BMJ Open

Comparison of the Journey II bicruciate stabilised (JII-BCS) and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility, blinded, randomised controlled trial

Iain McNamara ,[1,2] Valerie Pomeroy,[2] Allan B Clark,[3] Graham Creelman,[4] Celia Whitehouse,[1] J Wells,[2] B Harry,[5] Toby O Smith,[6] Juliet High,[7] Ann Marie Swart,[2,8] Celia Clarke[2]

To cite: McNamara I, Pomeroy V, Clark AB, *et al*. Comparison of the Journey II bicruciate stabilised (JII-BCS) and GENESIS II total knee arthroplasty for functional ability and motor impairment: the CAPAbility, blinded, randomised controlled trial. *BMJ Open* 2023;**13**:e061648. doi:10.1136/bmjopen-2022-061648

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2022-061648).

Received 11 March 2022
Accepted 16 November 2022

For numbered affiliations see end of article.

Correspondence to
Professor Iain McNamara; iain.mcnamara@nnuh.nhs.uk

ABSTRACT

Objectives To determine if a newer design of total knee replacement (TKR) (Journey II BCS) produces superior patient-reported outcomes scores and biomechanical outcomes than the older, more established design (Genesis II).

Setting Patients were recruited from an NHS University Hospital between July 2018 and October 2019 with surgery at two sites. Biomechanical and functional capacity measurements were at a University Movement and Exercise Laboratory.

Participants 80 participants undergoing single-stage TKR.

Interventions Patients were randomised to receive either the Journey II BCS (JII-BCS) or Genesis II TKR.

Primary and secondary outcome measures Primary outcome was the Oxford Knee Score (OKS), at 6 months. Secondary outcomes were: OKS Activity and Participation Questionnaire, EQ-5D-5L and UCLA Activity scores, Timed Up and Go Test, 6 min walk test, lower limb kinematics and lower limb muscle activity during walking and balance.

Results This study found no difference in the OKS between groups. The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20) respectively, adjusted effect size 0.35 (-2.01,2.71) p=0.771

In secondary outcome measures, the Genesis II group demonstrated a significantly greater walking range-of-movement (50.62 (7.33) vs 46.07 (7.71) degrees, adjusted effect size, 3.14 (0.61,5.68) p=0.02) and higher peak knee flexion angular velocity during walking (mean (SD) 307.69 (38.96) vs 330.38 (41.40) degrees/second, adjusted effect size was 21.75 (4.54,38.96), p=0.01) and better postural control (smaller resultant centre of path length) during quiet standing than the JII-BCS group (mean (SD) 158.14 (65.40) vs 235.48 (176.94) mm, adjusted effect size, 59.91 (–105.98, –13.85) p=0.01.).

Conclusions In this study population, the findings do not support the hypothesis that the Journey II BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at 6 months after surgery.

Trial registration number ISRCTN32315753.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is a two arm, superiority, observer-blind, participant-blind and clinical staff-blind, randomised control trial.
⇒ It uses a wide variety of patient reported outcomes measures and biomechanical measurements to determine if one implant is superior to the other
⇒ The required sample size was achieved with only one person lost to follow-up.
⇒ A potential limitation is the relatively large number of secondary outcomes.
⇒ The surgeons all had a much greater familiarity with the implantations of Genesis II implants.

Original protocol for the study is mentioned here: https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-4143-4.

INTRODUCTION

Despite total knee replacement (TKR) being a recommended surgical treatment for end-stage knee osteoarthritis,[1] up to 34% of all patients following TKR have poor functional outcomes.[2–6] With estimates of osteoarthritis of the knee affecting one in eight people in the USA[7] and 250 million individuals worldwide[8] the number of patients with intrusive symptoms after surgery is significant.

Multiple changes in implant design have been introduced to try to improve patient outcomes and while some implant design

alterations have led to improvements in patient-reported outcome measures (PROMS)[9–11] and kinematics[12 13] not all have led to differences.[14–20]

The Genesis II (Smith & Nephew, Memphis, Tennessee, USA) TKR has been reported to have good survivorship and patient satisfaction[13 21] and is commonly used in the UK[22] An evolutionary design, the Journey II BCS (JII-BCS; Smith & Nephew), also manufactured by Smith and Nephew, has been developed to improve kinematic outcome compared with the Genesis II by using a bicruciate design.[23] This design change has been supported by encouraging fluoroscopic studies. However, to date, no randomised controlled trials (RCTs) have been conducted to assess if there is a difference in the outcome compared with its predicate design.[24]

This trial aimed to assess whether the JII-BCS would produce better patient reported and movement outcomes than the Genesis II.

The published protocol included the aims for investigating: the rotational profile around the native knee and following TKR; and patients' experiences and surgeons' experiences.[25] These findings will be reported in subsequent manuscripts.

METHODS

Trial design, randomisation, blinding to intervention allocation, ethics and registration

A two-arm, superiority RCT comparing the JII-BCS knee implant (experimental intervention) to the Genesis II knee implant (control intervention) was performed. The trial was observer-blind, participant-blind and clinical staff-blind. Only the operating surgeon and theatre team knew which implant was used for an individual participant.

Trial participants were assigned to either the JII-BCS or Genesis II group using a computer-generated, 1:1 randomisation schedule stratified by site and age (<60 years = younger; ≥60 years = older).[26 27] Group allocation was revealed using REDCap,[28 29] the interactive web-randomisation system, to a member of the research team who was not involved in either the clinical care or assessments of any participant. Allocation was concealed from the surgical team until after the preoperation baseline measures were completed.

Sample size

The sample size was calculated from the Oxford Knee Score (OKS, primary outcome measure).[30] The RCT was powered at 80% with a 5% significance level to detect a minimally important clinical difference of five points[31 32] with an SD of 7.4 points.[33] Accounting for an estimated attrition rate of 10% at 6 months postsurgery the estimated sample size was 80 participants (40 per group).

Participants, setting and recruitment

Full eligibility criteria are provided in the published protocol.[25] In brief, participants were aged at least 18 years and met the clinical and radiological criteria for a single-stage TKR. People were excluded if they: had a fixed-flexion deformity of at least 15° or non-correctable varus/valgus deformity of at least 15°; had inflammatory arthritis or previous septic arthritis; had previous surgery to the collateral ligaments of the affected knee; had a contralateral TKR implanted less than 1 year earlier; had severe comorbidity that could present an unacceptable safety risk or were pregnant; were a private patient; were likely to be living outside the clinical centre catchment area at 6 months postsurgery or were enrolled on another clinical trial.

Patients were recruited at a university teaching hospital with surgery conducted at two sites. Outpatient physiotherapy was conducted in a single hospital. The Movement and Exercise Laboratory at the associated University (MoveExLab) was the setting for measures of functional capacity and biomechanics.

Interventions

All participants received routine NHS care for people with TKR irrespective of the implant received. This included following a standard postoperative rehabilitation of outpatient physiotherapy centred on knee strength and range of motion (ROM) exercises within the first 6 weeks after surgery. Patients received the same physiotherapy protocols and classes.

Experimental intervention

Participants in the experimental group received the JII-BCS. The JII-BCS is a dual-cam post designed to substitute for both the anterior cruciate ligament and posterior cruciate ligament. In addition the femoral and tibial components are asymmetric and the polyethylene insert is a medially concave and laterally convex shape. The device is designed to provide guided motion, and thus improve knee kinematics, and increase anteroposterior stability throughout knee flexion.

.Control intervention

- Participants in the control group received the Genesis II (Smith and Nephew), posterior stabilised (PS) TKR. The design features specific to the implant and a lateralised trochlear groove to improve patellar contact and tracking, an externally rotated femoral implant design and an anatomically shaped tibial baseplates.

Surgical techniques

All four surgeons had extensive experience, at least 5 years, of the Genesis II implant. All undertook cadaveric training on the JII-BCS and declared that they were competent in the surgical technique having completed their operative learning curve before starting the trial. Both implants are uncoated, cemented implants. The surgical procedure followed the standard manual surgical approach and technique through a medial parapatellar approach in all cases with intramedullary femoral and tibial rods to provide the alignment of the components. Patella resurfacing was used in both groups.

Data collection schedule

Data collection time points for the primary outcome measure were: at least 1 day before surgery (baseline), 7±2 days after surgery (1 week postoperatively), 6–8±2 weeks after surgery (2 months), 6 months±4 weeks after surgery (outcome, primary time point). Secondary outcomes were collected at baseline, 2 months and 6 months. Any differences from these time points are provided in the outcome measures section.

Outcome measures

Primary outcome measure

The OKS was the primary outcome measure. This is a 12-question patient self-assessment of knee function and pain[30] with values ranging from 0 (worst outcome) to 48 (best outcome).

Secondary outcome measures

1. Patient-reported outcome questionnaires
   1. The Oxford Knee Score Activity and Participation Questionnaire (OKS-APQ), which complements the OKS by assessing everyday activity and social participation.[34] The overall score is from 12 to 60 with 12 being the best outcome.
   2. The EQ-5D-5L is a self-report questionnaire consisting of five questions and a Visual Analogue Scale. Higher values indicate better quality of life.[35]
   3. The UCLA Activity score (UCLA) to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10 (participation in impact sport).
2. Walking and balance functional ability
   1. Timed Up and Go Test (TUG)—seconds to rise from chair, walk 3 m and return to sitting; mean of three trials.[36] The reported minimal detectable change after TKR is 2.27 s.[37] A lower value indicates better function.
   2. Six min walk test—metres walked in 6 min around a 20 m circuit.[38 39] The reported minimal detectable change from baseline after TKR is 26 metres.[40] A higher value indicates greater function.
   3. Modified Star-Excursion Test[41] (cm/leg length) where larger values indicate better balance.
3. Movement performance during walking and balance

   For these simultaneous measures, participants wore shorts and were bare-footed. Reflective sensors were placed in accordance with the Plug-In Gait model (Vicon) for the lower limb and three-dimensional motion data were collected, at 100 HZ, with eight wall-mounted infrared cameras (Vicon Motion System, Oxford, UK). Three embedded force plates (BERTEC, Ohio, USA) were used to collect kinetic data at 2000 Hz for walking tasks and 100 Hz for balance tasks. Surface electromyographic sensors (EMG: Delsys) were placed bilaterally on the Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Bicep Femoris and lateral head of the Gastrocnemius following SENIAM guidance. EMG data were collected at 2000 Hz.

   For walking tasks, participants were asked to walk in a straight line along a 10 m walkway at their self-selected speed. For double stance balance activities, participants were instructed to stand with their feet shoulder-width apart. For single stance balance activities, participants were instructed to stand on one leg with hands-on-hips. Three trials of 10 s were recorded for each activity.

   For the stair ambulation task, participants were asked to complete six ascents and six descents all unaided, leading with the operated limb for three trials and the non-operated limb for the remainder. The stairs had four steps. The first step was 16.5 cm, and the others were 15 cm high. Handrails were available if participants needed support.

   Movement data were processed in accordance with the Vicon Plug-in Gait Model (Oxford Metrics, Oxford, UK). Raw EMG was filtered with pass bands at 10 and 500 Hz, rectified and low pass filtered using a fourth order Butterworth with a 10 Hz cut-off. Walking data were normalised to 101 data points for the gait cycle. Three trials of tasks were used to create a mean for each measure per participant. Values were extracted using a purpose-built MATLAB script. Data were processed by motion analysis experts in the research team.

   a. Primary movement performance measures

      The JII-BCS is expected to provide more normal kinematics during knee movement than Genesis II due to the design changes discussed earlier. Other authors have indicated that the femotibial relationship may be more normal during deep knee bend[42] and more stable during walking[43] Accordingly, people with the Journey prosthesis may[44 45] or may[43] have greater knee ROM, may walk faster,[46 47] and may have a longer stride length[46 47] than people receiving a comparison knee replacement. In addition, greater stability of the femur on the tibia could produce greater knee flexion angular velocity as dynamic knee loading could be more normal. However, there is only one non randomised study of 18 patients comparing the JII-BCS directly with the Genesis II.[45] Based on the available literature, the hypothesis driving the kinematic investigation was that people receiving the JII-BCS compared with those receiving the Genesis II would have greater walking velocity, step-length symmetry (resulting from longer stride length), knee ROM and peak knee flexion angular velocity.

      i. Walking speed (metres/second). A higher value indicates better performance

      ii. Step length symmetry during walking. Step length ratio was calculated as ((2xOp)/Op+NOp))−1); where Op is the step length of the operated leg and NOp is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.

      iii. Knee ROM during walking (degrees). Higher values indicate better performance.

iv. Peak knee flexion angular velocity during walking (degrees per second). This was inadvertently omitted from the statistical analysis plan (SAP). Higher value indicates better performance.

b. Secondary movement performance measures.
   i. Double stance support (% of gait cycle). It was planned to measure cadence, (steps/min), step length (m) and stride length (m). However, there is redundancy with the temporal-spatial gait parameters of walking speed and step length symmetry which are included in the primary movement performance measures.
   ii. Peak extension and flexion moments of operated knee during the gait cycle (Nm/kg).
   iii. Hip and ankle ROM during walking.
   iv. Peak knee flexion angular velocity during stepping up onto a stair.
   v. Percentage of gait cycle for peak activation of Vastus Medialis, Vastus Lateralis, Tibialis Anterior, Biceps Femoris and Lateral head of Gastrocnemius (% of gait cycle).
   vi. Balance measures were derived from kinetic data (from force plates) during standing still: single stance on the operated lower limb for 10 s with eyes open (yes/no) and duration maintained; resultant centre of pressure path length (COP cm) in double stance with eyes closed; and resultant COP velocity (cm/s) in double stance with eyes closed.

Clinical context and adverse events

Data on length of hospital stay and complications related to the surgery (eg, anaesthesia-related problems, bleeding, morbidities) were collected from a notes review. At each visit, participants were asked about their pain medication and if they had received additional treatment since their surgery/previous visit and what this entailed. Any need for revision surgery was recorded. All adverse events identified were tracked until resolution.

Analysis

The SAP was finalised and agreed prior to database lock and analysis was completed blinded to group allocation (online supplemental file). For all outcomes the hypothesis tests and 95% CIs were two sided; and a $p<0.05$ was considered significant. An intention-to-treat analysis was conducted that is, all randomised participants regardless of their eligibility or adherence were analysed according to the treatment they were randomised to receive. The analysis was undertaken by the Trial Statistician using Stata V.16.

For the primary outcome, the mean OKS at 6 months was compared between the control and experimental groups using a general linear model adjusting for site and age (<60 years/≥60 years). An adjusted analysis was conducted using the same model but adjusting for the OKS at baseline. The model assumptions were checked graphically, and sensitivity analysis done using a non-parametric bootstrap using 5000 repetitions.

All the other outcomes were analysed separately at 2 months and 6 months using the same general linear model specified above and a corresponding adjusted analysis. The exception was ability to balance for 10 s. This was analysed using a logistic regression model adjusting for site and age.

Patient and public involvement

A patient representative, who had previously undergone knee replacement surgery, was involved in the protocol development, assessment of the burden of the intervention and time taken to participate in the research and oversight of the trial as a member the trial management group. The representative also contributed to the planning and writing of research dissemination materials.

RESULTS

Participants were recruited between July 2018 and October 2019. Last follow-up visits were in October 2020 with some impact and delayed visits due to COVID-19.

In the published protocol,[25] the analysis plan included a per-protocol and safety analysis. This was not undertaken as the implants were used as intended so these populations would be the same as the intention-to-treat population.

Flow of participants through the trial

In total, 105 of 153 people screened were eligible to take part, 16 declined participation and eight were excluded for other reasons. Therefore, 81 of 153 people (53%) were recruited. All participants in the Genesis II group (n=40) received their allocated intervention. In the JII-BCS group (n=41), one participant withdrew prior to surgery (postrandomisation exclusion). Full details are in the Consolidated Standards of Reporting Trials (CONSORT) flow chart (figure 1).

Participant characteristics

There were no discernible baseline differences between the groups (table 1).

Primary outcome comparison: 6 months postoperatively

The OKS scores for the JII-BCS and Genesis II groups were mean (SD) 42.97 (5.21) and 43.13 (5.20), respectively. There was no significant difference between the groups: adjusted effect size 0.35 (−2.01,2.71) p=0.771 (table 2).

Secondary outcome comparisons: 6 months postoperatively

Patient-reported outcome questionnaires

There were no differences between the two groups for any of the secondary patient reported outcomes (online supplemental tables S1).

Walking and balance functional ability

There was no difference between the JII-BCS and Genesis II groups in the time to complete the TUG Test or the

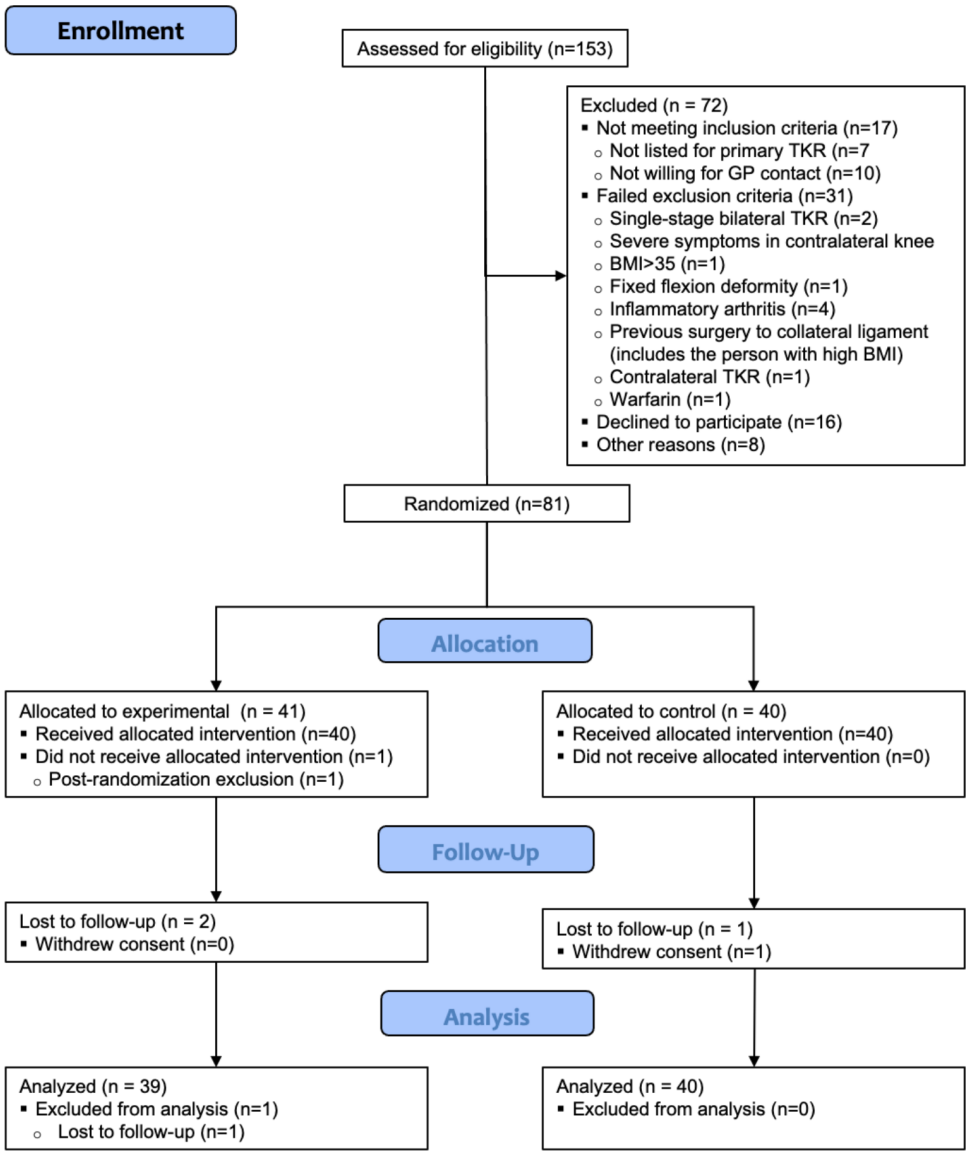

Figure 1 Consolidated Standards of Reporting Trials (CONSORT) diagram.

distance covered in the 6 min walk test (online supplemental table S2). The Star-Excursion Test was attempted by all participants but 59% of participants at baseline, 59% at follow-up and 63% at outcome were unable to complete it (online supplemental table S3). Therefore, statistical analysis was not undertaken.

Movement performance during walking and balance

The primary movement performance measures are reported in table 3. In summary at 6 months postsurgery, the Genesis II group had a significant advantage for knee ROM and peak knee flexion angular velocity during walking. There were no differences between the groups for walking speed or peak flexion angular knee velocity on stair climbing.

Data for all secondary movement performance measures are provided in online supplemental tables S4–S8. The only difference between groups that reached statistical significance was for COP path length in double stance with eyes closed (online supplemental table S7). The mean (SD) values for the Genesis II and JII-BCS groups were 158.14 (65.40) mm and 235.48 (176.94) mm, respectively. Adjusted effect size was −59.91 (−105.98, −13.85) p=0.01 in favour of the Genesis II group.

Postoperative clinical context

There were no between-group significant differences for: length of stay, change in pain medication from randomisation or physiotherapy received (online supplemental tables S9 and S10).

Adverse events

One patient with a JII-BCS developed acute swelling and pain in the knee and was systemically unwell at 4 months postoperatively. The joint aspiration demonstrated turbid fluid and an exchange of the polyethylene spacer and retention of the femoral and tibial components (Debridement And Implant Retention) was performed with postoperative antibiotic treatment. Subsequent microbiology was negative so infection was never conclusively

Table 1 The baseline characteristics of participants

	JII-BCS (n=40)	Genesis II (n=40)
Age, mean (SD)	69.28 (7.50)	67.95 (6.28)
Sex, female, no (%)	24 (60.0)	20 (50.0)
Body mass index, mean (SD)	28.77 (4.25)	29.86 (4.29)
Operated knee, right, no (%)	23 (57.0)	14 (35.0)
Intraoperative American Society of Anesthesiologists		
Score 1, no (%)	4 (10)	2 (5)
Score 2, no (%)	35 (88)	36 (90)
Score 3, no (%)	1 (3)	2 (5)
Previous contralateral knee implant		
Yes, no (%)	7 (17.5)	6 (15.0)
No, no (%)	26 (65.0)	22 (55.0)
Missing, no (%)	7 (17.5)	12 (30.0)
Previous hip surgery, yes, no (%)	5 (13.0)	5 (13.0)
Employment, retired, no (%)	25 (63.0)	24 (60.0)
Pain Self-Efficacy-2 Questionnaire, median (IQR)	8.0 (6.0–10.0)	6.0 (3.0–9.5)
Hospital Anxiety and Depression Scale		
Anxiety total, mean (SD)	6.32 (3.54)	7.43 (3.05)
Depression total, mean (SD)	6.03 (2.37)	8.05 (3.55)
Oxford Knee Score, mean (SD)	20.25 (5.69)	19.05 (5.28)
EQ-5D-5L utility score, mean (SD)	0.52 (0.16)	0.47 (0.20)
EQ-5D Visual Analogue Scale (VAS), mean (SD)	59.78 (17.70)	51.30 (17.71)
Timed Up and Go time (seconds), mean (SD)	11.34 (3.40)	11.04 (3.33)
Six min walk distance (metres), mean (SD)	304.03 (79.75)	299.09 (85.69)
Walking speed, mean (SD)	0.95 (0.21)*	0.93 (0.20)
Step length ratio, mean (SD)	−0.00 (0.04)*	−0.00 (0.04)
Operated knee range-movement (degrees), mean (SD)	42.11 (9.90)*	44.35 (8.56)
Operated leg single stance eyes open (secs), mean (SD)	5.60 (3.44)†	5.58 (3.28)†

EQ-5D-5L is a measure of health-related quality of life, in the range of −0.109 (worst possible state) and 1.0 (perfect health), anchored at 0 (death).
EQ-VAS is a health state assessment ranging between 0 and 100, in which 0 is worst imaginable health state and 100 is best imaginable health state.
OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).
Timed Up and Go Test—seconds to rise from chair, walk 3 m and return to sitting; mean of three trials. A lower value indicates better function.
Six min walk test—metres walked in 6 min around a 20 m circuit A higher value indicates greater function.
The UCLA Activity score to assess physical activity self-rating scale ranged from 0 (complete inactivity) to 10.
*Thirt-nine participants.
†Thirt-eight participants.

demonstrated. The numbers and type of complications are reported in online supplemental table S11.

DISCUSSION

The findings do not support the hypothesis that the JII-BCS produces a better outcome than the Genesis II for the primary outcome of the OKS at 6 months after surgery. No differences between groups were also found for: other patient-reported outcomes; measures of balance and walking function; hip and ankle ROM; knee moments during walking; double support time during walking and percentage of gait cycle for peak muscle activation. However, significant advantages for the control group (Genesis II) were found for: operated knee range-of-movement and peak knee flexion angular velocity during walking, and postural control (COP path length).

While some investigators have demonstrated differences between generations of knee designs[12] not all modern generation TKR designs have demonstrated an improvement in outcomes when compared with their predecessors.[15–20 48] One possible reason for this is that the predecessor is already producing good results and therefore is difficult to improve on. Regarding the JII-BCS, at the time of writing, only Bialy *et al*[45] have directly compared the Genesis II and the JII-BCS. Their study was non randomised and consisted of 18 patients between the two groups. They reported a greater supine range of movement of the JII-BCS compared with the Genesis II when measured with a long arm goniometer. They also reported an improvement in functional knee scores and stability when balancing. Their conclusions were that the JII-BCS restores more normal anatomy and kinematics

Table 2 Oxford Knee Scores (OKS, primary outcome), from baseline to 6 months after surgery (primary time point)

	Means (SDs) (No of participants)			Between groups comparison							
				Two months				Six months			
				Unadjusted		Adjusted*		Unadjusted		Adjusted*	
	Baseline	Two months after surgery	Six months after surgery	Effect size (95% CI)	P value	Effect size (95% CI)	P value	Effect size (95% CI)	P value	Effect size (95% CI)	P value
JII-BCS	20.25 (5.69) (n=40)	34.10 (7.10) (n=39)	42.97 (5.21) (n=39)	1.97 (−1.3 7 to 5.32)	0.24	2.5 (−0.71 to 5.71)	0.12	0.24 (−2.10 to 2.58)	0.84	0.35 (−2.01 to 2.71)	0.77
Genesis II	19.05 (5.28) (n=40)	36.00 (7.61) (n=40)	43.13 (5.20) (n=40)								

OKS is a 12-item knee function assessment, ranging from 0 (worst score) to 48 (best score).
Journey II BCS (JII-BCS)
*Adjusted for strata used in randomisation and for baseline scores.
†
APQ, Activity and Participation Questionnaire; VAS, Visual Analogue Scale.

which is correlates into the improvements that they found. None of the other papers reporting outcomes of the JII-BCS compared the JII-BCS to the Genesis II, none used a randomised design and none used methodology or outcomes that could be compared with the methodology used in this trial.[42–46] However, on the basis of the available literature, we measured outcomes that would be expected to be difference on the basis of the available literature, walking velocity, step-length symmetry (resulting from longer stride length), knee ROM and peak knee angular velocity.

Within our trial, we found differences in some biomechanical measures of motor impairment but not for others; patient-reported outcomes; and, walking and balance function. It is possible that knee range-of-movement during walking, walking symmetry, peak knee flexion angular velocity during walking and postural control (COP path length) are detecting motor impairment improvement for the Genesis II group and/or because statistical significance was a result of testing multiple outcomes. The latter explanation is clearly possible but knee range-of-movement is greater for people reporting good outcome after knee replacement than for those reporting poor outcome.[49] Moreover, knee range-of-movement has been found to be the main biomechanical effect of TKR[50] and to improve over time while other biomechanical measures do not.[50 51] Likewise, postural control improves over time[52 53] and approaches healthy control values.[52] Importantly, gait symmetry is an indicator of walking control[54] and, while of borderline statistical significance (p=0.05) can possibly detect differences following insertion of different prostheses. Peak knee angular velocity during walking is also an indicator of walking control[55] and has been found to change beneficially after insertion of the Genesis II prosthesis.[50] These findings indicate that secondary, in-depth, analysis of the biomechanical data should be undertaken.

A potential limitation is the relatively large number of secondary outcomes. However, this is also a strength as it ensured comprehensive examination of the potential impact of TKR on functional ability, motor impairment and health-related quality of life. Another potential limitation is that the surgeons all had a much greater familiarity with the Genesis II implants. However, all surgeons were very experienced with the Genesis II implant with at least 10 years of experience implanting the device. All surgeons received thorough training with the JII-BCS and the surgical technique and instrumentation are similar for both devices with only one additional femoral cut being necessary for the JII-BCS compared with the Genesis II. A key strength of this trial is that the required sample size was achieved with only one person lost to follow-up. Other strengths include minimisation of selection bias through a robust randomisation procedure and use of double blinding to minimise interpretation bias.

The lack of difference between implant designs is important for patients, surgeons, healthcare providers

Table 3 Movement performance primary measures during walking from baseline to 6 months postsurgery (primary time point): walk speed, step length symmetry, knee range of motion (ROM) and peak knee flexion angular velocity

	Means (SDs) (No of participants)			Between groups comparison							
				Two months				Six months			
				Unadjusted		Adjusted*		Unadjusted		Adjusted*	
	Baseline	Two months after surgery	Six months after surgery	Effect size (95% CI)	P value	Effect size (95% CI)	P value	Effect size (95% CI)	P value	Effect size (95% CI)	P value
Walking speed (ms/sec)											
JII-BCS	0.95 (0.21) (n=39)	0.90 (0.23) (n=37)	1.09 (0.22) (n=35)	0.08 (–0.02 to 0.17)	0.11	0.09 (0.01 to 0.17)	**0.03**	0.05 (–0.05 to 0.15)	0.34	0.03 (–0.04 to 0.09)	0.40
Genesis II	0.93 (0.20) (n=40)	0.97 (0.17) (n=37)	1.13 (0.18) (n=34)								
Step length symmetry (ratio)											
JII-BCS	–0.00 (0.04) (n=40)	0.03 (0.04) (n=37)	0.02 (0.04) (n=35)	–0.02 (–0.04 to 0.00)	**0.02**	–0.02 (–0.04 to 0.00)	**0.02**	–0.01 (–0.03 to 0.00)	0.10	–0.01 (–0.03 to 0.00)	**0.05**
Genesis II	–0.00 (0.04) (n=40)	0.01 (0.04) (n=37)	0.00 (0.04) (n=34)								
Knee ROM (degrees)											
JII-BCS	42.11 (9.90 (n=39)	37.87 (7.73) (n=38)	46.07 (7.71) (n=35)	4.51 0.39 to 8.64)	**0.03**	3.42 (–0.41 to 7.24)	0.08	4.77 (1.11 to 8.43)	**0.01**	3.14 (0.61 to 5.68)	**0.02**
Genesis II	40.31 (5.93) (n=40)	42.25 (9.75 (n=38)	50.62 (7.33) (n=34)								
Peak knee flexion angular velocity – walking (degrees/second)											
JII-BCS	283.10 (53.83) (n=39)	269.65 (36.75) (n=38)	307.69 (38.96) (n=35)	23.15 (–0.84 to 47.14)	0.06	16.47 (–6.21 to 39.14)	0.15	31.00 (10.34 to 51.66)	**0.01**	21.75 (4.54 to 38.96)	**0.01**
Genesis II	300.36 (55.56) (n=40)	321.65 (43.31) (n=38)	330.38 (41.40) (n=35)								
Peak knee flexion angular velocity—stairs (degrees/second)											
JII-BCS	283.10 (53.83) (n=39)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31 (16.67 to 91.96)	**0.01**	51.63 (15.36 to 87.89)	**0.01**	50.01 (5.97 to 94.04)	**0.03**	35.15 (–3.09 to 73.39)	0.07
Genesis II	300.36 (55.56) (n=40)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)								

Step length symmetry—step length ratio calculated as ((2xOp)/Op+NOP))–1); where Op is the step length of the operated leg and NOP is the step length of the non-operated leg. Zero indicates perfect symmetry and best performance.
Journey II BCS (JII-BCS)
Bold text is used to denote values achieving statisitcal significance
*Adjusted for strata used in randomisation and for baseline scores.

and implant companies. For the patient and surgeons, reassurance can be gained that older designs, with proven track record of function and survivorship, can provide the same patient reported and functional outcome as more modern designs. For the healthcare providers, older implants are often less expensive and, in the absence of clinical benefit with and demonstrable longevity, if the additional expenditure on more modern designs is avoided for the hundreds of thousands of patients undergoing surgery worldwide the cost savings are potentially significant. Finally, for the implant companies, it is more likely than not than implant design has reached a point when non-implant-related factors play a more important role in patient outcome. The future of design and innovation may come in the form of more modern surgical techniques such as robotic assisted implantation to assist in placing the knee in a more kinematically sympathetic position which in turn may allow the newer design philosophies to positively influence outcome. It is possible, only then in combination with modern surgical techniques, that improvements in patient outcomes can be realised but well-constructed surgical trials will need to answer such questions.

CONCLUSION

This study demonstrated no difference between the Genesis II and its successor the JII-BCS for PROMS, walking function, temporal-spatial gait parameters, balance ability and lower limb kinematic results at 6 months follow-up. However, significant advantages were seen in for the Genesis II in the operated knee range-of-movement, peak knee flexion angular velocity during walking and postural control.

Author affiliations
[1]Norfolk and Norwich University Hospital, Norwich, UK
[2]University of East Anglia, Norwich, UK
[3]Norwich Medical School, University of East Anglia, Norwich, UK
[4]Mental Health Act Review Panels, Norfolk and Suffolk, UK
[5]Department of clinical neurosciences, University of Cambridge, Cambridge, UK
[6]Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, UK
[7]Norwich Clinical Trials Unit, Norwich, UK
[8]Health Sciences, University of East Anglia, Norwich, UK

Twitter Toby O Smith @tobyosmith

Acknowledgements The team would like to thank all the participants and families who gave their time to be part of this study; Antony Colles, Martin Pond and the NCTU data management team; Estelle Payerne; Amanda Thacker; NNUH sponsorship team and the safety monitoring committee members, Prof Marcus Flather and Prof Simon Donell. Also: Mr Charles Mann, Mr Nish Chirodian, Mr David Calder, Dr Nicola Hancock, Nursing and clinic staff at the Spire Hospital and NNUH, Prof Andoni Toms and the Radiology department at NNUH and Addenbrooke's hospital, Cambridge, Dr Simon Horton and Dr Anne Killett

Contributors IM and VP drafted this paper. IM is the guarantor. All authors (IM, VP, ABC, GC, CW, JW, BH, TOS, JH and AMS) contributed to revisions of the manuscript, read and approved the final manuscript. All authors (IM, VP, ABC, GC, CW, JW, BH, TO, JH and AMS) contributed to the development of the trial protocol as well as conception or design of the work; the acquisition, analysis or interpretation of data for the work.

Funding This work was supported by an investigator initiated grant from Smith and Nephew, with both types of knee replacements supplied at the same cost.

Disclaimer The funders had no role in the design of the study, the data collection, the data analysis, interpretation of data, or writing of the manuscript.

Competing interests The trial was funded by Smith and Nephew via an unrestricted grant, administered by the Sponsor NNUH. Funding was used within NNUH for running the trial. Funds were provided via NNUH to UEA for the members of the trial team based in the movement and Exercise Laboratory (MoveExLab) at UEA and the clinical trials unit (CTU) based at UEA for statistics, and trial and data management.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by East of England – Cambridge Central Research Ethics Committee (reference 16/EE/0230). Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request. Reasonable requests for data will be considered by the trial team.

ORCID iD
Iain McNamara http://orcid.org/0000-0002-2051-8451

REFERENCES

1 Price AJ, Alvand A, Troelsen A, *et al*. Knee replacement. *Lancet* 2018;392:1672–82.
2 Judge A, Arden NK, Cooper C, *et al*. Predictors of outcomes of total knee replacement surgery. *Rheumatology* 2012;51:1804–13.
3 Beswick AD, Wylde V, Gooberman-Hill R, *et al*. What proportion of patients report long-term pain after total hip or knee replacement for osteoarthritis? A systematic review of prospective studies in unselected patients. *BMJ Open* 2012;2:e000435.
4 Heck DA, Robinson RL, Partridge CM, *et al*. Patient outcomes after knee replacement. *Clin Orthop Relat Res* 1998;356:93–110.
5 Kennedy LG, Newman JH, Ackroyd CE, *et al*. When should we do knee replacements? *Knee* 2003;10:161–6.
6 Jones CA, Voaklander DC, Suarez-Alma ME. Determinants of function after total knee arthroplasty. *Phys Ther* 2003;83:696–706.
7 Cisternas MG, Murphy L, Sacks JJ, *et al*. Alternative methods for defining osteoarthritis and the impact on estimating prevalence in a US population-based survey. *Arthritis Care Res* 2016;68:574–80.
8 Vos T, Flaxman AD, Naghavi M, *et al*. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the global burden of disease study 2010. *Lancet* 2012;380:2163–96.
9 Collados-Maestre I, Lizaur-Utrilla A, Gonzalez-Navarro B, *et al*. Better functional outcome after single-radius TKA compared with multi-radius TKA. *Knee Surg Sports Traumatol Arthrosc* 2017;25:3508–14.
10 Cook LE, Klika AK, Szubski CR, *et al*. Functional outcomes used to compare single radius and multiradius of curvature designs in total knee arthroplasty. *J Knee Surg* 2012;25:249–53.
11 Jacobs WCH, Christen B, Wymenga AB, *et al*. Functional performance of mobile versus fixed bearing total knee prostheses: a randomised controlled trial. *Knee Surg Sports Traumatol Arthrosc* 2012;20:1450–5.

12 Hamilton DF, Burnett R, Patton JT, *et al*. Implant design influences patient outcome after total knee arthroplasty: a prospective double-blind randomised controlled trial. *Bone Joint J* 2015;97-B:64–70.
13 Pennington M, Grieve R, Black N, *et al*. Cost-effectiveness of five commonly used prosthesis brands for total knee replacement in the UK: a study using the NJR dataset. *PLoS One* 2016;11:e0150074.
14 Dowsey M, Gould D, Spelman T, *et al*. A randomized controlled trial comparing a medial stabilized total knee prosthesis to a cruciate retaining and posterior stabilized design: a report of the clinical and functional outcomes following total knee replacement. *J Arthoplasty* 2020;35:1582–90.
15 Hauer G, Hörlesberger N, Klim S, *et al*. Mid-term results show no significant difference in postoperative clinical outcome, pain and range of motion between a well-established total knee arthroplasty design and its successor: a prospective, randomized, controlled trial. *Knee Surg Sports Traumatol Arthrosc* 2021;29:827–31.
16 Chua JL, Goh GS-H, Liow MHL, *et al*. Modern TKA implants are equivalent to traditional TKA implants in functional and patellofemoral joint-related outcomes. *Knee Surg Sports Traumatol Arthrosc* 2019;27:1116–23.
17 Molloy IB, Keeney BJ, Sparks MB, *et al*. Short term patient outcomes after total knee arthroplasty: does the implant matter? *Knee* 2019;26:687–99.
18 Ranawat CS, White PB, West S, *et al*. Clinical and radiographic results of attune and pFc sigma knee designs at 2-year follow-up: a prospective matched-pair analysis. *J Arthroplasty* 2017;32:431–6.
19 Song SJ, Kang SG, Park CH, *et al*. Comparison of clinical results and risk of Patellar injury between attune and PFC sigma knee systems. *Knee Surg Relat Res* 2018;30:334–40.
20 Behrend H, Zdravkovic V, Bösch M, *et al*. No difference in joint awareness after TKA: a matched-pair analysis of a classic implant and its evolutional design. *Knee Surg Sports Traumatol Arthrosc* 2019;27:2124–9.
21 Evans JT, Walker RW, Evans JP, *et al*. How long does a knee replacement last? A systematic review and meta-analysis of case series and national registry reports with more than 15 years of follow-up. *Lancet* 2019;393:655–63.
22 . Available from: National Joint Registry for England, Wales N ireland and the I of M. National joint registry, 2019. Available: https://reports.njrcentre.org.uk/portals/0/pdfdownloads/njr 16th annual report 2019.pdf
23 Moore C, Lenz N. The evolution of guided motional total knee arthroplasty – the journey II Bi-Cruciate stabilized knee system. *Bone Jt Sci* 2012;3:1–8.
24 Grieco TF, Sharma A, Dessinger GM, *et al*. In Vivo Kinematic Comparison of a Bicruciate Stabilized Total Knee Arthroplasty and the Normal Knee Using Fluoroscopy. *J Arthroplasty* 2018;33:565–71.
25 Clarke C, Pomeroy V, Clark A, *et al*. Capability: comparison of the journey II Bi-Cruciate Stabilised and genesis II total knee arthroplasty in performance and functional ability: protocol of a randomised controlled trial. *Trials* 2020;21:222.
26 Merle-Vincent F, Couris CM, Schott A-M, *et al*. Factors predicting patient satisfaction 2 years after total knee arthroplasty for osteoarthritis. *Joint Bone Spine* 2011;78:383–6.
27 Singh JA, O'Byrne M, Harmsen S, *et al*. Predictors of moderate-severe functional limitation after primary total knee arthroplasty (TKA): 4701 TKAs at 2-years and 2935 TKAs at 5-years. *Osteoarthr Cartil* 2010;18:515–21.
28 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
29 Harris PA, Taylor R, Minor BL, *et al*. The REDCap consortium: building an international community of software platform partners. *J Biomed Inf* 2019;95:103208.
30 Dawson J, Fitzpatrick R, Murray D, *et al*. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Jt Surg Br* 1998;80:63–9.
31 Bohm E, Loucks I, Tan Q, *et al*. Determining minimum clinically important difference and targeted clinical improvement values for the Oxford 12. In: *American Academy of orthopaedic surgeons 2012 annual conference*, 2012.
32 Beard DJ, Harris K, Dawson J, *et al*. Meaningful changes for the Oxford hip and knee scores after joint replacement surgery. *J Clin Epidemiol* 2015;68:73–9.
33 Williams DP, O'Brien S, Doran E, *et al*. Early postoperative predictors of satisfaction following total knee arthroplasty. *Knee* 2013;20:442–6.
34 Dawson J, Beard DJ, McKibbin H, *et al*. Development of a patient-reported outcome measure of activity and participation (the OKS-APQ) to supplement the Oxford knee score. *Bone Joint J* 2014;96-B:332–8.
35 Herdman M, Gudex C, Lloyd A, *et al*. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–36.
36 Podsiadlo D, Richardson S. The timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991;39:142–8.
37 Yuksel E, Unver B, Kalkan S. Reliability and minimal detectable change of the 2-minute walk test and timed up and go test in patients with total hip arthroplasty. *J Arthroplasty* 2017;32:426–30.
38 Kennedy DM, Stratford PW, Wessel J, *et al*. Assessing stability and change of four performance measures: a longitudinal study evaluating outcome following total hip and knee arthroplasty. *BMC Musculoskelet Disord* 2005;6:3.
39 Bennell K, Dobson F, Hinman R. Measures of physical performance assessments: Self-Paced Walk Test (SPWT), Stair Climb Test (SCT), Six-Minute Walk Test (6MWT), Chair Stand Test (CST), Timed Up & Go (TUG), Sock Test, Lift and Carry Test (LCT), and Car Task. *Arthritis Care Res* 2011;63 Suppl 11:S350–70.
40 Naylor JM, Mills K, Buhagiar M, *et al*. Minimal important improvement thresholds for the six-minute walk test in a knee arthroplasty cohort: triangulation of anchor- and distribution-based methods. *BMC Musculoskelet Disord* 2016;17:390.
41 Kinzey SJ, Armstrong CW. The reliability of the star-excursion test in assessing dynamic balance. *J Orthop Sports Phys Ther* 1998;27:356–60.
42 Smith LA, Nachtrab J, LaCour M, *et al*. In Vivo Knee Kinematics: How Important Are the Roles of Femoral Geometry and the Cruciate Ligaments? *J Arthroplasty* 2021;36:1445–54.
43 Tomite T, Saito H, Aizawa T, *et al*. Gait analysis of conventional total knee arthroplasty and Bicruciate stabilized total knee arthroplasty using a Triaxial Accelerometer. *Case Rep Orthop* 2016;2016:1–6.
44 Di Benedetto P, Vidi D, Colombo A, *et al*. Pre-operative and post-operative kinematic analysis in total knee arthroplasty. A pilot study. *Acta Biomed* 2019;90:91–7.
45 Biały M, Corte R, Dec J, *et al*. Evaluation of functional status in patients after total knee arthroplasty: a comparison of the journey II Bi-Cruciate stabilized total knee system and genesis II Cruciate-Retaining implant. *Physiotherapy Review* 2021;25:24–34.
46 Hyodo K, Kanamori A, Kadone H, *et al*. Gait analysis comparing kinematic, kinetic, and muscle activation data of modern and conventional total knee arthroplasty. *Arthroplast Today* 2020;6:338–42.
47 Amemiya K, Kaneko T, Omata M, *et al*. Anatomical bi-cruciate retaining TKA improves gait ability earlier than bi-cruciate stabilized TKA based on triaxial accelerometery data: a prospective cohort study. *Asia Pac J Sports Med Arthrosc Rehabil Technol* 2021;25:35–41.
48 Nunley RM, Nam D, Berend KR, *et al*. New total knee arthroplasty designs: do young patients notice? *Clin Orthop Relat Res* 2015;473:101–8.
49 Naili JE, Wretenberg P, Lindgren V, *et al*. Improved knee biomechanics among patients reporting a good outcome in knee-related quality of life one year after total knee arthroplasty. *BMC Musculoskelet Disord* 2017;18:122.
50 Rahman J, Tang Q, Monda M, *et al*. Gait assessment as a functional outcome measure in total knee arthroplasty: a cross-sectional study. *BMC Musculoskelet Disord* 2015;16:66.
51 Yoshida Y, Zeni J, Snyder-Mackler L. Do patients achieve normal gait patterns 3 years after total knee arthroplasty? *J Orthop Sports Phys Ther* 2012;42:1039–49.
52 Gauchard GC, Vançon G, Meyer P, *et al*. On the role of knee joint in balance control and postural strategies: effects of total knee replacement in elderly subjects with knee osteoarthritis. *Gait Posture* 2010;32:155–60.
53 Moutzouri M, Gleeson N, Billis E, *et al*. The effect of total knee arthroplasty on patients' balance and incidence of falls: a systematic review. *Knee Surg Sports Traumatol Arthrosc* 2017;25:3439–51.
54 Patterson KK, Nadkarni NK, Black SE, *et al*. Gait symmetry and velocity differ in their relationship to age. *Gait Posture* 2012;35:590–4 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3624763/pdf/nihms412728.pdf
55 Richards JD, Pramanik A, Sykes L, *et al*. A comparison of knee kinematic characteristics of stroke patients and age-matched healthy volunteers. *Clin Rehabil* 2003;17:565–71.