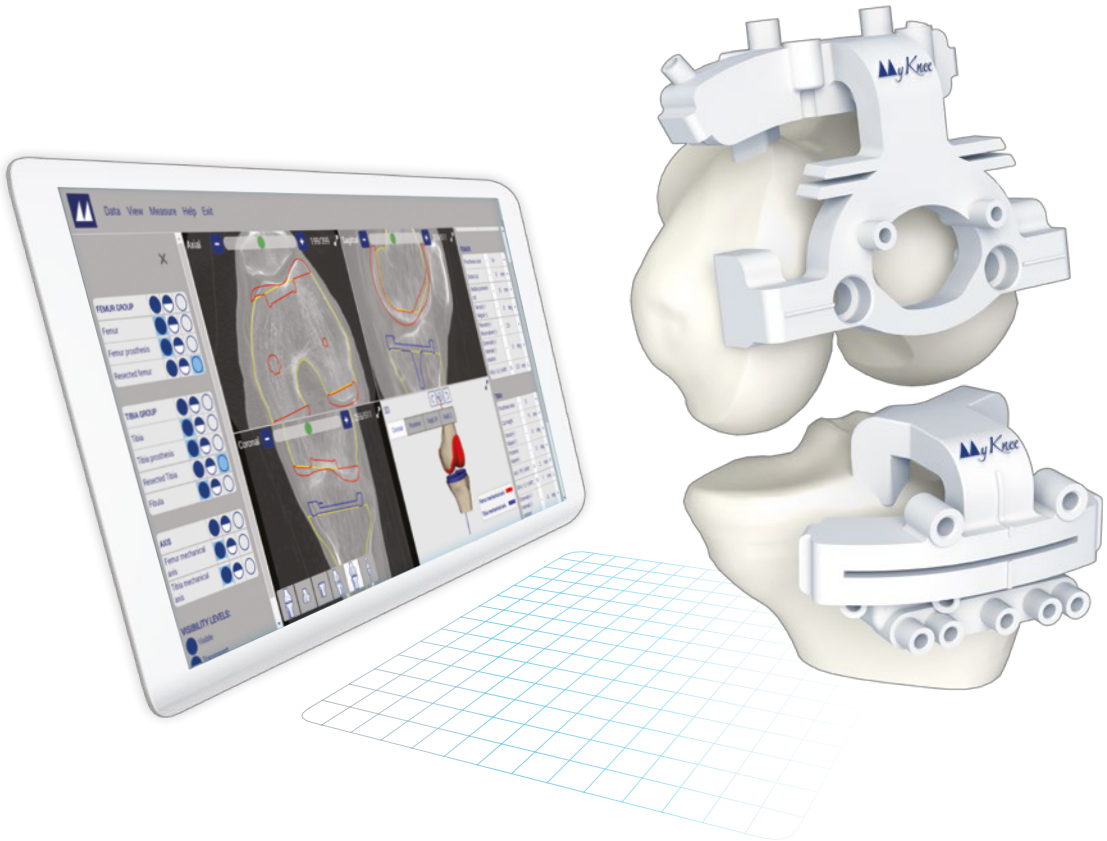
Medacta International

MyKnee®

PATIENT MATCHED TECHNOLOGY
IN KNEE REPLACEMENT



MYKNEE
VALUE DOSSIER

PERSONALIZING ACCURACY AND EFFICIENCY IN KNEE REPLACEMENT

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1. PERSONALIZING THE PATIENT'S JOURNEY

A NETWORK OF ADVANCED DIGITAL SOLUTIONS DESIGNED TO IMPROVE PATIENT OUTCOMES AND HEALTHCARE EFFICIENCY

Each patient is different and unique. So are diseases, which can cause pain and limit even the simplest daily activities. At Medacta, we believe that every patient deserves a personalized care pathway that meets their specific needs and expectations. By leveraging the latest technological advances, we are committed to constantly developing innovative solutions to empower the surgeon's practice, enabling data-driven decisions to provide more personalized, accurate, and efficient procedures aiming at better patient satisfaction and outcomes. This has led us to design a network of advanced digital solutions to improve patient outcomes and healthcare efficiency. The MySolutions Personalized Ecosystem embodies our vision to never stop improving the experience for patients, surgeons, and care facilities.

With a constantly growing number of procedures performed worldwide, this steadily evolving platform is based on cutting-edge technologies which are fine-tuned in collaboration with an international network of expert surgeons. The MySolutions Personalized Ecosystem is designed around the patient's needs and expectations, with the aim of delivering value throughout the entire patient journey. Advanced 3D planning for surgeons is at the core of our platform, followed by highly accurate execution tools such as patient-matched surgical guides, as well as a surgical platform and verification software based on augmented reality. To improve the patient experience and support them during the continuum of care we have set up a patient-optimized pathway tool. To let surgeons record and measure their clinical outcomes we offer a validated web-based archiving and analyzing system. Together with our comprehensive implant portfolio and surgical techniques, the MySolutions Personalized Ecosystem empowers our holistic approach to personalized medicine.

MYSOLUTIONS PERSONALIZED ECOSYSTEM

PERSONALIZED 3D PLANNING

PRECISE EXECUTION

PATIENT ENGAGEMENT

EFFICIENT CASE MANAGEMENT

2. MYKNEE: UNPARALLELED ACCURACY AND EFFICIENCY IN KNEE REPLACEMENT

Within the MySolutions Personalized Ecosystem, we offer enabling technologies that deliver a personalized approach to knee replacement, improving accuracy and efficiency, while promoting healthcare sustainability with multiple benefits for the surgeons, for the patients and for the healthcare facilities. One of the main actors of the MySolutions Personalized Ecosystem is MyKnee, which combines multiple features to provide benefits in terms of accuracy, reduced invasivity, and cost effectiveness in knee replacement surgeries. MyKnee is a complete platform for partial, total, and revision knee replacement that combines 3D preoperative planning and 3D printed patient-matched guides to accommodate many surgical approaches, including bone referencing, ligament balancing, muscle sparing, and kinematic alignment.

BENEFITS FOR THE SURGEON

MyKnee leverages on a CT- or MRI-based 3D reconstruction of each patient's knee allowing the MySolutions engineering team to design surgical guides that perfectly fit the specific anatomy and empowering the surgeons to produce their own surgical planning. The MyKnee guides allow for a highly reliable and stable position, in contact with the osteophytes, enabling the surgeon to achieve an optimal implant placement in every surgical scenario, including difficult anatomies and challenging total knee revisions. The implant placement achieved is thus more accurate than with the conventional technique and is in line with the computer-assisted surgeries.[1,2]

MyKnee®
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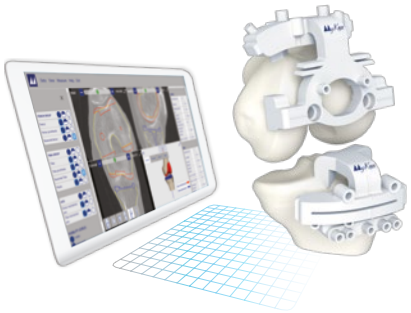


BENEFITS FOR THE PATIENT

The MyKnee surgical procedure does not require any intramedullary canal violation to set the implant's final alignment, thus reducing the risks of embolism, the need for transfusion, and blood and hemoglobin loss. Moreover, the patient-matched guides provide for a reduction of up to 60% in surgical steps and related time for bone resections. This may result in less tourniquet time, less time under anesthesia, and therefore less time in the operating theater, thereby possibly reducing the risk of postoperative infection. All these factors greatly impact the patient's rehabilitation and postoperative hospital stay, with high benefits on the final clinical outcomes.[3,4,5,6]

BENEFITS FOR HEALTHCARE FACILITIES

Thanks to an unparalleled sizing prediction capability and the ability to accurately replicate the preoperative planning, with MyKnee the surgical steps to size and position the final implant can be reduced by up to 60% compared to a conventional surgery, in which the cutting parameters are set by means of dedicated alignment jigs and sizing instruments. This unparalleled feature allows for the reduction of surgical time, as well as for the possibility to increase the number of cases per session. In addition, thanks to the drastic reduction of off-the-shelf surgical instruments necessary in the operating room and related time and costs associated with washing, sterilization, operating room setup and tidying up, it is possible to avoid up to 66% of the tasks associated to surgical instruments management. This makes MyKnee a powerful tool to reduce the time and costs associated to perioperative logistics in knee replacement procedures and to optimize the OR staff and sterilization unit workload.[7, 8, 9]

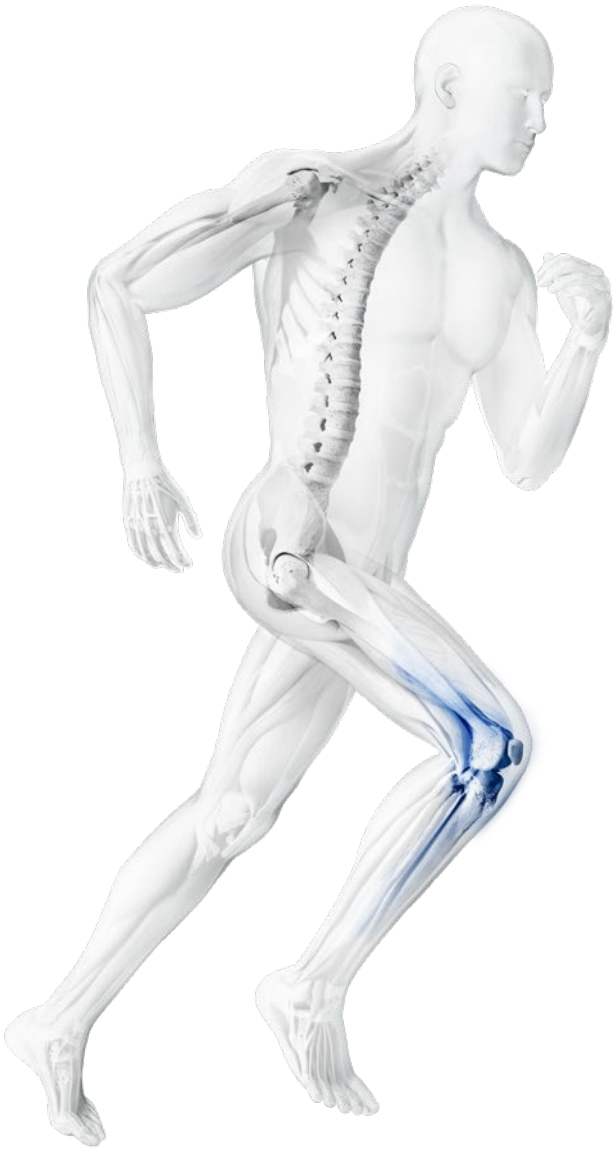
[1] Anderl W et al, CT-based patient-specific vs. conventional instrumentation: Early clinical outcome and radiological accuracy in primary TKA; Knee Surg Sports Traumatol Arthrosc. 2014. [2] Koch P, Müller D, Pisan M, Fucentese S, Radiographic accuracy in TKA with CT-based patient-specific cutting block technique, Knee Surg Sports Traumatol Arthrosc. 2013 Oct;21(10):2200-5. [3] V. J. León-Muñoz et al; Use of patient-specific cutting blocks reduces blood loss after total knee arthroplasty European Journal of Orthopaedic Surgery & Traumatology, December 2016. [4] Kalairajah Y. et al; Blood loss after total knee replacement: effects of computer-assisted surgery. JBJS Br. 2005 - Nov;87(11):1480-2. [5] Kalairajah Y et al; Are systemic emboli reduced in computer-assisted knee surgery?: A prospective, randomised, clinical trial. JBJS Br. 2006 Feb;88(2):198-202. [6] Peersman G et al; Prolonged Operative Time Correlates with Increased Infection Rate after Total Knee Arthroplasty. Hospital for Special Surgery Journal 2006 - Feb;2(1):70-2. [7] Müller et al- CT based patient-specific cutting blocks for total knee arthroplasty: technique and preliminary radiological results. Podium Presentation at the 71st Annual Congress of the SSOT, Lausanne, Switzerland, June 22-24, 2011. [8] Koch P et al- Guide de coupe sur mesure pour PTG : présentation de la technique opératoire et résultats radiologiques préliminaires. Podium Presentation at the 86th Annual Congress of the SOFCOT, Paris, France, November 7-11, 2011. [9] Goldberg TD - MyKnee economical and clinical results. Podium Presentation at the 6th M.O.R.E International symposium, Stresa, Italy, May 13-14, 2011.

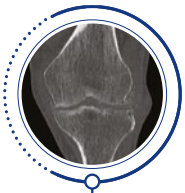
3. THE MYKNEE JOURNEY

The MyKnee process is kept entirely in-house from the 3D anatomical reconstruction to the manufacture of the patient-matched guides, with direct support and communication between the surgeon and a dedicated MyKnee engineer. Starting from a CT or MRI scan of the patient leg, our MyKnee Engineering department carefully plans the surgery, according to the cutting and alignment parameters set by the surgeon. Each surgeon is followed always by the same engineer, who develops a detailed understanding and awareness of the surgeon's surgical preferences to streamline and optimize the planning process. The planning is performed entirely off-site by the specific MyKnee engineer and once completed, is uploaded for the surgeon's check on the MyKnee webplatform, available 24/7 from any device. By accessing his personal area on the MyKnee website, the surgeon can check, evaluate, modify, and validate the upcoming cases by means of a dedicated 3D planning tool, that empowers the surgeon with multiple features, such as a DICOM-view of the implants positioning and a live response to each change performed to easily evaluate the outcomes.

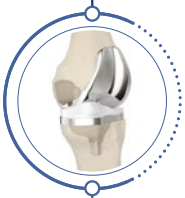
Once the surgeon validates the planning, the MyKnee engineers are then allowed to start the design process to create the patient-matched guides for the specific surgical case. We offer a wide range of different patient-matched guides type to match each surgeon's specific practice and approach. Together with the patient-matched guides, the bone models of patients' femur and tibia are provided. On the models, the femoral and tibial resections height, the landmarks used to define them and the guides' contact points on the patient's bone are etched to allow the surgeon for an intraoperative double check.

After the design is completed and fine-tuned on the specific patient's anatomy, the production starts. Medacta has a completely in-house manufacturing process that takes place in a dedicated production unit where the MyKnee guides are 3D printed and their quality is accurately checked to always ensure the best-of-class functionality of our products. When the production is completed, the MyKnee guides set is assembled and then shipped to the hospital by time of the surgery date requested. Medacta is able to deliver a complete set of MyKnee guides and patients' knee bone models in just three weeks. The complete set can be also provided already sterilized with only two additional weeks of lead- time.





CT OR MRI SCAN OF THE PATIENT'S KNEE



KNEE 3D RECONSTRUCTION AND PLANNING IN LINE WITH THE SURGEON'S PREFERENCES

WEB-BASED 3D PLANNING EVALUATION AND VALIDATION

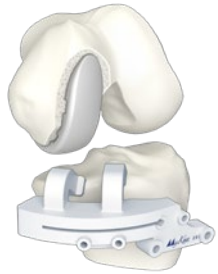
MYKNEE GUIDES PRODUCTION IN LINE WITH THE SET PARAMETERS

ACCURATE IMPLANT POSITION ACCORDING TO PLAN

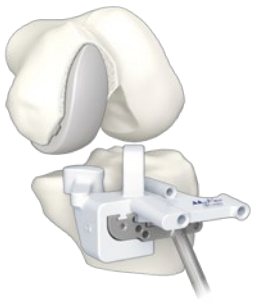
4. A PATIENT-MATCHED SOLUTION FROM UNICOMPARTIMENTAL TO REVISION KNEE ARTHROPLASTY

The streamlined surgical procedure, associated with the preoperative planning and the always available support of the engineers, enables an unparalleled comfort of use in every surgical scenario, also in total knee revision cases. Indeed, Medacta's patient-matched instrument platform includes solutions for partial, total and revision knee replacement, and accommodates many surgical approaches including bone referencing, ligament balancing and muscle sparing, while reducing the overall reusable instrument footprint in the operating room. CT- or MRI-based cutting guides and pin positioning blocks to implant knee prosthesis, or to revise total knee implants already in situ with a new one, are available to offer a wide range of options to every surgeon. A dedicated Kinematic Alignment planning protocol, MyKnee KA, is available to supplement the traditional mechanical alignment principles.

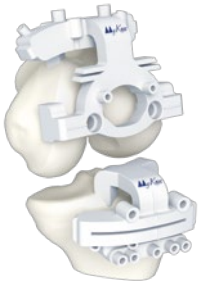
MyKnee® UNI



MyKnee® PPS UNI

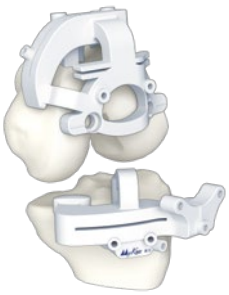


MyKnee®

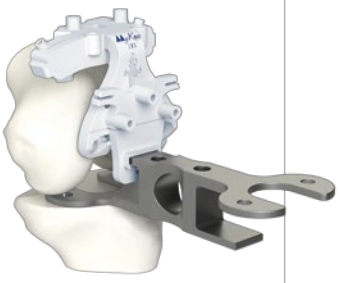


MyKnee® KA

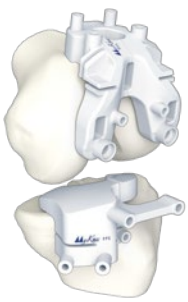
MyKnee® MIS



MyKnee® LBS



MyKnee® PPS



MyKnee® R

MYKNEE UNI

The MyKnee UNI patient-specific tibial cutting block allows the surgeon to carry out the tibial resection according to a preoperative 3D planning, achieving good results for accuracy of tibial component varus/valgus positioning, tibial slope, and internal/external rotation. The surgeon is also able to check both the horizontal and the sagittal resection levels marked on the bone model and the sagittal cut direction marked with a pin hole on the tibial guide. By means of the preoperative planning, it is also possible to assess the femoral component size. As an alternative, the MyKnee PPS UNI allows the surgeon to guide the positioning of the "shim-technique" tibial guide, to perform the first conservative resection in line with the planned thickness and alignment.

MYKNEE KA

MyKnee KA is the dedicated protocol for planning a Kinematically Aligned TKA by means of the MyKnee preoperative planning tool and for accurately replicating it intraoperatively with the preferred MyKnee guides. Kinematic Alignment (KA) aims to personalize joint line reconstruction through anatomic resurfacing, with little to no ligament releases, and it has shown the potential to improve knee function and patient satisfaction. As KA is a resurfacing technique, a reliable reference to reproduce the pre-arthritic alignment of the patient's knee must be defined. By leveraging the MyKnee technology, with a preoperative CT scan of the patient's knee, it is possible to create a 3D model of the patient's bones, disregarding the cartilage and its possible wear. Since the subchondral bone is not usually affected by wear, this is the optimal reference to replicate the pre-arthritic joint alignment. Medacta offers the most comprehensive platform for Kinematic Alignment (MyKA) including a particularly suitable implant for kinematic alignment supported by technologies and dedicated instruments, developed to perform a personalized, reproducible surgical technique based on measured bone resections, as well as a tailored M.O.R.E. Education Program.

MYKNEE MIS

MyKnee MIS, the minimally invasive patient-matched cutting blocks, feature reduced size, rounded edges and anatomical shape, and were designed to perfectly adapt to the midvastus or subvastus muscle-sparing approach. The MyKnee MIS medialized shape allows the surgeon to perform the total knee replacement while preserving the soft tissues and limiting the surgical incision.

MYKNEE LBS

MyKnee LBS is the only patient-matched system allowing the surgeon to accurately check soft tissue balance, both in extension and in flexion, before performing any femoral cut. After performing the tibial cut, the MyKnee LBS guide positioned on the femur replicates the thickness of the final implant in extension. The MyKnee LBS also features a rotating plate that, when assembled with the femoral guide,allows for checking the flexion gap balancing by means of a dedicated tool available in the Medacta total knee instrumentation. The plate rotates on the femoral guide according to the knee ligaments tension for the specific patient, allowing for setting the femoral rotation while respecting the soft tissue balancing.

MYKNEE PPS

MyKnee PPS is a set 3D printed pin-positioning patient-matched guides specifically designed for the MRI-based preoperative planning. The MyKnee PPS blocks, due to their large contact surface, anterior and posterior referencing, slim design, and possibility of intraoperative checks, allow the surgeon to find the most reliable and stable position without removing any cartilage from the patient's bones. Once the pins have been positioned through MyKnee PPS blocks on the patient's bone, the resections can be performed according to preoperative planning, using either the metal or the GMK Efficiency cutting blocks.

MYKNEE R

MyKnee R is a set of pin-positioning guides designed to fit directly on the total knee implant in situ and to guide the surgeon in positioning a Medacta total knee prosthesis, ranging from the GMK Sphere to the GMK Revision and GMK Hinge. By means of the MyKnee 3D preoperative planning, it is possible to accurately define the implants' size and position, and to evaluate the best direction of the extension stems or the need of augments and 3D Metal cones, both on the patient's tibia and femur. MyKnee R provides the benefits of the patient-matched technology also in the more challenging revision total knee replacement, with higher accuracy in the final implant positioning, improved prediction capability, reduction of surgical steps, OR time and number of instruments needed to perform the surgical procedure.

5. STRIVING TO IMPROVE OPERATING ROOM EFFICIENCY

Medacta is committed to providing innovative orthopedic solutions that improve patient well-being, safely and effectively, and deliver sustainability and efficiency to the healthcare system.

To further improve the clinical, logistic, and economical benefits of the MyKnee patient-matched technology, Medacta is able to provide a completely single-use set of instruments for total knee replacement: the GMK Efficiency instrumentation.

GMK Efficiency is a terminally sterile, easy-to-manage, time and cost-saving set of surgical tools for TKA which improves hospitals' logistics and instrumentation management. The instruments are organized in size-specific trays with an optimized layout, limiting the number of instruments needed for a surgery and facilitating the backtable set-up. Always complete and brand-new, GMK Efficiency drastically decreases the risk of cancellation of surgeries or delays in the surgical scheduling due to missing or worn-out items, issues which are typically associated with reusable instruments. In addition, coming already sterile to the hospital, GMK Efficiency helps limiting the issues like breaches in the sterile wrapping and it does not saturate the sterilization unit. It is the optimal solution for those clinics that rely on an external facility to wash and sterilize the surgical instruments after each usage.

As ultimate solution to maximize operating theatre efficiency and instruments management we developed the Efficiency KneePack. By leveraging on MyKnee platform prediction capability, this option combines in the same light-weight box the MyKnee guides, the GMK Efficiency instrumentation trays, and the GMK Sphere femoral and tibial implants in the planned sizes: all the necessary components to perform a total knee replacement!

GMK SPHERE
MEDIALLY STABILIZED KNEE

GMK Efficiency
SINGLE USE INSTRUMENTS
IN KNEE REPLACEMENT

MyKnee
PATIENT MATCHED TECHNOLOGY
IN KNEE REPLACEMENT

Efficiency
KNEEPACK

Everything you need in
JUST ONE BOX, STERILE
and **READY TO USE**

6. MYKNEE PROVEN CLINICAL AND ECONOMIC BENEFITS

The clinical and economic benefits of the MyKnee patient-specific guides for surgeons, patients and healthcare facilities have been evaluated and analyzed in a wide number of published papers. The MyKnee main clinically proven features are:

ACCURACY

The MyKnee cutting blocks are made to accurately replicate intraoperatively the surgeon's preoperative planning, based on each individual patient's anatomy.

EFFICIENCY

Only 3 surgical steps are needed with MyKnee: FIT-PIN-CUT! MyKnee efficiency may reduce the overall surgical time, potentially adding one extra case per surgery session.

REDUCED INVASIVITY

By avoiding intramedullary canal violation, the blood loss and the risk of embolism are drastically reduced, thereby speeding up the patient's recovery and limiting the needs for transfusions.

Below is a list of some of the main articles available regarding the MyKnee technology. The results of each one of them are displayed and analyzed in the next pages of this brochure:

Patient-specific instrumentation improved mechanical alignment, while early clinical outcome was comparable to conventional instrumentation in TKA

Anderl W, et al. KSSTA Journal, October 2014

Patient-specific instrumentation improved three-dimensional accuracy in total knee arthroplasty: a comparative radiographic analysis of 1257 total knee arthroplasties

Anderl W. et al. KSSTA Journal of Orthopaedic Surgery and Research, December 2019

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

Koch PP, Müller D, Pisan M, Fucentese SF. KSSTA Journal, October 2013

CT based patient specific instrumentation for total knee arthroplasty in over 700 cases: single use instruments are as accurate as standard instruments

Koch PP et al. Knee Surgery, Sports Traumatology, Arthroscopy, July 2020

Patient-specific instrumentation for total knee arthroplasty: Evaluation with computer-tomography tools

A. Nabavi et al. Journal of Orthopaedic Surgery, 2017

Restoration of the Mechanical Axis in Total Knee Artrhoplasty Using Patient-Matched Technology Cutting Blocks. A Retrospective Study of 132 Cases

R. Greenhow, MD, C. Loucks, MD Archives of Bone and Joint Surgery, March 2017

Use of patient-specific cutting blocks reduces blood loss after total knee arthroplasty

Vicente J. León-Muñoz et al. European Journal of Orthopaedic Surgery & Traumatology, December 2016

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

N. Helmy et al. Knee Surgery, Sports Traumatology, Arthroscopy 2015

Revision of total knee arthroplasty with the use of patient-specific instruments: an alternative surgical technique

Vicente J. León-Muñoz et al., Expert Review of Medical Devices, 2020

PATIENT-SPECIFIC INSTRUMENTATION IMPROVED MECHANICAL ALIGNMENT, WHILE EARLY CLINICAL OUTCOME WAS COMPARABLE TO CONVENTIONAL INSTRUMENTATION IN TKA.

W. Anderl, L. Pauzenberger, R. Kölblinger, G. Kiesselbach, G. Brandl, B. Laky, B. Kriegleder, P, Heuberer, E. Schwameis

Knee Surgery, Sports Traumatology, Arthroscopy

In a cohort of 300 TKA, MyKnee accuracy resulted significantly superior to the conventional approach.

Strong correlation between accurate implant alignment and improved clinical outcomes.

ABSTRACT

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 ± 5.2 months. At the early follow-up, the clinical outcome (KSS, VAS, WOMAC, OKS) was comparable between the two groups. Mean HKA-deviation from the targeted neutral mechanical axis (CVI: 2.2° ± 1.7°; PSI: 1.5° ± 1.4°; $p < 0.001$), 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° ± 3°) showed better clinical results than outliers at the 2-year follow-up.

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

This paper represents the most comprehensive, peer-reviewed study that compares the postoperative results of MyKnee with conventional total knee replacement (CVI) by means of postoperative, long-leg x-rays and CT assessment to evaluate the implant positioning. In addition, it has been investigated if a postoperative implant alignment in line with the planned parameters is correlated to better clinical outcomes at the 2-year follow-up. To clinically assess the patients' outcomes, the Knee-Society-Score (KSS), the visual-analog-scale for pain (VAS), the Western Ontario McMaster Universities Osteoarthritis Index (WOMAC), and the Oxford-Knee-Score (OKS) were collected at follow-up.

The most important findings of this paper are:

- MyKnee showed significantly superior accuracy in 3D-component positioning compared with CVI surgical approach in primary TKA.
- More than half of all MyKnee cases (57%) reached postoperative HKA within 1° of the target. Further radiological evaluation showed significant reductions of outliers regarding HKA (outlier >3° and >5°) and 3D-component positioning in the MyKnee group.
- All clinical parameters were significantly better in HKA non-outliers compared with HKA-outliers. Clinical outcomes were comparable between MyKnee and CVI groups at early follow-up, whereas KSS, VAS, WOMAC, and OKS were significantly better in the subgroup of knees within ±3° of deviation from the target postoperative HKA compared with the outlier group (more than 3° deviation from the target postoperative HKA).

READ THE STUDY

DOI: 10.1007/s00167-014-3345-2

PATIENT-SPECIFIC INSTRUMENTATION IMPROVED THREE-DIMENSIONAL ACCURACY IN TOTAL KNEE ARTHROPLASTY: A COMPARATIVE RADIOGRAPHIC ANALYSIS OF 1257 TOTAL KNEE ARTHROPLASTIES.

L. Pauzenberger, M. Munz, G. Brandl, J. K. Frank, P. R. Heuberer, B. Laky, B. Kriegleder, E. Schwameis, W. Anderl

Journal of Orthopaedic Surgery and Research

In a cohort of 1'200+ TKA, MyKnee registered significantly less outliers and totally prevented severe malalignment for all the radiographic parameters investigated.

ABSTRACT

Bakground: The purpose of this study was to compare restoration of mechanical limb alignment and three dimensional component-positioning between conventional and patient-specific instrumentation in total knee arthroplasty.

Methods: Radiographic data of patients undergoing mobile-bearing total knee arthroplasty (n = 1257), using either conventional (n = 442) or patient-specific instrumentation (n = 812), were analyzed. To evaluate accuracy of axis restoration and 3D-component-positioning between conventional and patient-specific instrumentation, absolute deviations from the targeted neutral mechanical limb alignment and planned implant positions were determined. Measurements were performed on standardized coronal long-leg and sagittal knee radiographs. CT-scans were evaluated for accuracy of axial femoral implant rotation. Outliers were defined as deviations from the targeted neutral mechanical axis of > ± 3° or from the intraoperative component-positioning goals of > ± 2°. Deviations greater than ± 5° from set targets were considered to be severe outliers.

Results: Deviations from a neutral mechanical axis (conventional instrumentation: 2.3°± 1.7° vs. patient-specific instrumentation: 1.7°± 1.2°; $p < 0.001$) and numbers of outliers (conventional instrumentation: 25.8% vs. patient specific instrumentation: 10.1%; $p < 0.001$) were significantly lower in the patient-specific instrumentation group. Significantly lower mean deviations and less outliers were detected regarding 3D-component-positioning in the patient-specific instrumentation compared to the conventional instrumentation group (all $p < 0.05$).

Conclusions: Patient-specific instrumentation prevented severe limb malalignment and component positioning outliers (> ± 5° deviation). Use of patient-specific instrumentation proved to be superior to conventional instrumentation in achieving more accurate limb alignment and 3D-component positioning, particularly regarding femoral component rotation. Furthermore, the use of patient-specific instrumentation successfully prevented severe (> 5° deviation) outliers.

This study, based on the analysis of prospectively collected radiographic data of more than 1,200 TKA patients, aims to compare restoration of limb alignment and 3D-component-positioning when using conventional instrumentation (CVI) and MyKnee. The analysis has been carried out by investigating postoperative weight bearing X-Rays of all the patients to evaluate postoperative HKA. In addition, postoperative CT scans of more than 130 patients have been collected to evaluate if implants positioning were in line with the planned parameters.

The results of this study showed that:

- Significantly fewer patients in the MyKnee group compared to the CVI group revealed postoperative outliers (> ± 3° deviation from planned value) with respect to all the radiographic and CT-based parameters analyzed.
- The MyKnee instrumentation totally prevented severe limb malalignment and component-positioning outliers (> ± 5° deviation from planned value).
- MyKnee significantly reduced the mean absolute deviation from the planned limb alignment and component position in all planes.

READ THE STUDY

DOI: 10.1186/s13018-019-1465-6

RADIOGRAPHIC ACCURACY IN TKA WITH A CT-BASED PATIENT-SPECIFIC CUTTING BLOCK TECHNIQUE

P. P. Koch, D. Muller, M. Pisan,S. F. Fucentese

Knee Surgery, Sports Traumatology, Arthroscopy

> The accuracy of 300+ MyKnee cases was found to be comparable to computer-assisted surgery (CAS) and definitely superior to the conventional approach.

ABSTRACT

Purpose: Patient-specific instrumentation (PSI) technology for the implantation of total knee arthroplasty (TKA) has a rising interest in the orthopedic 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° ± 2.0°. 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.

In this study, a comprehensive review of the results in terms of accuracy and capability of replicating preoperative planning values has been carried out. The MyKnee technology results have been compared with the data coming from the literature regarding computer assisted surgery (CAS) and the conventional instruments. To evaluate the MyKnee results, postoperative long-leg x-rays have been collected to measure coronal and sagittal alignment of the femoral and tibial implants, and postoperative HKA. The data collected have been compared with the planned parameters and the number of outliers (difference from planned value >3°) has been registered for all the parameters.

The results of this study showed that:

- MyKnee provides accurate radiological data comparable to the results achieved and published with computer-assisted TKA (CAS TKA) and clearly better than with conventional instrumentation.
- Comparing the results of component positioning between CAS TKA and data achieved with MyKnee, an identical precision for frontal tibial and femoral plane as well as for posterior tibial slope was achieved. The femoral component flexion had even better accuracy with MyKnee.

READ THE STUDY

DOI: 0.1007/s00167-013-2625-6

CT-BASED PATIENT-SPECIFIC INSTRUMENTATION FOR TOTAL KNEE ARTHROPLASTY IN OVER 700 CASES: SINGLE-USE INSTRUMENTS ARE AS ACCURATE AS STANDARD INSTRUMENTS

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Knee Surgery, Sports Traumatology, Arthroscopy

In 700+ TKA performed with MyKnee, the combination with GMK Efficiency has been demonstrated to be the most accurate solution in replicating the preoperative planning parameters.

ABSTRACT

Purpose: Efforts in total knee arthroplasty are made to improve accuracy for a correct leg axis and reduce component malpositioning using patient-specific instruments. It was hypothesized that use of patient-specific instruments (vs. computer-navigated and conventional techniques) will reduce the number of outliers. Our second hypothesis was that single-use instrumentation will lead to the same accuracy compared to patient-specific instruments made of metal.

Methods: 708 primary total knee arthroplasties between 2014 and 2018 using computer tomography (CT)-based patient specific cutting block technique and a preoperative planning protocol were retrospectively reviewed. Preoperative data [hip–knee–angle (HKA), lateral distal femoral angle (LDFA), medial proximal tibial angle (MPTA), tibial slope, femoral component flexion] was compared to postoperative performed standard radiological follow-up X-rays. Differences of > 3° between measurements were defined as outliers.

Results: Overall 500 prostheses using standard instrumentation and 208 prostheses using single-use instruments were implanted. Preoperative HKA axes (− 1.2°; $p < 0.001$), femoral component flexion (Δ 0.8°, $p < 0.001$), LDFA (Δ − 1.5°, $p < 0.001$), MPTA (Δ − 0.5°, $p < 0.001$) and tibial posterior slopes (Δ 0.5°, $p < 0.001$), respectively, were different from postoperative axes. More outliers occurred using standard (vs. single-use) instruments ($p < 0.001$) regarding postoperative HKA (ranges of standard- vs. single-use: instruments: HKA 178.0°–180.5° vs. 178.0°–180.5°, femoral component flexion 0.0°–6.0° vs. 0.0°–4.5°, LDFA 90.0°–91.0° vs. 90.0°–90.0°, MPTA 90.0°–90.0° vs. 90.0°–90.0°, tibial posterior slope − 10° to 10° vs. − 1° to 10°). No differences were observed for the other angles measured. Comparing both systems, the total number of outliers was higher when using standard (8%) vs. single-use instruments (4.3%).

Conclusion: This study shows a high accuracy of CT-based patient-specific instrumentation concerning postoperatively achieved knee angles and mechanical leg axes. Single-use instruments showed a similar accuracy.

In this study, the number of outliers (deviation of more than 3° from the planned value) registered with MyKnee combined with metal reusable instruments and GMK Efficiency has been evaluated for various radiological parameters. It has been found that:

- Overall, there were 49 out of 708 outliers (6.9%) in HKA, 96 outliers (13.6%) in femoral component flexion, 53 in femoral V/V alignment (7.7%), 16 in tibial V/V alignment (2.3%) and 86 in tibial slope (12.2%).
- Comparing the two systems used, GMK Efficiency showed a lower total rate of outliers with respect to all measurements combined (7/208 (4.3%)) than the standard metal instrumentation (40/500 (8.0%)) when coupled with the MyKnee technology.
- In comparison to published data regarding the accuracy of PSI, the present results are comparable to published data of CAS TKA and show more favorable outcomes than conventional techniques.

READ THE STUDY

DOI: 10.1007/s00167-020-06150-x

PATIENT-SPECIFIC INSTRUMENTATION FOR TOTAL KNEE ARTHROPLASTY: EVALUATION WITH COMPUTER-TOMOGRAPHY TOOLS

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Journal of Orthopaedic Surgery

> MyKnee accurately replicates the planned HKA and implant positioning in coronal and sagittal planes.
>
> At the 1-year follow up, the vast majority of MyKnee patients registered good-to-excellent clinical outcomes.

ABSTRACT

Purpose: To assess the accuracy of total knee replacements (TKRs) performed using CT-based patient-specific instrumentation by postoperative CT scan.

Methods: Fifty prospective and consecutive patients who had undergone TKR using CT-based patient-specific instrumentation (MyKnee, Medacta International) were assessed postoperatively using a CT scan and the validated Perth protocol measurement technique. The Hip-Knee-Ankle (HKA) angle of the lower limb in the coronal plane, the coronal, sagittal, and rotational orientation of the femoral component, and the coronal and sagittal orientation of the tibial component were measured. These results were then compared to each patient's preoperative planning. The percentage of patients found to be less than or equal to 3° of planned alignment was calculated. One patient was excluded as the femoral cutting block did not fit the femur as predicted by planning and therefore underwent a conventional TKR.

Results: Ninety-eight percent of patients were within 3° of planned alignment in the coronal plane reproducing the predicted HKA angle. Predicted coronal plane orientation of the tibial and femoral component was achieved in 100% and 96% of patients, respectively. The sagittal orientation of the femoral component was within 3° in 98% of patients. The planned sagittal positioning of the tibial component was achieved in 92% of patients. Furthermore, 90% of patients were found to have a femoral rotation within 3° of planning. Eighty-six percent of patients achieved good-to-excellent outcome at 12 months (Oxford Knee Score > 34).

Conclusions: We have found that TKR using this patient-specific instrumentation accurately reproduces preoperative planning in all six of the parameters measured in this study.

This study aims to carefully evaluate the accuracy obtained by means of the MyKnee patient-matched guides in TKA by performing a robust radiological assessment of postoperative alignment and positioning of the implanted prosthesis. Postoperative CT scans of 50 MyKnee TKA patients have been performed to measure the post-op HKA, the coronal, sagittal, and rotational orientation of the femoral component, and the coronal, and sagittal orientation of the tibial component. The values recorded have been compared to the planned values and the percentage of values with less than 3° of difference was calculated.

The results showed that MyKnee has been accurate in replicating the planned values in all the parameters analyzed. In particular:

- 99% of the patients evaluated had a postoperative HKA within 3° from the planned 180°.
- The planned femoral component alignment has been achieved in 96% of patients on the coronal plane and in the 98% of patients on the sagittal plane. In addition, 90% of patients were found to have the external rotation of the femoral component within 3° of the planned value.
- The planned tibial component alignment has been achieved in 100% of patients on the coronal plane and in the 92% of patients on the sagittal plane.
- At the one-year follow up, 86% of patients registered and Oxford Knee Score > 34 with good-to-excellent clinical outcomes.

READ THE STUDY

DOI: 10.1177/2309499016684754

RESTORATION OF THE MECHANICAL AXIS IN TOTAL KNEE ARTHROPLASTY USING PATIENT-MATCHED TECHNOLOGY CUTTING BLOCKS. A RETROSPECTIVE STUDY OF 132 CASES

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Archives Of Bone and Joint Surgery

> In 130+ TKA, MyKnee system resulted remarkably reliable in the coronal plane alignment, and in the prediction of the component size.

ABSTRACT

Background: The aim of this study is to evaluate the accuracy of bone cuts and the resulting alignment, using the MyKnee patient specific cutting blocks.

Methods: We retrospectively reviewed 132 patients undergoing primary TKR for osteoarthritis by one single surgeon. The operative time, the preoperative Hip-Knee-Ankle (HKA) axis based on the CT-scan, the postoperative HKA axis based on long axis standing x-rays, the planned and the actual size of the femoral and the tibial components, and the number of the recuts performed intraoperatively were measured.

Results: The average preoperative HKA axis was 177.5° (range 163.5° to 194°), whereas the average postoperative HKA axis was 179.4° (range 177.1° to 182.7°). No outliers were reported in the study (0%). Intraoperatively, 4 femoral components (3.03%), and 7 tibial components (5.30%) applied to the patients were different than the planned size. There was no need of recuts in any of our cases intraoperatively.

Conclusions: The MyKnee system evaluated in this study was shown to be remarkably reliable in the coronal plane alignment, and the prediction of the component size. However, further studies are needed to determine whether there are any clinically important improvements in the outcomes or patient satisfaction when using the patient-specific cutting blocks for TKA.

In this study, more than 130 patients who underwent TKA by means of the MyKnee patient-matched technology have been reviewed retrospectively. The operative time, the preoperative HKA (based on CT-scan), the postoperative HKA axis (based on long axis standing x-rays), the planned and the actual size of the femoral and the tibial components implanted, and the number of the recuts performed intraoperatively were measured by the surgeon. The accepted normal value for HKA was 0°±3° from the planned value.

The MyKnee technology has proven to be extremely accurate in replicating the planned leg alignment and implant size. The average postoperative HKA was 179.4° (range 177.1° to 182.7°), the femoral size has been modified from the one planned in only 4 cases and the tibial size has been modified in 7 cases. No outliers (postoperative HKA difference from planned >3°) has been registered and no recuts have been needed intraoperatively to obtain the planned results.

The MyKnee system has been shown to be reliable and accurate, also enhancing intraoperative efficiency, and reducing the surgical time by avoiding some steps, such as the intramedullary canal violation.

READ THE STUDY

DOI:10.22038/ABJS.2017.14182.1337

USE OF PATIENT-SPECIFIC CUTTING BLOCKS REDUCES BLOOD LOSS AFTER TOTAL KNEE ARTHROPLASTY

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European Journal of Orthopaedic Surgery & Traumatology

MyKnee is significantly faster than CAS and conventional instruments in TKA.

MyKnee helps reducing intraoperative blood loss by avoiding intramedullary canal violation.

ABSTRACT

Total knee arthroplasty (TKA) is associated with substantial blood loss. Sources of bleeding are the femoral and tibial intramedullary canals, which are violated during implantation using standard instrumentation. Patient specific instrumentation (PSI) and computer-assisted surgery (CAS) do not require violation of the intramedullary canals. Therefore, we sought to assess the impact of these methods on blood loss and transfusion requirement. A retrospective cohort study was conducted in a series of 107 consecutive primary TKAs. The first group (n = 32) was operated with standard instrumentation, the second group (n = 35) with CAS and the third group (n = 40) with PSI. A tourniquet was used in all cases. Mean (standard deviation) calculated total blood loss was 442 (160), 750 (271) and 700 (401) ml for the PSI, CAS and standard instrumentation groups, respectively ($p<0.001$), with no significant differences between CAS and standard instrumentation ($p = 0.799$). Significant differences were found in terms of transfusion requirements, with 12.5, 42.9 and 21.8% of the patients requiring transfusion ($p = 0.010$). Post hoc analysis revealed that only the difference between PSI and CAS were statistically significant ($p = 0.003$). In conclusion, PSI reduces blood loss when compared to both CAS and standard instrumentation TKA performed with the use of a tourniquet. In this study, more than 130 patients who underwent TKA by means of the MyKnee patient-matched technology have been reviewed retrospectively. The operative time, the preoperative HKA (based on CT-scan), the postoperative HKA axis (based on long axis standing x-rays), the planned and the actual size of the femoral and the tibial components implanted, and the number of the recuts performed intraoperatively were measured by the surgeon. The accepted normal value for HKA was 0°±3° from the planned value.

In this study, three groups of patients undergoing TKA have been created: 32 knees (31 patients) were operated with conventional instrumentation; 35 knees (35 patients) were operated with computer-assisted surgery (CAS); 40 knees (37 patients) were operated with MyKnee. For all patients, Hb and hematocrit (Htc) levels were determined by blood draws preoperatively, and exactly 24h and 48h postoperatively. Any instances of reinfusions or transfusions were noted with volumes recorded. Total blood loss (TBL) was estimated with the postoperative change in Htc.

The main findings of this study demonstrate that:

- MyKnee is significantly faster than CAS and conventional instrumentation ($p<0.001$) in performing a TKA. The surgical time has been measured and its mean vale (SD) for each group was 84 min (±13) for MyKnee, 119 minutes (±12) for CAS and 94 minutes (±15) min for conventional instrumentation.
- The usage of MyKnee intraoperatively reduced blood loss and the risk of transfusion when compared to both CAS and conventional instrumentation by avoiding the femoral and tibial intramedullary canals violation and by drastically reducing the surgical time.

READ THE STUDY

DOI: 10.1007/s00590-016-1893-5

IMPROVED POSITIONING OF THE TIBIAL COMPONENT IN UNICOMPARTMENTAL KNEE ARTHROPLASTY WITH PATIENT-SPECIFIC CUTTING BLOCKS

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Knee Surgery, Sports Traumatology, Arthroscopy

MyKnee UNI allows for accurate replication of the planned UKA implant component alignment. The results are comparable to CAS UKAs.

ABSTRACT

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 patient-specific 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 (Δ 0.3° ± 1.7°), posterior slope (Δ 1.1° ± 2.6°) and external rotation (Δ 1.5° ± 3.3°).

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

In this study, the accuracy in the unicompartmental tibial implant positioning by means of the MyKnee UNI patient-matched guides has been investigated. The MyKnee UNI guides allow the surgeon to replicate intraoperatively both the sagittal and the transverse tibial cuts planned on the MyKnee preoperative 3D webplanner. The femoral resections are then based on the cut performed on the tibia by using the conventional surgical tools available in the GMK UNI instruments trays.

The good positioning of the GMK UNI tibial component has been evaluated in this study by comparing a postoperative CT scan of the patients' knee with the preoperative planning performed. In addition, at the 6-month follow up, the patients received a long-leg standing x-ray.

The main findings of this study showed that:

- The MyKnee UNI cutting guides provide good results in terms of accuracy of tibial component varus/valgus positioning, tibial slope, and tibial rotation. The results are also comparable to those obtained for navigated UKAs.
- The postoperative neutral HKA could be maintained with a mean difference of 1.8° ± 3.3° (p = 0.02), statistically, but most likely not clinically significant. It must be noted that the surgeons in this study often aimed to a not complete correction of the preoperative varus alignment into a postoperative slight varus alignment.
- Compared with previous studies for UKAs implanted with conventional techniques, rotation of the tibial component was found to be superior with no-to-smaller variation from the planned value.

READ THE STUDY

DOI: 10.1007/s00167-014-2839-2

REVISION OF TOTAL KNEE ARTHROPLASTY WITH THE USE OF PATIENT-SPECIFIC INSTRUMENTS: AN ALTERNATIVE SURGICAL TECHNIQUE

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Expert Review of Medical Devices

> MyKnee R is extremely accurate in replicating the planned resection parameters also in complex cases as revision TKA

ABSTRACT

Introduction: The Accuracy in the placement of components in revision total knee arthroplasty (R-TKA) surgery is sometimes challenging. The applicability of patient-specific instruments (PSI) in knee surgery has progressively expanded to types of surgery other than primary arthroplasty. Could this assistive technology be used to facilitate accurate R-TKA surgery? The aim of the current manuscript is to describe this new application of PSI for revision of TKA-to-TKA and to provide a step-by-step technical guideline for use.

Methods: We will describe the application and provide a detailed, step-by-step description of PSI technology for TKA revision surgery, from the CT images acquisition for preoperative planning and PSI blocks production to the surgery.

Expert commentary: The system can facilitate the accomplishment of the bony cuts for optimal implant placement and this can be useful in minimally altering the femoral and the tibial joint line. It is obvious that technology alone will not replace surgical skills and that accuracy of the system will also depend on the quality of the CT images and the ability of the software to prevent metal artifacts. Despite that, our initial results are promising and prove that the concept of applying PSI technology to the R-TKA surgery is feasible.

In this study, the MyKnee R patient-matched guides for revision of total knee implants have been evaluated in terms of accuracy in replicating the surgeon's preoperative planning resections parameters and implants' sizes. To perform this evaluation, a comparison between the preoperative CT scans of the patients' knees and the postoperative long-leg standing x-rays HKA have been carried out. The parameters considered are: FLDA (femoral lateral distal angle), PTMA (proximal tibial medial angle), TS (tibial slope), FFA (Femoral flexion angle), and FR (Femur ext. rotation).

The main findings show that:

- MyKnee R has been extremely accurate in replicating the target neutral alignment for the postoperative HKA, FLDA, PTMA, TS, and FFA, and a FR = 3°.
- Facilitated and conservative bony cuts for optimal implant placement and no-to-minimal alteration of the femoral and the tibial joint line have been carried out.
- An optimized alignment of revision implant components in the coronal, sagittal and transverse planes has been reached.
- The sizes planned for the femoral and tibial implant components have been always confirmed intraoperatively.
- Thanks to the preoperative planning and the patient-matched approach, the number of intraoperative, unexpected complications can be drastically reduced.

READ THE STUDY

DOI: 10.1080/17434440.2020.1803737

7. MYKNEE & GMK EFFICIENCY: PROVEN SYNERGY TO OPTIMIZE EVERY TOTAL KNEE REPLACEMENT

The MyKnee patient-matched technology and GMK Efficiency single-use instrumentation work in sinergy to support the optimization of hospital and operating room logistics. It is possible to maximize the time and cost savings and to minimize the logistics associated with a total knee replacement by leveraging the benefits of the MyKnee preoperative planning and patient-matched guides, and of a complete, sterile, single-use instrumentation to perform the surgical procedure. The clinical, economic and logistics benefits associated with these technologies have been demonstrated in a wide range of published papers.

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