

# Early outcomes using a 'kinematic retaining' total knee replacement – A multicentre prospective study at two years follow-up

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## ABSTRACT

**Background:** Although predictable implant longevity in total knee replacement (TKR) is now established, work continues to satisfy the demands of patients who seek full restoration of the painless function of the native knee following TKR. This prospective study examines the early clinical outcomes of 156 patients implanted with a novel 'kinematic-retaining' (KR) implant.

**Methods:** 156 Physica KR TKRs were implanted for primary osteoarthritis at three European centres. Patients were reviewed up to two years using radiographic, clinical and functional evaluations.

**Results:** Of the 137 patients retained at two years' follow up, none had been revised. Within 6 post-operative months, 51.7% and 79.9% had excellent clinical and functional KSS values respectively, increasing to 81.8% and 88.3% beyond two years. Mean KSS improvement was 34.8 (from 48.6 to 83.4). All KOOS sub-scores improved significantly with total KOOS improving from a mean of 35.5 (SD  $\pm 13.0$ ) to 86.5 ( $\pm 13.7$ ) at two years post-operatively. Pain and sports KOOS sub-scores improved rapidly during the early post-operative periods, with sustained improvements beyond this. Mean OKS improved by 44.1 ( $\pm 5.1$ ) at two years. VAS satisfaction scores improved significantly at all time points beyond six weeks. Mean FJS-12 was 75.7 at two years, with no significant effects of age or gender. No progressive adverse radiographic features were noted.

**Conclusions:** Early clinical and radiographic outcomes of this kinematic-retaining knee prosthesis are promising, with improvements in clinical parameters similar to, or exceeding those published in other contemporary TKR designs.

**Level of evidence:** II, Multicentre Prospective cohort study.

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## 1. Introduction

Total Knee Replacement (TKR) has proved to be a successful and enduring treatment for severe degenerative knee disease [1]. Despite excellent long-term implant survivorship and incremental advances in arthroplasty design, there remains a

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cohort of high-demand patients who are unable to return to full activities post-operatively due to pain or poor function [2–5]. The failure of many knee replacement designs to reproduce the kinematics of the healthy native knee may play a part in this. The human knee is a complex joint which relies on a dynamic interplay between the incongruent joint surfaces and soft tissue restraint for normal function during range of motion and loading [6]. This results in a characteristic ‘rollback’ of the femur on the tibia during initial flexion with a dynamic lateral articular contact point and non-isometric ligament balance during movement [7]. Despite this, most current TKRs have symmetric medial and lateral articulating surfaces in sagittal profile, which does not support native knee kinematics and introduces paradoxical movement [8–10].

A key goal of new implant design for TKR is to reproduce normal kinematics after replacement and, in particular, to achieve the initial rollback. The Physica KR (Lima Corporate Spa, Udine, Italy) is a modular posterior cruciate ligament preserving knee prosthesis with a kinematic-retaining (KR) mechanism, designed to reproduce the native tibiofemoral joint anatomy in order to restore natural knee kinematics (Figure 1). Here we report the early clinical outcomes of 156 patients who underwent TKR using the KR knee implant.

The hypothesis formulated at the start of this study is that a knee prosthesis reproducing the tibiofemoral joint anatomy and the kinematics of the natural knee may contribute to ensure a rapid functional recovery and excellent clinical outcomes with superior pain relief, even in high-demand patients. This is a five year patient cohort study, we present here the intermediate results at two years’ follow-up.

## 2. Methods

The study was designed as a post-marketing, multicentre, prospective, open-label cohort study of the CE-certified Physica KR device with baseline control. A *pre-hoc* power calculation was performed with Power and Precision v4 software (Biostat, NJ, USA). Using standard methodology with an anticipated treatment difference of 44.0 points on the KSS, with a standard deviation of 20.0 and criterion for significance (alpha) set at 0.05, this defined the minimum sample size of 130 patients with a power of 0.80 to reject the null hypothesis. Assuming a 20% drop-out rate, an enrolment target of 156 patients was established. Following local and regional ethical approval 156 patients (87 men and 69 women, mean age 68 years) underwent TKR with the Physica KR knee implant at three European sites. Patients with primary knee osteoarthritis who had not responded to conservative treatment were recruited to the study once the decision for TKR had been made. 83 were ‘high-demand’ patients with moderate or intense pre-operative activity levels. All the surgical procedures were performed by the authors in each study site under spinal or general anaesthesia according to a standardised surgical technique. Exposure was achieved through a medial parapatellar approach, bone cuts were made using proprietary jigs referenced with intramedullary femoral and extramedullary tibial alignment. Antithrombotic and antibiotic prophylaxis was administered according to each institution’s standard protocol.

Patients were reviewed within one month pre-operatively (T0), and post-operatively at 6 weeks (T1), 6 months (T2), 1 year (T3) and 2 years (T4) using clinical and functional performance evaluations. Knee Society Score (KSS) served as the primary endpoint and Knee injury and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score (OKS), Visual Analogue Scale



**Figure 1.** The Physica KR implant, designed to reproduce native tibiofemoral joint anatomy and function. The articular surface is asymmetric but congruent, with a saddle shaped lateral tibial liner in the sagittal plane (red markings for emphasis).

(VAS) satisfaction, Forgotten Joint Score (FJS-12) and serious adverse incidents served as secondary endpoints. Radiographic assessment included anteroposterior, lateral and skyline projections as well as weight bearing long-leg alignment films, with pre-operative assessment of osteoarthritis severity according to Kellgren and Lawrence grading (Figure 2). Post-operative radiographic assessment included component and limb alignment, signs of loosening, heterotopic ossification and any adverse features according to the Knee Society radiographic criteria [11,12], to define any possible risk factors that may lead to failure. Data were analysed with SAS (SAS Analytics, NC, USA) using paired t-tests against pre-operative baseline measurements to detect functional and clinical outcome, satisfaction and safety profile. Outcome measures were compared across follow-up visits using the Wilcoxon signed-rank test and additionally sub-categorised across age and gender using the Wilcoxon rank-sum test at each review. P-values were adjusted for multiple comparisons using the false discovery rate (FDR) method, with values less than 0.05 considered significant.

### 3. Results

Of 156 patients who underwent TKR within the study, 137 (87.8%) patients were retained at two years' follow up. None of the TKRs had been revised and two patients had died of unrelated causes.

#### 3.1. Functional clinical outcomes and patient satisfaction

##### 3.1.1. Range of motion

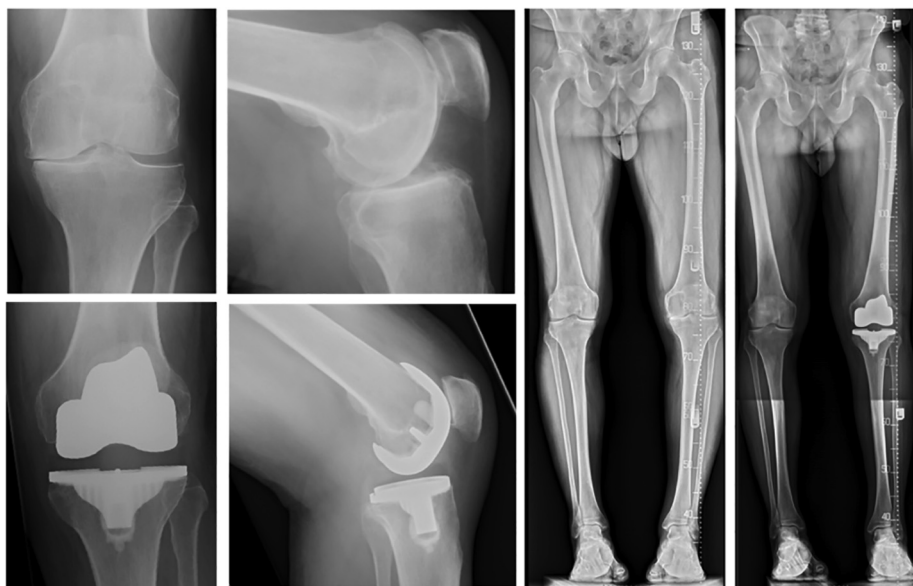
Pre-operative range of motion ( $116 \pm 14^\circ$ ) was largely regained by six months ( $113 \pm 14.6^\circ$ ).

##### 3.1.2. KSS

Overall, mean improvement at 2 post-operative years was 34.8 (from 48.6 to 83.4) (Table 1, Figure 3). Pre-operatively, only 1.3% and 14.1% of patients reported excellent clinical and functional scores respectively. This improved to 20.4% and 34.2% by six post-operative weeks. Excellent clinical and functional scores were seen in the majority of patients by six months, and in 81.8% and 88.3% of patients at two years, respectively (Tables 2 and 3). This was mirrored by mean KSS functional scores, which improved from 55.6 (SD  $\pm 18.5$ ) pre-operatively, to 65.5 ( $\pm 22.0$ ) at six weeks and 90.2 ( $\pm 18.1$ ) at two years (Table 1, Figure 4). There was a highly significant improvement ( $p < 0.0001$ ) in both median clinical and functional scores between each timepoint up to one year post-operatively. When comparing KSS by age or gender at each timepoint, there were no significant differences in outcome, except that male functional scores improved significantly more than females at six weeks and six months post-operatively ( $p = 0.0225$  and  $0.0002$  respectively).

##### 3.1.3. KOOS

All mean sub-scores improved significantly during the follow-up period with total KOOS improving from a mean of 35.5 ( $\pm 13.0$ ) to 86.5 ( $\pm 13.7$ ) at two years post-operatively (Table 4, Figure 5). Highly significant ( $p < 0.001$ ) incremental

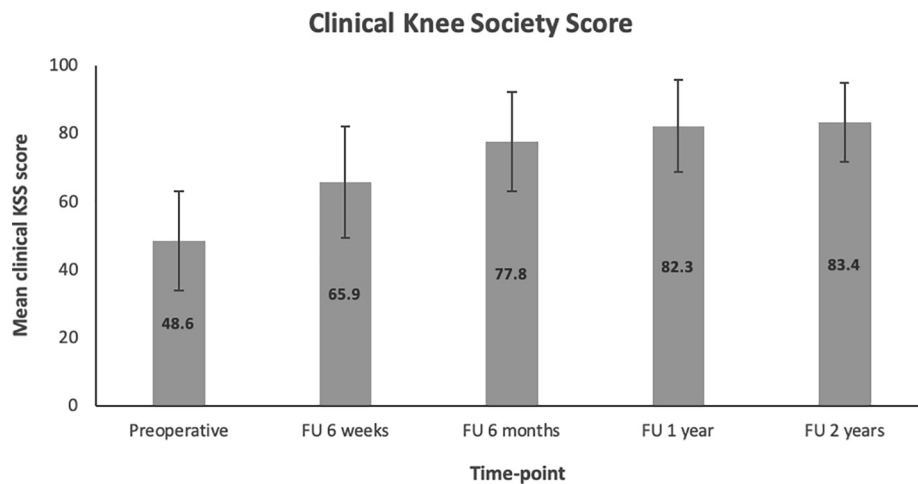


**Figure 2.** Radiographic analysis. Anteroposterior, lateral and long leg alignment views of a patient's left knee before and after implantation with the Physica KR total knee replacement.

**Table 1**

Summary of patient retention (*n* (%)), and clinical and functional scores through the first two post-operative years (mean ( $\pm$ SD)). VAS Satisfaction and FJS were measured from 6 weeks and 1 year post-operatively, respectively.

Score	Patients	KSS Clinical	KSS Functional	OKS	FJS	VAS Satisfaction
Pre-operative (T0)	156 (100%)	48.6 (14.6)	55.6 (18.5)	20.2 (6.8)	–	–
6 weeks (T1)	153 (98.1%)	65.9 (16.3)	65.5 (22.0)	30.5 (7.8)	–	73.8 (19.9)
6 months (T2)	149 (95.5%)	77.8 (14.6)	85.2 (19.0)	39.5 (6.9)	–	80.9 (19.6)
1 year (T3)	151 (96.8%)	82.3 (13.5)	90.0 (17.1)	42.3 (6.0)	64.4 (27.2)	87.1 (14.7)
2 years (T4)	137 (87.8%)	83.4 (11.7)	90.2 (18.1)	44.1 (5.1)	75.7 (26.5)	88.4 (16.6)

**Figure 3.** Mean Clinical Knee Society Score (KSS, FU = Follow up).**Table 2**

KSS Clinical scores through first two post-operative years (*n* (%)).

Visit	Poor	Fair	Good	Excellent
Pre-operative (T0)	122 (78.2%)	28 (17.9%)	4 (2.6%)	2 (1.3%)
6 weeks (T1)	53 (34.9%)	24 (15.8%)	44 (28.9%)	31 (20.4%)
6 months (T2)	19 (12.8%)	7 (4.7%)	46 (30.9%)	77 (51.7%)
1 year (T3)	10 (6.7%)	3 (2%)	30 (20.1%)	106 (71.1%)
2 years (T4)	8 (5.8%)	3 (2.2%)	14 (10.2%)	112 (81.8%)

**Table 3**

KSS Functional scores through first two post-operative years.

Visit	Poor	Fair	Good	Excellent
Pre-operative (T0)	88 (56.4%)	28 (17.9%)	18 (11.5%)	22 (14.1%)
6 weeks (T1)	51 (33.6%)	20 (13.2%)	29 (19.1%)	52 (34.2%)
6 months (T2)	12 (8.1%)	4 (2.7%)	14 (9.4%)	119 (79.9%)
1 year (T3)	8 (5.4%)	2 (1.3%)	9 (6%)	130 (87.2%)
2 years (T4)	6 (4.4%)	2 (1.5%)	8 (5.8%)	121 (88.3%)

improvements of each sub-score were noted at every post-operative timepoint, except for sports between six months and one year post-operatively which still reached significance ( $p = 0.0457$ ). When comparing KOOS by age or gender at each time point, there were no significant differences in outcome at any time point, except that patients over 65 had a significantly higher stiffness score at one year ( $p = 0.0118$ ). The pain and sports sub-scores improved particularly rapidly during the early post-operative periods, with sustained improvements beyond this (Figure 5, Table 4).

### 3.1.4. OKS

Poor scores were noted in 78% of the patients pre-operatively, but in fewer than 30% by six weeks post-operatively and just 1.5% of patients at two years. In contrast, good or excellent pre-operative scores were seen in 2.6% of patients, but was achieved by 36.2% by the sixth post-operative week and 95.5% by two years (Table 5). OKS improved rapidly for the first six

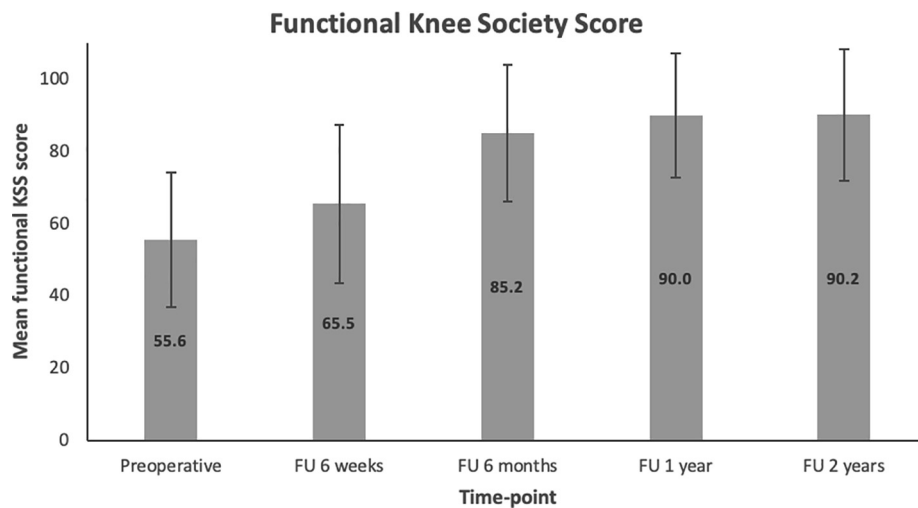


Figure 4. Mean Functional Knee Society Score (KSS).

Table 4

KOOS sub-scores and total scores by timepoint (mean ( $\pm$ SD)).

Visit	Symptoms	Pain	ADLs	Sports	QoL	Total
Pre-operative (T0)	44.9 (18.0)	40.7 (13.4)	46.0 (16.8)	17.9 (17.5)	22.5 (14.8)	35.5 (13.0)
6 weeks (T1)	63.6 (15.9)	67.0 (16.1)	75.4 (14.9)	36.3 (27.0)	52.0 (18.9)	62.0 (15.4)
6 months (T2)	79.0 (14.9)	82.6 (16.3)	84.9 (14.2)	63.1 (24.6)	68.9 (22.2)	76.7 (15.6)
1 year (T3)	83.6 (14.9)	88.5 (14.8)	89.0 (13.8)	69.2 (23.8)	77.5 (20.9)	82.2 (15.3)
2 years (T4)	88.2 (13.6)	92.5 (12.1)	92.8 (11.6)	74.3 (22.2)	82.1 (20.1)	86.5 (13.7)

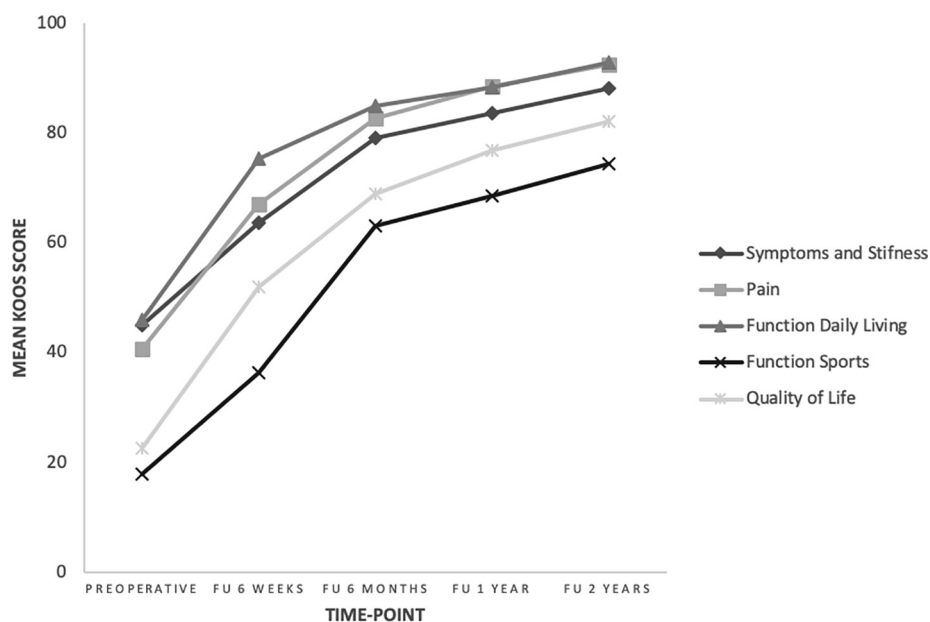


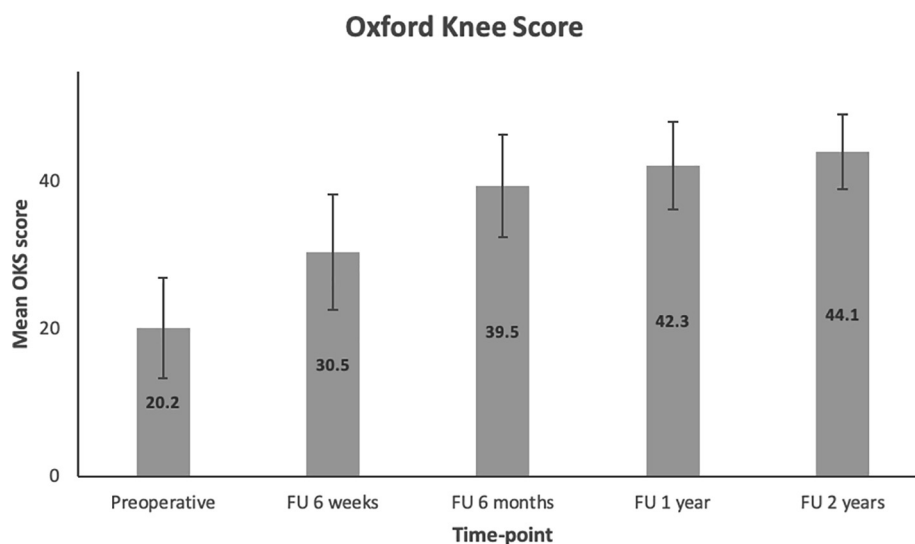
Figure 5. Knee injury and Osteoarthritis Outcome Score (KOOS).

months and then with a shallower trajectory to 44.1 ( $\pm$ 5.1) at two years (Table 1, Figure 6). Improvements at each time-point were all highly statistically significant ( $p < 0.0001$ ). When comparing by age or gender, there were no statistically significant differences at any time-point.

**Table 5**

OKS at time-points up to two years post-operatively.

Visit	Poor	Fair	Good	Excellent
Preoperative (T0)	122 (78.2%)	30 (19.2%)	4 (2.6%)	0
6 weeks (T1)	45 (29.6%)	52 (34.2%)	42 (27.6%)	13 (8.6%)
6 months (T2)	7 (4.8%)	18 (12.3%)	48 (32.9%)	73 (50%)
1 year (T3)	3 (2%)	6 (4.1%)	37 (25%)	102 (68.9%)
2 years (T4)	2 (1.5%)	4 (3%)	18 (13.3%)	111 (82.2%)

**Figure 6.** Oxford Knee Score (OKS).

### 3.1.5. VAS satisfaction

Scores improved significantly at all time points beyond six weeks (Table 1), although comparison by age and gender revealed no significant differences between these parameters at any post-operative time-point.

### 3.1.6. FJS-12

FJS was measured from one year post-operatively, with mean score of 64.4 at one year and 75.7 at two years. The improvement in this period was highly statistically significant ( $p < 0.001$ ) and there were no significant effects of age or gender on the score.

## 3.2. Radiographic outcomes

Post-operative component and limb alignment were maintained throughout the study period. 1 mm radiolucent lines were present in two patients (1.2%) on immediate post-operative films (tibia, zone 4, femur zone 1). By two years post-operatively there were two femoral lucencies over 2 mm wide (both in zone 1) and two around the tibial component (zone 1 and zone 4).

Zone 1 and 4 of both the tibial and femoral components demonstrated lucent lines of up to 1 mm at two years – seven femoral and 13 tibial lucencies were noted in zone 1 and two femoral and five tibial lucencies were noted in zone 4. A further two 1 mm lines were seen in femoral zone two, and in the tibia there was one in zone 5, three in zone 6 and one in zone 8. The majority of these lucencies were noted within six months post-operatively and appeared non-progressive up to the current study end-point. No patellar radiolucent lines were demonstrated at any time-point. Heterotopic ossification was noted in five knees during the study period, but had not progressed beyond Brooker grade II in any patient at two years.

## 3.3. Complications

There were complications in eight patients (5%) (Table 6). No cases of revision, loosening, implant migration or serious adverse events were reported.

**Table 6**

Complications (both intra-operative complications were identified and resolved during the index procedures).

Complications	
<b>Intra-operative</b>	
Tibial plateau fracture (minimally-displaced)	1 (0.6%)
Incorrect tibial prosthesis rotation (removed and re-implanted)	1 (0.6%)
<b>Post-operative</b>	
Deep vein thrombosis	3 (1.9%)
Post-operative anaemia requiring transfusion	2 (1.3%)
Haematoma (resolved conservatively)	1 (0.6%)
Total	8 (5.0%)

## 4. Discussion

Although TKR has had success in abolishing pain and correcting deformity from arthritis for many years, a significant minority of patients remain unsatisfied with their functional outcome and ongoing symptoms. In order to address this, an appreciation of the native knee's kinematics have allowed the design of novel implants that reproduce natural movements throughout the range of motion. Early clinical and radiographic outcomes of this kinematic-retaining knee prosthesis are promising, with improvements in clinical parameters similar to, or exceeding those published in other contemporary TKR designs. Varying design philosophies have recently been introduced to try to address the deficiencies in functional outcome.

### 4.1. Comparison with other contemporary TKR designs

#### 4.1.1. KOOS

Patients implanted with the cementless Triathlon Tritanium TKR achieved KOOS improvements from 33.1 pre-operatively to 84.1 at a mean follow up of 5.5 years, comparable with the improvement seen in the present study [13]. A retrospective study of the Persona Knee System reported three-year post-operative mean KOOS improvements of 39 for symptoms, 40 for pain and 29 for daily living [14]. The current study compares favourably at only two years post-operatively, with improvements of 43.3, 51.8 and 46.8, respectively. Another study assessing the outcomes of the Persona system at two years reported KOOS of 55.0 for sports and 78.2 for quality of life, compared to 74.3 and 82.1 respectively in the current study [15]. Scores reported for the Unity system at one year, demonstrated similar, but perhaps not as marked, improvements to those seen for each subscore in the current study [16].

#### 4.1.2. OKS

OKS for patients in the present study improved by an average of 19.3 points over the first six post-operative months and a further to 4.6 points (to 44.1) at two years. Two studies reporting the outcomes of the Attune TKR, demonstrated mean OKS improvements of 12.1 and 15.7 at six months [17,18], improving by just another 0.5 points at two years. A two year follow up study of the Persona demonstrated improvements of 18.9 at one year although in contrast to the Physica KR, little improvement was noted beyond this [19]. A study of the Unity knee demonstrated a mean OKS of 45.9 at two years, although baseline pre-operative scores were not published [20].

#### 4.1.3. KSS

The mean KSS clinical and functional scores in the current study had improved by 34.8 and 34.6 points respectively, at two years post-operatively. In a study of the Attune system, improvements of 49.9 and 18.4 points respectively, were noted [18]. Two further studies of the Attune system reported KSS functional score improvements of 37.2 and 37.3 at two years [21,22]. A study of the Journey II Bicondylar TKR reported clinical and functional KSS of 93.7 and 75.4 at six months, and 96.2 and 81.5 at two years. Although the clinical scores for the Journey II are slightly higher than the present study, the functional scores are lower. Additionally, this study was retrospective and no baseline pre-operative data or comparisons are available [23]. Another study of the Journey II reported improvements of clinical and functional KSS respectively from 26 and 21 to 91 and 88 at about two years follow up [24]. Again, this study was retrospective with undefined study entry points. Furthermore, even the second iteration of the Journey knee has a higher revision rate in clinical use (2.96% at three years) than benchmark figures within joint registry data [25]. A retrospective study of the Persona TKR reported KSS clinical improvements from 45 to 94 and functional improvements from 46 to 92 at three post-operative years [14], with another study demonstrating mean KSS improvements of 35.3 (57.3–92.6) for clinical and 26.3 (49.1–75.4) for functional scores at a mean 3.9 years' follow-up [26]. These results compare similarly to the present study's findings. KSS was also measured for the Unity TKR [20]. Although the mean clinical and functional KSS at two years' post-implantation were slightly superior (87.1 and 96.4, respectively), no pre-operative baseline scores are reported.



#### 4.1.4. FJS-12

FJS-12 for patients in the current study was 75.7 at two years post-operatively. This compares to other contemporary knee replacement designs. The Attune achieved FJS-12 of 67.6 [27], while the Vanguard CR and SAIPH medially stabilised knees achieved 63.8 and 79.9 respectively at one year [28]. Scores of 66.2 and 69.2 have been published at two years for the Triathlon knee implanted in mechanical and clinical alignment respectively [29].

#### 4.1.5. Radiographic measures

Radiographic outcomes were encouraging, with only a small minority demonstrating lucencies in any zone. Concerns have been raised with respect to the shorter keels in modern knee replacement designs, potentially predisposing to progressive loosening, but this has not been borne out in practice with other prostheses [26]. Studies of other modern, high-functioning knee implants frequently show a minority with non-progressive asymptomatic lucencies [15,20,26]. It remains to be seen if the small number of lucencies seen in the present study go on to progress beyond the current two year follow up, although we have seen no evidence of the early failure at the implant-cement interface experienced by another new implant [30–32]. We observed no significant malalignment or heterotopic ossification in the current study.

### Conclusion

Limitations of this study include a relatively small study sub-group, no direct control comparison and short initial follow-up period. However, further periodic follow-up of this cohort is planned. Despite these limitations, this study demonstrates prompt functional recovery with substantial pain relief even in high-demand patients, when implanted with this TKR. It is thought that these promising early results are a consequence of the implant exhibiting physiological kinematics. Confirmatory fluoroscopic kinematic studies of a sub-cohort of patients are being performed separately.

### Funding

This research received funding from Lima Corporate Spa, Italy.

### Authors' contributions

ARH, IWB and MI designed and coordinated the study. All the authors participated in patient recruitment, the surgical procedures and post-operative care and follow-up. JOS and ARH drafted the manuscript. All authors read, amended and approved the final manuscript.

### Ethical approval

Approval was obtained from the Regional Ethics Committee of the principal centres. The trial was registered through [ClinicalTrials.gov](https://clinicaltrials.gov) (NCT02118272). For UK sites: IRAS project ID is 137766/REC reference is 13/EE/0438. For Italian site: EC reference is SPE\_14.080.

The implant holds a European conformance CE Mark and has been registered with ODEP (Orthopaedic Data Evaluation Panel) and the Beyond Compliance Advisory Group for ongoing clinical assurance.

### Informed consent

All patients underwent appropriate informed consent for inclusion in this study and for measurement, storage and analysis of their data.

### Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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