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ORIGINAL ARTICLE • KNEE - ARTHROPLASTY

Ten-year results for a single-surgeon series of Scorpio non-restrictive geometry (NRG) posterior stabilised (PS) total knee replacement

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Abstract

Background To report the long-term results for a single-surgeon consecutive series of Scorpio non-restrictive geometry (NRG) posterior stabilised (PS) total knee replacement (TKR).

Materials and methods Forty-six consecutive patients who underwent 53 Scorpio NRG PS were identified. Change in range of motion (ROM) and Oxford Knee Score (OKS) over time were recorded. Radiographs were evaluated for alignment and radiolucent lines. Survival analysis for the prosthesis was calculated.

Results At a mean of 10.1 years (range 9.1–10.9) following exclusions thirty-seven (69.8%) knees in thirty-one (67.4%) patients (6 bilateral) were available for review. None of the patients required revision surgery. Mean OKS score at 10 years was 37.8. The mean ROM significantly improved from 95° pre-operative to 117.5° at 5 years and 115° at 10 years ($p = < 0.001$). This equates to a value-added range of motion (VAROM) of 19° at 5 years and 15.6° at 10 years. There was a correlation between OKS and VAROM at 5 and 10 years. Radiological assessment did not reveal any evidence of progressive cement radiolucent lines nor component migration.

Conclusion In this series the Scorpio NRG PS showed 100% 10-year survivorship. We found a significant improvement in ROM and VAROM over time. This was not associated with increased signs of loosening.

Keywords Total knee replacement · Survival · Alignment · Range of motion

Introduction

The Scorpio non-restrictive geometry (NRG) posterior stabilised (PS) (Stryker Orthopaedics, Mahwah, NJ, USA) total knee prosthesis was designed with modifications on the previous Scorpio Knee System (Stryker Orthopaedics) to improve range of movement and increase anterior–posterior stability without the associated patellofemoral complications. These include a reduction in the radius of curvature of the femoral component with a single anteroposterior (AP) radius from 0° to 95° and then a smaller deep flexion radius from 95° to 155°. The posterior aspect of the tibial insert of the NRG is less rotationally constrained than the Scorpio Flex (Stryker Orthopaedics). The increased femoral rollback when compared to the Scorpio Flex is driven by the redesigned post–cam system, which continues to drive the femur back past flexion on 120°. The single medial–lateral axis gives a reduced level of rotational constraint without sacrificing contact area. The post–cam mechanism of the Scorpio NRG is a round-on-round shape allowing for a larger contact area than flat-on-flat shape. Thus, the design of the posterior aspect of the Scorpio NRG can reproduce a femoral rotational freedom in deep knee flexion. The anterior flange of the femoral component of the Scorpio NRG is thinner to reduce tension on the extensor mechanism and retinaculum [1, 2]. However, concerns have been raised over some of the design features which may lead to increased failure rates. These include the single medial–lateral radius which can increase the risk of polyethylene edge loading thus leading to wear. Also, the open-box post–cam mechanism may predispose to cam impingement, post–cam wear and soft tissue entrapment [3].

This implant has been assigned a 7A rating on the Orthopaedic Data Evaluation Panel (ODEP) system [4]. According to the 14th National Joint Registry (NJR) Report (2017) the 4,728 Scorpio NRG PS prostheses have been implanted

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in the UK. The report states that the cumulative percentage probability of first time revision at 10 years since primary operation was 3.53 (2.77–4.50; 95% confidence interval; CI). This is equivalent to other well-known designs but lower than its Scorpio original design at 3.85 (3.35–4.43; 95% CI) [5]. Long-term results have been published on the Scorpio original arthroplasty showing good long-term survivorship and functional outcomes. Mahoney et al. [6] reported an overall survival of 95.8% at 7 years. Similarly, Martin et al. [7] reported on a cumulative survival for the Scorpio prosthesis of 99.5% for any cause at 5 years and 97.4% at 14 years. Mugnai et al. [8] reported on follow-up at 32 months for specifically Scorpio NRG with good outcome. However, to our knowledge no study has previously assessed the long-term survivorship specifically for the Scorpio NRG prosthesis. Therefore, we report the 10-year results including survival, patient-reported outcome and objective range of motion for a single-surgeon consecutive series of Scorpio NRG PS knee arthroplasties.

Materials and methods

This cohort study included a consecutive series of 46 patients that underwent 53 Scorpio NRG PS total knee replacements. These were undertaken by a single consultant surgeon at a tertiary referral institution between 2005 and 2007. At a mean of 10.1 years (range 9.1–10.9 years) since procedure, thirty-seven (69.8%) knees in thirty-one (67.4%) patients (6 bilateral) were available for review. Five (10.9%) patients (1 bilateral) were lost to follow-up. The reasons for loss to follow-up included patients unable to attend due to ill health (two patients) or inability to be contacted by mail or telephone (three patients). 10 (21.7%) patients (11 knees) had died of unrelated causes, but none of these had had their knee replacement revised. The final cohort consisted of 21 (67.7%) female and 10 (32.3%) male patients with an average age at time of surgery of 72 years (44–85 years). The pre-operative diagnosis was osteoarthritis in all the patients. Seven patients had bilateral procedures. All patients who underwent a knee arthroplasty with this implant were identified from a prospectively compiled database. Data obtained included basic demographic information including age, diagnosis and gender as well as pre-operative assessment including range of motion. All patients underwent a standard measured resection cemented arthroplasty technique through a medial parapatellar approach with patella resurfacing. All operations were performed without a tourniquet. Thromboembolic prophylaxis included foot pumps augmented with low molecular weight heparin, and on discharge 150 mg aspirin was given daily for 6 weeks. Intra-operative events including peri-operative complications were also reviewed. Post-operatively, patients were routinely reviewed at 6 weeks, 6 months, and then 1, 2, 5 and 10 years. During follow-up appointments complications and objective range of motion were recorded. The latter was recorded at 10 years by a surgical care practitioner independent of the operating surgeon utilising a combination of manual or validated radiographic method as previously described [9]. A value-added range of motion (VAROM; post-operative ROM minus pre-operative ROM) was then obtained at each clinical appointment. In addition, to evaluate outcome and effectiveness of treatment an Oxford Knee Score (OKS) was also completed. The OKS is a patient-reported outcome measure specifically designed to measure subjective outcome after a total knee replacement. It consists of 12 questions on a Likert scale assessing levels of pain and function (range 0–48 with 48 denoting best function). This was administered and calculated by a surgical care practitioner independent of the operating surgeon [10]. Radiographic assessment included AP and lateral views. Radiographs at the last clinical appointment were objectively examined according to the Knee Society Roentgenographic Evaluation and Scoring System (KSRESS) as previously described [11]. These were completed with the picture archiving and communication system (PACS) (InSight 8.0, Insignia's Viewer for DICOM images, Insignia Medical Systems Limited, Hampshire, United Kingdom). The KSRESS takes into account prosthesis positioning, alignment and prosthesis–bone fixation, all of which are considered the most important determinants of a successful arthroplasty.

Statistical analysis

The Minitab software package (version 17.0, Minitab Ltd., Coventry, UK) was used for all statistical analyses. For survival analysis Kaplan–Meier curves with 95% CIs were performed with an end point defined as revision (removal or exchange of any prosthetic components) for any cause including infection. Data were tested for normality using the Anderson–Darling test. As this showed that the data were not normally distributed a Wilcoxon signed-rank test was used to test differences in continuous dependent data. Correlation coefficient was analysed utilising Pearson (r) statistic. For all statistical analyses, P values of < 0.05 were considered significant.

Results

Five patients suffered early complications secondary to the surgery. One patient sustained a hemarthrosis following a fall which required a washout, one patient sustained an intra-operative patella fracture that required fixation, one patient had a superficial wound infection successfully treated with oral antibiotics, and two patients had persistent discomfort

in the knee post-operatively with no cause found. None of the patients required revision surgery. Cumulative survival for the prosthesis was 100% at 10 years. If all patients lost to follow-up (excluding deaths) were treated as failures requiring revision, the worst-case survival would be 90.3% (95% CI: 80.7%, 99.7%) at 10 years (Fig. 1).

Functional assessment showed a mean OKS score at 5-year follow-up (44 knees; 83%) of 39.2 (range 21–48) and 37.8 (range 19–48) at the final 10-year follow-up. Establishing a measurement of success of any prosthesis is imprecise. If the results are judged using an OKS of ≥ 25 points [12] then this was achieved in 97% at 5 years and 90.3% at 10 years. Similarly, if patient acceptable symptom states (PASS) using an OKS of > 37 is used then our mean scores showed good patient satisfaction with the procedure [13]. There was a significant improvement ($p = < 0.001$) in flexion between pre-operative (104°; range 100–130) and post-operative measurements at 2 years (116°; range 80–135), 5 years (115°; range 85–130) and 10 years (115°; range 90–130). The mean range of motion (ROM) significantly improved from 95° (range 75–120) pre-operatively to 117.5° (range 85–130) at 5 years ($p = < 0.001$) and 115° (range 90–135) at 10 years ($p = < 0.001$) (Fig. 2). This equates to a value-added range of motion (VAROM) of 19° (range 10–55) at 5 years and 15.6° (range 8–40) at 10 years. When evaluating the VAROM over the life time of the prosthesis this significantly improved from 6 weeks (mean 3°) to 6 months (mean 14°) ($p = < 0.001$). This improvement in VAROM continued to be sustained over time adding a further 5° until the 5-year review, albeit, decreasing by 4° between 5 and 10 years as described (Fig. 3). There was no correlation between VAROM and patient age at review. There was a moderate correlation between OKS and VAROM at 5 years (Pearson $r = 0.402$ $p = 0.028$) and 10 years (Pearson $r = 0.380$ $p = 0.035$).

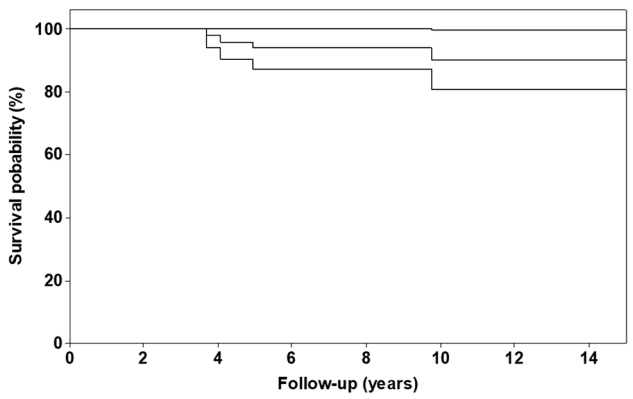

Fig. 1 Survival analysis Kaplan–Meier curve for all patients with 95% confidence intervals in a worst-case scenario where all patients lost to follow-up were treated as failures requiring revision

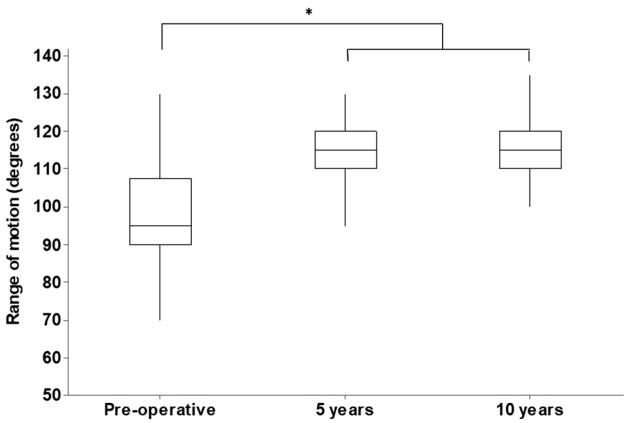

Fig. 2 Box-plots showing range of motion at different post-operative periods. The box centres around the median; the limits represent the 25th and 75th quartiles. The whiskers are based on the interquartile range (IQR). *$p < 0.001$

Radiological assessment of the 37 knees surviving to last follow-up was performed. KSRESS measures radiographic alignment of the prosthesis. On the AP radiograph a femoral component angle (angle α) and a tibial component angle (angle β) were measured; the two are then combined (α + β) to provide a total valgus angle for the prosthesis. Angle β was 88.04° (range 83.3°–91.7°), and α was 94.32° (range 92.3°–97.0°) with a combined valgus angle of 182.72° (range 177.3°–186.0°) indicating adequate alignment. Similarly, on the lateral view tibia slope angle (angle σ) was 89.34° (range 88.1°–91.9°). A total of 5 knees (13.5%) were noted to have evidence of radiolucent lines. These were all isolated tibia lucencies, with no knee showing evidence of femoral lucency. All radiolucent lines were stable (non-progressive), < 1 mm on measurement and partial. Of these

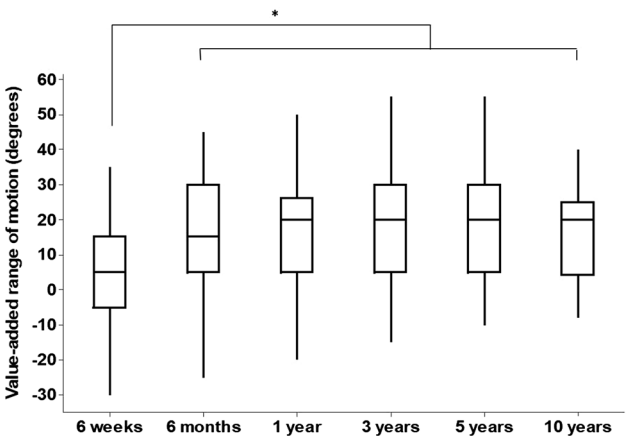

Fig. 3 Box-plots showing value-added range of motion (VAROM) at different post-operative periods. The box centres around the median; the limits represent the 25th and 75th quartiles. The whiskers are based on the interquartile range (IQR). *$p < 0.001$

patients 4 had medial (zone 1 or 2) and 1 lateral (zone 4) baseplate radiolucent lines. Radiological assessment did not reveal any evidence of component migration or osteolytic lesions.

Discussion

In this single-surgeon long-term follow-up series, the Scorpio NRG PS total knee replacement showed good survivorship with none of the prosthesis needing revision surgery at 10 years. Similarly, OKS showed good patient-reported outcome with the surgery. In addition, we found a significant improvement in ROM and VAROM over time. In particular, the patients achieved a significantly improved range of knee flexion.

Knee flexion following knee replacement is an important component of patient satisfaction and has been shown to generally fall between 100° and 120°. Even though activities of daily living can be achieved with flexion of approximately 110°, the maximum flexion after knee replacement is still significantly less than the native knee. As a result, knee arthroplasty designs such as the Scorpio NRG emerged allowing "high flexion" defined as ≥ 125° [14]. Colwell et al. [15] reported on an observational study of 94 knees treated with Scorpio NRG cruciate-retaining (CR) implant. At 1-year post-operative follow-up, flexion improved by 6.9° to 116.9° and total ROM improved by 10.6° compared to pre-operative values. Similarly, in our study we found an improved flexion by 12° at 2 years and 11° at 5 and 10 years. Also, on the VAROM we reported an increase of 17° at 2 years improving to 19° at 5 years utilising this prosthesis. These improved results might be secondary to the use of a PS polyethylene bearing [16–18]. However, even though we achieved a significantly improved flexion arc this was lower than the 125° accepted level of deep flexion [14]. This is like Colwell et al. [15] where only 23% patients achieved their target deep flexion aim. Several factors may be involved in limiting high flexion beyond implant design modification including pre-operative ROM, rehabilitation protocols and intra-operative techniques including soft tissue balancing [19, 20]. In fact, this high-flexion design is aimed to "allow" the patient to achieve deep flexion without impingement and polyethylene bearing wear rather than giving you deep or "high flexion" per se.

This is the first study to observe an increase in VAROM with time for up to 5 years post-operatively. This may be important as it allows us to advise patients that over time their ROM with this design may improve further. Other authors have previously identified a good ROM is associated with positive patient satisfaction [21]. Similarly, we found a positive correlation between VAROM and OKS. We also report a drop in VAROM at 10 years after surgery. There are several possibilities why this may have happened. To achieve deep flexion, it has been reported that a bicondylar rollback motion and external rotation of the femoral component relative to the tibia component are desirable [22]. In vivo kinematics of the Scorpio NRG PS showed posterior rollback and external rotation with medial pivot [23]. Over time, early polyethylene wear could alter the delicate kinematic function of this implant, restricting external rotation and therefore its ROM. However, further kinematic studies in the long term are required to confirm the latter, since none are available at this stage. Similarly, with age in healthy patients, muscle mass would start to decrease which could decrease muscle activity and power [24]. However, we were not able to confirm the latter in total knee replacement patients since we did not notice a correlation between age and VAROM at 5 or 10 years post-operatively. Further studies would be required to confirm this association.

There has been concern with "high-flexion" TKR designs due to early loosening. Retrieval analysis showed conflicting results with regard to wear. Paterson et al. [25] found post and backside damage in patients achieving high flexion with high-flexion design inserts. However, Daines et al. [26] showed that in both high-flexion and traditional PS designs which achieved "high flexion" there was no increased wear indicating that "high flexion" did not influence polyethylene wear [27]. Han et al. [28] reported a 38% incidence of early aseptic loosening of the femoral component at 2-year follow-up after TKA using the NexGen Legacy PS Flex prosthesis. However, our results show excellent long-term survivorship of 100% for all causes including aseptic loosening with the Scorpio NRG PS. Our results compare favourably with the 10-year survivorship of 96.47% published in the latest National Joint Registry Report (2017). The report also showed higher failure rates for PS implants (all makes) with a cumulative failure rate of 4.7% compared with 3.8% for unconstrained fixed bearing total knee replacement [5]. In our cohort we did not find an increased failure risk. These results are comparable with published series of more widely implanted original Scorpio prosthesis [7] and its modifications such as the Scorpio Flex [29]. Mahoney and Kinsey have published the largest mid-term series of 1030 consecutive cemented Scorpio PS by a single surgeon [6]. At a mean follow-up of 7 years (range 5–9.5 years), 32 knees required revision. The mean time to revision was 2.4 years (range 0.1–8.2 years). The leading cause of failure was deep infection (10 of 32 knees). The Kaplan–Meier survivorship with revision as an end point was 95.8%. With aseptic loosening as the end point, the survivorship was 98.6%. These studies indicate good results and survival for the single-radius Scorpio design. However, to our knowledge there are no long-term studies reporting on the Scorpio NRG PS design.

There are several limitations to the current study. Only 67.4% of patients achieved clinical review at final follow-up.

This is due to 21.7% of patients who died and 10.9% being lost to follow-up or being unable to attend due to illness. This is not unexpected and is similar to other long-term studies published in the literature [7]. We reviewed the medical records and operating theatre schedules and could find no evidence that patients who were lost to follow-up underwent revision surgery. Another limitation is the small cohort size achieved. However, the strengths of this study are the fact that it is a single-surgeon series over a 2-year period which allows for a homogenous surgical and rehabilitation technique between the patients compared to a large joint registry cohort. In addition, we reduced selection bias by enrolling a consecutive series of patients.

In conclusion, this study reports the survivorship and outcome results of the Scorpio NRG PS design at both mid- and long-term follow-ups. In this series the Scorpio NRG PS total knee replacement showed good long-term survivorship and functional outcomes. We found a significant improvement in ROM and VAROM over time. This was not associated with increased signs of loosening.

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Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest. No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

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