Revision Arthroplasty

Short-Term Outcomes and Complications After Rejuvenate Modular Total Hip Arthroplasty Revision

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Background: The early short-term outcomes and complications after revision of the recalled Rejuvenate modular neck hip arthroplasty have not been previously reported. This study’s purpose is to describe the early outcomes and complications after revision of the Rejuvenate modular femoral neck.

Methods: A retrospective cohort included 92 patients with 92 Rejuvenate modular neck total hip arthroplasty (THA) who underwent revision surgery between July 2011 and April 2014. Preoperative, 1-year, and 2-year patient-reported outcome measures including Western Ontario and McMaster Universities Arthritis Index (WOMAC) and Short Form 12 (SF-12) were described in 92 patients.

Results: Complications arose in 13% of patients including 8 greater trochanteric fractures, 1 intraoperative periprosthetic acetabular fracture, 2 dislocations, 1 early aseptic loosening, and 1 infection requiring a 2-stage revision. Overall, 66% of patients with a complication required reoperation. Significant changes were noted between preoperative and 1- and 2-year outcomes with respect to WOMAC pain score (P = .0031), WOMAC total score (P = .021), SF-12 mental component score (P < .0001), and physical component score (P < .0001).

Conclusions: Patients can expect an improvement in pain (WOMAC pain) and function (total WOMAC, SF-12 Physical Health Composite Scale), but overall worsening in the SF-12 mental component scores. Patients’ physical function improvements are offset by worsened mental function scores. Patients undergoing revision of Rejuvenate modular neck THA implants should be counseled on modest functional improvements and relative frequency of complications.

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The Rejuvenate Modular Hip Stem (Stryker Orthopedics, Mahwah, NJ) was voluntarily recalled in July 2012 after an elevated failure rate was noted during routine postmarket analysis [1,2]. Symptomatic patients were found to have pain, elevated chromium (Cr) and cobalt (Co) ion levels, and adverse local tissue reactions (ALTRs). Certain series have shown that up to 30% of patients with Rejuvenate stems are symptomatic [3]. The Rejuvenate modular stem was designed to allow the surgeon intraoperative flexibility to optimize stability, range of motion, and leg length by adjusting the neck length. The taper junction of the neck stem interface has fallen under scrutiny after several studies reported that mechanically assisted crevice corrosion at the dual-taper junction leads to elevated Co and Cr ions resulting in ALTR [2,4-7]. The diagnosis of a taper junction corrosion and metallosis usually relies on the patient history, physical examination, laboratory tests, and advanced imaging, specifically metal suppression magnetic resonance imaging (MRI) [8].

Since then, numerous studies have described imaging characteristics, serum metal ion levels, and intraoperative findings. However, the early short-term outcomes and complications after revision of this modular neck hip arthroplasty have not been previously reported. This study describes the early outcomes and complications after revision of the Rejuvenate modular neck total hip arthroplasty (THA). The preoperative, 1-year, and 2-year patient-reported outcome measures (PROMs) including Western
Ontario and McMaster Universities Arthritis Index (WOMAC) and Short Form 12 (SF-12) are described in 92 patients. The early 1-year complications of a modular neck THA revision are also described.

**Methods**

The retrospective cohort included 92 patients with 92 Rejuvenate modular neck THAs who underwent revision surgery between July 2011 and April 2014. This cohort was taken from the senior author’s series of 199 Rejuvenate modular stems implanted between April 2010 and March 2012 (Fig. 1). Patients whose revisions were completed <1 year ago were excluded. Clinical records including implants, complications, and PROMs were reviewed. PROMs were taken from an institutional review board–approved institutional registry that included WOMAC, University of California, Los Angeles Activity Scale (UCLA), SF-12, and Harris Hip Scores (HHSs). The preoperative, 1-year, and 2-year WOMAC, UCLA, SF-12, and HHSs were summarized using means and standard deviations (SDs). The preoperative, 1-year, and 2-year scores were compared using repeated analysis of variance (ANOVA). When a significant ANOVA test was observed, post hoc pairwise comparisons using paired t-test were performed.

Preoperative MRI using a standardized protocol (multi-acquisition with variable resonances image combination [MAVRIC]) optimized to reduce metallic susceptibility artifact was obtained in all patients (Fig. 2). Using the preoperative MRI score for aseptic, lymphocyte-dominated vasculitis-associated lesion (ALVAL) for metal-on-metal THA, 13 were mild, 18 were moderate, and 15 were severe grades. Using the histologic description of ALVAL for metal-on-metal hips, nearly 90% of the unilateral hips had an ALVAL score >5 and therefore were considered positive ALVAL cases [9]. The ALVAL scoring system was described by Campbell et al, the mean synovial lining score was 2.54 (SD, 0.65), the mean inflammatory infiltrate score was 3.19 (SD, 0.89), and the mean tissue organization score was 2.25 (SD, 0.86). The mean total histologic ALVAL score was 8.02 (SD, 2.07). Implant characteristics such as stem size, offset, neck and/or shaft angle, and neck version were also recorded. All implants were transferred into our institutional review board–approved implant retrieval system.

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**Fig. 1.** Left primary THA using the Rejuvenate modular neck femoral stem (Stryker, Mahwah, NJ).

**Fig. 2.** Severe adverse local tissue reaction (ALTR) as seen on magnetic resonance imaging using our institution’s metal suppression protocol (multiacquisition with variable resonances image combination).

**Fig. 3.** Modular neck with black corrosion material just after removal.

**Fig. 4.** Left revision THA using the Restoration Modular Stem and Trident PSL Acetabular Shell (Stryker Orthopedics, Mahwah, NJ).
All implants were revised at our institution by the senior author (G.H.W.). Revisions were done for pain or ALTR, which was diagnosed by increased metal ion levels and advanced axial imaging using the MAVRIC MRI protocol. All primary and revision surgeries were completed via a posterolateral approach. On visual inspection, all implants were noted to have corrosion at the modular neck-stem junction that was most severe on the medial aspect of both the male and female tapers (Fig. 3). No implants demonstrated corrosion or damage at the head-neck taper or articulating surface. All Rejuvenate modular neck implants were removed proximally in an identical fashion. No extended trochanteric osteotomies were used for stem removal. First, the pathologic soft tissues affected by the ALTR were resected and sent for culture and pathology. Next, the bone ingrowth surfaces were separated from the implant using a Midas Rex burr and flexible osteotomes. Finally, the implant was removed using a screw-in explantation tool.

Results

All patients had the Rejuvenate modular neck femoral stem, and 99% had a cobalt—chromium (CoCr) Restoration Anatomic Dual Mobility (ADM) Acetabular Shell (Stryker Orthopedics). One patient received a Trident PSL Acetabular Shell (Stryker Orthopedics). Overall, 96% had CoCr femoral heads at the index THA. The femoral component of all patients were revised to a Restoration Modular Stem (Stryker Orthopedics), which is a modular titanium diaphyseal-engaging revision stem, mated with a titanium shell.
The single well-fixed titanium Trident PSL acetabular shell was left in place, whereas all ADM cups were revised. Previous series have also suggested removal of ADM cups to address concerns over cobalt sensitization [10]. None of the ADM cups had visible scratching or evidence of damage. At revision, 99% of patients had 36-mm ceramic femoral heads; one patient required a 28-mm, −4 CoCr that was not available in ceramic. Overall, 96.3% had highly cross-linked polyethylene liners, one patient required a constrained liner and another a dual-mobility liner, both for instability. All Rejuvenate stems were removed proximally without an extended trochanteric osteotomy (ETO).

In this cohort of 92 patients, the mean follow-up was 2.07 (±0.595) years, and the mean implantation time of the Rejuvenate stem before revision was 1.94 (±0.784) years. The cohort was 63% female, including 54 right and 33 left THAs, and the average age at revision was 65.7 (±8.4) years. Complications arose in (12 of 92) 13% of patients including 8 greater trochanteric fractures, 1 intraoperative periprosthetic acetabular fracture, 2 dislocations, 1 early aseptic loosening, and 1 infection requiring a 2-stage revision. Overall, 66% of patients with a complication required reoperation. All greater trochanteric fractures were treated operatively, even though all were non-displaced or minimally displaced fractures. Two-thirds of greater trochanteric fractures occurred intraoperatively at the revision procedure [Figs. 5-9]. The single periprosthetic acetabular fracture was recognized on the recovery room radiograph and healed uneventfully without intervention. After all Rejuvenate revision surgeries, all patients were partial weight bearing for 6 weeks, so the fracture treatment did not alter their weight-bearing status. However, trochanteric precautions (no active abduction or passive adduction) were added to the physical therapy protocol after all the previously mentioned fractures.

The results from repeated-measure ANOVA showed that there was a significant time effect on WOMAC pain score ($P = .0031$), WOMAC total score ($P = .021$), SF12 mental component score ($P < .0001$), and physical component score ($P < .0001$; Figs. 10-13). WOMAC function and stiffness scores, UCLA activity score, modified HHS, and HHSs did not change significantly over time (Figs. 14-16). Pairwise comparisons found WOMAC pain scores significantly improved from preoperative (69.8 ± 23.18) to 1-year (81.0 ± 20.5; $P = .0301$) and 2-year (81.3 ± 17.1; $P = .0124$) values. Total WOMAC...
scores significantly improved from preoperative (68.4 ± 22.0) to 2-year (79.4 ± 17.7; \( P = .0162 \)) values, but no significant improvement between preoperative (68.4 ± 22.0) and 1-year WOMAC scores (75.7 ± 19.4; \( P = .21 \)). The SF12 mental component scores significantly worsened from preoperative values (51.5 ± 9.2) to 1-year (37.8 ± 10.6; \( P < .0001 \)) and 2-year (38.7 ± 11.4; \( P < .0001 \)) values. However, the SF12 physical component scores significantly improved from preoperative values (39.7 ± 10.8) to 1-year (51.1 ± 11.2; \( P < .0001 \)) and 2-year (55.8 ± 8.0; \( P < .0001 \)) values.

The Rejuvenate revision cohort’s patient-reported outcomes were compared to a control group of 72 patients who underwent revision THA with the same senior surgeon between 2007 and 2012 (Table 1). The control group underwent revision for all causes with the exception of revision for failed Rejuvenate THA. The control group included in 39 females (54.2%) and an average age of 64.8 (±12.0) years. The Rejuvenate revision THA patients had significantly higher WOMAC scores in all 3 domains (WOMAC pain, stiffness, and function) at baseline (\( P = .021, P = .025, P = .0009 \), respectively) than the all-cause revision cohort. There was no difference in the WOMAC pain, stiffness, or function scores at 2 years between the all-cause revision control group and the Rejuvenate study group. The Rejuvenate group had better SF-12 Physical Health Composite Scale (PCS) both at baseline and at 2 years (\( P = .005; P = .004 \), respectively). Finally, although there was no difference in SF-12 MCS scores at baseline between the 2 groups, the Rejuvenate revision cohort had significantly worse SF-12 MCS at 2 years (\( P = .0002 \)).

**Discussion**

Modular neck or dual-taper implants, such as the Rejuvenate stem, were designed to increase the surgeon’s ability to match the patient’s femoral offset, length, and version. Unfortunately, data from the 2012 Australian Registry Annual Report and UK National Joint Registry noted that some modular neck stems appeared to have an increased risk for early revision. Subsequently, a type II voluntary recall for the Rejuvenate stem was initiated by the manufacturer, Stryker Orthopedics in July 2012 [2]. A similar modular dual-taper stem, the ABG (Anatomique Benoist Gerard) II modular neck stem, was also recalled at the same time for similar increased risk of revision [11]. Since the initial reports, numerous articles have reaffirmed the poor performance of these implants and have also studied the elevated metal ion levels, abnormal soft tissue masses on MRI, and early onset pain experienced by patients [1,3,8]. Other manufacturer’s modular stems have also been implicated in poor performance because of metal ion release and pseudotumor formation [12]. In addition, early titanium modular stems were noted to have the risk of modular neck fracture [13,14].
However, the early short-term outcomes and complications after revision of this modular neck hip arthroplasty have not been previously reported. The study presented here is the first report of the results of revision of the Rejuvenate modular neck femoral stem with respect to early patient-reported outcomes and complications.

A 13.0% complication rate was identified in this series, and most of these patients required re-revision surgery. In the series, no patients underwent an extended trochanteric osteotomy (ETO), however five patients (5.4%) were noted to have a minimally displaced intraoperative greater trochanteric fracture requiring open reduction internal fixation with a trochanteric plate and cables. Postoperatively, 3 additional patients sustained a traumatic event leading to trochanteric fracture that required open reduction and internal fixation. No patient developed a nonunion of the trochanteric fracture that required further surgery. Although no patient underwent an ETO in this series, the relative frequency of complications may be counseled on modest functional improvements and relative frequency of complications.

Table 1

<table>
<thead>
<tr>
<th>Patient Reported Outcome Test and Follow-up Interval</th>
<th>All Non-Rejuvenate Revision THA</th>
<th>Rejuvenate Revision THA</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOMAC PreOp pain</td>
<td>55.59 (±21.2)</td>
<td>69.77 (±23.1)</td>
<td>.0211</td>
</tr>
<tr>
<td>WOMAC PreOp stiffness</td>
<td>48.68 (±33.3)</td>
<td>64.97 (±27.0)</td>
<td>.0247</td>
</tr>
<tr>
<td>WOMAC PreOp function</td>
<td>47.42 (±25.7)</td>
<td>68.56 (±22.9)</td>
<td>.0009</td>
</tr>
<tr>
<td>WOMAC Year 2 pain</td>
<td>84.67 (±21.3)</td>
<td>81.25 (±17.1)</td>
<td>.6252</td>
</tr>
<tr>
<td>WOMAC Year 2 stiffness</td>
<td>77.34 (±27.9)</td>
<td>78.16 (±18.0)</td>
<td>.9226</td>
</tr>
<tr>
<td>WOMAC Year 2 function</td>
<td>84.64 (±17.1)</td>
<td>77.68 (±20.6)</td>
<td>.3271</td>
</tr>
<tr>
<td>SF-12 PreOp PCS</td>
<td>31.13 (±10.7)</td>
<td>39.69 (±10.8)</td>
<td>.0052</td>
</tr>
<tr>
<td>SF-12 Year 2 PCS</td>
<td>40.64 (±14.5)</td>
<td>55.77 (±8.0)</td>
<td>.0035</td>
</tr>
<tr>
<td>SF-12 PreOp MCS</td>
<td>49.52 (±13.1)</td>
<td>51.46 (±2.2)</td>
<td>.5594</td>
</tr>
<tr>
<td>SF-12 Year 2 MCS</td>
<td>52.05 (±11.1)</td>
<td>38.67 (±11.4)</td>
<td>.0002</td>
</tr>
</tbody>
</table>

PreOp, preoperative; THA, total hip arthroplasty.

Patients undergoing primary THA can expect an improvement in their symptoms in approximately 90% of patients [16]. Hence, rarely do patients regret a THA that it has been called the operation of the century [17]. However, for patients whose implant is recalled, the future is less certain. This present study was undertaken to understand how pain, function, and satisfaction change in the years after revision of the Rejuvenate stem. Patients can expect an improvement in pain (WOMAC pain; Fig. 10), function (total WOMAC, SF-12 PCS; Figs. 11–12), but overall worsening in the SF12 mental component scores (Fig. 13). Patients’ physical function improvements are offset by worsened mental function scores. Patients undergoing revision of recalled modular neck THA implants should be counseled on modest functional improvements and relative frequency of complications.

References