

## **Preface: Local and Systemic Effects of Wear Particles from Orthopedic Devices**

Over the last two decades, multiple issues have arisen from local tissue effects from orthopedic implants and associated wear debris. Starting in the early 1990s, cement disease reports were quickly found to be caused by local inflammatory markers released from macrophages as they engulfed small polyethylene wear particles. During this era, it was determined that polyethylene sterilized in air caused excessive oxidation and released a much larger number of wear particles in many cases due to delamination. Manufacturing processes were also found to be significantly important; in the early part of the last decade, Sulzer recalled the Metasul metal-on-metal acetabular shell due to a residual film left on the ingrowth surface when the manufacturing process changed from a vegetable- to petroleum-based oil. This problem caused failed procedures in thousands of patients due to local effects of the oil residue interfering with local bony tissues that failed to incorporate into the porous coating. (The company was eventually sold to Zimmer, Inc.) The latest recall concerning local soft-tissue effects from orthopedic devices is a metal-on-metal total hip bearing, which represents one of the largest recalls among all joint devices. It was estimated that about 35% of all total hip devices implanted in 2007 had a metal-on-metal type of bearing. A smaller percentage had a total hip with the recalled ASR bearing from DePuy Inc, Johnson & Johnson. With the recall from this one manufacturer now resulting in billions of dollars in liability, a sharp eye is now focused on similarly designed metal-on-metal bearings of other manufacturers. As we delved into a new era of metal-on-metal bearings, we quickly realized that all bearings were not created equally and that the design parameters of bearing clearance, acetabular thickness, femoral head coverage, and alloy carbon content all play major roles in the performance of the bearing. The effects of local tissue lymphocytic-driven reactions along with necrosis and fluid collections, and even toxic levels of alloy material, have sent an alarming message regarding the need for improved standards concerning these and other hard-on-hard bearing designs.

Most recently, new effects from fretting corrosion of modular tapers are now being reported at an alarming rate. As newer designs and technology are brought to the marketplace, appropriate testing standards and guidance documents need to be in place prior to their clinical availability to assure their safety. In addition, combining design attributes that have a well-functioning predicate (e.g., modular taper junction designs) with a newer technology or designs (e.g., large diameter metal on metal bearings) may not have the safe and effective result that was intended.

In the case report section of this special issue, we aim to alert end users and scientists to the clinical problems that are now being encountered as well as the basic science of the inflammatory response to implant debris. The fact that patients with the same implant and surgical techniques may react differently to an implant's wear debris and corrosion products tells us that we may not understand the entire mechanism behind local tissue reactions to these orthopedic devices. Further testing and standards concerning corrosion effects *in vivo* are also necessary to assure the safety of these types of devices. As surgeons and end users of medical devices, we expect that the products we utilize have been properly tested for safety and effectiveness. Therefore, we must understand

these issues as well as the standards that these products undergo to assure their clinical applicability and appropriateness.

In this special section of this edition, we aim to help surgeons focus on these issues and to encourage involvement in research and standardization processes, and to increase awareness of remaining problems concerning orthopedic implant wear debris to assure that only the safest and most effective orthopedic devices are clinically available.

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