

Medical Device Surveillance and Assessment (MDSA)

Unit of Clinical Analysis

Newsletter



Postmarket Surveillance of Mesh Performance After Inguinal Hernia Repair

In a study published in *JAMA Surgery*, Kaiser Permanente general surgeons and Medical Device Surveillance and Assessment researchers evaluated inguinal hernia repair mesh performance using an automated safety surveillance system designed to detect emerging safety signals earlier.

“Automated, longitudinal surveillance of mesh performance enables health systems to identify potential safety concerns that may not be evident in clinical trials, supporting more informed, data driven decisions about device selection.”

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Study Details

The study included 104,241 adult patients undergoing 124,458 mesh based inguinal hernia repairs within Kaiser Permanente from 2010-2020. Mesh performance was assessed using DELTA (Data Extraction and Longitudinal Trend Analysis), an automated postmarket surveillance method that monitors reoperation for hernia recurrence over time.

The most commonly used inguinal hernia meshes demonstrated stable performance without evidence of increased reoperation risk. However, a small subset of meshes had higher than expected recurrence rates that persisted over multiple quarters, triggering safety alerts and prompting further clinical review. They included:

Open inguinal hernia repair

- Kugel mesh: sustained safety alert, consistent with known design related complications
- Surgipro mesh: safety alerts observed across multiple subtypes

Minimally invasive inguinal (robotic and laparoscopic) hernia repair

- Parietex mesh: sustained safety alert, potentially related to material properties and fixation
- Parietene, ProLite, and Surgipro meshes: safety alerts warranting additional evaluation

In contrast, higher volume meshes such as ProGrip, PerFix, and 3DMax/Dextile demonstrated stable performance without triggering alerts.

Practice Considerations

DELTA findings have already informed general surgeons in our organization to transition away from certain meshes with sustained alerts. For example, one of the three most commonly used meshes for minimally invasive inguinal hernia repair was associated with a sustained safety alert, prompting a recommendation that surgeons select an alternative implant.

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Beyond the Study

Automated surveillance can identify concerning trends early, allowing health systems and surgeons to reassess device choice before issues become widespread.

DELTA is now being implemented to monitor the safety and performance of other implantable medical devices, such as total knee and hip and shoulder arthroplasty implants. This system level- approach strengthens patient safety by enabling continuous, automated monitoring rather than relying solely on voluntary reporting or delayed external alerts.

[Link to Published Manuscript](#)

Brill ER, Chan PH, Chang RN, Prentice HA, Sucher K, Bell RL, Mostaedi R, Paxton EW (2025). **Postmarket Surveillance of Mesh Performance After Inguinal Hernia Repair** JAMA, Epub ahead of print ():

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