



Patient-reported outcomes after primary rotating hinge total knee arthroplasty: a multi-centre clinical cohort study

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Abstract

Purpose Rotating hinge prostheses for total knee arthroplasty (TKA) are mostly used in revision setting; however, evidence on the use of these constrained devices in primary setting is scarce and inconsistent. Therefore, we aimed to evaluate the functional outcomes after third-generation rotating hinge implants in primary TKA with a minimal follow-up of two years in a large dual-centre observational retrospective clinical trial.

Methods The hospital databases of two centres were searched for primary rotating hinge arthroplasty from January 2007 to January 2015. A minimum follow-up of at least two years was assured. Patients meeting the inclusion criteria were asked to fill out two self-reported functional scores, the Oxford Knee Score (OKS) and Forgotten Joint Score (FJS), to measure the functional status of the knee.

Results In total, 267 primary rotating hinge knee arthroplasties in 242 patients were performed in two centres. The three major indications were axial malalignment (valgus/varus > 15°), 87/267 (33%), persistent ligamentous instability (28%) and neuromuscular disorders (12%). 184 patients with 202 primary rotating hinge knee arthroplasties could be included that provided data of the self-reported outcome measures (OKS and FJS). A mean OKS score of 37.71 (± 9.23) and a mean FJS score of 63.65 (± 31.01) could be obtained.

Conclusion This large clinical study suggests that constrained devices provide the best results when treating bone-on-bone tricompartmental osteoarthritis of the knee with severe axial deviation (valgus/varus > 15°) and/or persistent ligamentous instability.

Keywords Total knee arthroplasty · Rotating hinge knee · Rotating hinge device · Primary knee replacement

Introduction

Rotating hinge prostheses for total knee arthroplasty (TKA) have been modified considerably since the first design by Judet and by Walldius and Shiers in the 1950s [1]. The first generation of these constrained devices had fixed hinge designs and only allowed motion in the sagittal plane, causing an excessive torsional pressure to be transferred to the bone-cement interface, ultimately causing fractures or loosening of the implant. Present-day modular, mobile-bearing hinged prostheses have overcome most of these problems as up to 25° internal–external rotation, and an improved patella-femoral tracking has been built into the implant design [2, 3]. Using these third-generation devices, several authors have reported good clinical results at short- and mid-term follow-up [4–7]. Nevertheless, due to their notorious history of unacceptable high failure rates and numerous complications, rotating hinge designs have mostly been reserved for salvage surgery and

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revision cases, especially involving persistent instability [8, 9]. Data reported in literature about rotating hinge prostheses in revision are abundant. However, pieces of evidence on the use of these constrained devices in primary TKA are scarce and inconsistent. Despite the lack of evidence, hinged knee prostheses are increasingly used in primary settings, especially in older patients with advanced axial deformity, severe bone defect and complex knee instability [1]. The small number of published reports suggests that these types of implants produce functional improvement and rates of survival comparable to conventional unconstrained TKA, when appropriate indications are applied [10–15]. Still, no high-level evidence studies exist. To reduce dissension, a large dual-centre observational retrospective clinical trial was performed to evaluate the functional outcomes after third-generation rotating hinge implants in primary TKA with a minimal follow-up of two years.

Materials and methods

Patient characteristics

This observational retrospective multi-centre clinical trial was approved by the ethical committee (S59541). The hospital databases were searched for primary rotating hinged knee arthroplasty procedures. Inclusion criteria involved patients older than 18 years with a primary rotating hinge knee implant from January 2007 to January 2015. To be included, patients had to be able to read and answer questions in a self-reported questionnaire. Patients who passed away were excluded. A minimum follow-up of at least two years was assured. An informed consent was given by every patient included in this study. All patients were preoperatively diagnosed with invalidating grade four tricompartmental osteoarthritis of the knee with advanced axial deformity, bone defect and/or knee instability according to their medical file. All patient records were specifically screened for indications, pre-operative status and post-operative complications.

Implants

Rotating hinged knee implants (NexGen Rotating Hinged Knee (RHK) (Zimmer-Biomet Inc., Warsaw, IN, USA)) were used in all patients. The polyethylene accompanied by this type of prosthesis was the same in each procedure: ultra-high molecular weight polyethylene (UHMWPE).

Evaluation of knee function by the Oxford Knee Score and Forgotten Joint Score

All patients included in the study were first contacted with a written letter in their mailbox accompanied by two questionnaires (the Oxford Knee Score and the Forgotten Joint Score) to assess the function of the replaced knee joint. The

patients who did not respond and did not send back the two surveys were contacted by telephone. The follow-up period was at least 24 months (mean of 28 months) after primary TKA. All patients were asked to answer honestly to the questions of the Oxford Knee Score (OKS) and Forgotten Joint Score (FJS). The former questionnaire has been validated to specifically assess patient's perspective of outcome following TKA, while the latter evaluates joint-specific patient's awareness after treatment. Both scores were enumerated on a total score of respectively 60 and 100.

Routine follow-up measures

Patients had clinical and radiological examinations routinely throughout the follow-up. Follow-up included medical history and clinical and radiological examination (X-rays). In cases of suspect aseptic loosening or periprosthetic infection, the following measures were applied. Blood samples were taken (including white blood cells, CRP and procalcitonin). Joint aspirations were done for white blood cell count. In addition, a SPECT/CT was performed in suspect cases. Intraoperative cultures were obtained during revision surgery. An alpha-defensin test was not used on a regular basis. Cases were considered as aseptic loosening in a positive SPECT/CT after ruling out periprosthetic infection.

Results

In total, 267 primary rotating hinge knee (RHK) arthroplasties in 242 patients were performed. Patients' characteristics can be seen in Table 1. Of these procedures, the majority was performed in the Delta Hospital (62%). No significant differences in gender distribution ($p > 0.05$), age ($p > 0.05$) nor BMI ($p > 0.05$) between the patients in the two centres were found. All patients were preoperatively diagnosed with tricompartmental osteoarthritis of the knee and advanced axial deformity, ligamentous instability, bone defect, muscular insufficiency and/or complex knee instability according to their medical record.

Of all evaluated procedures, the three major indications were axial malalignment (valgus/varus $> 15^\circ$) 87/267 (33%), persistent ligamentous instability 74/267 (28%) and neuromuscular disorders 33/267 (12%) (Table 2). Forty-five percent of the procedure was linked to obesity (BMI ≥ 30).

All patients had a minimum of at least 24 months since the time of surgery (mean of 28 months). In 14 cases, both the OKS and FJS were invalid because of incorrect completion of the two scoring lists. Furthermore, 18 cases were lost to follow-up (non-responders) and 30 patients, accountable for 33 TKAs, died of unrelated causes in the follow-up period of two years. Therefore, 202 primary rotating hinge knee arthroplasties in 184 patients could finally be

Table 1 Patient characteristics

| | UZ Leuven | Delta Hospital | Total |
|-----------------------------------|---------------|----------------|---------------|
| Patients | 94 | 148 | 242 |
| Surgical procedures (primary RHK) | 101 | 166 | 267 |
| Gender distribution (M/F) | 34.0%/66.0% | 37.2%/62.8% | 36.0%/64.0% |
| Mean age (years) | 71.97 ± 15.77 | 79.52 ± 7.66 | 76.77 ± 12.10 |
| Mean BMI (kg/m ²) | 27.17 ± 5.29 | 30.70 ± 4.84 | 29.33 ± 5.30 |

Table 2 Indications

| | UZ Leuven | Delta Hospital | Total |
|------------------------------|-----------|----------------|-------|
| Malalignment | 62 | 25 | 87 |
| Valgus > 15° | 42 | 19 | 61 |
| Varus > 15° | 20 | 6 | 26 |
| Ligamentous instability | 32 | 42 | 74 |
| Neuromuscular | 14 | 19 | 33 |
| Central paresis | 8 | 5 | 13 |
| Parkinson | 2 | 9 | 11 |
| Polio | 2 | 1 | 3 |
| Multiple sclerosis | 1 | 1 | 2 |
| Limb girdle dystrophy | 1 | 0 | 1 |
| Sensorimotor polyneuropathy | 0 | 1 | 1 |
| ARSACS* | 0 | 1 | 1 |
| Hypokinetic rigid syndrome | 0 | 1 | 1 |
| Posttraumatic osteoarthritis | 12 | 5 | 17 |
| Rheumatoid osteoarthritis | 3 | 2 | 5 |
| Septic osteoarthritis | 3 | 0 | 3 |
| Psoriatic osteoarthritis | 2 | 0 | 2 |
| Tuberculous osteoarthritis | 2 | 0 | 2 |
| Haemophilic arthropathy | 2 | 0 | 2 |
| Hyperextension | 2 | 0 | 2 |
| Charcot arthropathy | 1 | 0 | 1 |
| Oncological osteosarcoma | 0 | 1 | 1 |
| Bone loss | 0 | 1 | 1 |

*ARSACS autosomal recessive spastic ataxia of Charlevoix-Saguenay

appraised. After evaluating all patients, an OKS mean score of 37.71 (± 9.23) and a FJS mean score of 63.65 (± 31.01) could be obtained.

Furthermore, we investigated whether subgroups of patients scored significantly better functional results. The best postoperatively patient-reported scores were found in those with pre-operatively diagnosed axial malalignment (valgus/varus > 15°). In this subgroup, an OKS mean score of 41.85 (± 5.90) and a FJS mean score of 78.71 (± 25.26) were noted. Moreover, patients diagnosed with severe ligamentous instability also showed better post-operative results when compared with the whole study population, as a OKS mean score of 39.63 (± 8.76) and a FJS mean score of 70.06 (± 29.98) could be assessed in this subgroup. However, this result was not significant. Finally, we found an OKS mean

Table 3 Complications

| | UZ Leuven | Delta Hospital | Total |
|--|-----------|----------------|-------|
| No complications | 81 | 131 | 212 |
| Arthrofibrosis | 7 | 11 | 18 |
| Infection | 6 | 10 | 15 |
| Bleeding (<5 days) | 3 | 6 | 9 |
| Aspecific aseptic hydrops | 1 | 4 | 5 |
| Persistent patellar instability | 3 | 1 | 4 |
| Periprosthetic joint infection | 2 | 1 | 3 |
| Persistent knee pain | 0 | 2 | 2 |
| Traumatic rupture of the quadriceps tendon | 1 | 0 | 1 |
| Decubitus | 1 | 0 | 1 |

score of 35.47 (± 10.58) and a FJS mean score of 58.01 (± 28.59) in the patients with obesity. Nevertheless, we mention relatively better functional scores in patients with a BMI equal to or higher than 40, where an OKS mean score of 39.13 (± 9.16) and a FJS mean score of 76.38 (± 20.96) could be obtained.

Although the patient's perspective after treatment is the most important factor to appraise, we retrospectively searched for complications. The majority (79.4%) of the patients reported a flawless post-operative track. Of the complications reported, the major ones were arthrofibrosis (6.71%), joint infection (5.99%) and post-operative bleeding in the first five days after surgery (3.37%). Other complications were persistent aspecific aseptic hydrops (1.87%), persistent patellar instability (1.50%), periprosthetic joint infection (1.12%) and persistent knee pain (0.75%) (Table 3).

No case was revised due to aseptic loosening or polyethylene wear (with a minimum follow-up of 2 years).

Discussion

Rotating hinge implants in primary total knee arthroplasty (TKA) are increasingly appreciated as a valuable therapeutic option in patients with advanced axial deformity, severe bone defect and complex knee instability [1]. The aim of this clinical trial was to evaluate the self-reported functional outcomes after third-generation rotating hinge implants

(NexGen RHK, Zimmer-Biomet, USA) in primary TKA with a minimal follow-up of two years. A total of 267 procedures were retrospectively analysed. The patients were contacted and questioned with the OKS (Oxford Knee Score) and the FJS (Forgotten Joint Score). The results of the present clinical trial indicated a good functionality of primary rotating hinge TKA if correct indications were applied. We found an OKS mean score of 42 in patients operated because of axial malalignment and an OKS of 40 after severe ligamentous instability.

These results are comparable to the scores found by Giurea et al. [15]. In their prospective cohort concerning 90 primary RHK arthroplasties (EnduRo, Aesculap, Switzerland), an OKS of 35.8 (\pm 8.7) was reported 24 months after surgery [15]. Furthermore, the functional scores of our study population were higher than the OKS mean score of 31.8 (\pm 3.0) found by Baker et al. [16] in their systematic review of 46 patients.

Besides evaluating the functional score of the constrained prosthesis in the whole of our study population, we also investigated the post-operative results in subgroups of patients. We noted that patients with the highest degree of functional limitations prior to surgery more often improved in a more substantial manner than others with less impediments. This improvement was found to be independent of gender and age. Furthermore, we found that patients with severe axial malalignment (valgus/varus $> 15^\circ$) and persistent ligamentous instability reported the best post-operative results. Similar results were observed among patients with morbid obesity (BMI ≥ 40), while patients with lower BMIs reported non-significant lower post-operative functional improvements. These results are conforming to the findings of Lozano et al. [17] reporting that patients with a BMI > 35 showed better outcomes.

Notwithstanding the importance of the patient's perspective after treatment, we were also interested in the complications that occurred during the post-operative period, as the most important complications and mechanisms of mechanical failure occur most frequently within the first two years after implantation. The majority (79.4%) of the patients reported an immaculate post-operative track. When comparing our complication rate (20.6%) with earlier patient cohorts, we found a considerably lower complication rate in our patient population. Vaquero-Hernández et al. [18] reported complication rates of 30.0% in their patient cohort of 26 primary rotating hinge knee arthroplasties. Springer et al. [19] even presented a higher rate of 49.0% when assessing their cohort of 69 TKAs.

The major complications reported in our study were arthrofibrosis (6.71%), joint infection (5.99%) and bleeding in the first five days after surgery (3.37%). However, these complications are well-known issues that occur generally in primary TKA, regardless of the used prosthesis device.

Nevertheless, it should be mentioned that more complications might surface when following our patient cohort for a longer time.

The relatively short follow-up period in the present series may constitute one of the major limitations of this study, since it prevents long-term outcomes from being assessed and implant survival curves from being plotted. As we will follow our patient cohort for a prolonged period in the future, we will be able to overcome these limitations. On the other hand, the present study investigates one of the largest series of primary RHK arthroplasty described in medical literature.

Conclusion

The high failure and complication rates of earlier fully fixed hinges still play an essential role in the avoidance of using rotating hinge implants. Despite several recent improvements in prosthetic design, both indications and results of these constrained devices are still being discussed. In this multi-centre clinical trial, we assessed the patient-reported functionality following primary rotating hinge knee arthroplasty via the OKS and the FJS with a minimum follow-up of two years. The results delineated in this study suggest that constrained devices provide the best results when treating bone-on-bone tricompartmental osteoarthritis of the knee with severe axial deviation (valgus/varus $> 15^\circ$) and/or persistent ligamentous instability. The relatively short follow-up period of this study may constitute one of the major limitations, since it prevents long-term outcomes from being assessed. Nevertheless, this study presents a good overview of short-term results and complication rates in a large series of primary rotating hinge TKA.

Author contribution All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by Jan Dauwe, Bruno Vandekerckhove and Dirk Dauwe. The first draft of the manuscript was written by Jan Dauwe and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

Data availability The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

Declarations

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. The study was approved by the Ethics Committee of the University of Leuven (No. S59541).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Consent for publication Patients gave informed consent regarding publishing their data and photographs.

Competing interests The authors declare no competing interests.

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