Original research

Medium Term Radiographic and Clinical Outcomes Using a Modular Tapered Hip Revision Implant

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A B S T R A C T

Background: The rate of revision hip arthroplasty surgery is rising. Surgeons must use implants with proven outcomes to help overcome the technical challenges faced during revision surgery. However, outcome studies using these implants are limited. The aim of this study is to investigate the radiographic and clinical outcomes of the Stryker Restoration stem, the most commonly used hip revision stem in the United Kingdom (UK).

Methods: A retrospective review of a single surgeon case series was performed. Immediate postoperative radiographs were analyzed for offset and leg length discrepancy. Radiographic evidence of subsidence was assessed using follow-up radiographs. Kaplan-Meier survival analysis was applied using explanta-

ion and reoperation as endpoints. Patient-reported outcomes were measured using the Oxford Hip Score and EQ-5D-5L.

Results: One hundred ninety-eight cases were identified. Mean follow-up duration was 51.8 months (range: 24-121). Stem survival during this period was 98%. Reoperation for any reason was 13%. Mean subsidence was 4.18 mm. Analysis of variance testing showed no difference in mean subsidence between revision indications. Mean offset and leg length discrepancies were measured at 4.5 mm and 4.3 mm, respectively. The mean Oxford Hip Score for participants was 27.6.

Conclusions: This series demonstrates excellent implant survival, with radiographic parameters for reconstruction and subsidence levels comparable to those in the existing literature. The tapered modular hip revision stem provides surgeons with the intraoperative flexibility to overcome some of the anatomical difficulties encountered during revision surgery; this is reflected in the radiographic and clinical outcomes of the cohort in this study.

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Introduction

The British National Joint Registry projects a 134% rise in patients requiring hip surgery by 2030, associated with a projected rise of 31% for revision hip surgery [1]. It is imperative that surgeons are prepared for this predicted endemic of hip revision surgery with appropriate, outcome-proven implants. Several options for femoral revision prostheses are available, including monobloc and modular implants. Monobloc prostheses offer several potential advantages, including simplified equipment inventory and the associated costs, simplicity of use and avoidance of the potential problem of corrosion at the modular junction, which may lead to implant failure and osteolysis. However, restoration of normal hip anatomy and biomechanics is harder to achieve without modularity as the metaphyseal-diaphyseal mismatch cannot easily be addressed [2]. Paprosky and Weeden demonstrated high failure rates using fully coated monobloc prostheses, particularly in patients exhibiting type III and IV femoral defects [3].

Modular revision stems allow metaphyseal and diaphyseal components to be individually sized according to the femoral morphology. Modular tapered stems allow metaphyseal bone de-
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fects to be bypassed by means of a distal fix, with load transfer occurring in the isthmus of the femur. Stem bodies are available in varying diameters. Some have inbuilt splines enabling axial and rotational stability when directly resting against viable bone. Offset

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can also be increased according to required soft tissue tension, to optimize stability [4]. An example of such a stem is the Stryker Restoration stem (Kalamazoo, MI). This is the most used revision prosthesis in the UK [5]. Several studies have reported outcomes using such stems [6–11]. However, numbers of cases in these series have been limited (the largest reported cases series n = 125).

The aim of this study is to report the medium-term radiological and clinical outcomes of the Stryker Restoration stem (Kalamazoo, MI). We aim to compare local experience with existing data series and contribute to the body of evidence regarding these stems.

Material and methods

This is a single-surgeon, retrospective, consecutive case series at a single district general hospital. Ethical approval was applied for and granted by the hospital ethics committee.

A local orthopedic database was used to identify patients undergoing revision hip surgery between 2009 and 2016. The minimum follow-up period was 2 years. The database was cross-referenced with the hospital picture and communication system to identify patients undergoing revision surgery using the Stryker Restoration stem (Kalamazoo, MI).

Preoperative and postoperative clinic letters were reviewed to ascertain indications for revision, postoperative clinical outcomes, and adverse events including re-revision and complications that did not require the patient to return to theatre. Patients were routinely followed up at 6 weeks, 6 months, and yearly until discharge, unless there were concerns necessitating more frequent clinical follow-up. Demographic data were collected on patient age, discharge, unless there were concerns necessitating more frequent clinical follow-up. Radiographic analysis was performed by 2 independent assessors via telephone; verbal consent was obtained at this time.

Patient-reported outcomes were assessed using the EQ-5D-5L questionnaire was granted by the EuroQol Research foundation [16]. The questionnaires were performed by 2 independent assessors via telephone; verbal consent was obtained at this time.

All surgeries were performed by a single surgeon. The extensile posterior approach and same operative technique for stem implantation was used throughout. The postoperative protocol was the same for all patients. All patients were permitted to fully weight bear as tolerated on day one. Hip precautions were used in the early postoperative period. Pelvic and femoral radiographs were performed on postoperative day one. The postoperative thromboprophylaxis protocol involved low-molecular-weight heparin and pneumatic calf pumps while in hospital, followed by a 28-day course of aspirin and antithrombotic stockings. Postoperative analgesia was individualized to patient requirements.

Statistical analysis was carried out using the statistical package for the social sciences (SPSS, IBM, Armonk, NY). Analysis was undertaken using each stem implanted as an individual case. Means and ranges were reported for continuous data and percentages for nominal data. Subsidence was analyzed using analysis of variance (ANOVA) testing to observe the differences depending on the revision indication. Survival analysis was conducted by plotting Kaplan–Meier curves with revision of the stem and reoperation for any reason as endpoints.

Results

During the study period, 198 implanted restoration stems (Kalamazoo, MI) were identified in 182 patients. The mean age was 76 years (46–95), and 64% were female. Mean follow-up period was

| Subsidence (mm) | Indication |
|----------------|------------|
| 10.23          | IIIa       |
| 10.55          | AVN        |
| 10.70          | IIIa       |
| 11.09          | IIIa       |
| 12.29          | B2         |
| 13.29          | Failed IM nail |
| 13.33          | B2         |
| 13.38          | IIIa       |
| 14.28          | Revised hemiarthroplasty |
| 16.31          | IIIA       |
| 16.63          | Infection  |
| 20.91          | IIb        |
| 26.68          | B2         |
| 33.36          | B2         |

AVN, avascular necrosis; IM, intramedullary.

Table 1
Demographics of patients undergoing surgery.

| Age | Sex | Side | Right | Left | Bilateral |
|-----|-----|------|-------|------|-----------|
| 76  | 64  | 118  | 99    | 69   | 15        |

Table 2
Indication for all stems with subsidence >10 mm.
51.8 months (range: 24-121). Sixty-four percent (n = 125) of cases underwent cup and stem revision, and 36% (n = 73) underwent stem revision alone. Indications for the revision were aseptic loosening (43%), periprosthetic fracture (26%), hemiarthroplasty revision (14%), infection (10%), dislocation (3%), and other (4%).

Distribution of cases across each of the Paprosky femoral classification [6] was as follows: 24% type II, 58% type IIIa, 16% type IIIb, and 2% type IV. Patients undergoing revision for periprosthetic fracture were classified using the Vancouver classification [7]: Vancouver A (n = 3), Vancouver B2 (n = 47), and Vancouver B3 (n = 2). Demographics are shown in Table 1.

Mean offset difference was 4.5 mm (range: 0.7-16.9), and mean LLD was 4.3 mm (range: 0-11.5). One hundred and forty cases, with a minimum 2 years of postoperative radiological follow-up, were analyzed for evidence of stem subsidence. The mean subsidence was 4.2 mm (range: 0-33 mm). One hundred and five stems (75%) subsided <5 mm, 21 stems (15%) 5-10 mm, and 14 stems (10%) demonstrated subsidence >10 mm (range: 11-33 mm) (Table 2). Subsidence was analyzed according to indication for revision (Table 3). Revision for peri-prosthetic fracture demonstrated the highest level of subsidence (5.42 mm, standard deviation: 7.25). However, ANOVA testing showed no significant difference between each indication (P = 1.00).

ETO was performed in 62 cases. At follow-up, there was a 94% radiographic union rate of ETO. Patients treated for periprosthetic fracture with the modular tapered stem demonstrated radiographic union of 96% at the end of the follow-up period.

The survival rate of the stem was 98.5%, where stem explant was used as the end point. The indication for removal was deep infection in all (n = 4) cases. The survival curve for the stem is shown in Figure 1. Postoperative dislocation occurred in 15 cases (7.5%), with 5 cases requiring subsequent acetabular cup revision. In total, 26 cases required further surgery while retaining the stem, yielding an 89.6% survival using return to theatre as the end point (Fig. 2). The indications for return to theatre surgery are shown in Table 4. Postoperative complications that did not require reoperation were not identified in any case.

Attempts were made to conduct telephone interviews to assess the PROMs for the 122 patients that survived to the end of the follow-up period. The Oxford Hip Score and EQ-5D-5L was successfully collected for 47 patients. The remaining patients were uncontactable or did not consent to take part in the study. The average OHS was 27.6. Figure 3 shows the EQ-5D-5L scores for each domain.

Discussion

The survival rate of the stem was excellent at 98.5% and in accordance with other published studies investigating modular hip revision stems (Table 5). Four stems were removed during the follow-up period. The indication for stem removal was post-operative prosthetic joint infection in all. One of these patients had pre-existing prosthetic joint infection. The rate of return to theatre for any reason was 13%. Other published studies have reported similar rates of 2%-29%.

Results for LLD in this study were ±4.3 mm, within the acceptable limits for primary hip replacement [40]. This finding is reassuring in the revision scenario where anatomical reconstruction can be challenging. Few previous studies [6,15,34,35] have reported radiological measures of postoperative offset and leg length. Difficulty in accurately measuring leg length [41] may explain the lack of prior reporting. These inaccuracies are related to the requirement of true anterior-posterior radiographs of the pelvis and femora to make this analysis accurately, and this is only achievable through the use of computed tomography.
in some cases. Furthermore, inaccuracies in calibration of the radiographs make these measurements technically challenging. Stimac et al. achieved an LLD of 0.97 mm [6]. The methodology of this study reported the mean positive and negative leg length discrepancies, hence yielding a value close to zero. This means of descriptive analysis was not used in this study as a picture of overall LLD wanted to be obtained. If this alternative methodology had been used, the new value would be 0.9 mm. The mean offset change was calculated as ±4.5 mm, which is considered acceptable for primary hip arthroplasty [42]. To the authors knowledge, only one other study [6] has reported offset. This was measured using a different method of global offset, making the results incomparable.

Subsidence is a frequently reported complication of revision hip surgery. Modular tapered stems demonstrate higher rates of component osseointegration and lower rates of subsidence and re-revision when compared with modular cylindrical stems [43]. To avoid vertical downward migration, 4-5 cm of solid fixation in the isthmus is required [44]. Mean subsidence in this study was 4.18 mm, with 75% demonstrating <5 mm subsidence. Only 10% demonstrated subsidence >10 mm, with 6/10 of these stems used in cases with significant bone defects (IIa/b) or peri-prosthetic fracture. Other studies reported findings between 0.64 mm and 16 mm. Some articles primarily investigate femurs with smaller femoral defects and lower Paprosky classifications [10,29] where one would expect stronger anchorage of the stem and little subsidence. Periprosthetic fractures accounted for 26% of revisions in this present study. These are known to have an increased rate subsidence [45]. A postulated reason for this is the increased femoral canal width and cortical discontinuity following a fracture. The average subsidence in this study following peri-prosthetic fractures was 5.42 mm, which was higher than that for any other indication. Despite this, ANOVA testing showed no difference in mean subsidence between the indication groups.

Stem modularity offers a number of potential advantages related to accurate sizing and fixation of revision femoral stems. However, modularity also has specific complications related to the modular junction including stem fracture and corrosion [46—48]. None of these complications were identified in this study. There were also no cases of stem fracture in this study, which can be compared to the study by Richards et al., who recorded 4 cases of implant fracture of the Zimmer ZMR stem (Warsaw, IN) in their study [25] and Houwelingen et al., who reported 5 fractured stems using the same implant [26].

Postoperative dislocation occurred in 15 cases (7.5%). Five were treated with cup revisions; 1 was a chronic dislocation in a very frail, multimorbid, bed-bound patient which made further revision...
### Table 5
Summary of existing studies using modular revision hip implants.

| Author et al., 2014 [17] | Stem | Number of patients | Follow-up period | Indication | Survivorship | PROMS | Subsidence | LLD | Offset |
|--------------------------|------|-------------------|-----------------|------------|--------------|-------|------------|-----|--------|
| Link MP Restoration      | 29   | 4.5               | PP fracture     | 95         | 83           | 1 stem >5 mm | NJ  | NJ      |
| Huddleston et al., 2015 [18] | ZMR  | 132               | 9               | Femoral bone defects 1-3A | 91       | N.I          | N.I | N.I    |
| Abdel et al., 2017 [19] | LINK MP Restoration | 375                | 4.5             | Aseptic loosening | 96       | 75           | 12 had subsidence > 5 mm (mean 16 mm) | NJ  | NJ      |
| Koster et al., 2008 [20] | Profemur | 73                | 6.2             | Aseptic loosening | 93.9      | HHS 75       | Not calculated (divided) | NJ  | NJ      |
| Park et al., 2007 [21]  | Lima revision stem | 62                | 4.2             | Aseptic loosening, infection, periprosthetic fracture | 98.4%     | HHS 87.3     | 1.1 mm | NJ  | NJ      |
| Neumann et al., 2012 [22] | Modular plus S-ROM | 55                | 5.6             | Aseptic loosening, infection, instability | 96%       | HHS 72       | 2 cases >5 mm | NJ  | NJ      |
| Moreta et al., 2018 [23] | S-ROM | 211               | 6.5             | Aseptic loosening | 94%       | 96%          | N.I | N.I      |
| Cameron, 2002 [24]      | ZMR  | 109               | 3               | Aseptic loosening, Infection, periprosthetic fracture | 94%       | OHS 77       | 95% | N.I      |
| Van Houwelingen et al., 2013 [26] | ZMR | 65                | 7               | Aseptic loosening, fracture, instability | 84% 10-year cumulative survival | 96 | 6 pts >5 mm Average 12.3 mm nil | N.I | N.I      |
| Munro et al., 2014 [27] | ZMR  | 55                | 4.5             | Vancouver B2 and B3 fractures | 96%       | N.I          | N.I | N.I      |
| Wirtz et al., 2000 [28] | Titan | 142               | 2.5             | Aseptic loosening, infection | 96%       | HHS 89.3     | >5 mm, 6 cases | NJ  | NJ      |
| Schuh et al., 2004 [29] | Titan | 79                | 4               | Aseptic loosening | 96.21%    | HHS 86.8     | 1 stem >2 mm | NJ  | NJ      |
| Hoberg et al., 2015 [30] | Titan | 136               | 4.5             | Aseptic loosening, infection, periprosthetic fracture | 93.2%     | HHS 75.1     | N.I | N.I      |
| Girard et al., 2011 [31] | Revitan | 183              | 5.9             | Aseptic loosening | 98.4%     | HHS 83.2     | 3 mm | N.I      |
| Fink et al., 2012 [32]  | Revitan | 22                | 5.6             | Vancouver B2 and B3 fractures | N.I       | 81.6         | N.I | N.I      |
| Fink et al., 2014 [33]  | Revitan | 116              | 7.5             | Femoral bone defects | 91.7      | HHS 88.2     | N.I | N.I      |
| McNinns et al., 2006 [34] | Revitan | 70                | 3.9             | Aseptic loosening, infection, periprosthetic fracture | 92%       | OHS 21.1     | 9.9 mm | 11.7 N.I   |
| Wang et al., 2013        | Link MP | 58                | 4.3             | Femoral revision | 97        | 81.4         | 1.6 mm | 4.7 mm N.I   |
| Hashem et al., 2017 [35] | Link MP | 132               | 4.5             | Aseptic loosening, infection, periprosthetic fracture | 99.2%     | N.I          | N.I | N.I      |
| Kwong et al., 2003 [36]  | Link MP | 143               | 3.3             | Aseptic loosening, periprosthetic fractures, infection, instability | 97.2      | HHS 92       | 2.1 | N.I      |
| Rodriguez et al., 2009 [37] | Link MP | 102               | 3.3 | Aseptic loosening | 95%       | N.I          | 7% , 2 mm | N.I | N.I      |
| Weiss et al., 2011 [38]  | Link MP | 63                | 4               | Aseptic loosening, periprosthetic fracture, infection, instability | 98%       | N.I          | 2.7 >5 mm 15% | N.I | N.I      |
| Amanatullah et al., 2015 [39] | Link MP | 92                | 6.4             | Aseptic loosening, infections fractures | 697       | 69           | N.I | N.I      |
| Houdek et al., 2015 [40] | Link MP | 57                | 5.9             | Infections | 87        | HHS 76       | 4 mm | N.I | N.I      |
| Sticamo et al., 2014 [41] | Restoration | 125              | 4.3             | Aseptic loosening, | 98.6%     | HHS 85.7     | 0.64 mm | 0.97 mm Total offset 151.3 mm | N.I      |
| Palumbo et al., 2013 [7] | Restoration | 18               | 4.5             | Aseptic loosening, infection, periprosthetic fracture | 94%       | HHS 79       | 3.53 | N.I |
| Restrepo et al., 2011 [8] | Restoration | 118              | 4               | Aseptic loosening, infection, periprosthetic fracture | 99.2%     | HSS 77       | <5 mm 98% >5 mm 2% 95% 0-5 mm 16% restored 19% +3 – 5 mm 16% –3 –6 mm | N.I |
| Dzaja et al., 2014 [9]   | Restoration | 55                | 2.5             | Aseptic loosening, infection, periprosthetic fracture | 96%       | HSS 78       | N.I | N.I |
| Hernandez-Vaquero et al., 2015 [11] | Restoration | 12               | 3.7             | Vancouver B2 and B3 fractures | N.I        | 78           | 3.9 mm in 6 cases | N.I | N.I |
| Patel et al., 2010 [10]  | Restoration | 43                | 2.4             | Aseptic loosening, infection, osteolysis | 95%       | N.I          | 2.5 mm | N.I |
| This study               | Restoration | 198              | 4.3             | Aseptic loosening, infection, periprosthetic fracture, infection, instability | 98.5%     | OHS 4.18 mm | 4.34 mm | 4.51 mm |

PROMS, patient recorded outcome measures; HHS, Harris Hip Score; PP, periprosthetic.
surgery impossible. The remainder were treated with closed reduction and successful conservative management. The dislocation rate of 7.5% is in accordance with meta-analysis reporting an average dislocation rate after revision hip arthroplasty of 9.04% (range from 4%-30%) [49].

There is a paucity of evidence for the treatment of peri-prosthetic fractures with modular hip revision stems. The reported union rate for peri-prosthetic fractures ranges from 91% to 100% [22,45,50].

The union rate in this investigation was 96%, demonstrating the successful treatment of peri-prosthetic fractures with modular revision stems. The union rates after ETO is 94% in this study, which is comparable to those of other studies quoting over 90% [51].

Clinically, the Stryker Restoration stem (Kalamazoo, MI) proves to be successful, demonstrating an average OHS of 27.6. Only one other similar study by McMinnis et al. [25] used this score, with an average of 21.1. Richard et al. [34-35] normalized the OHS to 100, but because they failed to detail how they reached this conclusion, the OHS was not comparable. The EQ-5D-5L scores were again reported because they failed to detail how they reached this conclusion, with only 47 patients included. This may reflect the type of evidence is common among the other literature identified across this subject area and offers information that is useful as part of a wider body of evidence in lieu of higher quality studies. Recording of patient-reported outcomes in this study was poor, with only 47 patients included. This may reflect the difficulties with retrospective data collection from elderly patient groups. It may guide further studies to use prospective data collection where possible, to reduce missing data.

Conclusions

This retrospective analysis of the Stryker Restoration modular tapered hip revision stem (Kalamazoo, MI) demonstrates its ability to successfully reconstruct proximal femora despite scenarios of substantial bone loss and peri-prosthetic fractures. This particular implant is currently the most used revision stem in the UK according to registry data [5]. To our knowledge, this is the largest study to investigate the outcomes and survivorship of the Stryker Restoration stem (Kalamazoo, MI). Radiographic outcomes are correlated with successful clinical outcomes and longevity of the implant.

Conflicts of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

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