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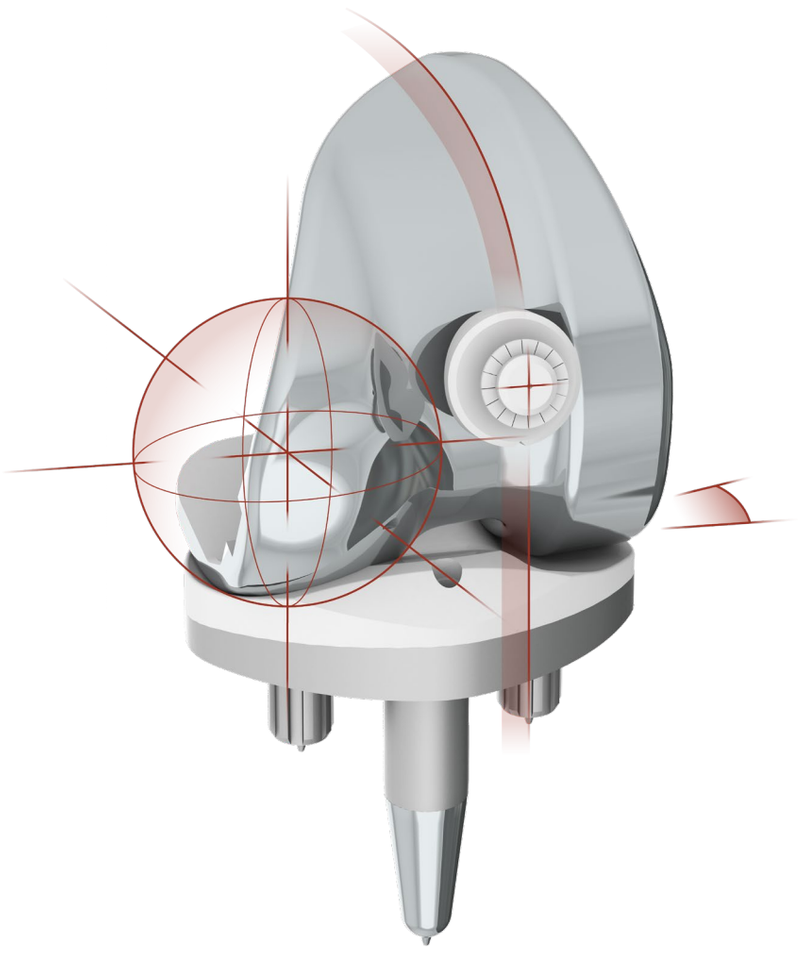

Medial Rotation Knee™ System

Clinical Data Summary

Physiological Stability and
Mobility for the Active Knee
Without Compromise

Forever **Active**

Contents

Patents

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1 Summary Overview of Clinical Data

Introduction

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 resulting pattern of movement during flexion is asymmetric: the medial condyle is stable throughout the range of motion, but on the lateral side there is limited freedom to move anterior-posterior (tibia with respect to femur).

The anatomy of the patellofemoral articulation is also asymmetric: the femoral trochlea is lateral to the midline and the patella has a larger lateral facet than medial. As a result, normal patellar tracking is asymmetric.

The Medial Rotation Knee™ (MRK™) was designed on the principle that by providing this asymmetry in all three compartments, better function and increased patient satisfaction can be achieved without the compromises of other total knee replacement (TKR) designs. The clinical data supports this philosophy.

The MRK™ is the original medial ball and socket knee. It has been in clinical use for over 20 years (first implanted in 1994) with 25,000 MRK™ knees implanted worldwide.

Clinical function: Tibiofemoral articulation

The design of the MRK™ is based on the principle of medial stability in the normal knee, described in historical literature[1] and widely in recent literature[2,3,4]. The principal understanding is that the shapes of the articular surfaces and the arrangement of stabilising soft tissue structures collectively provide greater stability about the medial condyle. The medial condyle is anterior-posterior (AP) stable with respect to the tibia throughout knee flexion. 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[1,2,3,4].

Provision of stability throughout flexion is crucial to normal knee function: a knee with 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 restore their functions. The MRK™ is different in that is 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[5,6,7]. A semi-conforming lateral articulation permits AP translation during activities that require it while limiting excessive (unnatural) movement[5,6].

Fluoroscopic evaluation of a series of patients 1-2 years postoperatively has shown that the MRK™ successfully restores a near-normal pattern of movement[5,6], which other designs do not[8].

Patients do notice the difference between types of knee replacement and can differentiate between left and right knees that have a different design of TKR[9]. When comparing design concepts, more patients state a preference for the medial ball and socket design over posterior stabilised (PS), cruciate retaining (CR) and mobile designs[9]. Reasons for their preference include feelings of stability, normality and strength on stairs[9].

Directly comparing between groups of patients with the MRK™ and groups of patients with alternative designs has shown that the MRK™ provides greater inherent stability than the comparator devices[7,10].

Clinical function: 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[11,12] and with an asymmetric patella, the normal patella tracks laterally in flexion[11,13]. The lateralised patella also plays a role in stabilising the lateral tibiofemoral articulation.

Most standard TKR devices are restricted to a centrally located trochlea, due to the femoral condylar design[14] and the resulting patella tracking does not compare well to that of the normal knee[15]. However, the MRK™

features a physiologically lateralised trochlea[14,15] and, true to design intent, when compared to patients with no TKR and patients with a PS knee, patients with the MRK™ exhibited similar amount of lateral translation of the patella in flexion as patients without a TKR, whereas patients with the PS knee did not[15].

Choosing not to replace the patella has not been shown to influence outcomes for this knee design with the trochlea being identified as the more important feature[16]. Nevertheless, the unique saddle-shaped patella, which can rotate to match the femur for a fully conforming interface, has almost 40 years of successful clinical heritage[16-20].

Functional and patient-reported outcomes

A combination of normal tibiofemoral and patellofemoral function is necessary for high-end knee function[21,22]. By accommodating natural function in all three compartments, the MRK™ has been shown to permit 140° of flexion[5] and in cohorts a better mean improvement in ROM when compared to a standard PS TKR design[23] and a mean ROM equal to that of a 'high-flex' knee[24].

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[10,17,23] and improved rates of success and satisfaction[7,10,17].

The MRK™ also provides better high-end function[23]. For categories of daily living, sport and exercise, and movement and lifestyle included in the total knee function questionnaire (TKFQ), MRK™ patients report significantly better scores at 1 and 2 years postoperatively than patients with a standard PS knee[23].

Survivorship

National Joint Registry (NJR)

Survivorship for the MRK™ is in line with the best TKR devices available, as reported for the first MRK™ cohort from 1994 onwards[19,20], the NJR Annual Report[18] and when compared directly to all other TKR devices recorded by the NJR[17].

The MRK™ is one of only three device brands with an overall revision rate below 3% at 10 years (2.69%; 95% CI: 2.28-3.18)[18]. The average 10-year revision rate for all TKRs in the NJR is 3.4%[18].

In 2018 the NJR published revision rates for TKR brands at the 14-year time point for the first time.

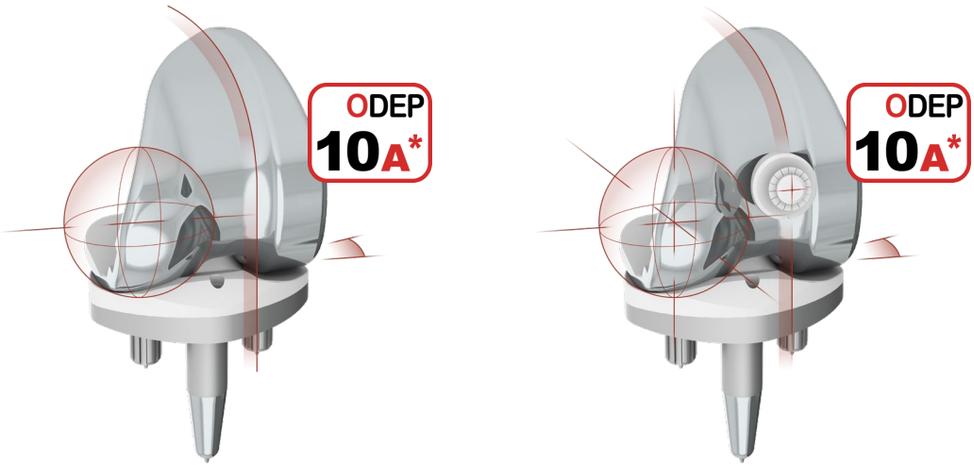
The MRK™ has the LOWEST revision rate of all TKR brands at 14 years: 3.13% (95% CI: 2.45-4.00).

From over 12,400 procedures included in a recent NJR summary data report, the Kaplan-Meier cumulative rate of revision is 2.8% (95% CI: 2.3-3.2%) at 10 years (average of all other TKR is 3.4%) and 3.1% (95% CI: 2.5-4.4%) at 13 years (average of all other TKR is 4.2%)[17].

When unadjusted and when adjusted for age, gender, year cohort and indications, the Cox Proportional Hazards model for revision risk are significantly lower for the MRK™ than for all other TKRs (unadjusted: 0.80, 95% CI: 0.69-0.92, p=0.002; adjusted: 0.81, 95% CI: 0.70-0.93, p=0.003)[17].

The MRK™ is significantly less likely to be revised when compared to all other TKRs ($p<0.05$) for instability, malalignment, aseptic loosening of the tibia, and all causes collectively[17]. Inherent stability can be provided without compromising the integrity of the tibial fixation.

Based on independent assessment of the quality of evidence and the clinical data, the Orthopaedic Data Evaluation Panel (ODEP) have awarded the MRK™ an ODEP 10A* rating when used with and without patellar resurfacing[25].



Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

The AOANJRR has sufficient data to present revision rates for some TKR devices up to 17 years post operation. The overall revision rate for all TKRs is 3.6% at 5 years, 5.3% at 10 years and 8.4% at 17 years for indication of osteoarthritis, which accounts for 97.6% of procedures[26].

The MRK™ was not used in Australia until 2006 and the AOANJRR has recorded 459 MRK™ procedures. Just 8 knees have been revised, providing a revision rate of 1.9% (95%CI: 0.9-3.7), which means that the MRK™ is on track to have one of the lowest revision rates of TKRs in Australia.

Uniquely, the AOANJRR now reports separately on the medially stabilised knee category (calling it 'medial pivot' despite the defining characteristic being provision for stability). The medially stabilised category is also compared to posterior stabilised, minimally stabilised (cruciate retaining), fully stabilised and hinged TKR categories. When a version of the Advance Knee (Wright Medical) that has been identified as a poor performing device (based on compromised fixation design), the medially stabilised knee category has the lowest rate of revisions of all knee categories up to 15 years postoperatively[26].

The medially stabilised knee category has the lowest rate of revisions of all knee categories.

Two medially stabilised TKRs (MRK™ and SAIPH® Knee) have the lowest revision rates of all medially stabilised knees: both are provided by MatOrtho®, the originators of the concept.

Summary

When compared to all other knees, the MRK™ medial ball-and-socket knee design consistently achieves superior functional performance and excellent survivorship. Clinical data for the MRK™ shows that patients can expect:

- Inherent full ROM stability[5,6,7,10], like the normal knee[4];
- A good range of motion[5,23,24], with a device that permits high flexion[5,24];
- Significant health gains and improvements in function[10,17,23];
- Excellent survivorship[17,18,19,20] with a device that has an ODEP 10A* rating[25].

2 Key Literature

Knee Arthroplasty with a Medially Conforming Ball-and-socket Tibiofemoral Articulation Provides Better Function.

Hossain F, Patel S, Rhee SJ, Haddad FS. Clin Orthop Relat Res. 2011; 469(1):55-63

Abstract

Background: A knee design with a ball-and-socket articulation of the medial compartment has a femoral rollback profile similar to the native knee. Compared to a conventional, posterior-stabilized knee design, it provides AP stability throughout the entire ROM. However, it is unclear whether this design difference translates to clinical and functional improvement.

Questions/purposes: We asked whether the medially conforming ball-and-socket design differences would be associated with (1) improved ROM; and (2) improved American Knee Society, WOMAC, Oxford Knee, SF-36, and Total Knee Function Questionnaire scores compared to a conventional, fixed-bearing posterior-stabilized TKA.

Patients and Methods: We enrolled 82 patients in a single-center, single-blinded, randomized, controlled trial comparing the medially conforming ball-and-socket design knee prosthesis to a posterior-stabilized total knee prosthesis. Our primary end point was ROM. Our secondary end points were American Knee Society, WOMAC, Oxford Knee, SF-36, and Total Knee Function Questionnaire scores. All patients were followed at 1 and 2 years.

Results: The mean ROM was 100.1 and 114.9 in the posterior-stabilized and medially conforming ball and socket groups, respectively. The physical component scores of SF-36 and Total Knee Function Questionnaire were better in the medially conforming ball-and-socket group. We found no difference in American Knee Society, WOMAC, and Oxford Knee scores.

Conclusions: Both implant designs similarly relieved pain and improved function. The medially conforming ball and socket articulation provided better high-end function as reflected by the Total Knee Function Questionnaire.

Sagittal Stability in Three Different Knee Designs. A Single Centre Independent Review.

Molloy D, Jenabzadeh R, Walter W and Hasted T. Bone Joint J 2013; 95-B SUPP 15 85

Abstract

Sagittal stability of the knee is believed to be of significant importance following a total knee arthroplasty. We examine three different knee designs at a minimum of twenty-four months postoperatively. Sagittal stability was measured at four degrees of flexion; 0°, 30°, 60° and 90° to examine the effect of design on mid-flexion stability. The knee designs included the rotating platform LCS design, the cruciate sparing Triathlon system and the medial rotating knee design, MRK™.

Following ethical approval 50 cases were enrolled into the study, 15 male and 35 female. Eighteen LCS, 18 MRK and 14 Triathlon knee designs were analysed. Sagittal stability was measured using the KT1000 device. Active range of movement was measured using a hand held goniometer and recorded as was Oxford knee score, WOMAC knee score, SF12 and Kujala patellofemoral knee score.

Mean follow-up was 37 months postoperative with a mean age of 73 years. Mean weight was 82.7kgs and height 164cm. There was no significant difference in preoperative demographics between the groups. Mean active postoperative range of motion of the knee was from 2–113° with no significant difference between groups. Sagittal stability was similar in all three groups in full extension; however the MRK™ design showed improved stability in the mid-range of flexion (30–90°). Patient satisfaction also showed a similar trend with MRK™ achieving slightly better patient reported outcomes than that of the LCS and Triathlon systems, although this was not statistically significant.

All three knee designs demonstrated good postoperative range of movement with comparative improvement of patient scores to other reported studies. The MRK™ knee design showed an improved mid-flexion sagittal stability.

Tibiofemoral Kinematic Analysis of Knee Flexion For a Medial Pivot Knee.

Moonot P, Mu S, Railton GT, Field RE, Banks SA. Knee Surg Sports Traumatol Arthrosc. 2009; 17(8):927-34.

Abstract

Knee arthroplasties are designed to accommodate flexion, axial rotation and anteroposterior (AP) translation. Axial rotation during extension varies, with some rotating platform devices allowing unrestricted rotation while some conforming fixed-bearing designs almost none. The purpose of this study was to examine in vivo kinematics of a fixed-bearing medial rotation-type arthroplasty (MRK) during weight-bearing activities. Fifteen knees with a medial pivot TKA design were studied during step and pivot activities using lateral fluoroscopy and model-image registration. Average knee kinematics during the step activity showed little AP translation or rotation from 0 degrees -100 degrees flexion. During the pivot activity, the mean tibial internal rotation in individual knees was 7 degrees (3°-19°). Mean condylar translations for individual knees were 3mm medially and 5mm laterally. The medial pivot prosthesis design provides anteroposterior stability during demanding activities, and exhibits a medial pivot motion pattern when subjected to twisting.

In Vivo Weight-Bearing Kinematics with Medial Rotation Knee Arthroplasty.

Moonot P, Shang M, Railton GT, Field RE, Banks SA. Knee. 2010; 17(1):33-7.

Abstract

The performance of total knee arthroplasty in deeply flexed postures is of increasing concern as the procedure is performed on younger, more physically active and more culturally diverse populations. Several implant design factors, including tibiofemoral conformity, tibial slope and posterior condylar geometry have been shown directly to affect deep flexion performance. The goal of this study was to evaluate the kinematics of a fixed-bearing, asymmetric, medial rotation arthroplasty design in moderate and deep flexion.

Thirteen study participants (15 knees) with a medial rotation knee arthroplasty were observed performing a weight-bearing lunge activity to maximum comfortable flexion and kneeling on a padded bench from 90 degrees to maximum comfortable flexion using lateral fluoroscopy.

Subjects averaged 74 years of age and nine were female. At maximum weight-bearing flexion, the knees exhibited 115 degrees of implant flexion (102 degrees-125 degrees) and 7 degrees (-3 degrees to 12 degrees) of tibial internal rotation. The medial and lateral condylar translated posteriorly by 2 and 5 mm, respectively. At maximum kneeling flexion, the knees exhibited 119 degrees of implant flexion (101 degrees-139 degrees) and 5 degrees (-2 degrees to 14 degrees) of tibial internal rotation. The lateral condyle translated posteriorly by 11 mm.

The medial rotation knee exhibited motion patterns similar to those observed in the normal knee, but less tibial rotation. The medially conforming articulation beneficially controls femoral AP position in deep flexion, in patients who require such motion as part of their lifestyle.

Patellar Tracking: A Comparison of an Implant with a Lateralised Trochlear Groove Compared to a Conventional Posterior Stabilised Design.

Rhee SJ, Hossain F, Konan S, Ashby E and Haddad F. J Bone Joint Surg Br 2012; 94-B no. SUPP IX 90

Abstract

Aim: The aim of our study was to assess lateral tracking of the patella with differing designs of Total Knee Arthroplasty (TKA) and compare to that of the native patella.

Method: A modified caliper was used to measure the width and position of the patella relative to the femur at different degrees of knee flexion. The relationship of the patella midpoint to that of the femur was subsequently assessed. Group 1 consisted of 25 native knees. Group 2 consisted of 25 patients with antero-posterior stabilized knee implant with a spherical medial condyle and a deep lateralised patellar groove, and Group 3 consisted of 25 patients with a conventional cam-and-post design with a midline patellar groove. The mean follow-up was 28 months.

Results: Lateral tracking corresponded well in all groups, but the mean lateral displacement of the patella in group 2 correlated more closely to that of group 1. At 90 degrees of flexion, the patella was displaced a mean of 7mm laterally in both groups 1 and 2, but a mean of 4mm in group 3. Lateral patellar displacement between groups 1 and 3, and that between groups 2 and 3 were statistically significant ($p<0.05$). However, the patellar displacement between groups 1 and 2 was not statistically different.

Conclusion: Our results indicate that lateral patellar displacement in group 2 is similar to that of native knees. The lateralised deep patellar groove of the femoral component in group 2 is more able to mimic that of the native femoral sulcus. This intrinsic implant design accommodates the natural tracking of the patella.

The Patellofemoral Joint In Total Knee Arthroplasty: Is The Design Of The Trochlea The Critical Factor?

Kulkarni SK, Freeman MA, Poal-Manresa JC, Asencio JI, Rodriguez JJ. J Arthroplasty. 2000; 15(4):424-9.

Abstract

The outcome at 10 years is reported of a prospective study of 2 cohorts of total knee arthroplasties treated with (center A) or without (center B) patellar replacement. The same tibiofemoral components were used in all knees. The cohorts were demographically similar. A total of 124 patellae were treated by replacement, and 143 were treated without replacement. The clinical outcome and the patellofemoral revision rates were the same in the 2 cohorts: 1 patient required analgesia for anterior knee pain after replacement, and 1 without replacement required patellar replacement for pain. In the replaced group, patellofemoral survival on a best-case scenario was 100% at 10 years; on a worst-case scenario, 96%. One of the unreplaced patellae had been resurfaced for pain by 10 years. In view of the satisfactory and similar outcomes with and without replacement, we suggest that an appropriate design for the prosthetic trochlea, rather than the replacement or otherwise of the patella, is the main determinant of patellofemoral outcome in total knee arthroplasty. Patella replacement may be optional. Desirable trochlea design features are described.

The Early Radiological Follow-up of a Medial Rotational Design of Total Knee Arthroplasty.

Amin A, Al-Taiar A, Sanghrajka AP, Kang N, Scott G. Knee 2008; 15(3):222-6

Abstract

The objective of this study was to investigate the hypothesis that the increased constraint of a medial rotational knee promotes earlier loosening of the prosthesis. All patients with a Freeman-Samuelson 1000 knee arthroplasty (medial pivot design), (group 1), or a Freeman-Samuelson Modular knee arthroplasty, (group 2), with a minimum follow-up of 2 years (mean follow-up 4 years) were identified from our unit's arthroplasty database, and matched as closely as possible for age, length of follow-up and pre-operative diagnosis. Standardised anteroposterior and lateral radiographs were analysed for component migration and radiolucent lines as recommended by the Knee Society.

There were 48 knees in each group. There were no failures in group 2. There was one failure requiring revision of the tibial component in group 1. There was no significant difference in overall radiolucent line scores between the two groups (p=0.66, at 5 years). Progressive radiolucent lines were detected in similar numbers of patients in both groups (FS1000 8/48, FSM 7/48, p=0.84). Our early radiological survey suggests that the increased constraint of the medial pivot knee prosthesis does not result in an increased incidence of radiographic loosening.

The Medial Rotation Total Knee Replacement: A Clinical and Radiological Review at a Mean Follow-Up of Six Years.

Mannan K and Scott G. J Bone Joint Surg Br. 2009; 91(6):750-6.

Abstract

We describe the survivorship of the Medial Rotation total knee replacement (TKR) at ten years in 228 cemented primary replacements implanted between October 1994 and October 2006, with their clinical and radiological outcome. This implant has a highly congruent medial compartment, with the femoral component represented by a portion of a sphere which articulates with a matched concave surface on the medial side of the tibial insert.

There were 78 men (17 bilateral TKRs) and 111 women (22 bilateral TKRs) with a mean age of 67.9 years (28 to 90). All the patients were assessed clinically and radiologically using the American Knee Society scoring systems. The mean follow-up was for six years (1 to 13) with only two patients lost to follow-up and 34 dying during the period of study, one of whom had required revision for infection.

There were 11 revisions performed in total, three for aseptic loosening, six for infection, one for a periprosthetic fracture and one for a painful but well-fixed replacement performed at another centre. With revision for any cause as the endpoint, the survival at ten years was 94.5% (95% CI 85.1 to 100), and with aseptic loosening as the endpoint 98.4% (95% CI 93 to 100). The mean American Knee Society score improved from 47.6 (0 to 88) to 72.2 (26 to 100) and for function from 45.1 (0 to 100) to 93.1 (45 to 100). Radiological review failed to detect migration in any of the surviving knees.

The clinical and radiological results of the Medial Rotation TKR are satisfactory at ten years. The increased congruence of the medial compartment has not led to an increased rate of loosening and continued use can be supported.

Knee Arthroplasty with a Medial Rotating Total Knee Replacement. Midterm Clinical Findings: A District General Experience of 38 Cases.

Jonas SC, Argyropoulos M, Al-Hadithy N, Korycki M, Lotz B, Deo SD, Satish V. The Knee. 2015; 22(2): 122-125.

Abstract

Background: The Medial Rotating Knee replacement (MRK™) was first used in 1994, reporting high rates of satisfaction. It is designed to replicate natural knee kinematics and improve stability and function. There are limited studies on the mid-term clinical outcomes, in particular in a district general hospital (DGH) environment. This is the first study that we are aware of that evaluates the learning curve of the implementation of this knee system in this environment.

Patients/method: Between 2007 and 2009 we performed 38 consecutive MRK™ replacements (MatOrtho Ltd., UK) in 36 patients. The mean follow-up was four years. Patients were evaluated clinically, using OKS and patient questionnaire and radiographically (good/acceptable/poor) to assess outcome.

Results: Mean age was 73.0 years. Mean pre-operative OKS was 17.7 (range 8–29), which rose to 38.1 (range 23–48) at latest follow up (p-0.005). Overall 71% of the patients were either satisfied (29%) or very satisfied (42%). 81% felt an improvement of the ability to go up or down stairs and 92% felt stable. All poor radiographic and the majority of acceptable outcomes were experienced in the first 50% of cases.

Conclusion: The MRK™ can be successfully implanted in a DGH environment. It improves pain and function comparably to standard TKRs, however, subjective improvement may be higher. Radiographic evaluation shows an acceptable learning curve.

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CE 0088 FDA K020214 TGA Health Safety Regulation ARTG209657 ARTG209896 ARTG210017 ARTG210093 ARTG210094 ARTG210345 ARTG210346

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