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KNEE ARTHROPLASTY

The survivorship of the link endo-rotational hinge total knee arthroplasty: 5–12-year follow-up of 100 patients

Leo R. Brown[1] · Nicholas D. Clement[2] · Deborah J. MacDonald[3] · Steffen J. Breusch[2]

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Abstract

Introduction There is a paucity of survival data reporting the medium to long-term outcome of the LINK® Endo-Model® rotational hinge total knee arthroplasty (ERH-TKA). Such information is essential when counselling patients and predictors of survival would help inform patients of their likely outcome.

Materials and methods A series of patients, who received an ERH-TKA, with a minimum follow-up of 5 years, were retrospectively identified from an established arthroplasty database. Data were collected from paper and electronic patient records. This included patient demographics, indication for surgery, complication rates and revision status. Our primary outcome of interest was joint implant survival.

Results One hundred patients underwent an ERH-TKA over an 11-year period. There were 66 females and 34 males, with a mean age of 73.8 years and 67.6 years, respectively. Indications were classified into primary ($n=41$), aseptic revision ($n=47$) and two-stage infective revision ($n=12$). The median follow-up was 8.2 (range 5–12) years. One-year implant survival amongst the cohort was 99%, falling to 95% at 5 years. Overall, there were eight revisions during the follow-up period. Considering only cases of aseptic failure, survival was 97% at 5 years and all failures occurred amongst revision cases. Implant failure was greater following revision arthroplasty but this was not statistically significant ($p=0.97$). Cox regression analysis identified male sex to be the only independent predictor of failure (hazard ratio 1.75, 95% CI 1.04–31.82, $p=0.04$) after adjusting for confounding variables.

Conclusions The ERH-TKA has a good medium- to long-term survival rate but male patients are nearly twice as likely to undergo revision, compared to females, and should be made aware of this preoperatively.

Keywords Endo-model · LINK · Total knee arthroplasty · Rotational hinge · Revision knee surgery · Primary knee arthroplasty

Abbreviation

ERH-TKA Endo-Model® rotational hinge total knee arthroplasty

Background

A traditional unconstrained total knee arthroplasty aims to replace the weight-bearing surfaces within the knee joint. In more complex cases, with global instability, severe contracture or extensive bone loss, a more constrained implant is often required. Walldius and Shiers designed the first hinged knee prostheses in the 1950s [1] allowing movement across one plane (flexion and extension) only. External rotation on a healthy knee, when walking, is between 9° and 13°. Implants' deviation from this physiologically normal motion was thought to cause greater torsional stress on the bone-to-cement interface of the implant [2]. This stress was considered to be a main contributor to the high rates of complications seen in early hinged implants [3]. As such, rotating hinge knee prostheses were designed, aiming to combine the flexion–extension movement of existing models with

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✉ Leo R. Brown
leorbrown1@gmail.com

[1] Health Education England North East, Waterfront 4 Goldcrest Way, Newburn Riverside, Newcastle Upon Tyne NE15 8NY, USA

[2] Department of Orthopaedic Surgery, Royal Infirmary of Edinburgh, 51 Little France Crescent, Edinburgh EH16 4SA, Scotland, UK

[3] University of Edinburgh, Edinburgh, UK

an element of axial rotation between the femur and tibial plateau. Development of more recent designs, such as the LINK® Endo-Model® rotational hinge prosthesis (Waldemar LINK GmbH and Co, Hamburg, Germany) have aimed to more closely mimic the physiological rotation within a healthy knee. These highly constrained prostheses are thought to maintain the correct anatomical axis within the knee and provide greater stability and alignment with better stress distribution [4]. They are, as such, used in both complex primary and salvage revision cases with severe bony or ligamentous defects and provide an alternative for patients in whom an un-constrained prosthesis would not be suitable.

When compared with complication rates as high as 80% in earlier rotational hinge prostheses [5], the LINK® Endo-Modell® rotational hinge total knee arthroplasty (ERH-TKA) is a much improved design [2, 6–13] for use within select patient groups. The implant's reputation is still relatively mixed within the literature with high complication rates and variable implant survival found in some case series [2, 10, 11, 14]. Some believe that the outcomes of all rotating-hinge prostheses are inherently poor while others would say it is implant specific [6]. It could also be postulated that success may vary depending on the indication for surgery. Authors who have analyzed their use in complex primary arthroplasty, in particular, have come to contradictory conclusions [7, 10, 14]. The decision to use a rotating hinge prosthesis is, therefore, often based predominantly on the surgeon's own experiences with these implants and, therefore, more high-quality research on this topic is required.

Aims and hypothesis

The primary aim of this study was to determine the ERH-TKA survival rates for complex primary and revision patients. The secondary aims were to describe the complication rate and identify pre-operative independent predictors of survival. The authors hypothesize that this prosthesis leads to good survivorship with acceptable complication rates.

Methods

Patients who underwent implantation of an ERH-TKA, between November 2002 and February 2010, were retrospectively identified from an established arthroplasty database in the author's institution. All operations were undertaken at a major acute teaching hospital by a number of arthroplasty specialists. Patient data were extracted from the NHS TRAKCare™ system electronic health record system and paper notes. This included demographics, co-morbidities and surgical indications and post-operative complications and outcomes. Mortality status was obtained from local government. Ethical approval was obtained locally.

Statistical analysis

All data were collected and handled using a standardised spreadsheet (Excel 2010; Microsoft, Redmond, Washington, USA). Results are presented in numbers and percentages for the qualitative variables and in mean ± standard deviation and range for the quantitative variables. The Kaplan–Meier method was used to estimate the survival of the prosthesis [15]. The endpoint of this survival was taken as removal or revision of the prosthesis. Cox regression analysis was used to identify clinically plausible predictors of implant failure. Fisher's exact test was used to determine the significance of relationships between categorical variables. These statistical tests were carried out using IBM SPSS Statistics V23 software. Statistical significance was defined as $p \leq 0.05$ in all analyses.

Patients

One hundred and forty-three patients were initially identified as having received the LINK Endo-Model® rotational hinge knee prosthesis between November 2002 and February 2010, at the author's institution. Forty-three patients were excluded owing to either insufficient follow-up, of less than 5 years, or paper clinical records being unavailable. All analyses are, therefore, based on a case series of one hundred patients.

Forty-one patients (34 women and 7 men) underwent primary arthroplasties and 59 patients (32 women and 27 men) underwent revision procedures. The mean ages at the time of operation were 74.2 ± 11.9 (range 37.4–89.6) years and 71.1 ± 11.9 (range 36.5–92.6) for each group, respectively. Nineteen patients (11 primary and 8 revision) had staged bilateral ERH-TKA and, in one case, both prostheses were implanted simultaneously. Of those who underwent primary arthroplasties, 46% of patients ($n = 19$) had bilateral total knee replacements with conventional resurfacing fixed bearing prosthesis in the contralateral knee. In the revision group, 54% ($n = 32$) of patients had undergone bilateral knee arthroplasties. 66 patients had a recorded BMI and of those, 49% ($n = 32$) were clinically obese, with a mean BMI of 30.3 ± 6.6 (range 16–46) observed amongst the cohort. Six patients died during the follow-up period, all from unrelated causes.

Indications

The main indications for surgery in primary cases were osteoarthritis, fractures and rheumatoid arthritis with ligamentous incompetence and/or severe contractures

Table 1 Surgical indications—primary

	Number of patients	Percentage
Total primary	41	100
Primary gonarthrosis	5	12
Primary gonarthrosis with ligamentous laxity	18	44
Fracture	11	27
Tumours	1	2
Avascular necrosis	1	2
Rheumatoid arthritis	5	12

(Table 1). There was one patient who received the prosthesis following excision of a sarcoma.

The majority of those with osteoarthritis had associated ligamentous laxity and within this group 75% were valgus deformities with incompetence of the medial collateral ligament.

Revision arthroplasties were mostly indicated for aseptic and septic loosening of previous prostheses; however, pain within the joint was also listed as an indication in a number of cases (Table 2).

Results

Implant survival

Patients were reviewed a mean of 99.8 ± 24.5 months (range 60.0–147.0) following implantation of the ERH-TKA. The prosthesis was deemed to have failed if it was revised or removed and this occurred in 8 of the 100 patients. A single prosthesis failed within the first year post-implantation owing to joint infection (Fig. 1). Implant failure was highest during the 1- to 2-year post-operative period with three prostheses being revised during this time. This led to a cumulative implant survival rate of 99% at 1 year and 95% at 5 years (Table 3).

Table 2 Surgical indications—revision

	Number of patients	Percentage
Total revision	59	100
Single stage	47	80
Two stage	12	20
Aseptic loosening	28	47
Septic loosening	19	32
Pain	10	17
Peri-prosthetic fracture	1	2
Avascular necrosis	1	2

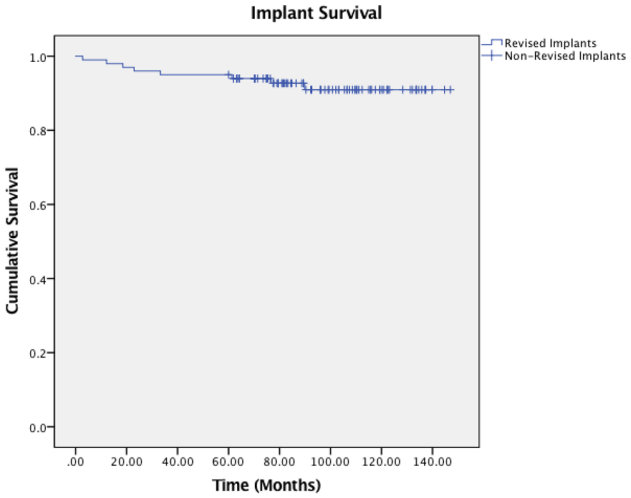

Fig. 1 Kaplan–Meier survival analysis: overall implant survival

Predictors of implant survival

There were no revisions for primary cases for aseptic failure. Implant failure was greater amongst those undergoing revision arthroplasty (Fig. 2). Cox regression analysis, however, showed that the type of arthroplasty (primary versus revision) did not have a significant effect on implant survival ($p = 0.97$) when adjusting for other co-variants. Age was also found not to impact on implant survival ($p = 0.54$). Male sex was found to be an independent risk factor for implant failure (hazard ratio 1.75, 95% CI 1.04–31.82, $p = 0.04$) when adjusting for these other covariates.

Indications for implant revision

Implant failure occurred in 8 of the 100 patients (5.7% of the sample). Of these, two (25%) failures occurred in primary ERH-TKA (Table 4). The causes were documented as joint infection in one patient and haemarthrosis (with subsequent infection) in the second. Six (75%) of the failures occurred in salvage revision arthroplasties, three of which were due to joint infection. Of the four cases where joint infection led to implant failure, two (50%) were recurrences of the infection for which the revision had initially been performed.

Two patients underwent surgery for exchange of implant bushings that had worn out (following 52 months and 48 months). One of these patients later went on to undergo a complete implant revision. Another patient required a subsequent operation to replace an axle and grub screw 5 months following implantation of the ERH-TKA.

Table 3 Life table for the study cohort

Years since operation	Number at start	Withdrawn	Number at risk	Failure	Annual survival rate (%)	Cumulative survival (%)	95% CI	
							Lower	Upper
0–1	100	0	100	1	99.0	99.0	97.1	100.9
1–2	99	0	99	3	97.0	96.0	93.9	98.1
2–3	96	0	96	1	99.0	95.0	92.2	97.8
3–4	95	0	95	0	100.0	95.0	91.6	98.4
4–5	95	1	94.5	0	100.0	95.0	91.2	98.8
5–6	94	14	87	1	98.9	93.9	89.7	98.1
6–7	79	19	69.5	1	98.6	92.6	88.0	97.1
7–8	59	10	54	1	98.1	90.8	86.1	95.6
8–9	48	13	41.5	0	100.0	90.8	85.8	95.9
9–10	35	13	28.5	0	100.0	90.8	85.5	96.2

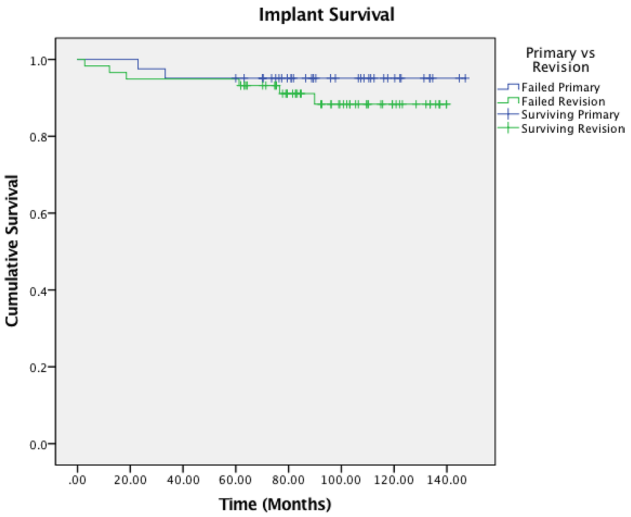

Fig. 2 Kaplan–Meier survival analysis: revision versus primary

Table 4 Causes of implant failure (revision/removal of implant)

	Number of patients	Percentage
Primary arthroplasties	2	25
Joint infection	1	12.5
Repeated haemarthrosis and subsequent infection	1	12.5
Revision	6	75
Joint infection	3	37.5
Aseptic loosening	1	12.5
Peri-prosthetic fracture	1	12.5
Severe pain and immobility	1	12.5

Post-operative complications

Overall, 29 patients were documented as having experienced a complication following implantation of the ERH-TKA. We observed a complication rate of 27% ($n=11$) for primary cases and 31% ($n=18$) for revisions, with no statistically significant difference between these groups ($p=0.82$).

Fourteen patients contracted joint infections and nine were successfully treated with antibiotic therapy and washout surgery while five underwent revision surgery. Four of these 14 patients had infection as their initial indication for implantation of the ERH-TKA prosthesis. Another three patients were documented as suffering from wound infections/cellulitis following surgery, all of which were successfully treated using antibiotic therapy. Six patients were recorded as having suffered from other post-operative medical complications. These were of varying severity but none directly led to patient death. Pulmonary oedema ($n=3$) was the most commonly seen medical complication.

Discussion

The key finding from this study is the good medium- to long-term survival observed with the LINK® Endo-Modell® Rotational Hinge Prostheses, when used for complex primary and revision total knee replacement. This case series is one of the largest described within the current literature and includes both salvage revision and complex primary arthroplasties.

Limitations

A number of limitations must be acknowledged with this work. Similar to much of the existing literature, this is a retrospective case series looking at relatively small patient numbers [2, 5–13, 15]. To ensure greater than 5 years of follow-up, a number of patients who had received the implant

more recently, or had died during the study period, were also excluded thus further limiting our patient numbers. While all available sources of data were utilised, it is possible that complications or failures may have been missed if patient's received care outwith the health service that had not been documented in their records or clinic follow-up. Another potential criticism is that our study lacks data on some more functional and clinical outcomes, such as the Knee Society score or Hospital for Special Surgery Knee score, that are utilised in much of the existing literature [6–11, 13, 14, 16].

Implant survival

Variable results for implant survival have been found across previous research in this area. This study's findings of eight implant failures with 99% survival at 1 year and 95% at 5 years were amongst the more favourable within the existing literature (Table 5).

Implant survival varies quite considerably when comparing previous similar case series (Table 5). Bistolfi et al. described implant survival rates of only 85.9% at 5 years, across a relatively large sample of primary rotating hinge implants with long-term follow-up [14]. A subset of the same authorship group showed similarly high rates of implant failure amongst 53 revision cases [16]. Efe et al. found similarly poor results across a mixed (primary and revision) case series with shorter term follow-up [10]. The implant survival reported by Sanguineti et al. [6] was more comparable with the described series but with a smaller sample size and a shorter follow-up. Petrou et al. found 96% implant survival amongst 100 patients undergoing primary arthroplasty [7]. Similar to our own results amongst the primary group, all cases of implant failure occurred early within the follow-up period.

Complication rate

Fewer studies commented on post-operative complication rates with ERH-TKA. Guenoun et al. [2] reported 28.2% of patients suffered complications following implantation, near identical to the 29% found in this study. Some authors documented even higher rates of complications [7, 14, 16]. Similar to Guenoun's findings [2], we noted joint infection was found to be the most frequently observed complication. Patients who had infection as their initial indication for surgery were at particularly high risk of further infection within the joint. Within our case series, 25% of this group experienced re-infection following ERH-TKA. Streitbuerger et al. found even higher re-infection rates of 30% amongst a similar case series of hinged revision arthroplasties [17]. The advanced age, co-morbidities and other risk factors present within this patient demographic will likely increase the risk of peri-operative and implant-associated complications [2, 17].

Predictors of implant failure

This study found no significant differences in terms of implant survival ($p = 0.97$) or complication rate ($p = 0.828$) between primary and revision groups. These findings are contrary to Efe et al. [10] who found, across a similar-sized patient cohort, that revision procedures carried a greater risk of implant failure. Our results identified male sex as a statistically significant predictor of implant failure, a finding not seen elsewhere in the literature. The clinical significance of this cannot be ascertained from the study and this may be a spurious finding. More evidence would be required before utilising this information to guide clinical decision-making or informing patients of their likely outcome.

Conclusions

This case series has shown that the LINK® Endo-Modell® Rotating Hinge prosthesis has a good medium- to long-term survival rate with 99% survival at 1 year and 95% at 5 years. This implant survival is amongst the most favourable within the existing literature. Complication rates were

Table 5 Literature comparison of implant survival with LINK® Endo-Modell® rotational hinge prostheses

Study	No. primary arthroplasties	No. revision arthroplasties	Mean follow-up (range), months	Failures (% of sample)
This study (2018)	41	59	99.8 (60–147)	8 (8%)
Bistolfi et al. [13]	98	0	174 (156–193)	18 (18.4%)
Bistolfi et al. [15]	0	53	155 (78–240)	11 (20.7%)
Efe et al. [9]	31	44	56 (10–133)	18 (24%)
Gudnason et al. [8]	0	42	106 (72–216)	9 (21.4%)
Petrou et al. [6]	100	0	132 (84–140)	4 (4.0%)
Pradhan et al. [7]	0	51	48 (24–72)	0 (0%)
Sanguineti et al. [5]	25	20	42 (20–128)	3 (6.7%)
Yang et al. [10]	50	0	180 (120–216)	7 (14%)

high but in line with previous studies. This implant should be considered in cases of complex primary and revision arthroplasty—where severe contractures, bone or ligament deficiency mean that unconstrained or semi-constrained prostheses are unsuitable.

Compliance with ethical standards

Conflict of interest Leo R. Brown, Nicholas D. Clement, Deborah J. MacDonald and Steffen J. Breusch declare that they have no conflicts of interest. The University of Edinburgh received a research grant from Aquilant Medical UK, which was utilised to partially fund a knee research salary post at the authors' institution. This person did not contribute to any noteworthy extent to this study and is not part of the author group.

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