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Impact of implant design on the Forgotten Joint Score: a retrospective study comparing two contemporary knee designs

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This retrospective study was designed to assess two fixed bearing total knee design concepts and their clinical outcomes, particularly in Forgotten Joint Score-12 (FJS-12).
Patients were assessed clinically using the Knee Society Score (KSS). Participants completed an FJS-12 and a short form of the Knee Injury and Osteoarthritis Outcome Score (KOOS-PS). A total of 216 knees –76 with Genesis II and 150 with Vanguard total knee arthroplasties – were included.
Patients in the Vanguard group had significantly better postoperative FJS-12 scores (by 10.1 points, p = 0.019). Differences in KSS subscores also reached the level of statistical significance. KOOS-PS did not differ significantly.
Statistically significant differences between the two knee designs on FJS-12, KS and FS assessments were revealed, but overall, these differences may not reach the threshold of clinical significance.

Keywords: ????

INTRODUCTION

After modern total knee arthroplasty (TKA), residual symptoms and limitations are reported by about 30% of patients[1,2]. Continuous clinical studies are therefore required to assess the factors associated with this outcome. Functional outcomes after arthroplasty can be assessed using a variety of tools[3,4]. Reducing surgeon bias in the outcome evaluation requires combining surgeons' ratings with patient-reported outcome (PRO) tools[5-8]. However, many PRO tools are limited by the 'ceiling effect' in differentiating between good and excellent patient outcomes[9,10], and subtle differences in outcome between implantation techniques or designs may not be captured[11]. When capturing changes at follow-up after arthroplasty, responsiveness to floor/ceiling effects and change are essential[12-14]. A recently published PRO scale, the 'Forgotten Joint' Score-12 (FJS-12) assesses patients' awareness of knees and hips during various daily-living activities[4,9]. The ultimate goal in joint arthroplasty is the ability to forget the artificial joint in everyday life, since being unaware of the joint indicates the greatest possible patient satisfaction[9]. For a greater than 12-month follow-up after TKA, FJS-12 has been found to offer good responsiveness as well as high reliability and validity[4,15-17].

In the two participating clinics, investigators used two commonly used fixed bearing knee prosthesis models. Both models perform well in terms of longevity[18,19]. In the Genesis II prosthesis (Smith & Nephew, Memphis TN, USA), 3° of external rotation is incorporated into the femoral component, which is implanted in neutral rotation to the femur. The femur has a deep, lateralized trochlear groove to improve patellar contact. In contrast, the Vanguard knee system (Zimmer Biomet, Warsaw IN, USA) has a relatively wide and tilted femoral trochlear groove that is designed to allow optimal patella tracking[20]. Routine implantation of the Vanguard is in a 3° externally-rotated position to the posterior condylar axis (PCA).

The present study aimed to determine whether these two prosthesis philosophies lead to different clinical outcomes, in particular on the FJS-12. We hypothesized there would be no difference in functional outcome.

MATERIALS AND METHODS

We identified 320 patients (340 knees) in our hospital records for whom osteoarthritis (OA) was the primary

diagnosis. All patients were operated by two senior surgeons (GP and BS) between November 2010 and August 2014 with one of the two brands of implant used at our institutions in this period: the Genesis II (n = 116) and the Vanguard Complete Total Knee (n = 206) with posterior-stabilized inserts. Only posterior-stabilized primary TKAs were used. The study was approved by our institutional ethics committees.

Patients who consented to participate in the study were included; patients were excluded if they had significant comorbidities, such as tumour disease or neurological disease, or a primary diagnosis other than OA. Also, patients with bilateral replacement with Genesis II on one side and Vanguard on the other were ineligible. Demographic data, including sex, age and body mass index (BMI), were retrieved from their medical records.

In all patients, a medial parapatellar approach was applied. Cemented fixation of tibial and femoral components was applied in both study groups. Osteotomy of the femur was performed with an intermedullary guide; for the tibia, an extramedullary guide was used. Standard instrumentation was used. Cutting of the proximal tibia was perpendicular to the axis of the tibial shaft. A tourniquet was not applied.

Implantation of the Genesis II femoral component was in neutral rotation to the femur. The implantation of the Vanguard femoral component was in a 3° externally-rotated position to the PCA.

Postoperatively, patients were initially mobilized using a walker, and then, once sufficient stability was attained, a pair of crutches was used. Patients were routinely discharged on day 3 after surgery, with the vast majority discharged home.

All patients were invited to complete the FJS-12[9] and the Knee Injury and Osteoarthritis Outcome Score Physical Function Short Form (KOOS-PS)[21] at the time of the latest follow-up. The surgeon-completed Knee Society Score was used as the objective outcome[22]. The FJS-12 consists of 12 questions designed to assess patients' ability to forget their artificial joint in their daily lives. Scores range from 0 to 100, with 100 representing the most favourable outcome. The original publication[9] was used as the basis for calculating the score. The KOOS-PS is a self-administered questionnaire developed for objective measurement of physical function[23]. Scores range from 0 to 100, with lower scores reflecting better outcomes (i.e., a score of 0 indicates no difficulty in performing particular tasks). The KSS is an objective scoring system to rate the patient's functional abilities, such as stair climbing and walking (function score) and the knee (knee score), before and after TKA (22). Both function scores and knee scores range from 0 to 100, with 100 being the optimal score.

Statistical analysis

Categorical variables are presented as frequencies and percentages. Continuous data are presented as mean and standard deviation. The chi-squared test or Fisher's exact test for categorical variables and the student t-test for continuous variables were used to perform univariate analysis. In comparing postoperative clinical outcomes, multiple linear regression models were used, with gender, age and patella replacement added as control variables. A two-sided p-value of less than 0.05 was considered significant. Stata/SE 15.1 (StataCorp, College Station, TX, USA) was used to analyse the data.

RESULTS

Baseline data showed no statistically significant differences between the groups in terms of patient demographics (Table 1). Patella resurfacing was performed in 84 knees (72.4%) of the Genesis II group and in 119 knees (57.7%) of the Vanguard group (p = 0.009) (Table I).

Twelve patients (12 TKAs) died from unrelated causes during the course of the study, and 39 patients

Table I. — Baseline variables

	Genesis II (n = 116)	**Vanguard** (n = 206)	***p*-value**
Women (%)	74 (63.8)	138 (67.0)	0.561
Age at TKA [years]*	66.1 ± 11.4	66.5 ± 9.9	0.752
Weight [kg]*	79.9 ± 11.3	82.2 ± 16.3	0.495
BMI [kg/m^2]*	28.7 ± 4.3	29.5 ± 5.5	0.474
Patella replacement	84 (72.4)	119 (57.8)	0.009
Presented as number of observations (percentage) or as * mean ± standard deviation.			

Table II. — Follow-up status of implants

Follow-up status	**Genesis II**	**Vanguard**	***p*-value**
a. Total number at study start	116	206	
Number excluded from the study			
b. Died during study	8	4	0.032
c. Revision tibia and/or femur	0	2	0.538
d. Uncooperative, no revision, no data	4	8	1.000
e. Lost to follow-up, address unknown	17	22	0.294
f. Poor general health (no revision no data)	8	16	0.775
g. Excessive distance (no revision, no data)	3	4	0.711
i. Number clinically reviewed (= a – [b+c+d+e+f+g])	76	150	0.169
Presented as number of observations.			

Table III. — Complications

Complications	**Genesis II** (*n* = 76)	**Vanguard** (*n* = 150)	***p*-value**
Hematoma	0 (0.0)	1 (0.7)	1.000
Deep venous thrombosis	0 (0.0)	1 (0.7)	1.000
Limited range of motion, requiring manipulation under anaesthesia	0 (0.0)	1 (0.7)	1.000
Secondary patella resurfacing due to pain	0 (0.0)	3 (2.0)	0.260
Retropatellar pain of unresurfaced patella	2 (2.6)	1 (0.7)	0.295
Revision due to failed tibial insert	0 (0.0)	1 (0.7)	1.000
Presented as number of observations (percentage).			

Table IV. — Multiple linear regression analysis for postoperative clinical outcomes

	Genesis II (*n* = 76)	**Vanguard** (*n* = 150)	**Difference**	***p*-value**
FJS	57.2 (3.5)	67.3 (2.5)	10.1 (4.3)	0.019
KOOS-PS	28.0 (1.8)	24.6 (2.1)	–3.5 (2.2)	0.112
KS	86.8 (1.7)	91.0 (1.2)	4.3 (2.1)	0.042
FS	73.6 (2.1)	82.0 (1.5)	8.4 (2.6)	0.001
ROM	121.1 (1.5)	123.0 (1.1)	2.0 (1.8)	0.278
Presented as mean (standard error). Abbreviations: FJS, forgotten joint score; KOOS-PS, knee injury and osteoarthritis outcome score physical function short form; KS, knee score; FS, function score; ROM, range of motion.				

(39 TKAs) were lost to follow-up (Table II). Twelve patients (12 TKAs) declined to participate in the study, and 22 patients (24 TKAs) did not attend due to poor general health. Seven patients (7 TKAs) had relocated far away and declined to participate in the study. Two patients (2 TKAs) were not clinically assessed because their device had been explanted. Therefore, 217 patients (226 TKAs) were available for clinical follow-up assessment.

Mean follow-up time was 54.0 ± 11.0 months for Genesis II and 48.9 ± 10.1 months for Vanguard ($p < 0.001$). No differences in postoperative complication rates were noted (Table III).

In the linear regression model, after controlling for sex, age, BMI, and patella replacement, patients in the Vanguard group had significantly better postoperative FJS-12 scores (Table IV). Furthermore, the differences in KS and FS reached the level of statistical significance.

No statistically significant differences were found for KOOS-PS and ROM.

DISCUSSION

In this retrospective cohort study of two contemporary posterior-stabilized primary TKA designs, both prosthetic designs provided good clinical outcomes. Statistically significant differences were found on the FJS-12, KS and FS. However, differences in KOOS-PS and ROM were not statistically significant. The minimal clinically important difference (MCID) for the FJS-12 has been reported to be 14 points[24]. For KOOS-PS, an MCID of 7.8 was found[25]. The MCID identified for KS is between 6.1 and 6.4, and for the FS, between 5.3 and 5.9[26].

Although the between-group differences may have fallen below the MCID for the majority of outcomes (including the primary outcome), they may still be perceived by hospitals and surgeons as having a competitive advantage[27]. Functional outcome is considered one of the most important factors when surgeons choose an implant[28]. Even marginal advantages may influence choices in a competitive implant market[27].

A previous study comparing Genesis II and Vanguard has not demonstrated clinically important differences attributable to the two designs. Kahlenberg et al. found no significant differences in terms of both postoperative satisfaction and difference in Knee Injury and Osteoarthritis Outcome Score from preoperative to the two-year follow-up[27].

Built-in external rotation of the femoral component is a key design feature of the Genesis II knee system. It has been suggested that this balances the flexion gap correctly in spite of the neutral rotation of the femoral component to the femur[29,30]. However, neutral rotation of the femoral component can alter patellar tracking after TKA[29], which could contribute to an "unforgotten" knee. This hypothesis had not been confirmed previously. Kong et al. reported that Genesis II provides patellar tracking characteristics that are comparable to the Vanguard implanted in a conventional external femoral rotation position[29].

It is noteworthy that the FJS scores observed for the Vanguard fixed bearing were higher than those reported for the mobile-bearing Vanguard (mean FJS-12, 57), as reported by Van Parys et al[31], and they were approximately consistent with the results reported by Thienpont et al. for the Vanguard fixed bearing (mean FJS-12, 71)[32]. However, since the FJS-12 of the fixed-bearing Genesis II used in the present study did not significantly differ from those reported by Van Parys, the present study does not support the conclusion of a superior clinical outcome for the fixed-bearing design when measured using the FJS-12 score[32].

Our study must be interpreted in light of its limitations. This was an observational study that included outcome assessments in accordance with our standard practice only. Hence, data on femoral component rotation, patellar tilt and patellar displacement were not obtained. Such data would have been pivotal in assessing the association between clinical outcome and patellar tracking. Somewhat contradicting our expectations, differences in FS were deemed to be of clinical relevance. The Knee Society FS has limited responsiveness, and its correlation with patient satisfaction and PRO measures is weak[33]. Observed differences in this outcome may be indicative of confounding-by-indication. However, this could not be assessed in this study.

Another limitation was that a considerable number of patients were unable to participate in the study. Follow-up times between groups did differ significantly. Nevertheless, one could expect clinical outcomes to be reasonably stable between two- and five-year follow-ups[34,35]. Clinical scores were not documented at baseline. Hence, a degree of unmeasured, unknown bias may have been present. Regression analysis was performed to adjust for potentially confounding factors. Perversely, adjusting potential confounders can confound other unmeasured factors. The limitations of retrospective, observational studies cannot be completely overcome, so their results must be viewed with caution.

CONCLUSION

In conclusion, both prosthetic designs provide good clinical outcomes. Statistically significant differences between the Genesis II and the Vanguard were found on the FJS-12, KS and FS. Differences were relatively minor and may not exceed the threshold of clinical significance. The use of a prosthesis with built-in 3° of external rotation into the femoral component does not confer tangible clinical advantages compared with a prosthesis with a 3° externally-rotated position to the PCA.

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