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Clinical and radiographic outcomes of a hybrid fixation revision total knee arthroplasty system at short to mid-term follow-up☆

Kevin D. Stockwell [a,b], Sarfraz Malleck [a], Trevor C. Gascoyne [b], Thomas R. Turgeon [a,c,*]

[a] Department of Surgery, Section of Orthopaedics, University of Manitoba, Winnipeg, Manitoba, Canada
[b] Orthopaedic Innovation Centre, Concordia Hip & Knee Institute, Winnipeg, Manitoba, Canada
[c] Concordia Joint Replacement Group, Concordia Hip & Knee Institute, Winnipeg, Manitoba, Canada

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ABSTRACT

Background: Despite the extensive study of primary arthroplasty, revision surgery is rarely discussed due to the reduced frequency and variability between patients. A new revision knee system was introduced to build off the geometry of a successful knee replacement system. This study seeks to assess the survival, clinical outcomes and radiographic assessment of this revision system at the early to mid-term.
Methods: A consecutive cohort of 234 rTKAs was identified from an institutional database. Survival analysis was assessed for aseptic loosening and any-cause failure. Patient outcome measures were the Oxford Knee Score (OKS) and patient reported satisfaction. Radiographs were assessed in accordance with the Knee Society radiographic scoring system. Mechanical alignment was assessed on three-foot standing radiographs.
Results: Aseptic survivorship at one year, two years, and five years was 100%, 100%, and 99.1%, respectively. Any-cause survival at one, two, and five years was 99.6%, 98.7%, and 92.3%, respectively. OKS improved from pre-op (average 18.8) to one year (average 31.7), two years (average 30.7), and mid-term (average 30.6) follow-up ($p < 0.001$ for all). At all intervals, patient satisfaction exceeded 70%. One component (0.4%) failed radiographically and was later revised. Neutral mechanical alignment was achieved in 83% of cases. In the remaining cases, alignment was in varus (10%) or valgus (seven percent). No consistent relationship between radiographs or mechanical alignment and clinical outcomes was noted.
Conclusion: The survivorship, clinical, and radiographic outcomes of the single rTKA system studied are equivalent or superior to other hybrid fixation rTKA systems reviewed in the literature at similar follow-up intervals.

1. Introduction

Total knee arthroplasty (TKA) is a long-established and definitive treatment for osteoarthritis and other degenerative pathologies of the knee. Increases in life expectancy, obesity rates in western nations, and the introduction of primary TKA into younger

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* Corresponding author at: Concordia Joint Replacement Group, 310-1155 Concordia Avenue, Winnipeg, Manitoba R2K 2M9, Canada.
E-mail address: tturgeon@cjrg.ca. (T.R. Turgeon).

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patients has led to an increase in the number of TKAs performed [1,2]. By 2030, it is projected that 3.5 million primary TKAs will be performed in the United States alone [3]. Despite long-term survivorship above 90% for several primary TKA systems, and a stable revision burden, the need for revision total knee arthroplasty (rTKA) is expected to increase to 268,200 annual operations in the United States [1–7] with similar increases around the globe.

In contrast to primary TKA, revision TKA is associated with inferior functional outcomes and lower survivorship [1,8–15]. Outcomes in rTKA are dependent on several factors including ligamentous integrity, quality and quantity of bone stock, and the indication for revision which frequently includes infection [9–11]. Modular stems are regularly used in rTKA to improve stability of the components and to overcome the challenge of reduced bone stock. Among surgeons, equipoise exists surrounding the appropriate stem fixation method. Some advocate for the use of cemented stems to improve fixation of the implant, while risking additional bone loss should another revision be needed in the future [16]. Others report favorable outcomes with the use of press-fit stems [1,10,11,14,15,17]. The use of press-fit stems and cemented metaphyseal tibial and femoral components in rTKA was introduced by Bertin et al. and is termed hybrid fixation [15].

The purpose of this study is to report the short and mid-term results of a single hybrid fixation rTKA system and address the following questions: 1) What is the survivorship of the system of study at short to mid-term follow-up? 2) What are the clinical outcomes and patient satisfaction with the system of study? 3) Are there any radiographic changes suggestive of premature failure and do these correlate with clinical outcomes and patient satisfaction? 4) Has appropriate mechanical knee alignment been achieved, and is this correlated to clinical outcomes and patient satisfaction?

2. Materials and methods

After obtaining Institutional Review Board (IRB) approval, a query of the institutional database was performed to identify patients who had undergone rTKA. This query identified a consecutive cohort of 233 patients (234 knees) who received the hybrid fixation system of study (Legion Revision Total Knee Arthroplasty; Smith & Nephew, Memphis, TN). No exclusion criteria were defined. Patients who received the implant components of interest between April 2008 and March 2015 were included in the study. This includes patients with single-component revisions (i.e. tibia-only or femur-only revision) and patients who had undergone prior revision TKA (re-rTKA).

All surgeries were performed by one of four arthroplasty fellowship-trained orthopedic surgeons at the investigating institution. The surgical technique for all surgeons involved the extraction of the original implants and cement. In most cases, revision of both tibial and femoral components was performed, however, in selected cases, isolated femoral or tibial revision was performed at the discretion of the treating surgeon. Bone preparation involved diaphyseal reaming until solid bone contact was achieved. Bone cuts were made off the diaphyseal alignment followed by preparation of the bone to accommodate stem coupler housings. Offset couplers allowed proper coronal and sagittal alignment, appropriate metaphyseal engagement of the components, and good diaphyseal engagement of the press-fit stems. Implant trials were assembled and the motion and stability of the joint were assessed. Trial components were removed. Definitive implants were cemented to metaphyseal bone with diaphyseal engaging press-fit stems utilized in a line-to-line fashion based on the last reamer used. All patients received appropriate post-operative thrombosis prophylaxis, antibiotics and physiotherapy.

Survival analysis was assessed with a Kaplan–Meier curve with 95% confidence intervals at one, two, and five years. Two endpoints were considered: 1) aseptic loosening and 2) any secondary procedure.

Patients were followed post-operatively and seen in clinic at six weeks, six, 12, and 24 months and then every two years thereafter. Two patient reported outcome measures were collected at all follow-up appointments from six months on. These were the Oxford Knee Score (OKS) and patient reported satisfaction. The OKS consists of 12 questions, with each scoring the patient's knee pain and ability to perform daily activities on a scale from 0 to 4 [18,19]. The best possible outcome of 48 indicates no pain and high functional ability. The worst possible score is 0. Patients also completed an OKS assessment at initial clinical visit prior to revision surgery. Patient satisfaction with their surgery was recorded post-operatively on a five-point Likert scale with the following options: very satisfied, satisfied, neutral, dissatisfied, and very dissatisfied. Both questionnaires were completed in the patient waiting room without supervision of the operative surgeon. Patient follow-ups between four and six years after surgery were grouped as a single time-point in order to simplify analysis at mid-term follow-up.

Radiographic analysis was conducted by one author (KDS) and confirmed by a non-blinded co-author (SM). Antero-posterior (AP) and lateral (ML) radiographs at latest available follow-up were assessed for the presence of radiolucent lines in accordance with the Knee Society radiographic scoring system [20]. The femoral component was assessed for radiolucencies on the lateral view only, whereas AP and lateral films were reviewed for the tibial component. The width of radiolucencies was measured in millimeters in the local picture archive and communications system (PACS) (IMPAX v 6.6.1.4024, AGFA HealthCare N.V., Mortsel, Belgium). For each radiograph, the radiolucencies were summed to provide a final measurement. Components were classified as stable if radiolucencies were non-progressive and the final measurement was less than four millimeters. Scores between four and nine were classified as threatened-failures, and scores 10 or above were considered loose [20].

AP radiograph was taken at the six-month follow-up. The Hip–Knee–Ankle (HKA) angle was determined from the acute angle between two lines. The first line connected the center of the femoral head and the center of the knee joint, and the second line connected the center of the knee joint and the center of the ankle joint (Figure 1). Alignment was considered neutral if the HKA angle was between three degrees valgus and three degrees varus [21].

All data was analyzed using Statistical Package for Social Sciences (SPSS ; SPSS Inc., Chicago, IL) software. Other statistical analysis used Fisher's exact test and Student's t-tests where appropriate. p-Values <0.05 were considered significant.

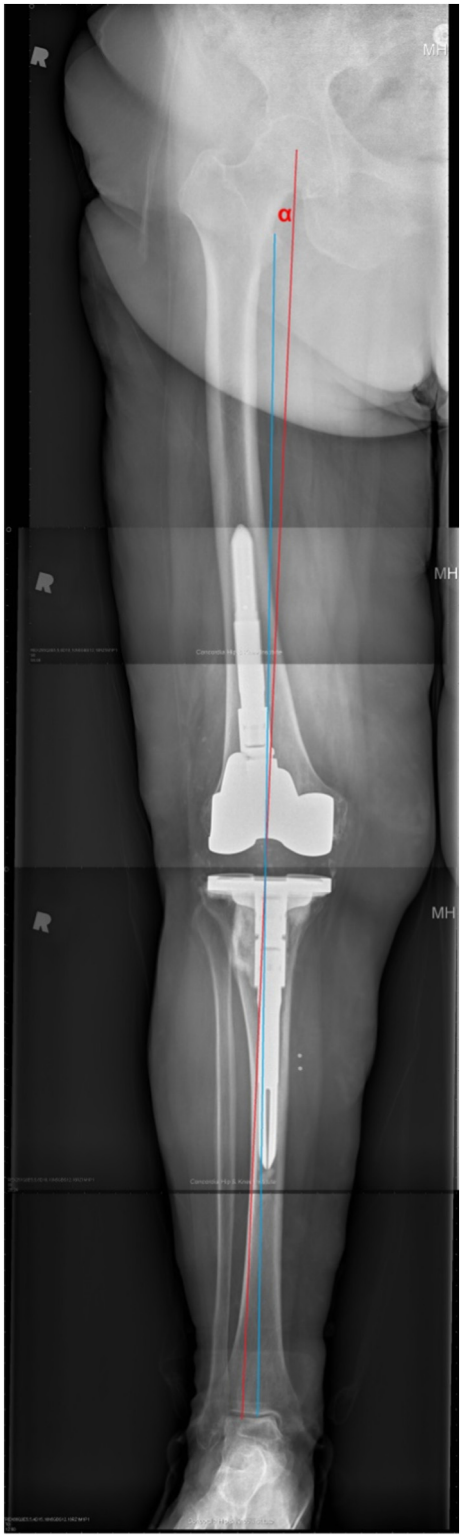

Figure 1. Hip–Knee–Ankle mechanical axis on three-foot standing radiograph.

Table 1
Patient demographics.

Population characteristics	Value
Total patients	233
Male:female	101:132
Mean age (range)	68 (27–89)
Mean BMI (range)	34 (21–86)
Total knees	234
No. of primary revisions (rTKA)	183
No. of previously revised TKA (re-rTKA)	51
1 prior revision	39
2 prior revisions	8
3 prior revisions	2
4 prior revisions	1
5 prior revisions	0
6 prior revisions	1

3. Results

Our cohort included 132 women and 101 men. Patient demographics are summarized in Table 1. The average age was 67.6 years (range, 27.4–89.7) at the time of surgery. Height and weight data were available for 221 patients, the mean Body Mass Index (BMI) was 34.4 (range, 20.9–85.5). The primary indications for revision to an rTKA system were: aseptic loosening (73 knees), stiffness/pain (54 knees), instability/component wear (49 knees), infection (42 knees), fracture/dislocation (seven knees), and other causes (nine knees). Most patients underwent revision of a primary TKA (183 knees). One patient received revision twice with the study components during their second and seventh revision surgeries. Most patients received both-component revisions (202 knees, 86%). Femoral-only revision occurred in 30 knees (13%) and a tibial-only revision occurred in two knees (one percent). Thus, this study includes 232 femoral implants, and 204 tibial implants.

Offset couplers two millimeters, four millimeters, or six millimeters in size were used for 220 of 232 femoral components (95%) and 188 of 204 tibial components (92%). The median diameter of the femoral stems was 16.9 mm (range 10–24 mm) and the median length was 157.5 mm (range, 80 to 220 mm). The median diameter of the tibial stems was 14.1 mm (range 10–20 mm) and the median length was 154 mm (range, 80 to 160 mm). A posterior stabilized insert was used in 168 cases (72%) and a constrained condylar insert was used in 61 cases (26%). No data was available on the type of insert used in five cases (two percent).

3.1. Survivorship

Of the cohort of 233 patients (234 rTKAs), 231 rTKAs had received a one-year follow-up, 224 had received a two-year follow-up, and 109 had received at least five years of follow-up. Mean follow-up for the cohort was 4.9 years (range, 0.2–8.3 years). In total, 16 knees required secondary procedures (Table 2). The reasons for revision included: patellar maltracking/pain, instability, infection, and quadriceps tendon repair. Two instances of aseptic loosening occurred at 2.1 and 2.9 years after revision surgery. Survivorship with aseptic loosening defined as the end-point at one year, two years, and five years was 100% (95% CI: 98.0% to 100%; Figure 1), 100% (95% CI: 98.0% to 100%), and 99.1% (95% CI: 96.6% to 99.8%), respectively. When any complication resulting in a secondary procedure was defined as the endpoint, the one-year, two-year, and five-year survival was 99.6% (95% CI: 97.3% to 99.9%; Figure 2), 98.7% (95% CI: 96.0% to 99.7%), and 92.3% (95% CI: 87.9% to 95.2%), respectively (Figure 3).

3.2. Clinical outcome measures

Patient reported outcome measures are summarized in Tables 3 and 4. The average pre-operative (pre-op) OKS was 18.8. At one-year, two-year and mid-term follow-up the average OKS was 31.7 (range, 0 to 48), 30.7 (range, seven to 48) and 30.6 (range, seven to 48). OKS improved from pre-op to one year, two years, and last follow-up ($p < 0.001$ for all). OKS did not improve between one and two years ($p = 0.589$), but showed improvement from one and two years post-op to last follow-up ($p = 0.008$

Table 2
Events requiring secondary procedure and time since revision.

Complication	Cases	Time since revision surgery (years)
Aseptic loosening	2	2.1; 2.9
Patellar maltracking/pain	2	1.4; 2.2
Instability	5	1.3; 2.2; 2.2; 3.4; 3.8
Infection	4	0.2; 2.4; 2.9; 4.3
Reverse tibial slope	1	3.0
Unknown (data not available)	2	2.6; 3.5
Total	16	

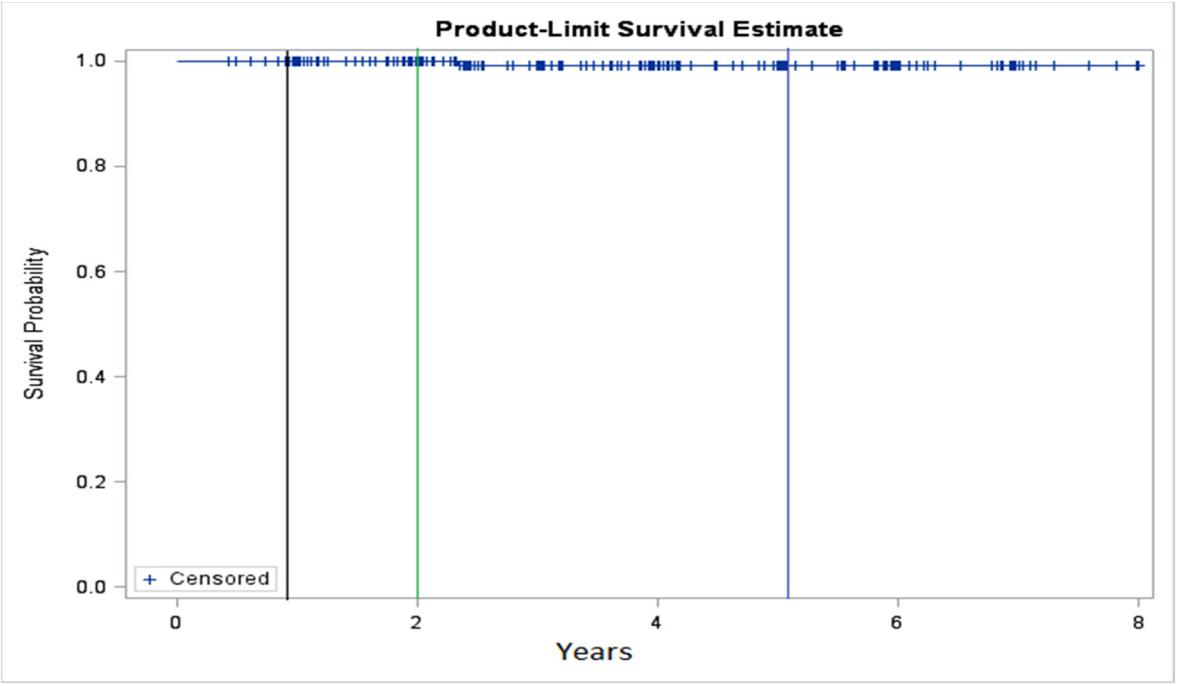

Figure 2. Kaplan–Meier aseptic (event: aseptic loosening) survivorship at one year (black line), two years (green line), and five years (blue line).

and p = 0.023, respectively). Patient satisfaction is reported in Table 4 and demonstrates acceptable patient satisfaction with revision surgery.

3.3. Radiographic analysis — radiolucencies

Radiographs were available for 225 (226 knees) of the 233 patients (234 knees) included in this study. Both components were revised in 195 patients (196 knees), femoral-only revision occurred in 28 patients (28 knees), and tibial-only revision occurred in two patients (two knees). Thus, radiographs were available for review of 224 femoral components, and 198 tibial components.

The frequency and magnitude of radiolucencies are summarized in Tables 5 and 6, respectively. Femoral radiolucencies were seen in 25% (57 of 224) of rTKAs with a mean width of 0.9 mm (range, 0.5–4.1 mm). Radiolucencies were isolated in 46 cases, and multiple in 11 cases. The majority were observed in zone 1 (67%) and zone 2 (13%). AP and ML radiographs were reviewed for tibial components. On AP views, radiolucencies were present in 19% (37 of 198) of rTKAs with a mean width of 0.7 mm (range, 0.5–1.5 mm). Radiolucencies were isolated in 33 cases and multiple in four, the majority were observed at the medial (68%) or lateral border (14%) of the tibial plateau. On ML view, radiolucencies were present in 13% (26 of 198) of rTKAs with a mean width of 0.6 mm (range, 0.5–1.0 mm). They were isolated in 21 cases and multiple in five. Again, the majority were observed near the tibial plateau at the anterior (61%) or posterior border (19%). One radiograph of the femoral component was classified as a 'threatened-failure' because the sum of the radiolucencies exceeded four millimeters. The sum of lucencies in all other radiographs reviewed did not exceed four millimeters and none were progressive. Thus 225 of the 226 knees available for radiographic review were considered stable. No significant difference was noted between the use of tibial (p = 0.52) or femoral (p = 0.73) offset couplers and the presence of radiolucent lines.

3.4. Radiographic analysis — alignment

Analysis of the mechanical axis consisted of 171 three-foot standing AP radiographs taken at the six-month visit. Seven were removed from analysis due to improper stitching of images or excess external rotation of the patient's knee following review by the senior author. Thus, 164 radiographs were reviewed. The mean alignment was neutral at 0.2° in varus (range, −6.8 to 7.0°). Alignment was considered neutral if the HKA angle fell between three degrees varus and three degrees valgus [21]. Neutral alignment was achieved in 136 of 164 knees (83%), varus alignment was noted in 16 of 164 knees (10%), and valgus alignment in 12 of 164 knees (seven percent). Three knees in either varus or valgus ultimately failed, whereas 13 knees in the neutral group went on to failure. No relationship between mechanical alignment and failure was noted (p = 0.71) and no relationship between mechanical alignment and the presence of radiolucencies was noted (p = 0.32). There was also no relation between mechanical axis and OKS at one year (p = 0.21) and two years (p = 0.17). Likewise, there was no relationship between mechanical axis alignment

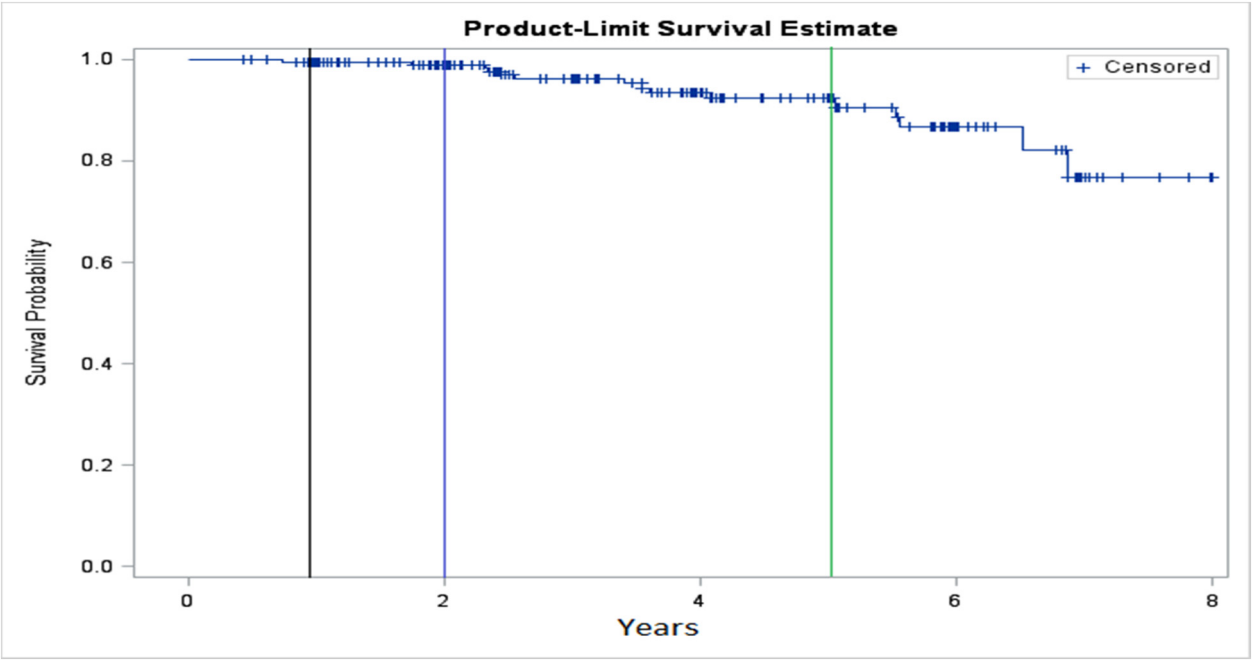

Figure 3. Kaplan–Meier all-event (aseptic loosening, instability, infection, etc.) survivorship curve at one year (black line), two years (blue line), and five years (green line).

and patient satisfaction at one-year ($p = 1.0$), two-year ($p = 0.75$), or last follow-up (0.50). At last follow-up, mean OKS was 35.5 in the varus–valgus group, and 29.5 in the neutral alignment group ($p = 0.03$).

3.5. Analysis of sub-groups

The cohort of 234 knees was heterogeneous in terms of the number of components revised (both-component vs. single-component), the indication for revision (septic vs non-septic), the number of prior revisions (rTKA vs. re-rTKA) and the type of liner inserted (posterior-stabilized vs constrained). The relationship between these variables and clinical and radiographic outcomes, and survivorship were analyzed.

When both-component revisions were compared to single-component revisions, no difference was present in patients' satisfaction at one-year, two-year, and last follow-up ($p = 0.49, 0.23, 0.76$, respectively). Likewise, there was no relationship between the number of components revised and OKS at the same follow-up intervals ($p = 0.56, 0.21, 0.72$, respectively) or the survivorship of the components ($p = 0.25$). Of note, the mechanical axis alignment was significantly different between the both-component and single-component revisions ($p = 0.036$). In the available radiographs, eight of 24 single-component revision knees were in varus or valgus alignment, whereas 20 of 140 both-component revisions were sub-optimally aligned.

Infection was the indication for revision in 42 knees. When compared to non-septic indications for revision, there was no difference in patient satisfaction at the one-year and two-year follow-ups ($p = 0.83, 0.50$, respectively). There was no difference between these two groups at one-year, two-year, or last follow-up in OKS values ($p = 0.17, 0.71, 0.41$, respectively) or survivorship ($p = 0.50$). At last follow-up, there was a trend toward lower patient satisfaction and OKS in the septic group. Only 57% of septic knee revisions were satisfied with their result at last follow-up, compared to 78% of non-septic cases ($p = 0.06$).

The number of prior revisions did not impact patient satisfaction at one-year or two-year follow-up ($p = 0.84, 0.79$, respectively) or OKS at the same follow-up intervals ($p = 0.27, 0.82$, respectively). Last follow-up OKS did not differ significantly between the two groups ($p = 0.26$). Mechanical axis alignment was sub-optimal in 20% of rTKAs compared to six percent of re-

Table 3
Oxford Knee Scores pre-operatively and at one-year, two-year, and four to six-year follow-up after revision TKA.

Follow-up	Pre-op	1-year	2-year	Last follow-up (mean: 5.1 years)
Number of respondents	224	209	170	139
Average Oxford Knee Score	18.8	31.7	30.7	30.6
Maximum Oxford Knee Score	48	48	48	48
Minimum Oxford Knee Score	1	0	7	7

Table 4
Patient satisfaction at one-year and two-year follow-up after revision TKA.

Follow-up	1-year		2-year		Mid-term (mean: 5.1 years)	
Number of respondents	187	%	125	%	128	%
Very satisfied	74	40%	48	38%	47	37%
Satisfied	57	30%	42	34%	48	38%
Neutral	26	14%	15	12%	13	10%
Dissatisfied	20	11%	9	7%	13	10%
Very dissatisfied	10	5%	11	9%	7	5%

rTKAs ($p = 0.04$). However, 30 of 32 single-component revisions were rTKAs which potentially confounds this result. When only both-component revisions were considered, the relationship between mechanical axis and number of revisions did not persist ($p = 0.16$). Patient satisfaction last visit was lower for the re-rTKA group, 11 of 28 respondents in the re-rTKA group were not satisfied with their outcomes, whereas only 22 of 140 respondents in the rTKA group were not satisfied ($p < 0.01$). Infection was the indication for revision in nine of the 11 non-satisfied patients in the re-rTKA group. A trend in survivorship was also noted between the two groups. Six of 51 re-rTKA failed, whereas 10 of 183 rTKA failed ($p = 0.12$).

There was no relationship between mechanical axis alignment ($p = 0.62$), patient satisfaction at one-year, two-year, or last follow-up ($p = 0.13$, 1.0, 0.35, respectively), or survivorship ($p = 0.57$) and the type of liner used. However, OKS was higher for the constrained liner when compared to the posterior stabilized liner at two-years (33.6 and 29.2, respectively, $p = 0.02$), there was a possible trend in favor of constrained liners at one-year follow-up (33.9 and 30.1, $p = 0.12$). This difference was not noted at last follow-up ($p = 0.78$).

4. Discussion

4.1. Survivorship

This study demonstrated one-year, two-year, and five-year survival was 99.6% (95% CI: 97.3% to 99.9%; Figure 2), 98.7% (95% CI: 96.0% to 99.7%), and 92.3% (95% CI: 87.9% to 95.2%) for this hybrid-fixation revision knee system. A review of recently published national registry data reveals revisions of primary TKA at one-year and five-years of one percent and 3.6% on 534,202 primary TKA [6]. Conversely, survivorship of rTKA in the short-term follow-up period has been cited to be as low as 60% [2]. A more contemporary study of survivorship rates in rTKA conducted by Sheng et al. stated an all-event survivorship of 95% and 89% at two year and five years when they considered 2637 rTKA in the Finnish Arthroplasty Registry data [22]. Additionally, the New Zealand Registry cites survivorship of 1684 rTKAs at one year and five years of 94% and 84% respectively.

Studies that specifically investigated survivorship in hybrid fixation rTKA systems cite survivorship rates of 83% to 100% at mid-term follow-up [1,11,12,14]. The findings of these studies are summarized in Table 7.

This study found that at the investigational institution, the short-term survival and mid-term survival of the studied knee system were consistent with or superior to other studies that have investigated survivorship of hybrid fixation rTKA systems. When compared against cited historical survivorship rates, our findings are strong and more closely resemble survivorship rates of primary TKAs.

4.2. Clinical outcome measures

Revision total knee arthroplasties are known to have inferior clinical outcomes and patient satisfaction rates when compared to primary total knee arthroplasty. This is often attributed to the increased complexity of revision procedures, the increased prevalence of septic knees in the revision population, and lower pre-operative functional levels of patients undergoing revision total knee arthroplasty [23,24]. This study reports mean Oxford Knee Score of 31.7 (range, 0–48), 30.7 (range, 7–48), and 30.6 (range, 7–48) at one-year, two-year, and last follow-up, respectively. Prior studies have reported OKS values of 26.6 to 32.8 following rTKA [23,25]. Baker et al. reported OKS values at a mean of seven months of follow-up (range: six to 12 months) on 797

Table 5
Frequency of radiolucencies by zone on femoral and tibial radiographs.

Radiograph	Offset coupler present (n)		Zones (n)								
			1	2	3	4	5	6	7	8	9
Femoral	Yes	213	46	9	6	2	0	1	1	0	2
	No	11	1	0	0	0	0	1	0	n/a	n/a
Tibial AP	Yes	185	28	0	0	5	0	0	1	6	n/a
	No	13	1	0	0	0	0	0	n/a	n/a	n/a
Tibial ML	Yes	185	19	5	0	1	1	0	0	4	n/a
	No	13	0	1	0	0	0	0	n/a	n/a	n/a

AP, antero-posterior. ML, medial-lateral.

Table 6
Magnitude of summed radiolucencies on femoral and tibial radiographs.

Radiograph	Radiolucency Single/multiple (n)		Sum of radiolucencies (n)							
			0.5–0.9 mm	1.0–1.4 mm	1.5–1.9 mm	2.0–2.4 mm	2.5–3.9 mm	3.0–3.4 mm	3.5–4.0 mm	>4.0 mm
Femoral	Single	46	36	9	1	0	0	0	0	0
	Multiple	11	0	4	3	1	1	1	0	1
Tibial AP	Single	33	28	5	0	0	0	0	0	0
	Multiple	4	0	3	1	0	0	0	0	0
Tibial ML	Single	21	19	2	0	0	0	0	0	0
	Multiple	5	0	5	0	0	0	0	0	0

AP, antero-posterior. ML, medial-lateral.

rTKAs (mean: 26.6) and on 23,393 primary TKAs (mean: 34.0). Similarly, Greidanus et al. reported two-year OKS values for 60 rTKAs and 199 primary TKAs with means of 32.8 and 37.6, respectively. This study reports OKS values within previously reported thresholds for OKS values in rTKAs.

Patient satisfaction at short-term and mid-term follow-up was favorable in 70% (one year), 72% (two years), and 75% (four to six years) of cases, respectively. Prior studies have reported patient satisfaction after rTKA of 66%–88% [23,25]. Patient satisfaction following primary TKA has been reported between 81 and 95% [9,24–26]. This study reports patient satisfaction within the threshold of satisfaction rates published in the literature for rTKA. Given the complex nature of revision surgery, satisfaction outcomes in this cohort remain below published values for primary TKA.

The number of prior revisions significantly impacted patient satisfaction. Only 60% of re-rTKA respondents were satisfied with their outcome while 84% of rTKA respondents were satisfied. This relationship, however, is thought to be the result of a higher proportion of re-rTKA cases having infection as their indication for revision. Of the 11 non-satisfied respondents in the re-rTKA cohort, nine were revised due to infection. Prior studies have shown that clinical outcome measures (such as the Oxford Knee Score) tend to be lower post-operatively when the indication for revision is infection [13,27,28]. However, they have also shown that patient reported satisfaction does not change based on the indication for surgery. In this study, a relationship is suggested between patient outcomes (satisfaction and OKS) and infection as the indication for revision at mid-term follow-up.

4.3. Radiographic analysis — radiolucencies

This study found that radiolucent lines were found in 25% of femoral component radiographs, 13% of tibial component ML radiographs, and 19% of tibial component AP radiographs. These findings are consistent with a cited incidence of partial radiolucencies of 19% to 74% in rTKA hybrid fixation systems [10]. In addition, three recent studies examining contemporary rTKA systems reported lucencies around two to 10% of femoral components and 11–57% of tibial components [1,8,11]. Of note, the reported prevalence of femoral component lucencies in this study is higher than the 10% upper threshold provided by these studies. The reason for this is unknown; however, all but two of our femoral radiolucencies were below two millimeters in size and were non-progressive, thus the increased prevalence is unlikely to be clinically relevant.

Except for two measurements, all radiolucent lines noted were less than two millimeters, non-progressive, and most were present on the initial radiograph taken at first follow-up. No correlation between the presence of small, non-progressive radiolucent lines and clinical outcome existed. This finding is supported by several other studies which have also found no significant relation between small (<2 mm), non-progressive radiolucent lines and clinical outcomes [1,11,17,29]. The two radiolucent lines that exceeded two millimeters were in the anterior portion of the femoral component of two patients. One measured 2.5 mm, was present on the first post-operative radiograph, and was non-progressive over four years of follow-up. This finding is likely related to incomplete cementing during the revision procedure. The sum of radiolucencies in the femoral component for this patient did not exceed four millimeters, and the component was not considered radiographically unstable. The other patient with a femoral radiolucency exceeding two millimeters, had two progressive lucencies at the anterior bone–cement interface measuring 2.3 mm and 1.8 mm. Since the sum of lucencies exceeded four millimeters, this radiograph was classified as unstable. Ultimately, this patient underwent a revision procedure for infection five weeks after the radiograph was taken. One of 226 rTKA radiographically reviewed in our study was considered radiographically unstable and was later revised due to infection. This finding is low and consistent with other studies which provided a radiographic failure rate of 0–6.3% [1,8,11,12,16,17].

Table 7
Summary of the literature of mid-term survivorship of hybrid component fixation in revision total knee arthroplasty.

Study (year)	No. knees	Average follow-up	Survivorship	No. aseptic loosening cases	No. re-operations
Sah et al. (2010)	88	65	92% @ 5 years (all-cause) 100% @ 5 years (aseptic)	0	9
Wood et al. (2009)	135	60	95% @ 5 years (all-cause) 98% @ 5 years (aseptic loosening)	2	6
Gofton et al. (2002)	89	69	93.5% @ 8.6 years (all-cause)	2	5
Haas et al. (1995)	76	42	83% @ 8 years (all-cause)	2	6

4.4. Radiographic analysis – mechanical alignment

The importance of achieving a neutral mechanical axis in TKA has long been established. Fang et al. demonstrated a significant difference in failure rates between neutral and sub-optimal alignment in primary TKAs. The highest failure rate was 1.8% at 6.6 years of follow-up and occurred in the varus group [30]. A more drastic difference in failure rate was reported by Jeffery et al. In their study of 115 primary TKAs, neutral alignment resulted in a failure rate of three percent, whereas non-neutral alignment resulted in a failure rate of 24% [31]. Clinical satisfaction has also been significantly linked to neutral mechanical alignment [32]. Despite the findings of prior studies, there was no relationship between mechanical alignment and failure rate ($p = 0.71$) or clinical satisfaction ($p = 0.36$) in this study.

This study reports alignments of 83% neutral, 10% varus, and seven percent valgus when 164 knees were reviewed radiographically. These findings are similar to those of Peters et al. who reported 62% neutral alignment, 22% varus alignment, and 16% valgus alignment in their radiographic review of 113 hybrid fixation rTKAs [17]. Using a similar fixation technique, Gofton et al. reported favorable alignment was achieved in all 79 cases when a variation of six degrees from anatomic axis was allowed [12]. The favorable incidence of neutral alignment in this study is likely a function of the hybrid fixation technique and use of offset components. Prior studies have reported the use of press-fit stems and offset couplers allow for superior coronal alignment when compared to cemented stems [1,33].

4.5. Study strengths and limitations

The strengths of this study include its relatively large sample size (234 knees) when compared to other contemporary studies evaluating outcomes of hybrid fixation revision total knee arthroplasty systems. An additional strength is the inclusion of outcomes of only four fellowship trained surgeons operating at a single academic center, thus limiting surgeon and center-specific variability in this study. Inclusion of only a single rTKA system removes possibly variability from different implant system designs.

There are recognized limitations to this study. This was a retrospective review of prospectively collected data with the inherent limitations and biases that ensue. The radiographs and patient outcome results were not available for all patients. Of 234 rTKAs considered in this study, 97% of radiographs were available for radiolucency analysis, and 70% of patients had radiographs for mechanical axis alignment review. OKS data was available for 76% and 74% of patients at short- and mid-term follow-ups, respectively. Satisfaction data was available for 68% and 88% at short- and mid-term follow-ups. Incomplete data may limit the generalizability of the results of this study. The cohort was heterogeneous with respect to the number of revisions and the number of components revised. Of 234 rTKAs, 183 were primary revisions and 51 were previously revised knees, 202 were both-component revisions, and 32 were single-component revisions. Given the varied nature of revision surgery, the authors believe this variation to be unavoidable.

5. Conclusion

The results of this study suggest that the hybrid knee revision system assessed in this study demonstrates survivorship, clinical outcomes, and radiographic stability, which are in keeping with or potentially superior to other hybrid fixation rTKA system previously reported in the literature. Future study will report on this cohort at long-term follow-up.

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Ethical statement

Ethics approval for this research was granted by the Health Research Ethics Board of the University of Manitoba (HS19905 (H2016:261)).

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