The Science Behind Wear Testing for Great Toe Implants for Hallux Rigidus

Judith F. Baumhauer, MD, MPH[a,*], Michele Marcolongo, PhD[b]

KEYWORDS

• Hydrogel • Toe implant • Hallux rigidus • PVA • Wear testing

KEY POINTS

- An orthopedic surgeon makes decisions about which implants to use to help his or her patients.
- Understanding the level of evidence supporting the use of the implant, and the rigor of the material testing, is critical to avoid repeating the failures resulting in bone loss and joint instability.
- The regulatory system allows for a 510K approval for implants as long as they can prove the new implant is "like" the old one in its use and application.
- Thus, no new knowledge is gained and the surgeon has no science to examine clinically, biomechanically, or histologically.

BACKGROUND

The function of articular cartilage is to provide a low-friction bearing surface enabling the joint to withstand weight bearing through the range of motion needed to perform activities of daily living. Various methods of repairing damaged articular cartilage surfaces have been proposed and a variety of implant materials have been tried in an attempt to decrease pain and improve function after cartilage repair. The majority of these techniques have significant limitations, including with loosening, malalignment/dislocation, implant fragmentation, and bone loss. A major cause of failure has been osteolysis and aseptic loosening owing to wear.[1]

The hydrogel made of polyvinyl alcohol and saline is a unique material used as an implant in the great toe for advanced stage arthritis. This material was developed to

Disclosure Statement: Dr J.F. Baumhauer is a paid consultant for Carticept Medical, DJ Orthopedics, Ferring Pharmaceuticals, Fidia Pharma USA Inc, Medtronic, Nextremity Solutions Inc, and Wright Medical Technology, Inc. Dr M. Marcolongo has nothing to disclose.
[a] Department of Orthopaedics, University of Rochester School of Medicine and Dentistry, Box 665 Elmwood Avenue, Rochester, NY 14642, USA; [b] Materials Science and Engineering, Drexel University, 3141 Chestnut Street, Philadelphia, PA 19014, USA
* Corresponding author.
E-mail address: Judy_Baumhauer@urmc.rochester.edu

Foot Ankle Clin N Am 21 (2016) 891–902
http://dx.doi.org/10.1016/j.fcl.2016.07.004
1083-7515/16/

mimic an artificial articular surface that has shock-absorbing ability, high wear resistance, and wear particulate biocompatibility, properties necessary for suitability as a biomaterial intended to replace damaged cartilage. Prior implants made of silicone were used for great toe arthritis and failed owing to poor wear characteristics. Understanding the differences between the various materials and the biomechanical testing performed on these materials allows the surgeon to make educated selection on implants to use in the treatment of their patients.

REGULATORY PATHWAY

The Food and Drug Administration (FDA) regulates medical devices in the United States with different levels of regulatory oversight depending on the classification of the device. The 2 most common regulator pathways are the 510(k) premarket submission and the more rigorous premarket approval (PMA).

The FDA evaluates medical devices including arthroplasty products by 2 main pathways, premarket notification or 510(k) PMA. The former requires demonstration that the device is substantially equivalent to a predicate device. Submitted data typically involve laboratory testing demonstrating that the new device introduces no new safety risks. Any devices not substantially equivalent to existing products follow the more stringent PMA pathway, requiring evidence of device safety and effectiveness. For a PMA application, clinical data from a large randomized clinical study is required to demonstrate safety and effectiveness, in addition to comprehensive laboratory studies characterizing the device properties, functionality, and safety.

The majority of total joint replacement and hemiarthroplasty implants (using materials already widely used such as titanium, ceramic, polyethylene, and silicone) reach market via a 510(k) submission that, depending on availability of predicate device data, may or may not include wear testing simulating indication-specific in vivo conditions and animal implantation of wear particulate.

Because this was the first use of a polyvinyl alcohol hydrogel material for cartilage repair, the FDA required the PMA pathway for this polyvinyl alcohol polymer (PVA) implant, the most stringent type of device marketing application required by the FDA. In addition to the PMA requirement for large randomized clinical studies to prove safety and effectiveness of the device, a PMA requires extensive testing of the material's suitability as a cartilage replacement material.

OTHER HEMIARTHROPLASTY MATERIAL CONCERNS

Hemiarthroplasty initially began with implants into the proximal phalanx, and have evolved to include 1 implant for the metatarsal head side of the joint. These implants are designed to resurface the first metatarsophalangeal (MTP) joint while maintaining or preserving motion.[2]

Although some of these implants have been available for more than 50 years, few studies have been published investigating the effectiveness of these implants. In addition, material concerns exist with silicone implants, as reported in the literature. Unlike hydrogels, silicone elastomers are nonbiphasic, hydrophobic, and not well-lubricated in the body.

Silicone orthopedic prostheses introduced in the early 1960s were initially believed to be durable and biocompatible with good initial clinical results. Occurrence of inflammatory responses is now well-recognized with these types of implants and is attributed to foreign body giant cell reaction to silicone particles.[3–5] Although the implant itself is inert, abrasion and fatigue fracture of the implants was found to produce microscopic particles that caused inflammatory synovitis, a complication not readily