Defective Metal on Metal Hip Implant Claims in Federal Multidistrict Litigation: More Than 8,500 Filed Cases

By Hadley L. Matarazzo

The first artificial hips with metal on metal articulation were introduced in 1953 in England and remained on the market until the mid-1970s.1 The first devices were removed from the market because of a high failure rate associated with their use of polyethylene. A second generation of metal on metal devices was developed in the early 1980s and shortly thereafter a third generation, which was in many respects similar to the second generation implant. However, the wear rates of these second and third generation devices far exceeded those of metal on polyethylene devices, leading to complications associated with metal debris and metal ions in the bloodstream. Device makers continued to work to improve the design of these implants, and the fourth and current generation of metal on metal implants was released in the late 1990s. This article focuses on the fourth generation devices.

Total Hip Replacement Surgery

Hip replacements are among the most common and successful orthopedic surgeries performed in the United States. The average age for a total hip replacement patient is 66 years.2 According to the Centers for Disease Control, 332,000 individuals had hip replacement surgery in 2010, and the demand for hip replacement surgery is expected to double from 2008 to 2030.3,4 A large portion of the rise in demand can be attributed to a growing percentage of the population that is over 65 years.

Patients who undergo a total hip replacement have their natural hip replaced with a prosthetic hip that is generally composed of a femoral stem, a femoral head and a cup fitted into the cavity in the hip known as the acetabulum. The components may include, but do not always include a liner or shell. In recent years, patients with arthritis can also undergo hip resurfacing where only the natural femoral head and acetabulum are replaced.5 There are several hip systems available today, including metal on metal, metal on polyethylene, ceramic on polyethylene and ceramic on ceramic.

The illustrations above, from a U.S. Food and Drug Administration (FDA) publication, show typical options for hip implants.6

Common causes of chronic hip pain and disability leading to total hip replacement are osteoarthritis, rheumatoid arthritis, post-traumatic arthritis, avascular necrosis, trauma and childhood hip disease.7

In the past, orthopedic surgeons primarily limited hip replacement to patients 60 years and older due to limitations on the life of the device.8 However, with improvements in the technology and the growing demand for replacement in the younger population, surgeons no longer have a threshold age and instead look at a patient’s overall health to determine whether the patient will benefit from a replacement.

The FDA Approval Process: 510(k) Versus Pre-Market Approval

The Medical Device Amendments of 1976 (MDA) created three classes of medical devices, Classes I-III, based on the potential to cause harm.9 Hip implant devices are Class III devices because they are considered high-risk devices. Under the MDA, less risky devices categorized as Class I and II devices can go through a process as defined by Section 510(k) of the Food, Drug and Cosmetic Act, which requires only a showing of substantial equivalence to devices already on the market.10

Class III devices, including hip implant devices, are supposed to undergo the more rigorous pre-market approval (PMA) process, which requires clinical trials.11 This is not, however, how the vast majority of hip implants get
to market. Instead, due to a loophole in the MDA, Class III devices were temporarily permitted to get to market via 510(k). This loophole was supposed to be closed by the FDA over time as it established effective dates for when each Class III medical device would begin to undergo PMA. As of today, the FDA has not closed this loophole and hip implant devices can still get to market under 510(k).

Under the 510(k) process, the manufacturer must show that the device is substantially equivalent to devices marketed through the 510(k) process (known as a predicate device) prior to May 28, 1976. A substantially equivalent device is one that has the same intended use and technological characteristics or has different technological characteristics, but does not raise new questions of safety and effectiveness and is at least as safe and effective as the predicate device. An FDA finding of substantial equivalence does not mean that the device is safe and effective.

Fourth Generation Metal on Metal Hip Implant Devices: The Promise and the Reality

Metal on metal hip implant devices were developed to provide an alternative to polyethylene and ceramic devices. Polyethylene wear debris causes an immunological reaction that results in osteolysis (destruction of bone tissue) and ceramic implants are prone to fracture. In addition to providing an alternative to avoid these problems, metal on metal devices were also supposed to generate less wear debris than other devices and decrease the risk of dislocation. As of November 30, 2012, the FDA cleared 190 metal device components for market with the vast majority cleared through 510(k). It is estimated that more than 500,000 patients in the United States received a metal on metal hip implant between 2003 and 2010.

No hip implant is without risk, including metal on metal hip implant devices. A significant risk with metal on metal devices is shedding of metal debris and release of metal ions into the bloodstream, which can result in soft tissue destruction and osteolysis. The soft tissue damage and osteolysis cause pain, implant loosening and device failure leading to revision surgery. Although there is not sufficient data to draw any conclusion, there is also concern about adverse systemic reactions to the circulating metal ions. For these reasons, metal on metal hip implants are contraindicated for use in, among others, patients who have known sensitivity to metal, patients with kidney problems, patients who have suppressed immune systems as well as patients who are very overweight or very active.

Unfortunately, the promise of metal on metal hip implant devices for many patients has not been fulfilled. Instead, data from other countries’ joint registries, such as the Australian and British, has shown that metal on metal hips have a lower survivorship rate than alternative devices. The high revision rate of metal on metal hips led regulatory agencies in several countries to release healthcare alerts and medical device makers to recall certain metal on metal implants, such as DePuy’s ASR device which had an anticipated failure rate of 49% at six years.

On May 6, 2011, the FDA ordered manufacturers of metal on metal hip devices to conduct postmarket surveillance. The manufacturers were required to study adverse events and pre- and post-implantation cobalt and chromium levels in patients’ blood—the metals used in such implants—but the results will not be available for years. On June 27-28, 2012, the FDA convened the Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee “to seek expert scientific and clinical opinion on the benefits and risk of MoM hip implants including: Failure rates and modes; Metal ion testing; Imaging methods; Local and systemic complications; Patient risk factors; and Consideration for follow-up after surgery.” This was followed by the issuance of an updated FDA Safety Communication on January 17, 2013 and the January 18, 2013 publication of a Proposed Rule in the Federal Register requiring manufacturers to conduct clinical trials if they sought to keep metal on metal hip implants on the market.

The medical literature regarding metal on metal hip implants is exploding. New articles come out monthly covering a range of topics, including the clinical significance of metal levels, ways to diagnosis soft tissue through imaging studies, how to determine when to replace an implant through what is known as revision surgery and methods for diagnosing adverse reactions to metal debris. Orthopedic surgeons continue to wrestle with questions as to whether the risk of revision surgery is outweighed by the damage a metal on metal hip implant is causing a patient, as well as the risk of a poor outcome from the surgery.

Metal on Metal Hip Implant Litigation

The United States Supreme Court in Riegel v. Medtronic, 552 U.S. 312 (2008), held that the pre-emption clause of the MDA bars state common-law claims that challenge the safety or effectiveness of a medical device that received premarket approval from the FDA. However, the Riegel court compared the PMA process to the 510(k) process and also held that under 510(k) there is no formal FDA review of safety and effectiveness. The Court thus allowed state law claims arising from injuries caused by Class III devices marketed via 510(k).

Thousands of cases have been filed around the country by patients who have alleged injury from their metal on metal hip implants. Where litigation is pending in multiple federal districts, either party or both parties can file a motion for centralization with the Judicial Panel on Multidistrict Litigation (the “Panel”). The Panel, after hearing argument, will determine whether there are issues of fact common to actions pending in different federal districts such that it would be appropriate to transfer
all the actions to one judge to handle all the pretrial proceedings. If the Panel determines transfer is appropriate, it will create a Multidistrict Litigation ("MDL") and select the venue and judge assigned. The purpose of centralization is to avoid duplication of discovery, inconsistent pretrial rulings and to conserve judicial resources as well as the resources of the parties. Once the pretrial proceedings are concluded, the cases that have not terminated in the MDL are remanded to the originating federal district for trial.

In addition to overseeing pretrial proceedings, an MDL judge can also conduct bellwether or test cases subject to the restrictions imposed by the Supreme Court decision in *Lexecon, Inc. v. Milberg Weiss Bershad Hynes & Lerach*, 523 U.S. 26 (1998). Under *Lexecon*, the Supreme Court held that an MDL court cannot transfer cases to itself for trial because the statute requires the Panel to remand cases back to the originating district court at the end of the pretrial proceedings. However, in many MDLs, the MDL court will issue an order permitting direct filing of cases into the MDL. In this situation, the MDL court can conduct a bellwether trial of the directly filed actions.

The case or cases chosen as bellweathers are deemed to be representative of the range of cases in the MDL. The hope is that these trials will enable the parties to gauge the strengths and weaknesses of their claims and defenses in an effort to facilitate resolution of the remaining cases in the MDL. In addition, the parties can consent to the application, where feasible, of the decisions made leading up to and during the bellwether trial or trials to all cases in the MDL. For example, motions in limine that are not specific to the evidence in a particular plaintiff’s case, but instead apply to evidence pertaining to the liability of the defendant or defendants can be binding on all cases in the MDL if and when they go to trial.

Metal on metal hip implant cases have been consolidated into several MDLs based on manufacturer and model. At the time this article was written, the following are the pending metal on metal hip implant MDLs as well as the most recent statistics from the Panel regarding the number of cases filed in each MDL:

- **MDL 2158 In re Zimmer Durom Hip Cup** (290 filed cases);  
- **MDL 2197 In re DePuy Orthopaedics, Inc. ASR Hip Implant** (8,858 filed cases);  
- **MDL 2244 In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant** (5,153 filed cases);  
- **MDL 2329 In re Wright Medical Technology, Inc. Conserve Hip Implant** (75 filed cases);  
- **MDL 2391 In re Biomet M2a Magnum Hip Implant** (978 filed cases).

Once an MDL is created, the MDL judge will set a schedule for the filing of applications to the court by plaintiffs’ attorneys who wish to be appointed to leadership positions in the litigation. Although there is some variation, the court generally appoints the positions of plaintiffs’ lead counsel or co-lead counsel, plaintiffs’ liaison counsel, and the members of the plaintiffs’ executive committee and plaintiffs’ steering committee. These individuals acting together as plaintiffs’ leadership are charged with representing the interests of all plaintiffs in the MDL by, among other things, conducting discovery of the defendant or defendants, hiring experts to help establish liability and otherwise moving the litigation forward. The plaintiffs’ leadership is also charged with negotiating settlement if there is an opportunity to do so. At some point during the litigation, the judge usually issues a Common Benefit Order that levies a cost and an attorneys’ fee assessment on every case filed in the MDL. This money is then used to compensate the members of the committees for their time and expenses incurred during the pretrial proceedings.

**Case Study: In re DePuy Orthopaedics, Inc. (MDL 2197), ASR Hip Implant Products Liability Litigation**

On August 24, 2010, DePuy Orthopaedics, Inc. ("DePuy") issued a worldwide, voluntary recall of its DePuy ASR XL Acetabular System and its DePuy ASR Hip Resurfacing System. The resurfacing system was not approved for use in the United States so, with limited exceptions, United States residents were implanted only with the ASR XL. The recall notice stated that DePuy received unpublished 2010 data from the National Joint Registry of England and Wales showing a higher than
expected revision rate at five years, which led the company to issue the recall.\textsuperscript{27} The recall notice was preceded by a Field Safety Notice that DePuy issued in March 2010 regarding a higher than expected revision rate at three years using smaller femoral head sizes, but stating that overall revision rates were normal when compared with other similar metal on metal hip implants.\textsuperscript{28}

In addition to the recall notice, on March 1, 2010 DePuy issued a letter to healthcare providers regarding the monitoring and follow up of patients with an ASR implant. Included in the letter was an updated DePuy ASR Hip Recall Resource Packet. Recommendations for monitoring included testing of blood for cobalt and chromium levels and imaging such as x-rays, ultrasounds and MRIs for symptomatic patients or patients experiencing pain. The letter cautioned that patients might develop progressive soft tissue reaction to metal wear debris without exhibiting symptoms. DePuy also stated that metal debris could cause soft tissue damage which might compromise the results of revision surgery, thus DePuy advised that the sooner a hip implant that was generating metal debris was removed the better the outcome.

Within months of the recall, seven cases were filed against DePuy and its parent company Johnson & Johnson in various federal district courts throughout the country, and shortly thereafter five motions were filed before the Panel seeking consolidation of the cases in an MDL.\textsuperscript{29} The Panel issued a Transfer Order on December 7, 2010 consolidating the cases before Judge Katz in the Northern District of Ohio, one of the venues proposed by Johnson in various federal district courts throughout the country, and shortly thereafter five motions were filed by defendants. Plaintiffs’ leadership was then appointed by court order on January 26, 2011 and discovery began.\textsuperscript{30}

Two years after the Panel issued its Transfer Order, Judge Katz set two bellwether cases for trial in the summer of 2013.\textsuperscript{31} Case specific discovery proceeded throughout the winter, spring and summer of 2013, including plaintiffs’, treating physicians’ and experts’ depositions.

As discovery went forward in the bellwether cases in the MDL, two state court cases involving DePuy’s ASR went to trial. In March 2013, a Los Angeles jury awarded approximately $8 million to a Montana plaintiff who had undergone revision surgery. The verdict was being appealed as of the time this article was written. In August, a Chicago jury went the other way and found that the defect in the ASR hip implant was not the cause of the plaintiff’s injuries.

On the eve of the first bellwether trial, Judge Katz issued an order postponing trial for two weeks and then for 90 days. On November 19, 2013, the parties announced that a global settlement had been reached.\textsuperscript{32} Under the agreement, DePuy agreed to pay nearly $2.5 billion to compensate plaintiffs in the MDL as well as in consolidated proceedings in California, Illinois and New Jersey state courts that met certain criteria.\textsuperscript{33} (For example, plaintiffs who had not undergone revision surgery by August 31, 2013 did not qualify for settlement under the agreement.)

Under the settlement agreement each plaintiff had until April 1, 2014 to decide whether to accept the settlement and DePuy had the right to walk away from the settlement if a 94% participation rate were not met. The settlement took into account variation in damages to the extent possible. For example, plaintiffs who had two ASR hips that were revised were eligible for an enhanced award. Plaintiffs who suffered from post-ASR revision dislocations, who had to be revised again and/or who suffered serious complications following revision surgery were also eligible for enhanced awards.\textsuperscript{34} In addition, the settlement agreement reduced awards for plaintiffs based on certain factors defendants would likely invoke at trial to minimize damages.

Although there are valid complaints about the MDL process, the DePuy ASR MDL is an example of an MDL that moved quickly, met the needs of most plaintiffs, and would provide defendants with finality for the majority of claims currently pending (assuming the settlement moves forward). In many ways, the DePuy ASR MDL is a model for multidistrict litigation.

\textbf{Endnotes}

10. Id.
14. Id.


20. Id.


23. Id. at 323.


31. Bellwether Designation Order, MDL 2197.

32. September 6, 2013 and September 20, 2013 Order in Case No. 1:11-dp-29485.


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Editor’s Note: The co-editor of The Senior Lawyer, Stephen Brooks, had a defective metal on metal hip implant replaced in 2013. He is not and has not been party to any litigation.

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