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## IRMC patient receives historic stem cell surgery



From left are Sarah Boyer, Antria chief operating officer; Morgan Glasser, clinical research coordinator; Dr. David Bizousky, IRMC Orthopedic surgeon; Dr. R. Brandon Trale, IRMC Orthopedic surgeon; and Trisha Sharp, Kelly Meyer, and Tara McClellan, clinical research coordinators.

- Submitted photo

A first for American medicine may have occurred on Sept. 12 at the Indiana Regional Medical Center.

The hospital said its orthopedic surgeon, Dr. Brandon Trale, performed a reduction of a hip fracture suffered by an 83-year-old man — who may have been the recipient of placental-derived stem cells meant to regenerate muscle tissue for a quicker recovery time.

“I did a partial hip replacement,” Trale said. “The technical term is a bipolar hemi arthroplasty.”

It was a critically needed surgery — the patient, a retired mathematics teacher in the Penns Manor Area School District, had fallen and broken the femoral neck portion of his hip — and there was a one-in-three chance he would be dead within a year if he hadn’t gotten it within 48 hours of his injury.

It was the most common form of hip fracture, one that can be dealt with in 40 minutes as was the case on Sept. 12, but a fracture that can disrupt the blood supply to the hip, causing complications, blood clots or worse.

“This was not an elective procedure,” Trale said. “(The patient has) an increased risk of death.”

What happened toward the end of the surgery may have made history for IRMC.

“At the end when we were closing the wound, I injected a solution on either side of the muscle,” Trale said.

It either was a placebo, a saline solution, or one that contained stem cells, in what the IRMC surgeon called a “randomized controlled” test where he and the patient were double blinded.

“I don’t know what he’s getting, he doesn’t know what he is getting,” Trale said.

The case of the Penns Manor teacher is part of an international trial being conducted for an Israeli company, Pluristem Therapeutics Inc. of Haifa, by multiple contractors including the White Township-based research company Antria, which shares quarters in the building also housing the state’s Indiana County CareerLink offices.

“Indiana Regional Medical Center is proud to participate in this landmark research trial,” IRMC Chief Medical Officer Dr. Brian Hawthorne said. “Our vision is to be the best community health system in the country. This trial is another recent example of our innovation and quest for excellence.”

Antria was established on Oct. 1, 2009, as “a multi-specialty site management organization committed to the care and improvement of human life by advancing science through cutting-edge treatments and transforming health care through clinical research.”

Or as Antria Chief Operating Officer Sarah Boyer put it, “we carry out clinical trials for large pharmaceutical companies for different phase studies.”

In a news release this week, IRMC officials said the teacher consented to the procedure.

“We have the opportunity for you to participate in a recent study,” Trale told the teacher. “The patient was involved in academia and was very receptive about participating in this study.”

And he is recovering well.

“He was a very active gentleman. He didn’t have any hip problems prior to this procedure,” Trale said. “He is in a rehab center now. Before he was discharged, he was up and ambulating with a walker and physical therapy. He had little pain.”

That isn’t always the end result for hip fractures.

“Following surgery,” IRMC noted in its release on the Sept. 12 event, “many patients do not regain their baseline capabilities due to poor muscle healing and regeneration, which leads to significantly increased morbidity and a lower quality of life.”

Pluristem is a leading developer of placenta-based cell therapy products.

In April, Pluristem received U.S. Food and Drug Administration clearance for a Phase III study of its PLX-PAD cell therapy in the treatment of muscle injury following surgical repair. PLX stands for “placental expanded,” while PAD refers to placental-derived adherent or mesenchymal stromal cells.

That’s a type of stem cell that can be used for numerous purposes in the body.

“We were the only site to be selected that is not academic,” Boyer said. “This is the first patient in the United States and the first patient enrolled in this trial.”

As pointed out by Pluristem and IRMC, that sort of fracture has mortality rates of up to 36 percent, with annual treatment costs estimated to be between \$10 billion and \$15 billion in the United States alone.

And, a spokesman for the Indiana hospital noted, the number of surgeries performed annually to treat femoral neck fractures is increasing as populations age.

“There are several different approaches you can take with a hip,” Trale said. “We took a direct lateral approach.”

The Sept. 12 surgery will be part of a far larger caseload to be studied by Antria and others for Pluristem.

“Once we get a big enough study, we compare the results,” Trale said. “We don’t want any bias in the study.”

The IRMC surgeon stressed that the Sept. 12 operation felt no different to him than other similar cases.

“I treat all my patients the same,” Trale said. “All my patients are VIPs for me. I didn’t think about it until after the case.”

IRMC ties to Antria include Trale, who also is one of several sub-investigators for the White Township company’s studies in fields ranging from diabetes to overactive bladders to orthopedics.

“We’ve done a lot of work in orthopedics,” Boyer said.

That was one reason why Antria was chosen by Pluristem.

Also, Boyer said, “sponsors communicate with one another. They make sure we met enrollment goals in previous tests. It was from word of mouth that they heard about us. We also have a background in stem cell research. We do our own in-house stem cell research (and they) found we would be a good fit.”

Antria received approval from IRMC’s Investigational Review Board to enroll patients in the Phase III clinical trial.

The chief investigator for the trial is Dr. David T. Bizousky, an orthopedic surgeon whose multiple roles including that of team physician for sports at Indiana University of Pennsylvania and area high schools.

Boyer also has IUP ties. The Apollo native started with Antria while working toward what would be a bachelor’s degree in human resource management and dual master’s degrees in health care administration and employee-labor relations, all from IUP.

The surgery and the Antria-Pluristem trial comes in a time of transition for IRMC.

Hospital spokesman Mark Richards said IRMC’s Centennial Building Project recently introduced seven new operating room suites including robotic surgery, a 12-bed Intensive Care Unit, and Ambulatory Care and Post-Anesthesia Care Units.

This fall, Richards said, IRMC will be migrating to a new electronic health record management system.

“These significant investments reinforce our commitment to remain an independent healthcare provider for our patients and the community we serve,” IRMC said in a news release.