

Supplement to

Comparison of the JOURNEY II bi-cruciate stabilised and GENESIS II

total knee arthroplasty for functional ability and motor impairment:

the CAPAbility randomised controlled trial

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Table S1. OKS-APQ, EQ5D-5L and UCLA from baseline to six months after surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months				Six months			
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value
OKS-APQ											
JII-BCS	2.81 (6.63) (n=40)	36.09 (27.05) (n=40)	70.83 (23.81) (n=39)	11.63 (-1.87,25.14)	0.09	12.09 (-1.63,25.8)	0.08	3.66 (-7.53,14.84)	0.52	3.31 (-8.05,14.67)	0.56
Genesis II	1.41 (3.39) (n=40)	47.34 (32.50) (n=40)	74.14 (25.46) (n=40)								
EQ5D Utility											
JII-BCS	0.52 (0.16) (n=40)	0.74 (0.10) (n=40)	0.90 (0.12) (n=39)	0.05 (- 0.01,0.1)	0.11	0.05 (0.00,0.11)	0.05	0.00 (-0.06,0.05)	0.89	0.00 (-0.06, 0.05)	0.95
Genesis II	0.47 (0.20) (n=40)	0.78 (0.14) (n=40)	0.89 (0.13) (n=40)								
EQ5D VAS											
JII-BCS	59.78 (17.70) (n=40)	77.85 (14.12) (n=40)	89.03 (9.44) (n=39)	0.65 (-6.18,7.48)	0.85	2.89 (-3.92,9.70)	0.40	-1.71 (-6.77,3.35)	0.50	-1.04 (-6.32,4.23)	0.70
Genesis II	51.30 (17.71) (n=40)	78.25 (16.11) (n=40)	87.55 (12.75) (n=40)								
UCLA											
JII-BCS	1.10 (0.78) (n=40)	4.82 (1.62) ^b (n=40)	6.87 (1.38) N=38)	0.23 (-0.5,0.95)	0.53	0.25 (-0.48,0.98)	0.49	-0.13 (- 0.74,0.48)	0.67	0.08 (- 0.69,0.53)	0.79
Genesis II	3.00 (0.85) (n=40)	5.05 (1.60) ^b (n=40)	6.68 (1.44) (n=40)								

^a adjusted for strata used in randomisation and for baseline scores, ^b median (IQR)

Table S2. Walking functional ability from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months		Six months		Unadjusted effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value				
Walking function											
Timed Up & Go Test (secs)											
JII-BCS	11.34 (3.40) (n=40)	11.89 (3.92) (n=37)	10.30 (2.90) (n=35)	1.61 (-3.11,-0.1)	0.04	-1.32 (-2.48,-0.16)	0.03	-0.62 (-1.91,0.66)	0.34	-0.37 (-1.25,0.50)	0.40
Genesis II	11.04 (3.33) (n=40)	10.42 (2.45) (n=37)	9.76 (2.36) (n=34)								
6-minute walk test (metres)											
JII-BCS	304.03 (79.95) (n=40)	272.20 (71.51) (n=39)	343.41 (73.44) (n=35)	30.12 (-1.16,61.39)	0.06	32.2 (5.74,58.65)	0.02	22.24 (-9.72,54.2)	0.17	20.19 (-1.60,41.98)	0.07
Genesis II	299.09 (85.69) (n=40)	298.87 (65.23) (n=37)	363.39 (58.85) (n=34)								

^a adjusted for strata used in randomisation and for baseline scores.

Timed Up and Go Test – seconds to rise from chair, walk 3m and return to sitting; mean of three trials. A lower value indicates better function.

Six-minute walk test - metres walked in six minutes around a 20-metre circuit. A higher value indicates greater function.

Table S3. Balance functional ability, Star Excursion Test, from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	Two months after surgery	Six months after surgery
Anterior reach (cm)– non-operated leg			
JII-BCS	40.98 (7.69) (n=37)	43.20 (8.11) (n=33)	43.09 (7.58) (n=31)
Genesis II	40.54 (6.12) (n=36)	41.87 (6.18) (n=34)	42.16 (9.37) (n=32)
Anterior reach (cm) – operated leg			
JII-BCS	41.83 (6.85) (n=34)	36.84 (7.45) (n=32)	44.98 (21.54) (n=30)
Genesis II	37.72 (7.41) (n=36)	35.92 (6.94) (n=35)	40.00 (7.47) (n=32)
Postero-medial reach (cm) – non-operated leg			
JII-BCS	63.79 (10.87) (n=36)	65.10 (13.59) (n=33)	67.74 (14.59) (n=31)
Genesis II	63.57 (9.81) (n=34)	65.11 (10.78) (n=34)	66.44 (16.73) (n=32)
Postero-medial reach (cm) – operated leg			
JII-BCS	64.18 (11.69) (n=34)	62.44 (12.74) (n=32)	66.10 (14.10) (n=31)
Genesis II	59.32 (10.23) (n=36)	59.57 (8.87) (n=34)	65.59 (11.43) (n=32)
Postero-lateral reach (cm) – non-operated leg			
JII-BCS	60.10 (11.77) (n=34)	62.03 (15.15) (n=31)	63.21 (14.49) (n=29)
Genesis II	59.86 (11.45) (n=32)	62.16 (11.73) (n=32)	62.81 (16.63) (n=30)
Postero-lateral reach (cm) – operated leg			
JII-BCS	58.73 (11.01) (n=32)	57.78 (14.08) (n=29)	62.83 (14.86) (n=30)
Genesis II	55.39 (10.78) (n=33)	55.19 (8.02) (n=31)	60.19 (12.70) (n=30)

^a adjusted for strata used in randomisation and for baseline scores.

No statistical analysis as insufficient number of participants could undertake the Star Excursion Test.

Table S4. Double stance support (percentage of the gait cycle) from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months				Six months			
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value
Double stance support (% gait cycle)											
JII-BCS	0.30 (0.07) (n=39)	0.32 (0.11) (n=37)	0.25 (0.08) (n=35)	-0.02 (-0.06,0.02)	0.33	-0.03 (-0.07,0.00)	0.07	-0.01 (-0.04,0.02)	0.60	0.00 (-0.02,0.02)	0.69
Genesis II	0.32 (0.09) (n=40)	0.30 (0.07) (n=37)	0.25 (0.05) (n=34)								

^a adjusted for strata used in randomisation and for baseline scores.

Double stance support (% of gait cycle). A lower value indicates better performance

Table S5. Joint parameters from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months				Six months			
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value
During walking											
Hip ROM (degrees)											
JII-BCS	40.00 (6.04) (n=39)	38.90 (5.44) (n=38)	41.56 (6.01) (n=35)	2.24 (-0.48,4.95)	0.11	1.93 (-0.20,4.06)	0.07	3.01 (0.20,5.82)	0.04	1.64 (-0.11,3.39)	0.07
Genesis II	40.31 (5.93) (n=40)	41.03 (6.15) (n=37)	44.44 (5.48) (n=34)								
Ankle ROM (degrees)											
JII-BCS	24.84 (6.57) (n=39)	21.69 (4.54) (n=38)	24.54 (6.63) (n=35)	0.75 (-1.21,2.71)	0.45	1.36 (0.22,2.94)	0.09	-1.37 (-4.01,1.28)	0.31	0.08 (-1.89,2.04)	0.94
Genesis II	23.10 (5.52) (n=40)	22.43 (3.76) (n=37)	23.22 (3.77) (n=34)								
Knee peak extension moment (Nm/Kg)											
JII-BCS	-0.34 (0.09) (n=37)	-0.30 (0.10) (n=38)	-0.41 (0.08) (n=34)	-0.03 (-0.08,0.01)	0.16	-0.03 (-0.07,0.02)	0.22	-0.02 (-0.05,0.02)	0.45	-0.02 (-0.05,0.02)	0.35
Genesis II	-0.32 (0.08) (n=40)	-0.33 (0.10) (n=37)	-0.42 (0.08) (n=34)								
Knee peak flexion moment (Nm/Kg)											
JII-BCS	0.52 (0.25) (n=37)	0.38 (0.22) (n=38)	0.55 (0.27) (n=34)	-0.06 (-0.16,0.04)	0.22	-0.06 (-0.15,0.04)	0.26	0.11 (-0.23,0.02)	0.10	-0.07 (-0.19,0.05)	0.22
Genesis II	0.44 (0.21) (n=40)	0.34 (0.21) (n=37)	0.45 (0.25) (n=34)								
During stepping onto a stair											
Peak knee angular velocity (degrees/sec)											
JII-BCS	221.70 (88.35) (n=37)	198.09 (62.56) (n=34)	271.84 (95.48) (n=32)	54.31 (16.67,91.96)	0.01	51.63 (15.36,87.89)	0.01	50.01 (5.97,94.04)	0.03	35.15 (-3.09,73.39)	0.07
Genesis II	243.74 (84.05) (n=38)	251.04 (87.88) (n=34)	318.82 (71.32) (n=30)								

^a adjusted for strata used in randomisation and for baseline scores. Higher values for measures indicate better movement.

Table S6. Muscle activity during walking from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months				Six months			
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value
Peak activation Vastus Medialis (% gait cycle)											
JII-BCS	28.62 (27.23) n=39	25.42 (24.93) n=38	23.20 (22.72) n=35	-1.22 (-12.1,9.65)	0.82	-1.13 (-11.98,9.72)	0.84	1.86 (-9.45,13.16)	0.74	1.4 (-9.43,12.22)	0.80
Genesis II	30.10 (27.73) n=40	23.18 (22.66) n=38	24.64 (24.94) n=33								
Peak activation Vastus Lateralis (% gait cycle)											
JII-BCS	18.44 (12.15) n=39	17.29 (11.51) n=38	13.03 (5.61) n=35	1.20 (-5.67,8.07)	0.73	1.11 (-5.78,8.01)	0.75	5.59 (-1.52,12.71)	0.12	5.63 (-1.65,12.9)	0.13
Genesis II	20.23 (20.35) n=40	18.47 (17.46) n=38	18.79 (19.89) n=33								
Peak activation Tibialis Anterior (% gait cycle)											
JII-BCS	23.46 (24.74) n=39	18.97 (20.91) n=38	15.20 (14.27) n=35	0.47 (-9.18,10.13)	0.92	0.54 (-9.21,10.28)	0.91	4.68 (-3.92,13.28)	0.28	6.06 (-2.14,14.26)	0.14
Genesis II	28.88 (27.88) n=40	19.82 (20.76) n=38	19.61 (20.32) n=33								
Peak activation Biceps Femoris (% gait cycle)											
JII-BCS	25.03 (25.32) n=39	21.87 (21.34) n=38	35.77 (34.01) n=35	6.76 (-5.49,19.01)	0.28	5.71 (-6.42,17.84)	0.35	-9.78 (-25.33,5.76)	0.21	-10.97 (-26.69,4.74)	0.17
Genesis II	29.98 (28.00) n=40	29.16 (31.55) n=38	25.30 (28.86) n=33								
Peak activation Lateral head of Gastrocnemius (% gait cycle)											
JII-BCS	24.67 (17.24) n=39	23.87 (19.34) n=38	20.66 (15.99) n=35	-1.18 (-8.9,6.53)	0.76	-1.01 (-8.55,6.52)	0.79	-1.84 (-8.61,4.93)	0.59	-1.89 (-8.79,5.01)	0.59
Genesis II	25.23 (22.36) n=40	23.39 (14.60) n=38	20.00 (13.80) n=33								

^a adjusted for strata used in randomisation and for baseline scores

Table S7. Balance parameters from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)			Between groups comparison							
	Baseline	Two months after surgery	Six months after surgery	Two months				Six months			
				Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value	Unadjusted effect size (95% CI)	p- value	Adjusted ^a effect size (95% CI)	p- value
Can stand for 10 secs only on operated leg, eyes open (number)											
JII-BCS	13/40 (32.5%)	13/39 (33.3%)	15/35 (42.9%)	0.92 (0.34,2.49)	0.88	1.17 (0.34,4.07)	0.80	0.56 (0.20,1.51)	0.249	0.62 (0.17,2.28)	0.47
Genesis	10/40 (25.0%)	11/37 (29.7%)	10/34 (29.4%)								
II											
Seconds standing only on operated leg, eyes open (secs)											
JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	235.48 (176.94) (n=35)	7.00 (-48.53,62.53)	0.80	23.72 (-10.93,58.37)	0.18	82.42 (-147.17,-17.67)	0.01	-59.91 (-105.98,-13.85)	0.01
Genesis	188.25 (125.93) (n=40)	226.09 (137.15) (n=36)	158.14 (65.40) (n=34)								
II											
COP path length standing on both legs, eyes closed (mm)											
JII-BCS	205.04 (176.11) (n=38)	215.39 (99.27) (n=39)	235.48 (176.94) (n=35)	7.00 (-48.53,62.53)	0.80	23.72 (-10.93,58.37)	0.18	82.42 (-147.17,-17.67)	0.01	-59.91 (-105.98,-13.85)	0.01
Genesis	188.25 (125.93) (n=40)	226.09 (137.15) (n=36)	158.14 (65.40) (n=34)								
II											

^a adjusted for strata used in randomisation and for baseline scores

Resultant centre of pressure path length (COP cm) in double stance with eyes closed: lower path length indicates better balance ability.

Table S8. Non-operated leg cadence (steps/minute), step length and stride length from baseline to six months post-surgery (primary timepoint)

	Means (SDs) (number of participants)		
	Baseline	Two months after surgery	Six months after surgery
Cadence			
JII-BCS	107.37 (10.62) N=39	103.09 (13.21) N=37	113.09 (9.51) N=35
Genesis II	102.7(10.8 3) n=40	105.25(10.21) n=37	112.98(9.71) n=34
Step length			
JII-BCS	0.53(0.08) n=39	0.5(0.09) n=37	0.56(0.1) n=35
Genesis II	0.54(0.09) n=40	0.55(0.08) n=37	0.6(0.08) n=34
Stride length			
JII-BCS	1.06(0.17) n=39	1.04(0.18) n=37	1.15(0.21) n=35
Genesis II	1.08(0.17) n=40	1.11(0.15) n=37	1.2(0.16) n=34

Cadence (Steps/min), step length (m), and stride length (m) of non operative limb

Table S9. Post-operative clinical context: days of in-patient stay and consequences of surgery

	JII-BCS Number (%)	Genesis II Number (%)	Effect size (95% CI)	p-value
Length of in-patient stay				
Three days	14 (35%)	13 (33%)		
Four days	21 (53%)	21 (53%)		
Five days	4 (10%)	5 (13%)		
Six days	1 (3%)	1 (3%)	NA	0.749 ^a
Median	4.00	4.00		
(IQR)	(3.00, 4.00)	(3.00, 4.00)		
Revision surgery for implant related problems*				
No	40 (100%)	40 (100%)		
Yes	0	0	NA	NA
Complications				
No	34 (85%)	35 (88%)	1.00	
Yes	6 (15%)	5 (13%)	0.83 (0.23,3.01)	0.780
Change pain medication				
No	1 (3%)	4 (10%)		
Yes	39 (98%)	36 (90%)	-7.5% (-18.0,3.0)	0.359 ^a

NA = not appropriate; ^a Fisher exact test.

Length of stay, complications, revision for implant related problems and change in pain medication

*One patient in the JII-BCS had a revision of the polyethylene component for possible infection which was never diagnosed. As this is not implant related it is not included in the table.

Table S10. Composition of out-patient physiotherapy treatment received following TKR by JII-BCS and Genesis II groups.

	Number of sessions where exercises were performed: median (IQR)	
	JII-BCS (n=40)	Genesis II (n=40)
In-patient sessions (JII-BCS n=27, Genesis II n=26)		
Gait re-education	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Step exercise	1.0 (1.0, 1.0)	1.0 (1.0, 2.0)
Knee ROM flexion exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Static quadriceps exercise	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)
Inner range quadriceps exercise	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Straight leg raise exercise	0.0 (1.0, 1.0)	0.0 (1.0, 1.0)
Knee extension strengthening exercise in sitting	1.0 (0.0, 1.0)	1.0 (0.0, 2.0)
Ice treatment	1.0 (0.0, 2.0)	1.0 (0.0, 2.0)
Advice and education	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Other body region rehabilitation exercises	3.0 (2.0, 3.0)	2.5 (2.0, 3.0)
Out-patient settings (JII-BCS n=33, Genesis II n=35)		
Other body region rehabilitation exercises	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Seat pedal exercises	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
Static bike exercises	1.0 (0.0, 3.0)	1.0 (0.0, 5.0)
Cross-trainer exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Calf stretch exercises	0.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Gait re-education	1.0 (1.0, 2.0)	1.0 (1.0, 5.0)
Stair practice	1.0 (0.0, 1.0)	1.0 (0.0, 1.0)
Step exercise	1.0 (0.0, 4.0)	1.0 (1.0, 5.0)
Sit to stand exercise (without arms of chair)	1.0 (0.0, 4.0)	1.0 (0.0, 5.0)
Sit to stand exercise (with arms of chair)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Knee ROM flexion (sat in chair)	1.0 (1.0, 5.0)	1.0 (1.0, 5.0)
Knee strengthening extension exercise with resistance band	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Static quadriceps exercise	1.0 (1.0, 1.0)	1.0 (1.0, 4.0)
Straight leg raise exercise	1.0 (1.0, 1.0)	1.0 (1.0, 3.0)
Inner range quadriceps exercise	1.0 (1.0, 3.0)	1.0 (1.0, 3.0)
Proprioceptive exercises in standing	0.0 (0.0, 5.0)	1.0 (1.0, 5.0)
Proprioceptive exercises in standing (with support)	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)
Proprioceptive exercises in standing (with eyes shut)	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)
Advice and education	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)
Glutei strengthening exercise	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)

Table S11. Complications and adverse events

Complication type	Numbers of participants	
	JII-BCS	Genesis II
Post operative reaction to analgesia requiring admission		1
Pulmonary embolus	1	1
Wound haematoma / swelling	2	4
Postoperative bleeding requiring blood transfusion		1
Iliotibial tract discomfort		1
Chest infection	1	1
Urinary tract infection		1
Debridement and implant retention (DAIR)	1	

