Retrieval Studies in Orthopaedic Surgery

Editorial Comment

Learning Every Implant's Story

William M. Mihalko MD, PhD

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Retrieval studies of failed implants in orthopaedic surgery have given surgeons, manufacturers, and oversight agencies insight into many implant problems in the past, including issues with bearing surfaces (titanium as a bearing, carbon fiber-reinforced polyethylene, sterilization technique issues with polyethylene), implant design (locking mechanisms for polyethylene, taper junctions for modularity, and corrosion), and manufacturing (cast versus forged alloys, laser etching, processing, and sterilization issues). Most recently, concerns pertaining to metal-on-metal bearings have led to an emphasis on retrieval analysis techniques, which can aid in our understanding of why devices fail in vivo and furthermore why in vitro studies may not always correlate to ensure all issues pertaining to a device's design and biomaterial structure are optimized and approved. In the future, as in the past, retrieval studies and analysis of failed and well-functioning implants will be important in our field as long as we continue to design and implant medical devices to reconstruct, replace, and correct traumatic and disease issues in our patients.

The field of retrieval analysis in orthopaedic surgery suffers from the lack of information on frequency since we usually do not know the numerator (number of failures) or denominator (number of implantations) of a device until red flags are raised with concerns that it may have adversely affected many patients. The American Academy

Fig. 1 Dr. William M. Mihalko is shown.

of Orthopaedic Surgeons Biomedical Engineering Committee [1] has reported on the importance of adverse event reporting through the FDA's MedWatch program [2]. Unfortunately, these reports are voluntary on the side of the users (surgeons in our case) and often go unreported. In the field of total joint arthroplasty, these concerns are being addressed using national joint registries. The registries can identify concerns with devices, surgical techniques, facilities, and surgeons earlier and aid in our understanding and optimization of the surgical care and techniques that go into improving patient care. It can be argued that retrieval studies could benefit from similar types of registries or regional repositories that collect failed devices. In this manner, retrieval laboratories could collect multiple

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W. M. Mihalko (✉)
Professor & JR Hyde Chair, Campbell Clinic Department
of Orthopaedic Surgery, University of Tennessee, 956 Court
Avenue, Suite E226, Memphis, TN 38163, USA
e-mail: wmihalko@campbellclinic.com

devices instead of a handful from tertiary care academic centers and have much more statistically powerful numbers of devices to analyze. There are also issues with tertiary specialized surgeons versus community generalized surgeons that may shed better light onto the issues with a device that may never make it into the literature without the establishment of these types of centers. Some of the road blocks to the establishment of regional retrieval repositories are funding and maintenance of patient data in a secured Health Information Protection and Portability Act compliant environment. These issues are similar to the joint registry problems that are facing our colleagues in the American Joint Replacement Registry. However, retrieved devices involve some unique issues. The devices would have to be voluntarily surrendered by patients since legally they have ownership of their devices. This, on top of legal issues with recalled devices, may make overcoming these unique issues much more cumbersome than with the American Joint Replacement Registry.

Another unique issue that may arise with any type of retrieval analysis study is that publication of the results is often met with some academic resistance. Many problems with a device could be unique to how it was implanted or to the surrounding biologic environment the patient provided rather than related to the device per se. In these types of cases, a traditional hypothesis-driven study/publication with high statistical power is often not possible. The opinions of retrieval analysis researchers and academic- and community-based surgeons may differ on this matter. It may not be appropriate in many cases to consider an analysis of a device with others due to patient- and surgical technique-related factors, but every device has a lesson to teach and a story to tell. Many of the stories devices have to tell concerning the events leading up to their failure are important and can aid end users and manufacturers alike to avoid problems for the patients they are intended to help. The maintained ownership of the device on paper and providing a report to the patient may be ways to overcome this obstacle. In a way, the regional repositories could become a “safety deposit box” for the patient’s retrieved device.

The retrieval analysis field will be more in the spotlight with recent events pertaining to orthopaedic device recalls. The FDA has now initiated mandatory Section 522 post-market surveillance studies on metal-on-metal total hip bearing devices. These types of studies can lead to the

mandatory analysis of any device removed in these cases for any reason. In these mandated studies, the implant’s story may be determined ahead of any large postmarket recall and avoid many issues in the future. It will take some federal regulatory oversight, however, to overcome some of the legal issues mentioned above.

This symposium on retrieval studies in orthopaedic surgery shows the diversity of analyses being performed on devices today. In this symposium, readers will find not only more traditional types of polyethylene assessments on wear and oxidation but also tissue analysis and interface analysis of retrieved devices, as well as ligament and fluid analysis pertaining to failed and well-functioning total knee devices. With the spotlight on many current annual meetings (American Association of Hip and Knee Surgeons, American Academy of Orthopaedic Surgeons, and Orthopaedic Research Society), there are also studies pertaining to metal-on-metal wear and tissue reaction. Another more advancing field in orthopaedics is now being applied to retrieval analysis and may aid in intraoperative assessment of total joint implant surgical implantation on an individualized or personal medicine basis. This involves computer modeling of wear patches and determining how implant alignment may affect the overall wear pattern and stresses within the polyethylene of a total knee design. The area of techniques to predict an implant’s survivorship on an individual basis may be one of the next advancements in our field and may be considered a different type of “personalized medicine” in orthopaedic surgery. Utilizing the stories that orthopaedic devices are telling us and have told us over the years will continue to advance our field of orthopaedics. The development of new tools and analysis techniques to discover and eventually avoid the pitfalls and optimize an implant’s performance and survivorship are what we are all striving to achieve for our patients.

References

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