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Expert Analysis

Claims of Artificial Hip Defects in U.S. Lead to Precedential Litigation

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As artificial hips have become increasingly common, "metal on metal" total hip replacement has become more and more a popular alternative to conventional hip arthroplasty. According to at least one piece of industry research, metal-on-metal total hip replacements now account for more than one-third of such procedures in the United States[1] and 14 percent of hip replacements recorded by the National Joint Registry of England and Wales.[2]

However, claims of defects in artificial hips, particularly the metal-on-metal sort, have led to a steady stream of products litigation over the devices, with outcomes that have varied. Though many consumers have successfully filed suit and obtained recoveries against the manufacturers, other cases have found harder sledding over the past 12 months.

THE U.S. MARKET

Of all replacements recorded by the National Joint Registry, about half are stemmed hip replacements and half are resurfacing procedures. As compared with resurfacing, replacements involving large-diameter, metal-on-metal bearing surfaces have the potential advantages of lower wear[3] and lower dislocation rates.[4] Recent National Joint Registry data, however, show a significantly higher failure rate with stemmed metal-on-metal hips[5] and an above-average failure rate with hip resurfacing, as compared with other hip implant designs.[6]

In addition, little is known about the biological effects of the metals — predominantly cobalt, chromium and molybdenum — that these implants release into the body. After hip replacement, metal particles disseminate throughout the body and can be detected in many organs, including marrow, blood, and the liver, kidneys and bladder.[7]

Patients who have undergone joint replacements have a higher than normal incidence of DNA damage to blood lymphocytes.[8] In the concentrations detected in the blood after hip replacement, cobalt and chromium can signal across intact barriers in the body and cause irreversible DNA changes to cells on the opposite side. This signaling calls into question the protective ability of the placenta and blood–brain barrier.[9]

At the close of 2010, a New York Times article confirmed the high failure rate associated with metal-on-metal artificial hips.[10] A year later, in "The High Cost of Failing Artificial Hips," the same newspaper gave front-page treatment to the continuing problems with the metal-on-metal devices.[11]

"Medical and legal experts estimate the hip failures may cost taxpayers, insurers, employers and others billions of dollars in coming years, contributing to the soaring cost of health care," Barry Meier reported. "The financial fallout is expected to be unusually large and complex because the episode involves a class of products, not a single device or just one company."

The article addressed individual examples of patients who were affected by defective hips and the amount of bills the patients are expected to pay because of the defect:

> The so-called metal-on-metal hips ... in which a device's ball and joint are made of metal, are failing at high rates within a few years instead of lasting 15 years or more, as artificial joints normally do. The wear of metal parts against each other is generating debris that is damaging tissue and, in some cases, crippling patients.
>
> The incidents have set off a financial scramble. Recently, lawsuits and complaints against makers of all-metal replacement hips passed the 5,000 mark. Insurers are alerting patients that they plan to recover their expenses from any settlement money that patients receive. Medicare is also expected to try to recover its costs.

According to the article, at the end of 2011, "until a recent sharp decline, all-metal implants accounted for nearly one-third of the estimated 250,000 hip replacements performed each year in the United States." The piece pointed to a study indicating that "no new artificial hip or knee introduced during a recent five-year period — implants that included some of the all-metal hips — were more durable than older devices, and 30 percent were worse.'

DePuy Orthopaedics Inc. and Zimmer Holdings Inc. were mentioned in the Times articles, and published news reports confirmed that DePuy's parent, Johnson & Johnson, knew about defects in DePuy artificial hip products for years but failed to correct the problem or warn patients.[12] In some cases, it was reported that J&J replaced defective articular surface replacement (ASR) XL model hips with other defective ASR hips after patients had initial problems.

In August 2009, a DePuy vice president wrote an email to senior J&J management saying that the Food and Drug Administration had refused to approve the DePuy ASR XL hip because of "significant" numbers of premature failures. This email message directly contradicted statements made by DePuy and J&J about the artificial hip assembly, which was subsequently recalled in 2010.[13]

In 2010, a motion was filed to consolidate all federal court litigation regarding DePuy hip product defects in a multidistrict litigation proceeding. On Dec. 10, 2010, all federal suits over DePuy metal-on-metal hip joints were consolidated before Judge David A. Katz of the U.S. District Court for the Northern District of Ohio. *In re DePuy Orthopaedics ASR Hip Implants Prods. Liab. Litig.*, No. MDL 2197, 2010 WL 4940348 (J.P.M.L. Dec. 3, 2010) (see *Westlaw Journal Medical Devices*, Vol. 17, Iss. 23). State court suits over allegedly defective DePuy implants will probably remain independent cases.

Typical symptoms alleged in these suits include serious/chronic pain, inflammation/swelling, loosening of the implant and fracture of the bone around the implant. Metal-on-metal construction, such as that in the DePuy ASR XL, creates metal particles that contaminate surrounding tissue. These particles, cobalt and chromium, enter the bloodstream and can migrate to other areas of the body.

Recent occupational research has found that high exposure to metal ions is associated with an increased incidence of certain cancers.[14] Therefore, researchers have queried whether metal exposure from hip replacements could also promote cancer development.

A 2006 study showed higher rates of prostate cancer and melanomas among patients after hip replacement than among the wider population. It also showed that the risk of renal cancers (affecting the bladder, ureters and kidney) increased over time among such patients, possibly through urinary excretion of metals.[15]

Furthermore, a Swedish study showed that patients with osteoarthritis and rheumatoid arthritis who had undergone knee replacement were at greater risk for the development of some hematologic malignancies and possibly at a greater risk for prostate cancer and malignant melanoma.[16]

THE DEPUY ASR XL

Data presented from four different surgeons at the annual conference of the British Hip Society in March 2011 showed a 21 percent revision rate at four years and a 49 percent revision rate at six years for the recalled DePuy ASR XL hip device.[17] Patients implanted with the ASR XL may suffer a variety of ailments, including metallosis, periprosthetic osteolysis and/or high levels of cobalt-chromium ions. With up to half of all DePuy ASR XL hips expected to fail, more consumers could face pain and suffering with such implants.

The main charge regarding DePuy's ASR XL model is typically design defect. The sub-hemispherical design of the implant's acetabular (cup) component and the low clearance between the cup and the femoral head (ball) were planned to permit a greater range of motion of a patient's hip.

These two design aspects have not delivered on their goals, according to the body of products litigation. DePuy ASR XL plaintiffs have claimed that the shallow cup does not present a sufficient "arc of cover" for the femoral head. This design leads to edge-loading, wear and the release of large amounts of metal debris.

The New York Times reported Feb. 29 — after suits against DePuy alleging defects in the ASR XL had been filed — that British health regulators are extending the monitoring period for patients who received a metal-on-metal hip implant, because of concerns about metal debris contamination.[18]

British patients were originally monitored for the first five years after receiving one of these implants, but now the period has been increased to an annual checkup for the full life of the implant, which could be 15 to 20 years. The warning and increased monitoring period apply only to British patients, but the same metal-on-metal implant was used widely in the United States.[19]

Some consumer advocates have called for more regulation of these devices. They contend that most implants recalled by the FDA in recent years because of deaths or life-threatening problems were approved under less stringent regulations that did

not require testing in humans — meaning the devices were never tested in patients before being implanted into hundreds of thousands of people.

Many artificial hip implants — and many other medical devices — are approved by the FDA under an abbreviated procedure known as the 510(k) certification process. The 510(k) process rests on the notion that if one device has been cleared by the FDA, then similar devices need little or no testing in patients.

If a new medical device is "substantially equivalent" to an already-marketed design, then clinical testing is not required.

The 510(k) approval process has been under attack on many fronts, and the New England Journal of Medicine agreed with the Institute of Medicine that the 510(k) approval process is "unfixable."

A recent NEJM editorial recommended that the FDA immediately stop using the 510(k) program for all class III devices, which are considered to pose the highest threat to patients. The editorial specifically discussed the ongoing problems with metal-on-metal hip implants.[20]

As reporting by Bloomberg News has noted, this safety debate has presented a conundrum for medical device manufacturers. On the one hand, they have avoided testing and close clinical scrutiny by claiming that these devices are similar to previous versions. On the other hand, they have marketed the devices to doctors and patients as having advanced far beyond the original versions.[21]

In case one wonders about the legitimacy of the data cited in many of the bodies of research described above, much of it was derived from the National Joint Registry of England and Wales, which was established in 2003 and is the largest arthroplasty database in the world. Its data are considered a valid industry source, since it records all primary and revision hip and knee replacements performed in England and Wales, including the National Health Service and independently funded operations. By April 2011, it contained records of 1,082,465 procedures.[22]

For the purposes of reliable data, coverage has "improved steadily over the last decade," with fully 97 percent of orthopedic units submitting data in 2010. The database of hospital episode statistics is the primary source of NHS inpatient data and contains details of all admissions to NHS hospitals in England, including private patients treated in NHS hospitals, patients who were living outside England and care delivered by treatment centers and private hospitals funded by the NHS.

Hospital episode statistics are based on medical records assessed by NHS clinical coding staff.[23]

What is at stake financially in these litigation matters? Bloomberg Businessweek reported in August that J&J said that it had spent about $800 million on the ASR XL hip recall over the past two years.[24] Although J&J declined to estimate its product liability costs, Eric Gordon, a University of Michigan business professor, told the magazine that "it may cost the drugmaker as much as $2 billion to resolve all litigation over DePuy's ASR XL hips." He added, "They're looking at a giant number before it's done because there are a giant number of cases."[25]

In short, metal-on-metal hip replacement involving large-diameter bearings has become a popular alternative to conventional total hip arthroplasty, but it is

nonetheless still associated with elevated levels of metal ions in local tissue and circulating levels of metal ions that may affect bone health.[26]

In fact, a team of researchers examined the effects of acute and chronic exposure to these metals on osteoblast and osteoclast formation and function in humans over a clinically relevant concentration range previously reported in serum and within hip synovial fluid in patients after replacement surgery. Their conclusions suggest that metal ions at equivalent concentrations to those detected after the procedure affect bone-cell health and may contribute to the observed bone-related complications of these prostheses.[27]

CLAIMS OVER OTHER HIP SYSTEMS

After reviewing data from lawsuits that were filed against Zimmer, one of the world's largest manufacturers of hip replacement parts, Zimmer suspended sales of the Durom acetabular component until it could update the label with instructions about special surgical techniques required during total hip replacements.[28] Because Zimmer reported finding no evidence of manufacturing or design defects, a recall of this particular product was not issued.

Nevertheless, class action and individual lawsuits have been filed against Zimmer over Durom cups, claiming it failed to provide proper warnings, instructions and training to surgeons. In April 2008 Dr. Lawrence Dorr, a prominent orthopedic surgeon, wrote an open letter to members of the American Association of Hip and Knee Surgeons complaining of problems with the Durom cup; of 165 Zimmer cup implants he performed, 14 were "revised or required revision" within the first two years after surgery.

Dorr indicated that the cup was defective; its fixation surface was problematic and a circular cutting surface on the periphery of the cup prevented it from fully seating.[29]

One month after that open letter, Zimmer Holdings Inc. sent a letter to health care providers indicating it was investigating Durom cup complications. This investigation led to the suspension of sales in July 2008.

The Stryker Corp. Rejuvenate and ABG II hip replacement systems, meanwhile, are not metal-on-metal devices, but include a metal-on-metal component: the modular-neck hip stem. The Rejuvenate is somewhat different than other metal-on-metal hip systems such as the DePuy ASR XL. Its components are ceramic, but it also has metal-on-metal parts, and they can fail just like other hip implant systems.

In May the Rejuvenate was recalled in Canada so that "instructions for use could be updated," according to Stryker Orthopedics. In July, Stryker voluntarily recalled its Rejuvenate and ABG II modular-neck stems from the market in the United States. The products were recalled due to reports of fretting and corrosion.[30]

According to Stryker's recall notice, post-marketing surveillance data suggest the recalled products may be prone to "fretting and/or corrosion at or about the modular-neck junction," which "may lead to pain, swelling and other adverse reactions in the surrounding tissue."

According to some estimates, there are approximately 30,000 Rejuvenate products globally, and 20,000 Rejuvenate hips have been implanted in patients in the United States. Specialists report that the majority of these products were implanted

in southern Florida, Detroit, Minnesota, Illinois, Cleveland, Boston and southern Arizona.[31]

Unlike other hip implant systems that have a one-piece fixed femoral neck and stem, Stryker's Rejuvenate and ABG II systems include several mix-and-match neck and stem components. The necks are an alloy of chromium and cobalt, and the stems are titanium-coated.

According to this body of products litigation, when the two metal components wear against each other, they can shed minute metallic particles into the body — the same problem seen in the hip implants mentioned above.

Metallosis occurs when ions of these metals leach into the soft tissue, bones or bloodstream of a hip transplant recipient. One investigation found that chromium and cobalt ions from these metals can damage the lymph nodes, spleen, liver and kidneys. Other studies suggest links to neurologic and heart problems.[32]

In the short term, metallosis can cause necrosis, or premature death, in tissue surrounding the implant site. Healthy pink tissue eventually becomes gray or black and dies. The longer the source of metal debris is present, the worse the tissue damage may be. Some affected patients may notice the growth of lumps, or pseudotumors, under their skin. These fluid-filled sacs are created by the body's immune system in an attempt to isolate the toxic metals.[33]

Researchers reporting in the Journal of Bone and Joint Surgery confirmed the damaging reaction of metals in orthopedic implants, stating: "All metals in contact with biological systems undergo corrosion. This electrochemical process leads to the formation of metal ions, which may activate the immune system by forming complexes with endogenous proteins. ... If cutaneous signs of an allergic response appear after implantation of a metal device, metal sensitivity should be considered." [34]

CAUSATION IN RECENT CASES

Though the August Bloomberg Businessweek piece reported on how much money could be at stake for these companies as they settle many waves of cases, not every case in the defective hips arena is created equal. In fact, there have been instances recently in which the hip manufacturer has made a successful defense, in spite of plaintiffs' arguments that lean on the science and symptoms mentioned above.

In a case last year before a federal court in Maryland, the plaintiff alleged that a defective DePuy hip replacement kit had caused her injury during a total hip arthroplasty performed in 2008. The court granted DePuy's motion to dismiss after it argued that the plaintiff, Sandra Bloom, failed to outline what product specifically was believed to cause her damage.[35]

On Feb. 11, 2008, Bloom underwent arthroplasty surgery on her left hip at Anne Arundel Medical Center in Annapolis, Md. Her complaint alleged that complications during her surgery required a separate abdominal incision in order to correct the problem and resulted in Bloom suffering problems. The alleged complications and resulting injuries included deep-vein and external iliac artery thrombosis (blood clots), cellulitis (skin infection) and permanent nerve damage.[36]

Bloom attributed her injuries to a "defect" in the hardware used in the surgery; this hardware was also manufactured by DePuy. DePuy objected that Bloom's complaint was vague and provided too little information in that DePuy knew "little more than

it would know if the complaint simply stated 'your bad product injured my hip and I'm suing you in tort and contract.'" Bloom's complaint contained causes of action for negligence, breach of warranty and strict product liability.

The lack of clear identification of which product contained the alleged defect and what the defect was led to the case being dismissed. In this dispute, six separate DePuy products were listed. Bloom's description of her claim read: "During the plaintiff's surgery when the hip was dislocated anteriorly, the trial head disassociated from the femoral component and the head and neck passed through a defect in the anterior capsule. The neck became stuck, after which the head slid along the iliopsoas tendon up into the hemipelvis anterior to the acetabulum."

According to the court, that description was deemed to convey nothing more than "something happened that should not have." The complaint also stated "the defendant had additionally failed to get the proper approvals necessary to sell a product such as this as a total hip arthroplasty kit" but never identified which product required approval, what sort of approval was needed or who was responsible for granting it.

The warranty breach claim was also deemed insufficient, since it asserted that "various warranties, both expressed and implied, were extended regarding this device(s)." However, it did not describe the terms or guarantees of these warranties or how DePuy allegedly breached them.[37]

Stryker also has, at times, successfully defended against claims in these cases. The 11th U.S. Circuit Court of Appeals affirmed summary judgment in favor of Stryker and Howmedica due to causation weaknesses in the product liability and negligence claims made regarding the failure of the defendants' hip prosthesis.[38]

The plaintiff, Judith Hughes, first protested the summary judgment on her product liability claim under the Alabama Extended Manufacturer's Liability Doctrine, or AEMLD. She also argued that "evidence raised genuine issues of material fact that the Trident implant's acetabular cup implanted in her hip was unreasonably dangerous as manufactured as it contained residues that impeded biological fixation."

Under the AEMLD, a plaintiff must show that the defendant manufacturer sold a defective product, the defect was the cause in fact of the plaintiff's injury and is traceable to the defendant, and the product reached the plaintiff without substantial modification to its condition at sale.

However, according to the appellate court, Hughes failed to provide expert testimony as required by Federal Rule of Civil Procedure 26(a)(2). Therefore, the trial court had to consider whether non-expert evidence offered was sufficient to allow the jury to find failure of the Trident acetabular cup to achieve fixation meant the product was defective and that the defect caused the product's failure and injury to Hughes.

Evidence in the case included medical records showing Hughes received a total right hip replacement Sept. 14, 2007, with a Stryker/Howmedica prosthetic device. Hospital records indicated that on July 1, 2008, her treating physician determined she "had suffered a hardware failure involving the acetabular cup with migration of the cup," such that she would require a revision.

Also produced was a 2007 "warning letter" sent from the U.S. Department of Health and Human Services to Stryker Ireland Ltd., stating that in the fall of 2006 it had

discovered several violations of the federal Food, Drug, and Cosmetic Act rules at Stryker facilities.

Finally, a Jan. 24, 2008, letter from Stryker Orthopaedics recalling all Trident hemispherical and PSL shells made at the company's Cork, Ireland, plant between January 2000 and December 2007 because "the average level of manufacturing residuals in some cases exceeded Stryker Orthopaedics self- imposed conservative acceptance criteria" was also evidence. The recall created "[t]he potential hazard ... that the device may not achieve biological fixation," but noted that "failure to achieve biological fixation may result from many factors related to the device." [39]

The District Court rejected Hughes' arguments related to the letters because they stated "in some cases" and that the "warning letter" was insufficient to prove existence of a defect. The plaintiff described Stryker's failure to establish and maintain certain general quality-control procedures but said nothing about the presence of residuals in any Trident acetabular cups. Nor were the medical records indicating a "hardware failure" enough to permit a jury to conclude the product was defective under the Alabama law. "Mere failure of a product does not presuppose the existence of a defect," the court said.

The court explained, "Without the benefit of expert testimony, a reasonable jury could not possibly make a determination on this summary judgment record that Hughes' injuries were caused by a manufacturing or design defect in the prosthetic hip." Hughes next argued that the district court erred in granting summary judgment on her negligence claims, which is distinct from a products liability claim under AEMLD. The District Court concluded that Hughes failed to establish genuine dispute as to causation.[40]

Hughes argued sufficient circumstantial evidence to permit a jury to find that the defendants' negligent manufacture of the Trident acetabular cup proximately caused the failure of the prosthesis in her hip replacement. The District Court found that "no evidence links the failure of that complex, technical medical device to any negligent or wanton conduct by defendants; to the contrary, it could have failed for myriad reasons totally unrelated to any negligent acts or omissions by defendants."

The court found that a jury could only speculate as to why the prosthesis failed in this case and such "[s]peculation does not create a genuine issue of fact."[41]

Another manufacturer, Biomet Inc., has also shown that, though companies are settling cases involving defective hip devices, claims that the court holds to be specious are being thrown out. In July 2011 Biomet was a defendant over its metal-on-metal hip joint, and it defeated a failure-to-warn claim.[42]

Biomet's M2a-Magnum Press-Fit acetabular shell and modular head were the subjects of this suit. The M2a-Magnum is a metal-on-metal hip joint that includes the modular head "ball" and the acetabular shell "cup."

On July 25, 2006, Elizabeth Sumner had hip replacement surgery involving a Biomet hip prosthesis. After discharge from the hospital, she returned for three postoperative appointments, each of which confirmed that the prosthesis was properly positioned but that particulate debris was floating nearby. Due to continued severe pain, the device was removed and replaced in March 2007.

Sumner filed a product liability action against Biomet on July 22, 2008, based on diversity jurisdiction. The amended complaint asserted claims under Georgia law of strict liability for the defective condition of the hip prosthesis and failure to warn, negligence and breach of warranty. She also brought a count requesting compensatory damages and punitive damages.

The expert metallurgy witness for the plaintiff examined the hip prosthesis under a scanning electron microscope and used energy-dispersive X-ray scans to map out the chemical composition of the surface of the prosthesis. In February 2009, he provided an expert report noting the presence of scratches and gouges on the surface of the ball of the hip prosthesis. The report said the scratches and gouges were caused by metal particles from the hip prosthesis itself.

The plaintiff's expert, Dr. Rex B. McLellan, concluded that the device showed "severe gouging, scratching and particle-dislodgment," and that "[t]he micro-mechanism for these effects is not known but with an overwhelming degree of probability ensues from the chemical in homogeneities observed on the bearing surface. On the basis of the report and other evidence, the plaintiff's counsel argued that "[t]he device was not suitable for its intended purpose."[43]

During his deposition, McLellan identified several areas where he believed metal had been "ejected from the surface" of the prosthesis through some mechanism other than gouging. He had no explanation of how metal could have been ejected from areas of inhomogeneity in the prosthesis.

McLellan proposed that the pressure applied to the surface of the prosthesis may have produced particles due to the varying degrees of chemical composition strength on the surface, but he cautioned that this theory was only "speculation."

In response to Biomet's summary judgment motion, Sumner attached an affidavit from McLellan. The affidavit reiterated that the ball of the prosthesis showed scratches and gouging both in photographs and electron microscope scans. The affidavit stated the X-ray scans of the hip prosthesis showed high levels of tungsten segregation on the surface of the ball, which is believed to produce hard particles of tungsten carbide.[44]

The court granted the Biomet motion because McLellan's testimony was the only evidence that the product was defective. It said summary judgment in Biomet's favor was proper as to all claims. Georgia law holds product manufacturers strictly liable to consumers injured by a product that "was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained."[45]

According to the appellate decision, "without Dr. McLellan's testimony there is no evidence of the prosthesis' alleged defective condition, and the district court did not err in granting summary judgment to defendant Biomet as to plaintiffs' failure to warn claim on this basis."

As these cases illustrate, not all product cases are created equal when dealing with defective hips. However, given the amount of such cases being settled by medical device makers, consumers are urged to consult their physician if they suffer from any of the symptoms mentioned above, since there may be fertile ground for a products suit against the maker of a defective hip implant.

NOTES

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[6] *See* NJR report, *supra* note 2.

[7] *Id.*

[8] *Id.*

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[31] *Id.*

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[33] *Rundle v. DePuy Orthopaedics*, No. A-11-636272 (Nev. Dist. Ct., Clark County).

[34] *See* Hallab, *supra* note 26.

[35] *Bloom v. DePuy Orthopaedics*, No. L-10-2170 (D. Md. Mar. 25, 2011).

[36] *Id.*

[37] *Id.*

[38] *Hughes v. Stryker Corp. et al.,* No. 10-13529, 2011 WL 1413281 (11th Cir. 2011)

[39] *Id.*

[40] *Id.*

[41] *Cordoba v. Dillard's, Inc.*, 419 F.3d 1169, 1181 (11th Cir. 2005).

[42] *Sumner et al. v. Biomet Inc.*, No. 11-10280, 2011 WL 2749640 (11th Cir. 2011).

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[44] *Id.*

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