilitation (AAPMR)
Board of Directors, American College of Regenerative Medicine (ACRM)
Registered Musculoskeletal Sonography, Alliance for Physician Certification and Advancement (APCA)
Voluntary Assistant Clinical Professor, Department of Orthopaedic Surgery, University of California, San Diego

Steven Sampson DO

Diplomate American Board of Physical Medicine and Rehabilitation
Assistant Clinical Professor of Medicine, David Geffen School of Medicine at UCLA
Assistant Clinical Professor, Western University of Health Sciences
Adjunct Assistant Professor, Touro University of California and New York
Founder and Chairman, The Orthobiologic Institute
Founder, The Orthohealing Center

Jaspal Ricky Singh, M.D.

Vice Chair & Associate Professor of Rehabilitation Medicine
Weill Cornell Medicine
Director of Interventional Spine
Weill Cornell Center for Comprehensive Spine Care

Christopher J. Williams, MD, FAAPMR

Adjunct Professor, Emory University Department of Physical Medicine and Rehabilitation

Emory School of Medicine
Founder and CEO, Interventional Orthopedics of Atlanta
Board Certified, Physical Medicine and Rehabilitation

References:

- (1) N.C. Dalkey, O. Helmer, An experimental application of the Delphi method to the use of experts, *Manag. Sci.* 9 (1963) 458–467.
- (2) J.W. Putnam, A.N. Spiegel, R.H. Bruininks, Future directions in education and inclusion of students with disabilities: a Delphi investigation, *Except. Child.* 61(1995) 553–576.