

Research Matters

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OrthoCarolina
RESEARCH INSTITUTE

The Institute—Background

The **OrthoCarolina Research Institute (OCRI)** is an independent, autonomous, 501(c)(3) research organization committed to developing and pioneering revolutionary treatments and techniques that will maximize the advancement of orthopedic research and offer major benefits in cost-effectiveness and improved clinical outcomes for patients.

MISSION

The mission of the Institute is to promote, develop and conduct state-of-the-art scientific research and educational programs for the advancement of orthopedic care.

ORGANIZATION

The Institute's research team consists of an Executive Director, two research managers (FDA Clinical Trials Manager and Scientific/Outcomes Manager), six clinical research coordinators and one data management specialist. Compared to other regional and national orthopedic research organizations, the productivity of OCRI relative to the size of the staff is extraordinary.

OCRI currently manages 14 FDA Clinical Trials and 50 Scientific/Outcomes Studies and annually monitors approximately 6,000 study patients. The research staff is also responsible for the preparation of abstracts, manuscripts, grant proposals, scientific posters and presentations, literature searches, local and regional conferences, community outreach programs, and multiple other research activities.



Left to right (back): Debbie Summey, Katherine Prassas, Amy Eshelman, Amanda Phillips, Anne Denno
Left to right (front): Mandi Merriott, Anne Schwoebel, Susan Odum, Caryn Thompson—*not pictured*, Jahleen Jenkins

Clinical Trials at the OrthoCarolina Research Institute

The OrthoCarolina Research Institute (OCRI) is currently participating in 14 FDA Clinical Trials. FDA Clinical Trials test potential treatments in human volunteers to determine if they should be approved for wider use in the general population. Treatments can be defined as a drug, medical device, or biologic (e.g., vaccine or gene therapy). Clinical Trials are required by the FDA before a new product can be approved for use and brought to the market.

New FDA Clinical trial at OCRI

One of OCRI's new trials, on-going since June 2007, is the Biomimetic Foot & Ankle Fusion study. Dr. Robert Anderson is the Principal Investigator. The purpose of the study is to determine whether GEM OS1™ is safe and effective for bone regrowth of lost or destroyed bone following bone fusion in patients with foot problems. GEM OS1™ is an investigational device that has not yet been approved by the U.S. Food and Drug Administration (FDA) for commercial, but has been approved for use in this clinical study.

Dr. Anderson and OCRI were recently spotlighted in Biomimetic's Newsletter, *Pivotal Press*, for achieving the highest enrollment in the GEM OS1™ clinical trial out of 19 participating sites. According to Dr. Anderson, the study's success is due to "good communication and excellent organization between the investigators and clinical research staff." Other study investigators include Bruce Cohen, MD; W. Hodges Davis, MD; Carroll Jones, MD.

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Two Orthopedic Device Clinical Trials Result in FDA Approval

Dr. Thomas McCoy, Principal Investigator, has participated in the NexGen® LPS-Flex Mobile Bearing artificial knee system clinical trial for the past three years. This system is used for knee joints worn out due to age and physical injury. The NexGen® LPS-Flex Mobile Bearing system (Zimmer, Inc.) received FDA approval on December 10, 2007.



Dr. Daniel Murrey, Principal Investigator, has participated in the ProDisc®-C Total Disc replacement trial since 2003. Fifty three patients continue in follow-up for safety and effectiveness of the product. The ProDisc®-C Total Disc replacement procedure is intended for patients with significant pain caused by cervical disc generation. Treatment allows for the removal of the diseased disc while restoring disc height and providing the potential for motion at the affected vertebral segment. The ProDisc®-C (Synthes, Inc.) received FDA approval in October 2007. Other investigators included Eric Laxer, MD; Alden Milam, MD; Al Rhyne, MD and Bruce Darden, MD.



Study Coordinators for the above studies are Katherine Prassas and Jahleen Jenkins.

Community Educational Event—Joint Celebration, April 18, 2008

In keeping with its mission, the Institute shares its research findings with healthcare professionals and patients through various educational forums.

For the past five years, **The Joint Celebration—Bionic Open Golf Tournament** has celebrated the improved quality of life of “bionic” patients, or those who have had total joint replacement surgery. **The Sixth Annual Joint Celebration** will take place on Friday, April 18th at the Ballantyne Resort in Charlotte, N.C

The goals of annual event are to raise awareness of how highly successful total joint replacement has become, to provide an educational opportunity for orthopedic patients, and to raise money for non-sponsored research projects on-going at the OrthoCarolina Research Institute.

The day begins at 9:00 a.m. with a **physician-led educational seminar** about living with arthritis and recent advances in total joint replacements. Topics will also include alternative medical treatments and how to “live well” with a total joint replacement.

The seminar is **free, and open to the public.**

The Bionic Open Golf Tournament begins at 11:30a.m. Play will begin with a shotgun start at noon. Roughly 100 bionic players will take part in the golf tournament. Other players will include OrthoCarolina physicians, guest physicians and corporate sponsors. The tournament is designed for serious golfers as well as those who just want to have fun!

The “Wellness Walk” begins at 11:30a.m. following a seminar lead by the OrthoCarolina Physical Therapy staff on “The Importance of Stretching.” The fun walk follows a path that winds through the beautiful Ballantyne Resort landscape and will conclude around 12:00p.m. with boxed lunches on the patio overlooking the 18th hole.

The Joint Celebration is also an occasion to raise funds that will support and continue critical research for the development of improved devices, better outcomes, and reduced healthcare costs for orthopedic patients. This year there will be a few additions to the event, and perhaps even a couple of surprises!



Photos from 2007 community seminar.

[Panelists \(right photograph\):](#)

Walter B. Beaver, MD;
Cheryl Robertson,
MD; Bryan D.
Springer, MD; John L.
Mason, MD



Embracing the past.
Branching into the future.

About The American Academy of Orthopaedic Surgeons (AAOS):

AAOS is the “world’s largest medical association of musculoskeletal specialists” with about 24,000 members internationally. The Academy’s focus is to “provides education and practice management services for orthopaedic surgeons and allied health professionals. The Academy also serves as an advocate for improved patient care and informs the public about the science of orthopaedics.”

Citations

1. The Hip & Knee Center, OrthoCarolina, PA
2. OrthoCarolina Research Institute, Inc.
3. Carolinas Medical Center, Department of Orthopaedic Surgery
4. Department of Orthopaedic Surgery, St. Vincent’s Hospital, Sydney, Australia
5. The Shoulder and Elbow Center, The Sports Medicine Center, OrthoCarolina, PA
6. Alabama Sports Medicine and Orthopaedic Center
7. The Foot & Ankle Institute, OrthoCarolina, PA
8. Plano Orthopedic & Sports Medicine, Plano Texas
9. Advanced Surgical Institutes, Dallas Texas

Research Projects Accepted to the American Academy of Orthopaedic Surgeons 75th Annual Meeting in San Francisco, CA, March 5-9, 2008.

Orthopedic physicians from around the world submit a short scientific description, or abstract, of their research or instructional course. After a thorough peer-review process, a selected number are chosen to be presented at the annual meeting. This year, the physicians of OrthoCarolina, PA and the staff of the OrthoCarolina Research Institute, Inc. are honored to have 5 projects accepted as scientific papers/podium presentations, 6 instructional courses, and 8 scientific poster and multimedia presentations. Please visit our website at www.orthocarolinaresearch.org/publications to view the final posters and podium abstracts that were presented at the 2008 Annual AAOS Meeting.

PODIUM PRESENTATIONS

Duong Nguyen, MD⁵; Ferreira L; Brownhill J; MacDermid J; Garvin G; King G; Johnson J; Drosdowech D; Faber K. “Improved accuracy and reliability with computer assisted glenoid implantation: A randomized controlled trial”

Stephen L. Brown, MD⁵; Brian J. Loeffler, MD⁵; Donald F. D’Alessandro, MD⁵; James E. Fleischli, MD⁵; Patrick M. Connor, MD⁵. “Increased incidence of false positive rotator cuff pathology in MRI’s of patients with adhesive capsulitis”

Juan Suarez, MD¹; William L. Griffin, MD¹; Susan M. Odum, MEd, CCRC²; Bryan D. Springer, MD¹. “Why do revision total knee arthroplasties fail?”

Marshall A. Kuremsky, MD³; Simon Tan, MD⁴; Alan D. Tyson, PT, SCS, ATC-L, CSCS¹; Patrick M. Connor, MD⁵. “Arthroscopic decompression of spinoglenoid notch ganglion cysts causing suprascapular neuropathy”

Marshall A. Kuremsky, MD³; E. Lyle Cain, Jr., MD⁶; James E. Fleischli, MD⁵. “Thromboembolic phenomena after arthroscopic shoulder surgery”

INSTRUCTIONAL COURSE LECTURES

Robert B. Anderson, MD⁷. “Sports injuries of the foot and ankle”

“The pathoanatomy and treatment of heel pain in the athlete”

“Management of complex foot and ankle injuries in the athlete”

“Surgical technique in the management of the adult flatfoot”

Thomas K. Fehring, MD¹. “Controversies for complex primary and revision knee replacement”

Thomas K. Fehring, MD¹; J. Bohannon Mason, MD¹. “Revision TKA: Planning, management and controversies”

Patrick M. Connor, MD⁵. “SC and AC injuries, glenoid and scapula fractures”

Bruce E. Cohen, MD⁷. “The fab five of foot and ankle”

POSTER PRESENTATIONS

Stephen L. Brown, MD⁵; Brian J. Loeffler, MD⁵; Donald F. D’Alessandro, MD⁵; James E. Fleischli, MD⁵; Patrick M. Connor, MD⁵. “Increased incidence of false positive rotator cuff pathology in MRI’s of patients with adhesive capsulitis”.

Gregory E. Raab, MD¹; Thomas K. Fehring, MD¹; Susan M. Odum, MEd, CCRC²; J. Bohannon Mason, MD¹; William L. Griffin, MD¹. “Aspiration as an aid to the diagnosis of prosthetic knee instability”.

Thomas K. Fehring, MD¹; Joseph Hughes, BS¹; Susan M. Odum, MEd, CCRC²; Bryan D. Springer, MD¹. “Gender differences in anterior condylar anatomy”

Thomas K. Fehring, MD¹; Susan M. Odum, MEd, CCRC²; John L. Masonis, MD¹; Bryan D. Springer, MD¹. “Early Failure in Unicondylar arthroplasty-are we doing enough to do them well?”

John L. Masonis, MD¹; Marshall A. Kuremsky, MD³; Susan M. Odum, MEd, CCRC²; Bryan D. Springer, MD¹. “Mid-term outcomes of oxidized zirconium femoral components for total knee arthroplasty.”

Bryan D. Springer, MD¹; William L. Griffin, MD¹; Thomas K. Fehring, MD¹; Juan Suarez, MD¹; Susan M. Odum, MEd, CCRC²; Caryn P. Thompson, CCRC². “Incomplete seating of press-fit porous coated acetabular components: The fate of zone 2 radiolucencies.”

Bryan D. Springer, MD¹; Thomas K. Fehring, MD¹; William L. Griffin, MD¹; Susan M. Odum, MEd, CCRC²; John L. Masonis, MD¹. “Why do revision total hip arthroplasties fail?”

Robert B. Anderson, MD⁷; F. Alan Barber, MD⁸; John McGarry, MD⁹; Morley Herbert, PhD⁹. “A biomechanical study of Achilles tendon repair augmentation using graft jacket matrix.”

MULTIMEDIA PRESENTATIONS

Stephen L. Brown, MD⁵; Patrick M. Connor, MD⁵; Donald F. D’Alessandro, MD⁵; James E. Fleischli, MD⁵. “The anatomy of the knee”

CONTACT INFORMATION

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Our mission: To promote, develop and conduct state-of-the art scientific research and educational programs for the advancement of orthopedic care.

Physician's Corner: Bryan D. Springer, MD

"Research, Industry and the Government: The Impact of the Deferred Prosecution Agreement"

In October 2007, five manufacturers of orthopedic implant devices entered into a Deferred Prosecution Agreement (DPA) with the federal government and the Department of Justice (DOJ). The action stemmed from investigations into perceived, potential "kickbacks" from orthopedic manufacturers to surgeons in return for use of their products. Although each company admitted no guilt and no criminal charges were filed by the DOJ, substantial monetary penalties were levied against each of the manufacturers. In addition, and as part of the DPA, the companies were required to disclose to the public any monetary funds that were paid to surgeons or institutions in 2007. A federal monitor was also assigned to each company for a period of 18 months to oversee and approve all interactions between companies and surgeons.

While there is little doubt that changes in industry policies and scrutiny over the relationships between surgeons and implant companies were needed, there is concern over the broad sweeping strokes that the DOJ has taken and the effects on innovations, technological

advancement, education, research, and ultimately patient care. Collaborative partnerships between industry and surgeons are essential for the advancement of new technologies, the development of new implants, providing important feedback to industry, and conducting research. Such relationships ultimately lead to improved patient care, the main focus of our profession.

A quick glance at one of the companies websites, where details of the DPA are listed, reveals no fewer than thirty research institutions that have received education and research support from industry. The majority of these institutions are private, non-profit organizations that rely on industry support to conduct clinical and basic science research. The concern is that without proper differentiation between funding to surgeons from industry deemed unethical and funding support judged to be legitimate, the advancement of science and patient care will suffer.



Support The Institute

The OrthoCarolina Research Institute is organized exclusively for charitable, educational and scientific purposes within the meaning of Section 501(c)(3) of the Internal Revenue Code.

Please detach and mail the form below



Yes, I'd like to support the educational and scientific efforts of the OrthoCarolina Research Institute. Please accept my donation in the amount of \$_____.

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