Adversary Events Associated with Synthetic Male Slings: An Analysis of the FDA MAUDE Database

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Abstract:

Introduction/Background:
The controversy and scrutiny towards polypropylene transvaginal mesh for pelvic organ prolapse has had significant repercussions towards the usage and perception of mid-urethral slings for stress urinary incontinence in women. We aim to explore whether there has been a similar effect for synthetic polypropylene male slings by describing and analyzing the adverse events associated with male slings reported to the FDA Manufacturer and User Facility Device Experience (MAUDE) database.

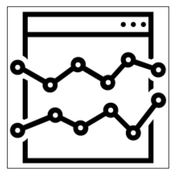
Methods/Materials:
We queried the MAUDE database for all entries with the brand name “Male Sling,” “Invance,” “Virtue,” or “Advance” from January 1st, 2009 to December 31st, 2018. We collected and analyzed information about the event type, date received, report source, source type, manufacturer, and event description text. Duplicate entries were removed.

Results:
A total of 497 adverse events related to the male sling were identified. The adverse events were classified on the MAUDE database as injury (95.4%), malfunction (4.2%), and other (0.4%). There were no deaths reported. The slings involved were the Advance or Advance XP (69.8%), Invance (15.5%), Virtue Quadratic (12.3%), or unknown (2.4%). There was no increase in medical device reports (MDRs) from 2011 and 2012 after the FDA safety communication. On review of the event description texts, a total of 232 (47%) events were related to urinary incontinence after sling placement. Other events included sling erosion (9%), mechanical malfunction (8%), pain or numbness (8%), infection (7%), urinary retention (5%), bladder or urethral injury (3%), or were unknown (13%). The report source was from a manufacturer for 490 (98.6%) reports. The rest were from a user facility (n=4) or voluntary (n=3). The source type was reported to be from a health care professional for 428 (86%) reports, consumer for 33 (7%) reports, or other for 36 (7%) reports. There were no reports generated by attorneys. `

Conclusions:
There are a modest number of MDRs related to male slings and almost half of them describe persistent urinary incontinence. The reporting of adverse events for male slings does not seem to be affected by the controversy toward transvaginal mesh and mid-urethral slings. Further work needs to investigate the safety of polypropylene slings for urinary incontinence

The controversy and scrutiny towards polypropylene transvaginal mesh for pelvic organ prolapse has had significant repercussions towards the usage and perception of mid-urethral slings

We reviewed the FDA MAUDE database to see if there was a similar effect on adverse event reporting for male slings



There were an average of 50 adverse events reported each year. There was no trend or peak in the years following the FDA warnings against urogynecologic mesh (2011).

The report source was a manufacturer for 98.6% of the adverse events. In the female mesh database, the report source was often a lawyer or was not even mentioned.

The most common adverse events were persistent urinary incontinence (47%), sling erosion (9%), mechanical malfunction (8%) and persistent pain or numbness (8%)

Adverse event reporting for male slings does not seem to be affected by the controversy toward transvaginal mesh

Images courtesy of https://thenounproject.com/

Sling Type	
Advance / Advance XP	347 (69.8%)
Invance	77 (15.5%)
Virtue Quadratic	61 (12.3%)
Unknown	12 (2.4%)

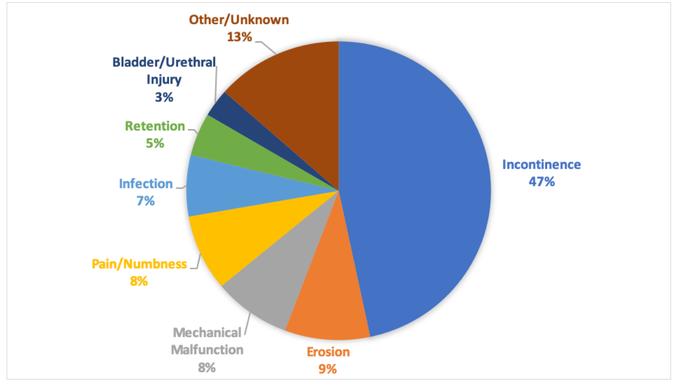


Figure 1. Reasons for Reported Adverse Events

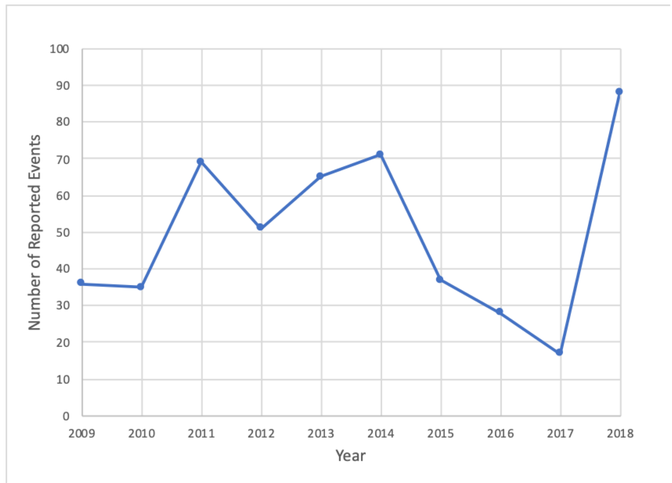


Figure 2. Annual Number of Reported Adverse Events

Adverse Event Report Source	
Manufacturer	490 (98.6%)
User Facility	4 (0.8%)
Voluntary	3 (0.6%)