‘Total Knee Replacement Done By A Single Surgeon with a Single Implant Design’

Prepared in confidence by

Author(s):

Andrew Hodge, MD

Janelle Garnique, APRN

Corey Scholes, PhD

Ronald Gardner, MD

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Abstract

Historically, patient satisfaction following knee replacement surgery (TKA) has been suboptimal, many times falling below 85%(ref). This study hypothesized that with consistent surgical practices and implant selection, that not only would patient satisfaction improve, but in addition, patient reported outcome measures (PROMs=KOOS & KSS), implant survivorship, implant placement and radiolucency would also get better. This study (247 patients) analyzed surgical outcomes and radiographic results of a single surgeon using a single knee implant design (Consensus Knee System-CKS) operated over a ten year period (from 2007 thru 2017). The results demonstrated an excellent satisfaction rate of 94%, KOOS scores of 94 to 99, KSS scores (function & pain) both 85, implant survivorship of 97% at 10years, consistent implant placement using the standard TKA instruments, as well as zero implant loosening and no progressive radiolucent lines (RLLs) during the study period. This ten year study of TKA results demonstrates the importance of a consistent surgical technique performed by a solo surgeon who used a single implant system.

Introduction

More than a million knee replacement surgeries are done each year in the US and studies have shown that patient satisfaction and patient reported outcome measures (PROMs) have been below the expected results (ref). Also, consistency of implant positioning has been reported as too variable by many authors (ref) although now with robotics and virtual/augmented navigation systems some have reported improvement in surgical placement of implants (ref). The number of failed total knee replacements have risen steeply with the increased surgical volumes and revision rates are reported as high as 5-10 % (ref).

The purpose of this study was to test the hypothesis that when limiting surgical variables, such as the surgeon and pre- & post-op protocols, the specific surgical technique, the design and type of implant used will improve PROMs (including satisfaction rates), survivorship and consistency of implant placement compared to historic controls.

Methods

442 knees were operated using a single surgical technique, by a single, private practice surgeon utilizing a single implant design (Consensus Knee System) between 2007 and 2017. 247 0f these patients were available for study. Data was collected through patient phone interviews and in-clinic exams with radiographic evaluations at latest follow-up, and the results are presented in terms of implant survival rates, radiographic findings, and patient-reported outcomes. The implant design was a cruciate-retaining, fixed bearing total knee replacement (Consensus Knee System) which had no design modifications over the time of these surgeries. Manual instrumentation (intramedullary femoral and tibial guidance for bone cuts) was used to establish mechanical knee alignment, with femoral and tibial components cemented in the methods described by the senior surgeon.

Clinical follow up was conducted comprising chart review, clinical in-person exams and phone follow-up to retrieve key clinical outcome data, as well as patient-reported outcomes. Patient-reported outcomes included the Knee Society Score (Noble et al., 2012), Knee Injury and Osteoarthritis Outcome Score (Roos et al., 1998) and a self-administered satisfaction scale (Mahomed et al., 2011). Radiographic ratings for radiolucency and component orientation were defined as per (Meneghini et al., 2015). Data was collected and organized into a spreadsheet file for further analysis.

Analysis

The spreadsheet(s) were read into the RStudio environment for further analysis. The data was prepared using functions from *tidyverse* to reformat variables, as well as identify and fix data transcription errors (e.g. date of birth with incorrect year). Additional variables were created for survival analysis and reformatting of variables to report radiographic findings. Component orientation was converted from angular measurements to deviation from neutral coronal alignment for the femur and tibia, as well as tibial slope (negative = posterior slope) and femoral flexion (positive = flexion). Radiological findings were categorized based on the following;

- Presence of radiolucency >=1mm
- Coronal alignment
    - Tibial; Target = 0°; Tolerance ±3°
    - Femoral; Target = 5° valgus; Tolerance ±2°
- Sagittal alignment
    - Tibial slope; Target = 5°; Tolerance ±3°
    - Femoral flexion; Target = 0°; Tolerance ±5°
    - Patellar tilt; Target = 0°; Tolerance ±5°

Patient characteristics were summarized for continuous variables (median and interquartile ranges) and proportions for categorical variables. Cumulative incidence functions were calculated for implant revision and patient mortality and CIF curves plotted with 95%

confidence intervals and the upper limit compared to the ODEP Rating 10A (*Methodology for Total Knees*, 2020). Patient-reported outcomes were summarized and distributions of the KOOS subscales visualized with median and interquartile range with fixed thresholds for patient acceptable symptom state as reported for 3-year follow up of primary TKR (Connelly et al., 2019).

Results

General population

Of the total eligible sample of 247 cases operated between 29-Jul-2007 to 28-Feb-2017 were available for the study with a subset of 92 of these patients submitting to follow-up exam in the clinic. Overall, the sample was predominantly female (57%), with a median age of 69 years at time of surgery and a diagnosis of isolated knee osteoarthritis. The majority of patients (72%) received a unilateral knee replacement (Table 1). No patients with previous open surgery or below the age of 18 years were considered.

Table 1: Baseline patient characteristics (All eligible)

Characteristic	N	N = 442[1]
AgeAtSurgery	441	69 (62, 75)
Sex	435	
Female		246 (57%)
Male		189 (43%)
Side	442	
Left		227 (51%)
Right		215 (49%)
Bilateral	442	
Simultaneous		10 (2.3%)
Staged		114 (26%)
Unilateral		318 (72%)
Staged Time (Months)	57	13 (4, 28)
Osteoarthritis	81	68 (84%)
Followup (Years)	272	8.49 (7.14, 10.39)

[1] Median (IQR); n (%)

Implant and patient survival

The competing risks regression identified mortality as a key competing risk for implant revision beyond 5 year follow up (Figure 2). Although the 10-year implant survival was estimated at 3.2%, the upper limit of the confidence limit exceeded the ODEP 10A rating of 5% (Table 2).

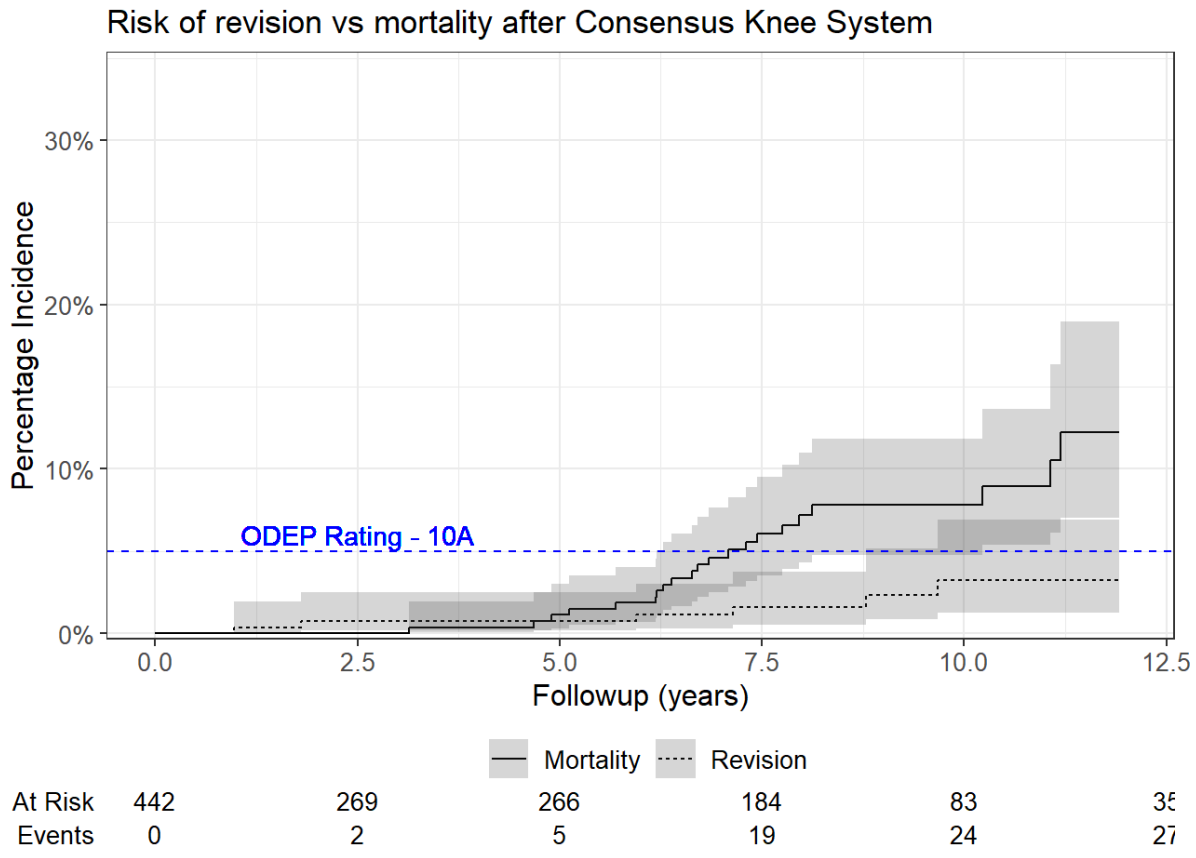

Figure 2: Cumulative incidence curves for *mortality* and *implant revision* after TKR with a Consensus Knee System

Table 2: Summary of competing risks incidence for the analyzed sample

Characteristic	Year 1	Year 2	Year 5	Year 10
Mortality				
Overall	0.00% (—%, —%)	0.00% (—%, —%)	1.1% (0.31%, 3.0%)	7.8% (4.7%, 12%)
Revision				
Overall	0.37% (0.04%, 1.9%)	0.74% (0.15%, 2.5%)	0.74% (0.15%, 2.5%)	3.2% (1.2%, 6.9%)

There were eight patients (3.2%) who had revision of their implants during this 10 year period. Of these, four (1.6%) were revised for chronic pain without loosening or infection but with positive nickel sensitivity, two (0.8%) had infections, one had severe poly wear (0.4%) and one had implant instability (0.4 %)

Patient-reported outcomes

Patients returning for their clinic visit returned median KOOS subscales >90 and more than 80% of patients contacted returned a rating of *very satisfied* or *somewhat satisfied* (Table 3). Visualization of the KOOS subscale distributions relative to the PASS threshold selected, illustrated the high proportion of patients returning patient acceptable symptoms (Figure 3).

Table 3: Summary of KOOS and patient satisfaction at latest follow up

Characteristic	**N**	**N = 250**[1]
KOOS - Symptoms	250	96 (89, 100)
KOOS - Pain	250	97 (89, 100)
KOOS - Activities of Daily Living	250	99 (93, 100)
KOOS - Sports	186	95 (80, 100)
KOOS - Quality of Life	250	94 (75, 100)
SatSubtotal	250	100 (94, 100)
Satisfaction - Overall	248	233 (94%)
Satisfaction - Improve Pain	239	239 (100%)
Satisfaction - Improve Work	230	230 (100%)
Satisfaction - Improve Recreation	233	217 (93%)

[1] Median (IQR); n (%)

Satisfaction reflects proportion of patients responding with "Very satisfied" rating

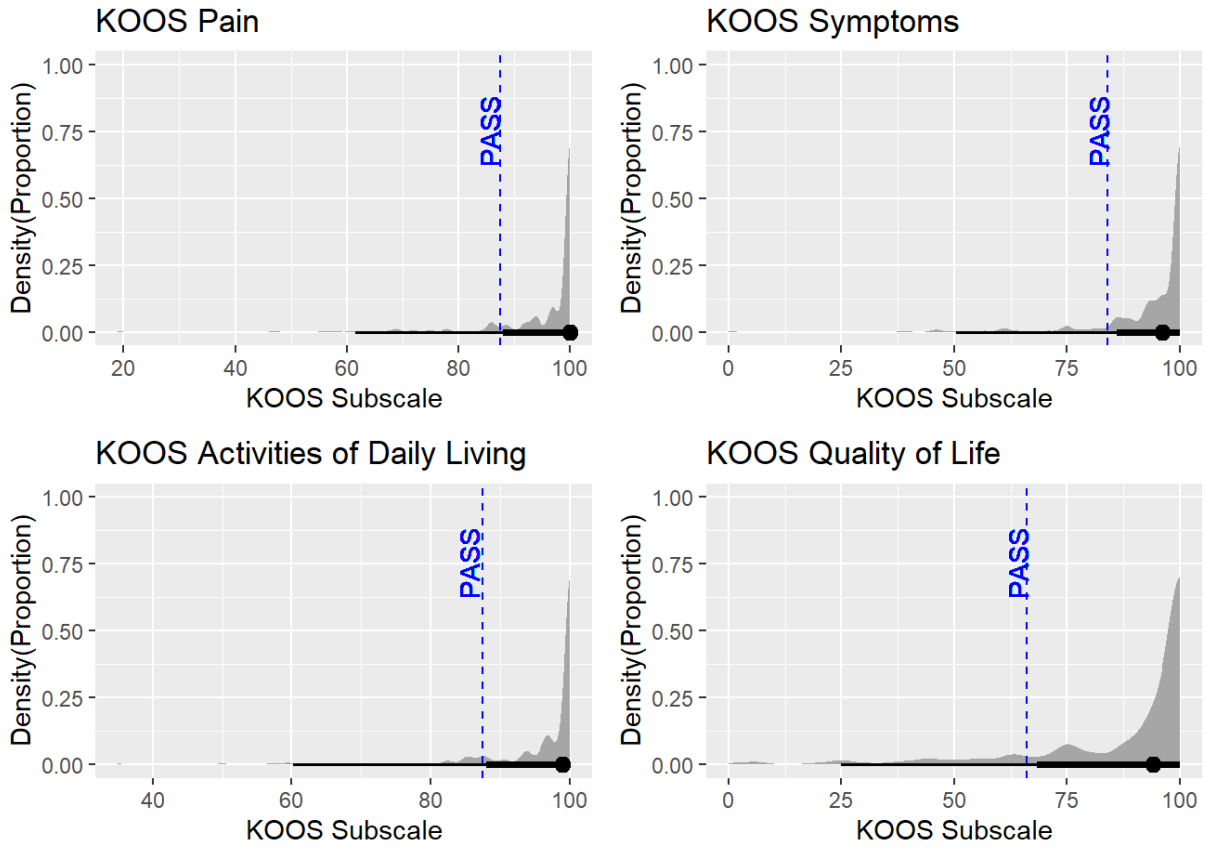

Figure 3: Summary of post-operative KOOS at latest follow up

Clinical findings

The subset of patients attending clinic review (N = 86) scored >80 on the Knee Society score with a median maximum flexion angle of >120° (Table 4).

Table 4: Summary of Knee Society Score and maximum flexion assessed in clinic

Characteristic	N	N = 250[1]
Knee Society Score - Pain	85	84 (78, 85)
Knee Society Score - Function	85	80 (70, 90)
Maximum Flexion	86	121 (115, 125)

[1] Median (IQR)

Radiological findings

Table 4b: Summary of patient characteristics undergoing follow up radiographs

Characteristic	N	N = 86[1]	95% CI[2]	add_stat_1
Datesurgery	80	2009-04-03 to 2017-10-06		
AgeAtSurgery	80	64 (9)	62, 66	
Female	78	45 (58%)	46%, 69%	
Right side	80	42 (53%)	41%, 64%	
Followup (Years)	80	8.92 (2.34)	8.4, 9.4	

[1] Range; Mean (SD); n (%)

[2] CI = Confidence Interval

Radiolucency (1mm minimum) was observed in 5 - 39% of cases available for review (Table 5). The majority of femoral components were orientated within tolerance of neutral in the sagittal plane, as well as valgus, the patella component remained in neutral tilt (Table 6), while the majority of tibial components were within tolerance of neutral (Table 7), although the incidence of deviation from target posterior slope was higher.

Table 5: Summary of radiolucency at latest follow up.

Characteristic	N	N = 86[1]	95% CI[2]
Tibial Radiolucency	82	4 (4.9%)	1.6%, 13%
Femoral Radiolucency	81	14 (17%)	10%, 28%
Patella Radiolucency	82	32 (39%)	29%, 50%

[1] n (%)

[2] CI = Confidence Interval

Table 6: Incidence of femoral and patella component orientation outside tolerance at latest follow up.

Characteristic	N	N = 86[1]	95% CI[2]
Femoral Valgus (5+-2deg)	82	2 (2.4%)	0.42%, 9.4%
Femoral Flexion (0+-5deg)	82	0 (0%)	0.00%, 5.6%
Patellar Tilt (0+-5deg)	82	3 (3.7%)	0.95%, 11%

[1] n (%)

[2] CI = Confidence Interval

Table 7: Incidence of tibial component orientation outside tolerance at latest follow up.

Characteristic	N	N = 86[1]	95% CI[2]
Tibial Coronal (0+/-3deg)	82	11 (13%)	7.2%, 23%
Tibial Slope (5+/-3deg)	82	27 (33%)	23%, 44%

[1] n (%)

[2] CI = Confidence Interval

Discussion

This study demonstrates that a single surgeon using a consistent surgical technique and a single implant design can produce 10-year survival of 97% of cases operated in addition to high patient-reported pain relief, function and satisfaction. These high outcome scores exceed published patient acceptable symptom rates.

This study reports implant survival of 97% at 10 years (a lower confidence limit of 93.1%). The majority of revisions (n=8) in this study were for pain and nickel sensitivity without loosening or infection (n= 4) , infection (n=2), poly wear (n=1) and implant instability (n=1). These results compares favorably with equivalent implants in both discrete series involving one center or one surgeon, or registry data from the Australian, Swedish, US, UK or European national registries. A cohort of 462 cruciate-retaining fixed bearing TKA (Triathlon, Stryker) implanted in Scotland, UK were followed up to 15 years postoperatively (Scott et al., 2023), with only 42% implant survivorship (retention) at last follow up. A larger retrospective institutional review from Minnesota (USA) of cruciate-retaining fixed bearing TKA (PFC, Depuy), predominantly cemented (96%) (N = 5389, N = 3325 at 10 years) reported all-cause implant survival of 92.2% (95%CI 91.0 - 93.4), which is also comparable to the present

analysis, particularly with respect to the lower bound of the confidence interval. The most recent report of the Australian Orthopaedic Association National Joint Replacement Registry (Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR), 2022) (Table KT9) reported cemented cruciate-retaining TKA with >3000 procedures with 10-year implant survival ranging from 94.1% (lower CI 93.5) to 97.1% (upper CI 97.3) . The present results also compare favorably to this data, although loss to follow up should be considered as a limitation in the estimation process. Patient-Reported Outcomes. A multi-surgeon database study (N = 621, N = 308 at latest follow-up) from Scotland (UK) reported an all-cause implant survival for a posterior-stabilized cemented TKA with selective patella resurfacing at 14 years of 96.5% (no confidence limits reported) (Arikupurathu et al., 2019) .

Mortality after TKA at 90-days reported in the literature has displayed a linear decrease over the course of implant usage in this single-surgeon practice (2007 - 2017) (Berstock et al., 2018) . The annualized estimate of mortality has decreased from 1.6% in 2005 to 0.76% in 2015 based on a meta-regression. This provides an overall estimate of mortality at 10 years that ranges from 7.6% to 16%. The estimated upper confidence limit for the present series is 12%, which is well within the boundaries estimated from the meta-regression.

This study reported overall patient satisfaction of 94% at 10 years. Scott et al in 2023 reported satisfaction amongst 88% of the sample at 10 year follow up, which was comparable to the 94% overall satisfaction in the present analysis.

PROMs in this study were both KOOS and KSS. Our reported KOOS varied between 94-99 points, while KSS pain and function were both at 85% at the 10 year mark.

A small New Zealand RCT of fixed (N = 46) vs mobile bearing (N = 39) cruciate-retaining TKA (PFC Sigma, Depuy) (Powell et al., 2018) reported KOOS scores at 10-year follow up (Table 8). Crude differences between the mean subscales and the *median* reported in the present analysis reveal superiority of the present series for *Symptoms*, but the differences for the remaining subscales were smaller than the anchor-based minimal clinically important difference (MCID) for TKA (Lyman et al., 2018).

Table 8: Summary of KOOS findings for fixed-bearing TKA at 10 year follow up.

	Powell et al 2018 Mean±SD	Difference to Present Report	MCID (Lyman et al 2018)
Pain	91.2 ±10.2	-5.8	18
Symptoms	87.2±6.8	-8.8	7
ADL	88.0±9.0	-11.0	16
Quality of Life	87.4±13.0	-6.8	17

The New Zealand cohort reported an overall KSS score of 87.4 (14.9) and the multi-surgeon cohort from Scotland () reported overall KSS of 89.0 at 10 years. In addition, a prospective cohort of cementless cruciate-retaining fixed-bearing TKA from New York (N = 114) reported a KSS pain score of 93 points.

Radiolucent lines between bone and cement were found in 4.9% of tibial implants, 17% of femoral implants and 39% of patellar implants, but no radiolucencies were progressive suggesting that the cases in this study will continue to remain asymptomatic.

A prospective cohort of *cementless* cruciate-retaining fixed-bearing TKA from New York (N = 114) reported 2.8% incidence of radiolucency (but their criteria and measurements were not as inclusive as the present study) at their 8-year follow up but did not report the information about progression (Harwin et al., 2018). However, the presence of radiolucency alone has not been associated with future adverse clinical or implant survival outcomes if it is stable (Garabano et al., 2023). It should be noted also that the incidence of radiolucency varies widely in the literature, regardless of the length of follow up, with others (Ng et al., 2022) reporting incidence as high as 48% at one year follow up (N = 135), in cemented TKA.

Implant positioning was found to be very consistent in this study, falling within standard tolerance guidelines (ref) for each implant component:

Femoral implant AP= 97.6%

Femoral implant LAT=100%

Tibial implant AP=87%

Tibial implant slope=67%

Recent studies comparing computer navigation, robotic surgery compared to standard instrumentation have found implant position variance from standards in 5% to 65%(ref) of patients.

The limitations of this study are length of follow up, percentage of patients lost-to-follow up, and selection bias.

Conclusions

This study found that when consistent surgical techniques & clinical practices were followed with a single implant design (Concensus Knee System), that patient satisfaction was improved compared to historic reports. In addition, patient reported outcome measures (PROMs=KOOS & KSS), implant survivorship, implant placement and measured bone/cement radiolucencies were also improved over other studies found in the literature. In addition, with this implant design over a ten year period (from 2007 thru 2017) the implant survivorship was 97% at 10years. These results demonstrate the importance of using both a consistent surgical technique and a single implant system. These factors were shown to be of crucial importance for obtaining excellent patient outcomes and survivorship in TKA.

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