Long-term results for intraperitoneal biomaterial repair of ventral hernias in a real-world, retrospective, multicenter study

Aim: To analyze device safety and clinical outcomes of ventral hernia repair with a hybrid composite mesh

Material and Methods: This retrospective, multicenter, case review analyzed device/procedure endpoints and patient-reported outcomes in patients treated for hernia repair ≤ 1 year from study enrollment.

Table 1. Patient Demographics, Baseline Medical History, and Baseline Hernia Characteristics of Patients With Ventral Hernia

Table 2. Procedure-related Events through 12 months

Table 3. Subgroup comparison for all type recurrence

Results: There were 459 patients with 469 ventral hernias with a mean age of 58 ± 15 years and 77% Ventral Hernia Working Group 2 (VHWG2). Mean hernia size was 18.9 cm² (Table 1). Laparoscopic or robotic approach were utilized in 95% of patients, incisional hernias accounted for 57%. Mesh location was 75% intraperitoneal and bridging repair was performed in 57%. Procedure related adverse events within 30-days occurred in 8.33% of subjects with any secondary endpoint event through 12-months.

Results continued: SSO events requiring procedural intervention (SSOPI) were 2.57% through 24-months. An estimated 7% of subjects had hernia recurrence through the study with a mean follow-up of 32-months (14-53 months) using a patient-reported outcome measure. Subgroup comparison of fixation type (permanent vs absorbable, p=0.93) and repair (bridging vs reinforcement, p=0.99) were conducted for recurrence and were not statistically significant. Diabetes was found to be statistically significant, p=0.0506 (Table 3).

Conclusions: In this analysis, ventral hernia repair with hybrid, composite mesh results in successful outcomes in the majority of patients. This study represents a heterogeneous patient population undergoing repair using various approaches, mesh fixation, and mesh placement locations. These data appear to confirm long-term acceptable safety and device performance with a low rate of recurrence in a predominantly VHWG2 population.

Funding: The work was supported by W. L. Gore & Associates, Flagstaff, AZ, USA. Written informed consent was obtained from all patients and the study was conducted in accordance with U.S. Federal regulations and with Institutional Review Board approval from each investigative site.

Abbreviations: SD=standard deviation; VHWG=Ventral Hernia Working Group, IPOM – Intraperitoneal Onlay Mesh Technique. *If subject had multiple types of events (e.g. SSI and bowel), subjects would only count once for the composite endpoint in this row but would appear in multiple rows below. All rows are counts of subjects with at least one qualifying event, not counts of events. A Type McNemar’s test-report device/procedure-related adverse event, mesh eros, mesh infection, mesh erosion, mesh exposure, device/procedure-related SSI, bowel perforation, unexplained or chronic pain, all events. **ANOVA for all categorical and continuous variables with a low rate of recurrence in a predominantly VHWG2 population.