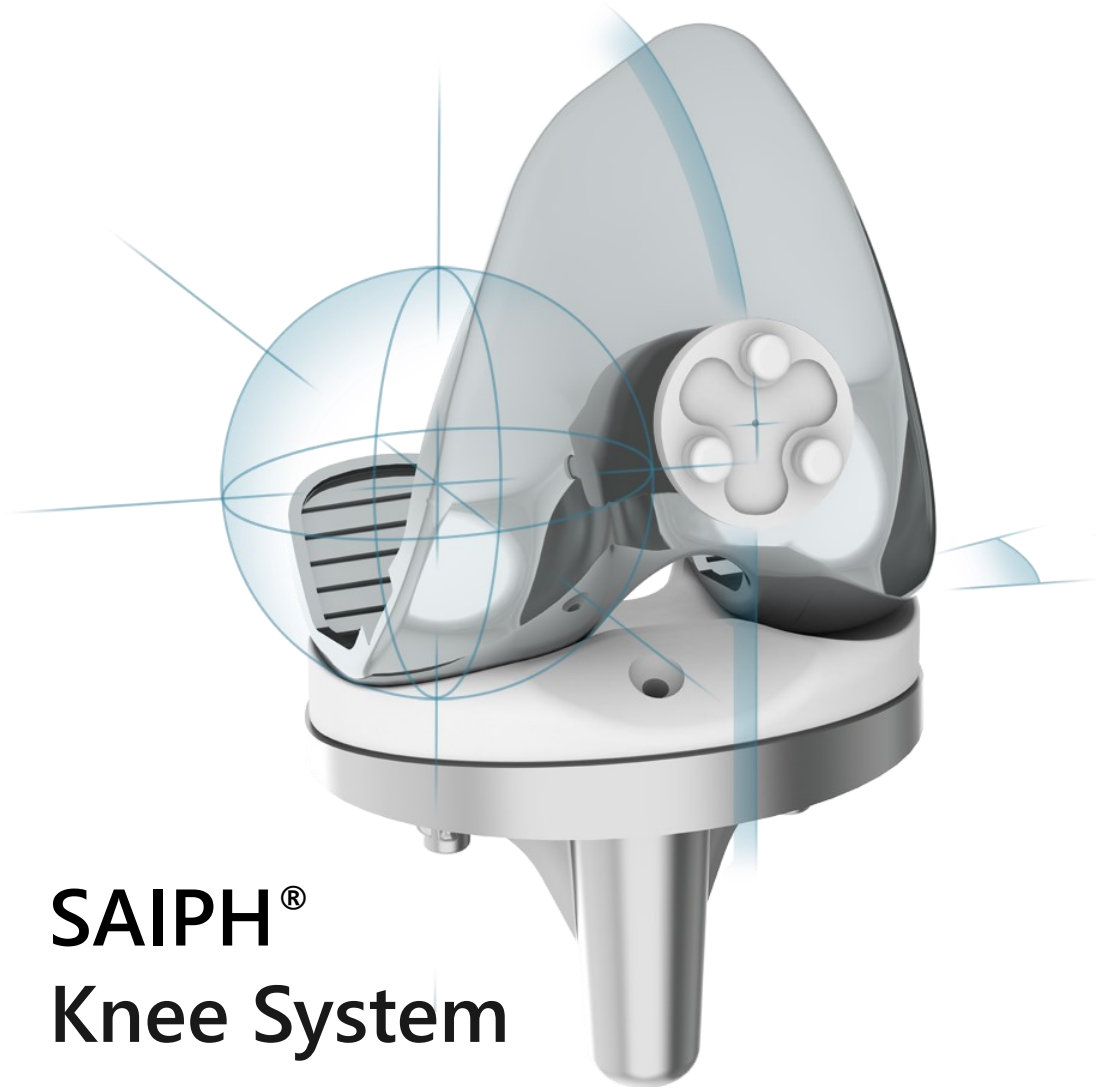
MatOrtho®



SAIPH®
Knee System

Clinical Data Summary

Physiological Stability and Mobility for the Active Knee *Without Compromise*

Forever Active

Contents

Patents

EP1329205 / US6869448

GB2306653 / US5800438

Manufactured by

Mat**Ortho** Limited | 13 Mole Business Park | Randalls Road | Leatherhead | Surrey | KT22 7BA | United Kingdom

T: +44 (0)1372 224 200 | info@Mat**Ortho**.com

For more information visit: www.Mat**Ortho**.com

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, while on the lateral side there is limited freedom for anterior-posterior translation (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: Success of the MRK™

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 better restoration of range of motion (ROM) when compared to a standard PS knee design [8] with 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 over 4,000 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. This demonstrates that the SAIPH® knee permits the maximum flexion that would be expected in a normal knee (152°-154° flexion) [17].

Multicentre study data: Australia

5-year postoperative data for a cohort of 100 SAIPH® knees (92 patients) performed in two centres has been reported. This study included comprehensive evaluation of knees with 7 patient reported measures (PROMs), 4 physical examinations (RoM, stability and efficiency) and 3 radiographic assessments (alignment and loosening) in line with demographics (typical population).

Significant improvements

The data for this cohort showed:

- Significant improvement postoperatively ($p<0.0001$) for all PROMs measures
- Higher OKS and KOOS than previous TKR cohorts[21-25]
- 98% responding Good or Excellent against the Kalairajah Scale[26]
- Better Forgotten Joint Score (FJS) than previous TKR cohorts and equal to UKA[27]
- No AP instability
- Good mechanical alignment
- No progressive lucent lines and no non-progressive lucent lines >2mm
- No osteolysis

Very high rate of satisfaction

Unlike recent reports on patient satisfaction after total knee replacement[28-30] the SAIPH® knee cohort did not display a 20% dissatisfaction rate (Figure 1).

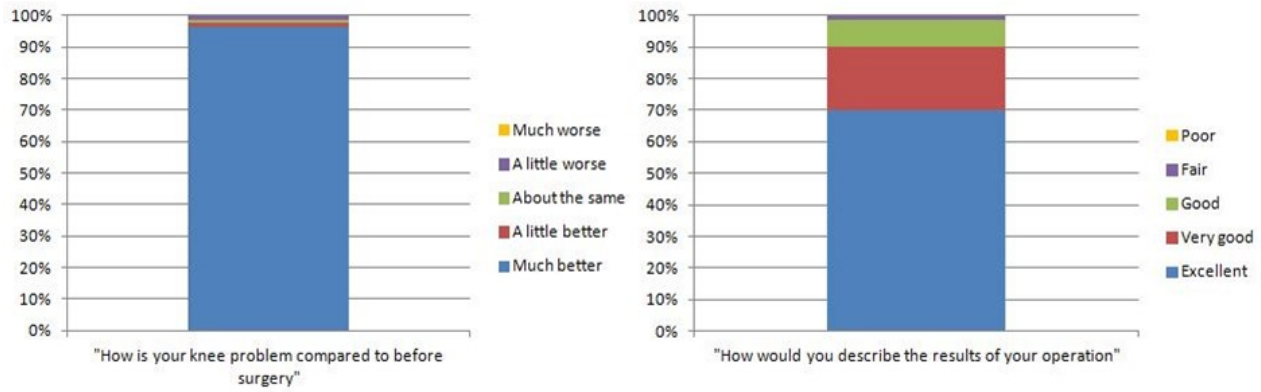


Figure 1 Results of self-rated outcomes

The study group report that the SAIPH® knee provides restoration of near normal knee movement, significant improvements in outcome measures, has a low rate of revisions and an extremely high rate of patient satisfaction.

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 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.

3 References

1. Moonot P, Mu S, Railton GT, Field RE, Banks SA. Tibiofemoral kinematic analysis of knee flexion for a medial pivot knee. Knee Surg Sports Traumatol Arthrosc. 2009; 17(8):927-34.
2. Moonot P, Shang M, Railton GT, Field RE, Banks SA. In vivo weight-bearing kinematics with medial rotation knee arthroplasty. Knee. 2010; 17(1):33-7.
3. Molloy D, Jenabzadeh R, Walter W and Hasted T. Sagittal Stability in Three Different Knee Designs. A Single Centre Independent Review. Bone Joint J 2013; 95-B SUPP 15 85 (presented ISTA 2012, The Great Debate 2013)
4. Pritchett JW. Patients prefer a bicruciate-retaining or the medial pivot total knee prosthesis. J Arthroplasty. 2011; 26(2): 224-8.
5. Jonas SC, Argyropoulos M, Al-Hadithy N, Korycki M, Lotz B, Deo SD, Satish V. Knee arthroplasty with a medial rotating total knee replacement. Midterm clinical findings: A district general experience of 38 cases. The Knee. 2014; http://dx.doi.org/10.1016/j.knee.2014.11.008.
6. Schindler OS. The controversy of patellar resurfacing in total knee arthroplasty: Ibisne in medio tutissimus? Knee Surg Sports Traumatol Arthrosc. 2012; 20:1227-1244 (ref. Figure 8, p1233).
7. Rhee SJ, Hossain F, Konan S, Ashby E and Haddad F. Patellar Tracking: A Comparison of an Implant with a Lateralised Trochlear Groove Compared to a Conventional Posterior Stabilised Design. J Bone Joint Surg Br 2012; 94-B no. SUPP IX 90
8. Hossain F, Patel S, Rhee SJ, Haddad FS. Knee arthroplasty with a medially conforming ball-and-socket tibiofemoral articulation provides better function. Clin Orthop Relat Res. 2011; 469(1):55-63
9. Kooijman CM and van Stralen GMJ. Having the confidence to change for a more stable future. June 2013. Presented at The Great Debate, London.
10. National Joint Registry and Northgate Information Solutions Ltd. Implant Summary Report, November 2017. Ref: PMS.Report.KP_Femoral_MRK. 18/11/2017.20:55 (held by MatOrtho Ltd.)
11. Amin A, Al-Taiar A, Sanghrajka AP, Kang N, Scott G. The early radiological follow-up of a medial rotational design of total knee arthroplasty. The Knee. 2008; 15(3):222-6
12. Mannan K and Scott G. The Medial Rotation total knee replacement: a clinical and radiological review at a mean follow-up of six years. J Bone Joint Surg Br. 2009; 91(6):750-6
13. National Joint registry for England, Wales, Northern Ireland and Isle Of Man. 14th Annual Report, 2017 Http://www.njrreports.org.uk/
14. Orthopaedic Data Evaluation Panel (ODEP). Latest ODEP ratings can be found at www.odep.org.uk
15. Shimmin A, Martinez Martos S, Owens J, Iorgulescu AD, Banks S. Fluoroscopic motion study confirming the stability of a medial pivot design total knee arthroplasty. The Knee. 2015; 22(6): 522-526.
16. Johal P, Williams A, Wragg P, Hunt D, Gedroyc W. Tibio-femoral movement in the living knee. A study of weight bearing and non-weight bearing knee kinematics using 'interventional' MRI. J Biomech. 2005; 38(2):269-76.
17. Dennis DA, Komistek RD, Stiehl JB, Walker SA and Dennis KN. Range of Motion After Total Knee Arthroplasty: The Effect of Implant Design and Weight-Bearing Conditions. J. Arthroplasty. 1998; 13(7): 748-752
18. Data held on file at MatOrtho Ltd. 2018
19. National Joint Registry and Northgate Information Solutions Ltd. Implant Summary Report November 2017. Ref: Pms.Report.KP_Femoral_Saiph.18/11/2017.21:23 (held by MatOrtho Ltd.)
20. Australian Orthopaedic Association National Joint Registry, Hip and Knee Arthroplasty, Annual Report 2017.
21. Ali et al. Similar patient-reported outcomes and performance after total knee arthroplasty with or without patellar resurfacing. Acta Orthop 87(3): 274, 2016
22. Williams et al. Long-term trends in the Oxford knee score following total knee replacement. Bone Joint J 95-B(1): 45, 2013
23. Breeman et al. Five-year results of a randomised controlled trial comparing mobile and fixed bearings in total knee replacement. Bone Joint J 95-B(4): 486, 2013
24. Dunbar et al. Results of a survey of 3600 patients from The Swedish Knee Arthroplasty Registry. J Bone Joint Surg Br 83(3): 339, 2001
25. New Zealand Joint Registry – 17 Year Report. Jan 1999 to Dec 2015. In: Association NZO, ed. 2016
26. Kalairajah et al. Health outcome measures in the evaluation of total hip arthroplasties--a comparison between the Harris hip score and the Oxford hip score. J Arthroplasty 20(8): 1037, 2005
27. Thienpont et al. Joint awareness in different types of knee arthroplasty evaluated with the Forgotten Joint score. J Arth 29(1):48-51, 2014
28. Baker PN, van der Meulen JH, Lewsey J, Gregg PJ. The role of pain and function in determining patient satisfaction after total knee replacement. Data from the National Joint Registry for England and Wales. J Bone Joint Surg Br 89(7): 893, 2007
29. Noble et al. Patient expectations affect satisfaction with total knee arthroplasty. CORR 452: 35–43, 2006
30. Bourne et al. Patient Satisfaction after Total Knee Arthroplasty: Who is Satisfied and Who is Not? CORR 468:57–63, 2010

MatOrtho®

Forever **Active**

CE 0088

FDA K140222

TGA Health Safety Regulation ARTG209556 ARTG209559 ARTG209557 ARTG209578 ARTG209558

MatOrtho Limited | 13 Mole Business Park | Randalls Road | Leatherhead | Surrey | KT22 7BA | United Kingdom | T: +44 (0)1372 224 200 | info@MatOrtho.com |
For more information visit: www.MatOrtho.com

Part No. ML-300-168 L | issue 3