



The 2019 FDA Breast Implant Recall And Subsequent Reporting Surge: A Controlled MAUDE Database Analysis

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BACKGROUND

- In 2019, the FDA recalled Allergan BIOCELL textured breast implants for their association with breast implant-associated anaplastic large cell lymphoma (BIA-ALCL).
- This decision was followed by a significant amount of patient and media attention regarding the safety of breast implants
- Whether the recall selectively increased reporting of the malignancy or instead triggered a broader attention to implant-related complications remains poorly characterized.



Is the recall associated with an increase in all breast implant reports driven by non-malignant complications, rather than a true increase in reported BIA-ALCL events?

METHODS

Data Source & Study Sample

119,942 breast implant device reports and 118,508 matched adverse event narratives from 2010–2024 were analyzed.

NLP-Based Narrative Classification

Natural language processing classified narratives into BIA-ALCL, rupture, capsular contracture, prophylactic removal, and litigation-related reports.

Natural Control Comparison

Non-recalled manufacturers, including Mentor and Sientra, were used as natural controls to distinguish recall-specific effects from media-driven reporting behavior.

Manufacturer-Stratified ITS Analysis

Interrupted Time Series analysis compared Allergan versus Mentor and Sientra using manufacturer-stratified Poisson regression with robust standard errors.

METHODS

Monthly Time-Series Modeling

Monthly-resolution ITS models were fitted with Newey–West standard errors.

Sensitivity Analyses

Sensitivity analyses included COVID-era exclusion, alternative intervention points, & litigation adjustment.

Multiple Testing Correction

Holm–Bonferroni correction was applied across seven event types to control for multiple comparisons.

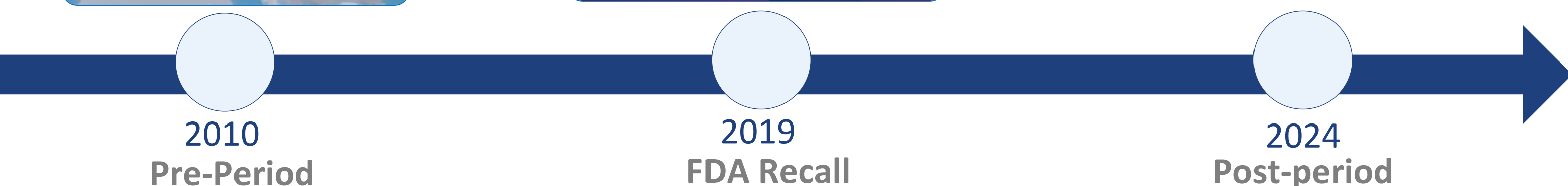
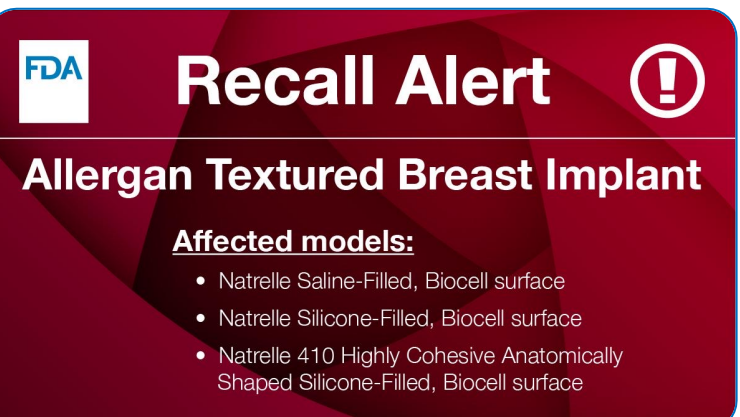
FDA Maude Database
• 119,942 Breast implants
• 118,508 matched narratives

Natural language processing and extraction

- BIA-ALCL
- Rupture
- Capsular contracture
- Prophylactic removal
- Litigation-related

Interrupted Time Series Analysis

- **Sensitivity analysis:** COVID, alternative intervention timing, litigation-adjusted



REPORT SURGES

Manufacturers	IRR	p-value
Allergan	126.2	<0.001
Mentor	239.7	<0.001
Sientra	193.5	<0.001

RESULTS

- Reports surged across all manufacturers and increased monthly ($p < 0.001$)
- Increase was driven by capsular contracture (IRR = 172.8) and rupture (IRR 63.6), $p < 0.001$.
- While BIA-ALCL reports increased in absolute number (IRR = 21.9), it declined proportionally from 1.6 to 0.7% of total reports.
- Prophylactic removal accelerated over time ($p < 0.001$)

DISCUSSION

- External events (recall, litigation, media) can drive temporary increases in reporting independent of true complication rates
- Rise in prophylactic removal likely reflects shifts in patient risk perception and clinician responsiveness

CONCLUSION

MAUDE data capture both clinical events and sociobehavioral responses during this period

REFERENCES

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