

# A KHEE DESIGNED FOR THE HEAD & HEART



## CREATING NATURAL FREEDOM OF MOVEMENT

CAN YOUR TOTAL KNEE IMPLANT CHOICE GIVE PATIENTS MORE OF THEIR LIFE BACK?

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Z O U

#### Who this eBook is for...

#### **Orthopaedic surgeon leaders**

As an orthopaedic leader, you're driven to provide the best possible care and outcomes for your total knee patients. Throughout this eBook, you'll read about current misconceptions relating to today's total knee arthroplasty (TKA) implants. You are likely to question whether alternative implant types support you in giving your patients a life more like the one they'd like to live.

#### Registrars

As you enter your final years of training, you'll seek ways to give your current and future patients the best outcomes. In this eBook, you'll see how to challenge current thinking with new approaches that could help you to better help your patients.

#### GPs

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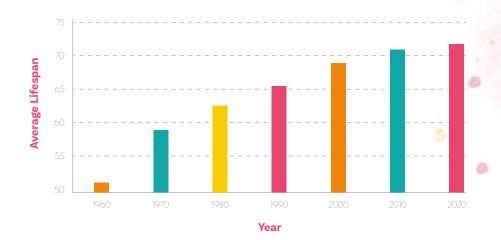
As the hub of your local community, you want to understand what's best for your patients so you can put them on the right path for further medical assistance. Throughout this eBook, you'll read about the latest thinking in total knee replacement to support you in making the best clinical recommendations for your patients.

#### In a world where pain relief is so ordinary, patients expect that there will always be relief available to target their current pains.

# Your patient expectations are on the rise.

Orthopaedic surgery patient demographics are changing, and patient expectations are on the rise.

Patients are living longer, the age they require a TKA is reducing, and they now expect more from their implants than ever<sup>1</sup>.



#### Figure 1:

Graph illustrating an average person's life expectancy based on the year from 1960 to 2020. Graph adapted from the World Bank website, which bases its data on the UN and national census reports<sup>2</sup>.

These changing patient demands are twofold:

- **1.** In a world where pain relief is so ordinary, patients expect relief always to be available to target their current pains. They believe there should be a way to reduce or eradicate knee pain.
- **2.** Once the pain is dealt with, they seek ability. Patients want to return to their normal and active lifestyle like they were used to pre-osteoarthritis.

Do you believe the current generation of knee replacement designs meet your patients' expectations?

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# MISCONCEPTION

#### **Current TKA outcomes meet patient expectations**

Most studies agree that the dissatisfaction rates for TKA are around 20%<sup>3</sup>.

This is in contrast to hip arthroplasty, which has a dissatisfaction rate of 7%<sup>4</sup>, and partial knee arthroplasty, which has a dissatisfaction rate of 4%<sup>5</sup>.

More recently, DeFrance has suggested that dissatisfaction may, on average,

be a little better at 10%<sup>6</sup>. Nevertheless, this equates to 100,000 patients annually in the US alone. This study highlighted the issues of poor patient coping skills, such as pain catastrophising and anxiety/depression as common causes of dissatisfaction.

Some might perceive that number as a substantial number of TKA patients with unmet expectations.

# MISCONCEPTION

#### All implants used are selected to deliver optimal patient outcomes

When selecting your patient's implant, you want to offer them the best option to alleviate pain, provide a better quality of life and enable them to return to activities they love.

Many patients and healthcare professionals believe that healthcare services always select implants to deliver the best patient outcomes.

However, with healthcare costs in key focus, public and private healthcare systems often place a short-term emphasis on saving on the cost of implants via bundled deals with large corporations rather than the performance of the implant, which should be the priority.

Clinicians must consider the clinical benefits when selecting implants. However, many implants being used do not have leading performance results.

Patients believe that healthcare services always select implants to deliver the best outcomes.

Currently, the invention and innovation of implant devices face more challenges than ever with the change in medical device regulations, such as MDD to MDR in Europe.

With new product development coming at an increased cost and market-approval timelines challenging to predict, a commercial shift to surgical alignment tools might represent a better commercial strategy for some companies rather than enhancing patient outcomes through implant development.

# MISCONCEPTION

#### We don't need new knee replacements; we just need to align our existing ones better

With fewer new TKA systems entering the market, many orthopaedic companies appear to have switched focus from implant innovation to perfecting the placement of their existing implants. Both alignment devices and robotic-assisted surgery have entered the market with the aim of better implant alignment in the hope of providing patients with better results in the long term.

MatOrtho<sup>®</sup> is currently the last remaining independent UK orthopaedic company.

Robots increase the cost of each operation and the timescales associated with the procedure. In addition, change management in the theatre environment to incorporate new surgical instrument devices can be challenging from a logistical, sterility and servicing perspective. There is little evidence to suggest better TKA patient outcomes associated with robotic-assisted surgery.

MatOrtho® is currently the last remaining independent UK orthopaedic company. The SAIPH® knee achieves the highest patient satisfaction rates on the UK National Joint Registry (NJR). It hasn't needed unconventional alignment tools to achieve this.

# 

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#### What problems are associated with the current TKA implants?

#### **High Revision Rates**

According to a recent study by the New Zealand Joint Registry, the current lifetime risk of revision of TKA for young males between 46 and 50 years is 25.2%<sup>7</sup>.

Some studies have reported that the revision of TKA is 2.8% at 5 years<sup>8</sup> and about 5% at 10 years<sup>9</sup>.

According to a recent study from Patel, by 2030, the UK will be performing an estimated 186,320 primary knee surgeries and 24,498 revision knee surgeries per annum. Over the years 1/1/2019 to 31/12/2021, there were 237,924 primary knee procedures in the UK. There have been 43,838 revisions linked to primary procedures in the NJR between 2003 and 2021<sup>10</sup>.

An increasing number of primary procedures, coupled with the current risk of revision, poses a significant burden ahead in all countries.

#### Reduced stability

After TKA, many patients expect to resume an active life. With that, they expect their 'new knee' to have the same range of motion (ROM) and stability as before.

However, postoperative instability is the third most common mode of TKA failure, reported as the cause of a revision procedure in 7.3%- 28.9% of the cases. <sup>11-15</sup>

#### Patellofemoral articulation not tracking as well

Most standard TKA devices have a centrally located trochlea, which does not replicate the natural tracking of the patella<sup>16</sup>. Tracking the patella is important in increasing the efficacy of the quadricep muscles, which helps facilitate knee extension<sup>17</sup>.

This maltracking of the patella can lead to increased pain<sup>18.19</sup> component wear, instability, and poor clinical outcomes<sup>20</sup>.

#### Paradoxical motion caused by the implant

Several studies have shown that, during flexion, a posterior sliding of the lateral femoral condyle on the tibial plateau can be observed while the medial compartment remains stable<sup>21-23</sup>. The axial rotation occurs about the medial compartment.

Most conventional TKAs were designed before we genuinely understood knee kinematics. As a result, most TKA designs alter normal knee kinematics<sup>24</sup>. They cause an abnormal anterior sliding of the femoral component on the tibial plateau, making the knee feel less natural for the patients. This phenomenon is shown to be common in traditional TKA designs and is known in the literature as "paradoxical motion" <sup>25,26</sup>. This phenomenon is evident in cruciate retaining (CR) and posterior stabilised (PS) implant designs<sup>25,26</sup>.

During knee flexion, the implant allows the weight of the body to push the femur forward on the tibia until it is stopped by the posterior cruciate ligament (PCL) or mechanical post. This is important as this motion causes a "mid-flexion instability"<sup>27</sup>, which is instability during the transition from extension to 90° of flexion<sup>27</sup>.

What other improvements could be made to TKAs to increase the patient's quality of life?

> Better replication of the normal pattern of movement of the knee

Better stability of the knee post-implant

Better replication of the flexion of the knee Increasing the longevity of the implant

#### What are the causes of the current problems associated with Total Knee Arthroplasty implants?

How do we increase patient satisfaction and solve current implant problems while improving the TKA procedure to improve our patient's quality of life?

We need to resolve the root causes of each problem.

#### **Satisfaction rates**

The current satisfaction rates in patients with TKA are lower than in other arthroplasty procedures, such as hip arthroplasty and partial knee arthroplasty.

A study by Halawi et al. has shown that patients' dissatisfaction has been narrowed down to the following<sup>28</sup>:

# Persisting pain

Surgical adverse events and reoperations

26%

Unmet expectations **4%** 

Staff or quality of care issues

Functional limitation

Another study by Bourne et al. found the link between patient dissatisfaction and functional ability to be overwhelming<sup>30</sup>. The study found that patient satisfaction was lower than 80% in several everyday activities, which include descending and ascending stairs and even just getting in and out of the car<sup>30</sup>.

A study by Noble reviewed TKA patients with their age-matched non-operated

equivalents. Significant discrepancies between the two groups and their abilities in the study support the results of Bob Bourne<sup>31</sup>.

Our aim should be to reduce these low dissatisfaction rates to similar levels as hip arthroplasty and partial knee replacements if we are to improve our patients' quality of life.

This could be achieved by:



Replicating the knee joint closely so patients feel like they have a normal knee.



Increasing the implant's Range of Motion (ROM) while maintaining high levels of stability.



Increasing the quality of materials of the implant to prevent loosening.

#### **High revision rates**

Over 22% of patients having a knee replacement aged between 46 and 50 can expect to have a revision in their lifetime, according to the New Zealand Joint Registry<sup>7</sup>.

In a study by Anne Postler, the most frequent reasons behind revision surgery are as follows<sup>9</sup>:

Periprosthetic fracture 13.7% Periprosthetic joint infection **36.1%** 

Aseptic loosening **21.9%** 

The results of this study were further supported by a more recent article by Matthew L. Brown, which aimed to determine the reason for TKA revision among early and late failures and assess if the aetiology has changed over 10 years<sup>32</sup>.

The results showed that "The most common reason for revision TKA was infection (29.3%), followed by aseptic loosening (19.7%), which together accounted for half of all revisions"<sup>32</sup>.

This study listed other reasons behind TKA revision surgeries, such as instability, osteolysis, and arthrofibrosis<sup>32</sup>.

This high rate of revisions needs to be solved, with the number of primary TKA procedures likely to increase. In 2019, 90,309 primary knee surgeries occurred in the UK<sup>33</sup>. Patel estimates 186,320 primary knee surgeries will occur annually by 2030<sup>34</sup>. This would mean an overburdened health service would also need to fund and provide almost 25,000 knee reoperations per year.

Coupled with the effects of revisions on the patient's physical and mental health, there is also the consideration that revision surgery associated with a TKA implant can take longer than the initial surgery - around 2 to 3 hours<sup>35</sup>. This causes issues with the surgical throughput of patients<sup>33</sup>.

To prevent further cases of aseptic loosening and periprosthetic fracture, we could improve the quality of materials used to manufacture implants.

We could also offer an alternative, more straightforward operative procedure to reduce stress and potential errors during surgery.

Revisions affect patients, overburdened healthcare workers and overstretched budgets.

#### Reduced stability compared to a normal knee

Having a stable knee throughout flexion is paramount.

In the natural knee, stability is provided by the articular shapes and constraining soft tissues, which include the menisci, the anterior and posterior cruciate ligaments (ACL and PCL) and the medial and lateral collateral ligaments (MCL and LCL).

During surgery, the bone surfaces, menisci and cruciate ligaments are removed. Traditional TKA designs do not fully substitute for their functions. Although some TKA procedures try to retain the PCL, this isn't always possible<sup>36</sup>.

Unless fully addressed by the implant design, removing these essential tissues will result in knee instability. Knee instability could also be for several other reasons, including loosening of the component or patella tracking.

If we could solve this problem, we could create a knee implant that the patient is satisfied with and improve the patient's quality of life.

To solve it, we have to find an alternative to current TKA procedures, with one that replaces the functionality of all the structures in the natural knee.

If we could solve this problem, we could create a knee implant that the patient is satisfied with and improve the patient's quality of life.

#### A normal patellofemoral articulation is not replicated

Whether or not the patella is resurfaced, the importance of replacing the patellofemoral articulation must be balanced. This means that in a high-functioning TKA implant, the quality and effectiveness of the patellofemoral joint (PFJ) are essential.

In a normal knee, the trochlea is lateral to the midline, and the patella is asymmetric<sup>37,38</sup>. This allows the patella to track laterally during flexion<sup>38,39</sup>. This also provides an important stabilising function to the lateral tibiofemoral articulation<sup>37,38</sup>.

In most standard TKA devices, the implanted trochlea is centralised<sup>16</sup>. This is a fallout from prioritising the tibiofemoral bearing, however this design results in the patella being forced to the midline in flexion<sup>16,40</sup>.

By having our implants replicate the PFJ more closely to a normal healthy knee, we could further increase the knee's stability during flexion, improving our patients' quality of life.

#### Why do we need to solve TKA implant problems as soon as possible?

#### To reduce the impact on our patients

There are currently more dissatisfied knee replacement patients than dissatisfied hip replacement patients<sup>41-43</sup>.

Studies tell us this is because:

- The patient's knee replacement functionality is limited after the operation<sup>30</sup>
- Patients suffer reduced stability of knee replacement compared to their native knee<sup>44</sup>
- This can impose significant postoperative limitations

All of which results in the need to lower patient expectations<sup>44</sup>

When looking at why certain patients are dissatisfied with the procedure, you may think that patients have unrealistic expectations for the outcome.

However, the truth is they just want to be able to return to their normal day-to-day lifestyle.

We understand that you want to meet your patient's expectations.

And we believe it is our job to help you meet them.

#### To reduce the impact on orthopaedic surgeons

A surgeon's primary goal is always to put the patient's well-being and needs first.

Current TKA procedures do get the job done but can be improved. As such, we should challenge the status quo on knee replacement procedures as we can always do better to improve our patient's quality of life. Dissatisfied patients may take up more of your time than happy patients, and an underperforming knee is unlikely to be fully resolved.

#### **Do you sometimes:**

#### 1

Question what the future of TKA will look like?

#### 2

Wonder if you are genuinely offering the best possible care and outcomes? Wonder if you are happy to continue doing what you've been doing? Employing dated technology which doesn't currently appear to provide the function your patients expect?

3

#### 4

Question if you provide long-term satisfaction to your patients, resulting in happier patients?

#### Many surgeons are dissatisfied with implant performance

With a dissatisfaction rate of up to 20%, it would not be surprising to know that many surgeons are unsatisfied. They may not be content with the status quo on TKA procedures and need help finding innovative ways to perform TKA due to companies not prioritising implant innovation.

A study has shown that the demand for TKA is increasing, with a predicted 673% increase in cases in the USA from 2005, leading to 3.48 million cases by 2030<sup>45</sup>.

Let us imagine we don't address the problems stated above. Would we expect more patients to have issues with their TKA? Would this cause future patients to be hesitant when considering surgery?

Might this cause unnecessary delay leading to disease worsening, poorer quality of life, and negative impact on health, general well-being, and lifespan?<sup>46,47</sup>

What is a possible way forward?

2005 2023 673% increase in TKA cases



### A SOLUTION: THE MEDIALLY STABILISED CONCEPT

One concept that could solve standard TKA problems is the medially stabilised design. In several recent case studies<sup>48</sup>, this implant design has shown promising results in resolving the problems caused by standard TKA.

#### How does it work?

Medially stabilised total knee replacements are designed to replicate the normal physiological kinematics of the knee.

By stabilising the medial compartment of the knee, paradoxical motion is eliminated<sup>49</sup>.

Medially stabilised TKAs can replicate the knee's function. They are designed with:

- A ball-in-socket compartment that is highly congruent, providing increased overall stability through the range of motion
- A lateral compartment that is characterised by less conformity to provide a natural freedom of movement.

Both these compartments work together to reproduce the physiological biomechanics of a normal knee.

medially stabilised **implants** can **replicate** the knee's **function** 

#### How can medially stabilised implants solve the problems caused by other TKA options?

#### **Higher satisfaction rate**

In a 274-patient multicentre study, Bare et al. reported a high degree of satisfaction. This study reported a satisfaction rate of 96.4% among medially stabilised patients<sup>50</sup>.

This study's results are further supported by a recent article by Sahil Battra and Vijay Kumar, which compares satisfaction scores between the medially stabilised and posterior stabilised TKA<sup>51</sup>. The study results show that the medially stabilised TKA has higher patient satisfaction and expectations than posterior stabilised knees<sup>51</sup>. The study stated that this higher satisfaction score could be related to the better replication of natural knee kinematics the medially stabilised knees provide.

#### **Increased stability**

The idea and principle of the medially stabilised knee replacement is to replicate the medial stability of a normal knee.

Due to this principle, the movement of a medially stabilised knee replacement is asymmetric during flexion, similar to a normal knee.

This principle is supported by a study by Fahad Hossain, which stated that higher stability is observed in the medially stabilised compared with a posterior stabilised knee replacement<sup>52</sup>.

The study concluded this increase in stability is due to the design having a "conforming, congruent, medial tibiofemoral articulation with a raised anterior and posterior lip".

## The future of medially stabilised knees

With ever-increasing patient expectations and the current market of conventional knee replacement struggling to meet expectations, we must consider alternatives to TKA solutions.

#### What if...

#### 2



You could deliver TKA outcomes closer to THA outcomes? You could more closely replicate the normal motion of the natural human knee, eliminating the instability exhibited by conventional TKA?

3

You could have a different conversation with your patient about their expectations and the potential outcomes?

> Wouldn't it be hugely beneficial if you could meet the expectations of your high-demand patients and enhance your practice using a TKA system designed to offer improved stability, normal freedom of movement, and improved patella function compared to conventional TKA?

FORWARD

C Z N O S

#### The SAIPH<sup>®</sup> knee: A Knee designed for the Head and Heart

### The SAIPH® knee, developed by MatOrtho®, is the market's best medially stabilised knee implant based on results from studies and registry data.

The SAIPH<sup>®</sup> knee is based on the success of the Medial Rotation Knee<sup>™</sup> (MRK<sup>™</sup>), the original knee system that tore up the established TKR blueprint to define the medially stabilised knee replacement segment.



Read our Patient Testimonials on the MRK<sup>™</sup> Here

The SAIPH® knee, developed by MatOrtho®, is the market's best medially stabilised knee implant based on results from studies and registry data. It incorporates all the features associated with the clinical success of the MRK<sup>™</sup> and improves upon them.

#### How do SAIPH® knees solve conventional TKA implant problems?

#### Proven to move like a normal knee

A study by Shimmin et al. aimed to evaluate the knee kinematics of the SAIPH® knee TKA by video fluoroscopy during four different weight-bearing activities (Internal-to-external pivot standing on the affected leg, kneeling activity, lunging, and stepping up/down)<sup>49</sup>.

The study showed that the SAIPH® knee exhibited an asymmetric movement pattern in all activities while maintaining complete stability. This result shows the pattern of movement of the SAIPH<sup>®</sup> knee during flexion is asymmetric, similar to a normal knee.

Additionally, the study stated that the SAIPH® knee permits a posterior translation of the lateral femoral condyle during knee flexion, with internal rotation of the tibia, and produces no paradoxical anterior motion. This was unlike other standard TKA designs in these four weight-bearing activities<sup>49</sup>.

**the SAIPH® knee** exhibited an asymmetric movement pattern **in all activities** while maintaining **complete stability.** 

## The SAIPH<sup>®</sup> knee allows a natural freedom of movement for a knee that feels like it's meant to

In a study using fluoroscopic evaluation to study patients' range of motion (ROM), it was found that the SAIPH® knee patients were able to exhibit a passive postoperative mean ROM of 127° (Range 100°-155°)<sup>49</sup>.

Additionally, the patients demonstrated a mean active weight-bearing ROM of 121° (Range 97°-151°).

These values are supported by other studies which show patients with the SAIPH $^{\circ}$  knees have a similar ROM $^{50,60,61}$ .

Furthermore, the SAIPH<sup>®</sup> knee can permit the maximum flexion expected in a normal knee (152°-154°)<sup>49</sup>.

In other words, the SAIPH® knee allows for the same maximum flexion expected in a normal knee.

#### Patellofemoral Articulation of the SAIPH® knee is more similar to a normal knee than conventional TKA

Like a normal knee, the SAIPH<sup>®</sup> knee features a physiologically lateralised trochlea. Its predecessor, the MRK<sup>™</sup>, also had this feature<sup>16,40</sup>.

Because of this, the SAIPH<sup>®</sup> knee can exhibit a similar amount of lateral patella translation during flexion as patients with a native knee<sup>40</sup>.

With the right trochlea design, whether or not the surgeon chooses to replace the patella has not been shown to affect the outcomes of TKA implants<sup>62</sup>.

Regardless, the SAIPH<sup>®</sup> knee has a unique saddle-shaped patella, which can rotate to match the femur for a fully conforming interface and has 40 years of successful clinical heritage<sup>33, 62-65</sup>.

The SAIPH<sup>®</sup> knee is also available with a cemented dome-shaped patella button.

#### TKA patients live better with a stable knee; SAIPH<sup>®</sup> knee patients are twice as likely to have a stable knee<sup>55</sup>

There is a misconception that a medially stabilised knee should always exhibit a medial centre of rotation. However, in a normal knee, the centre of rotation is not static, particularly during early flexion with limited AP movement in both condyles.

In truth, the one fundamental and essential characteristic of a normal knee is that it is always stable in all positions throughout flexion.

In a normal knee, stability is provided by its articular shapes and constraining tissue which is most significant on the medial side. However, all knee compartments play a role in stabilising the joint.

One defining principle of MatOrtho® knees is that they provide full-ROM stability through their ball-and-socket design. This stability is achieved using a medial deepdish ball-and-socket articulation.

The study by Andrew Shimmin, which used fluoroscopic evaluation on patients with the SAIPH® knee implants

described earlier, observed no paradoxical anterior translation of the femoral condyles during flexion in any activities<sup>49</sup>. This confirms that the design of the SAIPH® knee was able to achieve inherent full ROM stability.

A comparative study by Munir et al. was performed to observe the effect of four contemporary knee implant designs on mid-flexion stability following a minimum of two years after the patients' operations<sup>27</sup>.

By measuring stability from extension through to flexion, the study found that alternative designs were less stable in the mid-range of flexion: 30° to 60°, which is important for many activities such as walking down stairs<sup>27</sup>.

- In a further similar study comparing four TKA designs at 30° and 90°, Jones et al. also found significantly less AP movement for SAIPH® knees than the comparative cruciate-retaining and cruciate-retaining 'deep dish' implant<sup>66</sup>.
- These studies prove that SAIPH® knee implants can provide inherent stability throughout flexion, similar to a normal knee.

The saddle-shaped patella in the SAIPH<sup>®</sup> knee fully conforms to the femur and has 40 years of successful clinical heritage.

# 95%

of patients with a SAIPH® knee are satisfied<sup>50,61,67</sup>

# U Z I S S

#### Higher Overall Patient Satisfaction compared to conventional TKA

A visual analogue scale (VAS) was used in a 2-year follow-up study by Walter et al. to measure patient satisfaction with SAIPH<sup>®</sup> knees<sup>60</sup>.

It reported that 95.3% of the cohort responded positively, which the authors commented was unusual in their previous knee cohorts and equivalent to satisfaction responses for their hip cohorts (95.2% satisfaction score).

In another study by Bare et al., which has a cohort of 274 patients fitted with the SAIPH® knee implants, it was reported that 97.2% of patients described their knee problems as better than before surgery<sup>50</sup>. Furthermore,

92.6% of patients described their knee problems as 'much better' two years after the surgery<sup>50</sup>. The study also reported that the results produced were reproducible for all surgeons, as median satisfaction for every surgeon's cohort was at least nine out of ten<sup>50</sup>.

Further recent studies report a patient satisfaction rate of similar levels<sup>66-68</sup>. As a result, unlike recent articles reporting low patient satisfaction after conventional TKA, the SAIPH<sup>®</sup> knee cohorts do not display a 15-20% dissatisfaction rate among patients<sup>60, 61, 67, 69</sup>.

## **9 out of 10** patients **described** their **knee problems** as **'much better'** two years after the surgery<sup>60</sup>.

#### **Higher Patient-Reported Outcomes**

Patient-reported outcome measures (PROMs) provide a means to measure the success of knee surgery objectively.

In a study by Katchky et al., a cohort of 100 SAIPH® knee patients' data was retrieved five years post-operation<sup>61</sup>. The study recorded the patient's PROMs, including KOOS, WOMAC, Oxford Knee Score, Forgotten Joint Score (FJS) and EQ-5D.

Results show a significant improvement in PROMs measures.

This study's Forgotten Joint Score of the SAIPH® knee patients is similar to comparative research<sup>67</sup>.

It commented that the score was 'considerably better than previously reported TKA cohorts' and 'equal to reports for unicondylar knee arthroplasty' patients<sup>70,71</sup>.

Supporting the study by Katchky et al., the study by Bare et al. was run between December 2015 and July 2019, in which 293 knee patients completed the study<sup>50</sup>.

The study recorded PROMs, including KOOS, OKS, UCLA Activity, EQ5d-5L, and range of motion. The measurements were taken preoperatively and at one and two years postoperatively. Improvements were observed in all outcome measures, consistently achieving excellent scores.

When comparing the PROMs of the SAIPH® knee patients with other TKA designs, a K1000 study by Munir et al. on 64 patients found that the MRK<sup>™</sup> and the SAIPH<sup>®</sup> knee implants resulted in better patient-reported satisfaction and functional scores compared to the rotating platform and cruciate retaining designs<sup>27</sup>.

Patients with the SAIPH<sup>®</sup> knee implants have a better quality of life than those with conventional TKA implants post-operation.

A study performed on 103 patients randomly selected to receive cruciate retaining (50 knees) or the SAIPH® knee (53 knees) TKA was conducted to determine if the SAIPH® knee would benefit the patients objectively<sup>67</sup>.

The study measured PROMs as a primary measure of the study (including the KOOS, KOOS-12, KOOS-Shortform, KOOS-JR, WOMAC, OKS, EQ-5D-5L, and UCLA Activity Scale). The measurement was taken preoperatively and after one year in a follow-up. In addition, the patients' FJS and VAS-Satisfaction score was also taken during the follow-up.

The study reported no significant difference in scores between the groups for the majority of commonly-used PROMs measures. However, the SAIPH® knee patients reported significantly better outcomes in the KOOS Quality of Life section. These patients also scored significantly better for the Forgotten Joint Score overall.

Notably, the SAIPH<sup>®</sup> knee patients reported they were less likely to modify their lifestyle to accommodate their knee replacement.

#### SAIPH<sup>®</sup> knee implants last longer than conventional TKA implants

Total knee arthroplasty (TKA) platforms have undergone significant advancements in recent years. While traditional designs have featured a 'keel' tibial component on unconstrained bearings, manufacturers have started introducing a new asymmetric tibial constraint that employs a ball-and-socket design. Some manufacturers have even begun to produce cementless component versions<sup>72</sup>.

However, it has been found that these combined design characteristics correlate

with higher revision rates, especially tibial loosening<sup>33, 73, 74</sup>.

The SAIPH<sup>®</sup> knee utilises a different fixation design than traditional 'keel' designs. This design's main aim was to support the rotational torque at the implant-bone interface. The SAIPH<sup>®</sup> knee is further differentiated from other implants by its optimised stem-and-pegs design with a stippled cement interlocking interface with additional anti-rotation fins.

Low revision rates in SAIPH<sup>®</sup> knee patients after a follow-up of more than **5 years post-operation**.

As proof of the increased longevity of the SAIPH® knee implants, a radiographic analysis was done in a study by Katchky et al. on patients with the SAIPH® knee implants<sup>61</sup>. The research was performed during a five-year follow-up on the patients. Results show no progressive lucent lines, non-progressive lucent lines, and no incidences of osteolysis. Radiostereometric analysis (RSA) performed on the SAIPH® knees provided evidence of the stability of the components of the SAIPH® knee<sup>75</sup>. This is further supported by evidence in several registries showing low revision rates in the SAIPH® knee patients after a follow-up of more than 5 years post-operation<sup>33,73</sup>.

#### The SAIPH<sup>®</sup> knee offers surgeons a more straightforward procedure compared to other TKA option

A straightforward procedure can ease a surgical team's stress. From the start of the general preparation to the end of implantation, the SAIPH® knee operative technique procedure has instruments for all implant options in one complete set.

No need for change, no need for preoperative logistics. Everything for a simple procedure, in one place.

The SAIPH<sup>®</sup> knee surgical technique is available to download from the MatOrtho<sup>®</sup> SAIPH<sup>®</sup> knee site.

Read more here

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# The SAIPH<sup>®</sup> knee has lower revision rates, according to Orthopaedic Registries

#### The MRK<sup>™</sup> has the lowest revision rate at 18 years: the SAIPH<sup>®</sup> knee is set to outperform the MRK<sup>™</sup>.

#### Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR)

Medially stabilised knees are reported with low revision rates overall, with a 6.2% revision rate at 15 years<sup>76</sup>.

According to the AOANJRR 2022 annual report, over 18,776 medially stabilised implants are recorded<sup>77</sup>. In this category, MRK<sup>™</sup> makes up 3.5% of the medially stabilised knees, while the SAIPH<sup>®</sup> knees make up just over 2.5% of all medially stabilised knees. When compared to other medially stabilised knees, the SAIPH® knee by MatOrtho® has the lowest cumulative revision rate of 2.2% at 5 years and one of the lowest revision rates in all TKAs<sup>78</sup>.

#### National Joint Registry (NJR)

Although not reported as a separate category, medially stabilised knees have been a regular feature in the NJR. In the 2022 annual report, over 33,000 medially stabilised knees have been recorded since 2003<sup>33</sup>.

In this category, the MRK<sup>™</sup> and the SAIPH<sup>®</sup> knee account for more than half of the medially stabilised knee (55%)<sup>79</sup>. The MRK<sup>™</sup> accounts for 48% of medially stabilised implants, and the SAIPH<sup>®</sup> knee just over 7%<sup>79</sup>.

Furthermore, the MRK<sup>™</sup> has the lowest revision rate in all TKA procedures at 18 years (3.25%), with the SAIPH<sup>®</sup> knees set to outperform the MRK<sup>™ 79</sup>.

Based on almost 2,500 knees, the cumulative revision rate of the SAIPH® knees at 5 years post-operation was reported to be 1.4%<sup>79</sup>. This is lower than the best-in-class MRK<sup>™</sup> and lower than all other medially stabilised knees in the UK<sup>79</sup>. In the NJR's most recent Data Summary Report on the SAIPH® knee, published in November 2022, data from 2,895 SAIPH® knee implants show a mean implantation time of 3.2 years with a maximum of 12.9 years<sup>80</sup>.

In this document, it is reported that 32 knees have been revised, which is 1.1% of the total amount of SAIPH® knees implanted<sup>80</sup>. The SAIPH® knee has a reported cumulative revision rate of 2.2% at 8 years post-operation. This is an improvement from the 8-year cumulative revision rate of all TKAs in the NJR, which sits at 2.7%

The Orthopaedic Data Evaluation Panel is an independent, multidisciplinary panel of experts who evaluate and provide ratings for TKA devices.

The ratings are based on the number of years the product has been evidenced and cohort size (the number of available patients for the year being rated) to define the 'strength' of evidence for a given implant and where the evidence shows that the revision rate is below the defined threshold for that time point. A star may be awarded if the criteria for the specified rating is evidenced with a large cohort. However, this does not mean that the revision rate is lower than devices without a star but that have a smaller cohort.

How the ratings are based<sup>81</sup>:

The number represents the number of years for which the product has been evidenced.

The letter represents the strength of evidence. The star denotes a benchmark replacement rate of less than 1 in 20 (5%) at 10 years.

To introduce the new technology safely, MatOrtho® released the SAIPH® knee in limited availability and under close monitoring for the first ten years.

ODEP separates devices into their available constructs, which is why the SAIPH® knee UK data are divided into the following categories:

- Procedures with no patella.
- Procedures with a cementless patella.
- Procedures with a cemented patella.

This means that the cohorts on which the ODEP rating is based are relatively small, as each cohort represents a different construct. Even after being divided into separate categories with smaller patient cohorts, it is found that all the SAIPH® knee constructions have a considerably lower revision rate than the requirement for each rating. The SAIPH® knee has a current rating of 7A and is on track to receive an ODEP rating of 10A\*. The SAIPH® knee strength of evidence is in having such low revision rates and in having a much wider range of metrics, such as PROMS and satisfaction.

The ODEP ratings of all SAIPH® knees construct are as follows<sup>81</sup>:

#### ODEP 7A



#### ODEP 7A

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# **Could the SAIPH® knee improve your patients' lives?**

Recent evidence shows that the SAIPH<sup>®</sup> Knee implants are among the leading TKA implants in the world for clinical results.

The SAIPH<sup>®</sup> knee has been shown to:

- Replicate normal knee kinematics compared to other TKA, leading to better results in both ROM and stability.
- Have higher scores in PROMs and Forgotten Knee Score resulting in higher patient satisfaction compared to other TKA.
- Receive a high rating by ODEP, 7A, and is on track to receive a 10A\* rating.

Medially stabilised implants are shown:

• To have a lower rate of revision compared to most TKA. The SAIPH<sup>®</sup> knee currently has the lowest revision rate in the medially stabilised category.

#### SAIPH<sup>®</sup> is a knee designed for the head & heart

We understand that you are concerned with your patients' well-being and expectations. MatOrtho® is here to help you by providing the marketleading medially stabilised implant that improves your patients' well-being and clinical outcomes.

The SAIPH<sup>®</sup> knee is a knee for the head and the heart. Its results show you can be assured of meeting the high demands of your patients so that they can return to doing the things they love.

#### About the SAIPH<sup>®</sup> knee manufacturer MatOrtho<sup>®</sup>.

MatOrtho<sup>®</sup> is a UK-based orthopaedic medical devices manufacturer with an excellent heritage. We aim to become acknowledged as a pioneering trendsetter in the field of orthopaedic implant devices.

We're focused on improving the quality of life of all patients who receive one of our devices by supporting orthopaedic leaders with passion, knowledge and innovation applied dynamically and ethically.



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