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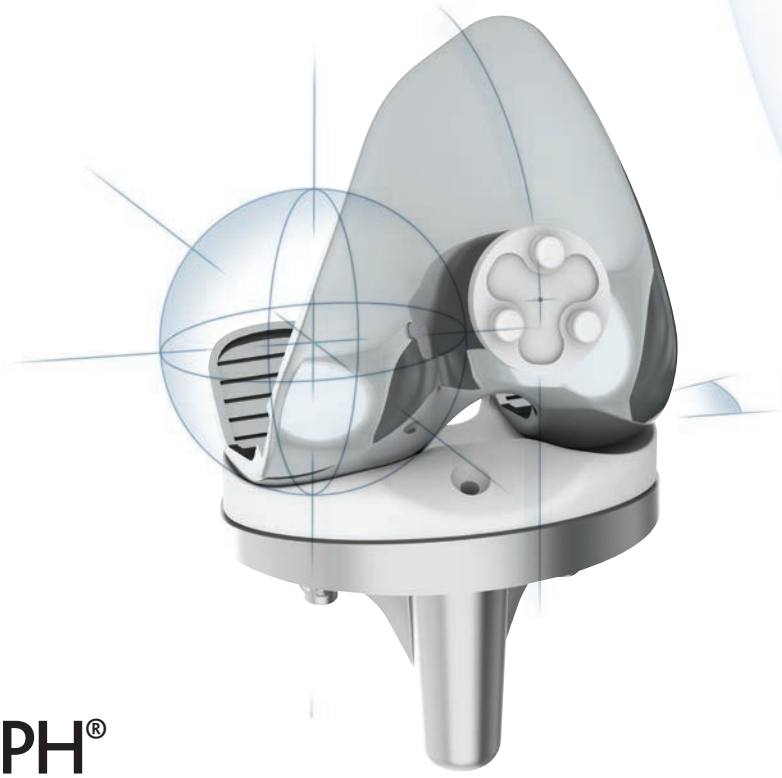

SAIPH®
Knee System

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; there is limited freedom for the lateral side 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 SAIPH® Knee is the 2nd generation medial ball and socket knee, evolved from the Medial Rotation Knee™ (MRK™) that has been in clinical use for over 20 years (first implanted in 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 designs. The design principle was proven with the Medial Rotation Knee™ and is now demonstrated with the SAIPH® Knee.

Clinical heritage

Overall, the MRK™ has been shown to provide greater inherent stability than comparator devices [1,2,3]. Patients notice the difference, and express that they prefer the medial ball and socket 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 [4,5]. With its lateralised trochlea – where standard TKR devices have a central distal trochlea [6], the MRK™ has been shown to exhibit a more normal patellar function [7].

By accommodating natural function in all three compartments, the MRK™ design provides a better mean improvement in range of motion (ROM) when compared to a standard PS knee design [8] and a mean ROM equal that of a 'high-flex' knee [9].

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 [5,8,10] and improved rates of success and satisfaction [3,5,10].

The MRK™ also provides better high-end function [8]. For categories of daily living, sport and exercise, and movement and lifestyle included in the total knee function questionnaire (TKFQ), patients scored significantly better 1 and 2 years postoperatively when they had received an MRK™ compared to patients who received a standard PS knee, where patients who received the comparator device were better preoperatively (although not significantly) [8].

Survivorship for the MRK™ is in line with the best TKR devices available, as reported for the first MRK™ cohort from 1994 onwards [11,12], the NJR annual report [13] and when compared directly to all other TKR devices recorded by the NJR [10]. The MRK™ is awarded an ODEP 10A rating (www.odep.org.uk) [14].

Clinical use of the SAIPH® Knee

The SAIPH® Knee has been in use since July 2009. Usage is growing, with approximately 1,000 procedures in the UK, Europe and Australia to date.

A global clinical data collection program on the SAIPH® Knee is ongoing, with excellent results to date.

Studies include:

- Multicentre user group PROMs studies (UK, Australia and Europe)
- NJR survivorship and PROMs (over 5 years)
- Australian Joint Registry data (over 5 years)
- Fluoroscopic evaluation of knee motion [15]
- Randomised controlled trial with high-level functional outcomes
- RSA study

Knee function

A fluoroscopic evaluation for the SAIPH® Knee included a consecutive series of 14 knees (mean 69 years old, range 51-83) with no exclusions. Knees were assessed at minimum 24 months postoperatively. The study found no anterior translation of the femur in flexion for any passive or weight-bearing activity, confirming the design's inherent full ROM stability [15]. Lateral translation (rotation) was permitted when required [15], like the normal knee [16].

The passive postoperative ROM was mean 127° (range 100°-155°) and the active weight-bearing ROM was mean 121° (range 97°-151°) [15], which are higher than values reported elsewhere for PS and CR designs and demonstrates that the SAIPH® knee permits the maximum flexion that would be expected in a normal knee (152°-154° flexion) [17].

Multicentre study data

A prospective, consecutive cohort of 204 knees was recruited between September 2011 and February 2014 [18]. The mean age of patients at the time of operation was 66.8 years (range 47 to 85) and 53.9% were female [18].

At mean 2 years after the operation, 3 knees had been recorded as revised, including one for infection, one for the addition of a patella component and one where the SAIPH® Knee had in fact been used as the revision prosthesis [18]. There have been no further reports of adverse events or complications related to the implant [18].

At the 1-year follow-up, the mean Oxford Knee Score (OKS) had increased to 42.8 (range 15 to 48) from a preoperative mean of 23.7 (range 6 to 42), where 48 is the best possible score [18]. Health gain, defined as average change in score from before the operation to 1 year after operation, was 39.0, 44.1, 37.6, 42.8 and 53.5 for KOOS score subsets of symptoms, pain, activities of daily living, sports and quality of life [18]. Kujala and EQ-VAS improved by 38.4 and 19.8, respectively [18]. From 51 patients, preoperative ROM was mean 106.8° (range 60° to 135°) increasing to mean 123.9° (range 60° to 145°) 1 year after the operation [18]. Data collection for this cohort is ongoing.

Survivorship

Published registry data shows a total of 745 SAIPH® procedures with maximum implant time of over 5 years [19,20]. A total of 1.07% of all knees have been revised [19,20].

Summary

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

- Inherent full ROM stability [15], like the normal knee [16];
- A good range of motion [15,18], with a device that permits over 150° flexion [15];
- Significant health gains and improvements in function [18];
- Excellent survivorship [19,20], with a device that has an ODEP 3A rating (www.odep.org.uk) [14]

2 Key **SAIPH**® 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 analyze knee kinematics of the SAIPH™ total knee arthroplasty (TKA) by videofluoroscopy during four different weightbearing activities.

Methods: Fourteen consecutive patients operated on by a single surgeon, with a minimum follow-up of 24months 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, lungeing 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, lungeing 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.

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