

# Medical Device Surveillance and Assessment

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2024 Annual Report

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# Message from the leadership team

Dear friends and colleagues,

**We are pleased to present our 2024 annual report highlighting our impact on clinical decision making, patient safety, clinical outcomes and cost-effectiveness.**

**Our impact in 2024:** MDSA continued to monitor over 4.23 million devices impacting over 826,126 patients with enhanced surveillance. We contributed to more than 21 peer-reviewed publications and 17 national and international presentations, influencing clinical care within and beyond our organization.

**Enhanced patient safety:** More than 9,000 patients immediately identified with recalled devices.

**Translating research into practice:** A recent publication in the [Joint Commission Journal](#) highlights how implant registries improve clinical practices and outcomes, leading to cost savings and enhanced patient safety.

**Enhancing value-based utilization:** MDSA's research collaborations have led to significant findings, such as the routine use of antibiotic-loaded bone cement in knee replacements not reducing infection risk while increasing costs influencing value-based utilization within our organization.

**Collaborations:** MDSA has engaged in numerous national and international collaborations, including a study with the FDA on mid-urethral sling outcomes and an international collaboration on ACL reconstruction influencing care nationally and globally.

## **Recognitions and awards:**

- ❖ Congratulations to Dr. Calvin Kuo and his co-authors on receiving the **2024 TPMG Morris Cullen Research Paper award** for his publication in collaboration with MDSA: "Are Octogenarians at Higher Risk of Complications After Elective Lumbar Spinal Fusion Surgery? Analysis of a Cohort of 7880 Patients From the Kaiser Permanente Spine Registry."
- ❖ Congratulations to Dr. Rouzbeh Mostaeedi and his co-authors on being selected for the New Member Prize for his abstract "Post-Market Surveillance of Mesh Performance Following Inguinal Hernia Repair in a US Cohort."
- ❖ An abstract recently submitted to AOSSM titled "Risk of Revision and Reoperation after ACL Reconstruction. Comparison of Quadriceps Tendon, Patellar Tendon, and Hamstring Autografts Stratified by Patient Gender and Age: A cohort study of 27,715 Patients" is a finalist for the O'Donoghue award.
- ❖ MDSA was recognized for improving outcomes and medical device safety in [STAT News](#), [Beckers Hospital Report](#), and [the Institute for Health Policy](#).

We would like to thank and acknowledge all of you for your important contributions to this work and look forward to another productive and impactful year in 2025.



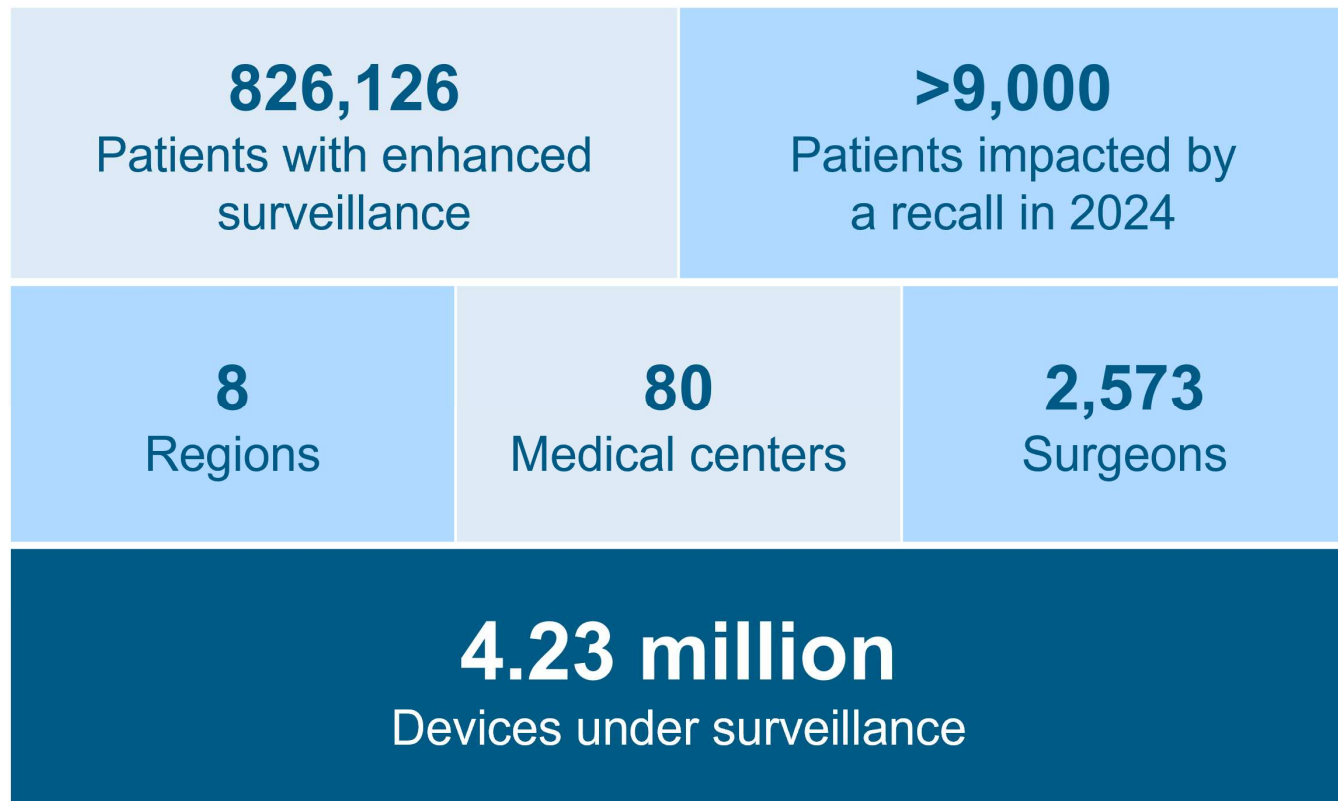
**Liz Paxton, PhD, MA**  
Senior Director, Medical Device Surveillance and  
Assessment Unit of Clinical Analysis



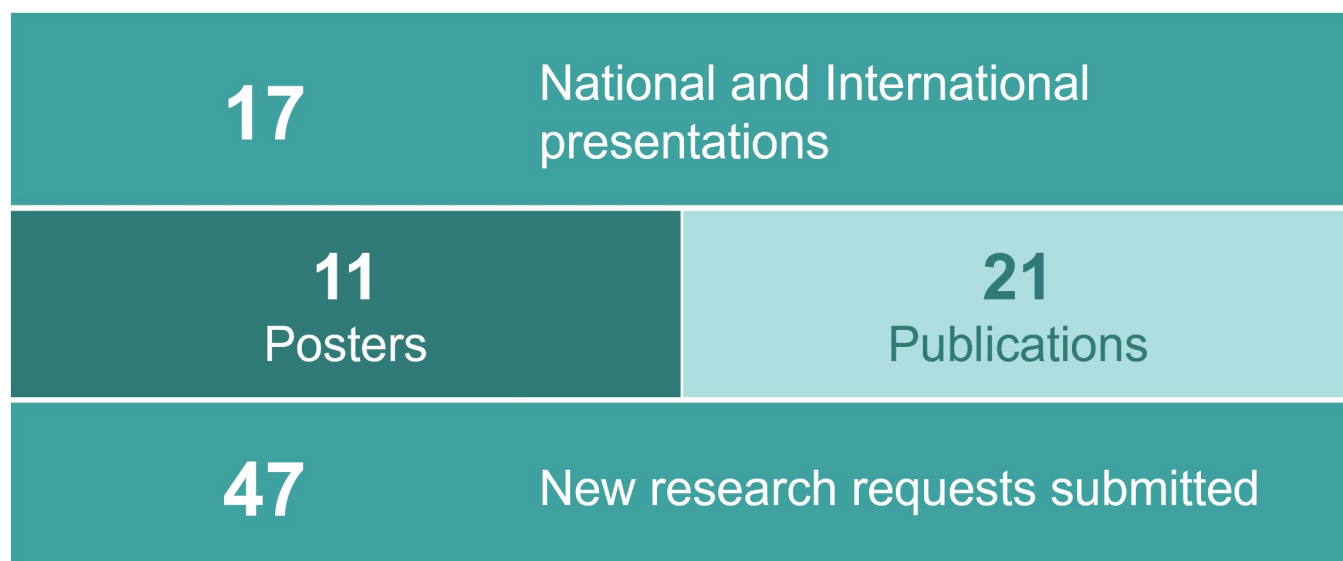
**Nolan Chang, MD**  
Chair, Medical Device Surveillance Committee;  
Regional Medical Director of Business Management,  
Southern California Permanente Medical Group

# Our impact in 2024

## People



## Research



# Impacting clinical care

## Kaiser Permanente researchers highlight the importance of implant registries on clinical practice and outcomes.

In a study published in *The Joint Commission Journal on Quality and Patient Safety*, Kaiser Permanente researchers [highlight clinical quality registries](#) as the foundation of our learning health system to identify variations in care and clinical best practices, disseminate findings, and implement change to enhance patient safety, quality of care, and cost effectiveness. Examples of changes in clinical practice based on registry findings and feedback included:



### Reduction in:

- Opioid utilization following orthopedic procedures.
- Use of bone morphogenic protein during lumbar fusion, allowing for cost savings.
- Allograft use for ACL reconstruction and subsequent decrease in organization-wide revision rates.



### Cost savings

through expansion of same-day discharge programs for total joint arthroplasty.



### Increase in

the use of cement fixation in the hemiarthroplasty treatment of hip fracture.



MDSA has had another productive year where our research teams collaborated with surgeon and physician researchers to publish research which is changing practice within and outside of Kaiser Permanente. Our publications are being cited by others: a tacit acknowledgement that our work is respected. In these times where health care needs proof of value, we continue to produce great findings and outcomes, publish them and lead in a way that our accomplishments create trust with our patients.

**Ronald A. Navarro, MD**  
Southern California Permanente  
Medical Group



## Enterprise-wide

### discontinuation of an endograft device associated with higher risk for adverse outcomes following endovascular aortic aneurysm repair.

Our unique integrated health system, EHR, low attrition rates as well as our organizational infrastructure and clinician leadership allows rapid real-world assessment and feedback to frontline clinicians and staff to practice evidence-based medicine and clinical excellence.

# Translating research into practice

Kaiser Permanente’s mission is to provide high-quality, affordable health care services and to improve the health of our members and the communities we serve. Publishing and collaborating with other organizations nationally and internationally provide an opportunity to improve patient care within and beyond our organization.

## International collaboration evaluates variation in use of antibiotics in cement and systemic antibiotics in primary total knee arthroplasties.

In a collaboration of 16 registries from around the world, [investigators identified](#) variation in use of antibiotic-loaded bone cement (ALBC) and systemic antibiotics across countries. ALBC is commonly used in European countries. In the United States, ALBC is recommended for revision joint surgery and high-risk patients only.



## Meta-analytic technique to investigate association between ALBC and post-operative joint infections.

In >2.9 million TKAs, [authors found evidence](#) suggesting ALBC was not associated with reduced infections for primary TKA. This international collaborative is also investigating the use of antibiotics in cement for patients with a higher risk of infection (higher BMI, higher ASA score, diabetics) and evaluating use of multiple doses of antibiotics in primary TKA.



This collaboration has shown the routine use of ALBC in knee replacement does not reduce the risk of prosthetic joint infection while significantly increasing the cost per case. We have used these findings to operationalize the reduction of ALBC usage within our organization to improve affordability while maintaining quality.

**Nithin C. Reddy, MD**  
Southern California  
Permanente Medical Group

**Research  
collaboration leads  
to Kaiser  
Permanente  
implementation of  
value-based use  
decision-making.**

# Collaborations

## Kaiser Permanente investigates mid-urethral sling outcomes in collaboration with the FDA.

In collaboration with the FDA, Kaiser Permanente researchers investigated the long-term outcomes of mid-urethral slings (MUS) used to treat stress urinary incontinence (SUI) in women. The study followed >35,000 women over 12 years and revealed these results:

- Overall rate of reoperation for primary synthetic mesh MUS was low at 3.7%.
- Reoperations for recurrent SUI were rare, with a rate of 3.67%.
- Long-term rates of reoperation for mesh revision or removal were less than 1% by the 12-year mark.
- Other complications also had low rates, such as mesh exposure, infection, and voiding dysfunction.



This study helped to identify trends in patient characteristics and MUS approaches used; differences in safety and effectiveness between approaches; and risk factors associated with reoperation.

**Shawn A. Menefee, MD**

Obstetrics/Gynecology/  
Urogynecology

Southern California Permanente  
Medical Group

**These findings are significant for patient care, reinforcing the long-term safety and efficacy of mid-urethral slings.**

## ACLR international collaboration to identify variation in patients, procedures, and outcomes across the globe.

This study serves as a baseline for understanding differences and similarities between different registry populations participating with International Society of Arthroscopy Knee Surgery and Orthopaedic Sports Medicine (ISAKOS), provides combined information on the largest set of ACLR dataset, and will guide registries to help them collaborate to address significant ACLR clinical and surgical technique questions.

Combining registries from 7 national/regional registries across Europe, North America, and Oceania, the global team will evaluate patient characteristics, mechanism of injury for primary ACLR, concurrent injuries and intraoperative findings, graft selection and fixation, and outcomes like revision and death after primary ACLR. The study population is over 218,000 primary ACLRs from 2005 to present.



As the largest ACLR registry in the U.S., Kaiser Permanente is participating in a global ACLR registry that is being supported by ISAKOS. This international effort will help to compare techniques and outcomes from registries around the world and by combining data should give insights into problems that require large datasets to understand.

**Greg Maletis, MD**

Lead Physician, Kaiser  
Permanente ACLR Registry  
Southern California Permanente  
Medical Group





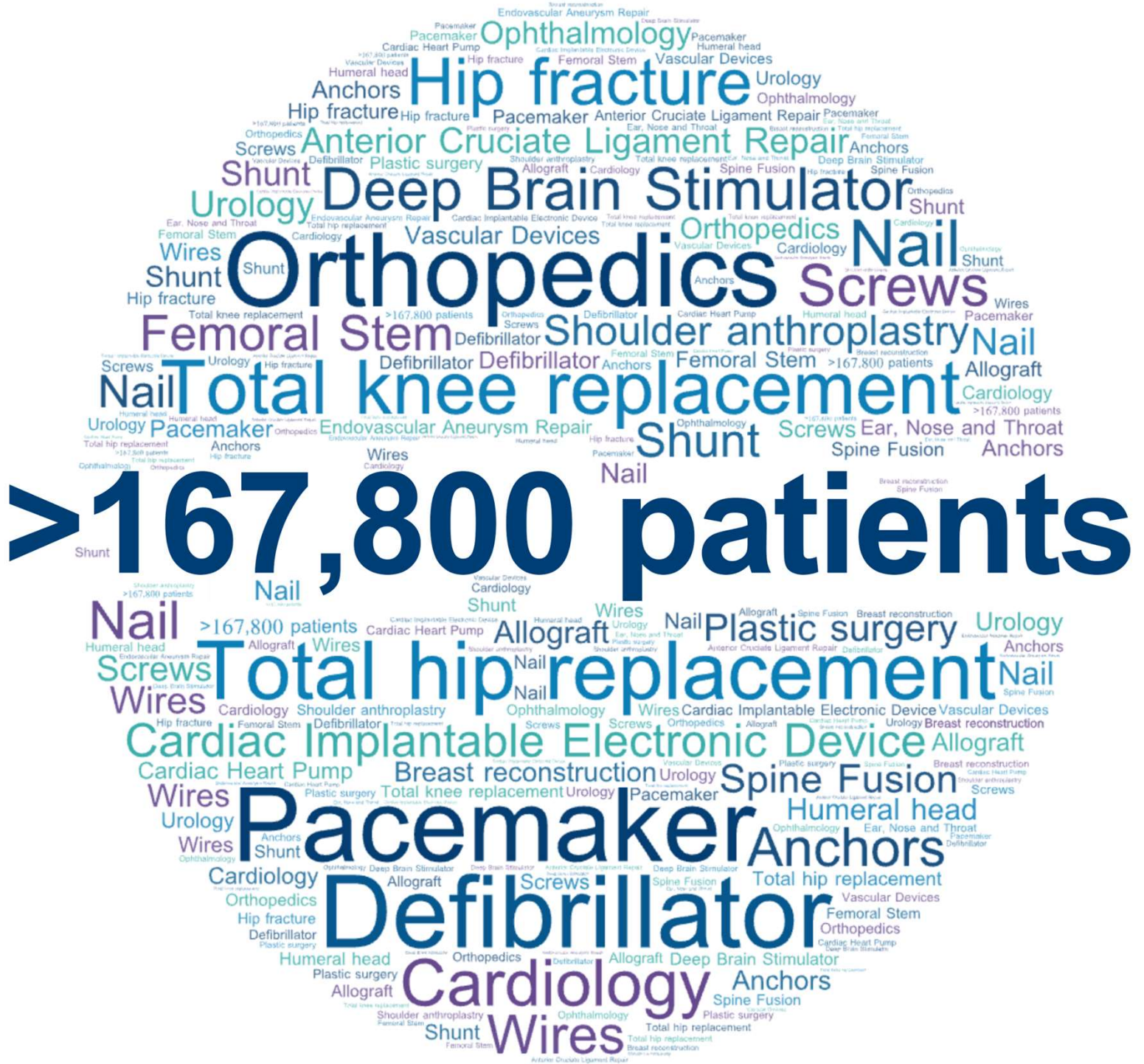
# Monitoring FDA device recalls

Tracking implantable device recalls includes collaborating with the FDA, vendors, and the Kaiser Permanente National Recall Department. In 2024, we screened over **360** recall notifications leading to **30** recalls that MDSA identified patients for distribution to appropriate clinical teams. This year more than **9,000** patients were affected by a recall.





# Recalled devices supported by MDSA



# Patients with enhanced device surveillance



## Cardiology

- Cardiac implantable electronic devices **143,064**



## Orthopedics, sports medicine

- ACL reconstruction **63,536**
- Bovine shoulder patch **932**
- Platelet-rich plasma **210**



## General surgery

- Hernia repair **90,050**



## Orthopedics, joints and trauma

- Hip fracture repair **76,186**
- Shoulder arthroplasty **28,094**
- Radial head **1,575**
- Total hip arthroplasty **147,834**
- Total knee arthroplasty **242,833**



## Head and neck surgery

- Cochlear implants **2,347**



## Neurosurgery

- Deep brain stimulator **1,735**
- Spine surgery **81,599**



## Urogynecology

- Mid-urethral slings **35,216**



## Vascular interventions

- Abdominal aortic aneurysm repair **8,271**
- Thoracic aortic aneurysm repair **774**
- Transcarotid artery revascularization **660**
- Peripheral stents **2,500**



## Plastic surgery

- Breast reconstruction **49,169**

# Research highlights

## Total Joint Arthroplasty



### **Dual mobility acetabular cups (DMC) showed no advantage compared to metal or ceramic heads on highly cross-linked polyethylene liners**

DMC aseptic revision at 6 years was 1.9% and not higher than the other articulations, indicating that the thinner polyethylene constructs of the DMC did not fail at higher rates. The DMC implants were not associated with aseptic revisions, either overall or when considering specific revision causes.

► [JOA Manuscript](#)

### **Dual-mobility articulations in revision total hip arthroplasty reduced risk of aseptic re-revision and dislocation compared to other options**

No increase in aseptic loosening was identified for dual-mobility acetabular constructs relative to metal on XLPE or ceramic on XLPE. Dual-mobility acetabular constructs had the lowest dislocation risk with significant improvements over XLPE.

► [JBJS Manuscript](#)



By allowing us to evaluate the effectiveness and appropriate use of new technologies like dual mobility hip implants and study our care protocols such as same-day discharge of total joint patients, the registry is key to our ongoing effort to provide optimal, value-based patient care.

**Matthew Kelly, MD**  
Department of Orthopedics  
Southern California Permanente Medical Group

### **Total joint replacement (TJR) model for hospital based same-day discharge in an integrated care setting provides increased value for patients**

Home recovery following TJR is preferable to an overnight stay for most patients, with 93% of patients in home recovery satisfied with their care. Home recovery also has a substantial impact on helping to curb costs associated with the episode of care.

Increasing safe home recovery on a population basis decreases chances of poor patient outcomes and increases available beds and hospital resources.

► [Perm J Manuscript](#)





## Total Joint Arthroplasty

*continued*

### **Use of systemic antibiotic prophylaxis in cemented primary total knee arthroplasty**

Antibiotic-loaded bone cement and plain bone cement entailed similar risk of periprosthetic joint infection revision when patients received systemic antibiotic prophylaxis (SAP) in primary TKAs, regardless of number of SAP doses. Antibiotic-loaded bone cement or plain bone cement used in combination with SAP in primary TKAs, with one single preoperative dose of SAP maybe sufficient without compromising patient safety.

► [JBJS Manuscript](#)

### **No difference in survivorship following primary total hip arthroplasty with or without acetabular screws**

Cementless acetabular cups for total hip arthroplasty typically have screw options to improve stability but screws were also associated with osteolysis. Modern cups and liners may have made both these concerns obsolete.

► [JOA Manuscript](#)

# Hip Fracture



While prior research has sought to determine which procedure – THA or hemiarthroplasty – is “better” for older patients with femoral neck fractures, our study was designed to identify the specific patients for whom each procedure would be preferred.

**Kanu Okike, MD**  
Department of  
Orthopedic Surgery  
Hawaii Permanente  
Medical Group

## **Total hip arthroplasty (THA) had lower revision risk than both unipolar and bipolar hemiarthroplasty for hip fracture in older individuals**

Among patients aged 60-79 and with ASA I or II, this study found a survivorship advantage for bipolar compared to unipolar hemiarthroplasty and that THA may be beneficial. THA may not confer any benefit over hemiarthroplasty for patients who are aged >80 years or have an ASA of III.

► [JBJS Manuscript](#)

## **Differences found in cementless femoral stem brand performance for hemiarthroplasty treatment of geriatric femoral neck fractures**

For individuals  $\geq 60$  years of age, study findings do not support use of Zimmer M/L Taper, DePuy Summit Basic, and Zimmer Versys LD/FX stems in the treatment of displaced geriatric femoral neck fractures with cementless hemiarthroplasty.

► [CORR Manuscript](#)

# Cochlear Implants



## **Most cochlear implant revisions are due to device malfunction in recalled implants**

Researchers found that for both pediatric and adult patients, most revision was due to a device malfunction in recalled implants. Cumulative survival, device failure, and medical failure rates were favorable compared with those reported in the literature. In addition, cochlear implant survival rates were better in adult than pediatric patients but varied by manufacturer in both groups.

► [Otology & Neurotology Manuscript](#)



# ACL Reconstruction

## Is there an association with revision when posterior tibial slope (PTS) is measured on plain radiograph versus MRI used for ACL reconstruction?

This study did not find a significantly steeper XR-PTS in patients who had to undergo revision ACL reconstruction when suboptimal radiographs were not included in the analysis. The present study's results confirmed the findings from a previous study of the same patient population that used MRI.

► [AJSM Manuscript](#)

## No differences found in revision or reoperation risk when quadriceps tendon autograft is used in ACL reconstruction

No difference was found in the risk of revision or reoperation of ACL reconstruction when quadriceps tendon (QT) was compared with bone-patellar tendon-bone (BPTB) or hamstring tendon (HT) autograft, but researchers did find a 1.5 times higher risk of revision when HT autograft was compared with BPTB autograft.

Surgeons may use this information when choosing the appropriate graft for ACLR in their patients.

► [AJSM Manuscript](#)



## Knee pain after ACL reconstruction may be an early sign of posttraumatic knee osteoarthritis

Surgeons should consider the adverse associations of a higher body mass index and an allograft or quadriceps tendon autograft with the development of posttraumatic knee osteoarthritis after a primary ACL reconstruction.

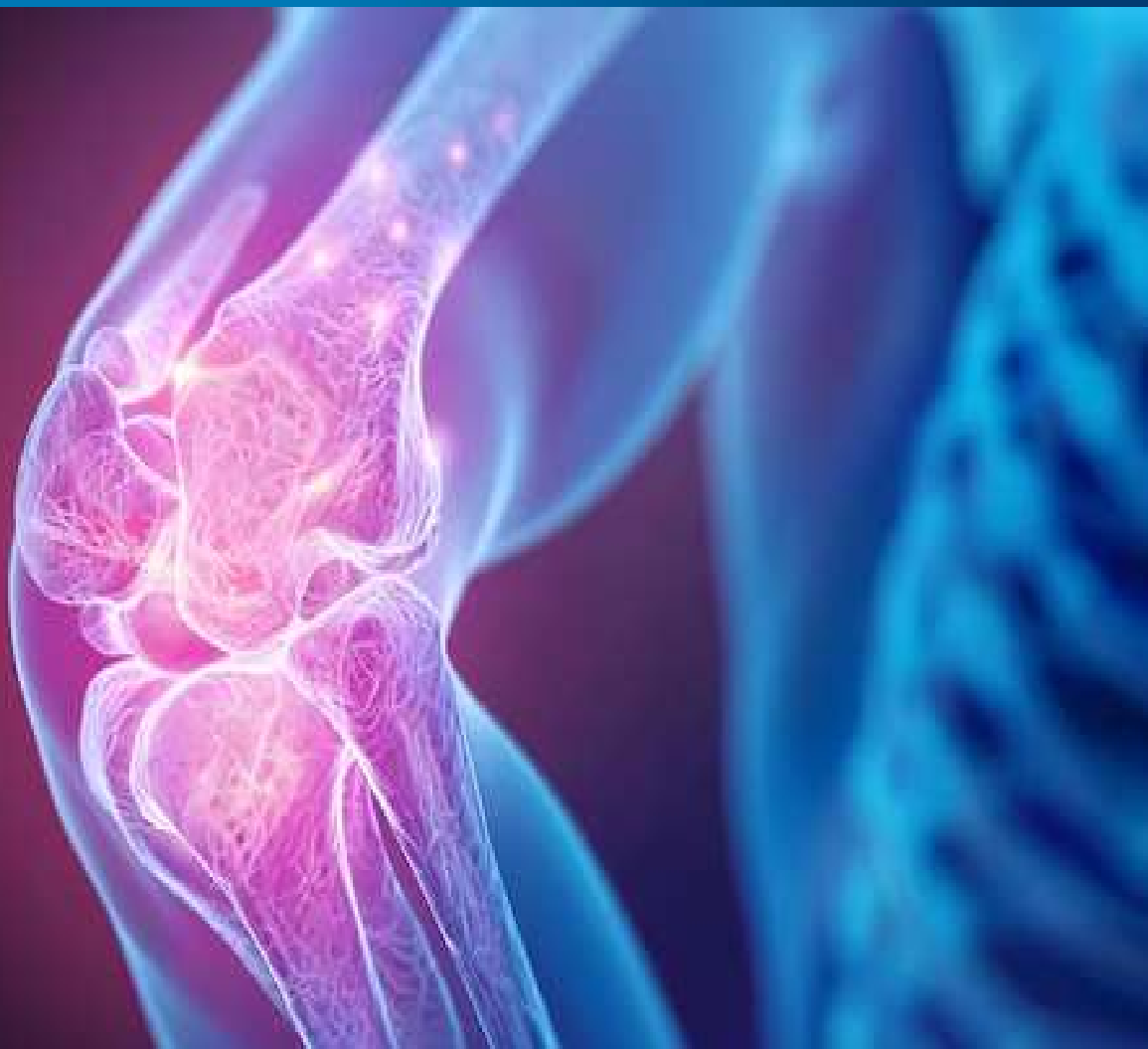
► [AJSM Manuscript](#)

# Radial Head Arthroplasty



When choosing an implant for radial head arthroplasty, surgeons should know that loose fit and press fit stems have similar outcomes in terms of revision and reoperation rates.

**David Zeltser, MD**  
Department of  
Orthopedic Surgery  
Washington Permanente  
Medical Group



## Similar outcomes found when evaluating stem design use in radial head arthroplasties (RHA)

Researchers did not observe a difference in risk of revision or reoperation following RHA based on stem design. The choice between using an implant with a loose or press fit stem may be based more on surgeon familiarity, implant availability and cost, and ease of use.

► [JSES Manuscript](#)



By the end of this year, we will have enrolled over 100,000 patients in our Spine Registry—an outstanding milestone made possible by the dedication and collaboration of our neurosurgeons and orthopedic spine surgeons. Beyond its academic achievements, the registry is invaluable to the KP organization. The data we've collected over the years has provided critical insights into the effectiveness of surgical techniques and instrumentation, helping us continually refine our practices to deliver the best possible care to our patients.

**Kern Guppy, PhD, MD**  
NCAL Spine Registry Neurosurgery Lead  
The Permanente Medical Group



## No difference in the reoperation rates found between 4 different interbody types with pedicle screws

Analysis of reoperation rates for operative adjacent-segment disease (ASD) among four types of lumbar interbody fusions (ALIF, PLIF, TLIF, and LLIF) combined with pedicle screws was conducted.

In a large cohort of over 5000 patients with an average follow-up of > 6 years, the authors found no differences in the reoperation rates for symptomatic ASD with an incidence rate of 8.37%. These findings highlight the complexity of biomechanical factors in lumbar fusions and their impact on ASD development, without establishing the superiority of any one technique.

► [J of Neurosurgery Spine Manuscript](#)

## Lower risk of nonunion with ALIF + PS compared with ALIF alone

Our recent study on anterior lumbar interbody fusion (ALIF) examined the technique's effectiveness and versatility in decompression, stabilization, and reconstruction. We found that the operative nonunion risk was lower for patients undergoing ALIF with posterior supplementation (ALIF+PS) compared to ALIF alone. However, the five-year ASD incidence showed no significant difference between the two adjusted cohorts, with 4.3% for ALIF only and 6.2% for ALIF+PS. Therefore, supplemental posterior fixation should be considered for patients at higher risk for operative nonunion, as concerns about future ASD risk should not necessarily influence the decision to use posterior instrumentation in ALIF procedures.

► [The Spine Journal Manuscript](#)

# Upcoming research projects

The following projects have been selected for first half of 2025:

## Hernia repair

- Comparison of mesh types in clean versus contaminated ventral hernia repairs

## Hip fracture repair

- Helical blade or lag screw in hip fractures treated with a cephalo-medullary nail

## Spine repair

- Association between race/ethnicity and outcomes following spine fusion in a large integrated health care system
- Modern morbidity and mortality after occipito-cervical fusion and instrumentation

## Total joint arthroplasty

- Survivorship of collarless-polished vs. collared-matted cemented femoral prosthesis designs and fracture, loosening in an arthroplasty population

If you have a research question focused on implantable devices to explore within Kaiser Permanente, [click here](#) to learn more and request a new research project.

### Submission deadlines

- Every March 31<sup>st</sup> and September 30<sup>th</sup>
- Email: [KPdeviceassessment@kp.org](mailto:KPdeviceassessment@kp.org)

Find the [Letter of Intent form](#) on our website.



# Medical Device Surveillance Committee members

The mission of the MDSC is to advance knowledge about implantable medical products outcomes and to apply that knowledge to enhance patient safety and quality of care, as well as provide leadership and expertise to lead the understanding of implant performance, internal and externally. The MDSC is a national quality program, governed by the Kaiser Permanente National Quality Committee.



**Nolan Chang, MD**

Chair, Medical Device Surveillance Committee; Regional Medical Director SCPMG; EVP, The Permanente Federation



**Liz Paxton, PhD, MA**

Director, Medical Device Surveillance and Assessment Unit of Clinical Analysis, SCPMG



**Tania Tang, PhD, MPH**

Executive Leader, Clinical Analysis, SCPMG; VP, Analytics, The Permanente Federation



**Barbara Crawford, MS, RN, NEA-BC**

Senior Vice President, National Health Plan and Hospital Quality



**Sande Irwin, MD**

Otolaryngology/Head and Neck Surgery; Chair, National Product Council; Co-Chair, Northwest Technology Coordinating Group; Co-Chair, Northwest Regional Product Council



**Jeffrey Klingman, MD**

Assistant Chief of Staff, Medical Services, Kaiser Permanente Walnut Creek Medical Center



**Tracey McLean, MD**

Obstetrics/Gynecology; NCAL Regional Kaiser Permanente Health Connect Leader



**Ronald A. Navarro, MD, FAAOS, FAOA**

Regional Coordinating Chief of Orthopedic Surgery, SCPMG; Interregional Orthopedic Chief, Lead, KP Shoulder Arthroplasty Registry



**Scott Young, MD**

Senior Medical Director, Clinical Quality and Safety; Executive Director, The Care Management Institute



**Ashish M. Mehta, MD**

Pediatric Ophthalmology & Adult Strabismus Regional Asst. Medical Director, Capital Equipment Co-Chair, Equipment Strategy Planning Group



**Elizabeth Loughren, MPH**

Managerial Senior Consultant, Interregional New Technologies Committee



**Emily Perdoncin, MD, FACC, FSCAI**

Structural Heart Program, Kaiser Permanente San Francisco

# Medical Device Surveillance and Assessment

## Interregional Scientific Subcommittee

The mission of the Interregional Scientific Subcommittee is to provide recommendations for prioritization and selection of research study proposals to identify the most impactful studies regarding medical device performance that will influence patient safety and quality of care across multiple specialties.

### **MDSC chair**

Nolan Chang, MD

### **MDSA senior director**

Liz Paxton, PhD, MA

### **MDSA research scientists**

Heather Prentice, PhD, MPH

Kathryn Royse, PhD, MPH, MSPH

### **Cardiology**

Nigel Gupta, MD

### **General surgery**

Francisca Maertens, MD, FACS

### **Neurosurgery**

Omid Hariri, DO, MSc, FACS

### **Orthopedics**

Ronald Navarro, MD, FAAOS, FAOA

Kanu Okike, MD, MPH

### **Plastic surgery**

Winnie Tong, MD

### **Vascular surgery**

Robert Chang, MD

## Department team members

### **Leadership**

Liz Paxton, PhD, MA

Jessica Harris, MS, RD

Kenneth Sucher, MS

### **Research scientists**

Heather Prentice, PhD, MPH

Kathryn Royse, PhD, MPH, MSPH

### **Biostatisticians**

Priscilla Chan, MS

Richard Chang, MPH

### **Project managers**

Brian Fasig, PhD

Chelsea Reyes

Janine Cruz, BA

### **Data reporting and analytics consultants**

Cindy Yuexin Chen, BS

Kim Phan, BA

Maggie Hong Sun, MS

Michael Reyes, BS

Tom Huon, BS

Juan Ruiz

### **Research associates**

Blanca Miskulin

Nicole Caballero, BS

Tia Mullane, BA

### **Administrative team**

Donna Leck

Raffaella Cowell