

# ***Association between deformity correction and clinical outcome post total knee arthroplasty***

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*“I, Ferdinand Hartzenberg, declare that the coursework Master's Degree mini-dissertation that I herewith submit in a publishable manuscript format for the Master's Degree qualification Orthopaedics at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education.”*

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## **Abstract**

### **Background:**

The aim of this study was to establish if the degree of deformity correction during total knee arthroplasty (TKA) has an influence on post-operative patient satisfaction.

### **Patient and methods:**

This was a retrospective, descriptive analytical study of 180 patients that underwent an elective TKA using computer assisted software. Patients were divided into two groups according to the degree of deformity correction required to obtain a neutral mechanical axis: 3-degrees-and-more or less-than-3-degrees. Knee injury and Osteoarthritis Outcome Scores (KOOS) were collected at the pre-operative, 6 week and 1 year post-operative intervals.

The mean KOOS scores were compared at each interval and the difference between mean KOOS scores were compared for the following intervals: pre-operative to 6 weeks post-operative; pre-operative to 1 year postoperative; 6 weeks to 1 year postoperative.

### **Results:**

The pre-operative mean KOOS scores for the group of patients that required a 3-degree-and-more deformity correction were statistically higher than the group requiring less-than-3-degree-deformity correction. At 6 week and 1 year follow ups there was no statistical difference between the two comparison groups.

With respect to mean KOOS score improvement between intervals, the group that required less than 3 degrees of deformity correction showed statistically significant improvement in symptoms for the pre-operative to 1 year follow up period.

### **Conclusion:**

Results of the study showed that patients requiring a lesser correction of their malalignment do better after TKA.

### **Keywords:**

Knee Arthroplasty, Outcome, Mechanical alignment, Deformity correction

## **Chapter 1: Literature review**

### **Association between deformity correction and clinical outcome post total knee arthroplasty**

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## **1. Introduction**

Arthroplasty has been done since the mid-nineteenth century. Fergusson started in 1861 with simple excision of ankylosed joints to produce an extra-articular pseudarthrosis. Due to the poor results of simple excision surgery, surgeons turned to interposition arthroplasty with the aim of preventing ankylosis.<sup>1</sup> Verneuil in 1863 performed the first interposition knee arthroplasty using a flap of knee capsule. Even though better results were obtained by interposition arthroplasty, it was still ineffective for the treatment of arthritic joints. This led surgeons to start and experiment with multiple manmade materials.<sup>1</sup>

The modern era of arthroplasty started in 1960 with Sir John Charnley. He developed a total hip prosthesis that consisted of a stemmed stainless steel femoral head that articulates with a high density polyethylene acetabulum implant. Gunston used Sir Charnley's concept and developed a similar knee prosthesis. Since then improvements have been made to the initial implant design, materials and fixation methods, but the basic concept of Charnley is still the same.<sup>1</sup>

Today total knee arthroplasty is one of the most successful and widely performed surgeries in the world, with the aim of relieving pain, improving function and correcting deformities. Currently 700 000 cases are performed annually in the USA and it is expected that this will rise to 3,48 million by 2030.<sup>1,2,3</sup>

Even with the advancements in surgical technique and implants up to 20% of patients are still dissatisfied post-operatively.<sup>4</sup> Multiple studies have been performed to try and assess for the cause of dissatisfaction that included; patient related factors, restoration of alignment and patient expectations.

This led surgeons to develop the concept of kinematic alignment that consists of positioning the implant according to the individual's anatomy. There is evidence to support that kinematic alignment results in better functional outcomes, but implant position was found not to be consistently aligned to the mechanical axis. There is a concern that the functional improvement will come at the expense of long-term durability.<sup>2</sup>

### **1.2 Background**

Total knee arthroplasty remains the treatment of choice for knees deformed due to arthritis. The arthroplasty results in reproducible outcomes of pain relief, improved function and longevity.<sup>6,7</sup> A small but significant number of patients are still dissatisfied with the outcome.<sup>8</sup> In a study

performed by *Noble et al.* they found that up to 14% of patients were “dissatisfied” or “very dissatisfied” post operatively. <sup>6</sup>

Multiple factors have been identified that affect outcome. Good outcomes are associated with greater pre-operative pain and/or disability, fulfilled patient expectations, improvement of function and pain relief. Poor results are associated with post-operative complications that require admission, ethnic factors and low socioeconomic circumstances.<sup>8</sup>

Due to this high prevalence of patient dissatisfaction with mechanical alignment via conventional and computer assisted instruments, kinematic alignment with patient-specific femoral and tibial cutting guides were introduced in 2005.<sup>4</sup> The concept of kinematic alignment is to position implants according to the individual patient’s anatomy.<sup>2</sup>

Most studies that have been performed to assess outcome, have focussed on the objective outcome by reviewing the patients function and x-ray findings. Limited studies have been performed to assess the subjective outcome.<sup>7</sup>

### **1.3 Biomechanics**

#### **1.3.1 Kinematics:**

Kinematics of the knee is determined by the joint surface, menisci and ligaments that result in a relative relationship of the femur, tibia and patella at any point of motion without any force applied.<sup>1</sup>

In a healthy joint there is a balance between the joint surface and ligamentous structures. Typically the lateral soft tissue is lax when the knee is in flexion and taught with the knee is in full extension.<sup>2</sup> This results in motion that occurs in multiple planes around the long axis of the limb.<sup>1</sup>

Instruments used for mechanical alignment have no bearing on the kinematics of the knee.<sup>9</sup>

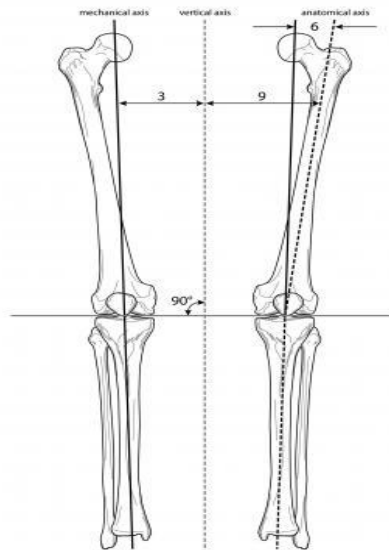
#### **1.3.2 Limb axis:**

Mechanical axis:

The mechanical axis is obtained by drawing a line from the centre of the femoral head to the centre of the talar dome. It is regarded as neutral if the line transects through the centre of the knee. During normal gait the mechanical axis is in 3 degrees valgus form the vertical axis due to the feet being placed closer to the midline.<sup>1</sup>

Anatomical axis:

The anatomical axis is obtained by drawing a line that bisects the medullary canal of the femur and tibia. The normal anatomical axis angle between the tibia and femur is 6 degrees valgus +/- 2 degrees.<sup>1</sup>

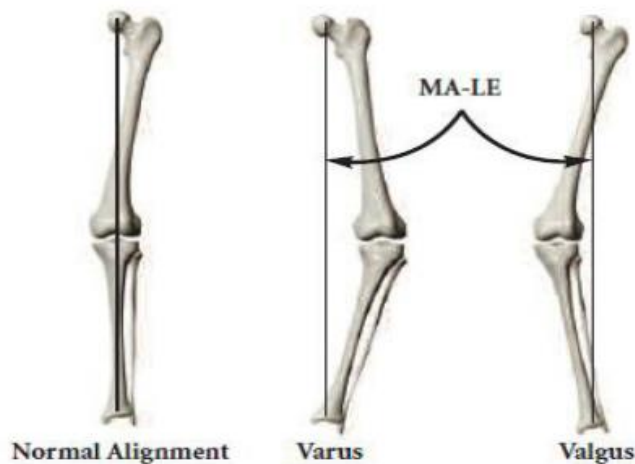


**Figure 1:** Illustrates difference between mechanical and anatomical axes

### 1.3.3 Valgus and varus deformities:

Valgus deformity is found when the mechanical axis transects lateral to the centre of the knee.<sup>1</sup>

Varus deformity is found when the mechanical axis transects medial to the centre of the knee.<sup>1</sup>



**Figure 2:** Illustrates varus and valgus deformities of knee according to mechanical axis

### 1.3.4 Kinematic knee axes:

Three axes govern kinematic movement of the tibia and patella in respect to the femur:

First axis:

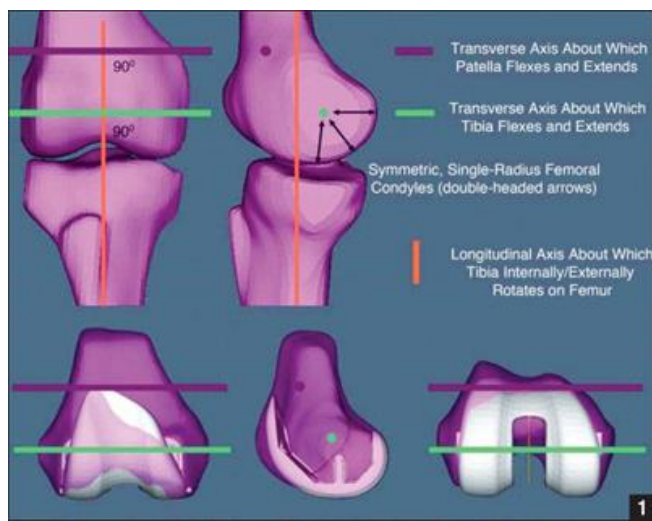
- The primary transverse axis passes through the centre of the medial and lateral femoral condyles – *Figure 3*.
- The tibia flexes and extends around this axis.<sup>5,10</sup>
- The medial and lateral femoral condyle have unique radii, with the medial condyle radius being larger than lateral condyle – *Figure 4*.<sup>2</sup>
- This leads to the primary transverse axis not being parallel to the condyles.<sup>2</sup>

Second axis:

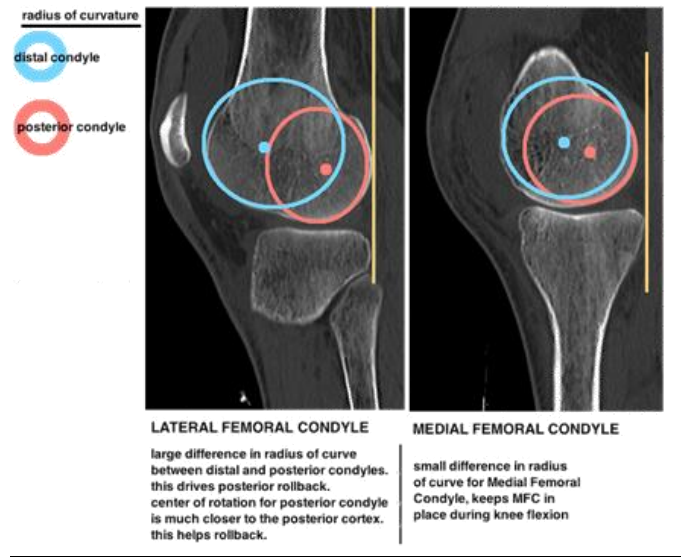
- The secondary transverse axis is in the distal femur around which the patella flexes and extends – *Figure 3*.
- The secondary axis is located anteriorly, parallel and proximal to the primary transverse axis.<sup>5,10</sup>

Third axis:

- The longitudinal axis of the tibia is the axis around which the tibia internally and externally rotates on the femur – *Figure 3*.
- The longitudinal axis is perpendicular to the primary and secondary transverse axes.<sup>5,10</sup>



**Figure 3:** Illustrates different kinematic axes around knee



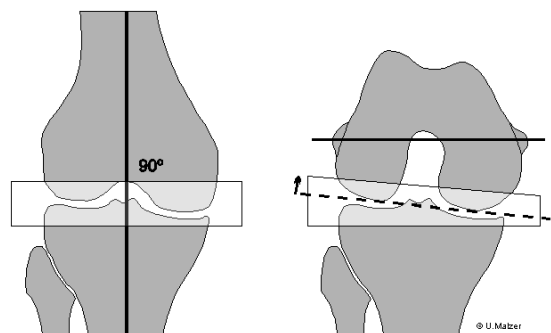
**Figure 4:** Illustrates difference in size of medial and lateral femoral

### 1.4 Surgical technique

Placement of the femoral and tibial components are the best predictors of clinical outcome.<sup>5</sup> The conventional alignment method of measured resection or gap balancing resulted in excellent implant longevity but had poor clinically outcomes.<sup>2</sup>

#### 1.4.1 Principles of classic mechanical alignment:

- The femoral cut is made perpendicular to mechanical axis of femur
- The tibial cut is made perpendicular to mechanical axis of tibia
- The anterior-posterior and internal-external position of the femoral component is adjusted so that the flexion and extension gap is equal
- Soft tissue releases are done to restore motion and stability<sup>5</sup>



**Figure 5:** Classic femoral and tibial cuts made perpendicular to mechanical axis

#### **1.4.2 Principles of kinematic alignment:**

- The femoral cut is co-aligned with the primary transverse axis of the femur
- The ligament length and stability are restored by removing osteophytes
- The tibial cut is aligned so that the longitudinal axis of the tibia is perpendicular to the primary transverse axis of the femur <sup>5</sup>

#### **1.4.3 Conventional technique:**

The conventional technique relies on surgeon pre-operative planning and templating.

Steps:

Pre-operative:

- Long leg standing cast
- Determine the mechanical axis, deformity and template prosthesis <sup>11</sup>

Intra-operative:

- Femoral and tibial cuts guided by extra- and intramedullary devices
- Size, orientation and alignment of implant determined by surgeon <sup>11</sup>

Post-operative

- Post-operative long leg cast to determine mechanical axis <sup>11</sup>

#### **1.4.4 Computer assisted knee arthroplasty:**

The aim of using computer navigation is to achieve a near neutral mechanical aligned knee. The system is a none x-ray based navigation system that relies on reflector spheres that is inserted into the proximal tibia and distal femur. <sup>11</sup>

Steps during surgery:

- “Morphing” – virtual image of mechanical alignment of lower limb
- Severity of deformity is then calculated
- Bone cuts navigated via computer and software
- Size, orientation and alignment of implants are determined by the computer
- Post implant insertion mechanical axis reviewed <sup>11</sup>

## **1.5 Computer assisted versus conventional alignment**

Success of total knee arthroplasty is measured by:

- Pain relief
- Improvement in function
- Patient satisfaction
- Implant longevity

All of these are determined and affected by the following factors:

- Prosthetic factors - implant size, tribology and position
- Patient factors - weight, size, activity level and existing co-morbidities
- Surgical factors - skill, experience, duration of surgery and implantation of prosthesis

Initially the focus was placed on surgical technique and its relationship with implant performance and longevity. It has been proven that malalignment of more than 3 degrees varus result in poorer implant survival. This is due to the shift of the mechanical axis that results in abnormal stresses at the bearing surface, resulting in accelerated wear. It was found that even at major arthroplasty centres, up to 25% of total knee arthroplasties had unacceptable alignment.<sup>11</sup>

In a study performed by *Choong et al.* to compare conventional alignment to computer-navigated alignment they found that there was a significant higher portion of patient within 3 degrees of the neutral mechanical axis with the use of computer-navigated systems. They also found that patient did better post-operatively if the mechanical axis was within 3 degrees of the neutral mechanical axis as compared to patient with greater than 3 degrees malalignment.<sup>11</sup>

There is no significant difference in complications between computer-navigated and conventional surgery. It has been stated that computer-navigated surgery results in lower rates of systemic emboli and blood loss. *Choong et al.* did not find any difference between the two groups.<sup>11</sup>

## **1.6 Disadvantages of mechanical alignment**

Studies from the United Kingdom and Canada revealed that 20% of patients at 1 year follow up were dissatisfied with the result. In all the cases conventional instruments were used to obtain mechanical alignment. The reasons for dissatisfaction were:

- Continued pain

- Poor function in activities of daily living <sup>5,10</sup>

With the use of computer assisted surgery, the mechanical alignment was improved but did not result in better clinical outcomes.<sup>5</sup>

To obtain normal knee kinematics with total knee arthroplasty the tibia and femoral components should be orientated that it resembles the three kinematic axes of the normal knee. None of these axes can be found with the use of conventional or computer assisted instruments.<sup>5</sup> These axes include: transepicondylar axis, centre of the femur and ankle. <sup>5</sup>

The conclusion was made that mechanical aligned total knee arthroplasties with conventional instruments and/or computer assisted devices still have a high prevalence of continued dissatisfaction from patients.<sup>5</sup>

### **1.7 Advantages of kinematic alignment**

A study was performed on 23,000 knees to assess if there was an early clinical benefit or a disadvantage to kinematic alignment. Patients were asked to fill in a questionnaire pre- and post-operatively and records containing information regarding the surgical procedure were also kept.<sup>5</sup>

The following results were obtained:

- The patients experienced less surgical stress
- There was a shorter post-operative recovery time
- Earlier return to activities of daily living
- Shorter surgical time was observed <sup>5</sup>

Patient experience post-operative:

- 94% of patients judged their knee as being normal or near normal
- 98% of patients judged the alignment of their limb as “just right”
- All the patients experienced less pain at the 4-5 weeks follow up period
- There was a significant improvement in return to activities of daily living <sup>5</sup>

### **1.8 Patient satisfaction**

Patient satisfaction is becoming increasingly important, especially in elective surgery as total knee arthroplasty.<sup>6</sup>

*Bullens et al.* found in study on patient satisfaction post total knee arthroplasty, that there is a poor correlation between the objective physician-assessed knee score and the subjective patient-assessed satisfaction score. They concluded that the priorities of the patient and surgeon are different.<sup>7</sup>

The priority of the surgeon is range of motion, alignment and stability, whereas the patient focus more on functionality.<sup>7</sup>

*Nobel et al.* concluded in a study on patient expectations and satisfaction:

- Patient's subjective perception of their knee function is more important than the biomechanical function.
- They found that three independent factors correlated with reduced patient satisfaction. These included:
  - Difficulty in performing activities that the patient deems important
  - Difficulty in performing activities that the patient love
  - Difficulty in performing activities of daily living
- Patient expectations include a diverse range of factors. This ranges from the objective joint deformity to the patient's subjective self-image. Most of them not related to joint function.
- Strongest reason for dissatisfaction was frequency of knee stiffness, perception than knee felt abnormal and frequency of use of pain medication.<sup>6</sup>

### **1.9 Failing total knee arthroplasties**

Total knee arthroplasty has a 90 - 95% patient satisfaction rate if pain relief and functional improvement are measured. 90% of total knee arthroplasties have a 10 - 15 year survival rate. Nonetheless some patients still have poor results and require revision surgery.<sup>12</sup>

Multiple studies have been performed and all came to the same conclusion. The main indications for revision surgery are:

- Polyethylene wear – 25%
- Aseptic Loosening – 24.1%
- Instability – 21.2%
- Infection – 17.5%
- Arthrofibrosis – 14.6%
- Malalignment or malposition – 11.8%

- Extensor mechanism deficiency – 6.6%
- Avascular necrosis patella – 4.2%
- Periprosthetic fracture – 2.8%
- Isolated patellar resurfacing – 0.9% <sup>12</sup>

### **1.10 Knee Injury and osteoarthritis outcome score**

The KOOS survey is a knee specific instrument and is used to assess:

- Patients between the ages of 14 and 79 years
- Patient's subjective opinion about their knee
- Short and long term follow up of knee symptoms
- Disorders resulting in knee complaints
  - Anterior cruciate ligament tear
  - Meniscus tear
  - Mild to severe osteoarthritis <sup>13</sup>

KOOS survey scored:

- Consists of 5 relevant categories that are scored separately:
  - Pain – 9 questions
  - Symptoms – 7 questions
  - Activities of daily living – 17 questions
  - Sport and recreational activities – 5 questions
  - Quality of life – 4 questions <sup>13</sup>
- The Likert score is used for each category:
  - 5 possible answers for each question with  
0 = No symptoms  
4 = Severe symptoms <sup>13</sup>
- Calculation of results:
  - The sum of all Likert scores for each category is obtained
  - Scores are transformed to a 0-100 percentage with  
0 = Extremely symptomatic  
100 = Asymptomatic <sup>13</sup>

## **2. Hypothesis**

From the above studies we have learned that total knee arthroplasty is an excellent procedure with predictable outcomes, but there is an unacceptable portion of patients that are still dissatisfied post operatively. Initially it was postulated that the cause for this dissatisfaction may be due to malalignment of the prosthesis. *Choong et al.* performed a study and found that malalignment of more than 3 degrees results in poorer outcome. They also concluded that with the use of conventional instrument in major arthroplasty centres a large portion of patients were misaligned. This led to the development of computer navigated surgery to try and improve on the alignment. With the use of computer navigation the alignment was improved but there was no improvement in the clinical outcome.

Studies were performed to assess what influences patient satisfaction post operatively. They found that there was a poor correlation between what the patient and surgeon deem important. Patients found the subjective perception of their knee function more important than the biomechanical function.

Surgeons then turned to kinematic alignment where implants are placed according to the individual patient's anatomy. Kinematic alignment showed good results in short term follow up studies with a large portion of the patient judging their knee as being near normal.

We want to perform a retrospective study on patients that received a total knee arthroplasty using computer assisted navigation to assess if the required degree of deformity correction influences the outcome. The outcome will be assessed only on the patient's perception of their knee.

We hypothesize that patients requiring a lesser deformity correction will do better post-operatively as this will result in a more kinematic type alignment.

## **3. Aims and objectives**

The aim of this study will be to establish if the degree of deformity correction during total knee arthroplasty has an influence on post-operative patient satisfaction.

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## **Chapter 2: Manuscript**

# Association between deformity correction and clinical outcome post total knee arthroplasty

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Association between deformity correction and clinical outcome  
post total knee arthroplasty

## **Abstract**

### **Background:**

The aim of this study was to establish if the degree of deformity correction during total knee arthroplasty (TKA) has an influence on post-operative patient satisfaction.

### **Patient and methods:**

This was a retrospective, descriptive analytical study of 180 patients that underwent an elective TKA using computer assisted software. Patients were divided into two groups according to the degree of deformity correction required to obtain a neutral mechanical axis: 3-degrees-and-more or less-than-3-degrees. Knee injury and Osteoarthritis Outcome Scores (KOOS) were collected at the pre-operative, 6 week and 1 year post-operative intervals.

The mean KOOS scores were compared at each interval and the difference between mean KOOS scores were compared for the following intervals: pre-operative to 6 weeks post-operative; pre-operative to 1 year postoperative; 6 weeks to 1 year postoperative.

### **Results:**

The pre-operative mean KOOS scores for the group of patients that required a 3-degree-and-more deformity correction were statistically higher than the group requiring less-than-3-degree-deformity correction. At 6 week and 1 year follow ups there was no statistical difference between the two comparison groups.

With respect to mean KOOS score improvement between intervals, the group that required less than 3 degrees of deformity correction showed statistically significant improvement in symptoms for the pre-operative to 1 year follow up period.

### **Conclusion:**

Results of the study showed that patients requiring a lesser correction of their malalignment had better improvement in their symptoms after TKA, but there was no statistical difference between the outcomes measured at 1 year follow up.

### **Keywords:**

Knee Arthroplasty, Outcome, Mechanical alignment, Deformity correction

## **Introduction**

Today, total knee arthroplasty (TKA) is one of the most successful and widely performed surgeries in the world; with the aim of relieving pain, maintaining motion and correcting deformities. It is expected that by the year 2030, 3.4 million arthroplasties will be performed annually in the USA.<sup>1</sup>

TKA has been proven to relieve pain and improve function, but even though the latest advancements in techniques and implants, up to 20% of patients are dissatisfied at one year follow up.<sup>2,3,4</sup>

Studies have identified multiple factors that affect the outcome of their surgery. Good outcomes are associated with increased pre-operative pain and/or disability, fulfilled patient expectations, improvement of function and pain relief. Poor results are associated with post-operative complications requiring admission, ethnic factors and low socioeconomic circumstances.<sup>5</sup>

*Bullens et al.* found in a study on patient satisfaction post TKA that there is a poor correlation between the objective physician-assessed knee score and the subjective patient-assessed satisfaction score. They concluded that there is a difference between the priorities of the patient and the surgeon. The priority of the surgeon is to optimise range of motion and obtaining neutral alignment in a stable knee; whereas the patient focuses more on functionality.<sup>6</sup>

The conventional alignment methods of measured resection or gap balancing show excellent implant longevity but there is still a subgroup of patients that are dissatisfied.<sup>7</sup> The main reasons being continued pain and poor function in activities of daily living. This led to the development of computer assisted surgery that resulted in improved alignment but no improvement in the clinical outcome<sup>8,9</sup>

The purpose of this study was to determine if there was an association between correction of deformity and subjective patient satisfaction.

## **Methods and Materials**

A retrospective, descriptive analytical study was performed at our institution. The following inclusion criteria was used:

- Elective unilateral TKA at Mediclinic Bloemfontein
- Final mechanical deviation less than 3 degrees

- Computer-navigated alignment
- Performed between 2009-2014
- No post-operative complications
- Complete data

All surgeries were performed by a single surgeon using the same implant, computer software and uniform surgical technique.

Patients were placed into one of two groups. The first group required a deformity correction of less than 3 degrees and the second group a deformity correction of 3 degrees and more. The angle of deformity correction was determined by subtracting the post-operative mechanical axis deviation from the pre-operative mechanical axis deviation. The mechanical axis deviations used for the calculations were obtained from the computer software during surgery – *Figure 1*.

KOOS scores were collected at the pre-operative, 6 week and 1 year post-operative intervals. The mean KOOS scores at each of the intervals and the difference in mean KOOS scores between the intervals were assessed and compared.

The Knee injury and Osteoarthritis Outcome Score (KOOS) survey is a subjective patient questionnaire. It is used for the short and long term follow up of knee symptoms. It consists of 5 relevant categories that are scored separately, with 5 possible answers for each question ranging from 0 - 4 with the latter indicating more symptomatology. The results are calculated as the sum of all the Likert scores for each category obtained. This is then transformed to a percentage, with 0 being a severely symptomatic knee and 100 being an asymptomatic knee.<sup>10</sup>

The raw data was submitted to the Department of Biostatistics at the University of the Free State for analysis.

## **Results**

A total of 180 patients were included in this study. There were 91 patients in the group that required a deformity correction of less than 3 degrees and 89 patients in the group that required a deformity correction of 3 degrees and more. In the group with 3 degrees and more deformity correction, the correction ranged from 3.5 to 14 degrees as seen in - *Table I*.

The pre-operative mean KOOS scores for the group of patients that required a deformity correction of 3 degrees and more were higher than those of the patients in the comparison group. As a group they scored higher in 4 of the 5 categories – *Table II*.

At the 6 weeks and 1 year follow up there was not a statistically significant difference between the two groups – *Table III and Table IV*. Of note, it was a coincidence that the patient obtained similar results in 4 of the 5 categories at 1 year follow up.

With regards to the results from both deformity groups, there was a statistically significant improvement in symptoms in the pre-operative to 1 year follow up period in the group of less than 3 degrees deformity correction ( $p=0.03$ ) – *Figure 2*.

## **Discussion**

TKA remains the treatment of choice for deformed knees caused by arthritis. Despite repeated good results, up to 20% of patients are still dissatisfied at 1 year follow up without any apparent cause.<sup>4,9</sup> Today, patient satisfaction is becoming increasingly important, especially in elective surgery such as TKA.<sup>4</sup>

The success of TKA is determined by prosthetic, patient and surgical factors. Up to now the focus has been on surgical technique and its relationship with implant performance and durability. This led to studies assessing alignment and the effect it has on the implant survival. *Choong et al.* demonstrated that malalignment results in poorer implant survival due abnormal stresses that result in accelerated wear.

Studies demonstrate that even at major arthroplasty centres, up to 25% of TKA have unacceptable alignment post operatively.<sup>8</sup> This led to the development of computer assisted surgery. *Choong et al.* demonstrated that a significantly higher portion of patients were within the 3 degrees neutral mechanical axis with the use of computer-navigated systems. But even with the improvement in mechanical alignment, studies in the United Kingdom and Canada found no improvement in clinical outcome.<sup>7</sup> They concluded that mechanical aligned TKA with conventional instruments and/or computer assisted devices still has a high prevalence of continued dissatisfaction.<sup>7</sup>

Most studies that have been performed to assess outcome have focussed on the objective outcome by reviewing the patient's function and x-ray findings. Limited studies have been

performed to assess the subjective outcome. *Nobel et al.* performed and concluded in a study of patient expectations and satisfaction that the patient's subjective perception of knee function is more important than the biomechanical function. Patient expectations include a diverse range of factors, ranging from objective joint deformity to subjective self-image. Most of these factors are unrelated to joint function. They found that the strongest reason for dissatisfaction was the frequency of knee stiffness, perception that the knee felt abnormal and the frequency of the usage of pain medication.<sup>4</sup>

This study has a number of limitations. These include the retrospective nature of the study, small study sample and short period of follow up. A further limitation is the fact that the groups were not divided pre-operatively into varus and valgus deformities and studied separately.

It is the opinion of the researcher that follow up studies should be performed as TKA is a multiplane deformity correction that includes coronal, sagittal and rotational elements. Only coronal deformity correction was taken into consideration. Other pathologies that can contribute to knee symptoms were not taken into account.

## **Conclusion**

Study results show that patients requiring less correction of their malalignment had better improvement in their symptoms between the pre-operative to 1 year post-operative period. Of note is that there was no statistical difference between the outcomes measured at 1 year follow up. The reason for this improvement can be attributed to the fact that the group that required a deformity correction of less than 3 degrees was statistically more symptomatic at initial presentation.

This has been confirmed in recent literature showing under-correction leads to improved clinical results.

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Figure 1 – Illustration showing mechanical axis deviation generated with computer software

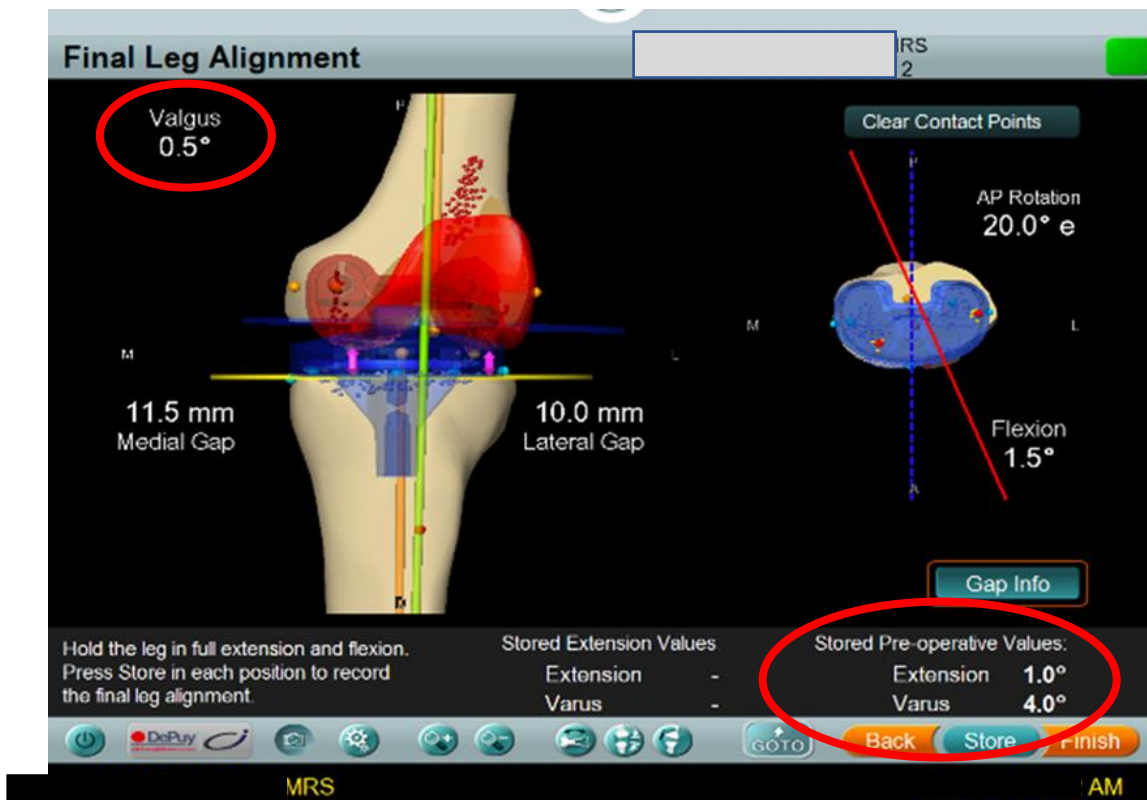


Figure 2 – Graph showing difference in mean KOOS scores at given intervals

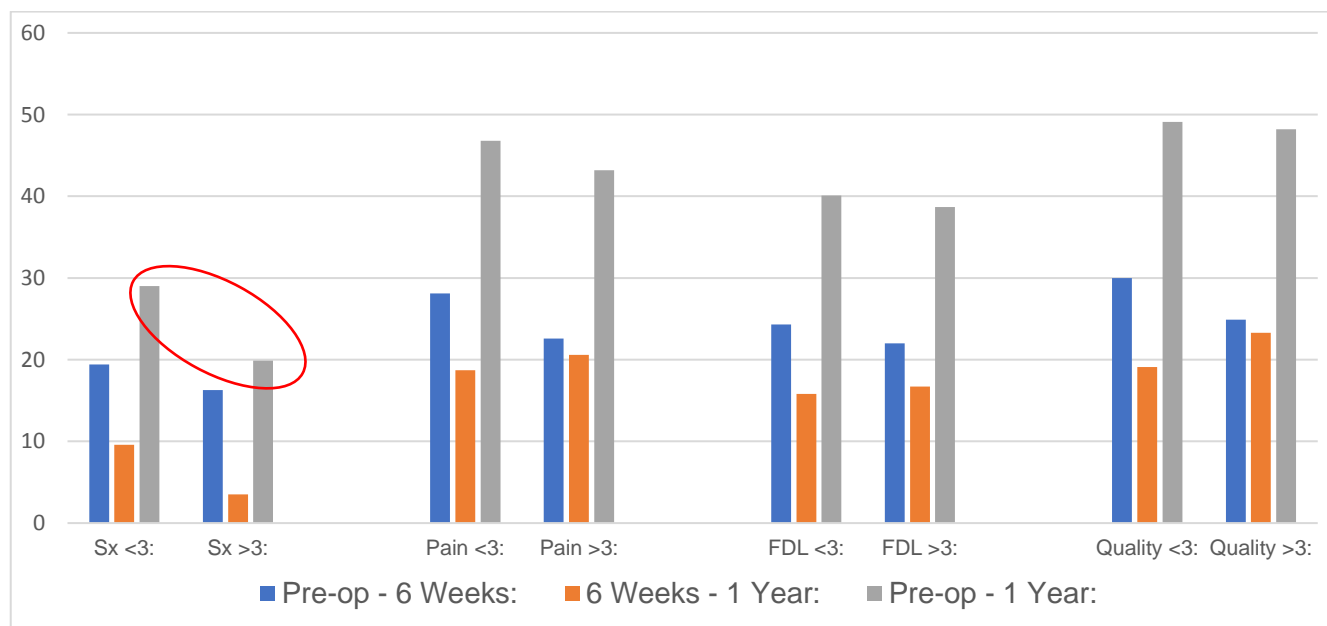


Table I – Division of patients according to required deformity correction

<b>&lt; 3 Degrees deformity correction:</b>		<b>&gt; 3 Degrees deformity correction:</b>	
0	7	3.5 - 5	52
0.5	11	5.5 - 7	21
1	16	7.5 - 9	11
1.5	19	9.5	2
2	15	10	1
2.5	9	10.5	1
3	14	14	1
<b>Total:</b>	<b>91</b>		<b>89</b>

Table II

<b>Pre-operative mean KOOS scores:</b>			
<b>KOOS Category:</b>	<b>&lt; 3 Degrees Correction:</b>	<b>&gt; 3 Degrees Correction:</b>	<b>P-Value:</b>
Symptoms:	42.9	53.6	0.0246
Pain:	38.9	50	0.0028
Function, daily living:	38.2	47	0.0242
Functional, sport and recreational:	0	0	0.7743
Quality:	25	37.5	0.0259

Table III

<b>6 weeks mean KOOS scores:</b>			
<b>KOOS Category:</b>	<b>&lt; 3 Degrees Correction:</b>	<b>&gt; 3 Degrees Correction:</b>	<b>P-Value:</b>
Symptoms:	67.9	71.4	0.1979
Pain:	72.2	72.2	0.6478
Function, daily living:	67.7	70.6	0.2799
Functional, sport and recreational:	0	0	0.4098
Quality:	56.2	62.5	0.2958

Table IV

<b>1 year mean KOOS scores:</b>			
<b>KOOS Category:</b>	<b>&lt; 3 Degrees Correction:</b>	<b>&gt; 3 Degrees Correction:</b>	<b>P-Value:</b>
Symptoms:	71.4	71.4	0.1955
Pain:	94.4	94.4	0.9292
Function, daily living:	88.2	88.2	0.5018
Functional, sport and recreational:	0	0	0.9686
Quality:	87.5	81.3	0.6258

## **Appendix A: Protocol**

### **Association between deformity correction and clinical outcome post total knee arthroplasty**

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## **1. Introduction**

Arthroplasty has been done since the mid-nineteenth century. Fergusson started in 1861 with simple excisions of ankylosed joints to produce extra-articular pseudarthrosis. Due to the poor results of simple excision surgery, surgeons turned to interposition arthroplasty with the aim of preventing recurrence of bone. <sup>1</sup>

The modern era of arthroplasty started in 1960 with Sir John Charnley. He developed a total hip prosthesis that consisted of a stemmed stainless-steel femoral head that articulates with a high-density polyethylene acetabulum implant. Gunston used Sir Charnley's concept and developed a similar knee prosthesis. Improvements have been made to the initial implant design, materials and fixation methods, but the basic concept of Charnley is still the same. <sup>1</sup>

Today total knee arthroplasty is one of the most successful and widely performed surgeries in the world, with the main aim to relieve pain, maintain motion and to correct deformities. In the United Kingdom 80 000 cases and in USA 700 000 cases are performed annually. It is expected that by 2030, 3.48 million total knee arthroplasties will be performed annually in the USA. <sup>1,2,3</sup>

Even with the advancements in surgical technique and implants there are still up to 20% patient dissatisfaction post-operative. <sup>5</sup> Multiple studies have been performed to try and assess for the cause of dissatisfaction that included; patient related factors and expectations, restoration of alignment and patient expectations.

### **1.2 Background**

Total knee arthroplasty remains the treatment of choice for deformed knees due to arthritis, resulting in repeatable pain relief, improved function and longevity. <sup>7,8</sup> A small but significant number of patients are still dissatisfied with the outcome. <sup>12</sup> In a study performed by *Noble et al.* they found that up to 14% of patients were "dissatisfied" or "very dissatisfied" post operatively. <sup>7</sup>

Multiple factors have been identified that affect outcome. Good outcomes are associated with greater pre-operative pain and/or disability, fulfilled patient expectations, improvement of function and pain relief. Poor results are associated with post-operative complications that require admission, ethnic factors and low socioeconomic circumstances. <sup>12</sup>

Most studies have been performed to assess outcome, have focussed on the objective outcome by reviewing the patients function and x-ray findings. Limited studies have been performed to assess the subjective outcome. <sup>8</sup>

## **1.3 Biomechanics**

### **1.3.1 Kinematics**

Kinematics of the knee is determined by the joint surface, menisci and ligaments that result in a relative relationship of the femur, tibia and patella at any point of motion without any force applied. <sup>1</sup>

In a healthy joint there is a balance between the joint surface and ligamentous structures. Typically, lateral soft tissue is lax with the knee in flexion and taught with the knee in full extension. <sup>2</sup>This results in motion that occurs in multiple planes around the long axis of the limb. <sup>1</sup>

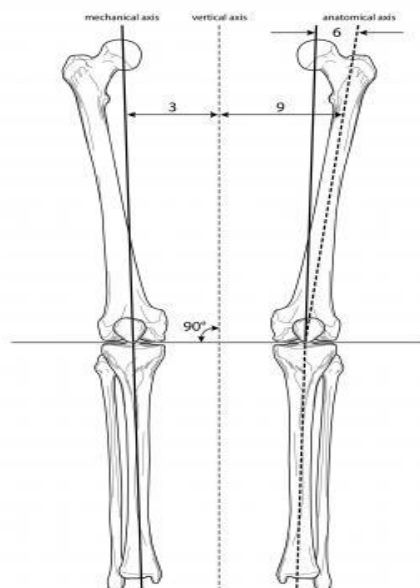
### **1.3.2 Limb axis**

Mechanical axis:

Line drawn from the centre of the femoral head to the centre of the talar dome. It is a neutral axis if the line transects through the centre of the knee. <sup>1</sup>

Anatomical axis:

Line drawn that bisects medullary canal of femur and tibia. Normal anatomical axis angle between tibia and femur is 6 degrees valgus +/- 2 degrees. <sup>1</sup>

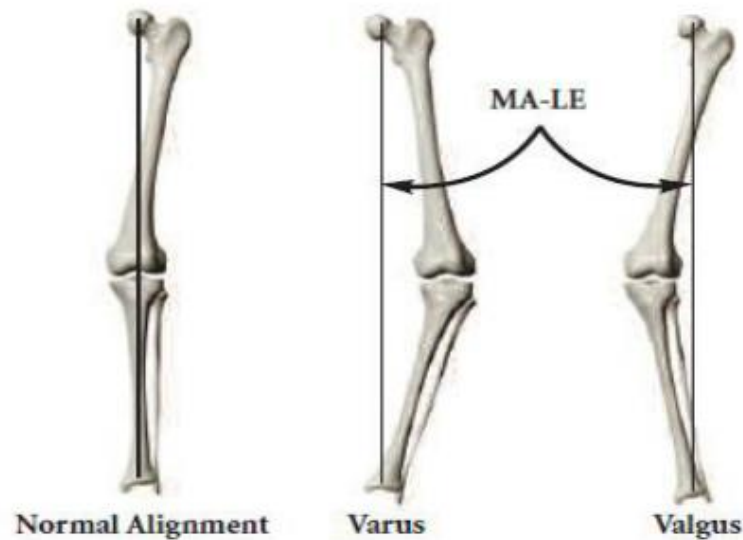


**Figure 1:** Illustrates difference between mechanical and anatomical axes

### 1.3.3 Valgus and varus deformities

Valgus: Mechanical axis transect lateral to the centre of the knee. <sup>1</sup>

Varus: Mechanical axis transect medial to the centre of the knee. <sup>1</sup>



**Figure 2:** Illustrates varus and valgus deformities of knee according to mechanical axis

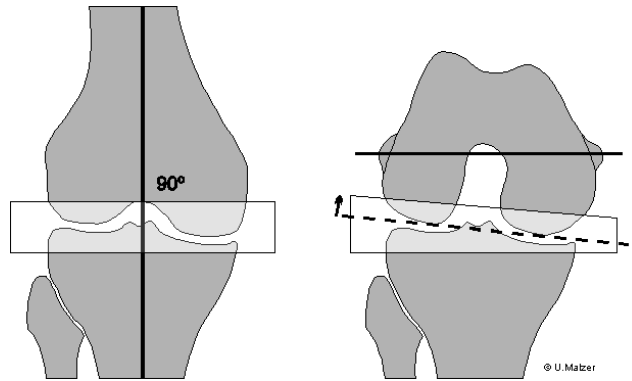
### 1.4 Surgical technique

Placement of the femoral and tibial components are the best predictors of clinical outcome. <sup>4</sup>

The conventional alignment method of measured resection or gap balancing resulted in excellent implant longevity but had poor clinically outcomes. <sup>2</sup>

#### 1.4.1 Principles of classic mechanical alignment:

- Femoral cut made perpendicular to mechanical axis of femur
- Tibial cut made perpendicular to mechanical axis of tibia
- Anterior-posterior and internal-external rotation position of femoral component is adjusted so that the flexion and extension gap is equal
- Restoration of motion and stability by releasing ligaments <sup>4</sup>



**Figure 3:** Classic femoral and tibial cuts made perpendicular to mechanical axis

#### 1.4.2 Computer assisted knee arthroplasty

The aim of using computer navigation is to achieve a near neutral mechanical aligned knee. The system is a none x-ray based navigation system that relies on reflector spheres that is inserted into the proximal tibia and distal femur. <sup>11</sup>

Steps during surgery:

- “Morphing” – virtual image of mechanical alignment of lower limb
- Severity of deformity is then calculated
- Bone cuts navigated via computer and software
- Size, orientation and alignment of implants are determined by the computer
- Post implant insertion mechanical axis reviewed <sup>11</sup>

#### 1.4.3 Conventional technique

The conventional technique relies on surgeon pre-operative planning and templating.

Steps:

- Pre-operative long leg cast
- Determine: Mechanical axis, deformity and template prosthesis
- Femoral and tibial cuts guided by extra- and intramedullary guides
- Size, orientation and alignment of implant determined by surgeon
- Post-operative long leg cast to determine mechanical axis <sup>1</sup>

## **1.5 Computer assisted versus conventional alignment**

Success of total knee arthroplasty is measured by:

- Pain relief
- Improved function
- Patient satisfaction
- Implant longevity

All of these are determined and affected by:

- Prosthetic factors - Implant size, tribology, size and position
- Patient factors - Weight, size, activity level and existing co-morbidities
- Surgical factors - Skill, experience, duration and implantation of prosthesis

Success of total knee arthroplasty is determined by prosthetic, patient and surgical factors. Focus was placed on surgical technique and its relationship with implant performance and longevity. It has been proven that malalignment of more than 3 degrees varus result in poorer implant survival and shifts from the mechanical axis lead to abnormal stresses at the bearing surface that can result in accelerated wear. It was found that even at major arthroplasty centres, up to 25% of total knee arthroplasties had unacceptable alignment. <sup>11</sup>

In a study performed by *Choong et al.* to compare conventional alignment to computer-navigated alignment they found that there was a significant higher portion of patient within 3 degrees of the neutral mechanical axis with the use of computer-navigated systems. They also found that patient did better post-operatively if the mechanical axis was within 3 degrees of the mechanical axis as compared to patient with greater than 3 degrees malalignment. <sup>11</sup>

Post-operative complications:

There is no significant difference in complications between computer-navigated and conventional surgery. It has been stated that computer-navigated results in lower rates of systemic emboli and blood loss. *Choong et al.* did not find any difference between the two groups. <sup>11</sup>

## **1.6 Disadvantages of mechanical alignment**

Studies from the United Kingdom and Canada revealed that 20% of patients at 1 year follow up were dissatisfied with the result. In all the cases conventional instruments were used to obtain mechanically alignment. The reasons for dissatisfaction was:

- Continued pain
- Poor function in activities of daily living <sup>4,9</sup>

With the use of computer assisted surgery, the mechanical alignment was improved but did not result in better clinical outcomes. <sup>4</sup>

The conclusion was made that mechanical aligned total knee arthroplasties with conventional instruments and/or computer assisted devices still has a high prevalence of continued dissatisfaction from patients. <sup>4</sup>

### **1.7 Patient satisfaction**

Patient satisfaction is becoming increasingly important, especially in elective surgery as total knee arthroplasty. <sup>7</sup>

*Bullens et al.* found in study on patient satisfaction post total knee arthroplasty, that there is a poor correlation between the objective physician-assessed knee score and the subjective patient-assessed satisfaction score. They concluded that the priorities of the patient and surgeon are different. <sup>8</sup>

The priority of the surgeon is range of motion, alignment and stability, were as the patient focus more on functionality. <sup>8</sup>

*Nobel et al.* concluded in a study on patient expectations and satisfaction:

- Patient's subjective perception of knee function is more important than biomechanical function.
- They found that three independent factors correlated with reduced patient satisfaction. These included; difficulty in performing activities that patient deems important, difficulty in performing activities that the patient love and difficulties in performing activities of daily living.
- Patient expectations include a diverse range of factors, ranging from objective joint pathology to subjective self-image. Most of them not related to joint function.
- Strongest reason for dissatisfaction was; frequency of knee stiffness, perception than knee felt abnormal and frequency of use of medication for pain. <sup>7</sup>

### **1.8 Failing total knee arthroplasties**

Total knee arthroplasty has a 90-95% patient satisfaction rate if pain relief and functional improvement is measured. It has 90% 10-15 years survival rate. Nonetheless some patients still have poor results and require revision surgery. <sup>6</sup>

Multiple studies have been performed and all came to the same conclusion. The main indications for revision surgery are:

- Polyethylene wear – 25%
- Aseptic Loosening – 24.1%
- Instability – 21.2%
- Infection – 17.5%
- Arthrofibrosis – 14.6%
- Malalignment or malposition – 11.8%
- Extensor mechanism deficiency – 6.6%
- Avascular necrosis patella – 4.2%
- Periprosthetic fracture – 2.8%
- Isolated patellar resurfacing – 0.9% <sup>6</sup>

### **1.9 Knee Injury and osteoarthritis outcome score**

The KOOS survey is a knee specific instrument and is used to assess:

- Men and woman – 14-79 years of age
- Patients subjective opinion about their knee
- Short and long term follow up of knee symptoms
- Disorders resulting in knee complaints
  - Anterior cruciate ligament tear
  - Meniscus tear
  - Mild to severe osteoarthritis <sup>10</sup>

KOOS survey scored:

- Consist of 5 relevant categories that is scored separately:
  - Pain – 9 questions
  - Symptoms – 7 questions
  - Activities of daily living – 17 questions

- Sport and recreational activities – 5 questions
- Quality of life – 4 questions<sup>10</sup>
- Likert score is used for each category:
  - 5 possible answers for each question with
    - 0 = No problem
    - 4 = Severe problem <sup>10</sup>
- Results:
  - Sum of all Likert scores for each category is obtained
  - Transformed to a 0-100 percentage score with
    - 0 = Extreme knee problem
    - 100 = No knee problem<sup>10</sup>

## **2. Aims and objectives**

The aim of this study will be to establish if the degree of deformity correction during total knee arthroplasty has an influence on post-operative patient satisfaction.

## **3. Methodology**

### **3.1 Research design**

Retrospective descriptive analytic study

### **3.2 Study population**

- Retrospective data will be collected and analysed from a single surgeon in Mediclinic Bloemfontein
- Data will include pre-and postoperative x-rays and relevant KOOS surveys
- Data from patients that received elective total knee arthroplasties
- All patient received total knee arthroplasty using computer assisted surgery to obtain mechanical alignment
- Permission will be obtained from all relevant parties
- There will be no interaction with patients

### **3.3 Sample size**

- Pre-and post-operative x-rays will be reviewed, the amount of deformity correction obtained with surgery will be calculated
- From data obtained patient will be divided into two groups

- 1<sup>st</sup> group will consist of patient that received a correction of less than 3 degrees
- 2<sup>nd</sup> group will consist of patient that received a correction of more than 3 degrees
- The study aim is to obtain at least 90 patients per group.

### **3.4 Exclusion criteria**

- Bilateral total knee arthroplasties
- Revision arthroplasties
- Post op complications; infection, revision, ligamentous disruption
- Incomplete data
- Final alignment > 3 degrees

### **3.5 Measurement**

#### **3.5.1 Location**

Patient's data will be analysed at Mediclinic Bloemfontein

#### **3.5.2 People involved**

Authors of the study

#### **3.5.3 Equipment needed**

Patient records, including all relevant data

#### **3.5.4 Procedure**

- All patients in study will have had a pre-operative and post-operative x-ray to determine the mechanical axis of the lower limb
- Difference in mechanical axis on the coronal plane from pre-and post-operative scans will be used to divide patients into two large study groups
- The one group will have received a mechanical correction of less than 3 degrees and the comparison group a correction of more than 3 degrees
- Example: Pre-operative mechanical axis = 10 degrees, post-operative mechanical axis = 2. Correction obtained with surgery:  $10 - 2 = 8$  degrees.
- Division into one of the two groups will be based on correction that patient has already received
- The KOOS scores completed pre-operative, at the 6 weeks and 1 year follow up post-operatively

- The percentage achieved for each of the categories of the KOOS score will be captured on a data sheath
- All data will be collected and analysed to determine if there is an association between pre-operative deformity and post-operative subjective satisfaction

### 3.5.5 Data collection

Data collected will be transferred to data sheet and handed over to the Department of Biostatistics for analysis.

Example of data sheet is included.

### 4. Statistical analysis

Results will be summarized by the Department of Biostatistics.

### 5. Proposed timetable

Action:	Time:	By whom:
Literature review:	May 2019	Researcher
Obtaining consent:	May 2019	Researcher
Finalizing protocol:	May 2019	Researcher
Presentation to ethical committee:	June 2019	Researcher
Data collection:	July – November 2019	Researcher
Article:	December 2019	Researcher and supervisor
Submission of thesis:	January 2020	Researcher

### 6. Budget

Researcher will be responsible for funding study.

Description:	Amount:
Paper	R60
Binding of thesis	R250
<b>Total:</b>	<b>R310</b>

## **7. Ethical considerations**

- Permission to conduct study will be obtained from:
  - Health Sciences Research Ethics Committee of the University of the Free State
  - Dr S Matshidza, Head of Department Orthopaedic Surgery UFS
  - Dr Werner van der Merwe, private orthopaedic surgeon, Mediclinic Bloemfontein
- All patient data will be reviewed at Mediclinic Bloemfontein and will not be removed from the premises
- Study number will be assigned to patient to replace the name of the patient in order to maintain confidentiality
- All precautions will be taken to ensure patient confidentiality of their personal details as well as data collected. The researcher will be only one handling patient's files to acquire data

## **8. Implementation of findings**

Should our findings indicated that there is a relevant difference in outcome between the two groups, we will write an article to be published in a peer reviewed Orthopaedic Journal. We also intend to present finding at next available orthopaedic congress.

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**Figures:**

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8. <https://yt.umalzer.de/Component%20Alignment%20in%20TKA-Dateien/ali05.gif>

**10. Appendix**

**Knee injury and Osteoarthritis Outcome Score (KOOS), English version LK1.0 1**

Today's date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Date of birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name: \_\_\_\_\_

INSTRUCTIONS: This survey asks for your view about your knee. This information will help us keep track of how you feel about your knee and how well you are able to perform your usual activities.

Answer every question by ticking the appropriate box, only one box for each question. If you are unsure about how to answer a question, please give the best answer you can.

**Symptoms**

These questions should be answered thinking of your knee symptoms during the last week.

S1. Do you have swelling in your knee?

Never      Rarely      Sometimes      Often      Always

S2. Do you feel grinding, hear clicking or any other type of noise when your knee moves?

Never      Rarely      Sometimes      Often      Always

S3. Does your knee catch or hang up when moving?

Never      Rarely      Sometimes      Often      Always

S4. Can you straighten your knee fully?

Always      Often      Sometimes      Rarely      Never

S5. Can you bend your knee fully?

Always      Often      Sometimes      Rarely      Never

**Stiffness**

The following questions concern the amount of joint stiffness you have experienced during the last week in your knee. Stiffness is a sensation of restriction or slowness in the ease with which you move your knee joint.

S6. How severe is your knee joint stiffness after first wakening in the morning?

None          Mild          Moderate          Severe          Extreme

S7. How severe is your knee stiffness after sitting, lying or resting later in the day?

None          Mild          Moderate          Severe          Extreme

**Pain**

P1. How often do you experience knee pain?

Never          Monthly          Weekly          Daily          Always

What amount of knee pain have you experienced the last week during the following activities?

P2. Twisting/pivoting on your knee

None          Mild          Moderate          Severe          Extreme

P3. Straightening knee fully

None          Mild          Moderate          Severe          Extreme

P4. Bending knee fully

None          Mild          Moderate          Severe          Extreme

P5. Walking on flat surface

None          Mild          Moderate          Severe          Extreme

P6. Going up or down stairs

None          Mild          Moderate          Severe          Extreme

P7. At night while in bed

None          Mild          Moderate          Severe          Extreme

P8. Sitting or lying

None          Mild          Moderate          Severe          Extreme

P9. Standing upright

None          Mild          Moderate          Severe          Extreme

## Function, daily living

The following questions concern your physical function. By this we mean your ability to move around and to look after yourself. For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your knee.

A1. Descending stairs

None          Mild          Moderate          Severe          Extreme

A2. Ascending stairs

None          Mild          Moderate          Severe          Extreme

For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your knee.

A3. Rising from sitting

None          Mild          Moderate          Severe          Extreme

A4. Standing

None          Mild          Moderate          Severe          Extreme

A5. Bending to floor/pick up an object

None          Mild          Moderate          Severe          Extreme

A6. Walking on flat surface

None          Mild          Moderate          Severe          Extreme

A7. Getting in/out of car

None          Mild          Moderate          Severe          Extreme

A8. Going shopping

None          Mild          Moderate          Severe          Extreme

A9. Putting on socks/stockings

None          Mild          Moderate          Severe          Extreme

A10. Rising from bed

None          Mild          Moderate          Severe          Extreme

A11. Taking off socks/stockings

None          Mild          Moderate          Severe          Extreme

A12. Lying in bed (turning over, maintaining knee position)

None          Mild          Moderate          Severe          Extreme

A13. Getting in/out of bath

None          Mild          Moderate          Severe          Extreme

A14. Sitting

None          Mild          Moderate          Severe          Extreme

A15. Getting on/off toilet

None          Mild          Moderate          Severe          Extreme

For each of the following activities please indicate the degree of difficulty you have experienced in the last week due to your knee.

A16. Heavy domestic duties (moving heavy boxes, scrubbing floors, etc)

None          Mild          Moderate          Severe          Extreme

A17. Light domestic duties (cooking, dusting, etc)

None          Mild          Moderate          Severe          Extreme

**Function, sports and recreational activities**

The following questions concern your physical function when being active on a higher level. The questions should be answered thinking of what degree of difficulty you have experienced during the last week due to your knee.

SP1. Squatting

None          Mild          Moderate          Severe          Extreme

SP2. Running

None          Mild                  Moderate                  Severe                  Extreme

SP3. Jumping

None          Mild                  Moderate                  Severe                  Extreme

SP4. Twisting/pivoting on your injured knee

None          Mild                  Moderate                  Severe                  Extreme

SP5. Kneeling

None          Mild                  Moderate                  Severe                  Extreme

**Quality of Life**

Q1. How often are you aware of your knee problem?

Never          Monthly                  Weekly                  Daily                  Constantly

Q2. Have you modified your life style to avoid potentially damaging activities to your knee?

Not at all          Mildly                  Moderately                  Severely                  Totally

Q3. How much are you troubled with lack of confidence in your knee?

Not at all          Mildly                  Moderately                  Severely                  Extremely

Q4. In general, how much difficulty do you have with your knee?

None          Mild                  Moderate                  Severe                  Extreme

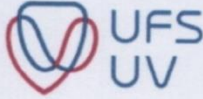
Thank you very much for completing all the questions in this questionnaire.

**Data sheet**

Pt:	Deformity:			KOOS Pre-op %:					KOOS 6 weeks post-op %:					KOOS 12 months post-op %:				
	Pre -op	Post -op	Dif f	Sx :	Pain :	FDL :	FSR :	Quality :	Sx :	Pain :	FDL :	FSR :	Qualit y:	Sx :	Pain :	FDL :	FSR :	Qualit y:
1																		
2																		
3																		
4																		
5																		
6																		
7																		
8																		

# Appendix B: HOD approval

UNIVERSITY OF THE  
FREE STATE  
UNIVERSITEIT VAN DIE  
VRYSTAAT  
YUNIVESITHI YA  
FREISTATA



Dr S Matshidza  
Department of Orthopaedic Surgery  
University of the Free State  
Universitas Academic Complex  
Bloemfontein  
9300

30 January 2019

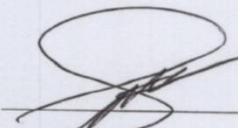
Health Sciences Research Ethics Committee of the University of the Free State

Dear Sir / Madam

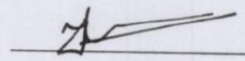
**Research study: Dr F Hartzenberg (2005006925)**

I, Dr S Matshidza, hereby acknowledge that Dr F Hartzenberg has been working as a registrar in the Department of Orthopaedics since 01 July 2016. He has completed the FCS(SA) Primary and Intermediate Examinations. I confirm and approve his research topic namely: Association between deformity correction and clinical outcome post total knee arthroplasty using kinematic alignment. His study leader is Dr J van der Merwe, a senior consultant in our department.

Yours Sincerely

  
\_\_\_\_\_  
Dr S Matshidza  
HOD Department of Orthopaedic Surgery

**DR S MATSHIDZA**  
Head of Dept - Orthopedics  
UFS / Universitas Hospital

  
\_\_\_\_\_  
Dr F Hartzenberg  
Registrar Orthopaedic Surgery

## Appendix C – HSREC approval

UNIVERSITY OF THE  
FREE STATE  
UNIVERSITEIT VAN DIE  
VRYSTAAT  
YUNIVESITHI YA  
FREISTATA



UFS·UV  
HEALTH SCIENCES  
GESONDHEIDSWETENSAPPE

### Health Sciences Research Ethics Committee

13-Sep-2019

Dear **Dr Ferdinand Hartzenberg**

Ethics Clearance: **Association between deformity correction and clinical outcome post total knee arthroplasty**. Principal Investigator: **Dr Ferdinand Hartzenberg**

Department: **Orthopaedics Department (Bloemfontein Campus)**

#### APPLICATION APPROVED

Please ensure that you read the whole document

With reference to your application for ethical clearance with the Faculty of Health Sciences, I am pleased to inform you on behalf of the Health Sciences Research Ethics Committee that you have been granted ethical clearance for your project.

Your ethical clearance number, to be used in all correspondence is: **UFS-HSD2019/1105/0110**

The ethical clearance number is valid for research conducted for one year from issuance. Should you require more time to complete this research, please apply for an extension.

We request that any changes that may take place during the course of your research project be submitted to the HSREC for approval to ensure we are kept up to date with your progress and any ethical implications that may arise. This includes any serious adverse events and/or termination of the study.

A progress report should be submitted within one year of approval, and annually for long term studies. A final report should be submitted at the completion of the study.

The HSREC functions in compliance with, but not limited to, the following documents and guidelines: The SA National Health Act. No. 61 of 2003; Ethics in Health Research: Principles, Structures and Processes (2015); SA GCP(2006); Declaration of Helsinki; The Belmont Report; The US Office of Human Research Protections 45 CFR 461 (for non-exempt research with human participants conducted or supported by the US Department of Health and Human Services- (HHS), 21 CFR 50, 21 CFR 56; CIOMS; ICH-GCP-E6 Sections 1-4; The International Conference on Harmonization and Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH Tripartite), Guidelines of the SA Medicines Control Council as well as Laws and Regulations with regard to the Control of Medicines, Constitution of the HSREC of the Faculty of Health Sciences.

For any questions or concerns, please feel free to contact HSREC Administration: 051-4017794/5 or email [EthicsFHS@ufs.ac.za](mailto:EthicsFHS@ufs.ac.za).

Thank you for submitting this proposal for ethical clearance and we wish you every success with your research.

Yours Sincerely

**Dr. SM Le Grange**  
**Chair : Health Sciences Research Ethics Committee**

Health Sciences Research Ethics Committee

Office of the Dean: Health Sciences

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# **Appendix D: Author guidelines SAOJ**

<http://journal.saoa.org.za/index.php/saoj/information-for-authors>

## **Information for Authors**

### **Criteria for publication**

- The article falls within the scope of the journal.
- Methods, statistics, and other analyses are performed to a high technical standard and are described in sufficient detail.
- Results reported have not been published elsewhere.
- Conclusions are presented in an appropriate fashion and are supported by the data.

The article is presented in an intelligible fashion and is written in standard English (British usage).

- The research meets all applicable ethical standards.
- The article adheres to guidelines provided in the instructions for authors section.

### **Guidelines for authorship**

- Each author should participate and is responsible for the content and design of the study, the preparation of the manuscript and its revisions, and final approval.
- Other 'contributors' can be acknowledged at the end of the manuscript together with their contribution.
- Authors of manuscripts representing a multi-centre study may list members of the group in the footnote on the title page of the published article and their affiliations are listed in an appendix.
- The authors should clearly indicate the predominant surgeon or surgeons who have contributed patients to the study.
- On submission of your article the ORCID (Open Researcher and Contributor ID) identifier of at least the corresponding author will be required. ORCID provides a persistent digital identifier that distinguishes you from every other researcher and supports automated linkages between you and your professional activities ensuring that your work is recognised. To register and find more information please visit: <http://orcid.org>

## Registration of clinical trials

- A clinical trial is defined as any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects of health outcomes. Interventions include drugs, surgical procedures, devices, behavioural treatments, dietary interventions, and process-of-care changes.
- Clinical trials should be registered in a public trials registry in accordance with [International Committee of Medical Journal Editors](#)
- Trials must be registered and approved by the relevant authorities before the onset of patient enrolment.
- The Medicines Control Council (MCC) reference number and the SA National Clinical Trial Register (SANCTR) registration number should be included at the end of the abstract of the article.
- Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) do not require registration.

## Reporting guidelines

- All articles should be prepared in accordance with the guidelines relevant to the study design, as described in the Equator Network Guidelines (<https://www.equator-network.org/reporting-guidelines/>)
- Randomised trials should be accompanied by a flow diagram that illustrates the progress of patients through the trial, including recruitment, enrolment, randomisation, withdrawal and completion, and a detailed description of the randomisation procedure.

## Formatting of submissions

### *Text formatting*

- Use Helvetica or Arial font, size 11.
- Use 1,5 spacing throughout the document.
- Number the pages of the blinded manuscript consecutively.
- Use italics for emphasis.
- When referring to an article with multiple authors please use the following format: Rabinowitz *et al.* published their retrospective review.
- Do not use field functions.
- Use tab stops or other commands for indents, not the space bar.

- Use the table function, not spreadsheets, to make tables.
- Use the equation editor or MathType for equations.
- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

### *Headings*

- Use no more than three levels of displayed headings.

### *Abbreviations*

- Define abbreviations and acronyms at first mention and use consistently thereafter.

### *Units*

- Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

### *Figures*

- Figures should be numbered consecutively with illustration Arabic numbers 1, 2, 3, etc.
- The figure should be listed in the text as follows: ... wound irrigation and splinting (*Figure 1*).
- Figures should be clear and easily understandable with a full descriptive legend stating any areas of interest and explaining any markings, letterings or notations. All figures should be understandable without the main text.
- For radiographs please ensure you state the view used and the time point at which it was taken, as well as the demographic details of the patient if applicable.
- Figures should not be imbedded in the text file but should be submitted as separate individual files. Each figure should be a separate file, entitled Figure 1, Figure 2, etc.
- Remove all markings, such as patient identification, from radiographs before photographing.
- All line or original drawings must be done by a professional medical illustrator.
- We accept a maximum of six figures.
- Do not submit any figures, photos, tables, or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

## Tables

- Tables should carry uppercase Roman numerals, I, II, III, etc.
- Tables should always be cited in the text in consecutive numerical order.
- The table should be identified in the text as follows: Details of results are listed in *Table I*. Or, alternatively, ... high-energy trauma that is often associated with these fractures (*Table II*).
- Tables should be used to present information in a clear and concise manner. All tables should be understandable without the main text.
- For each table, please supply a table heading explaining the components of the table.
- Identify any previously published material by giving the original source in the form of a reference at the end of the table heading.
- Footnotes to tables should be indicated by superscript lower-case letters and included beneath the table body.
- Please submit tables as editable text and not as images. They should be created using the Table tool in Word.
- Do not embed tables in the text file but submit them as separate individual files. Each table should be a separate file, entitled Table I, Table II, etc.
- We accept a maximum of eight tables.
- Do not duplicate information given already in the text.
- Do not submit any figures, photos, tables or other works that have been previously copyrighted or that contain proprietary data unless you have obtained and can supply written permission from the copyright holder to use that content.

## References

- References should be numbered consecutively in the order that they are first mentioned in the text and listed at the end in numerical order of appearance.
- Identify references in the text by Arabic numerals in superscript after punctuation.
- References should not be a listing of a computerised literature search but should have been read by the authors and have pertinence to the manuscript.
- Accuracy of references is the author's responsibility and the author is to verify the references against the original documents.
- Manuscripts in preparation, unpublished data (including articles submitted but not in the press) and personal communications may not be included in the reference listing. They may be listed in the text in parentheses only if absolutely necessary to the contents and meaning of the article.

- The titles of journals should be abbreviated according to the style used in Index Medicus, obtainable through the website <http://www.nlm.nih.gov/should>
- The following format should be used for references:

Journal article:

Sidhu GS, Ghag A, Prokuski V, Vaccaro AR, Radcliff KE. Civilian gunshot injuries of the spinal cord: a systematic review of the current literature. *Clin Orthop Relat Res* 2013;**471**:3945-55.

Ideally, the names of all authors should be provided, but the usage of 'et al.' in long author lists (more than six authors) will also be accepted: Fong K, Truong V, Foote CJ, et al. Predictors of nonunion and reoperation in patients with fractures of the tibia: an observational study. *BMC Musculoskeletal Disord* 2013;**14**:103.

On-line journal article:

Caetano-Lopes J, Lopes A, Rodrigues A, et al. Upregulation of inflammatory genes and downregulation of sclerostin gene expression are key elements in the early phase of fragility fracture healing. *PLoS One* 2011;**6**:e16947.

Web reference (with authors):

Cierny G, DiPasquale D. Adult osteomyelitis protocol. [http://www.osteomyelitis.com/pdf/treatment\\_protocol.pdf](http://www.osteomyelitis.com/pdf/treatment_protocol.pdf). (date last accessed 05 March 2013).

Web reference (no authors listed):

No authors listed. International commission on radiological protection. <http://www.icrp.org> (date last accessed 20 September 2009).

Chapter in a book:

Young W. Neurophysiology of spinal cord injury. In: Errico TJ, Bauer RD, Waugh T (eds). *Spinal Trauma*. 3rd ed. Philadelphia: JB Lippincott; 1991: 377-94.

### Dissertation:

Borkowski MM. Infant sleep and feeding: a telephone survey of Hispanic Americans [dissertation]. Mount Pleasant (MI): Central Michigan University; 2002.

### Abstract:

Peterson L. Osteochondritis of the knee treated with autologous chondrocyte transplantation [abstract]. ISAKOS Congress, 2001.

### **Structure and content of submission**

- We accept a maximum of 3 500 words including the abstract and body of the text (excluding references).
- Exceptions to this rule may be made for systematic reviews and meta-analysis, at the discretion of the Editor-in-Chief.
- Please follow the following structure when preparing your submission. Each of the following should be submitted as a separate file.
- Title page (title, authors and affiliations, corresponding author and declarations)
- Blinded manuscript (Abstract, key words, introduction, methods, results, discussion, funding sources, conflict of interest statement, ethics statement, acknowledgements and references)
- Tables (with headings), each table as a separate file.
- Figures (with legends), each figure as a separate file.

### **Title page**

#### *Title*

- The title should be concise and informative.

#### *Author names and affiliations*

- Please provide the following information for each author:
  - Full names and surname, as well as title
  - Qualifications
  - Designation

- Affiliation and address
- ORCID ID (see Article Submission section)
- Please check that all names are accurately spelled.
- Indicate all affiliations with a lower-case superscript letter immediately after the author's name and in front of the appropriate affiliation details.
- Provide the full postal address of each affiliation, including the country name and, if available, the e-mail address of each author.

### *Corresponding author*

- Clearly indicate who will handle correspondence at all stages of refereeing and publication, including post-publication.
- Ensure that the e-mail address and permanent address is given and that contact details are kept up to date by the corresponding author.
- Please note that the corresponding author's contact details will be provided in the final article.
- Provide the following information for the corresponding author:
  - Full names and title
  - Affiliation
  - Physical address
  - Postal address
  - Telephone number
  - E-mail address

Please suggest two reviewers and include their email addresses.

### *Declarations*

Authors are to insert a section at the end of the title page entitled declarations (please provide name of author, signature and date). The following statements are required under the declarations section.

### Authorship

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting the article or its critical revision for important intellectual content.

- Final approval of the version to be submitted.

### Sound scientific research practice

The authors further confirm that:

- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

### Plagiarism

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have been given (this includes material that is closely copied, summarised and/or paraphrased); quotation marks are used for verbatim copying of material.
- Permissions have been secured for material that is copyrighted.

### Conflict of interest statement

A conflicting interest exists when professional judgment concerning a primary interest (such as the patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It represents a situation in which financial or other personal considerations from authors, reviewers or editors have the potential to compromise or bias professional judgment and objectivity. It may arise for the authors when they have a financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. All potential conflicts of interest need to be declared. The conflict of interest statement should list each author separately by name, e.g.,

'Author A.B. (*use initials of relevant author, not full name in order for the document to remain blinded*) has received research grants from Company A. Author B.C. has received a speaker honorarium from Company X and owns stock in Company Y. Author C.D. is a member of committee Z.'

If no conflicts of interest exist, state this as follows:

'The authors declare they have no conflicts of interest that are directly or indirectly related to the research.'

### Funding sources

All sources of funding should be declared. Also define the involvement of study sponsors in the study design, collection, analysis and interpretation of data; the writing of the manuscript; and the decision to submit the manuscript for publication.

List all funding sources as follows: 'This work was supported by the xxxx (grant numbers xxxx, yyyy).'

When funding is from a block grant or other resources available to a university, college or other research institution, submit the name of the institute or organisation that provided the funding.

If no funding was received, state as follows: 'No funding was received for this study.'

### Compliance with ethical guidelines

For all publications: 'The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.'

Available from: <http://publicationethics.org/resources/international-standards-for-editors-and-authors>

Institutional Review Board (IRB) ethical approval must have been given if the study involves human subjects or animals. Please provide the approval number. IRB documentation should be available upon request.

'Prior to commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number*'

For studies with human subjects include the following: 'All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.'

'Informed written consent was or was not obtained from all patients for being included in the study.'

For studies with animals include the following sentence: 'All institutional and national guidelines for the care and use of laboratory animals were followed.'

For articles that do not contain studies with human or animal subjects: 'This article does not contain any studies with human or animal subjects.'

If doubt exists whether the research was conducted in accordance with the Helsinki Declaration, the authors must explain the rationale for their approach, and demonstrate that the institutional review body explicitly approved the doubtful aspects of the study. If any identifying information about patients is included in the article, the following sentence should also be included: Additional informed consent was obtained from all patients for which identifying information is included in this article. The Helsinki Declaration 2008 can be found at <http://www.wma.net/en/30publications/10policies/b3/>

*Title Page Example*

Title of Submission

John Smith\*

MBChB, FC Orth SA, MMed (Ortho)

University of South Africa, 123 High Street, Pretoria

ORCID No <https://orcid.org/1234-1234-1234-1234>

Paula Taylor

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e-mail: [johnsmith@unisa.ac.za](mailto:johnsmith@unisa.ac.za)

## **Declarations:**

### *Authorship*

The authors confirm that all authors have made substantial contributions to all of the following:

- The conception and design of the study, or acquisition of data, or analysis and interpretation of data.
- The drafting the article or its critical revision for important intellectual content.
- Final approval of the version to be submitted.

### *Sound scientific research practice*

The authors further confirm that:

- The manuscript, including related data, figures and tables has not been previously published and is not under consideration elsewhere.
- No data have been fabricated or manipulated (including images) to support conclusions.
- This submission does not represent part of a single study that has been split up into several parts to increase the quantity of submissions and submitted to various journals or to one journal over time (e.g. 'salami-publishing').

### *Plagiarism*

The authors confirm that the work submitted is original and does not transgress the plagiarism policy of the journal.

- No data, text or theories by others are presented as if they were the authors' own.
- Proper acknowledgements of others' work have been given (this includes material that is closely copied, summarized and/or paraphrased); quotation marks are used for verbatim copying of material.

- Permissions have been secured for material that is copyrighted.

*Conflict of interest statement*

John Smith declares that he has no conflict of interest. Paula Taylor has received research grants from Drug Company A.

*Funding sources*

No funding was received for the purposes of performing this study

*Compliance with ethical guidelines*

The author/s declare that this submission is in accordance with the principles laid down by the Responsible Research Publication Position Statements as developed at the 2nd World Conference on Research Integrity in Singapore, 2010.

Prior to commencement of the study ethical approval was obtained from the following ethical review board: *Provide name and reference number.*

All procedures were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008.

Informed written consent was or was not obtained from all patients for being included in the study.

<b>Author Name</b>	<b>Signature</b>	<b>Date</b>
J Smith		15/8/2017
P Taylor		16/8/2017

## **Appendix E: Declaration of authorship**

I, Ferdinand Hartzberg, declare that the coursework Master's Degree mini-dissertation that I herewith submit in a publishable article format for the Master's Degree qualification MMed Ortho at the University of the Free State is my independent work, and that I have not previously submitted it for a qualification at another institution of higher education.

## Appendix F: Turnitin plagiarism report

# Association between deformity correction and clinical outcome post total knee arthroplasty

*by* Ferdinand Hartzenberg

---

**Submission date:** 11-May-2020 11:29AM (UTC+0200)

**Submission ID:** 1321559038

**File name:** Artikel\_-\_2.docx (422.73K)

**Word count:** 1966

**Character count:** 11074

# Association between deformity correction and clinical outcome post total knee arthroplasty

Hartzenberg, F <sup>1</sup>

Van der Merwe, JF <sup>2</sup>


Van der Merwe, W <sup>3</sup>

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<sup>2</sup> MBChB(Stell), MMed Orth(UFS), FC Ortho(SA); Consultant, Department Orthopaedic Surgery, University of the Free State, Universitas Hospital, Bloemfontein, South Africa

<sup>3</sup> MBChB(UFS), MMed Ortho(UFS), FC Ortho(SA); Mediclinic Hospital, Bloemfontein, South Africa

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Article Error 

Association between deformity correction and clinical outcome  
post total knee arthroplasty

7

Missing ", " ETS

## **Abstract**

### **Background:**

The aim of this study was to establish if the degree of deformity correction during total knee arthroplasty (TKA) has an influence on post-operative patient satisfaction.

### **Patient and methods:**

This was a retrospective, descriptive analytical study of 180 patients that underwent an elective TKA using computer assisted software. Patients were divided into two groups according to the degree of deformity correction required to obtain a neutral mechanical axis: 3-degrees-and-more or less-than-3-degrees. Knee Injury and Osteoarthritis Outcome Scores (KOOS) were collected at the pre-operative, 6 weeks, and 1 year post-operative intervals. The mean KOOS scores were compared at each interval and the difference between mean KOOS scores were compared for the following intervals: pre-operative to 6 weeks post-operative; pre-operative to 1 year postoperative; 6 weeks to 1 year postoperative.

### **Results:**

The pre-operative mean KOOS scores for the group of patients that required a 3-degree-and-more deformity correction were statistically higher than the group requiring less-than-3-degree-deformity correction. At 6 week and 1 year follow ups there was no statistical difference between the two comparison groups.

With respect to mean KOOS score improvement between intervals, the group that required less than 3 degrees of deformity correction showed statistically significant improvement in symptoms for the pre-operative to 1 year follow up period.

### **Conclusion:**

of the study showed that patients requiring a lesser correction of their malalignment do better after TKA.

### **Keywords:**

Knee Arthroplasty, Outcome, Mechanical alignment, Deformity correction

## Introduction

Today, total knee arthroplasty (TKA) is one of the most successful and widely performed surgeries in the world; with the aim of relieving pain, maintaining motion and correcting deformities. It is expected that by the year 2030, 3.4 million arthroplasties will be performed annually in the USA.<sup>1</sup>

TKA has been proven to relieve pain and improve function, but even though the latest advancements in techniques and implants, up to 20% of patients are dissatisfied at one year follow up.<sup>2,3,4</sup>

Studies have identified multiple factors that affect the outcome of their surgery. Good outcomes are associated with increased pre-operative pain and/or disability, fulfilled patient expectations, improvement of function and pain relief. Poor results are associated with post-operative complications requiring admission, ethnic factors and low socioeconomic circumstances.<sup>5</sup>

*Bullens et al.* found in a study on patient satisfaction post TKA that there is a poor correlation between the objective physician-assessed knee score and the subjective patient-assessed satisfaction score. They concluded that there is a difference between the priorities of the patient and the surgeon. The priority of the surgeon is to optimise range of motion and obtaining neutral alignment in a stable knee; whereas the patient focuses more on functionality.<sup>6</sup>

The conventional alignment methods of measured resection or gap balancing show excellent implant longevity but there is still a subgroup of patients that are dissatisfied.<sup>7</sup> The main reasons being continued pain and poor function in activities of daily living. This led to the development of computer assisted surgery that resulted in improved alignment but no improvement in the clinical outcome.<sup>8,9</sup>

The purpose of this study was to determine if there was an association between correction of deformity and subjective patient satisfaction.

## Methods and Materials

A retrospective, descriptive analytical study was performed at our institution. The following inclusion criteria was used:

- Elective unilateral TKA at Mediclinic Bloemfontein
- Final mechanical deviation less than 3 degrees

- Computer-navigated alignment
- Performed between 2009-2014
- No post-operative complications
- Complete data

9 All surgeries were performed by a single surgeon using the same implant, computer software and uniform surgical technique.

Patients were placed into one of two groups. The first group required a deformity correction of less than 3 degrees and the second group a deformity correction of 3 degrees and more. The angle of deformity correction was determined by subtracting the post-operative mechanical axis deviation from the pre-operative mechanical axis deviation. The mechanical axis deviations used for the calculations were obtained from the computer software during surgery – Figure 1.

KOOS scores were collected at the pre-operative, 6 week and 1 year post-operative intervals. The mean KOOS scores at each of the intervals and the difference in mean KOOS scores between the intervals were assessed and compared.

11 The Knee injury and Osteoarthritis Outcome Score (KOOS) survey is a subjective patient questionnaire. It is used for the short and long term follow up of knee symptoms. It consists of 5 relevant categories that are scored separately, with 5 possible answers for each question ranging from 0 - 4 with the latter indicating more symptomatology. The results are calculated as the sum of all the Likert scores for each category obtained. This is then transformed to a percentage, with 0 being a severely symptomatic knee and 100 being an asymptomatic knee.<sup>10</sup>

The raw data was submitted to the Department of Biostatistics at the University of the Free State for analysis.

## 2 Results

A total of 180 patients were included in this study. There were 91 patients in the group that required a deformity correction of less than 3 degrees and 89 patients in the group that required a deformity correction of 3 degrees and more. In the group with 3 degrees and more deformity correction, the correction ranged from 3.5 to 14 degrees - Table 1.

The pre-operative mean KOOS scores for the group of patients that required a deformity correction of 3 degrees and more were higher than those of the patients in the comparison group. As a group they scored higher in 4 of the 5 categories – Table II. At the 6 weeks and 1 year follow up there was not a statistically significant difference between the two groups – Table III and Table IV.

With regards to the results from both deformity groups, there was a statistically significant improvement in symptoms in the pre-operative to 1 year follow up period in the group of less than 3 degrees deformity correction ( $p=0.03$ ) – Figure 2.

## Discussion

TKA remains the treatment of choice for deformed knees caused by arthritis. Despite repeated good results, up to 20% of patients are still dissatisfied at 1 year follow up without any apparent cause.<sup>4,9</sup> Today, patient satisfaction is becoming increasingly important, especially in elective surgery such as TKA.<sup>4</sup>

The success of TKA is determined by prosthetic, patient and surgical factors. Up to now the focus has been on surgical technique and its relationship with implant performance and durability. This led to studies assessing alignment and the effect it has on the implant survival. Choong *et al.* demonstrated that malalignment results in poorer implant survival due to abnormal stresses that result in accelerated wear.

Studies demonstrate that even at major arthroplasty centres, up to 25% of TKA have unacceptable alignment post operatively.<sup>8</sup> This led to the development of computer assisted surgery. Choong *et al.* demonstrated that a significantly higher portion of patients were within the 3 degrees neutral mechanical axis with the use of computer-navigated systems. But even with the improvement in mechanical alignment, studies in the United Kingdom and Canada found no improvement in clinical outcome.<sup>7</sup> They concluded that mechanical aligned TKA with conventional instruments and/or computer assisted devices still has a high prevalence of continued dissatisfaction.<sup>7</sup>

Most studies that have been performed to assess outcome have focussed on the objective outcome by reviewing the patient's function and x-ray findings. Limited studies have been performed to assess the subjective outcome. Nobel *et al.* performed and concluded in a study of patient expectations and satisfaction that the patient's subjective perception of knee function is more important than the biomechanical function. Patient expectations include a diverse range of factors, ranging from objective joint deformity to subjective self-image. Most

of these factors are unrelated to joint function. They found that the strongest reason for dissatisfaction was the frequency of knee stiffness, perception that the knee felt abnormal and the frequency of the usage of pain medication.<sup>4</sup>

This study has a number of limitations. These include the retrospective nature of the study, small study sample and short period of follow up. A further limitation is the fact that the groups were not divided pre-operatively into varus and valgus deformities and studied separately.

It is the opinion of the [redacted] that [redacted] up studies should be performed as TKA is a multiplane deformity correction that includes S/V, sagittal and rotational elements. Only coronal deformity correction was taken into consideration. Other pathologies that can contribute to knee symptoms were not taken into account.

### **Conclusion**

Study results show that patients requiring less correction of their malalignment do better after TKA.

This has been confirmed in recent literature showing under-correction leads to improved clinical results.

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Figure 1 – Illustration showing mechanical axis deviation

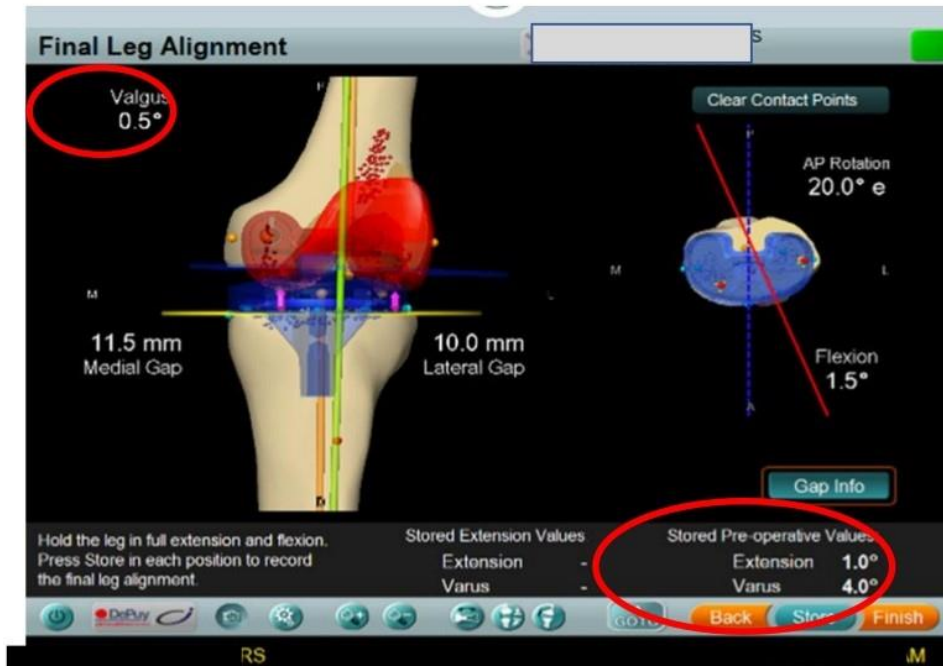


Figure 2 – Graph showing difference in mean KOOS scores at given intervals

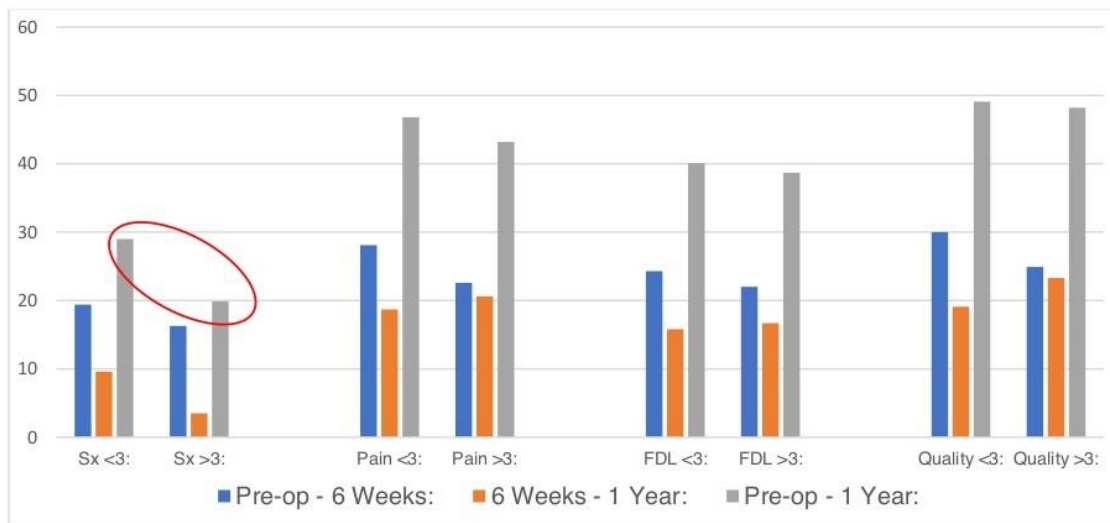


Table I – Division of patients according to required deformity correction

< 3 Degrees deformity correction:		> 3 Degrees deformity correction:	
0	7	3.5 - 5	52
0.5	11	5.5 - 7	21
1	16	7.5 - 9	11
1.5	19	9.5	2
2	15	10	1
2.5	9	10.5	1
3	14	14	1
<b>Total:</b>	<b>91</b>		<b>89</b>

Table II

KOOS Category:	KOOS scores:		P-Value:
	< 3 Degrees Correction:	> 3 Degrees Correction:	
Symptoms:	42.9	53.6	0.0246
Pain:	38.9	50	0.0028
Function, daily living:	38.2	47	0.0242
Functional, sport and recreational:	0	0	0.7743
Quality:	25	37.5	0.0259

Table III

<b>6 weeks mean KOOS scores:</b>			
<b>KOOS Category:</b>	<b>&lt; 3 Degrees Correction:</b>	<b>&gt; 3 Degrees Correction:</b>	<b>P-Value:</b>
Symptoms:	67.9	71.4	0.1979
Pain:	72.2	72.2	0.6478
Function, daily living:	67.7	70.6	0.2799
Functional, sport and recreational:	0	0	0.4098
Quality:	56.2	62.5	0.2958

Table IV

<b>1 year mean KOOS scores:</b>			
<b>KOOS Category:</b>	<b>&lt; 3 Degrees Correction:</b>	<b>&gt; 3 Degrees Correction:</b>	<b>P-Value:</b>
Symptoms:	71.4	71.4	0.1955
Pain:	94.4	94.4	0.9292
Function, daily living:	88.2	88.2	0.5018
Functional, sport and recreational:	0	0	0.9686
Quality:	87.5	81.3	0.6258

# Association between deformity correction and clinical outcome post total knee arthroplasty

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# Association between deformity correction and clinical outcome post total knee arthroplasty

*by* Ferdinand Hartzenberg

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**between deformity correction and  
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## **1. Introduction**

Arthroplasty has been done since the mid-nineteenth century. Fergusson started in 1861 with simple excision of ankylosed joints to produce an extra-articular pseudarthrosis. Due to the poor results of simple excision surgery, surgeons turned to interposition arthroplasty with the aim of preventing ankylosis.<sup>1</sup> Verneuil in 1863 performed the first interposition knee arthroplasty using a flap of knee capsule. Even though better results were obtained by interposition arthroplasty, it was still ineffective for the treatment of arthritic joints. This led surgeons to start and experiment with multiple manmade materials.<sup>1</sup>

The modern era of arthroplasty started in 1960 with Sir John Charnley. He developed a total hip prosthesis that consisted of a stemmed stainless steel femoral head that articulates with a high density polyethylene acetabulum implant. Gunston used Sir Charnley's concept and developed a similar knee prosthesis. Since then improvements have been made to the initial implant design, materials and fixation methods, but the basic concept of Charnley is still the same.<sup>1</sup>

Today total knee arthroplasty is one of the most successful and widely performed surgeries in the world, with the aim of relieving pain, improving function and correcting deformities. Currently 700 000 cases are performed annually in the USA and it is expected that this will rise to 3.48 million by 2030.<sup>1,2,3</sup>

Even with the advancements in surgical technique and implants up to 20% of patients are still dissatisfied post-operatively.<sup>4</sup> Multiple studies have been performed to try and assess for the cause of dissatisfaction that included; patient related factors, restoration of alignment and patient expectations.

This led surgeons to develop the concept of kinematic alignment that consists of positioning the implant according to the individual's anatomy. There is evidence to support that kinematic alignment results in better functional outcomes, but implant position was found not to be consistently aligned to the mechanical axis. There is a concern that the functional improvement will come at the expense of long term durability.<sup>2</sup>

## **1.2 Background**

Total knee arthroplasty remains the treatment of choice for knees deformed due to arthritis. The arthroplasty results in reproducible outcomes of pain relief, improved function and longevity.<sup>6,7</sup> A small but significant number of patients are still dissatisfied with the outcome.<sup>8</sup> In a study performed by Noble *et al.*, they found that up to 14% of patients were "dissatisfied" or "very dissatisfied" post operatively.<sup>6</sup>

Multiple factors have been identified that affect outcome. Good outcomes are associated with greater pre-operative pain and/or disability, fulfilled patient expectations, improvement of function and pain relief. Poor results are associated with post-operative complications that require admission, ethnic factors and low socioeconomic circumstances.<sup>8</sup>

Due to this high prevalence of patient dissatisfaction with mechanical alignment via conventional and computer assisted instruments, kinematic alignment with patient-specific femoral and tibial cutting guides were introduced in 2005.<sup>4</sup> The concept of kinematic alignment is to position implants according to the individual patient's anatomy.<sup>2</sup>

Most studies that have been performed to assess outcome have focussed on the objective outcome by reviewing the patients function and x-ray findings. Limited studies have been performed to assess the subjective outcome.<sup>7</sup>

### **1.3 Biomechanics**

#### **1.3.1 Kinematics**

Kinematics of the knee is determined by the joint surface, meniscus and ligaments that result in a relative relationship of the femur, tibia and patella at any point of motion without any force applied.<sup>1</sup>

In a healthy joint there is a balance between the joint surface and ligamentous structures. Typically the lateral soft tissue is lax when the knee is in flexion and taught with the knee is in full extension.<sup>2</sup> This results in motion that occurs in multiple planes around the long axis of the limb.<sup>1</sup>

Instruments used for mechanical alignment have no bearing on the kinematics of the knee.<sup>9</sup>

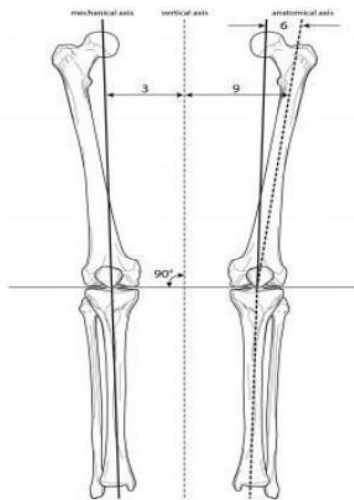
#### **1.3.2 Limb axis:**

Mechanical axis:

The mechanical axis is obtained by drawing a line from the centre of the femoral head to the centre of the talar dome. It is regarded as neutral if the line transects through the centre of the knee. During normal gait the mechanical axis is in 3 degrees valgus form the vertical axis due to the feet being placed closer to the midline.<sup>1</sup>

Anatomical axis:

The anatomical axis is obtained by drawing a line that bisects the medullary canal of the femur and tibia. The normal anatomical axis angle between the tibia and femur is 6 degrees valgus +/- 2 degrees.<sup>1</sup>

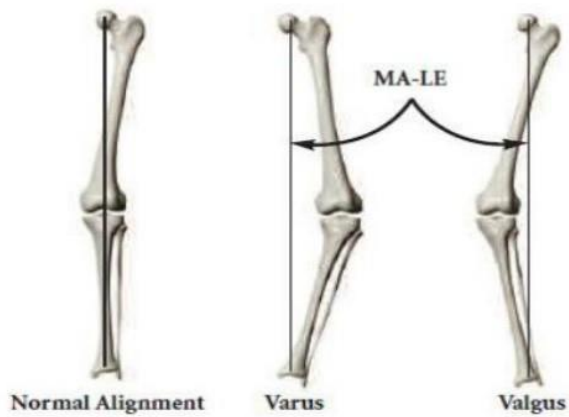


**Figure 1:** Illustrates difference between mechanical and anatomical axes

**1.3.3 Valgus and varus deformities:**

Valgus deformity is found when <sup>10</sup> [redacted] transects lateral to the centre of the knee.<sup>1</sup>

Varus deformity is found when the <sup>10</sup> mechanical axis transects [redacted] knee.<sup>1</sup>



**Figure 2:** Illustrates varus and valgus deformities of knee according to mechanical axis

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### 1.3.4 Kinematic knee axes:

Three axes govern kinematic movement of the tibia and patella in respect to the femur:

First axis:

- The primary transverse axis passes through the centre of the medial and lateral femoral condyles – Figure 3.
- The tibia flexes and extends around this axis.<sup>5,10</sup>
- The medial and lateral femoral condyle have unique radii, with the medial condyle radius being larger than lateral condyle – Figure 4.<sup>2</sup>
- This leads to the primary transverse axis not being parallel to the condyles.<sup>2</sup>

Second axis:

- The secondary transverse axis is in the distal femur around which the patella flexes and extends – Figure 3.
- The secondary axis is located anteriorly, parallel and proximal to the primary transverse axis.<sup>5,10</sup>

Third axis:

- The longitudinal axis of the tibia is the axis around which the tibia internally and externally rotates on the femur – Figure 3.
- The longitudinal axis is perpendicular to the primary and secondary transverse axes.<sup>5,10</sup>

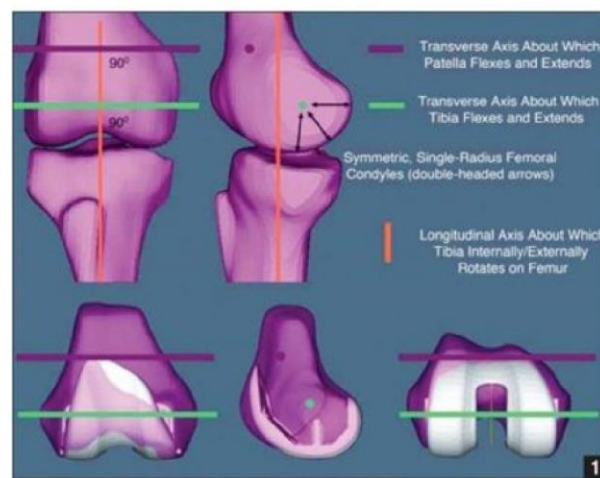


Figure 3: Illustrates different kinematic axes around knee

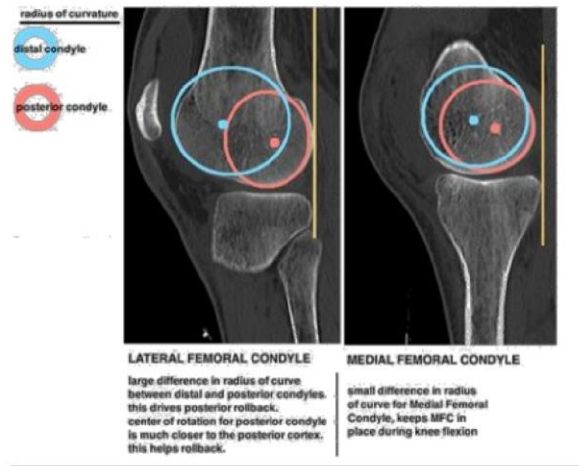


Figure 4: Illustrates difference in size of medial and lateral femoral

### 1.4 Surgical technique

Placement of the femoral and tibial components are the best predictors of clinical outcome.<sup>5</sup>

The conventional alignment method of measured resection or gap balancing resulted in excellent implant longevity but had poor clinically outcomes.<sup>2</sup>

#### 1.4.1 Principles of classic mechanical alignment:

- The femoral cut is made perpendicular to mechanical axis of femur
- The tibial cut is made perpendicular to mechanical axis of tibia
- The anterior-posterior and internal-external position of the femoral component is adjusted so that the flexion and extension gap is equal
- Soft tissue releases are done to restore motion and stability<sup>5</sup>

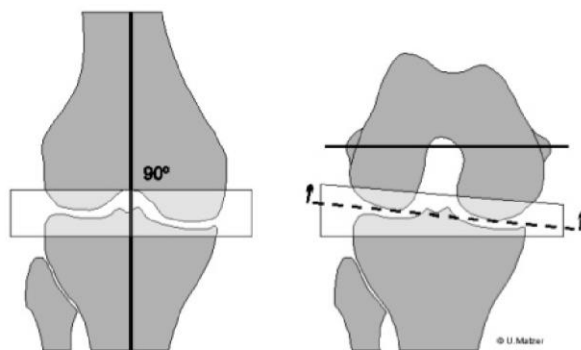


Figure 5: Classic femoral and tibial cuts made perpendicular to mechanical axis

#### 1.4.2 Principles of kinematic alignment:

- The femoral cut is co-aligned with the primary transverse axis of the femur
- The ligament length and stability are restored by removing osteophytes
- The tibial cut is aligned so that the longitudinal axis of the tibia is perpendicular to the primary transverse axis of the femur<sup>5</sup>

#### 1.4.3 Conventional technique:

The conventional technique relies on surgeon pre-operative planning and templating

Steps:

Pre-operative:

- Long leg standing cast
- Determine the mechanical axis, deformity and template prosthesis<sup>11</sup>

Intra-operative:

- Femoral and tibial cuts guided by extra- and intramedullary devices
- Size, orientation and alignment of implant determined by surgeon<sup>11</sup>

Post-operative

- Post-operative long leg cast to determine mechanical axis<sup>11</sup>

#### 1.4.4 Computer assisted knee arthroplasty:

The aim of using computer navigation is to achieve a near neutral mechanical aligned knee.

The system is a none x-ray based navigation system that relies on reflector spheres that is inserted into the proximal tibia and distal femur.<sup>11</sup>

Steps during surgery:

- "Morphing" – virtual image of mechanical alignment of lower limb
- Severity of deformity is then calculated
- Bone cuts navigated via computer and software
- Size, orientation and alignment of implants are determined by the computer
- Post implant insertion mechanical axis reviewed<sup>11</sup>

#### 1.5 Computer assisted versus conventional alignment

Success of total knee arthroplasty is measured by:

- Pain relief

- Improvement in function
- Patient satisfaction
- Implant longevity

All of these are determined and affected by the following factors:

- Prosthetic factors - implant size, tribology and position
- Patient factors - weight, size, activity level and existing co-morbidities
- Surgical factors - skill, experience, duration of surgery and implantation of prosthesis

Initially the focus was placed on surgical technique and its relationship with implant performance and longevity. It has been proven that malalignment of more than 3 degrees varus result in poorer implant survival. This is due to the shift of the mechanical axis that results in abnormal stresses at the bearing surface, resulting in accelerated wear. It was found that even at major arthroplasty centres, up to 25% of total knee arthroplasties had unacceptable alignment. <sup>11</sup>

In a study performed by *Choong et al.* to compare conventional alignment to computer-navigated alignment they found that there was a significant higher portion of patient within 3 degrees of the neutral mechanical axis with the use of computer-navigated systems. They also found that patient did better post-operatively if the mechanical axis was within 3 degrees of the neutral mechanical axis as compared to patient with greater than 3 degrees malalignment. <sup>11</sup>

There is no significant difference in complications between computer-navigated and conventional surgery. It has been stated that computer-navigated surgery results in lower rates of systemic emboli and blood loss. *Choong et al.* did not find any difference between the two groups. <sup>11</sup>

### **1.6 Disadvantages of mechanical alignment**

Studies from the United Kingdom and Canada revealed that 20% of patients at 1 year follow up were dissatisfied with the result. In all the cases conventional instruments were used to obtain mechanical alignment. The reasons for dissatisfaction were:

- Continued pain
- Poor function in activities of daily living <sup>5,10</sup>

With the use of computer assisted surgery, the mechanical alignment was improved but did not result in better clinical outcomes. <sup>5</sup>

To obtain normal knee kinematics with total knee arthroplasty the tibia and femoral components should be orientated that it resembles the three kinematic axes of the normal knee. None of these axes can be found with the use of conventional or computer assisted instruments.<sup>5</sup> These axes include: transepicondylar axis, centre of the femur and ankle.<sup>5</sup>

The conclusion was made that mechanical aligned total knee arthroplasties with conventional instruments and/or computer assisted devices still have a high prevalence of continued dissatisfaction from patients.<sup>5</sup>

### 1.7 Advantages of kinematic alignment

A study was performed on 23,000 knees to assess if there was an early clinical benefit or a disadvantage to kinematic alignment. Patients were asked to fill in a questionnaire pre- and post-operatively and records containing information regarding the surgical procedure were also kept.<sup>5</sup>

The following results were obtained:

- The patients experienced less surgical stress
- There was a shorter post-operative recovery time
- Earlier return to activities of daily living
- Shorter surgical time was observed

Patient experience post-operative:

- 94% of patients judged their knee as being normal or near normal
- 98% of patients judged the alignment of their limb as "just right"
- All the patients experienced less pain at the 4-5 weeks follow up period
- There was a significant improvement in return to activities of daily living<sup>5</sup>

### 1.8 Patient satisfaction

Patient satisfaction is becoming increasingly important, especially in elective surgery as total knee arthroplasty.<sup>6</sup>

*Bullens et al.* found in study on patient satisfaction post total knee arthroplasty, that there is a poor correlation between the objective physician-assessed knee score and the subjective patient-assessed satisfaction score. They concluded that the priorities of the patient and surgeon are different.<sup>7</sup>

The priority of the surgeon is range of motion, alignment and stability, whereas the patient focus more on functionality.<sup>7</sup>

Nobel *et al.* concluded in a study on patient expectations and satisfaction:

- Patient's subjective perception of their knee function is more important than the biomechanical function.
- They found that three independent factors correlated with reduced patient satisfaction. These included:
  - Difficulty in performing activities that the patient deems important
  - Difficulty in performing activities that the patient love
  - Difficulty in performing activities of daily living
- Patient expectations include a diverse range of factors. This ranges from the objective joint deformity to the patient's subjective self-image. Most of them not related to joint function.
- Strongest reason for dissatisfaction was frequency of knee stiffness, perception than knee felt abnormal and frequency of use of pain medication.

### **1.9 Failing total knee arthroplasties**

Total knee arthroplasty has a 90 - 95% patient satisfaction rate if pain relief and functional improvement are measured. 90% of total knee arthroplasties have a 10 - 15 year survival rate. Nonetheless some patients still have poor results and require revision surgery.

Multiple studies have been performed and all came to the same conclusion. The main indications for revision surgery are:

- Polyethylene wear – 25%
- Aseptic Loosening – 24.1%
- Instability – 21.2%
- Infection – 17.5%
- Arthrofibrosis – 14.6%
- Malalignment or malposition – 11.8%
- Extensor mechanism deficiency – 6.6%
- Avascular necrosis patella – 4.2%
- Periprosthetic fracture – 2.8%
- Isolated patellar resurfacing – 0.9%<sup>12</sup>

### **1.10 Knee Injury and osteoarthritis outcome score**

The KOOS survey is a knee specific instrument and is used to assess:

- Patients between the ages of 14 and 79 years
- Patient's subjective opinion about their knee

- Short and long term follow up of knee symptoms
- Disorders resulting in knee complaints
  - Anterior cruciate ligament tear
  - Meniscus tear
  - Mild to severe osteoarthritis <sup>13</sup>

KOOS survey scored:

- Consists of 5 relevant categories that are scored separately:
  - Pain – 9 questions
  - Symptoms – 7 questions
  - Activities of daily living – 17 questions
  - Sport and recreational activities – 5 questions
  - Quality of life – 4 questions <sup>13</sup>
- The Likert score is used for each category:
  - 5 possible answers for each question with
    - 0 = No symptoms
    - 4 = Severe symptoms <sup>13</sup>
- Calculation of results:
  - The sum of all Likert scores for each category is obtained
  - Scores are transformed to a 0-100 percentage with
    - 0 = Extremely symptomatic
    - 100 = Asymptomatic <sup>13</sup>

## 2. Hypothesis

From the above studies we have learned that total knee arthroplasty is an excellent procedure with predictable outcomes, but there is an unacceptable portion of patients that are still dissatisfied post operatively. Initially it was postulated that the cause for this dissatisfaction may be due to malalignment of the prosthesis. Choong et al. performed a study and found that malalignment of more than 3 degrees results in poorer outcome. They also concluded that with the use of conventional instrument in major arthroplasty centres a large portion of patients were misaligned. This led to the development of computer navigated surgery to try and improve on the alignment. With the use of computer navigation the alignment was improved but there was no improvement in the clinical outcome.

Studies were performed to assess what influences patient satisfaction post operatively. They found that there was a poor correlation between what the patient and surgeon deem

important. Patients found the subjective perception of their knee function more important than the biomechanical function.

Surgeons then turned to kinematic alignment were implants are placed according to the individual patient's anatomy. Kinematic alignment showed good results in short term follow up studies with a large portion of the patient judging their knee as being near normal.

We want to perform a retrospective study on patients that received a total knee arthroplasty using assisted navigation to assess if the required degree of deformity correction influences the outcome. The outcome will be assessed only on the patient's perception of their knee.

We hypothesize that patients requiring a lesser deformity correction will do better post-operatively as this will result in a more type alignment.

### **3. Aims and objectives**

The aim of this study will be to establish if the degree of deformity correction during total knee arthroplasty has an influence on post-operative patient satisfaction.

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