SAWBOB SE37
AAOS Biomedical Engineering Committee - Success or Cause for Concern: Analyses of Device Outcomes
William M. Mihalko, MD, PhD, Collierville, TN
Jack E. Lemons, PhD, Birmingham, AL
Introduction: Clinical outcomes of adult reconstructions utilizing devices with decades of pain free function are considered successful. Analysis of outcomes beyond revisions now includes devices from post mortem donors. The clinical aspects of total joint replacement, trauma and spine, BMI, function and device registries are considered. Methods: Analyses combined: clinical, biological and physical studies; >7000 retrievals; >2000 donors; recent case reports; and concerns about future outcomes from multiple centers were analyzed for this report from multiple retrieval centers. Results: Most orthopaedic prostheses perform as intended over decades for middle and older age patients. Assessments of younger patients, those with higher Body Mass Index (BMI >40) and more active patients raise questions. Analysis of these devices in this patient group show concerns that current standards testing may not go far enough. Discussion and Conclusion: Overall analyses of orthopaedic devices and records show that most orthopaedic procedures reduce pain, increase function and remain stable as intended. Concerns exist about treatment of younger, more obese and active patients. Studies combined with registries should provide recommendations to further enhance outcomes.

Research Development Committee - Importance of Comparative Effectiveness Research
Kristy L. Weber, MD, Baltimore, MD
Peter C. Amadio, MD, Rochester, MN
Erin L. Ransford, Rosemont, IL
In May of 2011, the AAOS and ORS held a consensus conference on Comparative Effectiveness Research (CER) in orthopaedics. This exhibit will highlight the findings of the symposium with audio/video and poster excerpts from presentations with the overall goal of educating orthopaedic physicians on how to implement CER and ultimately make better decisions leading to improved patient care.

BASIC RESEARCH

SCIENTIFIC EXHIBIT NO. SE38

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- Overview and History of CER: Providing evidence for patient-centered, individualized care
- CER in the Federal Government: Examining programs of the AHRQ, NIH, and PCORI
- Using CER to Make Better Health Decisions: Shared Decision Making Using Patient Decision Aids
- Research Design Methods: Adaptive Designs and Observational Studies
- Cost Effectiveness Analysis: Role of Cost in CER, Challenges, and Methodologies for analyses
- CER as a Foundation for Measuring Quality: Providing a Foundation for Quality Improvement Algorithms
- CER in Clinical Trials: Translating Gaps in Evidence to Funded Trials

SCIENTIFIC EXHIBIT NO. SE39

- Radiation Protection to Surgeons’ Hands With a Novel Radiation Attenuating Lotion
- Smiresh S. Shah, MD, Chicago, IL
- Kevin W. Chen, MD, Chicago, IL
- Alfonso Mejia, MD, Chicago, IL

Introduction: Orthopaedic surgeons frequently expose their hands and fingers to radiation with the use of fluoroscopy during procedures. An NIH study on fluoroscopically guided procedures spanning the past four decades revealed high exposure to clinicians’ hands and underscored the need to reduce occupational radiation doses. The maximum annual limit to hands is 50 rem. This can be reached in 30 minutes of exposure to direct C-arm radiation, depending on X-ray intensity. Current radiation attenuating gloves lower the surgeon’s dexterity and tactile sensation. This paper is the first report of the attenuation characteristics of a novel radiation attenuating lotion, that can be applied in a manner similar to sun-block lotion. The results indicate that this lotion effectively reduces radiation exposure and does not affect dexterity and sensation. Methods: The lotion consists of an aqueous organic carrier and 75 weight % of bismuth oxide (Bi2O3) ceramic powder (Alfa Aesar, 99.99%). The organic carrier comprises lubricants, humectants and surfactants such as glycerin, glycol sterate and polyethylene glycol sterate, and emulsifiers such as glyceryl stearate. The ceramic powder was blended to make a lotion with a creamy texture qualitatively similar to hand lotions. Biocompatibility of the lotion and its constituent ceramic powder ingredient was assessed using ISO 10993 protocols. A standard C-arm fluoroscope was used to image cadaveric hands on a hand table, simulating an operative field configuration. Dosimeters measured direct radiation and scatter for 300 seconds at 53 kilovolts. This specific kilovolt setting was calculated from the average of five cadaveric hands with the fluoroscope on an automatic setting. Dosimeters were implanted subcutaneously on the ipsilateral side or superficially on the contralateral side of each hand. Each configuration had five controls and five specimens with the attenuating lotion placed topically on the side nearest the source of radiation. Results: Measured radiation exposure at the subcutaneous level and the contralateral side of the hand demonstrated that the lotion provided 81.5% and 63.7% attenuation (p-values of 0.00000006 and 0.0002) compared to bare cadaver hands. Measured scatter indicated no significant difference in radiation levels (p-values of 0.09 and 0.07). Discussion and Conclusion: This novel topical radiation attenuating lotion showed significant reduction in radiation exposure to hands. There was also no significant scatter, which is a key difference from previous glove designs for radiation protection. Use of this lotion may allow up to 5 times more radiation exposure before safety thresholds are reached. Orthopaedic surgeons from the study group evaluated the texture and consistency of the product and concluded there was no impairment in tactile sensation. The lotion consists of a radio-contrast agent bismuth oxide and common ingredients found in hand lotions all of which were tested for safety, biocompatibility, skin irritation, skin sensitization, cytotoxicity, and acute and chronic systemic toxicities using well-established US FDA recognized standard ISO 10993 protocols. This lotion provides surgeons with a new and better option for radiation protection for their hands that can be applied in a sterile fashion prior to wearing
surgical gloves and easily be washed off with soap and water.

Introduction: Pharmacologic agents, both anabolic and anti-catabolic, are being used at an increasing rate to improve rates of fracture healing and spinal fusion, improve osseointegration of metal implants, prevent osteoporotic fractures, and improve a patient's overall bone quality. Translational research can provide the clinician insight into emerging pharmacologics in orthopaedic surgery, allowing them to make educated decisions on appropriate use of the agents, as well as elicit the limitations of both systemic and local agents. Methods: We will provide the clinician a “need to know” version of pharmacology in orthopaedic surgery. Anti-catabolic agents will be discussed including bisphosphonates and osteoprotegrin (OPG), as well as anabolic agents like parathyroid hormone (PTH). Indications and contraindications will be presented in a clear manner. In addition, emerging medications that have been used to treat other pathology, such as “statins”, which have now been found to play an active role in bone, will also be discussed. Finally, we will present novel agents that may have a future role in clinical medicine, based on results in basic science and translational research, such as anti-sclerostin antibody, anti-dickkopf-1 antibody, denosumab, and odanacatib. Results: For each agent discussed, we will present the proposed pharmacologic mechanism of action, and results from basic science research. While clinical data is often limited, we will present clinical results of the these medications that have been FDA approved for clinical use, in terms of fracture healing rates, spinal fusion rates, osseointegration, and changes in bone mechanical structure and morphology. In addition, known complications of these medications will be presented (e.g. atypical femur fractures, osteonecrosis of the jaw). Discussion and Conclusion: As a means to improve patient outcomes, pharmacologic agents are becoming increasingly used by the orthopaedic community. However, often times, clinicians are unaware of the basic science behind these medications, or their approved indications and limitations. We will present medications that have well established roles in bone; in addition, we will present future directions and potential future “impact” medications, based on literature from the basic science and translational research realms.