

Objective

To review published data on legal cases against the major synthetic mesh/sling (SMS) manufacturers and analyze relevant outcomes to date.

Materials and Methods

- Accessible Internet sources:
 - PACER (Public Access to Court Electronic Records)
 - Multidistrict Litigation (MDL) websites created by Federal Court
- Cases against Manufacturers:
 - Bard
 - AMS
 - Coloplast
 - Boston Scientific
 - Ethicon
- TIMELINE: 2009 to PRESENT
- Data collected:
 - Number of legal cases in Federal Courts
 - Number of settlements
 - Range of awards
 - Ongoing/upcoming trials

Results

- ❑ At nearly 100,000 cases, the SMS litigation is the biggest pharmaceutical/device MDL to date.
- ❑ Table 1 summarizes the most recent information for the 5 main manufacturers.

Summary of current MDL, website, and volumes of cases ongoing/closed for each involved SMS manufacturer (n=83,821)

Ethicon

MDL No. 2327 - In Re Ethicon, Inc., Pelvic Repair System Products Liability Litigation
<http://www.wvsc.uscourts.gov/MDL/ethicon/>
29,440 cases. 1039 are closed

Bard

MDL No. 2187 - In Re C. R. Bard, Inc., Pelvic Repair System Products Liability Litigation
<http://www.wvsc.uscourts.gov/MDL/2187/>
12,735 cases. 433 are closed.

AMS

MDL No. 2325 - In Re American Medical Systems, Inc., Pelvic Repair System Products Liability Litigation
<http://www.wvsc.uscourts.gov/MDL/amsinc/>
19,972 cases. 9429 are closed.

Boston Scientific

MDL No. 2326 - In Re Boston Scientific Corp. Pelvic Repair System Products Liability Litigation
<http://www.wvsc.uscourts.gov/MDL/boston/>
19,351 cases. 938 are closed.

Coloplast

MDL No. 2387 - In Re Coloplast Corp. Pelvic Support Systems Products Liability Litigation
<http://www.wvsc.uscourts.gov/MDL/2387/>
2,323 cases. 266 are closed

- ✓ In June 2012, Johnson and Johnson/Ethicon withdrew Gynecare Prolift, Prolift + M, TVT secur, and Prosima from the US market. Soon after, in July 2012, Bard stopped selling the Avaulta mesh (1).
- ✓ Seven MDLs are in front of Judge Goodwin in West Virginia. The judicial panel on MDL (JPML) website and each manufacturer MDL docket information were useful to review but terribly long documents (2). Docket control orders (DCO) provided updated number of cases being worked up in waves of 200 to 300 cases whereas Inactive DCO (from PACER and court websites) implied on-going settlement.
- ✓ Lawsuits dropped before trial, lawsuits with a settled amount not disclosed, and Defense verdicts were more difficult to track (3).
- ✓ The range of awards varied tremendously: 1 to 100+ millions.
- ✓ Bellwether cases (exemplar cases chosen by the lawyers and Judge) and State court litigations (TX, FL, OK, NJ (4), DE, MN, PA, MA, CA...) are on-going into 2016 for product liability litigations and punitive damages.

Conclusions

- Despite the lack of a national registry to track SMS implanted so far, the sheer number of litigations against SMS manufacturers in the US is staggering.
- It is not clear when this trend will end.
- Until then, practicing pelvic floor specialists should be aware of the rapidly evolving litigation scene in this matter.

REFERENCES

1. <http://www.accessdata.fda.gov/scripts/cdrh/cfPMA/pss.cfm>
2. <http://jpml.uscourts.gov/>
3. <http://carolynstclair.com/practice-areas/transvaginal-mesh/>