



## New Surgical Technologies: When Does Innovation Mean Improvement?

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In the weeks and days leading up to Steve Jobs's January 27 announcement about the new Apple iPad tablet computer, excitement over the anticipated product launch was running at a fever pitch. With Apple's past innovations including the Macintosh computer, the iPod, and the iPhone, many expected Jobs to introduce another trend setting, lifestyle changing product. Few of us remember that, in addition to some amazing successes, Apple has also released some flops, such as the Cyberdog, Newton, Macintosh TV, iPod HiFi, Pippin, and eWorld. Only time will tell where on that spectrum the iPad will fall, but already many technology reviewers have expressed disappointment with the iPad and its capabilities. Personally, I will reserve my judgment until I thoroughly evaluate the device—by reading expert reviews and trying it out for myself.

Just as we consumers tend to think that the next electronic innovation must be an improvement over what we currently have, many patients believe that innovation in surgery predictably produces something better. Open heart surgery; kidney transplants; reimplantation of severed fingers; and hip, knee, and shoulder replacements are just a few of the surgical innovations that have worked out well and improved the lives of our patients.

But surgery's track record, much like Apple's, is not perfect. A number of years ago, surgeons began using a new fixation device to stabilize the anterior spine. The early results looked promising, so more and more devices were used. After a while, it

became apparent that this device had an unintended long-term effect—namely, the erosion of the nearby aorta, which in a few cases caused it to rupture resulting in the sudden death of the patient. Needless to say, the device is no longer on the market, and the patients who received the device have had it removed.

A more recent example of an innovation in knee surgery is minimally invasive total knee replacement. No one wants maximally invasive surgery, so the name alone suggests an improvement. After this new technique was introduced, many patients came to my office, article in hand, asking if I performed this type of surgery. Most orthopedic surgeons would admit that performing an operation through a small incision can be a struggle; a larger incision makes it easier to see and align the implants. Since the patients only see the scar, smaller looks better to them. The goal of the procedure, however, is the proper implantation of a knee prosthesis designed to last many years, and if a larger incision helps accomplish this goal more effectively, many experts now agree that a slightly longer scar is an acceptable consequence.

Capitalizing on the common belief that newer is better, manufacturers market new products directly to patients to increase sales, often before evidence has demonstrated that the new product is better. At times, we surgeons respond to this patient demand and start using new technologies before we know for sure they are superior.

Fortunately, compared with how consumers must evaluate the latest

electronic gadget, we have better tools for evaluating new surgical technology. The best way to test the effectiveness and safety of such technology is to construct a prospective, double-blind, randomized, controlled trial (also known as level I research). In this type of research, both the random assignment of patients to treatment groups and the blinding of patients and investigators to which treatment they are receiving help avoid bias and produce reliable data.

Notably, however, many new orthopedic products have not been subjected to level I research before being released and marketed to surgeons and patients. In recent years, level I articles have composed 11.3%<sup>1</sup> to 21%<sup>2</sup> of the clinical research articles published in leading orthopedic journals. While these numbers represent an improvement over decades past,<sup>2</sup> they are still lower than ideal. Researchers are being encouraged to design studies that meet this higher level of evidence.

At my institution, my colleagues and I are currently performing a level I research study to determine whether a new method of placing total knee implants is better than the conventional method we have used for more than 20 years. The new method aligns the implants "kinematically"—that is, along the axes of the knee—with the goal of allowing the knee to move more normally than is possible with the conventional method. It relies on proprietary software (OtisMed, Alameda, CA) that uses magnetic resonance images of the patient's knee to generate a three-dimensional model of the knee. Based on this model, the

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program selects the best sized implant for each bone and places the implant so that the kinematics of the knee are reproduced. The computer then machines the patient-specific cutting guide from plastic, allowing the surgeon to transfer the position of the knee implants from the computer to the patient in surgery.<sup>3</sup>

The newer method is faster, requires only one eighth of the surgical equipment currently used, and is uniquely designed for each individual patient. Its potential benefits include a more rapid recovery and better clinical outcomes. But is it better? We won't really know until we complete the study and analyze the outcomes. Then we will need to submit our work to a peer-reviewed journal for an independent review and publication. Once our study is published, other surgeons can review the methods, data, and analysis to help them decide whether they would like to use the new technology.

Since we began this research two years ago, other companies have de-

veloped and are now marketing their own patient-specific cutting guides to patients and surgeons. Although these guides appear similar to the ones we are testing, they use the principle of mechanical rather than kinematic alignment, so the theory behind them is different. Only carefully constructed, double-blind, prospective, randomized, clinical trials can determine whether one method for implanting a total knee replacement is better than another.

Given the past marketing strategies of our industry, the coming year likely will see more dollars spent trying to convince patients and surgeons that one system is better than another. Rather than simply responding to marketing, we need to carefully evaluate results from well designed, level I studies to determine what is best for our patients. ●

#### *Author disclosures*

*The author reports no actual or potential conflicts of interest with regard to this editorial.*

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