

PERMANENTE MEDICINE®

# Medical Device Surveillance and Assessment 2023 Annual Report

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# Message from the Leadership Team

Dear friends and colleagues,

We are excited to share our key 2023 achievements in medical device surveillance with you. In 2023, we continued to support national orthopedic, neurosurgery, cardiac, and vascular registries and expanded medical device surveillance in multiple specialty areas identifying clinical best practices to enhance patient safety and quality of care for our members.

## Key 2023 accomplishments include:

- Recipient of the American Association of Hip & Knee Surgeons (AAHKS) best poster in the Large Database Study Category: Matched-cohort Survivorship Comparison of Cemented vs Cementless TKA From a Single Manufacturer ([Link to poster](#))
- Continued to support expanded interregional medical device surveillance in breast, hernia, cochlear, peripheral stent, urethral sling, deep brain stimulators, radial head arthroplasty, bovine shoulder patches, platelet-rich plasma, and transcarotid artery revascularization
- Monitoring >4.2 million devices to enhance quality and safety for >800,000 members
- Identified regional variations, clinical best practices, best-performing implants, and risk factors to pre-operatively optimize patients who receive medical devices in existing registries and new surveillance initiatives
- Expanded medical device surveillance to new medical devices: craniotomy, brain stents, spinal cord stimulators, and thoracic endovascular aneurysm repair
- Prioritized and selected 8 new research projects in multiple specialty areas supporting interregional evidence-based medicine
- 31 peer-reviewed publications spanning 6 clinical specialties with 18 national/international presentations and 14 posters demonstrating the influence of our work on clinical practice within and beyond our organization
- Supported 3 Kaiser Permanente Bernard J. Tyson School of Medicine student milestone research projects
- Immediately identified patients with recalled devices for medical device recalls affecting >5,000 patients in 6 specialties

We would like to thank and acknowledge the physicians, chiefs, and front-line staff at Kaiser Permanente who contributed to these important achievements. We look forward to another successful year!



**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 2023

## Optimizing patient care

### Breast reconstruction

Analyzed ADM material effects on risk of return-to-OR to decrease readmissions.

### Endovascular aneurysm repair

Identified regional variations in post-operative imaging to develop best practices.

### Hernia repair

Evaluated types of surgical approaches to improve gender-specific decision-making and outcomes.

### Cervical fusion

Refined instrumentation usage at C6-C7 vs C7-T1 to improve surgical technique.

### Cardiac devices

Developed proactive feedback processes to increase remote monitoring to catch acute issues.

## Quality improvement

### Surgeon specific reports

Personalized performance feedback for 615 surgeons' enterprise-wide, providing individualized outcome and return-to-care metrics.

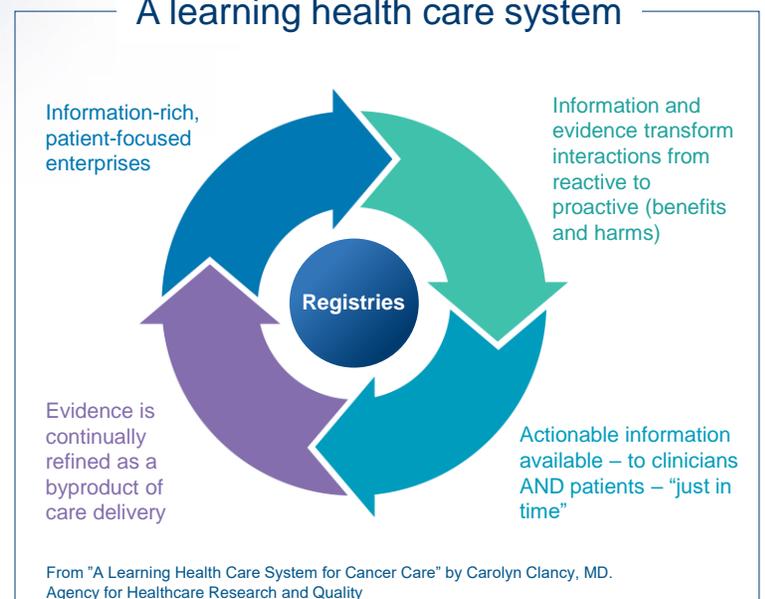
### Monitoring new technology

Ongoing assessment of safety and effectiveness of new-to-market implants.

### Patient safety

Identified >5,000 patients impacted by a recalled implanted device in numerous specialties.

## A learning health care system





# Our impact in 2023

## Evidence-based medicine

**31** peer-reviewed publications spanning

**6** clinical specialties with

**18** conference presentations



## Recognition

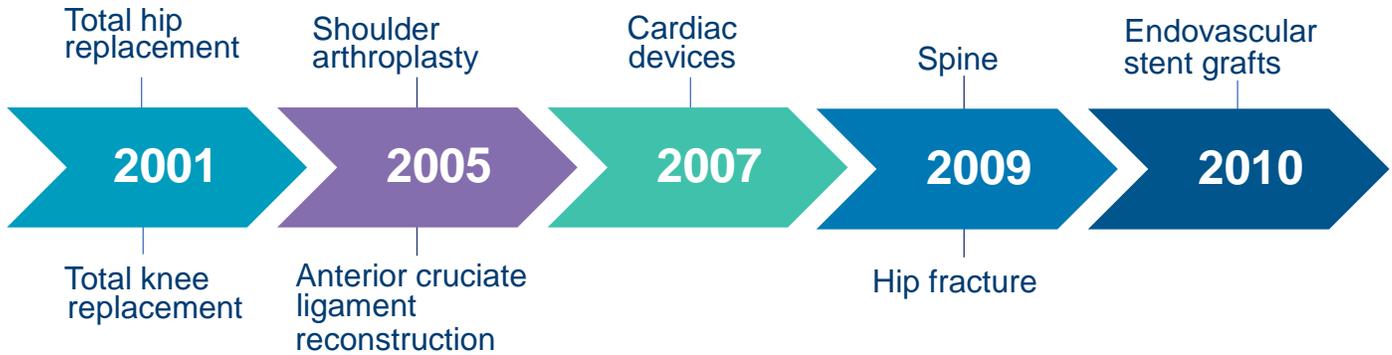


2023 AAHKS Annual Meeting recipient of the **Best Poster Award** in the Large Database Study category. The poster evaluated refining decision-making on cemented vs. cementless total knee replacement.

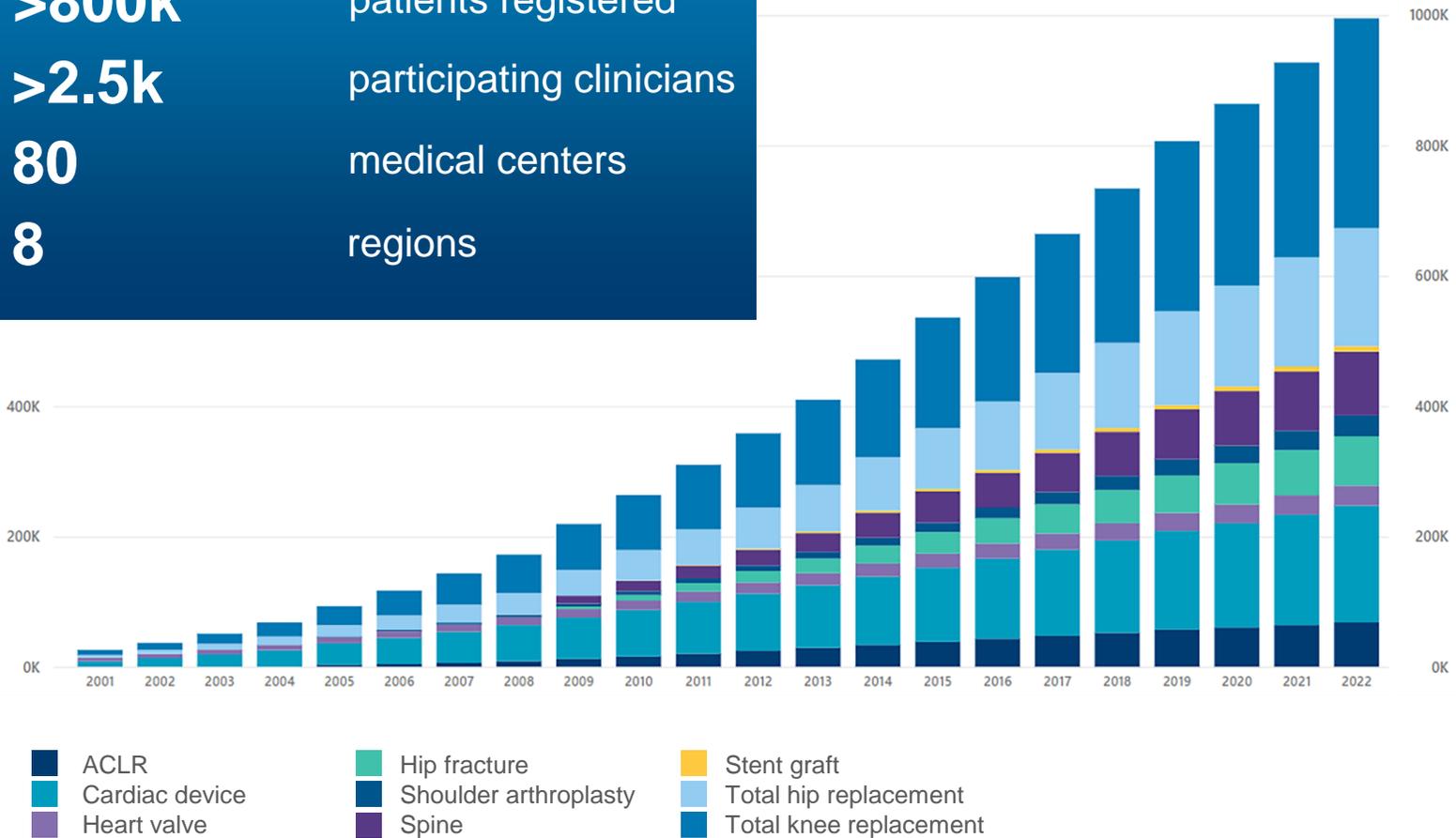


# Foundational medical device surveillance

More than 20 years ago, device surveillance was implemented at Kaiser Permanente. With the widespread interregional data capture, MDSA has worked alongside surgeons to enhance patient safety using evidence-based medicine. To date, our team has more than 290 published papers, facilitating enhancements in practice and influencing clinical decision-making.



**4.2 million** implanted devices  
**>800k** patients registered  
**>2.5k** participating clinicians  
**80** medical centers  
**8** regions



# Expanding medical device surveillance

As technological innovation continues to transform health care, the need for medical device surveillance is critical to provide overall risk assessment to enhance patient safety. MDSA expanded surveillance to include new technologies and high-risk implantable devices.



**General surgery**  
Hernia repair



**Plastic surgery**  
Breast reconstruction



**Head and neck surgery**  
Cochlear implants



**Urogynecology**  
Mid-urethral slings



**Neurosurgery**  
Deep brain stimulators  
Craniotomy plates  
Spinal cord stimulators



**Vascular interventions**  
Thoracic endovascular aneurysms  
Transcarotid artery revascularization  
Peripheral stents



**Orthopedics and sports medicine**  
Bovine shoulder patch  
Platelet-rich plasma

## Upcoming projects

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.

### The following projects have been selected for 2024:

#### Knee repair

- Risk in knee replacement after anterior cruciate ligament reconstruction
- Adjustable-loop or fixed-loop devices for femoral fixation

#### Hernia repair

- Plug versus flat mesh outcomes in inguinal hernias
- How does mesh weight affect inguinal hernia repair postoperative complications and recurrence rates?

#### Breast reconstruction

- Autologous versus implant-based breast reconstruction

#### Spine repair

- Cervical disc arthroplasty versus anterior cervical discectomy and fusion
- Reoperation rates between stand-alone and plated anterior cervical discectomy and fusion
- To cross or not to cross the lumbar-thoracic junction: reoperation rates for adjacent level disease and nonunion

# Enhancing patient safety by monitoring device recalls

To date, we have identified **157,700** patients who have been affected by **184** recalls of an implanted device.

In 2023 alone, more than **5,000** patients were identified in **6** different clinical specialties:

**Neurosurgery**  
~3,200 patients

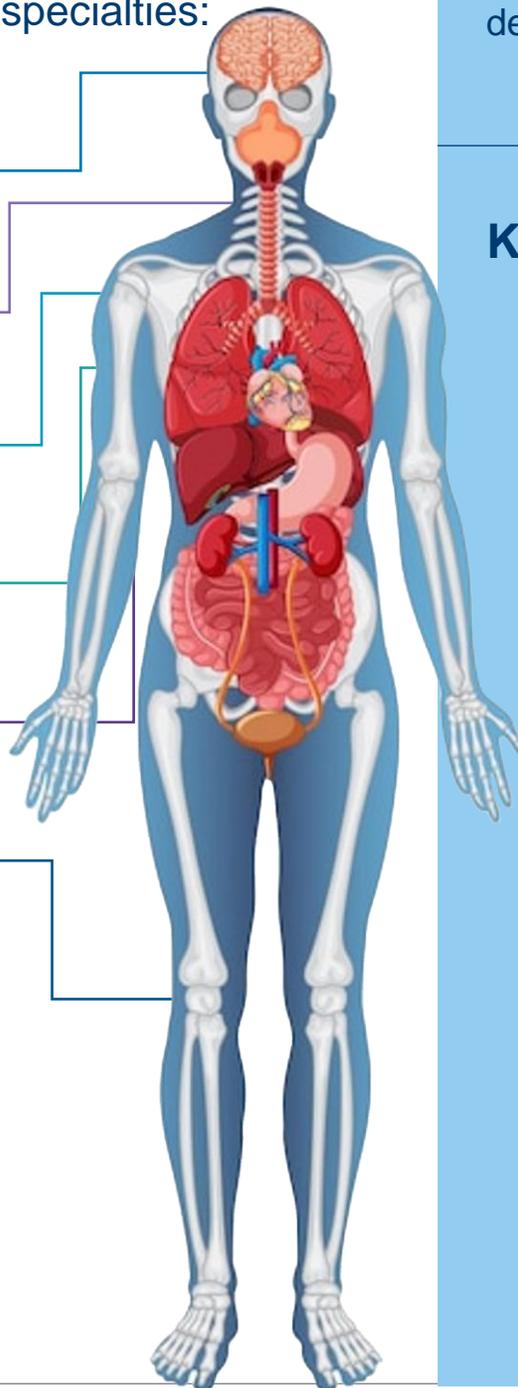
**Spine**  
~180 patients

**Shoulder arthroplasty**  
~280 patients

**Plastic surgery**  
~30 patients

**Cardiology**  
~1,400 patients

**Total joint arthroplasty**  
~400 patients



## Our unique implanted device recall system

Our patient-specific recall system identifies and collaborates with clinical care teams. This provides a resource to identify patients affected by a recall of an implanted device.

## Keys to success

- ✓ Close partnership with the National Product Safety & Recall Team
- ✓ Validation of vendor data using internal data
- ✓ Engagement of clinical experts to determine correct course of action
- ✓ Follow up to monitor guideline adherence and clinical outcomes



# Patient-centered research highlights

## Anterior cruciate ligament reconstruction

### **No differences found in revision risk for hamstring autograft sized < 8 mm compared to hybrid graft sized ≥ 8 mm**

Hamstring autograft (HA) is commonly used for primary anterior cruciate ligament reconstruction (ACLR). However, if the harvested HA is inadequate in diameter, it is often augmented with an allograft tendon, forming a hybrid graft (HY). This study sought to evaluate aseptic revision risk following HA versus HY ACLR. In a U.S.-based cohort of ACLR patients aged ≤ 25 years, we did not observe any differences in aseptic revision risk for HA < 8 mm compared to HY ≥ 8 mm. Augmentation of a HA as small as 7 mm is not necessary to prevent a revision surgery.

► [Read more](#)

### **To minimize the risk of re-revision of ACLR, surgeons should consider using autograft for ACLR revision when possible**

Study findings published in *The American Journal of Sports Medicine* found that when accounting for all reoperations outside of re-revision ACLR after revision ACLR, no

significant difference was found in risk between autograft and allograft. With adjustment for covariates, a 70% lower re-revision ACLR risk was observed for autografts compared with allografts. To minimize the risk of re-revision ACLR, surgeons should consider using autograft for revision ACLR when possible.

► [Read more](#)

### **Decrease in the ACLR revision rate observed after implementation of an allograft reduction program in our health care system**

We sought to evaluate whether allograft utilization for primary ACLR within our health care system changed following the implementation of an allograft reduction intervention and whether revision rates within the health care system changed following the initiation of the intervention. We saw a decrease in allograft utilization following the implementation of an allograft reduction program. During the same period, a decrease in the ACLR revision rate was observed.

► [Read more](#)

## Endovascular aneurysm repair

### Higher surgical intervention for Endologix AFX or AFX2 devices after endovascular aneurysm repair

Findings from a study published in the *Journal of Vascular Surgery* reported patients who received an Endologix AFX System during their primary endovascular aneurysm repair (EVAR) had a higher risk for several adverse longitudinal outcomes, as well as aneurysm-related mortality, when compared with patients who received other high-volume devices. Patients who have received these devices should be monitored closely after EVAR.

▶ [Read more](#)



This study is a good example of the importance of lifelong monitoring of EVAR procedures. With information from the registry, we identified devices that require more rigorous surveillance compared to others leading to customized device specific post-operative image surveillance for our patients.

Robert Chang, MD, study author

## Hernia repair

### Surgeons with higher laparoscopic surgery volumes had a lower reoperation risk

One of 3 recent publications in *Hernia* evaluated the risk for post-operative events by surgeon and hospital volume within each surgical approach finding high-volume surgeons may reduce reoperation risk following laparoscopic inguinal hernia repair.

▶ [Read more](#)

### For Females, Lower risk of reoperation after laparoscopic hernia repairs

The second found a higher risk for reoperation in females after an open repair approach compared to males. Lower risk was observed for females for laparoscopic, which may be due to the ability to identify an occult femoral hernia through these approaches.

▶ [Read more](#)

### Several risk factors associated with reoperation following inguinal hernia repair were identified

The third publication examined risk factors for reoperation following inguinal hernia repair and found a higher risk for reoperation associated with female gender, increasing age, increasing body mass index, white race, chronic pulmonary disease, diabetes, drug abuse, peripheral vascular disease, and bilateral procedures.

▶ [Read more](#)

### Considering risk factors can minimize prolonged opioid usage by elderly hip fracture surgery patients

A study published in *The Journal of Arthroplasty* identified younger age, female gender, current/former smoker, anxiety, and specific hip fracture surgical procedure as risk factors for prolonged opioid usage in elderly hip fracture patients. Initial prescription amounts and prolonged opioid medication usage can be reduced.

► [Read more](#)

### Use of bipolar hemiarthroplasty associated with lower risk of aseptic revision

Study findings published in *The Journal of Bone and Joint Surgery, Open Access* indicate that bipolar hemiarthroplasty had a lower risk of aseptic revision than unipolar hemiarthroplasty, without any additional risk of revision for periprosthetic fracture. Given that bipolar implants typically cost more than unipolar implants, cost-effectiveness studies may be required to determine the circumstances under which the additional cost of the bipolar device is worthwhile.

► [Read more](#)

### Use of direct anterior surgical approach with total hip arthroplasty for displaced femoral neck fracture patients

A study published in the *Journal of Orthopedic Trauma* found no observed differences in 90-day and 1-year complications, dislocations, reoperations, and mortality comparing direct anterior (DAA) and posterior surgical approach



By understanding these trends and the characteristics of patients at highest risk of chronic usage, orthopedic surgeons may be in a better position to minimize the risk of prolonged opioid usage following hip fracture surgery in elderly individuals.

Kanu Okike, MD, study author

with total hip arthroplasty for displaced femoral neck fracture. DAA was associated with shorter operative time, lower likelihood of blood transfusion, and lower 90-day postoperative narcotic prescription amounts. This study supports the increasing utilization of DAA for total hip arthroplasty (THA) in patients with femoral neck fractures.

► [Read more](#)

### Comparison of THA, unipolar, and bipolar hemiarthroplasty for hip fracture treatment

Study findings published in *The Journal of Bone and Joint Surgery* found that comparing THA, unipolar, and bipolar hemiarthroplasty in treatment of hip fracture, THA was associated with fewer revisions among patients aged 60–79 or ASA classification I or II. In contrast, no significant differences were observed among patients aged 80 or above or ASA classification III. Final choice of procedure should be individualized based on the specific characteristics of each patient.

► [Read more](#)

## Shoulder arthroplasty

### Risk factors for early return to care following same-day shoulder arthroplasty

Study findings published in *Seminars in Arthroplasty: JSES* indicate that patients with a history of chronic pulmonary disease and use of continuous catheter anesthesia were associated with higher likelihood of returning to care within one day.

“It is worth noting that neither underlying diagnosis nor procedure type were identified as risk factors for return to care and that risk factors for returns varied depending on the post-discharge timeframes examined,” said study author Matthew D. McElvany, MD.

► [Read more](#)

### No advantage in using antibiotic-loaded bone cement for primary elective shoulder arthroplasties

A study published in *ScienceDirect* did not find any reduced risk of periprosthetic infection when comparing use of antibiotic-loaded bone cement (ABC) and plain bone cement for primary elective shoulder arthroplasties.

“We found the risk of deep infection to be similar between surgeries with ABC and plain cement and failed to observe any advantage of using ABC over plain cement,” said study author Ryan C. Egbert, MD.

► [Read more](#)

### Same-day discharge shoulder arthroplasty safe alternative for patients ASA class $\geq 3$

A study published in *Journal of Shoulder and Elbow Surgery* found that same-day discharge shoulder arthroplasty in patients ASA class  $\geq 3$  does not increase the likelihood of ED visits, readmissions, or complications compared with an inpatient stay.

“Adoption of expanded indications for shoulder arthroplasty with same-day discharge in the hospital-based setting can be considered a safe alternative to inpatient shoulder arthroplasty in appropriately selected patients,” said study author Michael Hachadorian, MD.

► [Read more](#)

### Similar revision rates for anatomic and reverse shoulder arthroplasty in older glenohumeral osteoarthritis patients

A study published in the *Journal of Shoulder and Elbow Surgery* found similar rates of revision surgery following primary anatomic total shoulder arthroplasty (TSA) and reverse total shoulder arthroplasty (RTSA) in patients aged 70 years or older with glenohumeral osteoarthritis, with TSA having more rotator cuff tears and RTSA more glenoid component loosening.

“Patients who undergo primary RTSA may have an advantage over TSA patients in terms of eliminating the risk of rotator cuff failure, but the all-cause revision rates between the 2 procedures are similar,” said study author Nathan D. Orvets, MD.

► [Read more](#)

## Shoulder arthroplasty (continued)

### Tranexamic acid use does not decrease infection risk in shoulder arthroplasty patients

A study published in the *Journal of Shoulder and Elbow Surgery* found that the 5-year probability of revision for deep infection was <1% for those with and without preoperative Tranexamic acid.

“The safety profile appeared similar between groups with no differences in infection risk after adjustment for confounders and surgeon differences,” said study author Jacob Gorbaty, MD.

► [Read more](#)

### Preoperative CT scans and patient-specific instrumentation does not reduce risk of aseptic revision

Study findings published in the *Journal of Bone and Joint Surgery, Open Access* found no reduction in the risk of aseptic revision with the use of preoperative CT scans and patient-specific instrumentation (PSI), with CT having higher venous thromboembolism and PSI higher deep infection.

“It remains to be seen whether clinical benefit of these innovations will be realized and whether their use is justified in view of their cost in money and time,” noted study author Ronald A. Navarro, MD.

► [Read more](#)

## Spine repair

### No benefit found by extending cervical fusion

The challenges of posterior cervical fusions (PCF) at the cervicothoracic junction (CTJ) are widely known. Two recent publications in *Spine* and the *Journal of Neurosurgery*, supported by MDSA research scientists, neurosurgeons, and orthopedic spine surgeons, reported on the implications of crossing the CTJ.

In one of the largest cohort of patients with PCFs stopping at C7 or T1/T2 with an average follow-up of > 4 years, the authors found no statistically significant difference in reoperation rates for symptomatic nonunion or for adult spinal deformity. These findings show that there is no additional benefit of extension to T1/T2 and surgeon choice based on patient diagnosis should be the deciding factor on fusions crossing the cervicothoracic junction.

► [Read more](#)



The KP spine registry study puts this controversy to rest. It was one of the largest cohorts and showed there was no significant difference in ASD and nonunions between the two techniques.

Kern Guppy, MD, PhD,  
study author

### Lower risk of operative nonunion when adding posterior fusion to anterior lumbar interbody fusion

In a study published in *Spine Journal*, the addition of posterior instrumentation in anterior lumbar interbody fusion (ALIF) is associated with lower risk of operative nonunion compared with ALIF alone; operative nonunion is rare in both techniques (<5%). Accordingly, surgeons should evaluate the added risks associated with the addition of posterior instrumentation and reserve the supplemental posterior fixation for patients that might be at higher risk for operative nonunion.

► [Read more](#)



## Total joint arthroplasty

### Cementless primary total hip arthroplasty single-wedge femoral stems have higher risk of revision

Study findings published in *The Journal of Arthroplasty* indicate that cementless primary THA single-wedge stem designs were associated with a higher risk of revision due to aseptic loosening. Men in particular had a higher revision risk. No differences were found for septic revision, instability, periprosthetic fracture, or revisions for other reasons. Femoral stem geometry should be considered when selecting a cementless femoral implant.

► [Read more](#)

### Risk factors for emergency department visits in total joint arthroplasty patients

A study published in *The Journal of Arthroplasty* found that patients who were seen in the emergency department (ED) or who were high users of outpatient care in the year preceding surgery had a higher likelihood of ED visit within 90 days of an elective total knee arthroplasty (TKA) or THA. Also, patients that had lower

copays showed higher ED service utilization.

“Future strategies to reduce post-operative ED returns should include directed patient outreach for patients who had ED visits and mental health in the year prior to TKA and THA,” stated study author Adrian D. Hinman, MD.

► [Read more](#)

### Use of antibiotic-loaded bone cement and systemic antibiotic prophylactic in primary total knee arthroplasties varies internationally

A study published in *Acta Orthopaedica* found international variation in use of ABC and systemic antibiotic prophylactic (SAP) for primary TKA, with gentamicin the most common agent for ABC and cefazolin for SAP.

Study author Tesfaye H. Leta said, “The type of ABC and type and dose/duration of SAP varies internationally and needs national and regional consensus in practice guidelines based on high-quality evidence.”

► [Read more](#)

### Preoperative patient optimization improves patient outcomes and resource utilization

A study published in the *Journal of the American Academy of Orthopaedic Surgeons* found that utilization of evidence-based protocols before total joint arthroplasty to improve patient selection based on modifiable patient factors was associated with fewer post-operative complications. Adoption of standardized optimization programs have the potential for improved patient outcomes and earlier, safe discharge, which can improve cost effective care and resource utilization.

► [Read more](#)

### Osteoarthritis patients living in rural areas have a higher rate of total joint arthroplasty surgery

Study findings published in *The Journal of Arthroplasty* found that in hip and knee osteoarthritis (OA) patients enrolled in a universal coverage system, patients living in urban areas had lower total joint arthroplasty (TJA) utilization compared to patients living in rural areas.

“Race, social support networks, and the severity of OA may influence these observed differences and are areas for further investigation to help better understand the difference in TJA surgery between rural and urban areas and helping to reduce that difference,” noted study author Adrian Hinman, MD.

► [Read more](#)

### Patients with prior revision history have higher risk of aseptic revision

Study findings published in *The Journal of Arthroplasty* found that patients who had a prior revision history had over a 2-fold higher risk of aseptic revision in the index knee.

“Primary TKA patients with an aseptic revision history, particularly in the contralateral knee, should be closely monitored by clinicians,” noted study author Heather A. Prentice, PhD.

► [Read more](#)

### Aspirin effective and safe for venous thromboembolism prevention in primary total joint arthroplasty

A study published in *The Journal of Arthroplasty* found that aspirin was effective compared to low molecular weight heparin (LMWH) and warfarin. In patients considered higher risk for venous thromboembolism (VTE), aspirin was not inferior compared to warfarin, but evidence did not support noninferiority of aspirin compared to LMWH or factor Xa inhibitors.

► [Read more](#)



Given the lower or similar risk of bleeding-related events and either better or comparable protection against VTE compared to potent anticoagulation, aspirin can be safely considered in patients considered higher risk for VTE.

Gurpreet Singh, MD  
Study Author

# 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 Permanente Federation



**Liz Paxton, PhD, MA**

Director, Medical Device Surveillance and Assessment Unit of Clinical Analysis



**Tania Tang, PhD, MPH**

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**Ronald A. Navarro, MD,  
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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

# 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 C. Chang, MD

### **MDSA senior director**

Liz W. Paxton, PhD, MA

### **MDSA research scientists**

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Kathryn E. Royse, PhD, MPH, MSPH

### **Cardiology**

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### **Neurosurgery**

Omid R. Hariri, DO, MSc, FACS

### **Orthopedics**

Ronald A. Navarro, MD, FAAOS, FAOA  
Kanu M. Okike, MD, MPH

### **Plastic surgery**

Winnie M. Tong, MD

### **Vascular surgery**

Robert W. Chang, MD

## Department Team Members

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