Preface: Retrieval Analysis of Implanted Medical Devices

Each year millions of patients improve their quality of life through surgical procedures that involve implanted medical devices. As the rising cost of health care continues to be debated within our country, it is clear that we must be certain that Americans are receiving the best, most cost effective health care treatments. Advances in medical technology continue to be a large part of the rising cost of health care, and the decision to provide the increased cost of care due to new technology must be determined from evidence-based studies.

The Food and Drug Administration this past year issued an internal report where they stated that science-based reviews must be strived for and that the agency must first provide safe devices for patients while making sure not to impede the advancement and innovation of technology in the medical field. With the focus on both cost and innovation, it is clear that everything must be done to make certain that the devices we utilize in medicine are safe and that they are given a pathway to be improved on using science and lessons learned from device retrieval studies. Retrieval analysis studies of medical devices have been utilized for decades to learn lessons from failed devices removed at the time of revision or repeated procedures, as well as from those that functioned well for the life of a patient and were obtained at necropsy.

The value of implant retrieval analysis in orthopaedic surgery has been well recognized in advancing implant longevity. If we use the example of total hip and knee arthroplasty, we know that analysis of devices has provided insight into wear, corrosion, design characteristics, and material issues that have advanced the design and longevity of these devices. Prosthetic implants retrieved at revision surgery (for implant failure) or devices retrieved postmortem from patients with clinically successful reconstructions provide a unique set of specimens that can be studied to evaluate the effect of the implant on the host environment and vice versa. In this issue, there are two articles that try to determine commonalities of patellar polyethylene buttons from total knee arthroplasty, with one obtained from necropsy retrievals and the other from implants obtained at time of revision surgery. A systematic analysis of retrieved components, in combination with histologic, radiographic, and clinical data, can provide valuable insights into the mechanisms of failure of the biomaterials and implant designs used in joint replacement applications. If computer modeling can be added to properly predict wear patterns and kinematics of the joint, then the first steps toward intraoperative computer assistance for optimal functionality and implant longevity may be realized. This type of analysis can be seen in this issue's article that utilizes a 3D dynamic TKA model to show how the kinematics and contact stresses change after wear of the polyethylene insert (Williams et al.).

The first retrieval observations were performed for failures of implants during their subsequent revision surgeries. While these studies gave valuable insight into the failure modes of early designs and biomaterials, it was not until the 1980s when donor-related studies were organized. At that time, usually the establishment of a retrieval program within a practice of orthopaedic surgeons allowed for the analysis of a series of patients who had a specific implant utilized at the time of surgery. There are few retrieval programs that encompass a large variety of implants, and many times those laboratories only receive the implant itself without the surrounding joint and musculoskeletal tissues. It has been evident from past

studies that several significantly important modes of wear and or implant failure have been reported that have allowed changes in the field of hip and knee arthroplasty to further the design-related and surgical-related techniques in the field. We must continue to update our investigative techniques of these devices, and this issue also has reports from London, Ontario, investigators evaluating new techniques to evaluate the wear of polyethylene components.

Ultimately, it is the patient and the improvement in their quality of life that benefit from retrieval analysis studies. It is imperative that the field of medicine continue these kinds of studies to investigate newer, more modern implant designs and surgical techniques since the in vitro testing and the computer modeling techniques cannot always predict the in vivo wear or failure mechanisms that may have a negative impact on the longevity or functional result for the patient.

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