Research Square

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Adverse Event Reports for Semi-Constrained Mobile Bearing and Hinged Metal/Metal Knee Prostheses: An Analysis of the FDA MAUDE Database (2011–2026)

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Abstract

Background

The FDA MAUDE database provides postmarket surveillance of orthopedic device adverse events. No prior study has examined reports for the patellofemorotibial semi-constrained metal/polymer mobile bearing knee prosthesis (Product Code: MBV) and the knee hinged metal/metal prosthesis (Product Code: HRZ). The purpose of this study was to characterize MBV and HRZ annual trends, device problems, patient outcomes, and manufacturer reporting patterns.

Materials and Methods

The database was queried retrospectively from January 1, 2011 through March 31, 2026. Event date, manufacturer, device problems, patient problems, and event type (injury vs. malfunction) were recorded. Each product code was analyzed independently.

Results

66 MBV reports and 12 HRZ reports were identified. For MBV, the most common device problems were fracture, loosening unrelated to bone ingrowth, and loss of or failure to bond (each n = 7, 9.2%). Pain (n = 22) and limited joint mobility (n = 9) predominated, and clinically significant events included four implant failures, four bone fractures, and one death. Zimmer Biomet accounted for most MBV reports (72.7%). For HRZ, fracture was the leading device problem and implant failure the most frequent patient problem, with Aesculap AG contributing the largest share (41.7%).

Conclusion

This analysis identified loosening as a leading device problem for mobile bearing designs, consistent with registry evidence of elevated mechanical loosening risk, while fracture and implant failure predominated in hinged prostheses. These findings demonstrate that MAUDE detects clinically meaningful signals that complement registry-based revision endpoints, supporting integrated postmarket surveillance combining passive reporting, arthroplasty registries, and prospective studies.

Level of Evidence: IV

Introduction

Postmarket surveillance is critical for orthopedic implants, as most devices reach the market through the 510(k) pathway without premarket clinical efficacy or safety data [1, 2]. The FDA's Manufacturer and User Facility Device Experience (MAUDE) database serves as the primary passive surveillance system for capturing medical device reports (MDRs) of deaths, serious injuries, and malfunctions submitted by manufacturers, user facilities, and voluntary reporters [2, 3]. Although the MAUDE database has well-recognized limitations, it remains an important signal-detection tool for identifying patterns of device-related adverse events that may warrant further investigation [2].

Total knee arthroplasty (TKA) is one of the most commonly performed orthopedic procedures worldwide, with device design continuing to evolve to address varying degrees of ligamentous insufficiency, bone loss, and instability [4]. The patellofemorotibial semi-constrained metal/polymer mobile bearing knee prosthesis (Product Code MBV) and the knee hinged metal/metal prosthesis (Product Code HRZ) represent two distinct design philosophies along the constraint spectrum. Mobile bearing designs were developed with the theoretical advantages of improved patellar tracking and reduced polyethylene wear. However, registry data have raised concerns about increased revision risk, particularly for mechanical loosening, compared with fixed-bearing designs [5–8]. Hinged knee prostheses, by contrast, are typically reserved for complex primary or revision TKA in the setting of severe instability, ligamentous deficiency, or substantial bone loss. These devices carry higher overall complication rates, including infection, aseptic loosening, and periprosthetic fracture [9–11].

Prior MAUDE-based studies have examined adverse events associated with specific orthopedic technologies such as robotic-assisted arthroplasty systems but have not focused on individual knee prosthesis product codes or compared adverse event profiles between distinct implant design categories [3, 12, 13]. Meanwhile, national and international joint replacement registries have generated robust data on revision risk for mobile bearing and hinged knee designs, but capture revision as the primary endpoint and do not characterize the full spectrum of device problems, patient outcomes, and manufacturer reporting behaviors available through the FDA's passive surveillance system [5–7, 10]. This study addresses that gap by leveraging MAUDE data to systematically analyze and compare adverse event reporting trends, device problem profiles, and patient outcomes specifically for MBV and HRZ knee prostheses.

Therefore, this study aimed to characterize annual reporting trends, device problems, patient outcomes, and manufacturer reporting patterns associated with MBV and HRZ devices..

Materials and Methods

The FDA's Manufacturer and User Facility Device Experience (MAUDE) database was queried retrospectively from January 1, 2011 through March 31, 2026 for adverse event reports associated with two distinct knee prosthesis device classifications: (1) the patellofemorotibial semi-constrained metal/polymer mobile bearing knee prosthesis (Product Code MBV) and (2) the knee hinged metal/metal prosthesis (Product Code HRZ). The database was accessed through the FDA's publicly available online portal by a single investigator. Because the MAUDE database is a publicly available, de-identified regulatory data source, Institutional Review Board approval was not required.

All reports returned by each product code query and exported from the database were included in the analysis without further exclusion. No additional filtering was applied. Data fields extracted included event date, manufacturer name, device problem codes, patient problem codes, and event type (injury vs. malfunction). Device problem codes and patient problem codes were recorded as returned directly by the MAUDE database export. Within the MAUDE database, each report is classified by event type, with an injury report denoting an event in which the device may have caused or contributed to a patient injury or illness, and a malfunction report denoting a failure of the device to meet its performance specifications or otherwise perform as intended, irrespective of whether patient harm occurred. Each product code was analyzed independently.

Descriptive statistics were used to summarize all data for each product code independently. Annual report frequencies were tabulated to characterize trends over the study period (Figs. 1 and 3). Device problem codes were cross-tabulated by manufacturer for each product code (Table 1; Table 4). Patient problem codes were tabulated as overall frequency counts (Table 2; Table 5) and further cross-tabulated by manufacturer (Table 3; Table 6). Event type distribution by manufacturer was examined using grouped comparison for each device (Figs. 2 and 4).

Results

Product Code MBV: Patellofemorotibial Semi-Constrained Metal/Polymer Mobile Bearing Knee Prosthesis

A total of 66 adverse event reports associated with product code MBV were identified in the MAUDE database between January 1, 2011 and March 31, 2026. Annual submission volume was variable across the study period, with no reports submitted in 2013 or 2023 (Fig. 1). Submission volume was modest in the early years of the study period, increased progressively through 2019 (n = 12), declined to a nadir of 2 reports in 2021, and remained low through 2024 (n = 1).

Among the 66 total MBV reports, Zimmer Biomet, Inc. accounted for the largest share with 48 reports (72.7%), including 37 injury reports and 11 malfunction reports. Biomet Orthopedics contributed 11 reports (16.7%), all classified as injury events. Smith & Nephew, Inc. contributed 7 reports (10.6%), all classified as injury events. The distribution of event type by manufacturer is shown in Fig. 2.

Cross-tabulation of device problem codes by manufacturer is presented in Table 1. Zimmer Biomet, Inc. accounted for the largest share of device problem codes across nearly all categories (Grand Total n = 76). Adverse events without an identified device or use problem were the most frequently coded device problem overall (n = 13). Fracture (n = 7), insufficient information (n = 7), loosening of implant not related to bone-ingrowth (n = 7), and loss of or failure to bond (n = 7) were each equally represented as the next most common categories. Migration or expulsion of device was coded in 6 reports, with Biomet Orthopedics contributing 5 of these.

Table 1
Device Problem Codes by Manufacturer: Patellofemorotibial Semi-Constrained Metal/Polymer Mobile Bearing Knee Prosthesis (Product Code MBV), MAUDE Database, 2011–2026

Device Problem	Biomet Orthopedics	Smith & Nephew, Inc.	Zimmer Biomet, Inc.	Grand Total
Adverse Event Without Identified Device or Use Problem	—	4	9	13
Compatibility Problem	1	—	—	1
Degraded	—	2	—	2
Delivered as Unsterile Product	—	—	1	1
Detachment of Device or Device Component	—	—	3	3
Device Packaging Compromised	—	—	2	2
Failure to Adhere or Bond	1	—	—	1
Fracture	2	—	5	7
Incomplete or Missing Packaging	—	—	1	1
Insufficient Information	3	—	4	7
Loosening of Implant Not Related to Bone-Ingrowth	1	—	6	7
Loss of or Failure to Bond	—	—	7	7
Malposition of Device	—	—	1	1
Material Erosion	1	—	2	3
Migration	—	—	1	1
Migration or Expulsion of Device	5	—	1	6
Misassembled	—	—	2	2
Naturally Worn	—	—	1	1
Noise, Audible	—	—	2	2
Osseointegration Problem	1	—	2	3
Packaging Problem	—	1	—	1
Tear, Rip or Hole in Device Packaging	—	—	2	2
Unstable	—	—	1	1
Grand Total	**15**	**7**	**54**	**76**

MAUDE, Manufacturer and User Facility Device Experience; —, no reports in this category.

The distribution of patient problem codes across all 66 MBV reports is presented in Table 2. Pain was the most frequently coded patient problem (n = 22), followed by limited mobility of the implanted joint (n = 9) and no information (n = 8). MBV reports with no known impact or consequences included 2 patients (3.0%). The remaining 64 patients (97.0%) had clinically significant problems. Clinically significant problems included ambulation difficulties (n = 4), bone fracture(s) (n = 4), failure of implant (n = 4), swelling (n = 5), reaction (n = 4), and death (n = 1). A total of 88 patient problem codes were recorded across the 66 reports, reflecting that some reports carried more than one patient problem code. The cross-tabulation of patient problem codes by manufacturer is shown in Table 3, with Zimmer Biomet, Inc. accounting for the majority of coded patient problems (Grand Total n = 88). However, because the total number of devices implanted by each manufacturer is unknown, these counts reflect reporting volume rather than relative failure rates

Table 2
Patient Problem Code Frequency: Patellofemorotibial Semi-Constrained Metal/Polymer Mobile Bearing Knee Prosthesis (Product Code MBV), MAUDE Database, 2011–2026

Patient Problem	Count
Adhesion(s)	1
Ambulation Difficulties	4
Bone Fracture(s)	4
Death	1
Discomfort	1
Erosion	2
Failure of Implant	4
Fall	1
Foreign Body in Patient	1
Foreign Body Reaction	1
Inadequate Osseointegration	1
Insufficient Information	4
Itching Sensation	1
Joint Dislocation	1
Limited Mobility of the Implanted Joint	9
Local Reaction	1
Loss of Range of Motion	2
Metal Related Pathology	3
Muscle Weakness	2
Muscular Rigidity	1
No Clinical Signs, Symptoms or Conditions	3
No Code Available	4
No Consequences or Impact to Patient	3
No Information	8
No Known Impact or Consequence to Patient	2
No Patient Involvement	4
Ossification	1
Osteolysis	1
Osteopenia/Osteoporosis	2
Pain	22
Rash	1

Patient Problem	Count
Reaction	4
Sepsis	1
Swelling	5
Swelling/Edema	2
Synovitis	2
Unspecified Infection	3
Unspecified Tissue Injury	1
Wound Dehiscence	2
Grand Total	**116**

MAUDE, Manufacturer and User Facility Device Experience.

Table 3
Patient Problem Codes by Manufacturer: Patellofemorotibial Semi-Constrained Metal/Polymer Mobile Bearing Knee Prosthesis (Product Code MBV), MAUDE Database, 2011–2026

Patient Problem	Biomet Orthopedics	Smith & Nephew, Inc.	Zimmer Biomet, Inc.	Grand Total
Adhesion(s)	—	—	1	1
Ambulation Difficulties	1	—	3	4
Bone Fracture(s)	—	1	3	4
Death	1	—	—	1
Discomfort	—	—	1	1
Erosion	—	—	2	2
Failure of Implant	—	—	4	4
Fall	—	—	1	1
Foreign Body in Patient	1	—	—	1
Foreign Body Reaction	1	—	—	1
Inadequate Osseointegration	—	1	—	1
Insufficient Information	—	4	—	4
Itching Sensation	1	—	—	1
Joint Dislocation	1	—	—	1
Limited Mobility of the Implanted Joint	—	—	9	9
Local Reaction	1	—	1	2
Loss of Range of Motion	—	—	1	1
Metal Related Pathology	—	—	3	3
Muscle Weakness	1	—	1	2
Muscular Rigidity	1	—	1	2
No Clinical Signs, Symptoms or Conditions	—	—	3	3
No Code Available	1	—	3	4
No Consequences or Impact to Patient	—	—	3	3
No Information	4	—	4	8
No Known Impact or Consequence to Patient	1	—	1	2
No Patient Involvement	4	—	4	8
Ossification	—	—	1	1
Osteolysis	—	—	4	4
Osteopenia/Osteoporosis	1	—	—	1
Pain	—	—	20	20
Rash	2	—	—	2

Patient Problem	Biomet Orthopedics	Smith & Nephew, Inc.	Zimmer Biomet, Inc.	Grand Total
Reaction	1	—	1	2
Sepsis	3	1	5	9
Swelling	—	1	2	3
Swelling/Edema	—	—	2	2
Synovitis	—	—	2	2
Unspecified Infection	—	—	3	3
Unspecified Tissue Injury	—	—	1	1
Wound Dehiscence	—	—	2	2
Grand Total	**21**	**7**	**88**	**116**

MAUDE, Manufacturer and User Facility Device Experience; —, no reports in this category.

Product Code HRZ: Knee Hinged Metal/Metal Prosthesis

A total of 12 adverse event reports associated with product code HRZ were identified in the MAUDE database between January 1, 2011 and March 31, 2026. No reports were identified from 2011 through 2014. Annual submission volume was low throughout the study period, with single reports submitted in 2015, 2016, 2017, 2019, 2022, and 2023, and two reports in 2020 (Fig. 3). Submission volume increased to 4 reports in 2025, representing the highest annual total in the study period.

Among the 12 total HRZ reports, 11 (91.7%) were classified as injury events and 1 (8.3%) as a malfunction event (Fig. 4). Aesculap AG contributed the greatest number of reports (n = 5, 41.7%), all classified as injury events. Implantcast GmbH contributed 2 reports (16.7%), both injury events. Aesculap Implant Systems, Biomet UK Ltd., Unknown, Waldemar Link GmbH & Co. KG, and Zimmer Biomet, Inc. each contributed 1 report (8.3%). The sole malfunction report was attributed to Aesculap Implant Systems.

Cross-tabulation of device problem codes by manufacturer is presented in Table 4. A total of 12 device problem codes were recorded across the 12 HRZ reports. Fracture was the most frequently coded device problem overall (n = 4), with contributions from Aesculap AG (n = 2), Waldemar Link GmbH & Co. KG (n = 1), and Biomet UK Ltd. (n = 1). 2 reports of Aesculap AG implant loosening not related to bone-ingrowth were recorded. Adverse events without an identified device or use problem (n = 2) were contributed by Implantcast GmbH and Zimmer Biomet, Inc. Break (n = 1), incorrect device or component shipped (n = 1), loose or intermittent connection (n = 1), and osseointegration problem (n = 1) were each coded once.

Table 4
Device Problem Codes by Manufacturer: Knee Hinged Metal/Metal Prosthesis (Product Code HRZ), MAUDE Database, 2011–2026

Device Problem	Aesculap Implant Sys.	Aesculap AG	Biomet UK Ltd.	Implantcast GmbH	Unknown	Waldemar Link GmbH & Co. KG	Zimmer Biomet, Inc.	Grand Total
Adverse Event Without Identified Device or Use Problem	—	—	—	1	—	—	1	2
Break	—	1	—	—	—	—	—	1
Fracture	—	2	—	1	—	1	—	4
Incorrect Device or Component Shipped	—	—	1	—	—	—	—	1
Loose or Intermittent Connection	—	1	—	—	—	—	—	1
Loosening of Implant Not Related to Bone-Ingrowth	—	2	—	—	—	—	—	2
Osseointegration Problem	—	—	—	1	—	—	—	1
Grand Total	**1**	**5**	**1**	**3**	**—**	**1**	**1**	**12**

MAUDE, Manufacturer and User Facility Device Experience; —, no reports in this category.

The distribution of patient problem codes across all 12 HRZ reports is presented in Table 5. A total of 17 patient problem codes were recorded across the 12 reports, reflecting that some reports carried more than one patient problem code. Failure of implant was the most frequently coded patient problem (n = 7), followed by no known impact or consequence to the patient (n = 2) and pain (n = 2). Bone fracture(s), hypersensitivity/allergic reaction, joint dislocation, loss of range of motion, scar tissue, and unspecified infection were each coded once. The cross-tabulation of patient problem codes by manufacturer is shown in Table 6. Aesculap AG accounted for the largest share of coded patient problems (Grand Total n = 6), predominantly failure of implant (n = 5) and hypersensitivity/allergic reaction (n = 1).

Table 5
Patient Problem Code Frequency: Knee Hinged Metal/Metal Prosthesis (Product Code HRZ), MAUDE Database, 2011–2026

Patient Problem	Count
Bone Fracture(s)	1
Failure of Implant	7
Hypersensitivity/Allergic Reaction	1
Joint Dislocation	1
Loss of Range of Motion	1
No Known Impact or Consequence to Patient	2
Pain	2
Scar Tissue	1
Unspecified Infection	1
Grand Total	**17**

MAUDE, Manufacturer and User Facility Device Experience.

Table 6
Patient Problem Codes by Manufacturer: Knee Hinged Metal/Metal Prosthesis (Product Code HRZ), MAUDE Database, 2011–2026

Patient Problem	Aesculap Implant Sys.	Aesculap AG	Biomet UK Ltd.	Implantcast GmbH	Unknown	Waldemar Link GmbH & Co. KG	Zimmer Biomet, Inc.	Grand Total
Bone Fracture(s)	—	—	—	—	1	—	—	1
Failure of Implant	—	5	—	1	—	1	—	7
Hypersensitivity/Allergic Reaction	—	1	—	—	—	—	—	1
Joint Dislocation	—	—	—	—	1	—	—	1
Loss of Range of Motion	—	—	—	—	—	—	1	1
No Known Impact or Consequence to Patient	1	—	1	—	—	—	—	2
Pain	—	—	—	—	1	—	1	2
Scar Tissue	—	—	—	—	—	—	1	1
Unspecified Infection	—	—	—	1	—	—	—	1
Grand Total	**1**	**6**	**1**	**2**	**3**	**1**	**3**	**17**

MAUDE, Manufacturer and User Facility Device Experience; —, no reports in this category.

Discussion

This analysis of the FDA MAUDE database identified 78 adverse event reports across two knee prosthesis classifications over approximately 15 years. The semi-constrained mobile bearing device (MBV) accounted for the majority of reports (n = 66), with

fracture, loosening unrelated to bone-ingrowth, and loss of or failure to bond predominating among device problems and pain the most frequently coded patient problem. The hinged metal/metal device (HRZ) accounted for substantially fewer reports (n = 12), with fracture the leading device problem and implant failure the most frequent patient problem. To our knowledge, no prior study has characterized the MAUDE adverse event profiles of these two specific product codes, and the present analysis addresses that gap by describing their reporting trends, device and patient problem patterns, and manufacturer distributions over a 15-year period.

The markedly lower number of HRZ reports likely reflects not only the well-documented limitations of passive surveillance systems but also the declining clinical utilization of metal-on-metal (MoM) hinged knee prostheses. Multiple studies have demonstrated critically elevated serum cobalt and chromium ion levels in patients with MoM hinge designs, with one study reporting cobalt levels exceeding 5 ppb in 86% (19/22) of MoM hinge TKA patients, along with pseudotumor formation requiring revision in 18% of cases [14]. Similarly, elevated metal ion levels above the critical threshold have been observed in 70% of patients at mid-term follow-up with MoM hinged revision prostheses, and a comparative study of two MoM hinged TKA systems found critically high cobalt and chromium concentrations across both designs, with 81% of patients in one system exceeding 7 µg/L [15, 16]. These safety concerns have led investigators to recommend consideration of alternative bearings, which may have contributed to reduced implantation volumes and, consequently, fewer adverse event reports captured in the MAUDE database.

Device Problem Patterns and Clinical Correlation

The most frequently coded device problems for MBV were fracture, loosening not related to bone ingrowth, and loss of or failure to bond. These are consistent with the failure modes described in the broader arthroplasty literature. Notably, mechanical loosening has emerged as a particular concern for mobile bearing TKA designs. A 2025 follow-up analysis of the American Joint Replacement Registry (AJRR) involving over 445,000 TKAs demonstrated that mobile bearing designs were associated with a significantly increased risk of revision specifically for mechanical loosening in both posterior-stabilized (HR 2.1, 95% CI 1.8–2.5) and cruciate-retaining (HR 1.8, 95% CI 1.3–2.5) configurations, even when no difference existed for other revision causes [7].

Earlier AJRR analyses similarly demonstrated an overall increased revision risk with mobile bearing TKA (HR 1.36, 95% CI 1.24–1.49), and international registry collaborations involving over 300,000 non-posterior-stabilized TKAs confirmed a higher failure risk for mobile bearing designs (HR 1.43, 95% CI 1.36–1.51) [5, 6]. The finding that loosening-related device problem codes were among the most frequently reported in the MBV MAUDE dataset is qualitatively consistent with these registry-level signals. While MAUDE lacks a denominator and therefore cannot establish incidence or be directly compared with registry-derived rates, the recurrence of this failure mode across passive surveillance reports lends descriptive support to its clinical relevance for mobile bearing platforms.

For HRZ, fracture was the most frequently coded device problem, and implant failure was the most common patient problem. These findings are concordant with the known complication profile of hinged knee prostheses. A multicenter study of 290 non-tumoral hinged TKAs reported a 37% overall complication rate, with aseptic loosening (8%), periprosthetic fracture (3%), and mechanical failure (0.7%) among the device-related complications, and a 19% reoperation rate [10]. Nordic Arthroplasty Register data on over 2,500 primary rotating hinge TKAs demonstrated 15-year cumulative revision risks of approximately 14%, with periprosthetic joint infection accounting for nearly half of all revisions [17]. Notably, a nationwide Danish cohort study of over 143,000 primary TKAs found that the 10-year cumulative proportion of periprosthetic fracture was 12.4% for hinged designs, compared with 6.9% for condylar constrained knees and just 1.7% for standard minimally stabilized or posterior-stabilized TKAs, underscoring the substantially elevated fracture risk associated with increasing implant constraint [18]. The higher constraint inherent in hinged designs transmits greater stress to the bone-implant interface, which may predispose to both fracture and loosening, particularly in patients with compromised bone quality [11, 19].

Patient Outcomes

Pain (n = 22) and limited joint mobility (n = 9) were the most common patient problems reported for MBV, reflecting the predominant symptom burden that drives clinical evaluation after TKA. Notably, pain is the cardinal presenting symptom of multiple failure mechanisms after TKA, including aseptic loosening, instability, and component malposition, and has been identified as the primary cause of failure in up to 31% of revision TKAs [20–22]. The predominance of pain in MBV reports is notable given that AJRR data have demonstrated a two-fold increased risk of revision for mechanical loosening with mobile bearing compared to fixed-bearing designs (HR 2.1 for PS, HR 1.8 for CR) [7]. However, pain is multifactorial and may arise from infection, instability, malalignment, soft-tissue pathology, or other causes, and cannot be attributed specifically to loosening. These pain-related reports should therefore be interpreted as a nonspecific signal rather than a direct marker of this failure mode. Additionally, bearing dislocation or "spinout", a complication unique to mobile bearing designs occurring in approximately 0.2–0.6% of cases, represents another mechanism by which these devices may present with acute pain and limited mobility, particularly in the setting of flexion gap imbalance or ligamentous laxity [23, 24]. The clinically significant outcomes including one death, four bone fractures, and four implant failures underscore that while the absolute number of serious events captured in MAUDE is small, the consequences of device-related complications in this population can be severe. Periprosthetic fractures after TKA carry in-hospital mortality rates of approximately 6.4% and one-year mortality of 8–15%, with high rates of morbidity and reoperation, comparable to native hip fracture outcomes [25–27].

Manufacturer Concentration and Reporting Patterns

The concentration of MBV reports among a single manufacturer (Zimmer Biomet, 72.7%) and HRZ reports among Aesculap AG (41.7%) most likely reflects market share and device utilization volumes rather than differential safety profiles. This is a recognized phenomenon in MAUDE analyses: manufacturers with larger installed bases generate proportionally more reports [3, 13]. Furthermore, nearly a third of all manufacturer adverse event reports to MAUDE may not be submitted within the required 30-day regulatory window, with late reporting concentrated among a small number of manufacturers and devices, which may further distort temporal trends [13].

Limitations

Several important limitations must be acknowledged. First, the MAUDE database is a passive surveillance system subject to significant underreporting and variable report quality. However, all reports returned by each product code query were included without further exclusion, and data fields were recorded as returned directly by the database export, minimizing the introduction of selection or abstraction bias into the available reports. Second, the total number of devices implanted is unavailable, precluding calculation of incidence rates or comparison of safety profiles between device classifications. However, each product code was analyzed independently and reported using descriptive frequencies rather than derived rates, ensuring that conclusions are framed in terms of reporting patterns rather than implied incidence. Third, causality between the device and the reported adverse event cannot be established from MDRs alone; the most frequently coded device problem for MBV, "adverse event without an identified device or use problem" (n = 13), highlights the difficulty in attributing causation within this reporting framework. These findings should therefore be considered hypothesis-generating and interpreted alongside higher-quality evidence from arthroplasty registries and controlled studies.

Conclusion

This 15-year MAUDE analysis of MBV and HRZ knee prostheses identified loosening as a leading device problem for mobile bearing designs, corroborating registry evidence of increased mechanical loosening risk compared with fixed-bearing alternatives, while fracture and implant failure predominated in hinged prostheses, consistent with the higher mechanical demands of constrained designs used in complex reconstructive settings. Although limited by passive surveillance underreporting and the absence of implant denominators, these findings demonstrate that MAUDE can detect clinically meaningful adverse event signals that complement registry-based revision endpoints, supporting an integrated postmarket surveillance approach combining passive reporting, national arthroplasty registries, and prospective studies to optimize device safety monitoring.

Declarations

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Author Contribution

L.S. conceived and designed the study, performed the data analysis, developed the methodology, and drafted the original manuscript. K.E.E. contributed to the data analysis and revised the manuscript critically. A.S.C., J.M., J.S. (Satalich), and J.S. (Satpathy) contributed to the interpretation of the data and revised the manuscript critically. All authors approved the final version to be published and agree to be accountable for all aspects of the work.

Data Availability

The data used in this study are publicly available from the U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database.

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Figures

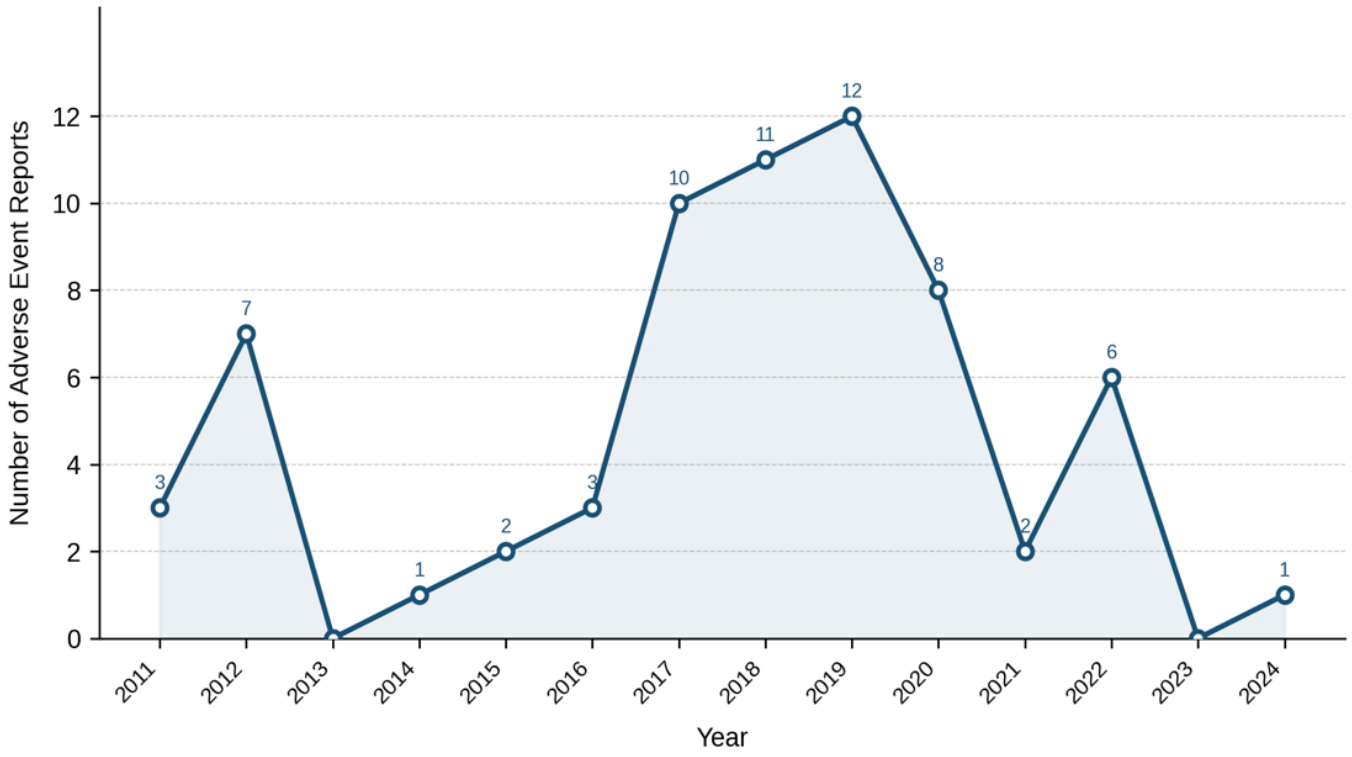


Figure 1

Annual adverse event report volume for the patellofemorotibial semi-constrained metal/polymer mobile bearing knee prosthesis (Product Code MBV) submitted to the FDA MAUDE database, January 1, 2011 through March 31, 2026. No reports were submitted in 2013, 2023, 2025 or 2026.

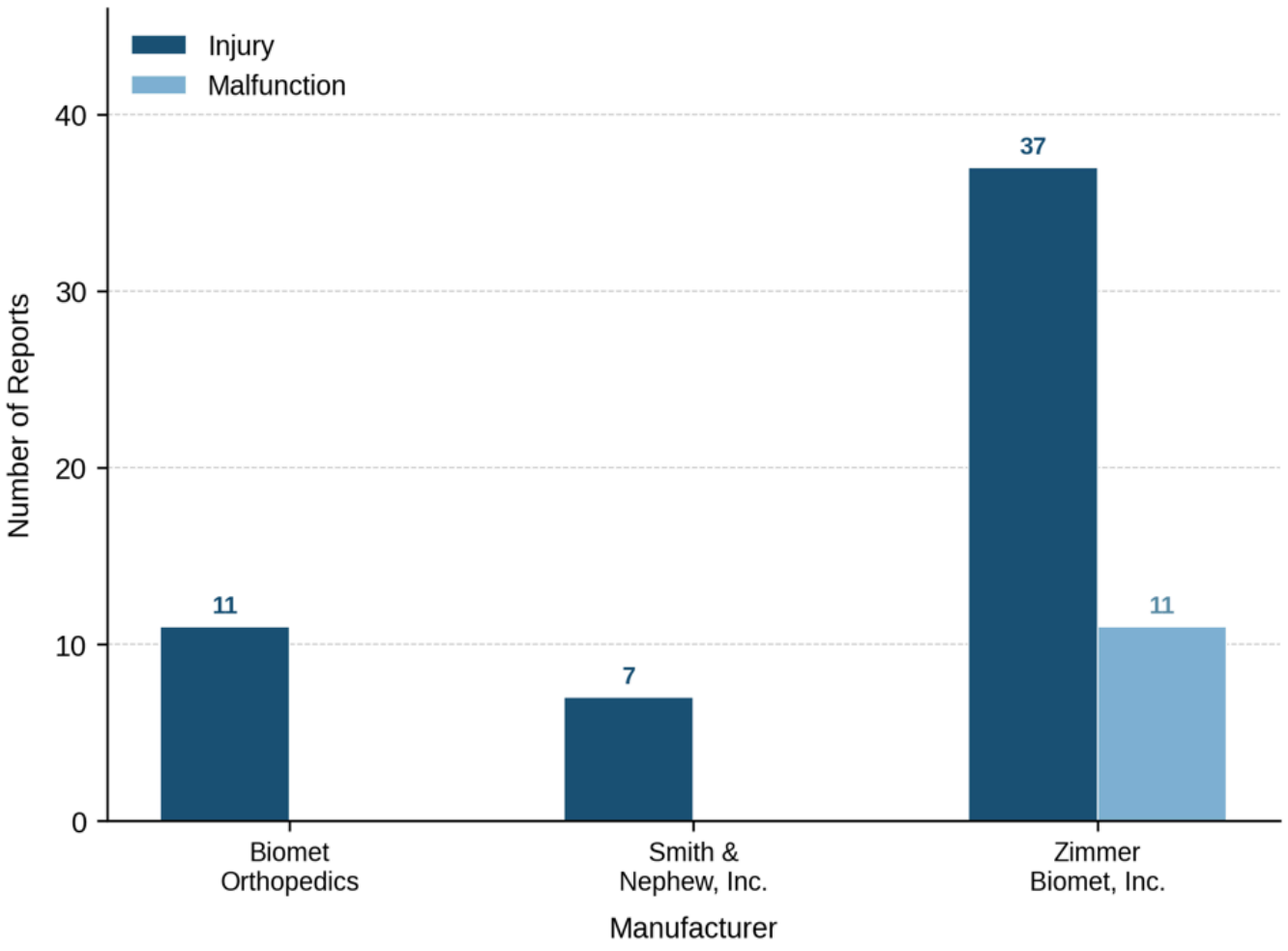


Figure 2

Adverse event reports by manufacturer and event type (injury vs. malfunction) for the patellofemorotibial semi-constrained metal/polymer mobile bearing knee prosthesis (Product Code MBV).

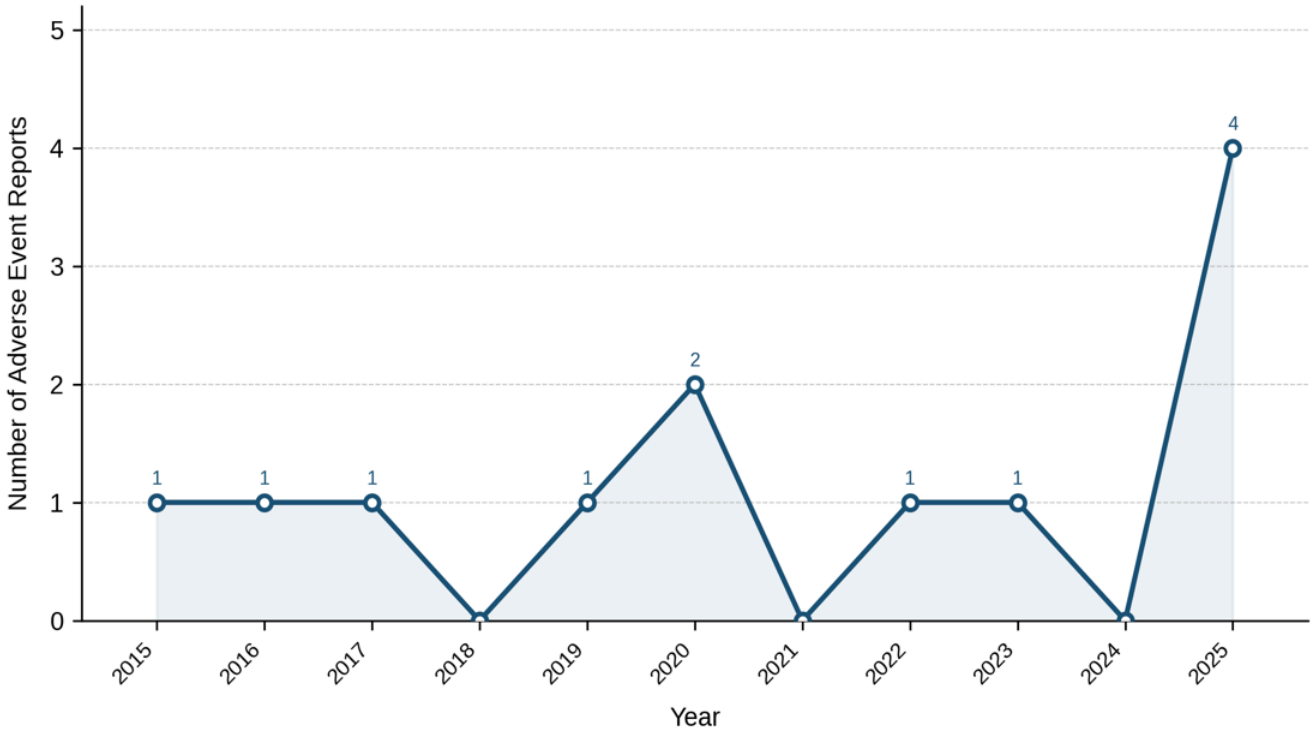


Figure 3

Annual adverse event report volume for the knee hinged metal/metal prosthesis (Product Code HRZ). No reports were identified from 2011 through 2014. No reports were submitted in 2018, 2021, 2024, or 2026.

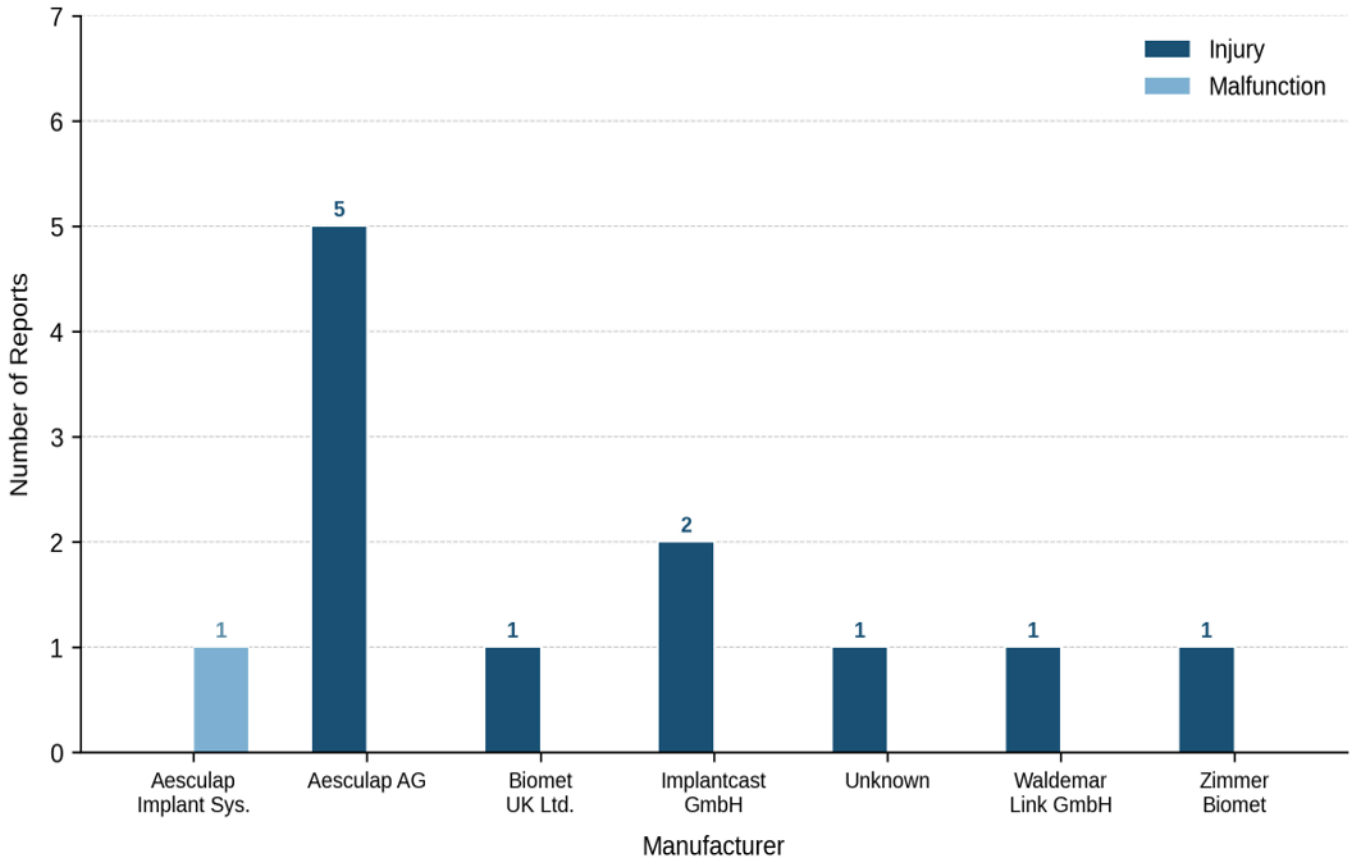


Figure 4

Adverse event reports by manufacturer and event type (injury vs. malfunction) for the knee hinged metal/metal prosthesis (Product Code HRZ).