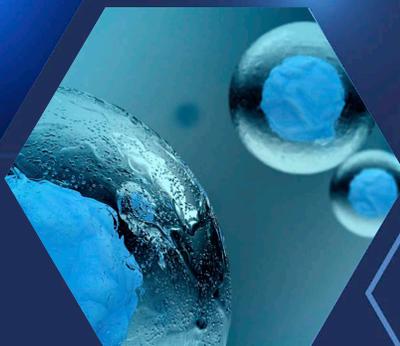


STEADMAN PHILIPPON RESEARCH INSTITUTE

ORTHOPAEDIC RESEARCH JOURNAL

2018-2019



STEADMAN PHILIPPON RESEARCH INSTITUTE

MISSION

BUILDING ON OUR LEGACY OF EXCELLENCE IN ORTHOPAEDIC SPORTS MEDICINE, STEADMAN PHILIPPON RESEARCH INSTITUTE IS UNLOCKING THE SECRETS OF HEALING, FINDING CURES AND ENHANCING LIVES THROUGH GLOBAL LEADERSHIP IN REGENERATIVE MEDICINE, SCIENTIFIC RESEARCH, INNOVATION AND EDUCATION.



DEAR FRIENDS,

Our third edition of Steadman Philippon Research Institute's (SPRI) *Orthopaedic Research Journal* is a collection of the leading-edge scientific research being conducted at SPRI's Vail, Colorado campus. Picking up where our second edition left off in July 2018, this publication will take you through the key research highlights of each of SPRI's departments from the past year.

With a tradition of over thirty years of science, SPRI is recognized all over the world for its innovative research. Comprised of diverse, collaborative departments including the Center for Outcomes-Based Orthopaedic Research, Center for Regenerative Sports Medicine, Department of Biomedical Engineering and Department of Imaging Research, SPRI is dedicated to translational science that impacts people all over the world.

In the past twelve months, SPRI has maintained its focus on bench-to-bedside research, accelerating its clinical trials and working closely with its clinician partners at The Steadman Clinic. SPRI remains one of the most highly published institutions in the field of orthopaedic sports medicine and through hosting international conferences and academic meetings, SPRI has helped the small town of Vail, Colorado become a true hub of innovation and science.

Each scientist and researcher within SPRI is motivated by the goal of finding cures and enhancing lives. SPRI is a passionate, invigorated team, and I am excited at the opportunity to share its excellent work over the past twelve months.

Thank you for supporting Steadman Philippon Research Institute. The incredible work we do at SPRI is made possible not only by our accomplished scientists and physicians, but also by our research partners and invested community.

I hope you will join us for the Fifth Annual Vail Scientific Summit, August 24–27, 2019.

Respectfully yours,

Johnny Huard, Ph.D.
Chief Scientific Officer

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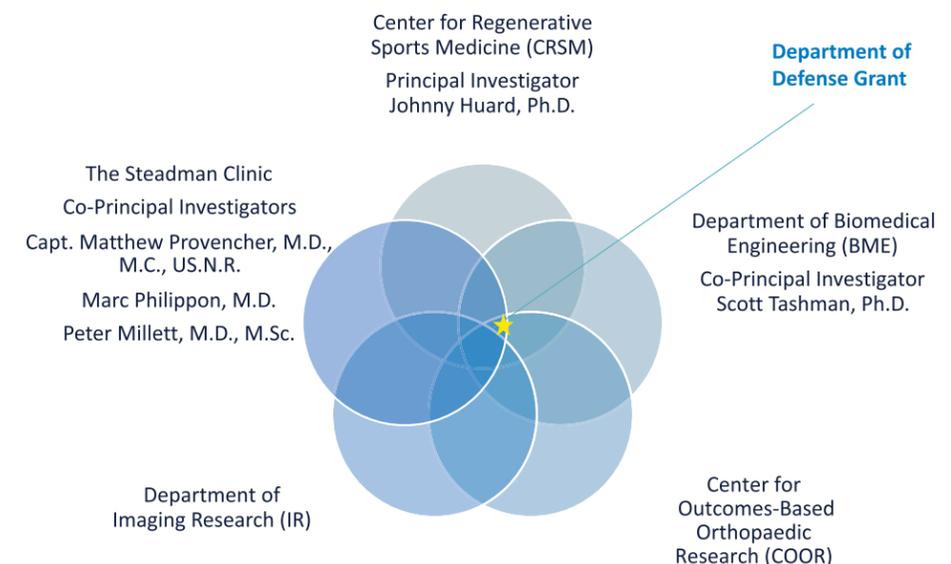
TEAM SCIENCE AND A HISTORIC FIRST FOR SPRI

In early 2019, Steadman Philippon Research Institute (SPRI) received confirmation that it had been awarded its first federal grant, a multimillion-dollar award from the Department of Defense (DOD) to complete four projects over the next three years. Including clinical trials, these projects are focused on improving and enhancing lives—a core tenet of SPRI’s mission.

SPRI’S DOD PROJECTS ARE:

1. **Prospective Evaluation of Platelet-Rich Plasma and Bone Marrow Concentrate Treatment to Accelerate Healing after Anterior Cruciate Ligament Reconstruction**
2. **Biologically Regulated Marrow Stimulation by Blocking Fibrosis to Improve Cartilage Repair: A Randomized, Double Blind, Placebo-Controlled Study**
3. **Senolytic Drugs Attenuate Osteoarthritis-Related Articular Cartilage Degeneration: A Clinical Trial**
4. **Optimization of Return-to-Duty Protocols after Knee Injury**

The success of these projects relies on SPRI’s commitment to collaborative, team science. Each of SPRI’s four research departments—the Center for Regenerative Sports Medicine (CRSM), Department of Biomedical Engineering (BME), Center for Outcomes-Based Orthopaedic Research (COOR) and Department of Imaging Research (IR)—is integrally involved in this grant, alongside physician investigators from The Steadman Clinic. The result is a cohesive, collective pursuit of science that exemplifies SPRI’s spirit of teamwork and community. The outcomes of these projects may have groundbreaking impact for military personnel and veterans, as well as upon the athletic civilian population.



This award is a major milestone for SPRI and its scientists, researchers and physician collaborators; it has validated the team’s efforts to consistently produce high-impact science and inspired further pursuit of DOD and National Institutes of Health (NIH) funding opportunities for future projects.

RESEARCH AND EDUCATION DEPARTMENTS

Steadman Philippon Research Institute (SPRI) is a true innovator in orthopaedics and sports medicine research. With a history of publishing in top journals and producing cutting-edge science, SPRI is a leader amongst independent institutions. The skilled scientists and researchers at SPRI work in the following departments:

Department of Biomedical Engineering: SPRI's Biomedical Engineering team enhances patient care by focusing on injury and re-injury mechanisms and prevention, develops and validates novel surgical treatments and rehabilitation techniques, and teaches advanced research protocols using state-of-the-art biomedical research techniques and technologies.

Center for Outcomes-Based Orthopaedic Research: SPRI's robust outcomes database is now tracking over 40,000 surgeries. The center conducts evidence- or outcomes-based research using actual clinical data, which helps both physicians and patients in making better and more informed treatment decisions.

Center for Regenerative Sports Medicine: With a focus on the basic science of regenerative medicine, SPRI's Regenerative Sports Medicine staff engage in research designed to translate discoveries into practical orthopaedic treatments.

Department of Imaging Research: The Imaging Research team develops and evaluates noninvasive imaging techniques of the joints for the purpose of directing and monitoring clinical treatment and outcomes, and to enhance the clinical relevance of biomechanics research.

Department of Education: A multifaceted department, SPRI's Education team administers and coordinates the clinical fellowships and international scholars programs, hosts conferences and international academic meetings, produces and distributes publications and educational media, and organizes educational outreach programs with local students from Eagle County, Colorado.

SPRI Microbiome Center: A new addition to SPRI, the Microbiome Center utilizes Niche Dynamics, Biomic Integration and Panomics to inform clinically relevant results that complement the other research departments within SPRI.

A PROLIFIC PUBLISHER

SPRI's research is widely published in professional journals. In fact, because of SPRI, Vail, Colorado has the highest number of publications per surgeon of any city in the United States, as well as the highest number of publications per capita. All publication counts are based on the top 15 highest impact factor journals in orthopaedics over the last 5 years.

SPRI's widely published research is also presented both in the United States and internationally to educate peers interested in advancing the field of orthopaedics. SPRI's elite fellowship programs attract top physicians from around the world to participate in its highly sought-after training programs. With an enduring focus on bench-to-bedside research, SPRI scientists work closely with physicians at The Steadman Clinic to develop new treatments and techniques that can be translated to patient care.

RESEARCH ADVISORY COMMITTEE MEETING CHAIRMAN



JOHNNY HUARD, PH.D.
CHIEF SCIENTIFIC OFFICER

Director, Center for Regenerative Sports Medicine
Chairman, Research Advisory Committee, Steadman Philippon Research Institute

Dr. Johnny Huard is a world-renowned scientist and serves as Chief Scientific Officer and Director of the Center for Regenerative Sports Medicine at Steadman Philippon Research Institute (SPRI) in Vail, Colorado. Dr. Huard also holds an affiliate faculty position within the Department of Clinical and Biomedical Sciences, College of

Veterinary Medicine at Colorado State University. From 2015 to 2019, Dr. Huard was Distinguished Professor and Vice Chair for Research in the Department of Orthopaedic Surgery at the University of Texas Health Science Center at Houston (UTHealth). In addition, he was the Director of The Brown Foundation Institute of Molecular Medicine Center for Tissue Engineering and Aging Research in Houston, Texas. Dr. Huard also held the Henry J. Mankin Professor and Vice Chair for Musculoskeletal Cellular Therapeutics and the Director of the Stem Cell Research Center in the Department of Orthopaedic Surgery at the University of Pittsburgh for 20 years. He also held joint appointments in Microbiology and Molecular Genetics, Bioengineering, Pathology and Physical Medicine and Rehabilitation, Pediatrics at the University of Pittsburgh Cancer Institute (UPCI) at the University of Pittsburgh. Dr. Huard was the Deputy Director of Cellular Therapeutic Research at the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. The discoverer of muscle-derived stem cells, Dr. Huard has over 25 years of research and innovation experience.

Dr. Huard is the Chair of SPRI's Research Advisory Committee (RAC) and also chairs the Vail Scientific Summit annual meeting each August. Dr. Huard is also a member of the Orthopaedic Research Society (ORS) Board of Directors and serves as Program Committee Chair, an appointment he will hold through 2020.

Dr. Huard's research laboratory focuses on the identification, characterization and clinical applications of muscle-derived stem cells for the treatment of conditions including Duchenne muscular dystrophy (DMD); critical sized long bone and cranial bone injuries; acutely injured articular cartilage and articular cartilage damaged by osteoarthritis; compartment syndrome limbs that involve injury to the muscles, nerves, circulatory, lymphatic system vasculature, etc.; infarct injured hearts and cardiomyopathy due to DMD. Much of Dr. Huard's stem cell research has been used clinically (over 700 patients in Canada and the United States) for the treatment of urinary incontinence and myocardial infarction and is now part of an FDA-approved Phase III clinical trial.

Having received over 40 federal grant awards (NIH and DOD) in his career, Dr. Huard has a proven history of extramural research and funding. Dr. Huard and his team have authored over 380 manuscripts including peer-reviewed articles, review articles, invited papers, and book chapters for various high-impact scientific journals including *Nature Cell Biology*, *Nature Biotechnology*, *Journal of Cell Biology*, *Journal of Clinical Investigation*, *Cell Stem Cell*, and more. Dr. Huard and his research team have received 87 awards including the Orthopaedic Society's prestigious Kappa Delta Awards (2004 and 2018) and was also the recipient of the University of Pittsburgh's Chancellor's Distinguished Research Award. He has had 900 abstracts accepted for presentation at national and international conferences. Dr. Huard currently serves on multiple editorial boards of scientific journals and reviews numerous scientific papers for a wide variety of scientific journals in his area of expertise. He serves on numerous study review groups at the National Institutes of Health and has over 35,845 google scholar citations with an h-index of 100.

RESEARCH ADVISORY COMMITTEE MEETING CO-CHAIRS:

MARC J. PHILIPPON, M.D., PETER J. MILLETT, M.D., M.SC. AND MATTHEW T. PROVENCHER, M.D.



MARC J. PHILIPPON, M.D.

SPORTS MEDICINE/HIP DISORDERS, HIP ARTHROSCOPY

Managing Partner, The Steadman Clinic

Co-Chairman; Co-Director of Sports Medicine Fellowship, Steadman Philippon Research Institute

Research Advisory Committee Member, Steadman Philippon Research Institute

Dr. Marc J. Philippon is the Managing Partner at The Steadman Clinic and is one of the world's leading orthopaedic surgeons. Dr. Philippon joined The Steadman Clinic in 2005 from the University of Pittsburgh Medical Center, where he served as Director of Sports Medicine/Hip Disorders Fellowship. He was also the Director of the University of Pittsburgh Medical Center's Golf Medicine Program. Previously, Dr. Philippon was Chief of Orthopaedic Surgery at Holy Cross Hospital in Fort Lauderdale, Florida.

Dr. Philippon is recognized by his peers in *U.S. News and World Report* as being among the top one percent in the nation in his specialty.

Dr. Philippon is internationally known for performing joint preservation techniques utilizing arthroscopic hip surgery to treat painful joint injury in high-level athletes who constantly use powerful hip rotation. He has treated nearly 1,000 professional and Olympic athletes successfully, many of them returning to high performance, winning Olympic Medals, setting new NFL, NHL and MLB records and winning PGA tournaments. Dr. Philippon is a consultant to the NHLPA and the Royal Spanish Tennis Federation and to many professional and Olympic organizations. In addition, Dr. Philippon serves as a member and trustee for both the U.S. Ski and Snowboard Team Foundation and the United States Olympic and Paralympic Foundations. A frequent invited speaker at national and international sports medicine and orthopaedic meetings, Dr. Philippon has also authored many peer-reviewed scientific articles. He has performed surgery in fifteen different countries and has designed many instruments to improve surgical techniques in hip surgery. In 2017, he was honored as the 21st Robert K. Kerlan MD Memorial Lecturer at the Keck School of Medicine of University of Southern California.

Dr. Philippon initially came to the United States as a student-athlete, playing NCAA soccer and tennis on an athletic scholarship. He earned his medical degree with an academic scholarship from McMaster University Medical School in Hamilton, Ontario, Canada in 1990, and completed his orthopaedic surgery residency at the University of Miami, Jackson Memorial Hospital in 1995.

Board-certified by the American Board of Orthopaedic Surgery, Dr. Philippon is an active member of many medical organizations. He is also a Fellow with the American Academy of Orthopaedic Surgeons and is a Master Instructor with the Arthroscopy Association of North America. Dr. Philippon is an elected member of the Herodicus Society and is a founding member of the International Society of Hip Arthroscopy (ISHA). He is currently serving as president of ISHA for the 2018–2019 term.

In 2012, Dr. Philippon received an Achievement Award from the American Academy of Orthopaedic Surgeons (AAOS) in recognition of outstanding contributions to the profession of orthopaedic surgery. In 2016 he received the 1st Annual Joseph McCarthy Award for Achievement in Advancing Knowledge and Scholarship in Hip Joint Preservation. His recognition continued as the leading researcher and surgeon in hip preservation with the "Vinci" Sports Health Award from The Vincera Foundation in 2018. In 2019, Dr. Philippon was honored with the prestigious Cabaud Memorial Award from the American Orthopaedic Society for Sports Medicine (AOSSM).

Dr. Philippon lives in Colorado with his wife and three children. He enjoys spending time with his family and participating in sports such as cycling, skiing, ice hockey, swimming and golf.

RESEARCH ADVISORY COMMITTEE MEETING CO-CHAIRS (CONT.)



PETER J. MILLETT, M.D., M.SC.

SHOULDER, KNEE, ELBOW SURGERY & SPORTS MEDICINE

Partner, The Steadman Clinic

Chief Medical Officer, Steadman Philippon Research Institute

Research Advisory Committee Member, Steadman Philippon Research Institute

Medical Director, Ski & Snowboard Club Vail

Peter J. Millett, M.D., M.Sc. is a partner at The Steadman Clinic who specializes in disorders of the shoulder, knee, elbow and sports-related injuries. Dr. Millett is a researcher and Chief Medical Officer at Steadman Philippon Research Institute.

Consistently selected as one of the "Best Doctors in America," Dr. Millett has been ranked in the top one percent of orthopaedic surgeons by *U.S. News and World Report*.

As a shoulder and sports medicine specialist, Dr. Millett has treated elite athletes from the NFL, NBA, MLB, NHL, PGA, Formula One, X-Games and the Olympics. Dr. Millett is a member of the American Orthopaedic Society for Sports Medicine, the American Shoulder and Elbow Surgeons, the Orthopaedic Research Society, the Arthroscopy Association of North America, the German Arthroscopy Association, the Sports Council and the Herodicus Society. Dr. Millett was recently honored by being an invited keynote speaker at the German Shoulder and Elbow Society, where he was also made an honorary member. Dr. Millett was also honored as the keynote speaker for the British Shoulder and Elbow Society.

Among other journals, Dr. Millett serves on the editorial board of the prestigious journals, *American Journal of Sports Medicine*, *Arthroscopy* and the *Journal of Shoulder and Elbow Surgery*. Dr. Millett has authored over 300 peer-reviewed scientific papers and four books on orthopaedic surgery and is renowned for his work on double-row rotator cuff repair, AC joint injuries, shoulder instability and the arthroscopic treatment of glenohumeral osteoarthritis. As an innovator, Dr. Millett also has a number of patents for his inventions. As an educator, Dr. Millett has been very involved in medical education—training residents, medical students and fellows. During his career, he has trained over 80 fellows from the United States and abroad.

Dr. Millett attended the University of Scranton in Scranton, Pennsylvania and Dartmouth Medical School in Hanover, New Hampshire. While studying skeletal biology at the University of Cambridge in England, Dr. Millett earned a Master of Science (M.Sc.) degree. He completed his orthopaedic residency at Hospital for Special Surgery and Cornell University Medical Center in New York City. After a fellowship in shoulder, knee and sports medicine in Vail with Steadman Philippon Research Institute, Dr. Millett joined the faculty at Harvard Medical School, working with Professor Jon J.P. Warner. While at Harvard, Dr. Millett had a busy clinical practice and was active academically, teaching Harvard orthopaedic residents and medical students and serving as the Co-Director of the Harvard Shoulder Service and Shoulder Fellowship. While in Boston, he also started the Musculoskeletal Proteomics Research Group. In 2005, Dr. J. Richard Steadman of The Steadman Clinic and Steadman Philippon Research Institute recruited Dr. Millett to return to Vail to join the clinic and institute.



CAPT. MATTHEW T. PROVENCHER, M.D., M.C., U.S.N.R.
COMPLEX SHOULDER, COMPLEX KNEE & SPORTS SURGERY

Partner, The Steadman Clinic
 Co-Director of Sports Medicine Fellowship, Steadman Philippon Research Institute
 Research Advisory Committee Member, Steadman Philippon Research Institute

Captain Matthew T. Provencher, M.D., M.C., U.S.N.R, joined The Steadman Clinic and Steadman Philippon Research Institute in 2016. He attended the United States Naval Academy, where he graduated with Distinction. He was also inducted into Phi Kappa Phi (The National Honor Society), Tau Beta Pi (The National Engineering Honor Society),

and Sigma Pi Sigma (The National Physics Honor Society). He completed his medical education at Dartmouth Medical School, where he graduated with honors and was elected to the Alpha Omega Alpha Honor Society.

Dr. Provencher completed his orthopaedic residency at the Naval Medical Center San Diego and his orthopaedic surgery fellowship in Chicago at Rush University. A prolific researcher, he has received numerous academic and research awards, including the International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS) Science Award; the ISAKOS Richard Caspari Award and the American Orthopaedic Society for Sports Medicine (AOSSM) Aircast Research Award. He has received numerous peer-reviewed grants from funding agencies, using these funds to establish programs for studying musculoskeletal outcomes, value-driven care and mechanics and basic science studies on the shoulder and knee.

CAPT Provencher served as an orthopaedic surgeon at the Naval Medical Center San Diego from 2004 to 2013 and was Director of the Sports Medicine and Surgery program from 2007 to 2013. As the Head Orthopaedic Team Physician for Navy Seal Teams 1, 3, 5 and 7, he was instrumental in setting up the Special Forces Tactical Athlete Program (TAP), a comprehensive wellness, injury prevention and rehabilitation program for Naval Special Forces. In addition to his military orthopaedic duties, CAPT Provencher performed extensive Humanitarian and Disaster Relief work. He continues his duties in the Navy as a Reservist.

After fulfilling his Navy obligation in 2012, Dr. Provencher became the Chief of Sports Surgery at Massachusetts General Hospital, Visiting Professor of Harvard Medical School, and Medical Director and Head Team Physician for the New England Patriots football team. He was the Medical Director of the Patriots during the 2014 Super Bowl Championship season and pioneered a wellness and injury prevention program for the team. He also serves as a second opinion orthopaedist for the NFL, MLB and the NHL.

Dr. Provencher was elected into the prestigious Herodius Society in 2010. In 2017, he was honored with the Colonel Brian Allgood Award, which is the most significant leadership award given by the Society of Military Orthopaedic Surgeons (SOMOS).

Dr. Provencher was nominated to The Board of Directors for AOSSM from 2011-2013. He serves on numerous national and international committees, the Arthroscopy Association of North America (AANA) 2014 Program Director, as well as the Co-Director of the San Diego Shoulder Institute Annual Meeting. He is on the Board of Directors for AOSSM, AANA, SOMOS and serves as the Exhibits Chairman for the AAOS (American Academy of Orthopaedic Surgeons) Annual Meeting. He is also chairman of the AOSSM Research Committee, Program Director for the AOSSM 2018-2019 meetings, and Chairman of the AANA Education Committee. Dr. Provencher was the Assistant Editor-in-Chief of the *Arthroscopy Journal* from 2012-2018. He is an active member of numerous surgical associations.

Dr. Provencher was recently named one of the Top 28 Shoulder Surgeons and Top 28 Knee Surgeons in the United States by *Orthopaedics Today*. He is recognized by *Becker's Orthopaedics* as "One of 59 Great Orthopaedic Surgeons." His research includes over 264 peer-reviewed publications and articles, 148 chapters, and six textbooks. He has given over 500 peer-reviewed and invited national and international presentations in the realm of sports medicine and leadership.

Dr. Provencher resides in Edwards, CO with his wife and four children.

JOHNNY HUARD, PH.D.

Chief Scientific Officer
 Director, Center for Regenerative Sports Medicine
 Chairman, Research Advisory Committee
 Steadman Philippon Research Institute
 Vail, Colo.

MARC J. PHILIPPON, M.D.

Co-Chairman; Co-Director of
 Sports Medicine Fellowship
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 Managing Partner and Orthopaedic Surgeon
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 Vail, Colo.

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RANDY W. VIOLA, M.D.

Hand, Wrist, Elbow & Orthopaedic Trauma Specialist
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SAVIO LAU-YUEN WOO, PH.D., D.SC. (HON.)

Ferguson Professor & Director,
 Musculoskeletal Research Center
 University of Pittsburgh
 Pittsburgh, Penn.

BUILDING ON A TRADITION OF CLINICAL TRANSLATION: SPRI'S UNPRECEDENTED YEAR

A Reflection by Dan Drawbaugh, CEO of SPRI and The Steadman Clinic



DAN DRAWBAUGH
CEO of SPRI
and The Steadman Clinic

This past year, we've talked a lot about our history here in Vail. Celebrating thirty years in 2018, Steadman Philippon Research Institute has built and maintained one of the largest orthopaedic and sports medicine databases in the world. Its partner, The Steadman Clinic, has treated thousands of patients from all over the world, including Olympians and professional athletes. Together, the institute and clinic are committed to keeping people active, by offering the best evidence-based treatments, thoughtfully selected for each individual patient.

SPRI's research is grounded in a bench-to-bedside focus, meaning that all of the science being conducted at the lab bench is destined for the patient's bedside. It means that everything we do is designed with a patient focus in mind. We want to discover the best treatments and therapies, validate them and get them in the hands of our skilled physicians.

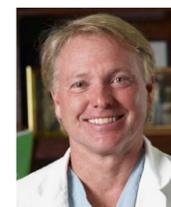
ProofPoint Biologics, a unique bridge between clinical and research practices, was founded in 2017. A distinctive partnership between ProofPoint Biologics, The Steadman Clinic and Steadman Philippon Research Institute has allowed us to advance our prospective clinical trials, which has been truly groundbreaking for SPRI. ProofPoint Biologics has processed 1245 patient samples, initiating six new clinical trials in our Center for Regenerative Sports Medicine. These clinical trials allow us to test and validate biologic treatments—a huge component of regenerative medicine with remarkable potential in clinical practice—which accelerates our clinical translation efforts. Thanks to these trials, we're optimizing treatments and getting them to our patients fast.

From this jumping off point, we've initiated new trials in regenerative medicine and biomedical engineering, and have recently had three trials awarded from the Department of Defense (DOD). By the close of 2019, we anticipate that SPRI will be running at least 10 clinical trials, with many more in the pipeline.

These trials build on our history. SPRI has always performed retrospective clinical trials with its outcomes research. Now, Drs. Philippon, Provencher, Millett, Evans, Kim, Vidal and Kuppersmith—alongside our elite scientists—continue to innovate with these prospective clinical trials for the DOD. It's another way SPRI is constantly evolving in its mission of unlocking the secrets of healing, finding cures and enhancing lives.

I'd like to congratulate our scientists, researchers and physician partners on a groundbreaking year of science at SPRI.

THE STEADMAN CLINIC SURGEONS AND PHYSICIANS



MARC J. PHILIPPON, M.D.
Managing Partner
Sports Medicine, Hip Disorders,
Hip Arthroscopy



RANDY W. VIOLA, B.A., M.D.
Hand, Wrist, Elbow and
Orthopaedic Trauma Specialist



DONALD S. CORENMAN, D.C., M.D.
Spine and Neck Specialist



DAVID C. KARLI, M.B.A., M.D.
Spine, Sports Rehabilitation and
Regenerative Medicine Specialist



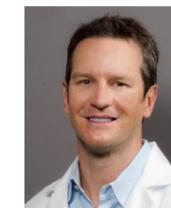
TOM R. HACKETT, M.D.
Complex Knee, Shoulder and
Elbow Surgeon



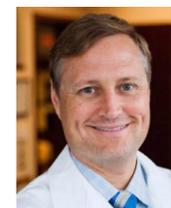
PETER J. MILLETT, M.D., M.SC.
Shoulder, Knee and Elbow Surgery
Sports Medicine



THOMAS O. CLANTON, M.D.
Foot and Ankle Sports Medicine



THOS A. EVANS, M.D.
Orthopaedic Interventional & Regenerative
Pain Medicine Specialist



MATTHEW T. PROVENCHER, M.D.
Complex Shoulder, Complex Knee and
Sports Surgery



RAYMOND H. KIM, M.D.
Adult Joint Reconstruction,
Knee and Hip Arthroplasty



DAVID A. KUPPERSMITH, M.D.
Internal Medicine



JOEL M. MATTA, M.D.
Hip Disorders: Preservation,
Replacement and Fractures



C. THOMAS HAYTMANEK, JR., M.D.
Foot, Ankle and Trauma Surgery



ARMANDO F. VIDAL, M.D.
Complex Knee and Sports Medicine Surgeon



Dr. Armando Vidal attends the 3rd Annual Injury Symposium

SPRI and The Steadman Clinic welcomed a new complex knee and sports medicine surgeon to its ranks in May 2019. **Dr. Armando F. Vidal, a top-rated orthopaedic surgeon, joined The Steadman Clinic from the University of Colorado Denver School of Medicine**, where he served as the Executive Vice Chair in the Department of Orthopaedics. While in this post, Dr. Vidal also served as head physician for the Denver Nuggets.

Dr. Vidal specializes in shoulder and knee surgery with a focus on complex knee and ACL reconstruction surgeries. His work involves complex revisions, osteotomies, articular cartilage restoration and multi-ligament knee injuries.

Although Dr. Vidal joined The Steadman Clinic in May, he was already well-acquainted with the clinic beforehand—Dr. Vidal completed his orthopaedic surgery residency at the University of Pittsburgh Medical Center under Dr. Marc Philippon’s mentorship in his final year at UPMC. Dr. Philippon said, “it was evident at that time that Armando would become a highly respected orthopaedic surgeon. His passion for helping patients is unquestioned. He is constantly seeking better and more efficient ways to treat, repair and rehabilitate injuries, and that is a trait that we all share at The Steadman Clinic.”

A native of Miami, Florida, Dr. Vidal graduated high school at 17 and enrolled at the University of Miami. His accelerated educational track got him admitted to medical school at Miami right out of high school; he finished the last year of his undergraduate degree during his first year of medical school at age 19.

Dr. Vidal has published over 70 peer-reviewed articles and has been awarded several prominent research awards including the AOSSM Aircast Award; he was also a two-time recipient of both the AOSSM O’Donoghue Award and ASES Neer Clinical Science Award.

A COLLABORATION WITH HISTORY

With a 25-year history of working together, SPRI and Colorado State University (CSU) furthered their partnership in 2019. With Chief Scientific Officer and Director of the Center for Regenerative Sports Medicine (CRSM) Dr. Johnny Huard joining SPRI in a full-time capacity, he needed new lab space where his team of scientists could perform necessary preclinical work. Dr. Huard and the SPRI team looked to Fort Collins to work with Dr. Nicole Ehrhart, a veterinarian and scientist who completed a sabbatical under Dr. Huard at SPRI last year. Dr. Ehrhart is the director of the Columbine Health Systems Center for Healthy Aging and a professor in orthopaedic



Dr. Nicole Ehrhart presents at the 4th Annual Scientific Summit



Dr. Nicole Ehrhart is presented the “Best Poster Award” by Dr. Huard, Dr. Philippon and Dr. Millett at the Vail Scientific Summit

oncology at the Flint Animal Cancer Center at CSU. Dr. Huard and his team have procured laboratory space in Fort Collins, near Dr. Ehrhart’s laboratory. The scientists will work in both locations, completing the necessary research to support Dr. Huard’s National Institutes of Health (NIH), Department of Defense (DOD) and philanthropically funded research. This team will collaborate closely with the Center for Regenerative Sports Medicine at SPRI in Vail.

These new studies will expand on a history of productive collaboration between SPRI and CSU. International Scholar Dr. Hajime Utsunomiya won the ON/ORS and Cabaud Memorial awards for his preclinical studies at CSU. CRSM scientist Dr. Chelsea Bahney and Dr. Ehrhart are currently conducting an NIH-funded clinical trial focused on promoting salivary gland regeneration in dog patients with cancer. The Steadman Clinic physician and SPRI Chief Medical Officer Dr. Peter Millett, along with international scholar Dr. Lucca Lacheta, is performing surgical research in models in Dr. Ehrhart’s lab at CSU.

In the course of their history working together, SPRI and CSU have co-written dozens of publications for high-impact journals. Expanding upon this collaboration by establishing a SPRI presence in Fort Collins will benefit both organizations in pursuit of research collaborations and federal funding.

This expanded collaboration between SPRI and CSU officially launched in July 2019.



CENTER FOR REGENERATIVE SPORTS MEDICINE

JOHNNY HUARD, PH.D.

Director
Chief Scientific Officer

CHELSEA S. BAHNEY, PH.D.

Principal Investigator
Program Director for Bone Repair
and Skeletal Engineering

SUDHEER RAVURI, PH.D.

Deputy Director

AIPING LU, M.D.

Senior Scientist Manager

XUEQIN GAO, M.D., PH.D.

Senior Scientist

PING GUO, PH.D.

Senior Scientist

WILLIAM S. HAMBRIGHT, PH.D.

Scientist I

HAJIME UTSUNOMIYA, M.D., PH.D.

Regenerative Sports Medicine Scholar

NAOMASA FUKASE, M.D., PH.D.

Regenerative Sports Medicine Scholar

YOICHI MURATA, M.D., PH.D.

Regenerative Sports Medicine Scholar

RUTH MCCARRICK-WALMSLEY

Laboratory Operations Manager

KAITIE WHITNEY

Clinical Translation Research Coordinator

ALEX SCIBETTA

Research Associate

LIZZIE MORRIS

Research Associate

ANNA LAURA NELSON, M.S.

Research Associate

MICHAEL MULLEN

Research Technician

JUSTIN HELLWINKEL, M.D.

Research Assistant

JACOB BILLINGS

Research Assistant

The focus of the **Center for Regenerative Sports Medicine (CRSM)** is to understand basic stem cell biology and translate that knowledge to the clinic to aid in the healing and regeneration of a variety of tissues. In the past twelve months, the CRSM team has launched the Regenerative Medicine Program on Healthy Aging, expanded its orthobiologics research and continued its robust study into gene therapy, tissue engineering and regenerative medicine applications.

CRSM is highly funded and one of the largest research departments at SPRI. Led by Director Johnny Huard, Ph.D.—who also serves as Chief Scientific Officer of SPRI—CRSM is home to several elite scientists. Chelsea Bahney, Ph.D., joined CRSM in August as Principal Investigator and Program Director for Bone Repair and Skeletal Engineering. The department's Deputy Director, Sudheer Ravuri, Ph.D., is actively involved in adipose-derived stem cell research, clinical translation and healthy aging.

This year, the department focused on obtaining additional funding in the form of NIH and DOD grants and recruiting top Ph.Ds. CRSM continues to present high numbers of abstracts at the Orthopaedic Research Society (ORS) annual meeting and publish papers in high-impact research journals. The department takes a significant role in the annual Vail Scientific Summit, hosting elite scientists and physicians in the fields of regenerative medicine, aging, biomechanics and orthopaedic surgery.

Previously sharing a joint appointment, Dr. Johnny Huard joined CRSM and SPRI in a full-time capacity, which will expand and further strengthen the research being conducted at SPRI.

The CRSM lab receives significant funding each year, including over \$3.2 million in philanthropic gifts over the last 12 months.



Dr. Sudheer Ravuri at work in the Center for Regenerative Sports Medicine

AWARDS

CRSM PRIDES ITSELF ON CONDUCTING VALUABLE RESEARCH THAT MAKES AN IMPACT IN THE SCIENTIFIC AND MEDICAL COMMUNITIES.

IN 2018–2019, THE DEPARTMENT WON SEVEN SIGNIFICANT AWARDS FOR ITS RESEARCH:

1. International Cartilage Repair Society (ICRS) Generation Next Forum: Best Clinical Paper Award, 2018
2. American Society of Bone and Mineral Research (ASBMR): Young Investigator Travel Grant, 2018
3. International Society for Fracture Repair (ISFR): Best Talk, Kyoto, Japan 2018
4. Orthopaedic Research Society (ORS) Orthoregeneration Network (ON) Foundation: Orthoregeneration Award, 2019
5. ORS: International Section for Fracture Repair Poster Award, 2019
6. American Orthopaedic Society for Sports Medicine (AOSSM): Cabaud Memorial Award, 2019
7. AOSSM: Fellow Research Award in Basic Science, 2019

ABSTRACTS & PUBLICATIONS

41 ABSTRACTS / 29 PUBLICATIONS

KEY HIGHLIGHTS:

- CRSM Director and SPRI Chief Scientific Officer Dr. Johnny Huard co-edited a special edition of the *Journal of Orthopaedic Research* on stem cells, published in July 2019. Dr. Huard co-edited the edition with Dr. Linda Sandell and Dr. Farshid Guilak.
- SPRI will receive DOD federal funding for the first time in SPRI's history, conducting research on preventing and treating osteoarthritis by utilizing orthobiologics and other therapies.
- CRSM has received an Investigational New Drug (IND) approval from the United States Food and Drug Administration (FDA) to use fisetin, a well-studied healthy aging supplement to begin a clinical trial.
- CRSM scientist Dr. Chelsea Bahney initiated a clinical trial to validate a novel fracture biomarker with physician collaborators Dr. Randy Viola and Dr. Matthew Provencher, both of The Steadman Clinic. This is a multi-center clinical trial with SPRI serving as the coordinating site. The team has collected almost 100 patients for the study.
- CRSM scientist Dr. Sudheer Ravuri identified an FDA-approved anti-helminthic drug as a potential senolytic drug that could be used in healthy aging research.

NEW SCIENTISTS JOIN CRSM

Building off a robust roster of scientists and researchers, CRSM welcomed several new scientists to its ranks this year. All PhDs, these new CRSM team members provide the expertise and credibility to further expand CRSM's position as a leader in regenerative medicine.



CHELSEA S. BAHNEY, PH.D.

In August 2018, Dr. Chelsea Bahney joined SPRI and CRSM from the University of California, San Francisco (UCSF). In her new appointment with CRSM, Dr. Bahney serves as Principal Investigator and Program Director for Bone Repair and Skeletal Engineering. Dr. Bahney earned her B.S. in Chemical Engineering and Biochemistry from the University of Colorado Boulder and worked as a Research & Development Engineer on electrosurgical medical device development for five years before enrolling at Oregon Health & Sciences University, where she earned her Ph.D. in Stem Cell & Developmental

Biology. Dr. Bahney completed her Post-Doctoral Fellowship in Orthopaedic Trauma at UCSF, where she later served as Assistant Professor and ran the Bahney Laboratory for Musculoskeletal Regeneration. She maintains an adjunct appointment at UCSF and mentors two Ph.D. students. Dr. Bahney is a member of the Orthopaedic Research Society (ORS) Board of Directors and serves as Chair of Communication Council, an appointment she will hold through 2020. She also serves on the Board of Directors as Treasurer for the Tissue Engineering and Regenerative Medicine International Society (TERMIS) and will retain that appointment through 2022. Dr. Bahney holds 14 patents and her research is currently funded by the National Science Foundation (NSF), National Institutes of Health (NIH), foundation and philanthropic grants. Dr. Bahney's research approach represents a commitment and focus on bench-to-bedside science.



AIPING LU, M.D.

Dr. Aiping Lu has worked with Dr. Huard since 2002 and joined SPRI from the University of Texas Health Science Center (UTHealth). As Senior Scientist Manager, Dr. Lu leads the SPRI Fort Collins laboratory that collaborates with Colorado State University (CSU). Dr. Lu has over 18 years of experience in regenerative medicine, specializing in gene and stem cell therapy, tissue engineering, Duchenne muscular dystrophy (DMD) and Healthy Aging. She has published 31 manuscripts, including 14 since 2015 in high-impact publications that include *The Journal of Clinical Investigation*, *Molecular*

Therapy, *Biomaterials*, *Human Molecular Genetics*, *The Journal of Cell Biology* and *Stem Cells*. Dr. Lu has had 13 abstracts accepted at ORS since 2017 and has worked on over 20 federal grants as a Co-Primary Investigator and Co-Investigator.



XUEQIN GAO, M.D., PH.D.

Dr. Xueqin Gao has over 33 years of biomedical research experience, including 10 years in stem cell, tissue engineering and regenerative medicine applications focusing on bone and cartilage biology, microfracture and cartilage repair. Dr. Gao is a Senior Scientist in CRSM, working out of the SPRI Fort Collins laboratory. She has over 76 peer-reviewed publications, including nine publications on stem cells and tissue regeneration since 2009. Dr. Gao has received extensive honors in her career including 14 awards won in the United States since 2009 and nine science and technology awards and three paper

awards in China. She holds 9 patents including 5 first inventor patents in China and has had 12 funded grants. She has had 59 abstracts accepted since 2007, including 42 since 2015. As an educator, Dr. Gao has mentored 13 graduate students in China, 2 Ph.D. students and 1 post-doctoral fellow.



PING GUO, PH.D.

Dr. Ping Guo has worked with Dr. Huard since 2000 and joined SPRI from UTHealth. As a Senior Scientist, Dr. Guo works out of the SPRI Fort Collins laboratory. His research focus includes gene therapy, tissue engineering and regenerative medicine. Dr. Guo has published 44 manuscripts including 11 published since 2015. His publications can be found in high-impact journals like *Human Molecular Genetics*, *Diabetes*, *Cell Stem Cell*, *The American Journal of Pathology*, *Cancer Research*, *Proceedings of the National Academy of Sciences of the United States of America* and *The Journal of Clinical*

Investigation. Dr. Guo has had nine abstracts accepted at ORS since 2016 and has worked on over 10 federal grants as Co-Primary Investigator and Co-Investigator.



WILLIAM S. HAMBRIGHT, PH.D.

Dr. William "Sealy" Hambright joined CRSM as a Scientist I in March 2019. He earned his B.S. in Biology from the University of Texas at Tyler and completed his M.S. in Microbiology at the University of Texas at Arlington. Dr. Hambright's Ph.D. training was in the Biology of Aging Training Program at the University of Texas Health Science Center at San Antonio at the Barshop Institute for Longevity and Aging Studies. Dr. Hambright's focus is to develop strategies that target fundamental properties of aging including senescent cell accumulation, telomere erosion and inflammation to improve

ortho-regenerative medicine therapies. At SPRI, Dr. Hambright coordinates basic science projects and helps design and initiate clinical studies targeting age-related diseases such as osteoarthritis and osteoporosis.

INTERNATIONAL REGENERATIVE SPORTS MEDICINE SCHOLARS

In addition to CRSM's new full-time scientists, two new scholars from Japan joined the department in 2019. As clinician-scientists, both scholars are medical doctors and hold PhDs.



NAOMASA FUKASE, M.D., PH.D.

With over 15 years of surgical experience, Dr. Fukase has performed thousands of surgeries in Japan. He earned his Ph.D. in 2012, and specializes in antitumor research and bone regeneration, as well as cartilage repair. Dr. Fukase joined CRSM in April 2019 and works on bone and cartilage regeneration research using innovative and regenerative medicine technologies like mesenchymal stem cells, platelet-rich plasma and biomaterials. Dr. Fukase joined SPRI from Kobe, Japan, where he worked under the directorship of Drs. Kurosaka and Kuroda.



YOICHI MURATA, M.D., PH.D.

Dr. Murata is an orthopaedic surgeon, specializing in surgeries of the hip including osteotomy, arthroplasty and arthroscopy. Dr. Murata earned his Ph.D. in medical science, focusing on mesenchymal stem cells in the hip joint. Having joined CRSM in March 2019, Dr. Murata conducts animal studies on articular cartilage using biologically regulated marrow stimulation (a newly coined term by SPRI for next-generation microfracture technique) with peptide amphiphile (PA). He also performs clinical outcomes, anatomical and biomechanical studies at SPRI. Dr. Murata joined SPRI from the Wakamatsu Hospital in Fukuoka, Japan, where he worked under the directorship of Dr. Uchida.



INTRODUCING THE REGENERATIVE MEDICINE PROGRAM ON HEALTHY AGING

With its proximity to The Steadman Clinic, **SPRI has grounded its research into the cause, effect and potential treatment of orthopaedic and musculoskeletal conditions like osteoarthritis.** Since its founding in 2015, CRSM has looked at these conditions as age-related diseases, and considered Healthy Aging as an important way to study and improve these conditions. This year, the department launched the Regenerative Medicine Program on Healthy Aging. Its mission is to understand the influence of age on biologics, develop rejuvenating therapies and translate these discoveries into clinical applications for healthy aging.

RESEARCH APPROACH

The Regenerative Medicine Program on Healthy Aging takes a four-tier approach in pursuit of its mission.

BIOLOGICS

Biologic treatments include stem cell therapies, bone marrow concentrate, platelet-rich plasma and adipose tissue-based therapeutics. This tier of the Regenerative Medicine Program on Healthy Aging focuses on the necessary basic science studies to understand the impact of aging on cellular fitness. In performing these studies, SPRI researchers will develop translational approaches to rejuvenating biologics for their best uses.

EXOSOMES

Exosomes are a new and exciting element of SPRI's healthy aging research. Exosomes are microscopic vesicles secreted from stem cells, and SPRI scientists believe they may have the potential to be even more translational than stem cells.

THERAPEUTICS

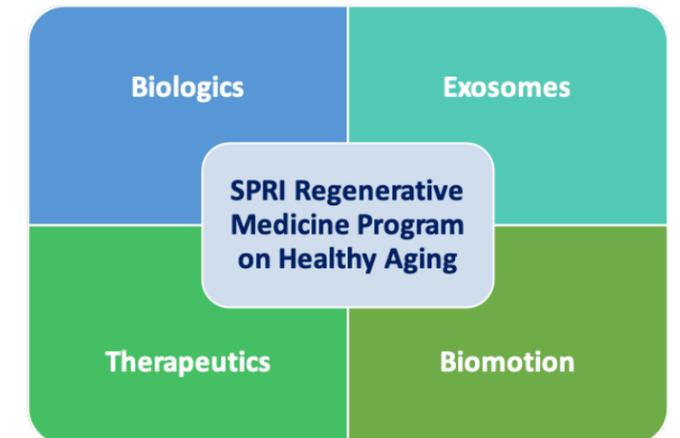
Therapeutics are an important aspect of SPRI's healthy aging research—our scientists aim to discover whether certain drugs and supplements can improve treatments, delay the effects of aging on cells and tissues and improve cell and tissue function.

BIOMOTION

Evidence suggests that exercise is a force that may be used to rejuvenate cell function. For example, adult stem cells come from blood vessels, and promoting blood vessel formation through exercise could improve stem cell function.

CLINICAL TRIALS AND HEALTHY AGING

CRSM is currently engaged in several clinical trials involving biologic treatments like platelet-rich plasma (PRP) and bone marrow concentrate. In addition to these clinical trials, the team is launching new trials in 2019 that will involve therapeutics, including a senolytic supplement and an FDA-approved hypertension drug, proven to prevent



or improve fibrosis in preclinical models. The department is currently engaged in the following trial through the Regenerative Medicine Program on Healthy Aging: *Improving Musculoskeletal Regeneration through Preclinical and Clinical Trials of Senolytic Therapies.*

Several other projects in the program are underway including: *Applying Senolytic Therapies to Eliminate Senescence from Harvested Stem Cells, Elimination of Pre-Existing Senescent Cells in the Body by Senolytic Treatment Prior to Tissue or Cell Harvest, Stem Cell Enrichment by Elimination of Senescent Cells in Bio-Banked Stem Cell Pool, Optimizing Regenerative Therapies through Preservation of Stem Cell Niche, Developing Stem-Cell-Derived Exosome Therapies to Promote Regeneration, Bio-Banking of Biologics, Cells and Tissues for Future Clinical Implications, Development of Home-Brew Techniques to Evaluate Senescence, and Innovative Therapies for Tissue Regeneration and Musculoskeletal (MSK) Repair,* amongst other studies.

CRISPR/CAS9 TECHNOLOGY AND DUCHENNE MUSCULAR DYSTROPHY

A major research focus of Dr. Huard and his team has been in finding a treatment for Duchenne muscular dystrophy (DMD), a severe form of the genetic condition muscular dystrophy. DMD is caused by mutations in the dystrophin gene and is characterized by muscle wasting and degeneration, which is due to impaired regeneration capacity, a property conferred by a resident population of muscle progenitor cells (MPCs). DMD more frequently occurs in males, affecting 1 in 5,000 at birth. Symptoms usually begin about the age of four, with many being unable to walk by 12. The life expectancy of this genetic disorder is 26, although with the best care, some patients live into their 30s and 40s.

Without a cure for this disease, many scientists and clinicians have looked to gene therapy as a possible treatment. Dr. Huard and his team of scientists have employed CRISPR/Cas9—a genome editing tool—to investigate a potential therapy for the disease.

WHAT IS CRISPR/CAS9?

An acronym for Clustered Regularly Interspaced Short Palindromic Repeats, CRISPR is the naturally occurring mechanism by which bacteria protect themselves against viruses. The CRISPR/Cas9 system takes that concept and moves beyond just viral infection, effectively editing any type of DNA. The CRSM team uses muscle progenitor cells (MPCs) in its research because they are valuable cells for therapeutic application and can contribute to muscle regeneration.

Dr. Huard and his team hypothesized that in older *mdx* mice (the animal model used in their study), MPCs will be depleted and the restoration of dystrophin through CRISPR/Cas9 will be impaired. Thus, the team proposed to restore the dystrophin gene using the genome-editing approach in the dystrophic MPCs.

What This Research Means

The preliminary results indicate that these gene-edited dystrophic MPCs better resist oxidative and other metabolic stresses, a significant feature that could allow those cells to survive the dystrophic microenvironment in post-implantation. These findings further support the recent report that dystrophin may play a role in the function of muscle stem cells. Overall, CRSM's preliminary transplantation studies demonstrated that CRISPR/Cas9 gene-edited dystrophic MPCs can restore dystrophin gene function in the dystrophic muscle.

Further *in vivo* animal studies are being performed to explore the use of CRISPR/Cas9 genome-edited dystrophic MPCs to delay stem cell depletion to consequently render this gene-editing technology applicable to older dystrophic animals. This is extremely significant, because CRSM has the potential to establish CRISPR/Cas9 mediated gene editing as a potential therapy for DMD in humans, a truly revolutionary discovery.

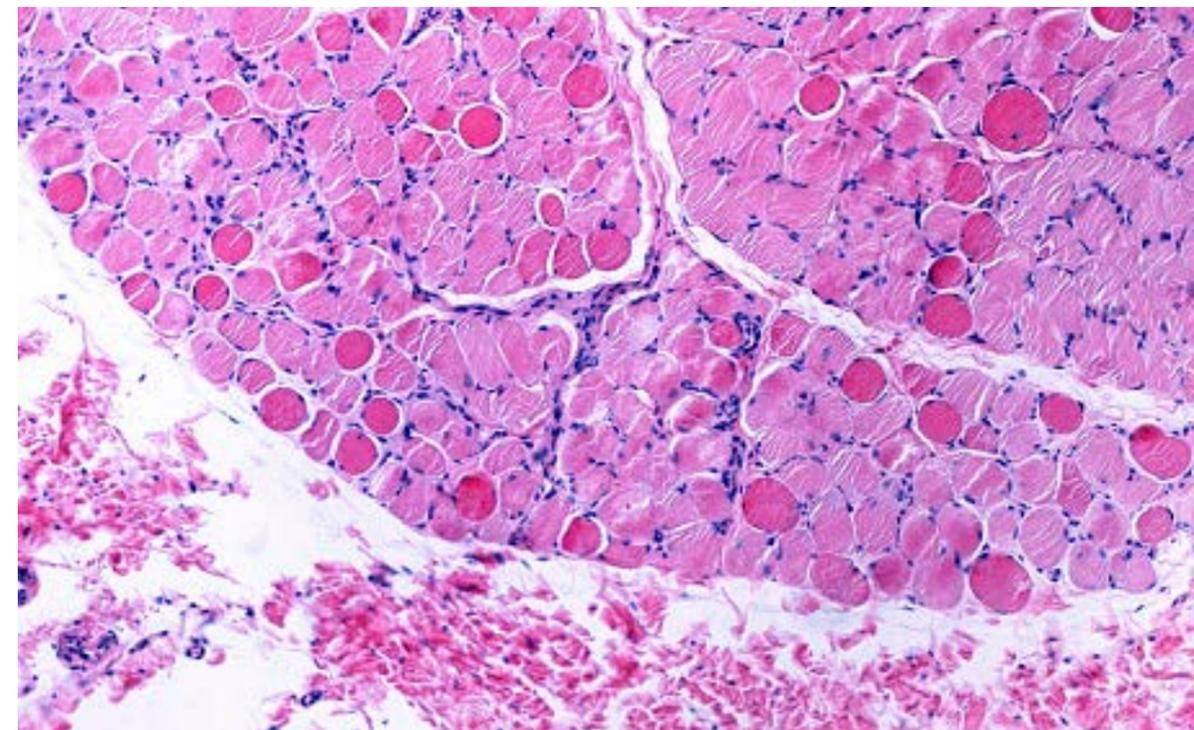
RESEARCH PROCESS

1. Constructed and tested the CRISPR/Cas9 system, confirmed the on-target activity
2. Confirmed that *Dmd* gene correction in *mdx* MPCs resulted in modified dystrophin gene and restoration of dystrophin protein
3. Using flow cytometry (FACS), sorted, transfected MPCs were analyzed for the irreversible genomic deletion of Exon 23 carrying a point of mutation

KEY FINDINGS

1. After performing cell viability assay to assess changes in cellular properties; no changes were present under normal conditions
2. Following exposure to oxidative and ER stresses, the viability of modified dystrophic MPCs was higher than the control, indicating that dystrophin restoration improves resistance of MPCs to stress
3. CRISPR/Cas9 therapies hold the promise of long-term dystrophin restoration due to changes at the genomic level
4. The work performed so far indicates that CRISPR/Cas9 can restore dystrophin gene expression in *young* dystrophic mice; it remains unclear whether this technology can be applied to older dystrophic mice

The results of this study were accepted for publication in the top scientific journal, STEM CELLS.



Necrotic muscle fiber, as seen in a DMD patient

FRACTURE HEALING: FINDING SOLUTIONS TO A PERVASIVE PROBLEM

With approximately 15 million fractures per year occurring in the United States alone, fractures are a widespread injury with significant potential consequences. In older populations, fractures occur at a frequent rate; one in three women and one in five men will experience an osteoporotic fracture. Where 10-20% of fractures result in poor healing in a normal population, the rate of poor healing and non-unions increases to 50% in the aging population, in cases of severe trauma or when the patient has a disease like diabetes. For an older patient experiencing a hip fracture, there is a 30% mortality rate and 80% disability rate within one year of the fracture. The annual cost of hospitalizations due to fracture injuries is \$23 billion in the United States.

DIAGNOSTIC RESEARCH

With poor fracture healing being a significant issue, scientists like CRSM's Dr. Chelsea Bahney are investigating ways to improve it. Before scientists and clinicians are able to treat a patient to heal better from a fracture, there first needs to be an effective tool for diagnosing poor healing earlier in a healing trajectory. Currently, the medical gold-standard in fracture care is a subjective physical examination and x-ray imaging to visualize tissue mineralization to evaluate bone healing. Because the majority of fractures heal through a cartilage intermediate (an unmineralized tissue), these tools are limited in their ability to evaluate the first stages of fracture repair. Before a poorly healing or non-union fracture can be diagnosed, current clinical standards require six to nine months or more of regular monitoring. Because of this standard, and the lack of tools, non-unions are rarely detected early in a patient's recovery.

15M FRACTURES/YEAR
IN USA

50% NON-UNION RATE IN
AGING POPULATION OR IN
TRAUMATIC INJURIES

30% MORTALITY
80% DISABILITY WITHIN 1 YEAR:
ELDERLY HIP
FRACTURE

\$23B COST OF HOSPITALIZATION
DUE TO FRACTURES IN USA

Fracture Plates to Monitor Fracture Healing

Dr. Bahney was co-senior author on a study called “Smart Fracture Plates that Can Monitor Fracture Healing,” which was recently published in *NATURE Scientific Reports*. Alongside her co-author Dr. Michele Maharbiz, a University of California, Berkley professor of electrical engineering, Dr. Bahney utilized *in vivo* mouse fracture models to assess whether sensor-enabled implants could provide a more effective method of monitoring in postoperative fractures. These plates use electrical impedance spectroscopy (EIS) to longitudinal tissue healing with much higher sensitivity than standard x-ray imaging methods can. Using external fixators and bone plates, Dr. Bahney and her team fixed long bone fractures and used EIS measurements within the fracture to distinguish between mice with good healing and those that were healing poorly. The results of this preclinical study suggest that EIS-augmented fracture plates would provide physicians with more information regarding the state of a patient’s fracture and could enable them to make more informed decisions regarding a patient’s recovery.

A Novel Biomarker to Quantify Fracture Healing

Biomarkers represent an exciting opportunity to identify the biological progression of healing and personalize medicine for patients. Prior to forming bone during fracture healing, the body generates a cartilaginous scaffold to provide temporary mechanical stability. Conversion of cartilage to bone is characterized biologically by the presence of a provisional type X collagen extracellular matrix. Collagen X is not normally expressed by skeletally mature, healthy adults—therefore its expression pattern is distinctive from baseline during bone repair. Dr. Bahney and her team recently published the development of this bioassay in *SCIENCE Translational Medicine*, demonstrating repeated and reliable measurement of Collagen X in serum (CXM) from a simple finger prick.

The long-term goal of this research is to expand on the published proof-of-principal studies and validate the ability

of this novel bioassay to quantify fracture healing. Toward this, Dr. Bahney has launched a multi-center clinical trial with SPRI serving as the coordinating site. This trial also engages the University of California, San Francisco (UCSF) and Oregon Health & Sciences University (OHSU). Currently underway with almost 150 patients enrolled to date, 64 of those collected through SPRI, the study’s central hypothesis is that monitoring CXM will correlate with fracture healing and reveal aberrant fracture healing through changes in the shape of the concentration versus time curve. The biomarker could significantly improve clinical care by providing clinicians with a diagnostic tool to monitor the progress of fracture healing through a simple, non-invasive method, allowing for early identification of poor healing and subsequently, early intervention.

THERAPEUTIC RESEARCH

A major focus within CRSM is using novel therapeutics in clinical applications. While half of the fracture healing research focuses on diagnostic research, the other half of CRSM’s fracture healing studies looks to *accelerate* fracture healing. To do so, scientists are looking into a combination of biomaterials and therapeutics to help aid a patient’s fracture healing.

Biomaterials

This two-part research begins with nano- and micro-biomaterials, which are designed to be injectable to a fracture to administer a therapeutic treatment. These biomaterials ensure sustained and controlled release of the therapy. Biomaterial development and optimization is being done in collaboration with top biomaterial groups across the country, including Dr. Tejal Desai (UCSF), Dr. Bill Murphy (University of Wisconsin) and Dr. Eben Alsberg (University of Illinois, Chicago). This localized approach to providing treatment is important, because it prevents a patient from

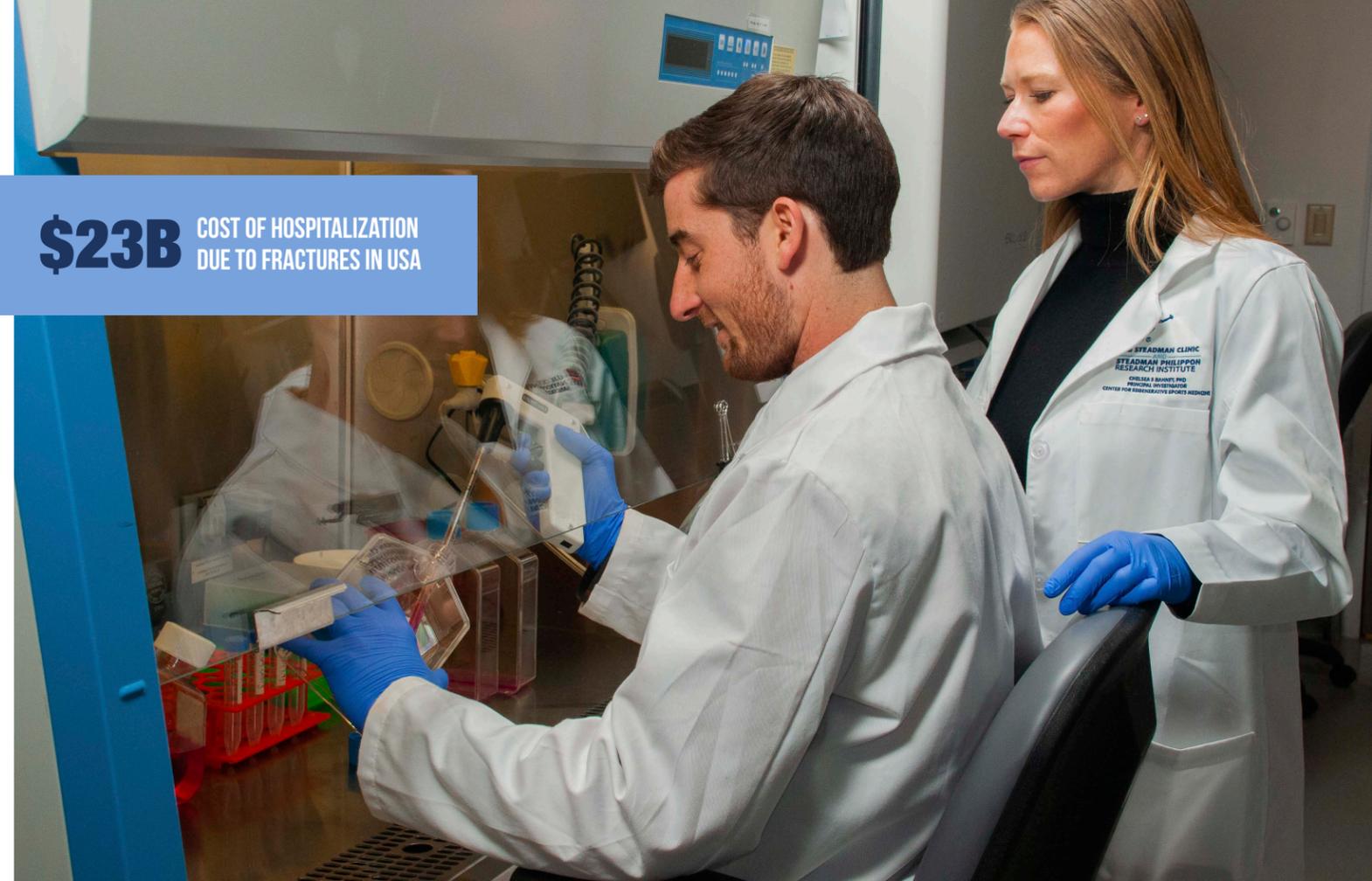
experiencing unwanted side effects from taking a drug orally or intravenously; it is activated only where it is needed. In this case, this occurs within the fracture site to accelerate recalcitrant healing and prevent non-unions.

Therapeutics

CRSM currently has several therapeutic studies underway that seek to stimulate fracture healing. In the last few years, Dr. Bahney’s laboratory has published key findings to show that chondrocytes (the cartilage cells that set up fracture healing) turn into bone by activating a transient, stem-cell-like state during healing progression. The discovery of this new pathway in fracture healing offers the opportunity to test new therapeutic strategies designed to accelerate the conversion of cartilage to bone during fracture repair. Dr. Bahney’s group is currently testing several different therapeutic approaches to improve bone regeneration. One example is NIH-funded research testing efficacy of Nerve

Growth Factor (NGF) embedded in a microrod delivery system. Another approach is activating the local, endogenous stem cells involved in fracture healing using delivery of either growth factors or state-of-the-art mRNA gene therapy techniques. Data from these studies has been accepted for presentation at multiple national and international conferences over the last year and is the basis for new NIH and DOD grant applications submitted by CRSM.

The combined therapeutic and diagnostic methods to understanding and accelerating fracture healing at CRSM provide a multifaceted approach to this vital research.



Dr. Bahney and Research Associate Mike Mullen work in the CRSM lab at SPRI



DEPARTMENT OF BIOMEDICAL ENGINEERING

SCOTT TASHMAN, PH.D.

Director

TRAVIS TURNBULL, PH.D.

Deputy Director

ALEX BRADY, M.S.

Senior Robotics Engineer

KIMI DAHL, M.S.

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SARAH WILSON, M.S.

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BRENTON DOUGLASS

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JACQUELINE FOODY

Research Assistant

KIRA TANGHE

Research Assistant

NICK MATTA

Summer Research Assistant

THOMAS SINGLETON

Summer Research Assistant



The Department of Biomedical Engineering (BME) is a collection of multidisciplinary laboratories that apply quantitative, analytical and integrative methods to the field of orthopaedic medicine. With focuses on injury and re-injury prevention and restoration techniques, BME is dedicated to integrating clinical care, research and education alongside the resources of renowned medical doctors to improve the treatment of musculoskeletal diseases and orthopaedic injuries. The team focuses on biomechanics, musculoskeletal mechanics, biomedical imaging and orthopaedic engineering.

The past twelve months have been extremely productive for BME, including collaborations with eight orthopaedic surgeons from The Steadman Clinic. A clinical lens is an important aspect for all of the research conducted at SPRI, and in BME's investigations of injury and re-injury prevention, these collaborations are especially significant.

The department welcomed new technologies to its one-of-a-kind Robotics Laboratory, adding video-motion analysis to assess multibody kinematics and 3D laser scanning to capture musculoskeletal geometry. The laboratory's advanced analytical capabilities have made it one of the most advanced facilities of its kind in the world. The lab had another productive year of research, including 20 completed studies and an additional 15 active and planned projects in robotics. The Robotics Lab receives significant funding each year, including over \$320,000 in industry grants and in-kind support in 2018.

The Biomotion Laboratory is now in full swing, taking advantage of its state-of-the-art equipment: video-motion analysis, instrumented treadmill, force plates, EMG sensors, IMU sensors, insole pressure sensors and Dynamic Stereo X-ray system. This past year, the Biomotion Lab completed testing for two projects and has eight projects in various stages of execution. The lab began testing for a new hip femoroacetabular impingement (FAI) study in September 2018 with Dr. Marc J. Philippon and is currently starting up a new program investigating the evaluation and treatment of chronic ankle instability with Dr. Thomas O. Clanton. The lab received a philanthropic donation to support the purchase and integration of flat panel X-ray detectors, which will keep the Biomotion Lab's Dynamic Stereo X-ray system at the cutting edge of radiographic imaging technology. Most of the Biomotion Lab's research is supported through external funding, including over \$1 million in philanthropic gifts in 2018–2019, alongside industry grants and in-kind support.

AWARDS

IN THE PAST YEAR, BME HAS RECEIVED TWO MAJOR AWARDS:

1. American Orthopaedic Society for Sports Medicine (AOSSM): Cabaud Memorial Award, 2018
2. *Orthopaedic Journal of Sports Medicine (OJSM)*: William A. Grana Award for Best Original Research, 2018

ABSTRACTS AND PUBLICATIONS

ABSTRACTS:

WORLD CONGRESS OF BIOMECHANICS (WCB) 2018: 5
ORTHOAEDIC RESEARCH SOCIETY (ORS) 2019: 2
INTERNATIONAL SOCIETY FOR SKIING SAFETY (ISSS) 2019: 2
INTERNATIONAL SOCIETY OF BIOMECHANICS (ISB) 2019: 1

PUBLICATIONS: 9 (INCLUDING 6 IN THE AMERICAN JOURNAL OF SPORTS MEDICINE, THE #1 JOURNAL IN ORTHOPAEDICS)

KEY HIGHLIGHTS

- Previously sharing a joint appointment, BME Director Scott Tashman, Ph.D. joined SPRI in a full-time capacity in May 2019, and the department anticipates even more productivity and advanced research with Dr. Tashman's permanent placement.
- BME's Biomotion researchers—Research Scientist Kimi Dahl, Research Engineer Sarah Wilson and Research Assistant Kristin Dunford—were selected to present at the launch event for IF/THEN on March 4, 2019, an initiative focused on bringing together preeminent science institutions with pop culture names and brands to raise the profiles of women in STEM and inspire the next generation to pursue STEM careers.
- Both the Biomotion and Robotics programs, in close collaboration with The Steadman Clinic surgeons, have continued to expand the breadth of their research to include studies of ligament and tendon injuries, arthritis and other musculoskeletal disorders of the ankle, knee, hip and shoulder.
- With collaboration as an integral component of SPRI's research, BME is engaged in several interdepartmental studies, including collaborations with the Center for Regenerative Sports Medicine (CRSM), Center for Outcomes-Based Orthopaedic Research (COOR) and Department of Imaging Research (IR).
- The combination of advanced MRI (using SPRI's state-of-the-art 3T magnet) for evaluating tissue structure and the dynamic imaging capabilities of the Biomotion Lab for assessing musculoskeletal function is ideal for assessing the efficacy of regenerative medicine therapies for restoring injured joints. This powerful combination of imaging tools and technologies will play a key role in several upcoming clinical trials.



Over
300
 cadaveric joints tested in robotics lab

July 2018 – July 2019

THE SCIENCE OF SKIING INJURY PREVENTION

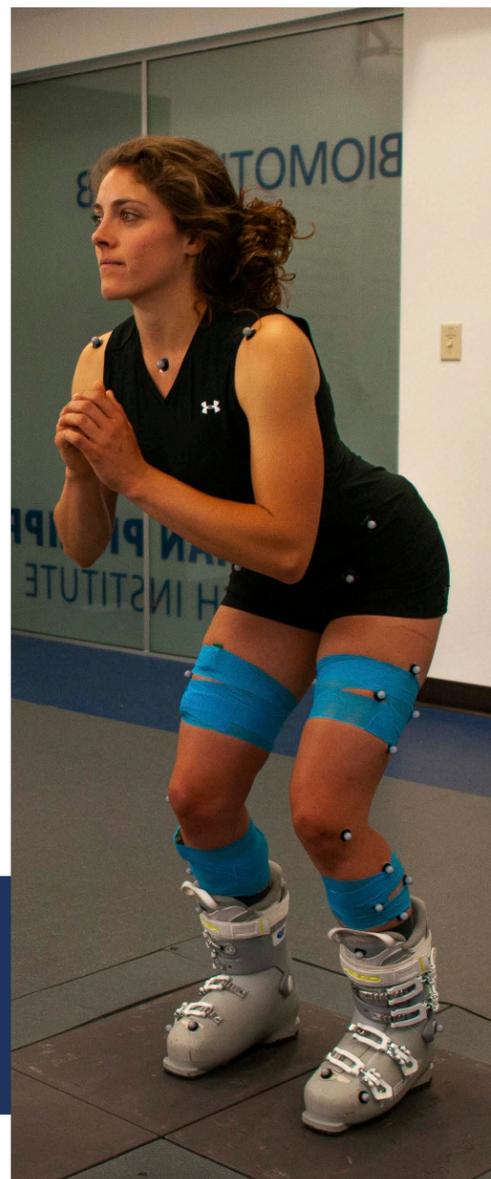
With its proximity to Vail ski resort, clinical appointments within the United States Ski and Snowboard Teams and numerous sponsorships and volunteer engagements, it's no surprise that there is a natural connection between SPRI and the sport of skiing. Much of that connection is dedicated to injury prevention research, which is the concept of moving science into action, creating effective ways to prevent injuries before they occur, as well as strategies for preventing re-injury. With this thought in mind, the Biomotion team at SPRI has conducted studies into ski injury prevention research with the goal of discovering new approaches that will reduce overall ski injury risk across recreational ski populations.

In its *Effects of Ski Boot Alignment Adjustments on Balance and Biomechanics in Recreational Skiers* multi-phase study, the Biomotion team took a closer look at knee injuries, which account for nearly one third of all injuries in adult skiers. Among those knee injuries, nearly 50% involve the anterior cruciate ligament (ACL).

While other researchers have previously considered the role of ski equipment in injury risk, the majority have focused on the ski boot/binding interface, assessing the “releasability” of the ski from the foot in a crash situation. But SPRI's Biomotion team took a different view, that recreational skiers don't get hurt because of incorrect binding retention settings, but rather, they get hurt because they are out of balance, which causes them to fall. With previous research proving that female ACL skiing injuries are not fatigue-related, another factor—like biomechanical imbalance—must contribute to injury risk. The team investigated the effect of common boot modifications (heel lifts, ramp angle and lateral canting) on biomechanical balance, first in the SPRI Biomotion Lab, where study participants engaged in a series of ski-related activities. After compiling data from the lab, researchers took participants onto the ski mountain, where they could track the movements of participants while they skied with the different modifications. Both the in-lab and on-mountain testing utilized wearable sensor technology to analyze human movement.

With these initial studies completed and analyzed, Research Engineer Sarah Wilson and the Biomotion team wrote a paper entitled, “The Effect of Canting on Knee Movements in Recreational Alpine Skiers,” explaining the initial results from the studies, which indicated that simple modifications like heel lifts and lateral canting can significantly improve the balance of some skiers. She presented the paper at the International Society of Skiing Safety (ISSS) meeting at Squaw Valley in April 2019.

AFTER COMPLETING THESE TWO SMALLER STUDIES, THE BIOMOTION TEAM HAS PLANNED A COMPREHENSIVE STUDY INVOLVING 50 SKIERS, WHICH IS PLANNED FOR THE 2019–2020 SKI SEASON.

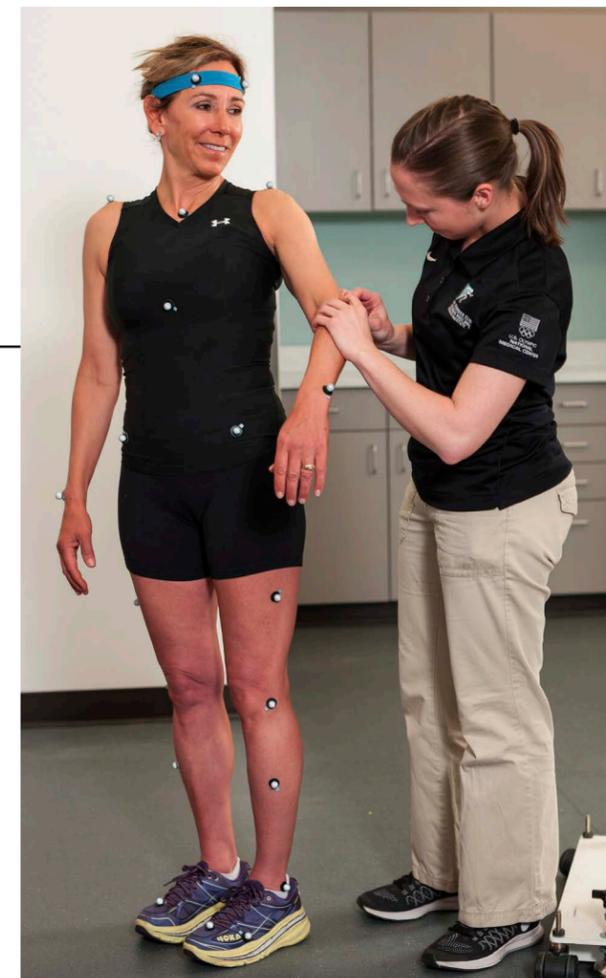


WEARABLE SENSOR TECHNOLOGY MAKING AN IMPACT IN THE FIELD

SPRI's 3D imaging in the Biomotion Lab is enhanced by wearable sensor technology, which enables researchers to record the movement of joints and ligaments outside of the laboratory setting. The portable, wireless sensors are worn at key points on a subject's body to accurately measure whole-body movement patterns. For the ski injury prevention study mentioned on the previous page, these sensors were placed on the participant's ankle, knee and hip joints, as they were focused on assessing biomechanical balance.

BME is currently engaged in several studies using wearable sensor technology, including its Mobile Platform for Optimizing Warfighter Rehabilitation (M-POWER), a study designed to help reduce the rate of re-injury following ACL reconstruction. With re-injury rates occurring in 10-15% of surgical cases and ACL injuries being frequent in military personnel, BME and The Steadman Clinic surgeon collaborator Captain Matthew Provencher, M.D., M.C., U.S.N.R, considered whether existing return-to-duty protocols were ineffective. These tests often occur in a controlled environment, which don't do an adequate job of replicating what movement will truly be like in the field. Military personnel may pass an indoor test and be sent back to the field before they are truly healed.

The BME team made use of natural mountain features including creeks, boulders, logs and hills to create an outdoor course in Vail, Colorado that replicates real, outside terrain. This course is designed to mimic the environment that military personnel will encounter when they return to active duty. The team uses wearable sensor technology to capture body movements, seeing how the ACL (and other ligaments and joints) perform on the outdoor course. The results from this study will enable scientists and clinicians to create improved Return-to-Duty testing protocols that are relevant to what a military member's movement actually demands, ensuring that they only return to service when they are biomechanically ready.



AN AWARD-WINNING LEGACY

Winning a major national or international award that measures clinical impact and quality of research is a life-long goal for many researchers. At SPRI, it's one of the ways the institute earns credibility amongst its peers. Over the past six consecutive years, the BME team has had incredible success winning research awards, culminating in these highlights:

- At least one major national or international research award each year
- Three major research awards in one year (2017)
- A total of 11 major awards, 2013–2018

These impactful statistics indicate that SPRI's BME team is conducting valuable, high-impact research within the orthopaedic research community.

BIOMEDICAL ENGINEERING MAJOR AWARDS 2013–2018

YEAR	SPONSOR	AWARD NAME	ABSTRACT / MANUSCRIPT TITLE
2013	International Society of Arthroscopy, Knee Surgery and Orthopaedic Sports Medicine (ISAKOS)	Albert Trillat Young Investigator's Award	<i>Biomechanical Consequences of a Complete Radial Tear Near the Medial Meniscus Posterior Root Attachment Site: In-Situ Pullout Repair Restores Derangement of Joint Mechanics</i>
2013	International Society for Hip Arthroscopy (ISHA)	Richard Villar Trainee Excellence in Clinical Research Award	<i>The Effect of an Acetabular Labral Tear, Repair, Resection and Reconstruction of the Hip Fluid Seal</i>
2014	American Orthopaedic Society for Sports Medicine (AOSSM)	Excellence in Research	<i>Posterior Cruciate Ligament Graft Fixation Angles: Biomechanical Evaluation for Single- and Double-Bundle Reconstruction</i>
2015	ISAKOS	Achilles Orthopaedic Sports Medicine Research Award	<i>Biomechanical Consequences of a Nonanatomic Posterior Medial Meniscus Root Repair after a Root Tear</i>
2016	AOSSM	Excellence in Research	<i>Anatomic Anterolateral Ligament Reconstruction of the Knee Leads to Overconstraint at any Fixation Angle</i>
2016	European Society of Sports Traumatology, Knee Surgery & Arthroscopy (ESSKA)	Basic Scientist Travel Grant	<i>Robotic assessment of anterolateral ligament: Reconstruction of the anterolateral and anterior cruciate ligament</i>
2017	American Academy of Orthopaedic Surgeons (AAOS)	Best Scientific Exhibit	<i>Optimization of Tunnel Position and Orientation in Complex Multiple Knee Ligament Reconstructions: Preoperative Planning and Intraoperative Techniques</i>
2017	ISAKOS	Achilles Orthopaedic Sports Medicine Research Award	<i>The Lateral Meniscus Posterior Root and Meniscomfemoral Ligaments are Stabilizing Structures in the ACL Deficient Knee: A Biomechanical Study</i>
2017	AOSSM	Cabaud Memorial Award	<i>Use of Platelet-Rich Plasma Immediately Post-Injury to Accelerate Ligament Healing was not Successful in an In Vivo Animal Model</i>
2018	AOSSM	Cabaud Memorial Award	<i>The Influence of Graft Tensioning Sequence on Tibiofemoral Orientation during Bicruciate and Posterolateral Corner Knee Ligament Reconstruction: a Biomechanical Study</i>
2018	Orthopaedic Journal of Sports Medicine (OJSM)	William A. Grana Award for Best Original Research	<i>Lateral Meniscus Posterior Root and Meniscomfemoral Ligaments as Stabilizing Structures in the ACL-Deficient Knee</i>



CENTER FOR OUTCOMES-BASED ORTHOPAEDIC RESEARCH

GRANT J. DORNAN, M.S.

Director and Biostatistician

**KAREN K. BRIGGS, M.B.A.,
M.P.H.**

Director of Hip Research

LAUREN PIERPOINT, PH.D.

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MARILEE HORAN, M.P.H.

Upper Extremity Coordinator

LAUREN MATHENY, M.S.

Foot and Ankle Research Coordinator

SARA ROBINSON, M.S.

Spine and Pain Management
Research Coordinator

JAMES SPRATT, M.D.

Research Assistant

ASHLEY PERRIGAUD

Data Collection Coordinator

MITCHELL KENNEDY

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NICOLE ANDERSON

Research Assistant

LIAM PEEBLES

Research Assistant

BRANDON GOLDENBERG

Research Assistant

PATRICK QUINN

Research Assistant

NEW STAFF 2019–2020

RICKY POULTON

Research Assistant

THOMAS WOOLSON

Research Assistant

RUI SOARES

Research Assistant

BRYANT ELRICK

Research Assistant

JARED HARDIE

Research Assistant



COOR Hip Research Manager Dr. Lauren Pierpoint welcomes attendees to the 3rd Annual Injury Prevention Symposium

For twenty-seven years, the **Center for Outcomes-Based Orthopaedic Research (COOR)** has been tracking and studying patient outcomes. This year, the team reached a major milestone—tracking over 40,000 surgeries in the COOR database. COOR has also collected over 150,000 patient-centered outcomes surveys, following patients throughout their recoveries.

As the first SPRI department, COOR has a robust history, and has established one of the richest and most valuable orthopaedic databases in the world. Outcomes research has significant clinical relevance, because it allows surgeons to validate their treatments—COOR researchers investigate how

patients are performing after their surgeries, which can impact the way clinicians approach patients with similar cases. This collected information, when investigated by the scientists and physicians within COOR and The Steadman Clinic, is used to produce long-term outcomes studies on pioneering techniques. In the case of SPRI's Co-Chairs, Dr. J. Richard Steadman and Dr. Marc J. Philippon, recent outcomes studies for their groundbreaking surgical techniques provided further endorsement that their treatments were the gold standard of care in well-selected patients. These publications also highlight the importance of tracking patient outcomes.

COOR's history of tracking patient outcomes also has exciting, future-looking applications. Researchers are able to look at specific surgery types, analyze patient data and use the compiled data to create predictive modeling apps. These apps can be used by clinicians as a tool to preview a new patient's anticipated recovery, and may even be used as diagnostic support in the future. Currently, the department has created predictive modeling apps for the shoulder and hip, with more joints in the pipeline.

For the past three years, COOR has been instrumental in organizing SPRI's Injury Prevention Symposium alongside its partner the United States Olympic Committee (USOC), bringing in top scientists, researchers and clinicians from all over the world to engage on topics related to injury prevention and protecting athlete health.

PUBLICATIONS

- 63 peer-reviewed pubmed.gov indexed publications since July 1, 2018
- 16 publications utilizing Patient Outcomes Database

KEY HIGHLIGHTS:

- As a preeminent orthopaedic surgeon and pioneer of hip arthroscopy, Dr. Marc J. Philippon was honored to be elected president of the International Society of Hip Arthroscopy (ISHA) for the 2018–2019 term. A founding member of ISHA, Dr. Philippon has committed his career to practicing evidence-based medicine, and has been lauded across the field of orthopaedics for his outcomes research. Dr. Philippon's appointment as ISHA president affirms that he is at the top of his field both in terms of clinical practice and scientific research, and it is a tremendous honor for SPRI.



Dr. Philippon was elected ISHA president for the 2018–2019 term

- Over the past year, COOR played a key role in SPRI's Injury Prevention efforts, including presenting at several major meetings including an International Olympic Committee (IOC) meeting in Amsterdam and two meetings of the United States Coalition for the Prevention of Illness and Injury in Sport.
- COOR was instrumental in SPRI's application for re-appointment as one of only 11 research centers worldwide for prevention of injury and protection of athlete health.
- Under the leadership of The Steadman Clinic physician and SPRI Chief Medical Officer Dr. Peter J. Millett and COOR Upper Extremity Research Coordinator Marilee Horan, COOR launched an innovative injury prevention program with Ski & Snowboard Club Vail, introducing specific exercise training protocols to the elite athletes, who are monitored for injury to determine the efficacy of the training program.

40,682

SURGERIES BEING FOLLOWED

156,179

PATIENT-CENTERED OUTCOME SURVEYS COLLECTED

27

YEARS OF TRACKING PATIENT OUTCOMES

MENTAL HEALTH: A Factor in Patient Outcomes?

Mental health has become a topic of interest in research of athletic orthopaedic populations, and researchers at COOR have recently conducted a study looking at the relationship between preoperative mental health and postoperative outcomes following hip arthroscopy for femoroacetabular impingement (FAI). Specifically, would a patient's preoperative mental health status impact his or her reported outcome measures?

Depression, anxiety and a decrease in mental well-being are not only common in patients who suffer from chronic musculoskeletal pain, but also correlate with the duration and intensity of symptoms. On average in the United States, 70% of patients undergoing surgery for FAI have had hip symptoms for at least one year—a delay in diagnosis and treatment can lead to a higher incidence of low mood and depression in young adults with hip disorders like FAI.

Currently, only two studies have investigated the impact of mental health on outcomes following hip arthroscopy. In one study, researchers discovered superior results in patients with minimal or mild depression compared with those suffering from moderate to severe depression in 77 patients. The other study reported that patients with less severe depression were more likely to meet the minimally clinical important difference in pain

reduction in the early phases of recovery following hip arthroscopy.

The purpose of COOR's retrospective cohort study was to determine the relationship between preoperative mental health and postoperative patient reported outcome measures. Institutional Review Board (IRB) approval was obtained for a review of 566 patients treated with hip arthroscopy by a single orthopaedic surgeon between 2008 and 2015. The minimum follow-up was two years and all subjects with FAI syndrome were included. All subjects completed validated patient-reported outcome measures (PROMs) before and following surgery, which included:

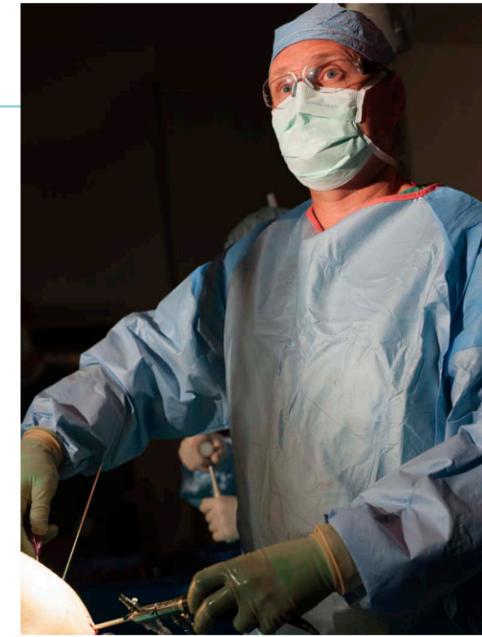
- **Modified Harris Hip Score (mHHS)**
- **Hip Outcome Score Activities of Daily Living (HOS-ADL)**
- **Hip Outcome Score – Sports (HOS-Sport)**
- **Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)**
- **Short-Form 12 Health Survey (SF-12)**

The change in all scores was calculated by taking the difference between postoperative scores and preoperative scores. Minimally clinical difference for the HOS-ADL, HOS-Sport, WOMAC and mHHS were determined from previously published studies. Patient satisfaction with outcome, measured on a 1 to 10 scale with 10 being very satisfied, was collected at follow-up.

The SG-we, a generic health-related quality of life instrument, includes items related to functional impairment due to mental challenges, as well as experience of distress as a consequence of psychological symptoms. COOR researchers divided patients into two groups: Lower Mental Health (LMH) individuals with a mental health score (MCS) less than 50 and Higher Mental Health (HMH) individuals with a MCS of 50 or more.

All preoperative scores were in the LMH group when compared to the HMH group. Following surgery, all postoperative outcomes improved across both groups, but there were no significant differences in change scores for any PROM apart from mental health, in which the LMH group experienced an 11-point increase in mental health compared to a 3.5-point decrease in the HMH group. Patients were equally satisfied with their outcomes (median of 9 for both groups).

The results of COOR's study show that hip arthroscopy for treating patients with FAI is associated with improved physical function and mental well-being in patients with LMH. Therefore, LMH should not be considered a relative contraindication to surgery, though future studies should address the effect of raising mental health prior to surgery, as postoperative scores were still lower in the LMH group.



Dr. Provencher performs surgery on a shoulder in the operating room

Management of the Failed Latarjet Procedure: **A STUDY OF OUTCOMES REVISION SURGERY**

Outcomes research not only looks to validate effective surgical techniques, but also is an important method of investigating surgeries that were not initially successful. In the case of the Latarjet Procedure, COOR researchers and The Steadman Clinic physician Dr. Matthew T. Provencher investigated the effectiveness of revision surgery for unsuccessful Latarjet procedures, specifically those that used a fresh distal tibia allograft.

First introduced in 1954, the Latarjet procedure is a surgical intervention for recurrent shoulder instability. The procedure employs a coracoid bone (paired shoulder bone) transfer and the transfer of an osseous autograft (a bony graft from the patient undergoing the Latarjet), which has proven to be effective for the primary management of anterior shoulder instability. However, the Latarjet procedure can become complicated and experience its own postoperative failures, which can lead to recurrence of shoulder dislocation, non-unions, pain, osteoarthritis and other conditions in a patient, all of which may constitute the need for revision surgery. This study looked at the outcomes of patients who underwent revision surgery for recurrent shoulder instability after a failed Latarjet procedure, utilizing a fresh distal tibia allograft (a donor graft from the tibia).

Patients were included in the study if they'd had a prior Latarjet failure and presented recurrent anterior shoulder instability. All patients were treated with hardware removal, capsular release and subsequent repair with the fresh distal tibia allograft to the shoulder. Pre- and post-revision outcomes were assessed and statistically compared across all patients.

Thirty-one male patients were enrolled with a mean age of 25.5 years and mean follow-up time of 47 months after revision with the allograft. Researchers found that patient-reported outcomes scores improved significantly following revision, and there were no cases of recurrence. Final CT scans of the revisions demonstrated a complete union in 92% of patients, and at the time of follow-up, all patients demonstrated excellent clinical outcomes and near complete osseous union at the graft location. Although patients who present with recurrent anterior shoulder instability following a failed Latarjet procedure are challenging to address, this study demonstrates that fresh distal tibia allograft augmentation is a viable and highly effective revision procedure to treat this patient population.

Studies proposing Latarjet revision techniques have been limited, primarily consisting of small patient cohorts. The findings of the SPRI study demonstrate a viable technique for the correction of a failed Latarjet, and further long-term outcomes studies are needed to continue validating this revision technique.

TREATING SHOULDER INSTABILITY IN ELITE ATHLETES

The Steadman Clinic treats many professional athletes who are focused on returning to a high-level of play in their sport.

In 2019, Dr. Peter J. Millett and the COOR team analyzed how professional athletes return to their sports following surgery for anterior shoulder instability. Athletes suffering from anterior shoulder instability experience pain, physical limitation and time away from sports. Most cases occur in young athletes who participate in contact sports, and without surgery, athletes can experience recurrent shoulder dislocations.

The COOR team collected pre and postoperative data from 23 professional athletes—mostly football and hockey players—who underwent Latarjet or Bankart procedures to treat anterior instability. Through early mobilization physical therapy protocols and close surveillance, researchers found that 96% of these professional athletes were successful in returning to their same level of sport after only a few months following their surgery. They also found that professional athletes returned to their sports faster than the times reported in literature for recreational athletes. Dr. Millett and his team concluded that professional athletes can have excellent outcomes and still compete at the same level of sport after suffering injury and undergoing surgery for anterior instability.

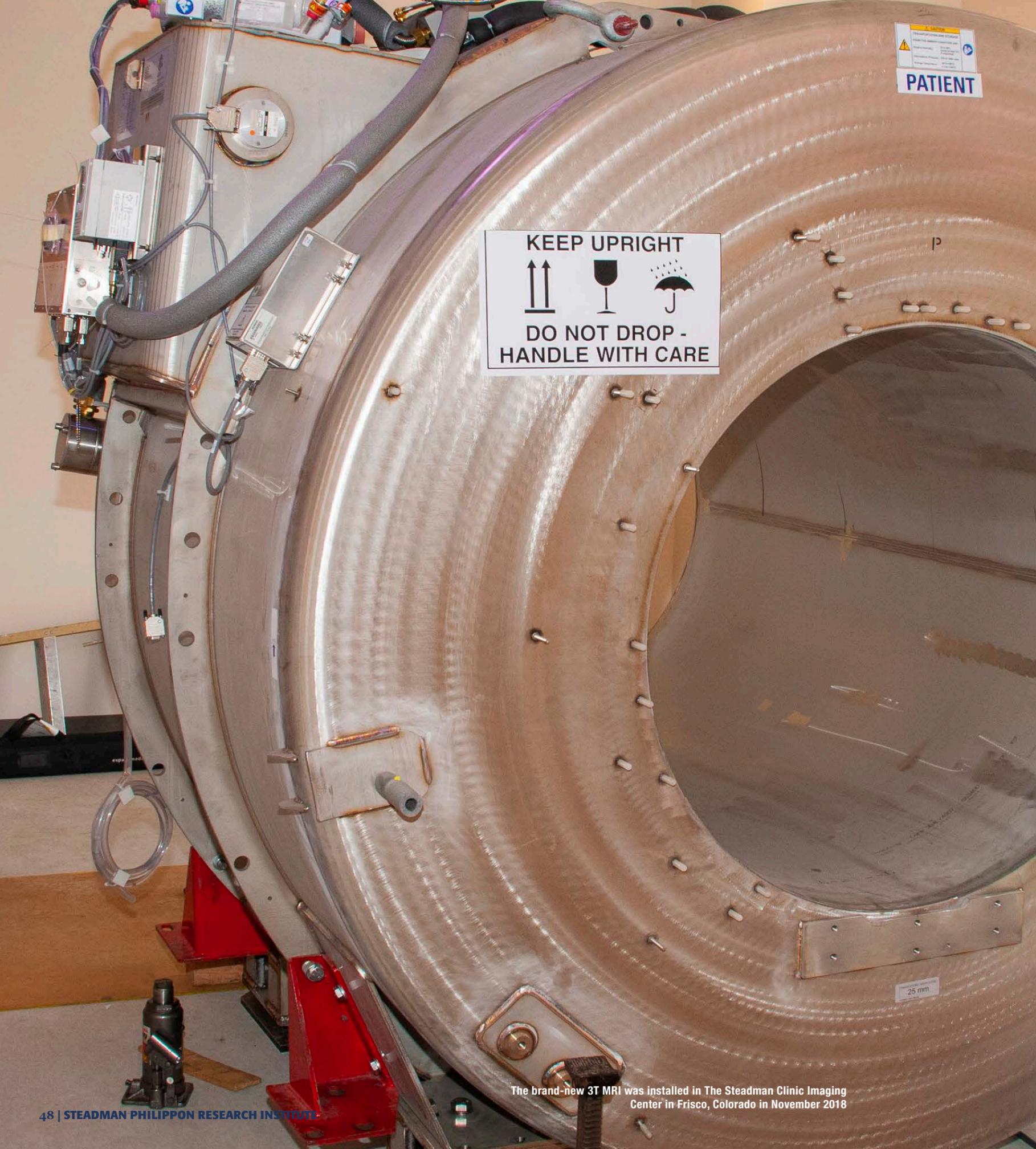
VALIDATING A NEW TECHNIQUE

Dr. Millett and the COOR team recently completed a groundbreaking new study regarding rotator cuff repair. For patients with irreparable rotator cuff tears, Dr. Millett has been using a new surgical technique called superior capsule reconstruction (SCR). The functional outcomes and repair integrity of over 20 patients were analyzed at a minimum of two years following their surgery. In this study, COOR researchers found that patients were reporting excellent satisfaction, high improvements in clinical outcomes and a very low complication rate.

Studies like this one allow surgeons to assess real data from patients to determine the efficacy of a procedure. Because of this research, surgeons have a validated technique—the SCR—that they can use to repair large rotator cuff tears.



Dr. Millett and the COOR team track patient outcomes following rotator cuff repair



DEPARTMENT OF IMAGING RESEARCH

CHARLES HO, M.D., PH.D.

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CARLY LOCKARD, M.S.

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Research Scientist, Consultant

Helium, refrigerated liquid
HELIUM, REFRIGERATED LIQUID

The brand-new 3T MRI was installed in The Steadman Clinic Imaging Center in Frisco, Colorado in November 2018

SPRI's **Department of Imaging Research** develops and evaluates noninvasive imaging techniques with an emphasis on joint health. Imaging Research complements and enhances the clinical relevance of research conducted by the other SPRI departments, including the Center for Regenerative Sports Medicine (CRSM), Department of Biomedical Engineering (BME) and the Center for Outcomes-Based Orthopaedic Research (COOR).

The Imaging Research team is committed to performing leading-edge research with its state-of-the-art MAGNETOM Skyra 3.0 Tesla magnetic resonance imaging (MRI) scanner while applying imaging tools to improve patient outcomes.

The Skyra 3T MRI provides significantly higher resolution images at a greater speed than what can be expected from lower field scanners, allowing accurate evaluation of injuries with shorter patient MRI exams. Shorter exams decrease the chance of compromised images and the need for repeated scans. This high-quality imaging supports identification of precise diagnoses of injuries effecting the meniscus, labrum, cartilage, ligaments and tendons. 3T MRI lends itself to advanced research work with cutting-edge MRI techniques and optimal research data quality.

Through a unique partnership with Canon, SPRI installed a second 3T MRI Scanner at The Steadman Clinic's Frisco campus—it is the only 3 Tesla MRI in all of Summit County, Colorado.

Imaging Research is a multifaceted department, assisting physicians with developing improved non-invasive techniques for diagnosis, treatment planning and monitoring, and patient recovery evaluation. One of the department's primary goals is to develop imaging-based tools for comprehensive understanding of each specific patient's issues and how they can effectively be treated.

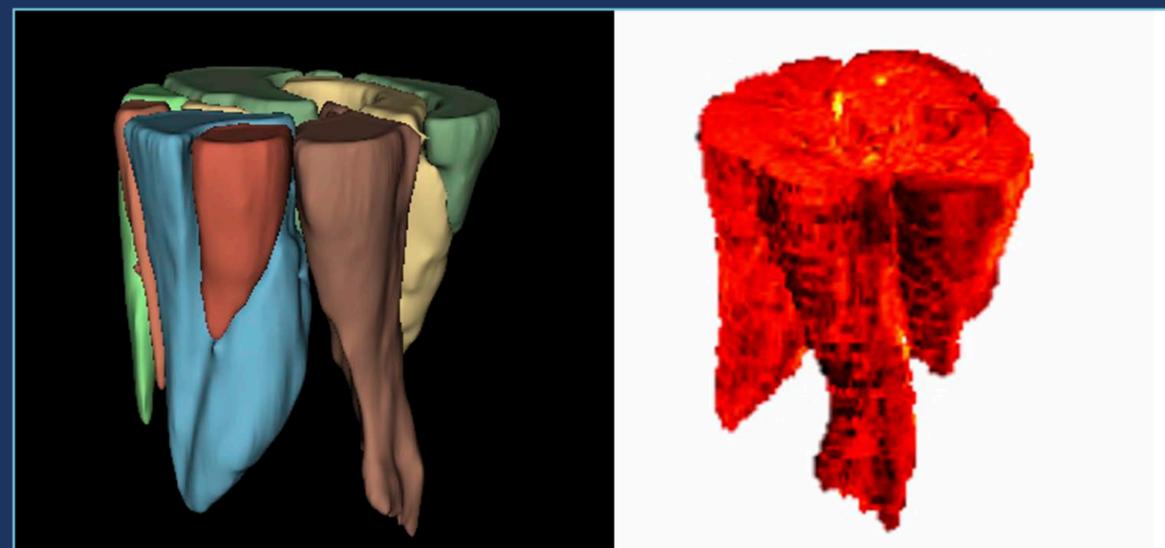
ABSTRACTS & PUBLICATIONS

2 ACCEPTED ABSTRACTS AT ORTHOPAEDIC RESEARCH SOCIETY (ORS) 2019 MEETING

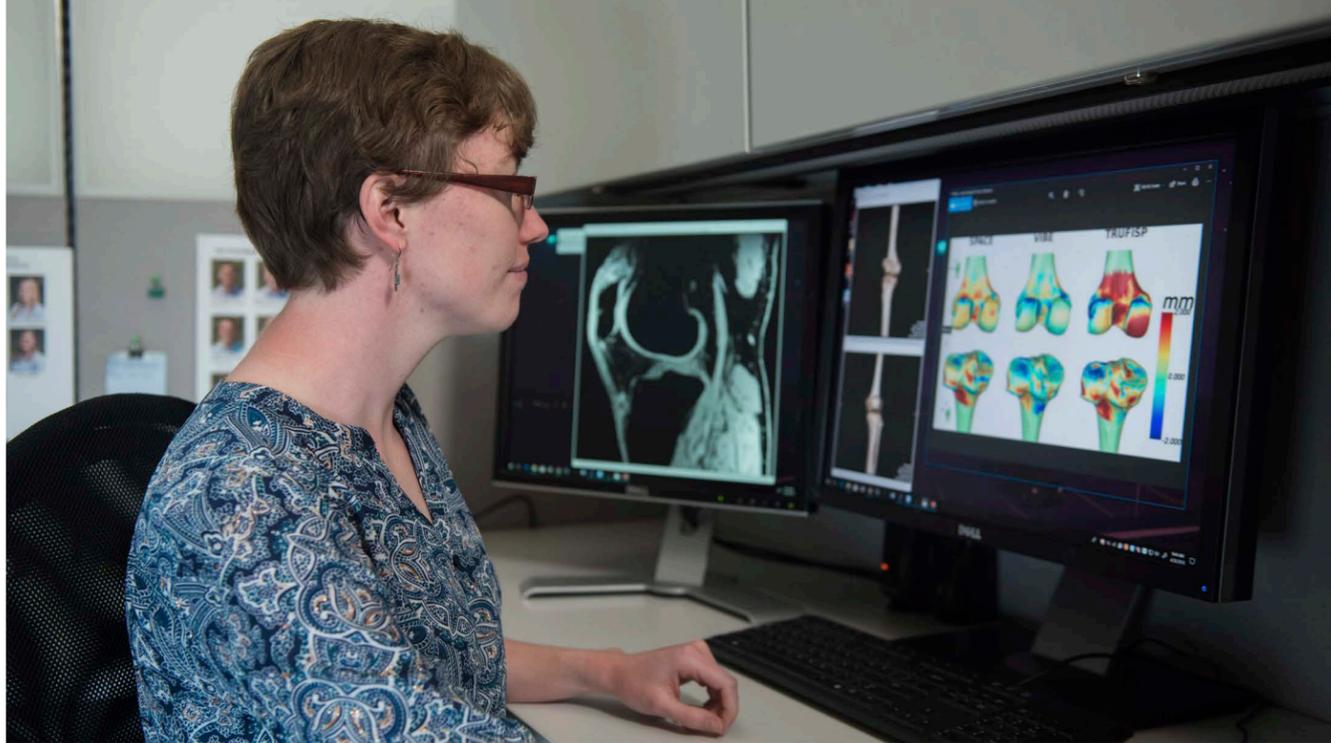
5 PUBLICATIONS

KEY HIGHLIGHTS:

- The installation of a second 3 Tesla MRI scanner in Frisco has brought new research opportunities to SPRI, complementing Imaging Research's existing collaborative work. The additional MRI location allows SPRI more opportunities to scan patients for studies, which can both accelerate the speed of testing and also introduce more subjects into a research study.
- Imaging Research obtained industry funding for initial work in muscle health quantitative MRI, which is critical for improving understanding regarding the impact of injury and surgery, as well as exercise, therapeutic and biologics treatments on muscle health.
- The department presented work on MRI-based bone modeling in simulated injuries to the shoulder as a podium presentation at the Orthopaedic Research Society (ORS) 2019 meeting.
- Imaging Research published its work on quantitative MRI of ankle cartilage in the *European Journal of Radiology*.



The Imaging Research Team has launched new studies investigating muscle tissue health with MRI scans



Senior Research Engineer Carly Lockard reviews 3D bone models

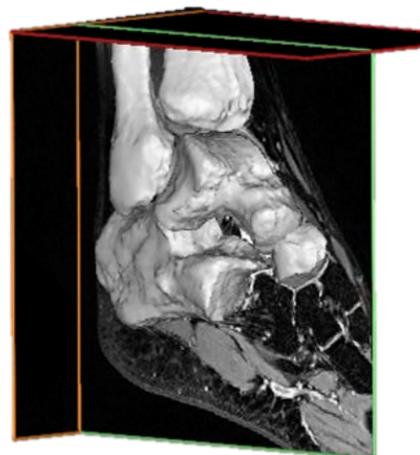
BONE MODELING: A 3D VIEW OF THE ANKLE AND HIP

SPRI's Imaging Research team began its bone modeling research using uninjured cadaveric knees, taking MRI scans and manually creating 3D models on the computer. The team collaborated with the University of Queensland and Commonwealth Scientific and Industrial Research Organisation in Australia, which created automatic 3D models. Though the bone models were created with different methods, researchers found them to be quite similar.

With a foundation established with the knee joint, the Imaging Research team began creating models of other bones and joints, including the ankle and bones of the foot. Creating a 3D model of the ankle was more involved than the initial work on the knee—the bones are smaller in the foot and ankle; there is a more complex geometry within this anatomical region. Researchers worked to create baseline models of uninjured feet and ankles, with plans to create 3D models of injured joints as well. These injured models will create helpful comparative tools for patients experiencing ankle pain or suffering an injury.

In addition to adding the ankle joint to its library of bone models, SPRI researchers used MRI scans to create 3D bone models of the hip. One of the goals of creating hip bone models is to specifically look at the femoroacetabular impingement (FAI) pathology. Creating models of FAI cases would allow clinicians and researchers to get a 3D view of the deformity, which is typically only seen in 2D images. This model will create a more complex picture of the FAI hip, which will help clinicians to diagnose the issue and determine the correct course of treatment.

All of the bone modeling work conducted within the Department of Imaging Research is centered around the patient—these 3D models will help diagnose a patient's condition, plan the proper treatment and also provide a useful tool for educating the patient on his or her condition. The team plans to continue this modeling work, both on injured knees, ankles and hips, as well as adding upper extremity joints like the shoulder.



3D Ankle Model

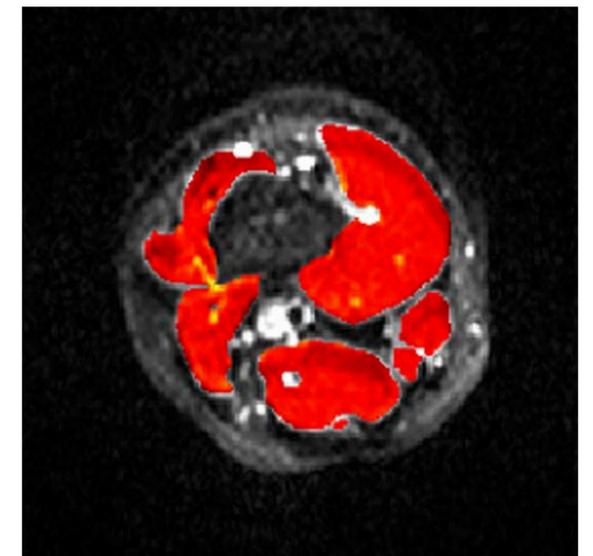
Collaborating with Physicians to Evaluate Muscle Tissue Health

Much of Imaging Research's clinical focus is in quantitative imaging of joint tissues. For example, when a person suffers an ACL injury, scans are focused on what is occurring within the knee joint. But in the course of treating hundreds of knee injuries at The Steadman Clinic, physicians Dr. Peter J. Millett and Dr. Matthew T. Provencher know that the ligament within the joint is not the only thing to investigate. That's why they're collaborating on a study in the Department of Imaging Research to investigate the health of muscle tissues.

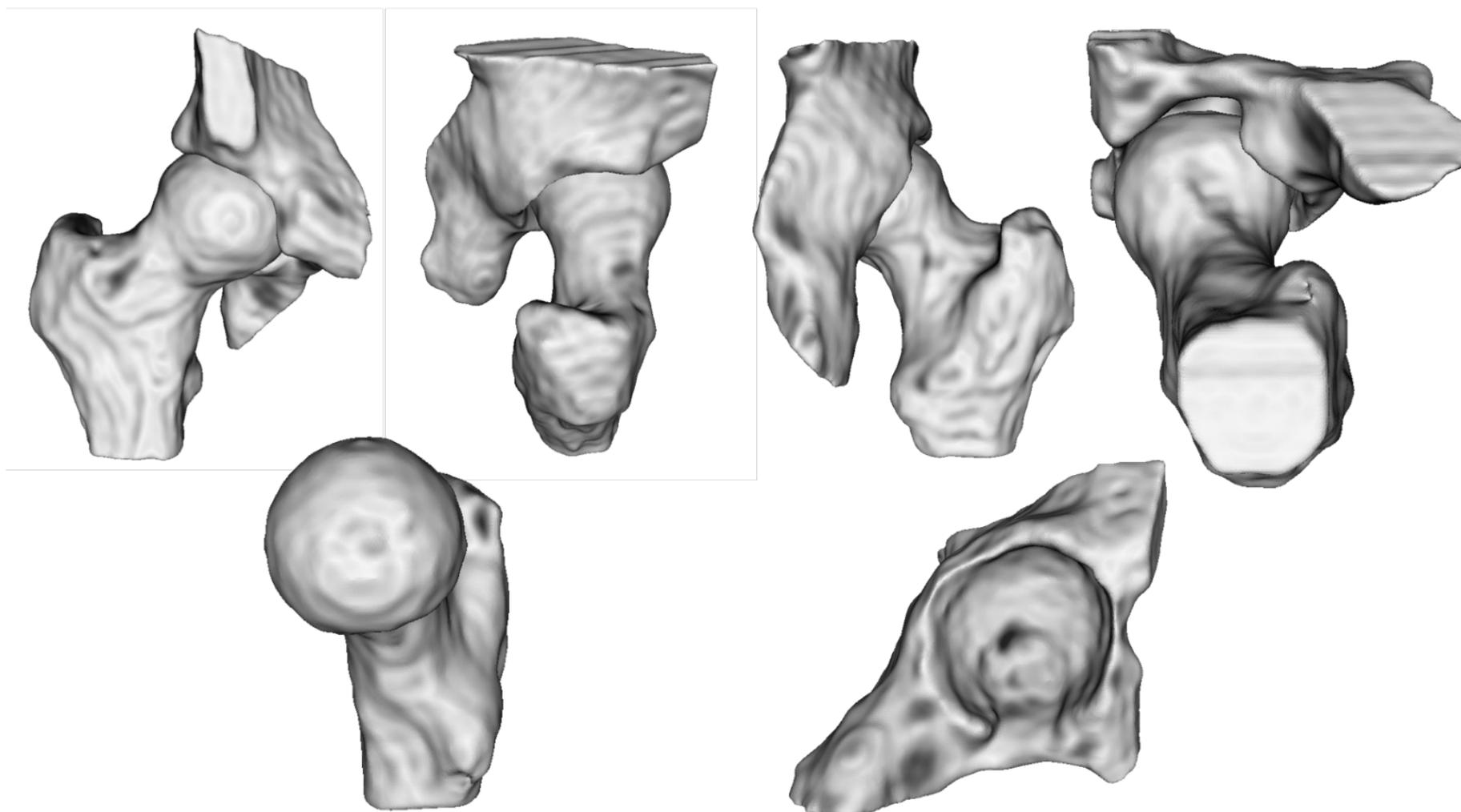
Muscle atrophy is a common condition that can both lead to injury and also delay a successful recovery after a patient has been treated surgically. In the case of ACL repair, a patient may experience atrophy in the quadriceps or hamstring muscles following surgery, which can inhibit the success of the procedure. While other SPRI departments are investigating ways to prevent or improve muscle atrophy, Imaging Research is taking a closer look at what is actually occurring within the muscle tissues. The team is beginning by scanning healthy muscle tissue from uninjured research volunteers to establish the normal baseline values.

Once these baselines have been established, researchers will expand the study to look at injured patients, measuring muscle tissue quality to determine how patients are responding to their treatment. If muscle atrophy is occurring, clinicians will be able to intervene sooner, working to repair the health of the muscle.

As the Center for Regenerative Sports Medicine studies potential biologics and therapeutics treatments for muscle atrophy, Imaging Research will support these studies by conducting scans of the muscle tissues to see how they are responding to these treatments. This is just one example of how the collaborative research being conducted at SPRI is constantly building, leading to new future projects that will have significant impact in the orthopaedic community.



Single slice through thigh showing color scale representation of quantitative MRI values in thigh muscles



An example of an auto-segmented hip

Utilizing New Technology in Imaging Research

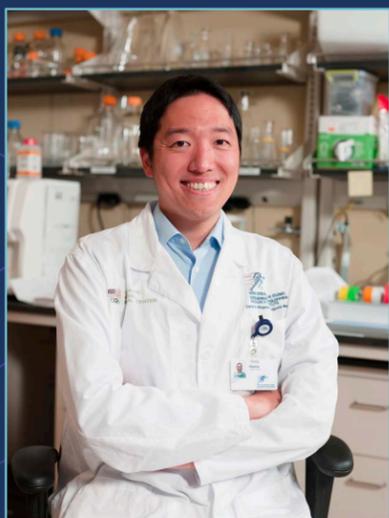
The Imaging Research team conducts its work using state-of-the-art technology every day, and the department continually looks for ways to expand upon their existing technology to improve processes. Specifically, the team has begun using automated technology to enhance segmentation of anatomical regions.

Before using automated segmentation, researchers would take images of a region and manually select them. The process was time consuming—it could take eight or more hours to properly segment one bone. Additionally, reproducibility for manual segmentation was always in question, because there is some subjectivity to how one researcher may view the images versus another researcher. Automated segmentation, however, is faster and more consistent. Computers process the images objectively and quickly, making the output more clinically feasible. The automated workflow can create a product in minutes that would have previously taken an entire work day.

Looking ahead, the Imaging Research team is confident that automated tools will improve multiple aspects of its research. Automated tools can help provide more objective diagnostic tools for clinicians and help analyze scans in a comprehensive way. A computer aid will be able to point out something that could have been missed with the human eye; it can also take precision measurements to get the most accurate information available from an image.

The department will also utilize artificial intelligence to help develop biomechanical models of patient joints, conduct research and develop tools to help enhance diagnosis and treatment planning for future patients.

AN AWARD-WINNING MILESTONE FOR SPRI



The 2019 American Orthopaedic Society for Sports Medicine (AOSSM) Cabaud Memorial Award was awarded to Dr. Hajime Utsunomiya, an international regenerative medicine scholar at SPRI.

Dr. Utsunomiya was the lead author on the project, working under the leadership of Dr. Marc J. Philippon and Dr. Johnny Huard, who were senior authors on the project. Each year, the Cabaud Memorial Award is given to the best paper submitted concerning hard or soft tissue biology, in-vitro research, laboratory or “bench-type” research, or in-vivo animal research. It is one of the most prestigious research awards given annually in the field of orthopaedics. SPRI has now been awarded the Cabaud Memorial Award for three consecutive years, which is a remarkable achievement for the institute.



(TOP) International Scholar Dr. Hajime Utsunomiya, recipient of 2019 Cabaud Memorial Award

(BOTTOM) Dr. Philippon and Dr. Hajime Utsunomiya at the 2018 Hail and Farewell Event

The winning study, “Biologically Regulated Marrow Stimulation by Blocking TGF- β 1 with Losartan Oral Administration Results in Hyaline-like Cartilage Repair: A Rabbit Osteochondral Defect Model,” was an in-vivo study that investigated how the hypertension drug Losartan could help repair cartilage in rabbit models with osteochondral defects. Dr. Philippon proposed the research topic to scientists in the Center for Regenerative Sports Medicine (CRSM) and designed the project, and Dr. Huard provided director supervision of the research performed by Dr. Hajime Utsunomiya. The authors on this project are listed: Hajime Utsunomiya, Xueqin Gao, Zhenhan Deng, Haizi Cheng, Gilberto Nakama, Alex C. Scibetta, Sudheer K. Ravuri, Julia L. Goldman, Walter R. Lowe, William G. Rodkey, Tamara Alliston, Marc J. Philippon, Johnny Huard.

During the course of the study, scientists administered Losartan orally to the rabbit models. They found that the damaged cartilage was repaired and appeared much like normal cartilage. The next steps for the research will be investigating the effects of Losartan administered via intra-articular injection, delivering Losartan via nanofiber and ultimately, conducting clinical trials in human patients.

The science performed in this initial study has major clinical significance. Drs. Utsunomiya, Philippon and Huard—alongside the other CRSM scientists and researchers—are actively working on a therapeutic solution for repairing damaged cartilage, which has revolutionary potential in the field of orthopaedics.

SPRI AWARDS 2018–2019

SPRI CELEBRATED ANOTHER YEAR OF MAJOR RESEARCH AWARDS! CONGRATULATIONS TO THE SCIENTISTS AND RESEARCHERS INVOLVED IN THESE AWARDS:

American Orthopaedic Society for Sports Medicine (AOSSM): Cabaud Memorial Award, 2018

AOSSM: American Journal of Sports Medicine Systematic Review Award, 2018

AOSSM: Fellow Research Award for Basic Science, 2018

Orthopaedic Journal of Sports Medicine (OJSM): William A. Grana Award for Best Original Research, 2018

International Cartilage Repair Society (ICRS) Generation Next Forum: Best Clinical Paper Award, 2018

American Society of Bone and Mineral Research (ASBMR): Young Investigator Travel Grant, 2018

International Society for Fracture Repair (ISFR): Best Talk, Kyoto, Japan 2018

Orthopaedic Research Society (ORS): Orthoregeneration Network (ON) Foundation: Orthoregeneration Award, 2019

ORS: International Section for Fracture Repair Poster Award, 2019

AOSSM: Cabaud Memorial Award, 2019

AOSSM: Fellow Research Award for Basic Science, 2019



Dr. Provencher receives Dr. Steven Gitelis Inspiration Award

Congratulations to The Steadman Clinic physicians Dr. Marc J. Philippon and Dr. Matthew T. Provencher on their awards this year.

Dr. Philippon was honored with the 2019 Cabaud Memorial Award (see previous page) at the AOSSM annual meeting in Boston in July.

In May 2019, Dr. Provencher was awarded the Dr. Steven Gitelis Inspiration Award from AlloSource, an organization dedicated to advancing the science and use of transplantable allogenic cells and tissues.

SPRI CONTINUES ITS GLOBAL APPROACH TO RESEARCH

The scientists, physicians and researchers who work at SPRI have always maintained two truths: the small size of the institute is a strength, and the research being performed at SPRI is not just for its own benefit; scientists conduct research with the intention of having a global impact.

As an independent institution, SPRI is more nimble than larger organizations and universities. Add its close connection to The Steadman Clinic, and the research being conducted at SPRI is happening faster and more efficiently.

SPRI's commitment to bench-to-bedside research means that all of the research in SPRI's laboratories has a patient focus. It's not just patients at The Steadman Clinic, but rather, patients from all over the world whom researchers and their physician collaborators want to help.

This focus on helping others directly correlates with SPRI's relationship with the United States Olympic Committee (USOC). As a National Medical Center—one of only two in the country—The Steadman Clinic provides treatment for Olympic and Paralympic athletes. SPRI is partnered with the USOC and the University of Utah in the United States Coalition for the Prevention of Illness and Injury in Sport, which was momentarily appointed a research center by the International Olympic Committee in 2017. A historic first for the United States, this appointment made the country—and SPRI's joint research venture—the tenth research center for the prevention of injury and protection of athlete health in the entire world.

In summer 2018, all of the IOC research centers, including the United States, reapplied for their appointments. This included completing a detailed application of SPRI's education efforts, grants history, Olympic and Paralympic athlete treatment and Injury Prevention Research. After reapplication, Dr. Philippon presented on behalf of SPRI at an IOC meeting in Amsterdam in November 2018.

In January 2019, the IOC announced its reappointments, including the United States and SPRI. The United States Coalition for the Prevention of Illness and Injury and Sport will hold this appointment through 2022.



COLLABORATION IS CRITICAL AT SPRI

SPRI is committed to collaboration, whether it is on interdepartmental research projects that involve multiple SPRI teams, the unique partnerships established between SPRI scientists and surgeon investigators from The Steadman Clinic or the many important research networks that have been established with scientists and institutions outside of SPRI. One of the ways that SPRI promotes these collaborative efforts is through the hosting and co-hosting of several major academic meetings each year.



Dr. Huard opens the Fourth Annual Vail Scientific Summit with a Keynote Address

Each year, SPRI hosts two major academic meetings—the Vail Scientific Summit, which is in its fifth year in 2019, and the Injury Prevention Symposium, which held its third conference in May 2019. In addition to these two meetings, SPRI Co-Chair Dr. Marc J. Philippon welcomes top hip surgeons to the Vail Hip Symposium each January, a conference hosted by Smith & Nephew.

VAIL SCIENTIFIC SUMMIT

SPRI hosted its Fourth Annual Vail Scientific Summit August 19–21, 2018. Entitled “Regenerative and Translational Medicine: a Focus on Human and Clinical Applications,” the conference emphasized clinical advances in biologics and cell therapies. Over fifty speakers presented at the conference, including top physicians, scientists, surgeons and researchers.

The annual conference event began in 2015, shortly after Chief Scientific Officer Dr. Johnny Huard first joined SPRI. As Chair of the Vail Scientific Summit and Director of the Center for Regenerative Sports Medicine (CRSM), Dr. Huard has invited the top international scientists in regenerative medicine to speak at the conference each year. In the 2018 event, Dr. Huard was joined by Dr. James Kirkland, Director of the Robert and Arlene Kogod Center on Aging at Mayo Clinic, for the opening keynote, “Aging 101: Basic Answers to Universal Questions.” The summit included nine distinct sessions, ranging topics focused on specific parts of the body like bone, ligaments and cartilage to innovative technologies and the clinician’s perspective on biologics and cell therapies.

As in the previous Vail Scientific Summits, much of the fourth annual event was centered around the concept of collaboration. In his keynote address, Dr. Huard shared his current research networks, demonstrating that these scientific collaborations had already been successful in launching research projects that utilized the strengths of each individual scientist in his or her area of expertise. Together, these networks created a comprehensive approach to their research topics, which is a benefit not only to the scientists working together, but also to the research outcomes. The meeting encouraged the reinvigoration of existing collaborations and the establishment of new ones, making the summit a full, cohesive event.

Presented by Canon, the Fifth Annual Vail Scientific Summit will be held August 24–27, 2019 at the Vail Mountain Marriott Resort.

INJURY PREVENTION SYMPOSIUM

The Injury Prevention Symposium is hosted by SPRI and the United States Olympic Committee (USOC), its partner. Held in early May 2019, the prestigious event was an international gathering that featured researchers and physicians committed to discussing and collaborating on how to improve injury prevention for elite and recreational athletes alike.

The Third Annual Event featured two scientific keynotes from international scientists, Dr. Caroline Finch, Deputy Vice-Chancellor of Edith Cowan University and Director of the Australian Centre for Research into Injury in Sport and Its Prevention and Dr. Lars Engebretson, Professor at the Orthopedic Clinic at the University of Oslo, Co-Chair of Oslo Sports Trauma Research Center and Head of Medical Sciences of the International Olympic Committee (IOC). Both Dr. Finch and Dr. Engebretson are pillars of the international injury prevention community; it was an honor for SPRI to host them in Vail.



A group of presenters from the Third Annual Injury Prevention Symposium

The symposium featured eight distinct sessions centered around the concept of injury prevention. This included topics like sports-related concussion, injury surveillance, innovation and clinical perspectives on injury prevention. As in previous years, the symposium also included an “Olympic hour,” which featured several key members of the United States Olympic Committee, sharing their insights on injury prevention, strategies and programs for Team USA athletes.

The symposium featured a range of speakers including surgeons, scientists, physical therapists, biomechanical researchers, statisticians and more. This convergence of professionals in the field of injury prevention provided a wide-ranging perspective on the topic, inspiring discussion and collaboration on ways to advance the protection of athlete health across disciplines. As in previous years, the conference was defined by the Olympic spirit of working together and sharing ideas. The Fourth Annual Injury Prevention Symposium will be held April 29–May 2, 2020.

VAIL HIP SYMPOSIUM

Each January, SPRI and The Steadman Clinic join with host Smith & Nephew to present the Vail Hip Symposium, an innovative three-day event that highlights the latest methods of treating hip injuries and rehabilitation. SPRI Co-Chair and Managing Partner of The Steadman Clinic Dr. Marc Philippon has been the director of the event since its inception. The event features impactful presentations on the newest and most effective treatments for hip conditions, diagnosis and preoperative planning, hip instability, cartilage repair, postoperative care, outcomes and more. In addition to the sessions, Dr. Philippon conducts a live hip arthroscopy surgery for conference attendees.

Over its 13-year history, the hip symposium has reached more than 1,000 physicians. Doctors who have presented at the symposium are among the top 1% of leading hip preservation physician experts in the world.



Dr. Philippon welcomes attendees to the 2019 Vail Hip Symposium



The 2018 Summer Scholars join SPRI Co-Chairs Dr. Richard Steadman and Dr. Marc Philippon on Steady's Deck on the top of Vail Mountain

CONTINUING A LEGACY OF EDUCATION

SPRI's mission statement not only highlights its commitment to scientific research, but also calls to enhancing lives through education. Every year, SPRI educates more than 1,000 individuals from elementary school students through career professionals. The robust education offerings include elite clinical fellowships, international scholarship appointments, inspiring programs for local youth, lecture series, community engagement and much more.

Youth Education

SPRI's youth programs are dedicated to students of Western Colorado, and include tours for local fifth grade students, which include visits to SPRI's state-of-the-art Biomotion, Regenerative Medicine, Robotics and Surgical Skills Laboratories.

For students in middle school, SPRI researchers travel to local schools for interactive sessions and participate in judging science fair projects.

After being selected by their high school science teachers, ten local juniors and seniors participate in a year-long Science Club, performing hands-on research alongside SPRI researchers and scientists. In 2018, the high school programs expanded to include a Summer Scholars Program, providing a week-long intensive Science, Technology, Engineering & Mathematics (STEM) course to students. In its first year, the program welcomed 20 local high school students, and the program expanded to include 32 students in the 2nd Summer Scholars Program, held June 24–28, 2019.

In addition to the youth program offerings, students of all ages can participate in tutoring and shadowing programs with SPRI scientists and researchers.

Collegiate Education

SPRI offers unique opportunities for undergraduate and graduate students. Each year, 15 or more college, graduate or

medical students work in research assistantships, accounting for 35% of SPRI's workforce. While in these research assistantships, students have the opportunity to co-author publications for high-impact journals and attend nationally acclaimed academic conferences.

Community Education

Local community members and SPRI benefactors enjoy enrichment opportunities at SPRI, including tours of SPRI's leading-edge laboratories and the opportunity to participate in research studies being performed in Vail. Community members and SPRI donors are also invited to attend SPRI's academic conferences, including the Injury Prevention Symposium and Vail Scientific Summit.

Professional Education

Through meetings and academic symposia, SPRI reaches more than 400 professionals in the fields of orthopaedics, sports medicine, regenerative medicine and more each year. The conferences serve as professional development, continuing education and tremendous networking opportunities for all participants.

The hallmark of SPRI's professional education programs are its clinical fellowships and international scholarships, which welcome visiting orthopaedic surgeons from around the world for a world-class, year-long appointment in Vail.

Sports Medicine, Clinical Fellowships and International Scholarships

The educational programs that started it all—the clinical fellowships—include the ACGME-accredited Sports Medicine Fellowship, Foot & Ankle and Adult Reconstruction Fellowships. This year was the largest group of clinical fellows in SPRI's history, including ten fellows across the program. This included six fellows in Sports Medicine, two Foot & Ankle Fellows and two Adult Reconstruction Fellows. These post-residency programs are considered some of the world's best, and SPRI and the faculty from The Steadman Clinic are committed to training tomorrow's orthopaedic experts.

International Scholars join SPRI from all over the world, and this year's scholars include Japanese, German and Danish surgeons. These scholars come to Vail to participate in research and learn from the renowned surgeons and researchers at SPRI. Practicing surgeons in their respective countries, International Scholars focus on research while at SPRI, learning the best techniques to take home with them following their year in Vail.

While in Vail, fellows and scholars have the unique opportunity to perform research in their areas

of interest, including biomechanics, basic science, imaging and clinical outcomes research. They work closely with surgeons and scientists, and refine their orthopaedic skills in the Surgical Skills Laboratory. Fellows and scholars investigate the causes, prevention and cure of degenerative diseases, as well as the treatment and prevention of joint injuries. The fellows and scholars not only advance their own knowledge and expertise, but also improve patient care through the research they complete while at SPRI.

SPRI's network of clinical fellowship alumni now includes over 230 surgeons practicing in communities all around the world. SPRI alumni often serve in academic positions at leading universities, maintain chief positions at hospitals and work in elite private practices. Three former clinical fellows practice as orthopaedic surgeons at The Steadman Clinic: Dr. Randy W. Viola, Dr. Peter J. Millett (SPRI Chief Medical Officer) and Dr. C. Thomas Haytmanek, Jr.



Dr. Thomas Clanton and Dr. C. Thomas Haytmanek, Jr. (CENTER) with 2018-2019 Foot & Ankle Fellows Dr. Chris Larkins (L) and Dr. Erik Nott (R)

SPORTS MEDICINE FELLOWS**DAVID BERNHOLT, M.D.**

Dr. Bernholt completed his undergraduate education at Case Western Reserve University where he was an NCAA Academic All-American wrestler and graduated summa cum laude. He graduated from Johns Hopkins University Medical School and completed his orthopaedic residency at Washington University in St. Louis, where he was awarded the OREF Resident Clinician Scientist Training Grant and the Mid-American Orthopaedic Association Multipurpose Residence Grant to fund his research. His research interests include anatomy and reconstruction of the ulnar collateral ligament of the elbow, diagnosis and management of patellar instability and outcomes following arthroscopic partial meniscectomy.

**MATTHEW CRAWFORD, M.D.**

Originally from Durham, North Carolina, Dr. Crawford attended the University of North Carolina: Chapel Hill for his undergraduate degree where he played Division I soccer. After graduating, Dr. Crawford played professional soccer for the Colorado Rapids Major League Soccer team for four years. Following his professional soccer career, he attended medical school at the University of California, San Francisco and completed his orthopaedic surgery residence at Duke University.

**TRAVIS DEKKER, M.D.**

An Albuquerque, New Mexico native, Dr. Dekker graduated from the United States Air Force Academy with a B.S. in Biochemistry. He also played four years of football while at the Academy. He attended Georgetown University School of Medicine and completed his orthopaedic residency at Duke University. While at Duke, Dr. Dekker was selected for the Feagin Leadership Development Program and provided physician coverage for the Duke wrestling, basketball, lacrosse and football teams. His research interests include cartilage repair and replacement, proximal biceps pathology and sports foot and ankle and ACL injuries.

**WILLIAM GRANTHAM, M.D.**

Dr. Grantham graduated summa cum laude from St. John's University, where he was an NCAA All-American baseball player. Dr. Grantham attended Columbia University College of Physicians and Surgeons for medical school and completed his orthopaedic residency at Vanderbilt University Medical Center. While in residency, he provided physician coverage for the East Nashville High School football team. His research interests include the throwing shoulder and upper extremity trauma.

**BRIAN SAMUELSEN, M.D., M.B.A.**

Dr. Samuelsen completed his undergraduate education at Union College where he was a member of the crew team. He earned his M.B.A. with a focus on healthcare management at Union University and attended Temple University School of Medicine, where he graduated with honors. Dr. Samuelsen completed his orthopaedic residency at the Mayo Clinic where he was selected as an American Orthopaedic Association (AOA) resident leader. His research interests include ACL injuries, meniscus repair and shoulder arthroplasty.

**WILLIAM SCHAIRER, M.D.**

A Palo Alto, California native, Dr. Schairer attended the University of California, Berkeley for his undergraduate education where he earned a B.S. in Biology. He attended the University of California, San Francisco for medical school. Dr. Schairer completed his orthopaedic residency at the Hospital for Special Surgery in New York, New York.

FOOT & ANKLE FELLOWS**CHRISTOPHER LARKINS, M.D.**

After graduating from high school, Dr. Larkins enrolled in the United States Army Infantry, where he was selected to go to Emergency Medical Technician School. He later attended Arizona State University for his undergraduate degree. Dr. Larkins attended medical school at the University of Arizona College of Medicine and completed his orthopaedic residency at the University of Texas Health Science Center at San Antonio, where he participated in medical missions to Haiti and Mexico.

**ERIK NOTT, M.D.**

Dr. Nott completed his undergraduate education at Friends University where he studied biology and chemistry and played basketball. He attended the University of Kansas School of Medicine and completed his orthopaedic residency at the University of Texas Health Science Center at San Antonio. He has served a variety of assignments in the United States Air Force, including the U.S. Air Force Academy, where he served as team physician for the USAFA Prep School and Chief of Orthopaedic Surgery and Chief of Surgery.

ADULT RECONSTRUCTION FELLOWS**DIMITRI DELAGRAMMATICAS, M.D., M.S.**

Originally from San Diego, California, Dr. Delagrammaticas earned his B.S. and M.S. in Biomedical Engineering from Cal Poly, San Luis Obispo. He attended medical school at Georgetown University School of Medicine and completed his residency at Northwestern University. Dr. Delagrammaticas served as Administrative Chief Resident at Northwestern and participated in international work with the AO Foundation and Operation Walk. He has published on clinical outcomes and radiographic assessment in total hip and knee arthroplasty.

**JOSHUA ROZELL, M.D.**

Dr. Rozell attended Emory University as an undergraduate where he led the student-run Emergency Medical Services Unit. He attended medical school at Drexel University College of Medicine, graduating AOA and as a Humanities Scholar. Dr. Rozell completed his orthopaedic residency at the University of Pennsylvania, where he served as Administrative Chief Resident and was awarded the Marvin E. Steinberg Award in arthroplasty and the DeForest Willard Award for performance as a senior resident. Dr. Rozell has published on arthroplasty outcomes and was awarded the James Rand Award and the health policy poster award at AAHKS.

**NAOMASA FUKASE, M.D., PH.D.**

With over 15 years of surgical experience, Dr. Fukase has performed thousands of surgeries in Japan. He earned his Ph.D. in 2012, and specializes in antitumor research and bone regeneration, as well as cartilage repair. Dr. Fukase joined SPRI in April 2019 and works on bone and cartilage regeneration research using innovative and regenerative medicine technologies like mesenchymal stem cells, platelet-rich plasma and biomaterials. Dr. Fukase joined SPRI from Kobe, Japan, where he worked under the directorship of Drs. Kurosaka and Kuroda.

**LUCCA LACHETA M.D.**

Dr. Lacheta completed both his undergraduate and medical education at the University of Bern in Switzerland. Born and raised near Frankfurt, Germany, Dr. Lacheta completed his surgical residency at the Technical University of Munich, Germany. His focus during residency was in joint preservation surgery, arthroscopy and research. He has written and co-written book chapters and several research papers in peer-reviewed orthopaedic journals. Dr. Lacheta is a member of several orthopaedic societies including the German Speaking Association of Arthroscopy and Joint Surgery, the German Shoulder and Elbow Society and the German Speaking Society of Orthopedic and Trauma Sports Medicine.

**YOICHI MURATA, M.D., PH.D.**

Dr. Murata is an orthopaedic surgeon in Japan, specializing in surgeries of the hip including osteotomy, arthroplasty and arthroscopy. Dr. Murata earned his Ph.D. in medical science, focusing on mesenchymal stem cells in the hip joint. Having joined SPRI in March 2019, Dr. Murata conducts animal studies on articular cartilage using biologically regulated marrow stimulation (a newly coined term by SPRI for next-generation microfracture technique) with peptide amphiphile (PA). He also performs clinical outcomes, anatomical and biomechanical studies at SPRI. Dr. Murata joined SPRI from the Wakamatsu Hospital in Fukuoka, Japan, where he worked under the directorship of Dr. Uchida.

**MARC STRAUSS, M.D.**

Dr. Strauss is originally from Denmark and attended junior high school and high school in the United States. He completed his undergraduate and medical education at the University of Southern Denmark. Dr. Strauss completed his residency at Vejle County Hospital and Odense University Hospital in Denmark before moving to Norway to complete a two-year clinical fellowship at Oslo University Hospital, where he has worked since completing his fellowship. Dr. Strauss specializes in arthroscopic and ligament surgery of the knee and has worked as a consultant for the Norwegian Olympic Training Center and served as team physician for the Norwegian Alpine Ski Team. He is a member of the arthroscopy committee of ESSKA.

**HAJIME UTSUNOMIYA, M.D., PH.D.**

Dr. Utsunomiya joined SPRI as an International Research Scholar in May 2016 from Wakamatsu Hospital of University of Occupational and Environmental Health in Japan. He is an orthopaedic surgeon who specializes in arthroscopy and sports medicine and earned his Ph.D. in medical science. Since joining SPRI, Dr. Utsunomiya has focused on researching cartilage injuries using regenerative technologies like stem cells, platelet-rich-plasma and therapeutics. Dr. Utsunomiya works closely with SPRI Chief Scientific Officer and Director of the Center for Regenerative Sports Medicine Dr. Johnny Huard and SPRI Co-Chair and Managing Partner of The Steadman Clinic Dr. Marc Philippon. He and his SPRI team were awarded the prestigious 2019 Cabaud Memorial Award from AOSSM.

Each of SPRI's clinical fellows and international scholars is committed to not only advancing their own knowledge and expertise, but also to improving patient care by conducting groundbreaking research while at SPRI. Although they are only at SPRI for a short time, each fellow and scholar makes a significant impact on the institute, and ensures SPRI's global legacy of education by taking what they've learned to their future patients.

PUBLICATIONS JULY 2018 – JUNE 2019

An important aspect of SPRI's research is publishing; publications in top, peer-reviewed journals are a way for each department to validate the research being conducted at SPRI. Since July 2018, SPRI has been published in over 110 high-impact publications, including 33 in *The American Journal of Sports Medicine*, the top-rated journal in the field of orthopaedics.

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GUIDELINES FOR RESEARCH, INFORMATION DISSEMINATION AND AUTHORSHIP

Preamble

*This statement provides general guidelines for the conduct and presentation of research done under the umbrella of **Steadman Philippon Research Institute (SPRI or Institute)** and which uses any SPRI resources whatsoever. These guidelines are intended to help strengthen the quality of research, both written and orally presented, that is produced by SPRI. *This statement affects all SPRI employees, The Steadman Clinic (Clinic) attending physicians, Clinic Fellows, International Research Scholars, visiting surgeons, consultants, interns, students, and other visitors in perpetuity.* It also provides guidance and assurances to all collaborators (e.g., universities, private laboratories, commercial entities, etc.) involved in research projects with SPRI.*

Guidelines for Conducting Research

1. Internal Research Proposals

Before beginning any research project which uses any Institute resources, the Principal Investigator (PI) who is an Institute employee or Clinic attending must submit a written proposal to his/her SPRI Department Director, or if the PI is not an Institute employee, then to the Department Director who will be providing the necessary support, for internal review and approval. If the proposal is from other than a SPRI employee or Clinic attending and does not require support from a specific department, then the proposal must be submitted to the Chief Scientific Officer (CSO) for review and approval. Research proposals (protocols) should follow a standard format (see Appendix) and must be signed by the SPRI Department Director and all participants who are listed on the written protocol or proposal. Furthermore, all research and grant proposals must be signed by the Department Director before the proposals can be submitted to the IRB or the outside granting/funding agency. After the Department Director has approved and signed the proposal, it must then be sent to the CSO for review before submission to the IRB or the outside granting/funding agency. A detailed study format for proposals requiring Institutional Review Board (IRB) approval, outside funding review, etc., is at the Appendix. If desired, a more formal proposal may be submitted, provided it contains all of the requested information and essential elements, including all elements of informed consent required by Federal regulations and the responsible IRB. The CSO and responsible SPRI Department Director will determine whether the submitted proposal is approved or if the proposal requires further refinement before the investigator is given approval to conduct the study. The CSO and Department Director may also seek additional review from other sources/individuals as a part of this decision making process.

2. The Role of the Principal Investigator (PI)

The Principal Investigator has overall responsibility for the conduct and completion of the study project. The PI may delegate any part of the study project to another individual, but the responsibility for its completion may not be delegated. It is also the responsibility of the PI to assure that the study stays within its deadlines and budget.

To be the PI of a SPRI in-house study, that person must be one of the following:

1. Director of one of the SPRI research departments;
2. An MD, including The Steadman Clinic permanent attendings;
3. A DVM; or,
4. A PhD.

Those specifically prohibited from being a PI include Clinic Fellows, International Research Scholars, interns, part-time employees, and visitors. In the case of collaborative studies which are performed at a university or other outside agency, it is anticipated that the PI or co-PI will be a faculty or staff member at that university or agency, especially if the study involves use of animals or human subjects.

The PI sets the hypothesis for the study and supervises the experimental design (power analysis, sample size determination, etc.) and conduct of the research. The PI is ultimately responsible for the reports and publications and must confirm their accuracy and authenticity. Specific criteria include:

1. The PI must be aware of all aspects of the science being done in the study.
2. The PI is present on site and supervises the laboratory in which the research is carried out, especially if the research is conducted at a university or other agency.
3. The PI has overall responsibility and is in charge of the project.
4. Once the PI is established (and it must be established prior to submission to the IRB or for funding or commencement of the project), he/she has full responsibility for all aspects of the study, including obtaining all regulatory approvals, both initial and any required periodic reviews.
5. Because the PI may not necessarily be the person who had the original idea for the project, there needs to be a clear understanding as to what role the person with the idea serves in the study. For example, the person who had the original idea may not meet the qualifications to be a PI, or the person with the idea may not desire to serve as the PI for other reasons.
6. The PI is not necessarily the first author of any subsequent publications. NOTE: *Publication of the results is a separate matter and is addressed below.*
7. The PI may re-assign projects, authority for certain functions, authorship requirements and rights, etc. The PI may not delegate or re-assign ultimate responsibility for the project.

Although NIH typically does not allow co-principal investigators, one (maximum) co-principal investigator may be necessary for some specific purpose. If there is a co-principal investigator, then it must be clearly and unambiguously specified in writing in both the protocol and the informed consent form (if applicable) which co-PI is responsible for which aspects of the study. Except as noted above, a co-principal investigator in a different institution is to be discouraged unless there is a clear and compelling reason.

If there is a clinical study directed from The Steadman Clinic or SPRI, a staff member permanently affiliated with the Clinic or SPRI and qualified to be a PI as noted above will be the PI of record rather than a Fellow or International Research Scholar. Fellows and Scholars typically are only present for a maximum of 12 months, and they may lack the necessary time for project completion. If a Fellow or Scholar designs a definitive project that can be done within the period of the fellowship, then the PI would still be responsible for oversight.

All individuals who have a major role in the research study and who are not the PI should be listed in all documents as co-investigators. A co-investigator is a person who contributed significantly to the study idea, has secondary responsibility for a part of the study, and will significantly contribute to the study throughout its conduct.

Those who have less than a major role may be listed as a research associate. A research associate is someone who brings additional expertise and responsibility to the study and does not fall under the direct supervision of one of the investigators. Anyone involved in the study who does not qualify as an investigator and who works under the direct supervision of an investigator does not need to be listed on the research protocol.

NOTE: It is emphasized here that authorship and author order on any subsequent publications are completely separate from the research protocol itself. Authorship is discussed below.

3. Study Approval

A proposed research project is eligible for approval after:

1. Its goals/objectives/premise are clearly stated and deemed relevant to the clinical/medical community as well as the Clinic and/or Institute;

2. The study's key activities are listed, with timelines attached to each activity;
3. The projected starting and ending times of the study are established;
4. Staff requirements/time allocation are determined and related to the tasks needed;
5. The budget is developed, including both expenses as well as projected support/income;
6. The degree of difficulty to complete the study is described accurately. A justification for additional/new equipment, computer software, etc., is required along with a statement of whether staff has the knowledge and skill required to complete the project feasibly;
7. The SPRI Department Director and CSO have given approval;
8. All necessary regulatory and oversight approvals (e.g., IRB, Animal Care Committee, etc.) have been obtained; and,
9. Any clinical study must have The Steadman Clinic Service Chief's review and approval signature. The review and approval does not mean that the Service Chief is necessarily a part of the study. Furthermore, this review and approval has nothing whatsoever to do with authorship of any publications that may result from the study. This requirement does not pertain to non-clinical (i.e., laboratory) studies. As of the date of this document, the Service Chiefs are Dr. Marc Philippon (Hip), Dr. Randy Viola (Hand), Dr. Don Corenman (Spine), Dr. David Karli (Regenerative Medicine), Dr. Tom Hackett (Knee, Shoulder, Elbow), Dr. Peter Millett (Shoulder, Knee, Elbow), Dr. Tom Clanton (Foot and Ankle), Dr. Robert LaPrade (Knee), Dr. Thos Evans (Regenerative Medicine), Dr. Matthew Provencher (Shoulder, Knee), Dr. Raymond Kim (Arthroplasty), Dr. David Kupper-Smith (Internal Medicine), Dr. Joel Mata (Arthroplasty), and Dr. Thomas Haytmanek (Foot and Ankle).

At the time of approval, the project will be placed on a priority list of other research projects within both the originating Department and the Institute.

4. IRB Approval

Once the proposal has been approved internally as noted above, and if the study requires human subjects or use of human tissue, the investigators must submit the proposal for IRB approval. It is the responsibility of the PI to see that IRB approval is obtained, if appropriate, in a timely fashion. No study may begin without IRB approval if required. If a study requires IRB approval, then a Department Director or permanent staff member with M.D., D.V.M., or Ph.D. credentials must act as PI for purposes of medical intervention and judgment.

5. Obtaining Informed Consent from Participants of Approved Studies

Only individuals with the following degrees or who hold the designated position are permitted to obtain informed consent from a participant in an approved study:

- MD (including Clinic Fellows and International Research Scholars)
- DVM
- PhD
- RN
- PA
- Department Directors

Staff members, research interns and Athletic Trainers (ATC) who do not possess one of the above degrees are not permitted to obtain informed consent from a study participant.

6. Project Funding

If the project is approved but does not yet have funding, but requires external funding, the PI must immediately send a copy of the proposal to the CEO, CSO, and CFO, who will then work with the Development Department in identifying and approaching potential funding sources.

7. Conference Presentations and Abstracts

Once the study data are analyzed and a report is prepared, all researchers (excluding outside collaborators such as university researchers or private laboratory scientists) are encouraged to present their work to an internal group of their peers before any presentations are made at a scientific meeting. To schedule a presentation, please see the Institute CEO or CSO. This presentation will be reviewed in light of the intended audience and the desired impact. It is likely that the presentation will be

held at an open meeting for all Institute and Clinic staff. The spirit of this recommendation is to help insure preparedness and give ample time to incorporate edits and suggestions to improve the presentation.

In the case of a public relations related request (article or presentation) from an outside group, the Department Director in conjunction with the Institute CSO will determine when and if the request will be met.

Conference papers should be directed to the most appropriate audience and meeting. A scientific paper, once presented to a national or international meeting, should not be presented in exactly the same format to additional meetings of the same constituency as original research and data. Presenting a paper at a clearly local or regional meeting does not preclude presenting the same paper to a national or international meeting. Presenting the same paper to different audiences at multiple meetings may be acceptable if all authors agree. This guideline does not preclude presentation multiple times as a portion of an invited presentation.

Authorship guidelines for conference presentations should be identical to the guidelines for papers submitted for publication to peer-reviewed journals (see below). All authors must meet the same criteria of substantial contribution to the paper, justifying inclusion as an author for the conference paper for presentation as well as for the manuscript submitted for publication. Anyone who is not an author of a paper is precluded from presenting it at a national or international meeting unless there are unforeseen or extenuating circumstances in which no author of the paper is available. The act of presenting the paper does not justify changing authorship or order of authorship for the conference paper or for the manuscript submitted for publication.

8. Publications

To maintain the highest level of research quality, the responsible Institute Department Director and, if a clinical study, the Clinic Service Chief (even if the Department Director or Clinic Service Chief is not an author) and all authors and co-authors of the material must review and give written feedback of all written products representing SPRI before they are submitted for publication or presentation. Additionally, the PI is strongly encouraged to seek responses from appropriate members of the Research Advisory Committee (RAC) as well. This requirement covers all manuscripts, papers, and public relations pieces. The same is also encouraged for abstracts and presentations. Furthermore, the PI and corresponding author will review with all authors any comments received from journal editors, reviewers, and referees to help determine why an article is accepted or rejected. Revised articles should go through the same review process as for initial submission.

9. Ownership of Study Data (Rights and Responsibilities)

SPRI owns all study data generated in all Steadman Clinics and SPRI laboratories if any Institute resources were used in any manner whatsoever. The Institute owns all rights to all data, findings, and material, written or otherwise, which were created during any part of studies undertaken in the Institute's facilities. This policy applies in perpetuity. The Institute cannot claim ownership to data that have been generated in a collaborating laboratory under the directorship of a Principal Investigator who is not an Institute staff member. In other words, each collaborating PI would own the data that are generated by his/her respective laboratories. If the Institute contracts with any outside organization to perform a specific study for a fee, then all data generated under the contract are property of the Institute. To limit potential problems, it is necessary that these issues be clarified and agreed upon in writing before any collaborative study is to begin.

The Principal Investigator (or Director of the outside laboratory) is responsible for the validity of data and veracity of the report. While all those involved in the study have equal rights to access the data, no one (laboratory staff or collaborators) should be permitted to disseminate the data (in published or presentation format) without the express written approval of SPRI. This prior approval is particularly important when it comes to the correct interpretation of the findings. For example, in a presentation, one could present (or discuss) the data wrongly if one is not fully aware of the background and does not comprehend the meaning of the data fully. Hence, that is why such a responsibility for the Principal Investigator (or Director of the laboratory) exists.

In the case of contract research, a company which paid for the project may wish to have partial or complete ownership of the data generated by the Institute. As such, the said company must cover all costs for the research done (including appropriate overhead), and a mutually acceptable written agreement should be signed beforehand. However, an unrestricted gift to SPRI or sponsorship of SPRI from an industrial/commercial concern does not entitle the company to the ownership of any data generated using such funds. Data are also owned by SPRI when generated on site by Ph.D. candidates, International Research (Visiting) Scholars, and research Fellows/Interns who are sponsored by an individual or commercial concern.

If any investigator, attending surgeon, Fellow, or participating staff member should leave the Institute's or Clinic's employment at any time, that individual must leave all materials, including equipment and data, with the Institute, unless and only unless, written permission is granted in advance from the Principal Investigator (or Director of the laboratory) as well as the Institute CEO and CSO. With written permission, the individual may take a copy of the material for the purpose of completing his/her analysis, writings, etc. All materials, original data, equipment, etc., will remain the property of SPRI in perpetuity. Furthermore, that individual is still required to follow all guidelines set forth in this document regarding presentation and/or publication of said data. All publications and presentations as a result of the work supported in any part by or done in the Institute must acknowledge the Institute. These guidelines on ownership of data also apply to former Fellows who already have or may in the future wish to access data owned by SPRI. Penalty for not abiding by these SPRI guidelines will preclude former Fellows, employees, and others temporarily associated with SPRI from having access to data in the future. Acts of misconduct may be referred to the Research Advisory Committee for recommendations for further sanctions.

10. Research Conducted Outside of the Institute

In the case of research funded by the Institute and conducted by an outside university or organization, a liaison for each organization will execute a Scope of Services Agreement or an appropriate Memorandum of Understanding. The liaison for each organization shall be a current permanent employee. In the case of SPRI, the liaison shall be the CSO. The Institute will not pay overhead surcharges to any organization conducting research in its behalf or at its request.

In the case of an Institute employee involved in research which is not conducted under the Institute's auspices and for which the Institute may or may not receive credit, the individual must inform the CEO and CSO in writing prior to involvement. The Institute has a right to limit time spent on such projects, assuming such work is performed during normal working hours or if it might affect the employee's work-related performance. In certain circumstances, the Institute has a right to ask for and receive acknowledgment in the project.

11. Contesting Decisions Made During the Study Preparation

Should any individual involved in a study wish to dispute a decision he/she cannot resolve with the PI or the Department Director, that individual must submit a timely query **in writing** to the Institute CSO. At that time the CSO will consult with the Department Director and Principal Investigator to arrive at a decision in an expedited manner. The Institute CSO may consult the Institute CEO and/or a managing partner of the Clinic; however, the Institute CEO and CSO shall have sole authority to act as the judge for final resolution.

12. Guidelines on Authorship for Manuscripts and Abstracts [Refs. 1-7]

The Institute recognizes the issues raised in such publications as the *Guide to the Ethical Practice of Orthopaedic Surgery*, the *New England Journal of Medicine's* policy on authorship, the authorship policy of *The Journal of Bone and Joint Surgery*, and the *International Committee of Medical Journal Editors (ICMJE)* on authorship and contributorship. It is the purpose of this section of the SPRI Guidelines for Research, Information Dissemination, and Authorship to discuss authorship in particular, but also to identify possible authorship abuse and how to resolve such problems and abuse. Table 1 defines types of authorship abuse.

Table 1. *Types and descriptions of authorship abuse* [Ref. 6]

Type of Authorship Abuse Description	Description
<i>Coercion authorship</i>	Use of intimidation tactics to gain authorship. Arguably a serious form of scientific misconduct.
<i>Honorary, guest, or gift authorship</i>	Authorship awarded out of respect or friendship, in an attempt to curry favor and/or to give a paper a greater sense of legitimacy.
<i>Mutual support authorship</i>	Agreement by two or more investigators to place their names on each other's papers to give the appearance of higher productivity.
<i>Duplication authorship</i>	Publication of the same work in multiple journals.
<i>Ghost authorship</i>	Papers written by individuals who are not included as authors or acknowledged.
<i>Denial of authorship</i>	Publication of work carried out by others without providing them credit for their work with authorship or formal acknowledgment. A form of plagiarism and therefore scientific misconduct.

Generally speaking, the naming of authors to articles from the Institute will abide by the following standards:

Definition of Authorship

An “author” is generally considered to be someone who has made substantive intellectual contributions to a published study. An author must take responsibility for at least one component of the work, should be able to identify who is responsible for each other component, and should ideally be confident in their co-authors’ ability and integrity. Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it for important intellectual content; and 3) critical revision and final approval of the version to be published. Authors should meet conditions 1, 2, and 3, above. All persons designated as authors should qualify for authorship as detailed above, and all individuals who qualify should be listed.

Individuals who have contributed to only one segment of the study or have contributed only cases or case material should be credited in a footnote, and such individuals should not be considered or listed as authors. Merely proposing a new idea or hypothesis, without active participation in the study, does not qualify that individual for authorship. Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.

Table 2 summarizes authorship requirements.

Table 2. *ICMJE requirements for authorship and examples of contributions that do not qualify for authorship* [Ref. 6]

Requirements for authorship

“Authorship credit should be based on

- 1) substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data; and
- 2) drafting the article or revising it critically for important intellectual content; and
- 3) final approval of the version to be published; and
- 4) Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Authors should meet all conditions 1, 2, 3 and 4.”

All authors should be able to take public responsibility for their contribution to the work.

Examples of contributions that do not qualify for authorship but that should be acknowledged in the paper

- 1) Providing funding, technical advice, reagents, samples, or patient data.
- 2) Providing students or technical personnel who perform studies.
- 3) Routine collection of data.
- 4) General supervision of the research group.

Responsibility of Authors

Individuals listed as authors must be thoroughly familiar with all aspects of the study and should be willing to take responsibility for the accuracy and content of the portion of the manuscript to which he/she contributed. That is, each listed author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

Table 3 summarizes the requirements and responsibilities of all categories of authors.

Table 3. *Requirements and responsibilities of all co-authors* [Ref. 6]

Author Category	Contribution and Responsibility to the Work and Publication
<i>First author</i>	Fulfills ICMJE authorship criteria. Performs bulk of the experimental work and manuscript preparation.
<i>Senior author</i>	Fulfills ICMJE authorship criteria. Typically the last person on an authorship list. Directs, oversees, and guarantees the authenticity of the work. Takes responsibility for the scientific accuracy, valid methodology, analysis, and conclusions of all work described in the paper. Able to explain all of the results described in the paper.
<i>Corresponding author</i>	Fulfills ICMJE authorship criteria. Typically assumed by the first or senior author. Must be a permanent employee of SPRI or a Steadman Clinic attending. Communicates with editors and readers. Provides specific information on the contributions of all coauthors to the paper. Ensures that all authors are aware of and approve the submission of the manuscript, its content, authorship, and order of authorship.
<i>Middle/contributing author</i>	Fulfills ICMJE authorship criteria. Contributions do not rise to those of first or senior author. Order of middle/contributing authors should reflect their relative contributions to the paper.

Order of Authors

Author order must be determined and agreed to prior to commencement of writing a manuscript. Prior to manuscript submission, the Department Director, participating Attending Surgeon(s), and participating Senior Staff are required to meet to determine and agree upon the final author order and contributorship per the above definition. This agreed upon final determination will ensure that all listed authors meet the above authorship definition and criteria prior to manuscript submission.

Authors will be listed in the order of importance to the execution of the three study segments listed above: Plan, do, write. The PI (or senior author) has the right to determine order of authors, but typically the first author should be that individual who has contributed the most overall effort followed in succession by the individual who contributed the second most, and so on. **Such author order is separate from and not to be confused with investigator order as it appears on the research protocol.** It is extremely important to realize that “gift authorship” or adding any author who has not participated as noted above is considered literary fraud and must not be allowed to occur. Original signatures of all authors are required on copyright releases, conflict of interest and disclosure forms, or on memoranda of agreement. The corresponding author for any manuscript coming from SPRI must always be a permanent employee of SPRI or The Steadman Clinic. That is, the corresponding author may **not** be a Fellow, an International Research Scholar, an intern, a visitor, or any other individual holding a temporary position within SPRI or the Clinic.

Authorship Dispute Resolution and Adjudication Subcommittee

Should any individual who is a co-author on a manuscript wish to dispute an authorship decision he/she cannot resolve with the first author or senior author, that individual must submit a timely query/complaint **in writing** to the SPRI RAC Chairman. At that time the SPRI RAC Chairman will consult with the Department Director and the first author and senior author to arrive at a resolution of the dispute. If a satisfactory resolution cannot be reached, the SPRI RAC Chairman will appoint three (3) extramural RAC members who are and must be free of any involvement or conflict of interest with the subject manuscript to serve on a RAC Authorship Dispute Resolution and Adjudication Subcommittee. The SPRI RAC Chairman will provide the written complaint to the subcommittee and describe what actions have been taken along with any other pertinent facts. The subcommittee will then function independently by reviewing the facts presented, having teleconferences with the parties involved if deemed appropriate, and taking any other actions necessary. The subcommittee will then attempt to mediate an agreement between the parties to reach a final resolution. If a resolution cannot be reached, the subcommittee will make a specific recommendation to the SPRI RAC Chairman. The SPRI RAC Chairman will then consult with the Institute CEO and/or a managing partner of the Clinic on the recommendations of the subcommittee; however, the Institute CEO and SPRI RAC Chairman shall have sole authority to determine the final resolution of the dispute. Table 4 further describes means to minimize and resolve authorship disputes. It also outlines additional actions that the Authorship Dispute Resolution and Adjudication Subcommittee may take if deemed necessary and appropriate.

Table 4. Recommendations for minimizing and resolving authorship disputes

1. All research institutions, journals, and scientific societies should have in place formal authorship policies. This present document is intended to serve as the formal authorship guidelines for Steadman Philippon Research Institute. The threshold for authorship on a scientific paper should be a direct and significant intellectual contribution to the study. [Refs. 1-8] All authors should have contributed to the writing of the manuscript. At a minimum, each author should have written at least the portion of the manuscript in which his/her contribution is discussed and should be able to take public responsibility for that contribution. [Refs. 1-7]
2. This present document sets forth how extramural members of the SPRI Research Advisory Committee (RAC) will serve as an Authorship Dispute Resolution and Adjudication Subcommittee of the RAC. The Authorship Dispute Resolution and Adjudication Subcommittee will be free from all real and perceived conflicts of interest. This subcommittee will be composed of three disinterested extramural RAC members appointed by the RAC Chairman. A different subcommittee may be constituted for each incidence that requires adjudication.

3. The Authorship Dispute Resolution and Adjudication Subcommittee will not be the final decision making body in authorship disputes. Rather, the role of this subcommittee is to provide a fresh set of eyes on the problem and to assist the individuals involved in the dispute to arrive at an ethical and professional solution.

4. The Authorship Dispute Resolution and Adjudication Subcommittee will have the authority to recommend that disciplinary action be pursued if clear evidence of abusive authorship practices is uncovered. “Coercion authorship” and “denial of authorship” (see Table 1) should be treated as scientific misconduct and be referred to appropriate institutional authorities for further investigation and disciplinary action.

5. All letters of submission accompanying manuscripts submitted by the corresponding author should include an authorship verification statement that is signed by each co-author and that describes his/her specific contributions.

6. The specific roles of all co-authors should be included in the published article, depending upon specific journal requirements. Deliberate falsification of the description of co-author contributions should be viewed as scientific misconduct.

7. Every effort should be made to avoid authorship problems from the outset. Authorships should be negotiated and defined in writing at the beginning of an investigation. Frequent communication between all co-authors should occur while study investigations are ongoing. Authorship should be discussed regularly and redefined in writing if necessary. These actions will obviate the need for the Authorship Dispute Resolution and Adjudication Subcommittee to become involved.

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SPRI Authorship Agreement for All Publications

Check one box:

- Start of study
 Start of manuscript preparation
 Interim (if necessary)
 Prior to manuscript submission
 Revision

Working Title of Paper: _____

PI of Study: _____

Proposed Author Order _____

Author Name	Comments	Signature
1. _____	_____	_____
2. _____	_____	_____
3. _____	_____	_____
4. _____	_____	_____
5. _____	_____	_____
6. _____	_____	_____
7. _____	_____	_____

In keeping with the International Committee of Medical Journal Editors (ICMJE) on authorship and contributorship, I attest that I have contributed to the following.

(INITIAL all that apply in the numbered line that corresponds to your number above.):

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Study conception OR**

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Study design OR**

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Data collection OR**

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Data analysis and interpretation**

AND

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Drafting initial manuscript OR**

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Editing initial draft of the manuscript**

AND

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Approval of the final manuscript to be published**

AND

1. _____ |2. _____ |3. _____ |4. _____ |5. _____ |6. _____ |7. _____ **Finally, I agree with and will be accountable for the findings and conclusions presented in this paper.**

Corresponding Author _____ Signature _____

Department/Laboratory Director _____ Signature _____

Chief Scientific Officer Signature _____

Date _____

Steadman Philippon Research Institute Formal Proposal Format

This format should be followed for all formal proposals, submissions to Institutional Review Boards, and proposals for outside funding. If a reviewing body has a specific format that must be followed, then that format must take precedence. (Additional formatting information and requirements are available from the Vail Health IRB administrator.)

TITLE PAGE: Include title of the proposal, principal investigator, all co-investigators, name of institution(s), contact information for PI, and proposed initiation and completion dates.

ABSTRACT: Briefly state the problem, hypothesis, specific aims, methods, expected results, and significance.

INTRODUCTION AND BACKGROUND: State the problem clearly and in detail, including the significance of the problem. Provide a thorough review of the literature on this problem. Either attach the literature search or state when it was completed. Cite only pertinent references.

PREVIOUS WORK BY THE AUTHORS: Describe any work already completed. Cite published literature by the authors.

HYPOTHESIS: State clearly the hypothesis/null hypothesis of this study and what specific question is to be answered. Include the purpose and specific aims of this study

OBJECTIVES/STUDY QUESTION: Be specific.

CLINICAL RELEVANCE: Provide a clear statement of how results of this study will influence clinical practice.

MATERIALS AND METHODS: Give specific details of how the study will be carried out (i.e., the study design). Describe resources to be used. Explain and justify the sample size, including a power analysis. State how the data obtained will be analyzed, including statistical tests to be used. Describe the subjects or patients. For the inclusion criteria, describe clearly the patient/subject population to be included. For the exclusion criteria, be specific and include the following statement: “No exclusion criteria shall be based on race, ethnicity, gender, or HIV status, unless exceptions are stated and justified.”

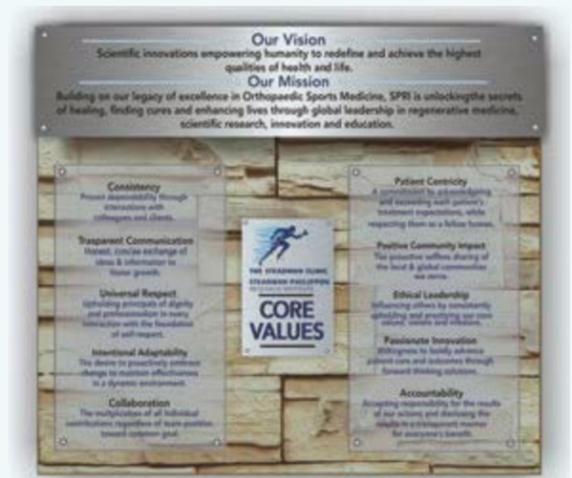
RISKS AND BENEFITS: State any anticipated risks to human subjects if applicable. State if there are any direct benefits for subjects enrolled in this study (there rarely are any). State a justification for use of animals if applicable. If radiation is involved, you must use the standard Vail Health IRB verbiage.

CONFIDENTIALITY: Explain how data and patient/subject privacy will be protected.

REFERENCES: List pertinent references cited above. Use a standard medical journal format.

BUDGET: Provide a detailed budget and justification for additional expenditures. Include human resources.

SIGNATURE PAGE: Include the signatures of the PI, all co-investigators, the Department Director who will be called upon to provide support to the study if not an investigator, and the Clinic Service Chief (noted above), if applicable for a clinical study.





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