

## **Preface: Evaluation of the Performance of Implants**

Implantation technology has reduced our pain, as well as made us live longer and have healthier lives, through engineering design and production of replacement parts, or through other novel procedures such as modification of natural grafts or tissue engineering and regenerative medicine using stem cell engineering. While pacemakers, heart valves, and bone implants have been recognized as viable therapies for some time, implants for cochlear malfunction, intraocular therapy, and left ventricular assist devices have achieved critical mass only recently for them to be claimed as mainstream therapy. Additional paradigms that are now a part of the physician's tool kit include devices for targeted drug delivery, regenerative therapy using stem cells, and continuous monitoring of the body's internal physiological variables, just to name a few. In this context, the role of engineers in better designing and developing novel and viable devices places them under greater scrutiny. Also, there is a need to study and document limitations and deficiencies of all existing implants so as to improve their performance and efficacy with the next generation of implantable devices. Performance metrics have to be adjusted upward regularly based on experience.

In this issue of the journal, a paper by Lodder et al. reviews how efficacies of different implanted devices have been measured. Specific devices that augment the function of eyes, cochlea, and left ventricle and modulate glucose are examined with a view toward understanding their efficacy.

Cardiac electronic devices have been implanted in millions of patients with extraordinary success. Primarily, implantable cardiac pacemakers and defibrillators fall into this category. Drs. Bennett and Tung describe these devices, including their components and how they function, in their paper. Failure can take place in any one of the components of the device such as the battery, electrical waveform generator circuitry, leads, insulation, and dislodgement of leads. In addition, Drs. Bennett and Tung identify several common failure mechanisms of cardiac electronic devices and their clinical manifestations. They also provide clinical guidelines for the physician for therapeutic interventions. One of the modes of failure is through infection of cardiac electronic devices, an issue that is receiving increasing attention. Dr. Margey documents the epidemiology, causes, pathogenesis, management, and outcomes of cardiovascular implantable electronic device (CIED) infections and also presents an algorithm that can be used for dealing with such infections.

While stem cell therapy is the most modern entry into the world of implants, its potential for ameliorating a number of diseases is being unravelled at a very rapid rate. Stem cells have graduated from being a research curiosity to providing therapeutic alternatives in a relatively short time span. An extensive review of stem cell sources and their clinical applications, along with an up-to-date bibliography, is provided by Mr. Mankikar. The variety of sources of stem cells makes it relatively straightforward to harvest and process them, whether it is for animal-based research or for treating human diseases, within the ethical and legal boundaries that the present day society places on the scientific community.

Vagal nerve stimulation has been employed for controlling drug-resistant epilepsy since the early 1980s. More recent applications include treatment of clinical depression, Alzheimer's disease, pain, and autism among others. These are explored in this issue in a review by Kamath et al. The efficacy of vagal nerve pacing has been evaluated both in the short and the longer term by a large number of researchers. While epileptic seizures were reduced by as much as 50% and the treatment was deemed safe, it did not result in total cessation of seizures in a large number of patients. Further studies are underway to evaluate the vagal pacemaking over the longer term in several pathological conditions.

Efficacy of an implant over the longer term depends not only on the engineered product and how it functions in the body's hostile environment, but also on a large number of factors such as the patient's condition, his/her physiological responses, side effects, skill of the medical team that performs the implant surgery, and postsurgical management of the patient. Therefore, evaluation of longer-term effects of medical implants is essential for their continuing innovation, safety, and evolution.

Markad V. Kamath, PhD, PEng  
Associate Professor, Department of Medicine  
McMaster University, School of Biomedical Engineering  
Hamilton, Ontario, L8N 3Z5, Canada

Adrian Upton, MD, FRCP (C)  
Professor of Medicine  
McMaster University, Department of Medicine  
Hamilton, Ontario, L8N 3Z5, Canada