

Orthopedic Medical Devices: Ethical Questions, Implant Recalls and Responsibility

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ABSTRACT

The hip replacement is a surgical procedure to replace the femoral head and acetabulum with prosthetic implants to improve function, increase mobility, and relieve pain caused by damage from disorders such as osteoarthritis and fractures. In recent years, we have seen several recalls of poorly functioning implant systems, most recently, the Johnson and Johnson (J&J) Articular Surface Replacement device. Product recalls are often the results of premature failure of implants requiring additional surgery to exchange the failed device. This raises many questions – technical, medical, regulatory, ethical, and legal – that ultimately put patients at risk, compromise confidence in medicine and regulatory agencies, and important relationships including those between the physician-patient and physician-industry. Where do the responsibilities lie for the patients' suffering, morbidity, and costs of removing the failed device? This article discusses the current recall of the J&J implant, the responsibilities of the manufacturer, surgeons, and the regulatory agency.

KEYWORDS: Orthopedic implant failures, product recalls, federal regulations, medical industry responsibilities, physician-industry relationships

Why the Articular Surface Replacement Implant Failed

A metal-on-metal total hip replacement system consists of a metal acetabular component (socket or cup), a metal femoral head that articulates with the acetabular component, and a metal stem that fits into the femur (Figure 1). In recent months, J&J, one of the world's largest manufacturers of medical devices, has been under scrutiny for the failure of its Articular Surface Replacement (ASR) metal-on-metal hip implant. The implants are alleged to be defective due to design flaws. Several have been identified: (1) One flaw is claimed to be a groove on the inside of the acetabular component that limits the surface area and increases friction and wear. The limited surface area causes the head to abut against the cup's edge during movement.¹ (2) Another reported flaw is that the acetabular cup and femoral head are too small, also resulting in a limited surface area and increased frictional wear. Other design flaws include (3) very low tolerances between the socket and ball, and (4) deformation of the

socket on implantation, both of which contribute to accelerated wear and the generation of metal debris. Corrosion releases metal ions. Manufacturing errors reduce the clearance (tolerance) between the ball and socket. The crucial issue is that these flaws all contribute to metal-on-metal wear that causes the generation of metallic debris and metal-

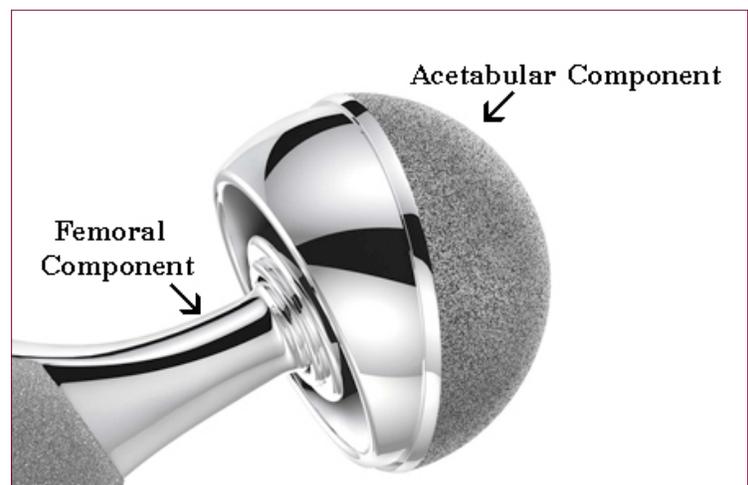


Figure 1. Hip arthroplasty device demonstrating metal-on-metal articulation with low tolerances.

lic ions. Reactions to the metal particles include local inflammation and erosions of bone resulting in implant loosening, dislocation, and cracking and popping sensations, or surrounding soft tissue masses, pseudotumors, and areas of frank necrosis.²⁻⁴ Loosening of the components requires revision surgery that is complicated and expensive and puts patients at additional risk. Systemic reactions to the metal ions (cobalt and chromium) may include hypersensitivity

reactions, cardiomyopathy, auditory or visual impairments, depression, cognitive impairment, renal function impairment, and thyroid dysfunction.²

Responsibilities of Johnson and Johnson

In 2008, executives at DePuy, the J&J subsidiary that produces the ASR implant, were told by a number of surgeons, including its own consultants, that the ASR device had design flaws. The flaws were never disclosed to other surgeons although they were implanting the device.⁵

In 2010, the National Joint Registry of England and Wales reported that the ASR hips were failing prematurely within 5 years in 12%-13% of patients.⁶ DePuy publicly challenged data from the Registry but recalled approximately 93,000 ASR hip implants, about one-third of them in the United States.^{1,7} An internal analysis conducted by DePuy/J&J in 2011 indicated that 37%-40% of the ASR hips were likely to fail within 5 years; however these findings were not made public.^{6,7} In 2011, J&J appointed Andrew Ekdahl to head its orthopaedic implant division, DePuy. Prior to the recall, Ekdahl held a senior marketing position at J&J, supervised the ASR implant's introduction in the United States, and had been told by consultants three years prior to its recall that it was faulty.⁸ At the same time, J&J failed to notify officials outside the United States that the U.S. Food and Drug Administration (FDA) prohibited the sale of one version of the ASR in this country.⁸

According to an internal engineering report in 2010, DePuy/J&J engineers found that it had used incorrect or inadequate standards for assessing implant performance before the sale

of the implant in 2003.⁹ The company only tested the *in vitro* performance on laboratory equipment at one angle of implantation and, because of the implant's design flaw, the normal variance from the single angle in which it was tested made it likely for the components to impinge upon one another, leading to wear and premature implant failure.⁹ In addition, depending on the surgical technique and the patient's body type, orthopaedic surgeons can implant the acetabular component at a variety of angles. DePuy/J&J claims that the ASR socket must be implanted at a vertical angle of 45° relative to the pelvis and that any other angle is unacceptable for this implant. However, one study of socket positioning by experienced implant surgeons demonstrated that only 63% were within this tolerance.¹⁰ Another study reported that optimal placement of sockets was achieved in only 71% of implants.¹¹ While the tolerances of implantation were acceptable for other implant devices, the ASR hip was designed with a tolerance unachievable on a consistent basis by experienced implant surgeons.

When asked about the analysis of this data, a DePuy spokeswoman confirmed that "... it was based on a limited data set that could not be used to generalize."¹² J&J maintains it acted appropriately and reacted in a timely fashion to the device's problems.⁹ The device itself required a 510(k) application to illustrate it was "substantially equivalent" to a device already on the market; the FDA approved the ASR through this channel.⁷ The company now faces at least 10,000 lawsuits due to the ASR hip implant failure. The first one has been settled with damages in excess of \$8M.

Responsibilities of the Medical Community

Implant design is a multidisciplinary undertaking with input from orthopedic surgeons, bioengineers, and materials scientists. This collaboration is critical to the design and evaluation of new devices but contains potential conflicts of interest that need to be managed. What are the responsibilities of surgeons involved in device design and what are the impediments to full disclosure? Clearly, surgeons have an ethical responsibility to the patient as well as to their peers to caution against faulty or harmful devices.¹³ However, surgeons may have financial ties to companies that are often essential to the design of new devices but can sometimes be in conflict with their clinical responsibilities. Another conflict is the compromise of professional reputation that some surgeons have alleged against device companies. One prominent orthopedic implant surgeon has reported that when he alerted peers to faulty devices, his surgical skill implanting the device was publicly criticized by the company and his reputation suffered.¹³

The ASR experience also raises disturbing questions about the monitoring of clinical science by some surgeons in a rapidly changing field. Orthopaedic researchers have been studying metal-on-metal hip implants for the better part of a decade with multiple publications concerning metal particles and ion release. In a review article in 2009, the orthopedic community was warned about the biologic consequences of metal release from metal-on-metal bearings and suggested that a better understanding of the mechanisms of wear along with premarket testing would mitigate adverse biologic responses to the metal

debris.^{14,15} In an orthopaedic forum, it was recommended that surgeons, insurers, manufacturers, and regulators engage in a continuous dialogue that respects their separate roles, while the interests of patients take precedence.¹⁶ Despite multiple alerts in professional publications and meetings, the information was, for the most part, ignored.

Federal Regulation of Medical Devices

According to the FDA's 21 CFR Part 803 (Medical Device Reporting [MDR]), if a device may have caused or contributed to a death or serious injury, the incident must be reported to the FDA. The objective is to detect and correct issues in a timely manner.¹⁷ The Safe Medical Devices Act (SMDA) of 1990 requires physicians who utilize devices to report associated serious injuries either to the manufacturer or to the FDA. This can be confusing, as regulations are amended,

so are the responsible parties; who should be reported to, the FDA, the manufacturer? It also requires the manufacturer to certify to the FDA the number of MDR reports filed or that no reports have been filed. The question arises: Did J&J file their MDR reports from the doctors who were warning them?

The FDA can impose legal sanctions and fines; however, "...it relies on the goodwill and cooperation of all affected groups to accomplish the objectives of the regulation."¹⁸ The professional responsibility is unclear. Is notification of either the manufacturer or the FDA sufficient? If the manufacturer is notified and no action is taken, has the professional obligation of the physician been satisfied? In 2007, as a result of noncompliance, the FDA required all new clinical trials conducted in the United States to post their findings on clinicaltrials.gov within a year or face

a fine. However, in 2012, one report disclosed that four out of five clinical trials covered by the regulations had disregarded the reporting requirements, and no fines were assessed.¹⁹

Several federal regulatory agencies have been criticized for compromising their regulatory functions by having inherent conflicts of interest with the industries they regulate. The FDA developed documents to assist manufacturers in the regulatory review process.²⁰ It was meant to be used as an assurance tool; however, FDA data exists which demonstrates that these documents can shorten review times for devices that are to be sold.²⁰ According to an editorial in *The New York Times*, the devices were not adequately tested due to an FDA loophole.⁵ If the processes that are in place are to protect the patient, the manufacturer, and the physicians, where is the follow-up? Where is the accountability?

CONCLUSIONS

Evidence-based medicine has become increasingly fundamental to patient care. Dr. Ben Goldacre said it best in a *New York Times* op-ed, "the entire evidence base for medicine has been undermined by a casual lack of transparency."¹⁹ To conceptualize this, Schemitsch, et al describes the medical product development process as three areas: the conscientious delivery, which implies the need for surgical expertise and cost-conscious approach, the best evidence by using the hierarchy of evidence during implant development, and patient-important outcomes by using the relevant and important measures of safety and efficacy.²⁰ As described in Figure 2, development begins in the laboratory and moves to translational

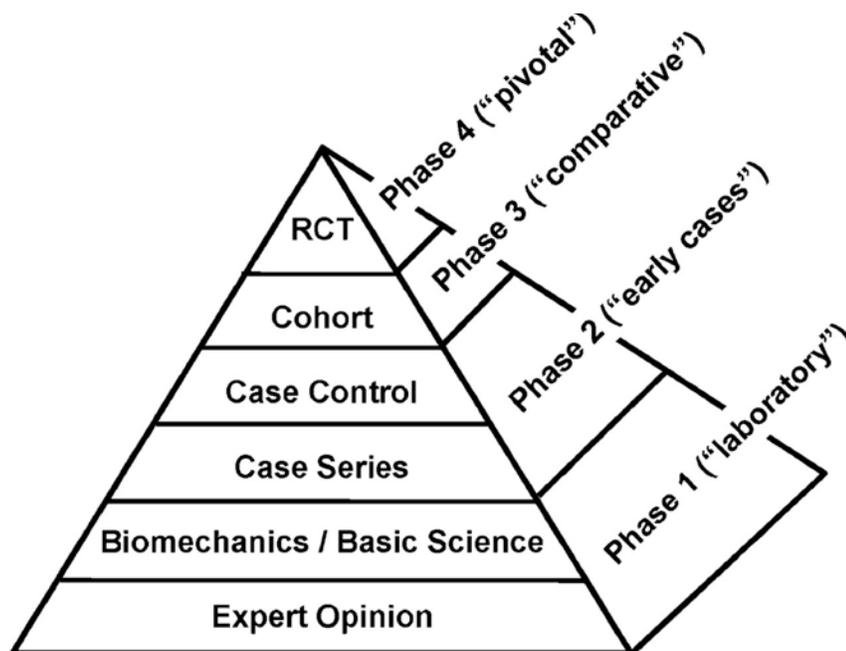


Figure 2. The orthopaedic pyramid is a proposal for an evidence-based approach to product development and assessment of new orthopaedic devices and techniques. RCT= Randomized Controlled Trial. Reprinted with permission from JBJS Volume 92-A, No 4, April 2010.

medicine. Phase I describes that the initial research begins with biomechanics, basic science, and expert opinions. Phase II provides evidence using predicate cases and case control studies. Phase III uses comparative assessment with cohort studies, and Phase IV would perform the pivotal randomized controlled trials; the final stage in translational research.²⁰

Where do the responsibilities lie for the failure of the ASR hip? The inherent design of the device appears to have had multiple potential flaws. Is there appropriate preclinical design testing in place? Are the "FDA criteria for clinical testing" sufficient? Do implant manufacturers act with appropriate scientific and clinical transparency? Is there an adequate post-market surveillance in place? Is the FDA capable of enforcing its adverse event disclosure rules and do they act responsibly with their data? What about the loophole? Are the clinical and scientific implant design communities acting in the best interests of patients and are their acknowledged conflicts of interest properly managed? Innovation of new technology is crucial; however, a high level of evidence must be demanded when adopting new technologies into clinical practice.²⁰

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