



The VizMark **VM-1 Study**



Advancing Long-Term
Monitoring for High-Risk Women



The VizMark VM1 gadolinium-enhanced visual tumor marker was evaluated in a multi-year observational study to assess its performance in long-term monitoring of biopsy-confirmed benign breast masses, specifically fibroadenomas.

This study, presented at RSNA 2023, tracked patients over periods of up to **seven years** and found that VM1 markers remained exceptionally stable—with **no migration, no degradation, and no change in brightness**. These findings support VM1's value as a reliable, long-term reference point for tracking tissue changes, especially in **high-risk patients** who require ongoing surveillance.





Study Design

Patient Cohort

36 total patients received VM1 tumor markers

Biopsy-confirmed fibroadenomas

7 patients

Analyzed follow-up cases

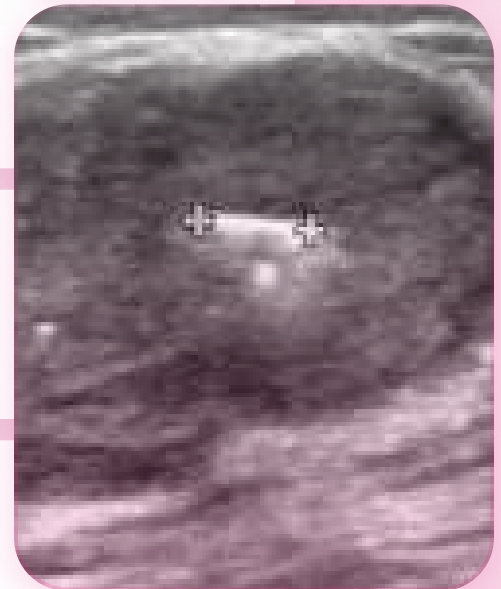
3 patients
(6-month, 2-year, and 7-year data)

Imaging modalities

Mammography, Ultrasound, **MRI**

Timeline

Markers placed between 2016–2020,
followed through 2023

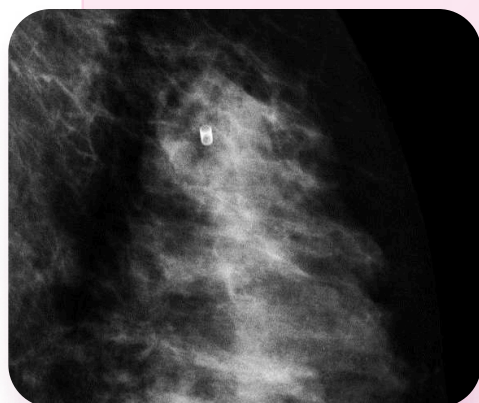


Subsequent imaging studies were reviewed to assess changes in marker position, brightness, and the surrounding tumor bed over time.



Clinical Highlights

7-Year Stability & Imaging Performance



The VM1 marker showed **no migration** or shift in position



Maintained **brightness and clarity** over time



No degradation of the marker or surrounding tumor bed

One patient followed for 7 years retained full marker visibility across all imaging sessions

Marker showed **increased brightness over time in Ultrasound**, aiding visualization

Tumor beds remained unchanged, supporting stability of benign diagnosis

These results confirm that VM1 can remain in the body indefinitely when placed in benign tissue and serve as a long-term imaging aid without causing complications.



MRI Compatibility & Multimodal Benefits

The VM1 marker was developed to be **MRI-compatible** and **artifact-free**, a major advantage for patients requiring regular MRI follow-ups. This aligns with **ACR recommendations**, which prioritize MRI screening for high-risk women due to its superior sensitivity.

VM1's **visibility across multiple modalities**—MRI, mammography, and ultrasound—provides flexibility in care planning, enabling radiologists to confidently track changes using the most appropriate tool for each patient.





Why It Matters

10% of women

will develop
fibroadenomas



Up to 75% of breast biopsies are benign

but markers often remain in place for life

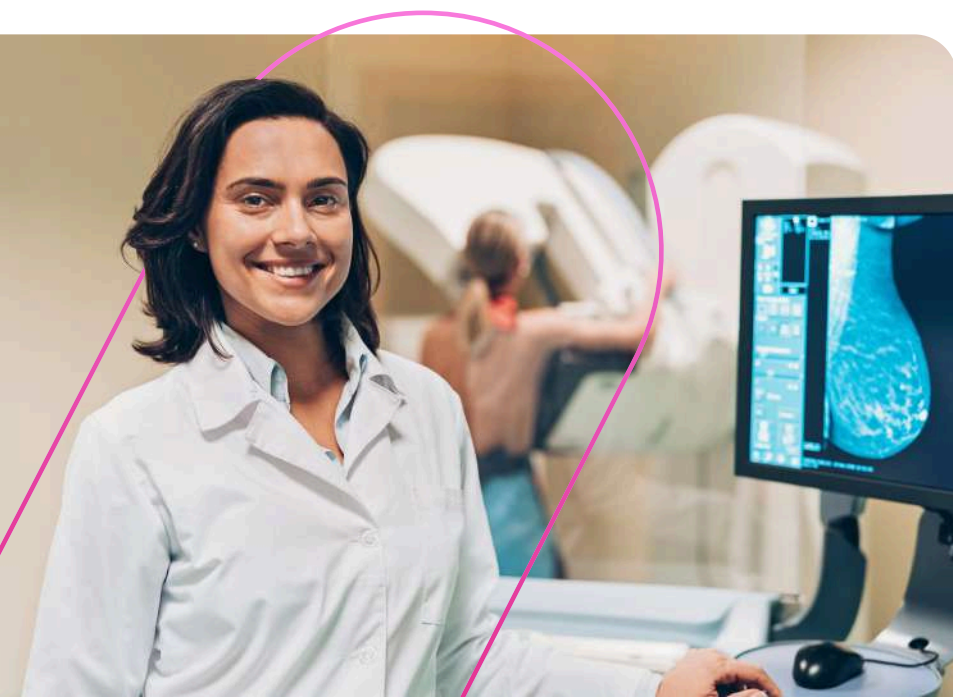
MRI is the standard

for high-risk patients with
dense tissue or genetic
predisposition



VM1 is the first FDA-approved soft tissue marker in nearly a decade

optimized for MRI use



For radiologists and patients, this means **fewer repeat procedures, greater imaging confidence, and better continuity of care** over time.



Conclusion

The RSNA clinical review confirms that VM1 is a significant innovation in breast health monitoring. For patients undergoing biopsy for benign lesions, VM1 delivers:



A long-term reference point

Reliable, multi-modality visibility

Increased MRI clarity over time

Reduced need for follow-up biopsies

This is more than a marker. It's a new foundation for **resilient, proactive breast care**—especially for women who need it most.



Learn more at
www.vizmark.com