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Perspectives in Managing an Implant Recall: Revision of 94 Durom Metasul Acetabular Components

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The Metasul LDH Large Diameter Head with Durom Acetabular Component (Zimmer, Warsaw, Indiana) was launched in Europe in 2003¹ and was approved by the United States Food and Drug Administration (FDA) in April 2006². The Durom acetabular component was designed as a monoblock, truncated hemispherical cup with a 165° arc, and had performed well in the Swedish Arthroplasty Registry and in early European studies^{3,4}.

The senior author (M.A.M.), a fellowship-trained surgeon specializing in adult reconstruction who had more than twenty years' experience with total hip arthroplasty, performed approximately 400 primary total hip arthroplasties annually during the past five years and 100 to 150 annually during the preceding years. Prior to October 2006, he utilized the Trabecular Metal Modular Acetabular System (Zimmer) with good success. Utilization of the Durom cup began in October 2006 because of the good results that had been reported internationally and the purported benefits of increased range of hip motion, enhanced stability, and greater durability.

The senior author implanted 297 Durom acetabular cups during the subsequent two years. All procedures were performed at a large community hospital with a company representative present in the operating room. None of the patients was part of a clinical trial, and the surgeon had no current industry ties. All cups were inserted according to the manufacturer's instructions. The learning curve was rapid, and no obvious intraoperative complications developed.

A minority of patients (seventy-six of 297, 26%) progressed slowly with therapy, reporting vague symptoms of groin discomfort, mild pain with initial weight-bearing, and difficulty with ambulation. Furthermore, several patients who had a non-Durom cup on the contralateral side reported worse performance on the side with the Durom cup. Nevertheless, there was little objective evidence to support the existence of a widespread problem. Because there were minimal radiographic signs of cup failure and because of the very low rate of acetabular loosening in his experience with previous designs, the surgeon was not highly concerned at this point and attributed the symptoms to other causes such as typical postoperative pain. No patient had demonstrated osteolysis or obvious radiographic signs of loosening. Three of the patients underwent bone scans and twelve underwent hip aspiration, but all results were negative. The serum erythrocyte sedimentation rate and C-reactive protein level were not elevated in these patients.

The first revision of a Durom cup was performed in April 2008 on a physician who had had persistent hip pain for five months. A computed tomography scan of the sacroiliac joint serendipitously diagnosed a fulminant pseudotumor⁵ in the hip, an entity that had not yet received substantial attention in the literature concerning metal-on-metal bearings. However, as the senior author probed deeper into the symptoms of other patients who had received the Durom implant, the insidious nature of the problem began to be apparent. Many of the patients reported symptoms indicative of aseptic loosening, such

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as severe episodic pain and difficulty with alternating-leg stair-climbing, exiting vehicles, initiating ambulation, and bending maneuvers. On physical examination, the resisted hip flexion test was typically positive, most likely indicating either implant loosening or iliopsoas tendinitis.

Ninety-four (32%) of 297 hip arthroplasties performed during the two-year period were revised, representing the largest published single-surgeon series involving this implant. Only two (2%) of the ninety-four revisions were performed for traditional causes (e.g., infection or periprosthetic femoral fracture); the remaining ninety-two (98%) were performed because of aseptic cup loosening. Three of the ninety-two loose cups had an associated pseudotumor⁵. The vast majority of the cases of aseptic loosening were difficult to detect on radiographs. Inconclusive radiolucent lines were seen in eight hips, and delayed movement of the cup was seen subtly in one hip and grossly in another. These patients underwent prompt revision. The preoperative demographic characteristics of the patients with well-functioning implants and of those with failed implants were similar (Table I). Although the average time to revision was seventy-seven weeks (range, fourteen to 201 weeks), this time interval became shorter once the surgeon became aware of the correlation between symptoms and cup loosening even in the absence of radiographic signs of loosening. Ninety-nine percent of the revisions performed for loosening were based on clinical rather than imaging evidence. The senior author's decision in April 2008 to stop using the Durom cup was based largely on the first revision and was reinforced by descriptions of similar failures reported by other surgeons^{6,7}. Revisions continue to be performed approximately once every other month.

Consistent with other studies, there was no evidence of osseous ingrowth or even soft-tissue attachment on the porous surface at the time of cup revision^{2,8,9}. All cups were removed with use of a tamp and a mallet by engaging the backside of the peripheral circumferential fin. Some cups required less aggressive taps than others, and three were grossly loose. Although the symptoms reported by patients prior to the revision could also have been due to iliopsoas tendinitis, the typical improvement that occurred after revision, despite the absence of specific treatment of the iliopsoas tendon, did not support tendinitis as the cause of the symptoms. The consequences of early revision

were not limited to the physical, psychological, and emotional toll of undergoing another major surgery; three patients underwent further surgery for deep infection of the revision implant.

Initially, the Durom cups were replaced with the Trabecular Metal Modular Acetabular System. However, after experiencing a dislocation rate of 10% (seven of seventy-two) with this system, the senior author began utilizing the Pinnacle revision system (DePuy Orthopaedics, Warsaw, Indiana), which was not subsequently associated with any dislocations. The Pinnacle system incorporates a Charnley bore into the liner, providing a cylinder of polyethylene extending to the rim in order to increase stability^{10,11}. In addition, the surgeon upsized the femoral neck length by one or two increments, resulting in several additional millimeters of leg length and offset to augment soft-tissue tension and help to compensate for the patulous capsule that was often found during revision of the Durom component.

The Durom story reveals the medical, societal, and political ramifications of a product failure. In late April 2008, a letter from a prominent surgeon, Lawrence Dorr, that highlighted his concerns and initial experience with the implant was circulated among the members of the American Association of Hip and Knee Surgeons². The first adverse event reports also began to appear on the FDA's Manufacturer and User Facility Device Experience Database⁶ at this time. These communications, in conjunction with his personal experience of multiple impending failures, prompted the senior author to cease implantation of the Durom cup. In response to Dr. Dorr's initial communication, Zimmer released a letter to all surgeons on May 29, 2008, that described the initiation of an investigation into all complaints and reassured users that, according to an internal company database of outcomes, only three of 480 Durom cups implanted in the U.S. had been revised¹². Two months later, Zimmer temporarily suspended marketing and distribution of the Durom cup and issued a press release to all U.S.-based arthroplasty surgeons instructing them to stop using this implant until they received further surgical training¹³. This was followed one week later by an article in *The New York Times* alerting the public to the problem¹⁴, and two months later by a class-II recall by the FDA¹⁵. According to Zimmer, the failures were not due to a defect in the materials, manufacture,

TABLE I Demographic Data for Well-Functioning and Failed Implants

	Well-Functioning	Failed
Age* (yr)	69 (44 to 94)	64 (43 to 83)
Sex (M:F)	85:118	37:57
Side (R:L)	104:99	46:48
Body mass index* (kg/m ²)	29.8 (15.5 to 72.0)	30.0 (15.2 to 50.3)
Radiographic inclination of cup* (deg)	42.5 (30 to 56)	42.7 (32 to 51)

*The values are given as the mean, with the range in parentheses.

or design of the implant, but rather to incomplete operative instructions that had initially been distributed to surgeons^{2,13,16}. The senior author contacted all of his affected patients, fully disclosed all available information from both Zimmer and the published literature, and monitored the patients closely with frequent office visits and serial radiographs for signs of loosening. In July 2010, Senator Charles Grassley, the Ranking Member of the U.S. Senate Committee on Finance, requested more information from Zimmer regarding the company's policies regarding monitoring of its devices and handling any safety concerns raised by its consultants¹⁷. A Zimmer news release in January 2011 indicated that the company cooperated fully with the investigation and that no further questions or requests are pending¹⁸.

The personal toll of this recall was substantial, and it was a very trying time for the senior author. As a surgeon, it was initially very difficult to make the decision to operate solely on the basis of symptoms and vague findings on physical examination, without any other objective evidence, yet every patient had resolution of the preoperative symptoms following the revision surgery. Hundreds of hours were spent sitting with patients and listening to their emotions, which ranged from tearful despair to intense anger. Considerable time was devoted to proactively contacting primary care physicians to explain the difficult situation and preserve a referral base that had taken nearly two decades to establish. A response that occurred among all patients was a sense of frustration that arose from not knowing whom to blame. In retrospect, however, the senior author's clinical practice did not suffer, and he seemed to have gained respect from patients, primary care physicians, and surgeons alike by the manner in which this situation was handled.

There are four important lessons to be learned from this experience. First, there is a tendency for surgeons to divorce themselves from such a problem in an attempt to absolve themselves from responsibility. However, in doing so, the surgeon would effectively abandon his or her patients in their most dire time of need. Despite a flood of personal emotions ranging from anger to guilt to defensiveness that accompany the failure of a medical device, the surgeon should always remember that it is his or her first and last duty to be the patient's advocate¹⁹. Poor communication and lack of attention have been shown to be major factors in precipitating a lawsuit²⁰. To help his patients through this ordeal and at the recommendation of his corporate attorney, the senior author met one-on-one with each patient to discuss the situation. This individual attention, careful communication, and strong doctor-patient relationship may have contributed to the fact that none of his patients has filed lawsuits against the surgeon to date as a result of the implant failures. When confronted with an implant recall, it is essential to understand that although the manufacturer and, perhaps unjustly, the insurance companies often bear the primary financial obligation²¹, the time commitment by the surgeon and the effect on his or her practice are largely unavoidable.

Second, informed consent and the ethical implementation of new technology are inseparable aspects of the practice of medicine. It is a curious discrepancy that consent during a

research phase requires multiple pages of documentation and explanation, yet often becomes an obligatory and cursory undertaking after approval of the treatment^{22,23}. The ready availability of medical literature to the public and the high prevalence of favorable results in industry-sponsored studies²⁴ can inflate patient expectations and deflate their appreciation of the experimental nature of new technology. The fiduciary responsibility of the surgeon refers not to any financial obligation, but rather to the trust that he or she will act on behalf of the patient²⁵. Advocacy begins preoperatively; patients demanding new technology should be counseled about the risks of new products. As stated aptly by Holt et al., a definite line between innovation and unacceptable experimentation should always be established when considering new techniques and technology; "to embrace a technique before it has been suitably validated may result in a step backwards in our surgical evolution."²⁶ It is incumbent on the surgeon to choose proven implants and methods unless there is a compelling reason for change. Indeed, very few of the hip implants introduced over the past several decades have achieved the prolonged popularity and durability to result in long-term follow-up studies^{27,28}. Of these, most have reported satisfactory outcomes and >95% survivorship²⁹⁻³³. Although further improvement in function and greater durability in young patients are well-intentioned goals, they may not justify the large number of implants being introduced into the market without adequate trials.

Third, relationships in medicine—not only those between the patient and the physician but also those between the physician and industry—must transcend the common *caveat emptor* ("buyer beware") interaction. Failure of the profession to maintain a positive, responsible public image may lead to an irreversible erosion of trust. It is the surgeon, not the manufacturer, who is ultimately entrusted by the patient to select an appropriate and reliable implant and to apply it correctly. The standard of care, both ethically and medicolegally, dictates that the surgeon must have knowledge of the procedure and competence in its performance, exercise care in diagnosis and planning, and exercise diligence in patient treatment³⁴. Although companies are intimately involved in providing education in implementing their technology and can serve as a partner in patient care³⁵, it is the responsibility of the surgeon to become an expert in all aspects of a procedure. In the event of an untoward outcome, patients often naturally look for an entity to blame²⁰. Even if neither the surgeon nor the manufacturer accepts blame for the failed device, a large "runaway jury verdict" can be leveled against all defendants, leaving each party to argue over relative responsibilities³⁶.

Finally, unlike consumer product recalls, surgical implant recalls are communicated by the manufacturer to the physician instead of directly to the patient³⁷. Unfortunately, companies typically do not admit the existence of a product failure until that becomes necessary, and they often attempt to shift blame away from themselves³⁶. While the establishment of a national joint replacement registry, recently introduced as a bill in the U.S. House of Representatives³⁸, may or may not be more effective in identifying "bad" implants sooner than well-designed prospective studies do, such a registry could help to protect

surgeons from being blamed for the use of faulty techniques². National registries have resulted in decreased arthroplasty revision rates and fewer complications³⁹. Although several mechanisms, such as the Manufacturer and User Facility Device Experience Database and the Medical Product Surveillance Network, are available for hospitals, manufacturers, and physicians to report adverse events, implant revisions are frequently underreported⁴⁰, and the need for a better “early warning system” necessitates a more systematic approach⁴¹. Even timely investigations by companies can take weeks to months, leading to countless additional adversely affected patients nationwide^{41,42}. Also, despite the most scrupulous intentions, the ability of any business to remove bias in these situations must be questioned. Finally, internal company databases encompass only a small fraction of the surgeons using the device, and company press releases may lag behind current use by external surgeons. For instance, the senior author performed three revisions due to cup loosening in the five weeks preceding the initial Zimmer communication. Accurately documenting and reporting all implant-related complications, staying abreast of the current medical news, and communicating with fellow surgeons can help to disseminate vital information¹⁹. Multiple unusual or unexpected patient symptoms should not be dismissed or rationalized even in the absence of any warnings issued by the manufacturer or supporting radiographic or laboratory evidence, especially in the context of a new implant. Indeed, a novel method or technology should be introduced to a select group of surgeons as a controlled prospective trial with adequate follow-up and early reporting prior to widespread dissemination.

Arthroplasty implants that fail exact a heavy toll on all of society. Innovation is critical to the advancement of medicine, but new ideas should not replace proven methods without a thorough evaluation and a compelling need. With recent advances in orthopaedic technology and increased marketing campaigns by implant companies, patients and physicians alike have come to expect nearly ideal clinical outcomes²⁶. Despite the general reliability of most total joint implants, rare but notable failures⁴²⁻⁴⁴ can undermine public confidence in arthroplasty. Surgeons must be prepared to protect their patients, the community, and themselves from ongoing damage. Although federal regulatory agencies and national databases can serve as supervisory bodies, the true responsibility of acting as detective and reporter lies with the surgeon. It is he or she who is at the center of patient care and ultimately delivers the final product to the patient.

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