

Unity Knee™

The evidence base



Corin

Connected Orthopaedic Insight

Unity Knee™

Stability and satisfaction through joint line preservation

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ODEP ratings and Joint Registry data

ODEP ratings

The Orthopaedic Data Evaluation Panel (ODEP) in the UK assigns benchmark ratings to implants based on a simple and independently verified assessment of implant performance against clinical best practice guidelines. Each implant given an ODEP rating is assigned a number (15, 13, 10, 7, 5, or 3) according to the available follow-up and a letter (A or B) that indicates the strength of the data provided¹.

Unity Knee system currently holds four ODEP ratings confirming strong evidence at 5 years follow-up for the following combinations:

- Unity Knee CR with domed patella: ODEP 5A
- Unity Knee CR with offset domed patella: ODEP 5A
- Unity Knee CR without patella: ODEP 5A
- Unity Knee PS with offset domed patella: ODEP 5A

Joint Registry data

Unity Knee is the total knee replacement brand with the **lowest** reported cumulative revision rate of 1.29 (0.78-2.13) at **5 years** [Table 3.K7 (a), NJR 2022] as shown by the National Joint Registry's 19th Annual Report in the UK².

Unity Knee is the total knee replacement brand with the **lowest** cumulative percent revision rate of 0.3 (0.1-1.3) at **3 years** [Table KT9, AOANJRR 2022] as reported in the 2022 Annual Report of the Australian Orthopaedic Association National Joint Replacement Registry³



Early functional recovery with gap balancing technique

Title Gap balanced adjusted mechanical alignment versus measured resection mechanical alignment: a randomised controlled trial

Authors Waterson, H., Walker, R., Koopmans, P., Stroud, R., Phillips, J., Mandalia, V., Eyres, K., Toms, A.

Publication Archives of Orthopaedic and Trauma Surgery (2022)⁴

Methods 94 knees (Unity Knee CR or PS) were enrolled in this randomised controlled trial. The surgical protocol used a measured resection (MR) technique for mechanical alignment or a gap balancing (GB) technique for individualised alignment. No additional soft tissue releases for knee balancing were performed in the GB group.

- Primary outcome was quadriceps strength.
- Secondary outcomes included validated functional tests and PROMs as well as patient satisfaction. Outcomes were assessed pre-operatively, at 6 weeks, 3, 6 and 12 months post-operatively.

Results At 12-month follow-up, there was no significant difference in the change from baseline mean quadriceps peak torque between the two groups ($p = 0.988$). Significant improvement in the change in range of motion in the GB group compared to the MR group at 3 months (13° vs 6° $p = 0.028$) but this improvement was not significant at 1 year (20° vs 17° $p = 0.21$). The functional test of balance showed statistically significant improvement at 6 weeks ($p = 0.03$) in the GB group but this difference was not maintained.

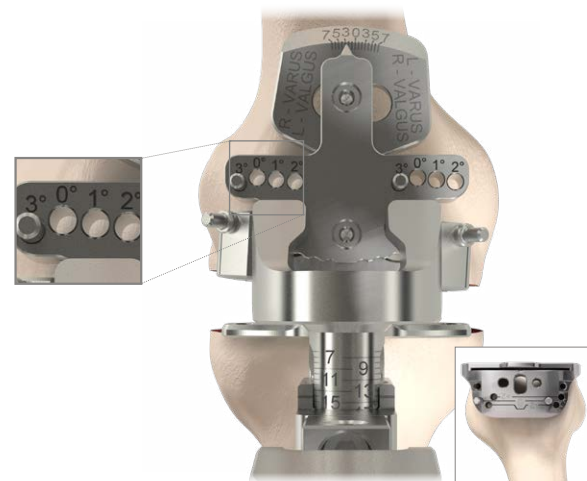
PROMs favoured the GB group, with the KOOS pain scoring statistically better ($p \leq 0.05$) at 6 weeks, 3, 6 and 12 months.

Conclusions

Individualised alignment philosophy utilising a GB technique did not demonstrate an improvement in the primary outcome measure quadriceps peak torque. Gains that were seen in functional assessment with GB, although significant at some time points, were no longer significant at 1 year and no difference was seen in quads strength.

Improvement was seen in the GB group in KOOS pain scores that was significant, both statistically and clinically, out to at least 1 year. Reduced soft-tissue trauma may have helped reduce post-operative pain as experienced in the GB group. National Joint Registry of England and Wales data has previously shown that persistent pain following TKR is the strongest predictor of patient dissatisfaction and reduced functional outcomes including the Oxford Knee Score and that pain is the most important prognostic indicator for long-term dissatisfaction following TKA.

Compared to a MR technique, the individualised GB technique appears to confer some improvement in pain, ROM and some functional tests following TKR in the short-term.



The GB technique (EquiBalance™) illustrating the 3° varus/valgus cut correction that can be made in extension.

Efficient instrumentation for surgical simplicity

Title Process Mapping Total Knee Arthroplasty: A Comparison of Instrument Designs
Authors Slick GS, Davis III CM, Elfar JC, Nikkel LE
Publication Journal of Arthroplasty, 2021 Mar;36(3):941-945⁵

Methods TKA implant systems representing over 90% of all TKAs performed in USA were evaluated. Instrumentation required for femoral, tibial, and patellar preparation was compared. The number of steps including surgical technician assembly steps, instrument handoffs, and surgeon steps were tabulated based off application of a standardized surgical flow, adjusted for manufacturer-recommended steps during completion of a TKA operation.

Results

- Cruciate-retaining (CR) knee instrumentation in studied systems required 158 to 225 discrete steps and posterior-stabilized (PS) knees required 181 to 230 steps.
- Unity Knee was among the implant systems requiring the fewest steps among both CR (167 steps) and PS (187 steps) systems.

Discussion Unity Knee instrumentation is focused on reducing required surgical steps for preparation and implantation.

Excellent early outcomes through Beyond Compliance

Title The first knee prosthesis to go through beyond compliance: A new standard for the safe introduction of orthopaedic implants.

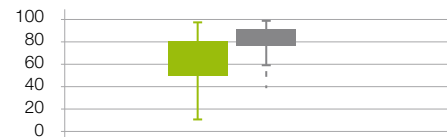
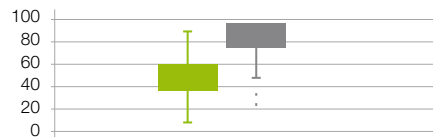
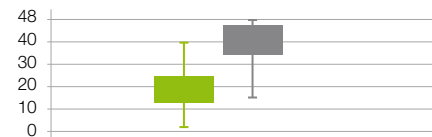
Authors Patel N G, Napier R J, Phillips J R A, Toms A D.

Publication The Surgeon 2020 Dec; vol18(6): e27-e32^o.

Methods 100 patients were implanted with Unity Knee TKR under the Beyond Compliance programme and prospectively followed up to 2 years after the surgery.

Results PROMs results showed significant improvement at 2 years follow-up with 96% of the patients satisfied with their surgery.

Conclusion Early results suggest that Unity Knee is safe and effective.



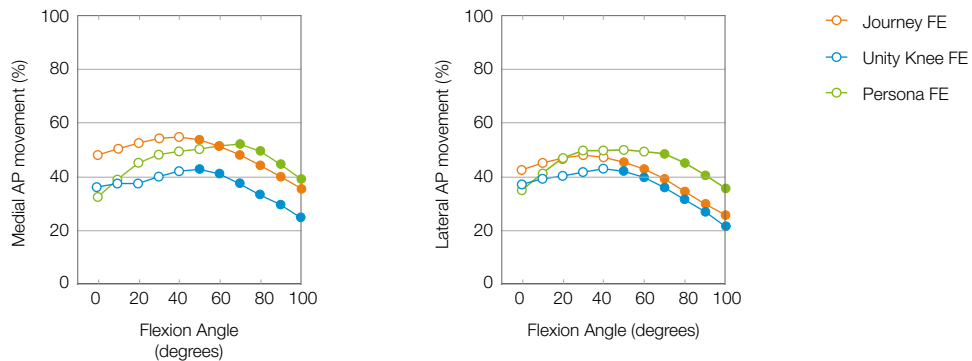
Kinematics linked to patient satisfaction

Title Knee kinematics determine patient satisfaction after TKA.
Authors Stefaan Van Onsem.
Publication The objective substrates of patient satisfaction after total knee arthroplasty, Chapter 3, 2018, Ghent University⁷.

Methods Kinematics of 30 total knees (Unity Knee, Journey II, and Persona) with up to 2yr follow-up were measured fluoroscopically during three different activities:

- Flexion-Extension (FE): non weight bearing from 0-120 degrees
- Squatting (SQ): weight bearing from 0-120 degrees
- Chair rise (CH): weight bearing from 0-90 degrees

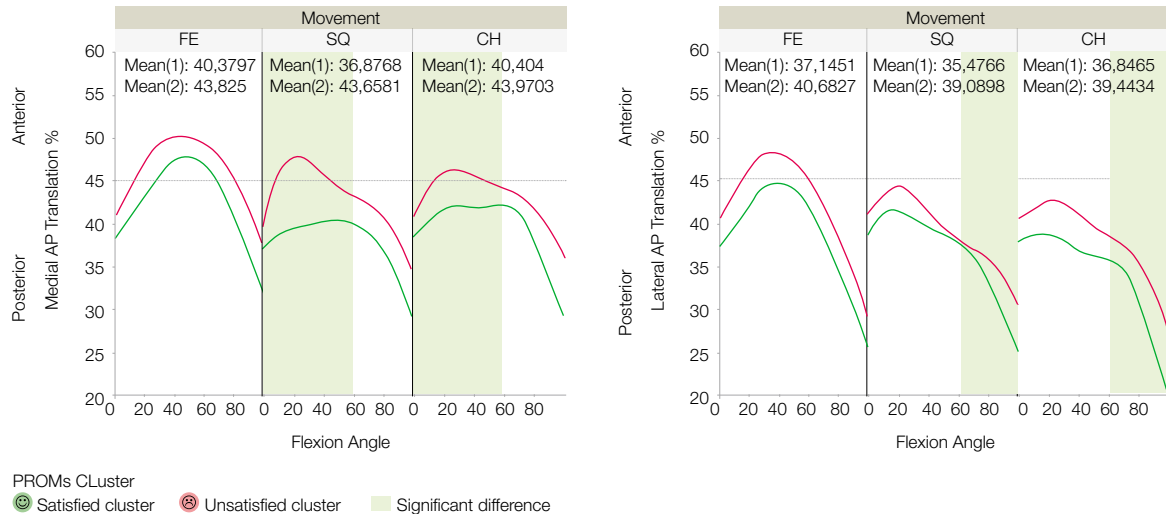
Patient-reported outcome measures (PROMS) were gathered, segregated into two clusters (satisfied vs. unsatisfied) and correlated to the implant-specific kinematic profiles.



AP translation of medial and lateral compartments during open chain extension flexion movement.

Results

Significant differences were observed between the kinematic profiles of satisfied versus unsatisfied patients during the weight-bearing activities of squatting and chair rise. In general, a more posterior position throughout the range of motion was associated with satisfied patients. Medially, the satisfied patients were statistically more stable in early and mid-flexion. Laterally, the satisfied patients were statistically more posterior in deep flexion.



Although there were no statistically significant differences in patient satisfaction when comparing implant designs, all Unity Knee patients were within the satisfied cluster.

Conclusion

Satisfied patients demonstrated statistically less paradoxical anterior movement in early flexion in the medial compartment, had a more stable medial compartment in mid-flexion, and exhibited greater posterior motion in deep flexion in the lateral compartment.

Significant improvements in functional outcomes

Title Comparison of Functional Outcomes of Total Knee Arthroplasty Using Two Different Single Radius Implants.

Authors Pourmoghaddam A, Dettmer M, Malanka S, Kreuzer S.

Publication Reconstructive Review, 2016 Mar, Vol 6 (1):43-48⁸.

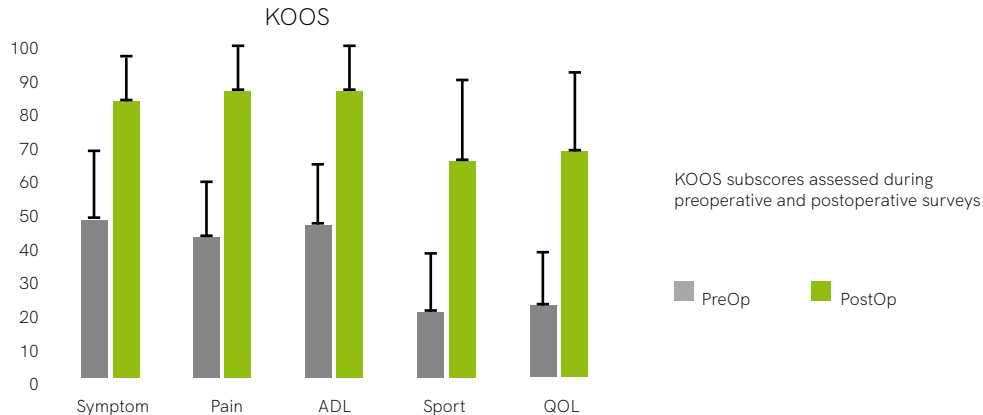
Methods A retrospective review of preoperative and postoperative clinical outcomes measured by KOOS, of 78 patients who received a cemented Cruciate Retaining (CR) Unity Knee implant in a single surgeon series.

- Standard medial parapatella surgical approach.
- Distal femoral resection followed by proximal tibia.
- The proximal tibia slope and varus/valgus angle was adjusted to the natural tibial plateaus of the patients.
- The extension gap was then balanced by soft tissue releases.
- Femoral rotation was adjusted using the ligament balancer and femoral sizer with the knee in 90 degrees of flexion.
- Patella resurfaced with implant to re-establish preoperative thickness.



Results

Improvement in functional outcome was significant for all subscores and post-surgery subscores were significantly higher in all patients. Average follow-up range 361 ± 228 days.



Discussion

Molt et al⁹. have reported the 1 year postoperative clinical outcomes measured by KOOS for patients who received a competitor single radius CR implant, Triathlon TKA. The scores in this study are comparable to those of patients who were treated with Triathlon CR in the earlier study by Molt et al.

Conclusion

This study reports the short term clinical outcome of a new single radius knee prosthetic design - Unity Knee. Patients in the study demonstrated excellent improvement in functional outcome indicating the short term success of this implant design.

Two years excellent follow up

Title Early Experience with a Modern Generation Knee System: Average 2 Years' Follow-up.
Author Paszicsnyek T.
Publication Reconstructive Review, 2015 Dec, Vol 5 (4):23-28¹⁰.

Methods Retrospective/prospective study to analyse 2-year clinical and radiographic outcomes of patients in a consecutive single surgeon series who received a PS Unity Knee TKR. A total of 89 patients were assessed using the AKSS, OKS and radiographs. Mean follow-up was 1.95 years (range 1.1-2.9). Average age of 68 years (range 45-87) and average BMI 28.6 (range 19.8-45.5).

Results Correlation of Age and BMI on 2-Year AKSS scores

	Age	BMI
AKSS knee score	r = 0.1238 NS	r = -0.0434 NS
AKSS pain score	r = 0.2546 p = 0.0167 R2 = 0.0648	r = -0.0697 NS
AKSS function	r = 0.1741 NS	r = -0.0327 NS
AKSS ROM	r = 0.0609 NS	r = -0.148 NS
OKS	r = 0.1098 NS	r = -0.1565 NS
	*Pearson correlation N=70 due to missing BMI	

The analysis demonstrated a significant correlation between age and 2-year AKSS pain score; the results showed that older patients experienced less pain at 2-year follow-up than younger patients. Coefficient of determination demonstrated that 6% of the variation in the AKSS pain score is predicted by age. There was 1 revision due to infection at 1.1 year post-op and Kaplan-Meier survivorship was 98.9% at 2 years.

Conclusion All clinical and radiological results were excellent at 2 years postoperatively; the reported mean OKS was 46 out of maximum score of 48. Anteroposterior and mediolateral stability and flexion also demonstrated good results which may suggest optimised quadriceps function and posterior condylar offset balance.

Unity Knee reference papers

Featured references

1. Latest ODEP ratings can be found at www.odep.org.uk.
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9. Molt M, Toksvig-Larsen S. (2014). Similar early migration when comparing CR and PS in Triathlon TKA: A prospective randomised RSA trial. *The Knee*. 2014 *21*(5): 949-954.
10. Paszicsnyek T. Early Experience with a Modern Generation Knee System: Average 2 Year's Follow-up. *Reconstructive Review*. 2015 Dec, Vol 5 (4):23-28.

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