Use of a Novel Reverse Hip Replacement System to Address Dislocation and Instability

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ABSTRACT

While total hip arthroplasty (THA) is an enormously successful treatment for patients with end-stage degenerative arthritis of the hip, and surgeons have optimized existing hip implants and techniques, dislocation and instability persist as a leading cause of failure. Given the tremendous success of reverse total shoulder arthroplasty in enhancing the stability of shoulder reconstruction by reversing the anatomic seating of the ball and socket components, one manufacturer (Hip Innovation Technology, LLC, Woodstock, Georgia) has developed a novel Reverse Hip Replacement System (Reverse HRS) to address the need for greater stability in reconstruction of the arthritic hip joint. Rather than the traditional anatomic components that replace the head of the femur with a spherical ball and the acetabulum with a socket with polyethylene liner mounted into the pelvis, the Reverse HRS features a cup with polyethylene liner attached to the femoral stem and a spherical metal head attached to a central trunnion inside of the porous-coated acetabular shell fixed into the pelvis. This design provides dramatically enhanced stability and improved range of motion. This article reviews relevant published literature, including results from a Canadian clinical trial and case reports from a multicenter American clinical trial monitored by the U.S. Food and Drug Administration. It also describes the components and surgical technique of reverse THA.

INTRODUCTION

Since the introduction of total hip arthroplasty (THA) in the late 1950s, the basic design of hip implant systems remains essentially the same: all systems maintain a femoral stem with an attached spherical ball and an acetabular cup component. Although skilled surgeons have optimized existing hip implant system offerings, and THA has been proven as an enormously effective treatment for patients with degenerative arthritis of the hip, the utility of these implant systems is limited by instability, the inability to maintain a reduced joint, and implant dislocation, which occurs when the ball-shaped head of the femoral stem dislodges from the acetabular cup. In the 2023 Annual Report of the American Joint Replacement Registry, instability-related diagnosis codes were associated with 20.74% of all hip revisions in the United States from 2012–2022 (n=95,495), second only to infection (22.51%) and virtually tied with mechanical complications (20.80%).[1] In an in vivo fluoroscopic study done at our center over two decades ago, patients with conventional THA experienced a mean femoral head/acetabular component separation of 1.2mm (range 0.8 to 2.8mm) during normal gait on a treadmill.[2] These shortcomings underscore the need for device improvement and innovation in THA.

For total shoulder arthroplasty, reverse geometry procedures (rTSA)—in which an upward facing cup is attached to a humeral stem superiorly and replaces the humeral head, while an articulating sphere is mounted into the glenoid cavity—have become increasingly favored with expanding indications, growing utilization, and improved outcomes compared with traditional anatomic total shoulder replacement (aTSA).[3,4] In a review of the national registries of Australia and the United Kingdom (UK), involving 9,711 patients who underwent primary TSA from 2011–2022 with a single implant system, aTSA use increased annually by rates of 38.3% in Australia and 14.0% in the UK while rTSA use increased annually by rates of 148.9% and 32.4% respectively.[3] Overall incidence of revisions was low with rates of 4.9% for aTSA (99 of 2,004) and 2.8% for rTSA (216 of 7,707). Likewise, in a systematic review and meta-analysis by Dragonis et al. involving four studies and 2,731 patients aged 70 or older without full thickness rotator cuff tear (1,472 aTSA and 1,259 rTSA) with minimum follow up of two years, a statistically significant lower revision rate was observed for rTSA compared to aTSA (odds ratio 0.50, 95% confidence interval: 0.30, 0.84, $p<0.05$).[4]

The Reverse Hip Replacement System (Reverse HRS, Hip Innovation Technology, LLC, Woodstock, Georgia) was developed to address the need for greater stability. Like other conventional anatomic hip replacement systems, the Reverse HRS consists of a femoral stem, an acetabular cup, a spherical ball, and a polyethylene liner. An investigational device, the Reverse HRS is designed for use without bone cement in THA. Like the reverse total shoulder arthroplasty, the Reverse HRS implements reverse geometry, whereby a spherical cobalt-chromium ball is affixed inside the press-fit acetabular shell, and a polyethylene-lined femoral cup is attached superiorly to the femoral stem. The femoral cup thus glides around the fixed acetabular ball.

By reversing geometry, the Reverse HRS is designed to expand the contact area between its acetabular and femoral components, providing enhanced stability even at extended ranges of motion in all directions with minimal risk of dislocation. The stability of the construct is less dependent on the positioning of the acetabular and femoral components. It is designed to improve overall contact between articulating surfaces to reduce edge loading and subsequently lessen wear.

The Reverse HRS device is not approved for marketing in the United States. The Reverse HRS for primary THA is an investigational device currently in a randomized, controlled, multi-center pivotal clinical trial monitored by the United States Food and Drug Administration that began in January 2023 to evaluate its safety and effectiveness at up to 20 investigational sites. The device has undergone extensive and successful preclinical testing.[5] Clinical experience with the device at minimum two-year follow up is available from an ongoing study in Canada[6] and a case report of a patient with six months of follow up who is participating in the American IDE clinical trial.[7] This article provides an overview of the components and surgical use of the Reverse HRS.

Figure 1. Reverse HRS femoral components. (Reproduced with permission of Hip Innovation Technology, LLC.)

Figure 2. Reverse HRS acetabular components. (Reproduced with permission of Hip Innovation Technology, LLC.)

FEMORAL COMPONENTS

The Reverse HRS femoral components are being studied in a variety of sizes ranging from size 9 to 21 in Standard (128°) and High Offset (133°) (Fig. 1). The proximal femoral stem is porous coated using a plasma spray of commercially pure titanium, which is intended to facilitate uncemented biological fixation and provide secure intermediate fixation with the prepared bone surface at the site of implantation. All femoral stems incorporate a female Morse taper for assembly with the femoral cup to prevent inadvertent connection with an acetabular ball component during assembly in situ.

Femoral cups (Fig. 1) are being evaluated in a variety of lengths, including 0mm, +3mm, +6mm, and +9mm offsets, to determine proper anatomic fit and musculature tension. The femoral cup is combined with a highly cross-linked ultrahigh molecular weight polyethylene (UHMWPE) liner to make a robust articulating surface. The UHMWPE liner is hemispherical in shape with a circular tab. The rim and circular tab are fluted for torsional stability when implanted.

ACETABULAR COMPONENTS

The Reverse HRS acetabular cup is a hollow hemisphere with a male taper that mates with an acetabular ball (Fig. 2). It is being studied in sizes ranging from 52–58mm in 2mm increments, with expansion to a broader size range anticipated. Similarly to the proximal femoral stem, the acetabular cup is porous coated using a plasma spray of commercially pure titanium to facilitate bone in-growth and to provide secure intermediate fixation with the prepared bone surface at the site of implantation.

The 26mm cobalt-chromium acetabular ball is highly polished for reduced friction and wear at the surface of the UHMWPE liner. The acetabular cup incorporates a cluster of three threaded holes for placement of custom fixed-angle titanium bone screws.

SURGICAL INSTRUMENTATION AND TECHNIQUE

Specialized ancillary surgical instruments are required to correctly perform the reverse hip arthroplasty procedure and to remove the Reverse HRS total joint implant components if revision becomes necessary (Fig. 3).

Figure 3. Reverse HRS surgical instruments. (Reproduced with permission of Hip Innovation Technology, LLC.)

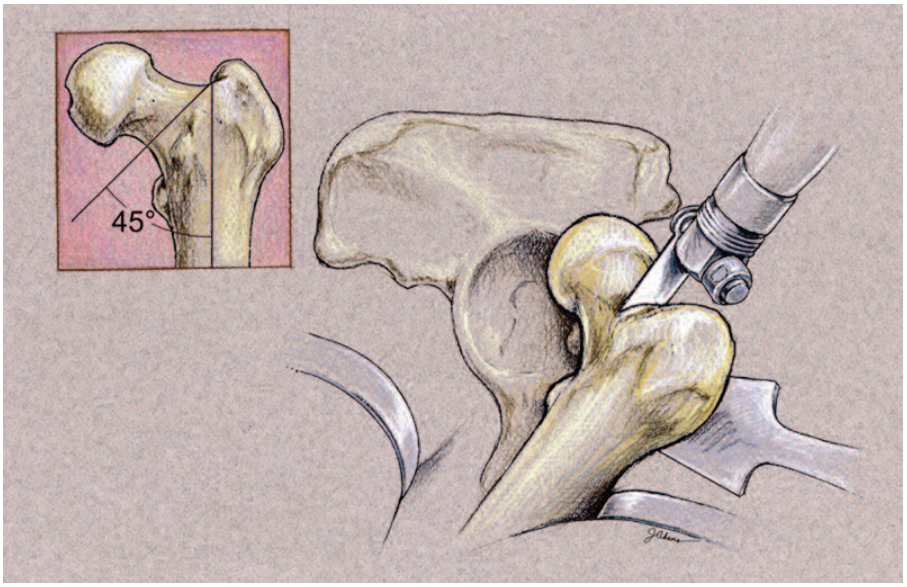

Figure 4. The femoral neck is osteotomized in situ at a 45° angle to the longitudinal axis of the femur, commencing medially and distally from the superior aspect of the greater trochanter. (Reproduced with permission, JIS Orthopedics.)

Surgical approach is at the discretion of the operating surgeon. The first step in the procedure is to resect the femoral head to open the joint space and improve access to the acetabulum. While it is possible to do a flexion, external rotation, and abduction maneuver to dislocate the femoral head, the current author uses a somewhat anterior direct lateral approach and prefers to cut the femoral head in situ, which is less disruptive to the soft tissues. The femoral neck is osteotomized in situ at a 45° angle to the longitudinal axis of the femur, commencing medially and distally from the superior aspect of the greater trochanter (Fig. 4). Attention is then turned to preparation of the

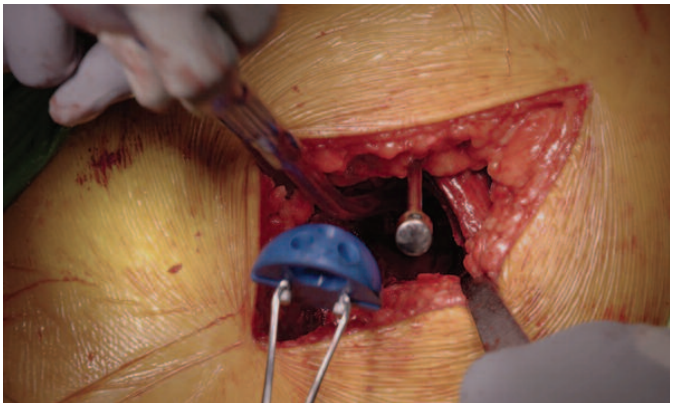

Figure 5. An acetabular drill guide must be used to ensure proper drilling and placement of one to three acetabular bone screws. (Reproduced with permission, JIS Orthopedics.)

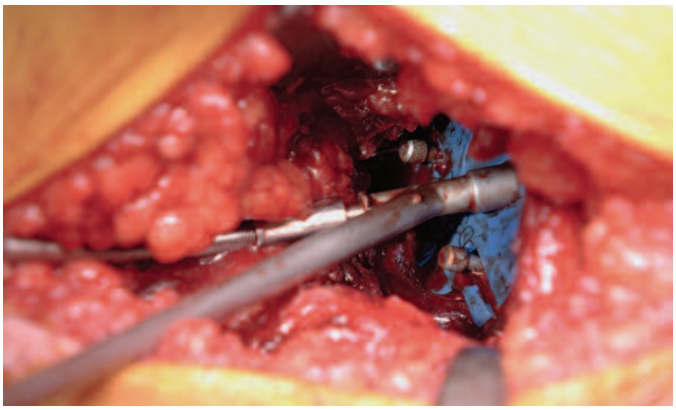

Figure 6. One to three titanium locking bone screws are used to provide adjunct acetabular fixation. (Reproduced with permission, JIS Orthopedics.)

Figure 7. The femoral canal is broached sequentially until adequate contact with cortical bone is achieved. (Reproduced with permission, JIS Orthopedics.)

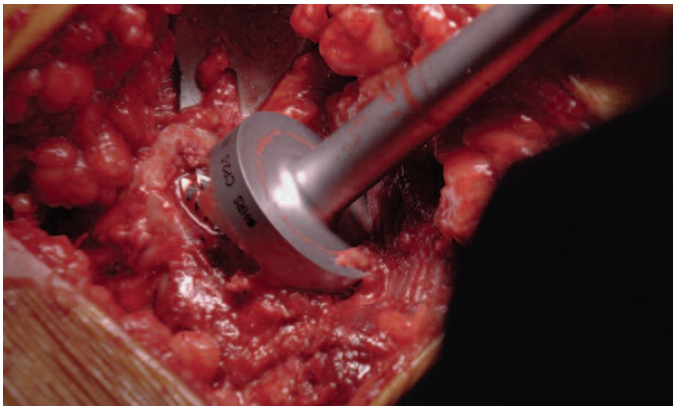

Figure 8. Once the final broach is inserted to the proper level, the calcar planer may be inserted over the broach trunnion to plane the femoral neck. (Reproduced with permission, JIS Orthopedics.)

acetabulum and begins with progressively reaming the acetabulum until healthy bleeding bone is exposed and a hemispherical dome is achieved at the site of implantation. The final reamer will rock the pelvis slightly, and we anticipate that the diameter of the definitive acetabular shell will be 1mm smaller than the final reamer size to accommodate 1mm of press fit. The surgeon has the option to place a trial cup into the reamed acetabulum. Then, the universal inserter is removed and an acetabular ball trial is placed onto the acetabular cup to prepare for a range of motion test to determine the most appropriate size and fit using trial components. Once range of motion and impingement are satisfactorily checked, the trial components are removed, the wound is irrigated with pulsatile lavage, and all debris is removed. Alternatively, if the surgeon is confident that acetabular templating and preparation are accurate, he or she may proceed directly to implantation of the definitive acetabular component. The inserter is applied to the cup. The porous plasma sprayed cup with a clustered set of holes has a trunnion in the center of it. The operating surgeon's discretion and preference will determine selection of the degree of inclination (45 to 50°) and anteversion (25 to 35°). Once positioned in an appropriate inclination and anteversion, the cup is ready to be impacted. If bone screws are required, a drill guide (Fig. 5) must be used to ensure proper drilling and placement of up to three bone screws (Fig. 6). These titanium locking bone screws have a micro-thread on the screw head that engages the acetabular cup threaded screw holes. Bone screws are provided in lengths ranging from 15 to 40mm, in 5mm increments. A trial acetabular ball is placed on the acetabular tapered trunnion to protect it during femoral preparation. Instrumentation includes a modular head holder with silicone-coated jaws, which may be used for placing both the trial and final heads.

To prepare for the femoral components, a femoral box chisel osteotome is used to open the femoral canal. A femoral rasp may be used to further open the canal. The surgeon may opt to ream the femoral canal, use a broach-only technique (preference of the current author), or a combination of reaming and broaching. The femoral reamer with T-handle attached may then be used to ream the femoral canal to provide proper pilot guidance for the final broach; this step may require distal reaming due to the size of the distal end of the femoral stem. Using broach instruments, the femoral canal is then sequentially broached until adequate contact with cortical bone is achieved (Fig. 7). Once the final broach is inserted to the proper level, the calcar planer may be inserted over the broach trunnion to plane the femoral neck (Fig. 8). The preoperative template serves as a guideline to determine the correct offset for the femoral cup. After connecting the corresponding femoral cup trial to the broach trunnion (Fig. 9), the trial construct is reduced by lifting the femoral cup onto the trial acetabular ball while downward traction is applied to the leg. The limb is then evaluated for leg length difference, stability, and range of motion. Additional offset may be added as needed to the femoral cup to achieve stability and leg length equality. The trial femoral components are removed and the definitive components are assembled. The porous plasma-sprayed femoral stem is somewhat

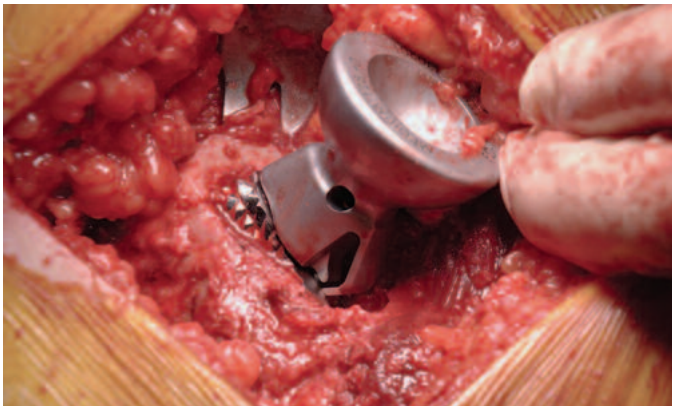

Figure 9. A femoral cup trial is attached to the trunnion of the final fully seated broach/femoral stem trial. (Reproduced with permission, JIS Orthopedics.)

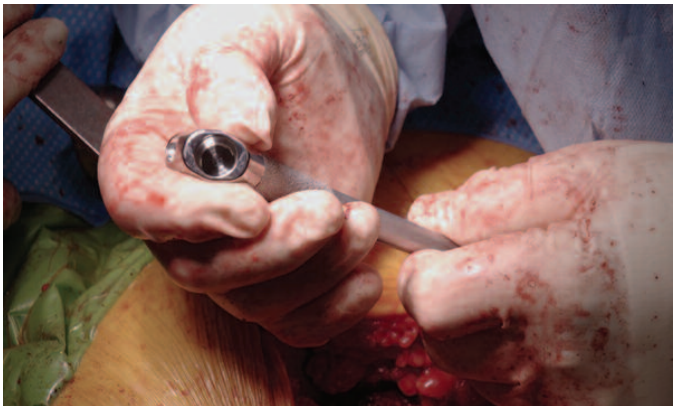

Figure 10. The porous plasma-sprayed femoral stem is somewhat bulkier than a blade-type stem and is proximally large to accommodate the female Morse taper to seat the femoral cup, which is a traditional, well-proven Morse taper type junction. (Reproduced with permission, JIS Orthopedics.)

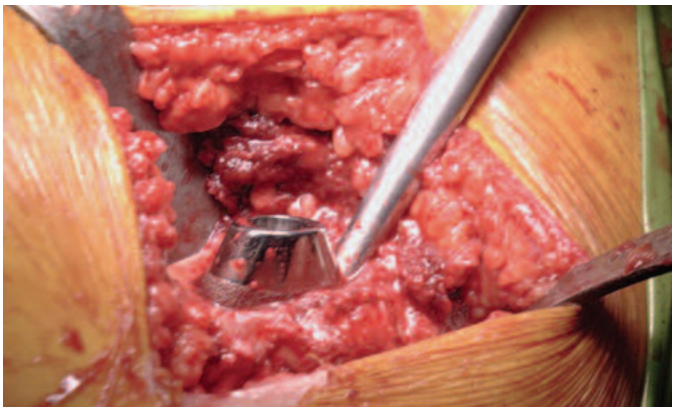

Figure 11. The loaded prosthesis is then inserted into the femoral canal, rotated into correct orientation, and driven into the bone such that the final stem is seated down to the same level as the final broach trial. (Reproduced with permission, JIS Orthopedics.)

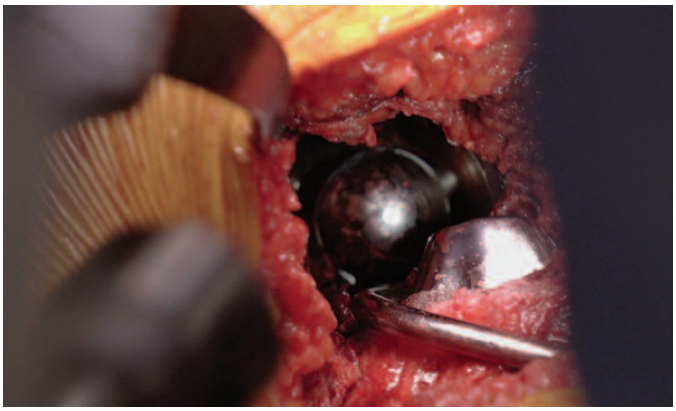

Figure 12. After the acetabular trunnion is cleaned, rinsed, and dried, the final cobalt-chromium ball is inserted, first manually onto the trunnion then impacted with the appropriate impactor tool. (Reproduced with permission, JIS Orthopedics.)

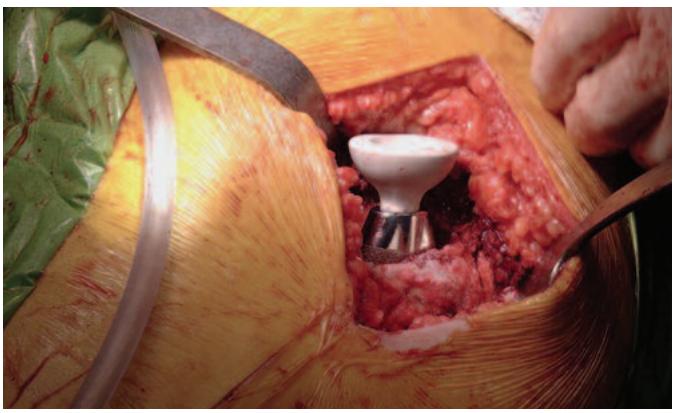

Figure 13. Another check of stability and range of motion may be performed with the trial femoral cup. (Reproduced with permission, JIS Orthopedics.)

Figure 14. The polyethylene liner is snapped into the metal femoral cup. (Reproduced with permission, JIS Orthopedics.)

bulkier than a blade-type stem and large proximally to accommodate the female Morse taper to seat the femoral cup, which is a traditional, well-proven Morse taper type junction. (Fig. 10). There are a couple of different inserter options that include a threaded inserter and a bullet-type inserter (preferred by current author). The loaded prosthesis is then inserted into the femoral canal, rotated into correct orientation, and driven into the bone such that the final stem is seated down to the same level as the final broach trial (Fig. 11). The trial acetabular ball is removed, the acetabular trunnion is cleaned, rinsed, and dried, and the final cobalt-chromium ball is inserted, first manually onto the trunnion then impacted with the appropriate impactor tool (Fig. 12). If the surgeon chooses to do so, another check of stability and range of motion can be performed with the trial femoral cup (Fig. 13) or proceed directly to placement of the final femoral cup if the femoral stem is seated fully according to plan. The polyethylene liner is snapped into the metal femoral cup (Fig. 14). The Morse taper surfaces, including both the female taper of the femoral stem and male taper of the femoral cup, are cleaned and

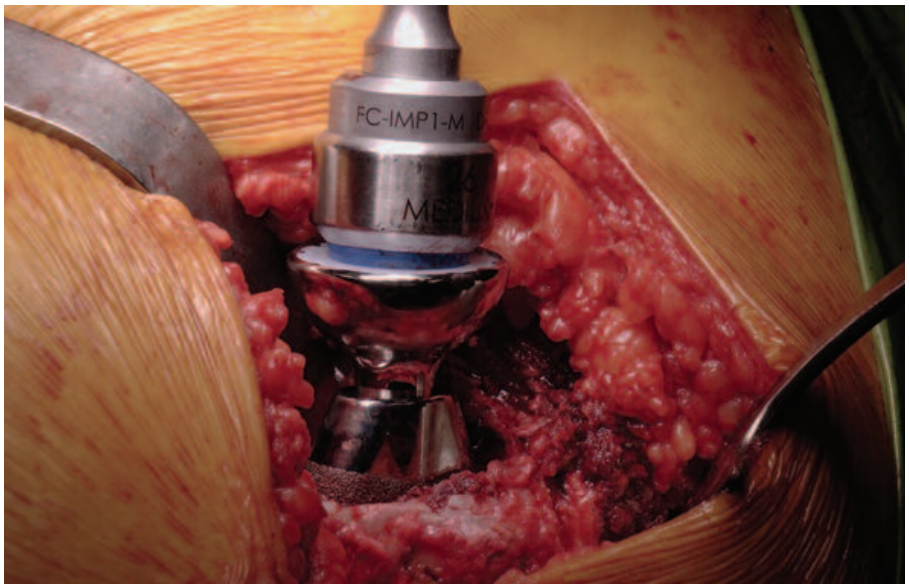

Figure 15. The femoral neck is osteotomized in situ at a 45° angle to the longitudinal axis of the femur, commencing medially and distally from the superior aspect of the greater trochanter. (Reproduced with permission, JIS Orthopedics.)

dried, and the femoral cup is inserted first manually then impacted with the provided femoral impactor tool (Fig. 15).

The hip is then reduced with the surgeon lifting and guiding the femoral cup over the acetabular ball while the assistant maneuvers and turns in the leg as needed. A final check is made to verify the stability of the construct and ensure there is no impingement. The leg is brought to full extension then rolled back with the foot straight up. For the direct lateral approach, maneuvers include bringing the leg to its most vulnerable position at approximately 45° of flexion, adduction, and full external rotation, then flexing up at the hip with palpation of the posterior capsule and then lowering the leg slightly. If all remains stable and secure, the team can proceed with wound closure.

The joint separator can be used to assist with the distraction of the femoral and acetabular implants. If removal of the acetabular ball or acetabular cup becomes necessary, the corresponding extractor tools should be used. Tools are also provided for removal of the femoral cup and polyethylene liner assembly, if necessary.

CLINICAL EXPERIENCE

The HIT Reverse HRS device has been under clinical investigation under authorization by Health Canada. Turgeon et al. recently reported clinical outcomes and radiostereometric analysis (RSA) with minimum two-year results in 23 patients treated for end-stage osteoarthritis with primary THA utilizing the novel reverse construct at a single center.[6] One patient with early deep periprosthetic infection requiring debridement prior to six months was excluded from analysis. RSA revealed that mean acetabular subsidence from baseline to 24 months was 0.087mm (SD 0.152), below the critical threshold of 0.2mm ($p=0.005$), and mean femoral subsidence from baseline to 24 months was -0.002mm (standard deviation [SD] 0.194), below the published reference of 0.5mm ($p<0.001$). There was significant improvement in patient-reported outcome measures from preoperative levels to 24 months with good to excellent results, including Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Harris hip score, Oxford hip score, Hip Disability and Osteoarthritis Outcome Score (HOOS), EuroQol five-dimension health questionnaire (EQ-5D), and 36-item Short-Form survey (SF-36), both physical and mental component summaries. At 24 months, 19 patients reported being "very satisfied" with the outcome of their hip surgery, one reported being "somewhat satisfied," and two reported being "somewhat dissatisfied."

In a case report involving a 64-year-old male patient who underwent primary reverse THA via an anterior approach using the HIT Reverse HRS device at another center participating in the U.S. FDA clinical trial, the patient's clinical

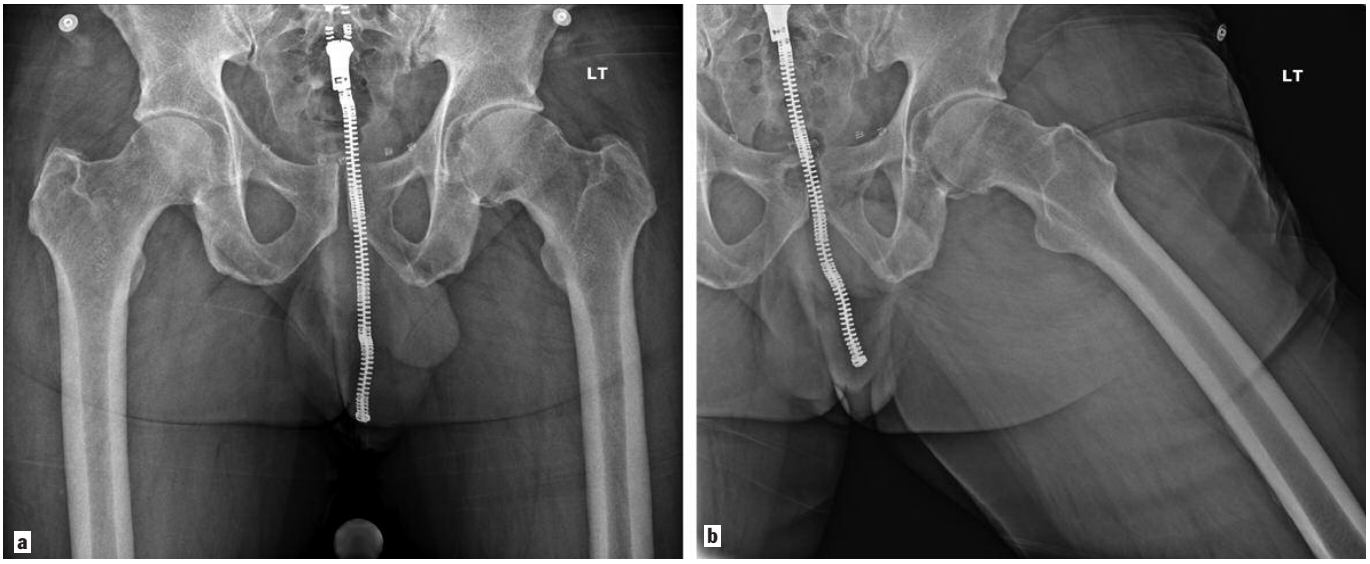

Figure 16a. Preoperative anteroposterior (AP) pelvis radiograph of a 60-year-old male patient, and (b) a preoperative lateral radiograph of the left hip. (Reproduced with permission, JIS Orthopedics.)

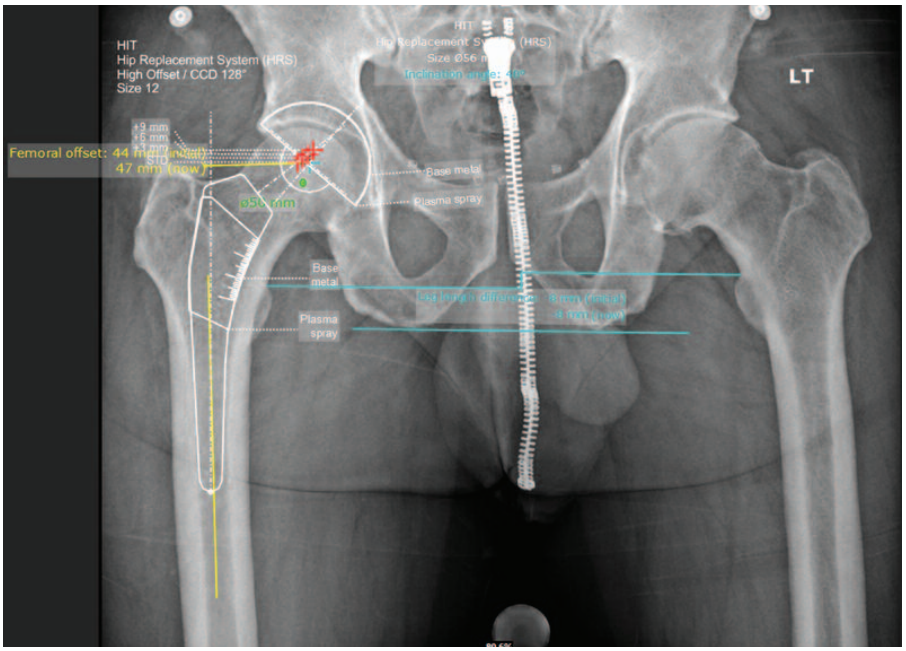

Figure 17. Preoperative AP pelvis radiograph with templating of the more normal contralateral right hip. (Reproduced with permission, JIS Orthopedics.)

result at six months postoperative was excellent.[7] His surgeon reports that while the patient had occasional pain, he was feeling well, had excellent motion, full strength, and no instability. The biggest lesson noted is the vital importance of correctly setting the leg length and the tension of the soft tissues. When done correctly, this implant delivers incredible stability.

CASE EXAMPLE

A 60-year-old male patient with a body mass index of 33.9kg/m^2 presented to our clinic with bilateral hip pain, left side greater than right. Pain in the patient's left hip is severe, constant, and stabbing, localized in his groin and buttock and radiating both to the back and down the leg. The pain in his left hip began with an injury three months ago when he stepped into a hole, twisted his leg which became stuck, heard a pop, and experienced excruciating pain. He reports a remote injury to his contralateral right hip involving dislocation with a gluteus minimus tear that occurred 13 years prior resulting from a motor vehicle accident. The patient is currently employed in a job that requires him to be on his feet most of the day. He has had no relief with activity modification, physical therapy, over-the-counter pain medications, corticosteroid injections, or oral corticosteroids. He is weight bearing as tolerated and ambulates with no assistive devices. He is unable to cross his legs or put on socks and shoes. He has painful, limited range of motion of the left hip with active flexion from 0° to 75°, neutral internal rotation, and external rotation of 15°. Log roll test is positive and the flexion, adduction, internal rotation (FADIR) test is positive. Preoperative radiographs, including anteroposterior pelvis (Fig. 16a) and lateral views (Fig. 16b), demonstrate severe left hip grade IV osteoarthritis, marked joint space narrowing, severe sclerosis, and definite bone-on-bone end-stage arthritis. Templating of the contralateral, more normal right hip (Fig. 17), suggests a size 13 high offset femoral component and a 56mm acetabular component to be appropriate. Offset in this system is achieved by changing the neck angle. A leg length difference of 8mm shorter on the left is noted radiographically. After discussion of the risks and benefits of total hip arthroplasty, as well as the expected and potential outcomes of surgical intervention and recovery as the patient's best course of treatment, we further discussed with the patient the option to enroll in the Reverse HRS Clinical Trial. After viewing models of both conventional total hip arthroplasty components and the Reverse HRS components and a thorough review of all aspects of study participation, the patient consented to enroll in the IDE trial and was randomized to receive the study device.

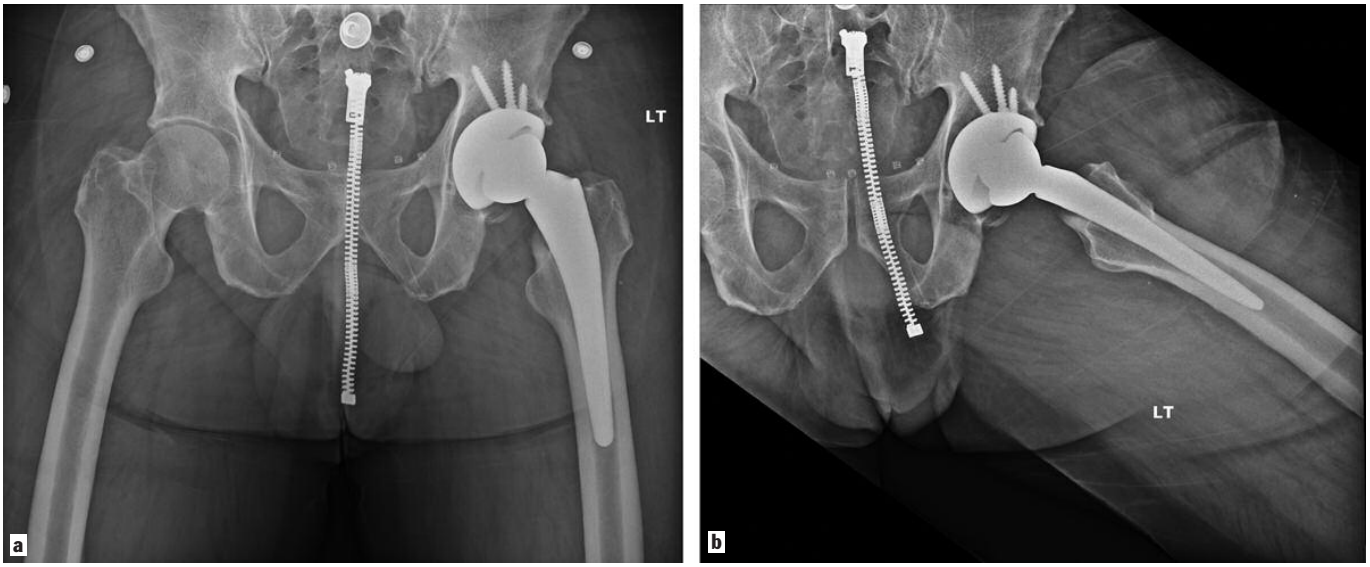

Figure 18a. Postoperative AP pelvis radiograph after treatment of the patient with left primary cementless reverse total hip arthroplasty. b) Postoperative lateral radiograph of the left hip. (Reproduced with permission, JIS Orthopedics.)

Figure 19. The patient at a golf driving range practicing his swing at two weeks postoperative to left primary reverse total hip arthroplasty (reproduced courtesy of patient who shall remain anonymous).

After preoperative medical assessment and optimization by our medical consulting team, and evaluation and clearance by the anesthesia team on the morning of surgery, the patient underwent cementless primary reverse THA via a minimally invasive direct lateral approach at our ambulatory surgery center. A 58mm diameter porous plasma spray-coated (PPS) Ti-6Al-4V titanium alloy hemispheric acetabular shell was press fit into the bony acetabular socket in abduction of 45° and 20° of anteversion. Three titanium screws were applied for adjunct acetabular fixation and a 26mm cobalt-chromium ball was placed and impacted onto the central dome trunnion. On the femoral side, a size 14 standard 128º offset titanium alloy femoral component with proximal PPS was impacted into the femoral canal. A neutral offset femoral cup was assembled with highly crosslinked ultrahigh molecular weight polyethylene liner and impacted into the femoral stem. At our surgery center, the patient generally stays in postoperative phase 1 for about 30–40 minutes, then moves to phase 2 and is usually walking within an hour or two after surgery followed by discharge to home. Postoperative radiographs taken at three weeks, including AP pelvis (Fig. 18a) and lateral views (Fig. 18b), demonstrate well-fixed components in satisfactory position and alignment. The patient is completely pain-free, tolerating physical therapy and is happy with his range of motion and surgical outcome. He reports having visited a golf driving range at two weeks postoperative with no issues (Fig. 19).

CONCLUSION

A novel reverse hip replacement system in which a spherical head is mounted inside the acetabular component and articulated with a cup affixed to the femoral stem has been developed with the goal of affording greater stability in reconstruction of the arthritic hip. Early results from an ongoing Canadian study are promising, and the device is currently under investigation in a randomized, controlled, multicenter pivotal clinical trial that is being monitored by the FDA. STI

AUTHORS' DISCLOSURES

Research funding was received for this study from Hip Innovation Technology, LLC (Woodstock, Georgia). Dr. Lombardi is a paid consultant to Zimmer Biomet, receives royalties from Zimmer Biomet and Innomed, and has minority investment interests in JIS Ventures, Joint Development Corporation, Prescribe Fit, and Parvizi Surgical Innovation.

A research foundation of the authors, JIS Research Institute, receives support for other studies from Zimmer Biomet, Total Joint Orthopedics, Firstkind, Parvizi Surgical Innovations Research Institute, Recovery Rx, SPR Therapeutics, Prescribe Fit, Smith & Nephew, S-I Bone, and Medacta.

Ms. Adams has no conflicts of interest to disclose.

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