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Functional Alignment Restores Native Kinematics More Consistently than Mechanical Axis Alignment in Total Knee Arthroplasty

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Faculty Disclosure Information

Our disclosures are:

- S. L. Whitehouse reports grants or contracts from Stryker, unrelated to this study.
- D. Collopy reports grants or contracts, consulting fees, and participation on a data safety monitoring board or advisory board from Stryker, as well as payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events from Stryker, Zimmer Biomet, and AO Recon, all of which were unrelated to this study.
- G. W. Clark reports grants or contracts, consulting fees, payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events, and support for attending meetings and/or travel from Stryker, unrelated to this study.
- The Verasense monitors were provided by Stryker (USA).



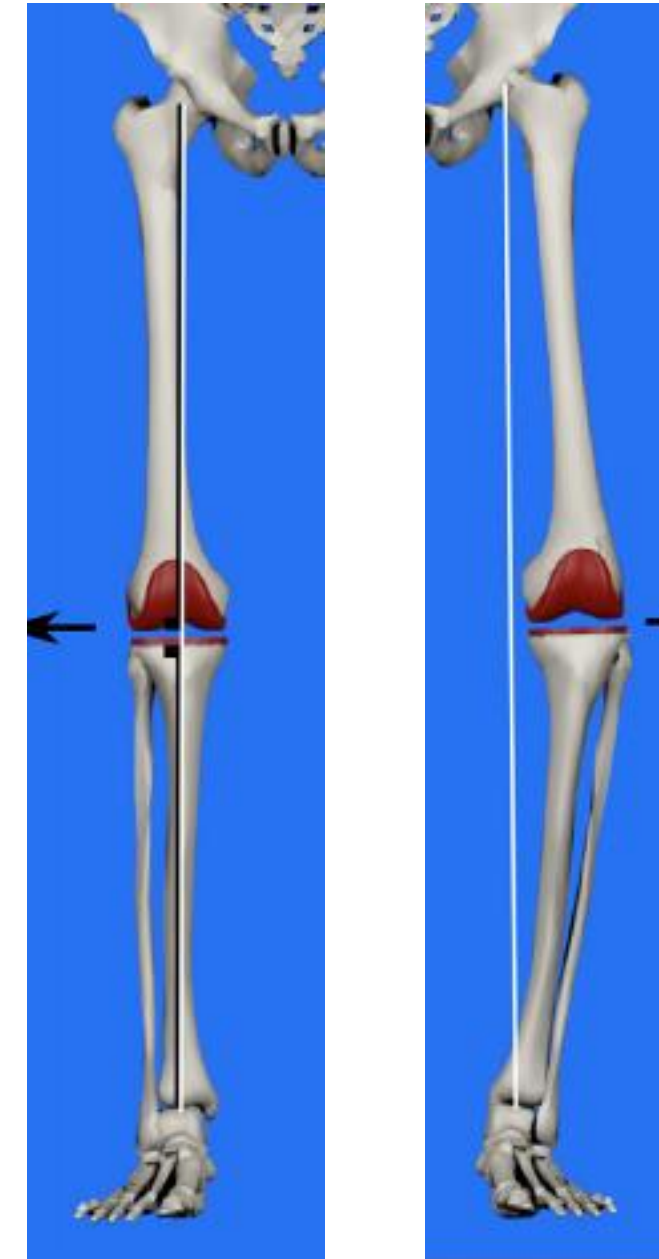
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Introduction

- Adjusted Mechanical Alignment (aMA) and Functional Alignment (FA) are both recognised treatments for patients undergoing total knee arthroplasty (TKA)¹⁻³.
- aMA is a “systematic alignment” technique whereas FA is a form of “individualised alignment”.
- The native femur is known to disproportionately roll back further on the lateral tibial plateau than the medial side during flexion, resulting in a medial pivot pattern of movement^{4,5,6}.
- The aim of this study was to assess the kinematic pattern observed in patients undergoing robotically assisted (RA) TKAs using FA and aMA techniques.



Methods 1



- After ethical approval and registration with the Australian, New Zealand Clinical Trials Registry (ANZCTR: U1111- 1257- 2291), a prospective cohort were consented and enrolled into a larger randomized controlled trial where 100 patients were randomized to either an aMA or FA-TKA⁷.
- 60 consecutive patients also consented to this study; to have a Verasense pressure monitor (Stryker, USA) of the corresponding polyethylene insert thickness inserted, after the definitive prostheses were implanted to examine the kinematic pattern.
- The contact points were recorded between the femoral component and the pressure monitor, in both the medial and lateral compartments, as the knee was taken through a range of motion, using the standard technique for the Verasense pressure monitor ^{8,9}. The contact pressures at 0, 45 and 90 degrees of flexion were also recorded.
- Prospectively collected PROMs and Demographic data was obtained preoperatively and also assessed at 12 months following surgery along with range of motion and strength testing.



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Methods 2

- Patients and Physiotherapists collecting data post-operatively were blinded to the treatment arm. The surgeon was also blinded to the Verasense screen whilst readings were taken.
- All patients underwent a Robotic-Assisted TKA using the Mako Robotic Arm Interactive Orthopaedic system (TKA1.0; Stryker) receiving a CR implant (Triathlon Total Knee implant; Stryker).
- A screenshot of the Verasense tracking image was calibrated to the size of the tibial implant. This produced a scaled image whereby the true translation of both the medial and lateral tibiofemoral contact points could be calculated (Figure 1).
- A ratio of the rollback in both the medial and lateral compartment was then calculated. A lateral: medial ratio of 1.5 or greater was defined as a medial pivot, a ratio of less than 0.66 was defined as a lateral pivot, and a ratio between 0.66 and 1.5 was defined as symmetrical rollback.

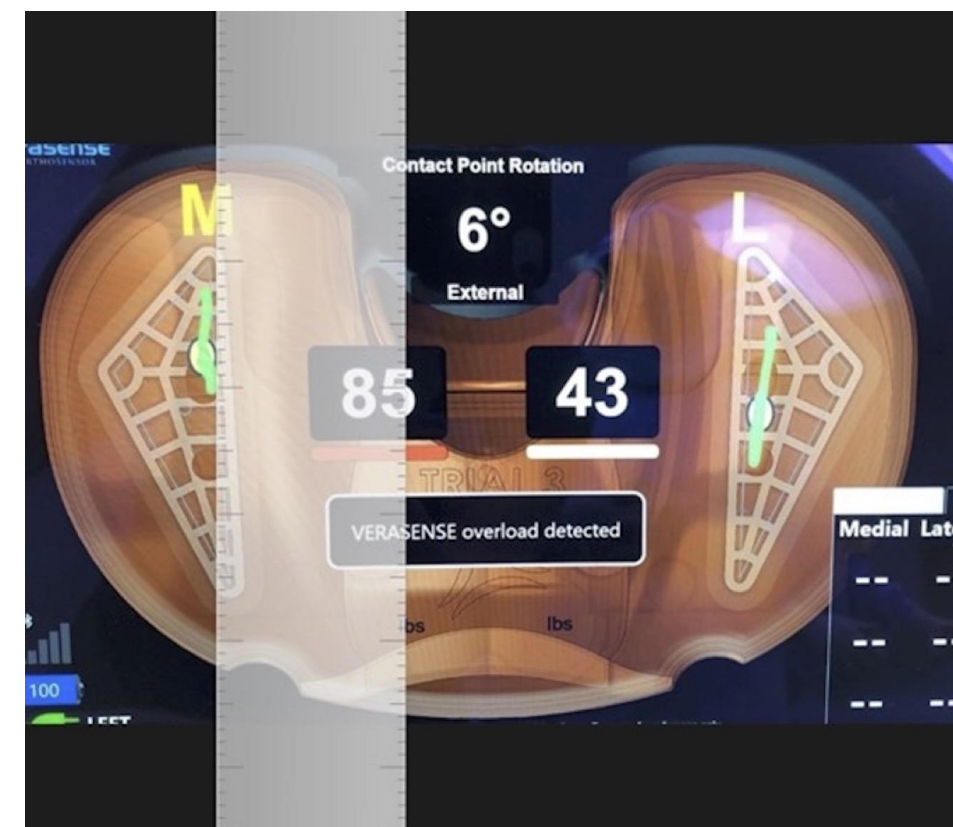


Figure 1: Calculation of amount of rollback in the medial and lateral tibiofemoral compartments.



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Surgical Technique

- The FA technique and alignment limits used in this study have previously been described¹⁰. Components were initially set to a kinematic plan on the Mako virtual bone model, with tibial rotation set to Akagi's line¹¹, and tibial slope set to match the lateral plateau.
- Those undergoing aMA had the implants on the virtual bone model placed perpendicular to the mechanical axis with alteration of up to 2° to optimize balance. The femoral rotation was set parallel to the transepicondylar axis and the tibial cut was fixed to 3° of posterior slope.
- If a coronal imbalance of 2 mm or greater was present due to the alignment boundaries being reached, then soft-tissue releases were performed at the trialling stage.

Alignment Parameter	Functional Alignment (FA)	Adjusted Mechanical Alignment (aMA)
HKA	-6° to 3°	-2° to 2°
Femoral coronal	-3° to 6°	-2° to 2°
Femoral flexion	0° to 7°	0° to 7°
Femoral rotation to TEA	-6° to 6°	-2° to 2°
Tibial coronal	-6° to 3°	-2° to 2°
Tibial slope	0° to 7°	3°

Table1: Alignment boundaries for Functional alignment and adjusted Mechanical alignment. Varus is negative and valgus is positive. Internal rotation is negative and external rotation is positive.



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Hypotheses and Example Kinematic Patterns



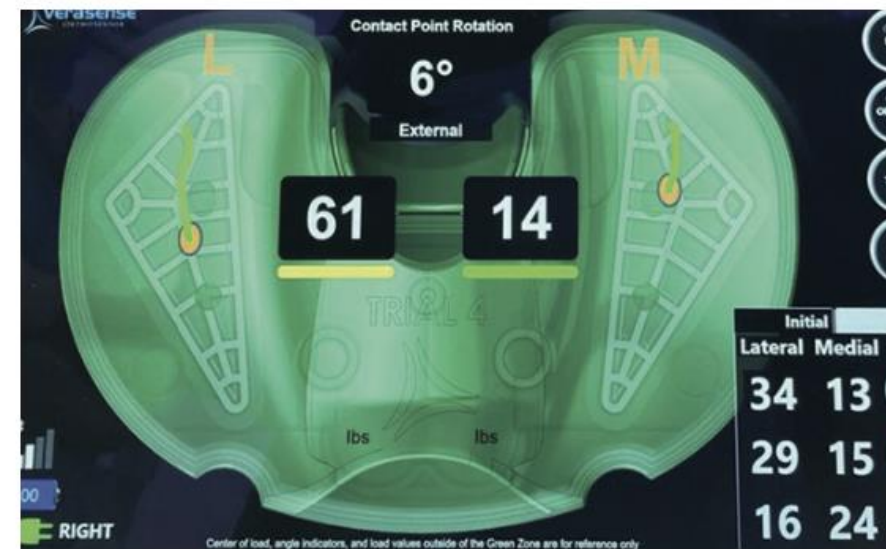
Our primary hypothesis being that there would be no difference between the kinematic pattern observed between those patients undergoing an aMA and FA- TKA.

Our secondary hypothesis was that there would be no effect of kinematic patterns observed on clinical outcomes at 12 months postoperatively.

Medial Pivot



Symmetrical Roll Back



Lateral Pivot



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Results 1

- **Kinematic Pattern**

- FA-TKA produced a medial pivot in 58.6% of cases (17/29), symmetrical roll back in 37.9% (11/29) and a lateral pivot in 3.4% (1/29). Patients with an aMA-TKA, 19.4% (6/31) produced a medial pivot, 45.2% (14/31) had symmetrical rollback and 35.5% (11/31) a lateral pivot ($p < 0.001$, chi-squared test).

- **Clinical Outcomes**

- Those that produced a medial pivot had significantly higher Forgotten Joint Score ($p = 0.005$), EQ- 5D- 5L VAS ($p = 0.003$), and VAS rest scores ($p = 0.004$, all Mann- Whitney U test) than those that did not produce a medial pivot.
- There were no significant differences in the OKS or KOOS JR between the alignment groups or kinematic pattern produced.
- The one-year Kujala scores were significantly lower in those patients that produced a lateral pivot ($p = 0.017$ vs medial pivot; $p = 0.049$ vs symmetrical rollback; Kruskal- Wallis test) compared to other kinematic patterns.

- **Balance**

- All 60 knees were balanced on the MAKO virtual bone model, with 19 (61.3%) in the aMA group and 23 (79.3%) in the FA group having zero difference in maximal gaps in extension between compartments, the remainder being within 1mm ($p = 0.128$; χ^2 test). The mean was 2.0 (± 1.4) mm of greater flexion laxity on the lateral side, with no statistical difference between the aMA and FA groups (1.9mm (± 1.5) vs 2.1mm (± 1.4); $p = 0.406$, Mann-Whitney U test).
- There was no significant difference in the number of cases with greater than 15 psi imbalance in extension between aMA (19/31) and FA (16/29) ($p = 0.631$, chi-squared) on the pressure monitor.



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Results: One-year outcomes by alignment group

Variable	FA	aMA	p-value*
Flexion ROM	125.1 (SD 5.4, 115-135)	124.8 (SD 6.0, 118-140)	p=0.663
EQ5D VAS	83.4 (SD 14.1, 35-100)	80.0 (SD 15.0, 45-100)	p=0.288
FJS	64.9 (SD 32.3, 2.1-95.8)	68.4 (SD 23.5, 2.1-100)	p=0.711
KOOS Jr	80.7 (SD 14.9, 44.9-100)	82.9 (SD 13.3, 52.5-100)	p=0.619
Kujala	77.2 (SD 16.5, 29-98)	76.6 (SD 15.1, 38-98)	p=0.673
OKS	41.9 (SD 7.2, 19-48)	41.8 (SD 5.7, 25-48)	p=0.517
Satisfaction			
Normal	79.2 (SD 26.9, 18-100)	81.3 (SD 21.8, 9-100)	p=0.271
Medical care	87.1 (SD 22.3, 20-100)	87.4 (SD 18.5, 24-100)	p=0.243
Pain	9.0 (SD 11.5, 0-40)	14.7 (SD 20.68, 0-86)	p=0.352
VAS			
Worst pain	14.6 (SD 19.6, 0-67)	21.0 (SD 26.0, 0-99)	p=0.234
Rest pain	8.6 (SD 19.2, 0-89)	8.7 (SD 12.8, 0-54)	p=0.190
Strength			
Flexion	8.3 (SD 4.7, 2.4-21.6)	8.9 (SD 3.9, 2.5-15.8)	p=0.332
Extension	25.7 (SD 14.1, 10.2-72.4)	26.8 (SD 9.0, 12.8-52.1)	p=0.332
Stability			
20°	6.6 (SD 1.6, 4.0-10.1)	6.8 (D 1.7, 3.1-10.1)	p=0.651
90° neutral	5.0 (SD 1.1, 3.5-8.9)	4.9 (SD 1.1, 3.1-7.2)	p=0.627
90° full	6.3 (SD 1.6, 3.5-11.5)	5.9 (SD 1.3, 3.5-10.0)	p=0.559



Table 2 Mean (SD, range) one-year outcomes by alignment group. No adjustment for multiple testing. *Mann-Whitney U-test

Results 3: One- year outcomes by kinematic pattern



Variable	Medial pivot	Symmetrical roll back	Lateral pivot	p-value*
Flexion ROM	125.5 (5.2; 117-135)	123.5 (5.9; 115-140)	126.7 (5.9; 120-140)	p=0.182
EQ5D VAS	87.9 (11.5; 50-100)	77.2 (15.2; 35-98)	79.3 (15.3; 49-100)	p=0.013
FJS	77.7 (22.9; 16.7-95.8)	59.8 (29.9; 2.1-100)	60.2 (27.8; 2.1-97.9)	p=0.037
KOOS Jr	84.5 (12.6; 54.8-100)	82.7 (15.6; 44.9-100)	75.2 (11.6; 54.8-92.0)	p=0.122
Kujala	80.8 (14.3; 42-98)	77.9 (16.8; 29-98)	67.3 (12.7; 49-91)	p=0.016
OKS	43.2 (5.6; 24-48)	41.7 (6.5; 19-48)	39.6 (7.3; 25-47)	p=0.251
Satisfaction				
Normal	87.2 (16.9; 27-100)	78.0 (26.1; 20-100)	71.7 (29.8; 9-92)	p=0.118
Medical care	92.8 (14.4; 31-100)	87.2 (20.4; 20-100)	76.9 (26.2; 24-97)	p=0.015
Pain	6.6 (10.0; 0-39)	11.6 (15.1; 0-55)	23.0 (25.9; 2-86)	p=0.019
VAS				
Worst pain	10.6 (15.0; 0-60)	15.9 (19.3; 0-67)	35.8 (33.6; 0-99)	p=0.044
Rest pain	2.4 (4.9; 0-15)	12.8 (21.9; 0-89)	11.4 (11.4; 0-38)	p=0.010
Strength				
Flexion	9.3 (4.8; 2.4-21.6)	7.9 (4.1; 2.8-15.8)	8.7 (3.7; 2.5-15.1)	p=0.578
Extension	27.6 (13.9; 11.0-72.4)	24.2 (11.4; 10.2-52.1)	27.6 (7.8; 14.8-38.4)	p=0.433
Stability				
20°	6.4 (1.7; 3.6-9.3)	6.6 (1.8; 3.1-10.1)	7.2 (1.1; 5.7-9.1)	p=0.355
90° neutral	4.8 (0.8; 3.1-6.9)	4.9 (1.3; 3.1-8.9)	5.3 (1.2; 3.5-7.2)	p=0.510
90° full	5.8 (1.0; 3.5-7.4)	6.1 (1.7; 3.5-11.5)	6.6 (1.4; 5.1-10.0)	p=0.400



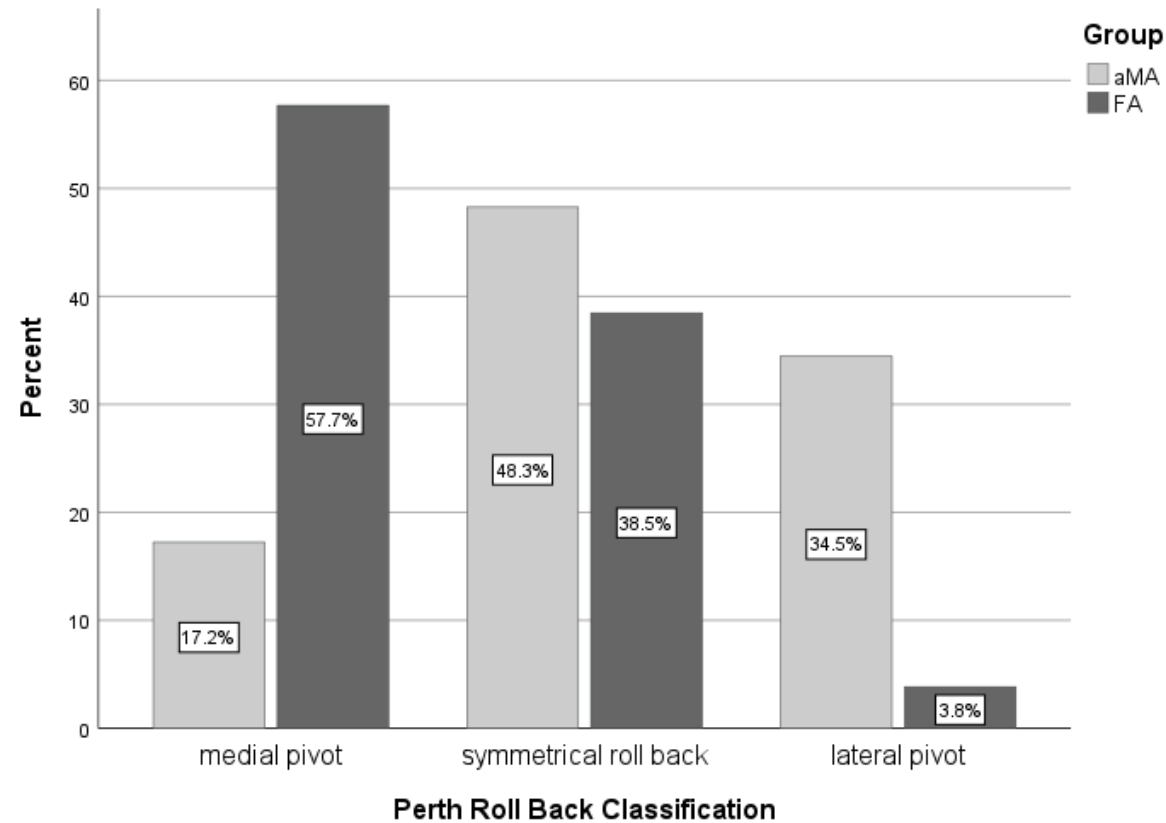
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Table 3: Mean (SD, range) one-year outcomes by kinematic pattern. No adjustment for multiple testing. *Kruskal-Wallis test
No adjustment for multiple testing.

Results 4: Kinematic Pattern produced and Forgotten Joint Score



Kinematic pattern by alignment group.

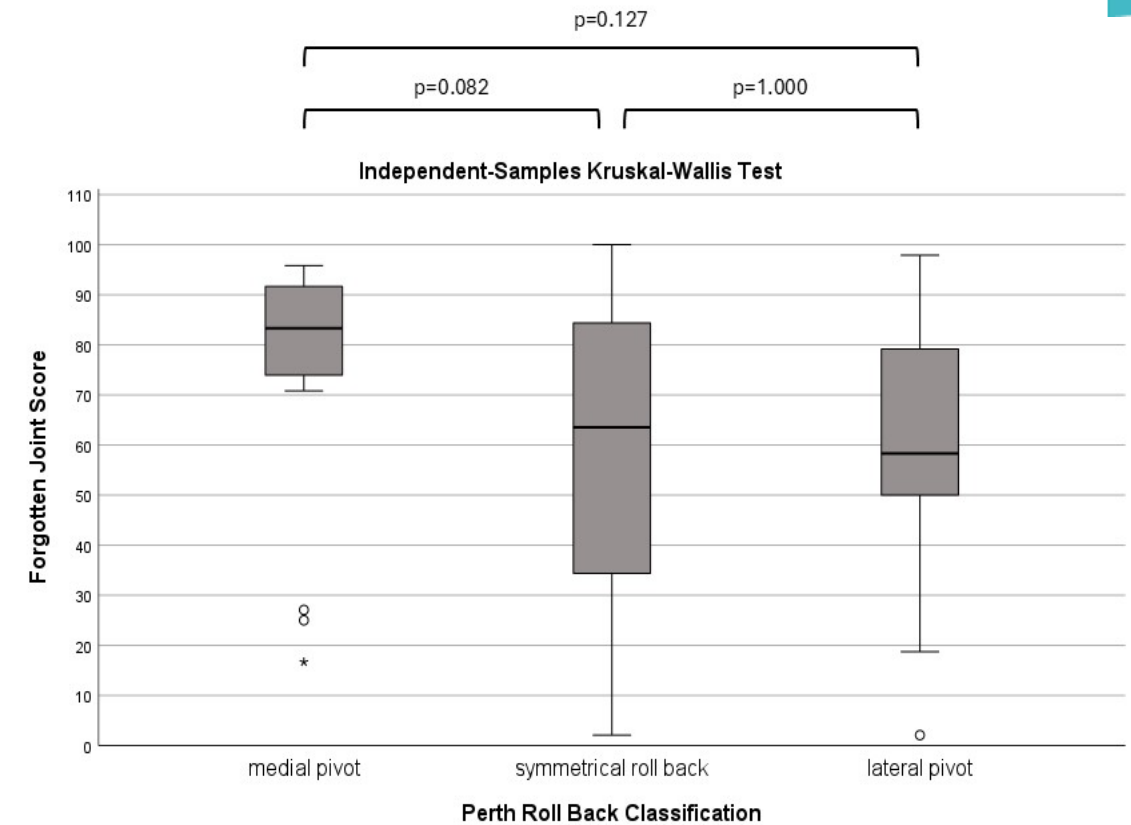
aMA, adjusted mechanical alignment; FA, functional alignment.



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Forgotten Joint Score at one year by kinematic pattern.

Adjusted p-values calculated with the Kruskal-Wallis test. Circles represent outliers. Asterisks represent extreme outliers.

Discussion

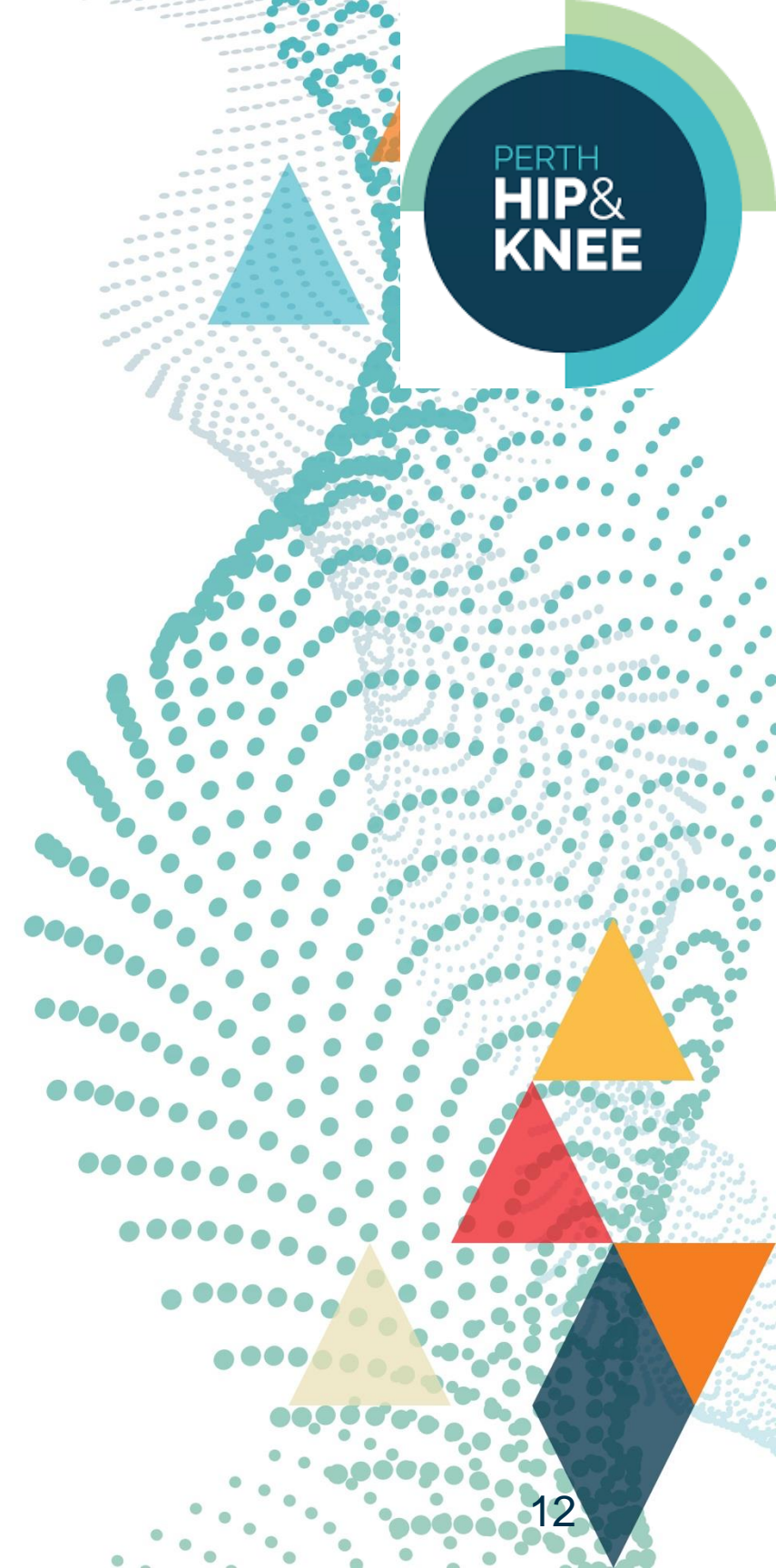
- Our study demonstrates that FA in knee arthroplasty produces similar percentages of kinematic patterns to the native knee¹², unlike adjusted mechanical axis alignment. The kinematic pattern produced also influences clinical outcomes, therefore, we have rejected our hypotheses.
- A well-balanced RA-TKA can be achieved using both FA-TKA and an aMA-TKA alignment philosophy.
- The limitations of our study are that it is a single- centre, single- surgeon (GWC) study, assessing one implant and one robotic system. As with other studies of kinematic patterns using pressure sensors, non-weightbearing passive motion was used.
- Component design is an important factor in TKA sagittal stability, and hence the results of this study may not be transferable to other implants and levels of insert constraint. It also raises the possibility of a 'kinematic conflict' occurring if a medial constrained insert is used with a MA philosophy.
- Those TKA with medial pivot patterns were associated with superior clinical outcomes compared to those with an intraoperative lateral pivot.



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