SHOULDERING TREATMENT DECISIONS

OREF-funded study measures shoulder joint replacement outcomes

Total shoulder joint replacement lessens pain and improves function for patients with severe osteoarthritis of the shoulder, severe rotator cuff tears, or other serious damage to the shoulder joint. There are two general procedures: anatomical total joint replacement and reverse total joint replacement.

Reverse joint replacement was developed in Europe in the 1980s and approved by the U.S. Food and Drug Administration (FDA) in 2004. Because it is a relatively new procedure, published research about patient outcomes is limited. **Mark A. Frankle, M.D.**, orthopaedic surgeon at the Florida Orthopaedic Institute in Tampa and director of the Biomechanical Shoulder and Elbow Research Lab at the University of South Florida College of Engineering, received a 2008 OREF Research Grant. He used the OREF grant, which was funded by the **Dr. Dane and Mrs. Mary Louise Miller Endowment Fund**, to study range of motion and range-specific strength following anatomical and reverse total shoulder joint replacement. OREF Research Grants provide seed money and start-up funding up to $50,000 annually for up to 2 years.

▲ (l-r) Page Dunning, Mark A. Frankle, M.D., and Derek Pupello with a model of the reverse shoulder prosthesis.

Photo courtesy of FORE.

"This in-depth study requires bringing patients back for follow-up," added **Mr. Derek Pupello**, chief executive officer of the Foundation for Orthopaedic Research and Education (FORE), a nonprofit organization that coordinates research with surgeons at the Florida Orthopaedic Institute. "If we didn't have funding from OREF, it would not have been possible to support the labor involved. It's an honor to receive this grant, and we're doing our best to ensure that we get enough data and publish what we find."

TOTAL JOINT REPLACEMENT OPTIONS

In an anatomical joint replacement, usually the first choice for total shoulder reconstruction, the surgeon substitutes the damaged joint with an artificial joint that closely resembles the original shoulder anatomy. A metal hemisphere replaces the upper end of the humerus, and a plastic socket attached to the shoulder blade replaces the glenoid. The mechanics of the joint are unchanged. The rotator cuff stabilizes the joint and enables rotation and elevation of the arm.

The reverse procedure alters the mechanics of the shoulder. The articulation of the ball and socket joint is reversed. The surgeon attaches a metal ball to the shoulder blade and a plastic socket to the head of the humerus. The deltoid muscle stabilizes the joint and controls movement.

A surgeon may recommend the reverse procedure if a previous shoulder joint replacement hasn't lessened pain or improved function, or if there is irreparable damage to the rotator cuff tendons.

OBJECTIVITY: IMPROVING MEASURES OF PATIENT OUTCOMES

Dr. Frankle and his research team at Florida Orthopaedic Institute were among the first surgeons in the United States to use the reverse joint replacement procedure under an investigational device exemption from the FDA. This exemption enabled them to use the reverse joint device in clinical studies.

"We didn't really know how well the device was going to work," said Dr. Frankle. "We had some preconceived ideas, but we were a little skeptical."

This skepticism provided motivation to improve outcome analysis, develop novel objective measures, and improve the objectivity of tools that are inherently biased.

For example, when patients respond to a surgeon's questions about how they are doing, there may be some bias based on the doctor and patient's relationship. Dr. Frankle noted, "If they like you as a doctor, they might tend to say, 'Oh yes, things are great, doc. I'm wonderful.'" To diminish the potential for bias, Dr. Frankle and his research team have a research assistant — someone with no role in clinical care or treatment decisions — administer questionnaires about shoulder pain and function.

Dr. Frankle also described how the experience of gathering data for outcome analysis has helped them identify gaps in information. "We realized there were some pieces of information that we really wanted to know that we didn't collect." One gap was the need for objective strength data before and after a procedure.

"**Murray Maitland, Ph.D.**, a kinesiologist from the University of South Florida, came to our research meetings, and he thought it was interesting that some patients have passive range of motion, where you can lift their arm up, but they couldn't do it on their own, while other patients had very limited range of motion, both actively and passively, said Mr. Pupello.

Explained Dr. Frankle, "Range of motion is a very important parameter that we measure in orthopaedics, but that is only part of it. If someone can raise his arm but it's not very strong, that's not as good as someone who can raise his arm with significant strength."

A BROAD SPECTRUM OF OUTCOME MEASURES

In this current investigation, Dr. Frankle and his research team are using objective tools to measure both the range of motion and range-specific strength. Complete data collection before and after surgery for each patient includes:

- **Patient assessment forms.** These questionnaires administered by a research assistant pose questions regarding the degree of pain, the patient's perception of range of motion, and the patient's ability to perform tasks, such as reaching a back pocket or combing hair.
- **Clinician assessments.** The surgeon assesses the range of motion during a clinic visit, and the assessment is recorded in the patient's record.
- **Goniometer measurements.** A physical therapist not involved in the patient's treatment measures the affected arm's range of motion with a hand-held device called a goniometer.
- **Video-based, range-of-motion measurements.** Each patient is videotaped while moving the affected arm through various positions, and a researcher not involved in patient care measures the range of motion in a subsequent viewing of the video.
- **Range-specific strength measurements.** Isometric strength, or the amount of pressure a patient can exert against a lever when the arm is in different positions, is measured with a computerized, pressure-sensitive device called a dynamometer.

"We're collecting patient comorbidities, strength-testing, range of motion and function results, and pain scores," said **Ms. Page Dunning**, clinical research and education manager for FORE, and research coordinator on this project. "The information we collect is entered into a database. We'll analyze the data and look for improvements pre- to post-op, and any correlations between strength and range of motion, and strength and comorbidities."

This spectrum of measurements will enable Dr. Frankle and his research team to study outcomes of the anatomical and reverse joint replacements. By correlating data from objective and subjective sources, they will also assess the

reliability of patient and clinician reporting of post-procedure pain and function.

Finally, the researchers will correlate treatment outcomes with other factors such as patient age and sex, initial diagnosis, comorbidities, subsequent complications from the procedure, and the failure of previous shoulder joint replacement. Stratifying the treatment outcomes by these various factors may help surgeons communicate more effectively with patients about the expected benefits and risks of total shoulder joint replacement.

COORDINATING CLINICAL CARE AND RESEARCH

Research conducted by surgeons at the Florida Orthopaedic Institute, a private practice, is coordinated through a nonprofit partner organization, the Foundation for Orthopaedic Research and Education (FORE), which is housed in the same building as the clinic.

"There's very little bureaucracy, and there's very high efficiency," explained Dr. Frankle. He believes the model allows for practical and timely cooperation among surgeons, research scientists, project coordinators, clinical staff, and patients. He added, "We try to make it so that patients aren't going to take an extra day out their life to come and do research. If they're coming in for a follow-up exam, we can expedite getting critical information we need for research."

> "PATIENTS NEED TO FEEL THAT THEIR CONTRIBUTION MAKES A DIFFERENCE."

Said Ms. Dunning, "A lot of times patients need to feel that their contribution makes a difference. I encourage them to take an active role in their health care even if they had a bad outcome. If they don't let us know that the treatment wasn't effective, nothing will change. We have to know the good and the bad to be able to help everyone more effectively."

Dr. Frankle noted that this cooperation has been valuable in eliciting better participation in follow-up assessments after total shoulder replacement. His research team and he have been able to identify obstacles — such as travel expenses, limited insurance coverage, or lack of interest — that inhibit patient participation. The foundation partners have, in turn, found solutions, such as more frequent calls, assistance with travel and other expenses, and improved communication about the value of research.

Dr. Frankle believes that health care is a partnership between the clinician and the patient and that a part of his role as an orthopaedic surgeon — and researcher — is to help patients understand the value of reporting, whether good or bad, how they are doing. "If you can do that," he tells his patients, "you provide information to get us a little bit closer to knowing what's effective and what's not." ■