

Malfunction of All-Inside Meniscus Repair Devices and Associated Patient Injury: A Review of the Manufacturer and User Facility Device Experience Database

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Introduction:

All-inside meniscal repair devices have gained widespread adoption due to reduced surgical time and avoidance of accessory incisions; however, device-related malfunctions remain a concern. This study aimed to identify common device problems, associated patient injuries, and to determine whether specific device design categories demonstrate distinct failure patterns.

Methods:

The U.S. Food and Drug Administration Manufacturer and User Facility Device Experience (MAUDE) database was queried for adverse events involving all-inside meniscal repair devices reported from 2023–2024. Data extracted included device malfunctions, patient injuries, manufacturer information, and time to reporting. Events were categorized into clinically relevant groups. Descriptive statistics were performed using frequency counts and percentages, and differences in reporting delay were assessed using ANOVA, with significance set at $p < 0.05$.

Results:

A total of 2,058 adverse events were reported during 2023–2024, of which 114 involved patient injury (5.5%). The most frequent device malfunctions were detachment of the device or a device component (486, 23.6%), failure to fire (473, 23.0%), device fracture (362, 17.6%), device–device incompatibility (347, 16.9%), and unintentional simultaneous firing (215, 10.4%). Reporting delays varied significantly among manufacturers, ranging from a mean of 14.4 to 324.3 days ($p < 0.001$). Device design categories demonstrated distinct malfunction profiles: rigid anchor (meniscal knot) devices most frequently exhibited simultaneous firing of both implants (215, 19.9%), whereas all-suture anchor devices commonly experienced device fracture (101, 41.6%).

Discussion:

All-inside meniscal repair systems continue to exhibit notable malfunction rates, though only a minority result in patient harm. The observed variation in failure mechanisms across device designs suggests that specific engineering and mechanical features contribute to distinct malfunction patterns. Limitations include reliance on passive surveillance data, underreporting, inconsistent event detail, and the inability to calculate true failure incidence rates.

Significance/Clinical

Understanding device-specific malfunction patterns may guide safer device selection, refine surgical technique, and inform manufacturer-driven design improvements to reduce preventable complications and improve patient outcomes.

Relevance: