RESEARCH ARTICLE

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

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Abstract

Background: The aim of this study is to evaluate the accuracy of bone cuts and the resultant 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 which has been made intraoperative were measured.

Results: The average preoperative HKA axis was 177.5^0 (range 163.5^0 to 194^0), whereas the average postoperative HKA axis was 179.4^0 (range 177.1^0 to 182.7^0). 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.

Conclusion: The MyKnee system evaluated in this study was shown to be remarkable 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 outcomes or patient satisfaction when using patient-specific cutting blocks for TKA.

Keywords: CT scan, HKA ankle, Knee alignment, Patient specific instruments, Total knee arthroplasty

Introduction

Total Knee Replacement (TKR) is the gold standard treatment for degenerative knee joints (1). During the years, TKR has become one of the most successful procedures in orthopaedics, with survival rates greater than 90% after 15 years (2, 3). There are several factors which are responsible for the success of a TKR. Preoperative patient characteristics, implant selection, implantation technique, and the component and limb alignment are the most important among those factors (4). It has been clearly documented, that an error in the coronal positioning of more than 3^0 significantly increases the rate of the component failure (5, 6).

In an attempt to improve implant positioning and limb alignment, computer assisted navigation systems have been developed. It is supposed that these systems improve component positioning and limb alignment when compared to traditional jigs (7, 8). Computer assisted navigation systems are accurate to within 1 mm and 1°, thereby justifying their use as a validation tool for emerging technologies (9). However, the high cost, the extra surgical time associated with setting up the navigation system, and the lack of evidence regarding improved clinical outcome are the main

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disadvantages and barriers, which explains why computer assisted navigation system is not adopted universally (10, 11).

Given this situation a new system was developed, with patient matched cutting blocks created on preoperative imaging data. Patient-matched technology utilizes data from preoperative medical imaging enable the creation of a 3-dimensional model of the distal femur and proximal tibia. After visualization, proprietary software is used to virtually map all bone resections and to accurately size and position the knee implant. Disposable cutting blocks are then manufactured to fit the patient's unique articular deformity (12). Improved accuracy of component placement as well as increased efficiency through reduced operating time, equipment use and patient length of stay, are the suggested benefits of this method (13).

Despite the purported benefits, there remains a lack of data regarding the accuracy of patient matched technology systems. Therefore, the aim of this study is to evaluate the accuracy of bone cuts and the resultant alignment, using the MyKnee patient specific cutting blocks (MyKnee, Medacta International S.A., Castel San Pietro, Switzerland).

Materials and Methods

We retrospectively reviewed all patients undergoing primary TKR with the MyKnee technology for osteoarthritis by one single surgeon (CL) at a single center (Sky Ridge Medical Center, Lone Tree, Colorado, USA) between May 2010 and December 2013. During this period 132 patients received the same cemented total knee system (GMK Sphere, Medacta), using the patient-specific cutting blocks technology (MyKnee, Medacta). All patients were evaluated in the outpatient clinic of the surgeon (CL), and judged good candidates for TKR, while a non-operative treatment had failed for these patients. There were no exclusion criteria. All the patients who were candidates for a primary TKR, and the extra cost of the implant was not an issue for them, were included in the study.

All patients underwent preoperative imaging as per Medacta protocol. This involved Computer Tomography (CT) imaging of the hip, the knee, and the ankle of the affected limb. These images were sent to Medacta International and were used to create the anatomical cutting blocks that can fit a patient's knee morphology without using any alignment jigs to position them. The goal of the preoperative planning is to assess the surgical parameters regarding femoral and tibial implantation in order to manufacture dedicated single patient use cutting blocks. Parameters are to be planned by the surgeon and include: Femoral implant size, Tibial implant size, Femoral resections (Posterior cut height, on both condyles medial and lateral, Distal cut height, on both condyles medial and lateral, Femoral angles (Varus / valgus - Flexion / extension), Femoral rotation (Internal / external rotation vs posterior condyles line and vs epicondylar axis), Tibial resection (Proximal cut height related to both plateaus (medial and lateral), Tibial angles (Varus / valgus, Posterior slope) [Figure 1].

Along with the cutting blocks, a plastic 3D model of the patient's distal femoral and proximal tibial bone was provided, in order to simulate the correct positioning of the cutting blocks to the patient's bones. During the operation, the correct fitting between the bone model and the distal cutting block was initially checked. Afterwards, both distal and anterior cut depth were checked by using the angel wing. According to manufacturer guidelines, the block has to be positioned manually on the distal femur. Considering the anatomical shape of the block, only one orientation is allowed. The correct placement corresponds to the maximum stability position of the block. The femoral cutting block has 4 contact points with the femur, and the tibial block has 3 contact points with the tibia. While CT scan represents the bony anatomy, it is mandatory to remove the cartilage and the soft tissues covering the femoral and tibial contact points. Full exposure of the bone is crucial, in order to obtain the correct and most stable placement of the cutting blocks.

Although the manufacturer gives to the surgeon the capability of choosing a CT or a MRI scan for preoperative planning, we have used only the CT scan based protocol. The reason is that we have seen intraoperative that the cutting blocks based on CT scan matched much better to the bone after removal of the cartilage and the soft tissues, than the MRI scan based cutting blocks.

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 which has been made intraoperative were measured by the surgeon (CL). The accepted normal value for HKA was $0^0 \pm 3^0$ (5, 14).

Results

The patient characteristics revealed an average age of 65 years. There were 52 men and 80 women. 67 patients were operated on their right knee (50.8%), and 65 patients on their left knee (49.2%).

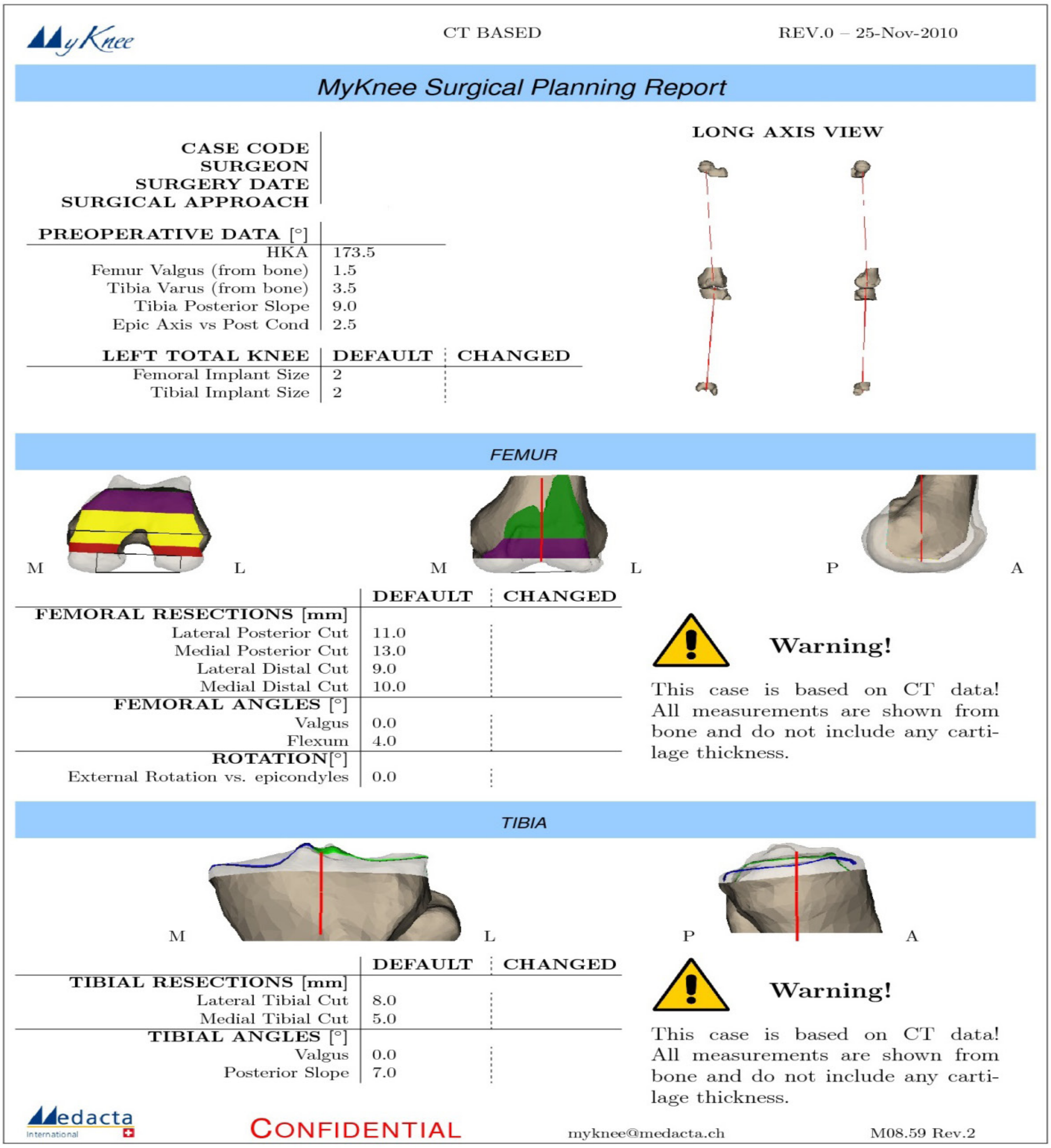
The average preoperative HKA axis was 177.5^0 (range 163.5^0 to 194^0), whereas the average postoperative HKA axis was 179.4^0 (range 177.1^0 to 182.7^0) [Figure 2]. There was no significant difference between the pre- and postoperative HKA axis *(P= 0.23)*.

Intraoperatively, 4 femoral components (3.03%), and 7 tibial components (5.30%) applied to the patients were different than the planned size. The number of the components which has been changed in size intraoperatively represents the 8.33% of all cases [Figure 3]. There was no need of recuts in any of our cases intraoperatively.

For statistical analysis, IBM SPSS 20.0 was used and the level of significance was set as 0.05.

Discussion

It is well known that a postoperative malalignment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MyKnee Surgical Planning Report

CASE CODE
SURGEON
SURGERY DATE
SURGICAL APPROACH

PREOPERATIVE DATA [°]	
HKA	173.5
Femur Valgus (from bone)	1.5
Tibia Varus (from bone)	3.5
Tibia Posterior Slope	9.0
Epic Axis vs Post Cond	2.5

LEFT TOTAL KNEE	DEFAULT	CHANGED
Femoral Implant Size	2	
Tibial Implant Size	2	

LONG AXIS VIEW

FEMUR

M L M L P A

	DEFAULT	CHANGED
FEMORAL RESECTIONS [mm]		
Lateral Posterior Cut	11.0	
Medial Posterior Cut	13.0	
Lateral Distal Cut	9.0	
Medial Distal Cut	10.0	
FEMORAL ANGLES [°]		
Valgus	0.0	
Flexum	4.0	
ROTATION[°]		
External Rotation vs. epicondyles	0.0	

Warning!

This case is based on CT data! All measurements are shown from bone and do not include any cartilage thickness.

TIBIA

M L P A

	DEFAULT	CHANGED
TIBIAL RESECTIONS [mm]		
Lateral Tibial Cut	8.0	
Medial Tibial Cut	5.0	
TIBIAL ANGLES [°]		
Valgus	0.0	
Posterior Slope	7.0	

Warning!

This case is based on CT data! All measurements are shown from bone and do not include any cartilage thickness.

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Figure 1. Preoperative planning based on CT images.

of the mechanical axis of the leg after a TKR results to an increased incidence of aseptic loosening and subsequent failure of the prosthesis. There are several studies which showed superior results if 3^0 of varus / valgus deviation in the coronal plane were not exceeded (5, 6, 15).

However, there is a current controversy in literature concerning limb alignment. The proposal of a kinematically aligned TKA and the theory of constitutional varus knee (16, 17). Kinematic alignment considers the 3D alignment of the components with respect to the knee instead of the 2D alignment of the components with respect to the center of the femoral head and ankle. The intent of kinematic alignment is

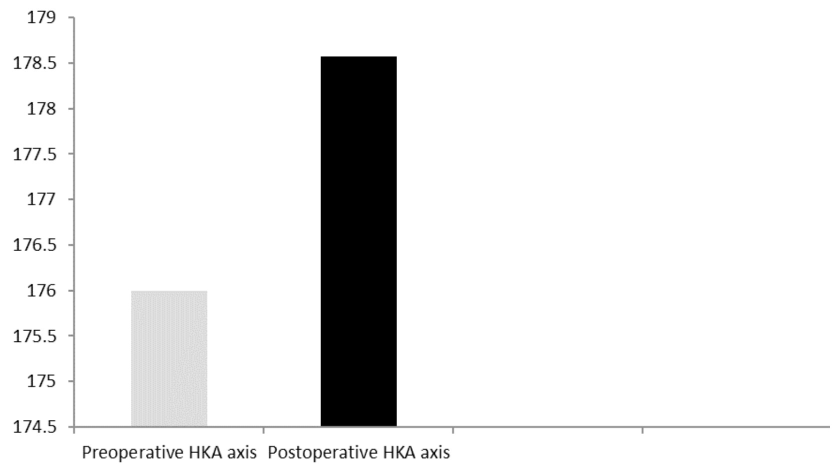

Figure 2. The mean preoperative and postoperative HKA axis.

the restoration of the normal 3D orientation of the three axes that describe normal knee kinematics. In that way, the kinematically aligned TKA restores function by aligning the femoral and tibial components to the normal or prearthritic joint lines of the knee (16). On the other hand, Bellemans et al supports that there are patients with so-called "constitutional varus" knees who have had varus alignment since they reached skeletal maturity. Restoring neutral alignment in these cases may in fact be abnormal and undesirable and would likely require some degree of medial soft tissue release to achieve neutral alignment (17). However, both theories are complicated and new. More studies and long term results are needed to establish or not a different gold standard regarding the alignment in TKA.

In order to improve the alignment of the components, computer-assisted systems have been developed.

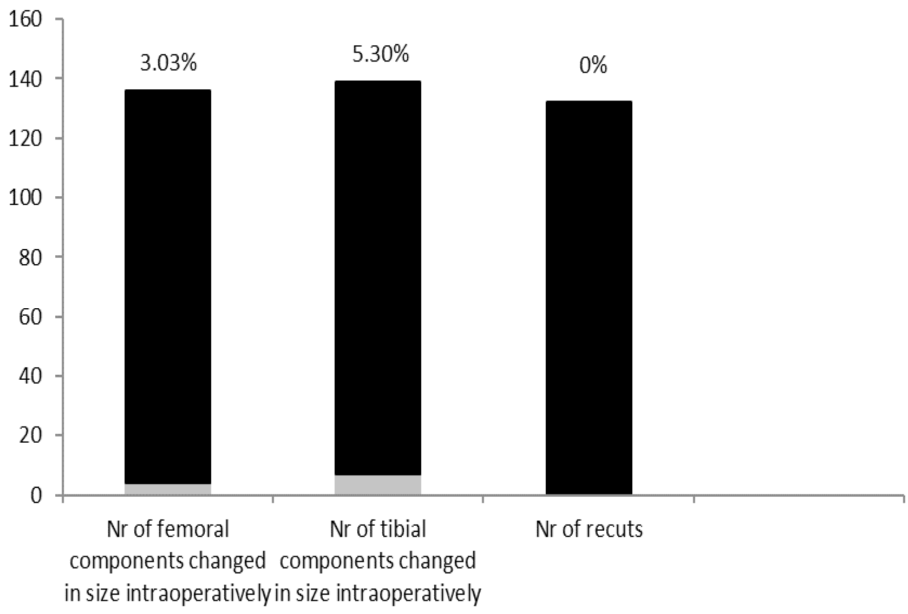

Figure 3. The number of the planned femoral and tibial components which are changed in size intraoperatively, and the number of the recuts required.

Computer-aided surgery has been used for more than a decade, but continues to have high initial capital costs, extended surgical time, and although it has shown some improvement in component positioning, it has not completely eliminated component outliers (18, 19).

Patient-specific cutting blocks have many proposed advantages, including accurate implant positioning, no intramedullary canal violation, reduction of surgical steps for bone resection and related time, reduction of time and cost in washing, assembling and sterilization procedures, but they impose a considerable cost to the healthcare system with expensive imaging in the outpatient setting and additional implant charges to the hospital (20).

The primary finding of this study was that the mean postoperative mechanical axis was 178.57^0, and more important that none of our patients exceeded a 3^0 of varus / valgus deviation. The role of the mechanical axis of the leg in the TKR is well documented. Rand and Coventry found a rate of survival of 90% at ten years for patients with less than 4^0 of deviation from the neutral axis. On the other hand, it decreased to 73% (varus) and 71% (valgus) when the axis of the limb exceeded 4^0 (15). In another study, 421 TKAs were analyzed with regard to the femorotibial angle. In this study, the highest rate of aseptic loosening was found in patients with a varus malalignment (6). Jeffrey et al analyzed the outcome after TKA in 115 patients. They found a rate of 24% of prosthetic loosening when the mechanical axis exceeded $\pm 3^0$ varus/valgus deviation, while it was only 3% in those patients with an axis within a range of $\pm 3^0$ (5).

Our results regarding the limb alignment are superior to those from other studies. In the study of Nunley et al, 15 of the 57 patients (26.3%) who received a patient-matched technology TKR were outliers whereas in the study of Lustig et al the 20.7% of the patients would be outliers if the alignment was not additionally checked with a computer navigation system (9, 20). In another study, Conteduca et al reported that the 16.7% of the patients who received the patients-specific cutting blocks were outliers (21). All these studies concluded that the patients-specific instruments used were unreliable.

On the other hand, the number of the outliers was smaller in the study of Ng et al (9%), suggesting that patient-matched technology provides accurate positioning of the components (22). Additionally, Noble et al showed that there are significant reductions in the number of instrument trays used, duration of hospital stay, and skin to skin time of operation (13).

There are only two studies available in the literature regarding the MyKnee system. The first one is the study of Koch et al. A CT scan based preoperative planning was used in this study as well. The authors reported a postoperative average HKA angle of $180.1^0 \pm 2.0^0$, and a 12.4% of outliers in the frontal plane, with more than 3^0 deviation from the neutral axis (23). The second study is that of Anderl et al, which also a CT-scan based study. The aim of the study is the comparison of early clinical outcome, radiological limb alignment, and three-dimensional (3D)-component positioning between conventional and CT-scan based patient-specific instrumentation (PSI) in primary total knee arthroplasty (TKA). 22.2% of patients in the conventional group were outliers, whereas only 9.6% of patients in the PSI group where counted as outliers (24).

It is very difficult to explain why we have achieved a limb alignment in the coronal plane in the 100% of our patients, whereas all the other authors have demonstrated malalignment in percentages ranging from 9% to 26.3%. One reason could be the fact that we have used a different patient-matched technology system than the other authors. It is possible that the differentiation in the manufacturing process between the companies plays a major role to the final result. Although we have used the same system as in the studies of Koch and Anderl, we have reported significant different results (0% outliers in our study vs 12.4% of outliers in the study of Koch and 9.6% of outliers in the study of Anderl) (23, 24).

Another very important factor is that the cutting blocks used in our study were based on CT images. All other authors, except the study of Koch et al, have used MRI based cutting blocks. The reason for our choice is that at an early stage we have met some difficulties with the MRI based cutting jigs, regarding the accurate fitting of the jigs to the bone. While this was not an issue for the CT based cutting blocks, we decided to use only CT based instruments. We assume that bone models obtained from CT images are more accurate than cartilage models obtained from MRI images. Bone surfaces generated from manually segmented CT scans provide accurate models. However, cartilage surface models segmented from MR tended to over-estimate cartilage thickness for both femur and tibia by 1.15 mm. Such deviation is significant, considering overall cartilage thickness between femur and tibia at the joint is about 6 mm (25).

Another study showed that the accuracy of thickness measurement of articular cartilage in MRI-derived cartilage models is affected by its actual thickness. The thickness of thin cartilage less than 2.5 mm was significantly overestimated in MRI, whereas the cartilage thicker than 2.5 mm was accurately estimated in. This study implies that the accuracy of cartilage thickness measurements in cartilage models should be considered in the context of the native thickness of the articular cartilage specimens. It is expected that the error would be lower in measuring cartilage thickness of healthy articular cartilage (26).

Regarding the comparison between the planned and the actual component size, our results showed that this patient-matched technology system is accurate in the 83.6% of cases. Thus, the proposed advantage of reduction of time and cost in washing, assembling and sterilization procedures is enhanced.

Our study was subject to certain limitations. First, there is only one patient-matched technology group, without a control group, and the comparison of our results have been made with reference sources. Second, we limited our assessment of the mechanical alignment to the coronal plane and did not include any lateral measurements or assessments of rotational alignment. Third, we have not included parameters to determine the cost effectiveness of this method, and we have not included patient satisfaction scores as well. Finally, no blinded observer was used in the study. The surgeon has made all the measurements.

The MyKnee system evaluated in this study was shown to be remarkable 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 outcomes or patient satisfaction when using patient-specific cutting blocks for TKA.

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