M.O.R.E. Journal
SUPPLEMENT
MARCH 2013

The official Journal of the M.O.R.E. INSTITUTE
MEDACTA ORTHOPAEDIC RESEARCH AND EDUCATION

MyKnee
PATIENT MATCHED CUTTING BLOCKS

THIS ONE WORKS!
Proven accuracy and effectiveness of MyKnee
Medacta® Orthopaedic Research and Education Institute, M.O.R.E. Institute, has been created to provide continuous support for healthcare professionals in the field of Research and Education.

The M.O.R.E. Institute offers Surgeon to Surgeon educational opportunities to share experience and improve patient outcome.
Index

This document is a review performed on all the available literature on MyKnee and other patient matched technologies for total knee arthroplasty. It is intended to explain the reasons for the early controversial results of the Patient Matched Technology. It consists of a summary of multiple articles and presentations, followed by a technical introduction that explains the reasons behind the controversial results from currently marketed PMT products and finally a review of the available literature on MyKnee and other patient matched technologies.

5  Summary

9  Introduction

11 Patient matched knee instrumentations – are they all the same?

15 Review of the available literature on MyKnee and other patient matched technologies
Review of the available literature on MyKnee and other patient matched technologies

Summary

**ACCURATE IMPLANT POSITIONING: COMPARISON WITH CONVENTIONAL PROCEDURES AND CAS**

**MyKnee**

MyKnee is more accurate than conventional procedures and CAS.


**SIGNATURE BIOMET**

“Patient specific instrumentation, may not be as accurate as navigated or conventional total knee replacement…”.


**SIGNATURE BIOMET**

Higher outliers for the tibial and femoral component compared to conventional procedures and CAS.


**SIGNATURE BIOMET**

“No improvement in component alignment with decreased accuracy in tibial slope” compared to conventional instrumentation.


**SIGNATURE BIOMET**

Bigger outliers with Signature’s group for the mechanical axis and frontal alignment.


**SIGNATURE BIOMET**

With Signature there was a low accuracy on the overall alignment (70.7%), hence this “PSI is not able to reproduce the same degree of alignment accuracy as CAS techniques”.


**VISIONAIRE SMITH AND NEPHEW**

This study “did not show any advantage of PSI over CI” (conventional instrumentation) “in primary TKA(…) PSI based on a standing long-leg radiograph should be reconsidered”.

## ACCURATE IMPLANT POSITIONING: CONSISTENCY OF PREOPERATIVE PLANNING

### MyKnee

*“Out of 98 cases, the planned size of the components has been changed only twice”.*


*“Recuts were not required in the majority of case” Reliable MyKnee femoral size planning: 95% size matching.*


### SIGNATURE BIOMET

*“The preoperative plan was only able to predict the implanted femoral component size in 23% of the time (...) The proposed tibial resection was unacceptable in five knees”.*


### VISIONAIRE SMITH AND NEPHEW

*“the sagittal alignment was not reliable”, as the Visionaire system is based on MRI scan only.*

Misur P, Strick N, Puna R - The accuracy of implant positioning using the Visionaire patient matched knee arthroplasty system. Podium presentation at the AOA NZOA Meeting, Rotorua, New Zealand, October 9-14, 2011.

### VISIONAIRE SMITH AND NEPHEW

*“The VISIONAIRE system achieved unacceptable accuracy...”.*


### SHAPEMATCH STRYKER

*“The potential for malalignment with this system places implant at high risk of failure”.*


### ZIMMER PATIENT SPECIFIC INSTRUMENTATION

*“the use of patient-matched cutting blocks is not accurate...”.*

THIS ONE WORKS! Proven accuracy and effectiveness of MyKnee

**ACCURATE IMPLANT POSITIONING: POSTOPERATIVE ANALYSIS**

**Postoperative CT scans demonstrate a “perfect preoperative reliability and anatomical reconstruction”, resulting in a “great advantage during the surgery”.
**

**Mean postoperative HKA of 179.6° with a standard deviation of just 2°.
**

**“Optimal mechanical alignment can be achieved with very high accuracy comparable with CAS”.
**

**“The present study shows definitively that intraoperative resections and post-operative alignments can be accurately achieved with pre-operative CT planning and using patient-specific instrumentations”.
**

**SIGNATURE BIOMET**

**No improvement in component alignment postoperatively.
**

**SIGNATURE BIOMET**

**With Signature PMT, “Malalignment was present in 30% of cases…”.
**

**SIGNATURE BIOMET - SHAPEMATCH STRYKER**

**“Signature and OtisMed do not reduce the number of coronal alignment outliers”.
**

**VISIONAIRE SMITH AND NEPHEW**

**The use of Visionaire, patient-matched cutting blocks, validated by postoperative CT scans, “is not accurate […] resulting in increased outliers particularly when compared with standard computer navigation”.
**

**VISIONAIRE SMITH AND NEPHEW**

**Bigger outliers in Visionaire group (mean post-op HKA: Visionaire 1.7°, from 0° to 6°, vs conventional 2.8°, from 0° to 5°).
**

**VISIONAIRE SMITH AND NEPHEW**

**“Consistent risk of error of more 3° especially in the sagittal plane”.
**

**VISIONAIRE SMITH AND NEPHEW**

**Visionaire showed a poorer performance against CAS technique regarding the outliers (14% vs 10.2%).
**
Danilidis K, Tillesku C O - Frontal plane alignment after total knee arthroplasty using patient-specific instruments. International Orthopaedics (SICOT), Published online: December 2012.

**VISIONAIRE SMITH AND NEPHEW**

**“the PSI system based only on data acquisition with A-P radiograms and RMN cannot be defined as accurate”.
**

**SHAPEMATCH STRYKER**

**Comparing only with CAS, this PMT presented worst implant alignment results, not only for the femur but also for the tibia with bigger outliers for both of these parameters.
**
## Economic Advantages of Patient Matched Technology

### MyKnee

MyKnee allows to increase the number of cases per surgery session, resulting in an increase of the hospital profit!


“With reduced setup time and turnover time the number of cases will doubtlessly increase”.


In comparison to a conventional approach, MyKnee with a personalized pre-operative planning allows:

- less sterilisation cost,
- less transfusion cost,
- less surgical time,
- less hospitalisation cost.


### Visionaire Smith and Nephew

Reduction in duration of hospital stay and operative time.

Introduction

In total knee arthroplasty, a way to define the success of a surgery is to evaluate the final implant and limb alignment. Incorrect positioning and malalignment can lead to negative postoperative outcomes\(^1\). In fact, it is believed that the optimal postoperative alignment to avoid negative outcomes is between 0° to ±3° from the mechanical axis, while a deviation from that shows higher failure rates\(^2\)\(^-\)\(^4\). To address this situation and improve implant and limb alignment, computer assisted surgery (CAS) for total knee arthroplasty was developed. In spite of better results than standard instrumentation, CAS presents some limitations since it requires accurate landmark registration, increased surgical time and cost, long set-up time and a considerable learning curve\(^5\)\(^6\).

Recently, patient matched technology (PMT) appeared as a solution to preserve (or even enhance) the good clinical results of CAS without its limitations. This new technology uses preoperative imaging (plain radiographs, computed tomography and magnetic resonance imaging) to manufacture guides specific to a patient’s anatomy (cutting blocks or pin positioners). Proposed benefits of patient-matched cutting guides include an improvement in postoperative mechanical alignment, without violation of intramedullary canal, a decrease of the instrument trays required, optimizing the O.R. time and logistics, and the ability to preoperatively plan the patient’s components size, position and alignment.

A relatively novel technology, many studies are now being performed in order to evaluate the feasibility of the technology. Different PMTs are now available in the market. Nevertheless, they present different characteristics, especially regarding the choices for the production of the patient specific cutting guides, where the image protocols differ the most. The different paths chosen by the companies to reach the final patient specific guide can explain the scattered results disclosed in the literature now available.

In fact, the literature findings are controversial and the majority of the published results do not support the increase of accuracy that patient-matched technology was created to provide.

These outcomes can damage the reliability of this new technology, leaving one to conclude that patient-matched systems are marketing tools, providing few benefits to patients. However, when investigating these results, we can find a clear correlation between the image acquisition technology used for bone model reconstruction and the quality of results. The CT based patient-matched systems seem to have better outcomes than a system based on MRI, long leg radiographs or referring to cartilage for cutting block positioning.

In fact CT based MyKnee cutting blocks show proven accuracy and effectiveness in more than 10 publications\(^16\)\(^,\)\(^22\)\(^,\)\(^23\)\(^,\)\(^32\)\(^-\)\(^38\), while competitors’ patient-matched systems based on MRI, long leg radiographs and referring to cartilage have struggled to provide consistent outcomes.

This demonstrates that PMT is a feasible, reliable, and advantageous new technology that may provide benefits such as a decrease in set-up time, instrument trays needed and surgical steps, ability to preoperatively plan the implant size, position, and alignment. In addition, this technology is expected to improve postoperative mechanical alignment and promote a reduction in costs\(^7\). The reported problems may lie on the poor choices made during the development of some PMTs. Nevertheless, it is important to note that the weaker results should not compromise the effectiveness of this technology. MyKnee is the proof that it works, it is safe, trustworthy, with excellent results and high surgeon satisfaction and approval. In fact, the literature reports evidence that MyKnee is the only patient-matched system on the market with consistent positive outcomes and proved clinical benefits.
This is possible thanks to a set of unique benefits that only MyKnee can provide:

- CT based (MRI available as option)
- Actual cutting block, not only positioner
- In house technology ensuring 3 weeks lead time with the assistance of a personal technician
- Gold standard material (Nylon PA 2200)
- Gold standard manufacturing process (SLS - Selective Layer Sintering)

In the following chapters a list and a review of available publications on patient-matched technology in TKA are reported. Before analyzing these publications, we will clarify the most probable reasons of the controversial results of the patient-matched systems in the market and, consequently, discuss the factors behind the success of MyKnee.
Patient matched knee instrumentations – are they all the same?

By analyzing recent literature about patient-matching technology in TKA, we see that the results are controversial. In fact, the majority of the published results do not support the improvement of accuracy that patient-matched technology was created to provide. These results may jeopardize the perceived reliability of the technology, leaving one to conclude that patient-matched systems do not work. In reviewing the causes of the clinical results currently available, we notice a clear correlation between the image acquisition technology used for bone model reconstruction and the quality of results. CT based patient-matched systems seem to have better results than systems that prefer MRI, long leg radiographs or referring to cartilage for cutting block positioning.

In fact CT based MyKnee cutting blocks have shown proven accuracy and effectiveness in more than 10 publications\cite{16,22,23,32-38}, while controversial outcomes have been identified with patient matched systems based on MRI (Signature-Biomet, PSI-Zimmer, Visionaire-S&N, ShapeMatch-Stryker), long leg radiographs (Visionaire-S&N) and referring to cartilage (Signature-Biomet, PSI-Zimmer, Visionaire-S&N, ShapeMatch-Stryker, Trumatch-DePuy).

This demonstrates that not all technologies are equal. Patient-matched technology in total knee arthroplasty is an accurate and reliable method, only if the final product is well planned and designed.

The aim of this document is to provide technical insight and clarification into the most probable reasons for the clinical performance of several patient-matched systems on the market as well as an overview of the clinical performance of MyKnee.

CT vs MRI: why MRI is not a right choice in PMT

PM Systems using MRI: Signature – Biomet (MRI), PSI - Zimmer (MRI), Visionaire – S&N (MRI + Long Leg X-Ray), ShapeMatch – Stryker (MRI)

CT may be preferred to MRI for the following reasons:

1. **Image quality**: The higher accuracy of CT in bone reconstruction is demonstrated in the following pictures. It is evident that the bone boundaries can be accurately detected from the CT scan. In the MRI image the delineation of femur and tibia is harder to identify, especially in the joint area, where the femoral and tibial cartilage overlaps. This results in potential reconstruction errors cutting block mismatch and lack of accuracy.

2. **Scan duration**: The duration of obtaining the needed imagery also plays a crucial role in the accuracy of the bone model reconstruction. An MRI may last five times longer than a CT (40min vs 7min), increasing the likelihood of patient movements during the exam. This potentially leads to image distortion which can’t be detected during the image quality control. This may result in mechanical axis mismatch.

3. **Contraindications**: MRI may not be performed on patients who present with pacemakers, obesity or who are claustrophobic.

4. **Hardware**: MRI based cutting blocks can’t be used to revise unicompartmental knee or to perform TKA in presence of screws, nails, contralateral or ipsilateral implants (knee or hips).
These limitations of MRI technology have been confirmed in the literature by an independent study from the Royal National Orthopaedic Hospital of Stanmore. The authors demonstrate that “bone models generated from MRI scans were dimensionally less accurate than those generated from CT scans”[8]. MyKnee offers to the surgeon the possibility to choose between CT- or MRI-based cutting blocks, according to their preferences. Since launching this technology, Medacta has believed that that CT was the best method for bone reconstruction in PMT. In order to confirm this preliminary intuition, a study was conducted in collaboration with the University of Geneva, demonstrating “better precision with MyKnee CT based cutting blocks for advanced arthritis”[9].

More evidence confirming the use of CT over MRI in bone reconstruction is demonstrated in a current market trend. Biomet and Zimmer, pioneers in introducing this technology, are moving away from MRI-based patient-matched systems in favor of CT-based. This, together with controversial clinical outcomes of MRI-based patient matched guides, confirms that CT is the most suitable image acquisition technology in PMT.

CT vs Long Leg Radiograph: why long leg radiograph is not the right choice to define HKA in PMT

*PM Systems using long leg X-Ray: Visionaire – S&N (MRI + Long Leg X-Ray)*

Mechanical axis definition is crucial for an optimum alignment of the prosthesis. The accuracy of the CT (3D) measurement is higher than a 2D measurement, as seen in a long leg XRay where the result may be strongly affected by limb position. In the figures below, two consecutive long leg XRays are shown. Between the two measurements, the leg rotates externally. The result is 2.5° discrepancy in measured HKA on the same patient.

MyKnee defines the mechanical axis on CT. This same image is used to reconstruct the bone models. Visionaire (S&N) couples the 3D images of the knee (MRI) to a long leg radiograph (2D) in an attempt to determine HKA. This procedure is very delicate, and the results may depend on matching the accuracy of the two separate image acquisition processes.
HKA vs Flexion Extension Axis: why Flexion Extension Axis axis is not the right choice for limb alignment in PMT

*PM Systems using Flexion Extension Axis: ShapeMatch – Stryker*

The standard reference for the knee prosthesis alignment is the leg mechanical axis (HKA), as it is the axis where the force coming from the body weight is directed. In fact, it is believed that the optimal postoperative alignment of the limb to avoid negative clinical outcomes is between 0° to ±3° from the mechanical axis, whilst its deviation shows higher failure rates [2-4].

In spite of these evidences, some studies have questioned the actual need of the postoperative alignment to HKA [20,31,39-41], proposing an alternative reference for knee prosthesis alignment, the knee flexion extension axis (FEA), supposed to be the kinematic axis of the knee (i.e. the axis describing the knee movements).

The main problem linked to this theoretical reference is the lack of fixed anatomical landmarks. The HKA mechanical axis is defined as a line passing from the hip, knee and ankle centers, which are fixed anatomical landmarks, easily detectable on a limb radiological image. On the contrary, FEA is the transverse axis in the femur about which the tibia flexes and extends and it is designed as an axis passing through the center of the circles approximating the articular surface of the femoral condyles in different degrees of flexion. All patient-matched system in the market, but Stryker, use HKA as reference for limb alignment.

Stryker, with its patient-matched system ShapeMatch, tried to use FEA as reference for knee prosthesis alignment. They calculated this axis on a MRI scan of the knee, processed to create a virtual model of the normal knee joint, before its arthritic conditions. Thus, FEA is the result of an estimation performed on a MRI image of the knee and estimation is by definition liked to inaccuracy and poor reproducibility. The suspension of the ShapeMatch system distribution due to very poor preliminary clinical outcomes [20,31] is a confirmation that the FEA is not yet a reliable reference for limb alignment in PMT.

Bone and Osteophytes vs Cartilage: why cartilage is not an ideal anchoring area for patient-matched guides

*PM Systems anchoring on cartilage: TruMatch – Depuy (Long leg CT + cartilage estimation), Visionaire – S&N (MRI + Long Leg X-Ray), Signature – Biomet (MRI), PSI- Zimmer (MRI)*

It is now clear that MRI is not a reliable method to accurately define the cartilage. However, even if the method to define cartilage from MRI is improved, the cartilage itself would not be a good anchoring point for the cutting blocks. The more irregular and rougher the anchoring points are the more stable the cutting block are. Cartilage is a soft and slippery tissue. Most of the areas where the patient matched guides are anchored are quite flat. In fact, cartilage may be deformed by the pressure of the cutting blocks. Therefore the position of the cutting guides can be unstable and ambiguous.

All MRI based patient-matched cutting blocks use cartilage as anchoring points. Furthermore, DePuy’s patient-matched system – TruMatch, even if CT-based, use cartilage as reference for the cutting blocks, asking the surgeon to estimate thickness, as it can’t be identified on CT.

MyKnee CT-based cutting blocks are designed to anchor on osteophytes and bone landmarks where cartilage has been removed. In this way, the cutting block is stabilized in a locked position, which can be identified unambiguously.
CT drawback: is radiation coming from CT scans dangerous?

PM Systems using CT: TruMatch – Depuy (Long leg CT + cartilage estimation), MyKnee – Medacta (3 CTs)

The most common criticism of CT based cutting blocks is linked to the radiation dose that the patient is exposed to.

The radiation dose coming from a CT scan performed following MyKnee protocol (3 acquisitions of hip, knee and ankle, see image on the left) has been calculated by the radiological deparent of the Balgrist University Hospital of Zurich. In the following table the equivalent dose are summarized.

<table>
<thead>
<tr>
<th>Where</th>
<th>Ankle</th>
<th>Knee</th>
<th>Hip</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dose</td>
<td>0.07 mSv</td>
<td>0.16 mSv</td>
<td>5 mSv</td>
</tr>
<tr>
<td>Comparable to</td>
<td>Chest X-Ray</td>
<td>Transatlantic flight</td>
<td>Yearly radiation dose for each Swiss citizens</td>
</tr>
</tbody>
</table>

The dose of radiation appears to be of little concern, particularly if the benefits of a well-functioning prosthesis can reduce the requirement for further radiographs if complications arise[37]. This dose increases if the CT is extended to the whole leg, rather than scanning the region of interest (Hip, Knee and ankle only) and this is the case of Trumatch (DePuy), which acquires the image information from a CT of the whole leg. This procedure raises the amount of radiation without any addition benefits for the image quality, as femoral and tibial diaphysis included in the scan are not useful for the reconstruction of the bone models.

Summarizing

Why is CT the ideal imaging acquisition technology for PMT?

• Accurate (precise bone and HKA definition, cartilage is bypassed and osteophytes are stable and reproducible)
• Faster (less movement artifacts)
• Less contraindications (obesity, claustrophobia, pacemaker, surrounding metal are not a problem)
• Not all CT protocols are the same, the MyKnee CT protocol is optimized to give a negligible radiation dose.

And remember! MyKnee is the only patient-matched system in the market offering a unique set of benefits

• CT based (MRI available as option)
• Actual cutting block, not only positioner
• In house technology ensuring 3 weeks lead time with the assistance of a personal technician
• Gold standard material (Nylon PA 2200)
• Gold standard manufacturing process (SLS - Selective Layer Sintering)
Review of the available literature on MyKnee and other patient matched technologies

Abstract

Patient-matched technology (PMT) is a relatively novel alternative in total knee arthroplasty (TKA) with many claimed benefits. However, considering all the PMTs available in the market, the published studies on this technology report controversial results.

The goal of this literature review is to evaluate the effectiveness of this new technology comparing results of the different PMTs available. The features addressed will be focused on the accuracy of implant positioning (assessed by comparing the results with PMT and conventional and navigations procedures, checking the consistency of preoperative planning and analyzing the postoperative results) and economic advantages of PMT.

This review concludes that PMT is a feasible, reliable, and advantageous technology. The effectiveness of it should not be compromised by initial controversial results. MyKnee is the proof that this technology works when proper choices are made during the production of PMT guides, especially regarding image acquisition protocols. One can understand that the MRI/MRI plus standing long radiograph based patient matched guides show a low degree of accuracy when comparing with CT based protocols.

Introduction

Recently, patient matched technology (PMT) appeared as a solution to improve total knee arthroplasty clinical results. This new technology uses preoperative imaging (plain radiographs, computed tomography and magnetic resonance imaging) to manufacture guides specific to a patient’s anatomy (cutting blocks or pin positioners). Proposed benefits of patient-matched cutting guides include an improvement in postoperative mechanical alignment, without violation of intramedullary canal, a decrease of the instrument trays required, optimizing the O.R. time and logistics, and the ability to preoperatively plan the patient’s components size, position and alignment.

Many PMTs in the market have demonstrated controversial early results. MyKnee® is the only PMT that consistently reports positive feedback in its studies. This review intends to assess the available studies on PMTs, compare its results, and understand why some PMTs cannot reproduce positive outcomes.

Below the list of the PMT’s, whose results are reported in this review, and the respective image acquisition protocol*. Most of the studies evaluate the accuracy of implant positioning achieved. Others, however, address the economic advantages anticipated with this technology.

<table>
<thead>
<tr>
<th>System</th>
<th>Company</th>
<th>Image Protocol*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signature</td>
<td>Biomet</td>
<td>MRI</td>
</tr>
<tr>
<td>Visionaire</td>
<td>Smith and Nephew</td>
<td>MRI plus standing long radiograph</td>
</tr>
<tr>
<td>Shapematch</td>
<td>Stryker</td>
<td>MRI</td>
</tr>
<tr>
<td>Zimmer PSI</td>
<td>Zimmer</td>
<td>MRI</td>
</tr>
<tr>
<td>MyKnee</td>
<td>Medacta®</td>
<td>High resolution CT for the knee, low resolution CT of hip and ankle</td>
</tr>
</tbody>
</table>

* The described protocols are the ones described in the articles reported in this review, other protocols may be made available by the manufacturers of the PMTs.
Accurate implant positioning

Implant positioning accuracy may be assessed in different ways. By comparing PMT results with other known techniques, conventional procedures and CAS, matching the final results with the preoperative planning or analyzing the postoperative results.

Comparison with conventional procedures and CAS

One way to address the accuracy of final implant positioning is comparing PMT results to the results of other known techniques, such as conventional or CAS procedures.

One PMT product that has been evaluated in peer reviewed journals is the Signature from Biomet Inc. Signature results have been met with mixed reviews. Webb et al reported the early experience with Signature comparing the results with CAS and conventional techniques. This study demonstrated inferior results with Biomet’s PMT. This led the authors to conclude that Signature may not be as accurate as CAS or conventional total knee replacement[10]. Other authors compared Signature only to standard manual procedures. Stronach et al, found no difference in overall implant alignment obtained by this particular PMT product, compared to traditional instrumentation. Furthermore, with Signature the accuracy of the posterior slope actually decreases, with only 36% of the knees matching the planned value. Again, the conclusion was that this PMT does not improve the component alignment when compared to conventional instrumentation[11]. Ng et al reported acceptable results regarding the hip-knee-ankle (HKA) angle but with a higher number of outliers regarding the tibial and femoral component angles with the Signature PMT technology used[12]. Boonen et al also reported inadequate results regarding the outliers. Comparing manual instrumentation and Signature, the number of outliers of the mechanical axis alignment was statistically similar but with a wider range of outliers with Biomet’s PMT (Signature 171-188° vs conventional instrumentation 175-185°). In addition to this, inaccurate implant size matching was observed. The authors concluded that accuracy of the production of Signature guides should be questioned[13]. When comparing Signature only with navigation techniques, Nam et al concluded that this PMT is unable to achieve the same results in alignment as navigation, since the overall implant alignment was within 3° only 70.7% of the times[14].

Other PMT studies in peer reviewed journals include the Visionaire from Smith and Nephew plc. Hamadouche’s et al sought to compare the Visionaire system with conventional instrumentation. This study showed no advantages between the Visionaire when
compared to conventional instrumentation. In fact, not only was the mechanical axis measurement less accurate, but the coronal alignment of the femoral component tended to a significant varus position as well. The author concluded that the Visionaire should reconsider its leg alignment reconstruction method\(^{15}\).

MyKnee technology has also been evaluated in peer reviewed journals. One study compared PMT with conventional and navigated instrumentation. Léon et al. was able to demonstrate the accuracy and reliability of the MyKnee system. In this study, MyKnee was shown to be most accurate of the three instrumentation options, especially with regard to outliers. The authors concluded to continue to utilize MyKnee technology based on the clinical results obtained\(^{16}\).

**Consistency of preoperative planning**

To evaluate the accuracy of PMT, planned resections and actual resections are compared.

In this study, Signature was evaluated by Stronach et al. The authors aimed to assess the number of intraoperative changes needed with this PMT. It was highlighted that the Signature product struggled to reproduce preoperative planning. There was need for intervention in 90% of the presented cases, in order to improve the alignment preoperatively suggested by the PMT guides. Other issues identified by the authors consisted of the Signature’s poor fit on the patient’s anatomy, inconsistent size matching for the femoral and tibial implants and inaccurate proposed tibial resection. The authors concluded that users of this product should prepare to deviate from the preoperative plan, and should use caution. They also advised against blindly accepting the preoperative surgical plan\(^{17}\).

Regarding Visionaire, Lustig et al reported on the accuracy and alignment of the guides. The claimed accuracy of this system was not supported by the results. The authors discussed a lack of accuracy for total limb alignment in the coronal and sagittal plane (worse results for the sagittal plane), for femoral alignment in the sagittal and rotational planes, and for tibial slope. Outliers in this group were large as well. Also, deficiencies in the planned size matching the actual size were reported. The authors concluded that this system does not have the accuracy needed for clinical use, and discussed the possibility of inappropriate image acquisition\(^{18}\). Additionally Misur et al addressed the accuracy of implant positioning. In spite of satisfying coronal alignment, it was revealed that with this technology the sagittal and rotational alignment was not reliable\(^{19}\).

Another PMT discussed in the literature is the Shapematch system from Stryker Corporation. Klatt et al evaluated its accuracy intraoperatively with a navigation system, concluding that there was a concerning risk of limb malalignment with this technology, potentially rendering it unreliable and unsafe. It was stated that with Shapematch the potential for positioning the implants, or even the limb, outside of the acceptable range of alignment is increased\(^{20}\).

Zimmer Patient Specific Instruments (PSI) from Zimmer Holdings Inc. was also tested for preoperative planning accuracy by Coolican et al. Using navigation intraoperatively, the authors registered significant differences between the planned alignment and what was achieved intraoperatively, especially regarding femoral component alignment. Increased outliers were also reported. These preliminary results led to the authors to conclude that Zimmer PSI is not accurate, with an unacceptable degree of potential limb malalignment\(^{21}\).

Concerning obtaining consistency with preoperative planning, MyKnee was also evaluated. Koch et al reported that accurate radiological results were achieved in addition to an accurate planned implant size of the components in 98% of the cases\(^{22}\). Positive results were also achieved by Dussault et al. The authors describe satisfying results related not only with implant size matching, but also with the planned resections. In both studies, the authors concluded that MyKnee is a reliable, accurate and safe system to use\(^{23}\).

**Postoperative analysis**

Postoperative analysis allows the ultimate evaluation of the surgery’s success, therefore demonstrating the true difference between the various technologies.

Nunley et al compared postoperative results achieved with Signature, Shapematch and conventional instrumentation. In this study, there was no clear advantage from the use of these PMTs. The alignment was not improved when compared to results obtained with the use of traditional instrumentation. In fact, the HKA angle was less accurate with the PMTs (with conventional instrumentation, 84% of the cases were in the acceptable range of \(\pm 3^\circ\), while Signature achieved 82% and Shapematch only 56%) presenting an increased number of outliers (conventional instrumentation had 16% of outliers against 18% for Signature and 44% for Shapematch), which lowers their credibility. The authors also pointed that MRI based PMTs, such as Signature and Shapematch, might produce a lack of accuracy. CT may be more advantageous\(^{24}\). The same main author,
Nunley et al, evaluated Signature in another study and, once again, no improvement was observed in postoperative component alignment versus standard instrumentation, with statistically similar results for all parameters analyzed. Actually, regarding the femorotibial angle (FTA) and HKA angle, Signature presented slightly inferior results (59% against 61% for FTA and 74% against 82% for HKA). Hilliard et al also assessed Signature’s alignment efficiency. No improvement of alignment, with results comparable to traditional instrumentation, was found. As a matter of fact, some parameters showed worse results, as the number of outliers (with Signature was 33% versus 29% with conventional instrumentation).

Visionaire system’s reliability is also assessed postoperatively in the literature. Parker et al evaluated this product using computer navigation during surgery and assessing postoperative CT scans. Important differences were reported regarding the PMT planned resections and planned alignment in the coronal and sagittal planes with the Visionaire. The least accurate parameter was the sagittal femoral alignment, which differed by an average of 4.0° from the planned alignment. The authors concluded that this particular PMT is not accurate, showing an intolerable potential for limb malalignment, while also producing an increase in outliers. Conteduca et al also evaluated Visionaire’s accuracy with navigation software, but in this case, only the accuracy of the tibial cutting jigs was assessed and compared with extra-medullary (EM) tibial instrumentation. Once again, the results for Visionaire were not satisfying as this study revealed that this PMT might induce a high risk of implant malposition. There was less alignment accuracy in the coronal plane, with a higher mean of deviation from the ideal alignment, for Signature of 1.29° versus 0.7° for standard instrumentation and a higher number of outliers (0% vs 17%), and less tibial slope accuracy. Signature presented a mean of +1.16° (therefore, anterior slope vs -1.62° for standard instrumentation again with a higher number of outliers (75% vs 33%) [28]. The same authors, Conteduca et al, conducted one other Visionaire test in order to assess the overall accuracy of this PMT with navigation. They found an unacceptable lack of accuracy, with the sagittal plane presenting concerning results, with only 41.1% of proper alignment in the tibial sagittal plane, 71% in the femoral sagittal plane and 79% for the overall correct alignment. In both articles, the authors claimed that this result might be attributed to the pre-operative studies, identifying insufficient data regarding knee reconstruction. In short, it was said that this PMT, based on MRI and standing long leg radiograph, cannot be defined as accurate. Noble et al also assessed the accuracy of Visionaire PMT. They identified increased outliers regarding the mechanical alignment, 0°-6° vs 0°-5°30. Daniilidis et al, with the goal of analyzing the frontal alignment, showed an inferior performance of Visionaire against a CAS technique regarding the outliers (14% vs 10.2%) [11].

With Shapematch, Spencer et al described the postoperative analysis of their initial experience. Their goal was to assess the intraoperative events and long-leg coronal alignment while comparing the results with standard and computer-assisted techniques of previous studies. The authors noted a higher deviation of the tibial component from the mechanical axis when compared to the other techniques (Shapematch 2.9° vs conventional instrumentation 2.0° vs navigation 1.4°). Comparing to CAS, Stryker’s PMT presented the worst implant alignment results, not only for the tibia but also for the femur (1.6° vs 1.0°) with increased outliers for both of these parameters (6° valgus to 4° varus vs 3° valgus to 3° varus and 4° valgus to 2° varus vs 2° valgus to 3° varus). Post-operative analysis has also been assessed with MyKnee. Baldo et al evaluated the preoperative planning reliability with CT scans in the postoperative period. Preliminary results revealed a greater preoperative planning reliability with higher accuracy of anatomical reconstruction with MyKnee [32]. The same positive feedback was reported by Müller et al. Their preliminary radiological results reported satisfying match between the preoperative plan and postoperative results. Good implant alignment was achieved, with a mean HKA angle of 179.6°. The authors concluded that MyKnee technology is a reliable and straightforward technique, with high possibility of reducing operative time [33]. Another preliminary prospective study with the MyKnee was reported by Goldberg et al. In this study, the reliability of the MyKnee system was assessed. Not only was the final alignment accurate, with 93% of the cases within 3° of neutral, but the resections where measured and shown to match the preoperative plan, with the actual resection differing only 0.7mm or less from the planned resection. The authors concluded that PMT based on CT allows one to achieve accurate intraoperative resections and postoperative alignment. It was also reported that there was a considerable reduction in surgical time and estimated blood loss with MyKnee technology [34]. Trong et al shows the improved accuracy of mechanical alignment with MyKnee, presenting very high rates of success regarding the HKA alignment with 92.9% of success rate, proximal tibial angle with 98.2% of success rate, distal femoral angle
with 99.1% of success rate (within ±4°) and tibial slope with a mean of 2.86°, which are comparable to navigation results. The authors concluded this way that optimal mechanical alignment may be achieved with MyKnee. They also discussed the reduction of surgery time with the use of this technique[35].

Economic advantages of patient matched technology

Finally, other studies aim to demonstrate the specific benefits of PMT. Most authors agree that this novel technology has the potential of reducing surgical steps and operative time, therefore improving O. R. logistics and turnover in addition to the reduction of costs associated with instruments sterilization. One other theoretical benefit consists on the increase of cases due to enhanced efficiencies.

The Noble et al Visionaire study, in addition to the already referred system results, served to support the claimed economic advantages of PMT technology. The authors revealed significant reductions in instruments trays, operative time, and duration of hospital stay, highlighting the financial benefits that may accompany the utilization of this technology[30].

Goldberg addressed potential economic benefits from utilizing MyKnee technology. In addition to the alignment advantages, reduction of outliers (more homogeneous results), accuracy, and very good implant size matching, the author reported that with reduced operative and set-up times with MyKnee, the possibility of an increase of 2 cases per week would exist. Reporting a profit of $2,500 per case, a potential profit of $230,000 may be realized at this Hospital[36]. Also, Koch demonstrated MyKnee economic benefits as well. In a description of MyKnee technique, the author discusses the reduced set-up times and turnover, which allow to decrease costs in sterilization, operative time, and O. R. utilization. Moreover, the author claims that this PMT enables a more efficient and simple surgery, since it is simpler not only for the surgeon but also for his operative team[37]. The economic benefits of MyKnee were also studied by Gagna. He revealed that a well-planned surgery with MyKnee will allow the hospital to reduce costs associated with sterilization, O. R. time usage and increase efficiency[38].

Conclusions

The goal of this literature review was to assess the feasibility of PMT technology. As mentioned, there are multiple options from multiple manufacturers for this technology, all with different features and specifications.

After analyzing these studies, it is clear that clinical results have not been consistent. However, in many cases these inconsistencies can be explained.

As stated, multiple PMT systems on the market present different characteristics. This is especially evident with regard to the choices used during the production of the patient matched guides, where image acquisition protocols may differ the most. Taking this into account, it is easy to understand that the MRI/MRI plus standing long radiograph based patient matched guides show a low degree of accuracy when comparing with CT based protocols, with results that do not support the benefits claimed for this technology.

MyKnee, with a preference to CT image acquisition, has performed very well clinically. It has proven to allow precise preoperative planning, correct alignment, excellent size matching, and improved O. R. efficiency with less trays, reduced surgical steps and surgical time.

The other PMTs evaluated in this report were based on MRI/MRI plus a standing long leg radiograph. Reported results were not what was expected, especially in regards to accuracy in limb alignment, implant alignment and preoperative planning accuracy. Some authors pointed out that the problem might lie with the preoperative planning process. It was claimed that MRI may not produce the best results for the data needed to be obtained[29]. Insufficient data collection will not allow an accurate knee reconstruction and, therefore, the 3D bone models and patient matched guides may lack in precision.

Other benefits of PMT technology appear to be universally accepted in the reports discussed. These would include a marked reduction in surgical steps and increased O. R. efficiency, leading to the potential of additional procedures.

In conclusion, PMT is a feasible, reliable,
and advantageous technology. Adaptation of this technology will permit the benefits that have been discussed, including: decrease in setup time, instrument trays needed and surgical steps, ability to preoperatively plan the implant size, position, and alignment, in addition to an expected improvement of the postoperative mechanical alignment and cost reduction\[7\]. The problem underlined in this review may lie on the poor choices made on the development of some PMTs. However, these weaker results should not compromise the effectiveness of this technology. While research will continue, MyKnee is the proof that this technology will achieve the intended goals that the industry has aimed for with PMT technology.

References


Copyright © 2012 by Medacta® International SA, all rights reserved
Swiss Company - Your Global Partner
PATIENT MATCHED CUTTING BLOCKS

The MyKnee technology provides a unique set of potential benefits:

- **THIS ONE WORKS!** Proven accuracy and effectiveness of MyKnee
- Actual cutting blocks, not just pin positioners
- CT or MRI based
- Significant time and costs savings for the hospitals, allowing for **one extra case per surgery session**
- Online interactive 3D planning
- Complete in-house technology ensuring the assistance of a personal MyKnee technician and **only 3 weeks lead time**!


More than 10,000* MyKnee

MyKnee® LBS

The first patient matched cutting blocks with integrated Ligaments Balancing System