

# M.O.R.E. Journal s u p p l e m e n t

### MYKNEE PUBLICATION REVIEW

The official Journal of the



**APRIL 2016** 

MEDACTA ORTHOPAEDIC RESEARCH AND EDUCATION

My Knee

PATIENT MATCHED TECHNOLOGY IN KNEE REPLACEMENT





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### 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<sup>[1]</sup>. In fact, it is believed that the optimal postoperative alignment to avoid negative outcomes is between 0° to  $\pm$ 3° from the mechanical axis, since a deviation from that shows higher failure rates<sup>[2-4]</sup>. 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 against 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<sup>[5,6]</sup>.

Recently, patient matched technology (PMT) appeared as a solution to preserve (or potentially enhance) the good clinical results of CAS without its limitations. This new technology uses preoperative imaging (2D 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.

PMT is a relatively novel technology which is currently being evaluated through many studies. Different PMTs are now available on 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 significantly. 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, 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 15 publications<sup>[16,22,23,32-38,45-50]</sup>, 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<sup>[7]</sup>. 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.

This is possible thanks to a set of unique benefits that only MyKnee can provide:

- CT based (MRI available as option)
- Actual Cutting Blocks, not just pin positioners
- Complete in-house technology including the assistance of a personal MyKnee technician and only 3 weeks lead time
- Gold standard material (Nylon PA 2200)
- Gold standard manufacturing process (SLS Selective Layer Sintering)

This document is a review performed on available literature about MyKnee and other patient matched technologies for knee arthroplasty. It consists of a summary of various articles and presentations, followed by a commented discussion on what literature tells us on PMT.

Finally, it is explained why MyKnee is different from other PMT, being able to deliver consistently accurate and reproducible outcomes.



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### Literature review on patient matched technologies

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

#### A My Knee

"CT-based MyKnee cutting blocks provides a number of outliers >3° for the frontal mechanical axis comparable to CAS TKA and clearly better than with conventional instrumentation"

Koch PP1, Müller D, Pisan M, Fucentese SF.- Radiographic accuracy in TKA with a CT-based patient-specific cutting block technique. Knee Surg Sports Traumatol Arthrosc. 2013 Oct;21(10):2200-5.

### 👌 🖊 y Knee

### "CT-based MyKnee cutting blocks compared with CVI improves accuracy of mechanical alignment restoration and 3D-component positioning in primary TKA"

Anderl W. et al. Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA. Knee Surg Sports Traumatol Arthrosc. 2016 Jan;24(1):102-11.

### 8 My Knee

"CT-based MyKnee cutting blocks produce statistically improved clinical outcomes when compared to the standard approach in the short term (12 months) following TKR surgery. 88% of patients achieved good-toexcellent outcome (Oxford Knee Score of >34)"

Arash Nabavi, Caroline M Olwill. Early outcome after total knee replacement using computed tomography-based patient specific cutting blocks versus standard instrumentation. Journal of Orthopaedic Surgery 2015;23(2):182-4

#### 🔨 🖊 y Knee

#### MyKnee is more accurate than conventional procedures and CAS.

Leon V - Patient matched technology vs conventional instrumentation and CAS. Poster at the 13th EFORT Congress, Berlin, May 23-25, 2012.

#### SIGNATURE BIOMET; VISIONAIRE SMITH AND NEPHEW; ZIMMER PSI; TRUMATCH DEPUY

"PSGs from these four different implants suppliers do not improve accuracy in TKA. PSGs were abandoned in 14 patients (22%) and modified in 18 (28%). The magnitude and frequency of erroneous cuts resulting from the use of PSGs do not currently support their use in clinical practice."

Victor J, Dujardin J, Vandenneucker H, Arnout N, Bellemans J.Patient-specific Guides Do Not Improve Accuracy in Total Knee Arthroplasty: A Prospective Randomized Controlled Trial. Clin Orthop Relat Res. 2014 Jan;472(1):263-71.

#### SIGNATURE BIOMET

# "Accuracy was comparable between TKAs done with PSI and those done with conventional instruments. PSI procedure was abandoned intraoperatively in eight knees (16%) because of malrotation of the femoral components and decreased slope of the tibia"

Roh YW, Kim TW, Lee S, Seong SC, Lee MC. Is TKA using patient-specific instruments comparable to conventional TKA?A randomized controlled study of one system. Clin Orthop Relat Res. 2013 Dec;471(12):3988-95.

#### SIGNATURE BIOMET

### "Patient specific instrumentation, may not be as accurate as navigated or conventional total knee replacement...".

*Webb J, Beaver R, Harvie P, Sloan K - Early experienced with customized patinent instrumentation in knee arthroplasty. Podium presentation at the 12th EFORT Congress, Copenhagen, June 1-4, 2011.* 

#### **SIGNATURE BIOMET**

**Higher outliers for the tibial and femoral component compared to conventional procedures and CAS.** *Ng VY, DeClaire JH, Berend KR, Gulick BC, Lombardi AV, Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. Clin Orthop Relat Res, 2012, 470:99-107.* 

edacta



Both PSCGs and conventional instrumentation restore limb alignment and place the components with the similar accuracy. The minimal advantages of PSCGs in terms of consistency of alignment or operative time are unlikely to be clinically relevant.

Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C. A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. Bone Joint J. 2013 Mar;95-B(3):354-9.

#### ACCURATE IMPLANT POSITIONING: CONSISTENCY OF PREOPERATIVE PLANNING

#### 🐴 🖊 y Knee

**"Out of 98 cases, the planned size of the components has been changed only twice".** *Koch P, Müller D A, Fucentese S F - Guide de coupe sur mesure pour PTG: présentation de la technique opératoire et résultats rediologiques* 

*préliminairs. Podium presentation of the 86<sup>th</sup> annual congress of the SOFCOT, Paris, France, November 7-11, 2011.* 

#### 👌 🖊 y Knee

### "Recuts were not required in the majority of case" Reliable MyKnee femoral size planning: 95% size matching.

Dussault M, Goldberg T, Greenhow R, Hampton D, Parry S, Slimack M - Preoperative planning accuracy of MyKnee system. M.O.R.E. Journal, 2012, 2:22-25.

#### 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".

Stronach B, Pelt C, Erckson J, Peters C L - Patient-specific instrumentation in TKA required frequent surgeon directed intraoperative changes. Poster presentation at the AAOS Annual Meeting, San Francisco, CA, February 7-11, 2012.

### 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, Ocotber 9-14, 2011.* 

### VISIONAIRE SMITH AND NEPHEW

#### "The VISIONAIRE system achieved unacceptable accuracy...".

Lustig S, Scholes C J, Oussedik S I, Kinzel V, Coolican M R J, Parker D A - Unsatisfactory Accuracy as Determined by Computer Navigation of VISIONAIRE Patient-Specific Instrumentation for Total Knee Arthroplasty. J Arthroplasty, 2013 Mar, 28(3):469-73.

#### SHAPEMATCH STRYKER

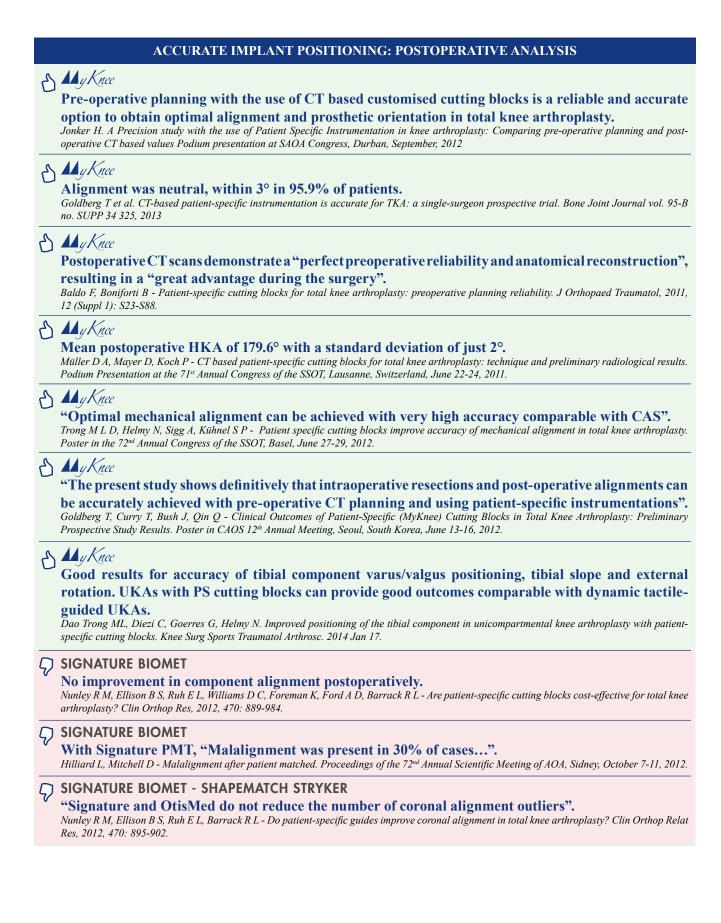
#### "The potential for malalignment with this system places implant at high risk of failure".

Klatt B Å, Goyal N, Austin M S, Hozack W J - Custom-Fit total knee arthroplasty (OtisKnee) results in malalignment. J Arthroplasty, 2008, 23(1): 26-29.

### CZIMMER PATIENT SPECIFIC INSTRUMENTATION

#### "the use of patient-matched cutting blocks is not accurate...".

Coolican M, Scholes C, Sahni V, Guiffre B, Parker D - Evaluation of the Zimmer PSI system for total knee arthroplasty using computer navigation. Proceedings of the 72<sup>nd</sup> Annual Scientific Meeting of AOA, Sidney, October 7-11, 2012.



#### VISIONAIRE SMITH AND NEPHEW

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

Parker D, Kinzel V, Scholes C, Giuffré B, Coolican M - Evaluation of the Visionaire instrumentation for total knee arthroplasty using computer navigation. Podium presentation at the AOA NZOA Meeting, Rotorua, New Zealand, October 9-14, 2011.

#### 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°).

Noble J W, Moore C A, Liu N - The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty, Jan 2012, 27(1):153-5.

#### VISIONAIRE SMITH AND NEPHEW

#### "Consistent risk of error of more 3° especially in the sagittal plane".

Conteduca F, Iorio R, Mazza D, Capern L, Bolle G, Argento G, Ferretti A - Are MRI-based patient matched cutting jigs as accurate as the tibial guides? International Orthopaedics, Mar 18, 2012.

#### **VISIONAIRE SMITH AND NEPHEW**

**Visionaire showed a poorer performance against CAS technique regarding the outliers (14% vs 10.2%).** Daniilidis K, Tibesku 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".

Conteduca F, Iorio R, Mazza D, Capern L, Bolle G, Argento G, Ferretti A - Evaluation of the accuracy of a patient-specific instrumentation by navigation. Knee Surg Sports Traumatol Arthrosc, June 27, 2012.

#### **SHAPEMATCH STRYKER**

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

Spencer B A, Mont M A - Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment. International Orhtopaedics (SICOT), 2009, 33:1571-1575.

ECONOMIC ADVANTAGES OF PATIENT MATACHED TECHNOLOGY
<ul> <li>My Knee</li> <li>MyKnee allows to increase the number of cases per surgery session, resulting in an increase of the hospital profit!</li> <li>Goldberg TD - MyKnee economical and clinical results. Podium presentation at the 6<sup>th</sup> M.O.R.E. International symposium, Stresa, Italy, May 13-14, 2011.</li> </ul>
<ul> <li>Wy Knee</li> <li>"With reduced setup time and turnover time the number of cases will doubtlessly increase". Koch P - MyKnee System: A new vision in total knee replacement. Leading Opinions - Orthopädie &amp; Rheumatologie 2, 2011: 32-35.</li> </ul>
<ul> <li>My Knee</li> <li>In comparison to a conventional approach, MyKnee with a personalized pre-operative planning allows: less sterelisation cost, less transfusion cost, less surgical time, less hospitalisation cost.</li> <li>Gagna G - Aspects economiques de la tecnologie sur mesure MyKnee en chirurgie prothetique du genou. Podium presentatiuon at the 87<sup>th</sup> Annual Congress of the SOFCOT, Paris, November 11-14, 2012.</li> </ul>
<ul> <li>VISIONAIRE SMITH AND NEPHEW</li> <li>Reduction in duration of hospital stay and operative time.</li> <li>Noble J W, Moore C A, Liu N - The value of patient-matched instrumentation in total knee arthroplasty. J Arthroplasty, Jan 2012, 27(1):153-5.</li> </ul>
VISIONAIRE SMITH AND NEPHEW Patient-specific TKA was cost neutral to cost-effective for the hospital as a result of shorter surgical time, fewer instrument trays requiring sterilization, and the benefit of increased turnover time efficiency. Alexander DeHaan, MD; Jacob Adams, MD; Matthew DeHart, BS; Thomas W. Huff, MD. Patient-Specific versus Conventional Instrumentation for Total Knee Arthroplasty: Peri-operative and Cost Differences. The Journal of Arthroplasty 29 (2014) 2065–2069

#### ECONOMIC ADVANTAGES OF PATIENT MATACHED TECHNOLOGY

# Patient matched technologies: what can we learn from literature?

LITERATURE REVIEW IN SUPPORT OF MYKNEE PERFORMANCE

Patient-matched technology (PMT) is a relatively novel alternative in total and unicompartmental knee arthroplasty (TKA, UKA) 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 most common PMTs. 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. Patient matched guides designed on MRI or MRI plus standing long radiograph show a low degree of accuracy when compared 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.

The table below shows 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.

System	Company	Image Protocol*		
Signature Biomet		MRI (CT not promoted)		
Visionaire         Smith and Nephew		MRI (3D) plus standing long leg radiograph (2D)		
Shapematch Stryker		MRI (Global Class I Recall, April 2013)		
TruMatch Depuy		LongLeg CT + cartilage estimation		
MyKnee Medacta International		High resolution CT for the knee, low resolution CT of hip and ankle		

\* 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

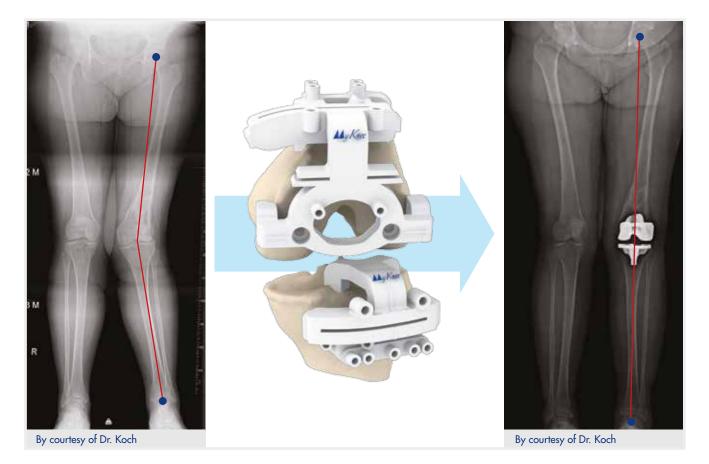
Implant positioning accuracy may be assessed in different ways. By comparing PMT results with other known techniques, conventional procedures and CAS, matching the final results with the preoperative planning or analyzing the postoperative results.

#### **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. Roh et al in a postoperative radiographic study reported a comparable accuracy between TKAs done with CTbased Signature patient-specific instruments and those done with conventional instruments. However, the patient-specific instruments were found to be unreliable: the use of the patient-specific guides was abandoned intraoperatively in eight knees (16%) during the surgery because there were discrepancies greater than 3° in the femoral component rotation and decreased posterior slope of the tibia. compared with the conventional gap method<sup>[42]</sup>. 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<sup>[10]</sup>. 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<sup>[11]</sup>. Ng et al reported acceptable results regarding the hip-kneeankle (HKA) angle but with a higher number of outliers regarding the tibial and femoral component angles with the Signature PMT technology used<sup>[12]</sup>. 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<sup>[13]</sup>. 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<sup>[14]</sup>.Kerens et al compared the results of medial UKA using Signature patient-specific instruments or conventional instruments, reporting that implant position was not different between both groups, even in the early phase of the learning curve and that perioperative results were not different between both groups<sup>[43]</sup>.

Other PMT studies in peer reviewed journals include the Visionaire from Smith and Nephew plc. Abanes'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 authors concluded that the Visionaire should reconsider its leg alignment reconstruction method<sup>[15]</sup>.

One PMT study compared the accuracy of limb alignment and component positioning after TKA performed using Zimmer Patient Specific Instruments (PSI) from Zimmer Holdings Inc. or conventional instrumentation. Chareancholvanich et al demonstrated that both the patient-specific instruments and conventional instrumentation restore limb alignment and place the components with the similar accuracy. The authors concluded that the minimal advantages of patientspecific instrument in terms of consistency of alignment or operative time are unlikely to be clinically relevant<sup>[44]</sup>. Victor et al compared the alignment between patientspecific instruments of four different companies (Signature from Biomet, Visionaire from Smith and Nephew, TruMatch from DePuy and Zimmer PSI) and conventional instrumentation and the need for applying changes in the suggested position of the patient-specific instruments.

They reported that these patient-specific instruments do not improve accuracy in TKA and that the patient specific instruments procedure was abandoned in 14 patients (22%) and modified in 18 patients (28%).

A change in sizing was the most common reason for modifying the use of the patient-specific instruments. In 13/64 patients, the implant size as determined by the patient-specific instruments preoperative planning was incorrect (5% for the femur and 16% for the tibia). Furthermore, in 9/64 patients the level of the cut was inappropriate and required intraoperative correction (8% for the femur and 6% for the tibia). The authors concluded that the magnitude and frequency of changes made in the level of the distal femoral and proximal tibial cut and in component size resulting from the use of patient-specific instruments do not currently support their use in clinical practice<sup>[41]</sup>.

MyKnee technology has also been evaluated in peer reviewed journals. Koch et al reported that CT-based MyKnee patient-specific cutting blocks provides accurate and constant radiological data with a number of outliers  $>3^{\circ}$  for the frontal mechanical axis (12.4 %) comparable to the results achieved and published with computerassisted TKA (CAS TKA) and clearly better than with conventional instrumentation. A total of 12.3 % of outliers were found for posterior tibial slope. Femoral component flexion had even better accuracy (17.3–18.1% for CAS vs. 9 % for our PSI group). The planned size of components was changed intraoperatively in a total of 10.8 % of all 602 implanted components (8.8 % for the tibial and 2 % for the femoral component). The authors concluded that comparing the outcome of the current study with the data from the literature, there does not seem to be any difference compared to computer-assisted surgery<sup>[45]</sup>. Anderl et al compared early clinical outcome (evaluated 2 years after surgery), radiological limb alignment, and 3D-component positioning between conventional and CT-based MyKnee patient-specific instrumentation. The importance of this study lies in the findings that MyKnee compared with CVI significantly improved accuracy of mechanical alignment restoration and 3D-component positioning in primary TKA. Clinical outcome was comparable between the two instrumentation groups at early follow-up, whereas significantly better clinical scores were detected in the subgroup of knees within  $\pm 3^{\circ}$ of deviation from a neutral HKA compared with outliers, demonstrating a strong correlation between accurate implant alignment and improved clinical outcomes<sup>[46]</sup>. Nabavi et al compared early outcome of TKA using CT-based MyKnee patient-specific cutting blocks versus standard instrumentation. The authors reported improved clinical outcomes when using the MyKnee, with 88% of patients achieved good-to excellent outcome (Oxford Knee Score of >34) at 12 months, while standard technique reports only 71%. It was also reported that patients in the PSI group result in lower blood loss and transfusion rate and and better joint kinematics<sup>[47]</sup>. Léon et al was able to demonstrate the accuracy and reliability of the MyKnee system by comparing it to conventional and navigated instrumentation. 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<sup>[16]</sup>.

#### **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<sup>[17]</sup>.

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<sup>[18]</sup>. 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<sup>[19]</sup>.

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<sup>[20]</sup>.

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<sup>[21]</sup>. 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<sup>[22]</sup>. 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<sup>[23]</sup>.

#### **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<sup>[24]</sup>. 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)<sup>[25]</sup>. 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<sup>[26]</sup>).

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<sup>[27]</sup>. 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 extramedullary (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 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%)<sup>[28]</sup>. The same authors, Conteduca et al, conduced 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<sup>[29]</sup>. 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  $(14\% \text{ vs } 10.2\%)^{[1]}$ .

With Shapematch, Spencer et al described the postoperative analysis of their initial experience. Their goal was to assess the intraoperative events and longleg 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)<sup>[31]</sup>. Post-operative analysis has also been assessed with MyKnee. Jonker compared post-operative CT scans to the pre-planned surgery finding the same values for AP and lateral limb alignment, femoral external rotation and flexion as the pre-operative, with no significant deviation (maximum 2° of difference). The authors concluded that pre-operative planning with the use of MyKnee CT based customised cutting blocks is a reliable and accurate option to obtain optimal alignment and prosthetic orientation in TKA<sup>[48]</sup>. Goldberg et al evaluated results of TKA using CT-based MyKnee, finding a neutral alignment, within 3° in 95.9% of patients. The results also indicated a strong correlation between planned vs. actual bony cuts and good short term clinical and radiographic results, demonstrating the efficacy of CT-based PSI for TKA<sup>[49]</sup>.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<sup>[32]</sup>.

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<sup>[33]</sup>. 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 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<sup>[34]</sup>. 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  $\pm 4^{\circ}$ ) and tibial slope with a mean of 2.86°, which are comparable to navigation results. The authors concluded that optimal mechanical alignment may be achieved with MyKnee. They also discussed the reduction of surgery time with the use of this technique<sup>[35]</sup>. Again Trong et al investigated, using postoperative CT scan, tibia component alignment of medial UKAs implanted with patient specific MyKnee cutting blocks. They reported good results for accuracy of tibial component varus/valgus positioning, tibial slope and rotation with only very little deviation to the preoperative planning. In all of the 25 investigated cases, the implanted size of the tibial and femoral component was the same as planned preoperatively. The authors suggest that UKAs with patient-specific cutting blocks can provide good outcomes comparable with those with dynamic tactile-guided UKAs, improving the accuracy of tibia component positioning<sup>[50]</sup>.

#### ECONOMIC ADVANTAGES OF PATIENT MATCHED TECHNOLOGY

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<sup>[30]</sup>.



Surgical table with the instruments needed for a MyKnee procedure. (By courtesy of Dr. Koch)

DeHaan et al investigated the role of Visionaire patientspecific instrumentation in TKA evaluating peri-operative and cost differences against conventional technique. The authors reported that patient-specific instrumentation in TKA averaged 20.4 min less surgical time and resulted in no increase in peri-operative morbidity as opposed to conventional TKA and had a 42% decrease in O.R. turnover time.The authors concluded that the routine use of patient-specific instrumentation is associated with considerable cost savings for hospital as a result of shorter surgical time, fewer instrument trays requiring sterilization, and the benefit of increased turnover time efficiency<sup>[51]</sup>.

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<sup>[36]</sup>. 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<sup>[37]</sup>. The economic benefits of MyKnee were also studied by Gagna. He revealed that a wellplanned surgery with MyKnee will allow the hospital to reduce costs associated with sterilization, O. R. time usage and increase efficiency<sup>[38]</sup>.

#### CONCLUSIONS

The goal of this literature review was to assess the validity of PMT technology. As mentioned, there are multiple options from various 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.

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 significantly. Taking this into account, it is easy to understand that the 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 for CT image acquisition, has performed very well clinically. It has been 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 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 in the preoperative planning process. It was claimed that MRI may not produce the best results for the data needed to be obtained<sup>[29]</sup>. 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 valid, reliable, and advantageous technology. Adaptation of this technology will permit the benefits that have been discussed, including: decrease in set-up 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<sup>[7]</sup>. 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.

# Patient matched knee instrumentations: are they all the same?

LITERATURE REVIEW IN SUPPORT OF MYKNEE DESIGN RATIONALE

By analyzing recent literature about patient-matching technology in TKA and UKA, we see that the results are controversial. In fact, the majority of the published results do not support the improvement of accuracy that patientmatched technology was created to provide.

These results may jeopardize the perceived reliability of the technology, leaving 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 15 publications<sup>[16,22,23,32-38,45-50]</sup>, 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). And one of them, the Stryker ShapeMatch, was also the subject of a Class I Urgent Medical Device Recall on April 10, 2013.

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 THE BEST CHOICE IN PMT

System	Company	Image Protocol	
Signature	Biomet	MRI	
PSI	Zimmer	MRI	
Visionaire	Smith and Nephew	MRI + Long Leg X-Ray	
ShapeMatch	Stryker	MRI	

PM Systems promoting 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 wear pacemakers, are obese or claustrophobic.

**4. Hardware**: MRI based cutting blocks can't be used to revise unicompartmental knee or to perform TKA and UKA 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 demonstrates that "bone models generated from MRI scans were dimensionally less accurate than those generated from CT scans"<sup>[8]</sup>. 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 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"<sup>[9]</sup>.

More evidence confirming the use of CT over MRI in bone reconstruction is demonstrated in a current market trend. Zimmer-Biomet, 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.

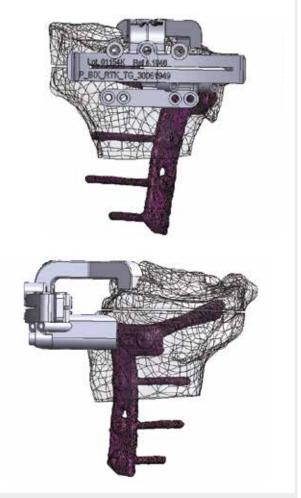
#### ENHANCED CT ADVANTAGES: COMFORT OF IMPLANTATION IN CHALLEN-GING PRE-OPERATIVE SCENARIOS<sup>[39,40]</sup>

A very interesting opportunity that MyKnee offers to both surgeons and patients is the possibility to address special cases with challenging pre-operative condition. CT has been proven to be an accurate and straightforward tool to achieve consistent and reproducible results in patient matched technology thanks to clear image processing and limited examination time minimizing potential artefacts. The wide range of CT applications allows MyKnee to address an extensive number of preoperative conditions that are impossible to be faced with MRI technology. Patients with preexisting metal hardware around the joint can be easily addressed with CT-based MyKnee patient matched cutting blocks. MyKnee technicians have been asked countless times to plan monocompartmental knee revisions or primary knee replacements in presence of tibial or femoral plates or screws. Through the MyKnee planning tool, they are able to predict conflicts between the existing hardware and the final implant and to suggest special MyKnee cutting block positioning.

Plate with screws on the medial side of the tibia:



Pre-operative CT Scan



MyKnee analysis



Post-operative CT Scan

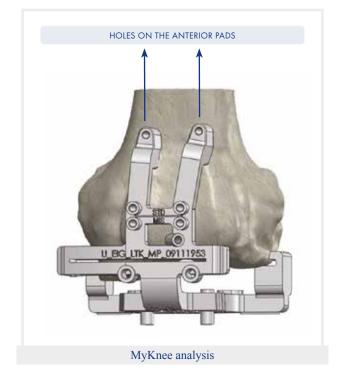
#### Patello-femoral joint implant revision:



Pre-operative CT Scan



Post-operative CT Scan



#### CT VS LONG LEG RADIOGRAPH: WHY LONG LEG RADIOGRAPH IS NOT THE RIGHT CHOICE TO DEFINE HKA IN PMT

System	Company	Image Protocol	
Visionaire	S&N	MRI + Long Leg X-Ray	

PM Systems using 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.



#### BONE AND OSTEOPHYTES VS CARTILAGE: WHY CARTILAGE IS NOT AN IDEAL ANCHORING AREA FOR PATIENT-MATCHED GUIDES

System	Company	Image Protocol
TruMatch	Depuy	Long leg CT + cartilage estimation
Visionaire	S&N	MRI + Long Leg X-Ray
Signature	Biomet	MRI
PSI	Zimmer	MRI

PM Systems anchoring the guides on cartilage

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, the more stable the cutting block will be. 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.



TruMatch



MyKnee

System	Company	Image Protocol
TruMatch	Depuy	Long leg CT + cartilage estimation
MyKnee	Medacta	3 separated CT scans (hip, knee and ankle)

### CT DRAWBACK: IS RADIATION COMING FROM CT SCANS DANGEROUS?

PM Systems promoting CT

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 department of the Balgrist University Hospital of Zurich. In the following table the equivalent dose are summarized.

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<sup>[37]</sup>.



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 additional benefits for the image quality, as femoral and tibial diaphysis included in the scan are not useful for the reconstruction of the bone models.

Where	Ankle	Knee	Нір
Dose	0.07 mSv	0.16 mSv	5 mSv
Comparable to	Chest X-Ray	Transatlantic flight	Yearly radiation dose for each Swiss citizens

### Key features

### 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.

#### **MYKNEE OFFERS YOU MORE**

- CT based (MRI available as option);
- Actual Cutting Blocks, not just pin positioners;
- Complete in-house technology including the assistance of a personal MyKnee technician and only 3 weeks lead time;
- Gold standard material (Nylon PA 2200);
- Gold standard manufacturing process (SLS Selective Layer Sintering).



### Abstracts

Radiographic accuracy in TKA with a CT-based patient-specific cutting block technique.

KOCH P., MÜLLER D., PISAN M., FUCENTESE S. - Knee Surg Sports Traumatol Arthrosc. 2013 Oct;21(10):2200-5.

#### PURPOSE

Patient-specific instrumentation (PSI) technology for the implantation of total knee arthroplasty (TKA) has a rising interest in the orthopaedic community. Data of PSI are controversially discussed. The hypothesis of this paper is that the radiological accuracy of CT-based PSI is similar to the one of navigated TKA published in the literature.

#### METHODS

Since 2010, all 301 consecutively performed PSI TKAs (GMK MyKnee\_) were included in this study. The radiological assessment consisted in a preoperative and postoperative standard X-ray and long-standing X-ray. Changes from the planned to the definitively implanted component size were documented. Postoperative analysis included limb alignment and position of femoral and tibial components (for varus/valgus and flexion or tibial slope).

#### RESULTS

The postoperative average hip-knee-ankle angle was  $180.1^{\circ} \pm 2.0^{\circ}$ . In the frontal plane a total of 12.4 % of outliers >3°, for the tibial components 4.1 % of outliers >3° and for the femoral components 4.8 % of outliers >3° were measured. A total of 12.3 % of outliers for posterior tibial slope and 9 % of outliers >3° for the femoral flexion were noted. 10.8 % of the 602 planned size components were adapted intraoperatively.

#### CONCLUSION

Although it is still unknown which limb axis is the correct one for the best clinical result, a technology providing the aimed axis in a most precise way should be chosen. Comparing the outcome of the current study with the data from the literature, there does not seem to be any difference compared to computer-assisted surgery. Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA.

ANDERL W. ET AL. - Knee Surg Sports Traumatol Arthrosc. 2016 Jan;24(1):102-11.

#### PURPOSE

The aim of this prospective study was to compare early clinical outcome, radiological limb alignment, and three-dimensional (3D)-component positioning between conventional and computed tomography (CT)based patient-specific instrumentation (PSI) in primary mobile-bearing total knee arthroplasty (TKA).

#### **METHODS**

Two hundred ninety consecutive patients (300 knees) with severe, debilitating osteoarthritis scheduled for TKA were included in this study using either conventional instrumentation (CVI, n = 150) or PSI (n = 150). Patients were clinically assessed before and 2 years after surgery according to the Knee-Society-Score (KSS) and the visual-analog-scale for pain (VAS). Additionally, the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC) and the Oxford-Knee-Score (OKS) were collected at follow-up. To evaluate accuracy of CVI and PSI, hip-knee-ankle angle (HKA) and 3D-component positioning were assessed on postoperative radiographs and CT.

#### RESULTS

Data of 222 knees (CVI: n = 108, PSI: n = 114) were available for analysis after a mean follow-up of  $28.6 \pm 5.2$ months. At the early follow-up, clinical outcome (KSS, VAS, WOMAC, OKS) was comparable between the two groups. Mean HKA-deviation from the targeted neutral mechanical axis (CVI:  $2.2^{\circ} \pm 1.7^{\circ}$ ; PSI:  $1.5^{\circ} \pm 1.4^{\circ}$ ; p < 0.001), rates of outliers (CVI: 22.2 %; PSI: 9.6 %; p = 0.016), and 3D-component positioning outliers were significantly lower in the PSI group. Non-outliers (HKA:  $180^{\circ} \pm 3^{\circ}$ ) showed better clinical results than outliers at the 2-year follow-up.

#### CONCLUSION

CT-based PSI compared with CVI improves accuracy of mechanical alignment restoration and 3D-component positioning in primary TKA. While clinical outcome was comparable between the two instrumentation groups at early follow-up, significantly inferior outcome was detected in the subgroup of HKA-outliers.

## Early outcome after total knee replacement using computed tomography-based patient specific cutting blocks versus standard instrumentation.

NABAVI A., OLWILL C.M. - Journal of Orthopaedic Surgery 2015;23(2):182-4

#### PURPOSE

To compare early outcome of total knee replacement (TKR) using computed tomography (CT)–based patient-specific cutting blocks versus standard instrumentation.

#### **METHODS**

40 men and 44 women (90 knees) aged 45 to 88 (mean, 65) years who underwent TKR using standard instrumentation were compared with 39 men and 43 women (90 knees) aged 44 to 85 (mean, 64) years who underwent TKR using CT-based patient specific cutting blocks. A single surgeon performed all TKRs through the medial parapatellar approach using a cemented prosthesis, with the posterior cruciate ligament retained and the patella resurfaced.

#### RESULTS

Respectively in the standard and patient specific instrumentation groups, 74 and 70 patients were followed up for a mean of 30 and 14 months. The mean Oxford Knee Score was 19 and 19 preoperatively, 34 and 34 at 3 months, and 37 and 40 at 12 months (p=0.02). 71% and 88% of patients achieved good-to excellent outcome (Oxford Knee Score of >34) at 12.

#### Patient matched technology vs conventional instrumentation and CAS.

LEON V. - Poster at the 13th EFORT Congress, Berlin, May 23-25, 2012.

#### INTRODUCTION

There is surprisingly little evidence to support the widely held assumption that restoring the coronal alignment to  $180^{\circ} \pm 3^{\circ}$  in total knee arthroplasty leads to improved function and longevity. Some publications consider a deviation from the neutral mechanical axis greater than  $\pm 3^{\circ}$  is demonstrated to decrease the implant longevity. On the other hand, some authors affirm that there is no statistical difference between outliers in mechanical alignment and well aligned knees. We ignore a strict correlation between the preoperative deformity and the optimum postoperative axis and more work must be done to clearly define the appropriate target for limb alignment in various patient groups after total knee arthroplasty.

#### **OBJECTIVES**

The aim of this study is to assess the accuracy of patient matched technology with MyKnee system and to compare this to conventional mechanical instrumentation and to computer assisted surgery.

#### **METHODS**

The mechanical axes of the long leg before and after operation were evaluated. Lateral radiographs were taken too. We have analyzed the Hip-Knee-Ankle angle (HKA), the Condylar-Hip angle (CH), the Plateau-Ankle or medial proximal tibial angle (PA), the lateral angle of the femoral component and the posterior tibial slope. We have analyzed 129 total knee prosthesis performed by the same team with four instrumentation systems: conventional mechanical instrumentation (A), computer assisted surgery for the tibial time combined with the ligament balance system (B), Medacta®'s navigation system (C) and our first twenty cases with MyKnee® patient matched technology (D). 100% of the implants were all cemented and fixed bearing with ultracongruent insert. Mean age at time of surgery: 70 years, ranging from 47 to 84. Mean body mass index of 32.49 Kg/m2. 78.3% of the patients are female and 21.7% male.

#### RESULTS

HKA preoperative:  $172,74^{\circ} \pm 6,14^{\circ}$ , with remarkable predominance of varus knees. Preoperative evaluation ordered by the different systems: HKA angle: A 171,91° ± 5,23°, B 174° ± 4,37°, C 173,84° ± 6,98° and D 170,9°  $\pm$  6,43°. CH angle: A 90,2°  $\pm$  3,49°, B 90,64°  $\pm$  2,62°, C  $91,55^{\circ} \pm 3,15^{\circ}$  and D  $89^{\circ} \pm 3,39^{\circ}$ . PA angle: A  $86,23^{\circ} \pm$  $4,94^{\circ}$ , B  $87^{\circ} \pm 2,51^{\circ}$ , C  $86,55^{\circ} \pm 2,05^{\circ}$  and D  $85,8^{\circ} \pm 2,31^{\circ}$ . Postoperative HKA angle: A  $178,8^{\circ} \pm 3,97^{\circ}$ , B  $179,14^{\circ} \pm$  $3,74^{\circ}$ , C 180,37°  $\pm 2,05^{\circ}$  and D 180,5°  $\pm 2,8^{\circ}$ . Postoperative CH angle: A 89,52° ± 3,43°, B 90,21° ± 3,04°, C 90,94°  $\pm$  1,67° and D 90,8°  $\pm$  2,14°. Postoperative PA angle: A  $89,3^{\circ} \pm 2,88^{\circ}$ , B  $89,21^{\circ} \pm 1,67^{\circ}$ , C  $89,31^{\circ} \pm 1,1^{\circ}$  and D  $89,7^{\circ} \pm 1,56^{\circ}$ . No significant difference among different alignment systems was obtained, but there is a difference if we consider the frequency distribution between outliers in mechanical alignment and well aligned knees. HKA angle 180° ± 3°: A 68,18% (31,82% outliers), B 57,14% (42,86% outliers), C 88,24% (11,76% outliers) and D 90% (10% outliers). CH angle 90° ± 2°: A 59,10% (40,90% outliers), B 35,71% (64,29% outliers), C 74,50% (25,50% outliers and D 90% (10% outliers). PA angle  $90^{\circ} \pm 2^{\circ}$ : A 81,82% (18,18% outliers), B 78,57% (21,43% outliers), C 94,12% (5,88% outliers) and D 85% (15% outliers).

#### CONCLUSION

In spite of being in the learning curve of MyKnee technique, the percentage of patients with neutral alignment, with a tolerance of  $\pm$  3°, increased from 5% pre-operatively to 90% postoperatively. Attending to the obtained results, our current preference to perform TKA surgery is MyKnee system. This system offers additional advantages, but further studies are needed to address this.

Guide de coupe sur mesure pour PTG: présentation de la technique opératoire et résultats rediologiques préliminairs.

KOCH P., MÜLLER D., FUCENTESE S. - Podium presentation of the 86<sup>th</sup> annual congress of the SOFCOT, Paris, France, November 7-11, 2011.

#### INTRODUCTION

Le positionnement correct des implants lors de prothèses totales du genou (PTG) reste encore aujourd'hui un problème majeur. Plusieurs études montrent que la chirurgie assistée par ordinateur (CAO) améliore la précision de manière significative par rapport à la chirurgie conventionnelle. Cependant, la CAO a également ses limites et engendre non seulement des coûts supplémentaires, mais aussi un temps opératoire plus long avec tous les risques de complications additionnelles associés. Durant les deux dernières années, la technologie de sintérisation laser des poudres de polyamide, pour la création des guides de coupe sur mesure pour chaque patient se basant soit sur un IRM ou un scanner préopératoire, a émergé. Nous présentons notre expérience avec le système MyKnee (Medacta International SA, Suisse), qui combine en une seule pièce le guide et le bloc de coupe.

#### MATÉRIEL

49 patients consécutifs ont été choisis et analysés prospectivement pour évaluer la précision de l'implantation des composants.

#### MÉTHODE

A l'aide d'un CT scan, un modèle osseux tridimensionnel du genou du patient est créé sur la base de l'axe hanchegenou-cheville. Ce modèle servira de base à la mise sur pied des guides de coupe sur mesure. Le chirurgien peut planifier ses repères, définir la taille de l'implant, les niveaux de résection, la rotation fémorale et la pente tibiale. Après un abord conventionnel, les guides de coupe tibial et fémoral sont mis en place de manière univoque en se servant des repères osseux et les coupes se font directement à travers les guides. Les étapes successives sont faites de la technique conventionnelle. Des radiographies axe "long" pre- et postopératoire étaient disponibles pour les analyses. La taille des implants planifiée et implantée a été comparée.

#### RÉSULTATS

L'axe mécanique postopératoire était entre  $3^{\circ}$  de va rus et 4.2° de valgus en comprenant 6 exceptions en dehors des +/- 3°. La pente tibiale var ie entre 0° et 10° (10 exceptions) et la flexion du composant fémoral variait entre 0.2° et 6.4° (8 exceptions). Sur 98 cas, la taille planifiée des composants a été changée à deux reprises seulement.

#### DISCUSSION

Comparés aux études effectuées, les résultats radiologiques de poses avec notre technologie de guides de coupe sur mesure est équivalente aux techniques les plus précises de CAO du genou. Le nombre d'exception est identique pour tous les paramètres calculés, mais plus de données sont nécessaires avant de définir une statistique significative.

Conclusion: Notre expérience préliminaire avec la technologie de guides de coupe sur mesure Mynee basé sur CT scan s'est avérée être précise, fiable et efficace.

#### Preoperative planning accuracy of MyKnee system.

DUSSAULT M., GOLDBERG T., GREENHOW R., HAMPTON D., PARRY S., SLIMACK M. - M.O.R.E. Journal, 2012, 2:22-25.

Errors in surgical technique and small changes in component positioning compromise postoperative performance of a prosthesis, potentially decreasing implant survival. A patient-matched approach to total knee arthroplasty, when compared to the traditional approach, should show improvements which are potentially beneficial to both surgeon and patient. The main purpose of the MyKnee patient-matched instruments is to provide 3D pre-operative planning, for a total knee replacement, and create anatomical cutting blocks which are reproduced from CT or MRI scans of each individual patient.

This should provide easier and more stable positioning of the cutting block, more accurate positioning of components and improve patient satisfaction as a result of reduced surgical stress. The data collected from 155 MyKnee cases, shows this system provides accuracy. The difference between the planned and the performed resections was on average less than 0.8mm. Recuts were not required in the majority of cases. The size matching, between the planned and the actual component implanted, was shown to be accurate, particularly the femoral component with only one size error recorded in 5% of cases. This data confirms the precision of the system and potential increase in prosthesis survival. The surgeons were completely satisfied with the technique in 97% of cases, and confirmed cutting blocks were easily positioned and felt stable.

A Precision study with the use of Patient Specific Instrumentation in knee arthroplasty: Comparing pre-operative planning and post-operative CT based values.

JONKER H. - Podium presentation at SAOA Congress, Durban, September, 2012

#### BACKGROUND

In our pursuit of surgical accuracy and precision we often neglect to evaluate our results objectively. With the use of Computerised Tomography (CT) in pre-operative planning we can use the same technology in order to evaluate surgical accuracy.

#### HYPOTHESIS

The use of Patient Specific Instrumentation (CT based) produces an accurate intra operative guide for precision cutting in knee arthroplasty.

#### METHOD

A prospective study using Patient Specific Instrumentation (customized cutting blocks) was performed on 35 patients. The small cohort value is due to the high costs of postoperative CT. A CT based software was used to evaluate the pre-operative knee alignment. Surgery was planned and verified on a web based programme with the use of 3D models. Cutting blocks were custom made and used as intra operative guide to make the relevant cuts.

Pre and post-operative CT scans were compared for AP and lateral alignment, femoral external rotation and flexion and tibial slope. Knee Society scores were also used to evaluate the clinical outcome.

#### RESULTS

The values for AP and lateral limb alignment, femoral external rotation and flexion were the same as the preoperative values with no significant deviation (maximum 2 degree difference). The posterior tibial slope was the only value that showed significant deviation from the pre-planned values.

#### CONCLUSION

There was a significant difference for the posterior tibial slope but otherwise we found no difference in pre and post-operative limb alignment measurements. Preoperative planning with the use of CT based customised cutting blocks is a reliable and accurate option to obtain optimal alignment and prosthetic orientation in total knee arthroplasty.

## CT-based patient-specific instrumentation is accurate for TKA: a single-surgeon prospective trial.

GOLDBERG T. ET AL. - Bone Joint Journal vol. 95-B no. SUPP 34 325, 2013

The present IRB approved study evaluates the early results of 100 TKAs using CT-based Patient-Specific Instrumentation (PSI) (MyKnee®, Medacta International, SA, Castel San Pietro, Switzerland). For this technique, a CT scan of the lower extremity is obtained, and from these images, the knee is reconstructed 3-dimensionally. Surgical and implant-size planning are performed according to surgeon preference, with the goal to create a neutral mechanical axis. Once planned and approved, the blocks are made.

Outcomes measured for the present study include surgical factors such as Tourniquet Time (TT) as a measure of surgical efficiency, the actual intraoperative bony resection thicknesses to be compared to the planned resections from the CT scan, and complication data. Furthermore, pre- and post-operative long standing alignment and Knee Society Scores (KSS) were obtained. During surgery, the PSI cutting block is registered on the femur first and secured with smooth pins. No osteophytes are removed as the blocks use the positive topography of the osteophytes for registration. The distal femoral resection is performed directly through the block. An appropriate sized 4-in-1 block is placed and the remaining resections are performed. The tibial resection block is registered and resection performed. Final bone preparation, patella resurfacing, and trialing is performed as is standard to all surgical techniques.

There were 50 Left and 50 Right TKA's performed in 61 females and 39 males. All patients had diagnosis of osteoarthritis. The average BMI was 31.1 and average age was 64.5 (range 41–90). 79 patients had pre-operative varus deformities with Hip Knee Angle (HKA) average of 174.7° (range  $167^{\circ}$ – $179.5^{\circ}$ ). 19 patients had pre-operative valgus deformities averaging  $184.4^{\circ}$  (range  $180.5^{\circ}$ – $190^{\circ}$ ). Three patients were neutral.

Average TT was 31.2 minutes (range 21–51 minutes). With regard to the bony resections, the actual vs. planned resections for the distal medial femoral resection was 8.7 mm vs. 8.9 mm respectively. Further actual vs. planned femoral resections include distal lateral 7.2 vs. 6.7 mm; posterior medial 8.3 vs. 8.9 mm; and posterior lateral 6.2 vs. 6.8 mm. The actual vs. planned tibial resections recorded include medial 6.4 vs. 6.3 mm and lateral 8.3 vs. 8.2. The planned vs. actual bony cuts are strongly correlated, and highly predictive for all 6 measured cuts (p=<.001). No intraoperative complications occurred.

Average KSS improved from 45.9 to 81.4, and KSS Function Score improved from 57.7 to 73.5 at 6 weeks postoperative visit. There were no thromboembolic complications. Two patients had a post-operative infection requiring surgical intervention.

Post-operative alignment was 179.36° (range 175°–186°) for all patients. Alignment was neutral, within 3° in 95.9% of patients. There were only 4 outliers with maximal post-operative angulation of 6°.

In conclusion, these early results demonstrate efficacy of CT-based PSI for TKA. The surgery can be performed efficiently, accurately, and safely. Furthermore, excellent short term clinical and radiographic results can be achieved.

# Patient-specific cutting blocks for total knee arthroplasty: preoperative planning reliability.

BALDO F., BONIFORTI B. - Journal of Orthopaedics and Traumatology, 2011, 12 (Suppl 1): S23-S88.

#### **INTRODUCTION**

The main purpose in knee surgery is anatomic axis reconstruction, in order to grant the best function and the lowest failure rate. Computer-assisted surgery was a great technical improvement, but disadvantages were higher complexity, with longer operating time and costs. Given this situation a new system was developed, with patient matched cutting blocks created on preoper-ative imaging data. Purpose of this work is to verify anatomic reconstruction obtained and preoperative planning reliability.

#### MATERIALS AND METHODS

Five patients with knee arthrosis were included in this study, 1 male ad 4 female, mean age 69.2 years (range 60-74 years). They underwent a baseline CT scan of the knee and scout images of the hip and ankle before surgery. For each patient images were elaborated with Medacta My Knee System, creating a preoperative planning. The surgeon inspected and validated the planning concerning the implant size, the different resection levels and femoral rotation. The planning was used to create a threedimensional bone model on the specific patient anatomy. This bone modeling acts as the base used to create the anatomical cutting blocks. These were used during surgery for resection, fitting the patient's knee morphology without using any alignment jigs to position them. Each patient underwent a further CT after surgery, to verify correct anatomic reconstruction and preoperative reliability.

#### RESULTS

Data are still on elaboration, but preliminary ones show perfect preoperative reliability and anatomical reconstruction.

#### DISCUSSION

Looking at preliminary results MyKnee system allows, respect to computer-assisted surgery, greater precision in preoperative planning, and consequently during surgery, shorter operative time, low number of instruments on operative table and lower costs. Other studies show a reduction of blood loss and lower systemic emboli.

#### CONCLUSION

From preliminary results My Knee system allows a greater preoperative planning reliability and higher accuracy in ana- tomical reconstruction, with also greater advantages during surgery.

# CT based patient-specific cutting blocks for total knee arthroplasty: technique and preliminary radiological results.

MÜLLER D., MAYER D., KOCH P. - Podium Presentation at the 71<sup>st</sup> Annual Congress of the SSOT, Lausanne, Switzerland, June 22-24, 2011.

#### **INTRODUCTION**

Accuracy in component positioning for total knee arthroplasty (TKA) remains a major concern. Computerassisted surgery improves the precision significantly compared with standard manual techniques. However, computer navigation has limitations such as investment costs, longer operation time and additional complication risks. The technology of polyamide laser sintering to create patient-specific orientation tools according to preoperative CT-data has been emerging. Here we present our experience with the MyKnee technique (Medacta International SA) which combines the guidance block and cutting block in one.

#### **METHODS**

A preoperative CT scan is used to define simultaneously the hip-kneeankle axis (HKA) and to create tridimensional bone model of the patient specific knee anatomy. By Internet, the surgeon can plan the operation according to his preferred landmarks. After a standard surgical approach the sterilized cutting blocks are mounted to the tibial plateau and the distal femur, adapted to unambiguous bony landmarks such as prominent osteophytes and an extramedullar position control can be performed. After pinning, the cuts are performed directly through that block. Further surgical steps are following according standard techniques. The first clinical and radiological control of the patient was six weeks postoperative. The radiographs are analyzed for the HKA and the positioning of the femoral and tibial components in comparison to the preoperative planning.

#### RESULTS

Until January 2011, 49 patients (53 knees, 33w, 16m; mean age 69.9 years) have been operated with the new MyKnee technique by two experienced surgeons. In two patients the definitive implant size differs from the preoperative planning. The mean HKA preoperative was  $181.6^{\circ} (\pm \text{SD} 7.5^{\circ})$  postoperative a mean HKA of  $179.6^{\circ} (\pm \text{SD} 2.0^{\circ})$  was reached. The difference between the planned and the realized posterior tibial slope was on average  $1.0^{\circ} (\pm \text{SD} 2.8^{\circ})$ . The flexion of femoral component differs from the planning  $0.4^{\circ} (\pm \text{SD} 1.8^{\circ})$  The mean operation time was 79 minutes ( $\pm \text{SD} 18 \text{ minutes}$ ).

#### CONCLUSION

Our preliminary experience indicates that the MyKnee technology of CT-based patient-specific cutting blocks represents a reliable and straightforward technique, equal in precision to computer-assisted total knee replacement. Through the reduced number of operating steps and instruments the operation time could be shortened.

# Patient specific cutting blocks improve accuracy of mechanical alignment in total knee arthroplasty.

TRONG M.L.D., HELMY N., SIGG A., KÜHNEL S.P. - Poster in the 72<sup>nd</sup> Annual Congress of the SSOT, Basel, June 27-29, 2012.

#### **INTRODUCTION**

Long-term survival of TKA is mainly determined by optimal positioning of the components and prosthesis alignment. Implant positioning can be optimized by computer assisted surgery (CAS). However, CAS requires specially educated surgeons and operating staff, is time consuming and costly. This study was performed to evaluate the relatively new surgical technique, based on patient-specific cutting blocks regarding implant position and operating time.

#### **METHODS**

113 knees (62 right, 51 left) in 106 patients with a mean age of 70 years were included in this study. Our surgical technique uses patient-specific cutting blocks (PSCB), allowing to realize pre-operative planning of axial and rotational alignment, based on CT images of the patient's knee. Pre- and postoperative mechanical axis, represented by the hip knee ankle (HKA), the proximal tibial angle (PTA), the distal femoral angle (DFA) and the tibial slope (TS) were measured on lateral x-rays and on longleg-standing x-rays. For all patients the deviation from expected ideal values was calculated. Furthermore the operating time of the whole procedure was recorded.

#### RESULTS

With a margin of error for alignments each within  $\pm 4^{\circ}$ , we obtained a success rate of 92.9% for the HKA, 98.2% for the PTA and 99.1% for the DFA. With a margin of error within  $\pm 3^{\circ}$ , success rates were 81.4% for HKA, 92% for TPA and 94.7% for DFA. The TS showed postoperative results of 2.86 $\pm 2.02^{\circ}$  (mean change 1.76 $\pm 2.85^{\circ}$ ). Mean surgical time of the procedure was in general lower than for CAS in current literature.

#### CONCLUSION

With the PSCB-technique for TKA, optimal mechanical alignment can be achieved with very high accuracy compared with CAS. Concerning mechanical leg axis, our results were slightly inferior. However, the values of each single component alignment showed excellent results. We explain this discrepancy due to postoperative ligamentous laxity in patients with extreme preoperative varus/valgus deformity which are emphasized in weight bearing x-rays.

Those cases should have initially been discussed for constrained implants. Furthermore, the operating time can be reduced compared to CAS due to a reduced number of surgical steps in this easy technique. We think that PSCB-technique for TKA is a relatively easy method with very good radiological results concerning mechanical alignment in coronal and sagittal planes in comparison to CAS. Clinical Outcomes of Patient-Specific (MyKnee) Cutting Blocks in Total Knee Arthroplasty: Preliminary Prospective Study Results.

GOLDBERG T., CURRY T., BUSH J., QIN Q. - Poster in CAOS 12th Annual Meeting, Seoul, South Korea, June 13-16, 2012.

#### **INTRODUCTION**

#### RESULTS

There is a paucity of published data available to support patient specific technology in performance of total knee arthroplasty (TKA). A prospective study is currently underway, designed to evaluate clinical outcomes resulting from this technique. This technique uses a pre-operative CT scan of the lower extremity to plan the surgery. Cutting blocks are built, based on the positive topography of the bones, to achieve a neutral mechanical axis after the surgery (Figures 1,3). The surgeon has oversight throughout the process, with the ability to evaluate the CT data and make changes to the plan prior to construction of the cutting blocks. The blocks are designed to achieve pre-planned bony resection depths, and thus appropriate intraoperative implant placement. The theoretical benefits are that speed of surgery should increase and intraoper-ative complexities should be reduced. IRB approval for prospective research was obtained prior to study conduct.

#### **METHODS**

One hundred (100) patients of the senior author are now consented into the research study, and will undergo TKA using the MyKnee (Medacta, CSP) technique. Preoperative assessments, including patient pain and quality of life scores, long-standing radiographs, CT scans, and relevant clinical data are considered. Intraoperative data includes tourniquet time (TT), estimated blood loss (EBL), complications, and actual vs. intended bone resections of the femur and tibia. Femoral resections captured include distal medial cut, distal lateral, posterior medial and posterior lateral. Medial tibia, and lateral tibia cuts are likewise compared. Post-operative follow-up for this report includes data captured for the first 50 research subjects.

Results from 50 consecutive subjects, were available for review using the MyKnee technique. Forty one subjects had pre-operative varus deformities with a mechanical axis average of 4.5° (range .5°-12.5°). Nine subjects had valgus deformities with an alignment of 4° (range .5°- 9.5°). Regardless of pre-operative deformity, the post-operative alignment for all subjects averaged 0.6 ° varus (range 0°-5.5°). 93% were aligned within 3° of neutral. Bony resection data of the distal medial femur actual vs. planned was 8.8 vs. 9.0 mm respectively. The distal lateral femur was 7.1 vs. 6.4 mm; posterior medial femur 8.6 vs. 9.2 mm; and posterior lateral femur 6.2 vs. 6.9 mm. Furthermore, the actual vs. planned tibial resections include medial 6.2 vs. 5.9 mm and lateral 8.4 vs. 8.3 mm (Figure 2). The correlation between all actual vs. planned bone resections is 0.84 (p <.001). All patients had cartilage "scraped" by the surgeon, to remove cartilage that may cause erroneous measurements, as CT scans don't account for cartilage. Also, two tibia cutting blocks weren't used by the surgeon because he wasn't comfortable with the fit, and standard instrumentation was used seamlessly and successfully.

## Improved positioning of the tibial component in unicompartmental knee arthroplasty with patient-specific cutting blocks.

TRONG M.L.D., DIEZI C., GOERRES G., HELMY N. - Knee Surg Sports Traumatol Arthrosc. 2014 Jan 17.

#### PURPOSE

Unicompartmental knee arthroplasty (UKA) has recently regained popularity for the treatment of osteoarthritis of the knee. Numerous authors have cited alignment as an important prognostic factor in the survival of UKA. Limb alignment affects not only the longevity of UKA by influencing wear of polyethylene, but also affects the unreplaced contralateral compartment. Malpositioning of the components may result in unequal wear patterns, thus further leading to early failure and additionally influencing clinical outcome as well. However, there is a lack of techniques to assure a high accuracy of the implant positioning.

#### **METHODS**

In this study, we investigated tibia component alignment of 28 medial UKAs implanted with patientspecific cutting blocks. Three patients were excluded due to bad imaging. Measurements of tibial component alignment from postoperatively computed tomography (CT) scans were compared to respective CT-based preoperative plannings to assess the accuracy of implant positioning.

#### RESULTS

Our results show excellent high accuracy of tibial implant position in tibial varus/valgus ( $\Delta 0.3^{\circ} \pm 1.7^{\circ}$ ), posterior slope ( $\Delta 1.1^{\circ} \pm 2.6^{\circ}$ ) and external rotation ( $\Delta 1.5^{\circ} \pm 3.3^{\circ}$ ).

#### CONCLUSION

We conclude that patient-specific cutting blocks improve the accuracy of tibia component positioning in unicompartmental knee arthroplasty.

#### MyKnee economical and clinical results.

GOLDBERG T. - Podium presentation at the 6th M.O.R.E. International symposium, Stresa, Italy, May 13-14, 2011.

#### **INTRODUCTION**

MyKnee patient-specific technology for TKA potentially improves surgical efficiency by reducing surgical steps, decreasing sterilization costs, and decreasing instruments required to perform the procedure. Furthermore, patient outcomes are improved. The present study compares clinical and economical results of 10 consecutive TKA patients performed using conventional and MyKnee techniques.

#### **METHODS**

Each patient had pre- and post-operative longstanding radiographs analyzing the HKA mechanical axis, the Femoral Component Angle (FCA), and Tibial Component Angle (TCA). Surgical data collected included tourniquet time, EBL, and implant correlation. Economical data assessed includes hospital fixed and variable costs/case and potential hospital profit.

#### RESULTS

HKA improved from 5.2 to 2.1 using MyKnee and from 6.6 to 1.7 using conventional technique. The FCA for MyKnee and Conventional was 90.2 and 89.4 respectively while the TCA was 91.2 and 90.7. Although the averages were not different, the variances were significantly different with tighter outcomes demonstrated in the MyKnee technique with fewer outliers. Average tourniquet time was 34.3 minutes for MyKnee versus 31.6 for conventional. Once again, there was less variance for the MyKnee technique. EBL and post-op hemoglobin were the same for both techniques. The MyKnee technique successfully predicted 70% of the femoral implants and 90% of the tibia implants. Operative setup times could be reliably improved at least 14 minutes/ case with MyKnee. Hospital fixed and variable costs average \$37/case; however, more importantly, hospital profits \$2,500/case. For the present surgeon, increased efficiency of 2 cases/week would improve hospital profit by \$230,000/year.

#### CONCLUSION

MyKnee technique for TKA provides surgical and radiographic outcomes that are less variable in both time radiographic results than conventional TKA. Instrumentation is reduced and OR efficiency is improved. Surgeon, industry, and hospital revenue is potentially improved with the technique.

### Aspects economiques de la tecnologie sur mesure MyKnee en chirurgie prothetique du

#### genou.

GAGNA G. - Podium presentatiuon at the 87th Annual Congress of the SOFCOT, Paris, November 11-14, 2012.

Ces nouvelles procédures ont un surcoût, pour le patient et l'assurance maladie avec l'imagerie supplémentaire et pour l'établissement de soins avec le coût de cet ancillaire jetable. Pour diffuser cette technique, les fabricants annoncent une économie en stérilisation, temps d'intervention, transfusion et durée d'hospitalisation. Le but de ce travail est de vérifier la réalité de cette économie.

Notre étude porte sur 70 patients opérés par le même opérateur d'une prothèse GMK Primary MEDACTA dont 20 cas avec un ancillaire conventionnel sans navigation (série A), 20 cas avec le système sur mesure MyKnee (série B). Dans cette série B, la planification opératoire impose toujours une coupe fémorale à 3° de rotation externe et une coupe tibiale avec une pente de 3°. Une 3ème série (série C) regroupe 30 opérés avec l'ancillaire sur mesure mais avec une planification personnalisée (pente tibiale naturelle, rotation externe fémorale égale à l'axe trans-épiphysaire). Dans les trois séries, l'utilisation du tenseur vérifie l'équilibre des espaces imposant parfois recoupe et release.

Une comparaison de coûts a été ainsi réalisée entre ces trois séries.

Le gain en stérilisation existe entre la série A (5 boites) et la série B et C (2 boites) s'il n'y a pas de recoupe. Le temps d'utilisation du bloc est identique dans les séries A et B et inférieur de 10 minutes dans la série C. Les temps de garrot sont voisins. Les pertes en hémoglobine sont équivalentes dans les séries A et B (-4,1g et -4,2g d'hémoglobine), mais moindre dans la série C (-3,7g). La fréquence des transfusions nécessaires est de 7/20 pour A, 5/20 pour B et 6/30 pour C. Le séjour est raccourci de 2 jours pour la série C. Il n'y a pas de bénéfice économique entre les séries A et B car l'absence de planification adaptée conduit à un taux important de recoupe et de release (deux fois plus que A) allongeant d'autant le temps de garrot, les pertes sanguines et le temps de séjour. Il y a eu par contre une économie certaine pour la série C chiffrée pour notre établissement à  $180 \in$  pour la stérilisation,  $125 \in$  pour la durée de salle d'intervention et à  $400 \in$  pour le gain en journée d'hospitalisation. Il faut y ajouter l'économie en produit sanguin.

En conclusion, des gains en efficacité et en coût n'existent que si la planification préopératoire est parfaitement réalisée limitant reprise des coupes et release.



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### Notes

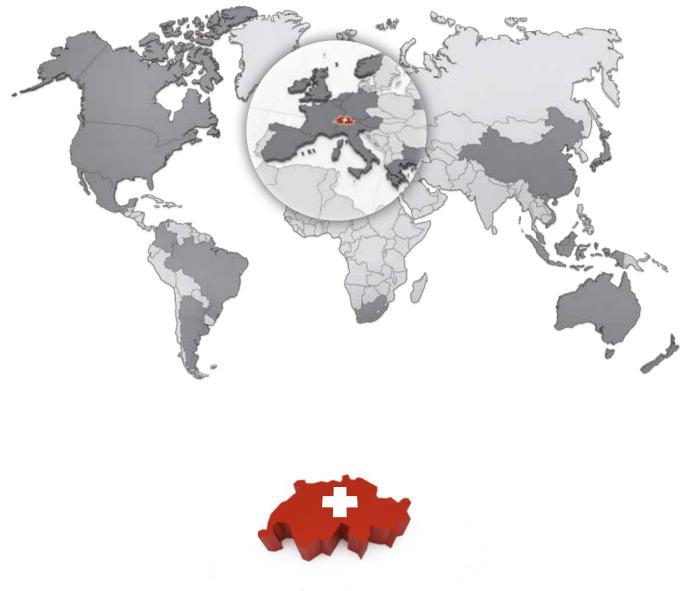




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