■ ONCOLOGY

Evaluating polyethylene, polyether-ether-ketone, and metal-on-metal locking mechanism survival in Modular Universal Tumour and Revision System knee reconstructions for oncological indications

INSIGHTS FROM THE MUTARS ORTHOPEDIC REGISTRY EUROPE

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Aims

Over time, the locking mechanism of Modular Universal Tumour and Revision System (MUTARS) knee arthroplasties changed from polyethylene (PE) to polyether-ether-ketone Optima (PEEK) and metal-on-metal (MoM) in an attempt to reduce the risk of mechanical failure. In this study, we aimed to assess the cumulative incidence of locking mechanism revision for symptomatic instability by type of material, and assess potential associated risk factors.

Methods

The MUTARS Orthopaedic Registry Europe was used for a retrospective review of 316 patients (54% male (n = 170), median age 44 years (IQR 23 to 61)) who underwent a MUTARS knee arthroplasty for oncological indications between December 1995 and January 2023. The minimum follow-up was 12 months, and the median follow-up was 7.9 years (IQR 3.3 to 13.0). A competing risk model was used to estimate the cumulative incidence of first locking mechanism revision with death and revision for any other reason as competing events. Possible risk factors were assessed employing a univariate cause-specific hazards regression model.

Results

Symptomatic instability of the hinge or locking mechanism due to wear (n = 20) or breakage (n = 14) occurred in 34 patients (11%): 9% of PE (n = 4/45), 20% of PEEK (n = 9/44), and 9% of MoM locking mechanisms (n = 21/227). The cumulative incidences of revision for instability due to wear or locking mechanism breakage at two, five, and ten years were 0%, 5% (95% CI 1 to 15), and 5% (95% CI 1 to 15) for PE, 5% (95% CI 1 to 14), 14% (95% CI 5 to 26), and 16% (95% CI 7 to 29) for PEEK, and 0%, 3% (95% CI 1 to 6), and 10% (95% CI 5 to 16) for MoM. With PE as the reference category, the cause-specific hazard ratio for PEEK and MoM were 3.6 (95% CI 1.1 to 11.9; p = 0.036) and 3.2 (95% CI 1.1 to 9.5; p = 0.043), respectively. Age, BMI, resection length, and extra-articular resections were not associated with the time to locking mechanism revision.

Conclusion

Alterations in prosthetic materials have not decreased the revision risk for locking mechanism failure. Besides locking mechanism material, no other patient- or prosthesis-related risk factors for locking mechanism failure were identified. Improvement of the locking mechanism is warranted since revision exposes patients to the risk of serious secondary complications.

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Introduction

The Modular Universal Tumour and Revision System (MUTARS; Implantcast, Germany), introduced in 1992, is one of the most commonly used systems for reconstruction of large tumour defects around the knee. The knee endoprostheses consist of a femoral and tibial component, connected with a hinged locking mechanism. Originally, the locking mechanisms of the distal femoral reconstructions were constructed of metal-on-polyethylene interface (PE). Previous studies reported that in 13% to 19% of cases, wear or even breakage of the locking mechanism occurred, leading to severe instability of the endoprosthesis and often necessitating revision of the locking mechanism.[1-4] In an attempt to reduce the risk of early structural failure, the PE was replaced by polyether-ether-ketone Optima (PEEK) in 2003. Although PEEK has obvious mechanical advantages over PE,[5] other studies reported early to mid-term breakage of the locking mechanism in 11% to 38% of cases.[3,4,6,7] The locking mechanisms of distal femur reconstructions were changed to a metal-on-metal (MoM) version in 2013, aiming to reduce this risk of mechanical failure. Proximal tibia reconstructions, on the other hand, were equipped with a MoM locking mechanism from the beginning. Despite the use of MoM hinges, locking mechanism failure persisted, affecting up to 25% of cases according to previous reports.[3,4,8] To date, larger series focusing on locking mechanism failure of MUTARS knee arthroplasties are lacking.

Therefore, we aimed to: report the incidence of locking mechanism revision for symptomatic instability due to hinge wear or breakage; identify associated risk factors for locking mechanism failure; and evaluate the cumulative incidences of locking mechanism revision for symptomatic instability for PE, PEEK, and MoM at two, five, and ten years.

Methods

In this international multicentre observational retrospective study, data from the MUTARS Orthopaedic Registry Europe (MORE) were used. All patients who had a MUTARS distal femur, proximal tibia, total knee (distal femur and proximal tibia arthroplasty combined), or total femur reconstruction for an oncological indication between December 1995 and January 2023 were included. Patients with a follow-up of less than 12 months were excluded. A total of 316 patients from four tertiary referral centres were included (54% male (n = 170), median age 44 years (IQR 23 to 61)). The median follow-up was 7.9 years (IQR 3.3 to 13.0), with time to failure estimated using the reverse Kaplan-Meier methodology.[9] A total of 45 (14%) patients received a PE locking mechanism, 45 (14%) a PEEK-Optima, and 226 (72%) a MoM (Table I). Overall, 83 (26%) patients had prior surgery to the same site. The median resection length was 16 cm (IQR 13 to 20), and 67 patients (25%) underwent an extra-articular resection.

Prosthetic details. The MUTARS system consists of a hexagonal stem that is available in different sizes, both for uncemented and cemented fixation. Uncemented press-fit fixation of a hydroxyapatite-coated stem was preferred, unless adequate primary stability could not be obtained (for example in case of conically shaped bones, or poor bone quality such as that of irradiated bones). Extension pieces are used to add to the desired implant implant reconstruction length. The femoral and tibial components are connected with a rotating hinged locking mechanism.

Variables. Demographics, surgical and prosthesis details, and complications were obtained from the electronic patient records. Locking mechanism failure was defined as symptomatic instability or a restricted range of motion requiring revision surgery due to bushing wear or breakage of the locking mechanism. Complications and the reason for implant revision were scored according to the Henderson classification.[10]

Statistical analysis. A competing risks model was used to estimate the cumulative incidence of locking mechanism revision with death and revision for any other reason as competing events. To assess the difference among the cumulative incidences of different locking mechanism materials, a Gray test was used. A univariate cause-specific hazards regression model was employed to study the effect of possible prognostic risk factors on locking mechanism failure. Cause-specific hazard ratio (HRcs) with 95% CIs are reported. The log-rank test was employed to assess the effect of prognostic factors on the outcome. The score test was employed to assess the validity of the proportional hazards assumption for each prognostic factor and a visual inspection of the Schoenfeld Residuals was performed. Median time and IQR for revision due to locking mechanism revision were calculated. Data analysis was performed using SPSS v. 25.0. (IBM, USA), and R v. 4.2.1 (R Foundation for Statistical Computing, Austria). The R-studio package 'cmprsk' was used to estimate the cumulative incidence of implant revision. The level of significance was set at a p-value < 0.05.

Results

Surgical revision for instability due to wear or breakage (Henderson 3A) was observed in 34/316 patients. Of these 34 patients, five were previously revised for aseptic loosening (n = 2) or infection (n = 3), and were later revised for symptomatic instability due to hinge-wear or breakage. These patients had a median age of 36 years (IQR 20 to 52), versus 46 years (IQR 23 to 62) for those without locking mechanism failure. The median time to first locking mechanism revision for 14 patients experiencing breakage was 5.1 years (IQR 3.4 to 6.7) versus 8.7 years (IQR 4.7 to 11.7) for 20 patients requiring a revision due to wear. Nine patients (3%) had recurrent locking mechanism failures: six patients had two revisions, three patients had three revisions. The median time to first locking mechanism failure for patients with recurrent failures was 4.1 years (IQR 2.7 to 7.0), versus 7.7 years (IQR 4.3 to 10.3) for those with a single failure.

Four out of 45 patients (9%) with a PE locking mechanism were revised: three (7%) due to hinge-wear, and one (2%) due to breakage. All revised implants were distal femoral reconstructions. The median time to first locking mechanism revision was 6.8 years (IQR 3.7 to 12.5). One patient underwent three revisions; the initial reconstruction was with a PE locking mechanism, which was revised to PEEK, and then subsequent PEEK revisions due to wear and recurrent breakage (Table II).

Revision of the PEEK locking mechanism. Nine out of 44 patients (20%) with a PEEK locking mechanism were revised: five (11%) due to hinge-wear, and four (9%) due to breakage.

Table I. Study population.

Variable	Total
Sex, n (%)	**316**
Male	170 (54)
Female	146 (46)
Median age, yrs (IQR)	44 (23 to 61)
Median BMI, kg/m² (IQR)	24 (21 to 27)
ASA grade, n (%)	**288**
I	93 (32)
II	161 (56)
III	34 (12)
Smoking n (%)	**196**
Yes, currently	36 (18)
Yes, former (stopped > six months)	29 (15)
Diabetes, n (%)	9 (4)
Indication for reconstruction, n (%)	**316**
Osteosarcoma	142 (45)
Chondrosarcoma	43 (14)
Soft-tissue sarcoma	26 (8)
Ewing's sarcoma	14 (4)
Metastatic carcinoma	41 (13)
Giant cell tumour	29 (9)
Sarcoma NOS	5 (2)
Leiomyosarcoma of bone	7 (2)
Other	9 (3)
Previous surgery at same site, n (%)	**316 (26)**
Reconstruction lower limb	43 (52)
Arthroplasty	3 (4)
Excision/curettage tumour	17 (20)
Osteosynthesis for oncological reasons	10 (12)
Osteosynthesis after trauma	4 (5)
Arthroscopy	3 (4)
Other	3 (4)
Soft-tissue involvement, n (%)	197/267 (74)
Pathological fracture at diagnosis, n (%)	60/300 (20)
Neoadjuvant chemotherapy, n (%)	125/298 (42)
Neoadjuvant radiotherapy, n (%)	15/296 (5)
Adjuvant chemotherapy, n (%)	131/293 (45)
Adjuvant radiotherapy, n (%)	19/295 (6)
Resection type, n (%)	**263**
Intra-articular	196 (75)
Extra-articular	67 (25)
Location of reconstruction, n (%)	**316**
Distal femur	**223 (71)**
Uncemented	163 (73)
Proximal stem cemented	16 (7)
Distal stem cemented	20 (9)
Proximal and distal cemented	24 (11)
Proximal tibia	**82 (26)**
Uncemented	71 (87)
Proximal stem cemented	5 (6)
Distal stem cemented	1 (1)
Proximal and distal cemented	3 (4)
Total knee	**2 (1)**
Distal stem cemented	1 (100)
Total femur, n (%)	**9 (3)**
Uncemented	8 (89)
Distal stem cemented	1 (11)
Material of locking mechanism, n (%)	**316**
Polyethylene	45 (14)
Polyether-ether-ketone	44 (14)
Metal-on-metal	227 (72)

ASA, American Society of Anesthesiologists; NOS, not otherwise specified.

All revised implants were distal femoral reconstructions. The median time to first locking mechanism revision was 4.5 years (IQR 2.9 to 7.3). Two patients underwent three revisions from PEEK to MoM and subsequent MoM revisions due to recurrent wear and breakage (Table II).

A total of 21 out of 227 patients (9%) with a MoM locking mechanism were revised: 12 (5%) due to hinge-wear, and nine (4%) due to breakage. Among the revised implants, 11 were distal femoral, eight proximal tibial, one total knee, and one total femoral. The median time to first locking mechanism revision was 7.5 years (IQR 4.1 to 10.5). Six patients underwent two revisions from MoM to MoM due to recurrent hinge-wear or breakage (Table II).

Risk factors. With PE as the reference category, the cause-specific hazard ratio (HRcs) for PEEK and MoM locking mechanisms were 3.6 (95% CI 1.1 to 11.9; p = 0.036), and 3.2 (95% CI 1.0 to 9.5; p = 0.043), respectively. Age, BMI, resection length, and extra-articular resections were not associated with the time to locking mechanism revision (Table III). The proportional hazards assumption was not violated for all risk factors.

Cumulative incidence. The cumulative incidence of locking mechanism failure as reason for first revision at two, five, and ten years were 0%, 5% (95% CI 1 to 15), and 5% (95% CI 1 to 15) for PE, 5% (95% CI 1 to 14), 14% (95% CI 5 to 26), and 16% (95% CI 7 to 29) for PEEK, and 0%, 3% (95% CI 1 to 6), and 10% (95% CI 5 to 16) for MoM, respectively (Figure 1).

Secondary infections. Among 34 patients with revision for locking mechanism failure, nine (26%) developed acute secondary infections (within two months after revision surgery). Eight were successfully treated; six with debridement, antibiotics, and implant retention, and two with two-stage procedures. One patient developed a chronic infection (occurring after the third locking mechanism revision) which was non-responsive to antibiotics and surgical therapy, and resulted in an amputation.

Discussion

In this MORE study, the clinical outcomes of three different locking mechanism materials of the MUTARS knee reconstructions were evaluated, with a particular emphasis on implant wear or breakage. Regardless of the type of articulation, we observed symptomatic instability caused by wear or fractures of the locking mechanism, necessitating revision surgery. Furthermore, we identified that PEEK and MoM locking mechanisms have a significantly increased revision risk for locking mechanism failure over time compared to PE.

In the current study, the cumulative incidence of revision surgery for implant wear or breakage of 5% (95% CI 1 to 15) at both five and ten years, and an overall locking mechanism revision rate of 9% for PE locking mechanisms, compares

Table II. Information on patients suffering of recurrent locking mechanism failures.

Sex	Age, yrs	BMI, kg/m²	Failures, n	Locking mechanism type				Location	Problem	Years to next revision
				Initial	Second	Third	Fourth			
M	54	29	2	MoM	MoM	MoM	N/A	PT	Wear, wear	5.1/3.3
M	25	21	2	MoM	MoM	MoM	N/A	PT	Breakage, wear	2.7/3.8
M	52	35	2	MoM	MoM	MoM	N/A	DF	Breakage, breakage	2.6/3.3
M	22	20	2	MoM	MoM	MoM	N/A	PT	Wear, wear	8.8/6.7
F	14	24	2	MoM	MoM	MoM	N/A	PT	Wear, acute symptomatic instability without evident abnormalities	12.0/0.8
M*	58	-	2	MoM	MoM	MoM	N/A	DF	Breakage, breakage	4.1/0.7
F	15	25	3	PEEK	PEEK	PEEK	MoM	DF	Wear, breakage, wear	4.4/3.6/3.3
M	19	19	3	PEEK	PEEK	PEEK	MoM	DF	Breakage, wear, breakage	1.7/0.8/2.9
M*	24	-	3	PE	PEEK	PEEK	PEEK	DF	Wear, breakage, breakage	3.9/1.7/5.5

*BMI data unavailable.
DF, distal femur; LM, locking mechanism; MoM, metal-on-metal; N/A, not applicable; PE, polyethylene; PEEK, polyether-ether-ketone; PT, proximal tibia.

Table III. Cause-specific hazard ratios for locking mechanism failure.

Risk factors	HRcs (95% CI)	p-value
Age	0.99 (0.98 to 1.02)	0.658
Sex (male)	1.39 (0.70 to 2.76)	0.346
BMI (kg/m²)	1.02 (0.96 to 1.09)	0.513
Surgical duration (hrs)	0.99 (0.75 to 1.29)	0.920
Blood loss (L)	1.90 (0.92 to 3.94)	0.083
Resection length (cm)	1.03 (0.99 to 1.08)	0.120
Location of reconstruction		
Distal femur	Reference	
Proximal tibia	0.78 (0.35 to 1.74)	0.543
Type of resection		
Intra-articular resection	Reference	
Extra-articular resection	0.76 (0.33 to 1.80)	0.537
Locking-mechanism material		
PE	Reference	
PEEK	3.59 (1.08 to 11.92)	0.036
MoM	3.15 (1.04 to 9.53)	0.043

HRcs, cause-specific hazard ratio; MoM, metal-on-metal; PE, polyethylene; PEEK, polyether-ether-ketone.

favourable to previous studies, with reported incidences ranging from 13% to 19%.[1–4] However, caution should be used when interpreting these results, since the statistical analyses used in these studies did not account for patients who died without revision, nor for patients requiring revision for other reasons. Additionally, Hardes et al[4] only included extra-articular resections, while these resections are presumed to increase the risk of mechanical failure. Kinkel et al[1] observed an overall locking mechanism failure rate of 19% in MUTARS PE locking mechanisms and identified a significant correlation with extra-articular resections, or cemented implants. Notably, 80% of their 11 patients with locking mechanism failure underwent extra-articular resections, and 73% received cemented femoral fixation. This contrasts our results with none of the cemented resections and one (25%) extra-articular resection among the four PE locking mechanism failures. Furthermore, the authors state that their aggressive approach toward tumours with potential joint capsule invasion or knee effusion leads to frequent extra-articular resections with accompanying extensive resection of stabilizing structures around the knee.[1] They believed that this results in higher mechanical stress on the joint coupling mechanism, although our results showed no difference between intra- and extra-articular resections.

There are several other commonly used systems for endoprosthetic knee reconstructions available, with revision rates for locking mechanism or bushing failure ranging from 0% to 42%.[2,11,12] Myers et al[2] found a 16% locking mechanism revision rate, and 2% locking mechanism breakage in a cohort of 428 Stanmore distal femur reconstructions with PE bushing, which is comparable to the results of the MUTARS knee reconstructions. Capanna et al[11] report a 42% locking mechanism revision rate in a cohort of 95 uncemented Kotz Modular Femur-Tiba Reconstruction System (Stryker, UK) distal femur reconstructions with PE bushing, with a mean of 5.3 years after implantation. On the other hand, Ilyas et al[12] reported no PE bushing fractures or revisions due to wear in a cohort of 48 patients reconstructed with an uncemented HMRS distal femur (Stryker), with a median follow-up of 5.6 years. Additionally, Sharma et al[13] reported no bushing fractures or revisions due to wear in a cohort of 77 cemented HMRS distal femur reconstructions, but observed a 4% fracture rate of the tibial bearing component. Variations in implant designs and approaches to tumour implants may yield distinct failure patterns. The use of a "sloppy" hinge as opposed to a more rigid constrained system might reduce mechanical stresses on the stem, although the clinical relevance remains uncertain at this moment.

In the current study, the cumulative incidence of revision surgery for implant wear or breakage at five and ten years of 14% (95% CI 5 to 26) and 16% (7 to 29), and an overall locking mechanism revision rate of 20% for PEEK locking mechanisms, are comparable to previous studies describing an overall locking mechanism failure rate of 11% to 18% in patients reconstructed with the MUTARS PEEK locking mechanism.[3,4,6] Cho et al[6] observed a higher BMI in ten patients with locking mechanism breakage (BMI 24 kg/m² (standard error (SE) 2.1) compared to those without (BMI 22 kg/m² (SE 3.3); p = 0.05). Remarkably, they reported a median time to locking mechanism failure of 2.2 years (range 1.0 to 6.0), compared to 6.4 years (IQR 4.0 to 9.7; range 1.7 to 19.4) years in our cohort. However, a proper comparison cannot be made due to differences in statistical methodology and the fact that we included all revisions for

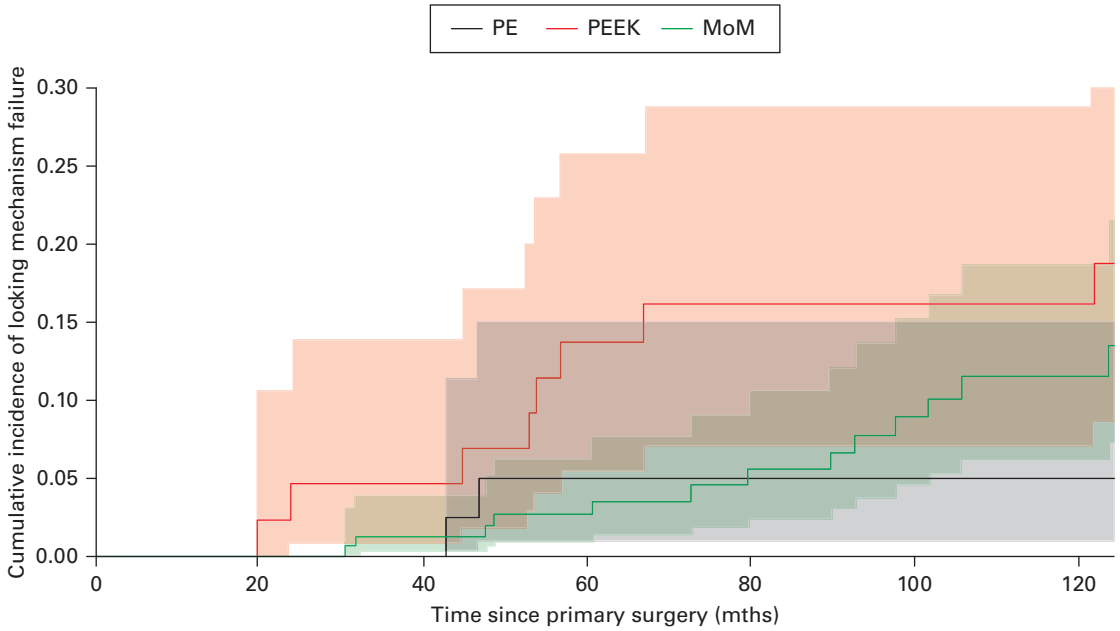

Fig. 1

Cumulative incidence of implant revision due to wear or breakage for polyethylene (PE), polyether-ether-ketone (PEEK), and metal-on-metal (MoM).

symptomatic instability due to breakage or wear, whereas Cho et al[6] focused on breakage only. Hardes et al[8] reported a 20% locking mechanism failure rate and a mean of 3.6 years (0.8 to 6.8) after implantation, in a cohort of patients with MUTARS endoprosthetic reconstructions after extra-articular resections of the knee. Three of 16 (19%) were PE, 3/17 (18%) PEEK, and 6/24 (25%) MoM locking mechanisms. In line with our results, they found no association between locking mechanism failure and patient BMI or resection length. According to Hardes et al,[4] the extent of resection of the extensor apparatus contributed to the relatively high proportion of patients experiencing locking mechanism failure, due to high mechanical demands. Interestingly, Merose et al[7] observed a 38% overall locking mechanism failure rate in 56 PEEK hinged MUTARS distal femur reconstructions. They identified male sex and higher weight at failure as significant risk factors, contrary to our findings. New-onset knee instability, often triggered by physical activity, was commonly observed years after implantation. A retrieval analysis from Merose et al[7] for three failed locking mechanisms revealed fretting and microcracks in high-stress areas, culminating in complete fracture at the tip of the PEEK slot in full extension.

The cumulative incidence of revision for implant wear or breakage of the MoM locking mechanisms at five and ten years is 3% (95% CI 1 to 6) and 10% (95% CI 5 to 16), respectively. Additionally, the overall locking mechanism revision rate for MoM in the current study is 9%, which is favourable compared to previous studies describing an overall locking mechanism revision rate of 20% to 25% for locking mechanism wear in patients reconstructed with the rotating MoM hinge.[4,8] Hardes et al[8] observed no prosthetic fractures in a cohort of 98 patients who underwent an intra-articular resection and subsequent proximal tibia reconstruction, which is in contrast with our 3% MoM locking mechanism revision for breakage. However, they found a 20% locking mechanism revision rate for wear at a median of 5.8 years (range 0.7 to 14.3) after implantation.[8]

A retrieval analysis conducted by Bormann et al[14] identified a relatively high incidence of locking mechanism wear, assessed through a semiquantitative scoring-system and coordinate measurements. As expected, increased wear was observed in patients who had the implant in situ for a longer duration. In turn, corrosion and mechanical wear of the MoM locking mechanism can lead to both local metallosis and systemic metal ion side effects. Local reactions include adverse reactions to metal debris, resulting in osteolysis and pseudotumour formation.[15,16] This is especially concerning in high-demand young patients reconstructed with MoM articulations, as prolonged exposure may result in elevated metal-ion levels of cobalt and chromium. Such elevated metal ion levels may result in systemic cardiovascular and neurological adverse effects.[17–19] Moreover, repetitive hyperextension of the knee during the landing phase may contribute to cyclic fretting damage and therefore locking mechanism failure. Based on our results, the question arises about the appropriate course of action to improve implant survival. Should it involve the development of new materials possessing enhanced strength and non-toxic properties, or should the focus be on modifying the implant design? Currently, a new carbon-reinforced PEEK locking mechanism is under post-marketing surveillance; however, clinical results are not yet available.

This study has several limitations. First, our dataset contained a limited number of patients with a PE or PEEK reconstruction. Second, investigating the degree of quadriceps compromise

resulting from tumour resection and conducting gait analysis would be valuable, as it could influence mechanical stresses on the locking mechanism, potentially serving as an indicator for locking mechanism failure. To address this limitation, we evaluated whether the resection was intra- or extra-articular, yet identified no significant association with the occurrence of locking mechanism revision over time. Future studies should evaluate the impact of compromised knee muscles and conduct gait analysis in patients with MUTARS knee reconstructions to determine their potential association with locking mechanism failure.

This study showed that the cumulative incidence of locking mechanism revision for symptomatic instability due to hinge breakage or wear was comparable or favourable compared to other systems. Thus far, alterations in prosthetic materials have not decreased the risk of locking mechanism failure. Besides locking mechanism material, no additional factors contributing to locking mechanism failure were identified. Improvement of the locking mechanism is warranted since recurrent revision of the locking mechanism increases the risk of serious secondary complications. Anticipated advancements could come with the introduction of a novel carbon-reinforced PEEK locking mechanism design.

Take home message

- This multicentre series represents the largest cohort to date, studying various locking mechanisms in Modular Universal Tumour and Revision System knee reconstructions.
- Thus far, alterations in prosthetic materials have not decreased the risk of locking mechanism failure.
- The cumulative incidences of locking mechanism revision at ten years were 5% for polyethylene, 16% for polyether-ether-ketone, and 10% for metal-on-metal.

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