

GMK SPHERE STUDY REPORT - SIX-YEAR FOLLOW-UP

INTERNATIONAL, MULTI-CENTRE, MULTI-SURGEON SIX-YEAR STUDY RESULTS TO MONITOR THE SURVIVAL RATE AND THE POST-OPERATIVE OUTCOMES OF THE MEDACTA GMK SPHERE

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MEDIALY STABILIZED KNEE

Stability for life



INTRODUCTION

The Medacta GMK Sphere, ethics committee approved, post-market, multi-centre, multi-surgeon surveillance study was initiated in October 2012 with completion of recruitment in September 2018. Study subjects were recruited from the South-West London Elective Orthopaedic Centre (SWLEOC), Epsom (UK), Royal London Hospital, London (UK), Royal National Orthopaedic Hospital, Stanmore (UK), HKU Hip Knee Unit, Gent (Belgium).

OBJECTIVE

The project is being undertaken as a ten-year, prospective, post-market, surveillance study to assess the survival, patient reported outcomes (Oxford Knee Score, EQ-5D and EQ-5D Health State), clinical outcomes (Knee Society Score) and radiological outcomes of the GMK Sphere Knee replacement. This report provides an update on the study with up to 6-year results.

PATIENTS & METHODS

Patients undergoing primary total knee replacement (TKR) with all pathologies were recruited for the study. Patients undergoing revision procedures and those with pre-existing co-morbidities likely to preclude long-term follow-up, older than 80 years at the time of the surgery and with a BMI > 40kg/m² were excluded from this study. 553 TKRs, using GMK Sphere were performed on 208 males and 345 females. 214 cases were undertaken at SWLEOC, 234 at HKU Hip Knee Unit, 68 at Royal London Hospital and 37 at Royal National Orthopaedic Hospital. The mean age of the study subjects, at the time of the surgery, was 67.7 years (range 31-80) with a mean BMI of 29.9 (range 16.8 - 39.9).

RESULTS

The table below shows a summary of the recorded outcomes.

	Pre-op	6 months	1 year	2 years	3 years	4 years	5 years	6 years
EQ5D SCORE								
# forms	551	484	438	357	369	164	192	95
Mean	0.45	0.77	0.79	0.80	0.82	0.78	0.81	0.78
StDev	0.26	0.22	0.23	0.25	0.23	0.26	0.22	0.22
HEALTH STATE								
# forms	549	483	438	356	372	168	198	96
Mean	66	78	78	79	78	77	77	78
StDev	21	16	18	18	18	21	18	20
OXFORD SCORE								
# forms	550	479	432	352	370	158	190	95
Mean	19.8	36.9	38.3	38.9	39.7	38.3	39.5	38.3
StDev	8.0	8.7	9.2	9.4	8.8	10.0	9.1	9.1
KSS - FUNCTION SCORE								
# forms	551	528			362		186	
Mean	48.9	83.2			86.3		86.6	
StDev	18.4	19.3			19.4		18.8	
KSS - KNEE SCORE								
# forms	550	519			360		177	
Mean	45.7	89.3			92.0		92.9	
StDev	16.0	14.4			12.7		11.2	

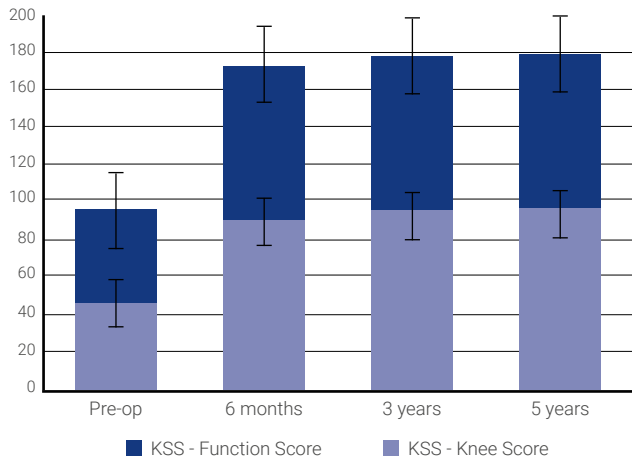
¹South West London Elective Orthopaedic Centre, Epsom (UK); ²Royal London Hospital, London (UK); ³Royal National Orthopaedic Hospital, Stanmore (UK); ⁴HKU Hip Knee Unit, Gent (Belgium)

RESULTS

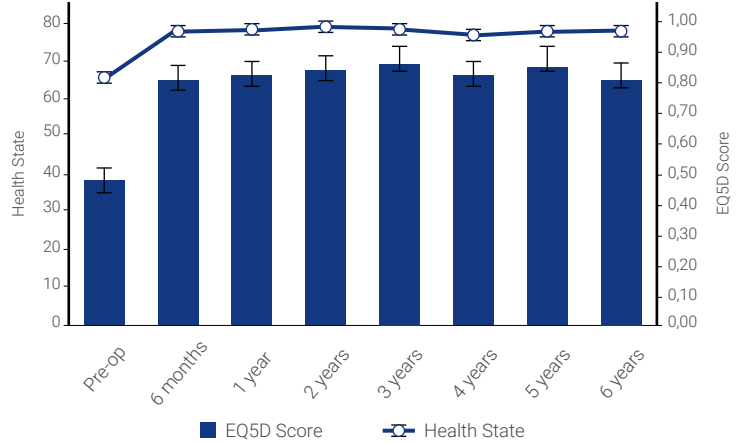
The cumulative survival rate at 6 years after surgery is **99.35%** (95% CI, 98.62-100), regardless of the reason for revision considered as an endpoint. Of the 553 knees, 3 have been revised (0.54%); 1 for infection, 1 for insert change and 1 for tibial aseptic loosening. Under UK NJR revision root cause analysis, two of the three are classified as minor complications (insert change) and complication not related to implant (infection).

The 6-month EQ-5D, Health State and Oxford scores (0.77, 78 and 36.9 respectively) were consistent with the scores reported in the UK National Joint Registry (NJR) for all TKRs (0.737, 74 and 35.4, respectively). At five years, 90% of GMK Sphere patients report excellent satisfaction (KSS-Knee Score ≥ 80) and good or excellent clinical results (KSS-Function Score ≥ 70). All the analysed scores demonstrate a significant improvement in joint functionality by six months and all improvements have been maintained.

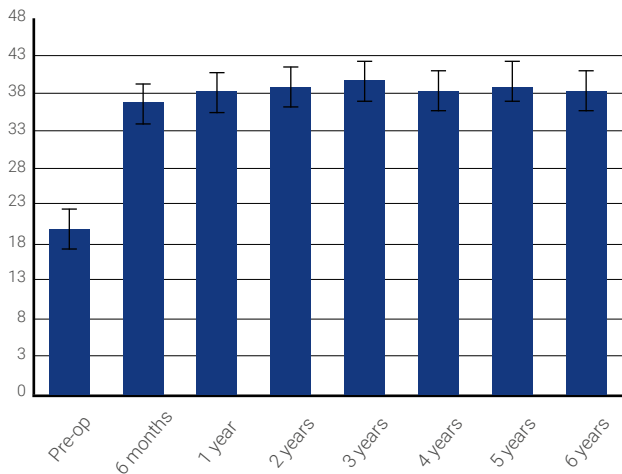
KNEE SOCIETY SCORE⁵



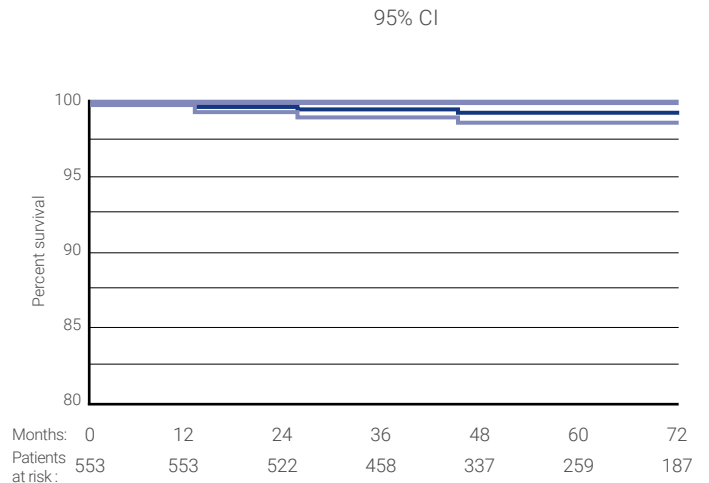
EQ5D SCORE AND HEALTH STATE⁵



OXFORD SCORE⁵



KAPLAN-MEIER SURVIVAL ANALYSIS



CONCLUSIONS

The results from this multi-surgeon, multi-centre, prospective, surveillance study demonstrate that the GMK Sphere provides excellent medium-term results:

- **an excellent survival rate at 5 years** (<1% revision rate compared to 3% revision rate reported by the UK NJR)
- **significant and maintained improvement in joint function and patient satisfaction**

⁵Graphs show mean values and standard errors

