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Timely recognition of total elbow and radial head arthroplasty adverse events: an analysis of reports to the US Food and Drug Administration

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Background: Recent recalls of several commonly used elbow arthroplasty implants have prompted interest in the modes by which elbow implants fail and the timing of reports of these failures.
Methods: We reviewed the adverse event reports to the US Food and Drug Administration's Manufacturer and User Facility Device Experience (MAUDE) database from 2012 to 2015 regarding elbow arthroplasty to determine the event date and the type of each adverse event.
Results: Among 179 total elbow adverse event reports, the most common modes of failure were implant dissociation (23%), loosening (22%), and infection (16%). The most common modes of failure among 58 radial head replacement reports were component dissociation (19%) and linkage screw failure (19%). The percentage distribution of adverse event types differed among different arthroplasty systems and from that reported in published reviews of elbow arthroplasty. Three implant recalls were implemented 2, 5, and 9 years after the first adverse event report in the MAUDE database. For 2 of the recalls, the first reports of the device failures were published 2 and 5 years after the first MAUDE reports.
Conclusions: The MAUDE database is a publicly funded and publicly available means by which surgeons can identify adverse events for the prostheses they use before such information becomes available through journal publication or recall notification. In this study, MAUDE data revealed a higher relative frequency of mechanical dissociation of elbow implants than what has been represented in the literature. Early identification of these adverse events may help surgeons by informing their implant selection and surgical technique.
Level of evidence: Level IV; Case Series From Large Database Analysis; Treatment Study

Keywords: Elbow arthroplasty; failure; recall; MAUDE database; dissociation; loosening

The prevalence of elbow arthroplasty has been increasing at a rate of 7.6% per year—a growth rate greater than that for hip or knee arthroplasty.[11,25] The current understanding of elbow arthroplasty adverse events is primarily based on the experience reported from high-volume centers with substantial experience with this procedure.[1,2,9,12,14,17,18,21,24,29-32,34-37,42,45] However, these reports do not capture the adverse events for

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the large percentage of elbow replacement procedures carried out by community surgeons with lower annual patient volumes; database studies have shown that the majority of elbow replacements are performed by surgeons performing fewer than 5 elbow replacements per year.[13,20] Surgeons and facilities with lower case volumes have been shown to have higher revision rates for elbow arthroplasty; in these instances, the percentage distribution of the different failure modes may differ from that of higher-volume practices.[13,20,38]

To gain a broader understanding of elbow arthroplasty failure modes, we investigated the Manufacturer and User Facility Device Experience (MAUDE) database of the US Food and Drug Administration (FDA) to which manufacturers, distributors, and user facilities are required to report all medical device–related adverse events, including those from community surgeons, as well as those from high-volume centers. It is accessible online[16] so that interested parties can search for reports of device-related adverse events by year, manufacturer, type of product, or specific device name. A number of publications have reported on medical device failures contained in this database,[3,4,8,19,23] including a recent analysis of adverse events after anatomic and reverse total shoulder arthroplasty.[39]

Nearly 9 of 10 orthopedic implants brought to market are granted clearance by the FDA through a pathway referred to as "510(k)," which allows for exemption from clinical trials on the premise that the new devices are "substantially equivalent" to existing devices.[10] However, orthopedic devices approved through this pathway have an unusually high failure rate. One study showed that 17.8% of orthopedic devices cleared through the 510(k) process were eventually recalled.[10]

Against this background, we were interested in determining whether the MAUDE database could provide early evidence of implant-related adverse events that might prove useful in the timely identification and avoidance of device failure. In this study, we analyzed recall and adverse events of total elbow arthroplasty (TEA) and radial head replacement that were reported to the FDA between 2012 and 2015 in an attempt to answer the following questions: (1) What were the commonly reported adverse event types for total elbow and radial head replacement implants? (2) Were the adverse event types different among various makes of total elbow and radial head implants? (3) How did the distribution of adverse events from the MAUDE database compare with that reported in the literature? (4) What was the lag time from the date of the report of an adverse event in the MAUDE database to journal publication and to implant recall?

Methods

Data acquisition and classification

The FDA database of medical device–related adverse events from 2012 to 2015 was obtained from the MAUDE website.[16] Total and partial elbow arthroplasty devices were identified based on the following product device classifications as listed in the FDA's published Device Classification list: JDB ("Prosthesis, Elbow, Semi-Constrained, Cemented"); JDC ("Prosthesis, Elbow, Constrained, Cemented"); KWI ("Prosthesis, Elbow, Hemi-, Radial, Polymer"); KWJ ("Prosthesis, Elbow, Hemi-, Humeral, Metal"); and PIX ("Elbow Joint Metal/Polymer, Constrained, Porous Coated, Uncemented Prosthesis").[15] The adverse event database was limited to these 3-letter device codes, which identified 710 reports of elbow device–related adverse events. Many of these events were duplicate reports for a single event, which were identified manually by sorting the list of reports by date, manufacturer, and event narrative. After removal of reports that were not related to elbow arthroplasty, reports without adequate information to determine the type of adverse event, reports without an event date, and duplicate reports for a single event, 238 unique device-related adverse event reports remained (Fig. 1).

The type of implant was then classified as TEA (n = 179), radial head arthroplasty (RHA, n = 58), or radiocapitellar joint replacement (n = 1). Although some adverse events had multiple modes (eg, infection and loosening), a primary failure mode was assigned based on the narrative report description using a consistently applied hierarchy of failure modes (Table I) so that each adverse event was counted only once. For total elbows and for radial head replacements, the percentage distribution of each of the primary failure modes among the total of all failure modes was calculated. The percentage distribution of primary failure modes was also determined for each event year and for each prosthesis manufacturer.

The same codes were used to search the FDA database of device recalls,[28] and a list was tabulated. For the 3 recently withdrawn radial head prostheses, all reported adverse events were downloaded from the MAUDE database and the cumulative number of events was graphically depicted as a function of time.

Results

Device-related adverse events

For the 179 total elbow replacement adverse event reports, the most common mode of failure was implant dissociation (23%), followed by loosening (22%) and infection (16%) (Table II). The majority of implant dissociation cases were due to hinge pin failure (13%) or linkage screw failure (4%). Isolated humeral loosening (13%) was more common than ulnar loosening (4%). Additional adverse event types included bearing failure (8%), stem breakage (6%), insertion difficulties (6%), and periprosthetic fracture (6%). The percentage distribution of the total elbow adverse events showed a decline in the relative percentage of failures due to hinge pin failure and an increase in the relative incidence of humeral loosening over the period studied (Fig. 2). The relative percentage distribution of total elbow adverse event types showed substantial differences among manufacturers (Fig. 3). The distribution of these adverse events was different than the distribution of adverse events in a recent systematic review of elbow arthroplasty failures, in which implant dissociation was not commonly reported.[44]

For the 58 radial head implant adverse event reports, the most common failure modes were dissociation (19%) and linkage screw failure (19%) (Table III). Other modes included difficulty of insertion (12%), loosening (12%),

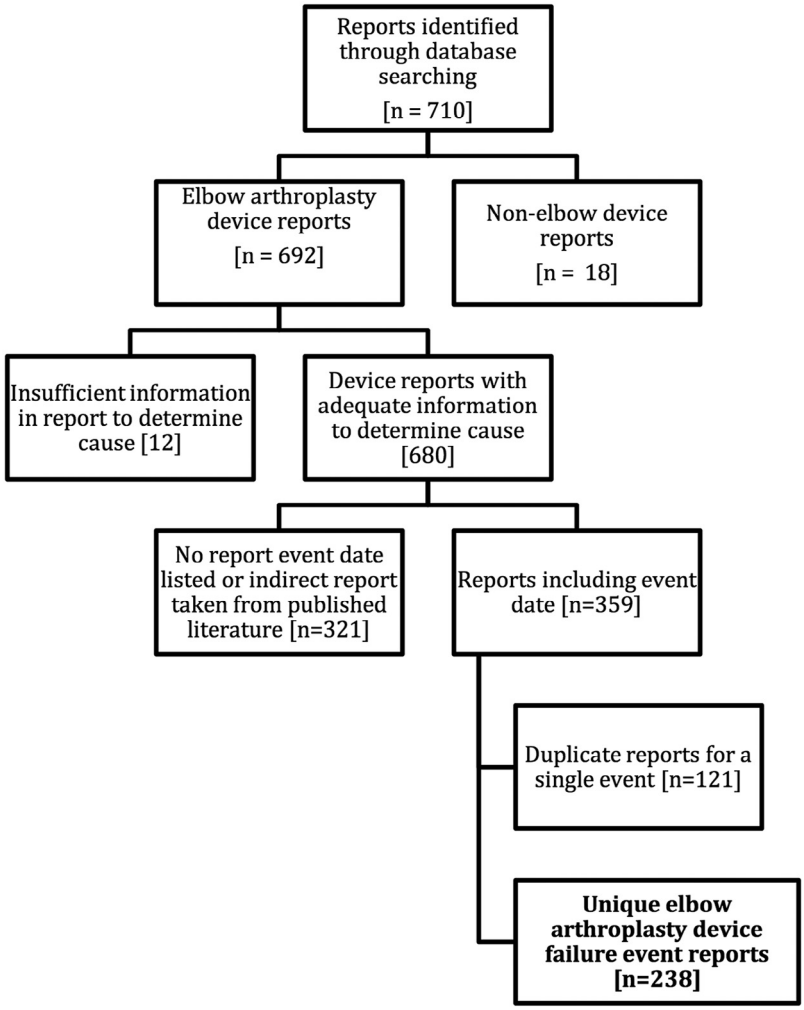

Figure 1 Selection of reports for analysis.

Table I FDA and publication data on 3 recalled elbow implants

Implant	510(k) number	FDA clearance date	Year of first MAUDE report	Year of first journal publication	Year of recall	Quantity in commerce
Stryker (formerly SBi/Avanta, San Diego, CA, USA) rHead	K011819	June 19, 2001	2008	2010[43]	2017[40]	16,992[6]
DePuy Synthes Radial Head	K112030	June 1, 2011	2012	2017[41]	2017[7]	50,311
Acumed Slide-Loc radial head	K131845	September 30, 2013	2015	None known	2017[5]	13,076

FDA, US Food and Drug Administration; *MAUDE*, Manufacturer and User Facility Device Experience.

packaging irregularities (10%), and stem breakage (7%). The relative percentage distribution of radial head implant adverse events showed an initially high rate of dissociation in 2012, followed by a decline in subsequent years (Fig. 4). The adverse event reports included implants from 8 different manufacturers. Each of the 3 prostheses with a substantial number of reported adverse events during the observation period ($n \geq 7$ cases from 2012 to 2015) showed markedly different percentage distributions of the common adverse event types (Fig. 5). The solitary report on radiocapitellar arthroplasty indicated failure due to humeral loosening.

Recalls

Review of the FDA recall database showed 9 recalls of TEA devices and 6 recalls of RHA devices (Table IV). One additional recall (Stryker rHead; Stryker, Kalamazoo, MI, USA)[40] was reported by communication from the manufacturer to

Table II Primary failure modes for elbow arthroplasty devices

Failure mode in hierarchical order
Infection
Device breakage
Linkage screw failure
Hinge pin failure
Dissociation
Periprosthetic fracture
Bearing wear
Loosening
Triceps failure
Elbow instability
Insertion or trial problem
Heterotopic ossification
Overstuffing
Metal sensitivity
Pain
Packaging issue
Part unavailability

Table III Primary failure modes among total elbow arthroplasties in order of percentage of all total elbow failure modes

Mode of failure	n (% of total)
Dissociation	41 (22.9)
Hinge pin failure	24 (13.4)
Linkage screw failure	8 (4.5)
Other dissociation	9 (5.0)
Loosening	39 (21.7)
Humeral component loosening	24 (13.4)
Ulnar component loosening	7 (3.9)
Unspecified loosening	8 (4.5)
Infection	29 (16.2)
Bearing wear	14 (7.8)
Stem breakage	11 (6.1)
Problem with implant insertion	11 (6.1)
Unavailability of correct parts	11 (6.1)
Periprosthetic fracture	10 (5.6)
Elbow instability	7 (3.9)
Miscellaneous	6 (3.4)

surgeons and did not yet appear in the FDA database at the time of our data collection. Among these devices, 1 TEA (DePuy Acclaim; DePuy, Warsaw, IN, USA) and 3 radial head devices (Synthes Radial Head [Synthes, West Chester, PA, USA], Acumed Slide-Loc [Acumed, Hillsboro, OR, USA], and Stryker–Small Bone Innovations rHead [Small Bone Innovations, Morrisville, PA, USA]) have been withdrawn from the market. For the 3 recent radial head recalls (Table V), the MAUDE database was searched for all adverse event reports using the code KWI (Prosthesis, Elbow, Hemi-, Radial, Polymer) and the manufacturer name. The cumulative number of adverse event reports to the MAUDE database is depicted by year for the Synthes (Fig. 6), Acumed (Fig. 7), and Stryker–Small Bone Innovations (Fig. 8) radial head prostheses. Adverse event reports were first submitted to the

Table IV Primary failure modes among radial head arthroplasties in order of percentage of all radial head arthroplasty failure modes

Mode of failure	n (% of total)
Dissociation	22 (38.0)
Linkage screw failure	11 (19.0)
Other dissociation	11 (19.0)
Loosening	7 (12.1)
Problem with implant insertion	7 (12.1)
Problem with implant packaging	6 (10.3)
Stem breakage	4 (6.9)
Miscellaneous	4 (6.9)
Unavailability of correct parts	3 (5.2)
Problem with implant trials	3 (5.2)
Infection	2 (3.4)

MAUDE database starting 2 to 9 years before the recalls in 2017 (Synthes, 2012; Acumed Slide-Loc, 2015; and Stryker–Small Bone Innovations, 2008). Published reports regarding the recalled devices first appeared in 2017 for the Synthes implant[28] and 2010 for the Stryker–Small Bone Innovations implant[43] (then marketed by Avanta, San Diego, CA, USA); we were unable to identify any publication that specifically referenced the recalled Acumed Slide-Loc implant.

Discussion

In contrast to systematic reviews of published literature, which capture primarily the adverse events from high-volume centers, the MAUDE database includes the adverse events that have occurred in community practice as well. In 2011, Voloshin et al[44] systematically reviewed the literature for complications after TEA. They identified 64 studies of TEA including 2938 TEA procedures with an overall complication rate of 24.3 ± 5.8%. Loosening (either clinical or radiographic) was the most common complication, accounting for 24% of complications among linked designs, followed by dislocation (8% of complications), deep infection (6% of complications), intraoperative fracture (5%), prosthesis fracture (5%), and ulnar nerve complications (5%). Disassembly accounted for only 4% of their reported complications. Similar results were published in 2017 in a systematic review by Prkic et al[33]; in their study, the most common complications were aseptic loosening (43%), infection (22%), periprosthetic fracture (13%), and dislocation (9%). Again, disassembly made up a small percentage (3%) of their published complications. By contrast, in our study of the MAUDE database, dissociation was the most common failure mode (23% of the total number of adverse events), followed by loosening (22%), infection (16%), bearing wear (8%), and stem breakage (6%). It is possible that the higher observed relative frequency of dissociation in the MAUDE database is related to inclusion of data from community surgeons that are not reflected in published literature. In any event, the MAUDE database provides insight that is not apparent from publications.

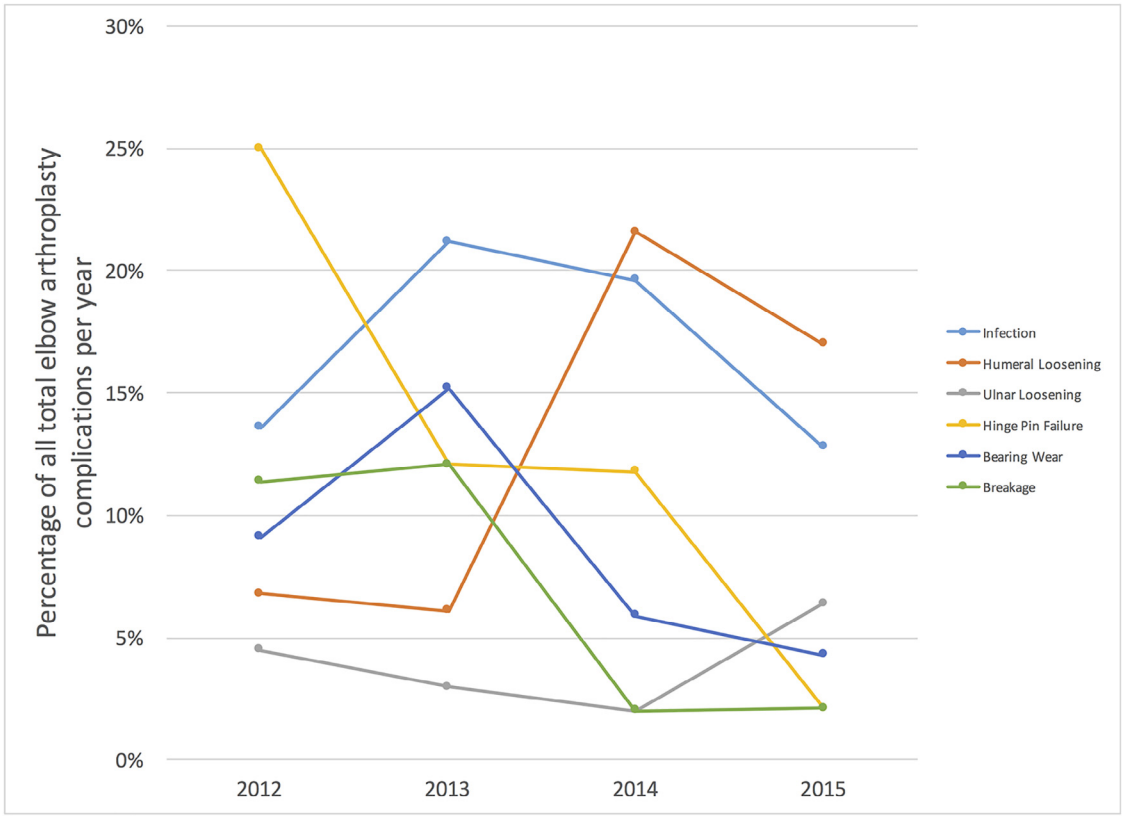

Figure 2 Percentage distribution of the 6 most common total elbow arthroplasty failure modes by year.

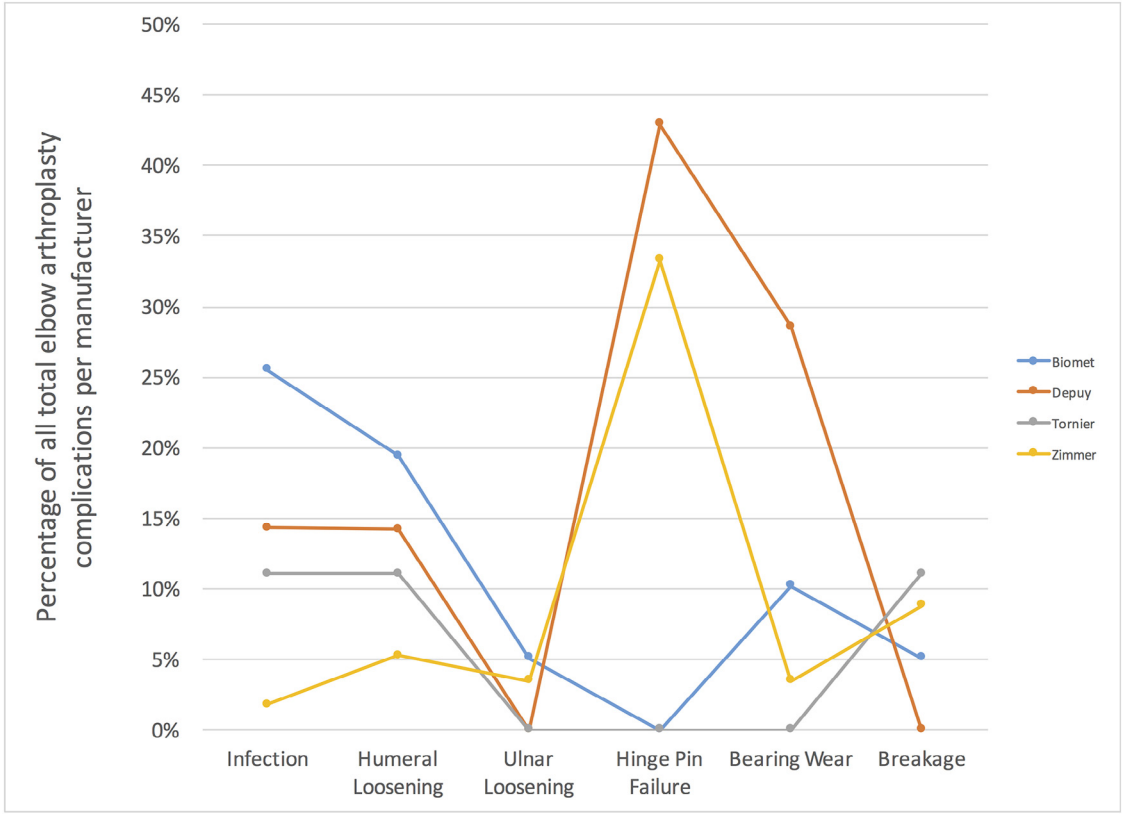

Figure 3 Percentage distribution of the 6 most common total elbow arthroplasty failure modes by manufacturer.

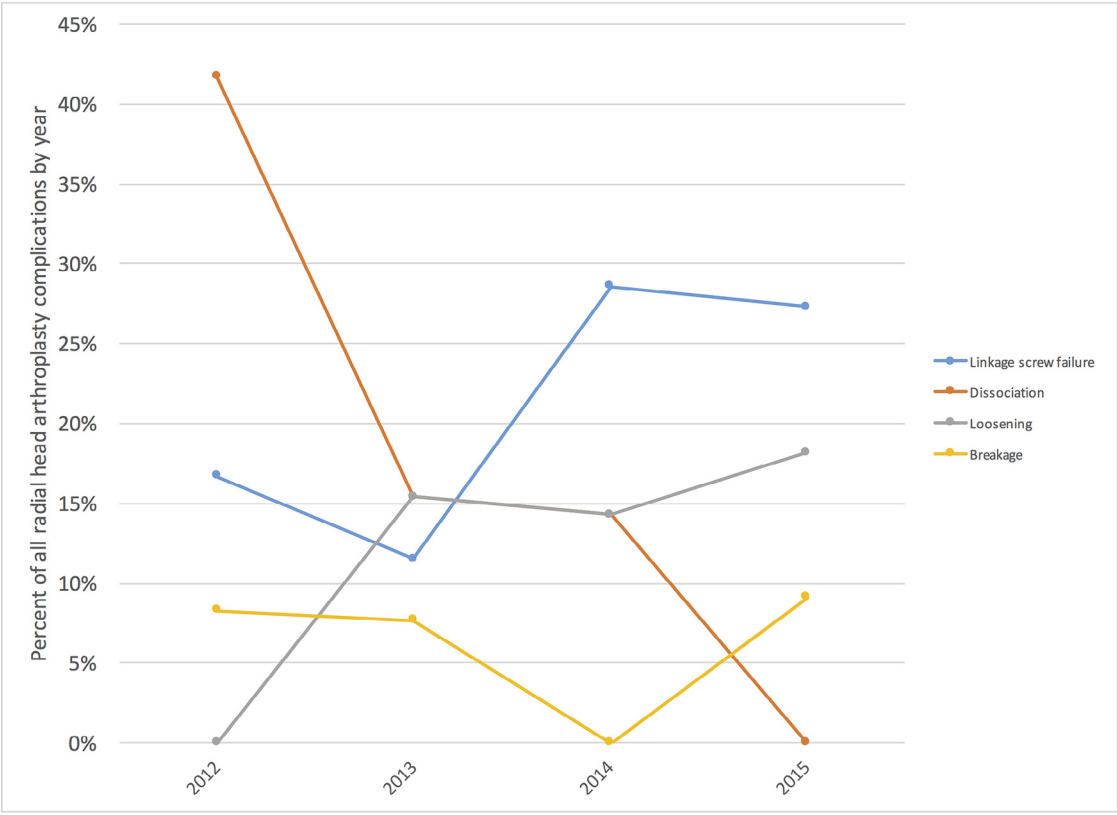

Figure 4 Percentage distribution of the 4 most common radial head arthroplasty failure modes by year.

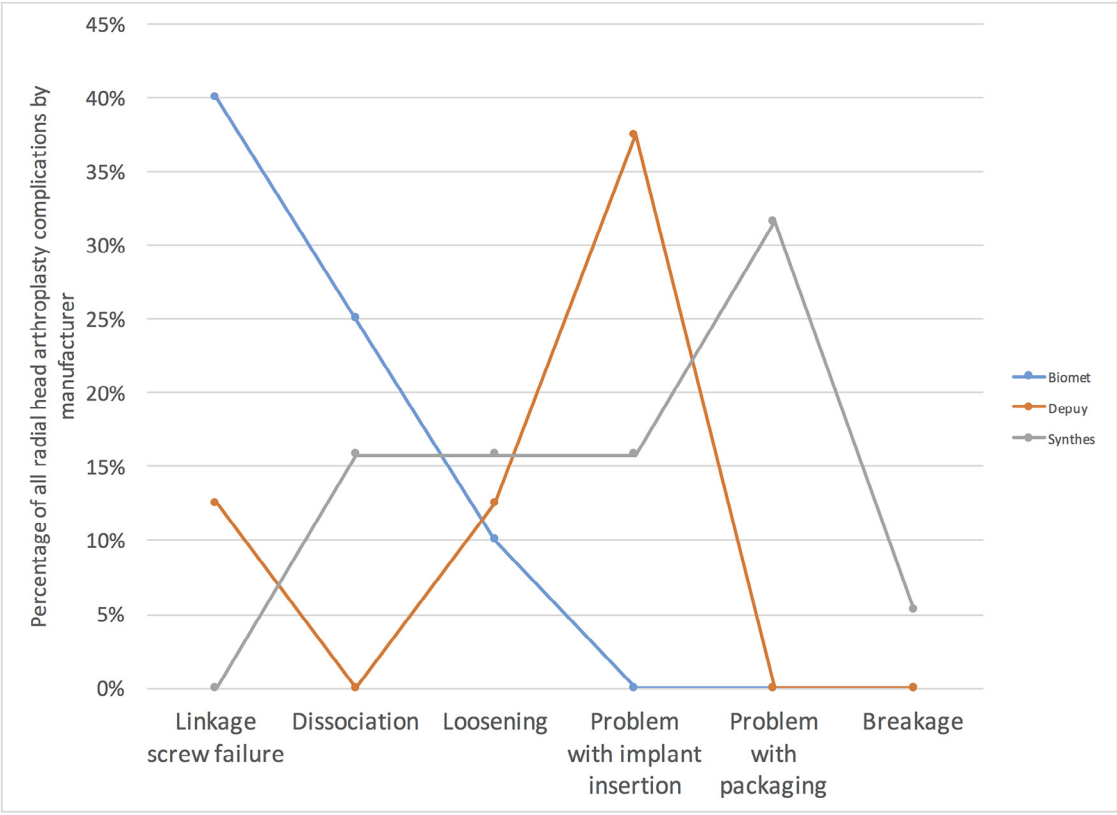

Figure 5 Percentage distribution of the 6 most common radial head arthroplasty failure modes by manufacturer.

Table V Recalls of total elbow and radial head arthroplasty devices

Recall year	Manufacturer	Implant type	Recall type	Recall reason
2004	Zimmer (Warsaw, IN, USA)	Coonrad-Morrey total elbow	Limited	Some right-sided components were incorrectly etched as "left."
2006	DePuy	Acclaim total elbow	Market withdrawal	The ulnar bearing may have damaged the implant's polyethylene sleeve.
2008	Biomet (Warsaw, IN, USA)	Discovery total elbow	Limited	Some components had the incorrect size on the package.
2009	Zimmer	Coonrad-Morrey total elbow	Limited	Extra-small implant trials were difficult to remove.
2011	Biomet	Discovery total elbow	Limited	A package was found to contain 2 male condylar components rather than a female component and a male component.
2011	Tornier (Memphis, TN, USA)	Latitude total elbow	Limited	Some models had a humeral screw that did not function as designed.
2012	Zimmer	Coonrad-Morrey total elbow	Limited	Some kits included an extra-small hinge pin rather than a regular inner pin.
2013	Small Bone Innovations	Radial head	Limited	There was an increased risk of implants breaching the sterile pouches.
2013	Synthes	Radial head	Limited	The trial head may have come loose from the implant stem during manipulation of the arm.
2014	Skeletal Dynamics (Miami, FL, USA)	Align radial head	Limited	A report was received in which the Align radial stem fractured.
2014	Biomet	ExploR radial head	Limited	One lot may have been missing threads for the set screw.
2014	Biomet	Discovery total elbow	Limited	The surface finish was coated with grit blast instead of glass bead blast as specified.
2016	Zimmer	Coonrad-Morrey total elbow	Limited	One bushing replacement lot did not contain a humeral bushing.
2017	Synthes	Radial head	Market withdrawal	There was the possibility that the radial stem may loosen postoperatively.
2017	Acumed	Slide-Loc radial head	Market withdrawal	Complaints were made regarding instrumentation performance, trial product design, and implant dissociations.
2017	Stryker	rHead radial head	Market withdrawal	The device may not have performed at an acceptable level.

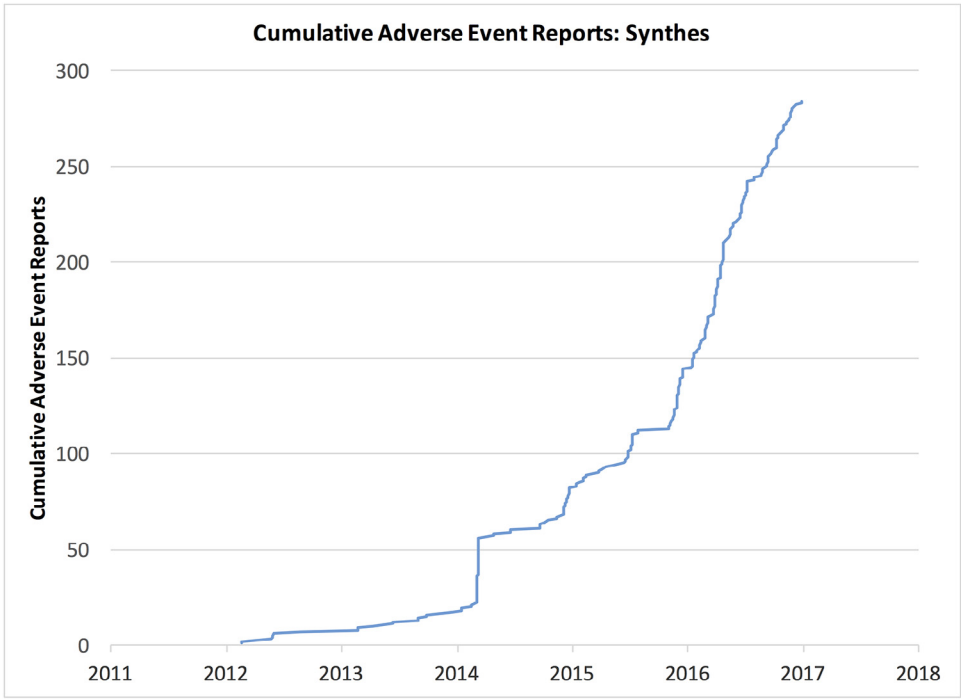

Figure 6 Cumulative number of adverse event reports among radial head arthroplasty devices searching for the manufacturer Synthes.

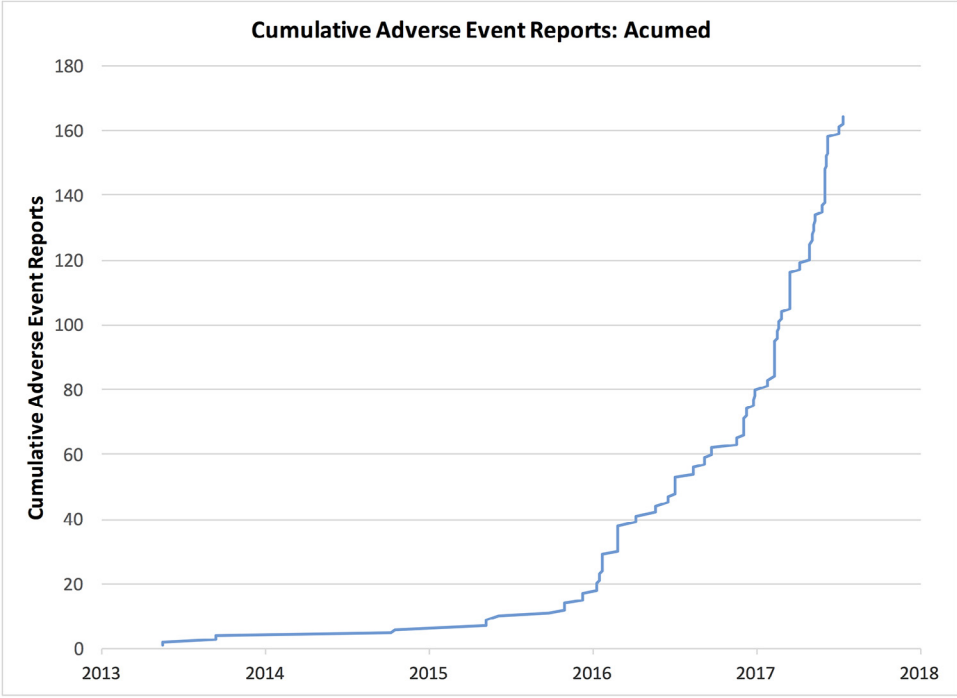

Figure 7 Cumulative number of adverse event reports among radial head arthroplasty devices searching for the manufacturer Acumed (it should be noted that this includes all Acumed radial head implants).

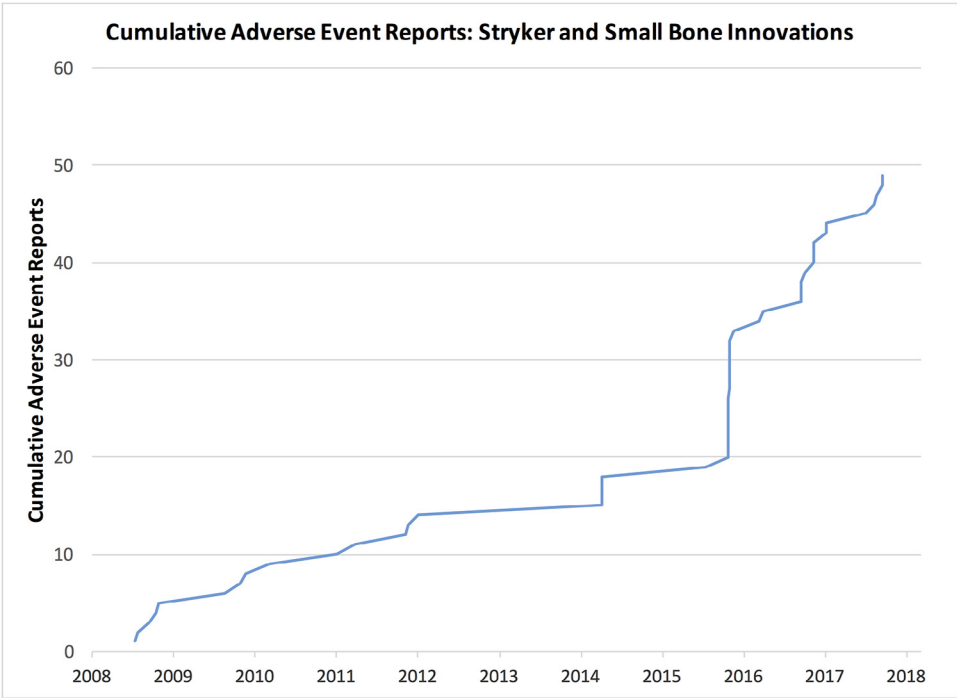

Figure 8 Cumulative number of adverse event reports among radial head arthroplasty devices searching for the manufacturer Stryker–Small Bone Innovations.

Few studies have reviewed the failures of RHA. One recent meta-analysis identified 82 cases of reoperation after RHA[27] taken from 3 case series published by high-volume tertiary centers.[22,26] Among these cases, loosening (n = 22, 27% of all reoperations) was the most common reason for failure, followed by stiffness (n = 21, 26%), overstuffing (n = 10, 12%), and elbow instability (n = 9, 11%). By contrast, in our review of the MAUDE data, component dissociation (n = 22, 38%

of failures) was the most common adverse event, followed by loosening (n = 7, 12.1%) and problems with implant insertion (n = 7, 12.1%).

The results of this study draw attention to certain trends in the adverse events reported for TEA and RHA. The relative frequency of hinge pin failure has, for example, declined over the study period and is likely because of a design change in one of the most commonly used implants. However, an increase in the relative frequency of humeral loosening among TEA implants has occurred over time. When implants from different manufacturers are compared, different modes of failure become apparent. The 3 recent recalls of radial head implants all showed a dramatic increase in the MAUDE adverse event reports in advance of the date of recall.

This study should be viewed in light of certain limitations. First, as with any database study, the completeness and accuracy of the data cannot be independently verified. Second, the MAUDE data cannot be used to determine the absolute rate of adverse events with a given prosthesis because the total number of cases for that implant in the sampled population is not known.

Conclusions

This analysis of the FDA MAUDE and recall databases for elbow arthroplasty demonstrates the value of these resources to practicing surgeons. Compared with the distribution of failure modes taken from published literature on TEA and RHA, the MAUDE database showed a higher relative frequency of implant dissociation, indicating that this may be an under-recognized problem. The increase in adverse event reports in the years prior to 3 recent recalls of radial head devices suggests that surgeons may benefit from studying relevant MAUDE reports to obtain timely data on the failure modes for implants that they currently use or are considering using in the future before the failure modes are reported in publications or before a device is recalled. Knowledge of prevalent failure modes may help inform surgeons' choices of implant and surgical technique.

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