Early Experience with a Modern Generation Knee System: Average 2 Years' Follow-up

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Abstract

Arthritis in the knee is a leading cause of pain and disability with total knee arthroplasty (TKA) often the treatment of choice after failure of more conservative treatments. TKA has been demonstrated to be one of the most successful procedures performed. However, despite the good long-term survivorship rates, patient satisfaction is still an issue post TKA with over 20% of patients exhibiting patient dissatisfaction most commonly due to anterior knee pain (over 18-28% patients) and mediolateral or varus-valgus instability. Recent studies have demonstrated that collateral ligament strains are altered post TKA which may lead to laxity and/or tightness of the ligaments resulting in patient discomfort, pain, stiffness and/or instability post TKA. As a result, it may be beneficial to ensure ligamentous strains after TKA are similar or close to the native situation. The purpose of this study was to evaluate the clinical and radiographic results of the Unity Knee™ Total Knee System (Corin Ltd, Cirencester, UK), a modern generation, single-radius total knee replacement (TKR) and its accompanying instrumentation which is designed to help maintain proper ligament balance and restore the medial joint-line. A total of 89 knees (89 patients) were implanted with the device in a single surgeon series. All patients were assessed using the American Knee Society Score (AKSS), the Oxford Knee Score (OKS), and radiographs. There was 1 revision due to infection and Kaplan-Meier survivorship was 98.9% at 2 years. The mean AKSS knee score for the total cohort was 87.1 ± 7.98 and the mean Oxford Knee score was 45.89 ± 3.69 . Radiographic review found no signs of radiographic failure in any of the knees. This study demonstrates good survivorship, clinical, and radiographic results at 2 years for this TKR.

Unity Knee™
Total Knee System

Keywords: total knee arthroplasty; total knee replacement; knee prosthesis; treatment outcome; single radius, joint line preservation
Level of Evidence: AAOS Therapeutic Level IV

Introduction

Arthritis in the knee is a leading cause of pain and disability [1] and when non-surgical treatments like medications and walking supports are no longer effective, total knee arthroplasty (TKA) is frequently the treatment of choice. It has been demonstrated to be a safe and effective procedure and one of the most successful procedures per-

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formed [2].

Despite the good long-term survivorship rates, patient satisfaction is still an issue post TKA with over 20% of patients exhibiting patient dissatisfaction [3]. In particular anterior knee pain is a persistent issue post-surgery with over 18-28% patients demonstrating pain. [4] In addition mediolateral or varus-valgus instability is the most common cause of instability resulting in early clinical failure post total knee arthroplasty [5,6,7]. Recent studies [8] have demonstrated that collateral ligament strains alter post TKA which may lead to laxity and/or tightness of the ligaments and subsequent instability and loss of motion. In order to prevent patient discomfort, pain, stiffness and/or instability post TKA, it may be beneficial to ensure ligamentous strains after TKA are similar or close to the native situation. It has been shown that structural damage occurs in ligaments from 5.14% strain levels [9]. Therefore, as a minimum, attempts should be made to keep strain levels below this by ensuring medial collateral ligament (MCL) isometry post TKA.

Studies have highlighted that both the medial and lateral posterior femoral condyles, in the native knee, are a single radius in the sagittal plane between 10° and 120° of flexion [10,11]. Modern TKA femoral implants which mimic this geometry have demonstrated improved mid-flexion stability, preventing anterior movement of the femoral component during flexion [13]. The cohort studies published on these designs have demonstrated faster rehabilitation, reduction in anterior knee pain and improved range of motion over traditional knee designs [13,14,15]. However, there have also been studies which do not demonstrate an improvement in function over traditional knee systems [16,17,18]. Hall et al [16] found comparable knee extensor mechanism function after TKA with either a single-radius or multi-radius implant. Jo et al [17] found no differences in Hospital for Special Surgery (HSS) knee scores, Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), and visual analog scale (VAS) of anterior knee pain during stair climbing in a single-radius knee design compared to a multi-radius knee design.

Biomechanically, the MCL is significant in maintaining knee stability post TKA. Unlike the lateral collateral ligament (LCL), the MCL remains near isometric with length changes less than 2% throughout the range of motion of the knee [19]. The MCL contributes 78% of the restraining force against valgus injuries in mid-flexion [20,21]. Given this significance of the MCL in maintaining knee stability post TKA, knee implant systems that focus on the optimization of MCL isometry through the range of motion may lead to improved outcomes.

The purpose of this study is to evaluate the early clinical

and radiographic results of a modern, single-radius total knee replacement system that uses a unique instrumentation system to maintain balance throughout the range of motion. This study reports on 2 year post-operative outcomes of a modern knee system in a single surgeon series and compares this to published literature on more established traditional knee implants.

Materials and Methods

This retrospective/prospective study analyzes 2 year clinical and radiographic outcomes of patients in a consecutive single surgeon series who received the Unity™ Total Knee System (Corin Ltd., Cirencester, UK). The design of this total knee system utilizes a single radius implant geometry with an instrument platform which aims to maintain the medial joint-line throughout range of motion in order to optimize MCL isometry post TKA. In addition, the patellofemoral track in this design has a lower profile and an early lateralized anatomic patellar track compared with traditional knee systems, with the aim to reduce constraint on the patellofemoral mechanism and therefore minimize anterior knee pain [22]. The goal of this TKR system is to maintain balance throughout the range of motion, resulting in improved patient outcomes.

Eligibility criteria included skeletally mature male and female patients diagnosed as having severe osteoarthritis with clinical and radiological symptoms. The study was ethics approved and patients were properly consented to participate in the study. Retrospective data included pre-operative, operative, and early post-operative data obtained from clinic records and prospective data was collected during a clinic visit at the 2 year post-operative interval.

A total of 89 patients (31 males and 58 females) were implanted with the Unity knee system between March 2012 and January 2014 with an average of 68 years of age (SD = 8.49; range 45 – 87) and average BMI of 28.6 (SD = 5.33; range 19.8 – 45.5) at time of surgery. All patients had a primary diagnosis of osteoarthritis (Table 1).

All surgeries were conducted after extensive pre-operative planning which used long leg radiographs to assess the degree of deformity. All surgeries used the implant specific surgical technique and unique instrumentation to confirm rotation and ligament balance intra-operatively. All patients were implanted with posterior-stabilized (PS) implants using a minimally invasive approach under general anaesthesia. The patella was resurfaced on all patients using a domed patellar implant.

Survivorship, clinical outcomes and radiographic review were assessed at 2 years post-operative. Clinical out-

comes included the American Knee Society Score (AKSS), AKSS pain score, AKSS function score, and range of motion (ROM). The Oxford Knee Score (OKS) was also collected since it is a patient reported assessment of post-operative results. Weight-bearing anteroposterior (AP), lateral, skyline patella and long-leg x-rays were completed. Pre-operative x-rays were evaluated by each surgeon and post-operative x-rays were evaluated by an independent reviewer. Radiographs were assessed for signs of aseptic loosening including radiolucent lines >2mm in 50% or more of zones around a single component, measurable changes of tibial vertical migration and/or subsidence >2mm, measurable changes in angular orientation of any component >2 degrees, and progressive radiolucent lines, extending

into one or more contiguous zones or expanding in width >2mm. Post-operative adverse events (AEs) were also reported.

Demographic and baseline characteristics were tabulated and descriptive analysis of patient outcomes (frequency, mean, standard deviation, minimum & maximum values) were completed. Additional analysis included Student t-tests for difference in means of outcomes scores for comparisons based upon gender and Pearson correlation for analysis of interval data age and BMI.

Table 1
Patient Demographics and Surgical Details

	All		Male		Female	
	n		n		n	
Number of procedures	89		31	34.83%	58	65.17%
Number of patients	89		31	34.83%	58	65.17%
AGE & BMI	mean	SD (R)	mean	SD (R)	mean	SD (R)
Age at surgery (yrs)	68	8.49 (45.0-87.0)	67	9.73 (45.0-84.0)	69	7.66 (53.0-87.0)
BMI ¹ at surgery	28.6	5.33 (19.8-45.5)	26.8*	3.21 (21.0-34.4)	29.5*	5.99 (19.8-45.5)
Primary Diagnosis	n	%	n	%	n	%
Osteoarthritis	89	100	31	100	58	100
Side	n	%	n	%	n	%
Left	34	38.2	9	29.03	25	43.1
Right	55	61.8	22	70.97	33	56.9
Implant Type	n	%	n	%	n	%
Cruciate Retaining (CR)	0	0	0	0	0	0
Posterior Stabilized (PS)	89	100	31	100	58	100
Patellar Resurfacing	n	%	n	%	n	%
Patella Resurfaced ²	89	100	31	100	58	100
Patella Not Resurfaced	0	0	0	0	0	0
Approach	n	%	n	%	n	%
Minimally invasive (MIS)	89	100	31	100	58	100
Anaesthesia	n	%	n	%	n	%
General	89	100	31	100	58	100

*Significant difference $p < 0.05$

¹Due to missing height and weight some BMI are incalculable

²All patellar implants were domed.

Results

The mean follow-up for all subjects (n=89) was 1.95 years (SD 0.301; range 1.1 – 2.9 years). There was 1 revision for infection in a 72 year old male which occurred at 1.1 years post-operative. Kaplan-Meier survivorship at 2 years was 98.9%. There have been no deaths.

Female patients were on average 69 years of age with an average BMI of 29.5 at time of surgery with their male counterparts respectively 67 years of age and a BMI of 26.8. There was a significant difference between female and male patients on BMI ($p<.05$). See Table 1.

The mean AKSS knee score at 2 years post-operative for the total study group of 89 patients was 87.10 ± 7.98 (range 36 – 100), mean AKSS pain score of 48.64 ± 4.27 (range 20 – 50), AKSS function score of 96.42 ± 8.84 (range 60 – 100), and a mean ROM score of 24.63 ± 1.44 (range 16 – 25). The mean patient reported OKS was 45.89 ± 3.69 (range 23 – 48) out of a possible score of 48 (best outcome). This is consistent with the good AKSS results.

On examination, all patients had excellent anteroposterior and mediolateral stability in the knee. Three patients had a fixed flexion deformity (2 of 5° and 1 of 10°) and for one patient this was associated with quadriceps weakness (<10 degree lag). Average flexion was 136.31 ± 12.09 degrees (range 90 – 155).

Analysis examined the comparison of the AKSS outcomes scores by gender, which showed no significant difference between male and female patients (Table 2).

Analysis also demonstrated that age was significantly correlated to AKSS pain score ($p=0.01$) (Table 3). However, age and BMI are not predictive of any of the other

AKSS scores or the OKS. The results demonstrated that older patients experienced less pain at 2 year follow-up than younger patients. The coefficient of determination ($R^2 = 0.0648$) demonstrated that 6% of the variation in the AKSS pain score is predicted by age.

Radiographic review by an independent reviewer found no signs of aseptic loosening, no radiolucent lines >2 mm in 50% or more of zones around a single component, no measurable changes of tibial vertical migration and/or subsidence >2 mm, measurable changes in angular orientation of any component >2 degrees, or progressive radiolucent lines. One patient had a stable lucency around the tibial keel at 6 months which had not progressed at the 2 year radiograph. Myositis Ossificans was identified in one patient at 3 months post-operative.

Discussion

This paper reports the early clinical outcomes and radiological results for a single surgeon series using a modern total knee implant system which includes a single sagittal femoral radius in the active flexion arc and unique instrumentation designed to optimize MCL isometry by maintaining the medial joint-line throughout the range of motion. The short-term results reported in this study demonstrate good survivorship and patient outcomes using the PS prosthesis.

In comparison to the published literature on more established traditional knee implants, total knee implants with a single sagittal femoral radius have demonstrated good to excellent results. Mahoney et al. [13] reported mean AKSS

Table 2
Comparison of 2 Year AKSS Scores by Gender

	GENDER			
	All (89)	Female (n=58)	Male (n=31)	
	Mean (SD, range)	Mean (SD, range)	Mean (SD, range)	Sig*
AKSS knee score	87.10 (7.98, 36 - 100)	87.02 (8.81; 36 - 100)	87.27 (6.21; 71 - 100)	NS
AKSS pain score	48.64 (4.27, 20 - 50)	48.53 (4.49; 20 - 50)	48.83 (3.87; 30 - 50)	NS
AKSS function	96.42 (8.84, 60 - 100)	97.33 (6.89, 70 - 100)	94.67 (11.67, 60 - 100)	NS
AKSS ROM	24.63 (1.44, 0 - 25)	24.53 (1.65; 16 - 25)	24.80 (0.93; 0 - 25)	NS
OKS	45.89 (3.69, 23 - 48)	45.74 (4.09, 23 - 48)	46.17 (2.82, 34 - 48)	NS
*t-test difference in means between female and male patients				

Table 3
Correlation of Age & BMI on 2 Year AKSS scores

	AGE	BMI
AKSS knee score	$r = 0.1238$ NS	$r = -0.0434$ NS
AKSS pain score	$r = 0.2546$ $p = 0.0167$ $R^2 = 0.0648$	$r = -0.0697$ 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		

knee scores improving from an average 44.0 (range: 30 – 59) pre-operatively to 95.3 (range: 85 – 100) at 2 years. Molt and Toksvig-Larsen [23] also reported significant improvements in Knee injury and Osteoarthritis Outcomes Score (KOOS) and AKSS scores from pre-operative to 2 years post-operative. Similarly, Cook et al. [15] reported a mean pre-operative AKSS score of 57.5 ± 14.9 and a mean post-operative AKSS score of 90.1 ± 18.0 at a minimum of 2 years follow-up. Dixon et al. [14] reported significant improvements in WOMAC pain scores (mean score: 75; SD = 17.5), WOMAC function scores (mean score: 71; SD = 17.1) and Knee Related Quality of Life (KRQoL) (mean: 57; SD = 20.8) at one year. Martin et al. [29] reported a mean OKS and WOMAC score at final follow-up of 30.64 (range 12-48 and 74 (range 18.9-100) respectively for a cohort of 456 consecutive patients who underwent a primary Scorpion TKR.

Molt and Toksvig-Larsen [23] reported no significant difference in AKSS or AKSS range of motion between Triathlon CR and PS implants at 2 years post-operative. Sur et al. [24] reported no significant difference in ROM between Triathlon CR and PS implants at final follow-up (mean 5.2 years; range 5.0 - 5.5 years) with mean ROMs of $135.8^\circ \pm 9.0^\circ$ (range: $120^\circ - 145^\circ$) and $133.6^\circ \pm 12.2^\circ$ (range: $100^\circ - 145^\circ$), respectively. However, they did find a significant difference between CR and PS for AKSS scores ($p = 0.017$) due to a significant difference in anteroposterior stability scores with the CR implants having a mean score of 4.1 ± 3.3 (0 – 10) and PS having a mean score of 9.2 ± 1.7 (0 – 10) ($p = 0.000$). There was no significant difference in mean AKSS pain, mediolateral stability, flexion contracture, extension lag, alignment, or functional scoring at final follow-up.

The literature reports discussion on the clinical benefit of resurfacing the patella. Baker et al. [25] looked at Patient Reported Outcome Measures (PROMS) data for 23,393 patients to compare results for patellar resurfacing versus non-resurfacing and found no significant difference in post-operative Oxford Knee Scores (OKS) ($p = 0.96$). Chen et al [26] found that the rate of re-operation was lower in total knee replacements with resurfacing, but resurfacing did not have any effect on anterior knee pain. They did find that the patellar resurfacing group had better AKSS scores in studies with 5 years or more of follow-up. Certain traditional knee implants have been designed with a constrained patellar articulation and tend to function best when the patella is resurfaced. Snir et al. [27] reported a significantly higher ($p < 0.001$) incidence of patellar clunk syndrome in patients that received a mobile-bearing, high-flex, PFC Sigma implant (DePuy) as compared with a fixed-bearing, single-radius, Scorpion implant (Stryker)

with 22 knees (11.7%) and 4 knees (1.8%) reporting patellar clunk, respectively.

While this is a single surgeon series, comparison to the most recent Registry data for the total knee system used in this study has also demonstrated excellent survivorship. The Implant Summary report produced for the manufacturer by the National Joint Registry England, Wales and Northern Ireland (NJR) [28] comprising primary total knees implanted up to 4 June 2015 showed 1 revision in 165 implantations (158 patients) since the first recorded usage of this knee in the NJR (maximum implant time 3.1 years; mean: 0.9 years). This is a revision rate of 0.61%. Cumulative revision rate KM 1.3% (range: 0.2% - 4.35%) in comparison to the combined revision rates for all other TKAs listed on the NJR were 0.4% (range: 0.4% - 0.4%) at 1 year, 1.0% (range: 1.0% - 1.0%) at 2 years and 1.5% (range: 1.5% - 1.5%) at 3 years. The implant cohort in the NJR had a mean age of 73.8 years; a median BMI of 29 (90.9% of BMIs available); 46.1% male and 53.9% female; and primary diagnoses of osteoarthritis (98.18%), rheumatoid arthritis (0.61%), other inflammatory arthropathy (1.21%), previous trauma (1.21%) and Other (0.615) (NOTE: More than one indication can be listed per case). The NJR cohort is similar to the cohort in this study with the exception of patient sex which was more skewed towards females in the study cohort (65.17% female).

This cohort follow-up study utilized a surgical procedure to facilitate restoration of native knee kinematics. All patients were implanted with a PS implant, the system was designed to restore femoral rollback, maintain the joint line, and cam post engagement at 50-55 degrees of flexion with the expectation that anterior knee pain will be minimized and knee kinematics facilitated throughout the range of movement [30]. The patella was resurfaced in all subjects. Long leg radiographs to assess the degree of deformity were used pre-operatively as part of the extensive pre-surgical planning and, unique to this system, the intra-operative procedure combined both measured resection and ligament balancing to preserve the postero-medial joint line and balancing of the MCL. Post-operative patient management included intensive physiotherapy, CPM and pain management.

Survivorship and patient outcomes were excellent in these short term results. Age was significantly correlated with AKSS pain scores such that older patients in this group had less pain than younger patients. It is interesting to note that the mean age at time of surgery was 68 years which is younger than those reported in the NJR data. Mean BMI in this single surgeon series was comparable to the NJR data. There were no significant differences on patient outcomes between males and females.

Conclusion

This paper reports on the early clinical and radiological outcomes using a modern generation total knee system. All clinical and radiological 2 year post-operative results were excellent, including the patient reported Oxford Knee Score. Patients reported an Oxford score of 46 out of a possible 48 which is the very best possible outcome. Anteroposterior and mediolateral stability and flexion also demonstrated good results which may suggest optimized quad function and posterior condylar offset and balance.

Further research is needed to evaluate these clinical and radiological outcomes including a randomized controlled study comparing the results of this total knee system and its unique instrumentation and surgical philosophy to other total knee systems in orthopaedic use. Multi-center studies with larger patient cohorts and longer-term follow up are needed. Specific functional assessments such as knee stability across a range of activities would provide data more sensitive to variations across knee systems. A comparison of the PS to CR variants in this system, patella resurfacing vs non- resurfacing, and a comparison of post-operative treatment programs are also areas for further investigation.

Whilst this study is short-term and patients in this cohort were younger than reported in the NJR and more skewed towards females, the results published in this cohort highlight that this modern knee design performs equally well when compared to the literature on other traditional knee implants available today.

Disclosure Statement

The author has disclosed information that may present potential for conflict of interest with this work. For full disclosures refer to last page of this journal.

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