

Campbell researchers test effectiveness, safety of treatments in clinical trials

A research team working in a high-tech laboratory learns that a certain treatment helps bones heal in mice or tissue grow in pigs. But will it work in humans? And, is it safe? Those are two major questions that clinical trials can help answer.

Clinical trials are research studies that involve people. Because clinical trials are vital to the development of new and better musculoskeletal procedures, treatments, and devices to benefit patients, Campbell Clinic doctors and researchers participate in a variety of these important research projects.

A LESS-PAINFUL ALTERNATIVE

Dr. Drew Murphy, a Campbell Clinic surgeon who is a foot and ankle specialist, is currently overseeing Campbell's participation in a clinical trial involving the use of the GEM OS™1 bone graft treatment in patients who have had foot and ankle fusion surgery.

"Many elective surgeries for correction of deformity of the ankle and foot involve fusion of one or more joints for stability and improved function," Dr. Murphy said. "Most fusions require some type of supplementary graft to improve the success of the fusion."

Traditional graft techniques involve harvesting bone from other sites on a patient's body, which may result in more pain and potential complications. GEM OS1, a synthetic bone graft material developed by BioMimetic

Therapeutics, can replace autogenous (from the patient) bone graft in foot and ankle fusion applications. The GEM OS1 material is placed directly into an open surgical site to stimulate bone regeneration.

Dr. Murphy has performed a number of fusion surgeries using the GEM OS1 graft. "Most situations that require bone graft are amenable to using this type of product," he said.

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COMPARING RESULTS

Campbell Clinic's large patient base makes it a good site for recruiting participants in clinical trials. The GEM OS1 research was a nationwide study, involving numerous centers.

In the clinical trial supervised by Dr. Murphy, researchers compared two groups of patients who had undergone fusion surgery: those who had autogenous bone grafts, and surgeries in which the GEM OS1 material was used. Working with Dr. Murphy in the trial were

Campbell Clinic surgeons Dr. Greer Richardson, Dr. Susan Ishikawa, and Dr. David Richardson.

The GEM OS1 study was a non-inferiority trial. Researchers were looking at whether bone regeneration following use of the GEM OS1 material was at least comparable to regeneration following autograft bone graft, without the pain and other negatives associated with the harvesting of the autograft. Assessment of bone regenera-

ABOUT FOOT AND ANKLE FUSION



- Fusion procedures are commonly done to eliminate chronic pain associated with joints in the foot and ankle that are damaged as a result of traumatic injury, rheumatoid arthritis, or osteoarthritis.
- In a fusion procedure, the joint space between adjacent bones is surgically prepared and treated with a graft material to stimulate a fusion, or permanent connection of the two bone ends.
- Finding an effective substitute for autogenous (from the patient's body) bone graft can mean less pain at the location from which the graft material would have been taken; reduced inconsistency in the volume and quality of the bone material harvested; and reduced operating room time due to elimination of the need to procure the graft material.

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—DR. DREW MURPHY

tion was based on CT scans performed six months after surgery.

Dr. Murphy and his fellow researchers completed their report on the Campbell Clinic-based trial in December 2008. “The final outcome of the multi-center clinical trials is not known yet, but the initial results look promising for the ability to substitute this product for autograft,” Dr. Murphy said.

SUBJECTING THEORY TO REALITY

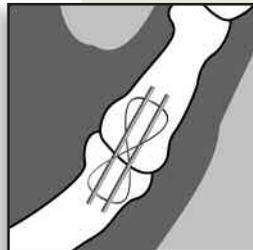
“Clinical trials are the best way for doctors to learn what is safe and effective in new devices, procedures, and treatments,” said Dr. Terry Canale, President of The Campbell Foundation and chairman of the Foundation’s Research Committee. “We can observe and assess whether a product or treatment produces the desired result, and how well it works, using very specific and consistent guidelines set forth in the trial. Thousands of people are helped each year as a result of clinical trials, and we participate because we want to help our patients and improve the practice of medicine.”

The Campbell Foundation Research Committee receives and approves applications for research projects from Campbell Clinic staff physicians and assisting residents, both for basic science and clinical trial projects. The Committee discusses the objective of the study, research method, possible outcome, benefits and funding needs. The Committee also reviews the status of current projects and the publication of completed research papers in national orthopaedic and medical journals.

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VEPTR



Thumb MP
Joint Fusion

ADDITIONAL TRIALS

Dr. Jeffrey Sawyer, who specializes in pediatric orthopaedics, is participating in several clinical trials. His research involves studies of:

- Children with severe scoliosis treated with the VEPTR (Vertical Expandable Prosthetic Titanium Rib) to correct rib deformities
- ATV-related injuries in children and the types of injuries and complications that occur
- Children involved in motor vehicle accidents to see if obesity and age play a role in injury patterns

Dr. James Calandruccio, a hand specialist, is leading a clinical study of outcomes on patients having undergone a fusion of the thumb metacarpophalangeal (MP) joint. The goal of this study is to report the results of a tension-band technique for this procedure to assist surgeons with educating patients on the anticipated results of the thumb MP joint fusion.

Dr. Edward Perez, who specializes in trauma surgery, is participating in several clinical trials, including the study of two types of surgical treatments to determine the best way to repair distal femur fractures and proximal tibia fractures using intramedullary nails and locking plates.

The results of a clinical trial conducted by Campbell Clinic total joint surgeon, **Dr. John Crockarell**, was published recently in the *Journal of Arthroplasty*. The objective of the study was to evaluate the results for patients who had the Genesis 2 total knee implant for an average of just over six years. The implant, put into 224 knees, performed well for patients and did not require additional surgeries. The patients did require a tendon release when the knee was implanted more frequently than described in earlier studies.