OPENFDA MEDICAL DEVICE ADVERSE EVENT ANALYSIS

Analysis of FDA Medical Device Adverse Event Reports

BVI Medical

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1. Executive Summary

This report analyzes **12,814** FDA medical device adverse event reports submitted between **June 04, 2009** and **October 31, 2025** (a period of **196.9** months). The dataset includes **6** unique manufacturers and **10** unique device brands. The average reporting rate was **65** reports per month, with peak reporting of **206** reports in **May 2015**.

Table 1: Summary statistics of FDA MAUDE reports

Metric	Value
Total Reports	12,814
Date Range	June 04, 2009 to October 31, 2025
Reporting Duration	5993 days (196.9 months)
Unique Manufacturers	6
Unique Device Brands	10
Average Monthly Reports	65 reports/month
Maximum Monthly Reports	206 reports in May 2015

2. Methodology

2.1. Data Source

The search of the FDA Manufacturer and User Facility Device Experience (MAUDE) database was conducted using the openFDA Device Event API. Retrieved JSON-formatted data were downloaded directly from the API and subsequently processed and cleaned for analysis.

2.2. Data Standardization and Fuzzy Matching

The analysis uses automated text matching to standardize manufacturer and brand names across reports. FDA MAUDE reports often contain variations in spelling, capitalization, and formatting (e.g., “INC”, “Inc.”, or “LLC”).

Names with ≥75% similarity are grouped together under a single standardized name. This reduces data fragmentation and provides more accurate counts.

> **i** Note
>
> For technical details on the fuzzy matching algorithm, see Section 8.3.2 in the Technical Appendix.

2.3. Problem Classification and Data Quality Filters

Patient and product problems are extracted and categorized, excluding non-informative categories to focus on meaningful data patterns.

Key Considerations:

- Individual reports may list multiple product problems per incident
- Individual reports may list multiple patient problems per incident
- Total problem occurrences can exceed the total number of reports
- Each problem occurrence is counted separately to identify the most frequent failure modes and issues

> **i** Note
>
> For the complete list of excluded categories, see Section 8.4 in the Technical Appendix.

2.4. Concentration-Based Analysis Methodology

This analysis identifies the critical few problems, manufacturers, and brands that account for the majority of occurrences. Rather than selecting an arbitrary "top 10", we dynamically identify categories that collectively represent approximately 80% of all reported occurrences.

Categories are ranked by frequency, and those accounting for approximately 80% of the data are analyzed in detail. The remaining items are grouped as "Other(s)". This approach ensures no category is artificially split.

> **i** Note
>
> For implementation details, see Section 8.3.3 in the Technical Appendix.

2.5. Statistical Analysis of Temporal Trends

Monthly reporting patterns are analyzed using standard statistical methods to identify unusual increases or decreases in reporting activity.

Variability Metrics: Standard deviation and coefficient of variation measure how much monthly reports fluctuate around the average.

Peak and Valley Detection: Months with unusually high or low reporting (more than 2 standard deviations from average) are flagged as statistically significant.

> **i** Note
>
> For detailed statistical methodology, see Section 8.3.4 in the Technical Appendix.

3. Manufacturer Analysis

3.1. Top Manufacturers

A total of **1** manufacturer(s) account for **92%** of all reports (**11,783** reports), as shown in Table 2 .

The remaining **1,031** reports (**8%**) are from other manufacturers.

The top manufacturer, **ALCON RESEARCH**, accounts for **11,783** reports (**92%** of total).

The following table presents the detailed breakdown of manufacturers and their report volumes.

Table 2: Manufacturer(s) representing 92% of reports

Rank	Manufacturer	Reports	% of Total
1	ALCON RESEARCH	11,783	91.95%
NA	Other(s)	1,031	8.00%

4. Device Brand Analysis

4.1. Top Device Brands

A total of **2** device brand(s) account for **87.6%** of all reports (**11,228** reports), as shown in Table 3 .

The remaining **1,586** reports (**12.4%**) are from other brands.

The top device brand, **ACRYSOF**, accounts for **8,345** reports (**65.1%** of total).

The following table presents the detailed breakdown of device brands and their report volumes.

Table 3: Device brand(s) representing 87.6% of reports

Rank	Brand	Reports	% of Total
1	ACRYSOF	8,345	65.12%
2	ACRYSOF IQ PANOPTIX TRIFOCAL IOL	2,883	22.50%
NA	Other(s)	1,586	12.40%

4.2. Brand Distribution by Product Code

A total of **4** product code(s) account for **89.4%** of all reports with product codes (**11,450** reports).

The remaining **1,364** reports (**10.6%**) are from other product codes.

Table 4: Product code(s) representing 89.4% of reports

Rank	Product Code	Reports	% of Total
1	HQL	4,242	33.10%
2	MFK	3,841	29.98%
3	MJP	1,835	14.32%

Rank	Product Code	Reports	% of Total
4	KYB	1,532	11.96%
NA	Other(s)	1,364	10.60%

4.3. Brand Distribution with Product Code Breakdown

The following figure shows the top device brands with their composition by product code.

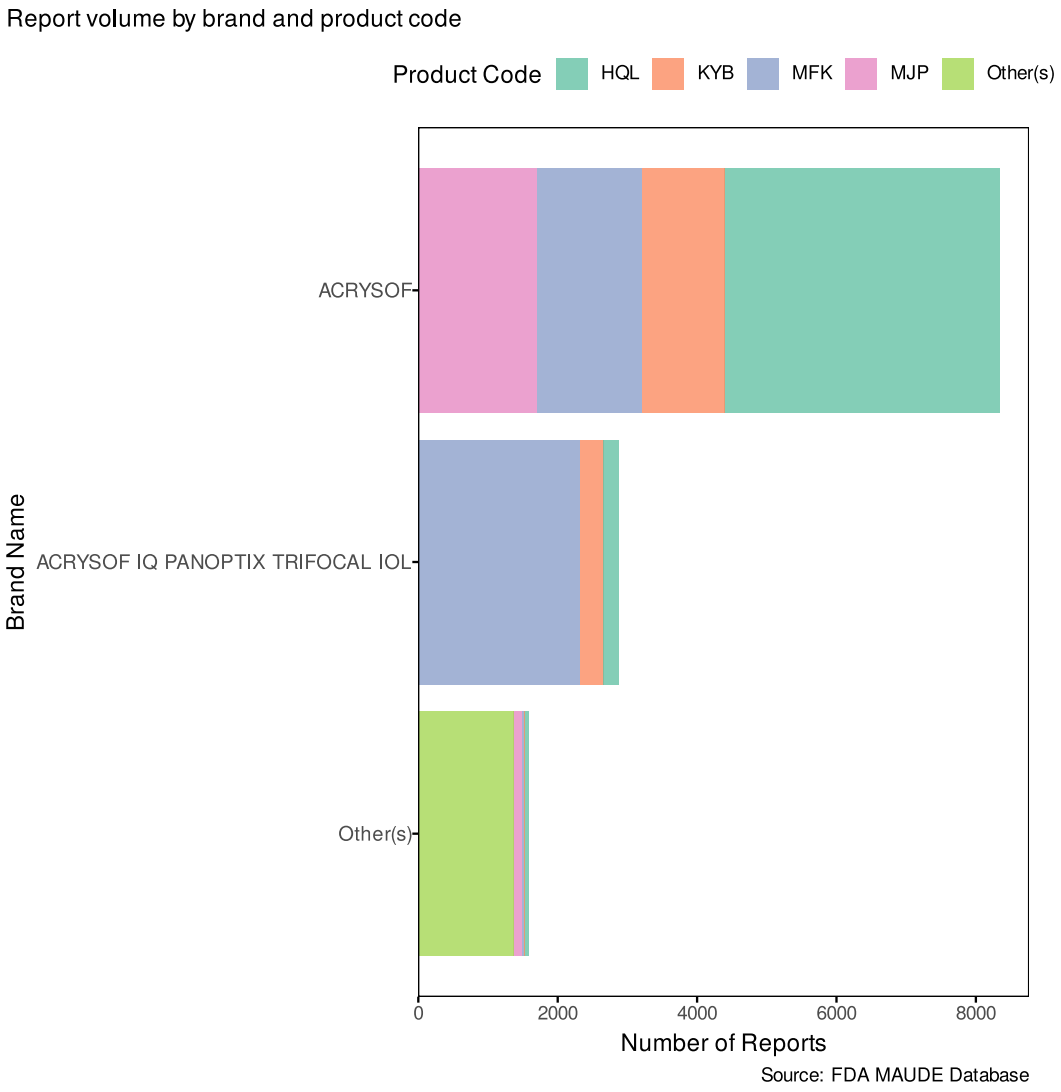

Figure 1: Device brand(s) representing 87.6% of reports, colored by product code

4.4. Brand Temporal Trends

The following figure illustrates the cumulative growth of adverse event reports for the top 5 device brands over time.

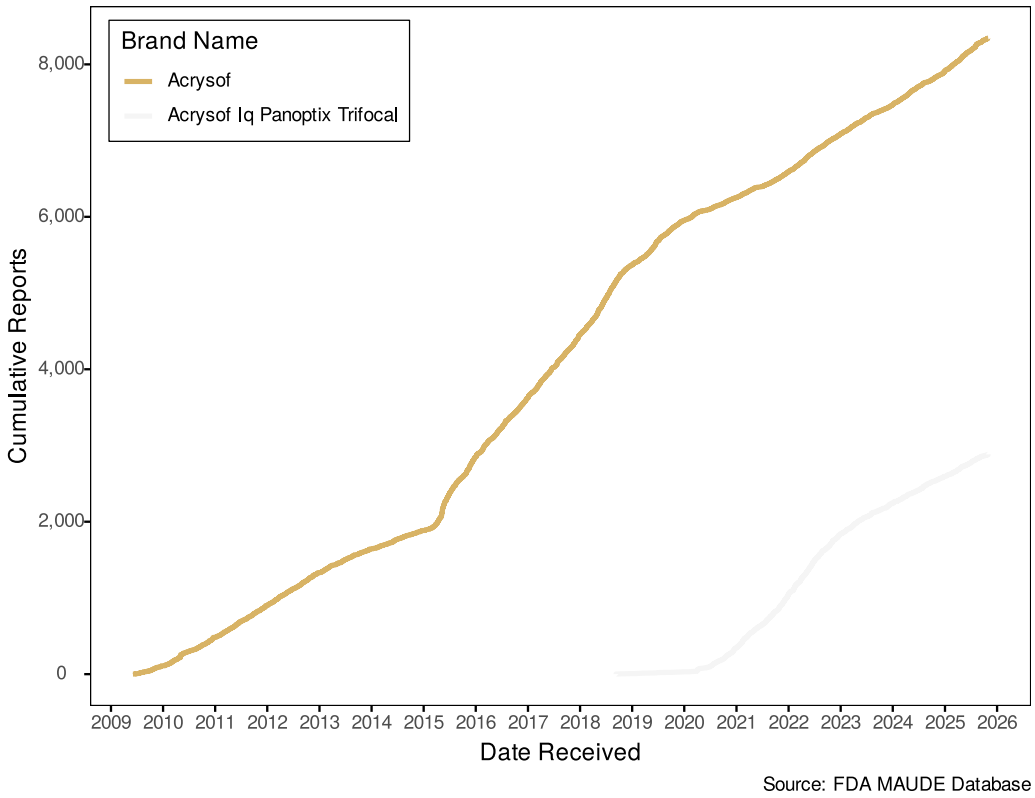

Figure 2: Cumulative adverse event reports by top 5 brands

5. Temporal Trend Analysis

5.1. Overall Reporting Trends

The following figure presents the monthly trend of adverse event reports over the analysis period.

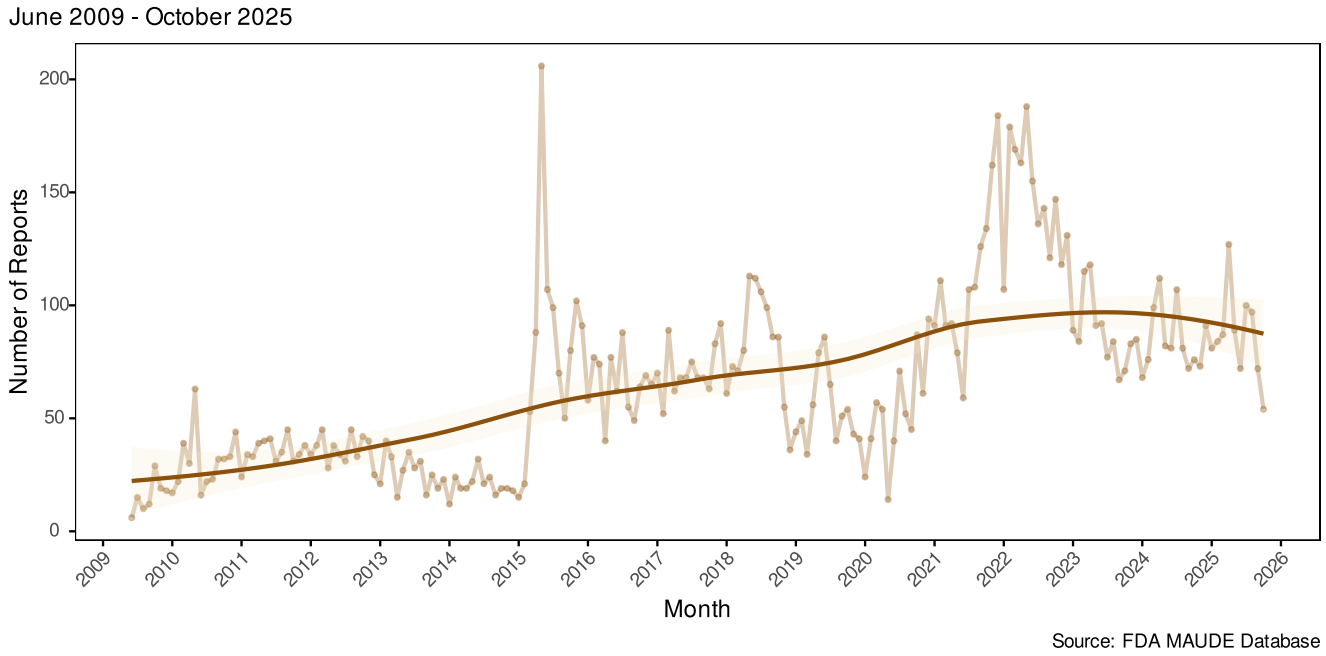

Figure 3: Monthly trend of FDA MAUDE reports

5.2. Statistical Trend Analysis

Reporting Variability: The average monthly reporting rate is **65** reports (SD = **39.4**, CV = **60.5%**).

Statistically Significant Peaks (≥2 SD above mean, $p < 0.05$):

9 month(s) identified:

- **May 2015**: 206 reports (z=3.58, +216.7%)
- **May 2022**: 188 reports (z=3.12, +189%)
- **December 2021**: 184 reports (z=3.02, +182.9%)
- **February 2022**: 179 reports (z=2.89, +175.2%)
- **March 2022**: 169 reports (z=2.64, +159.8%)
- **April 2022**: 163 reports (z=2.49, +150.6%)
- **November 2021**: 162 reports (z=2.46, +149.1%)
- **June 2022**: 155 reports (z=2.28, +138.3%)
- **October 2022**: 147 reports (z=2.08, +126%)

5.3. Cumulative Reports Over Time

The following figure shows the cumulative accumulation of adverse event reports throughout the study period.

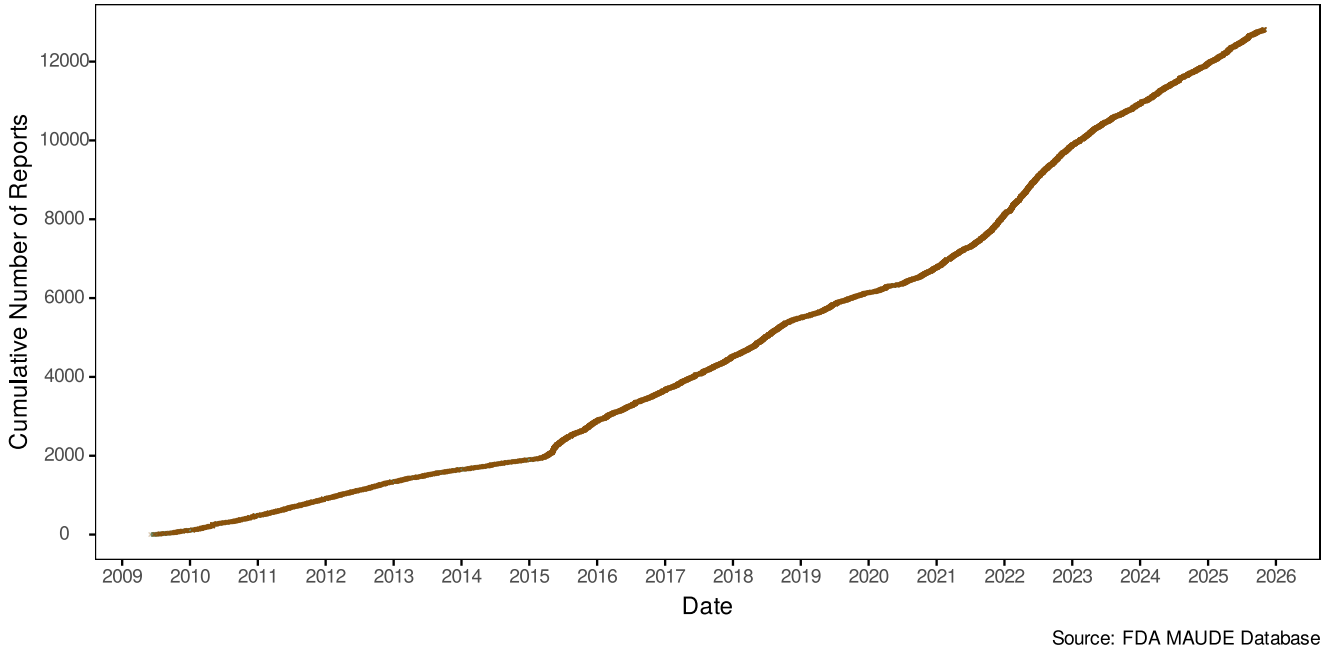

Figure 4: Cumulative FDA MAUDE reports over time

6. Product Problem Analysis

6.1. Product Problems Analysis

A total of **24** product problem type(s) account for **80.1%** of all reported problem occurrences (**5,977** occurrences).

The remaining **1,481** problem occurrences (**19.9%**) are categorized as “Other(s)”.

The following figure displays the most frequently reported product problems, accounting for the majority of problem occurrences.

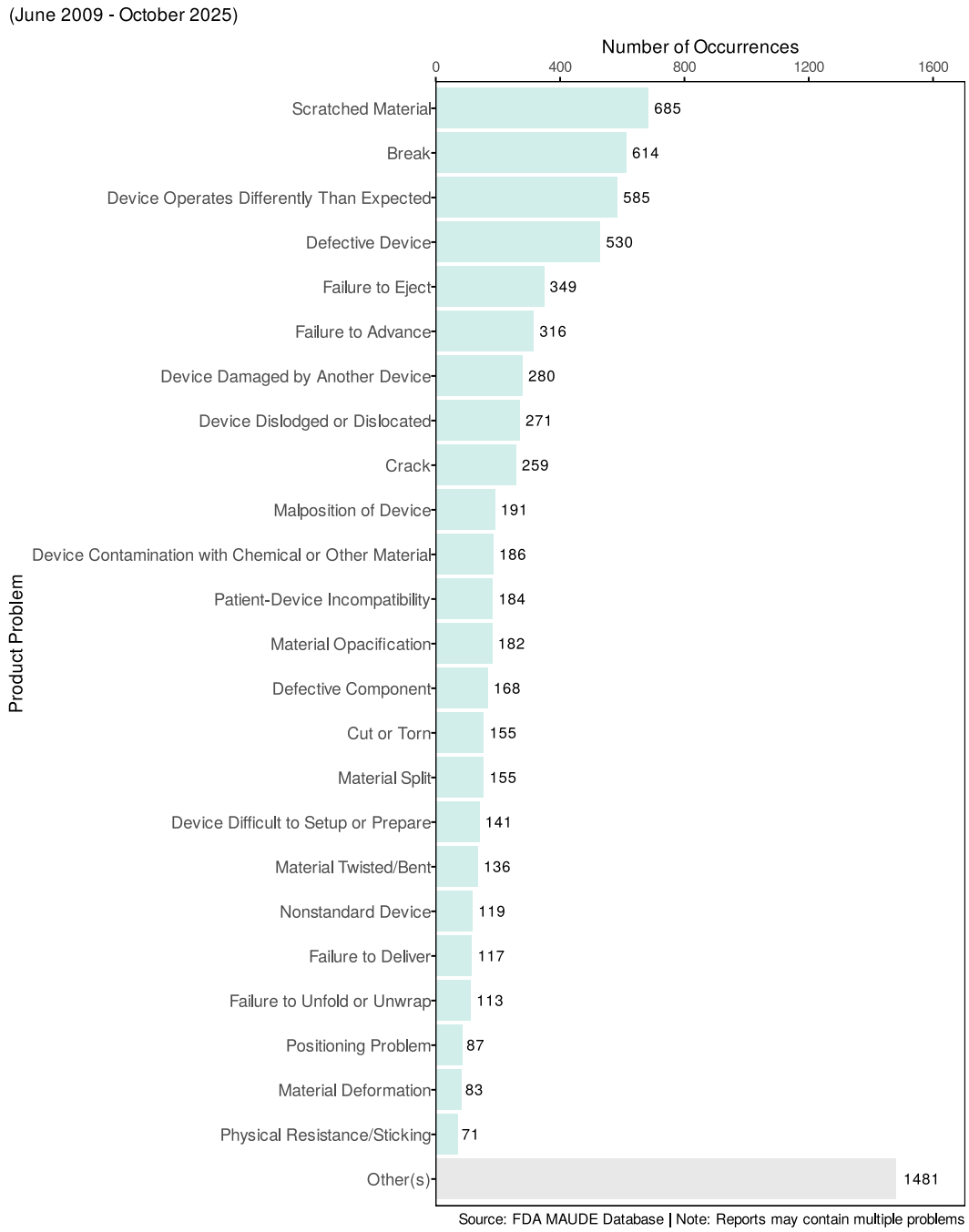

Figure 5: Product problems representing 80.1% of problem occurrences, plus Other(s) category

All Product Problems Representing 80.1% of Data:

1. **Scratched Material** - 685 occurrences (9.2%)
2. **Break** - 614 occurrences (8.2%)
3. **Device Operates Differently Than Expected** - 585 occurrences (7.8%)
4. **Defective Device** - 530 occurrences (7.1%)
5. **Failure to Eject** - 349 occurrences (4.7%)
6. **Failure to Advance** - 316 occurrences (4.2%)
7. **Device Damaged by Another Device** - 280 occurrences (3.8%)

8. **Device Dislodged or Dislocated** - 271 occurrences (3.6%)
9. **Crack** - 259 occurrences (3.5%)
10. **Malposition of Device** - 191 occurrences (2.6%)
11. **Device Contamination with Chemical or Other Material** - 186 occurrences (2.5%)
12. **Patient-Device Incompatibility** - 184 occurrences (2.5%)
13. **Material Opacification** - 182 occurrences (2.4%)
14. **Defective Component** - 168 occurrences (2.3%)
15. **Cut or Torn** - 155 occurrences (2.1%)
16. **Material Split** - 155 occurrences (2.1%)
17. **Device Difficult to Setup or Prepare** - 141 occurrences (1.9%)
18. **Material Twisted/Bent** - 136 occurrences (1.8%)
19. **Nonstandard Device** - 119 occurrences (1.6%)
20. **Failure to Deliver** - 117 occurrences (1.6%)
21. **Failure to Unfold or Unwrap** - 113 occurrences (1.5%)
22. **Positioning Problem** - 87 occurrences (1.2%)
23. **Material Deformation** - 83 occurrences (1.1%)
24. **Physical Resistance/Sticking** - 71 occurrences (1.0%)

7. Patient Problem Analysis

7.1. Patient Problems Analysis

A total of **16** patient problem type(s) account for **80.4%** of all reported patient problem occurrences (**8,493** occurrences).

The remaining **2,076** problem occurrences (**19.6%**) are categorized as “Other(s)”.

The following figure presents the most frequently reported patient problems associated with these adverse events.

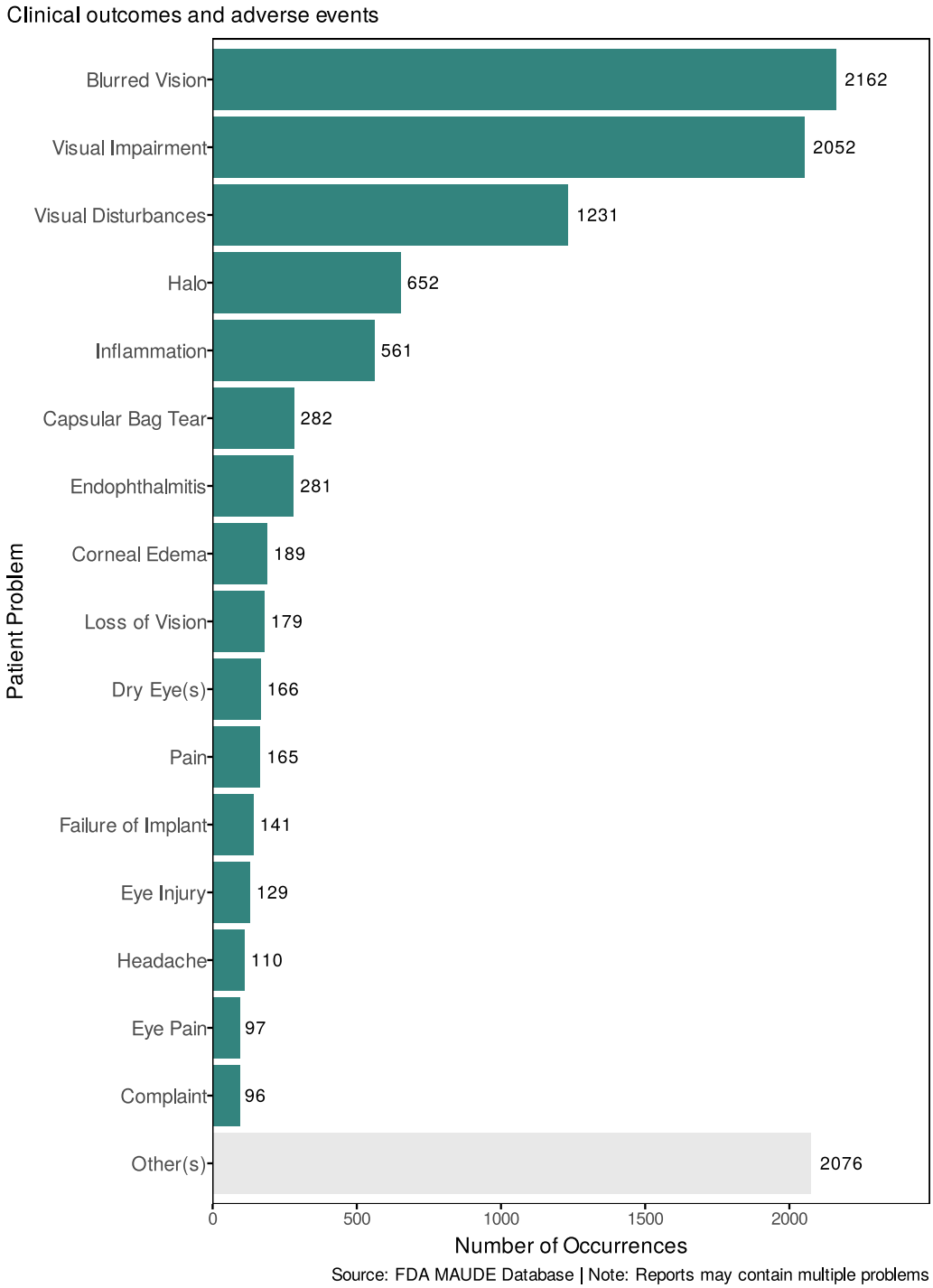

Figure 6: Patient problems representing 80.4% of problem occurrences, plus Other(s) category

All Patient Problems Representing 80.4% of Data:

1. **Blurred Vision** - 2,162 occurrences (20.5%)
2. **Visual Impairment** - 2,052 occurrences (19.4%)
3. **Visual Disturbances** - 1,231 occurrences (11.6%)
4. **Halo** - 652 occurrences (6.2%)

5. **Inflammation** - 561 occurrences (5.3%)
6. **Capsular Bag Tear** - 282 occurrences (2.7%)
7. **Endophthalmitis** - 281 occurrences (2.7%)
8. **Corneal Edema** - 189 occurrences (1.8%)
9. **Loss of Vision** - 179 occurrences (1.7%)
10. **Dry Eye(s)** - 166 occurrences (1.6%)
11. **Pain** - 165 occurrences (1.6%)
12. **Failure of Implant** - 141 occurrences (1.3%)
13. **Eye Injury** - 129 occurrences (1.2%)
14. **Headache** - 110 occurrences (1.0%)
15. **Eye Pain** - 97 occurrences (0.9%)
16. **Complaint** - 96 occurrences (0.9%)

8. Technical Appendix

8.1. Data Source

- **Database**: OpenFDA Medical Device Adverse Events
- **API Access**: `https://open.fda.gov/apis/device/event/`

8.2. Analysis Tools

- **Python 3.x** with pandas and rapidfuzz for data processing
- **R** with tidyverse, ggplot2, and lubridate for visualization
- **Fuzzy Matching**: RapidFuzz library for text standardization
- **Visualization**: ggplot2 with custom base R theme
- **Report Generation**: Quarto for reproducible analytics

8.3. Detailed Methodology

8.3.1. Data Query Information

Search Query: Acrysof IQ

OpenFDA Database: event

API Endpoint: https://api.fda.gov/device/event.json

Search Executed: 2025-11-20 14:59:44

Data Last Updated: 2025-11-11

Total Results: 15,345 records found in OpenFDA database

Records Retrieved: 15,345 records

Records Analyzed: 12,814 records (after data cleaning)

8.3.2. Fuzzy Matching Algorithm

Algorithm: The analysis uses the Levenshtein distance algorithm, which calculates the minimum number of single-character edits (insertions, deletions, or substitutions) needed to transform one string into another.

Implementation: The RapidFuzz library implements partial ratio matching, which finds the best matching substring and calculates similarity as a percentage (0-100%).

Matching Process: 1. Text is normalized: converted to uppercase, special characters removed, whitespace standardized 2. Similarity scores are calculated between all name pairs 3. Names with ≥75% similarity are grouped together 4. The shortest variant in each group becomes the canonical name

Example: "MEDTRONIC INC", "Medtronic Inc.", and "MEDTRONIC" would all be grouped under "MEDTRONIC" (shortest variant).

8.3.3. Concentration-Based Analysis

Implementation Details: 1. Items are sorted by frequency (descending order) 2. Cumulative percentages are calculated for each item 3. Items are included if the *previous* item's cumulative percentage was below 80% 4. This ensures complete categories—no category is split between main analysis and "Other(s)"

Key Features: - The exact percentage may exceed 80% to maintain category integrity - All categories meeting the threshold are listed, not just a predetermined number - The "Other(s)" category provides perspective on the long-tail distribution

8.3.4. Statistical Methods

Variability Metrics: - **Standard Deviation (SD)**: Measures the typical spread of monthly reports around the average - **Coefficient of Variation (CV)**: Expresses SD as a percentage of the mean (CV = SD/Mean × 100) - **Interpretation**: CV < 15% = low variability, 15-30% = moderate, >30% = high variability

Outlier Detection: - **Z-scores**: Measure how many standard deviations each month's report count deviates from the mean - **Threshold**: Months with |z-score| ≥ 2 are flagged as statistically significant ($p < 0.05$) - **Interpretation**: Indicates unusually high (peaks) or low (valleys) reporting activity beyond ~95% of normal distribution

8.4. Exclusion Criteria

Patient Problems Excluded:

- No Code Available
- No Known Impact Or Consequence To Patient
- Symptoms or Conditions
- No Information
- No Consequences Or Impact To Patient
- Appropriate Clinical Signs
- No Clinical Signs
- Conditions Term / Code Not Available
- Appropriate Term / Code Not Available
- Insufficient Information
- No Patient Involvement
- Reaction
- Patient Problem/Medical Problem

Product Problems Excluded:

- Adverse Event Without Identified Device or Use Problem
- Appropriate Term/Code Not Available
- Appropriate Term / Code Not Available
- Unknown (for use when the device problem is not known)
- Insufficient Information
- No Apparent Adverse Event

8.5. Report Metadata

- **Generated**: 2025-11-20 14:59:48
- **Dataset Version**: 2025-10-31
- **Total Records Analyzed**: 12,814
- **Analysis Pipeline**: OpenFDA Medical Device Adverse Event Analysis v2.1

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