

T. Tran, P. McEwen, Y. Peng, A. Trivett, R. Steele, W. Donnelly, G. Clark

From three instututions across Australia: Melbourne, Victoria; Townsville, Queensland; and Perth, Western Australia

# KNEE

# Kinematic alignment in total knee arthroplasty: a five-year prospective, multicentre, survivorship study

# Aims

The mid-term results of kinematic alignment (KA) for total knee arthroplasty (TKA) using image derived instrumentation (IDI) have not been reported in detail, and questions remain regarding ligamentous stability and revisions. This paper aims to address the following: 1) what is the distribution of alignment of KA TKAs using IDI; 2) is a TKA alignment category associated with increased risk of failure or poor patient outcomes; 3) does extending limb alignment lead to changes in soft-tissue laxity; and 4) what is the five-year survivorship and outcomes of KA TKA using IDI?

# Methods

A prospective, multicentre, trial enrolled 100 patients undergoing KA TKA using IDI, with follow-up to five years. Alignment measures were conducted pre- and postoperatively to assess constitutional alignment and final implant position. Patient-reported outcome measures (PROMs) of pain and function were also included. The Australian Orthopaedic Association National Joint Arthroplasty Registry was used to assess survivorship.

# Results

The postoperative HKA distribution varied from 9° varus to 11° valgus. All PROMs showed statistical improvements at one year (p < 0.001), with further improvements at five years for Knee Osteoarthritis Outcome Score symptoms (p = 0.041) and Forgotten Joint Score (p = 0.011). Correlation analysis showed no difference (p = 0.610) between the hip-knee-ankle and joint line congruence angle at one and five years. Sub-group analysis showed no difference in PROMs for patients placed within 3° of neutral compared to those placed > 3°. There were no revisions for tibial loosening; however, there were reports of a higher incidence of poor patella tracking and patellofemoral stiffness.

# Conclusion

PROMs were not impacted by postoperative alignment category. Ligamentous stability was maintained at five years with joint line obliquity. There were no revisions for tibial loosening despite a significant portion of tibiae placed in varus; however, KA executed with IDI resulted in a higher than anticipated rate of patella complications.

Cite this article: Bone Jt Open 2022;3-8:656-665.

Keywords: Knee, Arthroplasty, Replacement, Kinematic, Alignment

# Introduction

Satisfaction with the outcome of total knee arthroplasty (TKA) is highly variable, dependent on complex interactions between implant design, surgical technique, patient selection, and management of patient expectations.<sup>1-3</sup> Recently, there has been a growing interest in alternative alignment approaches that differ from traditional mechanical TKA alignment, which relies on establishing a straight limb through the centre of the knee by perpendicular resections to the mechanical axis of the femur and tibia.<sup>4,5</sup> In an attempt to improve patient satisfaction and outcomes, a kinematic alignment (KA) approach to the knee has been adopted by an increasing number of surgeons. The KA target has been described as correction of the

Correspondence should be sent to Gavin Clark; email: gavin@hipnknee.com.au

doi: 10.1302/2633-1462.38.BJO-2021-0214.R1

Bone Jt Open 2022;3-8:656–665.

Table I. Demographics of clinical trial patients.

Variable	Data
Sex, M:F, %	35:65
Side, left:right, %	45:55
Mean age at surgery, yrs, (SD; range)	68.0 (8.3; 49.2 to 85.6)
Meam follow-up length, yrs (SD; range)	4.7 (1.8; 0.5 to 6.6)
Mean preoperative BMI, kg/m <sup>2</sup> (SD; range)	30.9 (4.7; 20.2 to 41.3)

SD, standard deviation.

arthritic deformity to the pre-arthritic or native constitutional alignment of the individual patient by co-aligning the rotational axes of the femoral, tibial, and patella components with the three kinematic axes of the knee.<sup>6-10</sup>

KA of TKA continues to be a topic of discussion due to surgeon's differing interpretations of kinematic alignment and the mixed results, with little evidence at long-term follow-up of kinematically aligned TKAs. One method of executing a kinematically-aligned TKA was to use image derived instrumentation (IDI) (Shapematch Cutting Guides; OtisMed, USA), where the patient's native kinematic axes and joint lines were derived from 3D scans. This technology is no longer commercially available, but experience from the design surgeon's patient cohort has shown encouraging short-term results following kinematically aligned TKA.<sup>11,12</sup> However, a recent metaanalysis of randomized control trials using the same kinematic technique showed minimal difference to mechanical alignment.<sup>13</sup> The long-term evidence on nonmechanically aligned TKA stem from two sources, one from the aforementioned design surgeon reporting the ten-year survivorship,<sup>14</sup> and the other from a retrospective analysis reporting no difference in 20-year outcomes between patients who had a mechanical postoperative alignment within 3° of neutral and those who were outside the range.<sup>15</sup> While these studies report survivorship, an understanding of potential changes in limb and joint line obliquity over time is an area not yet explored.<sup>16</sup> Concerns often raised with KA, such as increased risk of tibial baseplate loosening, polyethylene wear, and patella maltracking, may be a result of residual imbalance, which develops over time from non-neutral alignment.<sup>16</sup>

Therefore, this paper seeks the answer to the following research questions: 1) what is the distribution of alignment of TKAs using IDI; 2) is a TKA alignment category associated with increased risk of failure or poor patient outcomes; 3) does KA TKA lead to changes in soft tissue laxity over time due to joint line obliquity; and 4) what is the five-year survivorship and outcomes of kinematically-aligned knees using IDI? These questions are addressed at mid-term follow-up using outcomes of a prospective, multicentre cohort of patients who received kinematically aligned TKAs executed with IDI and using data from the Australian Orthopaedic Association National Joint Arthroplasty Registry (AOANJRR).

# Methods

Clinical trial enrolment and follow-up methods. A prospective, multicentre trial enrolled 100 patients undergoing KA TKA between November 2010 and July 2011. The trial was conducted in accordance with the Declaration of Helsinki, and was approved by the local human research ethics committees at each participating institution (Dandenong Hospital (HREC Ref: 10050B), The Mater Hospital Pimlico (HREC Ref: MHS20100801-01, Royal Perth Hospital (HREC Ref: EC 2010/030), and St John of God (Subiaco HREC Ref: 1046), with consent collected prospectively at the preoperative visit. This trial was registered in the Australian New Zealand Clinical Trials Registry (registration no: ACTRN12610000192088) and ClinicalTrials.gov (Identifier: NCT02527161). The planned sample size was calculated on a 15-point improvement in the Knee Society Score<sup>17</sup> reported by Howell et al,<sup>10</sup> which represented a clinically significant improvement. Using a standard deviation (SD) of 35, 80% power, and significance level of 5% ( $\alpha = 0.05$ ) yielded a planned sample size of 87 patients. Accounting for potential lost to follow-up brought the target to 100 patients.

Patients selected for the study underwent TKA by five experienced arthroplasty surgeons (TT, PM, AT, BS, GC). Inclusion criteria allowed patients aged 50 to 90 years who had a primary diagnosis of osteoarthritis requiring a primary TKA and had the ability to undergo MRI scanning of the affected limb to be enrolled. Patients were excluded if they had a history of arthroscopic surgery, high tibial or femoral osteotomy, morbid obesity (BMI  $\ge$  40 kg/m<sup>2</sup>), varus or valgus malalignment  $\ge$  15°, presence of metal hardware within the affected limb, or were pregnant.

All patients received an MRI of the affected lower limb prior to surgery, with the data from this MRI allowing for the manufacture of patient-specific ShapeMatch Cutting Guides, of which the surgical procedure has been described previously.<sup>18</sup> Following preoperative plan approval by the surgeon, a standard surgical procedure for a Triathlon Cruciate Retaining Primary Total Knee System (Stryker, USA) was performed with either a cruciate retaining or a cruciate substituting polyethylene insert. Table I describes patient demographics.

Patients were followed up at six weeks, three and six months, and one, two, and five years postoperatively (Figure 1). Three months postoperatively patients under underwent CT scans of the lower limb in accordance to the Perth protocol.<sup>19</sup> The CT scans were used to confirm final component position by measuring the angle formed between the mechanical axis and the prosthetic joint line, which follows the principles for lateral distal femoral angle (LDFA) and medial proximal tibial angle (MPTA). LDFA was measured as the lateral angle formed between



Fig. 1 Strobe diagram outlining patient follow-up in the clinical trial.

the mechanical femoral axis and the prosthetic joint line of the distal femur.<sup>20</sup> MPTA was measured as the medial angle formed between the mechanical tibial axis and the prosthetic joint line of the proximal tibia.<sup>20</sup> Furthermore, patients also received anteroposterior, mediolateral, and long-leg weightbearing x-rays at one- and five-year follow-up. The long-leg x-rays were used to determine limb alignment using the hip-knee-ankle (HKA) angle, which was expressed as a deviation from 180° with a negative value for varus and a positive value for valgus alignment. The joint line congruence angle (JLCA) was also measured using a technique previously described.<sup>16</sup> All radiological measurements were completed by a single reviewer. Patient-reported outcome measures (PROMs) were evaluated using the full Knee Osteoarthritis Outcome Score (KOOS),<sup>21</sup> the pain and function components of the Knee Society Score (KSS),<sup>17</sup> the Forgotten Joint Score (FJS),<sup>22</sup> 12-item Short-Form Survey physical and mental composite scores,<sup>23</sup> and pain visual analogue scales measuring pain at rest and when mobilizing.<sup>24</sup>

**AOANJRR data.** To answer the fourth research question, we used a data matching procedure in the AOANJRR to track the KA TKAs enrolled in the clinical trial. This negated any lost to follow-up and ensured a full cohort was available for revision analysis. Further, a matched cohort in the AOANJRR of other Triathlon Cruciate Retaining Primary Total Knees performed over the same operative period (1 January 2011 to 31 December 2013) was assessed as a time-matched comparator. We assumed the majority of the comparator group (n = 19,692) of osteoarthritic patients were implanted with a mechanical alignment target, because at the time there were no other IDIs or calipered techniques available in the market to execute KA. The data-matching procedure accounted for those patients lost to follow-up in the clinical trial.

Statistical analysis. Data from the clinical trial is summarized using mean, median and standard deviation (SD) for continuous variables, and frequencies and percentages for categorical variables. Statistical analysis and graph preparation were completed using GraphPad Prism V7.0 (GraphPad Software, USA). Alignment as measured from all imaging methods is reported using a histogram of frequency distribution. A Pearson normality test was used to determine the Gaussian distribution of the data and subsequent statistical method for outcome analysis. Longitudinal PROM outcomes were determined using analysis of variance (ANOVA) with the Sidak correction for multiple comparison adjustment. Sub-group analysis by alignment classification was assessed using either linear regression or an unpaired t-test with Welch's correction for unequal variances. A p-value < 0.05 was considered significant.

Registry analysis was performed by an AOANJRR biostatistician (YP) using SAS software V9.4 (SAS Institute, USA), and was assessed using Kaplan-Meier estimates of survivorship to estimate the time to first revision. Censoring for death or closure of the database at the time of analysis was applied during assessment. Data is presented as unadjusted cumulative percent revision (CPR) with the 95% confidence interval (CI). Hazard ratios (HRs), calculated using Cox proportional hazard models and adjusted for age and sex, were used to make statistical comparisons between each group. All registry tests were two-tailed at the 5% level of significance, and p-values were not adjusted for multiple testing.

### Results

The mean postoperative HKA of the kinematically aligned knees measured on one-year postoperative x-rays was 0.4° valgus (-8° varus to 12°; Figure 2). TKA components in this cohort were placed with more femoral valgus (mean LDFA was 1.4° preoperative vs 1.8° postoperative), and with less tibial varus (mean MPTA was -2.5° preoperative vs -1.5° postoperative). In this study, 35% of the tibial components were placed with > 3° varus (Figure 2).

There was a significant improvement in PROMs after TKA (Table II). All scores showed significant improvements from preoperative to one-year postoperative timepoints, and significant improvements from one to five years were found for KOOS Symptoms (p = 0.041) and the FJS (p = 0.011). There was a trend toward improved range of motion (p = 0.064) and KOOS Pain (p = 0.081) over this time, although these did not reach statistical significance.

When we classified knees as those with standing HKA within  $\pm$  3° (n = 32) of the mechanical axis or outside  $\pm$  3° (n = 35), we found no statistical difference in any five-year outcome scores (Table III).

To evaluate soft-tissue integrity, we compared the correlation between JLCA and standing HKA at both oneand five-year follow-up. There was a strong correlation at both timepoints and no significant difference in slope (p = 0.610; Figure 3).

The AOANJRR data showed a significant difference in revision (HR 2.20 (1.05 to 4.64); p = 0.037) in KA TKA when compared against the same implant used over the reporting period, (Figure 4 and Table IV).

Seven revision surgeries occurred after kinematic TKA, which are described in Table V. None of the revisions in the kinematically aligned group was performed for loosening. In contrast, 131 tibial revisions occurred in the non-kinematic Triathlon TKAs during the same time (seven years' follow-up). The majority of revision surgeries were performed to address patella issues including mal-tracking, patellar pain or patellar erosion (four out of seven revisions). In these cases, the patella was not initially resurfaced, so a patella component was added during the revision. All other revisions were due to infection (three out of seven revisions).

Of the seven revisions from the AOANJRR, three were captured within the five-year follow-up in the clinical trial. One infection occurred within 54 days of surgery and was treated successfully by a two-stage wash-out and debridement and polyethylene exchange with implant retention. The second revision was performed due to degenerative arthritic changes on the native patella, which was resurfaced to a cemented all-polethylene component. The third revision was for patella erosion secondary to avascular necrosis and underwent resurfacing two years



#### Fig. 2

Alignment distribution of Kinematic total knee arthroplasties. Dotted line represents the mean value, arrow represents shift in the mean from preoperative to postoperative. a) One-year postoperative hip-knee-ankle angle measured on long leg weightbearing radiograph; b) preoperative and three-month postoperative lateral distal femoral angle derived from MRI/CT; and c) preoperative and three-month postoperative medial proximal tibial angle derived from MRI/CT.

postoperatively. Subsequently, there were four revisions traced through the AOANJRR, which occurred outside of follow-up in the clinical trial; two of these were for

mid-term infection, while the remaining revisions were patella related. Five surgical related adverse events were recorded during the clinical trial, which did not result in a revision. Of these, three manipulations under anaesthetic were performed within 90 days of surgery for stiffness, one patient received surgical repair for lateral subluxation of the patella within the same time frame, and the fifth patient underwent manipulation under anaesthetic for mid-flexion instability and pain three years postoperatively. Details of relative component position, which may have led to stiffness and instability, are detailed in Table VI.

### Discussion

To our knowledge, this is the first study to report outcomes and survivorship five years after KA TKA with IDI using a multicentre, multi-surgeon cohort of patients in conjunction with AOANJRR data. We found improved patient outcomes and no difference in PROMs between patients inside  $(\pm 3^{\circ})$  or outside (<-3° varus or > 3° valgus) traditional targets for knee alignment. Strong association between JLCA and HKA were identified, with no significant change measured over the follow-up period, indicating that the soft-tissue envelope in patients with high joint line obliquity remain stable over the first five years postoperatively. We report no revisions for aseptic loosening, but found patellar problems to be a risk of revision surgery.

Recent meta-analyses have shown at the very least clinical equivalence or superiority of KA in terms of ROM and early functional scores.<sup>13</sup> In our study, 49% of kinematic TKAs were placed in neutral, 25% were placed in varus and 26% were placed in valgus. We report good patient outcomes following kinematic TKA using IDI and equivalent outcomes and survivorship for patients classified as varus or valgus outliers (Tables III and IV), which is consistent with other reports.<sup>11</sup> Currently, the furthest follow-up on aKA cohort has been conducted by Howell et al.<sup>14</sup> In this study, 222 knees, which underwent KA using IDI guides, have a ten-year survivorship of 97.5% for revision for any reason and 98.4% for aseptic failure. The 100 knees in our clinical trial are a subset of all the KA TKAs done in Australia and New Zealand with IDI guides from 2011 to 2013. A recent joint registry study reviewing the 416 knees using the same IDI guides in the wider national cohort found zero revisions for tibial loosening at seven years' follow-up.<sup>25</sup> Our study supplements this registry study as it provides a spread on implant alignment, where 35% of these TKAs had tibiae placed in > 3° varus. Figure 4 suggests a difference in the survivorship between the two groups, but the larger combined joint registry paper shows the entire cohort of KA TKAs performing just as well as MA TKAs. This provides evidence regarding the concern of potentially poor survivorship of tibial components placed in high varus.

1	11	
ю	σı	

PROMs	Preoperative, mean (SD)	1 year, mean (SD)	p-value*	Five years, mean (SD)	p-value*
KOOS Pain	36.2 (17.6)	85.1 (16.7)	< 0.001	89.6 (24.3)	0.081
KOOS Symptoms	40.9 (20.9)	83.1 (15.3)	< 0.001	87.9 (13.1)	0.041
KOOS ADL	38.1 (20.1)	88.1 (14.4)	< 0.001	88.8 (15.1)	0.786
KOOS Sport & Rec	14.5 (21.0)	65.9 (27.3)	< 0.001	64.8 (27.0)	0.953
KOOS QoL	19.9 (17.6)	77.1 (20.8)	< 0.001	80.2 (21.7)	0.374
SF Physical Component Score	34.1 (7.5)	48.3 (8.9)	< 0.001	47.0 (8.7)	0.356
SF Mental Component Score	47.1 (12.5)	52.9 (9.3)	< 0.001	53.0 (10.4)	0.999
VAS Rest	5.8 (2.5)	1.2 (1.80	< 0.001	1.0 (1.7)	0.522
VAS Mobilization	7.3 (2.1)	1.4 (2.2)	< 0.001	1.2 (1.9)	0.524
International Knee Society Score - Pain	33.0 (14.1)	76.8 (16.5)	< 0.001	75.6 (14.0)	0.654
International Knee Society Score - Functional	43.5 (19.3)	77.0 (19.8)	< 0.001	71.4 (2.50	0.132
IKSS ROM	109 (17.0)	115 (12.0)	< 0.001	119 (13.0)	0.064
Mean FJS	N/A	54.5 (30.6)	N/A	68.8 (31.20	0.011

Table II. Longitudinal analysis of patient-reported outcome measure scores in the clinical trial (two-year data removed for brevity). All p-values are measured against sequential time-points.

\*Analysis of variance used in longitudinal data.

ADL, activities of daily living; FJS, Forgotten Joint Score; KOOS, Knee Osteoarthritis Outcome Score; QoL, quality of life; ROM, range of motion; SD, standard deviation; VAS, visual analogue scale.

**Table III.** Summary of patient-reported outcome scores at five-year follow-up, with patients divided into subgroups of within  $\pm$  3° and outside  $\pm$  3° (defined as a conservative safe limit) in postoperative limb alignment measured from long-leg weightbearing x-rays.

PROMs	HKA within ± 3° from the mechanical axis	HKA > 3° from the mechanical axis		
	n (mean; SD)	n (mean; SD)	Difference between means (95% CI)	p-value*
KOOS Pain	31 (88.1; 16.9)	34 (90.0; 12.8)	1.9 (-5.7 to 9.3)	0.637
KOOS Symptoms	31 (88.2; 15.0)	35 (81; 10.8)	-0.1 (-6.5 to 6.5)	0.996
KOOS ADL	31 (88.2; 16.8)	34 (89.8; 12.9)	1.6 (-5.9 to 9.1)	0.677
KOOS Sport & Rec	31 (65.3; 24.6)	31 (68.7; 28.4)	3.4 (-10.1 to 16.9)	0.617
KOOS QoL	31 (81.3; 22.2)	35 (79.8; 22.1)	-1.5 (-12.4 to 9.4)	0.786
SF PCS	31 (46.1; 9.3)	35 (48.3; 7.5)	2.3 (-2.0 to 6.5)	0.287
SF MCS	31 (51.2; 9.4)	35 (53.7; 11.8)	2.5 (-2.7 to 7.7)	0.337
/AS Rest	30 (0.9; 1.3)	35 (1.1; 1.8)	0.2 (-0.6 to 0.9)	0.626
/AS Mobilization	30 (1.1; 1.9)	35 (1.3; 2.0)	0.2 (-0.8 to 1.1)	0.791
KSS Pain	31 (76.1; 13.3)	32 (77.9; 10.6)	1.8 (-4.2 to 7.9)	0.546
KSS Functional	30 (68.2; 25.1)	34 (74.9; 23.3)	6.7 (-5.5 to 18.8)	0.275
KSS ROM	32 (119; 11.0)	35 (120.0; 14.0)	0.3 (-5.9 to 6.5)	0.932
-IS	31 (74.8; 36.0)	35 (64.3; 31.9)	-10.5 (-25.9 to 4.9)	0.179

\*Welch's t-test.

CI, confidence interval; FJS, Forgotten Joint Score; HKA, hip-knee-ankle; KOOS, Knee Osteoarthritis Outcome Score; PROMs, patient-reported outcome measures; QoL, quality of life; ROM, range of motion; SD, standard deviation; VAS, visual analogue scale.

However, a high number of patella-related revisions were recorded in the AOANJRR, with a further subgroup of surgical interventions required for poor patella tracking and stiffness, which highlights the need for continued follow-up of TKAs placed in KA.

One of the main concerns for KA is that the valgus of the femoral component might lead to an abnormal patella tracking and high-contact stresses, resulting in an increased patella complication rate.<sup>26</sup> We reported complications for stiffness and instability, which were surgically treated with full implant retention. Our complications may be a combination of both an inaccuracy in executing the planned rotation of the femur using IDI and a bias for components placed in more unintended valgus alignment. In our patient cohort, the preoperative limb alignment was centred around mild varus alignment, which has been described by Bellemans et al<sup>8</sup> in a non-arthritic population sample. However, the final component alignment was placed in slight valgus, which may be due to the high female bias, which others have shown to predispose towards a valgus alignment.<sup>8</sup> In regard to the inaccuracy, this study found a larger



Fig. 3

Scatterplot correlation between joint line convergence angle (JLCA) and standing hip-knee-ankle (HKA) angle at one and five years postoperatively.



Fig. 4

Cumulative percent revision of primary total knee arthroplasty by model (primary diagnosis = osteoarthritis).

change of the intended tibial component position, which has been reported for the same IDI technology,<sup>27</sup> and may have also contributed in the overall shift in valgus HKA. Additionally, excessive femoral component flexion stemming from inaccuracy of the same IDI technology has been linked to patellofemoral complications and instability.<sup>14</sup> Femoral component position in the sagittal plane may also impact the patellar tracking, as Borukhov et al<sup>28</sup> have reported a correlation between the LDFA and the trochlear anatomy in the sagittal plane, highlighting potential limitations of current TKA designs in resurfacing the patellofemoral joint. To avoid these issues in KA, we recommend the use of more accurate tools and 3D planning, such as computer-assisted surgery or robotics, to ensure higher accuracy in component placement.<sup>29–31</sup> Furthermore, resurfacing the patella at primary surgery may help minimize potential revisions.

Model	1 yr	2 yrs	3 yrs	4 yrs		
Shapematch, CPR (range)	2.1 (0.5 to 8.0)	2.1 (0.5 to 8.0)	3.1 (1.0 to 9.3)	5.2 (2.2 to 12.0)		
Other Triathlon, CPR (range)	0.8 (0.7 to 1.0)	1.6 (1.4 to 1.8)	2.0 (1.8 to 2.2)	2.3 (2.1 to 2.5)		
Model	5 yrs	6 yrs	7 yrs	8 yrs		
Shapematch, CPR (range)	5.2 (2.2 to 12.0)	6.3 (2.9 to 13.4)	6.3 (2.9 to 13.4)	7.4 (3.6 to 14.9)		
Other Triathlon, CPR (range)	2.5 (2.3 to 2.8)	2.7 (2.5 to 3.0)	3.0 (2.7 to 3.2)	3.4 (3.1 to 3.7)		

Table IV. Yearly cumulative percent revision of Triathlon CR/Triathlon primary total knee arthroplasty by model between 1 January 2011 to 31 December 2013 (primary diagnosis = osteoarthritis).

CPR, cumulative percent revision.

Table V. Revision diagnosis of Triathlon CR/Triathlon primary total knee arthroplasty by model between 1 January 2011 to 31 December 2013 (primary diagnosis = osteoarthritis).

	Shapematch	Other Triathlon n (% primaries revised; % revisions)		
Revision diagnosis	n (% primaries revised; % revisions)			
Infection	3 (3.1; 42.9)	185 (0.9; 30.9)		
Instability		74 (0.4; 12.4)		
Loosening		73 (0.4; 12.2)		
Patellofemoral pain	1 (1.0; 14.3)	67 (0.3; 11.2)		
Patella erosion	1 (1.0; 14.3)	57 (0.3; 9.5)		
Pain	1 (1.0; 14.3)	47 (0.2; 7.8)		
Arthrofibrosis		23 (0.1; 3.8)		
Fracture		11 (0.1; 1.8)		
Malalignment		11 (0.1; 1.8)		
Incorrect sizing		9 (0.0; 1.5)		
Wear tibial insert		9 (0.0; 1.5)		
Lysis		8 (0.0; 1.3)		
Patella maltracking	1 (1.0; 14.3)	7 (0.0; 1.2)		
Implant breakage tibial insert		5 (0.0; 0.8)		
Synovitis		4 (0.0; 0.7)		
Metal-related pathology		2 (0.0; 0.3)		
Wear patella		1 (0.0; 0.2)		
Other		6 (0.0; 1.0)		
Total revision	7 (7.2; 100.0)	599 (3.0; 100.0)		
Total primary		19,692		
-	97			

Table VI. Component position for patients reporting stiffness or instability.

Complication	Treatment	Time since surgery	HKA (+ valgus), °	Combined flexion and posterior slope, °	Tibial rotation relative to posterior condylar axis <b>(+ external),</b> °
Stiffness	MUA	30 days	-2.4	6	-1
Stiffness	MUA	90 days	4.3	16	1
Stiffness	MUA	90 days	5.2	5	7
Lateral patella subluxation	Surgical repair	90 days	N/A	4	4
Mid-flexion instability and pain	MUA	3 yrs	-1.0	6	8

HKA, hip-knee-ankle; MUA, manipulation under anaesthetic; N/A, not available.

Theoretically, KA should also restore the native joint lines and constitutional alignment without releasing ligaments, which provides more physiological strains in the collateral ligaments than a mechanically-aligned TKA. Furthermore, a kinematically-aligned TKA may result in a joint line, which has a more parallel orientation in relation to the floor during single- and double-leg standing, and more neutral weightbearing than a mechanically-aligned TKA.<sup>32</sup> We found a similar correlation between HKA and JLCA to previous work by one of the authors,<sup>16</sup> and report no change in this relationship over time. The consistency of this correlation indicates clinically that joint line obliquity in KA does not lead to developmental instability due to increasing ligament laxity over time. This may be linked to the lower adduction moment in KA, and explains the low risk of varus tibial loosening in this cohort.<sup>33</sup> The correlations between these findings and the biomechanics through gait warrant further investigation.

This study has several limitations. First, patient x-rays were not assessed for radiological loosening. However, patients generally complain about their knee when radiological changes occur. Second, the comparison group in the AOANJRR includes a range of techniques, and even though majority of surgeons tend to aim for a mechanical alignment, we cannot confirm this for all AOANJRR cases. Third, the interpretation of the results pertains to PCL-sparing TKA, and further work is required to determine the outcomes of KA with posterior stabilized implants. Finally, patients were operated by different surgeons, and the soft-tissue balancing technique may have differed between them.

In conclusion, this paper reports equivalent outcomes regardless of alignment category for KA TKA executed with IDI. There were no revisions for loosening, with significant portion of tibiae placed in varus. We also report the novel finding of consistent association over time between the JLCA and HKA, which may add confidence in extending alignment boundaries. There was a higher than anticipated rate of patella complications which may be due to the poor rotational accuracy of IDI. We advocate for more accurate tools when executing KA, along with continued follow-up to determine the long-term outcomes of KA.

### Take home message

- Kinematic alignment produces good patient outcomes and stable ligament laxity at five years for a wide range of hipknee-ankle angles and joint line obliguities.

- There were no incidents of tibial loosening but a higher than anticipated rate of patella complications when performing kinematic alignment with image derived instrumentation.

#### References

- 1. Noble PC, Conditt MA, Cook KF, Mathis KB. The John Insall Award: Patient expectations affect satisfaction with total knee arthroplasty. Clin Orthop Relat Res. 2006:452:35-43
- 2. Dai Y, Scuderi GR, Bischoff JE, Bertin K, Tarabichi S, Rajgopal A, et al. Anatomic tibial component design can increase tibial coverage and rotational alignment accuracy: a comparison of six contemporary designs. Knee Surg Sports Traumatol Arthrosc. 2014;22(12):2911-2923
- 3. Ibrahim MS, Khan MA, Nizam I, Haddad FS. Peri-operative interventions producing better functional outcomes and enhanced recovery following total hip and knee arthroplasty: an evidence-based review. BMC Med. 2013;11:1-9.
- 4. Oussedik S, Abdel MP, Victor J, Pagnano MW, Haddad FS. Alignment in total knee arthroplasty. Bone Joint J. 2020;102-B(3):276-279.
- 5. Begum FA, Kayani B, Magan AA, Chang JS, Haddad FS. Current concepts in total knee arthroplasty. Bone Jt Open. 2021;2(6):397-404.
- 6. Howell SM, Howell SJ, Hull ML, Assessment of the radii of the medial and lateral femoral condyles in varus and valgus knees with osteoarthritis. J Bone Joint Surg Am. 2010:92-A(1):98-104
- 7. Eckhoff DG, Bach JM, Spitzer VM, et al. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. J Bone Joint Surg Am. 2005;87 Suppl 2-A:71-80.

- 8. Bellemans J, Colyn W, Vandenneucker H, Victor J. The Chitranjan Ranawat award: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. Clin Orthop Relat Res. 2012;470(1):45-53.
- 9. MacDessi SJ, Griffiths-Jones W, Harris IA, Bellemans J, Chen DB. Coronal Plane Alignment of the Knee (CPAK) classification. Bone Joint J. 2021;103-B(2):329-337
- 10. Howell SM, Kuznik K, Hull ML, Siston RA. Results of an initial experience with custom-fit positioning total knee arthroplasty in a series of 48 patients. Orthopedics. 2008:31(9):857-863
- 11. Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML. Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? Clin Orthop Relat Res. 2013;471(3):1000-1007.
- 12. Howell SM, Papadopoulos S, Kuznik K, Ghaly LR, Hull ML. Does varus alignment adversely affect implant survival and function six years after kinematically aligned total knee arthroplasty? Int Orthop. 2015;39(11):2117-2124.
- 13. Woon JTK, Zeng ISL, Calliess T, et al. Outcome of kinematic alignment using patient-specific instrumentation versus mechanical alignment in TKA: a metaanalysis and subgroup analysis of randomised trials. Arch Orthop Trauma Surg. 2018;138(9):1293-1303.
- 14. Howell SM, Shelton TJ, Hull ML. Implant survival and function ten years after kinematically aligned total knee arthroplasty. J Arthroplasty. 2018;33(12):3678-3684.
- 15. Abdel MP, Ollivier M, Parratte S, Trousdale RT, Berry DJ, Pagnano MW, et al. Effect of postoperative mechanical axis alignment on survival and functional outcomes of modern total knee arthroplasties with cement: a concise follow-up at 20 years. J Bone Joint Surg Am. 2018;100-A(6):472-478.
- 16. McEwen P, Balendra G, Doma K. Medial and lateral gap laxity differential in computer-assisted kinematic total knee arthroplasty. Bone Joint J. 2019:101-B(3):331-339
- 17. Insall JN, Dorr LD, Scott RD, Norman W. Rationale, of The Knee Society Clinical Rating System. Clin Orthop Relat Res. 1989;248(amp;NA):13.
- 18. Clark G, Leong A, McEwen P, Steele R, Tran T, Trivett A, et al. Intra-operative reliability of ShapeMatch cutting guide placement in total knee arthroplasty. Comput Aided Surg. 2013;18(5-6):159-165.
- 19. Chauhan SK, Clark GW, Lloyd S, Scott RG, Breidahl W, Sikorski JM, et al. Computer-assisted total knee replacement. A controlled cadaver study using A multiparameter quantitative CT assessment of alignment (the Perth CT Protocol). J Bone Joint Surg Br. 2004;86-B(6):818-823.
- 20. Nam D, Shah RR, Nunley RM, Barrack RL. Evaluation of the 3-dimensional, weightbearing orientation of the normal adult knee. J Arthroplasty. 2014;29(5):906-911.
- 21. Roos HP, Lohmander LS, Ekdahl C, Beynnon BD. Knee Injury and Osteoarthritis Outcome Score (KOOS)--development of a self-administered outcome measure. J Orthop Sports Phys Ther. 1998;28(2):88-96.
- 22. Behrend H, Giesinger K, Giesinger JM, Kuster MS. The "forgotten joint" as the ultimate goal in joint arthroplasty: validation of a new patient-reported outcome measure. J Arthroplasty. 2012;27(3):430-436.
- 23. Jenkinson C, Layte R, Jenkinson D, et al. A shorter form health survey: can the SF-12 replicate results from the SF-36 in longitudinal studies? J Public Health Med. 1997;19(2):179-186.
- 24. Wewers ME, Lowe NK. A critical review of visual analogue scales in the measurement of clinical phenomena. Res Nurs Health. 1990;13(4):227-236.
- 25. Klasan A. de Steiger R. Holland S. Hatton A. Vertullo CJ. Young SW. et al. Similar risk of revision after kinematically aligned, patient-specific instrumented total knee arthroplasty, and all other total knee arthroplasty: combined results from the Australian and New Zealand Joint Replacement Registries. J Arthroplasty. 2020;35(10):2872-2877
- 26. Ishikawa M, Kuriyama S, Ito H, Furu M, Nakamura S, Matsuda S, et al. Kinematic alignment produces near-normal knee motion but increases contact stress after total knee arthroplasty: A case study on A single implant design. Knee. 2015:22(3):206-212
- 27. Thienpont E, Schwab P-E, Fennema P. Efficacy of patient-specific instruments in total knee arthroplasty: a systematic review and meta-analysis. J Bone Joint Surg Am. 2017;99-A(6):521-530
- 28. Borukhov I, Esposito CI, Ismailidis P, et al. The trochlear sulcus of the native knee is consistently orientated close to the sagittal plane despite variation in distal condylar anatomy. Knee Surg Sports Traumatol Arthrosc. 2021.
- 29. Clement ND, Calliess T, Christen B, Deehan DJ. An alternative technique of restricted kinematic alignment of the femur and gap balanced alignment of the tibia using computer aided navigation. Bone Joint Res. 2020;9(6):282-284

664



- 30. Abhari S, Hsing TM, Malkani MM, et al. Patient satisfaction following total knee arthroplasty using restricted kinematic alignment. Bone Joint J. 2021;103-B(6 Supple A):59-66.
- 31. O'Callaghan WB, Gouk C, Wilkinson MPR, Haztratwala K. Computer-aided surgery-navigated, functional alignment total knee arthroplasty: a surgical technique. Arthroplast Today. 2022;14:121-127.
- 32. Matsumoto T, Takayama K, Ishida K, Hayashi S, Hashimoto S, Kuroda R, et al. Radiological and clinical comparison of kinematically versus mechanically aligned total knee arthroplasty. Bone Joint J. 2017;99-B(5):640-646.
- 33. Shelton TJ, Nedopil AJ, Howell SM, Hull ML. Do varus or valgus outliers have higher forces in the medial or lateral compartments than those which are in-range after a kinematically aligned total knee arthroplasty? limb and joint line alignment after kinematically aligned total knee arthroplasty. Bone Joint J. 2017;99-B(10):1319-1328.

- Author information: T. Tran, FRACS, Director of Orthopaedic Surgery
- A. Trivett, FRACS, Orthopaedic Surgeon
- R. Steele, FRACS, Orthopaedic Surgeon Monash Health, Melbourne, Victoria, Australia.
- P. McEwen, FRACS, Orthopaedic Surgeon, Mater Hospital Pimlico, Townsville, Queensland, Australia.
- V. Peng, IMIS, MMed(Epi & Stats), Statistician, South Australian Health and Medical Research Institute, Adelaide, South Australia, Australia.
- W. Donnelly, FRACS, Assistant Deputy Director, Australian Orthopaedic Association National Joint Replacement Registry, Adelaide, South Australia, Australia. G. Clark, FRACS, Orthopaedic Surgeon, Royal Perth Hospital, Perth, Western
- Australia, Australia; St John of God Subiaco, Perth, Western Australia, Australia.

#### Author contributions:

 T. Tran: Funding acquisition, Investigation, Methodology, Writing – original draft.
 P. McEwen: Funding acquisition, Investigation, Methodology, Formal analysis, Writing – original draft.

- Y. Peng: Formal analysis, Writing review & editing.
- A. Trivett: Investigation, Writing review & editing.
- R. Steele: Investigation, Writing review & editing.
   W. Donnelly: Writing review & editing.
- G. Clark: Funding acquisition, Investigation, Methodology, Writing review & editing

#### Funding statement:

The author(s) disclose receipt of the following financial or material support for the research, authorship, and/or publication of this article: Stryker Australia Pty Ltd.

#### ICMIE COI statement:

T. Tran reports that the clinical trial was sponsored by Stryker Orthopaedics, which is related to this work, and consultancy for Stryker and Medacta, and payments or honoraria for lectures, presentations, speakers bureaus, manuscript writing, or educational events from Osteosynthesis and Trauma Foundation South Pacific Chapter and AO Alliance, which is unrelated.

Acknowledgements: We would like to acknowledge that data and analysis by the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) was provided free of charge. We would like to thank Dr Jarome Bentley for assistance in measuring radiographic alignment. Finally, we would like to thank Stryker for the funding and support in running this sponsored clinical trial.

#### Ethical review statement:

Ethics was approved at each institution (Dandenong Hospital; HREC Ref: 10050B, The Mater Hospital Pimlico; HREC Ref: MHS20100801-01, Royal Perth Hospital HREC Ref: EC 2010/030, St John of God Subiaco; HREC Ref: 1046).

Open access funding
The authors report that they received open access funding for this manuscript from Stryker Australia Pty Ltd

© 2022 Author(s) et al. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial No Derivatives (CC BY-NC-ND 4.0) licence, which permits the copying and redistribution of the work only, and provided the original author and source are credited. See https://creativecommons.org/licenses/ by-nc-nd/4.0/