

# **Application of Orthopaedic Data Evaluation Panel Criteria for Shoulders for Shoulder Arthroplasty Humeral Implants Used in a United States-Based Shoulder Arthroplasty Registry**

Heather Ann Prentice<sup>1</sup>, Buu Truong<sup>2</sup>, Brian H Fasig<sup>3</sup>, Edward Yian<sup>4</sup>, Ronald Anthony Navarro, Liz Paxton<sup>1</sup>

<sup>1</sup>Kaiser Permanente, <sup>2</sup>Medical Device Surveillance & Assessment, <sup>3</sup>Kaiser Permanente National Implant Registries, <sup>4</sup>Scpmg

**INTRODUCTION:** Benchmarking allows for measurement and comparison of implant performance using agreed standards so that surgeons may be informed on best performing and poor performing implants. We sought to apply Orthopaedic Data Evaluation Panel (ODEP) criteria for Shoulders to rate implants used for shoulder arthroplasty in a US integrated healthcare system using information from a SA registry.

## **METHODS:**

A total of 10,082 primary elective anatomic total shoulder arthroplasties (TSA) and 929 primary hemiarthroplasties performed for proximal humerus fracture were identified (2009-2021). All-cause revision incidence during follow up was evaluated using one minus the Kaplan-Meier estimator and reported as cumulative percent revision (CPR) and 95% confidence interval (CI).

Using ODEP criteria, an A rating was given for implants where the upper bound of the 95% CI was <5.0%, <7.0%, <9.0%, or <12.0% at 3-, 5-, 7-, and 10-years follow up, respectively, and had  $\geq 40$  patients at-risk at the given follow-up interval of interest.

A B rating was given for implants where the lower bound of the 95% CI was <5.0%, <7.0%, <9.0%, or <12.0% at 3-, 5-, 7-, and 10-years follow up, respectively, and had  $\geq 10$  patients at-risk at the given follow-up interval of interest.

## **RESULTS:**

Twenty-five unique humeral implants for TSA were included in the registry. Of the 25 implants used, only 8 (32.0%) met criteria to receive an A rating (2 10A, 3 7A, 1 5A, and 2 3A). These 8 implants were used in 8,021 of the 10,082 (79.6%) TSA performed. Eight implants were given a B rating (3 7B, 2 5B, and 3 3B). Nine (36.0%) implants were ineligible for a rating due to too low of volume with <50 TSA per implant or not enough patients at risk at the benchmark follow up; these implants were used in a total of 287 (2.8%) TSA.

Twelve unique humeral implants for hemiarthroplasty were included in the registry. One 1 (8.3%) met the above ODEP Criteria to receive an A rating (7A); this implant was used in 249 of 929 (26.8%) hemiarthroplasty procedures. Three implants received 7B ratings while another received a 5B rating. Seven (58.3%) implants were ineligible for a rating due to too low of volume with <50 hemiarthroplasties per implant; these 7 implants were used in a total of 154 (16.6%) hemiarthroplasties.

**DISCUSSION AND CONCLUSION:** In a US-based healthcare system, only 8 of 25 identified humeral implants for TSA and 1 of 12 identified humeral implants for hemiarthroplasty had an A rating based on revision incidence during follow up. More implants received B ratings, largely due to the 95% CI of the CPR not being below the threshold to be eligible for an A rating. However, it remains unknown whether any of these implants were outlier poor performing implants based on the criteria used. Inter-registry collaboration may help increase sample sizes to properly rate low volume implants, as well as increase the number of implants with ratings as implant selection may vary across groups. Further, outlier detection methodology is needed to identify poor performing implants associated with higher revision rates.