

Hip Innovation Technology Announces Positive Clinical Study Data of its Novel Reverse Hip Replacement System for the Treatment of Total Hip Arthroplasty

Data Demonstrates Excellent Fixation with a Predicted Low Risk of Revision at Ten Years Patients Report Very High Levels of Satisfaction

BOCA RATON, FLORIDA, June 28, 2023 -- <u>Hip Innovation Technology</u>, LLC (HIT), a medical device company developing innovative orthopedic device solutions to advance the quality of life and quality of care for patients, today announces the publication of one of its clinical studies. The article entitled, "Radiostereometric analysis and clinical outcomes of a novel reverse total hip system at two years," was published in the most recent issue of <u>Bone & Joint Open</u> journal.

The study results with the Reverse Hip Replacement System (Reverse HRS) demonstrate excellent fixation with a predicted low risk of revision at ten years, mean migration below the level of radiostereometric analysis (RSA) detection for both the femoral and acetabular components, and high rates of patient satisfaction including no patients reporting symptoms consistent with soft-tissue impingement within the articulation and no symptoms consistent with adverse reaction to metal debris.

"These data demonstrate that the Reverse Hip Replacement System delivers excellent fixation with a predicted low risk of revision for loosening at ten years post-surgery," said Thomas Turgeon, MD, Director of Arthroplasty Research, Concordia Hip and Knee Institute, Associate Professor, University of Manitoba Site Head of Surgery, Concordia General Hospital, and lead study investigator.

This study enrolled 22 patients (11 male/11 female; median age 70.6 years) and evaluated implant fixation using radiostereometric analysis (RSA). RSA is a well validated technique used to predict long-term implant stability by studying the implants early behavior. RSA markers were viewed via radiologic imaging at six weeks (baseline) and 6, 12, and 24 months. Mean acetabular subsidence from baseline to 24 months was 0.087 mm (SD 0.152), below the critical threshold of 0.2 mm (p = 0.005). Mean femoral subsidence from baseline to 24 months was - 0.002 mm (SD 0.194), below the published reference of 0.5 mm (p < 0.001).

"We are highly encouraged with the data reported from this Phase 1 clinical study. Importantly, these results also demonstrate very high rates of patient satisfaction based on standard of care patient reported outcome measures," said George Diamantoni, Hip Innovation Technology's Co-Founder and Chief Executive Officer. "We remain focused on patient enrollment in our ongoing pivotal study and look forward to providing additional updates regarding our clinical program."

Hip replacement surgery, or total hip arthroplasty, is one of the most common joint replacement

procedures done in the United States. According to the Agency for Healthcare Research and Quality, more than 450,000 total hip replacements are performed each year in the United States. In fact, by 2030 approximately 850,000 patients are expected to undergo the procedure each year. Total hip replacements are one of the most effective ways to reduce joint pain and improve functioning for patients with advanced hip problems. During the 2015 calendar year, approximately 324,000 surgeries were performed in the U.S. and 50,000 in Canada.

The aging of the global population, along with other variables, such as osteoarthritis, obesity, Rheumatoid arthritis, Osteonecrosis, and hip fracture, among other things, is contributing to the increasing need for total hip arthroplasty.

HIT has extensively tested the Reverse HRS in over 100 standard and unique pre-clinical experiments to assess the product safety and clinical benefits anticipated by the unique system design.

About the Reverse HRS

The Reverse HRS is a Metal-on-Polyethylene reverse geometry hip prosthesis designed to improve stability at extended ranges of motion and reduce the risk of dislocation. Like most conventional systems, the Reverse HRS consists of a femoral stem, an acetabular cup and a cobalt-chrome ball that articulates within a polyethylene liner. Unlike existing total hip replacement systems, the ball is placed on a trunnion within the acetabular cup instead of the femoral stem, and the polyethylene liner is attached to a femoral cup, which then attaches to the femoral stem, as opposed to the polyethylene liner being attached to the acetabular cup. This technological difference does not change the center of rotation of the Reverse HRS and it remains similar to a normal physiological hip, or a well-positioned traditional Total Hip Arthroplasty. The advanced Reverse HRS implant is designed to provide greater range of motion in all planes, enhanced hip stability, and to reduce the risk of dislocation. Importantly, the Reverse HRS also provides variability of component placement including higher abduction angles and anteversion of the acetabular cup. The femoral cup articulates around the acetabular ball and overlaps with the acetabular cup as the hip undergoes flexion-extension, abductionadduction and internal-external rotation. This forgiving design may compensate for suboptimal component positioning which may provide benefits such as extended range of motion, hip stability and reduced likelihood of impingement. The Reverse HRS is designed to uncouple the relationship between component placement, wear and stability. This unique implant design of the Reverse HRS provides optimal surface area contact between the acetabular ball and femoral cup, which may eliminate edge loading. Elimination of edge loading may provide benefits that include reduced high-contact stresses, decreased implant wear and uniform wear, which minimizes generation of wear debris and associated concerns related to osteolysis.

About Hip Innovation Technology, LLC

Headquartered in Boca Raton, Florida, Hip Innovation Technology was formed in 2011 to provide market-leading orthopedic device solutions that advance the quality of life and quality of care for patients. In partnership with healthcare professionals worldwide, our goal is to identify unmet clinical need, then design, manufacture and ultimately market innovative orthopedic reconstructive and related surgical product solutions.

For more information, visit <u>www.hipinnovationtechnology.com</u>.

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