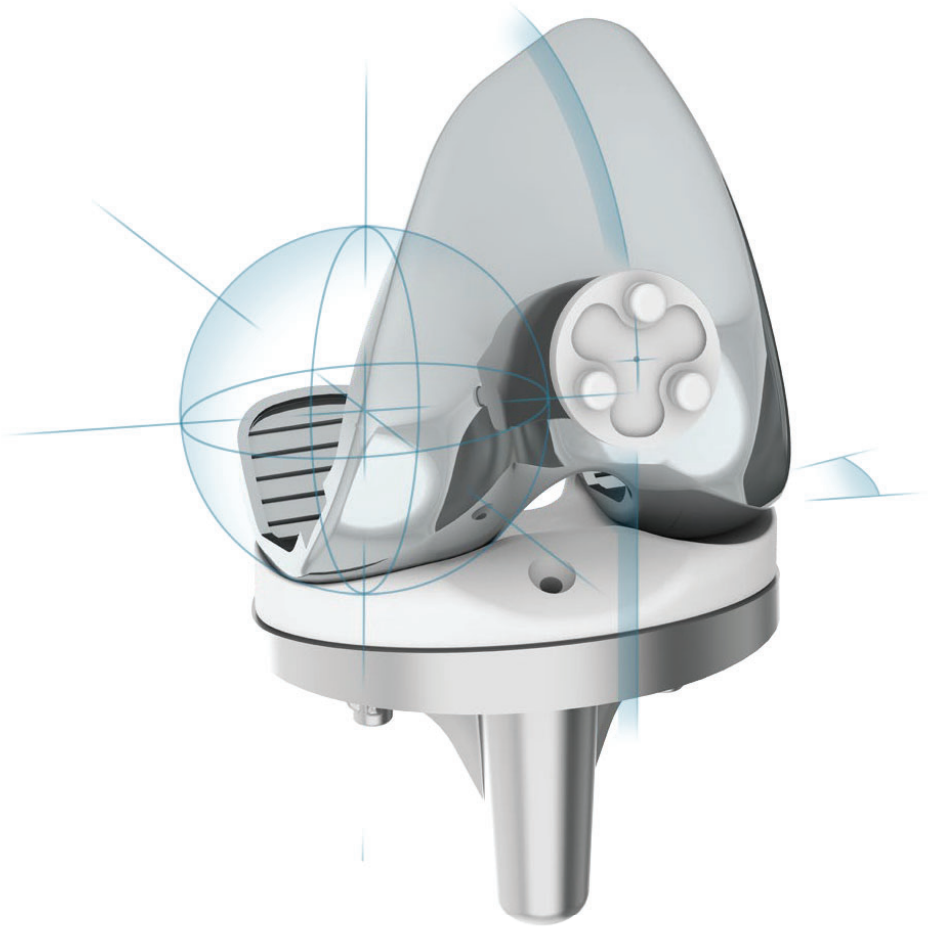
MatOrtho®



SAIPH® Knee System

Clinical Rationale

Physiological Stability and
Mobility for the Active Knee
Without Compromise

Forever Active

Contents

Patents

EP1329205 / US6869448

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1 Introduction

The SAIPH® Knee is a 2nd generation medial ball-and-socket knee. It is an evolved design based on the clinically successful Medial Rotation Knee™ (MRK™) that has been used since 1994. Like the MRK™, the SAIPH® Knee was designed on the principle that by providing natural asymmetry across all three compartments, better function and increased patient satisfaction can be achieved without the compromises of other total knee replacement (TKR) designs. The design principle was proven with the Medial Rotation Knee™ and is now demonstrated with the SAIPH® Knee.

The SAIPH® Knee has been in clinical use since 2009 with over 6,000[1] knees implanted worldwide

2 Principles of the SAIPH® 'Medially Stabilised' Knee

Tibiofemoral Articulation

The SAIPH® Knee design is based on the principle of medial stability in the normal knee, which has been described in historical literature[2] and widely in recent literature[3,4,5]. In normal, healthy knees the shapes of the medial and lateral tibial condyles are different: the medial side is concave; the lateral side is convex. Stability is provided collectively by the collateral ligaments (MCL and LCL), both cruciate ligaments (ACL and PCL) and the menisci. The shapes of the articular surfaces and the arrangement of stabilising soft tissue structures collectively provide greater stability about the medial condyle. Knee flexion is accompanied by axial rotation of the femur with respect to the tibia, which is achieved with a limited freedom for AP movement of the lateral femoral condyle relative to the tibia.

Provision of stability throughout flexion is crucial to normal knee function: a knee with a deficient ACL or medial meniscus, for example, is likely to be unstable and may require corrective surgery. Standard TKRs require removal of the menisci, ACL and commonly the PCL, but they do not fully restore their functions. The SAIPH® Knee is different because it substitutes for all removed structures. Inherent stability is provided throughout the full range of motion (ROM) with a medial deep-dish ball-and-socket articulation[6], and a semi-conforming lateral articulation permits AP translation during activities that require it while limiting excessive (unnatural) movement[6].

This clinical rationale presents **evidence** that the SAIPH® Knee provides **inherent stability**, **a near normal tibiofemoral kinematic pattern** and **no restriction to the patient's range of motion**. It also describes data that links these features to a **demonstrably higher rate of patient satisfaction**.

Patellofemoral Articulation

Whether or not the patella is resurfaced, TKR surgery includes replacing the patellofemoral articulation. Hence, the patellofemoral joint (PFJ) design is equally important for any high-functioning TKR device.

The normal trochlea is lateral to the midline[7,8] and with an asymmetric patella, the normal patella tracks laterally in flexion[8,9]. The lateralised patella also plays a role in stabilising the lateral tibiofemoral articulation.

Most standard TKR devices are restricted to a centrally located trochlea – a necessity given standard femoral condylar design[10] – and the resulting patella tracking does not compare well to that of the normal knee[11]. However, the SAIPH® Knee features a physiologically lateralised trochlea, like the MRK[10,11], which exhibits a similar amount of lateral translation of the patella in flexion as patients without a TKR[11].

With the right trochlea design, choosing not to replace the patella has not been shown to influence outcomes[12]. Nevertheless, the SAIPH® is available with the same unique saddle-shaped patella, which can rotate to match the femur for a fully conforming interface, and has 40 years of successful clinical heritage[12,13,14,15,16]. The SAIPH® Knee is also available with a cemented dome-shaped patella button.

3 Clinical Heritage: Success of the MRK™

The MRK™, also manufactured by MatOrtho® (previously Finsbury), was the original 1994 'medial ball-and-socket knee' and remains in popular use. Having evolved from this design, the clinical success of the MRK™ has strong relevance as a 'proof of concept' to the expected long-term outcomes for the SAIPH® Knee.

Overall, the MRK™ has been shown to provide greater inherent stability than comparator devices[17,18,19]. Patients with a medially stabilised knee notice the difference, and express that they prefer the design over posterior-substituting (PS), cruciate retaining (CR) and mobile designs, citing feelings of stability, normality and strength on stairs as reasons for their preference[20,21]. With its lateralised trochlea[10] the MRK™ exhibits a more normal patellar function[11]. It provides better restoration of range of motion (ROM) when compared to a standard PS knee design[22] and mean ROM is equal that of a 'high-flex' knee[23]. When compared to all other TKR designs, NJR collected patient-reported outcome measures (PROMs) show that the benefits of the MRK™ are reflected in higher functional scores[21,22] and improved rates of success and satisfaction when compared to other TKRs[19,21]. The MRK™ also provides better high-end function for categories of daily living, sport and exercise, movement and lifestyle included in the total knee function questionnaire (TKFQ). In this questionnaire, patients who received an MRK™ have scored significantly better 1 and 2 years postoperatively than counterparts who had received the most commonly used standard PS knee in the UK[22].

Survivorship for the MRK™ is the best of all TKR devices available: it has been reported with the LOWEST revision rate of ALL TKRs in the NJR more times than any other brand – 50% of all reporting instances since the NJR started reporting device brands in its 2009 Annual Report[16,24]. In the most recent 16th Annual Report (2019), the MRK™ has the LOWEST revision rate of all TKR brands at the benchmark 10 years: 2.73% (95% CI: 2.35-3.18)[16] and is among the best performing TKR options overall. The MRK™ has also been awarded an ODEP 13A rating[25].

The MRK™ has the LOWEST revision rate of all TKR brands at 10 years: 2.73% (95% CI: 2.35-3.18)[16] and is awarded an ODEP 13A rating[25].

The **SAIPH®** Knee has evolved from the original ball-and-socket device (MRK™) to incorporate all features associated with the clinical success of the concept**. It is the only TKR in the world designed wholly for the medially stabilised concept** without compromise, inherited or to accommodate other bearing options.

4 Clinical Function of the SAIPH® Knee

Normal Pattern of Movement (Knee Kinematics)

Balancing stability with freedom of movement is a principal goal of TKR design. How well a TKR achieves this can be determined by evaluating the pattern of movement in patients' knees during well-selected activities.

To evaluate the kinematics of the SAIPH® Knee, a consecutive series of one surgeon's first 14 patients (mean 69 years old, range 51-83), with no exclusions were assessed using video fluoroscopy at a minimum 24 months postoperatively[6]. Study participants were asked to perform clinically relevant functional activities, including: a full internal-to-external pivot standing on the affected leg to show the AP extents of medial and lateral condyles with large torque while under load; a kneeling activity to establish full passive flexion; lunge and step-up/down activities to establish ROM and AP stability in both condyles for the loaded knee.

In all activities the SAIPH® Knee exhibited an asymmetric pattern of movement: the knee was AP stable on the medial side and lateral translation was permitted when required (Figure 1)[6].

The pattern of movement in the SAIPH® Knee during flexion is asymmetric, like the normal knee.

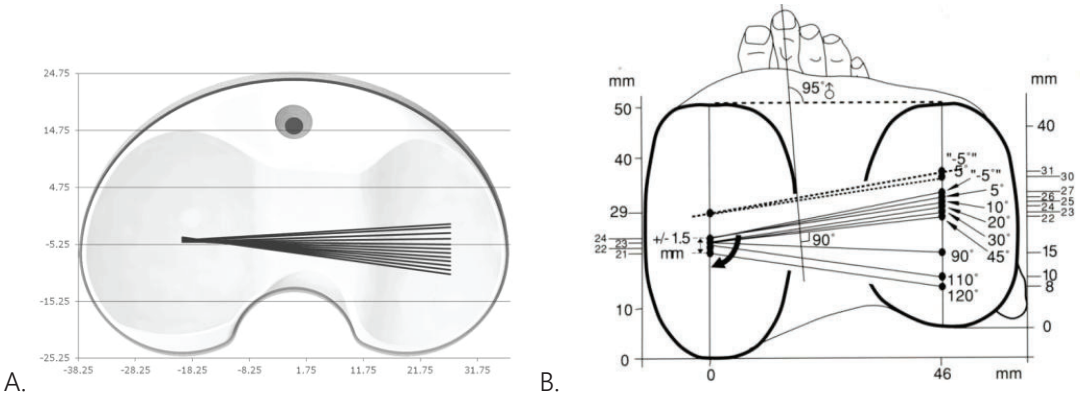

Figure 1 A. Near-normal freedom of movement in SAIPH® knees: medial stability with lateral AP translation when required (data presented in Shimmin *et al.* 2015[6]); B. A normal freedom of movement (Iwaki et al. 2000[3], Fig. 6a. ©2000 British Editorial Society of Bone and Joint Surgery. Reproduced with permission of the Licensor through PLSclear).

Range of Movement

The patients studied using fluoroscopic evaluation exhibited a passive postoperative mean ROM of 127° (range 100°-155°) and a mean active weight-bearing ROM of 121° (range 97°-151°)[6]. These values are higher than reported elsewhere for PS and CR designs and demonstrate that the SAIPH® Knee permits the maximum flexion that would be expected in a normal knee (152°-154° flexion)[26].

In a 60-patient study by three surgeons that compared the SAIPH® medially stabilised knees to CR, PS and deep dish knees, ROM was higher in the SAIPH® knees although not significant (mean 110° SAIPH® vs. mean 106° other knees)[27]. One surgeon comparing early use of the SAIPH® knee to his established successful practice with a contemporary CR knee found that SAIPH® knee patients achieved a similar ROM (mean 115°) to those receiving the CR knee (114°), with SAIPH® knee patients showing a greater improvement from pre-op to one-year post surgery (12.4° SAIPH® vs 6.5° CR), although this was not statistically significant[28]. A mean ROM of 124° was reported in a 4-centre 206-patient cohort at 2 years follow-up[29], a mean ROM of 124° was reported in a 2-centre 100-patient 5-year follow-up study[30] and a mean ROM of 119° (maximum 150°) was reported in a 13-hospital 274-patient study at 2-years follow up[32].

The SAIPH® Knee allows for the same maximum flexion that would be expected in a normal knee.

Stability

A 'medial pivot' design implies that a TKR is intended to conform to an idea that the normal knee always exhibits a medial centre of rotation. This is not the case: the normal knee centre of rotation is not static and in some activities lateral AP translation is suppressed[4]. Normal knees are however stable throughout flexion. The provision of stability by the articular shapes and constraining tissues is greatest on the medial side but both the lateral and patellofemoral compartments also contribute to stability. If any compartment is neglected, the outcome is compromised. As such, the defining principle of MatOrtho® ball-and-socket knees is the provision of full-ROM stability. Because this is achieved with a medial deep-dish ball-and-socket articulation the concept is better termed 'medially stabilised'. However overall stability is achieved with appropriate constraint in all compartments and this is demonstrated by assessment of total knee AP stability throughout ROM.

The defining principle of MatOrtho® ball-and-socket knees is provision of full-ROM stability.

Patients studied using fluoroscopic evaluation exhibited no paradoxical anterior translation of the femoral condyles during flexion in any activity, confirming the design intent for inherent full ROM stability (Figure 1)[6]. This feature is also confirmed in the 5-year follow up of 100 knees by Katchky *et al.*, who found no incidence of symptomatic AP instability in patients[30].

In a study of 64 patients (mean age 72 years; mean follow-up 33.7 months) with four different knee designs (rotating platform LCS design, DePuy; cruciate retaining Triathlon, Stryker; medially stabilised knees SAIPH® Knee and MRK™, MatOrtho®) sagittal stability was measured at four degrees of flexion: 0°; 30°; 60°; and 90°, to examine the effect of design on mid-flexion stability[33]. Sagittal stability was similar in all four groups in full extension; however the MRK™ and SAIPH® Knee designs showed significantly improved stability in the mid-range of flexion (30–60°) (Figure 2)[33].

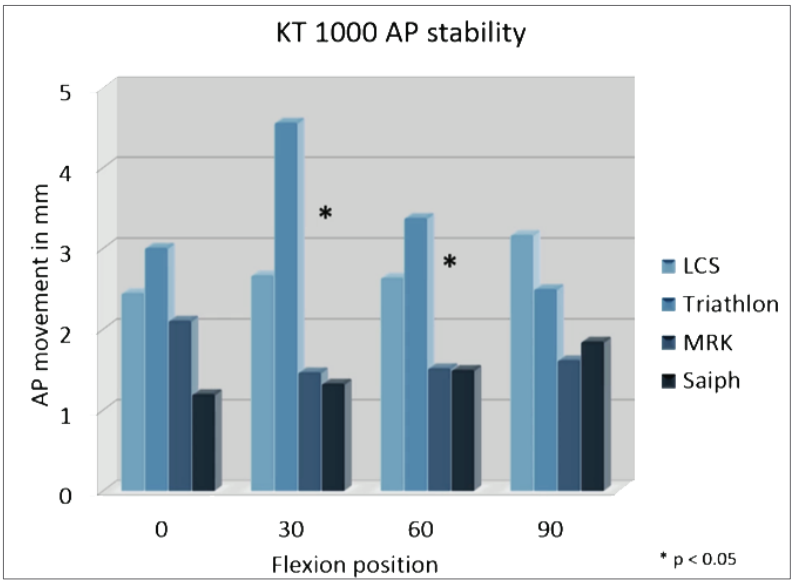

Figure 2 Sagittal stability for 4 knee designs at different degrees of flexion[33].

In a separate similar study of 60 patients with four TKR designs (medially stabilised, cruciate retaining '1', cruciate retaining '2' and cruciate retaining 'deep dish') sagittal stability was measured using the KT1000 at 30° and 90°[27]. Patients were recruited from three centres (three surgeons each implanting 10 SAIPH® Knees and 10 comparative knees). Patients were matched for age, gender, BMI and time to follow-up. When comparing medially stabilised knees (SAIPH® Knee) to cruciate retaining '1' knees, AP movement was significantly less in the SAIPH® Knees at both 30° (p=0.037) and 90° (p=0.030)[27]. When comparing SAIPH® Knees to cruciate retaining '2' knees, AP movement was significantly less in the SAIPH® Knees at 30° (p=0.013) and less at 90° although not significant (p=0.156)[27]. When comparing SAIPH® Knees to cruciate retaining 'deep dish' knees, AP movement was significantly less in the SAIPH® Knees at both 30° (p=0.030) and 90° (p=0.048)[27]. When

comparing all SAIPH® Knees to all non-medially stabilised knees, AP movement was significantly less in the SAIPH® Knees at both 30° (p=0.003) and 90° (p=0.008)[27].

To compare surgeons' perception of sagittal anteroposterior (AP) stability after total knee replacement, 60 videos were taken of an AP drawer test of 60 patients performed by an examiner who was blinded as to what knee design each patient had received. Nine surgeons, who were blinded as to what knee design each video presented, were asked to grade the stability of all knees by determining whether they exhibited <5mm, 5-10mm or >10mm AP translation. Results demonstrated that the SAIPH® Knees were consistently perceived to be more stable than the cruciate retaining and 'deep dish' designs: 74% stable SAIPH® Knees vs. 38-40% other knee types (Figure 3)[27].

The SAIPH® Knee is inherently stable throughout flexion, like the normal knee.

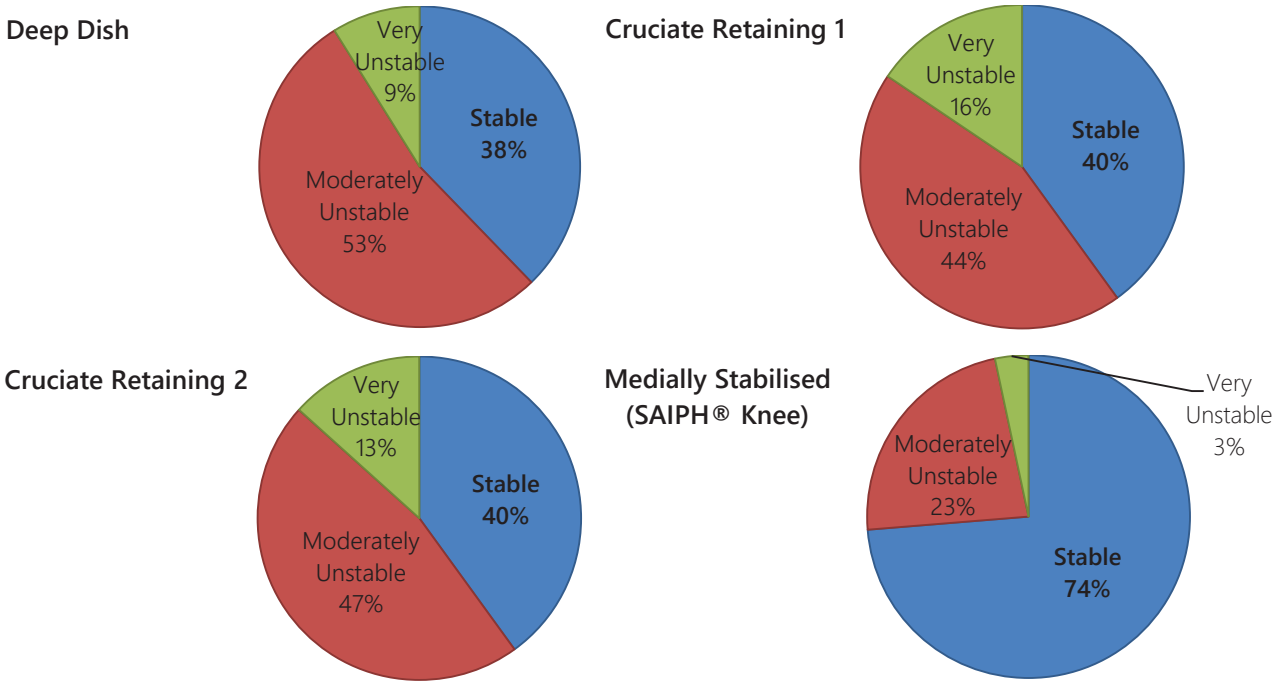

Figure 3 Stability assessment of 60 patients with four designs of knee, finding 74% of SAIPH® Knees were stable in contrast to 40% or less for other knee designs[27].

5 Patient Reported Outcome Measures (PROMs)

The early consecutive series of patients participating in the fluoroscopic evaluation reported PROMs outcomes including mean (range): KOOS pain, 92 (69-100); KOOS symptoms, 91 (82-100); KOOS daily activities, 91 (72-100); KOOS sports, 62 (0-100); KOOS QoL, 78 (38-100)[6]. These values are excellent when compared to reference mean values from a non-osteoarthritic population of similar age[35].

Between December 2015 and July 2019, 588 knees (549 patients) were enrolled into a multicentre study by 15 independent non-inventor surgeons in 13 hospitals. At the time of reporting, 293 knees (274 patients) patients across 12 sites (9 surgeons) had completed a minimum of 2-years post-operation[32]. Demographics were indicative of a standard TKR population including an average age of 68 years (46-92), a ratio of 51.5% male to 48.5% female and mean BMI 31 (15-59). The study collected patient reported outcome measures (PROMs) including KOOS, OKS, UCLA Activity and EQ5D-5L and range of motion preoperatively and 1 and 2 years postoperatively. The Forgotten Joint Score and 3 satisfaction questions were taken at the 1 and 2-year intervals. Surgical details, comorbidities, complications and radiological assessment were also completed. Improvements were observed for all outcome measures, consistently achieving excellent scores[32] based on expectations from population studies[35] (Figure 4).

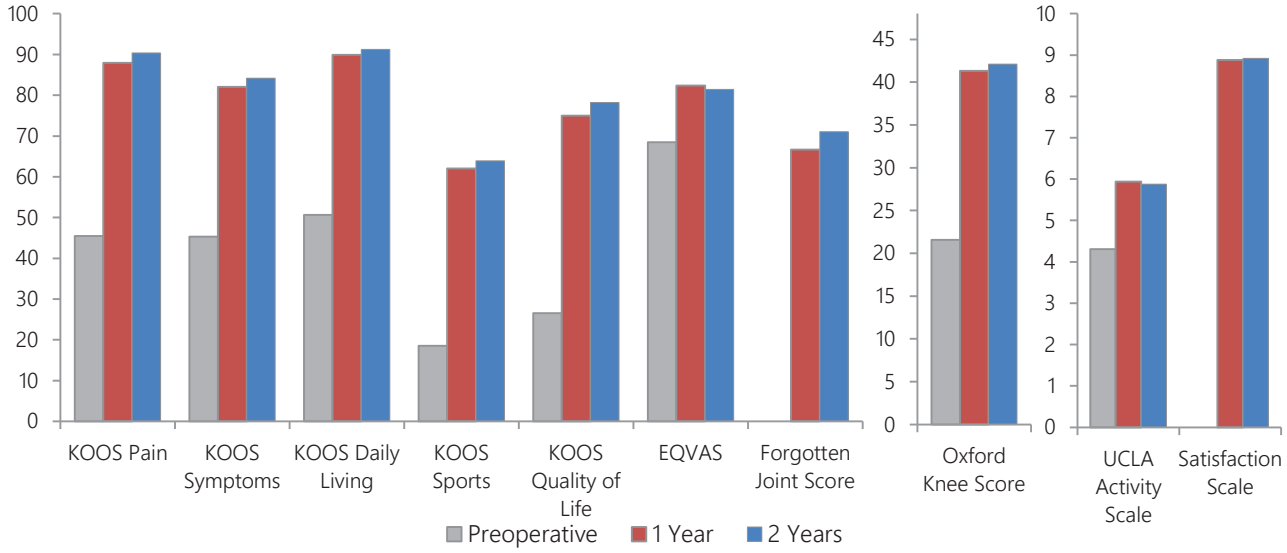

Figure 4 Improvements in all PROMs scores from a 274-patient SAIPH® Knee cohort at 2-year follow-up[32].

A study of 206 patients (mean 67 years old) followed up to 2 years from 4 centres reported on outcomes including the Oxford Knee Score (OKS), Kujala score, KOOS scores and EQ-5D visual analogue scale and found significant health gains in all measures with 95% responding good to excellent in the OKS according to the 'Kalairajah' method of categorising the OKS[34] (mean: OKS 42.8, health gain 19; KOOS pain 92; KOOS symptoms 87.8; KOOS daily living 91.6; KOOS sports 66.5; KOOS QoL 82)[29].

Five-year postoperative data for a cohort of 100 SAIPH® knees (92 patients; mean 68 years old) performed in two centres has been reported[30]. Patient-reported outcome measures included the KOOS, WOMAC, Oxford Knee Score, Forgotten Joint Score (FJS) and the EQ-5D score[30]. The data for this cohort showed significant improvement postoperatively ($p<0.0001$) for all PROMs measures[30], including excellent OKS (mean 44) and KOOS scores (mean pain 94.7; symptoms 92.4; daily living 93.5; sports 71.3; QoL 82.2)[30]. This study also reported a similar Forgotten Joint Score (mean 75.3[30]) to that found in the single-surgeon comparative study (mean 79.9)[28], commenting that this score is considerably better than previously reported TKR cohorts[36] and equal to reports for unicondylar knee arthroplasty (UKA) patients[37].

SAIPH® Knee patients are consistently achieving excellent outcomes in all PROMs.

In their KT1000 study of 64 patients with four knee designs, Munir *et al.* also measured Oxford knee score, WOMAC knee score, SF12 and Kujala patellofemoral knee scores and found better patient-reported satisfaction and functional scores in the MRK™ and SAIPH® Knee than rotating platform and cruciate retaining designs[33].

In their stability study of 60 patients Jacobs *et al.* found a significant difference in WOMAC score (p=0.016), Oxford Knee Score (OKS; p=0.015), short-form KOOS (p=0.040) and Forgotten Joint Score (FJS; p=0.009) between the SAIPH® Knee and all non-medially stabilised knees[27]. When comparing all stable and unstable knees in their study, highly significant correlations were found between stable knees and better scores (KOOS pain, p=0.008; KOOS daily activities, p=0.012; KOOS sport, p=0.001; WOMAC pain, p=0.004; WOMAC function, p=0.018; WOMAC overall, p=0.0; OKS, p=0.0; and FJS, p=0.049)[27].

SAIPH® Knee patients are associated with better scores than other TKR designs.

To objectively determine whether or not use of the SAIPH® Knee would benefit patients, one surgeon performed a consecutive series of 103 patients, randomly selected to receive a cruciate retaining (CR) knee established in the surgeon's practice (50 knees) or the SAIPH® Knee that was new to the practice (53 knees)[28]. PROMs were the primary outcome measure for the study and included the KOOS, KOOS-12, KOOS-Shortform, KOOS-Jr, WOMAC, OKS, EQ-5D-5L and UCLA Activity Scale pre-operatively and at 1-year follow-up and the FJS and VAS-Satisfaction at 1-year follow-up. There was no significant difference between groups for the majority of the commonly-used PROMs measures. However, the SAIPH® knee patients reported significantly better ($p<0.05$) outcomes for KOOS Quality of Life sections and concerning whether or not they had modified their lifestyle to avoid activities potentially damaging to their knee. Furthermore, patients scored significantly better for the Forgotten Joint Score overall 79.9 for the SAIPH® Knee group compared to 63.8 for the CR knee group (p=0.005), with significantly better scores for 8 of the 12 (sitting on a chair, p=0.001; walking for more than 15 minutes, p=0.011; taking a bath, p=0.003; travelling in a car, p=0.004; walking on uneven ground, p=0.018; standing up, p=0,016; doing housework, p=0.001; and taking a walk/hiking, p=0.003). For all remaining questions (in bed at night, climbing stairs, standing for a long time and doing favourite sport) the SAIPH® knee group scored better than the CR group but without statistical significance.

While both implants performed well with equivalent clinical and functional outcomes to other successful contemporary knee designs, there was a difference in the high-end functionality measures. SAIPH® knee patients reported that they were less likely to modify their lifestyle to accommodate their knee replacement, more likely to 'forget' their knee in everyday life and to report a better quality of life 1-year after their surgery.

SAIPH® Knee patients are more likely to report that they can 'forget' their knee during everyday life.

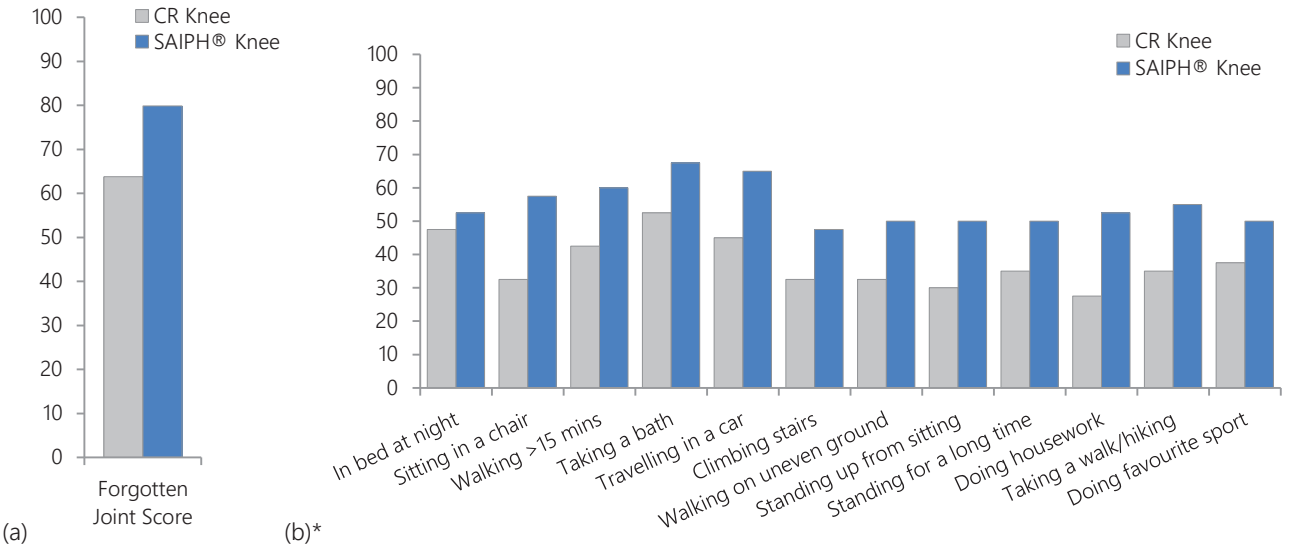

Figure 5 SAIPH® knee patients are more likely to 'forget' their artificial joint during everyday activities: (a) mean Forgotten Joint Score (FJS) for patients in the SAIPH® and CR knee groups reported by French *et al.*[28] and (b) responses to individual questions of the FJS for SAIPH® and CR groups based on raw data presented by French *et al.*[28]. *Each question has 5 possible responses scored 0 (never aware of their artificial joint) to 4 (mostly aware of their artificial joint). The FJS for each patient is produced using the sum of all scores divided by the number of questions answered by the patient. The mean score is multiplied by 25 to obtain a score out of 100 and is then subtracted from 100 to indicate a higher degree or 'forgetting' the artificial joint[38]. Values in graph (b) were produced in a similar way but using mean score for each individual question.

6 Patient Satisfaction with the SAIPH® Knee

In their 2-year follow up study, Walter *et al.* used a visual analogue scale (VAS) for patient satisfaction and found that 95.3% responded positively (responding 8-10 on a 10-point scale), which they commented was unusual in their previous knee cohorts and was equivalent to satisfaction responses for their own hip cohorts (95.2%) at the same timepoint[29]. In their stability study of 60 patients Jacobs *et al.* found that patients with SAIPH® knees were more likely to be satisfied with their outcome than patients with non-medially stabilised knees (>7.5 VAS satisfaction: 97% SAIPH® vs 83% other; p=0.08), which became significant (p=0.048) when comparing all stable to all unstable knees in their study[27]. In one surgeon's consecutive series comparing SAIPH® patients with those who had received his established device, SAIPH® patients scored mean 9.3 on the same VAS-satisfaction scale[28].

In their 5-year postoperative data for a cohort of 100 SAIPH® knees, Katchky *et al.* found that when asked: "How would you describe the results of your operation?" (Success), 98% of patients responded that the results of their operation were 'good' to 'excellent' (Figure 6)[31]. In their 274-patient multicentre study, Bare *et al.* reported an equally high degree of satisfaction: 96.3% of patients described the results of their operation as 'good' to 'excellent' (Figure 7)[32].

When asked "Overall, how are your problems now compared to before your operation?" (Satisfaction), Katchky *et al.* reported that 98% of patients responded with 'much better' (Figure 6)[31]. Bare *et al.* found 97.7% of their patients said their problems were 'better than before surgery' with 93.2% saying 'much better' 2 years after their surgery (Figure 7)[32]. Bare *et al.* reported that results were reproducible for all surgeons: median satisfaction for every surgeon's cohort was ≥9 out of 10[32]. Unlike recent reports on patient satisfaction after total knee replacement[39,40,41], SAIPH® Knee cohorts do not display a 15-20% dissatisfaction rate[27,28,29,30,32].

Unlike recent reports on patient satisfaction after total knee replacement, SAIPH® Knee cohorts do NOT display a 15-20% dissatisfaction rate.

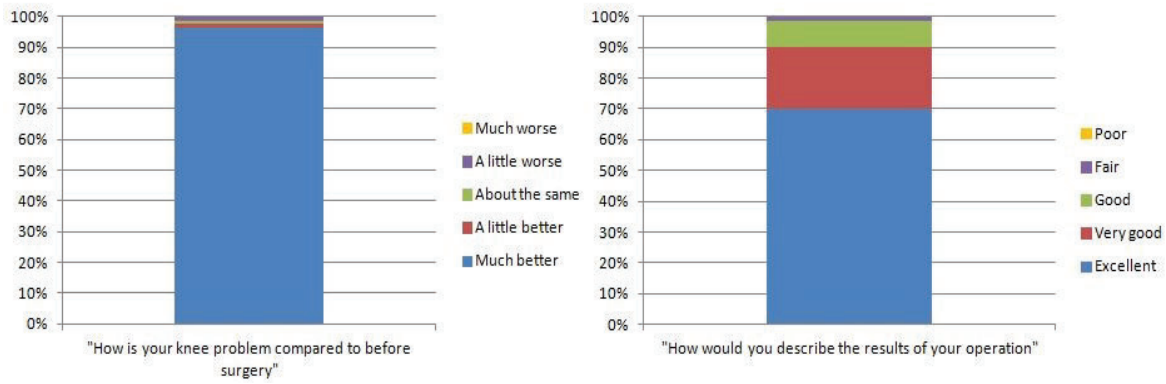

Figure 6 Success and satisfaction outcomes for a 100-patient SAIPH® Knee cohort at 5-year follow-up[31].

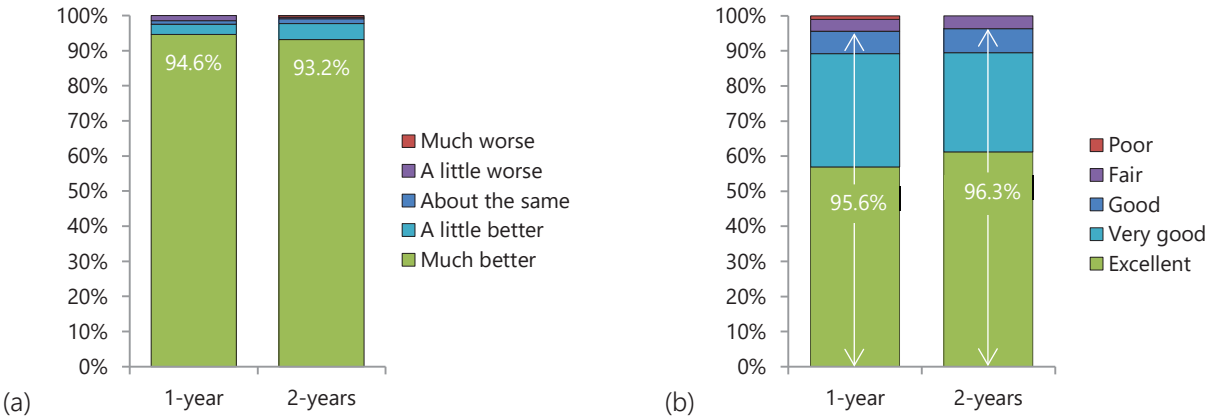

Figure 7 Patient satisfaction: (a) "overall, how are your problems now, compared to before your knee replacement?" and (b) "how would you describe the results of your knee replacement?"[32].

7 Longevity of the SAIPH® Knee

Secure Fixation

Other manufacturers have introduced a ball-and-socket asymmetric tibial constraint to platforms with a traditional 'keel' tibial design used on unconstrained bearing options. Some have also produced cementless component versions. Higher revision rates[16,42], particularly tibial loosening[43] have been associated with these combined design characteristics. The MRK™ and SAIPH® Knees include a different fixation design to traditional keel designs, which is intended to support rotational torque at the implant-bone interface.

The first clinical follow up on MRK™ patients who had received the implant from 1994 commented specifically on the matter and showed that the increased congruence of the asymmetric tibial bearing had not increased the rate of loosening[14]. From over 12,000 procedures recorded by the NJR over 15 years, the MRK™ has been revised for aseptic loosening of the tibia significantly fewer times ($p<0.001$) than all other TKRs in the UK[15].

The SAIPH® Knee features an optimised stem-and-pegs design with a stippled cement interlocking interface with additional anti-rotation fins. From radiographic analysis Katchky *et al.* found no progressive lucent lines, no non-progressive lucent lines >2mm and there were no incidences of osteolysis at 5 years follow-up[30]. Indeed, current reports show that to date, not one SAIPH® has been revised for aseptic loosening of the tibia[30,32,44].

Survivorship in Outcomes Studies

In their independent 15-surgeon multicentre study of the SAIPH® knee, from 588 SAIPH® Knees implanted, Baré *et al.* reported a survivorship of 98.6% at 2 years[32]. In their study of 225 patients, Walter *et al.* reported 98.7% survivorship at 2 years[29]. In their five-year outcomes study from two centres and 100 patients, Katchky *et al.* reported a 98% survivorship[30]. All studies reported comparable complications to other TKR populations[29,30,32].

Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

In its 2019 Annual Report, the AOANJRR has sufficient data to present revision rates for some TKR devices up to 18 years post operation. The overall revision rate for all TKRs is 3.5% at 5 years, 5.3% at 10 years and 8.6% at 18 years for indication of osteoarthritis, which accounts for 97.7% of procedures[42].

A trend to increasing use of medially stabilised knees is reported by the AOANJRR used since 2012. In 2018 use of medially stabilised knees increased to 8.9% of all TKRs. Given the recent rise in use, medially stabilised knees represent a shorter follow-up period and fewer knees than the traditional CR and PS knee types. Nevertheless, medially stabilised knees are demonstrating lower cumulative percent revision rates than other knee types in the longer term[45].

When compared to other medially stabilised knee designs, the SAIPH® and MRK™ knees are reported with the lowest cumulative rate of revisions for primary diagnosis of OA with mean **2.3% at 5 years post operation** (95% CI: 1.5-3.4) for the SAIPH® Knee (Figure 8), which compares favourably to the rate of revisions for all knees with primary diagnosis of OA at the same time point (3.6%) and is in line with the best-performing minimally stabilised knee designs[46].

The medially stabilised knee category has the lowest rate of revisions of all knee categories in the longer term and the SAIPH® and MRK™ knees have the lowest rates of revisions of all medially stabilised knees.

Insert	N Revised	N Total	1 Yr	3 Yrs	5 Yrs	10 Yrs	15 Yrs	18 Yrs
Advance	32	685	1.3 (0.7, 2.6)	4.5 (3.1, 6.5)	5.2 (3.7, 7.5)			
Advance I	5	15	6.7 (1.0, 38.7)	13.3 (3.5, 43.6)	13.3 (3.5, 43.6)	35.0 (16.3, 64.9)	35.0 (16.3, 64.9)	35.0 (16.3, 64.9)
Advance II	113	1665	1.8 (1.3, 2.6)	4.4 (3.5, 5.5)	5.4 (4.3, 6.6)	7.4 (6.1, 9.0)	8.1 (6.6, 9.9)	
Evolution	113	6448	0.9 (0.7, 1.2)	2.6 (2.2, 3.2)	3.4 (2.6, 4.5)			
GMK Sphere Primary	137	6956	1.4 (1.1, 1.7)	2.7 (2.3, 3.2)	3.4 (2.7, 4.3)			
MRK	13	588	0.9 (0.4, 2.1)	2.2 (1.3, 3.9)	2.2 (1.3, 3.9)			
Persona*	1	270						
SAIPH	33	2622	0.5 (0.3, 0.8)	2.0 (1.4, 2.9)	2.3 (1.6, 3.5)			
TOTAL	**447**	**19249**						

Figure 8 AOANJRR cumulative percent revision of primary total knee replacement with a medially stabilised design (primary diagnosis OA)[46].

National Joint Registry (NJR)

Medially stabilised knees have been a regular feature of the NJR, despite not being recognised as a separate category. Over 25,000 medially stabilised knees have been recorded since the NJR started collecting data in 2003[16]. The majority of those procedures used the MRK™. In its 2019 Annual Report including data up to 31 December 2018, the NJR includes over 1,000 knees and a cumulative revision rate of **1.62% at 5 years post operation** (95% CI: 0.87-3.02).

In the most recent Summary Data Report from the NJR on the SAIPH® Knee (August 2019), data is reported for 1,267 knees (1,145 patients) with mean implantation time of 2.5 years, maximum 9.6 years[44]. Overall 14 knees have been revised (1.1%) and the reported cumulative revision rate is **1.7% at 6 years post operation** (95% CI: 1.0-4.0), which compares well to the 6-year cumulative revision rate of 2.5% (95% CI: 2.4-2.5) for all TKRs in the NJR[44].

8 Orthopaedic Data Evaluation Panel (ODEP)

ODEP provide a service evaluation for TKR ratings and award ratings based on ongoing assessment of implant performance (rate of revision), and the number of patients for which principally UK data is available. The registries and clinical studies described in this document report excellent rates of survivorship for the SAIPH® Knee, with cumulative revision rates lower than the average TKR revision rates and among the lowest of all available devices[16,42,44].

Within the MatOrtho® philosophy for safe introduction of new technology, the SAIPH® Knee has been released with limited availability and under closely monitored use. In the 10 years since first use 1,500 of the 6,000 SAIPH® Knee procedures were performed in the UK and recorded by the NJR. To ensure versions of implant brands are reported appropriately, ODEP separate devices into their available constructs. For the SAIPH® Knee, this means separating UK data for SAIPH® procedures with no patella, with a cementless patella and with a cemented patella. Consequently, cohorts on which ODEP ratings are based for each construct remain small.

The SAIPH® Knee is most commonly used in the UK without a patella resurfacing. With a revision rate of **1.7% at 5 years** (95% CI: 0.7%-4.0%) and sufficient patients at the time of assessment, ODEP awarded the base construct a 5A rating. When used with a patella SAIPH® had a revision rate of **0.5% at 5 years** (95% CI: 0.1%-2.0%). The cementless patella (which is the same design as the 10A*-rated MRK™ patella) had **no revisions at 5 years**, yet with a smaller cohort meets ODEP criteria for a 5B rating. The cemented patella was introduced after the SAIPH® Knee was first used and, with fewer patients, meets the ODEP criteria for a 3A rating. ODEP ratings are shown in Figure 9.

The SAIPH® is demonstrating exceptional performance with a consistent low revision rate and, as the number of patients who receive it grows, is on track to receive an ODEP 10A* rating.

Figure 9 ODEP ratings for SAIPH® Knee constructs.

For those interested in ODEP ratings, further information on ODEP criteria and use of ratings by hospitals can be found on the ODEP website www.odep.org.uk[25,47,48].

9 Summary: Supporting Evidence-Based Decisions

New technologies are essential to advance quality of care. MatOrtho® introduces new technologies gradually and responsibly, so that fewer patients are exposed to potential risk of failure whilst, as the evidence grows, as many patients as possible can ultimately benefit. Proper surveillance ensures that surgeons can uphold their responsibility for evidence-based decision making.

Since it was first introduced, surveillance activities for the SAIPH® Knee have included: functional studies investigating kinematics, ROM and stability throughout ROM; inventor-surgeon patient outcomes; independent non-inventor multicentre study outcomes; single-surgeon studies comparing outcomes with established TKR device; development of registry data; and independent review of data (ODEP).

Outcome studies are reporting excellent outcomes[30,32]. The SAIPH® ODEP ratings[25,48] are on track for and showing better outcomes than others that already have a 10A* rating. Registry data continues to demonstrate superior performance of the SAIPH® Knee when compared to other technologies[42,44,46].

A combination of normal tibiofemoral and patellofemoral function is necessary for high-end knee function[49,50]. By demonstrating inherent stability throughout the full range of motion[6,27,30,33] without compromising freedom of movement[6,27,28,30,32], SAIPH® Knee patients are more likely to be satisfied with the results of their operation than is reported elsewhere[30,32,39,40,41].

The SAIPH® Knee has a very positive and broad spectrum of data to support surgeon and hospital evidence-based decision making processes.

10 Notes

11 Key Literature

Fluoroscopic motion study confirming the stability of a medial pivot design total knee arthroplasty.

Shimmin A, Martinez Martos S, Owens J, Iorgulescu AD, Banks S. The Knee. 2015; 22(6):522-526.

Abstract

Background: The ideal total knee arthroplasty should provide maximum range of motion and functional stability for all desired daily activities. The SAIPH® (MatOrtho; UK) knee has a medial pivot knee kinematic pattern designed to achieve medial stability and an asymmetric posterior translation of the lateral femoral condyle during knee flexion and in this way attempts to mimic the natural knee motion. This study aims to analyse knee kinematics of the SAIPH® total knee arthroplasty (TKA) by videofluoroscopy during four different weight-bearing activities.

Methods: Fourteen consecutive patients operated on by a single surgeon, with a minimum follow-up of 24 months were included in this IRB-approved study. There were no exclusions based on patient's functional level. A medially conforming knee was implanted in all cases. Participants in the study were asked to perform the clinically relevant functional activities of pivoting, kneeling, lunging and step-up/down activities while their knee motion was recorded by videofluoroscopy.

Results: Maximum knee flexion during the kneeling activity mean 127° (100°-155°). An asymmetric posterior translation of the lateral femoral condyle (LFC) was observed during pivoting, kneeling, lunging and stepping. No paradoxical anterior translation of the femoral condyles was observed in any activity.

Conclusion: The kinematics observed in this implant are similar in pattern, although smaller in magnitude, to normal functional knees, showing a posterior translation of the lateral femoral condyle during knee flexion, with internal rotation of the tibia, and no paradoxical anterior motion in any of the four weight bearing activities.

Medial ball and socket total knee arthroplasty. Five-year clinical results.

Katchky AM, Jones CW, Walter WL, Shimmin AS. The Bone & Joint Journal. 2019; 101-B (1 Supple A): 59-65.

Abstract

Aims: Between 15% and 20% of patients remain dissatisfied following total knee arthroplasty (TKA). The SAIPH knee system (MatOrtho, Surrey, United Kingdom) is a medial ball and socket TKA that has been designed to replicate native knee kinematics in order to maximize the range of movement, stability, and function. This system is being progressively introduced in a stepwise fashion, with this study reporting the mid-term clinical and radiological outcomes.

Patients and Methods: A retrospective review was undertaken of the first 100 consecutive patients with five-year follow-up following SAIPH TKA performed by the senior authors. The data that were collected included the demographics of the patients, clinical findings, the rate of intraoperative ligamentous release, patient-reported outcome measures (PROMS), radiological assessment, complications, and all-cause revision. Revision data were cross-checked with a national registry.

Results: A total of 100 TKAs in 92 patients were included. Three patients died (three TKAs) and a further two TKAs were revised. Of the remaining 95 TKAs, five-year follow-up data were available for 81 TKAs (85%) in 87 patients. There were significant improvements in all PROMs and high satisfaction. The mean ROM at final follow-up was from 0° (full extension) to 124° flexion. There were seven major complications (7%): one infection, two deep vein thromboses, one cerebrovascular event, and two patients with stiffness requiring a manipulation under anaesthesia. Two patients required a lateral retinacular release to optimize patellar tracking in valgus knees; no additional ligament releases were performed in any patient. Radiological analysis demonstrated no evidence of implant-related complications.

Conclusion: These results demonstrate satisfactory clinical and radiological outcomes at five years following a medial ball and socket TKA. The complication and revision rates are consistent with those previously reported for patients undergoing TKA. These results demonstrate the safety and efficacy of the SAIPH Knee TKA system and support its wider use.

A Single Surgeon Series comparing the Outcomes of a Cruciate Retaining and Medially-Stabilised Total Knee Arthroplasty using Kinematic Alignment Principles.

French SR, Munir DS, Brighton R. Journal of Arthroplasty. 2019; doi: https://doi.org/10.1016/j.arth.2019.09.021

Abstract

Aims: Total Knee Arthroplasty (TKA) designs are developed to optimize kinematics and improve patient satisfaction. The Cruciate Retaining (CR) and Medially-Stabilised (MS) TKA designs have reported good midterm follow up outcomes. However, reasons for consistently high rates of patient dissatisfaction following a TKA remain poorly understood. To further investigate this, we compared the short-term functional outcomes and quality of life, using patient-reported outcome measures (PROMs) and Range of Motion (ROM), between a CR and MS TKA.

Methods: A prospective comparison was made between 2 groups (44 CR-TKA vs 46 MS-TKA). The KOOS, KOOS-12, KOOS-Shortform, KOOS-JR, Oxford Knee Score, WOMAC, UCLA Activity Scale, and EQ-5D-5L were completed pre-operatively and one year post-operatively. The Forgotten Joint Score (FJS) and VAS-satisfaction were completed at one year post-operatively. ROM was collected pre-operatively and one year post-operatively.

Results: Patients who underwent an MS-TKA scored significantly better than the CR-TKA on the FJS (MS= 79.87, CR= 63.8, p =.005), the KOOS-12 Quality of Life subscale (MS= 82.8, CR= 74.4, p= 0.43) and the KOOS Quality of Life subscale (MS= 82.8, CR= 74.6, p= 0.44). There was no difference between the groups in all assessed PROMs or ROM, pre-operatively and one year post-operatively.

Conclusion: Patients who underwent the MS-TKA scored significantly better on the FJS and the quality of life subscale of the KOOS and KOOS-12 than those who underwent a CR-TKA. All other assessed PROMs and ROM were comparable between the two groups and demonstrated that both implants facilitated symptom relief and improved daily function at one year post-operatively. These findings suggest that at short-term follow-up, the MS device is more likely to allow a patient to "forget" that a joint has been replaced and restore their quality of life. Long-term assessment of MS-TKA design outcomes in larger cohorts is recommended.

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Part No. ML-300-168 | Issue 7