



■ KNEE

Early migration of a medially stabilized total knee arthroplasty

A RADIOSTEREOMETRIC ANALYSIS STUDY UP TO TWO YEARS

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Aims

Medial pivot (MP) total knee arthroplasties (TKAs) were designed to mimic native knee kinematics with their deep medial congruent fitting of the tibia to the femur almost like a ball-on-socket, and a flat lateral part. GMK Sphere is a novel MP implant. Our primary aim was to study the migration pattern of the tibial tray of this TKA.

Methods

A total of 31 patients were recruited to this single-group radiostereometric analysis (RSA) study and received a medial pivot GMK Sphere TKA. The distributions of male patients versus female patients and right versus left knees were 21:10 and 17:14, respectively. Mean BMI was 29 kg/m² (95% confidence interval (CI) 27 to 30) and mean age at surgery was 63 years (95% CI 61 to 66). Maximum total point motions (MTPMs), medial, proximal, and anterior translations and transversal, internal, and varus rotations were calculated at three, 12, and 24 months. Patient-reported outcome measure data were also retrieved.

Results

MTPMs at three, 12, and 24 months were 1.0 mm (95% CI 0.8 to 1.2), 1.3 mm (95% CI 0.9 to 1.7), and 1.4 mm (0.8 to 2.0), respectively. The Forgotten Joint Score was 79 (95% CI 39 to 95) and Knee Injury and Osteoarthritis Outcome Score obtained at two years was 94 (95% CI 81 to 100), 86 (95% CI 75 to 93), 94 (95% CI 88 to 100), 69 (95% CI 48 to 88), and 81 (95% CI 59 to 100) for Pain, Symptoms, Activities of Daily Living, Sport & Recreation, and Quality of Life, respectively.

Conclusion

In conclusion, we found that the mean increase in MTPM was lower than 0.2 mm between 12 and 24 months and thus apparently stable. Yet the GMK Sphere had higher migration at one and two years than anticipated. Based on current RSA data, we therefore cannot conclude on the long-term performance of the implant, pending further assessment.

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Introduction

Total knee arthroplasty (TKA) is a very common procedure for treating osteoarthritis of the knees in most countries, and incidence is expected to continue rising.^{1,2} However, not all patients are satisfied after a TKA.³ Several new implants have therefore been introduced to the market in recent decades, to meet patients' increasing functional demands. The medial pivot (MP) category was introduced in the 1990s to mimic

the kinematics of the native knee.⁴ The native knee is tight in the medial compartment, with a concave medial tibial plateau, and a circular medial femoral condyle fitting almost like a ball-on-socket. The lateral tibial plateau is rather flat. This, in addition to the laxity of the lateral collateral ligament (unlike the tightness of the medial collateral ligament), facilitates medial pivoting, lateral sliding, and a rolling motion of the joint during flexion and extension.^{5,6} The first generation

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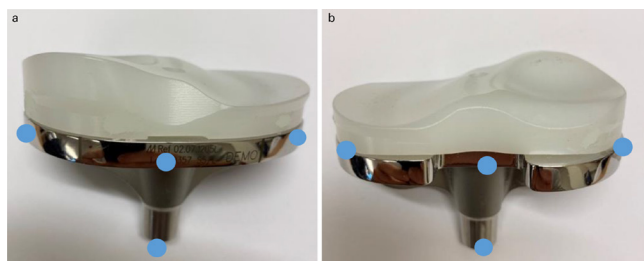


Fig. 1

a) Global Medacta Knee Sphere (GMK Sphere, anterior view) displaying the congruent medial and flat lateral parts of the insert designed to mimic the native knee motion during flexion and extension. Blue dots indicate position of feature points. b) The posterior view of the same implant displaying the congruent medial and flat lateral parts of the insert designed to mimic the native knee motion during flexion and extension.

of MPs consisted of The Medial Rotation Knee (1994, MRK; MatOrtho, UK) and the Advance Medial-Pivot Knee (1998, Wright Medical Group, USA).⁷⁻⁹ A second generation was later introduced with the SAIPH Knee System (2009, Matortho), Evolution Medial-Pivot Knee (2010, MicroPort Orthopaedics, USA), and the Global Medacta Knee Sphere (GMK Sphere) (2011, Medacta International, Switzerland)¹⁰⁻¹² (Figures 1a and 1b). The latter uses an ultra high molecular weight polyethylene (UHMWPE) insert,¹³ made from Granular-UHMWPE-Ruhrchemie (GUR) 1020 and sterilized with ethylene oxide (EtO).¹⁴ Several smaller studies have shown good clinical results in terms of function, kinematics, and longevity of these implants.¹⁵⁻¹⁸ Our primary aim was to assess the migration pattern of the tibial tray of the GMK Sphere using radiostereometric analysis (RSA), and to compare this with previously known limits of safe migration patterns with respect to aseptic loosening. Secondary aims included wear, alignment, and clinical performance.

Methods

A single series of 31 consecutive patients was recruited at Oslo University Hospital, Ullevaal, Oslo, Norway. The study protocol is shown in Table I and Figure 2. All patients received a cemented GMK Sphere TKA using Refobacin Bone Cement R (Zimmer Biomet, USA). One of two experienced surgeons performed all surgeries between April 2016 and February 2018. All patients underwent the same operative procedure and postoperative protocol including a medial parapatellar approach, without tourniquets. During surgery, five to eight tantalum 1 mm beads (RSA Biomedical, Sweden) were inserted in tibial bone with a fair geometrical spread.

Clinical evaluation. Baseline data such as age, sex, and BMI were retrieved. For clinical assessment, we used the Knee Injury and Osteoarthritis Outcome Score (KOOS)¹⁹ at baseline and all timepoints. The Forgotten Joint Score 12 (FJS-12)²⁰ was retrieved at three and 24 months postoperatively. Degrees of flexion and valgus/varus alignment

Table I. Inclusion and exclusion criteria of the study.

Inclusion criteria

Patients with knee osteoarthritis

Exclusion criteria

Preoperative flexion contracture more than 15°

Preoperative limited range of motion under anaesthetics (less than 110°)

Less than 50 or more than 75 years of age at the time of surgery

Use of walking aids because of other musculoskeletal and neuromuscular problems

Preoperative diagnosis other than osteoarthritis and avascular necrosis (e.g. rheumatoid arthritis, tumours)

Revision arthroplasty

Obesity with BMI > 35

Impaired collateral ligaments

Postoperative revision surgery due to deep wound infection

were recorded postoperatively using a manual goniometer. All complications were accounted for.

Conventional radiology. All patients had preoperative plain standing radiographs, including the hip-knee-ankle (HKA) exposures. These were repeated at three months postoperatively, together with a CT scan of the artificial joint. Valgus and varus knee angles were defined as positive and negative values respectively. Tibial tray rotation was evaluated using Berger's method.²¹

RSA. Supine RSA radiographs were taken postoperatively within a week and thus before discharge, and at three, 12, and 24 months using fixed ceiling-mounted x-ray tubes (Proteus XR/A, GE Healthcare, USA and Canon Triathlon T3, Japan) and knee cage number 10 (UmRSA; RSA Biomedical). All patients had double RSA examinations once for precision purposes. All RSA images were analyzed using RSAcore (v. 4.1, the Netherlands) Model Based RSA software. The first author analyzed all images and migration was reported for translations and rotations in all planes, feature point motions, as well as maximum total point motion (MTPM). Left-sided RSA knees were converted to right-sided by multiplying the segmental x-translations and y-z-rotations by a factor of -1,^{22,23} while x-, y-, and z-translations and rotations were reported with signed values and categorized as medial, proximal, and anterior translations and transversal, internal, and varus rotations, respectively.

Our upper limits for condition number (CN) and mean error (ME) were 120 and 0.35 respectively.^{22,23} Computer-aided design models (CAD) of both femoral and tibial components for all sizes were obtained from the manufacturer. They were implemented in the RSAcore software with the feature points positioned as anteriorly, medially, laterally, posteriorly, tip (all tibia model), and centre of the medial condyle (femoral model only) (Figures 1a and 1b). Feature point translations of the tibia were calculated. The change in sagittal distance of the centre of the femoral condyle and medial tibia feature points over time was calculated in terms of wear of the polyethylene of the

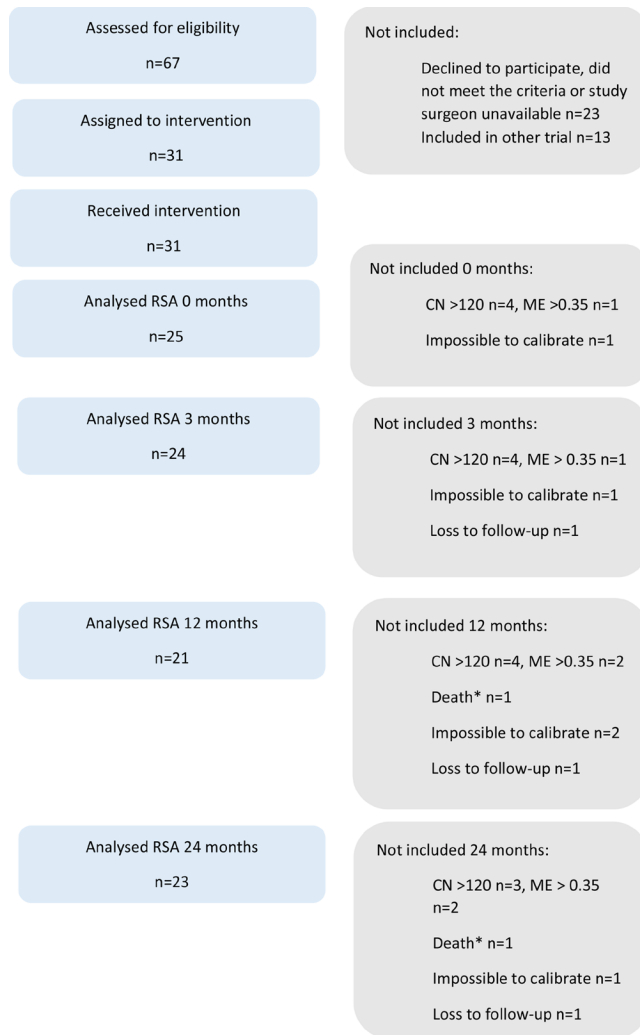


Fig. 2

Flow chart of the study. *Unrelated to the study; this patient already had condition number (CN) > 120. ME, mean error; RSA, radiostereometric analysis.

medial part of the insert. As the RSA radiographs were performed in supine position, only implants regarded as stable in the mediolateral direction, i.e. < 5° movement in any position, were included in this analysis.²⁴

Statistical analysis. We used SPSS for Windows v. 25 (IBM, USA) for statistical analysis. Data were normally distributed unless otherwise stated and presented with means and 95% confidence intervals (CIs). When appropriate, a paired *t*-test was used, presenting *p*-values with a significance level < 0.05. Non-normally distributed data were presented with median and interquartile range (IQR), and *p*-values calculated using the Wilcoxon signed-rank test.

We regarded a within-group change of 0.2 mm in MTPM from 12 to 24 months as clinically relevant.²⁵ With an α of 0.05 and a power of 80% and the assumption of a standard deviation (SD) of 0.3, we calculated that we needed a minimum of 20 patients.²⁶ To account for loss

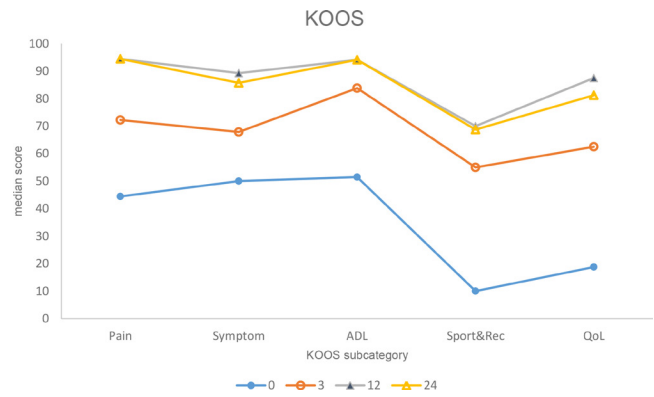


Fig. 3

Median Knee injury and Osteoarthritis Outcome Score (KOOS) from baseline to 24 months. ADL, activities of daily living, QoL, quality of life.

Table II. Demographic data.

Variable	Total
Total, patients (knees)	31 (31)
Sex, M:F	21:10
Side, R:L	17:14
Smokers, n	6
Mean BMI, kg/m ² (95% CI)	29 (27 to 30)
Mean age, yrs (95% CI)	63 (61 to 66)
Mean operation time, mins (95% CI)*	118 (114 to 124)
Mean LOS, days (95% CI)	4.0 (3.6 to 4.3)

*Data missing for one patient.

CI, confidence interval; LOS, length of stay.

to follow-up and the exclusion of some patients, we originally included 30 patients. One patient died unrelated to the study within one year, so one extra patient was included.

Precision of the RSA analyses was reported as SDs of the absolute mean of the difference of repeated measurements with 95% CI and thus reported as SD 1.96.²³

Results

Clinical evaluation. Table II shows patient demographics. KOOS improved from preoperatively to two years and FJS-12 from three months to two years (Table III and Figure 3). KOOS scores of patients identified as high-risk, based on the RSA analyses, are shown in Table IV. There was no difference in flexion of the knees from preoperatively to two years (Table V).

Conventional radiology. Mean preoperative and postoperative HKA angles were -6° (95% CI -8.5 to -3) and -1° (95% CI -2.3 to -0.25) respectively (*p* < 0.001, paired *t*-test). Mean postoperative tibial rotation using the Berger technique²¹ was 15.1° (5% CI 12.0 to 18.1).

RSA. Precision calculated by repeated RSA examinations is displayed in Table VI. The mean difference and SD of MTPM were 0.01 and 0.39 respectively. Because not all of these were suitable for analysis, the total number of double examinations was only 14. The mean CN and ME

Table III. Patient-reported outcome measures.

PROM	Preop median (IQR)	3-mth median (IQR)	1-yr median (IQR)	2-yr median (IQR)	Ceiling effect %*	P-value†
KOOS						
Pain	44 (33 to 56)	72 (64 to 97)	94 (74 to 100)	94 (816 to 100)	38	< 0.001
Symptoms	50 (46 to 64)	68 (57 to 84)	89 (6 to 93)	86 (75 to 93)	3	< 0.001
ADL	52 (34 to 59)	84 (64 to 96)	94 (82 to 100)	94 (88 to 100)	8	< 0.001
Sport&Rec	10 (5 to 26)	55 (36 to 75)	70 (55 to 82)	69 (48 to 88)	3	< 0.001
QoL	189 (13 to 31)	63 (47 to 78)	88 (63 to 97)	81 (59 to 100)	38	< 0.001
FJS-12	N/A	60 (27 to 83)	N/A	79 (39 to 95)	10%	0.002

*Ceiling effect at two years.

†Wilcoxon signed-rank test comparing change from preoperative to two years.

ADL, activities of daily living; FJS, Forgotten Joint Score; IQR, interquartile range; KOOS, Knee injury and Osteoarthritis Outcome Score; N/A, not applicable.

Table IV. Clinical and radiological data of high-risk patients. preoperative and postoperative hip-knee-ankle angle and CT rotation (Berger) > 18° means that the implant is internally rotated. Varus and valgus knee hip-knee-ankle angles defined as negative and positive values, respectively.

Patient	Pain	Symptoms	ADL	Sport & Recreation	QoL	Preop HKA, °	Postop HKA, °	CT rotation, °
10	64	54	87	60	44	0.1	6.2	29.6
11	47	39	51	5	38	-7.4	-1.8	11.6
20	100	100	97	90	10	-9.7	-1.7	23.1
25	89	100	92	83	100	12.4	1.6	14.3
28	100	89	100	95	100	-7.2	1.6	9.4
38	100	75	100	90	100	-6.0	-2.7	3.6

ADL, activities of daily living; HKA, hip-knee-ankle angle; QoL, quality of life.

Table V. Flexion from preoperatively to two years.

Variable	n	Preop mean, ° (95% CI)	3mth mean, ° (95% CI)	1-yr mean, ° (95% CI)	2-yr mean, ° (95% CI)	P-value*
Flexion	29	123 (118 to 128)	115 (109 to 120)	122 (119 to 127)	120 (117 to 124)	0.250

*Paired *t*-test comparing change from preoperative to two years.

CI, confidence interval.

Table VI. Migration, rotation, and wear of GMK Sphere.

Variable	3mths	1 yr	2 yrs	Precision
Mean MTPM, mm (95% CI)	1.00 (0.78 to 1.21)	1.30 (0.94 to 1.67)	1.40 (0.84 to 1.96)	0.01 (0 to 0.77)
Translation, mm (95% CI)				
Medial	0.01 (-0.08 to 0.09)	0.04 (-0.13 to 0.21)	0.05 (-0.14 to 0.24)	0.01 (-0.18 to 0.20)
Proximal	-0.03(-0.10 to 0.04)	-0.03(-0.16 to 0.1)	-0.10(-0.34 to 0.13)	0.03 (-0.07 to 0.13)
Anterior	0.04 (-0.16 to 0.23)	-0.01(-0.24 to 0.21)	0.06 (-0.11 to 0.22)	0.00 (-0.41 to 0.41)
Rotation, °(95% CI)				
Transversal	0.09 (-0.19 to 0.38)	-0.10(-0.33 to 0.12)	-0.32(-0.80 to 0.15)	0.04 (-0.97 to 1.04)
Internal	-0.37 (-0.71 to 0.02)	0.04 (-0.57 to 0.66)	-0.39(-0.81 to 0.03)	0.06 (-1.19 to 1.3)
Varus	0.09 (-0.08 to 0.26)	0.09 (-0.21 to 0.39)	0.16 (-0.45 to 0.78)	0.01 (-0.24 to 0.27)
Median wear, mm (IQR)	0.03 (-0.23 to 0.21)	-0.13(-0.48 to 0.25)	0.09 (-0.10 to 0.55)	0.116*

*Wilcoxon signed-rank test comparing change in wear from three to 24 months.

CI, confidence interval; IQR, interquartile range; MTPM, maximum total point motion.

for all examinations were 63.8 and 0.15. Segmental rotations and translations and mean and individual MTPMs are seen in Table VI and Figure 4 respectively. The mean MTPM increased the most before three months and towards one year. Subsequently, it seems stable. Otherwise,

segmental mean translations and rotations all seem to be within the range of their respective precisions. The wear data are also shown in Table VI.

Four of the patients had a higher than anticipated migration or transversal rotation (Table VII).

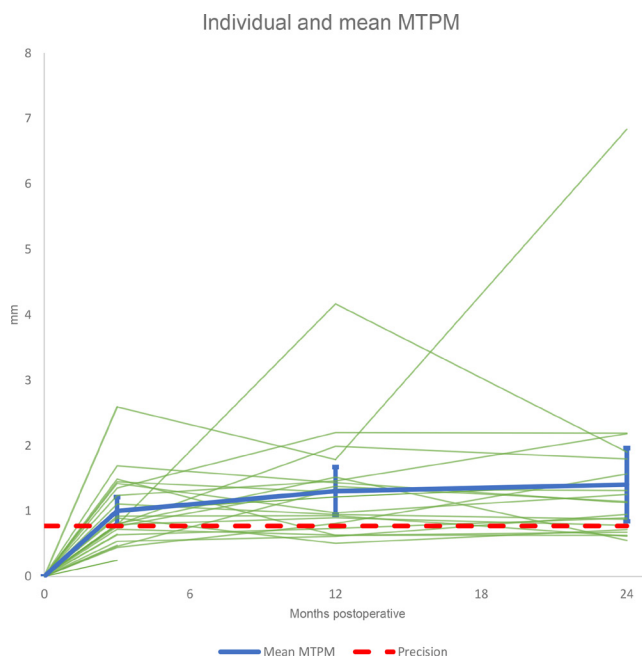


Fig. 4

Individual and mean maximum total point motions (MTPMs) with error bars showing 95% confidence intervals.

Table VII. High-risk patients qualifying based on Ryd et al²⁵ or Gudnason et al.²⁷

Thresholds	10*	11	20	25	28	38
> 0.2 mm 12 to 24 months†	X		X	X		X
Transversal rotation 24 months‡	X					
Peripheral distal translation > 0.6 mm‡	X	X	X		X	X
Peripheral proximal translation > 0.9 mm‡	X				X	

*Revised after 32 months.

†Based on Ryd et al.

‡Based on Gudnason et al.

Sagittal point movement of the tibial tray is depicted in Figure 5. An analysis of the peripheral distal or proximal translations did not reveal any specific migration pattern. However, we identified five implants with peripheral distal or proximal translation above 0.6 mm or 0.9 mm respectively (Table VII).²⁷

Adverse events. One death occurred within one year, not study-related. One patient was revised due to aseptic loosening.

Discussion

Our main finding is that this implant migrated initially and then stabilized after three to 12 months. This concurs with the literature on early migration of cemented implants.²⁵ A MTPM of 1.3 mm at 12 months puts the implant in the “at risk” category of Pijls et al.²⁸ In our study, based on the one-year MTPM results, we cannot state whether there is a higher or lower risk of revision due to aseptic loosening

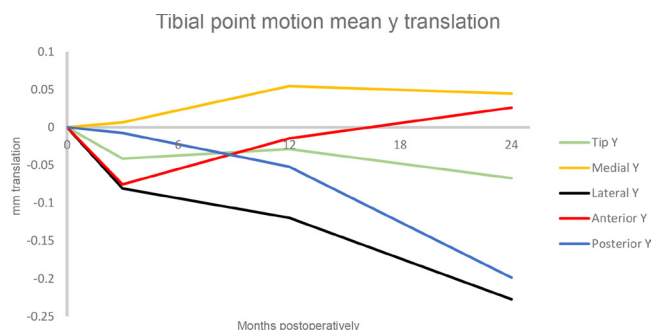


Fig. 5

Peripheral distal and proximal sagittal translations of the different feature points over time.

of 5% at ten years.²⁸ However, several implants with good long-term survivorship also fall into this category.^{29,30}

Segmental motion, measuring the movement of the centre of the implant, often underestimates real migration. Peripheral feature points (Figure 1) give a better impression of the real implant movement as the dominant failure mechanism for tibial baseplates is tilting (rotation) rather than general subsidence.³¹ Furthermore, we could identify some individual high-risk implants based on previous studies by Ryd et al,²⁵ using the strict continuous migration criteria, and by Gudnason et al,²⁷ using the transversal rotation or proximal or distal peripheral translation of the feature points of the tibial tray. One of these implants was revised due to aseptic loosening of the tibial tray 32 months after surgery (Patient 10). The postoperative HKA angle of this patient revealed a valgus alignment of 6°. We therefore attribute the failure to surgical reasons rather than implant-related reasons. Another characteristic feature of the patients with high-risk implants was inferior clinical scores (Patient 11). This implant was well aligned in the coronal plane but was 7° externally rotated on the CT scan. This would probably not cause any clinical problems.³² The other patients had excellent KOOS scores at two years, implying no symptoms of aseptic loosening. Nevertheless, we know from the literature that symptoms of loose implants can take up to ten years to become apparent.²⁵

It has been debated whether the use of a tourniquet is important for good fixation of implants. Several RSA studies have, however, proven that this is not the case.^{33–35} Another explanation of the somewhat high MTPM could be the cement used in the study. Refobacin Bone Cement R has been used for several years at our hospital, and several studies including registry and RSA studies suggest that this cement gives good fixation and long-term survivorship.^{36–38} The GMK Sphere has a shorter but wider wing of the keel than for instance the NexGen CR (Zimmer Biomet) and the Triathlon CR (Stryker, USA), both known for their excellent survivorship.³⁹ In theory, this could increase the rotation of the implant. We found that the mean internal and transversal rotation of the

implant is lower than the precision measured by double examinations, so we conclude that for that rotation it is unlikely.

It has been stated that the combination of early and continuous migration defines a specific migration pattern of each implant.⁴⁰ Most cemented implants seem to have a migration pattern with a lower mean MTPM than the GMK Sphere.⁴¹ A recent study by van Hamersveld et al⁴² shows, however, that PS implants have a migration pattern with a higher mean MTPM than CR implants. MP implants are actually constrained implants medially. No authors have studied their natural migration pattern, but they may have a higher initial migration before stabilizing. If so, this could partly explain the somewhat higher migration found in the current data.

Several studies indicate good mid- to long-term results of medial pivot implants.^{16,43} One review article found similar or even better survivorship of the Advance MP, compared to other TKAs.⁴⁴ Another article found no difference in survivorship at 13 years between MP and central mobile-bearing TKAs.⁴⁵ In a recent review article, Cacciola et al⁴⁶ found that primary MP implants in general provide overall mid-term survivorship comparable to standard cruciate-retaining and posterior-stabilized implants, according to the available data, and yield better high-end function than standard implants.

Most studies on the GMK Sphere focus on the implant's kinematics,^{47,48} rather than survival. We did, however, publish a registry study in 2020 on implants from the Norwegian Arthroplasty Registry and the Australian Orthopaedic Association National Joint Arthroplasty Registry (AOANJRR).⁴⁹ In that study we found a hazard ratio (HR) of 2.0 (95% CI 1.5 to 2.6; $p < 0.001$) for revision of any cause of the GMK Sphere compared to the three most used minimally stabilized TKAs in the AOANJRR. There was also a higher HR for revision of the MP category due to malalignment, instability, and patella erosion in the AOANJRR, but we could not stratify this by brand.

Although our study is not powered to evaluate clinical results, the scores on the FJS⁵⁰ and KOOS^{30,51} are consistent with other TKAs. The polyethylene wear over two years was not clinically relevant ($p = 0.116$, Wilcoxon signed-rank test).

According to the registries, the GMK Sphere has a cumulative five-year all-cause revision rate of 3.5% (95% CI 3.0 to 4.0) and 3.1% (95% CI 2.1 to 4.6) in the AOANJRR⁵² and the National Joint Registry⁵³ respectively. This is higher than the $< 3\%$ revision thresholds set by the registries,²⁸ and could be supported by our findings.

We did not find any static RSA studies on any implant from the MP design nor the GMK Sphere. Since this design has been on the market for over two decades, this is somewhat surprising. We agree with previous scholars that there should have been a phased or step-wise introduction of novel implants to the market.^{40,54,55}

This study therefore fills a significant gap of knowledge in the literature.

One weakness is the number of patients included, as the small number does not account for the random distribution in the baseline data in the general population. This could affect the external validity of the study. RSA studies are costly, yet provide high precision.²² Our power calculation shows that the number of implants is sufficient to study the migration of the implant over time, as do several other previously published RSA studies.^{22,26} Although we had some dropouts, the final number of patients was sufficient with respect to the power calculation at all timepoints. Because our RSA radiographs were taken in supine position, and thus without weightbearing, we could only use the images in patients with knees regarded as stable in the medial-lateral direction to assess polyethylene wear. The study by van Ijsseldijk et al²⁴ suggests that this could be done, as they found no difference in wear between non-weightbearing examinations of stable knees and weightbearing examinations.

This study has several strengths. Firstly, we assessed both the MTMP and all six degrees of freedom, which complies with the ISO standard.²³ Secondly, because of the feature points in the CAD models, we could study the peripheral point motions of the implants. We could thus identify implants at risk of mechanical loosening that would otherwise be regarded as stable. Thirdly, all the surgeries were performed by two experienced surgeons only. Given that this is a novel implant, with an anticipated learning curve, we believe this is a strength. Fourthly, numerous RSA studies have been published from this hospital.^{56–58} The staff are therefore experienced in using RSA technology.

In our study, one of 31 patients showed a clear migration pattern for mechanical loosening and was revised. This was probably due to non-implant-specific technical difficulties during the primary surgery, and we believe that the malalignment of the implant was a possible reason for early loosening.⁵⁹

In conclusion, we found that the mean increase in MTPM was lower than 0.2 mm between 12 and 24 months and thus seems stable. However, the GMK Sphere had a higher total migration at one and two years than anticipated. Based on current RSA data, we therefore cannot conclude on the long-term performance of the implant, pending further assessment.



Take home message

- The GMK Sphere showed good clinical scores, but had a higher short-term migration than anticipated.

- Based on the radiostereometric analysis data we cannot

conclude on the long-term performance yet, pending further assessment.

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