[www.nurse.com]

Nursing Spectrum

NEW YORK/NEW JERSEY METRO EDITION JUNE 4, 2007

Nurses at Every Step:

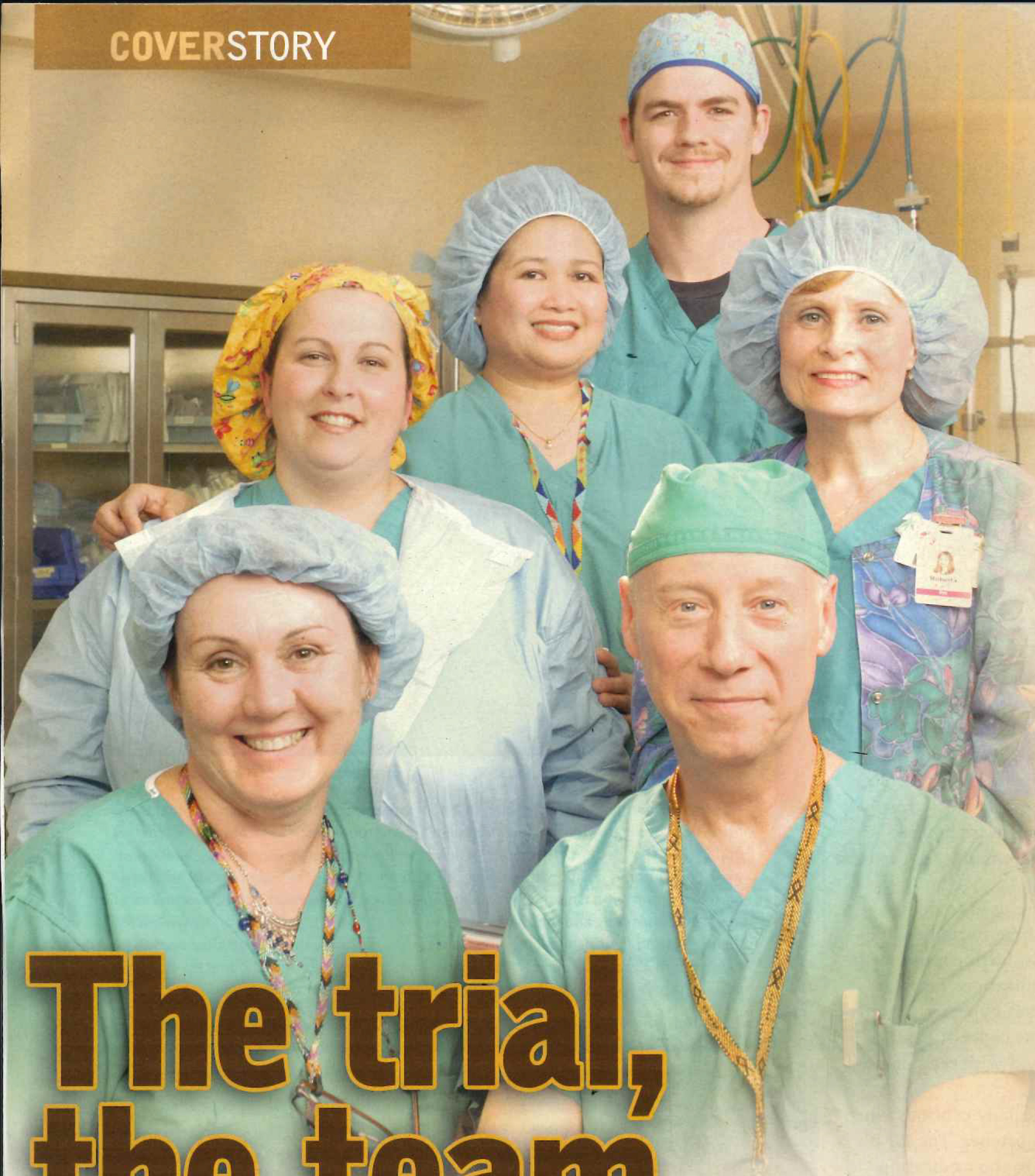
From Clinical Trial to Market

Page 10

Self-Study CE: New Discoveries Help in Diabetes Control

Page 18

ST. CATHERINE OF SIENA MEDICAL CENTER, SMITHTOWN, NY.



The trial, the team

A new spinal fusion methodology trial brings hope and relief to patients suffering from degenerative disc disease.

Janice Spillane, RN, MS

"The last 10 years have seen significant advances in orthopedics, especially in new implants, safer devices, and better imaging," says Marc Chernoff, MD, spinal specialist at St. Catherine of Siena Medical Center, Smithtown, N.Y., and St. Charles Hospital, Port Jefferson, N.Y. "Some new technology comes with inherent risk, but anything that can be used safely and at the same time improve patient outcomes makes sense to use," he adds.

One such technology, in use in the United States since 2004, is an intrabody spinal implant consisting of a small mesh bag of bone known as OptiMesh® that is being used to treat vertebral compression fractures (VCF). These fractures occur most often as a result of osteoporosis, trauma, or tumors.

In osteoporosis, spinal bone becomes porous and highly fragile. The statistics show that more than 10 million Americans have osteoporosis — the majority of them women. The data show that osteoporosis causes as many as 1.5 million vertebral fractures a year — more than 750,000 of them VCFs (Spineology www.spineology.com/page649.aspx). The OptiMesh® implant, which is introduced into a cavity created under the fracture, has been used successfully in treating these fractures.

Participating in a clinical trial

Recently, Spineology, the parent company of the OptiMesh® implant, received authorization from the FDA to conduct a phase II clinical trial to explore the use of OptiMesh® for interbody implants — insertion between two vertebrae to fuse the vertebrae to one another. These interbody clinical trials are being conducted in 10 locations around the country, and here in the New York area, Chernoff and his brother, Ira Chernoff, MD, also a spinal specialist, are participating.

"Intrabody OptiMesh® implants for spinal fractures have been used for the past few years, so we decided to become involved in the interbody trial because there was very little downside, and it had potential for significant benefit to the patient. Using an OptiMesh® implant as part of the spinal fusion process adds little risk," says Chernoff.

Getting ready

Preparing for the clinical trial starts with the doctors learning how to use the OptiMesh® implant system, first on cadavers, and then on select patients who agree to undergo its use. In a clinical trial it is used in combination with a standard posterior lumbar fusion.

During the learning period, patients who require a one-level lumbar spinal fusion (L2 to S1) and who might benefit from the addition of the OptiMesh® implant, are asked on a case-by-case basis if they will agree to its use. The procedure, its risks, and its benefits are fully explained — first by the doctors and then again by Cynthia Dibella-Price, RN, ANP-C, FA, the nurse practitioner who works with the doctors in the office and as their first or second assistant during surgery. Dibella-Price makes sure that every patient fully understands the procedure and answers whatever questions he or she may have.

Dibella-Price found that many patients readily agree to the procedure because there is so little risk involved. Additionally, those who might not qualify for the procedure once the clinical trial starts are glad to have the opportunity to benefit from the new technology during the learning period. The purpose of the study is to collect data on the safety and effectiveness of the procedure, and the hope is that the implant will provide added stability to the spine and reduce pain. "In all, eight patients underwent a posterior lumbar spinal fusion with the OptiMesh® implant prior to the start of the clinical trial and as part of the learning period," says Dibella-Price.

"Prepping" the OR

"New technology and new surgical procedures are what make the OR so interesting," says Wanda Cabaltica, RN, BSN, CNOR, Operating Room nurse, St. Catherine of Siena Medical Center, Smithtown, N.Y. "It's the continued opportunities for learning that make working in the OR exciting." When a new orthopedic procedure is introduced in the Operating Room, the OR staff undergoes training, which always includes the use of new equipment, surgical techniques required by new instruments such as the OptiMesh® insertion device, and patient-specific interventions. Roberta Kant, RN, CNOR, staff nurse on the orthopedic OR team, often becomes the lead nurse and trainer, as well as scrub nurse on these procedures.

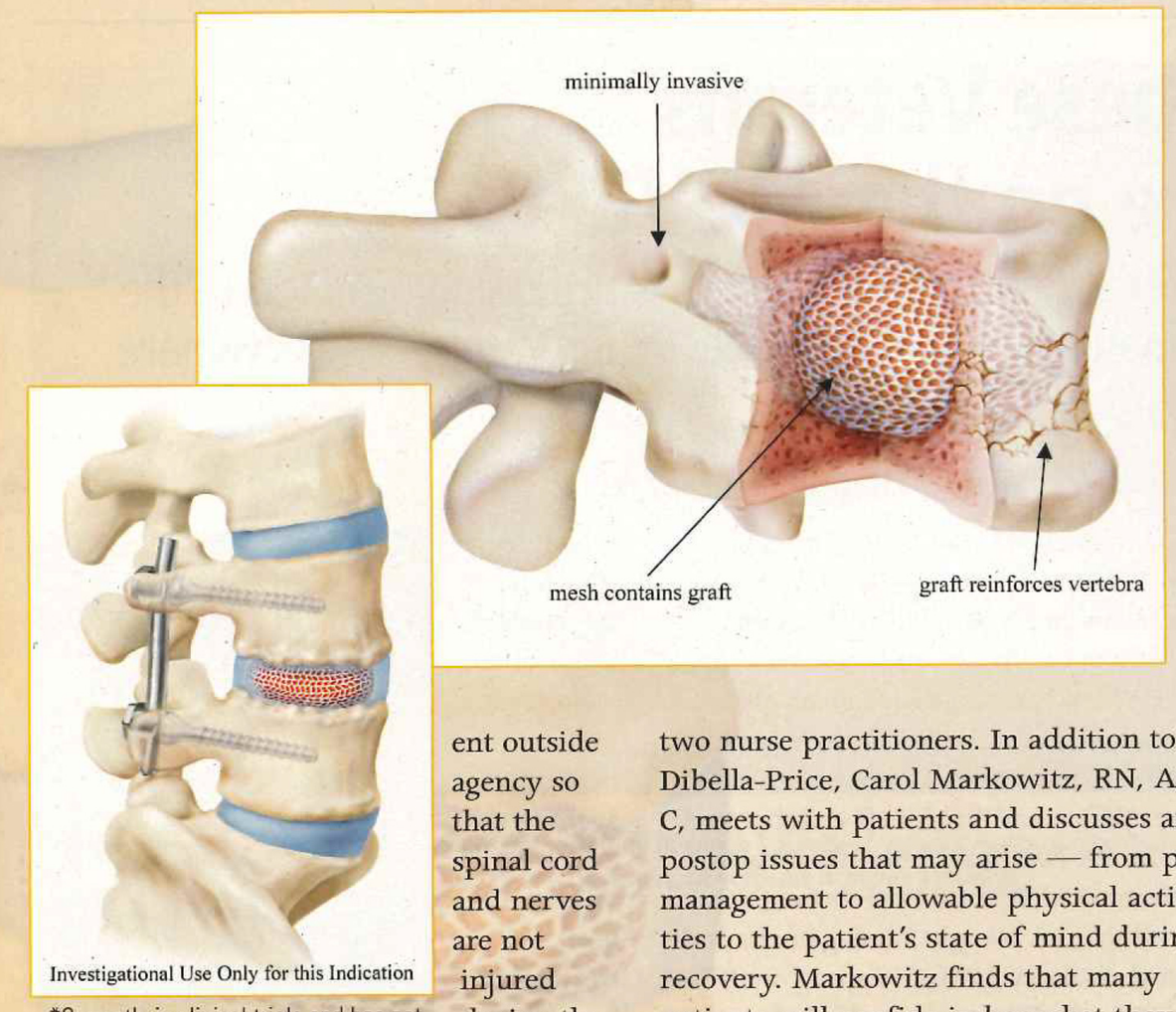
"There's a lot that goes into making sure the OR is fully functional for the surgical team and totally safe for the patient," says Kant. "We recently purchased a Jackson Spinal Table™ for use in orthopedic surgery, and learning how to use the table and position the patient properly became priorities," she says. The Jackson Spinal Table™, a multi-positional table, uses alternating pressure to reduce the chance of pressure sores during long operations, and its radiolucent frame and unrestricted C-Arm access make full spinal fluoroscopy possible. The table was first used during a posterior spinal fusion with OptiMesh® implant placement, and has since become a standard for many other orthopedic surgeries. Because the table has so many parts and features, Kant, on her own time, developed a picture-enhanced training manual for quick reference.

Also critical to any new surgery is scheduling sufficient time in the OR. "Time is always an issue," says Patrice Kelly, RN, BSN, CNOR, RNFA, director of Perioperative Services at the hospital. "However, our computer booking system tracks physician OR time by doctor, and that helps us to estimate how long a block of time will be needed. With new surgical procedures, we normally add on extra time," she says. As the doctors and staff get more experienced with the procedure, the time it takes usually decreases. Ultimately, it is expected that this surgery will take from four to five hours — depending on the degree of the patient's degenerative disc disease.

"No matter what the new technology, the basic nursing is the same," says Kant. "We apply standard nursing principles to each situation, and write a nursing care plan that takes into account all aspects of patient care, from positioning to medications to implants to pain management," she adds.

The day of surgery

The setup time for a posterior lumbar fusion takes about an hour. The patient is put under anesthesia, and after insertion of a Foley catheter and placement of leads for neuro and cardiac monitoring, he or she is transferred to the OR table for positioning. Carolyn Gangeni, CRNA, is often the nurse anesthetist on the OR team. A mirror, which is part of the table, allows her to see the patient's face and monitor him throughout the procedure. During surgery, the spinal cord and nerves are monitored by an independ-



*Currently in clinical trials and has not yet been approved for interbody use.

ent outside agency so that the spinal cord and nerves are not injured during the procedure.

The clinical study is randomized, so 50% of patients are assigned to the investigational group (which receives the OptiMesh® implant), and 50% are assigned to the control group (which receives an implanted allograph spacer). It is not until the day of surgery that physicians are told whether their patient is part of the investigational group or the control group.

The OptiMesh® implant is done after the posterior spinal fusion and after any bone graft procedure. Placement is made using an insertion device. Nerves are carefully moved aside, the device is inserted between the two vertebrae, and the mesh bag is deployed. Once in place, small amounts of bone are gradually added to the mesh bag until the bag is packed to the appropriate size. The OptiMesh® 1500 is designed to contain granular bone, autograft (patient's own), or allograft (bone bank) (Spineology.com). The natural ridge on the vertebrae keeps the implant in place during the fusion process.

Postoperatively, posterior spinal fusion patients are monitored for pain control, and are expected to be up out of bed the day of or day after surgery. Postop lengths of stay are not changed because of the introduction of the OptiMesh® implant; patients stay three to four days in the hospital, and are seen by one of the two doctors, or by Dibella-Price, who has privileges at both designated hospitals.

Recovery and beyond

Clinical trial patients are followed in the office at periodic intervals until full fusion of the OptiMesh® implant is achieved, which usually takes one year. Fusion is monitored by X-ray and CT scan at one year, and then again at year two.

As is customary with a spinal fusion, patients wear a brace postoperatively, and use a bone-growth stimulator for at least 4 hours a day to promote healing. Occasionally, a miniature stimulator is inserted during surgery and then removed in a day-surgery procedure at a later date.

During office visits, one of the two doctors sees each patient, as does one of the two nurse practitioners. In addition to Dibella-Price, Carol Markowitz, RN, ANP-C, meets with patients and discusses any postop issues that may arise — from pain management to allowable physical activities to the patient's state of mind during recovery. Markowitz finds that many patients will confide in her what they would not normally confide to the doctors. "Patients more often feel comfortable discussing their private lives with nurses. This is where we can have a real positive impact," says Markowitz.

It takes a team

When bringing new technology to market, nurses are involved every step of the way. I know, because I recently underwent this procedure at St. Catherine of Siena Medical Center, and I was glad to see so many nurses participating — from the very beginning with the two nurse practitioners in the physician's office to the scheduling nurse, scrub nurse, circulating nurse, nurse anesthetist, and first assistant in the OR, and the PACU and postop floor nurses. Also playing an active role were the many highly trained members of the hospital's ancillary staff, who assisted the doctors and nurses and contributed to my comfort and recovery. Each of them was a part of the team, and while it may not have "taken a village" to care for me, it certainly did take this team of highly trained doctors and staff from various specialties to help get me home safely and "on my feet" again.

Janice Spillane, RN, MS, is the editorial director of the New York/New Jersey division of Nursing Spectrum.

To comment on this story, e-mail jspillane@gannetthg.com.

OptiMesh 1500 OLIF Trial

• Clinical trial parameters

Trial population includes subjects with degenerative disc disease at one level, L2 to S1, whose condition requires a single level interbody fusion procedure with posterior fusion. The patients are randomly assigned to the investigational group or the control group at a ratio of one to one.

The investigational group will receive the OptiMesh® implant filled with a mixture of demineralized bone matrix and cortico-cancellous bone placed into the interbody space using supplemental pedicle screws. The control group will receive a structural allograft spacer with pedicle screws.

Source: Spineology.com