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Radiostereometric analysis and clinical outcomes of a novel reverse total hip system at two years

T. R. Turgeon, D. R. Hedden, E. R. Bohm, C. D. Burnell

From Concordia Hip & Knee Institute, Winnipeg, Canada

Aims

Instability is a common cause of failure after total hip arthroplasty. A novel reverse total hip has been developed, with a femoral cup and acetabular ball, creating enhanced mechanical stability. The purpose of this study was to assess the implant fixation using radiostereometric analysis (RSA), and the clinical safety and efficacy of this novel design.

Methods

Patients with end-stage osteoarthritis were enrolled in a prospective cohort at a single centre. The cohort consisted of 11 females and 11 males with mean age of 70.6 years (SD 3.5) and BMI of 31.0 kg/m² (SD 5.7). Implant fixation was evaluated using RSA as well as Western Ontario and McMaster Universities Osteoarthritis Index, Harris Hip Score, Oxford Hip Score, Hip disability and Osteoarthritis Outcome Score, 38-item Short Form survey, and EuroQol five-dimension health questionnaire scores at two-year follow-up. At least one acetabular screw was used in all cases. RSA markers were inserted into the innominate bone and proximal femur with imaging at six weeks (baseline) and six, 12, and 24 months. Independent-samples *t*-tests were used to compare to published thresholds.

Results

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). There was significant improvement in patient-reported outcome measures at 24 months with good to excellent results.

Conclusion

RSA analysis demonstrates excellent fixation with a predicted low risk of revision at ten years of this novel reverse total hip system. Clinical outcomes were consistent with safe and effective hip replacement prostheses.

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Keywords: Reverse total hip, Fixation, Instability, Primary

Introduction

Despite the success of total hip arthroplasty (THA), instability continues to be a concern for surgeons and patients alike. Registry data suggest revision for instability to be the most common reason for revision in the first year and in the top two reasons for revision long-term for primary hip arthroplasties, demonstrating that this continues to be an area for ongoing need for improvement in joint arthroplasty care. 1,2 While the use of increased femoral head diameter

implants does demonstrate an improvement in stability, other currently available implant strategies to improve stability such as constrained liners and dual-mobility articulations are generally not favoured in the routine primary setting due to some drawbacks around their use.³⁻⁷

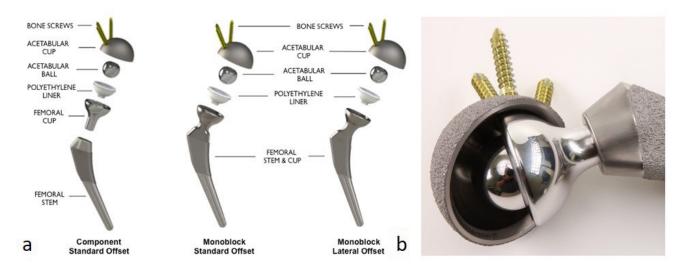
Reverse geometry articulations of the shoulder have been used with the articulation sphere mounted to the axial skeleton with a cup articulation mounted to the limb. These have seen increased use and success

Correspondence should be sent to Thomas R Turgeon; email: tturgeon@cjrg.ca

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The Hip Innovation Technology (USA) Hip Replacement System.

in recent years.1 A novel design of a reverse geometry THA has been created that uses this same principal. The benefits of the design are that load forces are maintained perpendicular to the polyethylene-lined cup throughout the entire flexion arc, resulting in stability that is far less dependent on the positioning of the acetabular and femoral components.^{7,8} The novel implant system had undergone comprehensive biomechanical and cadaveric testing, meeting or exceeding published standards.9 With the modifications to the mechanics of the THA, and the higher loads seen in the hip than in the shoulder, formal assessment of this novel device was undertaken in a multiphase clinical study. The first phase was initiated to characterize and assess the fixation stability of the femoral component and acetabular component with screw augmentation using radiostereometric analysis (RSA), as well as the clinical outcomes to ensure the safe introduction of this technology into hip arthroplasty.

Methods

Between September 2017 and June 2019, 23 patients volunteered to enrol in a Health Canada-monitored Investigational Device Trial for the first implantations of this novel device. Patient age restrictions on the investigational device trial were restricted to those between 65 and 79 years. The study protocol was approved by Health Canada, as well as local regional and facility research ethics boards. Patients were all made aware that this device was (as yet) untested, and agreed to participate in the study.

All patients underwent primary THA for end-stage osteoarthritis, a procedure which was performed by one of four arthroplasty fellowship-trained high-volume surgeons (TRT, DRH, ERB, CDB) with between 13 and 20 years of clinical experience. The surgical approach

was left to surgeon preference for either the posterior or lateral approach, and spinal anaesthesia with sedation was used. The reverse THA prosthesis was the HIT Hip Replacement System (Hip Innovation Technology, USA) (Figure 1) using the modular stem design variant. Cementless fixation of both the acetabular and femoral components was used. Acetabular bone preparation was under-reamed by one millimetre. Fixed-angle locking acetabular screws were used in all cases to augment the initial acetabular fixation. Prior to implant insertion, a minimum of four RSA tantalum beads measuring 1 mm in diameter (Halifax Biomedical, Canada) were inserted into the innominate bone and into the proximal femur (Figure 2). A standardized postoperative protocol was followed while the patients were in hospital. All patients were weightbearing-as-tolerated with no hip precautions.

RSA images were collected at six weeks, six months, 12 months, and 24 months from surgery. The six-week image was used as the reference assessment. Duplicate images were taken at six weeks with imaging repositioning between exposures to calculate intrapatient measurement error. This limit of precision is defined as the 95% confidence interval (CI) of mean error (standard deviation (SD) \times *t*-statistic corresponding to n patients).

RSA image capture was performed with dual ceiling-mounted X-ray sources and used the Halifax Biomedical carbon fibre calibration box. MBRSA software v. 4.1 (RSAcore, the Netherlands) was used for analysis with computer-assisted design (CAD) models of the implants provided by the manufacturer. All MBRSA was performed by Halifax Biomedical. Migration was measured as a difference between the CAD model of either the femoral or acetabular components, and the adjacent tantalum beads embedded in bone between the six-week reference exam and subsequent follow-up. This was measured by



a) Pre- and b) postoperative radiographs of the Hip Innovation Technology Hip Replacement System implanted with radiostereometric analysis beads.

superior/inferior movement of the implant relative to the bone. Pijls et al¹⁰ have published threshold criteria for migration at 24 months for cementless acetabular cups. The threshold assumes an acceptable revision rate of 5% at ten years. Acetabular cups that demonstrate a mean migration of 0.2 mm or less are deemed to have "acceptable" performance, those greater than 0.2 mm and less than or equal to 1.0 mm are "at risk", and over 1 mm are "unacceptable". Van der Voort et al¹¹ published similar work for initial 24-month migration for femoral components. Of the uncemented hip stems assessed, no stems with migration less than or equal to 0.5 mm demonstrated a revision rate greater than 5% at ten-year follow-up. In the stems assessed to the stems are greater than 5% at ten-year follow-up. In the stems as the stems as the stems are greater than 5% at ten-year follow-up. In the stems are stems as the stems are greater than 5% at ten-year follow-up. In the stems are stems as the stems are stems are stems are stems as the stems are stems as the stems are stems as the stems are stems are stems as the stems are s

Clinical outcome metrics were collected preoperatively and at six, 12, and 24 months following surgery. Scores collected for this study included the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) v. 3.0,¹² the Harris Hip Score,¹³ Oxford Hip Score (OHS),^{14,15} the 36-item Short Form survey v. 2 (SF-36),¹⁶ the Hip disability and Osteoarthritis Outcome Score (HOOS) v. 2,¹⁷ the EuroQol five-dimension health questionnaire (EQ-5D),¹⁸ and patient-reported satisfaction. Patients satisfaction was recorded on a five-point Likert scale as very satisfied, satisfied, neutral, dissatisfied, and very dissatisfied.

Sample size. The principal concern expressed with the novel design has been the perception of altered forces at the acetabular component/bone interface potentially disrupting bone ingrowth. There are multiple publications with mean RSA acetabular migration of 0.3 mm. ¹⁰ Assuming a conservative standard deviation of 0.8 mm, a sample size of 16 patients will have 90% power to reject the null hypothesis that mean migration is not ≥ 1.0 mm,

which is the cut-off point for an acetabular component design being "at risk" for aseptic loosening greater than 5% at ten years. ¹⁰ To allow for attrition of up to 20%, the study planned for an enrolment of 20 patients. Due to technical difficulties with acetabular bead insertion and visualization early in the study enrolment, three additional patients were added with full ethical approval to ensure that the minimum sample size of 16 would be achieved at two years with potential loss to follow-up.

Statistical analysis. Independent-samples t-tests were used to compare to published migration thresholds. Linear regression was used to assess acetabular cup migration relative to the number of screws used to augment fixation. Paired t-tests were used to compare preoperative to postoperative patient-reported outcome measures (PROMs) with continuous outcomes. The threshold for statistical significance was defined as $p \le 0.05$. Minitab Statistical Software Release 14.11 (USA) was used for the statistical analyses.

Results

A total of 23 patients were enrolled over the course of the trial. One patient experienced an early deep post-operative infection resulting in staged revision to non-study components prior to six-month data collection. Their results were followed but removed from analysis due to absence of the device of interest. This resulted in data collection on 22 patients evenly split between male and female. The mean age at surgery was 70.6 years (SD 3.5) and mean BMI was 31.0 kg/m² (SD 5.7). While the surgical goal was to insert two to three fixed-angle acetabular screws for additional fixation, in one case only one screw was able to be inserted due to anatomical defects and screw placement safety. Three acetabular screws were inserted into eight patients and two screws into 13 patients.

RSA data can be found in Table I and Figures 3 and 4. Acetabular migration data were available in 18 patients. The remaining patients were unable to be assessed due to inadequate innominate bone RSA bead visualization relative to the implant. Mean migration of the acetabular component by 24 months was 0.087 mm (SD 0.152) and differed significantly from the published threshold of 0.2 mm (p = 0.005, independent-samples t-test).¹⁰ Linear regression did not find evidence that the number of screws used to augment initial fixation affected acetabular migration (p = 0.673). Intrapatient error, or RSA precision, was calculated as 0.113 mm from 17 patients with duplicate six-week exams. Mean rigid body error of acetabular bone beads was less than 0.250 across all patients and condition number was better than 90 for all patients.

Femoral migration data were available in 20 patients. The remaining patients were unable to be assessed due to inadequate femoral bone RSA bead visualization

Table I. Translation and rotation along and around the x, y, and z axes and maximum total point motion of the acetabular and femoral components relative to six-week reference at 12 and 24 months.

	Tx, mn	1	Ty, mm	1	Tz, mm	1	Rx,°		Ry,°		Rz, °		MTPM	, mm
Component	12	24	12	24	12	24	12	24	12	24	12	24	12	24
Acetabular cup														
Mean	-0.102	-0.110	0.103	0.087	-0.301	-0.292	0.105	-0.046	0.005	0.120	0.013	0.045	0.446	0.440
SD	0.296	0.314	0.125	0.152	0.489	0.480	0.863	0.822	0.913	0.856	0.533	0.453	0.500	0.508
Femoral stem														
Mean	0.023	0.024	-0.004	-0.002	-0.015	0.011	-0.071	-0.066	0.236	0.086	-0.047	-0.087	0.755	0.780
SD	0.184	0.199	0.195	0.194	0.157	0.181	0.343	0.361	0.956	0.772	0.325	0.355	0.895	0.910

MTPM, maximum total point motion; R, rotation; SD, standard deviation; T, translation.

Table II. Patient-reported outcome measures comparing preoperative and 24-month postoperative scores.

PROM	Mean preoperative score (SD)	Mean 24-mth postoperative score (SD)	p-value*
WOMAC	56.3 (12.5)	10.0 (13.3)	< 0.001
Harris Hip Score	50.5 (14.6)	88.9 (11.8)	< 0.001
Oxford Hip Score	18.0 (6.6)	42.4 (7.4)	< 0.001
HOOS	37.1 (13.3)	87.4 (15.9)	< 0.001
SF-36 PCS	29.9 (8.8)	46.1 (11.7)	< 0.001
SF-36 MCS	52.9 (13.2)	56.0 (8.4)	0.272
ED-5D	0.740 (0.099)	0.847 (0.159)	0.004

^{*}Paired t-test.

EQ-5D, EuroQol five-dimension health questionnaire; HOOS, Hip disabilty and Osteoarthritis Outcome Score; MCS, mental component summary; PCS, physical component summary; PROM, patient-reported outcome measure; SD, standard deviation; SF-36, 36-Item Short-Form survey; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

relative to the implant. Mean migration of the femoral component by 24 months was -0.002 mm (SD 0.194) and differed significantly from a reference of 0.5 mm (p < 0.001, independent-samples *t*-test) extracted from published data. Intrapatient error was 0.104 mm from 18 patients with duplicate six-week exams. Mean rigid body error of femoral bone beads was less than 0.270 for all patients and condition number was better than 80, except in one patient (122.4) due to nearly colinear bead placement. This patient's data were included in the analysis as the value was only just above the suggested threshold of 120, and the bead colinearity would have only effected rotation about the long axis and had no substantive effect on stem subsidence, the principal femoral metric of interest. In

Patient-reported outcome data are found in Table II. All PROMs showed significant improvement in outcomes from preoperative to 24 months post-surgery with the exception of the SF-36 Mental Component Summary (MCS), which showed a non-significant trend toward improvement. 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".

Complication data were collected at each visit. As mentioned previously, one patient, with a history of diabetes, experienced an acute wound infection with methicillin-sensitive *Staphylococcus aureus*. After

presenting with new onset wound drainage, they underwent debridement and implant retention with modular component exchange. Wound pain and drainage recurred three months post-revision and they were revised to an antibiotic-laden articulating spacer. The infection was resolved and the patient has opted to avoid further surgery on the hip. One patient experienced a femoral neuropraxia due to errant retractor placement with resolution during the follow-up period. One patient experienced a calcar crack that was recognized during broaching and was treated with a single cerclage cable. No change to the rehabilitation programme was made; the patient has declined to have the cable removed. Two patients reported recalcitrant iliotibial band syndrome confirmed by diagnostic and therapeutic local injections (one patient is the aforementioned patient who suffered the calcar crack and cerclage cable placement). These two patients were the same two patients referenced earlier who reported being "somewhat dissatisfied" with the outcome of their hip surgery at 24 months. No patients have reported symptoms consistent with softtissue impingement within the articulation. No patients have experienced symptoms consistent with adverse reaction to metal debris.

One patient experienced a traumatic dislocation on postoperative day 4 while still in hospital. Postoperative radiographs showed good implant positioning with appropriate leg length and offset restoration, but

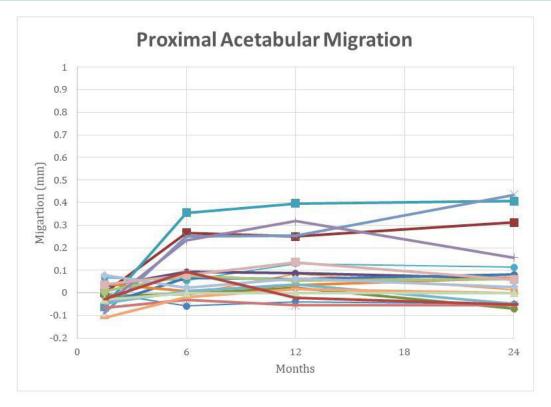


Fig. 3
Patient-level radiostereometric data of proximal acetabular component migration.

required the maximum implant offset options available at the time to achieve that position. The patient was standing at the bedside when they caught their surgical foot on a bedside table and fell to the ipsilateral side. The leg was forced into an adducted position and was associated with increased hip pain. Radiographs showed a direct lateral translation of the femoral cup relative to the acetabular ball with the capsular repair likely intact due to the small degree of displacement. Sedation and in-line traction were successful in achieving reduction. There have been no recurrences of instability or dislocation and the patient reports being "very satisfied" with their outcome. No other patients have reported instances of implant instability or dislocation.

Discussion

The novel reverse-geometry THA demonstrated minimal migration between 12 and 24 months for both the femoral or acetabular components. In both cases, the mean migration was effectively below the detection limit of RSA and well below the published reports for implants with greater than 5% risk of revision at ten years.¹¹ The femoral component fixation appears to be at least equivalent to other well-established dual-taper stems both with and without hydroxyapatite coatings.^{20–23} No individual patient demonstrated migration of concern. Acetabular component fixation is also consistent with clinically

successful products.^{24,25} This suggests that the device is at low risk for aseptic loosening and revision at ten years.

Given the sample size, PROM data cannot be statistically compared to existing datasets of other wellaccepted THA devices. Aggregate data do suggest significant improvement from pre- to postoperative in all domains, with the exception of SF-36 MCS, which showed a small non-significant improvement. This is likely due to a known issue in the scoring algorithm in orthopaedic use of the SF-36 where low PCS values will increase the MCS.26 This would artificially raise the preoperative MCS and make a difference more difficult to detect. WOMAC and OHS were consistent with shortterm clinical outcomes with other successful arthroplasty components.^{25,27} In comparison to Nebergall et al,²⁰ the EQ-5D score is marginally better, while the HHS and SF-36 PCS are slightly lower. This likely relates to the patients in that study being, on average, nearly a decade younger (mean age of 61 years) and healthier (mean BMI 27.8 kg/ m²) in the paper by Nebergall et al.²⁰ In larger samples of accepted dual-taper stems and uncemented acetabular components, the HHS and SF-36 PCS results appear to be at least equivalent.^{21,23,28} While not definitive, this suggests that this device is a viable option for THA.

There are limitations to this study which need to be addressed. Restrictions applied as part of the approval for the Investigational Device Trial limited the age for

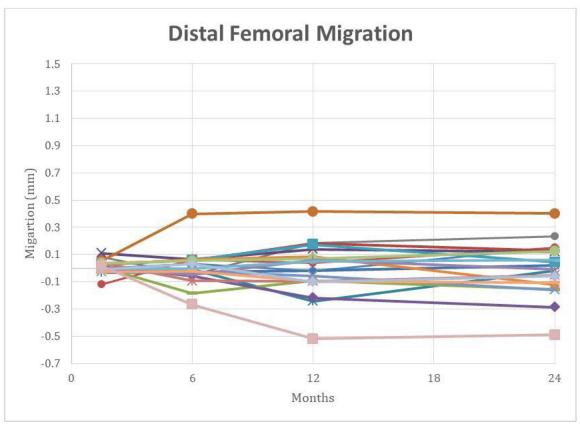


Fig. 4
Patient-level radiostereometric data of distal femoral component migration.

enrolment to 65 to 79 years. While there were restrictions on severe medical comorbidities, patients in this sample likely had a larger burden of comorbidity compared to the general population of THA patients. This may have contributed to some of the complications documented in this trial. While bone density was not documented as part of the trial, these patients would be expected to have lower bone mineral density than in a younger cohort. While this may have contributed to the intraoperative calcar crack, it may also demonstrate good implant fixation despite the potential for poorer bone quality in this population. As a requirement of the Investigation Device Trial, no acetabular cups were inserted without fixedangle screw augmentation. Press-fit acetabular fixation without screws is under current study at the investigation site, but prior publications have not shown a difference in short-term press-fit fixation between augmented and non-augmented cups.²⁴ The baseline RSA measurement was collected at six weeks rather than at the time of discharge which was used in several (but not all) of the papers used in the meta-analyses to create the reference points for both femur and acetabular component migrations. 10,11 This was a practical issue given that the RSA suite is not located at the surgical facility. While this may have led to an under-representation of the implant

migration, we believe that any effect is small given the longer hospital stays in the historical papers used in the meta-analyses and the relatively short difference in the duration out to six weeks. This study was not intended to assess the impact of this novel device on instability. Given the relatively low rates of dislocation in the general hip arthroplasty population, a large sample size would be required to detect a difference.^{1,2} Further study of specific subsets of patients, such as those with spinopelvic movement disorders, aberrant variants of native femoral or acetabular version, or other factors that predispose to implant malpositioning, is warranted to further characterize the device.

The novel reverse hip arthroplasty system achieved consistent, solid bony fixation of the femoral components and acetabular components with screw augmentation. PROMs were consistent with published reports of currently marketed, and commonly used, THA devices. There were high rates of patient satisfaction with what appears to be a new, successful hip arthroplasty design. Further work to characterize acetabular fixation without screw augmentation is ongoing, as are larger clinical cohort trials to further characterize the functional performance of this novel device.



Take home message

- Radiostereometric analysis demonstrates excellent fixation with a predicted low risk of revision at ten years of this novel reverse total hip system.
- Clinical outcomes were consistent with safe and effective hip arthroplasty prostheses.

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Author information:

- T. R. Turgeon, MD, MPH, FRCSC, Orthopaedic Surgeon D. R. Hedden, MD, FRCSC, Orthopaedic Surgeon
- E. R. Bohm, MD, MSc, FRCSC, Orthopaedic Surgeor
- C. D. Burnell, MD, FRCSC, Orthopaedic Surgeon Concordia Joint Replacement Group, Winnipeg, Canada; Department of Surgery, University of Manitoba, Winnipeg, Canada.

Author contributions:

- Turgeon: Conceptualization, Methodology, Funding acquisition, Project administration, Investigation, Data curation, Formal analysis, Writing – original draft, Writing - review & editing.
- D. R. Hedden: Conceptualization, Methodology, Investigation, Writing review &
- E. R. Bohm: Conceptualization, Methodology, Project administration, Investigation, Data curation, Writing – review & editing.
- C. D. Burnell: Conceptualization, Methodology, Investigation, Writing original draft, Writing - review & editing.

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Data sharing:

The datasets generated and analyzed in the current study are not publicly available due to data protection regulations. Access to data is limited to the researchers who have obtained permission for data processing. Further inquiries can be made to the corresponding author.

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