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ORIGINAL STUDY

Medium-term outcome with contemporary mobile-bearing implants : results from a retrospective multicentre study

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Previous studies report good clinical outcomes with the initial mobile-bearing implant design in TKA. Nevertheless clinical data on the subject system are scant and information is lacking to fully appraise the safety and performance of the subject device.

A population of 283 consecutive patients who received 307 primary Vanguard ROCC TKAs over a 5.5-year period was retrospectively assessed. At follow-up, Knee Society Scores, Forgotten Joint Scores and Knee injury and Osteoarthritis Outcome Scores were obtained, and patients underwent radiographic evaluation at 4.9 ± 1.0 years post-implantation. Survival analyses included the following endpoints : revision of the tibial or femoral component for any reason, and revision of any component for any reason. At a mean follow-up time of 5.0 (range, 3.0-8.2) years, 166 patients (183 TKAs) were available for clinical assessment. All postoperative clinical scores were deemed satisfactory. Survival with revision of the tibial and/or femoral component for any reason was 97.3% (95%, 94.5-98.7%) at 6 years. Radiolucent lines were observed in 32 (17.7%) out of 181 knees.

The present study showed that the Vanguard ROCC system demonstrates favourable clinical outcome with satisfactory medium-term survival.

Keywords : Osteoarthritis knee ; total knee arthroplasty ; mobile bearing knee ; clinical outcome.

INTRODUCTION

Total knee arthroplasty (TKA) is considered the "gold standard" for the treatment of osteoarthritis of the knee when conservative therapy has failed. TKA has demonstrated excellent longevity ; as a benchmark, Labek et al reported a revision rate of 1.26 per 100 OCY *(1)*. However, the occurrence of patient dissatisfaction is substantial, and the incidence of residual complaints has been reported to be as high as 55% *(2,3)*. As the incidence of primary TKA has steadily increased during the last decades, and is expected to increase further, the number of revision surgery procedures is also rising *(4,5)*. For this reason, development of implants that show both less residual complaints and better implant survival is required *(6)*.

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Unfortunately, this development process has resulted in several new devices that have caused serious adverse events. This seems to be partly a result of a flawed approval process, where approval of new devices is based on equivalence to other systems already available on the market, as well as the paucity of clinical data being collected *(6-8)*. A systematic review performed by Nieuwenhuijse et al concluded that for five orthopedic innovations introduced on the market over the last decade, no clinical evidence was available *(6)*. Post-market surveillance is the only tool for early identification of products with inferior outcome, and it is therefore of paramount importance in maintaining patient safety.

The Vanguard ROCC (Rotating Concave-Convex) (Zimmer Biomet, Valence, France) knee is based on the ROCC (Biomet, Valence, France). It is a mobile-bearing TKA sacrificing the posterior cruciate ligament. The Vanguard ROCC includes cemented and cementless implant options.The prostheses are manufactured from cobalt chromium alloy. Cementless implants are hydroxyapatite coated. Other features include its deep anatomical trochlea, which is compatible with resurfaced or non-resurfaced patellae, and a saddle-shaped bearing surface that guides the femur for full range of motion (ROM).

To replicate the kinematics of a natural knee during full ROM, the Vanguard ROCC knee design facilitates femoral roll-back and allows tibio-femoral rotation during flexion. Additionally, patellar tracking in all degrees of ROM is facilitated by a deeper, longer trochlear groove in the femoral component of the Vanguard ROCC prosthesis.

Good clinical outcomes with the initial design have been reported *(9)*, but clinical data on the subject system are scant, with only two studies reporting short-term outcome *(10,11)*. However, both papers focused on the clinical outcome in patients who had not undergone revision ; hence the publications lacked information to fully appraise the safety and performance of the subject device.

We therefore investigated the medium-term outcome of the Vanguard ROCC. The aim of this study is to demonstrate that the Vanguard ROCC has comparable results to other contemporary TKA systems with evaluation of implant survival and medium-term clinical and radiological performance in osteoarthritis patients.

Table I. — Follow-up status of implants and patients

Follow-up status	**Implants**	**Patients**
a. Total number at study start	307	283
Number excluded from the study		
b. Died during study	19	17
c. Revision tibia and/or femur	8	8
d. Lack of cooperation, without revision, no data	10	10
e. Lost to follow-up, address unknown	37	35
f. Poor general condition (no revision no data)	5	5
g. Far remote distance (no revision, no data)	3	3
h. Unavailable, PROMS	34	32
i. Unavailable, PROMS + radiography	8	7
Number reviewed clinically (=a-[b+c+d+e+f+g+h+i])	184	167
Number reviewed radiographically (=a-[b+c+d+e+f+g+h])	192	174
Number reviewed PROMS (=a-[b+c+d+e+f+g])	226	206

Abbreviations: PROMS, patient reported outcome measure.

MATERIALS AND METHODS

Between November 2010 and June 2016, 307 Vanguard ROCC TKAs were implanted in 283 consecutive patients at the institutions of the two senior authors (JDS and AB) (Table I). The study population comprised 93 males (32.0%) and 193 females (68.0%). Mean (± standard deviation) age of the population at the time of the surgery was 68.6 ± 9.3 (range, 43.0-91.5) years, and mean BMI was 30.7 ± 5.8 (range, 19.7-59.7) kg/m^2. The initial diagnosis was primary osteoarthritis in 259 knees (98.5%), rheumatoid arthritis in 3 knees (1.1%), and avascular necrosis and posttraumatic arthritis in 1 patient (0.4%).

All procedures were performed by the two senior authors (JDS and AB), without using a tourniquet, through a medial parapatellar approach in 297 knees (96.7%) and a subvastus approach in 10

knees (3.3%). An intra-medullary guide was used systematically on the femoral and tibial side. The choice of a cementless versus a cemented femoral component was based on intraoperative assessment of bone quality. A cementless femoral component was used in 291 knees (94.8%) and a cementless tibial component was used in 135 knees (44.0%). Patellae were generally not resurfaced (n = 302, 98.4%). A cemented all-polyethylene patellar component was used in 5 knees (1.6%).

During the first 24 postoperative hours, a broad spectrum antibioticum (Cefazoline) was given as a primary prevention measure for surgical site infection, and Intraoperative intravenous tranexamic acid (Exacyl, Sanofi, Paris, France) was administered after the induction of anaesthesia. Furthermore, on the day of surgery, pharmacological venous thromboembolism (VTE) prophylaxis was initiated via 10 mg oral rivaroxaban (Xarelto, Bayer, Leverkusen, Germany) daily for 28 days *(12)*. Mechanical compression devices were not used. As part of the rapid recovery protocol *(13)*, immediate mobilisation was applied on the day of surgery.

Clinical and radiographic evaluation were completed at final follow-up. Functional assessment was determined with the Knee Society Score (KSS) *(14)*, the Knee injury and Osteoarthritis Outcome Score (KOOS) *(15)* and the Forgotten Joint Score (FJS) *(16)*. Standardized standing anteroposterior and lateral radiographs were taken and analyzed for periprosthetic radiolucent lines (RLLs) and evidence of focal osteolysis. RLL measuring greater than 1 mm in all zones or a change in implant location constituted a loss of biological fixation *(17)*. Definitive biological fixation was noted upon radiological evidence of the absence of RLLs between the implant and bone at all radiographic zones of both prosthetic components *(18)*.

Prior to the study, ethics committee approval was obtained, and all patients provided informed consent.

For all measured outcomes reported in the study results, all values were calculated as mean ± SD. Kaplan Meier analysis and revision incidence with calculation of 95% confidence intervals (CI) were employed for survival analysis. Endpoints of interest included : revision of the tibial or femoral component for any reason, revision of any component (including secondary surgery to the patella and exchange of the polyethylene insert) for any reason, and revision of any component and pending revisions. Kaplan-Meier analysis was stopped at the time point where the population remaining at risk was <40 *(19)*. Where the failure date was unknown, the midpoint practice of estimating failure date was used, assuming that failure occurred halfway between the current date and the date of surgery. Revision rate was expressed in revisions per 100 observed component years (OCY).

RESULTS

Seventeen patients (19 TKAs) died from unrelated causes during the course of the study and 35 patients (37 TKAs) were lost to follow-up. Ten patients (10 TKAs) refused participation in the study, and 5 patients (5 TKAs) did not attend due to a poor general condition. Three patients (3 TKAs) relocated far away and refused participation in the study. In total, 39 patients (42 TKAs) were unable to participate or refused participation, but provided oral and/or written information on their health status. Seven patients (7 TKAs) were not assessed clinically and radiologically since their device had been explanted.

Therefore, 167 patients (184 TKAs), were available for clinical follow-up assessment. For an additional 39 patients (42 TKAs) a Patient Reported Ouctome Measure (PROM) could be obtained. The

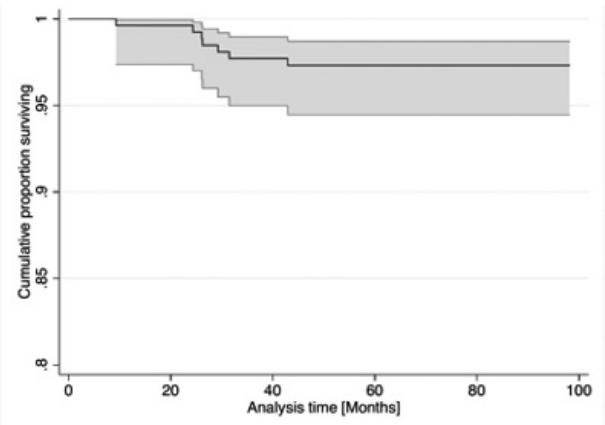

Figure 1. — Implant survival with revision of the femoral or tibial component for any cause as endpoint of interest is shown.

Table II. — Overview of revisions and pending revisions

Patient Nr	Timepoint (months)	Component	Reason
1	Unknown	Tibial baseplate (cemented), femur (cemented)	Implant malalignment
2	7	Polyethylene insert	Instability
3	9	Tibial baseplate (cemented), femur (cementless)	Stiffness
4	10	Patella resurfacing	Retropatellar pain
5	20	Patella resurfacing, (cementless)	Retropatellar pain
6	24	Tibial baseplate (cementless), femur (cementless)	Instability in the presence of femoral component malalignment
7	26	Tibial baseplate (cemented), femur (cementless)	Aseptic loosening
8	26	Tibial baseplate (cemented)	Aseptic loosening
9	29	Tibial baseplate (cemented), femur (cementless)	Aseptic loosening
10	43	Tibial baseplate (cemented), femur (cemented)	Aseptic loosening of tibial component.
11	43	Revision pending : patella replacement	Retropatellar pain
12	49	Revision pending : tibial baseplate (cemented), femur (cementless)	Stiffness, pain
13	52	Patella resurfacing	Retropatellar pain
14	53	Revision pending : tibial baseplate (cemented), femur (cementless)	Stiffness, pain
15	55	Patella resurfacing	Retropatellar pain
16	58	Revision pending : patella replacement	Retropatellar pain

Table III. — Clinical Outcome

Clinical outcome variable	Value
Knee Society Score	
- Knee Score	89 ± 14
- Function Score	82 ± 24
Forgotten Joint Score	54 ± 33
Knee injury and Osteoarthritis Outcome Score	
- Pain	81 ± 23
- Activity	75.9 ± 23.5
- Sports	38.3 ± 32.1
- Quality of Life	66.1 ± 29.3
- Symptoms	82.4 ± 16.7

All values presented as mean ± standard deviation.

mean follow-up time for these groups (clinical/PROMS) was 5.0 ± 1.0 (range, 3.0-8.2) years.

In total, 7 revisions of the tibial and/or femoral component were undertaken (Table II). The 6-year Kaplan-Meier survival rate was 97.3% (95%, 94.5-98.7%) (Figure 1), and the revision incidence was 0.54 (95% CI, 0.26-1.12) revisions per 100 OCY. In addition, 4 secondary patella replacements were performed, and 1 exchange of the polyethylene insert was undertaken due to instability. Implant survival for revision for any cause (component exchange and patella placement) was 95.0% (95% CI, 91.3-97.2%) at 6 years, and the revision incidence was 0.79 (95% CI, 0.45-1.38). There were 4 cases with a pending revision (Table II). Implant survival with revision for any cause and pending revisions as the endpoint of interest was 92.9% (95% CI, 88.4-95.6%) at 6 years, and the revision incidence was 1.26 (0.77-2.05) revisions per 100 OCY.

Other complications, not leading to a device revision were residual knee pain in 8 knees (including 5 with anterior knee pain), limited flexion in 7 patients (95.7° ± 10.2°), loosening of a patellar component which was grafted with autologous iliac crest bone in 1 patient, periprosthetic femoral fracture requiring open reduction and internal fixation in 1 patient, superficial wound infection in 4 patients, pulmonary embolism in one patient, and other complications in 4 patients. No patients with subluxation or dislocation of the patella were observed. Clinical scores are summarized in Table III. Radiographic assessment was performed in 191 knees. We did not observe any radiographic failures of the tibia or femur at follow-up. In 32 (16.8%) out of 191 knees, RLLs were observed. The distribution of RLL by zone is shown in Figure 2. There were no cases of continuous radiolucency, and all components were considered stable. Additionally, osteolysis of either the tibia or femur was not observed. Osseointegration of both components was observed radiologically in all evaluated knees.

DISCUSSION

The most important findings were that the Vanguard ROCC TKA system yielded good medium-term implant survival and satisfactory clinical outcome in this retrospective clinical study. At 6.5 years, we noted 97% implant survival with implant loosening as the endpoint of interest, or an incidence rate of 0.54 revisions per 100 OCY, which is substantially lower than the benchmark reported by Labek et al *(1)*. However, the endpoint in our analysis did not include any reoperations for secondary resurfacing or pending revisions. When those are included, it reduced the survival rate to 92.7% and increased the revision rate to 1.24 per 100 OCY, which is roughly comparable to the revision rate reported by Labek *(1)*.

Our study results are comparable to other authors reporting on the Vanguard system. In a study by Kievit et al, a 6-year survival of 96.5% with revision for any reason as endpoint of interest was reported, and secondary resurfacing of the patella was performed in 1.7% of the patients [20]. However, our results were lower than those reported for the ROCC by Bercovy et al, who cited a 14-year survival with revision for any cause as end-point of 97.5% [21]. The reason for this difference could not be elucidated.

We conducted a review of the revision surgeries to reveal the indications for the secondary procedures. In a meta-analysis by Pilling et al, 6% of knees in the non-resurfacing group and 1% in the resurfacing group had further procedures because of anterior knee pain *(22)*. Follow-up time was less than 5 years for most of the studies. In our study, it was assumed that revisions were performed as a result of the progression of patellofemoral arthritis rather than being completed for another reason such as trochlear groove design. With consideration of the aforementioned meta-analysis, the percentage of secondary resurfacing procedures in our study (3 out of 303 knees without patella resurfacing at the index surgery [1.0%] for revisions already performed, and 7 out of 303 [2.3%] including the pending revisions) seems acceptably low.

The FJS that was used in our study is a relatively new scoring instrument *(16)*. The score assesses joint awareness in hips and knees during various ADL following joint replacement. The score values found in the present study are similar to those reported by the developers of the scoring instrument (i.e., 56.5 ± 28.0 for males and 45.4 ± 28.0 for females), who employed a mobile-bearing TKA design (LCS Complete, DePuy Synthes, Warsaw, IN) *(16)*. More recently, Thienpont et al *(11)* and Thomsen et al *(10)* reported similar score values of 54.5 ± 30 and 57 ± 28, respectively, after implantation of the Vanguard ROCC knee. These findings add to the credibility of the present study.

As this was a retrospective, non-interventional study, each operating surgeon used his standard practice in terms of patient selection, surgical technique, implant fixation, and ligament balancing, all representative of the standard practice in Belgium. However, this could also be considered a limitation as it could introduce a lack of homogeneity. The study was also limited by the attrition due to loss to follow-up (12.1%), which is not uncommon for this type of multicentre retrospective study.

CONCLUSION

Our study results show the Vanguard ROCC system demonstrates a favourable outcome in patients with knee osteoarthritis with good medium-term survival of the system, which is consistent with the results of other contemporary TKA systems.

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