UNIVERSITAT DE BARCELONA

Final Degree Project

Biomedical Engineering Degree

"Assessment of the accuracy in the alignment of the extremity and positioning of implants in total knee arthroplasties"

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ABSTRACT

Osteoarthritis is the most frequent diagnosis of arthritis that requires for a Total Knee Replacement (TKA). This disease is characterised by a slowly degeneration of the cartilage within a joint causing pain, stiffness and swelling. TKA surgery consists of the resection of the affected joint surfaces, so they can be replaced by metal and polyethylene biomaterials (which reproduce the knee anatomy and function). Due to the variety of results between surgeries, an interest in assistive robotic technologies to standardize the procedure and more accurately place and align the implant with the limb has increased.

This thesis explains the realisation of an unicentric prospective cohort study that examines the accuracy of ROSA Knee System (Robotic Surgical Assistant) a surgical robot to assist and support surgeons during TKA achieved by Hospital Clinic recently. To study this feature, certain variables have been recorded intraoperatively by ROSA and compared with the same variables but extracted from Computed Tomography (CT) or X-Ray (XR) postoperative images. All the phases to conduct, from scratch, the clinical study are explained in detail in this project.

This project has been carried out under the supervision of the Knee Department of the Clinic hospital, which has allowed the use of data from their patients and their inclusion as participants in the study. This thesis will be attached to an extensive study conducted by the Knee Department regarding the ROSA robot that tries to answer the question: is the robotic assistance an improvement in TKAs surgeries?

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At last, but not least, I would like to dedicate my deepest appreciation and gratitude to my loving family. Their constant support, understanding and love have been the main pillars to pursue my dreams and accomplishing them. Thank you for showing me that sacrifices have their rewards and that with patience and perseverance one can get where he/she wants to go.

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GLOSSARY OF ABREVIATIONS

TKA	Total Knee Replacement
ROSA	Robotic Surgical Assistant
CT	Computed Tomography
XR	X-Ray
LLR	Long leg standing X-Rays
TFG	Treball de Final de Grau
HKA	Hip-Knee-Ankle angle
RaTKA	Robotically-assisted TKA
MTKA	Manual TKA
JLH	Joint Line Height
JLCA	Joint Line Converge Angle
mLDFA	mechanical Lateral Distal Femoral Angle
mMPTA	mechanical Medial Proximal Tibial Angle
PDFA	Posterior Distal Femoral Angle
PTTA	Posterior Proximal Tibial Angle
PCA	Posterior Bicondylar Axis
PCO	Posterior condylar offset
BMI	Body Mass Index
PERT-CPM	Program Evaluation and Review Technique with its Critical Path Method
WBS	Work Breakdown Structure
ISO	International Organization for Standardization

CONTENTS

INTRODUCTION

DEFINITION

The project is based on the execution of an unicentric prospective cohort study in order to study the accuracy of the robotically-assisted surgical system ROSA fabricated by *Zimmer Biomet (Warsaw, Indiana, USA)*. It is a system that supports surgeons in performing TKA to improve accuracy in bone cuts and implant positioning intra-operatively. To study this feature, certain variables of study will be recorded intra-operatively by ROSA and compared with the postoperative values, which will be obtained from CT and XR images of the research subjects.

Considering that the accuracy of robotic systems is already determined by the manufacturer of the medical product (in this case, *Zimmer Biomet*), this study evaluates the human-robot collaboration. In other words, the results obtained while positioning the prosthesis will not only be considered due to the robotic surgery system, but also to the human factor during the intervention. However, the aim of the project is not to study whether the surgeons correctly fulfilled the intervention, but to learn how to conduct a clinical study from the outset and use its results to study the accuracy in the intervention. This evaluation will contribute with valuable information to other studies that try to answer the following question: is the assistance of the surgical robots useful to improve the accuracy and precision of the interventions?

JUSTIFICATION OF THE PROJECT

In advanced osteoarthritis of the knee, TKA is one of the most common surgical interventions performed due to its effectiveness to decrease pain and improve knee functionality. The surgery consists of the resection of the affected joint surfaces, so they can be replaced by metal and polyethylene biomaterials (which reproduce the knee anatomy and function) (1). Nevertheless, recent studies have shown a 20% rate of dissatisfaction of the cases that in many of them is multifactorial because of pain or patient's expectations that has not been met (among others) (2).

Due to the worldwide aging, the total TKA's volume has increased substantially in recent decades, becoming the most common joint intervention. This fact is reflected with the predicted increase in annual TKA interventions in the United States from 0.5 million in 2019 to 3.4 million in 2040 (3) . Changes in demographic factors such as age, sex and life expectancy are the main causes of this rise of interventions for knee osteoarthritis. Because of that, it is needed a parallel and precise analysis of TKA epidemiology to improve public health care policy (4).

TKA is currently associated with excellent long-term implant survival outcomes (5). The determining factors for this success are the correct positioning of the implant components, an acceptable alignment with the knee and the restoration of the joint stability during the patient's functional activities (6). Although the success is related to different factors, the limb alignment is crucial as it directly affects the peri-articular functionality of the soft tissues, the biomechanics of the knee and, as it has been said, the survival of the implant. Due to misalignment, the probability of wear, poor functionality, and premature implant failure increase (and consequently, it could require a TKA revision). For this reason, an improvement in the understanding and execution of the optimal alignment technique for the patient will help to solve the problems discussed above (5).

In a nutshell, patient satisfaction will be directly related to the functionality of the implant which, in turn, seems to be (as stated by recent literature) associated to the accuracy of its placement and its alignment with the limb (7). The variety of results between surgeries has increased the interest in assistive robotic technologies to standardize the technical aspects of the procedure and, thus, achieve the expected results (6). Therefore, the aim of this study is to perform a clinical study in order to evaluate the accuracy of an assistive robotic technology.

OBJECTIVES

PRIMARY OBJECTIVES

- Learn how to conduct a clinical study from scratch, seeing first-hand all the intermediary steps required, in order to then be able to carry it out one.
- Study the whole process performed in the clinical trial to extract possible improvements and optimise it.
- Assess the accuracy in the alignment of the extremity and the position of the implants of the ROSA Knee System in TKA from postoperative CT and X Rays images.

SECONDARY OBJECTIVES

- Assess the inter-observer correlation analysis in the radiological measurements.

STRUCTURE AND METHODOLOGY

This project has been developed in two main parts: firstly, a comprehensive literature review in order to properly design the protocol of the clinical study was performed and then the correspondent protocol. Once it was accepted by the Research Ethics Committee (see later in the Concept Engineering section), the execution and obtention of results have been performed (thoroughly explained later in the Detail Engineering section).

To perform this study, I have been working together with the knee section of the Orthopaedic and Traumatology Department of the *Hospital Clínic de Barcelona*. Therefore, those patients who had been robotically assisted during their intervention are potential participants to the study. The interventions and the follow-up have been carried out at the *Hospital Clínic* (c./ Villarroel 170, Barcelona). Because of this study consists of a review of already operated patients, there is not any limitation in terms of space (availability of beds, operating rooms and personnel). Thus, the sample size will be given by the number of interventions performed at this site with the assistance of the ROSA robot, as all these cases could be possible candidates for the study.

Regarding the study period, it has lasted 14 months. It started in April 2022, and it has ended in June 2023 with the extraction of variables done intensively through the months of December and January. A considerable part of the study has been taken by the documentation and burecreatuic procedures related to designing and waiting the acceptance of the Research Ethics Committee. Due to the fact of performing a clinical study in this short period, there has been a time constraint, and the number of research subjects has been the maximum done with this time. Specifically, initially it was expected to include 68 patients, but in the end 21 patients have been included.

SCOPE

The realisation of this final degree project (TFG, Treball de Final de Grau) must be seen as a long process. From some ethical aspects to data analysis, the project requires knowledge about several different fields regarding biology, physics, programming, among others. It is for this reason that the biomedical engineer is very well considered for this type of studies. Therefore, this thesis will not only focus on the more engineering part of the clinical study but will pay attention to all the steps in order to learn how to perform a clinical study from start to finish as a complete process.

Due to the explained above, this TFG can be expected to have an extensive scope. It includes

- Review of knee anatomy and robotic assisted TKA (RaTKA) surgical procedures. This section will include the evolution of the technology and the actual market. Finally, it will be crucial to analyse Zimmer Biomet's ROSA Knee System as it is the one used in the clinical study.
- Literature review related to the study of the accuracy on the alignment and positioning of knee prosthesis implants from biomedical images (CT or XR).
- Design of a clinical study and redaction of its protocol to present to the Research Ethics Committee. It must include some of the essential sections such as the hypotheses, objectives, inclusion or exclusion criteria of the research subjects, variables that will be analysed or the statistical methodology to be carried out.
- Description of all the variables to be studied and creation of a manual for the extraction of all study variables. It must include a brief description of each variable, the methodology to obtain its value, sign criteria and normality range.
- Execution of the clinical study. It must include the writing of the informed consent of patients, the planification of CT scans and the subsequent study of the images based on the protocol for variables' extraction. Finally, the statistical tests of the collected data must be included with the evaluation of all the results in order to came up with some conclusions. Before this execution, an approval from the ethical committee to the study protocol must be granted.
- Writing of an article about the obtained results on a scientific website.

Nevertheless, it is also essential to remark all those aspects that are beyond the scope of this TFG. Firstly, the hospital internal procedures to order biomedical images or the interaction and communication with the Research Ethics Committee will be done by the healthcare professionals of the *Hospital Clínic Barcelona* of my research group. Similarly, I will not participate in the TKA interventions since my work will be focused on the extraction and analysis of the surgical results.

As commented before, this project contemplates the robot-human collaboration. That is why the technical accuracy and precision determined by robotics companies for their medical products may vary with respect to the results obtained in a clinical study.

Currently, due to the ROSA acquisition, an extensive study is being carried out to analyse the satisfaction, functional outcomes and quality of life of patients undergoing primary knee arthroplasty. Indeed, this TFG is attached to this extensive study, and it is focused on a little area of the research. There are many aspects of the technology which are being called into question in order to try the answer the question: is the robotic assistance an improvement in TKAs surgeries?

ANTECEDENTS

The symbiosis between robotics and medicine is a relationship older than expected. In 1992, it took place one of the first remarkable contacts between the orthopaedic knee surgeries and robotics: the ROBODOC system, a surgical robot used to perform total hip and TKA surgeries. It was a crucial precedent to persuade the technological companies to improve the robotic surgeries and it was used to acknowledge the principal limitations. Some of them were related to the complexity of the technique, the increase in operation time and the lack of versatility (8). Since then, it has not been until recent years than hospitals have begun to invest on robotic solutions as a, supposedly, more effective, accurate, repeatable, and efficient. This evolution is clearly represented in the following figure (Figure 1), where it is shown how many articles about surgical knee robotics are published in PubMed each year. As it can be seen, 2021 represented an important change in this trend.

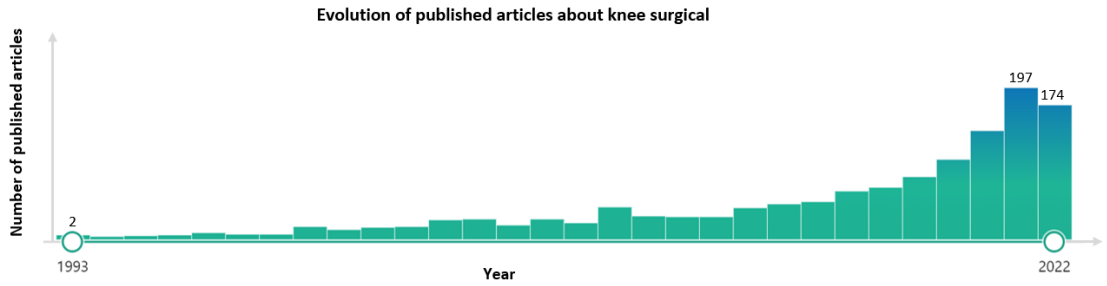


Figure 1 - Evolution of publications related to knee surgery that can be related to the appearance of new technologies

Nowadays, different hospitals and robotic companies are publishing the first performance evaluations of the assistance surgical robots incorporated into hospitals. Besides, not only will the future increase in TKAs result in a raise in the number of robotic systems in the hospitals, but also in the number of clinical studies and publications on the subject. Nevertheless, there is already small evidence about RaTKA. However, there are many parameters to study and consider, which implies a high diversity of objectives and different approaches.

ANTECEDENTS RESEARCH

The Orthopedic Surgery and Traumatology Department of the *Hospital Clínic* completes more than 24'000 visits each year. More than 2'400 surgeries are performed annually (1'500 fractures, 500 TKAs and 400 total hip replacements). Regarding knee interventions, in 2021, 542 TKAs were performed by its surgical team (9). Thus, their experience gained in TKAs have stood them in good stead for robotically assisted interventions. However, as the experience of these surgeons using smart tools was different, all the surgeons involved in the study received the same standardized training for ROSA. It consisted of a training workshop and a visit to a cadaver lab (cadaver surgery) of a pioneer center in Europe in order to see the operation and workflow in the operating room. Once the training was ended, Dr. Pere Torner, head of the Orthopaedic Surgery and Traumatology Department, and Dr. Juan Carlos Martínez, head of the knee section at the *Hospital Clínic*, performed on the 11th of December 2020 the first operation robotically-assisted with Zimmer Biomet's robotic arm, the ROSA Knee System. The first 100 robotic knee replacement surgeries

have been completed in 16 months, which has consolidated the Hospital Clinical group as a benchmark for this type of intervention (10). A learning curve between 10 and 20 cases is considered; however, what it changes is the surgical time and anxiety of the team rather than the accuracy (which is maintained during all surgeries). Due to the fact that this study is a unicentric prospective cohort study, the research subjects included had been operated prior to the start of this study. Specifically, the cases included in this study are the ones corresponding to the first robotically assisted interventions performed between December 2020 and November 2021.
The first conclusion extracted about the robot, according to Dr. Juan Carlos Martínez, is the improved accuracy provided (which is one of the main considered advantages of surgical robotics):

> "The accuracy provided by the surgical robotics is traduced in operations that require less surgical exposure, and, therefore, a minimum involvement of soft tissue and less bone resections. […] The system allows 0.5 mm modifications of bone cuts in any space plane to seek for the best possible adaptation of the prosthesis in each patient." (Extracted from (11))

In addition, both doctors assert that there is a clear improvement in the implant positioning during the operation which helps to restore the joint axis and the ligament equilibrium in the knee joint balance. Furthermore, another considered advantage is the upgrade acquired regarding the preintervention planning. Citing Dr. Pere Torner:

> "The planning prior to the intervention allows us to design better the size and type of prosthesis that each patient needs, adapting to the specific characteristics of each specific case." (Extracted from (11))

In terms of research, the *Hospital Clínic* is a leader in many areas. Several clinical studies have been carried out in the Knee Department of the Hospital from some that focus on the study of infections around implants of TKA to others related to implant positioning.
Currently, due to the ROSA acquisition, an extensive study is being carried out to analyse the satisfaction, functional outcomes, and quality of life of patients undergoing primary knee arthroplasty. Indeed, this TFG is attached to this extensive study, and it is focused on a little area of the research. There are many aspects of the technology which are being called into question in order to try to answer the question: is the robotic assistance an improvement in TKAs surgeries?
In summary, there is an important background learned by the Knee Department of the hospital both at the level of interventions and robotic surgery or research and clinical trials. For all these reasons, it is expected to obtain reliable results.

STATE OF THE ART

As it has been said before, there is already small evidence regarding RaTKA. This one has been reviewed to learn about clinical study procedures and protocols and all the actual technologies available on the market.

SCIENTIFIC ARTICLES PUBLISHED ON ACTUAL CLINICAL STUDIES

In 2021, 42 articles were published in PubMed on the evaluation of the accuracy and precision provided by the alignment guides of knee prosthesis implants. It is a different approach to most clinical studies that have been carried out to date because the normal imaging technique used is XR and long-leg standing XRays (LLR).

Some of the studies are cadaveric studies, which is not the case in this project. However, cadaveric studies are a perfect approach to define methodologies and procedures for surgeries, data extraction, data analysis, etc.

ACCURACY OF A NEW ROBOTICALLY ASSISTED TECHNIQUE FOR TOTAL KNEE ARTHROPLASTY: A CADAVERIC STUDY (12)

It was published in 2020 by Sebastien Parratte, Andrew Price, Lee Jeys, William Jackson and Henry Clark. The principal aspects were:

- Principal hypothesis: the use of robotics in surgeries will achieve high levels of accuracy for bone resections.
- Methodology: "For this study, 15 frozen cadaveric specimens (30 knees) were used. In this study, Zimmer Biomet knees navigation system, and ROSA Knee System (Zimmer Biomet) were used. Eight trained, board-certified orthopedic surgeons performed robotically assisted total knee arthroplasty implantation using the same robotic protocol with 3 different implant designs. […] The target angles obtained from the intraoperative plan were then measured and compared to the bone cuts performed with the robotic system as measured with a validated computer-assisted navigation system (ORTHOsoft; Zimmer Biomet) considered to be the gold standard as previously published. For each bone cut the resection thickness was measured using a calliper 3 times by 2 different observers and compared to the values given to the planned resections." (Directly cited from (12))
- Variables of study: *Hip-knee-angle* (HKA), angle between angle the femoral mechanical axis and the tibial mechanical axis in the coronal plane; *tibial cut* (in frontal and sagittal planes); *femoral cut* (in frontal and sagittal planes); and *bone resection thickness from bone cuts of proximal tibia and distal femur.*
- Statistic test: the values measured with ROSA and with the navigation system were compared to the target values recorded in the surgical planning in order to assess the capacity to execute the defined plan. Then, the intraoperatively values of all the variables of study were compared to the postoperatively with the statistical test *t-test* for paired sample.
- Results: the obtained results follow a normal distribution of sufficient sample size. In all cases, the mean and SD differences were below 1°. In almost all the variables, the mean differences between the planned angles and the measured values were close to 0 and not significantly different from 0. Except for the femoral sagittal angle mean difference which was −0.95° (see annex 1 to know the exact values).

The information related to this article can be used to know the basic methodology to perform the clinical study intended in this project. For this reason, next step is to carry out also an extensive literature research regarding the possible variables of study of this project.

ROBOTIC-ARM ASSISTED TOTAL KNEE ARTHROPLASTY DEMONSTRATED GREATED ACCURACY AND PRECISION TO PLAN COMPARED WITH MANUAL TECHNIQUES (13)

It is an article published in 2018 by Emily L. Haampp, Morad Chugtai, Laura Y. Scholl, Nipun Sodhi, Manosi Bhowmik-Stoker, David J.Jacofsky and Michael A. Mont. A summary of its important parts is:

- Principal hypothesis: “robotically-assisted TKA would, in fact, allow for more accurate and precise bone cuts as well as component position when compared with manual or conventional TKA.” (Cited from (13))
- Methodology: six cadaver specimens (12 knees) were prepared to receive RaTKA on the right leg and a manual TKA (MTKA) in the left one. This preparation helped minimize any potential variability with the setup and has not led to an apparent bias in RaTKA alignment outcomes. The surgeon, who had no prior clinical robotic experience, was trained on a single robotic case before performing the procedure on the cadavers assessed in this study. The robotic interventions were assisted by MAKO system (Stryker), a system that provides robotic software defined spatial boundaries for orientation, and reference information for anatomical structures. It includes a robotic arm, camera stand, guidance module, dedicated instrumentation and TKA application software (13). The prothesis implant positioning and bone cuts were evaluated using navigation reflection plane probes, some optical tracking navigation devices (they represent a flat surface that captures and projects a reflection to the camera on a surface, like a mirror). This way, the postoperative values of the variables of study could be compared to the intraoperative values.
- Variables of study: for sagittal measurements, *tibial anterior or posterior slope* (angle between the tibial mechanical axis and the tibial implant or bone cut surface) and *femoral flexion or extension rotation* (angle between the femoral mechanical axis and the distal femoral implant or bone cut surface) were studied. Regarding coronal measurements, *tibial varus or valgus rotation* (angle between the tibial mechanical axis and the tibial implant or bone cut surface) and *femoral valgus or varus rotation* (angle between the femoral mechanical axis and the distal femoral implant or bone cut surface) were the ones to be studied. Finally, in the axial plane, *femoral internal or external rotation* (angle between the surgical transepicondylar axis, line connecting the centre of the sulcus of the medial epicondyle and the most prominent point of the lateral epicondyle, and the posterior femoral implant or bone cut surface) and the *posterior femoral implant* were studied.
- Statistical test: the deviation or error was calculated as the angular difference between the planned cut and the actual cut alignment for each patient. However, since the principal objective of this project is to compare the RaTKA and MTKA, it is necessary to contrast the median errors and SDs of all the patients of both techniques for each planar bone cut and component position. Median values were used to assess the central tendency of the dataset. The data analysis consisted of a hypothesis testing using a two sample standard deviation test (*t* test). To compare it, the group of research used a *t test* between the postoperative and intraoperative values. “The α significance level for the test was 0.05 with a 95% confidence level. If the p-value was > 0.05, then the data provided insufficient evidence to reject the null hypothesis (Ho: s1/s2 = p) and accept the alternate hypothesis (Ha: s1/ s2 > p), where s1 = MTKA and s2 = RATKA. This decision was reached because the calculated p-value for the test was more than the preselected α level. If the p-value was ≤ 0.05, then the data provided sufficient evidence to reject the null hypothesis (Ho: s1/s2 = p) and accept the alternate hypothesis (Ho: s1/s2 > p) at a significance level of 0.05. This decision was

reached because the calculated p-value for the test was less than the preselected α level." (Cited from (13))

- Results: comparison of the medians show that MTKA bone cuts were less accurate to plan than RATKA (p-value ≤ 0.05). In addition, according to the results on SDs, it can be deduced that RATKA has better precision. In annex 2 a summary of the results is presented.

Thanks to this article, it is possible to know the methodology to compare the manual and robotic techniques. Although it is beyond the scope of this TFG, it is a close study because the results of this TFG could be used in a future to perform a similar study and some variables studied in this article can be of importance for the clinical study of this TFG.

Both articles revised were cadaveric studies. Although they are useful to get used to methodologies, it is crucial to also review clinical trials with real patients to obtain results applicable to the clinic.

ROBOTIC-ASSISTED TKA LEADS TO A BETTER PROSTHESIS ALIGNMENT AND A BETTER JOINT LINE RESTORATION AS COMPARED TO CONVENTIONAL TKA: A PROSPECTIVE RANDOMIZED CONTROLLED TRIAL (14)

It is an article published in 2020 by Narendra V. Vaidya, Ajinkya N. Deshpande, Taufq Panjwani, Rakesh Patil, Tanmay Jaysingani, Pratik Patil. The useful information about its protocol is the following one:

- Principal hypothesis: "mechanical axis alignment of the lower limb, post-operative joint line restoration, and femoral and tibial component alignment are more accurate in roboti-assisted TKA." (Cited from (14))
- Methodology: it is a prospective randomized study with a sample size of 60 patients. Participants were randomly assigned to RATKA or MTKA procedures. The robotic intervention was assisted by the Navio System (*Smith & Nephew Inc.)*, an imageless semiautonomous system which has a robotic tool that can be controlled by the surgeon and a navigation system for planning. This device works in three phases: registration, planning and execution. A postoperative CT of the knee joint was done in order to extract its radiographic measurements (the variables of the study). In this case, the expected results (preoperative) were not compared with those obtained in the postoperative CT. For each group the results were studied to identify those cases in which the variables exceeded a tolerance limit of 3°. This way, it is possible to calculate a percentage of cases who exceeded the tolerance limit and compare it between groups.
- Variables of study: in the coronal plane, *HKA*, *femoral coronal alignment* (FCA), *tibial coronal alignment* (TCA) and *joint line distance*; in the sagittal plane, *femoral sagittal alignment (FSA)* and *tibial slope*; and, finally, in the axial plane, *femoral component rotation (FCR)* (14).
- Statistical test: mean values were obtained from both the groups and for each variable of study measured. Then, for each angle, a two-sample *t test* was performed in order to find significant different between both groups. The level of statistical significance was set at $p<0.05$.
- Results: postoperative mechanical axis deviation (in absolute value) were more accurate in RATKA. This was concluded because eight cases from the MTKA group exceeded the

tolerance limit (while only one case in the RATKA group). Furthermore, the mean value in RATKA was 1.8°±1.2, when in MTKA the mean value was 3°±2.4. For femoral component position and tibial component position, both in the coronal plane, the deviation from mechanical axis was significantly lower for RATKA group than MTKA group. Only one tibial component case in the RATKA group exceeded the tolerance limit, whereas in the MTKA group about six cases of FCA and five cases of TCA exceeded the tolerance limit. Finally, the joint line of the MTKA group had a mean equal to 3.5 mm while the one of the other group was of 0.9 mm.

Overall, the RATKA group had been more accurate than the MTKA one.

To sum up, high accuracy and precision can be achieved in surgery due to the assistance of a robotic system according to these articles.

TECHNOLOGY: ROBOTICS, NAVIGATION AND SENSORS

Taking into account the exponential growth in the number of TKA performed worldwide and the actual rate of dissatisfaction, there is a great need to improve the results and the satisfaction of the patients (15). Currently there are different systems which can assist the positioning and alignment of implants prosthesis. Two large groups must be distinguished: computer assistance systems (navigation and robotics) and pressure sensors or soft part tensors that help control the tension in those softer parts and check the result after an implantation.

Three decades ago, navigation systems were introduced to assist TKA. The main goal was improving accuracy in the alignment of prosthetic components, and consequently reduce complications and improve functional recovery. The system virtually reconstructs an area of interest, so it is presented on the screen for surgeons monitor during the intervention. Reference methods include imaging systems such has CT or fluoroscopy. Nevertheless, there are methods that do not require them. On the one hand, CT images are required before or during the operation since the surgeon can plan the intervention or check in real time the best positioning. On the other hand, markers are needed in certain anatomical locations to be captured by fluoroscopic imaging techniques. Finally, non-imaging systems make use of an optical camera and infrared markers, and it is the surgeon who identifies the predefined anatomical locations, thereby he is able to locate the joint rotation using kinematics (which means the application of rotation or movement of the patient's leg passively) (16). An example of navigator is the Stryker's OrthoMap which helps to improve the accuracy regarding the orientation of the instruments and the alignment of the implants. Moreover, the system not only does not need any markers but also is efficient, which decreases the intervention time (17). After a few years with the implementation of navigation systems, new technologies are mainly deriving towards robotic systems since they are considered a crucial tool to face the exponential increase in TKA interventions. Given that this project analyses a robotic system, it is not needed a further study into the navigation systems.

Computed-assisted surgery systems interpret mathematically data from the patient's anatomy and shows its results: resection plans, degrees of varus or valgus needed, alignment measurements and the essential flexion and extension spaces to preserve the knee functioning and mobility. In function of the response of the system to the surgeon, three large groups can be differentiated in robotic surgery (18):

- Passive system: robotic system that guides the surgeons who manipulate and control all the robotic instrumentation to carry out the operation. Therefore, the robot is not able to perform any type of movement.
- Semi-active robotic system: robotic system that has the ability to restrict surgical manipulation through feedback in case of detecting unaccepted procedures.
- Active robotic system: a robotic system can perform tasks independently of human manipulation and surgeon control. For instance, the robot could directly cut or perform a bone resection until the final shape has been obtained.

In contrast to navigation-assisted arthroplasty, which provides real intraoperative information, robotic-assisted TKA must have a complementary software which converts the patient's anatomical information into a 3D reconstruction. This complementation is crucial to select the characteristics of the implant such as the size or the exact positioning.

Robotic assistance surgery technology for knee is primarily provided by the major knee replacement companies: *Stryker*, *Zimmer Biomet*, *Smith & Nephew*, and *Johnson and Johnson.* The main objective of this thesis is the analysis of the accuracy of these techniques. Thereby, it is essential to study the clinical evaluation results of these distribution companies.

MAKO SURGICAL, STRYKER

Stryker acquired the MAKO prototype in 2013 and the final product was presented in 2017. 650 MAKO robots were sold during this first year, and the expectations were to double that number within the course of 2018 (19). MAKO system is an image-based system which generates a 3D model of the patient's anatomy using CT images. Thus, it is easy to obtain a personalized preoperative plan to follow during the intervention. Nevertheless, it can be adjusted or modified by the surgeons. The haptic robotic arm contains the instrumentation needed to make cuts and it will be guided to perform femoral and tibial resections to a certain depth. This haptic system warns and guides the surgeon to prevent errors (20). The Stryker company has been carrying out different clinical trials with the collaboration of associated hospitals in order to study the performance of robotically-assisted interventions. The results demonstrate better accuracy in component positioning compared to conventional manual techniques (21):

- 95% of bone resections were ≤1 mm of the preoperative plan.
- Almost half of the knees (44%) had a difference between the final result and the proposed plan near to 0 or 0.

In another study ordered by *Stryker*, a higher percentage of the knees studied had a difference between the postoperative and preoperative plan lower than 2° (figure 2). With a small root mean square (RMS) and a smaller median error in all the variables studied ($p<0.01$), it has been possible to demonstrate that the MAKO system places the implant more consistently of knee prosthesis according to the preoperative plan (22).

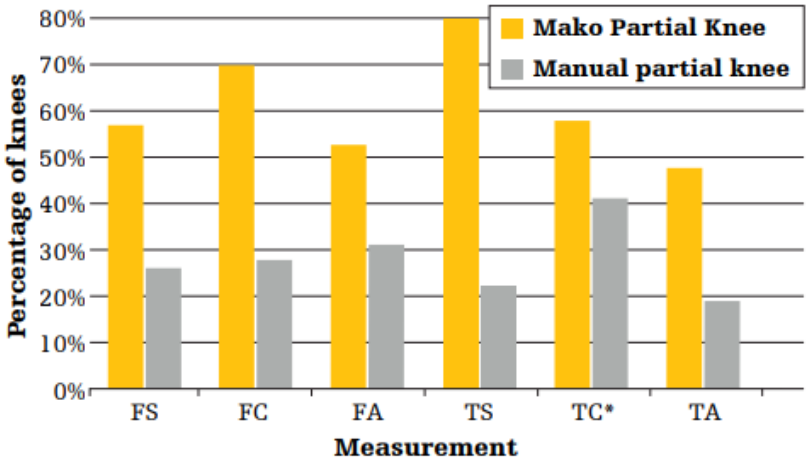


Figure 2 – There is a higher percentage of knees that have a difference with respect to the plan lower than 2º (so it is considered that the tibial and femoral components are placed more accurately). The variables studied are: femoral saggital (FS), femoral coronal (FC), femoral axial (FA), tibial sagittal (TS), tibial coronal (CT), tibial axial (TA).

In a nutshell, the results of these studies show very promising results regarding the accuracy of the MAKO robot.

ROSA, ZIMMER BIOMET

ROSA Knee System is a robotic platform used to assist surgeons in performing TKA with features to assist the bone resections. The device is composed of two units, one positioned on each side of the operating table (23): a robotic unit consisting of a robotic arm and a touchscreen, an optical unit and a touchscreen. The robot provides the spatial boundaries to orient and inform about certain anatomical references considered to precisely place the knee implant. The positioning of the robotic arm is based on preregistered anatomical landmarks in the system determined from the image-based mode (use of XR or Magnetic Resonance images of the anatomy) or imageless mode.

Figure 3 - Units of ROSA Knee System

In contrast with other knee robots, it studies the soft-tissue and bony anatomy of each patient, which allows the surgeon to personalize rotation of the femoral component based on ligament tension and plan the intervention. As a result, the placement of the cutting guide in relation with this planned location assisted by the robotic arm tends to be more accurate. Therefore, ROSA offers precision and accuracy through the cut flow and validation feature (24).

The system mainly assists for (23,25): determining the reference alignment axes in relation to anatomical landmarks, planning the orthopaedic implant's location based on these reference alignment axes and orthopaedic implant geometry, studying joint balancing, and, finally, precisely

and accurately positioning the cut guide relative to the planned orthopaedic implant location by using a robotic arm.

To demonstrate better results in terms of accuracy, *Zimmer Biomet* has also performed clinical studies to evaluate their robots (26). Statistically significant differences were found between: the planned and verified thickness of the medial and lateral tibial cuts (table 1), the average planned and validated angle of the femoral flexion (table 2), the average planned and validated angle of the tibial coronal axis (table 2). The average difference was in any case below 1 mm or under 1 degree with SD<1. Furthermore, the average difference between planned Hip-Knee-Ankle and measured was 1,2°±1,1°.

In conclusion, it has been found that ROSA Knee System provides accuracy and precision for certain aspects. All these findings are relevant to support the reliability of the robotic system. More studies are needed to assess whether the accuracy improves with respect all the variables and planes.

Table 1 - Average values of the planned cuts (APC), validated with ROSA system (AVC) and measured with calliper (AMC)

Results angles (°)		Average planned angle (APA) ± SD	Average validated with ROSA angle (AVA) ± SD	Average measured on the XR angle (AMA) ± SD
Femoral	Flexion	2,7 ± 1	2 ± 1	2,2 ± 1
	Varus/Valgus	1,3 ± 1	1,4 ± 1,1	1,0 ± 1,1
Tibial	Slope	3 ± 0,3	2,8 ± 0,8	2,6 ± 1
	Varus/Valgus	0,5 ± 0,7	1,1 ± 1,2	1,1 ± 1,1

Table 2 - Average values of the planned angles (APA), validated with ROSA system (AVA) and measured with XRs images (AMA)

Results cuts (mm)		Average values of the cuts planned (APC) ± SD	Average validated with ROSA cuts (AVC) ± SD	Average measured with calliper cuts (AMC) ± SD
Femoral	Distal medial resection	10,2 ± 1,4	10 ± 1,8	10,1 ± 1,3
	Distal lateral resection	8,9 ± 1,3	8,7 ± 1,7	8,9 ± 1,5
	Posterior medial resection	10,9 ± 1,5	-	10,4 ± 1,4
	Posterior lateral resection	9,2 ± 1,6	-	9,4 ± 1,1
Tibial	Lateral side	9,6 ± 1,4	8,9 ± 1,8	8,5 ± 2,1
	Medial side	7,2 ± 2,1	6,6 ± 1,9	7,8 ± 2

NAVIO, SMITH & NEPHEW

The NAVIO system is a manual cutting tool with robotic assistance used in total or unicompartmental knee arthroplasties. Previously to surgery, the size of the implant components,

the alignment and the bone resection to be performed are planned without any kind of imaging systems. Due to an insertion of percutaneous pins at tibia and femur, the software is able to obtain a 3D image adapted to the patient's anatomy. The program also includes different algorithms to determine the bone axes or to graph diagrams with the stress received by the soft tissues in all degrees of joint range (20).

NAVIO robot performance was measured through the calculated error in the resulting orientations of the femoral and tibial implants components. The maximum orientation error of the femoral component in conventional techniques (computed by RMS) was 7.52°; whereas, in robotically-assisted surgeries with NAVIO, it was 2.81°. Meanwhile, the orientation errors of the tibial component were 4.06° and 2.96° (conventional and robotic surgeries, respectively). The average error in all the studied variables was less than 1º (according to the clinical evidence provided by the study commissioned by Smith & Nephew) (27).

Table 3 (28) *- Mean RMS error of the different study variables in the two femoral and tibial components of the prosthesis.*

Error	Average RMS error	
	Femoral implant	Tibial implant
Varus/Valgus	0.7°	0.69°
Rotation (*femoral/tibial posterior slope)*	0.7°	0.88°
Distal resection	0.86 mm	0.68 mm

VELYS ROBOTIC-ASSISTED SOLUTION SURGICAL TECHNIQUE, JOHNSON & JOHNSON

It is a robotic system launched by *Johnson & Johnson* characterised by its efficient design which simplifies the workflow during the intervention. This simplification is based on a reduced footprint of the robotic device, components in the sterile field and components near the bed table (figure 4). Compared to other robotic systems such as MAKO, the system components space occupies 55% less which is a highly valued aspect by surgeons (29). Consequently, there might be an improvement on the operating room flow and surgical access.

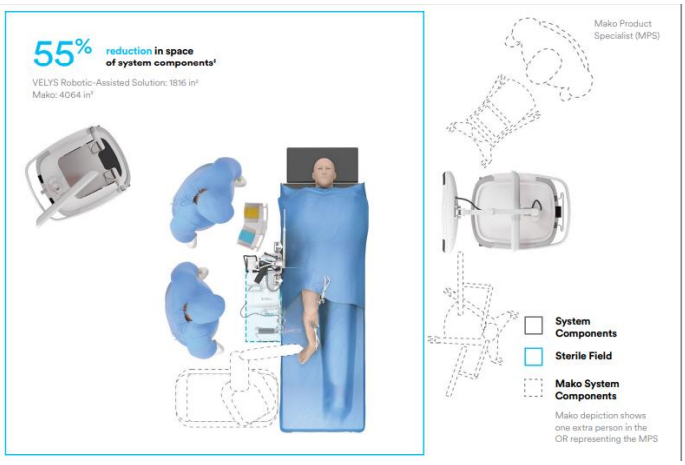


Figure 4 - Space reduction provided by VELYS.

As the main function of VELYS is to help surgeons to predict the knee stability using 3D recreations of patient's anatomy, it has intuitive interfaces showing customizable parameters to align properly the soft tissues of the knee or soft tissue stability graphs that afford valuable data about ligament balance (30). All these artifacts are valuable insights to accurately predict the joint stability, and consequently, design the best personalized intraoperative plan for each patient.

Finally, the evidence of precision presented on their clinical studies show a better accuracy in robotic surgeries than the conventional ones (figures 5 and 6) (31).

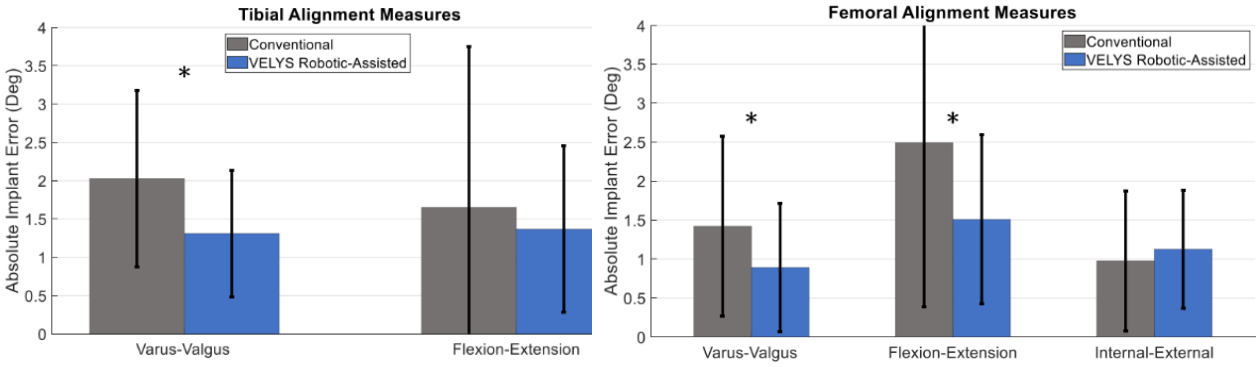


Figure 5 - Lower errors are found in VELYS robotic-assisted surgeries regarding tibial (left) and femoral (right) alignment variables.

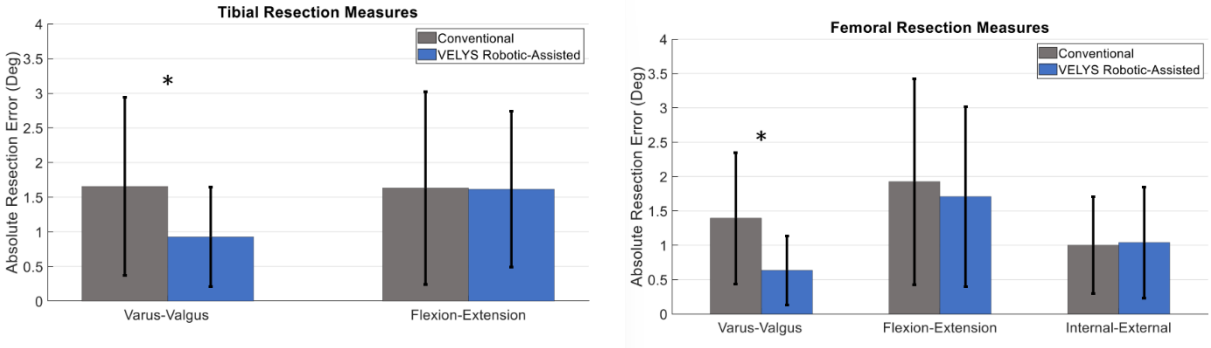


Figure 6 - Lower error have been found in VELYS robotic-assisted surgeries regarding tibial (left) and femoral (right) resection.

The results corresponding to the average error and standard deviations of these graphs are summarized in annex 3.

Once the current technology available in the market and its clinical studies about precision have been presented, it should be mentioned that although the 3D reconstruction presented by some robots or its accurate preoperative plan, the surgeons always are able to change some parameters of the plan according to the intraoperative situation. Furthermore, it must bear in mind that TKA are complex interventions and, as a consequence, little errors or imperfections can occur. However, what is expected is that the robotic assistance reduces the chances of error and s them less serious.

Summarizing this section, it has been observed the improvements that can be provided on TKA thanks to the introduction of alignment systems. New systems are being highly studied since the predictions regarding the amount of TKA interventions show a considerable raise. The leading health technology companies have already released their robotics systems; however, due to the market opportunity, more will appear. Furthermore, all research hospitals have or are carrying out clinical studies to provide scientific evidence on the improvement in interventions provided by these new alignment guides.

MARKET ANALYSIS

In this section, different aspects of the current market for TKAs will be discussed. The market will be analysed from the point of view of TKA in the world and the current prices of the robotic systems mentioned in the previous section of the project will also be compared.

TARGETED SECTORS

In recent years there has been a considerable increase in the number of TKAs, as commented before. Knee's osteoarthritis in almost 90% of cases, rheumatoid arthritis and post-traumatic osteoarthritis are the most frequent diagnoses for the implantation of knee prosthesis implants. Therefore, all hospitals that receive citizens with these symptomatologies will form the target sector for biomedical companies that sell medical robots (and, thus, the target sector of this project). The main criteria for indicating the need for TKA are from the radiological diagnosis of osteoarthritis or osteonecrosis to intermittent or constant knee pain for 3-6 months. Cases, in which the response after at least 3 months of pharmacological treatment has been inadequate and has had a negative impact on the patient's quality of life, are also considered. Furthermore, other subjects who have difficulties in carrying out activities of daily living may also to be subject to TKAs. In contrast, patients with (32): genital infection, systemic infection during the time when the operation is to be performed, incompetence of the extensor apparatus of the knee, chronic ischemia of the lower extremities, immature skeleton due to the proximity of the physis of the knee, acute cardiovascular problems, are not considered for this type of surgery.

In conclusion, TKA is considered the most optimal treatment for severe osteoarthritis. That is why there are several studies and articles (as seen in the previous section) regarding new advances in technology for this type of surgery in order to improve it.

HISTORICAL MARKET EVOLUTION

Nowadays, the four major companies that control the market are: Stryker, Zimmer Biomet, Smith&Nephew and Johnson&Johnson. As well as being leading companies in surgical robotics, they have been controlling the market for knee prosthesis implants around the world for years. Hospitals and private clinics are the sectors to which their products are sold.

The current distribution of the robotics market for ATR is dominated by Stryker. The pandemic has not diminished the popularity of its robotic systems, which make up 70% of all orthopaedic robots installed in the US (around 1'700 robotic systems for orthopaedics). Nevertheless, the market of knee products (including robotic systems and knee implants) is better divided between different companies (table 4) (33).

Table 4 - Knee prothesis market situation in years 2020 and 2021 in the US

	2020 Est Market Share	2021 Est Market Share	Change
Stryker	23.9%	24.9%	1.0%
Other Knee Suppliers	9.3%	9.2%	0.0%
Smith & Nephew	12.6%	12.5%	0.1%
Johnson & Johnson	17.9%	17.5%	0.4%

Zimmer Biomet	36.3%	35.8%	0.5%

In order to economically compare and contrast the presented robotic systems, it is interesting to study their market prices (table 5) (34–36).

Table 5 - Price and company of the main TKA assistance surgical robots

Robots	Company	Price (€)
MAKO	*Stryker*	954.0000
NAVIO	*Smith&Nephew*	381.461-429.144
ROSA	*Zimmer Biomet*	667.557
VELYS	*Johnson & Johnson*	238.413

There is a significant price difference that should be considered. In 2017 Stryker took MAKO to the market after having acquired it in 2013 for 1.7 billion dollars. In this way, Stryker found itself in a market with no competitors (34). As they were the first to move into this market, they were able to present their product in a significant number of facilities. Moreover, they have established a consolidated database and scientific articles from all over the world demonstrating the advantages of robotic surgery in TKA (37). After a while, in the same year, the company Smith & Nephew came onto the market with its NAVIO robotic system. The launch of this much cheaper product was acquired for 275 million dollars in 2016 (35). The price difference is due to the lower complexity of the product. Although NAVIO is not linked solely to Smith & Nephew's knee prosthesis implants, as is the case with MAKO, it does not have as many tools and characteristics (38). According to Jess H. Lonner, NAVIO's easy portability, low price and shorter system set-up time meant that it was considered a disruptive innovation. However, there are a few inefficiencies in operation that negatively counteract all the positive aspects. The need to perfect the tibial cuts or to smooth the surfaces are examples of the negative factors of NAVIO. Furthermore, after having been put into practice, it has been possible to discern some ergonomic challenges for surgeons, such as hand fatigue due to the long time the device is held, low back pain and strain from standing in a lumbar-flexed (39). All these factors allow us to understand the difference in the price of each company's products.

In 2019 Zimmer Biomet presented ROSA Knee System, a new robotic system that entered the market with the aim of being the largest competitor of Stryker (40). Many experts but consider that each system has its advantages and disadvantages without outweighing the other. Firstly, MAKO has a saw connected to the robotic arm, which is used to carve or make the cuts of the bone. In addition, it includes haptic technology such as tactile sensors. In contrast, ROSA has a carving guide connected to the robotic arm that helps to visualise where the surgeon makes the bone cuts (41,42). The fact that the positioning of the carving guides is robotised allows the surgeon to use the saw freely and still have a sense of control of the carving device. Nevertheless, many surgeons have felt forced in their movements and clearly limited in their control to perform the bone cuts due to the haptic systems. Another important difference is found in the preoperative and intraoperative study. MAKO uses a CT image of the patient to convert it into a 3D model of the patient's exact anatomy. In this way, the femur, the tibia, the genital joint and even the damaged surfaces can be

visualised to make a preliminary study of the operation. In contrast, the Zimmer Biomet can be used both ways, imageless and with a long leg standing scanogram. In this study, is used imageless. Although it is a faster technique, it is less precise.
Johnson&Johnson's entrance into the field of robotic surgery is still very recent (2021) and has received the CE mark recently in April 2023 (43). Some data from Johnson&Johnson assure great advances in the execution, as VELYS is much more versatile, easy and intuitive. What it does ensure is a 55% reduction in operating room space (44).

FUTURE MARKET PROSPECTS

The economic dimensions of TKA market were valued at around 9 billion dollars in 2022. According to *Global Market* Insights, between 2023 and 2032 it is set to increase 5% to $14.5 billion (45). The increasing prevalence of osteoarthritis, rheumatoid arthritis and post-traumatic arthritis is the main element for this market to grow steadily with many opportunities for the future. While in 2019 a total of 0.5 million of TKA were performed in the United States, the value is expected to increase to 3.4 million in 2040 (3). Unfortunately, the high cost associated with surgery can negatively affect the expansion of the market.
Emerging technologies have a promising role to play in order to reduce costs and improve the results of interventions. Despite the additional costs of robotic technology for the acquisition of the machinery, robotic surgery can reduce the cost per operation. Moreover, the good results obtained after the operations reduce the number of days of hospitalisation after the operation, the need for rehabilitation and the re-entry rate, which could counteract the costs of the new machinery (46).
Leaving aside the future prospects of TKA operations, the new robotic surgery technologies are very recent. It has not been more than 5 years since the most recent and reliable robots have been on the market, so that we are currently in the process of transition between more conventional techniques and those of robotic surgery. For this reason, we must first wait to see how the use of robots in TKAs stabilises before beginning to propose improvements to them. However, it is certain that new robotic technologies, similar to those presented above, will appear in the coming years.
Finally, it is interesting to contemplate and consider whether robotics could replace the current work of doctors. The speed with which information is currently processed is substantially increasing human knowledge. All the data that is generated day by day from biomedical images, medical examinations, laboratory tests, among others, is a huge source of information that needs to be processed. However, it is not possible to process such large sets of data in the human brain, which is why this interpretation of the data is done through increasingly faster processors. The use of this data will be crucial for artificial intelligence (AI) in making diagnostic or treatment decisions. New generations familiar with technology and the era of Big Data are strong indications of a greater introduction of artificial intelligence in the planning and implementation of robotic surgical procedures. For instance, Big Data can help us to decide the optimal and personalised prosthesis positioning for each patient, thus improving the clinical, radiological, functional and satisfaction results of our patients. However, what has been demonstrated so far is: "... more successful results can be obtained when technological applications are used with the doctor, not against the doctor" (8). Therefore, a clinical environment without humans is not currently contemplated.

CONCEPTION ENGINEERING

The entire execution of the clinical study is mainly defined by a protocol that has been previously developed. Therefore, in this section the different approaches to carry out the clinical study are presented. The study protocol will be designed and other possible aspects regarding the execution will be also commented. Moreover, it is worth mentioning that the study to be carried out is done around the ROSA robot, which is the one acquired by the Hospital Clinic. Therefore, there is not any possibility to choose between the different robots available in the market presented before. In addition, a comparison between them can be found in the previous section.

Firstly, the chapters that must include a clinical study protocol are the following ones:

1. Project justification
2. Primary, secondary, and tertiary objectives
3. Study design
    3.1. Methodology
    3.2. Participants selection (inclusion and exclusion criteria)
    3.3. Study variables
    3.4. Data extraction
4. Statistics
    4.1. Sample size
    4.2. Statistical analysis
5. Ethics and legal aspects
6. Data treatment and confidentiality
7. Publication policy

The chapters that will be commented hereafter are 3 and 4 since the rest have already been defined or are very standardised by the hospital's internal policy.

POSSIBLE SOLUTIONS

The first aspect to be analysed is the design of the study and statistics. Later, some other decisions to be considered during the execution will be presented.

DECISIONS REGARDING THE PROTOCOL (STUDY DESIGN AND STATISTICS)

1. METHODOLOGY

As for the methodology, it refers to the general idea and process that will be carried out.

- *Solution 1.1:* Study the difference between what is expected to be obtained and what has been obtained. For this reason, it is necessary to collect data before (or during) and after the operation. The pre-operative or intraoperative study variables (provided by the robot itself) are subtracted from the values obtained after the operation. In this way, a statistical analysis of the error obtained can be carried out. In this study, the accuracy will be studied thanks to variables related to the alignment, positioning and rotation of the prosthesis. The variables will be explained later.
- *Solution 1.2*: Study the patient's clinical signs after the operation and recovery. Those cases with proper rehabilitation, without symptomatology, and re-entries to the hospital shall be understood as patients with good alignment and accurate implant placement.

Questionnaires and assessment scales will be used. Data collection in this case will require interaction with the participants. The results obtained will be analysed statistically.

2. PARTICIPANTS SELECTION (INCLUSION AND EXCLUSION CRITERIA)

It is important to point out that there could be many inclusion criteria. However, a large number of criteria can limit the characteristics of the participants too much and thus lead to a loss of variability in the results (which should be avoided). For this reason, the most important and general **inclusion** criteria proposed are:

- *Solution 2.1:*
    - Age: over 18 years of age.
    - Patients who have undergone TKA with PERSONA prosthesis implantation.
    - Patient agrees to provide written informed consent to participate in the study.
    - In the opinion of the investigator, the patient has the capacity to understand the clinical research and agrees to carry out all study procedures and follow-up.
    - Patients with a minimum follow-up time of 6 months. Patients eligible to participate will be chosen from the first intervention with ROSA performed at *Hospital Clínic* de Barcelona (December 2020).
- *Solution 2.2:*
    - Age: over 18 and below 85 years of age.
    - Patients who have undergone TKA with PERSONA prosthesis implantation.
    - Patient agrees to provide written informed consent to participate in the study.
    - In the opinion of the investigator, the patient has the capacity to understand the clinical research and agrees to carry out all study procedures and follow-up.
    - Patients without a minimum follow-up. Since they have been operated that can be selected as participants. Patients eligible to participate will be chosen from the first intervention with ROSA performed at *Hospital Clínic de Barcelona* (December 2020).
- *Solution 2.3:*
    - Age: no restrictions.
    - There is no written informed consent from the patient.
    - There is no diagnostic indication of osteoarthritis of the genus, rheumatoid arthritis or post-traumatic arthritis.
    - The patient does not have the capacity to understand the clinical research or fully accept to carry out all the procedures and follow-ups of the study (according to the investigator's criteria).
    - Criteria of gender, ethnicity, or economic power

Once the inclusion requirements have been presented, the **exclusion** criteria must be also defined. Exclusion criteria are generally used to ensure patient safety. As before, a very large and specific list could be made, but as long as it can be avoided, it is necessary to look for those criteria that allow us to have a population with the maximum number of variables.

- *Solution 2.1:*
    - No consent to participate.

- Patients who underwent a TKA revision intervention (change of prosthesis).

- *Solution 2.2:*
  - No consent to participate.
  - Patient with a near-future surgical intervention or who has undergone an intervention recently.
- *Solution 2.3:*
  - No consent to participate.

3. STUDY VARIABLES

Solutions 1.1 and 1.2 (from the methodology) present different variables that will be used to study the alignment and placement of the prosthesis implant in the body and some other variables to study the feasibility of joint rotation once the prosthesis has been implanted. All these angles and distances have been chosen from the literature review done and all the bibliography studied due to their possible relationship with the alignment or rotation of the prosthesis in the knee. In this list only the name of the variable is included. The definition of each variable and the units of measurement can be found in annex 4. Therefore, solutions 3.1 and 3.2 are more in line with solution 1.1 proposed in the methodology (in which a difference between postoperative and preoperative results is used to study accuracy). In parallel, solution 3.3 presented is associated with solution 1.2 of methodology as there will be an analysis based on the patient's clinic and signs to study accuracy.

- *Solution 3.1:* the variables to obtain are visualized in different planes or axis.
  - Coronal plane: HKA, joint Line Height (JLH), Joint Line Convergence Angle (JLCA), mechanical Lateral Distal Femoral Angle (mLDFA), mechanical Medial Proximal Tibial Angle (mMPTA)
  - Sagittal plane: patellar height, Posterior Distal Femoral Angle (PDFA), Posterior Proximal Tibial Angle (PTTA), anterior condylar offset, posterior condylar offset ratio.
  - Axial plane: lateral patellar tilt, patellar displacement, femoral component rotational angle, tibial component rotational angle, rotational mismatch between femoral component and tibial component, combined rotation between femoral component and tibial component, femoral torsion, tibial torsion, femorotibial rotation.
- *Solution 3.2:*
  - Coronal plane: HKA, JLH, JLCA, mLDFA, mMPTA
  - Sagittal plane: patellar height, PDFA, PTTA, anterior condylar offset, posterior condylar offset (PCO).
  - Axial plane: femoral component rotational angle, tibial component rotational angle, resection bone thickness.
- *Solution 3.3*: pain scale, Knee injury and Osteoarthritis Outcome Score (KOOS), Knee Society Score (KSS), Forgotten Joint Score (FJS), joint balance, muscle strength, start of rehabilitation, initiation of bipedestation, re-entry, reintervention.

4. DATA EXTRACTION

The variables related to the bone cuts and resections, distances and angles between different anatomical references can be obtained during the intervention from a measuring system such as callipers, rulers or angle transporter rulers or automatically by ROSA. In contrast, the postoperative values of variables must be based on the biomedical images uploaded in the electronic health records (SAP) of the hospital. The options available for obtaining images are:

- XRs and LLR.
- CT or slit (depending on the angle or alignment to be studied).
- Ossian nuclear magnetic resonance.

Once we have the images, one must decide how to study them:

- Solution 4.1: Manually drawing lines and computing angles on top of DICOM images:
    - Use of RAIMVIEW software.
    - NovaPACS by Novarad.
    - UltraLinq.
- Solution 4.2: Use of automatic tools
    - TraumaCad (medical software for orthopedic surgeons that provides tools to plan Total Joints Replacement surgical procedures and analyse orthopedic images (47).
    - Healthcare software development by itranstition (a comprehensive medical software that includes tools from HER/EMR to imaging analysis) (48).
    - NovaPACS by Novarad (medical software that orthopedically templates, measures tools for specialized viewing and is able to plan preoperatively) (49).

Regarding the solution 3.3 (associated with the results of questionnaires or assessment scales), the data extraction can be obtained personally by interacting with the participant in the review appointments with the doctor or written questionnaires can be sent remotely for the participant to answer. Finally, other variables used in option 3 above, such as the start of bipedestation or re-entry, will be obtained from the patient's own clinical history.

Finally, in order to compile all the data obtained (whether intraoperative or postoperative), different computer programmes can be used:

- Microsoft Office Excel
- Microsoft Office Word
- Google Form

5. SAMPLE SIZE

There is still little reference on the accuracy of robotic machines as each study reviews one variable or another. Because of this fact, this observational clinical study will collect data that help to define the accuracy in robotic interventions. Because of this reason, there is no defined sample size. It will review as many participants as possible from December 2020, with a minimum follow-up of 6 months. Patients who meet the criteria will be included consecutively depending on the time for the completion of the final degree project.

6. STATISTICAL ANALYSIS

The options of the statistical test are closely linked to a series of factors of the clinical study such as the research question, the study design or the type of data to work with. Assuming that our data

will adhere assumptions of normality and homogeneity of variance, the most common types of parametric tests are (50) :

- **Regression tests** (*solution 6.1*): look for cause-and-effect relationships.
- **Comparison tests** (*solution 6.2*): look for differences among group means.
- **Correlation tests** (*solution 6.3*): studies the possible relation between variables without considering a cause-and-effect relationship.

In function of the characteristics of the clinical study, a specific statistical test will be directly chosen depending on the parametric test selected. Nevertheless, although is not a statistical test per se, a **concordance study** (*solution 6.4*) might be another possibility since it is commonly used to assess the level of agreement between measurements. Another possibility could be the **Pearson coefficient** (*solution 6.5)*.

OTHER DECISIONS DURING THE EXECUTION

As it has been commented before, the design of the study itself already includes a large part of all the decisions that will have to be taken and options for the execution of the project. Even so, other small details may arise as will be discussed below:

7. PATIENT APPOINTMENTS

Once patients have been selected, they must consent to participate in the study in order to have study their XRs images and to schedule a CT examination. Beforehand, in order to confirm their participation, they have to sign the informed consent form and the clinical study has to be explained to them. There are two possible ways to obtain their signature:

- *Solution 7.1:* schedule an appointment in the hospital and the investigators will explain the study to them.
- *Solution 7.2:* contact them by phone and explain the study. Subsequently, send the informed consent document by e-mail and obtain an electronic signature or digital certificate.

8. STATISTICAL SOFTWARE

Nowadays, there are different biostatistics software that can be used to obtain the results of standard statistical procedures and statistical significance tests. They tend to include statistical packages that provide facilities for data treatment and management. Some of the most possible options are listed below:

- *Solution 8.1:* SPSS (IBM)
- *Solution 8.2:* Python
- *Solution 8.3:* R
- *Solution 8.4:* SAS/STAT
- *Solution 8.5:* Matlab
- *Solution 8.6:* Mathematica Wolfram Research

PROPOSED SOLUTIONS

Once all the approaches of clinical studies to assess the accuracy in the extremity and positioning of knee prosthesis implants have been presented, the proposed solution is presented below. The

same division has been used as in the previous section, explaining the reasons for the chosen solution.

1. METHODOLOGY

The proposed option in the protocol is *solution 1.1*. It has been considered that the best way to study accuracy is to use the difference between what is desired/planned intraoperatively and what is obtained. In addition, variables that are directly related to the position and rotation of the prosthesis are included, unlike the other solution. The patient's clinical condition or signs should not be directly related to the accuracy of the positioning since there is no sufficient literature to ensure this fact. Only knowing that the patient can lead a normal life or is pain-free, there is no indication as to whether the prosthesis has been positioned as expected. Although there is a possible correlation between pain and poor placement, solution 1.2 does not directly study where the prosthetic implant has been placed and positioned. For instance, orthopaedists are observing that sometimes perfect positioning of prosthesis continues cause pain to patients while other surgeries without the best positioning and placement do not lead to patient's pain.

2. PARTICIPANTS SELECTION (INCLUSION AND EXCLUSION CRITERIA)

The inclusion criteria selected is *solution 2.1*. The minimum age to legally participate in a clinical trial is 18 years old because it is considered an age in which the user has the sufficient autonomy and responsibility to freely choose with all the necessary information. In case that the studies are to be carried out on minors, the decision will be up to the legal representatives, but then the clinical study is specific to minors. Solution 3 is therefore completely ruled out. On the other hand, a maximum age may or may not be specified. In this study we do not wish to define a maximum age because osteoarthritis in advanced age is very recurrent and represents a very representative public for knee prosthesis operations. Another mandatory requirement is the patient's written informed consent, so that anything that does not include it will be directly discarded. Any solution that does not include this consent will be illegal. Finally, there must be a clear diagnostic indication by the orthopaedic surgeon of the need for surgical treatment. Patients who do not suffer knee osteoarthritis, rheumatoid arthritis or post-traumatic arthritis are not operated on. No other inclusion criteria can be considered in relation to the diagnosis.

On the other hand, the exclusion criteria are also the one from *solution 2.1*. It is crucial that all those patients who do not wish to participate will not be obliged to do so. Moreover, all those patients who underwent a surgery to change the prosthesis (due to possible complications) cannot be considered since the intraoperative results recorded have changed and the situation is completely new in contrast with the initial one (that was going to be studied). Furthermore, the reintervention is an aggressive surgery that represent a challenge for surgeons since are more difficult and sometimes require specific prostheses or allografts because of bone loss or ligamentous insufficiency associated to the first TKA intervention (51). Therefore, the state of the knee in reintervention can vary to the one associated to a first TKA underwent to the patient and can bring outliers to our results.

3. STUDY VARIABLES

The selected variables are listed in *Solution 3.1*. All those study variables based on the clinic or the patient's signs such as pain scale, muscle strength or joint balance (solution 3.3) cannot be directly

associated with the exact position of the implant. For this reason, they will not be considered as the most optimal to fulfil the objective of the study and to perform the accuracy analysis.
At the same time, solution 3.1 and 3.2 are very similar. They are more optimal (in comparison with solution 3.3) because they include variables to study alignment, positioning and rotation. Although it is true that solution 3.1 has a high number of variables (which could imply a high complexity of the study since there are more relationships between the variables themselves to be taken into account), most of the variables are going to be used as descriptive data. Just some of them will be used to assess the accuracy of the robot comparing its intraoperative (recorded by ROSA Knee System) and postoperative values. Furthermore, the study of bone resections' thickness (*solution 3.2)* cannot be performed since during the interventions undergone the thickness was not measured with a calliper.

4. DATA EXTRACTION

Due to the variables selected in the previous subsection, the extraction of data will be performed from biomedical images. The internal protocol of the hospital requires preoperative and postoperative XR images and LLR. Therefore, these types of images will be automatically available for the study. Nevertheless, they do not allow to visualize a proper axial plane of the knee, which makes it difficult to study certain rotational variables. Until now, rotation has not been considered in the study of prosthetic positioning. However, emerging results try to demonstrate the opposite (52) . For this reason, this study will include the study of CT images of the knee in order to be able to provide descriptive variables on this aspect given the limited literature that currently exists and to also use some of them to assess ROSA's accuracy. The CT and slice images should be taken 2 or 3 months (minimum) after the operation, as this is the time in which the implant will be well implanted in the participant and will not cause problems (as there is a minimum of follow-up of 6 months, this requirement will be met by all participants).
Although CT make use of radiation, it is the gold standard technique to study the body in axial planes (which cannot be performed in XR or LLR) due to its great accuracy in imaging. Furthermore, the CT results can be used to perform a three-dimensional reconstruction of the whole body and to measure all other non-rotational variables. Although these variables can be studied with XR images and LLR, CT scans provide more accurate images. In addition, this could allow us, in case of time, to compare the two imaging techniques (XR or LLR vs CT) and discuss the possible use of CT in routine clinical practice. Both imaging techniques are available in Hospital Clinic's installations.
Regarding the extraction of data from the biomedical images of the knee, ideally the use of automatic tools would save time and would provide repeatability in data collection. This would ensure that all variables are always obtained in the same way and with minimum variability in the methodology. However, as the clinical study is not funded, the idea of acquiring or buying a new licence for some software for the extraction of these variables (as most of them are not normally used in the usual clinical pathway) has not been contemplated. In any case, TraumaCad will be used if possible, depending on co-ordination with other users of the hospital who are actually using it, as the hospital clinic has just one licence. Even so, the main method considered is to use RAIMVIEW (the software that Hospital Clinic already has) as an image viewer and draw lines on

top of the images in order to calculate the corresponding distances or angles. Therefore, the decisions to select this data extraction methodology has been based on what the tools already provided by the hospital itself so that it does not have to acquire more tools.
Summarizing, the following process will be carried out for each patient: as the patient has been already operated, the preoperative and intraoperative data is already available. Once we have met with them to explain the study and obtain their consent, they will be scheduled for CT imaging and the results will be studied by the hospital's radiological experts. At the same time, data needed will be extracted from the intraoperative reports (automatically created by ROSA) in order to be compared with the postoperative CT scans results (given by the technicians). In addition, all variables in the sagittal and coronal planes will also be extracted from the XR images and LLR following a protocol of variables extraction done previously so all the observers follow the same methodology. This way, the CT postoperative results can be compared to the XR or LLR postoperative results. All the data will be compiled in Microsoft Office Excel because is the one I am most used to and is the most intuitive and easy program to use for saving data and then loading it into statistical programmes.
This whole process will be carried out in parallel between patients, so, for instance, we will dedicate the whole day to appointments with patients (for the consent inform) while the cases of those who have already accepted are being studied and CT images are being obtained.

5. SAMPLE SIZE

As commented previously, there is not an exact sample size due to this study will provide descriptive data. As the design of the study protocol started approximately in May 2022, and the participants must have a minimum follow-up of 6 months, all the possible participants included in the study are those operated between December 2020 (first intervention assisted by ROSA) and November 2021. In total, there are 68 patients that meet these requirements. Assuming possible reinterventions, patients who do not want to participate and other external setbacks or inconveniences, around 30 participants are expected to be studied.

6. STATISTICAL TEST

The reliability of the postoperative values with the intraoperative values is the best indicator of accuracy. Therefore, *solution 6.4* (concordance study) is the most viable option. In this study, we are not interested on learning the cause-effect relationships (regression test, *solution 6.1*) or the relation between variables (correlation test, *solution 6.3*). Studying the difference among group means could be an option if we had more than one group (for instance, patients operated by conventional TKA and patients operated using ROSA assistance). Nevertheless, in our case, we just study some conditions of a same group, so *t-test* is also supressed as an option. Finally, the Pearson correlation coefficient between two measuring techniques is used to demonstrate a linear relationship. However, not finding a linear relationship does not mean that the data does not have a good agreement, which is what we want to study. Therefore, the concordance study is the most suitable option.

7. PATIENT APPOINTMENTS

In order to obtain the informed consent of patients, appointments will be scheduled (*solution 7.1*). Although this involves more work for the researchers, it is felt that in this way the participants can receive the best explanation of the study. The fact of explaining it in person means that patients become closer to the study and, as a result, they finally agree to participate. Moreover, considering that most of the participants are older, we want to avoid that they have to use technology and digital signatures due to a possible lack of control or comfort on their part in reference to this system.

8. STATISTICAL SOFTWARE

Finally, it was decided to use RStudio as it is the statistical software, I have used the most and I have the most control over it. In addition, more comprehensive software will not be needed because the statistical test to be performed is not very complex.

Furthermore, RStudio has the *cccrm* package which includes functions that calculate the concordance coefficient (53). In addition, the Bland-Altman method and plot can be also easily performed by RStudio. This way, the agreement interval where a certain percentage of the population is found will be possible to be studied.

DETAIL ENGINEERING

In order to carry out the whole clinical study, different steps must be accomplished. In general, the most important work done by me consists of:

- Describing and selecting the study variables from reviewing the current literature related.
- Design a study protocol that must be accepted by an ethics committee.
- Design a protocol that explains how to extract all the variables to study.
- Extract the variables from the biomedical images.
- Analyse the difference between the intraoperative and postoperative data to assess the ROSA accuracy.
- Provide descriptive data of our cohort group of study.

Nevertheless, other important small steps have also been taken for the good follow-up of the study including interaction with patients and other hospital departments to obtain all the necessary data which will be briefly described below. All the work done will be explained to understand the results obtained after choosing the protocol to follow discussed in the Concept Engineering. Furthermore, images, protocols written, and code will be presented or included in the annexes at the end, so that the reader can better understand the entire project.

LITERATURE REVIEW

As in most studies, one must start with a literature review in order to get ideas on how to achieve the proposed objectives. In this case, one has mainly made use of websites such as *Pubmed* or *Clinicaltrials.gov*. While the former presents results and methodologies on certain trials already conducted, the latter provides very focused information on the different clinical trial protocols with clearly identifiable sections such as inclusion and exclusion criteria.

Initially, the project was focused on comparing the accuracy of RATKA and the conventional ones. However, the study was intended to review past cases already intervened where in the case of conventional surgeries there was a lack of data on certain interesting variables to study. Therefore, together with my tutors we decided to approach this work solely on the accuracy of ROSA-assisted surgery and contemplating a future comparison between assisted and conventional surgeries once this one has been completed. Nevertheless, the literature required to design the protocol is similar. The main articles reviewed have been already summarized and commented before in the *Antecedents* section. Papers comparing robotic and conventional surgeries or those that study accuracy using CT scanning have been the principal sources of information to design the protocol and define the main variables.

The search in *Pubmed* has been performed using the advanced search builder option. In order to search the studies assessing the accuracy of a robotic-assisted surgery, the keywords used have been: *"TKA"*, *"robot"* and *"CT"*. In the case of the comparison in accuracy between robotic-assisted and conventional TKA the terms used have been: "*TKA", "robot", "conventional", "accuracy".*

PROTOCOL DESIGN

The protocol has been mainly described in the Concept Engineering section. It summarizes all the solutions proposed in the Concept Engineering section. One can find the final protocol attached in annex 5. Once the protocol was finished, it was sent to the Research Ethics Committee. In this one, it is described: the objectives the inclusion and exclusion criteria to select participants, the sample size, the study variables, the methodology to study accuracy and extract data and the statistical test to apply to the extracted data. Then the following minor clarifications were requested before the protocol was fully accepted:

1. "Please specify in the protocol if the ROSA Knee System robot (which is a medical product) has the CE marking."
2. "In the informed consent to show to patients, the *Real Decreto 1090/2015* is cited. This law refers to clinical tests with medicines. Please, remove it and instead cite the *Regulation EU 2017/745, on medical devices*."

After these small corrections, the protocol had to be resubmitted to obtain a favourable opinion to enrol the participants and start the study.

PATIENT'S SELECTION AND APPOINTMENTS

Following the criteria explained on the protocol, the patients must be selected. The possible participants are all those patients operated from the first intervention assisted by ROSA (December 2020) until November 2021. This fact is because they have had a minimum follow-up of 6 months during the protocol's design (May-June-July 2022). In total, 68 patients from the hospital have undergone a TKA assisted by ROSA, and consequently, can be selected as possible participants. Nevertheless, the list was reduced to 65 due to the patients who have been reintervened after the first TKA (reintervention implies a change of the prosthesis that is supposedly being studied).

For each patient, an appointment was scheduled to ask for its participation. Those patients who already had a follow-up or revision meeting scheduled with their respective surgeons, did not need another appointment with us because their doctors itself can ask for their informed consent to participate in our study. Meanwhile, those patients without a revision or follow-up appointment (or scheduled at long-term) had to be contacted to make one. More than one day was proposed to schedule the meeting. Finally, the appointments were scheduled in "*Consultes externes de l'Hospital Clínic"* (Rosselló Street 161) for the 17th November, 23rd November and 15th December from 8:30h to 12:30h (days selected according to the tutor's and mine availability). The summoning of participants has been a task beyond my scope as it has to be dealt with by the hospital's own organizations (due to legal and confidentiality issues). I only had to send the list with possible participants that did not have any revision. Finally, a total of 39 patients were summoned by the hospital clinic's office administrators. The rest, as already had a meeting scheduled, listened the proposition of participation through their own doctors of the knee surgical team.

The meeting with each candidate consisted of a fast session in which the main parts of the study that concerned the patient were explained and also their questions were answered. In case of accepting to participate, the informed consent was signed by both parts (patient and my tutors). An example of the informed consent given to patients can be found in annex 6. One copy of the document was handed out for each part.

From this point on, my tutors and I requested CT scanning's for all the participants via SAP (software coordinated with the clinical history of the hospital). The schedule of CT scanning was determined by the imaging department office administrators. Once the CT images were obtained, they have been analysed by CT technicians and the variables requested by our research group have been extracted following the protocol of extraction of variables that can be found in annex 4.
To sum up, it can be seen how the interaction with the patient is minimum in this clinical study since we will study their images (nevertheless, it must be taken into account that they previously underwent a surgical intervention). Therefore, the only contact with the participants on our part is at the appointment to explain the clinical study. However, it should be remembered that afterwards they had to underwent CT imaging to obtain postoperative images that will be used to assess accuracy. Finally, the list of 65 possible candidates has been reduced to 21 (see the results section for more details).

VARIABLES EXTRACTION

As defined in the Concept Engineering section, the variables of study selected are listed in solution 3.1:

- Coronal plane: HKA, joint Line Height (JLH), Joint Line Convergence Angle (JLCA), mechanical Lateral Distal Femoral Angle (mLDFA), mechanical Medial Proximal Tibial Angle (mMPTA)
- Sagittal plane: patellar height, Posterior Distal Femoral Angle (PDFA), Posterior Proximal Tibial Angle (PTTA), anterior condylar offset, PCO ratio.
- Axial plane: lateral patellar tilt, patellar displacement, femoral component rotational angle, tibial component rotational angle, rotational mismatch between femoral component and tibial component, combined rotation between femoral component and tibial component, femoral torsion, tibial torsion, femorotibial rotation.

Before extracting them, a protocol has been designed and drafted to make the process of obtaining values as objective as possible and minimise inter-observer assessment (annex 4). Also, annex 7 shows a table that summarizes all the variables to be studied and it includes the references that have provided the extraction methodology of the variables and shows the sign criteria followed and the normality values of the population found in the bibliography.
In order to study accuracy, the main idea has been to compare all the intraoperative and postoperative variables. While the former was going to be obtained automatically during surgery by ROSA; the latter ones were going to be extracted from the analysis of CT and XR images. Nevertheless, ROSA is only able to automatically extract some variables of the list: ***HKA, mLDFA, mMPTA, PDFA, PTTA and femoral component rotation angle***. Consequently, accuracy has been studied just with these variables (from here on I will refer to them as ***accuracy variables***). All the other variables have been used to describe our group and place it in reference to the normality defined in the literature (from here on, known as ***descriptive variables***)
On one hand, the extraction of postoperative values of the variables from the XR and TM images has been performed by a medicine resident of the team and me. This way, inter-observer assessment can then be studied. This type of images does not allow a proper visualization of the axial plane; therefore, all the variables found in axial plane have not been extracted.

On the other hand, the postoperative data extraction from CT images have been performed by the radiological team of *Hospital Clinic*. The initial idea was to obtain all the variables. However, as mentioned above, on March 5th *Hospital Clinic* received a 'ransomware' type cyber-attack from the Ransom House. As a result, some departments of the hospital were paralyzed and have been gradually recovering normal activity. Unfortunately, as of today there are some files and data that has not been recovered. Due to all these facts, the workload of the radiology department has increased exponentially, and the radiology team has only been able to provide us the accuracy variables. Because of this reason, the descriptive variables (variables that do not study accuracy) has been provided from the variables extracted from XR images.

Regarding the preoperative data, initially it was intended to be used and compared with the postoperative values (that is why it has been extracted). Nevertheless, they provided little information to the main objective of the work, so they have not been used. Because of this fact and although it has been extracted, this section will focus on how to extract the postoperative data. In case more information about the preoperative data extraction is wanted, see annex 4.

Finally, the following table summarizes which variables do we have for each type of images.

Table 6 - Summary of the variables that we have studied for each type of data source

		Preoperative	**Intraoperative**	**Postoperative**
Data source	**XR / TM**	Variables in coronal and sagittal plane	-	Variables in coronal and sagittal plane
	CT	-	-	Accuracy variables
	ROSA	-	Accuracy variables	-

EXTRACTION OF POSTOPERATIVE DATA

To begin with, it is necessary to present the visualization system of images (RAIMVIEW) with their tools. As angles and distances must be found, lines should be drawn on top of the images. When studying distances, the "*distància"* directly provides the distance of a line. Moreover, "*angle 2 segments"* directly returns the value of the angle between the two drawn lines. When identifying the exact centre of a region, a circumference can be drawn in the zone and its centre is automatically returned with "*diameter"*. Finally, it can be also useful the use of *"creu"* perpendicular lines to draw tangent lines from certain points.

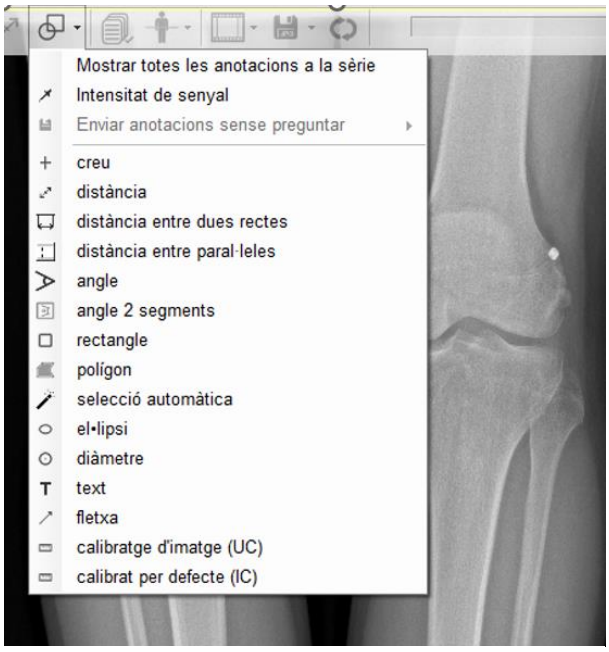


Figure 7 - List of available tools to use in RAIMVIEW

Another crucial aspect to consider when visualizing XR images or LLR via RAIMVIEW (imaging software already purchased by the hospital) is calibration. In other words,

make sure if 1 cm of distance in the image is really 1 cm with the measuring tools. If this is not the case, it is necessary to always use a conversion factor with all the variables that are extracted (multiply the millimetres obtained during the measurement by the ratio $\frac{1\ cm}{x\ mm}$ that were found at the beginning). Once these two principal aspects are known and understood, the extraction of variables can be carried out by both observers. Meanwhile, the CT images have been studied by expert members of the radiographic department of *Hospital Clínic*. Both cases will be briefly commented.

XR AND TM IMAGES

The variables studied in XR images and LLR are briefly defined and an image of the RAIMVIEW showing the methodology is attached for each variable. Generally, due to my inexperience with knee radiographs, I have had difficulty identifying certain anatomical references due to the great anatomical variability. For this reason, the experience is a positive aspect when measuring. The next table defines all the variables, and an image of the measuring is attached.

Table 7 - Summary of coronal and sagittal variables extraction

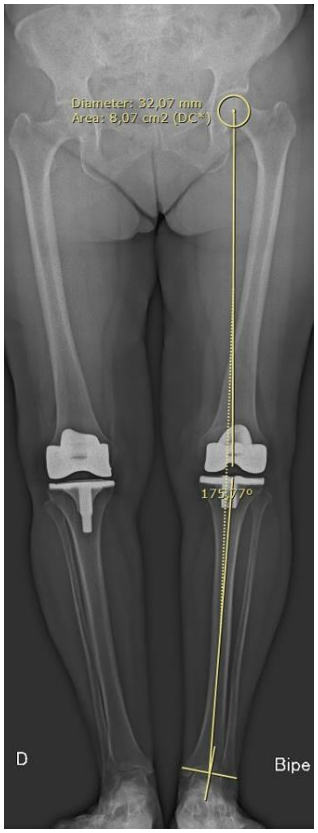
<table>
<tr><th colspan="2">Coronal plane</th></tr>
<tr><td>HKA</td><td>JLH</td></tr>
<tr><td>Angle between the mechanical axis of the femur and tibia in the coronal plane (54–56) .
 

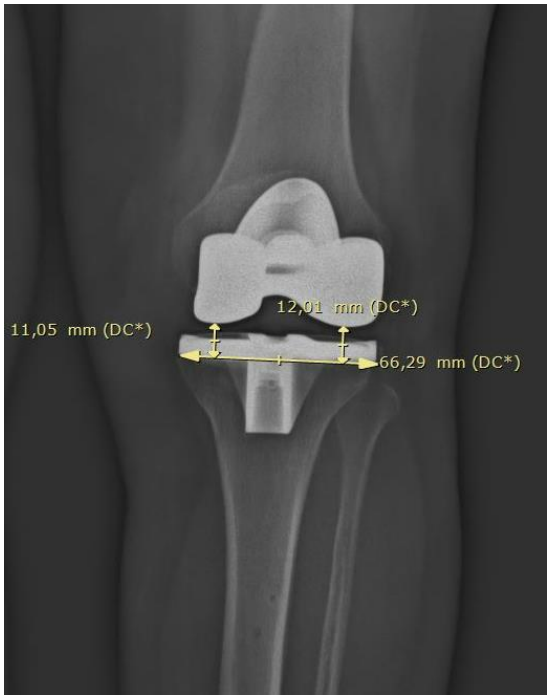
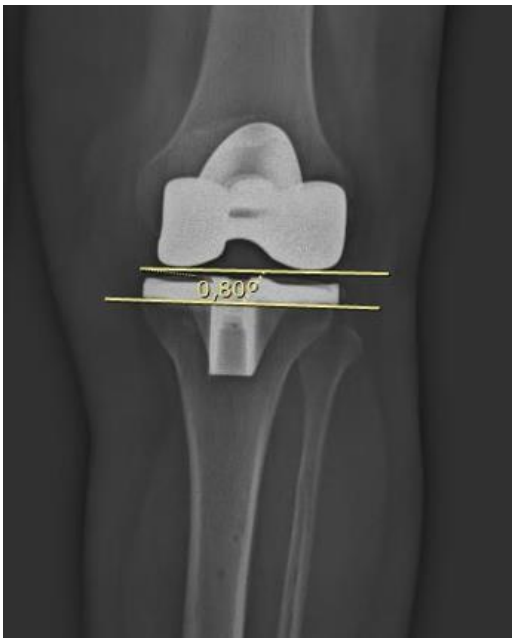
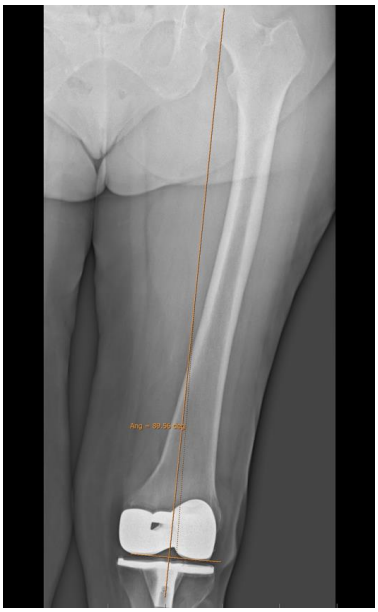
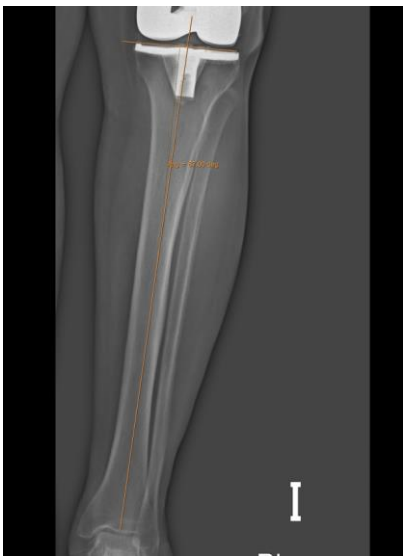
Figure 8 - HKA measurement (image of own property)</td><td>Mean between the distances of the medial and lateral condyles with the perpendicular of the anatomical tibial axis passing through the most proximal point of the fibula (57).
 

Figure 9 - JLH measurement (image of own property)</td></tr>
<tr><td>JLCA</td><td>mLDFA</td></tr>
</table>

Angle between the tangent to the most distal part of the medial and lateral femoral condyle and the subchondral plate of the tibial plateau (58).  *Figure 10 - JLCA measurement (image of own property)*	Lateral angle between the mechanical axis of the femur and the tangent line to both most distal points of medial and lateral condyles (55,59).  *Figure 11 - mLDFA measurement (image of own property)*
mMPTA	
Medial angle between the mechanical axis of tibia and the line representing the tibial plateau of the prosthesis (54–56).  *Figure 12 - mMPTA measurement (image of own property)*	
Sagittal plane	
Patellar height (Insall-Salvati method)	Patellar height (Caton-Deschamps method)
Ratio between *A* (length between the posterior surface of the tendon from the inferior pole of the patella to its insertion on the tibia at the tibial tuberosity) and *B* (maximum length of the patella,	Ratio between *A* (distance between the anterior corner of the tibial plateau to the inferior aspect of the patellar articular surface) and *B* (length of the patellar articular surface) (62).

measured from the distal to the proximal pole) (60,61).

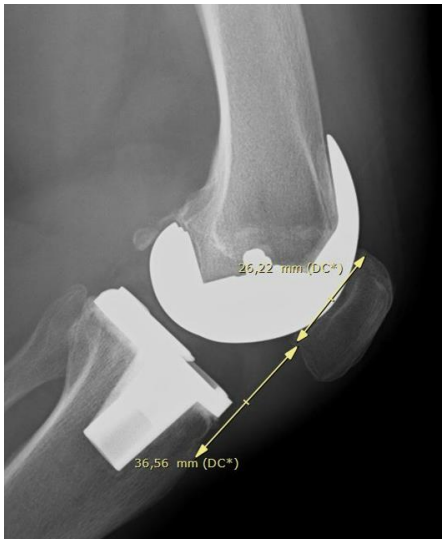


Figure 13 - Patellar heigh measurement according to Insall-Salvati methodology (image of own property)

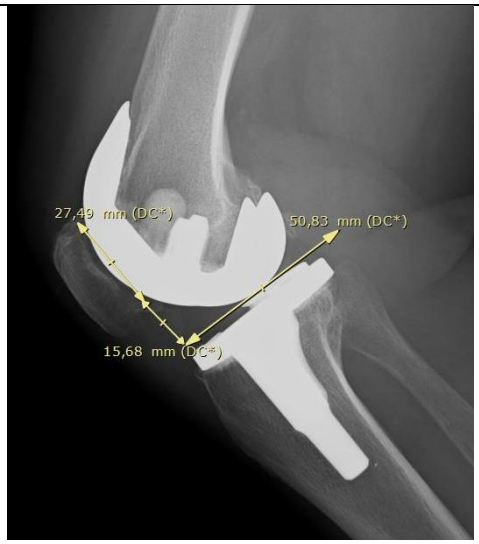


Figure 14 - Patellar height measurement according to Caton-Deschamps methodology (image of own property)

PDFA	Anterior condylar offset
It is defined as the angle between the distal femoral anatomical axis and the line of the distal femoral cut on its posterior aspect (54).	It can be found by calculating the distance (mm) between the anterior distal anatomical axis and a line parallel to it and tangent to the most anterior projection of the femoral trochlea (or of the anterior prosthetic shield in operated knees) (54).
Figure 15 - PDFA measurement (image of own property)	*Figure 16 - Anterior condylar offset measurement*
PCO ratio	**PTTA**
Ratio between the distance from the most posterior point of the condyles to the line tangent to the distal portion of the posterior femoral cortex (*a*) and the diameter measured at 25 cm from the end of the anterior shield of the implant (*b*). (54).	It is defined as the angle between the anatomical sagittal tibial sagittal axis and a line at the level of the base of the tibial plateau (54).

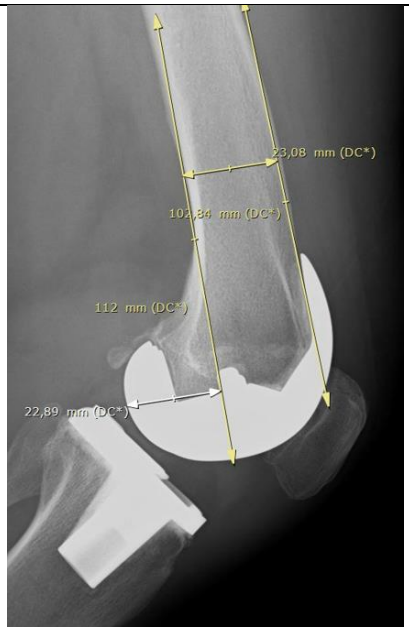


Figure 17 - PCO ratio measurement (image of own property)

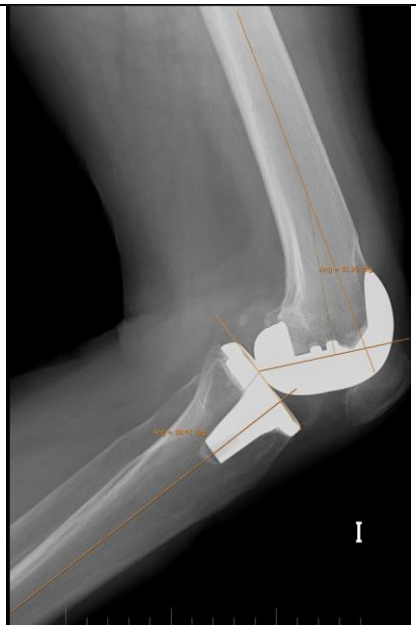


Figure 18 - PTTA measurement (image of own property)

During the extraction, the main problem that I have had is related to the PCO ratio variable. If the sagittal radiographs are not taken accurately, a perfect profile was not visible and the two condyles are visible. Thus, the distance to the most distal point when calculating this ratio, changes due to this camera angulation. As a solution, it has been proposed to take the average of the distances to the two most distal points of the condyles when they are very different (figure 19).

Finally, annexes 8 and 9 show the data of the preoperative and postoperative variables. For all cases, the values have been saved in Excel tables. As before, the tables have been anonymized according to a certain ID.

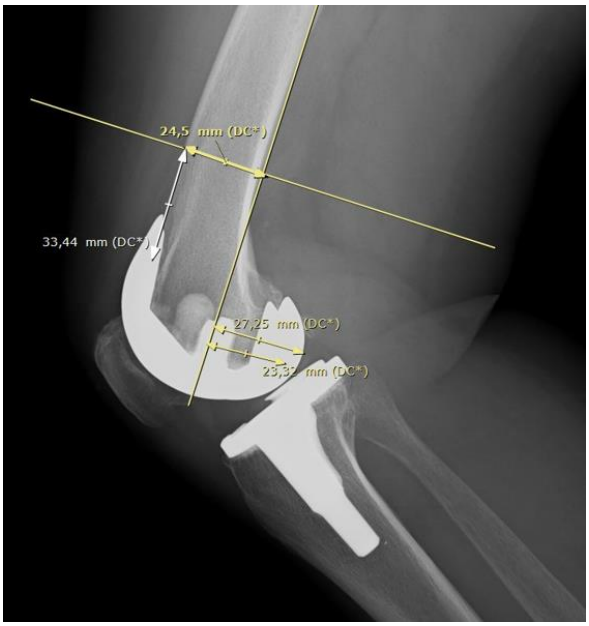


Figure 19 - Inaccurate angulation of the sagittal plane that arise problems when measuring.

CT

The CT images are acquired by the Siemens spiral CT scans. During the acquisition, the images obtained (RAW data-DICOM images) represent the axial plane of the patient. As the slices are very thin, isovoxels are generated which allow to obtain a 2D multiplanar reconstruction at the same moment of the acquisition (this way, coronal and sagittal reconstructions are obtained). The 3D reconstruction is done by a technician another day using a console with the Syngovia programme.

Finally, the images uploaded in SAP can be seen by the CT radiologists and using RAM VIEWER or RAIM ALMA 6.1 (images visualizers) the measurements in coronal and sagittal planes can be performed similarly as defined in the previous subsection. The axial measurements are described in table 8.

Table 8 - Summary of axial variables extraction

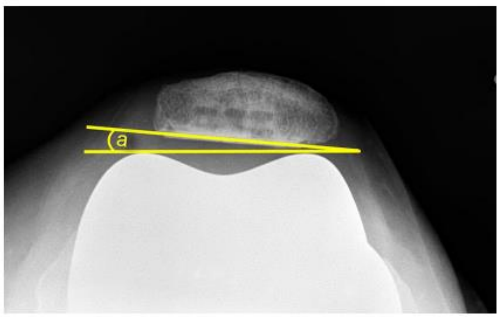
<table>
<tr><th colspan="2">Axial plane</th></tr>
<tr><td>Lateral patellar tilt</td><td>Patellar displacement</td></tr>
<tr><td>Angle formed by the line defined by the most anterior points of the femoral condyles and a line that follows the prosthesis-bone interface (63,64).
 

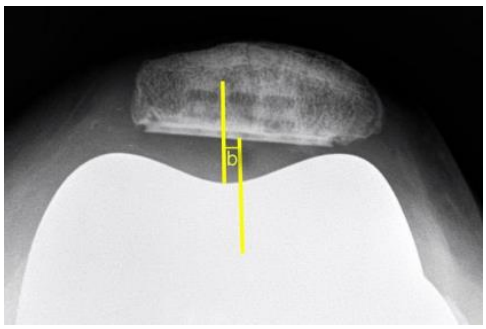
Figure 20 - Lateral patellar tilt measurement</td><td>Distance between a line that crosses the intercondylar fossa and is perpendicular to the line drawn by the anterior limits of the femoral condyles and its parallel that crosses the center of the patella (63,64).
 

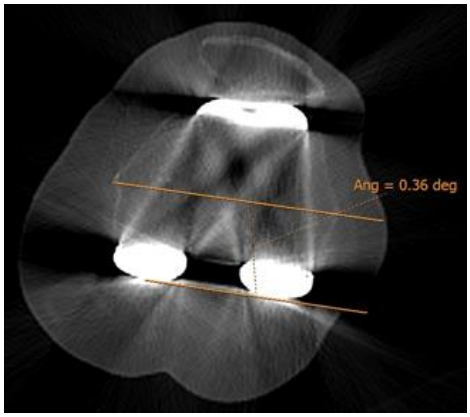
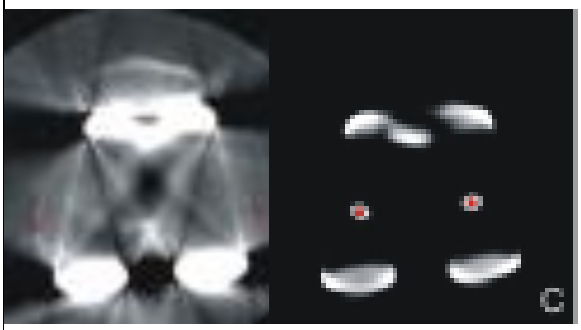
Figure 21 - Patellar displacement measurement</td></tr>
<tr><td>Femoral component rotation angle (Berger and Benazzo method)</td><td>Femoral component rotation angle (Lützner and Matziolis method)</td></tr>
<tr><td>It is defined as the angle between the surgical transepicondylar axis (sTEA) and the posterior bicondylar axis (PCA) (65–67).
 

Figure 22 - Rotation of the femoral component measurement (image of own property)</td><td>It is defined as the angle between the line connecting the femoral component fixation pins and the surgical epicondylar axis (66,68,69).
 
Figure 23 - Pins of the surgical epicondylar axis (left) and the femoral component fixation (right)</td></tr>
<tr><td colspan="2">Tibial component rotation angle</td></tr>
<tr><td colspan="2">As before, more than one methodology will be applied:
1. Berger: angle between the line perpendicular to the posterior axis of the tibial component and the line of the axis connecting to the axis end of the tibial tubercle (TCA and TTA) (66,70).</td></tr>
</table>

2. Insall, Zhang, Werneche, Klasan: The angle between the tibial anteroposterior axis (AP) and Insall's line (line joining the prosthesis center with the medial border of the patellar tendon) (71–73).

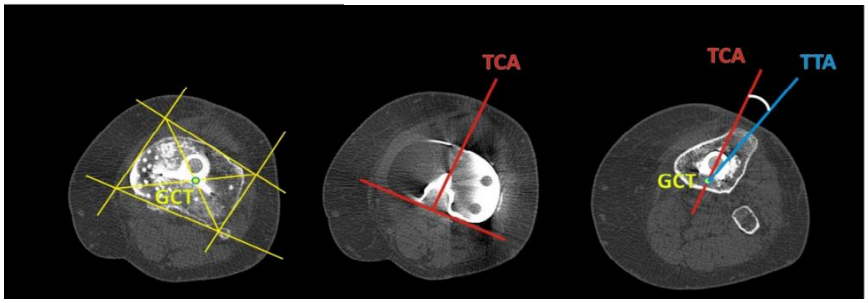


Figure 24 – Process to perform in the different slices to extract tibial rotation according to Insall

3. Akagi, Sahin: This methodology is very similar to the one defined by Insall. Only the last step changes since, instead of drawing the Inasll line, another axis is defined. The angle is represented between the tibial anteroposterior axis and the Akagi line (line joining the PCL center with the medial third of the patellar tendon) (71,74,75).

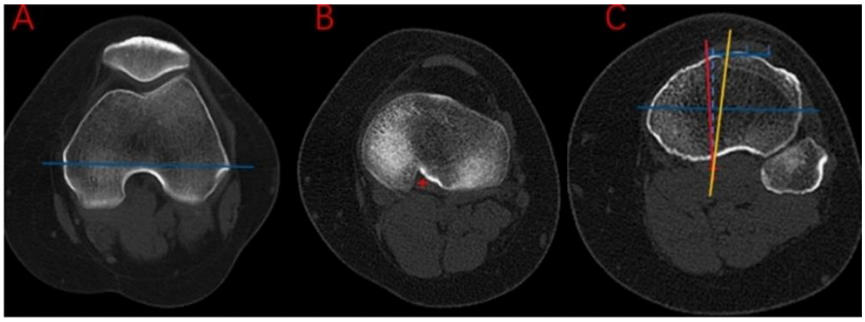


Figure 25 - Process to perform in the different slices to extract tibial rotation according to Akagi.

Combined rotation	Rotational mismatch
Sum of the angles obtained in the rotation of the femoral component and the tibial component (76).	Subtract the rotation angle of the femoral component minus the rotation angle of the tibial component (76).
Femoral torsion	**Tibial torsion**
Angle between the femoral transcervical axis (longitudinal line from the femoral neck to the centre of the femoral head) and the posterior bicondylar line (tangent line to femoral condyles) (77–80).	Angle between the tangent line to the posterior contours of the tibial plates and the transverse axis of the distal tibial epiphysis or bimalleolar ankle axis (77,79).

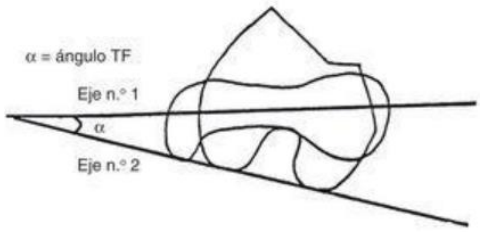
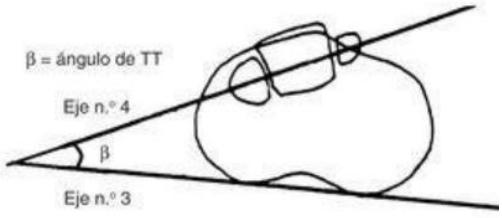

	

Figure 26 - Femoral torsion measurement	*Figure 27 - Tibial torsion measurement*

Femorotibial rotation
Angle formed between the posterior femoral bicondylar axis and the tangent line to the posterior contours of the tibial plates (77).

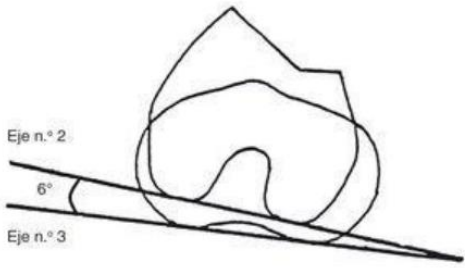


Figure 28 - Femorotibial rotation measurement

EXTRACTION OF INTRAOPERATIVE DATA

As mentioned above, the intraoperative variables have been recorded by the robot itself. All these data are automatically sent to the machine manufacturer (Zimmer Biommet), which is in charge of managing these data and sending them as excel documents to the hospital. Unfortunately, these excel documents are poorly prepared to exploit their data. For this reason, those data of interest have been selected from the ROSA excel documents and collected in a new table with a similar structure to the preoperative and postoperative data (already thinking to work with RStudio during the statistics). A real anonymized example of a excel document sent by Zimmer Biommet can be found in annex 10.

The data of our interest is found in the following sections of the complete excel table:

- Femur distal cut planned: the value that corresponds to *Slope [DEG]* or *Flexion [DEG]* is associated to PDFA, while *Varus/Valgus [DEG]* or *JLCA [DEG]* is the one for mLDFA. Finally, as the name indicates, *Planned HKA [DEG]* gives us the HKA value.
- Femur 4in1 cut planned: from here the rotation of the femoral component is the *Rotation from TEA [DEG]* cell. Since it refers to the angle between the anatomical transepycondylar axis (TEA) and a reference axis that is PCA.
- Tibial proximal cut planned: similarly to the femur, the *Slope [DEG]* or *Flexion [DEG]* shows the PTTA value, and *Varus/Valgus [DEG]* or *JLCA [DEG]* is the mMPTA.

The following table, is a fraction of the real Excel table with the three subsections mentioned above just to show how this data is organised and how has been selected. Highlighted in blue, one can find the cells mentioned above.

Table 9 - Example of intraoperative data provided by ROSA Knee System

FEMUR DISTAL CUT PLANNED	
Flexion/PDFA [DEG]	3.0 FLEXION
Varus/Valgus/JLCA [DEG]	1.6 VARUS
Distal medial resection [mm]	7.5
Distal lateral resection [mm]	8.6
Implant type brand	Persona PS Standard
Implant size	7
Planned HKA [DEG]	2.6 VARUS
FEMUR 4IN1 CUT PLANNED	

Rotation from PCA [DEG]	4.4 EXT
Rotation from TEA [DEG]	5.5 EXT
Rotation from Whiteside [DEG]	7.3 EXT
Posterior medial resection [mm]	13.3
Posterior lateral resection [mm]	9.8
Stylus height [mm]	0.4
Implant type brand	Persona PS Standard
Implant size	7
Instrumentation (4-in-1)	Anterior referencing
TIBIAL PROXIMAL CUT PLANNED	
Slope [DEG]	5.0 POSTERIOR
Varus/Valgus/JLCA [DEG]	1.0 VARUS
Rotation [DEG]	0.1 INT
Proximal medial resection [mm]	7.6
Proximal lateral resection [mm]	10.5
Implant type brand	Persona Stemmed Cemented Tibia
Implant size	C
Planned HKA [DEG]	2.6 VARUS

The sign criteria have been decided according to literature and our own criteria (as long as the same is applied to the data, the results will be valid). In our case, we decided:

- Varus/Valgus: *varus* has been considered positive, while *valgus* negative.
- External/Internal rotation: external rotation as positive; while internal, negative.
- Flexion/Extension: flexion as positive and extension as negative.
- Anterior/Posterior: anterior as negative and posterior as positive.

For mLDFA, mMPTA, PDFA and PTTA, the following equation to obtain the real angle (instead of the abbreviation using the varus/valgus, flexion/extension or anterior/posterior reference) has been applied:

$$Final\ angle = 90 - intraoperative\ value \qquad \textit{Equation 2}$$

This process of identifying and recording the values in a new table must be repeated for all the participants since each one has a similar excel document. The final collection of all values for each participant is summarised in annex 11.

STATISTICAL TEST

Taking into account the objectives defined in the introduction, in this subsection 4 different statistical analysis will be explained:

- Concordance study between the intraoperative and postoperative (CT) variables in order to study accuracy.
- Perform an inter-observer assessment with the postoperative XR and TM values
- Compare the postoperative values obtained from CT and XR images.
- Describe statistically our sample.

Before applying the statistical study, the data has been prepared in different tables. When comparing data of different methods or observers, a concordance study is the most suitable and viable option. The data must be organised according to the following criteria:

- Each patient will have two values for each variable: one for the methodology 1 (intraoperative/observer 1/CT) and one for methodology 2 (postoperative/observer 2/XR). One column will be dedicated to the method and two values will be given: 0 or 1 depending on the methodology.
- Each row is associated with a patient. Since we have two values per patient, we will actually encounter a new patient every two rows.
- The first three columns will be dedicated to the patient ID, intervention date and method. From here on, the next ones will be dedicated to the variables.

In annexes 12-14 can be found the tables used for each study and annex 15 contains all the RStudio code programmed. Table 10 is an extract from one of these tables to summarize the criteria discussed above.

Table 10 - Fragment of the table used for the accuracy study, id column anonymizes each participant, iq_date gives the date of intervention, and method identifies if the value has been recorded intraoperatively (0) or postoperatively (1). The other columns refer to the study variables.

id	iq_date	metode	HKA	MLDFA	MPTA	PDFA	PTTA	Berger
AR1	11/12/2020	0	2	89	89	87	87	5.4
AR1	11/12/2020	1	0.51	89.3	89.64	81.92	78.64	5.79
AR2	18/12/2020	0	2.1	88.9	89	87	87	1.6
AR2	18/12/2020	1	6.58	87.48	87.54	84.45	89.47	2.02

ACCURACY STUDY (INTRAOPERATIVE VS POSTOPERATIVE DATA)

As it has been justified in the concept engineering, the concordance study is used to measure the agreement of two methods (in our case, are the intraoperative and postoperative). To do so, qualitative, and quantitative approaches have been performed.

On one hand, the quantitative analysis has been performed using the *cccrm* package which estimates the Concordance Correlation Coefficient to assess agreement. Specifically, the function *cccvc* "estimates the concordance correlation coefficient for non-repeated measurements and non-longitudinal repeated measurements using the variance components from a linear mixed model" (Extracted from (81)). The arguments are: data set, name of the variable to study, name of the subject variable, and name of the method variable in the data set. In our case, it would be: *cccvc(dades,variable,"id","metode")* considering the names of the columns of table 10. The resultant coefficient can have values between 0 (no agreement) and 1 (perfect agreement). In the discussion, the results obtained will be commented.

On the other hand, a total deviation index has been calculated using the Bland-Altman method. Bland and Altman established a method to quantify agreement using a certain limit of agreement. These ones are computed as the mean of the difference plus/minus 1.96 times the standard deviation of the difference between two measurements. If the data is normally distributed, 95% of the data can be found within these limits. Once the limits of agreement are computed, the Bland-Altman plot can also be graphed. This plot consists of a scatter plot where the X-axis represents the average of the measures and Y-axis shows the difference between the paired data for each patient. Moreover, the mean of differences between paired data and the limits of agreement are drawn on top of the scatter plot defined.

In the case of PDFA and PTTA, the concordance correlation coefficient can not be applied due to the fact that these variables are planned intraoperatively almost always to 87°. The main reason is related to the type of implant that requires 3° of femoral and tibial flexion (which is the same as 87°). There are small and isolated cases where this may not be possible due to the patient's anatomy or severity of the disease and these values have to be adjusted. Therefore, PDFA and PTTA do not have any error associated with variability and are not random. The concordance coefficient is used when some variability or error is assumed between the two techniques. For this reason, for PDFA and PTTA just the limits of agreement have been studied taking 87 degrees as a reference value. Also, a boxplot of the differences between postoperative value and the reference value has been graphed in order to obtain a quick visual summary of the variability of the difference.

INTER-OBSERVER ASSESSMENT

The inter-observer assessment can be calculated as explained above. However, instead of working with intraoperative and postoperative data, each patient will also be in two rows: one for the values obtained by observer 1 (in the method column the value is 0) and the other for observer 2 (value equal to 1 in the method column). The observers studied are the ones that extracted data from XR and LLR images since, due to the cyber-attack, are the ones who have been able to extract the values for all the coronal and sagittal variables.

CT AND XR/LLR COMPARISON

For the imaging technique comparison, a concordance study can also be applied since we are comparing and assessing the agreement between two techniques. In this case, the table will have also two rows for each patient with the values extracted from CT images and the values extracted from XR and LLR images. As before, due to the cyber-attack, from the CT images we only have the accuracy variables. Therefore, I have just compared: HKA, mLDFA, mMPTA, PDFA, PTTA. As from the XR images the femoral component angle cannot be computed (because is an axial variable), it has been subtracted from the list. Methodology 1 (0 value in the method column) has been associated with CT variables, and XR variables to methodology 2 (value equal to 1 in the method column).

DESCRIPTIVE DATA

Finally, all the descriptive variables will be presented computing the mean, standard deviation and minimum and maximum value between all the participants.

RESULTS

The results obtained from the clinical study, are summarized in this section.

PARTICIPANTS

Of the 68 patients who have undergone a RaTKA in Hospital Clinic since the ROSA acquisition in November 2020, 1 was not able to be reached or contacted, 10 could not come to the 3 dates proposed as consultations days, and 2 missed the invitation to participate. Meanwhile, of those 55 patients who were assessed for eligibility, 5 were excluded because they were reintervened and 20 refused to participate. Due to the cyber-attack, data has been lost resulting on a decrease of the total recruited participants (from 30 to 22). Finally, one patient did not have the postoperative biomedical images to perform the imaging study. Therefore, the sample size has been finally of 21 participants. This information is clearly seen in figure 29 in which the flow diagram is presented.

From the total of 21 individuals, 11 women (52%) and 10 men (48%) participated in the study. The mean age of the participants was 72.1±4.97 years, ranging from 63 to 79, and the median 74. The mean age between men was lower than the one of women (71.1 and 73 years, respectively). Furthermore, the mean Body Mass Index (BMI) among the participants was 28.01±2.65 kg/m, indicating an overall overweight status, and the median was 27.34 kg/m. The BMI values ranged from 23.73 kg/m to 33.78 kg/m. In this case, the BMI was higher in men than women (28.37 kg/m and 27.7 kg/m, respectively).

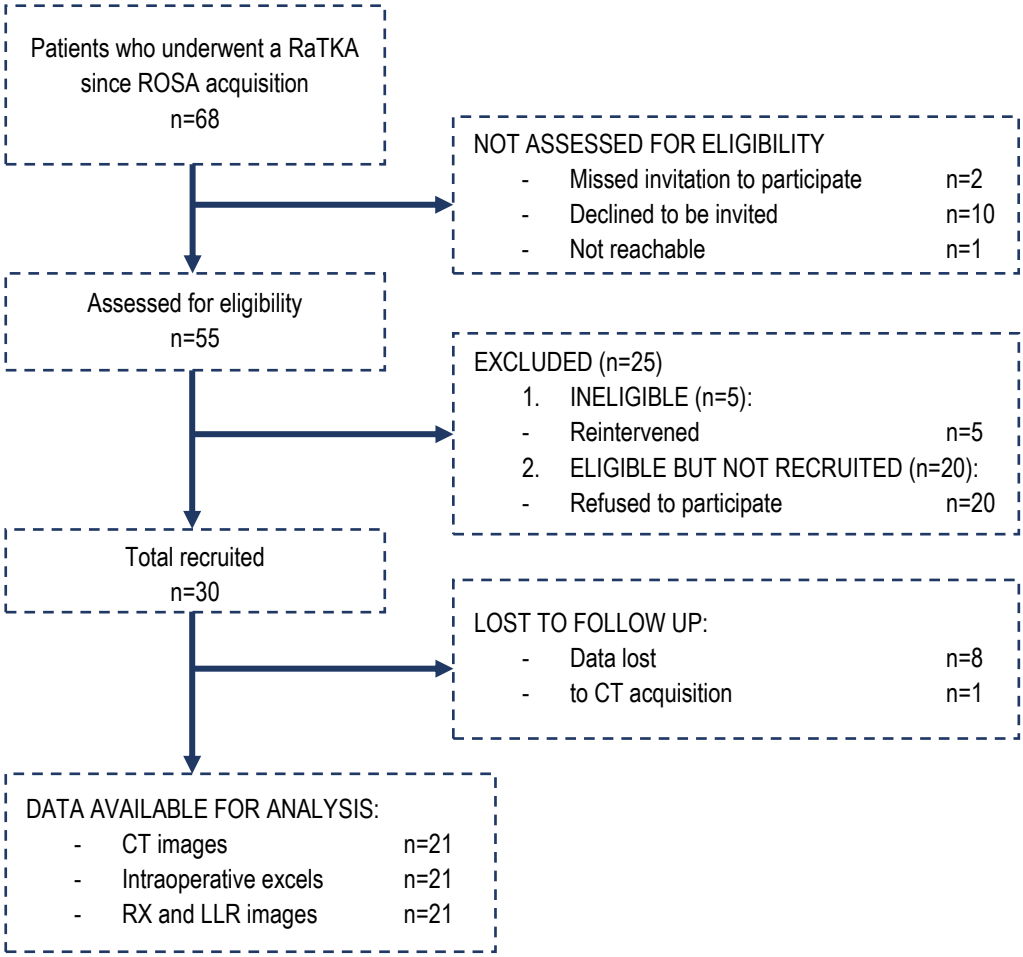


Figure 29 - Flow diagram of the participants of the study

All the participants have had all the variables extracted, so there was not any missing data of participants. Regarding the follow-up, the first discharge after intervention was in 14/12/2020 while last one 25/11/2021. Taking into account a follow-up until 30/05/2023 (date when CT data has been received), the mean of follow-up is 23.83 months, almost two years, being the higher follow up of nearly 30 months and the lower one of around 18 months.

ACCURACY STUDY

Although we initially associated several variables to the accuracy study, as commented in the Detailed Engineering, we ended up studying 2 variables from the coronal plane, 2 from the sagittal and 1 from the axial. The variables included in the statistical test, were those available in the intraoperative data provided by ROSA. Table 11 summarizes the concordance coefficient that assesses agreement between two measures, the mean of the differences between the intraoperative and postoperative values for each patient, and the limits of agreement defined in the Bland-Altman method which include 95% of differences between the two measurements. Results will be commented and discussed later.

Table 11 - Results obtained *from* the concordance study and the Bland-Altman method

Variable	Concordance coefficient	Mean of the differences [°]	Limits of agreement	
			Lower limit [°]	Upper limit [°]
HKA	0.3	1.54	-2.65	5.73
mLDFA	0.18	-0.63	-3.18	1.93
mMPTA	0.19	-1.19	-4.67	2.28
PDFA	-	-0.58	-5.96	4.79
PTTA	-	0.34	-5.50	6.18
Femoral component rotation (Berger)	0.18	1.05	8.8	-6.69

Figures 30-33 show the Bland-Altman plot of each variable. The limits of agreement can be seen as dotted orange lines, while the mean of the differences is highlighted in blue. The black lines shows the tendency of the values.

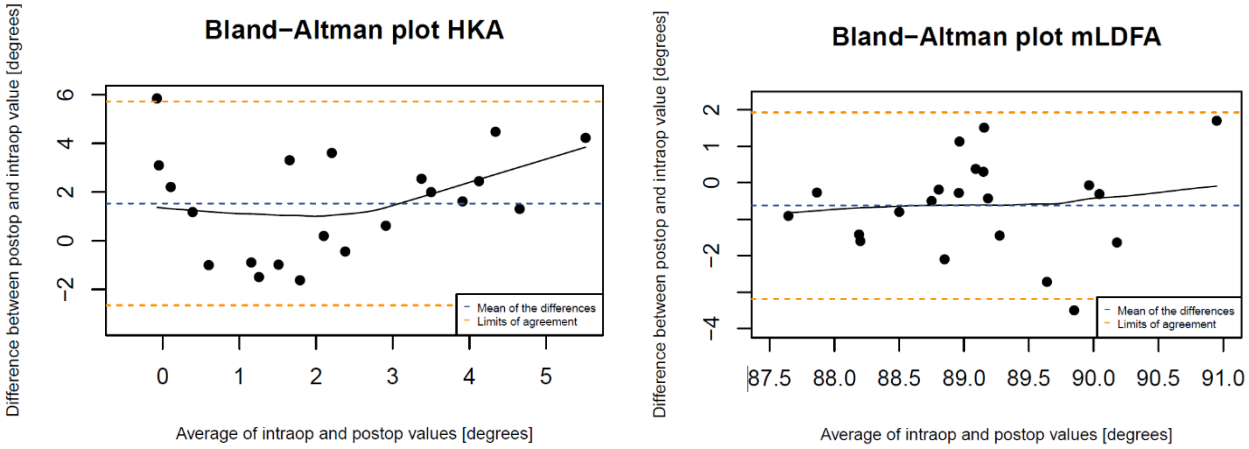


Figure 30 - Bland-Altman plot HKA (left) and mLDFA (right)

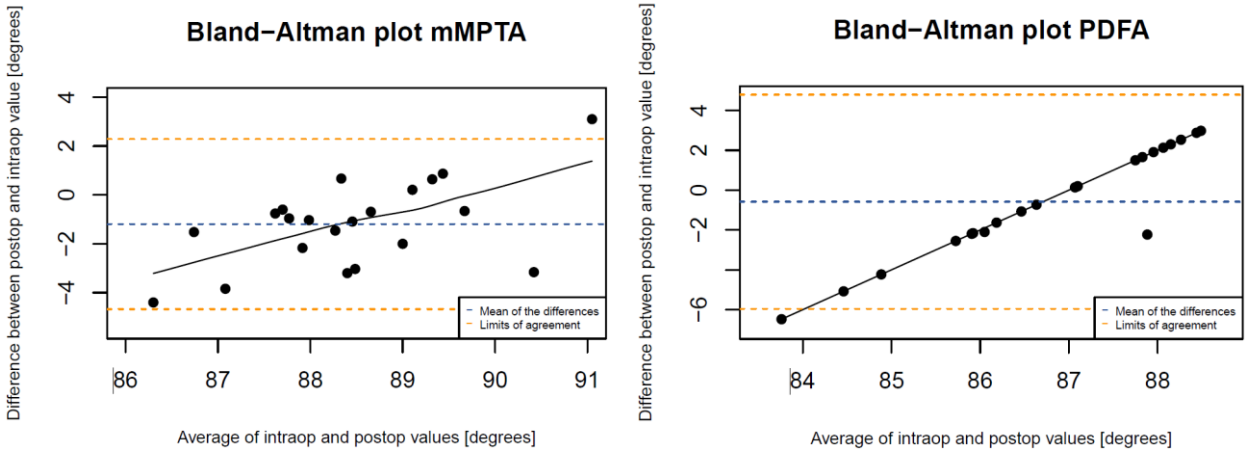


Figure 31 - Bland-Altman plot mMPTA (left) and PDFA (right)

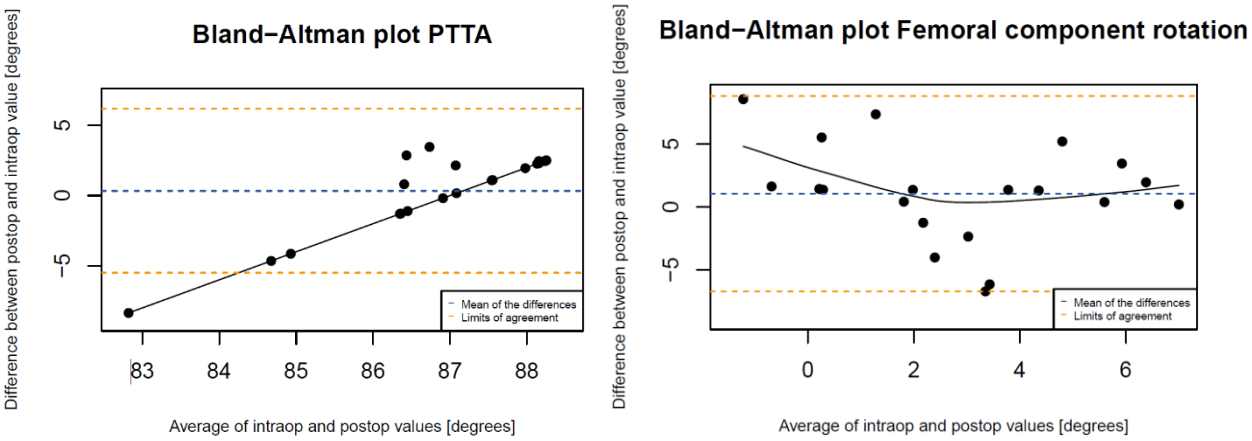


Figure 32 - Bland-Altman plot PTTA (left) and femoral component rotation (right)

Furthermore, as the intraoperative values of PDFA and PTTA are assigned to 37°, instead of computing the concordance coefficient, two boxplots of the differences have been graphed in order to see how far the postoperative values with respect to the reference are.

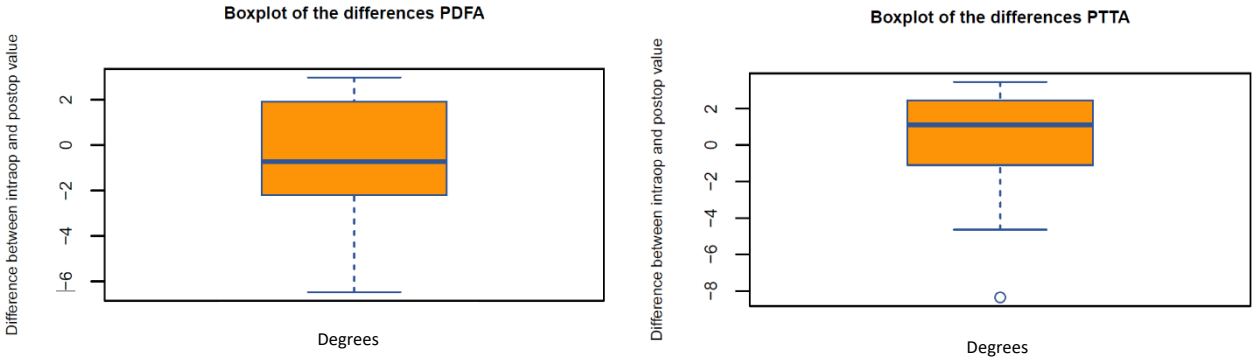


Figure 33 - Boxplots PDFA (left) and PTTA (right)

INTER-OBSERVER ASSESSMENT

In order to evaluate the consistency and reliability of observations or measurements made by different individuals, an inter-observer assessment study has been performed and the results are summarized in table 12 and figures 34-37. As the study is between the values obtained from the postoperative XR images, more variables have been included. Initially there were more variables; however, due to the high workload and data loss in Hospital Clinic resulted from the cyber-attack, the observer 2 have been only able to extract some variables.

Table 12 - Results obtained from the concordance study and the Bland-Altman method

Variable	Covariance coefficient	Mean of the differences [°]	Limits of agreement	
			Lower limit [°]	Upper limit [°]
HKA	0.60	1.59	-2.73	5.92
mLDFA	0.45	-0.16	-5.00	4.69
mMPTA	0.52	-0.11	-4.42	4.18
PDFA	0.39	-2.93	-8.08	2.23
PTTA	0.33	0.23	-5.46	5.93
JLCA	0.23	0.66	-1.27	2.60
Off-set anterior	0.53	0.1	-3.78	3.98
PCO	0.47	-1.17	-9.11	6.77

The corresponding Bland-Altman plots are presented from figure 34 to 37.

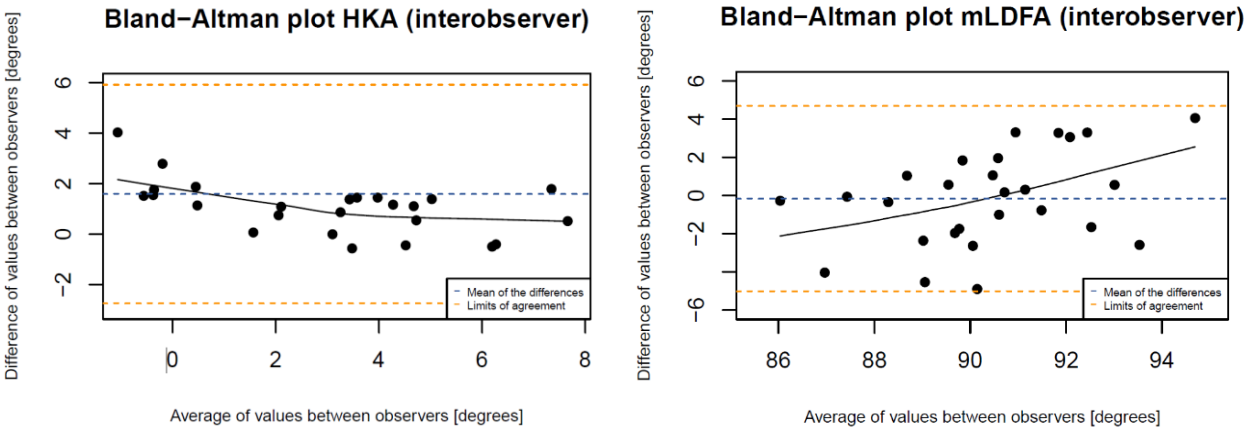


Figure 34 - Bland-Altman plots HKA (left) and mLDFA (right)

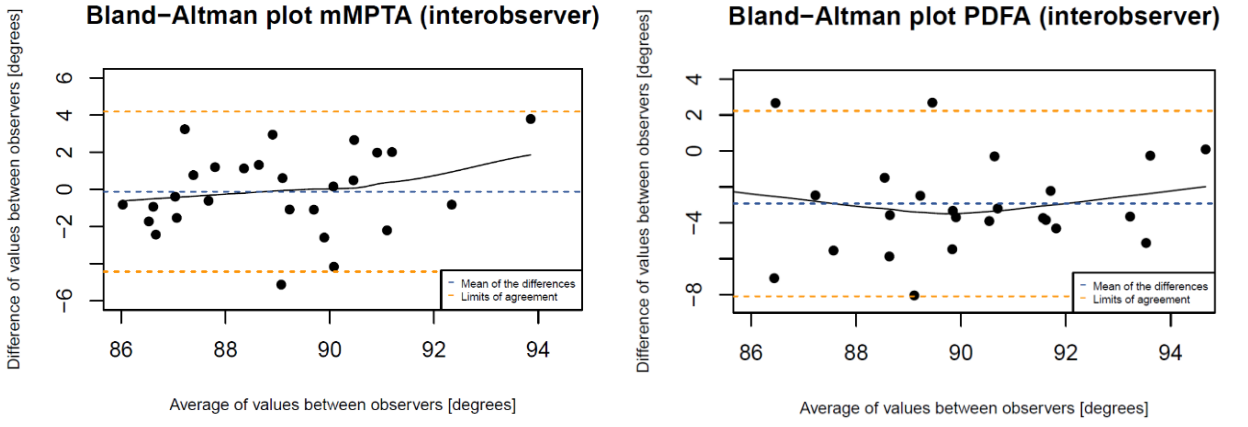


Figure 35 - Bland-Altman plots mMPTA (left) and PDFA (right)

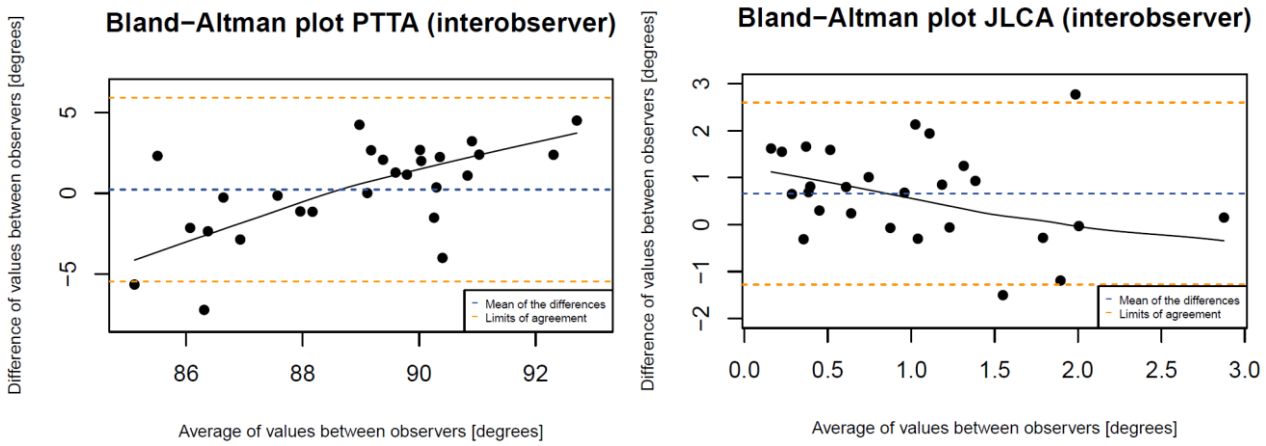


Figure 36 - Bland-Altman plots PTTA (left) and JLCA (right)

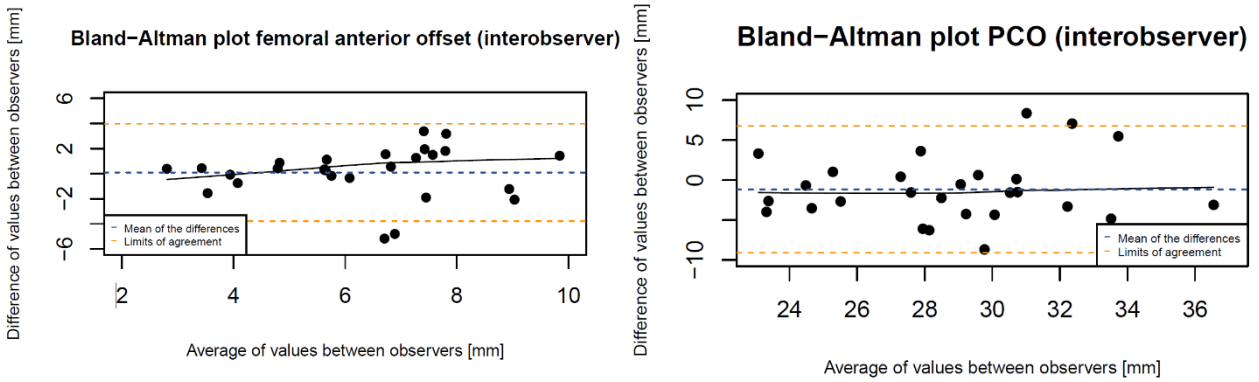


Figure 37 - Bland-Altman plots femoral anterior offset (left) and PCO (right)

CT VS XR

In order to study the effectivity of using CT as data, the agreement between postoperative values obtained from CT and X-ray images (current gold standard technique) has been studied (table 13). Thus, indicators of the feasibility of implementing CT in routine clinical practice are obtained. The Bland-Altman plots are shown between figures 38 and 40.

Table 13 - Results obtained from the concordance study and the Bland-Altman method

Variable	Covariance coefficient	Mean of the differences [°]	Limits of agreement	
			Lower limit [°]	Upper limit [°]
HKA	0.56	-0.91	-6.02	4.21
mLDFA	0	1.66	-2.29	5.6
mMPTA	0.23	1.25	-3.25	5.74
PDFA	0	4.35	-5.20	13.92
PTTA	0.04	1.94	7.98	-4.09

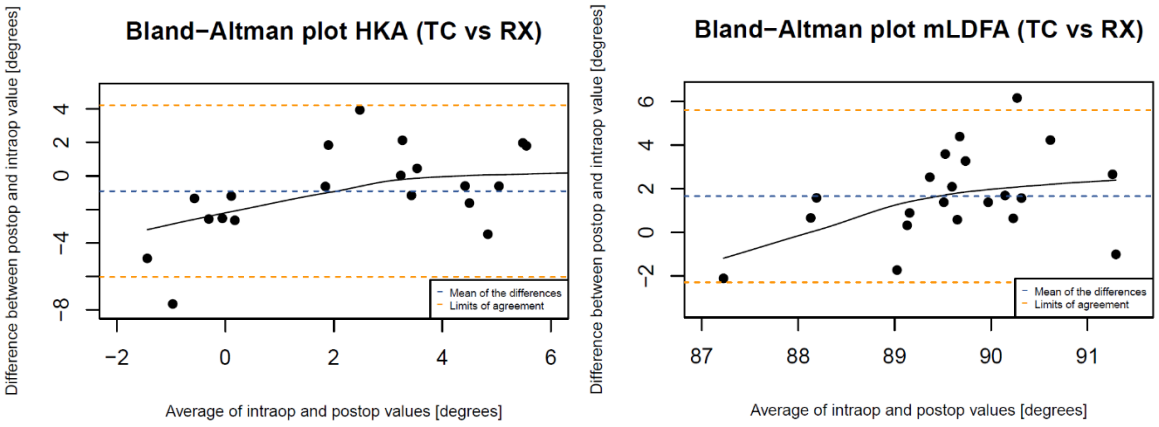


Figure 38 - Bland-Altman plot HKA (left) and mLDFA (right)

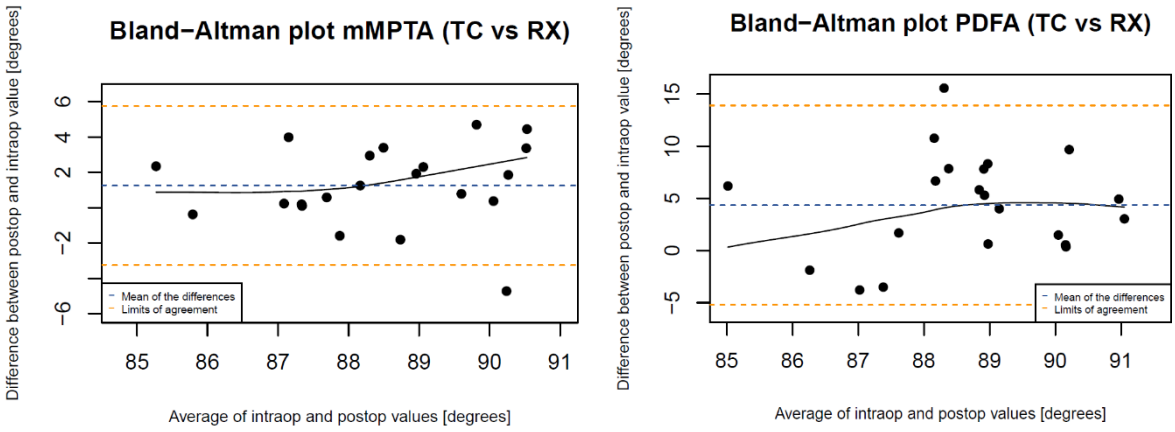


Figure 39 - Bland-Altman plot mMPTA (left) and PDFA (right)

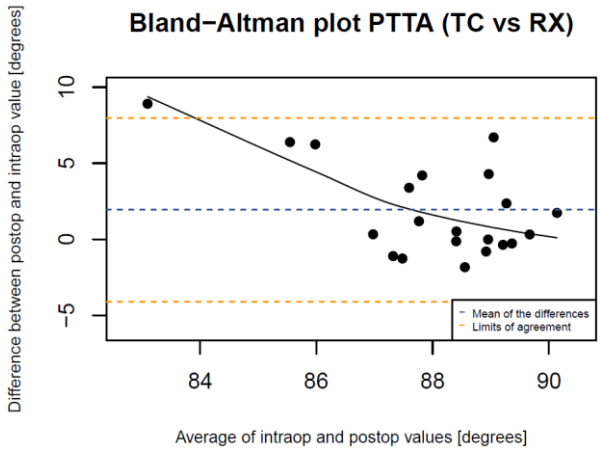


Figure 40 - Bland-Altman plot PTTA

DESCRIPTIVE POSTOPERATIVE DATA

In order to provide descriptive data for the scientific community, all the values I extracted from the biomedical XR images are presented in the table 14. In this way, they can be subsequently placed in relation to the normal values of the literature.

Table 14 - Results obtained from the concordance study and the Bland-Altman method

Variables	Mean±SD	Median	Minimum value	Maximum value
JLH [mm]	15.48±2.80	16.03	10.37	19.91
JLCA [°]	0.84±0.99	0.62	-0.65	2.8
HKA [°]	2.12±3.42	3.1	-4.79	7.4
MLDFA [°]	90.45±1.66	90.64	86.17	93.35
MPTA [°]	89.11±1.99	89.14	85.6	92.75
Patellar height (Insall-Salvati)	1.07±0.16	1.11	0.8	1.39
Patellar height (Caton-Deschamps)	0.78±0.21	0.71	0.46	1.33
PDFA [°]	90.88±3.01	91.51	85.13	96.09
PTTA [°]	89.00±1.45	88.95	86.77	92.4
Femoral anterior offset [mm]	6.29±2.05	6.22	2.61	10.07
PCO ratio	0.90±0.13	0.88	0.57	1.24

DISCUSSION OF RESULTS

KEY RESULTS

According to the literature review done, we hypothesized that current RaTKA using ROSA were accurate with differences between the postoperative and intraoperative variables below 1° (12) . Our hypothesis has not been confirmed. After the application of a concordance study in order to see the level of agreement between postoperative and intraoperative values, the coefficient values have been all equal or lower than 0.3. Considering that the coefficient takes values between 0 and 1, being 0 independence between variables or no agreement and 1 total agreement, the accuracy does not seem to be the expected one. Nevertheless, the means of the differences for each accuracy variable are all lower than 1.6°, which questions the importance of the concordance coefficient since it is a value that could be considered as enough accurate. The Bland-Altman plot graphed, show some tendencies in some variables that were not expected and may be related to a systemic error at some point in the project.

LIMITATIONS

Since the variables extraction has been performed manually by observers, our postoperative values may contain a certain amount of error due to the human factor. This phenomenon can be diminished thanks to the experience (which is a factor I lack). Although the surgeries were performed by professionals, some systematic errors done during the procedures might have affected to the results obtained. Furthermore, a low sample size implies obtaining results that are not very robust and may not be sufficiently representative of reality. Thus, some outliers may have had a larger weight than normal leading to distorted results.

INTERPRETATION

ACCURACY STUDY

Firstly, from the values of table 11 one can see that the higher concordance coefficient is 0.3 for HKA, while the minimum is 0.18. Taking into account that 0.8 is considered as a pretty good agreement and 0.6 a moderate agreement, our values are far from these two values. Therefore, according to the concordance coefficient, our intraoperative and postoperative values do not agree at all, which might mean that the accuracy is not enough. As the value of a coefficient is not enough to interpret this data, the results after applying the Bland-Altman method have been also studied. Different interpretations can be extracted from a single value of concordance correlation because it does not allow us to see which is the real difference between the intraoperative and postoperative variables. Thus, depending on the application, some low values of concordance correlation could be enough according to the limits of agreement, so the 0.6 of concordance correlation is not required. This fact would depend on the doctor's criteria.

When studying the mean of the differences, mLDFA, PDFA and PTTA show values similar to the ones obtained from the literature. For instance, the accuracy clinical study presented by Zimmer Biomet that justifies ROSA's accuracy, obtained average differences below 1 degree (26). Vaidya et. al published in 2020 a better accuracy in RaTKA than MTKA since the average of the differences

of the axis deviation were 1.8°±1.2 and 3°±2.4, respectively (14). This last RaTKA results are close to the average of the differences found on this clinical study of HKA, mMPTA and the femoral component rotation (1.54°, -1.19° and 1-05°, respecitvely). Furthermore, average difference between planned HKA and the measured one in the clinical study performed by Zimmer Biomet was 1.2°±1.1 (26), being similar to the obtained in this study (1.54°). Thus, results show a more acceptable accuracy since the average error is not very large. Therefore, the similarity in the averages with the literature supports the hypothesis of ROSA being an accurate robot and that the methodology and structure of the clinical study carried out may be the correct one.

Regarding the limits of agreement, within which 95% of the differences fall, they all are intervals of more than 5°. The interval that includes a higher range of degrees is the femoral rotation component (15.49° between one limit and another) while the narrowest interval is 5.11°(between the lowest and highest limit) in the case of mLDFA. Ideally, a low range indicates that in almost all cases, the difference between what was intended and what was obtained is low. Therefore, it could be associated with more accurate results. In our case, these intervals are high according to the literature reviewed and presented above. Therefore, although the average seemed to be similar to the literature presented, the interval shows worse results in terms of accuracy. The variability of the differences is clearly seen in the Bland-Altman plots (figures 30 - 33) that are commented below.

HKA and mMPTA Bland-Altman plots show a positive tendency of data. This phenomenon is reflected in the black line that increases with the mean of differences. That is to say, the difference tends to be more positive as the mean of differences increases. In the case of HKA, above the average differences of 3°, only positive difference values are seen. Ideally, we should see a balance between positive and negative differences, so trends could not be seen. From mMPTA plot the same phenomena can be observed: for lower averages we have only negative differences. Normally, Bland-Altman plots assume that the mean of the differences is constant along all the values (so approximately there are the same number of values below and above the mean). Nevertheless, from these two graphs we cannot say the same since there is this unbalanced proportion of positive and negative differences that change the average difference. The reason of this behaviour could be explained because of systematic errors during the clinical study procedure where human error is emphasized. The data extraction step might be one of most sources of error due to the fact that some anatomical references may not be sufficiently clear, and a small subjectivity factor contributes to this variability. Another possible explanation could be that maybe ROSA is more accurate for higher HKA values or that it is not taken into account that for patients where a larger varus is left (which is because they need more PTTA or MPTA), the ligament laxity is underestimated by the surgeons, so that when the patient stands up, the ligament is more lax than expected, and this leads to the deformation of this one. Nevertheless, in this thesis we are going to provide an overview of the results, instead of trying to search the causality of the results since it is not the main goal.

In contrast, mLDFA shows a different case where low values of the x-axis (average of intraoperative and postoperative values) reflect positive differences. After examining thoroughly the data, it was seen that CT values were all positive, which raised doubts as to whether the sign criteria ended up being the same, and therefore there was an error due to this. This aspect could be looked at further in future work.

Finally, for the two cases (PDFA and PTTA) in which the intraoperative values are, normally and except for more complicated cases, predefined to a reference value (87°), the plots obtained reflect how far are the postoperative values with respect to the reference. Therefore, as much far away, the higher will be the difference. That is why, a straight line with a positive slope is obtained. Those values that do not fall in the line are the exceptional cases in which the intraoperative value is not the reference value due to anatomical reasons. Visually we can see that in PDFA there was only one patient who did not plan to place the implant at 87°, while in PTTA there were up to 4. The two boxplots of PDFA and PTTA show how the postoperative values of each patient are different from the 87° reference. Most of them are found with 2° approximately (either because the intraoperative value is larger or smaller). Even so, there are cases that are farther away, as the outlier in PTTA boxplot.

CT VS XR

The concordance study between the postoperative values obtained from CT or XR images have provided, in general, low covariance coefficients (minimum 0 and maximum 0.56). Although these variables can be studied with XR images and LLR, CT scans provide more accurate images according to literature. For this reason, it is understood that if the results do not agree, one technique cannot replace the other. Taking into account that CT has already been shown to be more accurate, these results lead us to question whether XR as the gold standard technique is really the best.

The mean of the differences is less than 2° in exception of PDFA that was 4.35°. After checking the results, we have realized that the methodology to measure PDFA has been different since it took a slightly different anatomical landmark. Therefore, PDFA studied from XR images and CT has been extracted differently in each image technique, so the results do not have to be considered. This reason also justifies the value of the concordance coefficient of PDFA.

Finally, limits of agreement are not very narrow which coincides with the values of the concordance coefficient: there is a reasonable difference between the postoperative XR and CT values. Nevertheless, observing the Bland-Altman plots, the small increases of the black line should be studied with a higher sample size since for smaller one (such as in our study) all values have more weight and some outlier can negatively influence the results by simulating a trend that does not exist.

Therefore, from all the results obtained, it cannot be insured the level of agreement of CT and XR imaging techniques. Although XR is the gold standard in our hospital, knowing that CT is more accurate, we should question whether we should really continue to use XR instead of CT because seems to be more reliable. A cost-risk analysis of each technique would be necessary to make this decision since, for example, CT radiates more than XR. However, the variables lying in the axial plane must be obtained with CT images, because otherwise nothing can be visualized. Thus, the debate as to whether certain axial variables should be studied.

INTER-OBSERVER ASSESSMENT

When observing the results of the interobserver study, the values of the concordance coefficient have increased with respect to those of the accuracy study. This increase might be because data

come from the same XR images (in contrast of the accuracy study where data compared was provided by two different sources, ROSA and CT images) and both observers had a well-defined extraction protocol in order to reduce errors. In exception of JLCA, all variables have a coefficient higher than 0.32, reaching a coefficient of 0.6 (the maximum) for HKA. Although the coefficients still do not exceed 0.6 (moderate agreement), if contrasted with the accuracy values, in these cases there is much better agreement. The fact that HKA is the one with the best agreement could be due to the easiness to extreme the variable since it uses bone landmarks that are easy to recognize, and therefore, they help in the drawing of lines to obtain the angle. The mean of the differences of each variable is also good enough, since 5 of the 8 variables remain with very low values below 1 degree. Among them, JLCA (which is the variable with the lowest concordance coefficient). The most problematic variable is PDFA with a mean difference of -2.92°. This could be due to the difficulty in drawing the two middle points at 5cm and 10cm from the endomedullary anatomic apex since they depend on tangents and perpendicular to certain anatomic locations not specified in the protocol.

Some Bland-Altman plots show certain positive or negative tendency (especially those of mLDFA, PTTA and JLCA). HKA Bland-Altman plot shows, however, only positive differences at the beginning, which later stabilize and a certain balance between positive and negative differences is acquired. PTTA and mLDFA are the main variables with a certain tendency and bias that should be reviewed because it might indicate some kind of error during the extraction of these variable. For this reason, a possible aspect to improve would be to review the extraction protocol in order to make it more objective and try to systematize the identification of certain anatomical references. All the other plots, although some of them seem to have a positive or negative tendency, have a similar number of positive and negative differences, which supports the idea that the same average difference is maintained throughout all the data. Moreover, a larger sample size would be needed to further verify or confirm these positive or negative trends. Furthermore, it is seen how the sagittal variables (PDFA, PTTA and PCO) have poor results in terms of accuracy in some of the parameters studied: the first one has the worst average of the differences, the second shows a positive tendency in the Bland-Atlman plot and the third one has the higher interval of agreement. This could be due to the problems encountered with respect to the angulation of the radiographs that did not show a perfect profile (see the detailed engineering section where these aspects are discussed).

Overall, the results indicate that the data extraction process performed by two observers can be improved since the techniques used do not show a high level of precision. For this reason, factors such as experience or the use of algorithms and automatic programs can be decisive in improving this level of agreement.

GENERALISABILITY – POSTOPERATIVE DESCRIPTIVE DATA

The postoperative descriptive data is useful to situate our group and provide more information to the scientific community since some variables have been little studied. This data can be used to check the generalisability of the study results.

Popat et al. (57) obtained a JLH mean of 14.4±2.68 mm while in our sample the value has been 15.48±2.80 mm (all the results defined are from the XR images and extracted by observer 1). This

suggests that our group is not far from values provided in other clinical studies and that the methodology used to measure the variable may be the proper one.

Further studies have been performed to assess the JLCA or HKA for primary and revision TKA. Micicoi et al. (58) situated the JLCA values of their cohort group within 0° and 2°, while the normality of HKA is found between -1° and 3.2°. Compared to our JLCA and HKA provided by observer 1 (0.84°±0.99 and 2.12°±3.42); JLCA, taking into account the standard deviation, fits perfectly with the description of Micicoi while HKA, even having an average that falls within the interval, with the standard deviation we could find ourselves outside of it. This fact supports the idea commented previously that HKA, thanks to being very well defined with clear and objective anatomical landmarks, the inter-observer assessment is higher than in the other cases and, since it coincides with the normal values, this indicates that the methodology has been performed correctly by the observer 1.

The seminal work by Paley et al. (59) found that their group had [85°,90°] as the interval of normality of mLDFA and mMPTA. This study has found higher values of mLDFA and mMPTA (90.45°±1.66 and 89.11°±1.99, respectively). In contrast, the patellar height measured using the Insall-Salvati method or the Caton-Deschamps (1.07±0.16 and 0.78±0.21) lay between the normal values (between a ratio of 0.8 and 1.2 in the Insall-Salvati method (61)and within 0.6-1.3 in the Caton-Deschamps case) (62).

With respect to the anterior condylar there is no literature or evidence of normality, for this reason it is hoped that the values obtained in this study (6.29±2.05 mm) can be used for comparison with other future studies. On the other hand, the PCO was higher than the normal values proposed by Smith and Nephew. This could be related to the fact that some radiographs did not focus clearly on the profile, but that the two condyles could be recognized as discussed in the figure 19 from the Detail Engineering section.

Finally, both the PTTA and PDFA values obtained are higher than those defined by normality. In the CT vs XR study it has already been said that the PDFA by XR had been extracted following a different methodology than CT, which must be the source of this error since the average PDFA extracted from CT images is 86.52°±2.71 (which lays in the interval proposed by Smith & Nephew). However, in XR or CT postoperative values, the average PTTA is higher than the interval proposed by Smith & Nephew (82).

In a nutshell, all the differences between normality and our group of study could be explained because of different reasons. Firstly, demographic factors such as age could influence the average values of the variables (some studies have demonstrated that there can be variations in alignment across different ethnic groups). Secondly, during the data extraction, subjectivity can modify little details from the established measurement methodology, so variability or error is introduced. Finally, the sample size is little, so more data would help to confirm these results obtained and provide robustness. Nevertheless, in general, all the data has been found between the normality ranges, which leads us to believe that these data may be a small representation of larger groups of the population or of the population in general.

TECHNICAL VIABILITY

The conduct of a clinical study, as we have seen, involves a long-time span that relates different areas to be organised. From each area, different requirements are needed in order to complete its tasks. For this reason, all the requirements to be able to carry out the project are presented below together with different strengths, weaknesses, opportunities and threats of the project.

In order to identify the requirements, the work has been divided into "previous documentation", "approval", "execution" and "presentation". For each section, the requirements will be explained.

Regarding previous documentation, a clinical study always has a protocol defined before starting the study. For this reason, the main requirement of this section is to design a study protocol that includes all the aspects to be studied and it is definitive (it cannot be changed during its realisation). To do so, "little" objectives must be acquired such as a good understanding of TKA and all the concepts that involves along with knee's anatomy. Moreover, due to my inexperience (weakness) with respect to clinical protocols, I could easily focus on aspects that do not answer the clinical question of the study by, for instance, selecting study variables that are not sufficiently related to robotic accuracy or burden myself with a lot of work in terms of studying variables that are not essential. Even if I do not have much familiarity with knee's anatomy, TKA (weakness) and the other aspects mentioned above, as I work with a very professional group with years of experience (strength), this weakness can be fully controlled and solved. Furthermore, although the robotic machines studied are recent, articles and other clinical studies similar to this project are coming out which allow to obtain enough information to design the adequate protocol and use them as inspiration. There exist articles that study robot's accuracy but using other type of images and do not have intraoperative values extracted by the robot (strength), which can be considered as good references for our protocol. Thus, our results obtained from CT images can have great relevance in the scientific community (opportunity). Finally, the fact that this project is a sub-annex of a more general clinical study will also help to have references on how to write and design the protocol for my clinical study (strength).

Once the protocol is designed the Research Ethics Committee must accept it to carry out the project. One crucial requirement, therefore, is the protocol approval by the committee. One must bear in mind that the acceptance of the project may take a long time and then, in case corrections must be made, the approval time would also increase (threat). This would jeopardise the realisation of the whole project due to lack of time and the project would take longer than planned. Therefore, it is essential to design the best protocol possible to focus the project on what really matters and to be accepted by the Research Ethics Committee.

With respect to the execution of the study, it must be taken into account that the data studied comes from already undertaken surgeries. Consequently, the technical availability of free beds for hospitalization or surgeries organization do not have to be considered. This thesis studies XR and LLR obtained during the normal preoperative and postoperative performance as dictated by the hospital, intraoperative information from the ROSA Knee System and CT results ordered exclusively by this project from past patients who has already undergone the surgery. Consequently, the main requirements will be related to participants selection and data extraction.

The main technical problems that can arise from the participants selection are related with its availability and a huge hospital's coordination is required (threat). However, one positive aspect is

that there is no need to search for patients as the potential participants are patients of the hospital with whom the hospital already has all their personal information (strength). Moreover, patients cannot sign the informed consent until the protocol has been accepted. So, until the approval has not been obtained, the appointments cannot be organised. Furthermore, we cannot expect to have all the informed consents in one day or week since we have to offer more options to also adjust a little bit to patient's schedules. All these appointments must be supervised by one of the principal researchers (weakness). Thus, this procedure requires a high level of coordination between people with very different schedules (threat/weakness). What it must be also considered is the possibility that patients do not agree to participate in the study or that their abandonment during the realisation. Apart from the first appointment, those patients that accept the participation have also to undergo a CT scan which requires more time and coordination with the patient and other busy hospital areas such as radiology. Nevertheless, the clinical study takes place under a very important institution like Hospital Clinic which is prepared for a large volume of patients (strength). Therefore, it has prepared facilities to receive patients and explain them the project, a well-known electronic health record software (SAP) to control appointments and coordinate all the hospital's areas and, finally, a good administrative team which deals with the patient's appointments. Another positive aspect is the trust and doctor-patient relationship that helps patients to sign the informed consent (strength). Finally in this aspect, if the study has a small sample size, the results would not be robust enough (threat).

Regarding the data extraction procedure, in order to decrease the inter-observer's variability a manual for variables extraction is required (strength). The fact that there is a large body of literature describing our study variables with different strategies allows us to decide the methodology that better suits us (strength). As it has been said before, our clinical study extracts different characteristics of several images (at least, an XR and LLR before and after the operation along with a CT image) and the results provided by the intraoperative robot in an Excel file. Therefore, a requirement is to have sufficient storage space for all patient images. For instance, the average storage space for XR images is 16MB and for CT images, 20MB while for each excel file obtained from the ROSA robot is 20 KB on average (a (in total, approximately 84,02 MB considering 4 XR images with the LLR included, the postoperative CT image and the intraoperative excel file) (83–85) . In summary, the total storage needed for, at least, 100 participants (this is a huge value that exceeds our forecasts) would be 840,2 MB. This required storage is very small compared to all the data that the hospital clinic has to process, so it is not a big problem. Then, all this data must be stored securely, and it is advisable to have backup copies for possible cyber-attacks which actually are a common threat

As the images are uploaded in the electronic health records (SAP) of the hospital, they can only be accessed from the hospital's computer (weakness). Nevertheless, they have downloaded an imaging viewing programme (RAIMVIEWER) that allows you to edit and draw on top of images. Although is not the most accurate way to extract the variables of study, since it is rudimentary and not automatized, and it can exist a certain inter-observer assessment (this is why a manual is required), it allows the different variables of study to be extracted. Moreover, due to my inexperience with knee XR, the inter-observer variability may be larger than normal (weakness). Ideally, automatic programmes such as TraumaCad could be implemented. In the case of CT

images, specialised and much more precise software are used for the study of the variables that are then compared with those obtained by the robot intraoperatively (which also obtains data more accurately) (strength). There may be isolated cases of participants who during the normal clinical pathway have not pre- or post-operative LLR or XRs taken; consequently, its data extraction could not be carried out (threat). This is a risk as it would imply a lack of data. Another similar situation would be to have images acquired inaccurately so that the extraction of variables is impaired (as discussed above with some sagittal radiographs). However, in case of a sufficiently large sample size, this would not be a problem. Finally, a weakness is that intraoperative data recorded by ROSA is stored by Zimmer Biommet (and doctors have to ask for them) and as Zimmer does not exploit these data, the way they are recorded is impractical for its study. Furthermore, it is considered that data are not well exploited as the robot could obtain many more variables that could help to obtain a more complete study. Finally, a possible threat is that the data are not sent in time by the CT radiologists, or the intraoperative data recorded by the robot and sent directly to Zimmer. If I do not get organized in time, these data may arrive when I no longer have time.

At last but not least, there are little weakness regarding the statistical test such as inexperience with RStudio programme. Nevertheless, I have taken one biostatistics subject and I have several experience programming (strength). Also, external help can be obtained.

Finally, the realisation of this project implies the contribution of important data to the scientific community with regards to robotic surgeries. The results obtained will give us the opportunity to continue learning about advantages and disadvantages of all the emerging technologies. As they are expected to increase, the number of scientific studies studying them will also increase. Consequently, all these data contributed will provide information to improve the technologies used on the clinics. Which can be directly translated to the obtention of better results within the patient's quality of life.

In summary, considering all these requirements, the following SWOT analysis can be designed:

Table 15 - SWOT analysis of the project

Strengths	Weaknesses
• Extensive, well-founded advice and support for carrying out the study due to the high level of experience of my group of research. • Large literature to use when designing the study's protocol. • As the project is a sub-annex of a more general clinical study, protocol from the general study can be used too as inspiration. • As it is a prospective study, we do not care on hospital surgeries availability and internal organisation. • No need for searching new or external participants since patients of Hospital Clinical are the ones to select (all who undertook the surgery during a defined period of time). Therefore, it is easy to contact with them. • Good doctor-patient relationship (easier to patients to accept to participate).	• Inexperience with respect to designing clinical protocols. • Little familiarity with knee's anatomy and TKA. • Wait until protocol's acceptance to start with patient's selection. • Access to images from computer's hospital. • Although having RAIMVIEW, automatised (TraumaCad) extraction would have been faster. • Inexperience with knee XR. • Data from the robot is stored by Zimmer Biommet. Not exploited enough. • Basic knowledge in RStudio.

• Hospital Clinic is prepared to attend a huge volume of patients and coordinate them (regarding appointments or patients undergoing CT scans). • Enough storage to save data (XR images, LLR, CT images and intraoperative data). • Objective protocol for data extraction (reduce inter-observer assessment). Large literature to know how to do the extraction. • State-of-the-art technology applied in studying CT images. Variables extracted by professionals. • Large volume of literature to decide which strategy will be applied for the extraction of each variable.	
Opportunities	**Threats**
• ROSA accuracy will provide very relevant information for the current day-to-day work of doctors who carry out TKAs. More information about the Technology that they use. • The results obtained are also important for the robotic surgery community as they provide more data on its performance and using CT images as sources of information. • An expansion and increase in the number of clinical studies that study the precision of robotic machinery is expected. • The study or evaluation protocols could be an attraction for other doctors around the world. Thus, medical tourism is promoted. • Robotic surgery is a growing economy, which will support a constant technological improvement and, therefore, of the precision of the interventions themselves.	• Protocol must be accepted by the Research Ethics Committee. Thus, we have to adjust to their timetables/possible delays. • Small sample size would not provide robust results. • High level of coordination between different areas of hospital and persons (doctors, patients, researchers...) • Patient's abandonment during realisation of process. • Cyber-attacks that result in a loss of data or slowdown when working with it. • No reception of intraoperative data or CT data or data is received late. • Patients without pre or postoperative XR images and LLR or inaccurate acquired images. Some variables will not be studied or will be deviated. • Little time to carry out the clinical study, which may imply a delay in the delivery of the TFG.

ECONOMIC VIABILITY

The following section summarizes, a study of the economic aspects. The costs associated with these interventions and the follow-up must have been considered. In this clinical study, the extra expenses to the usual clinical practice has been the CT imaging of the participants. Table 16 has been performed thanks to the head of the *Instituto Clínico de Especialidades Médicas i Quirúrgicas* ICEMEQ). The costs considered are with respect one intervention (or patient).

Table 16 - Summary of costs of the our clinical study

Services	Cost (€)/patient
Hospitalization	1'143.8
Intervention in surgical room	1'767
Materials and drugs of intervention	479
XR and LLR images acquisition	150.98
CT image acquisition	129.68
Drugs	23.5
Zimmer Biomet prosthesis	1'927
ROSA Knee System	1'428.6
Consumables and maintenance of ROSA	337.59
Total	**7'387.15 €**

Firstly, the hospitalization service includes all aspects to be taken into account during the days of stay in the hospital after an operation such as the salary of workers (doctors, physiotherapists, among others) and all the costs of service and care of the patient. We have taken as a reference the price that a private patient would pay per day (457.52€). Taking into account an average of 2.5 days of stay for patients after hospitalization, the total cost of hospitalization rises to 1'143.8€.
Regarding to the cost of an intervention in a surgical room one has to consider: surgeons, nursing and anaesthesia (1'767€) and the fungible materials as drugs (479€). Moreover, the preoperative and postoperative images must be taken into account since they are essential in the patient's planification or follow-up. We have considered a minimum of two XR and two LLR (one preoperative and another one postoperative) because in each patient the number varied. However, it is worth mentioning that some patients had more than two of each of the following. The price of obtention one XR image is 30.66€, while for one LLR is 44.83€. In contrast, a CT image is more expensive and the cost for just one image raise to 129.68€. Finally the cost associated to the drugs needed by the patient is 23.5€, as an average since it varies according to patients (from 7€ to 40€).
Finally, the costs to be paid to Zimer Biomet are divided into different aspects: the prosthesis has a cost of 1'927€. As for the robot, although it has been loaned (and not purchased) by the hospital for the time being, if the purchase of the robot is considered, it has a price of 1 million euros. Assuming a 10-year amortization and assuming about 70 operations per year (numbers collected from December 2020 to November 2021, but it is thought that this number has increased), the price per operation associated with the robot is 1'428.6€. Finally, the cost of consumables and maintenance of the robot are 337.59€ for each intervention.
In a nutshell, if we consider the 7'387.15€/patient, the total cost for 21 patients is 155'130.15€. From this, we would have to add a salary of a supposed researcher (me) of 12'980€ (assuming a salary of 20€/h and 649 hours worked. Therefore, the final cost would add up to a theoretical cost of 168'110,15€. Nevertheless, as the project is a compulsory subject of the degree, no money has been paid.

EXECUTION SCHEDULE

A clinical study requires a high level of organisation of different structures and working groups from different areas. For this reason, project management is crucial to maintain the main objectives and the project's scope as the focus of all work without deviation or distractions. To do so, three techniques will be applied: a Work Breakdwon Structure (WBS), which subdivides and defines different tasks to complete; a Program Evaluation and Review Technique with its Critical Path Method (PERT-CPM) that helps to estimate the time to invest for each task; and, finally, a GANT diagram, which will show the work completed over time in relation with our planification.

WORK BREAKDOWN STRUCTURE (WBS)

The work to be carried out has been stratified into smaller and easier to manage tasks or workloads as it is reflected in the Work Breakdown Structure (WBS). This tool allows us to define the four most relevant areas of this project: the preliminary documentation, the approvals that will be made by the Research Ethics Committee, the execution of the clinical study and, finally, a last step that represents the publications and presentations related to the work. Each of these areas has different "packages" of work that are decomposed into smaller tasks. The WBS of this project can be seen in figure 41.

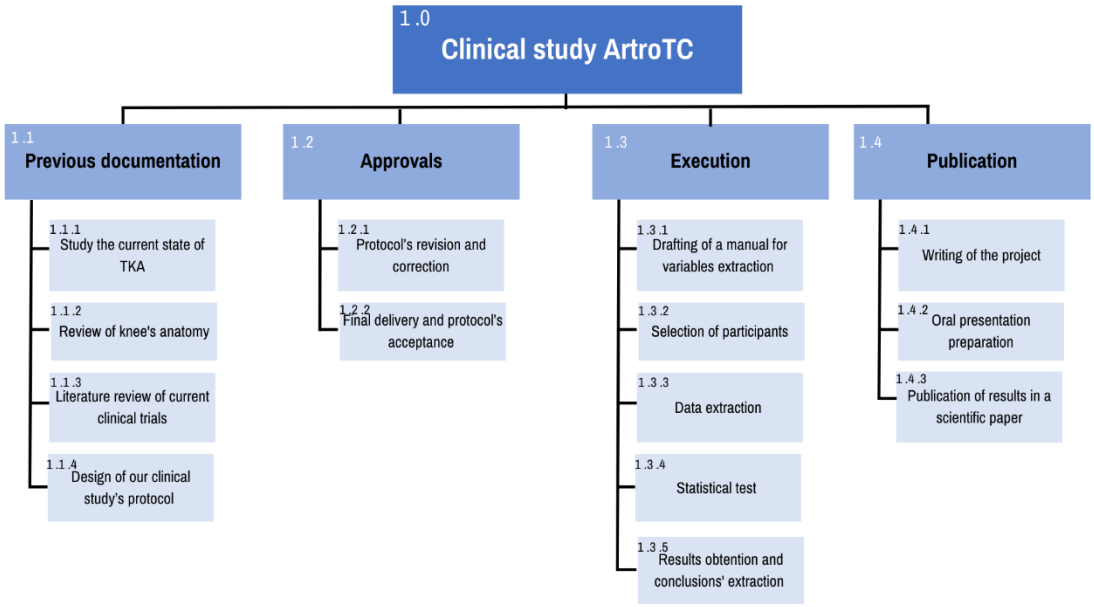


Figure 41 - WBS containing all tasks to be performed.

The definition of each task is included in the following WBS dictionary elaborated:

Table 17 – Summary of tasks and its description

	Number	Name	Description
Previous documentation (1.1)	1.1.1	Study the current state of TKA	Study of the current situation of TKA in the world: analysis of the prevalence of osteoarthritis and other diseases that require TKA. The future projections of these interventions will also be studied in order to justify the need for great precision and accuracy. Moreover, emerging technologies to assist TKA must be also studied as well as the conventional technique itself.
	1.1.2	Review of knee's anatomy	Study of knee's anatomy. There is no need for a report or explanation, it is simply a review of course notes.
	1.1.3	Literature review of current clinical trials that study the accuracy of robotically assisted surgeries	Review of literature. The first step is to check all the literature on clinical studies that analyse different aspects of knee. Once there is a good base and familiarity with this area, an exhaustive study of different clinical studies that estimate the precision and accuracy of robotic systems for TKA assistance will be carried out. Moreover, those studies that use CT to study the accuracy will be reviewed thoroughly.
	1.1.4	Design of our clinical study's protocol	Definition of the clinical study to be performed. It must include the following sections: hypothesis, objectives, participants' selection criteria, variables of study, methodology of study, selection of the statistical test to perform and explanation of the legal aspects to consider.
Approvals (1.2)	1.2.1	Protocol's revision and correction	The study will have to be revised and resubmitted in case that some clarifications are required. This process will be done many times until the protocol is accepted. It must be considered that the ethics committee will take some time to give its response.
	1.2.2	Final delivery and protocol's acceptance	Await final acceptance of the protocol by the ethics committee
Execution of the clinical study (1.3)	1.3.1	Drafting of a manual for variables extraction	Description of all the variables to be studied and creation of a manual for the extraction of all study variables. It must include a brief description of each variable, the methodology to obtain its value, sign criteria and normality range.
	1.3.2	Selection of participants	Revision of all the patients who had undergone a robotically assisted TKA and selection of the candidates for this project. A list of the final candidates will be sent to the hospital to schedule and appointment in which my tutor and I will explain the project and ask for informed consent. Then, the participants will have to be given an appointment with CT. The drafting of the informed consent must be done during the protocol's design.
	1.3.3	Data extraction	Wait for the CT results and extraction of preoperative and postoperative variables from radiographs and LLR. Also, the intraoperative data of interest will be selected.
	1.3.4	Statistical test	Preparation of all data obtained, and application of the statistical test defined in the protocol.
	1.3.5	Results obtention and conclusions' extraction	Interpretation of the results obtained and corresponding conclusions
Publication (1.4)	1.4.1	Writing of the project	Redaction of the written project that will be submitted.
	1.4.2	Oral presentation preparation	Preparation of a 20' presentation that highlights the most important aspects of this project. The text to be explained and some slides as visual support will have to be prepared.
	1.4.3	Publication of results in a scientific paper	Redaction of a scientific paper in order to publish the results obtained.

Once all these tasks have been defined, they must be coordinated to the project is delivered on time. For this reason, a PERT-CPM diagram has been used.

PERT-CPM DIAGRAM

In order to plan a project in which it is necessary to coordinate many people and activities, it is necessary to use control techniques such as the PERT method (especially when it is necessary to organise chaotic and unexpected environments such as hospitals can be). PERT provides a graphic representation of all the defined work packages necessary to meet the project's objectives. In this way, it is possible to foresee in advance the estimated duration of each activity, as well as the order in which they are to be carried out and the possible delays that cannot be allowed. The critical path calculates the longest possible route of the planned activities in order to acknowledge the time limitations and study the minimum terms to which the company can commit itself.
Firstly, all the work packages are associated with a letter and a duration time (in days). The precedence relationships are summarised as follows (table 18):

Table 18 - Precedence relation between tasks

WBS number	Workload name	Assigned letter	Previous workload
1.1.1	Study the current state of TKA	A	-
1.1.2	Review of knee's anatomy	B	A
1.1.3	Literature review of current clinical trials that study the accuracy of robotically assisted surgeries	C	A
1.1.4	Design of our clinical study's protocol	D	B, C
1.2.1	Protocol's revision and correction	E	D
1.2.2	Final delivery and protocol's acceptance	F	E
1.3.1	Drafting of a manual for variables extraction	G	D
1.3.2	Selection of participants	H	F
1.3.3	Data extraction	I	G, H
1.3.4	Statistical test	J	I
1.3.5	Results obtention and conclusions' extraction	K	J
1.4.1	Writing of the project	L	-
1.4.2	Oral presentation preparation	M	K, L
1.4.3	Publication of results in a scientific paper	N	M

The destined time for each workload can be computed using PERT technique which considers that an invested time for a certain activity follows a β Distribution. So, the final estimated time to be spent for activity has been calculated using the following equation:

$$t_e = \frac{t_o + 4 \cdot t_m + t_p}{6}$$ **Equation 1**

where *te* is the estimated time; *to*, optimistic time; *tm*, normal time to be invested for a certain activity; and *tp*, pessimistic time. The time units used are days, which are not considered pure working hours. The destined times for each workload are summarised in table 19.

Table 19 – Estimated time obtained when applying equation 1 for each task

Workloads and its allotted letter	Optimistic time (to) (days)	Normal time (tn) (days)	Pessimistic time (tp) (days)	Estimated time (te) (days)*
Study the current state of TKA (A)	3	4	5	4,00
Review of knee's anatomy (B)	2	4	5	3,83
Literature review of current clinical trials that study the accuracy of robotically assisted surgeries (C)	10	13	16	13,00
Design of our clinical study's protocol (D)	84	87	92	87,33
Protocol's revision and correction (E)	52	57	64	57,33
Final delivery and protocol's acceptance (F)	29	35	40	34,83
Drafting of a manual for variables extraction (G)	80	93	99	91,83
Selection of participants (H)	57	61	69	61,67
Data extraction (I)	114	117	142	120,67
Statistical test (J)	3	7	10	6,83
Results obtention and conclusions' extraction (K)	7	10	16	10,5
Writing of the project (L)	389	402	410	401,17
Oral presentation preparation (M)	8	10	15	10,50
Publication of results in a scientific paper (N)	4	7	10	7

*Those values with decimals have been decided to be put at the top in order to work with single dedicated days. It is complicated to work with a decimal day value. Thus, B, D, E, F, G, H, J, K, L, M have been left with a duration of 4, 87, 57, 35, 92, 62, 121, 7, 11, 401, 11 days, respectively.

Using the precedencies in table 18 and the estimated times in table 19, the PERT graph has been drawn (figure 42). The critical path to consider is composed by task L and M (highlighted in blue). It seems logic this result because the writing of the whole TFG must include the explanation of all the other tasks and parts and it has to be done once the activity has been finished.

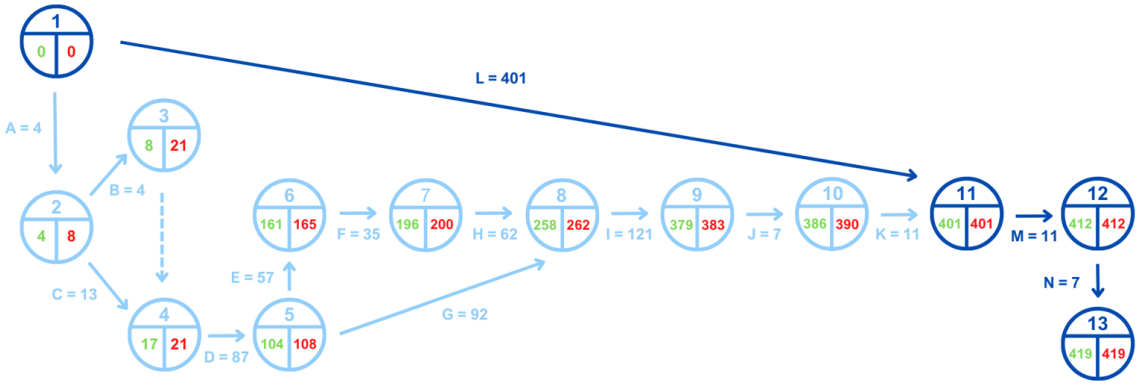


Figure 42. PERT-CPM diagram

GANTT DIAGRAM

A final work tool for the monitoring and control of the different work packages is the GANTT scheme. This shows the temporal planning of the project, indicating the start and end dates of all the activities to be carried out. In addition, it is possible to view the sequence of work defined in the PERT. The updating of this diagram is mandatory in order to see how the project is progressing.

Figure 43 shows two different GANTT diagrams: one is the original planned one and the other is the one that has been implemented. As can be seen, the original diagram has served as an approximation for carrying out the tasks and activities, as in more than one case they have had to be delayed. Another aspect to mention is that during the project, tasks have been carried out simultaneously (something that may not have been expected in the original planning or PERT-CPM) as it can be seen in activities A, B and C. The protocol's revision part has been as expected as we were in contact with the Research Ethics Committee to find out when they would review our protocol. However, the final acceptance took longer than expected and therefore the selection of participants started much later than expected. Consequently, this process had to be accelerated by compacting many appointments and giving to the participants fewer possible dates to sign the informed consent. In contrast, the drafting of the variable extraction protocol took longer as we realised that it was not necessary until we started extracting data (once all participants were selected). Although the data from the XR images were extracted as planned (performed by the resident physician and me), the CT data had different setbacks due to the cyber-attack. This one has resulted in a heavy workload for the CT experts who have not been able to send the data until a month later than expected. In addition, it should be noted that some data have been lost, which has caused some last-minute changes as mentioned above. Fortunately, the statistical tests have been prepared in advance with a part of the data to be able to move forward. Nevertheless, the obtention of results and its subsequent discussion and conclusions have been also delayed some days. Finally, the thesis has been presented on time and the presentation will be done according to the planning. One aspect that has been left for the future, due to all the problems encountered, is the writing of a scientific article that would include all the results. As it will be commented in the conclusion, this task will be done later together with the continuation of this project in order to obtain more data and to obtain more robust results.

In a nutshell, the original planning has been useful to put pressure on us to follow a certain order.

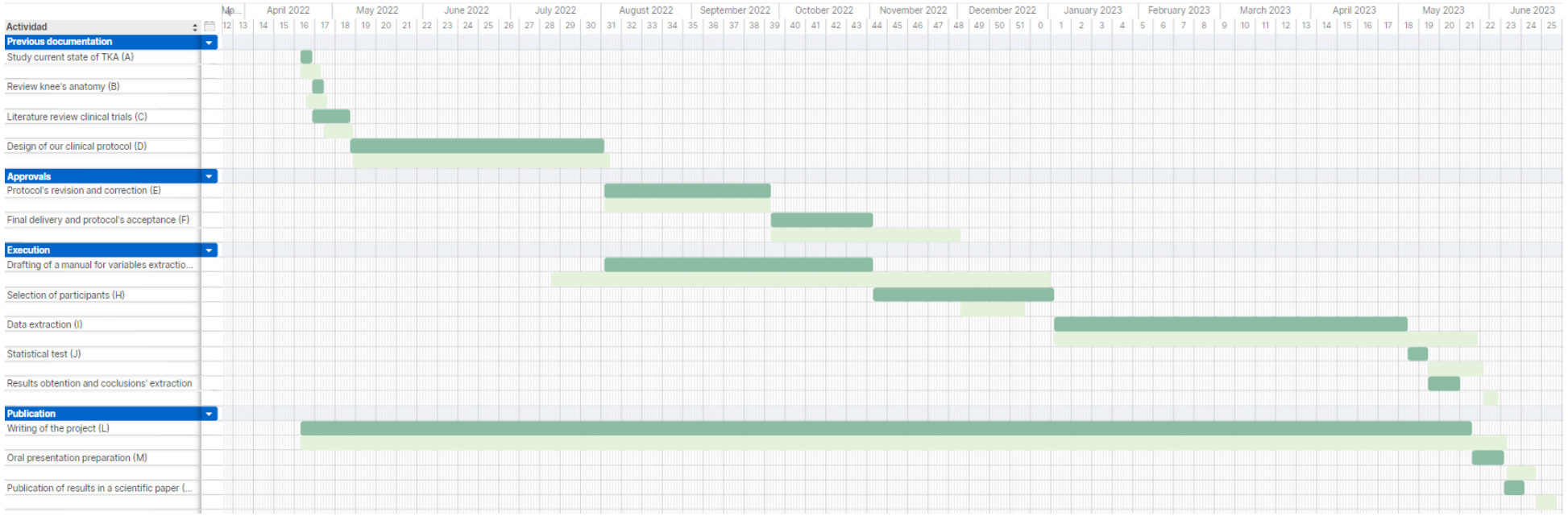


Figure 43 - GANTT diagram. In dark green the proposed or expected timings, while in light green the real timings followed.

REGULATIONS AND LEGAL ASPECTS

ETHICS AND LEGAL ASPECTS

The study has been carried out following the regulation of the Declaration of Helsinki (the version discussed at the 64th general assembly in Brazil in October 2013), a statement promulgated by The World Medical Association (WMA) that establishes the ethical principles for medical research on human beings or human material (88). The document is divided according to different aspects that must be considered while doing human research such as vulnerables groups, scientific requirements and research protocols, privacy and confidentiality or informed consent, among others. On the other hand, the study will also follow the protocol and required legal aspects specified in *Llei 14/2007 del 3 de juliol sobre la investigació biomèdica* (89).

Finally, informed consent will be requested from al the patients who accept the participation in the clinical study and if this one is changed, the participant will be notified.

DATA TREATMENT AND REGISTRATION FILES. CONFIDENTIALITY AND DATA PROTECTION

The data has been used to respond to the objectives set from the analysed variables. All the data collected from each patient has a unique code. This way, the data is anonymous since it does not include any type of information that can identify each patient. According to current legislation, it is necessary to always maintain confidentiality. For this reason, only the health authorities, the research ethics committees and the personnel authorized by the study promoter have been able to access to personal information in cases of need in order to check the data and procedures of the study. It must be taken into account, that only in cases of medical emergency or legal requirement, the identity of a participant may be revealed to a third person. The relationship between the anonymous data collected and the clinical history of the corresponding patient (de-anonymization) is only allowed for doctors or collaborators who participate in the study (previously determined in the study protocol). In the event of had needed to transfer the data to third parties or other countries, the data would have remained anonymous. Therefore, any type of reference that can identify directly the participant would have been contained (such as first and last names or social security number, among others). Furthermore, the data would have remained protected whether the transfer of the coded data had taken place outside the European Union (EU) because of established data protection mechanisms of the authorities (32).

All these treatment, communication and transfer of personal participants' data mentioned above, follows EU Regulation 2016/679 of the European Parliament and Council of 27th April 2016, mandatory from May 25 of 2018, regarding the protection of natural persons with regard to the processing and free movement of personal data (90). Furthermore, it also must be followed the *Llei Orgànica 3/2018* regarding Personal Data Protection and guarantee of digital rights. The legal basis that justifies the processing of data is the informed consent signed by the participants, as established in article 9 of EU Regulation 2016/679 (91).

All the researchers and collaborators of the study have committed to treat data according to EU Regulation 2016/679. For this reason, a record has been kept of the treatment activities carried out and a risk assessment about the treatments applied will be carried out to know which measure must be applied and how to do it. Apart from the rights already contemplated by the previous

legislation (in the new regulation known as access, modification, opposition and cancellation of data and deletion), the participants now can also: limit the processing of incorrect data collected at the project, request a copy and transfer them to a third party. To exercise these rights, participants must contact the principal investigator of the study or the Data Protection Officer of *Hospital Clínic de Barcelona* through protecciodades@clinic.cat . If they are not satisfied, the participants can address to the Data Protection Agency." (Quoted directly from (32))

Data cannot be deleted even if a patient leaves the study before its end in order to ensure the validity of the research and to comply with legal duties and drug authorization requirements. The researcher and the promoter are obliged to keep the data collected by the study for at least 5 years after its completion. Then, the personal information will be kept by the study centre to ensure their health and will also be kept by the promoter for other purposes of scientific research if the patient had given consent, and if this is allowed by the applicable law and ethical requirements.

REGULATORY AND LEGAL ISSUES IN ROBOTICS

As robots are considered medical devices, they must follow several safety regulations and technical requirements to be able to commercialise the product. When fulfilling these standards, the manufacturer company receives the approval of the Food and Drug Administration (FDA) in the United States of America and/or the European Union Certification (CE) to commercialise in the respective continents. Moreover, the International Organization for Standardization (ISO) is an independent, non-governmental international organization that tries to promote international standards for technology, scientific testing processes, working conditions (among others). To do so, after a committee reviews the conditions of the entity under study, ISO grants a quality certificate. Some of the main regulations and certificates stablished by CE and ISO to ensure the quality and safety of medical products are summarized in the following table (it includes some of the main important certificates; nevertheless, it must be beard in mind that can vary according to the characteristics of the technology):

Table 20 - Main certificates required to ensure quality and safety

Standard	Description
IEC 60601 (92)	Technical standards for the safety and essential performance of medical electrical equipment.
IEC 62366-1 (93)	Standards to the usability for the development of medical devices
IEC 62304 Ed. 1.0 (94)	Medical device software – Defines the life cycle requirements for medical device software.
IEC 60825-1 Ed. 3.0 (95)	Safety of laser products – Part 1: Equipment classification and requirements
ISO 13485:2018 (96)	Quality management systems – Specific requirements for a quality management system where the studied organization must demonstrate its ability to provide medical devices and related services that meet customer and applicable regulatory requirements.
ISO 10993:2018 (97)	Standards for evaluating the biocompatibility of medical devices to manage biological risk.
ISO 17664:2017 (98)	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices
ISO 17665-1:2006 (99)	Sterilization of healthcare products - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
ISO 10993-1:2018 (100)	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

CONCLUSIONS

In conclusion, it is important to highlight and review the objectives of the work. One of them, and as the most important, has been to learn and carry out a clinical study in order to, from an engineer's point of view, identify errors to be able to optimize it. Therefore, this thesis has been seen as a whole process that has been reviewed and that, due to certain errors or bad practices, can be improved. Taking into account, the scope of the work, I had to do a bibliographic review to be able to design a study protocol acceptable to the Ethics Committee. In general, it was accepted without any problem apart from some minor clarifications. Even so, the response time from the committee was long and, therefore, it is important to emphasize the importance of submitting it as soon as possible. Next, a selection of potential participants had to be made. Some possible sources of error in this area are unintentional changes to the Excel documents with the patient's information. As the documents were sent personally to the mail any change to the document, and then sending it, would imply the misassignment of data to the patients. However, at present, all the data is being transferred to the RedCap software, so that it will be centralized and protected (anonymously and in accordance with the data protection law), thus facilitating the work of the employees and reducing the possibility of errors.

With regards of the patients, they came to the meetings without knowing that it was not an appointment to review (as in the usual clinical practice), but to explain the possible participation in a study. For this reason, we have received some complaints about wasting their time or because they came thinking that it was a possible emergency. Also, one day, patients who were not eligible for the study and who came for a check-up were cited in the consultation where we presented the option of participating in the study. These two errors on the part of the administration staff of the traumatology service are associated to the human factor and are understandable. Simply, better communication is needed in order to be able to transmit these ideas. For this reason, I believe that the patient appointment system is the correct one: the researcher sends a list of participants to be appointed so that they can be contacted to arrange an appointment on the days when the offices for the study are open. Moreover, we only proposed three days for appointments since we have a time constraint in the study due to the delivery of the thesis. Surely, if more days had been proposed, more patients would have been able to come, so that we would have a larger sample size. Those cases in which patients complained because of losing time or make them wait, have made us consider the option of notifying by mail or calls (by the investigator or someone else) about the study and send by mail documentation to be digitally signed. However, currently this is not yet fully valid and is beginning to be accepted. In addition, space is always needed for the patient to express his or her opinion and to ask questions about protocol or consent, which is not always the case if the meetings are done by call or mail. Even so, there is a risk that not as many people will join the study because this telecommunication is less reliable than in a common meeting with a doctor. Moreover, considering that participants are of advanced age, we could lose patients due to stress generated or lack of knowledge of how technology works. Therefore, the best option is to continue as we are, but thinking about a possible future shift to videocalls or other aspects that do not bother the patient, in order to decrease the waiting time of patients or the trip to the hospital.

Once the patients have been selected, it is necessary to start extracting data from the XR already available from the usual clinical practice and to order the CT images. Currently, in clinical practice there is a protocol of when to order XR images. Even so, we have come across different cases in which some patients had LLR after a few months different from others (and the same for XR).

Finally, some cases did not have LLR or XR directly because they did not present and no one else has followed them until they return to have a check-up, which is when doctors see if the images are available. Therefore, it would be necessary to find some system to control which patients have or do not have the images, so that when they are needed, they are accessible as in the case of this study: when they should be used, they are available and do not have to be requested. The conclusion is that in order to avoid missing it is necessary to have this double follow-up check. We believe that in the future, artificial intelligence programs could be used to detect these messages and alert the clinical staff. Regarding the images, it is very important that the imaging process is carried out correctly in order to obtain quality images that allow a good study to be made of them. As has been commented previously in other sections, the sagittal plane XR, when they were not well angled, have caused problems for the calculation of variables such as the PCO. However, it is complicated by the fact that patients can be of advanced age and certain positions can be uncomfortable and painful for them.

Once the images have been obtained, it is necessary to extract data. The variables are described in a protocol. As the variables can be extracted using more than one methodology, it is important to ensure that everyone uses the same criteria. In general, it has been respected, although in the case of PDFA it has been calculated differently by CT and XR observers (it is clearly reflected in the results). Although we had many variables to study, we have not been able to study all of them due to the cyberattack such as CT variables. It is important that the protocol defines the variables as objectively as possible, since in those cases in which a degree of subjectivity or interpretation by the observer has been left, there have been differences in the results. However, it should be noted that experience is a very important factor that allows to reduce the source of human error since the interpretation of the images is performed more correctly.

Finally, at the time of working with the more statistical part, tables were created that contained a range of intraoperative and postoperative data, CT and X-ray or from different observers. This process has been rudimentary and manual (copying values from one table to another) which increases the possibility of error. Due to the human factor, possible erroneous associations of data to patients could have occurred. For this reason, we consider that this could have been done via the R code itself and create the data tables in the statistical program itself. In this way, the possibility of error decreases. Another option would be to try to use RedCap to create dynamic tables directly in the software and download them. These tables have been created by hand as it was the easiest option.

The second goal of the project has been to assess ROSA's accuracy in the alignment and positioning of the extremity. It is important to mention that this clinical study is observational. In this way, a series of data have been collected and studied in order to take a picture of the current situation. This work does not have at any time the objective of looking for a causal relationship between the data obtained and the possible clinical reason. On the contrary, these results are intended to give rise to hypotheses for new clinical studies to study certain specific facets of our results.

The accuracy results have not shown the expected results since the concordance coefficients have been low and the limits of agreement broad, leading to conclude that it was not as accurate as our hypothesis (formulated according to the literature reviewed). Nevertheless, it is important to mention that the required accuracy must be stated by the surgeons. In other words, although the concordance coefficient could be low and agreement between data cannot be ensured, the

surgeons are the ones to discuss whether the range of agreement limits are acceptable to them in performing the surgery. Also, it would be necessary to see if MKTA provides an even lower concordance coefficients and limits of agreement in order to compare them. Then we might consider the robotic machine to be more accurate. Therefore, it is difficult to state categorically that the robot is or is not accurate. Furthermore, our results are also not so far away (just a little bit greater) in terms of average of the differences between intraoperative and postoperative values from certain articles of the literature that confirm the accuracy of ROSA. It is interesting to note that many studies only present this mean difference as they show very good values (averages less than 1 degree of difference) to demonstrate this accuracy and obtain positive conclusions. It would be necessary to know what concordance values they obtain and the limits of agreement since they may be like ours, but they do not present them, so the public does not thing that their robotic machine is not accurate. In this way, the marketing strategy of these companies is to present positive results to sell their product.

Furthermore, from the accuracy study we have seen certain positive or negative tendencies of data that lead to think that there is a bias error. The next step should try to identify in which part of the process this systematic error is found. Could it be surgery? During data extraction? With this study is not possible to identify the cause of the problems and it would be necessary to make a more intensive study in some of these aspects. Moreover, we have noticed that few decimals come from ROSA results, which has made us wonder if it is the robot that is not accurate instead of thinking about possible inaccuracies in the extraction data. However, as commented before, our sample size is low, so more data would help to confirm these results obtained and provide robustness.

The explicit relationship between prosthesis positioning and patient pain or acceptance of the prosthesis is not yet fully known, and more research is needed. Results are beginning to come out demonstrating the different needs in terms of alignment and positioning of the implant of each person and rejecting a universal and appropriate solution for all patients. This fact would reaffirm the need to have techniques as accurate as possible in order to customize these treatments. This treatment individualization can be more easily acquired thanks to the assistance provided by robotic arm. For this reason, this technology it is seemed to be here to stay.

With regards to the TC vs XR assessment, agreement between the values have not been found. Since CT images allow better visualization, it is concluded that the extraction of variables from XR images performed in this study is not as accurate as from CT images (because the values do not agree). In this case, taking into account that the CT test irradiates more the patient, it would be important to perform a risk-benefit analysis: that is, to try to know to what extent it is clinically relevant to have the best postoperative results in terms of grade, in exchange for a higher radiation exposure. This answer is closely linked to the question discussed above about the relationship between patient satisfaction and accuracy in the positioning and alignment of the prosthesis. This study would also allow us to know if the axial variables studied only by CT are useful and should be added to the variables studied in the usual clinical practice.

The results obtained from the inter-observer assessment show a certain difference between the data extracted. As mentioned above, factors such as experience or a definition of the variables as objectively as possible are very important. In the future, programs such as TraumaCad, or the use

of artificial intelligence, could be very useful to avoid this difference in results between observers, as well as facilitating and speeding up the process of extracting variables.
In a nutshell, thanks to the postoperative data we have been able to place our group in comparison to the literature and we have been able to see how our results assimilate to normality. For this reason, we consider the work done as a success because we have been able to carry out the whole clinical study, thus providing important data. However, it should be mentioned that the sample size of the study is low and that therefore the results are not very robust. For this reason, before drawing conclusions about possible errors in the methodology, it would be necessary to make sure that the results obtained are representative and not a bias increasing the sample size.

FUTURE WORK

As mentioned above, this project has served to analyse the current situation of TKA assisted by ROSA. In this way, the different results can serve as a basis to see how the variables studied behave, so new hypotheses for new studies can be formulated. Firstly, the main idea is to continue working in this project in order to increase the sample size and obtain more robust results. This way, we will allow us to identify what we are doing wrong, so it might be improved, and the maximum accuracy is acquired. Also, the continuation of this project will have as an important goal provide the axial variables that have not been able to obtain in this thesis. Moreover, the measurement of the variables could be performed by automatic software such as TraumaCad because in a future artificial intelligence will be the one responsible for this.
From the results obtained in the project, it would be interesting to check if the if trends are still present in some variables to search for their cause. Another future study arising from our results is the assessment of the need to obtain postoperative CT imaging values (instead that from XR images) and the study of axial variables. This way, it would be known if obtaining very accurate postoperative imaging results is necessary in exchange for a higher radiation exposure.
Another aspect to complete or improve would be the collection of intraoperative variables. Currently, having information and data is a business. In this case, Zimmer Biomet is taking advantage of the opportunity to collect data from its customers (in this case the hospital) and use it as it sees fit. The data that Zimmer sends us is only a small part and is untapped. Thus, it would be necessary to make a consensus with Zimmer so we can get much more data on variables that we would be interested in studying and drawing conclusions from the clinic. For example, these data would allow us to investigate the accuracy-pain relationship mentioned above: study if the accuracy in positioning has a clinical relevance and, in this way, to justify the need (or not) of accurate positioning and alignment of the implants. This is an open question that is being attempted to be solved as it would imply a major change in the TKA paradigm.
Finally, once all these previous studies have been carried out and provided information to the scientific community, investigators should compare MTKA and RaTKA accuracies to check if robotics is really facilitating a better accuracy during the surgeries.

BIBLIOGRAPHY

1. Postler A, Lützner C, Beyer F, Tille E, Lützner J. Analysis of Total Knee Arthroplasty revision causes. BMC Musculoskelet Disord [Internet]. 2018 Feb 14 [cited 2022 May 7];19(1). Available from: /pmc/articles/PMC5813428/

2. Nakano N, Shoman H, Olavarria F, Matsumoto T, Kuroda R, Khanduja V. Why are patients dissatisfied following a total knee replacement? A systematic review. Int Orthop. 2020 Oct 1;44(10):1971–2007.

3. Singh JA, Yu S, Chen L, Cleveland JD. Rates of Total Joint Replacement in the United States: Future Projections to 2020-2040 Using the National Inpatient Sample. J Rheumatol [Internet]. 2019 Sep 1 [cited 2023 May 29];46(9):1134–40. Available from: https://pubmed.ncbi.nlm.nih.gov/30988126/

4. Kim YB, Choi HS, Kang EM, Park S, Seo GW, Chun D Il, et al. Trends of Total Knee Arthroplasty According to Age Structural Changes in Korea from 2011 to 2018. Int J Environ Res Public Health [Internet]. 2021 Dec 1 [cited 2022 May 7];18(24):13397. Available from: /pmc/articles/PMC8706676/

5. Begum FA, Kayani B, Magan AA, Chang JS, Haddad FS. Current concepts in total knee arthroplasty: mechanical, kinematic, anatomical, and functional alignment. Bone Jt Open [Internet]. 2021 Jun 1 [cited 2022 May 7];2(6):397. Available from: /pmc/articles/PMC8244789/

6. Han S, Rodriguez-Quintana D, Freedhand AM, Mathis KB, Boiwka A V., Noble PC. Contemporary Robotic Systems in Total Knee Arthroplasty: A Review of Accuracy and Outcomes. Orthopedic Clinics of North America. 2021 Apr 1;52(2):83–92.

7. Kayani B, Konan S, Huq SS, Tahmassebi J, Haddad FS. Robotic-arm assisted total knee arthroplasty has a learning curve of seven cases for integration into the surgical workflow but no learning curve effect for accuracy of implant positioning. Knee Surgery, Sports Traumatology, Arthroscopy [Internet]. 2019 Apr 5 [cited 2022 May 7];27(4):1132. Available from: /pmc/articles/PMC6435632/

8. Beyaz S. A brief history of artificial intelligence and robotic surgery in orthopedics & traumatology and future expectations. Jt Dis Relat Surg [Internet]. 2020 [cited 2022 Jun 15];31(3):653. Available from: /pmc/articles/PMC7607941/

9. Cirugía Ortopédica y Traumatología | Hospital Clínic Barcelona [Internet]. [cited 2022 Jun 15]. Available from: https://www.clinicbarcelona.org/servicio/cirugia-ortopedica-y-traumatologia

10. El Clínic se consolida como referente en cirugías robóticas de rodilla [Internet]. [cited 2022 May 15]. Available from: https://www.barnaclinic.com/blog/blog/cirugias-roboticas-de-rodilla/

11. Cirugía robótica de prótesis de rodilla, mayor precisión y personalización [Internet]. [cited 2022 Jun 15]. Available from: https://www.barnaclinic.com/blog/blog/cirugia-robotica-protesis-de-rodilla/

12. Parratte S, Price AJ, Jeys LM, Jackson WF, Clarke HD. Accuracy of a New Robotically Assisted Technique for Total Knee Arthroplasty: A Cadaveric Study. J Arthroplasty. 2019 Nov 1;34(11):2799–803.

13. Hampp EL, Chughtai M, Scholl LY, Sodhi N, Bhowmik-Stoker M, Jacofsky DJ, et al. Robotic-Arm Assisted Total Knee Arthroplasty Demonstrated Greater Accuracy and Precision to Plan Compared with Manual Techniques. Journal of Knee Surgery [Internet]. 2019 [cited 2022 Jun 15];32(3):239–50. Available from: http://www.thieme-connect.com/products/ejournals/html/10.1055/s-0038-1641729

14. Vaidya N V., Deshpande AN, Panjwani T, Patil R, Jaysingani T, Patil P. Robotic-assisted TKA leads to a better prosthesis alignment and a better joint line restoration as compared to conventional TKA: a prospective randomized controlled trial. Knee Surgery, Sports Traumatology, Arthroscopy [Internet]. 2022 Feb 1 [cited 2022 Jun 15];30(2):621–6. Available from: https://link-springer-com.sire.ub.edu/article/10.1007/s00167-020-06353-2

15. Bagaria V, Sadigale OS, Pawar PP, Bashyal RK, Achalare A, Poduval M. Robotic-Assisted Knee Arthroplasty (RAKA): The Technique, the Technology and the Transition. Indian J Orthop [Internet]. 2020 Nov 1 [cited 2022 Jun 15];54(6):745. Available from: /pmc/articles/PMC7572961/

16. Mavrogenis AF, Scarlat MM. Surgeons and robots. International Orthopaedics 2019 43:6 [Internet]. 2019 May 8 [cited 2022 Jun 15];43(6):1279–81. Available from: https://link-springer-com.sire.ub.edu/article/10.1007/s00264-019-04345-7

17. OrthoMap Software | Stryker [Internet]. [cited 2022 Jun 15]. Available from: https://www.stryker.com/us/en/navigation/products/orthomap-software0.html

18. Hernandez D, Garimella R, Eltorai AEM, Daniels AH. Computer-assisted Orthopaedic Surgery. Orthop Surg [Internet]. 2017 May 1 [cited 2022 Jun 15];9(2):152. Available from: /pmc/articles/PMC6584434/

19. 7 companies transforming orthopedics with robot-assisted surgery - The Robot Report [Internet]. [cited 2022 Jun 15]. Available from: https://www.therobotreport.com/7-companies-transforming-orthopedics-with-robot-assisted-surgery/

20. Negrín R, Duboy J, Iñiguez M, Reyes N, Wainer M, Infante C, et al. Cirugía Robótica en Artroplastia de Rodilla. Revista Chilena de Ortopedia y Traumatología [Internet]. 2019 Oct [cited 2022 Jun 15];60(02):067–76. Available from: http://www.thieme-connect.de/products/ejournals/html/10.1055/s-0039-1698417

21. Sires JD, Craik JD, Wilson CJ. Accuracy of Bone Resection in MAKO Total Knee Robotic-Assisted Surgery. J Knee Surg [Internet]. 2021 [cited 2022 Jun 15];34:745–8. Available from: https://doi.org/

22. Mako clinical evidence Mako ® Partial Knee arthroplasty: clinical summary.

23. Moving You Forward. ™ User Manual & Surgical Technique V1.2.

24. 3076.2-GLBL-en-ROSA-Knee-Detailed-Brochure-Digital_FINAL.pdf.coredownload.pdf.

25. Zimmer Biomet. ROSA ® Knee System. Surgical Technique V1.1.

26. Rossi SMP, Sangaletti R, Perticarini L, Terragnoli F, Benazzo F. High accuracy of a new robotically assisted technique for total knee arthroplasty: an in vivo study. Knee Surgery, Sports Traumatology, Arthroscopy [Internet]. 2022 [cited 2022 Jun 15];1. Available from: /pmc/articles/PMC8723813/

27. Khare R, Jaramaz B, Hamlin B, Urish KL. Implant orientation accuracy of a hand-held robotic partial knee replacement system over conventional technique in a cadaveric test. Comput Assist Surg (Abingdon) [Internet]. 2018 Jan 1 [cited 2023 May 12];23(1):8. Available from: /pmc/articles/PMC6309277/

28. NAVIO. NAVIO compendium of evidence [Internet]. [cited 2023 May 12]. Available from: chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://assets.website-files.com/5ea03bb60badecbd9c6d03cd/5ed75ff740bbe28f70d9e9a6_NAVIO%20compendium%20clinical%20evidence%20Sep%202019.pdf

29. The VELYS™ Robotic-Assisted Solution versus Mako ® A comparison of system compactness 1-2.

30. J&J Depuy Synthes. SIMPLICITY. THE NEXT CHAPTER IN ROBOTICS. VELYS. 2022;

31. Doan G, Courtis P, Wyss J, Green E, Clary CW. Resection Accuracy Improved using a Novel Concept for Robotic-Assisted Total Knee Arthroplasty Orthopaedic Research Society-Annual Meeting.

32. Secció de Genoll Hospital Clínic de Barcelona. Protocolo ArtroClinic. 2021;7(2):107–15.

33. Diller W. Community Blog - Robots in TKA: Market Update [Internet]. [cited 2022 Jun 15]. Available from: https://www.mystrategist.com/blog/article/robots_in_tka_2022_market_update.html

34. Newmarker C. Stryker strives for market share in orthopedic surgery robots - The Robot Report [Internet]. [cited 2022 Jun 15]. Available from: https://www.therobotreport.com/stryker-leads-orthopedic-surgery-robots/

35. Demaitre E. Orthopedics Firm Smith & Nephew Buys Blue Belt for $275M - Robotics Business Review [Internet]. [cited 2022 Jun 15]. Available from: https://www.roboticsbusinessreview.com/health-medical/orthopedics_firm_smith_nephew_buys_blue_belt_for_275m/

36. Wallick T. What's New at Depuy Synthes? [Internet]. [cited 2022 Jun 15]. Available from: https://blog.smarttrak.com/whats-new-at-depuy-synthes

37. BAHUGUNA D. Orthopedic surgical robotics market: Competitive landscape - Clarivate [Internet]. [cited 2022 Jun 15]. Available from: https://clarivate-com.sire.ub.edu/blog/orthopedic-surgical-robotics-market-competitive-landscape/

38. Sandle, Paul; Hirschler B. Robotic Knee Surgery Competition Heats Up - Scientific American [Internet]. [cited 2022 Jun 15]. Available from: https://www-scientificamerican-com.sire.ub.edu/article/robotic-knee-surgery-competition-heats-up/

39. Lonner JH. A Personal Journey through, and review of, the Landscape of Surgical Robotics in Knee Arthroplasty: My Transition from Mako® to NAVIO™ and finally to the ROSA® Knee System | Published in Journal of Orthopaedic Experience & Innovation [Internet]. [cited 2022 Jun 15]. Available from: https://journaloei.scholasticahq.com/article/33593-a-personal-journey-through-and-review-of-the-landscape-of-surgical-robotics-in-knee-arthroplasty-my-transition-from-mako-to-navio-and-finally-to

40. Community Memorial Health System. CMH Launches ROSA Total Knee Replacement Surgery Program – CMHS Blog [Internet]. [cited 2022 Jun 15]. Available from: https://blog.cmhshealth.org/2020/12/09/cmh-launches-rosa-total-knee-replacement-surgery-program/

41. Carfagno J. Mako Versus ROSA: Comparing Robotic-Assisted Surgical Systems - Docwire News [Internet]. [cited 2022 Jun 15]. Available from: https://www.docwirenews.com/docwire-pick/robot-wars-in-medicine-mako-versus-rosa/

42. Medical Device and Diagnostic Industry. Look Out Mako, Here Comes Rosa [Internet]. [cited 2022 Jun 15]. Available from: https://www.mddionline.com/robotics/look-out-mako-here-comes-rosa

43. DePuy Synthes Receives CE Mark for the VELYS™ Robotic-Assisted Solution Designed for Use with the ATTUNE™ Total Knee System | DePuy Synthes [Internet]. [cited 2023 May 29]. Available from: https://www.jnjmedtech.com/en-EMEA/news-events/depuy-synthes-receives-ce-mark-velys-robotic-assisted-solution-designed-use-attune

44. Medical Device Network. DePuy Synthes launches robotic-assisted knee surgery solution [Internet]. [cited 2022 Jun 15]. Available from: https://www.medicaldevice-network.com/news/depuy-synthes-robotic-solution/

45. Total Knee Replacement Market Trends | Growth Report, 2032 [Internet]. [cited 2023 May 29]. Available from: https://www.gminsights.com/industry-analysis/total-knee-replacement-market

46. Pierce J, Needham K, Adams C, Coppolecchia A, Lavernia C. Robotic arm-assisted knee surgery: An economic analysis. American Journal of Managed Care. 2020 Jul 1;26(7):E205–10.

47. TraumaCad Mobile on the App Store [Internet]. [cited 2023 May 13]. Available from: https://apps.apple.com/us/app/traumacad-mobile/id924396922

48. Healthcare Software Development Services & Solutions [Internet]. [cited 2023 May 13]. Available from: https://www.itransition.com/healthcare?gad=1&gclid=CjwKCAjw0ZiiBhBKEiwA4PT9z10vcfLhl-96WnDZZExmvUUudLmBlB4DxB6606OocmVAL5Vh_YWwmBoCY8MQAvD_BwE

49. PACS System with Enterprise Imaging - NovaPACS EI | Novarad [Internet]. [cited 2023 May 13]. Available from: https://www.novarad.net/novapacsenterpriseimaging#Ortho_Workflow_Module

50. Choosing the Right Statistical Test | Types & Examples [Internet]. [cited 2023 May 13]. Available from: https://www.scribbr.com/statistics/statistical-tests/

51. Schmidt A, Batailler C, Lording T, Badet R, Servien E, Bonnin MP, et al. Why Reintervention After Total Knee Arthroplasty Fails? A Consecutive Cohort of 1170 Surgeries. J Arthroplasty. 2020 Sep 1;35(9):2550–60.

52. Toms AP, Rifai T, Whitehouse C, McNamara I. CT measures of femoral and tibial version and rotational position of femoral and tibial components of knee replacements: limitations in reliability and suitability for routine clinical practice. Eur Radiol [Internet]. 2022 Jun 1 [cited 2023 May 14];32(6):3790–8. Available from: https://link.springer.com/article/10.1007/s00330-021-08483-8

53. Carrasco JL, Phillips BR, Puig-Martinez J, King TS, Chinchilli VM. Estimation of the concordance correlation coefficient for repeated measures using SAS and R. Comput Methods Programs Biomed. 2013 Mar 1;109(3):293–304.

54. León Muñoz VJ. Guía De Mediciones Para Cirugía Protésica De Rodilla. Serod [Internet]. 2017 [cited 2022 May 7]; Available from: https://www.serod.org/pdf/2.1.2_guia_mediciones.pdf

55. Lin YH, Chang FS, Chen KH, Huang KC, Su KC. Mismatch between femur and tibia coronal alignment in the knee joint: Classification of five lower limb types according to femoral and tibial mechanical alignment. BMC Musculoskelet Disord. 2018;19(1):1–9.

56. Knipe H, Weng N. Hip-knee-ankle angle. Radiopaedia.org [Internet]. 2021 Apr 1 [cited 2022 Dec 3]; Available from: http://radiopaedia.org/articles/88254

57. Popat R, Dhillon K, Mahapatra P, Khan H, Nathwani D. The Imperial Joint Line Congruency Measurement is a valuable tool in total knee arthroplasty. PLoS One [Internet]. 2021 Sep 1 [cited 2022 Sep 8];16(9):e0257325. Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0257325

58. Micicoi G, Khakha R, Kley K, Wilson A, Cerciello S, Ollivier M. Managing intra-articular deformity in high Tibial osteotomy: a narrative review. J Exp Orthop. 2020;7(1):1–10.

59. Paley D. Lower Limb Alignment. Measurements and Classifications in Musculoskeletal Radiology [Internet]. 2014 Jul 22 [cited 2022 Dec 3]; Available from: https://radiologykey.com/lower-limb-alignment/

60. Verhulst F V., van Sambeeck JDP, Olthuis GS, van der Ree J, Koëter S. Patellar height measurements: Insall–Salvati ratio is most reliable method. Knee Surgery, Sports Traumatology, Arthroscopy [Internet]. 2020 Mar 1 [cited 2022 Oct 3];28(3):869–75. Available from: https://link-springer-com.sire.ub.edu/article/10.1007/s00167-019-05531-1

61. Roberts D, Gaillard F. Insall-Salvati ratio. Radiopaedia.org. 2008 May 2;

62. Roberts D, Delgado J. Caton-Deschamps index (knee). Radiopaedia.org [Internet]. 2016 Aug 29 [cited 2022 Oct 5]; Available from: http://radiopaedia.org/articles/47666

63. Narkbunnam R, Electricwala AJ, Huddleston JI, Maloney WJ, Goodman SB, Amanatullah DF. Suboptimal patellofemoral alignment is associated with poor clinical outcome scores after primary total knee arthroplasty. Arch Orthop Trauma Surg [Internet]. 2019;139(2):249–54. Available from: http://dx.doi.org/10.1007/s00402-018-3073-z

64. Kleimeyer JP, McQuillan TJ, Arsoy D, Aggarwal VK, Amanatullah DF. Agreement and Reliability of Lateral Patellar Tilt and Displacement following Total Knee Arthroplasty with Patellar Resurfacing. Journal of Knee Surgery. 2021;34(7):717–20.

65. Bell SW, Young P, Drury C, Smith J, Anthony I, Jones B, et al. Component rotational alignment in unexplained painful primary total knee arthroplasty. Knee. 2014 Jan 1;21(1):272–7.

66. Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patellofemoral complications after total knee arthroplasty. Clin Orthop Relat Res. 1998;356(356):144–53.

67. Benazzo F, Rossi SMP, Danesino G, Klersy C, Perelli S, Ghiara M. Computed tomography evaluation of total knee arthroplasty implants position after two different surgical methods of implantation. Int Orthop. 2019;43(1):139–49.

68. Lützner J, Kirschner S, Günther KP, Harman MK. Patients with no functional improvement after total knee arthroplasty show different kinematics. Int Orthop. 2012;36(9):1841–7.

69. Matziolis G, Krocker D, Weiss U, Tohtz S, Perka C. A prospective, randomized study of computer-assisted and conventional total knee arthroplasty: Three-dimensional evaluation of implant alignment and rotation. Journal of Bone and Joint Surgery. 2007;89(2):236–43.

70. Reha N. Tandogan (1) , Pier Indelli (2) , Mo Saffarini (3) , Alfredo-Schiavone Panni (4) EE (5). Tibial Rotational Alignment in Total Knee Arthroplasty Preliminary Report of the Tibial Rotation Study Group of European Knee Associates (EKA).

(1):3–5. Available from: https://cdn.ymaws.com/esska.site-ym.com/resource/resmgr/docs/forms_and_documents/Tibial_Rotational_Prelim_rep.pdf

71. Zhang H, Cao C, Zhang H, Han S. Determining the rotational alignment of the tibial component referring to the tibial tubercle during total knee arthroplasty: the tibial tubercle–trochlear groove can be an aid. J Orthop Surg Res [Internet]. 2022 Dec 1 [cited 2022 Nov 2];17(1):1–10. Available from: https://josr-online.biomedcentral.com/articles/10.1186/s13018-022-03139-9

72. Wernecke GC, Harrris IA, Seeto BG, Chen DB, MacDessi SJ. Normal Femorotibial Rotational Alignment and Implications for Total Knee Arthroplasty: an MRI Analysis. HSS Journal. 2016;12(3):216–22.

73. Klasan A, Twiggs JG, Fritsch BA, Miles BP, Heyse TJ, Solomon M, et al. Correlation of tibial component size and rotation with outcomes after total knee arthroplasty. Arch Orthop Trauma Surg [Internet]. 2020;140(11):1819–24. Available from: https://doi.org/10.1007/s00402-020-03550-z

74. Akagi M, Oh M, Nonaka T, Tsujimoto H, Asano T HC. An anteroposterior axis of the tibia for total knee arthroplasty. Clin Orthop Relat Res. 2004;(420):213-219. Clin Orthop. 2004;(420):213–9.

75. Şahin N, Atici T, Öztürk A, Özkaya G, Özkan Y, Avcu B. Accuracy of anatomical references used for rotational alignment of tibial component in total knee arthroplasty. Knee Surgery, Sports Traumatology, Arthroscopy. 2012;20(3):565–70.

76. Nicoll D, Rowley DI. Internal rotational error of the tibial component is a major cause of pain after total knee replacement. Journal of Bone and Joint Surgery - Series B. 2010;92(9):1238–44.

77. Moreno Fernándeza F, Villanueva Martíneza M. Medición de la torsión del miembro inferior con tomografía computarizada | Revista de la Sociedad Andaluza de Traumatología y Ortopedia [Internet]. [cited 2022 Nov 22]. Available from: https://www-elsevier-es.sire.ub.edu/es-revista-revista-sociedad-andaluza-traumatologia-ortopedia-130-articulo-medicion-torsion-del-miembro-inferior-13085213

78. Álvarez R, Martín S, Velutini JA, Álvarez K, Velutini SMR&, Anatomía KJA, et al. Anatomía de la Cabeza Femoral Humana: Consideraciones en Ortopedia, Parte I. Anatomía y Relaciones Antropométricas del Fémur Proximal. International Journal of Morphology [Internet]. 2010 Jun [cited 2022 Nov 22];28(2):427–31. Available from: http://www.scielo.cl/scielo.php?script=sci_arttext&pid=S0717-95022010000200016&lng=es&nrm=iso&tlng=es

79. Manilov R, Maldonado S, Orellano O, Borbore A, Manilov M. Torsión interna de rodilla . Protocolo tomográfico patelofemoral en posición de marcha. 2021;28:181–91.

80. Boyadjiev Boyd SA. Torsión femoral - Pediatría - Manual MSD versión para profesionales [Internet]. [cited 2022 Nov 22]. Available from: https://www.msdmanuals.com/es-es/professional/pediatría/malformaciones-congénitas-craneofaciales-y-musculoesqueléticas/torsión-femoral

81. Lluis J, Edu> C <jlcarrasco@ub, Puig Martinez J, Josep M, Carrasco L. Package “cccrm” Title Concordance Correlation Coefficient for Repeated (and Non-Repeated) Measures Version 2.1.0. 2022;

82. smith&nephew. AP standard measurements. 2012 [cited 2022 Dec 17]; Available from: www.smith-nephew.com

83. Imágenes radiologicas, tamaño, peso y calidad | Eva [Internet]. [cited 2023 May 14]. Available from: https://evacenter.com/blog/imagenes-en-los-sistemas-pacs/

84. Necesidades de Almacenamiento en Radiología Digital - Imagenología [Internet]. [cited 2023 May 14]. Available from: https://imagenologia.robustiana.com/34-almacenamiento-radiologia-digital

85. Storage management: What radiologists need to know • APPLIED RADIOLOGY [Internet]. [cited 2023 May 14]. Available from: https://appliedradiology.com/articles/storage-management-what-radiologists-need-to-know

86. Declaración de Helsinki de la AMM – Principios éticos para las investigaciones médicas en seres humanos – WMA – The World Medical Association [Internet]. [cited 2022 Jun 16]. Available from: https://www.wma.net/es/policies-post/declaracion-de-helsinki-de-la-amm-principios-eticos-para-las-investigaciones-medicas-en-seres-humanos/

87. BOE.es - BOE-A-2007-12945 Ley 14/2007, de 3 de julio, de Investigación biomédica. [Internet]. [cited 2022 Jun 16]. Available from: https://www.boe.es/buscar/doc.php?id=BOE-A-2007-12945

88. REGLAMENTO (UE) 2016/ 679 DEL PARLAMENTO EUROPEO Y DEL CONSEJO - de 27 de abril de 2016 - relativo a la protección de las personas físicas en lo que respecta al tratamiento de d atos personales y a la libre circulación de estos datos y por el que se deroga la Directiva 95/ 46/ CE (Reglamento general de protección de datos).

89. Boletin Oficial del Estado B. Llei orgànica 3/2018, de 5 de desembre, de protecció de dades personals i garantia dels drets digitals.

90. IEC 60601 certification at DEKRA | DEKRA Product Testing [Internet]. [cited 2023 May 14]. Available from: https://www.dekra.nl/en/iec-60601?gclid=EAIaIQobChMI9oC0i5L1_gIVuBAGAB1aWw0ZEAAYAiAAEgJ3vPD_BwE

91. IEC 62366-1:2015 - Medical devices — Part 1: Application of usability engineering to medical devices [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/63179.html

92. IEC 62304:2006/Amd 1:2015 - Medical device software — Software life cycle processes — Amendment 1 [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/64686.html

93. IEC 60825-1 Ed.3.0 “Safety of Laser Products - Part 1” (PDF) at Rockwell Laser Industries [Internet]. [cited 2023 May 14]. Available from: https://www.rli.com/Products/Product.aspx?idproduct=850

94. ISO - ISO 13485 — Medical devices [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/iso-13485-medical-devices.html

95. ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/68936.html

96. ISO 17664:2017 - Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/62952.html

97. ISO 17665-1:2006 - Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/43187.html

98. ISO 10993-1:2018 - Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process [Internet]. [cited 2023 May 14]. Available from: https://www.iso.org/standard/68936.html

99. Tibial Rotational Alignment in Total Knee Arthroplasty Preliminary Report of the Tibial Rotation Study Group of European Knee Associates (EKA) Reha N. Tandogan (1) , Pier Indelli (2) , Mo Saffarini (3) , Alfredo-Schiavone Panni (4) , Ersin Ercin (5).

100. Hospital Clínic de Barcelona | Hospital Clínic Barcelona [Internet]. [cited 2022 May 7]. Available from: https://www.clinicbarcelona.org/ca/asistencia/sobre-el-clinic

101. Higuchi T, Koseki H, Yonekura A, Chiba K, Nakazoe Y, Sunagawa S, et al. Comparison of radiological features of high tibial osteotomy and tibial condylar valgus osteotomy. BMC Musculoskelet Disord. 2019;20(1):1–11.

102. Lin YH, Chang FS, Chen KH, Huang KC, Su KC. Mismatch between femur and tibia coronal alignment in the knee joint: classification of five lower limb types according to femoral and tibial mechanical alignment. BMC Musculoskelet Disord. 2018 Nov 24;19(1).

103. Vermue H, Luyckx T, Winnock de Grave P, Ryckaert A, Cools AS, Himpe N, et al. Robot-assisted total knee arthroplasty is associated with a learning curve for surgical time but not for component alignment, limb alignment and gap balancing. Knee Surgery, Sports Traumatology, Arthroscopy. 2022 Feb 1;30(2):593–602.

104. Tibial Rotational Alignment in Total Knee Arthroplasty Preliminary Report of the Tibial Rotation Study Group of European Knee Associates (EKA) Reha N. Tandogan (1) , Pier Indelli (2) , Mo Saffarini (3) , Alfredo-Schiavone Panni (4) , Ersin Ercin (5).

105. Scuderi GR, Bourne RB, Noble PC, Benjamin JB, Lonner JH, Scott WN. The new knee society knee scoring system. Clin Orthop Relat Res. 2012 Jan 1;470(1):3–19.

106. Rolfson O, Wissig S, van Maasakkers L, Stowell C, Ackerman I, Ayers D, et al. Defining an International Standard Set of Outcome Measures for Patients With Hip or Knee Osteoarthritis: Consensus of the International Consortium for Health Outcomes Measurement Hip and Knee Osteoarthritis Working Group. Arthritis Care Res (Hoboken). 2016 Nov 1;68(11):1631–9.

107. Hamilton DF, Lane J V., Gaston P, Patton JT, MacDonald DJ, Simpson AHRW, et al. Assessing treatment outcomes using a single question: the net promoter score. Bone Joint J. 2014;96-B(5):622–8.

108. Robotic-assisted Versus Conventional Total Knee Arthroplasty - Full Text View - ClinicalTrials.gov [Internet]. [cited 2022 May 7]. Available from: https://clinicaltrials.gov/ct2/show/NCT04982198

109. Comparison of Alignment Achieved Using the VELYS Robotic-Assisted Solution Versus Manual Instrumentation in Total Knee Arthroplasty - Full Text View - ClinicalTrials.gov [Internet]. [cited 2022 May 7]. Available from: https://clinicaltrials.gov/ct2/show/NCT04730271

110. Lee KJ, Moon JY, Song EK, Lim HA, Seon JK. Minimum two-year results of revision total knee arthroplasty following infectious or non-infectious causes. Knee Surg Relat Res. 2012 Dec 1;24(4):227–34.

111. Heesterbeek PJC, Beumers MPC, Jacobs WCH, Havinga ME, Wymenga AB. A comparison of reproducibility of measurement techniques for patella position on axial radiographs after total knee arthroplasty. Knee. 2007;14(5):411–6.

112. Abdelnasser MK, Elsherif ME, Bakr H, Mahran M, Othman MHM, Khalifa Y. All types of component malrotation affect the early patient-reported outcome measures after total knee arthroplasty. Knee Surg Relat Res. 2019;31(1):1–11.

ANNEXES

ANNEX 1 – SUMMARY OF RESULTS ARTICLE OF PARRATTE ET AL.

Table 21 – Descriptive statistics of the variables of study

Angles		Mean ± Standard Deviation (SD) (°)	Root Mean Square (RMS)
Femoral	Coronal	0,03 ± 0,51	0,5
	Sagital	-0,95 ± 0,88	1,29
Tibial	Coronal	-0,06 ± 0,69	0,68
	Slope	0,20 ± 0,84	0,84
Global	HKA	-0,03 ± 0,87	0,85

ANNEX 2 – SUMMARY OF RESULTS ARTICLE HAMPP ET AL.

Table 22 - Measurement of component position medians and standard deviations for RATKA versus MTKA

Anatomical location	Median		SD		
	RATKA (°)	MTKA (°)	RATKA (°)	MTKA (°)	T-test SD, p-value
Femoral distal varus or valgus deviation	0.6	3.2	0.3	1.4	0.003
Femoral distal flexion or extension deviation	0.6	2.8	0.5	2.1	0.009
Femoral internal or external deviation	0.8	3.1	0.5	1.6	0.045
Tibial varus or valgus deviation	0.9	0.9	0.4	0.8	0.022
Tibial anterior or posterior slope deviation	1.1	1.5	1.6	1.3	0.093

Table 23 - Measurement of bone cut medians and standard deviations for RATKA versus MTKA

Anatomical location	Median		SD		
	RATKA (°)	MTKA (°)	RATKA (°)	MTKA (°)	T-test SD, p-value
Femoral anterior internal or external deviation	0.9	3.3	0.5	1.9	0.018
Femoral anterior flexion or extension deviation	0.4	4.7	0.4	2.3	0.001
Femoral anterior chamfer varus or valgus deviation	0.5	3.9	0.1	2.2	<0.001
Femoral anterior chamfer flexion or extension deviation	0.3	1.8	0.2	1.0	0.019
Femoral distal varus or valgus deviation	0.5	2.6	0.3	1.6	0.004
Femoral distal flexion or extension deviation	0.8	0.8	0.5	1.1	0.091
Femoral posterior chamfer varus or valgus deviation	1.1	2.6	0.4	2.0	<0.001
Femoral posterior chamfer flexion or extension deviation	0.9	0.8	0.5	1.6	0.075
Femoral posterior internal or external deviation	1.0	2.5	0.6	1.6	0.043
Femoral posterior flexion or extension deviation	0.5	2.3	0.6	4.0	0.054
Tibial varus or valgus deviation	0.6	1.2	0.3	0.7	0.007
Tibial anterior or posterior slope deviation	0.7	0.9	1.0	0.3	0.9

ANNEX 3 – SUMMARY OF ACCURACY RESULTS OF VELYS ROBOT BY JOHNSON & JOHNSON

Measure		MTKA (°)	VELYS Robotic-Assisted (°)
Femoral resection	Flexion-Extension	1.9 ± 1.5	1.7 ± 1.3
	Varus-Valgus	1.4 ± 1.0	0.6 ± 0.5
	Internal External	1.0 ± 0.7	1.0 ± 0.8
Tibial resection	Flexion-Extension	1.6 ± 1.4	1.6 ± 1.1
	Varus-Valgus	1.7 ± 1.3	0.9 ± 0.7
Femoral Alignment	Flexion-Extension	2.5 ± 2.1	1.5 ± 1.1
	Varus-Valgus	1.4 ± 1.1	0.9 ± 0.8
	Internal External	1.0 ± 0.9	1.1 ± 0.8
Tibial Alignment	Flexion-Extension	1.7 ± 1.5	1.4 ± 1.1
	Varus-Valgus	2.0 ± 1.4	1.3 ± 0.8

Table 24 - Resection accuracy of conventional vs VELYS Robotic-Assisted TKAs

Para empezar, es muy importante destacar que en todas las imágenes radiológicas se tendrá que comprobar que estén bien calibradas ya que algunas variables se basan en distancias (medidas en milímetros). Es decir, asegurar cuantos mm se corresponden a 1 cm ya que no siempre 10 mm de imagen se corresponden a 1cm. En caso de que no sea así, es necesario usar siempre un factor de conversión con todas las variables que se extraigan (multiplicar los mm obtenidos durante la medición por la relación 1cm/x mm que se haya encontrado al inicio).

PLANO CORONAL

En el plano coronal, el criterio para asignar valores positivos o negativos se definirá siguiendo los términos de varo y valgo.

- Rodilla en valgo o genu valgum: la rodilla presenta una inclinación medial (hacia dentro). Por esta razón, la rodilla ejerce una mayor presión sobre la superficie externa (lateral) de la articulación.
- Rodilla en varo o genu varum: la rodilla presenta una inclinación lateral (hacia afuera). Por esta razón, la rodilla ejerce una mayor presión sobre la parte interna de la rodilla (más comprensión sobre el menisco interno).

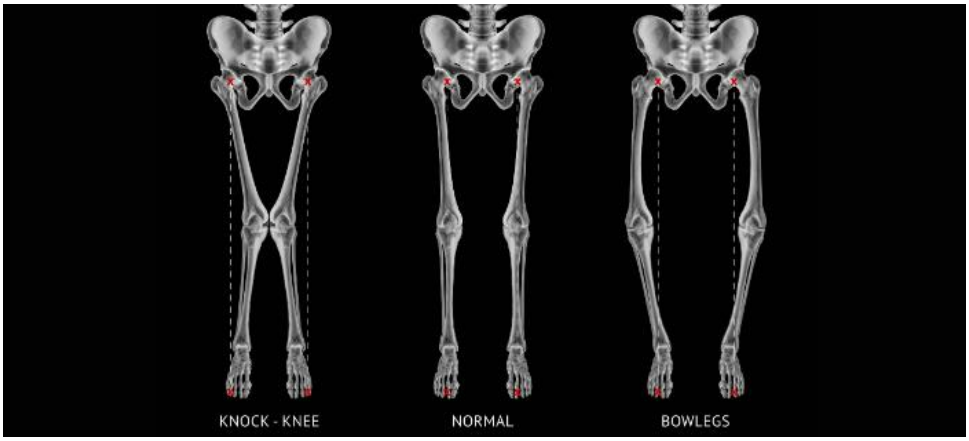


Figura 1 - Rodillas valgas, normales y varas (respectivamente)

Tal y como se puede identificar en la figura anterior, cuando el eje mecánico de la extremidad afecta (línea discontinua) se encuentra más lateral que los ejes a estudiar, se definirá un ángulo VALGO. Mientras que cuando el eje mecánico de la extremidad afecta se encuentre más medial que los ejes a estudiar, se definirá un ángulo VARO. A simple vista se puede reconocer que el genus valgus direcciona las rodillas hacia dentro (como una bailarina), mientras que el genus varus hacia fuera (como un "cowboy").

Eje mecánico de la extremidad afecta

Se dibuja con una línea recta desde el centro de la cabeza femoral hasta el centro de la articulación tibio-astragaliana (54).

- Para encontrar el centro exacto de la cabeza femoral se puede dibujar una circunferencia que rodee toda la cabeza femoral y, de ahí, marcar el centro (como en la figura 2).
- El centro de la articulación tibio-astragaliana se puede encontrar con la proyección del punto medio de la recta amarilla de la figura 3 (recta que une la punta del maléolo lateral y la cortical más

prominente del medial) sobre una recta que una toda la articulación tibio-astragalina (línea blanca de la figura 3) (54).

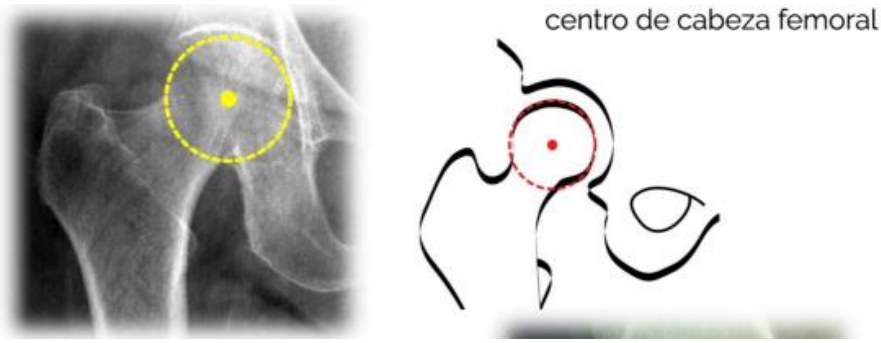


Figura 2 – Ejemplos para encontrar el centro de la cabeza femoral

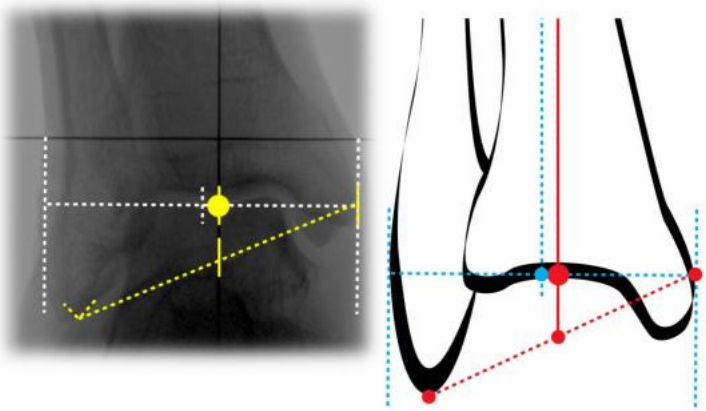


Figura 3 – Ejemplos para encontrar el centro de la articulación tibio-astragalina

En las siguientes fotografías se ejemplifica el eje mecánico de la extremidad afecta.

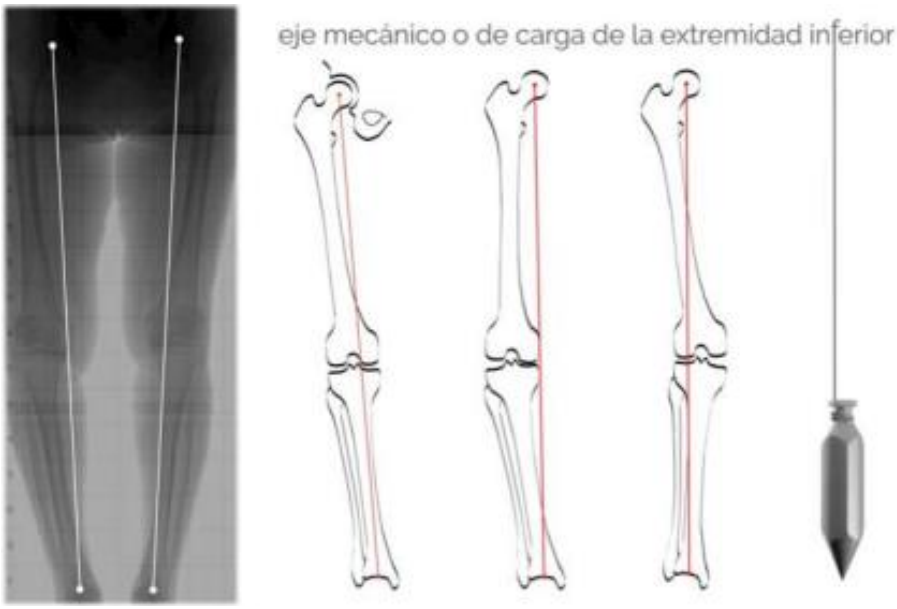


Figura 4 - Eje mecánico de la extremidad inferior sin intervención ATR

Figura 5 - Eje mecánico de la extremidad inferior intervenida con ATR

Altura de la interlínea articular/Joint Line Height (JLH)

Esta altura se definirá a partir de la técnica IJLCM (57). Se seguirán diferentes pasos para las rodillas sin operar o ya operadas y con la prótesis.

TÉCNICA IJLCM EN XR/TELEMETRÍA/TC PREOPERATORIAS

- Se establece el eje anatómico de la tibia (TibAx1 de la figura 6).
- Se dibuja la línea PF1 de la figura 6, cogiendo la perpendicular al eje TibAx1 a la altura del punto más proximal del peroné.
- Se dibuja la *Tibial Height* que representa una línea paralela a TibAx1 que connecta el punto más proximal de la platea tibial de la parte menos afecta con la línea PF1.
- Se dibuja la *Femoral condyle Height* que representa una línea paralela a TibAx1 que connecta el punto más distal del cóndilo femoral de la parte menos afecta con la línea PF1 (57).

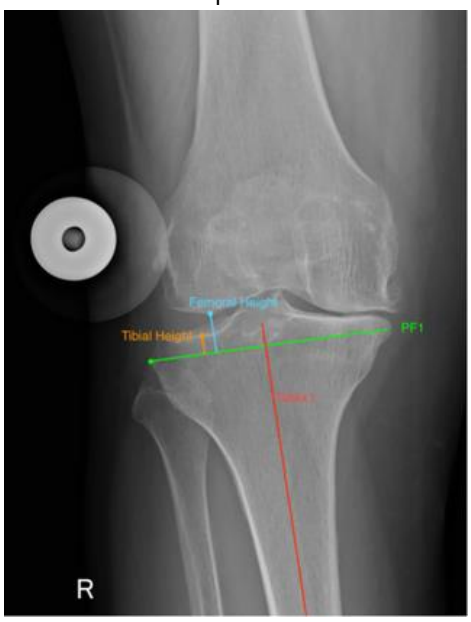


Figura 6 - JLH preoperatoria

Finalmente, se calcula la JLH preoperatoria como (57) :

$$Preoperative\ JLH\ (mm) = \frac{Tibial\ Height\ (less\ afected\ side) + Femoral\ Height\ (less\ affected\ side)}{2}$$

TÉCNICA IJLCM EN XR/TELEMETRÍA/TC POSTOPERATORIA

- Se establece el eje anatómico de la tibia (TibAx1 de la figura 7).
- Se dibuja la línea PF1 de la figura 7, para hacerlo se coge la perpendicular al eje TibAx1 a la altura del punto más proximal del peroné.
- Se dibuja la *Medial Joint Line Height* que representa una línea paralela a TibAx1 que empieza en el punto más distal del cóndilo medial femoral y termina en la intersección con PF1.
- Se dibuja la *Lateral Joint Line Height* que representa una línea paralela a TibAx1 que empieza en el punto más distal del cóndilo lateral femoral y termina en la intersección con PF1(57).

Finalmente, se calcula la media de las dos alturas calculadas para encontrar la altura intercondílea en imágenes postoperatorias. Es decir, se usa la siguiente fórmula (57):

$$Posoperative\ JLH\ (mm) = \frac{Medial\ JLH\ Height\ + Lateral\ JLH}{2}$$

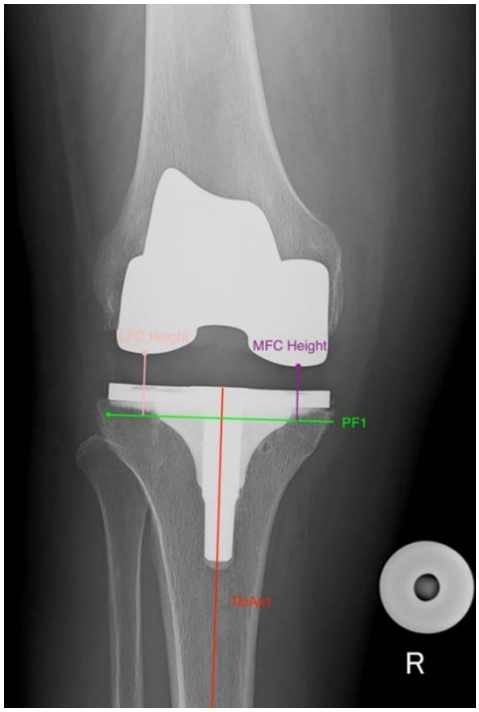


Figura 7 - Metodología para calcular postoperative JLH

Criterio de signos: siempre positivo.

Normalidad: Debido que no se ha encontrado un criterio unánime de normalidad de esta variable, se ha decido coger como referencia los resultados obtenidos del estudio de Popat et al. (57) (de donde se ha obtenido la técnica radiográfica IJLCM). La media de los resultados preoperatorios de JLH es 4.39 mm. En contraposición, no se ha recogido ningún valor posoperatorio.

Joint Line Convergence Angle (JLCA)

Ángulo definido entre el eje o línea articular femoral y el eje o línea articular tibial (58).

- El eje articular femoral se puede encontrar dibujando la tangente a los extremos más distales de ambos cóndilos del fémur. En el caso de las neo articulaciones (rodillas intervenidas), se usarán los cóndilos de la prótesis (como se puede ver en la figura 8).

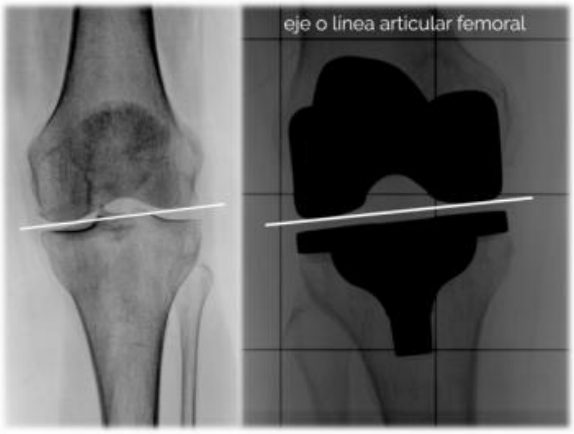


Figura 8 - Eje o línea articular femoral en rodillas sin intervención por ATR (derecha) o intervenidas por ATR (izquierda)

- El eje articular tibial es la línea entre los puntos de mayor concavidad de los platos tibiales. Debido a los cortes óseos realizados en la intervención ATR, el eje articular tibial se redefinirá como una línea a nivel de la base de la bandeja tibial en las neo articulaciones postoperatorias (figura 9).

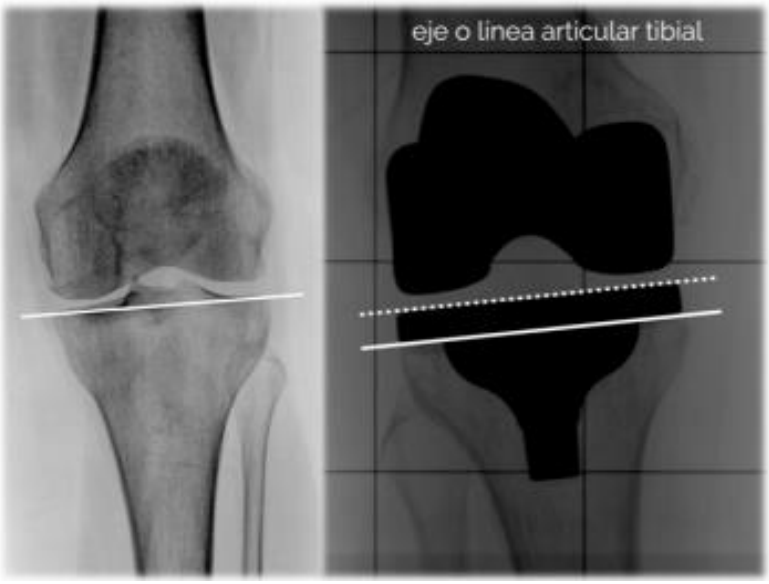


Figura 9 – Eje o línea articular tibial en rodillas sin intervención por ATR (izquierda) o intervenidas por ATR (derecha)

Fotografías ejemplo:

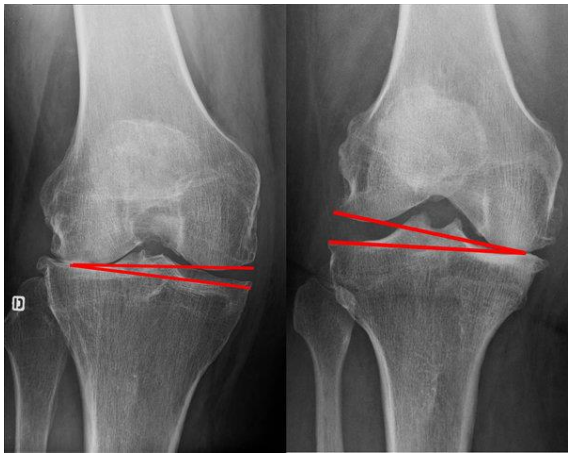


Figura 10 - JLCA en diferentes rodillas sin intervención ATR

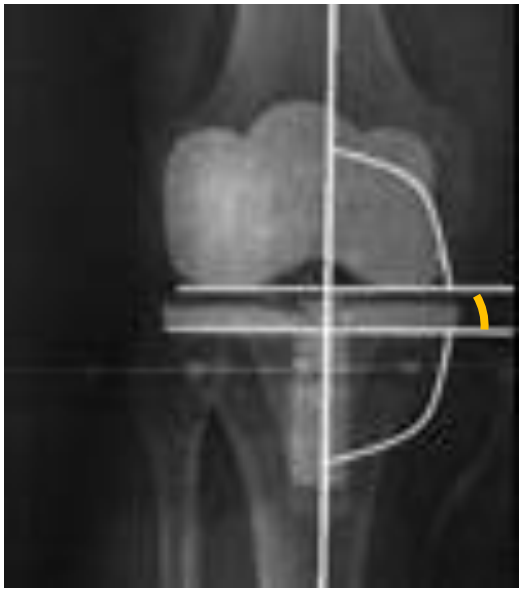


Figura 11 - JLCA (en amarillo) en una rodilla intervenida por ATR

Criterio de signos: Como se ha comentado anteriormente, en el plano coronal se usará los conceptos de varo-valgo. Para esta variable, se considerarán como valores positivos las rodillas varas (inclinación lateral, y como consecuencia se ejerce presión en la parte medial) y como valores negativos aquellas rodillas valgas (una inclinación medial, de modo que se ejerce presión en la parte más lateral de la rodilla). En la figura 10, por ejemplo, la rodilla izquierda se considera valga (tiene una inclinación medial y la altura de la interlínea articular muestra como en la parte más lateral se está ejerciendo más presión); mientras que la rodilla de la derecha sería del genus varus (58).

Normalidad: Los valores de normalidad asociados se encuentran entre los 0 y 2°, que incrementan en función de la severidad y el estado de la osteoartritis .

FÉMUR

Eje anatómico del fémur

Se dibuja con una línea recta entre una referencia proximal (que puede ser la espina iliaca anterosuperior, el punto central del istmo femoral, la punta del trocánter o la fosa piriforme) hasta el centro de la escotadura intercondílea (54).

- Referencia proximal: se pueden diferentes referencias proximales como indica la figura 12. Aun así, se recomienda usar el istmo femoral debido a su perfecta repetibilidad durante las mediciones. Para encontrar el istmo femoral se tiene que buscar la región de la diáfisis femoral con menor diámetro. Seguidamente, se dibujan dos circunferencias cercanas que tengan el mismo diámetro que el istmo femoral (tal y como se ve en la figura 13) y se usan ambos centros de las circunferencias para recrear la línea que se une con la referencia distal.

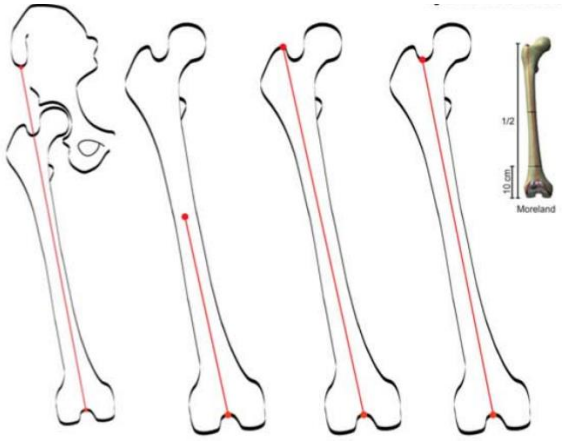


Figura 12 - Se pueden usar diferentes referencias proximales: (de izquierda a derecha)

Figura 13 - Metodología para encontrar el istmo tibial

- Referencia distal: el centro de la escotadura intercondílea de la rodilla preoperatoria o post.

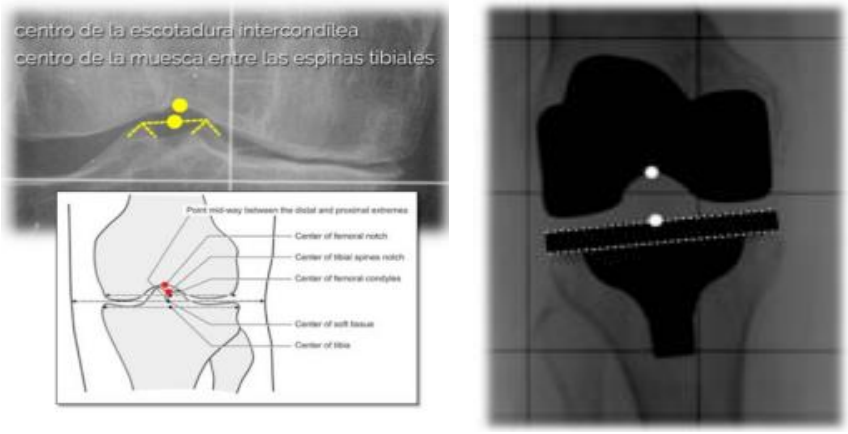


Figura 14 - Centro de la escotadura intercondílea de la rodilla antes de la operación y después

Fotografías ejemplo:

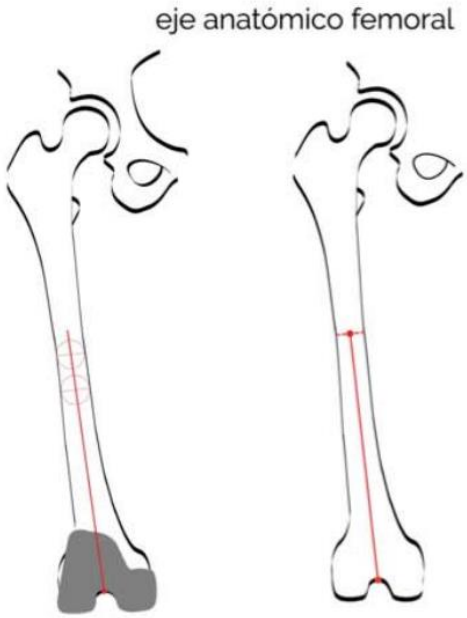


Figura 15 - Eje anatómico femoral

Eje mecánico del fémur

Se encuentra con una línea desde el centro de la cabeza femoral hasta el centro de la escotadura intercondílea (54). *La forma de encontrar el centro de la cabeza femoral o el centro de la escotadura intercondílea ya se ha definido con anterioridad.*

Fotografías ejemplo:

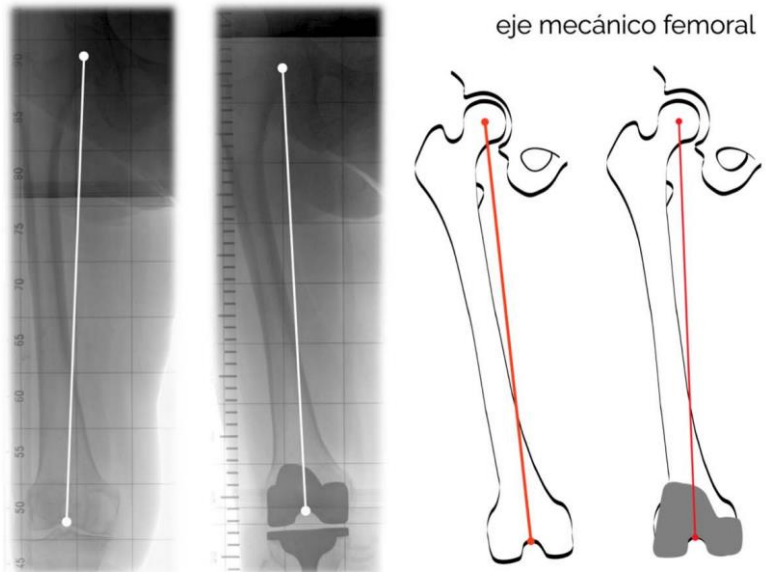


Figura 16 - Eje mecánico femoral

Mechanical Lateral Distal Femoral Angle (mLDFA)

Ángulo lateral entre el eje mecánico del fémur y el eje articular femoral (línea definida por los puntos distales de los cóndilos medial y lateral del fémur) (55). La línea articular femoral y el eje mecánico del fémur ya se han descrito en apartados anteriores.

Fotografías ejemplo:

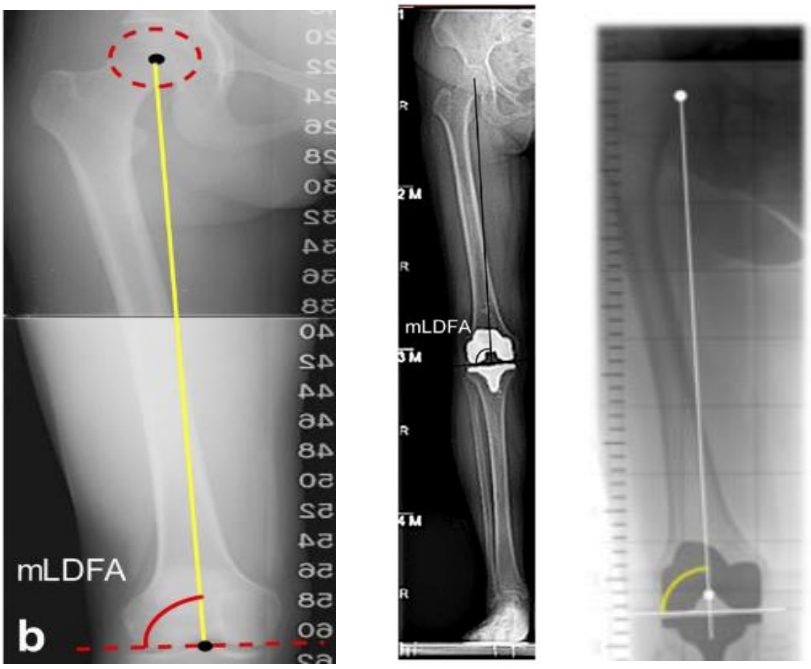


Figura 17 - mLDFA como el ángulo entre el eje mecánico femoral y la línea articular femoral

Criterio de signos: Se coge el ángulo obtenido al trazar los ejes.
Normalidad: los valores de normalidad asociados se encuentran en el siguiente rango: [85°, 90°] (59).

TIBIA

Eje anatómico o mecánico de la tibia

Se dibuja con una línea entre el punto medio del componente tibial o de las espinas tibiales hasta el centro de la articulación tibioastragaliana (54). En este caso se considera que el eje anatómico y mecánico son el mismo.

- El centro de la muesca entre los espines tibiales en la rodilla preoperatoria se puede encontrar dibujando una línea de unión entre la punta de cada meseta y cogiendo su centro (figura 17). En el caso de la neo articulación se usa el centro de la bandeja tibial.

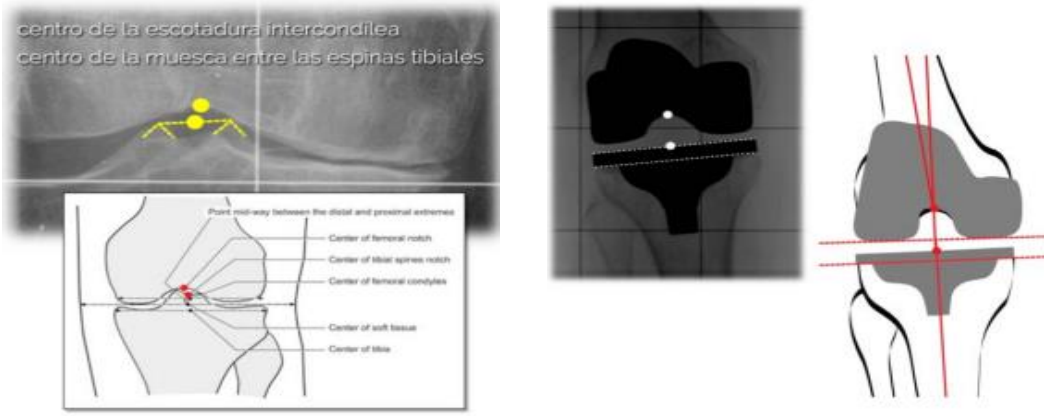


Figura 18 - En amarillo se pueden ver las marcas que se usan para reconocer el centro de la parte proximal tibial. En el caso de la bandeja tibial el proceso es más sencillo

Fotografías ejemplo:

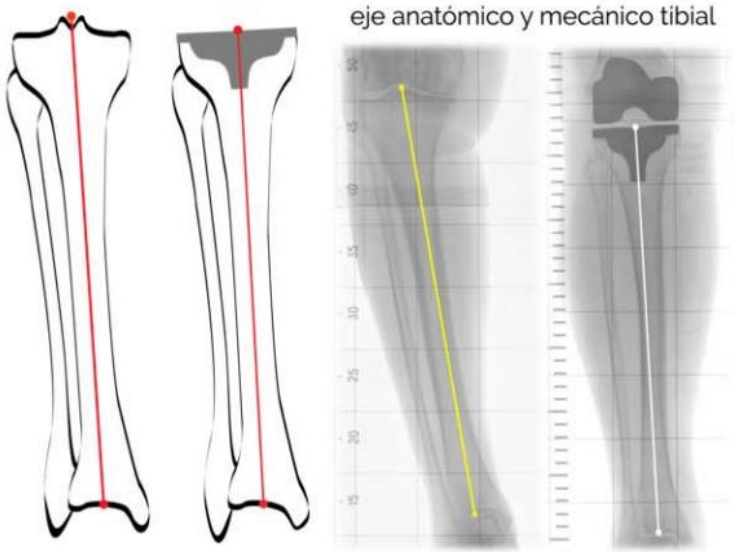


Figura 19 - Eje anatómico y mecánico tibial

Mechanical Medial Proximal Tibial Angle (mMPTA)

Ángulo medial entre el eje mecánico de la tibia y la línea articular tibial (55). El eje mecánico de la tibia y la línea articular tibial ya se han definido en apartados anteriores.

Fotografías ejemplo:

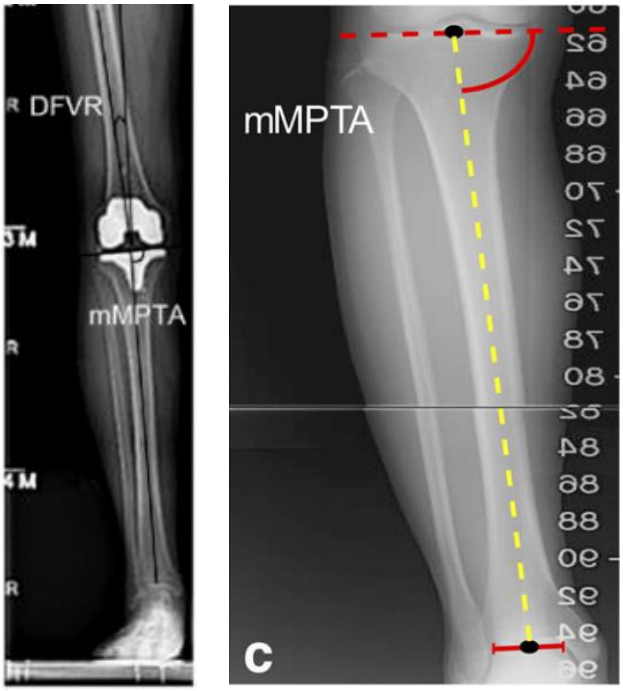


Figura 20 - mMPTA

Hip-Knee-Ankle angle (HKA)

Se define como el ángulo debido a la intersección de los ejes mecánicos femoral y tibial (definidos anteriormente) (54).

Fotografías ejemplo:

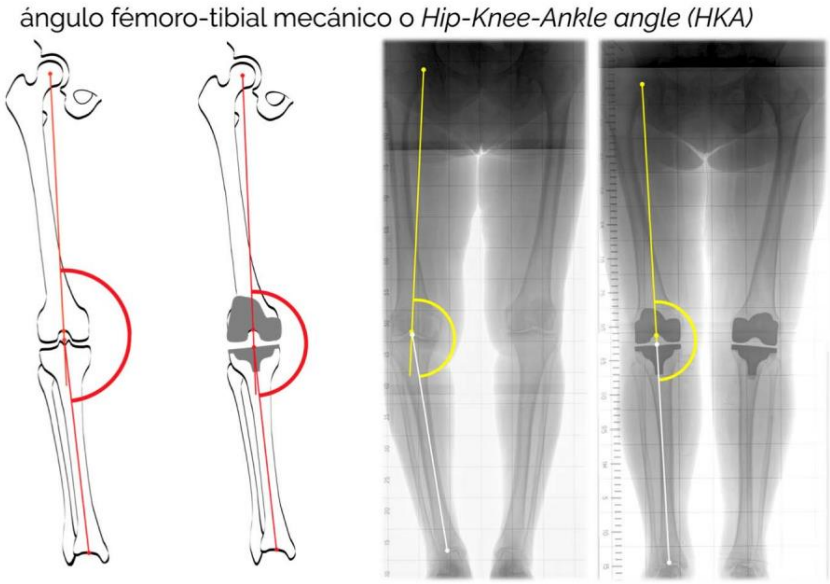


Figura 21 – HKA

Criterio de signos: Paralelamente, los valores angulares que el software RAIMVIEWer muestra se referenciaran respecto varo y valgo. Consecuentemente, el valor final que se guardará será: 180 – x (donde *x* es el valor obtenido entre los ejes mecánicos del fémur y la tibia). El valor se considerará como positivo para aquellas rodillas en genus varus, mientras que negativa para los casos valgo (55).
Normalidad: Una rodilla en alineación neutral se encuentra entre 1-1,5° varo. Aun así, se considera un HKA en individuos sanos de entre 1° valgo hasta 3,2° varo. Utilizando el criterio de signos comentado con anterioridad, el HKA en individuos sanos se sitúa entre -1° hasta 3,2° (valgo negativo y varo positivo) (56).

PLANO SAGITAL

Altura patelar

En este documento se plantearán dos metodologías a realizar: Insall-Salvati y Blackburne-Peel.

TÉCNICA INSALL-SALVATI

Define una ratio entre la *Patellar Tendon length* (TL) y la *Patellar length* (PL) (60).

$$Insall - Salvati\ ratio = \frac{TL}{PL}$$

- TL: longitud entre la superficie posterior del tendón des del polo inferior de la patela hasta su inserción en la tibia (en la tuberosidad tibial).
- PL: longitud máxima de la patela, medido des del polo distal al proximal.

Figura 22 – La letra A representa a TL, mientras que la B a PL.

Normalidad: Los valores de normalidad vienen definidos en función del valor obtenido en la ratio. En los estudios de radiografías se considera (61):

- Una patela baja cuando la ratio es menor a 0,8
- Una patela normal cuando la ratio se encuentra entre 0,8 y 1,2
- Una patela alta cuando es superior a 1,2.

CATON-DESCHAMPS INDEX

Define una ratio entre:

- A: distancia entre el ángulo anterior de la meseta tibial, a la cara más inferior de la superficie articular rotuliana

- B: longitud de la superficie articular rotuliana (62).

$$Caton - Deschamps\ Index = \frac{A}{B}$$

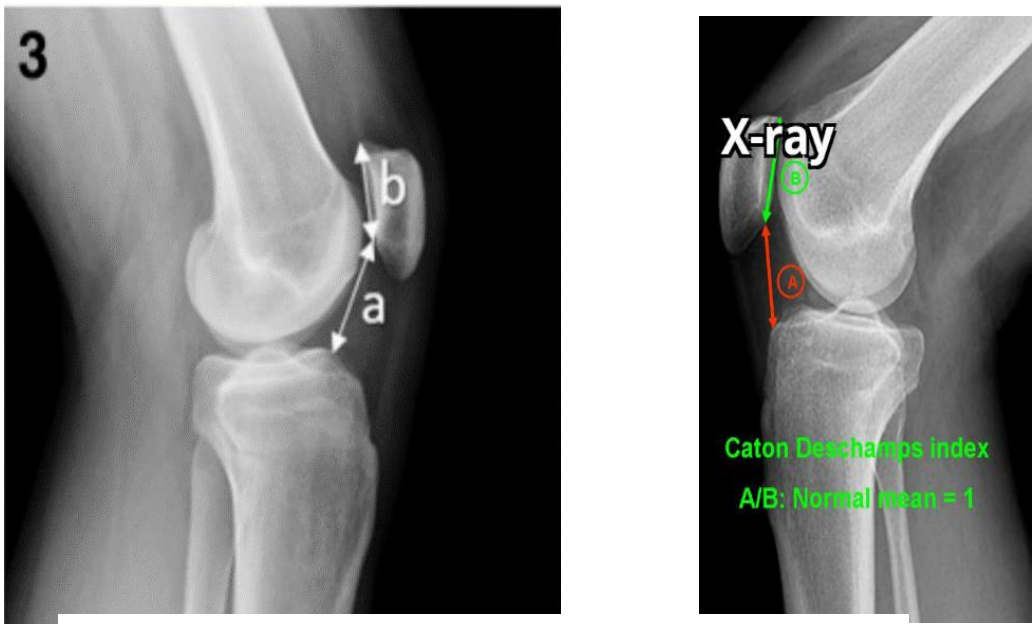
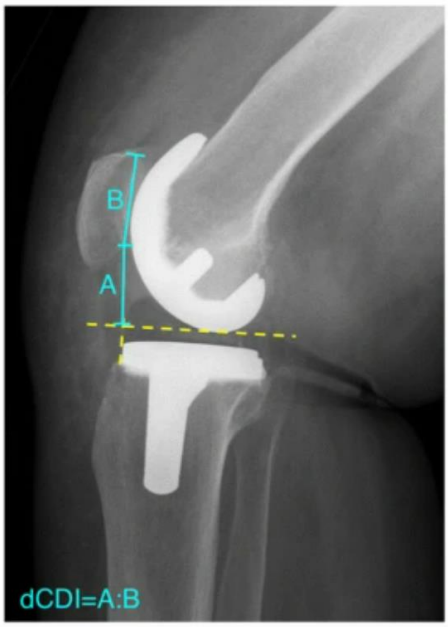


Figura 23 - Caton-Deschamps ratio

Normalidad: Los valores de normalidad vienen definidos en función del valor obtenido en la ratio. En los estudios de radiografías se considera (62):

- Una patela baja cuando la ratio es menor a 0,6
- Una patela normal cuando la ratio se encuentra entre 0,6 y 1,3
- Una patela alta cuando es superior a 1,3.



FÉMUR

Pendiente femoral/Posterior Distal Femoral Angle

TÉCNICA EN XR/TELEMETRÍA PREOPERATORIAS

Se define como el ángulo entre el eje anatómico femoral distal endomedular y la línea que une la parte posterior donde termina el cóndilo con la parte anterior donde empieza.

- Para encontrar el eje anatómico femoral distal endomedular se puede usar la siguiente metodología: se pueden unir los puntos medios del diámetro externo del canal a 5 y 10 centímetros de la interlínea como se puede ver en la figura 23. Los puntos medios se pueden encontrar gracias a la realización de circunferencias en el fémur en las posiciones establecidas (5 y 10 cm) (54).

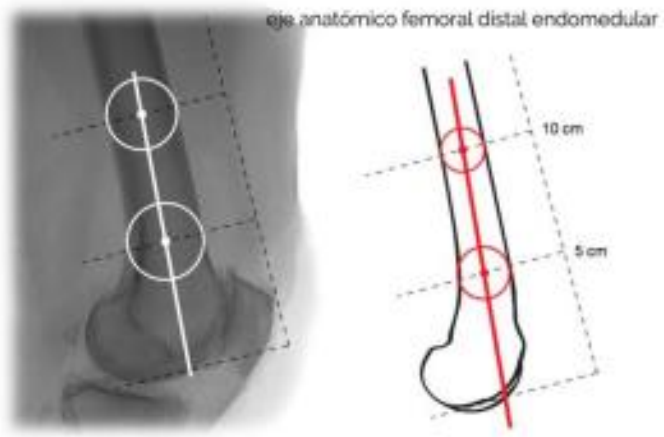


Figura 24 - Técnica para dibujar el eje anatómico femoral distal endomedular

- La línea que une la parte anterior donde empieza el cóndilo y la parte posterior donde termina se puede dibujada en la figura 24 en color amarillo.

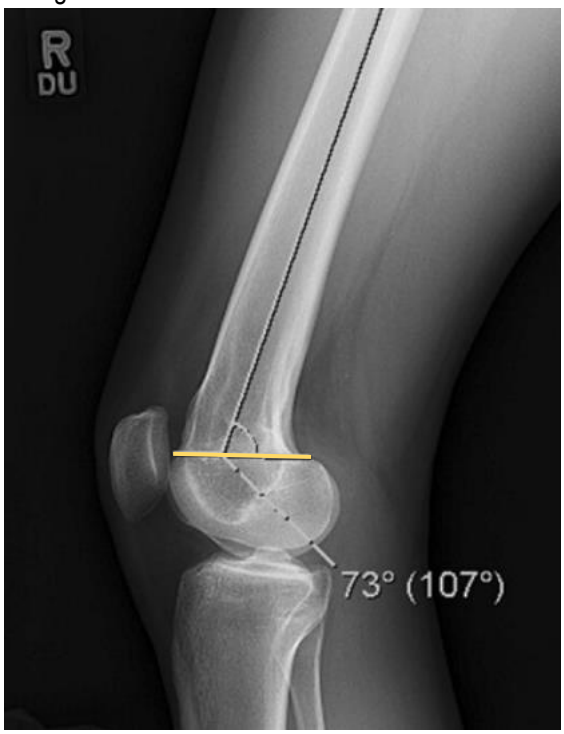


Figura 25 - PDFA en rodilla preoperatoria

TÉCNICA EN XR/TELEMETRÍA POSOPERATORIAS

Se define como el ángulo entre el eje anatómico femoral distal endomedular y la línea del plano de corte distal femoral en su vertiente posterior (54).

- Para encontrar el eje anatómico femoral distal endomedular se puede usar la siguiente metodología: se pueden unir los puntos medios del diámetro externo del canal a 5 y 10 centímetros de la interlínea como se puede ver en la figura 25. Los puntos medios se pueden encontrar gracias a la realización de circunferencias en el fémur en las posiciones establecidas (5 y 10 cm).

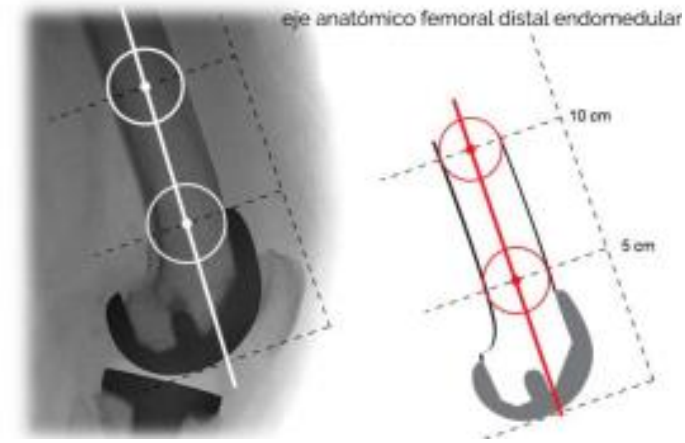


Figura 26 - Metodología para encontrar el eje anatómico femoral distal endomedular

- El corte distal femoral se traza con una línea paralela a la línea de corte realizada en la operación.

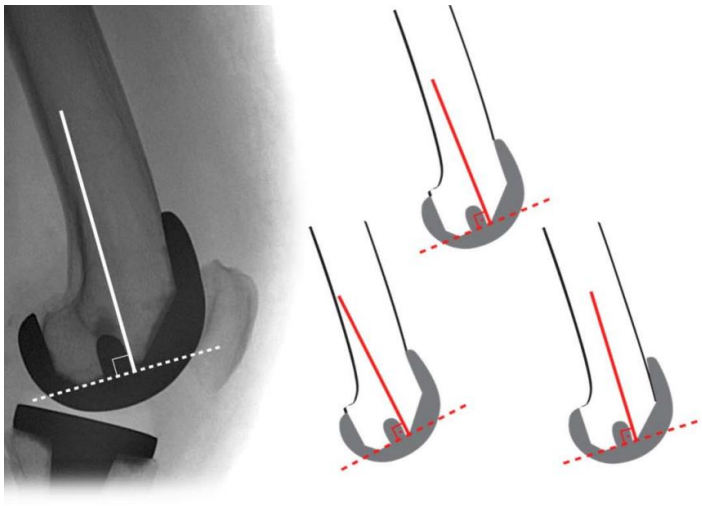


Figura 27 - La línea discontinua marca el corte distal femoral

Fotografías ejemplo:

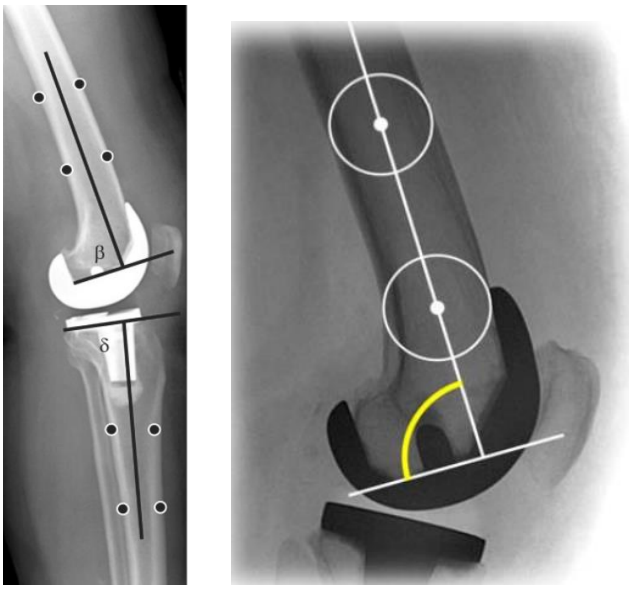


Figura 28 - Pendiente femoral

Offset condilar anterior

Se puede encontrar calculando la distancia (mm) entre el eje anatómico distal anterior y una línea paralela a esta y tangente a la proyección más anterior de la tróclea femoral (o del escudo anterior prostético en las rodillas intervenidas) (54).

- *El eje anatómico distal anterior representa una línea tangente a la cortical anterior femoral. Una metodología que seguir para dibujar el eje es la siguiente: coger dos puntos sobre la cortical anterior a 5 y 10 cm de la interlínea y unirlos para trazar una recta (figura 28).*

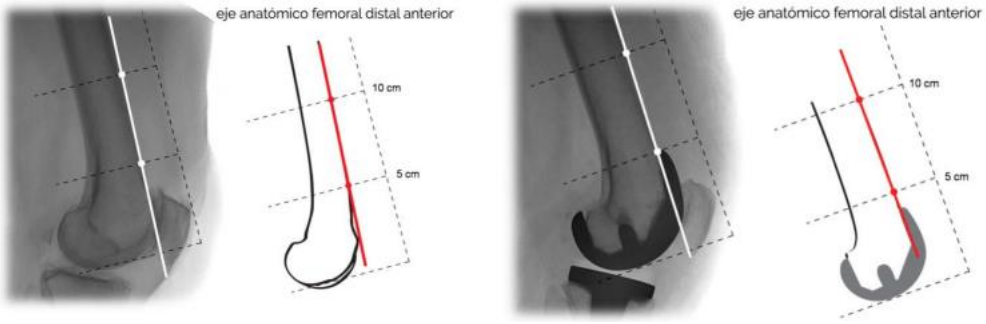


Figura 29 - Metodología para encontrar la tangente a la cortical femoral

- La tangente a la proyección más anterior de la tróclea femoral (o del escudo anterior prostético) se puede dibujar según la figura 29.

Figura 30 - La línea amarilla anterior representa la tangente a la proyección más anterior

Fotografías ejemplo:

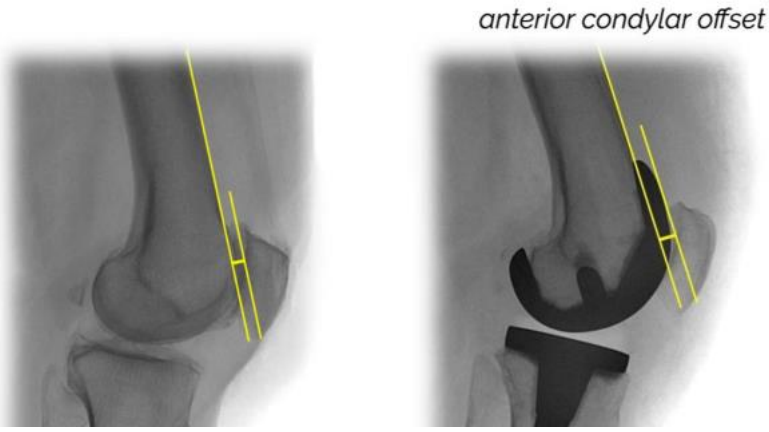


Figura 31 - La línea que une las dos rectas paralelas es el offset condilar anterior y representa una distancia

Offset condilar posterior

Se define como la distancia (mm) desde el punto más posterior de los cóndilos hasta la línea tangente a la porción distal de la cortical posterior femoral (54).

- Para dibujar una línea tangente a la porción distal de la cortical posterior femoral se puede seguir la misma metodología definida anteriormente para la cortical anterior. Se cogen dos puntos como referencia a 5 y 10 centímetros de la interlínea y con estos se traza una recta.
- El punto más posterior de los cóndilos se puede definir a simple vista.
- Es importante que el ángulo entre la recta que une el punto más posterior de los cóndilos y la tangente a la porción distal de la cortical posterior femoral sea de 90 grados (de esta forma se habla de la mínima distancia).

En la figura 31 se puede reconocer el offset condilar posterior (a).

Ratio offset condilar posterior

Paralelamente, también se recogerá la ratio offset condilar posterior con el fin de obviar sesgos debido a la magnificación radiográfica. De esta forma se usará como segundo dato el diámetro medido a 25 mm desde el final del escudo anterior del implante y después se calculará la relación entre las dos distancias calculadas (como se ve en la figura 31) (54).

Fotografías ejemplo:

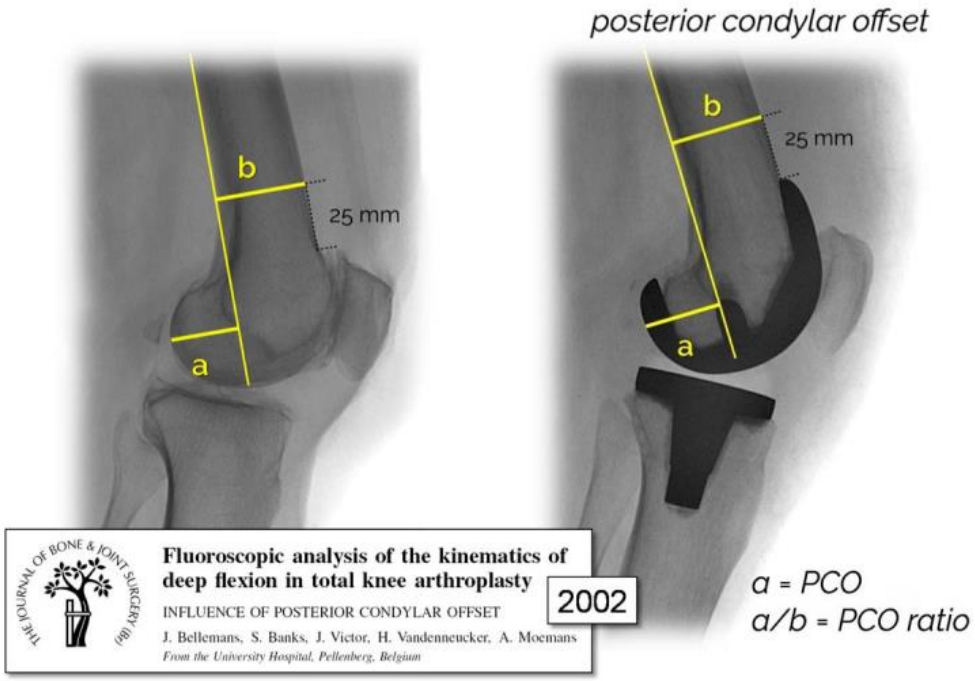


Figura 32 - En esta figura se puede ver el offset condilar posterior (a) y la ratio offset condilar posterior. Tal y como se puede ver el diámetro femoral (b) se calcula a 25 mm de distancia del escudo anterior del implante

TIBIA

Pendiente tibial posterior / Posterior Proximal Tibial Angle (PTTA)

Se define como el ángulo entre el eje tibial sagital anatómico y el eje articular tibial.

- El eje articular tibial ya se ha definido con anterioridad.
- El eje tibial sagital anatómico se encuentra uniendo el punto medio diafisario más caudal de la radiografía con el punto medio a 10 cm de la interlínea (para definir los puntos medios se usan circunferencias) (54).

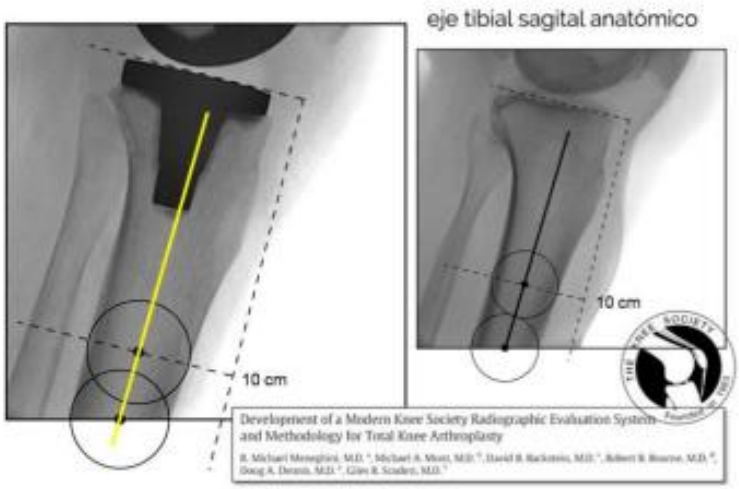


Figura 33 - Metodología para encontrar el eje tibial sagital anatómico

Fotografías ejemplo:

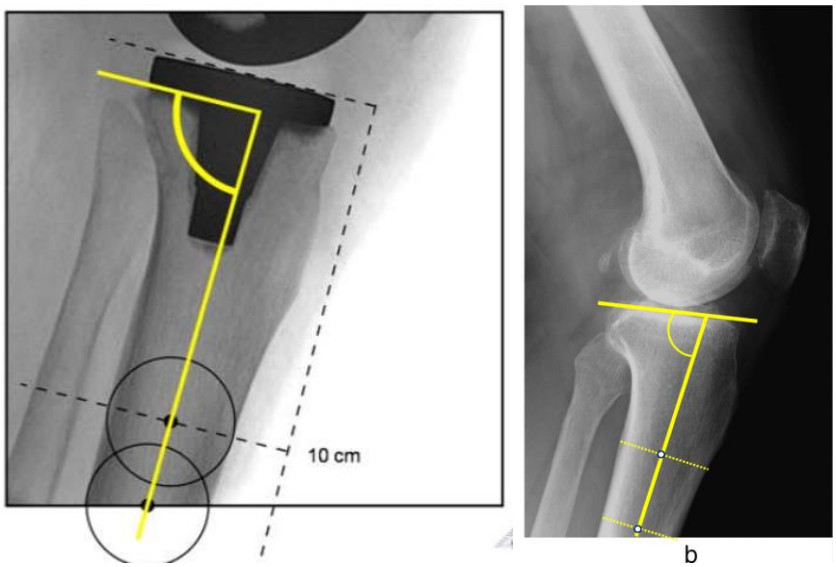


Figura 34 – PTTA

PLANO AXIAL

Lateral patellar tilt

Ángulo formado por la línea definida por los puntos más anteriores de los cóndilos femorales y una línea que resigue la interfase prótesis-hueso (63) (64).

Los valores se considerarán como positivos cuando haya una rotación externa (es decir, una inclinación lateral) (64).

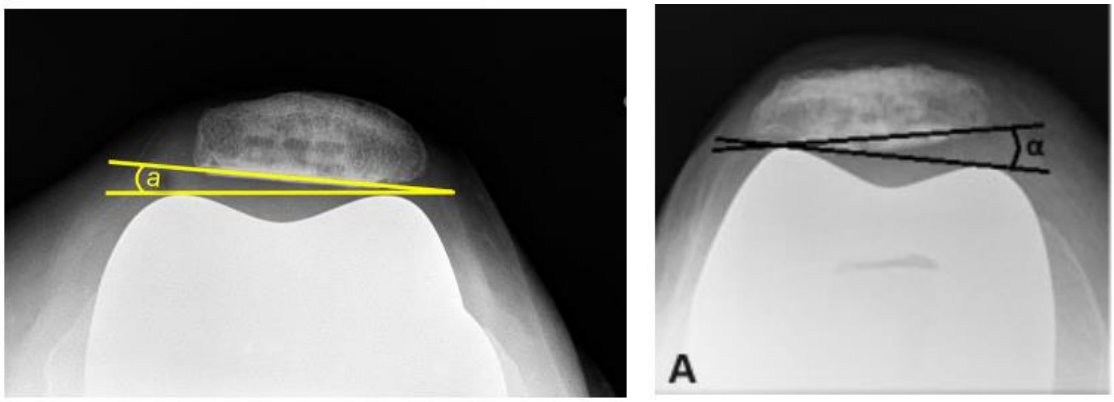


Figura 35 - Lateral Patellar Tilt medido como el ángulo entre la línea más anterior en contacto con los cóndilos femorales y una línea que resigue la interfaz prótesis-hueso

Patellar displacement

Distancia entre una línea que cruza por el surco intercondilar y es perpendicular a la línea dibujada por los límites anteriores de los cóndilos femorales y su paralela que cruza por el centro de la rótula (63) (64).
Los valores se considerarán como positivos cuando haya un desplazamiento lateral (64).

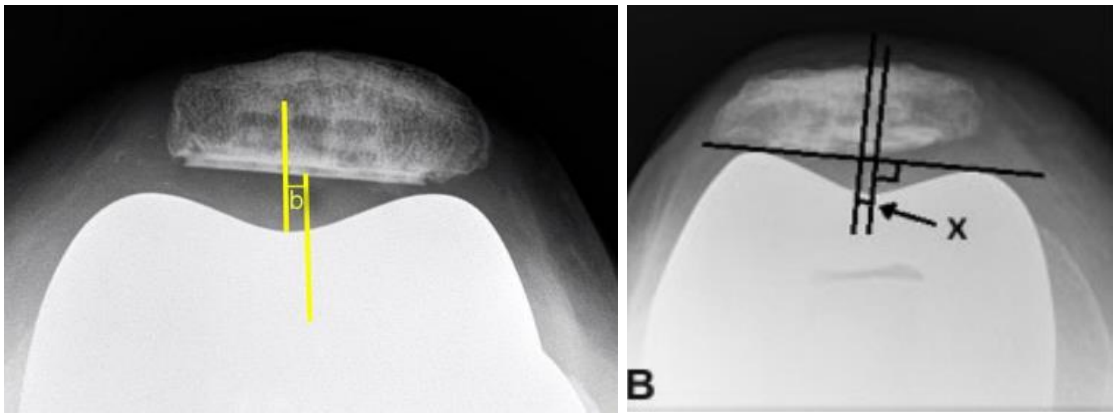


Figura 36 - Patellar displacement (X) medido entre las paralelas que cruzan el surco intercondilar y el punto medio de la rótula

Rotación del componente femoral

METODOLOGÍA 1 – STEA Y PCA. BERGER, BENAZZO

Se define como el ángulo entre los ejes transepicondíleo quirúrgico (sTEA) y el eje bicondíleo posterior (PCA) (65) (66) (67).

- El eje epicondíleo quirúrgico representa la línea que conecta el epicóndilo lateral y el surco del epicondíleo medial (en caso de que en la imagen axial del fémur distal no se visualice este punto, se puede usar el punto central del epicóndilo medial).
- El eje bicondíleo posterior se traza como la línea tangente entre la parte posterior de ambos cóndilos de la prótesis o de la rodilla.

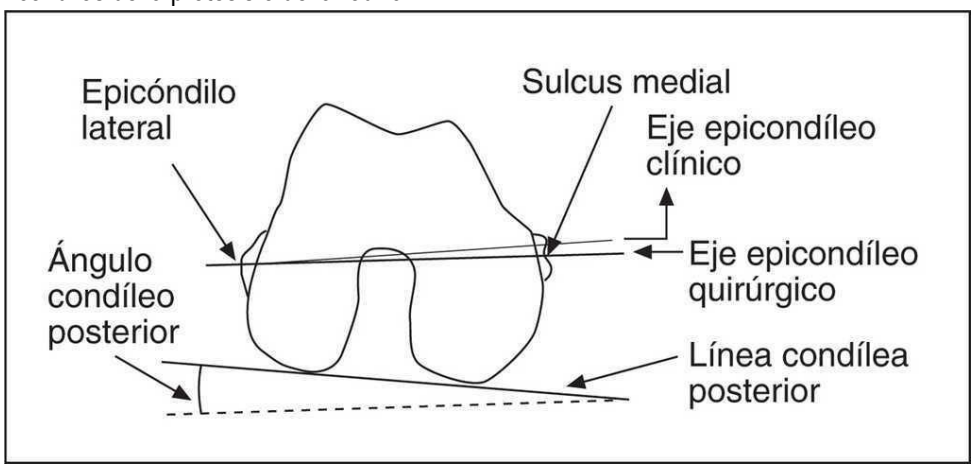


Figura 37 - En este dibujo se pueden ver diferentes ejes en el plano axial.

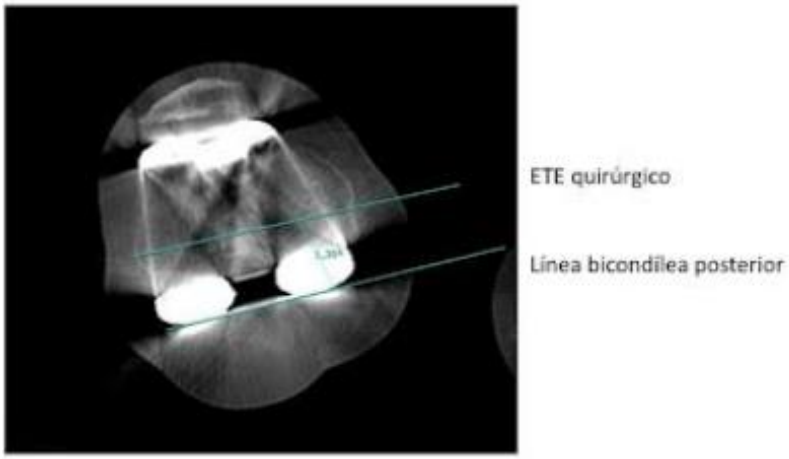


Figura 38 - El ángulo entre los dos ejes representa la rotación del componente femoral

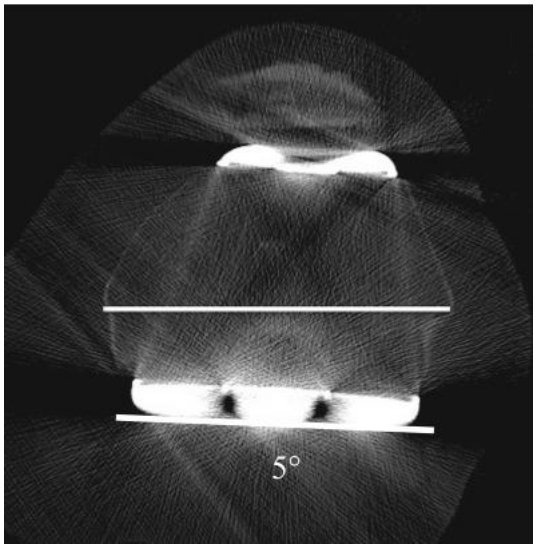


Figura 39 - Ejemplo de rotación del componente femoral

En caso de tener una rotación externa, el ángulo se va a considerar como un valor positivo; mientras que, si la rotación es interna, el ángulo será negativo (66). Se considera como rotación externa cuando la línea bicondílea posterior se inclina provocando así que la prótesis esté ligeramente direccionada en fuera.

METODOLOGÍA 2 – LÜTZNER (68), MATZIOLIS (69)

Se define como el ángulo entre la línea que conecta los "*pins*" de fijación del componente femoral y el eje epicondíleo quirúrgico. En las siguientes fotografías se pueden ver los epicóndilos lateral y medial que definen el eje epicondíleo quirúrgico y los "*pins"* de fijación del componente femoral.

En caso de tener una rotación externa, el ángulo se va a considerar como un valor positivo; mientras que, si la rotación es interna, el ángulo será negativo (66). Se considera como rotación externa cuando la línea bicondílea posterior se inclina provocando así que la prótesis esté ligeramente direccionada en fuera.

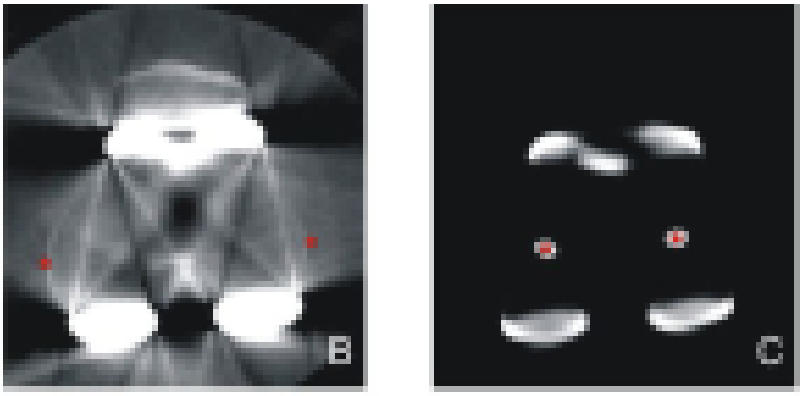


Figura 40 - El ángulo descrito por Lützner corresponde a la intersección de las dos líneas definidas por, por un lado, la unión de los puntos de la primera fotografía (B) y, por otro lado, los puntos de la segunda fotografía (C)

Rotación componente tibial

METODOLOGÍA 1 – BERGER

Se define como el ángulo entre la línea perpendicular al eje posterior del componente tibial y la línea del eje que conecta con el extremo de eje del tubérculo tibial (TTA, tibial tubercule axis), medido desde el centro del platillo tibial (66).

"Para calcular el ángulo se usará la técnica de Berger. Se requiere una selección de tres imágenes:

- *La primera imagen axial muestra justo por debajo de la bandeja tibial. En esta se dibuja el centro geométrico de la tibia (geometric centre of the tibia, GCT). La metodología para encontrar este punto medio se ve reflejada en la figura 40. Consiste en trazar líneas tangentes a los puntos más prominentes de cada lado y después juntar las intersecciones de estas líneas tangentes. El punto donde se cruzan las uniones de las intersecciones representa el centro.*
- *La segunda tiene que ser una imagen axial de la bandeja o platillo tibial, en esta se dibuja el eje del componente tibial (tibial component axis, TCA) que es la línea perpendicular a la tangente posterior del platillo tibia que pasa por el centro geométrico de la tibia.*
- *El TCA y el GCT se transponen en la última y tercera imagen (fotografía axial a nivel del tubérculo tibial). En este plano se dibuja una línea des del centro GCT hasta el punto más prominente del tubérculo, esta línea se llama eje tibial del tubérculo (tibial tubercule axis, TTA).*

Finalmente, la rotación del componente tibial es el ángulo entre el TCA y el TTA" (*EXTRAÍDO DE* (101)).

En caso de tener una rotación externa del eje TTA respecto el TCA, el ángulo se va a considerar como un valor positivo; mientras que, si la rotación es interna, el ángulo será negativo (66).

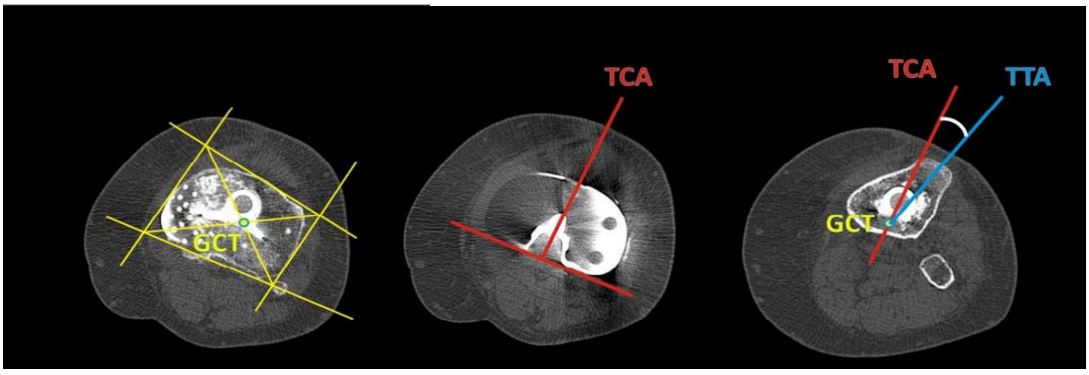


Figura 41 - Proceso para encontrar la rotación del componente tibial con todos los ejes marcados

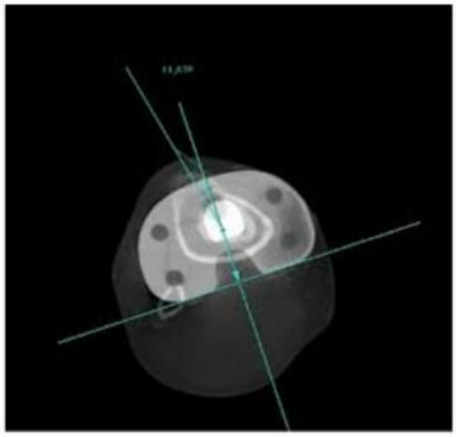


Figura 42 - Ejemplo de rotación del componente femoral

METODOLOGÍA 2 – INSALL, ZHANG, WERNECKE, KLASAN

Se define el ángulo entre el eje tibial anteroposterior (tibial anteroposterior axis, AP) y la línea de Insall (71) (72) (73).

- Primero se tiene que dibujar el eje epicondíleo quirúrgico (sTEA) y proyectarlo en el plano axial de la bandeja tibial.
- Respecto a la imagen axial de la bandeja tibial, se puede identificar el punto central del ligamento cruzado posterior (posterior cruciate ligament, PCL) en la escotadura condilar posterior tal y como se puede identificar en la figura 42.
- En el mismo plano se puede dibujar el eje tibial anteroposterior (AP) como la perpendicular del sTEA que pasa por el centro PCL.
- Finalmente, se transponen todos estos ejes y puntos en el plano en que el tendón rotuliano/patelar está completamente en contacto con el tubérculo tibial. En esta imagen se puede dibujar un punto justo en el borde medial del tendón rotuliano que servirá para dibujar la línea de Insall (línea que une el centro PCL con el borde medial del tendón rotuliano).
- El ángulo a estudiar es el de la intersección realizada por la línea de Insall y el eje AP.

Se va a definir una rotación positiva cuando las líneas definidas estén rotadas externamente respecto el eje AP (71).

METODOLOGÍA 3 – AKAGI, SAHIN

Esta metodología es muy similar a la definida por Insall. Únicamente cambia el último paso ya que, en lugar de dibujar la línea de Inasll, se define otro eje. Se define el ángulo entre el eje tibial anteroposterior (tibial anteroposterior axis, AP) y la línea de Akagi (71) (74) (75).

- Primero se tiene que dibujar el eje epicondíleo quirúrgico (sTEA) y proyectarlo en el plano axial de la bandeja tibial.
- Respecto a la imagen axial de la bandeja tibial, se puede identificar el punto central del ligamento cruzado posterior (posterior cruciate ligament, PCL) en la escotadura condilar posterior tal y como se puede identificar en la figura 42.
- En el mismo plano se puede dibujar el eje tibial anteroposterior (AP) como la perpendicular del sTEA que pasa por el centro PCL.

- Finalmente, se transponen todos estos ejes y puntos en el plano en que el tendón rotuliano/patelar está completamente en contacto con el tubérculo tibial. En esta imagen se puede dibujar un punto justo en el tercio medial del tendón rotuliano que servirá para dibujar la línea de Akagi (línea que une el centro PCL con el tercio medial del tendón rotuliano).
- El ángulo que estudiar es el de la intersección realizada por la línea de Akagi y el eje AP.

Se va a definir una rotación positiva cuando las líneas definidas estén rotadas externamente respecto el eje AP (71).

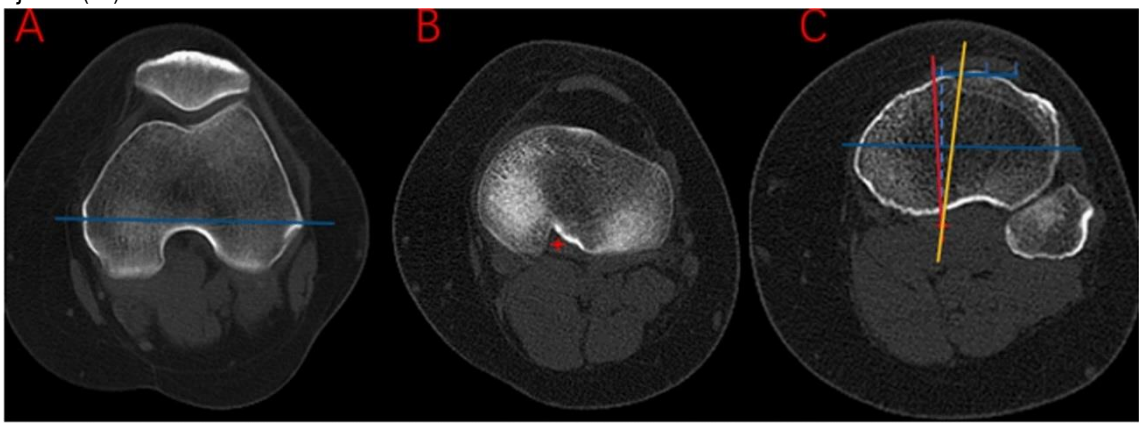


Figura 43 – a) sTEA connecta el sulco del epicnondilo medial con el epicóndilo lateral; b) centro del PCL; c) tenemos el ángulo entre el eje tibial AP (línea azul discontínua) con la línea de Akagi (línea roja) y un segundo ángulo formado por el eje tibial AP y la línea de Insall (línea amarilla)

Combined rotation

Suma de los ángulos obtenidos en la rotación del componente femoral y del componente tibial (76).

Rotational mismatch

Resta del ángulo de rotación del componente femoral menos el ángulo de rotación del componente tibial (76).

Lateral patellar tilt

Ángulo formado por la línea definida por los puntos más anteriores de los cóndilos femorales y una línea que resigue la interfase prótesis-hueso (63) (64).

Los valores se considerarán como positivos cuando haya una rotación externa (es decir, una inclinación lateral) (64).

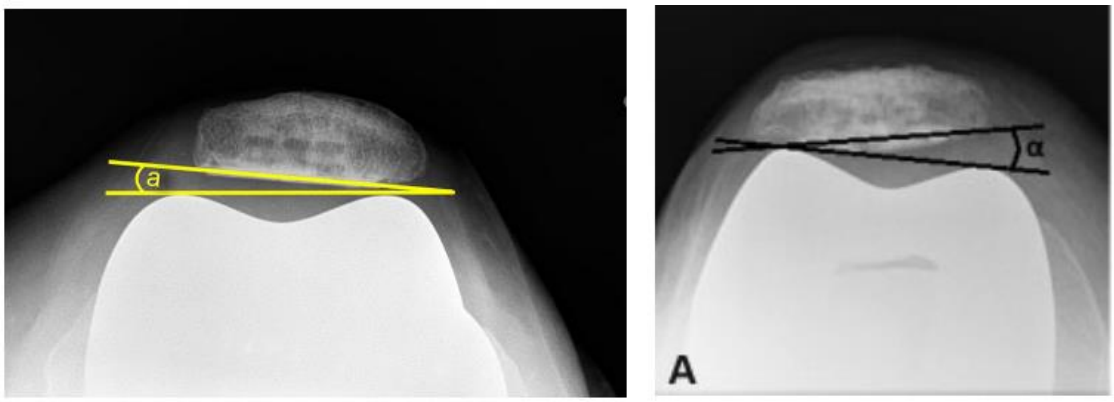


Figura 44 - Lateral Patellar Tilt medido como el ángulo entre la línea más anterior en contacto con los cóndilos femorales y una línea que resigue la interfaz prótesis-hueso

Patellar displacement

Distancia entre una línea que cruza por el surco intercondilar y es perpendicular a la línea dibujada por los límites anteriores de los cóndilos femorales y su paralela que cruza por el centro de la rótula (63) (64).
Los valores se considerarán como positivos cuando haya un desplazamiento lateral (la línea que cruza por el surco intercondilar se encuentra en una posición más lateral respecto a la línea que cruza por el centro de la rótula) (64).

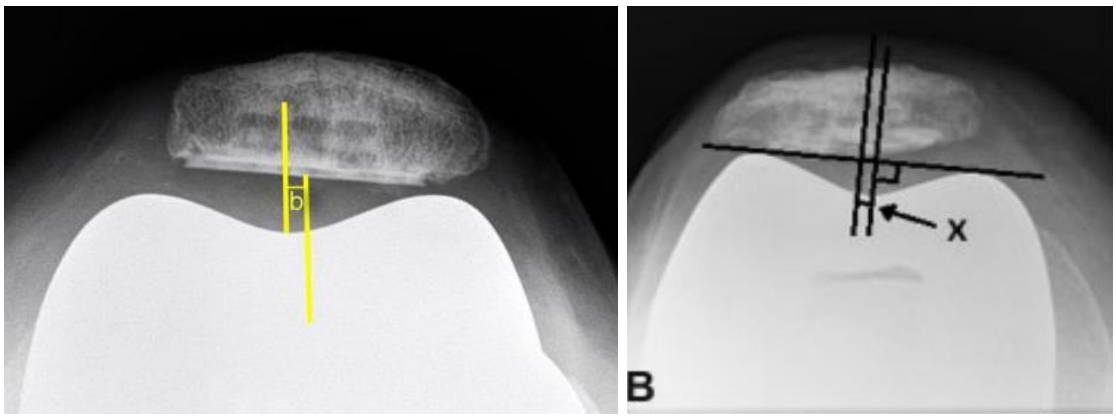


Figura 45 - Patellar displacement (X) medido entre las paralelas que cruzan el surco intercondilar y el punto medio de la rótula

Torsión femoral (TF)

Ángulo entre el eje transcervical femoral y la línea posterior bicondilar (77).

- El eje transcervical femoral se puede dibujar como una línea longitudinal del cuello femoral al centro de la cabeza femoral (78).

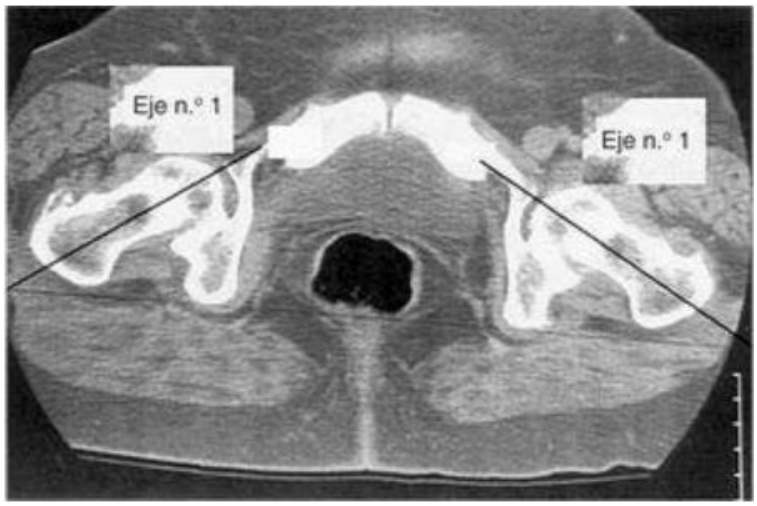


Figura 46 - Eje n.1 indica el eje transcervical femoral

- Tal y como se ha comentado anteriormente, la línea posterior bicondílea es la línea tangente a las partes posteriores de los cóndilos femorales.

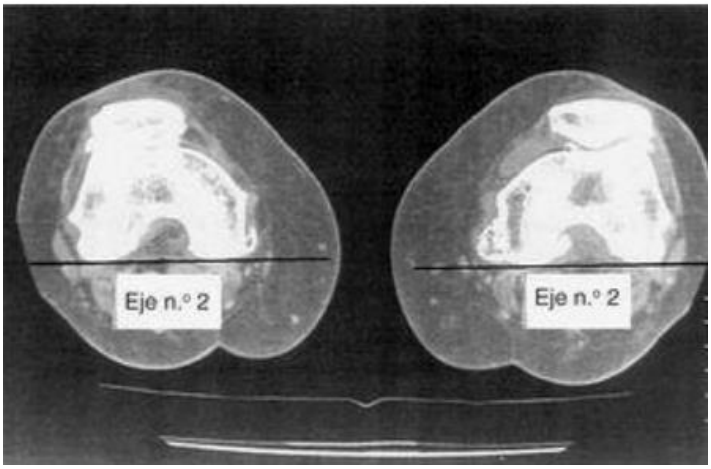


Figura 47 - Eje n.2 indica la línea posterior bicondilar

La metodología para obtener las imágenes TAC es la siguiente: la medición se realiza en extensión completa. Se seleccionan y superponen dos imágenes axiales: una donde se observa la cabeza, cuello femoral y trocánter mayor, con otra donde se visualiza el corte de la línea bicondílea. De este modo, se puede concluir que se necesita hacer una proyección de un plano de la cabeza del fémur con su parte más distal (donde se encuentran los cóndilos) (79). La siguiente fotografía muestra la anteversión femoral.

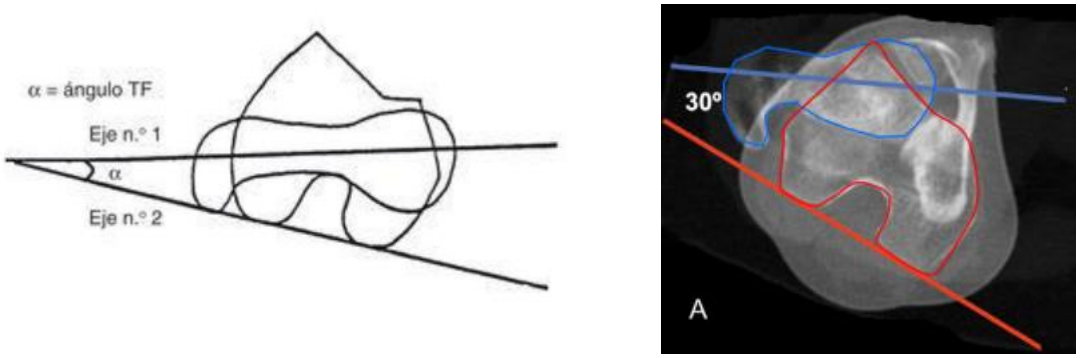


Figura 48 – La fotografía de la izquierda muestra un boceto de la cabeza femoral y los cóndilos femorales junto con los ejes dibujados. En la imagen TAC de la derecha también vemos la cabeza femoral y el eje transcervical femoral (azul) y los cóndilos femorales y el eje posterior bicondilar (rojo)

La limitación de la rotación interna (rodillas apuntando medialmente, una hacia la otra con los dedos de los pies hacia dentro) indica anteversión femoral (AVF), mientras que la limitación de la rotación externa (rodillas orientadas lateralmente, de modo que apuntan en direcciones opuestas) sugiere retroversión femoral (RVF) (80).

Criterio de signos:
Cuando existe una anteversión del cuello femoral, desde el punto de vista de la torsión del miembro inferior, se apunta como valor negativo ya que produce una disminución del ángulo de paso. Por esta razón, se considerarán como valores positivos los casos de retroversión femoral, y negativos lo de anteversión femoral (77).
Normalidad:
Los valores normales en el adulto están situados entre 10 y 15° de anteversión del cuello femoral.

Torsión tibial

La torsión tibial (TT) viene definida por el ángulo entre la recta tangente a los contornos posteriores de los platillos tibiales y el eje transversal de la epífisis distal tibial o eje bimaleolar del tobillo (79).

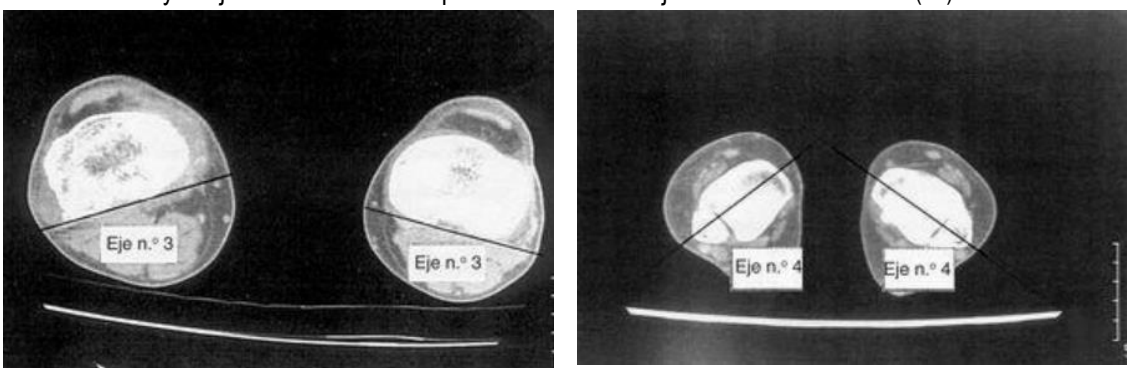


Figura 49 – Eje n.3 indica la recta tangente a los contornes posteriores de los patillos tibiales, mientras que el eje n.4 muestra el eje bimaleolar del tobillo

Esta medición se realiza en extensión completa. Se seleccionan y superponen dos imágenes: una axial del platillo tibial, lo más proximal posible donde se visualice cortical posterior, y la otra a nivel de la sindesmosis tibioperonea distal. La intersección de los ejes comentados anteriormente se muestra en la siguiente fotografía:

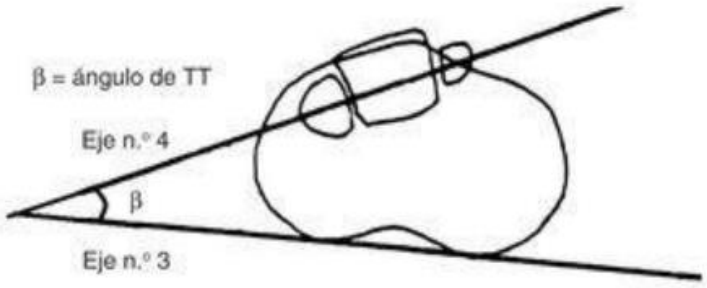


Figura 50 - La fotografía muestra un dibujo axial del platillo tibial y la sindesmosis tibioperonea distal con el ángulo de torsión tibial (con los ejes 3 y 4 dibujados)

Criterio de signos: Habitualmente es externa y, por tanto, apuntada como un valor positivo por producir un aumento del ángulo de paso. De este modo, cuando haya rotación interna se considerarán los valores como negativos (77).

Normalidad: Sus valores normales en adulto están entre 20 y 25° de torsión tibial externa (77).

Rotación femorotibial

Ángulo formado entre el eje bicondilar posterior femoral y la recta tangente a los contornos posteriores de los platillos tibiales (figura 46 y 48, respectivamente).

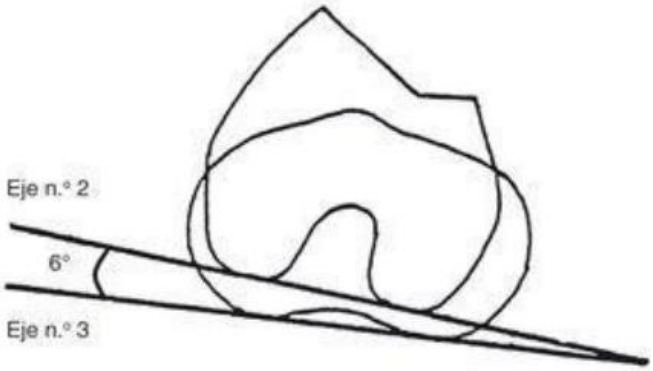


Figura 51 – Ángulo de rotación tibiofemoral como la intersección entre la línea posterior bicondílea femoral y la tangente a los contornes posteriores de los platillos tibiales

Criterio de signos: Es habitualmente positivo por situarse el eje tibial proximal a externo respecto al eje del fémur distal en la articulación de la rodilla. En caso contrario, se asignarán valores negativos (77).

Normalidad: Su valor normal es de 6° (77).

Resumen variables telemétricas

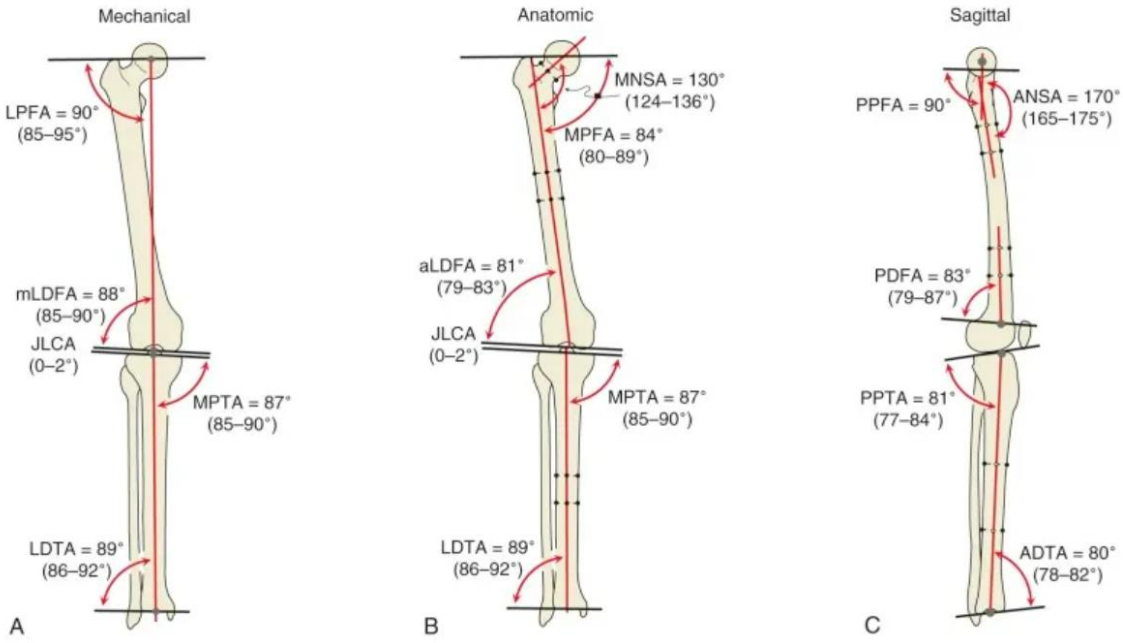


Figura 52 - Resumen de algunas variables a estudiar

ANNEX 5 – PROTOCOL OF OUR CLINICAL STUDY (IN SPANISH)

1. INFORMACIÓN GENERAL

1.1. Identificación del estudio

Título: Valoración de la precisión en la extremidad i posicionamiento de los implantes de prótesis total de rodilla.
Código o número de identificación del protocolo: ArtroTC
Versión y fecha: V.1.0 28/07/2022

1.2. Identificación del promotor

Nombre y dirección del promotor: Juan Carlos Martínez Pastor
Servicio de Cirugía Ortopédica y Traumatología. ICEMEQ
Hospital Clínic de Barcelona

1.3. Identificación de investigadores principales de nuestro centro

Juan Carlos Martínez Pastor
Mariano Balaguer Castro
Unidad de Rodilla. Servicio de Cirugía Ortopédica y Traumatología.
ICEMEQ. Hospital Clínic de Barcelona

1.4. Identificación de investigadores colaboradores

Xavier Tomás Batlle - Centro de Diagnóstico por la Imagen – Hospital Clínic
Montsant Jornet Gibert - Servicio de Cirugía Ortopédica y Traumatología – Hospital Clínic
Salvi Prat Fabregat - Servicio de Cirugía Ortopédica y Traumatología – Hospital Clínic
Pere Torner Pifarré - Servicio de Cirugía Ortopédica y Traumatología – Hospital Clínic
Clara Chimeno Pigrau - Servicio de Cirugía Ortopédica y Traumatología – Hospital Clínic
Leticia Torres Iñíguez - Servicio de Cirugía Ortopédica y Traumatología – Hospital Clínic
Jordi Albert Feliu. Universitat de Barcelona

2. JUSTIFICACIÓN

En casos de osteoartritis avanzadas de rodilla, la artroplastia total de rodilla (ATR) es una de las intervenciones quirúrgicas más frecuentes y uno de los tratamientos más efectivos debido a la disminución del dolor y la mejora de la función y movimiento de la parte del cuerpo afectada. Consiste en la resección de las superficies articulares afectadas y, gracias a biomateriales metálicos y de polietano, se puede realizar una sustitución de estas partes (1). No obstante, estudios recientes han demostrado una insatisfacción del 20% de los casos con la necesidad de revisiones quirúrgicas o cambios del implante (2).
Debido al envejecimiento de la población alrededor del mundo, el volumen total de ATR ha incrementado de forma sustancial en las últimas décadas y se ha convertido en la intervención relacionadas con las articulaciones más común en todo el mundo. Se ha predicho que el número de intervenciones anuales en Estados Unidos aumentará de los 1,37 millones que hubo en 2020 hasta los 3,48 millones en 2030. Las nuevas tendencias del uso de ATR, influenciadas principalmente por cambios en factores demográficos como la edad, el sexo y la esperanza de vida, están directamente correlacionadas con la prevalencia de la artrosis de rodilla. De este modo,

las predicciones sobre el aumento en el volumen de intervenciones requieren de un análisis paralelo y preciso de la epidemiología de la ATR para mejorar la política de atención de la salud pública (4). Aun así, la revisión de diferentes registros de intervenciones en las articulaciones ha demostrado que la ATR se asocia con unos excelentes resultados de supervivencia del implante a largo plazo (5).

Los factores determinantes para el éxito de las intervenciones mencionados más comúnmente son: el correcto posicionamiento de los componentes del implante, una alineación aceptable con la rodilla y la restauración de la estabilidad articular durante las actividades funcionales del paciente son factores determinantes en el éxito de la intervención (6). Dentro de este resultado de éxito multifactorial, es necesario destacar la gran importancia de la alineación de las extremidades ya que afecta directamente la funcionalidad periarticular de los tejidos blandos, la biomecánica de la rodilla y la supervivencia del implante después de la ATR. A causa de una alineación subóptima, existe un mayor desgaste de los componentes, una funcionalidad deficiente y una fallida prematura del implante (requerirá una ATR de revisión). Por esta razón, una mejora en la comprensión y ejecución de la técnica de alineación óptima ayudará a solucionar los problemas comentados anteriormente (5).

En resumen, se puede entrever que la satisfacción del paciente estará directamente relacionada con la funcionalidad del implante, en otras palabras, en la precisión de la colocación de este y su alineación con la extremidad (7). Sin embargo, la variedad de resultados entre cirugías ha incrementado el interés en tecnologías robóticas asistenciales para estandarizar los aspectos técnicos del procedimiento y, de esta forma, conseguir los resultados esperados para considerar las intervenciones como exitosas (6).

NUEVAS TÉCNICAS: ROBÓTICA Y SENSORES

Inicialmente, la asistencia con ordenadores durante la cirugía se basaba únicamente en una función de navegación. Así, se podía guiar al cirujano en la colocación manual de guías de corte y asistir durante la alineación de las extremidades una vez colocados los componentes del implante. Gracias a este desarrollo tecnológico, todos los sistemas robóticos actuales tienen la capacidad de implementar un plan quirúrgico (con la recreación de la anatomía única de la rodilla del paciente) y proporcionar, durante la operación, ayuda para la colocación de los componentes y previsión de la función de la rodilla. Consecuentemente, la ATR asistida por la robótica mejora la resección ósea y reduce los valores de alineación posoperatoria de las extremidades (7).

Los sistemas robóticos de cirugía se pueden dividir en tres categorías basadas en el grado de control que tiene el cirujano:

- Autónomo: el robot ejecuta el procedimiento definido anteriormente sin la necesidad de una guía por parte del cirujano.
- Semiactivo: tienen un sistema de retroalimentación intraoperatoria auditiva, táctil o visual con el fin de ayudar al cirujano a realizar cortes óseos (de esta forma, aumenta la precisión).
- Pasivo: en estos sistemas, se proporciona orientación y posicionamiento de los instrumentos. Todo el procedimiento se lleva a cabo por el cirujano.

La evolución de estas tecnologías ha permitido la utilización de sistemas de imagen para recrear un plan individualizado del paciente (gracias al conocimiento específico de la anatomía única de la rodilla del paciente). De este modo, otra posible clasificación que se puede hacer en los sistemas robóticos es: basados en imágenes o sin imagen. En el primer tipo, se puede modelar la anatomía del cuerpo del paciente gracias a la recreación tridimensional obtenida por radiografías simples, tomografía computarizada (TC) o resonancia magnética (MRI). Esta representación 3D se usa para determinar la profundidad y ubicación de las resecciones óseas, el tamaño de los componentes implantados y su alineación con el fémur y la tibia según la morfología esquelética específica del paciente (6).

3. HIPÓTESIS

La hipótesis principal es que la precisión y exactitud del robot *ROSA Knee System* en los cortes óseos y posicionamiento del implante de prótesis primaria de rodilla se adecúa con los resultados obtenidos con análisis de imágenes TC posquirúrgico.

4. OBJETIVOS Y FINALIDAD DEL ESTUDIO

4.1. Objetivo principal

Valorar la precisión en la alineación de la extremidad, posición de los implantes y precisión de los cortes óseos del robot *ROSA Knee System* en artroplastia de rodilla.

4.2. Objetivos secundarios

- Comparar la precisión y repetibilidad de las intervenciones de ATR asistidas con el robot *ROSA Knee System* y las realizadas de forma convencional.
- Comparar los resultados de precisión obtenidos a partir de las imágenes TC con los obtenidos en radiografías y telemetrías.
- Analizar la relación entre los antecedentes clínicos, la función y los resultados posquirúrgicos en ATR convencional y robótica.
- Realizar un análisis de fiabilidad intraobservadores en las medidas radiológicas.

5. DISEÑO DEL ESTUDIO

Se trata de un estudio de cohortes prospectivo.

5.1. Emplazamiento y período de estudio

Respecto al emplazamiento, el ámbito en el cual se efectuará el presente estudio clínico es el médico. Las intervenciones y seguimiento se ejecutarán en el *Hospital Clínic de Barcelona* (c/Villarroel 170, Barcelona).

El estudio es prospectivo, de forma que se estudiarán los casos de pacientes incluidos en el estudio ArtroClinic intervenidos mediante cirugía robótica o convencional con prótesis PERSONA que hayan recibido como mínimo 6 meses de seguimiento por parte del equipo de cirugía de rodilla del *Hospital Clínic de Barcelona*. Se realizarán diferentes estudios de las dos técnicas actuales de intervención de artroplastia de rodilla del hospital, realizadas con la ayuda del robot *ROSA Knee System* o de forma convencional, y se evaluarán los diferentes resultados para extraer conclusiones sobre su precisión (102).

5.2. Material y métodos

Este estudio revisará los casos de todos los pacientes que quieran participar intervenidos en el Hospital Clínic de Barcelona. Todas las cirugías se tienen que haber realizado por el mismo equipo quirúrgico y se habrá llevado a cabo con la asistencia de *ROSA Knee System* (*Zimmer Biomet, Warsaw, IN*) o de forma convencional. Todos los cirujanos implicados, por un lado, tienen experiencia en las operaciones convencionales, mientras que, por otro lado, se han sometido además al mismo entrenamiento estandarizado sobre el uso del sistema robótico *ROSA Knee System*. Todos los pacientes usan el mismo implante PERSONA (*Zimmer Biomet*) para evitar sesgos de desviación.

PRUEBAS Y VARIABLES DE ESTUDIO DE PRÁCTICA CLÍNICA HABITUAL

Las intervenciones ATR convencionales o asistidas con *ROSA Knee System* siguen las metodologías de la práctica clínica habitual. Este estudio usará diferentes datos de las variables que se recogen en la propia práctica clínica habitual y que están registradas en la historia clínica del paciente o que han sido registradas en la base de datos del estudio clínico ArtroClinic (HCB/2021/0558). Por esta razón, se incluyen todas las pruebas complementarias para recolectar datos que se realizan como parte del protocolo de práctica habitual para ATR.

PREOPERATORIO

- Radiografías de rodilla: AP en carga bilateral, lateral de rodilla y axial de rótula a 45º bilateral.
- Radiografía telemétrica AP +/- Lateral en carga bilateral (calibradas).
- Escalas de valoración
    - KSS
    - Dolor
    - WOMAC

POST ALTA

1. *Visita a los 3 meses*
    - Complicaciones
    - Reintervenciones
2. *Visita a los 6 meses*
    - Escalas de valoración:
        - KSS
        - WOMAC
        - Dolor (en reposo y después de movilización)
        - Satisfacción con el tratamiento
        - Net Promoter Score (NPS)
    - Radiografías AP en carga bilateral, lateral estricto a 30º y axial de rótula a 45º
    - Telemetrías AP +/- lateral
3. *Visita a los 12 meses (1 año)*
    - Escalas de valoración:

    - KSS
    - WOMAC
    - Dolor (en reposo y después de movilización)
    - Satisfacción con el tratamiento
    - Net promoter Score (NPS)
- Radiografías de rodilla: AP en carga bilateral, lateral de rodilla y axial de rótula a 45º bilateral.

PRUEBAS DE ESTUDIO EXCLUSIVAS DEL ESTUDIO ARTROTC

Como parte del estudio, se realizará una TC de toda la extremidad inferior intervenida. Las imágenes TC que se obtengan serán analizadas por los investigadores con el fin de extraer datos de las variables a estudiar. Estas serán comparadas con los resultados obtenidos previamente en el plan intraoperatorio que el sistema robótico propone. De esta forma, todos aquellos valores de alineación y posicionamiento del implante definidos por *ROSA Knee System* y fijados durante la operación por los cirujanos (según práctica clínica habitual) podrán ser contrastados con los valores obtenidos de las TC postoperatorias. Esta comparación entre los valores de las variables durante y después de la operación permitirán obtener la exactitud y precisión de la operación asistida con *ROSA Knee System.*

Por otro lado, las técnicas convencionales compararán los resultados obtenidos de las variables en las imágenes TC con aquellas referencias planificadas durante la operación. Así se obtendrá la precisión de la intervención convencional.

Finalmente, se compararán las precisiones obtenidas de las dos técnicas de intervención.

5.3. Variables y cronograma

En la siguiente tabla se especifican y definen todas las variables del estudio.

	Variable	Obtención de la variable / Recolección de datos			Valores/Unidades	Definición
		Preoperatorio	Intrahospitalario*	Post alta hospitalaria		
Variables demográficas	Sexo	x			- Hombre - Mujer	Sexo
	Edad	x			Años	Edad
	Lateralidad		x		- Izquierda - Derecha	Lateralidad de la rodilla afecta
Variables de la historia clínica	IMC	x			Kg/m^2	$Peso/Altura^2$
	Complicaciones			x	-	Complicaciones
	Reintervenciones			x	- Sí - No	Reintervenciones
Variables radiológicas	Eje mecánico de la extremidad afecta	x		x	Ángulo (grados)	Línea recta desde el centro de la cabeza femoral hasta el centro de la articulación tibio-astragaliana (54).
	Eje anatómico del fémur y la tibia	x		x	Ángulo (grados)	Femoral: Línea recta desde el punto central del istmo femoral hasta el centro de la escotadura intercondílea Tibial: línea recta desde el punto medio del componente tibial o las espinas tibiales hasta el centro de la articulación tibio-astragaliana (54).
	Altura de la interlínea articular	x		x	Distancia (mm)	Altura de la línea articular
	Joint Line Convergence Angle (JLCA)	x		x	Ángulo (grados)	Ángulo formado entre la tangente al cóndilo femoral distal y la tangente a la meseta tibial (103).

	Anterior condylar offset	x		x	Distancia (mm)	Distancia entre la tangente a la cortical anterior femoral y una línea paralela a esta y tangente a la proyección más anterior de la tróclea femoral (54).
	Posterior condylar offset	x		x	Distancia (mm)	Distancia entre la tangente a la cortical anterior femoral y una línea paralela a esta y tangente a la proyección más anterior de la tróclea femoral (54).
Variables telemétricas [a]	Eje tibial	x		x	Ángulo (grados)	Ejes mecánico y anatómico de la tibia.
	Eje femoral	x		x	Ángulo (grados)	Ejes mecánico y anatómico del fémur.
	Hip-knee-ankle angle (HKA)	x		x	Ángulo (grados)	Mide el ángulo entre el eje mecánico del fémur y la tibia (104).
	Mechanical lateral distal femoral angle (mLDFA) / Ángulo distal femoral lateral	x		x	Ángulo (grados)	Ángulo lateral entre el eje mecánico del fémur y la línea definida por los puntos distales de los cóndilos medial y lateral del fémur (104).
	Mechanical medial proximal tibial angle (MPTA) / Ángulo proximal tibial	x		x	Ángulo (grados)	Ángulo medial entre el eje mecánico de la tibia y la línea definida por las mesetas medial y lateral de la tibia (104).
	Posterior distal femoral angle (PDFA) o pendiente femoral	x		x	Ángulo (grados)	Ángulo entre la tangente al hueso cortical diafisario posterior femoral y la tangente al corte femoral distal (105).
	Posterior proximal tibial angle (PTTA) o pendiente tibial	x		x	Ángulo (grados)	Ángulo entre la tangente a la limitación del hueso cortical diafisario posterior y a la tangente a la meseta tibial (105).

Variables TC	Condylar twist angle o rotación del componente femoral		x[b]	x	Ángulo (grados)	Ángulo entre los ejes condilar posterior y epicondíleo (54).
	Rotación del componente tibial		x[b]	x	Ángulo (grados)	Ángulo definido por la técnica de Berger (106)
Escalas de valoración	Knee Society Score (KSS) (107)	x		x	0 a 100	La escala KSS es un método para evaluar de forma objetiva las capacidades funcionales del paciente y de la rodilla afecta
	Dolor (en reposo y después de movilización)	x		x	0 a 10	Escala de Valoración Numérica del dolor (NRS), en reposo y después de movilización
	Satisfacción con el tratamiento (108)			x	- Muy satisfecho - Satisfecho - Ni satisfecho ni insatisfecho - Insatisfecho - Muy insatisfecho	Escala de Valoración de la satisfacción con 5 opciones de respuesta. ¿Cómo está de satisfecho con el proceso? ¿Cómo está de satisfecho con los resultados de su tratamiento?
	Net Promoter Score (NPS) (109)			x	0 a 10	¿Con qué probabilidad recomendaría la operación a un familiar o a un amigo?
	Western Ontario McMaster Universities Osteoarthritis Index (WOMAC)	x		x	Se obtienen tres valores: - Dolor: escala de 0 a 20 - Rigidez: escala de 0 a 8 - Función: escala de 0 a 68	Mide la calidad de vida en personas con osteoartrosis de rodilla (en términos de discapacidad física y sintomatología)

Variables telemétricas[a]: Las variables telemétricas se pueden estudiar de forma más precisa con la TC realizada postoperatoriamente.

x[b]: Solamente se recogen de forma intraoperatoria en las intervenciones asistidas con *ROSA Knee System* debido que es capaz de dar los valores de las variables de telemetría y TC. Estos valores se compararán con los resultados de las variables obtenidos durante el análisis de la TC y telemetrías postoperatorias.

6. SELECCIÓN DE PARTICIPANTES (86,87)

Se incluirán los pacientes afectos de gonartrosis que hayan sido intervenidos de una artroplastia total de rodilla primaria. Siempre que cumplan los criterios de inclusión/exclusión.

6.1. Criterios de inclusión

- Edad: mayores de 18 años.
- Pacientes intervenidos de ATR con implantación de prótesis PERSONA.
- Paciente acepta proporcionar consentimiento informado escrito para participar en el estudio.
- A opinión del investigador, el paciente tiene la capacidad de entender la investigación clínica y acepta efectuar todos los procedimientos y seguimiento del estudio.
- Pacientes con un tiempo mínimo de 6 meses de seguimiento. Los pacientes que podrán participar se escogerán desde la primera intervención con ROSA realizada en el Hospital Clínic de Barcelona (diciembre de 2020).

6.2. Criterios de exclusión

- No consentimiento en participar.
- Pacientes recambiados.

6.3. Reclutamiento de participantes

El reclutamiento de los participantes se realizará mediante los pacientes de artroplastia de rodilla del Hospital Clínic de Barcelona incluidos en el estudio ArtroClinic. Los participantes deberán ser informados del estudio y tendrán que leer y firmar, de forma voluntaria, el consentimiento informado que se les entregará.

6.4. Asignación de las intervenciones y enmascaramiento

El estudio está planteado como un estudio de cohortes prospectivo unicéntrico. De este modo, se formarán dos grupos según la técnica utilizada para la implantación de la ATR.

La evaluación de las variables radiológicas se realizará de manera ciega por un evaluador ajeno al equipo responsable de la intervención.

7. ESTADÍSTICA

7.1. Tamaño de la muestra

En este estudio no hay un tamaño muestral definido. Se trata de un estudio observacional que revisará el máximo de participantes posibles desde diciembre 2020, con un seguimiento mínimo de 6 meses. Se incluirán pacientes de forma consecutiva que cumplan los criterios.

Actualmente no hay ningún tipo de referencia o información respecto las diferencias mínimas idóneas de las variables, antes y después de la operación, para suponer una buena precisión en la intervención. Por esta razón, el estudio tiene intención de recopilar datos al respecto y poder encontrar parámetros para definir la precisión de las intervenciones convencionales y robóticas.

7.2. Análisis estadístico

ROSA Knee System registrará durante la operación una serie de variables que se compararán con los resultados obtenidos después de la operación gracias a las telemetrías y las imágenes TC. De

este modo, el análisis estadístico se basará en un estudio de las varianzas (la diferencia entre el valor de la variable obtenido y el que se había planificado durante la operación). De todas las variables continuas a estudiar se calcularán diversos parámetros estadísticos como la media, la mediana, los errores de mediana y las desviaciones típicas estándar de la diferencia entre el resultado planeado intraoperatorio y el resultado obtenido. La comparación de estos valores definirá la precisión del robot.
Las técnicas convencionales compararán los resultados obtenidos de las variables con aquellas referencias planificadas durante la operación. Así se obtendrá la precisión de la intervención convencional.
Los resultados se compararán entre los dos grupos de estudio: aquellos intervenidos con técnicas robóticas y los intervenidos con técnicas convencionales. La mediana permitirá evaluar la tendencia central del conjunto de datos y describir la exactitud en que se realizará el estudio planeado.
Las variables continuas distribuidas normalmente se compararán usando el F test.
De manera general, los análisis estadísticos se realizarán con la herramienta estadística en qué los investigadores estén más familiarizados (RStudio, SPSS, entre otros).

8. ÉTICA Y ASPECTOS LEGALES

El estudio se realizará en cumplimiento de la Declaración de Helsinki (versión en vigor; actualmente Fortaleza, Brasil, octubre 2013).
El estudio será realizado de acuerdo con el protocolo y con los requisitos legales pertinentes:
Ley 14/2007 de 3 de julio, de Investigación biomédica, y Reglamento 2017/745 sobre los Productos Sanitarios.
Se solicitará el consentimiento informado a los pacientes antes de su inclusión en el estudio para la realización del TC.

9. GESTIÓN DE LOS DATOS

Los datos se recogerán de manera codificada. El personal del estudio tendrá acceso a los datos identificativos y a los datos codificados.
El sistema de recolección de datos se realizará mediante RedCap institucional, que permite el seguimiento de los datos incorporados y sus modificaciones.
El archivo se ubicará en la cuenta institucional OneDrive de los investigadores, y únicamente tendrán acceso los investigadores del estudio.

10. TRATAMIENTO DE LOS DATOS Y ARCHIVO DE LOS REGISTROS. CONFIDENCIALIDAD DE LOS DATOS

La finalidad de este estudio es Valorar la precisión en la alineación de la extremidad, posición de los implantes y precisión de los cortes óseos del robot *ROSA Knee System* en artroplastia de rodilla. La hipótesis principal es que la precisión y exactitud del robot *ROSA Knee System* en los cortes óseos y posicionamiento del implante de prótesis primaria de rodilla se adecúa con los resultados obtenidos con análisis de imágenes TC posquirúrgico.

El tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los participantes se ajustará al cumplimiento del Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 27 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, y a la Ley Orgánica 3/2018, de 5 de diciembre, de Protección de Datos Personales y garantía de los derechos digitales. La base legal que justifica el tratamiento de sus datos es el consentimiento que da en este acto, conforme a lo establecido en el artículo 9 del Reglamento UE 2016/679 .

Los datos recogidos para estos estudios se recogerán identificados únicamente mediante un código, por lo que no se incluirá ningún tipo de información que permita identificar a los participantes. Sólo el médico del estudio y sus colaboradores con derecho de acceso a los datos fuente (historia clínica), podrán relacionar los datos recogidos en el estudio con la historia clínica del paciente.

La identidad de los participantes no estará al alcance de ninguna otra persona a excepción de una urgencia médica o requerimiento legal.

Podrán tener acceso a la información personal identificada, las autoridades sanitarias, el Comité de Ética de Investigación y personal autorizado por el promotor del estudio, cuando sea necesario para comprobar datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de acuerdo a la legislación vigente.

Sólo se cederán a terceros y a otros países los datos codificados, que en ningún caso contendrán información que pueda identificar al participante directamente (como nombre y apellidos, iniciales, dirección, número de la seguridad social, etc.). En el supuesto de que se produjera esta cesión, sería para la misma finalidad del estudio descrito y garantizando la confidencialidad.

Si se realizara una transferencia de datos codificados fuera de la UE, ya sea en entidades relacionadas con el centro hospitalario donde participa el paciente, a prestadores de servicios o a investigadores que colaboren con nosotros, los datos de los participantes quedarán protegidos por salvaguardas como contratos u otros mecanismos establecidos por las autoridades de protección de datos.

Como promotores del proyecto nos comprometemos a realizar el tratamiento de los datos de acuerdo al Reglamento UE 2016/679 y, por tanto, a mantener un registro de las actividades de tratamiento que llevemos a cabo y a realizar una valoración de riesgos de los tratamientos que realizamos, para saber qué medidas tendremos que aplicar y cómo hacerlo.

Además de los derechos que ya contemplaba la legislación anterior (acceso, modificación, oposición y cancelación de datos, supresión en el nuevo Reglamento) ahora los participantes también pueden limitar el tratamiento de datos recogidos para el proyecto que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad). Para ejercitar estos derechos deberán dirigirse al investigador principal del estudio o al Delegado de Protección de Datos del Hospital Clínic de Barcelona a través de protecciodades@clinic.cat.Así mismo tienen derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho/a.

Los datos no se pueden eliminar aunque un paciente abandone el estudio, para garantizar la validez de la investigación y cumplir con los deberes legales y los requisitos de autorización de medicamentos.

El Investigador y el Promotor están obligados a conservar los datos recogidos para el estudio al menos hasta 5 años tras su finalización. Posteriormente, la información personal solo se conservará por el centro para el cuidado de su salud y por el promotor para otros fines de investigación científica si el paciente hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

11. FINANCIACIÓN

Este estudio no cuenta con fuentes de financiación.

12. POLÍTICA DE PUBLICACIÓN

Los investigadores se comprometen a hacer públicos los resultados del estudio tanto si fueran positivos como si fueran negativos.

Este estudio forma parte del Trabajo Final de Grado de Jordi Albert Feliu, tutorizado por el Dr. Juan Carlos Martínez Pastor y Mariano Balaguer Castro, del Grado de Ingeniería Biomédica de la Universitat de Barcelona.

ANNEX 6 – INFORMED CONSENT FOR PARTICIPANTS

TÍTULO DEL ESTUDIO: Valoración de la precisión en la extremidad i posicionamiento de los implantes de prótesis total de rodilla.

CÓDIGO DEL PROMOTOR: ArtroTC

PROMOTOR: Juan Carlos Martínez Pastor y Mariano Balaguer Castro

INVESTIGADOR PRINCIPAL*:* Juan Carlos Martínez Pastor y Mariano Balaguer Castro
Servicio de Cirugía Ortopédica y Traumatología. ICEMEQ. 932275533

CENTRO: Hospital Clínic de Barcelona

INTRODUCCIÓN

Nos dirigimos a usted para informarle sobre un estudio de investigación en el que se le invita a participar. El estudio ha sido aprobado por un Comité de Ética de la Investigación, de acuerdo a la legislación vigente, Ley de Investigación Biomédica 14/2007 y Real Decreto 1090/2015.
Nuestra intención es tan solo que usted reciba la información correcta y suficiente para que pueda evaluar y juzgar si quiere o no participar en este estudio. Para ello lea esta hoja informativa con atención y nosotros le aclararemos las dudas que le puedan surgir después de la explicación. Además, puede consultar con las personas que considere oportuno.

PARTICIPACIÓN VOLUNTARIA

Debe saber que su participación en este estudio es voluntaria y que puede decidir no participar o cambiar su decisión y retirar el consentimiento en cualquier momento, sin que por ello se altere la relación con su médico ni se produzca perjuicio alguno en su tratamiento.

DESCRIPCIÓN GENERAL DEL ESTUDIO

Este estudio clínico consiste en la evaluación de la exactitud y precisión de las intervenciones de artroplastia de rodilla. Tiene como objetivo principal la valoración de la exactitud en la alineación de la extremidad, posición de los implantes y precisión de los cortes óseos mediante cirugía robótica en artroplastia de rodilla. Además, se pretende recolectar información clínica y radiográfica respecto las artroplastias totales de rodilla realizadas de forma convencional o con nuevas técnicas de robótica.
La metodología que seguirá el estudio se basa en la comparación entre los resultados planificados durante la cirugía con aquellos realmente obtenidos. La comparación de unos con otros permitirá estudiar la precisión en qué se ha realizado la intervención. El procedimiento habitual clínico del hospital para artroplastias de rodilla se basa en la realización de diferentes pruebas de obtención de imágenes de telemetría y radiográficas del paciente antes y después de la operación. De este modo, por un lado, se puede planificar la intervención y, por otro lado, se estudian los resultados obtenidos. De forma complementaria a este procedimiento que se realiza como parte de la práctica clínica habitual, este estudio clínico realizará pruebas de tomografía computarizada (TC) al cabo de como mínimo un año para obtener imágenes de la extremidad inferior del paciente. De esta forma, el estudio de las imágenes obtenidas permitirá estudiar la exactitud del procedimiento quirúrgico.

Las imágenes se consiguen gracias a la realización de una prueba de tomografía computarizada. Esto implica que los participantes del estudio serán sometidos únicamente a una sesión de TC en el Hospital Clínic de Barcelona. Por tanto, la participación en este estudio clínico tiene como único inconveniente la realización de una sesión de TC ya que el resto de las pruebas complementarias a la cirugía forman parte del protocolo interno del hospital en artroplastias de rodilla.
El número total de sujetos que se incluirán en el estudio consiste en todos aquellos pacientes que cumplan con los criterios de inclusión.

BENEFICIOS Y RIESGOS DERIVADOS DE SU PARTICIPACIÓN EN EL ESTUDIO
Los participantes del estudio no obtendrán ningún beneficio para su salud debido a su colaboración porque ya lo habrán obtenido gracias a su tratamiento por artroplastia de rodilla en el hospital, el procedimiento de la cual se está valorando en este estudio.
Por el contrario, el estudio de la valoración de la precisión puede tener grandes beneficios para la sociedad. Las intervenciones de artroplastias de rodilla son consideradas exitosas debido a diferentes factores para tener en cuenta. Aun así, el correcto posicionamiento de los componentes del implante y una buena alineación con la rodilla son algunos de los más comunes porque están estrechamente relacionados con la supervivencia de los implantes. Puesto que una mala alineación provoca un aumento del desgaste de los componentes, una mala funcionalidad de la prótesis y un fallo prematuro del implante requiere una artroplastia de rodilla de revisión, es crucial mejorar la ejecución de la técnica de artroplastia de rodilla para que sea lo más precisa y exacta posible. Además, el número de artroplastias de rodilla está aumentando año tras año, de modo que es importante asegurar que todas las intervenciones sean lo más exitosas posible.
La única prueba exclusiva de este estudio es la tomografía computarizada (TC), un método de exploración que utiliza rayos X para obtener imágenes en múltiples planos y volumétricas del cuerpo humano. Las imágenes permiten estudiar con gran precisión las estructuras internas del organismo. Dado que esta prueba médica utiliza radiaciones, su uso es muy riguroso y controlado. Siempre se optimizan para que el nivel de radiación sea el más bajo posible sin perder información diagnóstica.

TRATAMIENTOS ALTERNATIVOS
La participación en el estudio no modifica el tratamiento actual. El estudio incluye únicamente una prueba de imagen (TC) que no forma parte del protocolo de práctica habitual para la artroplastia total de rodilla.

CONFIDENCIALIDAD
El Hospital Clínic de Barcelona, con CIF 0802070C, como responsable del tratamiento de sus datos, le informa que el l tratamiento, la comunicación y la cesión de los datos de carácter personal de todos los participantes se ajustará al cumplimiento del Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 27 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, siendo de obligado cumplimiento a partir del 25 de mayo del 2018. La base legal que justifica el tratamiento de sus datos es el consentimiento que da en este acto, conforme a lo establecido en el artículo 9 del Reglamento UE 2016/679 .
Los datos recogidos para estos estudios se recogerán identificados únicamente mediante un código, por lo que no se incluirá ningún tipo de información que permita identificar a los participantes. Sólo el médico del estudio y sus colaboradores con un permiso específico podrán relacionar sus datos recogidos en el estudio con su historia clínica.
Su identidad no estará al alcance de ninguna otra persona a excepción de una urgencia médica o requerimiento legal. Podrán tener acceso a su información personal identificada, las autoridades sanitarias,

el Comité de Ética de Investigación y personal autorizado por el promotor del estudio, cuando sea necesario para comprobar datos y procedimientos del estudio, pero siempre manteniendo la confidencialidad de acuerdo a la legislación vigente.
Sólo se cederán a terceros y a otros países los datos codificados, que en ningún caso contendrán información que pueda identificar al participante directamente (como nombre y apellidos, iniciales, dirección, número de la seguridad social, etc.). En el supuesto de que se produjera esta cesión, sería para la misma finalidad del estudio descrito y garantizando la confidencialidad.
Si se realizara una transferencia de datos codificados fuera de la UE, ya sea a entidades relacionadas con el centro hospitalario donde usted participa, a prestadores de servicios o a investigadores que colaboren con su médico, sus datos quedarán protegidos por salvaguardas como contratos u otros mecanismos establecidos por las autoridades de protección de datos.
Además de los derechos que ya contemplaba la legislación anterior (acceso, modificación, oposición y cancelación de datos, supresión en el nuevo Reglamento) ahora también puede limitar el tratamiento de datos que sean incorrectos, solicitar una copia o que se trasladen a un tercero (portabilidad) los datos que usted ha facilitado para el estudio. Para ejercitar estos derechos, o si desea saber más sobre confidencialidad, deberán dirigirse al investigador principal del estudio o al Delegado de Protección de Datos del Hospital Clínic de Barcelona a través de protecciodades@clinic.cat. Así mismo tienen derecho a dirigirse a la Agencia de Protección de Datos si no quedara satisfecho/a.
Los datos ya recogidos no se pueden eliminar, aunque usted abandone el estudio, para garantizar la validez de la investigación y cumplir con los deberes legales y los requisitos de autorización de medicamentos. Pero no se recogerán nuevos datos si usted decide dejar de participar.
El Investigador y el Promotor están obligados a conservar los datos recogidos para el estudio al menos hasta 5 años tras su finalización. Posteriormente, la información personal solo se conservará por el centro para el cuidado de su salud y por el promotor para otros fines de investigación científica si el paciente hubiera otorgado su consentimiento para ello, y si así lo permite la ley y requisitos éticos aplicables.

COMPENSACIÓN ECONÓMICA

Su participación en el estudio no le supondrá ningún gasto. Tampoco recibirá ninguna compensación económica por participar en el estudio.

OTRA INFORMACIÓN RELEVANTE

Cualquier nueva información referente al tratamiento utilizado en el estudio y que pueda afectar a su disposición para participar, que se descubra durante su participación, le será comunicada por su médico lo antes posible.
Si usted decide retirar el consentimiento para participar en este estudio, ningún dato nuevo será añadido a la base de datos.
También debe saber que puede ser excluido del estudio si el promotor los investigadores del estudio lo consideran oportuno, ya sea por motivos de seguridad, por cualquier acontecimiento adverso que se produzca o porque consideren que no está cumpliendo con los procedimientos establecidos. En cualquiera de los casos, usted recibirá una explicación adecuada del motivo que ha ocasionado su retirada del estudio.
Al firmar la hoja de consentimiento adjunta, se compromete a cumplir con los procedimientos del estudio que se le han expuesto.

Hoja de Consentimiento de Participante

Título del estudio:

"*Valoración de la precisión en la extremidad i posicionamiento de los implantes de prótesis total de rodilla*". Código de protocolo: *ArtroTC* (*V.1.0 04/07/2022*)

Yo, *(nombre y apellidos del participante)* .....

- He leído la hoja de información que se me ha entregado sobre el estudio.
- He podido hacer preguntas sobre el estudio.
- He recibido suficiente información sobre el estudio.
- He hablado con: *(nombre del investigador)* .....
- Comprendo que mi participación es voluntaria.
- Comprendo que puedo retirarme del estudio:
    - Cuando quiera.
    - Sin tener que dar explicaciones.
    - Sin que esto repercuta en mis cuidados médicos.
- De conformidad con lo que establece el Reglamento UE 2016/679 del Parlamento Europeo y del Consejo de 26 de abril de 2016 relativo a la protección de las personas físicas en cuanto al tratamiento de datos personales y la libre circulación de datos, declaro haber sido informado de la existencia de un fichero o tratamiento de datos de carácter personal, de la finalidad de la recogida de éstos y de los destinatarios de la información.
- Presto libremente mi conformidad para participar en el estudio.

Firma del participante	Firma del investigador
Fecha: ____/____/____	Fecha: ____/____/____

ANNEX 7 – SUMMARY OF VARIABLES OF STUDY

The following table contains all the variables of this study. Higlighted in green, the variables recorded intraoperatively by ROSA.

Table 25 - Summary of variables selected for our clinical study

Plano	Variable	Referencias	Criterio de signos	Normalidad
CORONAL	Altura de la interlínea articular / Joint Line Height (JLH)	(57) (110)	Siempre positivo	Preoperative values: 4.39 mm Posoperative values: - (57)
	Joint line convergence angle (JLCA)	(55) (58)	Positivo: varo Negativo: valgo	[0°; 2°] (58)
	HKA	(54) (58)	Positivo: varo Negativo: valgo	[-1°; 3,2°] (56)
	Mechanical lateral distal femoral angle (mLDFA)	(55)	Se coge el ángulo obtenido al trazar las dos líneas o ejes.	[85°, 90°] (59)
	Mechanical medial proximal tibial angle (mMPTA)	(55)	Se coge el ángulo obtenido al trazar las dos líneas o ejes.	[85°, 90°] (59)
SAGITAL	Altura patelar (Insall-Salvati)	(60)	Siempre positivo	En radiografías se considera: - Una patela baja cuando la ratio es menor a 0,8 - Una patela normal cuando la ratio se encuentra entre 0,8 y 1,2 - Una patela alta cuando es superior a 1,2. (61)
	Altura patelar (Caton-Deschamps)	(62)	Siempre positivo	En radiografías se consdiera: - Patela baja: <0.6 - Rango normal: 0.6-1.3 - Patela alta: >1.3 (62)
	Pendiente femoral/Posterior distal femoral angle (PDFA)	(54)	-	[79°; 87°] – Usar 83° (82)
	Offset condilar anterior	(54)	-	-
	Offset condilar posterior	(54)	-	-

	Ratio offset condilar posterior	(54)	Siempre positivo	Preoperative mean PCO: 0.44±0.02 Posoperative mean PCO: 0.47±0.02 Mean increase PCO: 0.03 (82)
	Pendiente tibial posterior/Posterior proximal tibial angle (PTTA)	(54)	-	[77°; 84°] – Usar 81° (82)
AXIAL	Lateral patellar tilt	(63) (64)	Positivo: rotación externa Negativo: rotación interna	≤ 10° (111) [1]
	Patellar displacement	(63) (64)	Positivo: desplazamiento lateral (respecto la línea que cruza por el centro de la rótula) Negativo: desplazamiento medial	[-5 mm, 5 mm] (111)
	Rotación del componente femoral (Berger)	(65) (66) (67)	Positivo: rotación externa Negativo: rotación interna	Neutral rotation men: -3.5° ± 1.2 (negative because it refers to internal rotation). Neutral rotation women: -0.3° ± 1.2 (negative because it refers to internal rotation). (76) (112)
	Rotación del componente femoral (Lützner)	(68) (69)	Positivo: rotación externa Negativo: rotación interna	
	Rotación del componente tibial (Berger)	(66) (70)	Positivo: rotación externa del eje TTA respecto el eje TCA	Neutral rotation (both genders): 18°±2. Surface (76) (112)

[1] Normalmente siempre está rotado externamente, de forma que los valores negativos son raros de encontrar.

			Negativo: rotación interna del eje TTA respecto el eje TCA	
	Rotación del componente tibial (Insall)	(71) (72) (73)	Positivo: rotación externa del eje respecto el eje AP Negativo: rotación interna del eje a estudiar respecto el eje AP	-
	Rotación del componente tibial (Akagi)	(71) (74) (75)	Positivo: rotación externa del eje respecto el eje AP Negativo: rotación interna del eje a estudiar respecto el eje AP	-
	Combined rotation	(76) (79)	Positivo: rotación externa del eje respecto el eje AP Negativo: rotación interna del eje a estudiar respecto el eje AP	7.42° ± 1.1
	Rotational mismatch	(76) (79)	-	9.31° ± 1.9
	Torsión femoral (TF)	(77)	Positivo: retroversión femoral (rodilla rotada hacia fuera) Negativo: anteversión femoral (rodilla rotada hacia dentro)	[-15°, -8°]. Se coge 11° como referencia. (79)
	Torsión tibial (TT)	(77)	Positivo: rotación externa Negativo: rotación interna	[20°, 25°] de rotación externa (por eso son positivos) (77)
	Rotación femorotibial	(77)	Positivo: eje tibial proximal es externo respecto eje del fémur distal Negativo: eje tibial proximal es interno respecto eje del fémur distal	[3°, 5°] (79)

ANNEX 8 – POSTOPERATIVE DATA EXTRACTED BY OBSERVER 1

Table 26 - Postoperative data extracted by observer 1

id	Intervention date	JLH (mm)	JLCA (º)	HKA (º)	mLDFA (º)	mMPTA (º)	Altura patellar (Insall-Salvati)	Altura patellar (Caton-Deschamps)	PDFA (º)	Anterior femoral offset(mm)	PCO (mm)	PCO_b (mm)	Ratio PCO	PTTA (º)
AR1	11/12/2020	14.12	0.3	4.45	90.99	87.83	1.11	0.93	88.11	4.41	27.41	32.65	0.84	87.55
AR2	18/12/2020	15.01	2.3	3.1	91.87	88.79	1.27	0.69	92.3	4.49	26.3	28.27	0.93	87.64
AR8	10/2/2021	18.93	2.49	3.76	90.64	87.2	0.90	0.89	85.13	2.61	29.31	35.64	0.82	89.92
AR10	22/2/2021	15.94	1.26	1.53	91.1	90.21	0.80	0.71	92.57	5.5	31.7	25.49	1.24	88.52
AR11	2/3/2021	20.47	0.51	-1.59	88.16	91.19	1.11	1.33	91.57	6.37	31.76	36.33	0.87	88.36
AR12	15/3/2021	18	-0.55	-1.32	89.94	90.19	0.94	1.31	93.43	6.01	32.57	34.2	0.95	91.01
AR14	17/3/2021	14.89	0.62	4.74	93.35	89.14	0.90	0.55	93.54	6.55	35.45	36.47	0.97	86.85
AR16	30/3/2021	16.96	-0.46	-4.79	86.17	92.2	1.25	0.92	95.05	6.52	26.99	47.31	0.57	88.74
AR17	14/4/2021	12.96	-0.01	-1.15	90.63	89.92	1.11	0.81	92.82	4.55	31.09	32.67	0.95	91.11
AR23	25/5/2021	14.15	0.04	2.74	89.26	87	1.16	0.75	90.47	5.81	31.84	32.86	0.97	84.35
AR24	26/5/2021	17.12	1.19	3.25	90.55	89.99	0.87	0.65	91.15	7.04	28.97	38.33	0.76	89.83
AR26	7/6/2021	15.18	0.24	-0.49	89.29	90.24	0.88	0.46	91.51	8.65	26.07	29.55	0.88	89.1
AR30	14/6/2021	10.92	2.02	4.12	90.66	87.98	1.04	0.66	85.63	3.22	29.46	34.5	0.85	92.4
AR36	7/7/2021	10.34	1.93	7.4	90.2	85.6	0.97	0.61	96.09	9.4	25.1	30.54	0.82	89.23
AR35	7/7/2021	16.26	0.6	4.33	92.59	87.43	1.39	0.74	90.34	6.94	29.32	33.19	0.88	89.29
AR41	6/9/2021	19.76	0.14	6.47	92.73	86.44	1.22	0.66	93.13	9.07	33.67	35.81	0.94	90.45
AR47	13/10/2021	17.03	-0.65	2.82	89.6	92.16	1.07	0.81	88.46	5.41	26.54	31.11	0.85	86.77
AR51	26/10/2021	19.66	-0.04	-3.08	88.92	91.63	1.06	0.81	94.62	4.33	21.52	30.62	0.70	90.11
AR54	2/11/2021	16.08	0.76	3.69	91.32	87.08	1.17	0.70	91.75	5.58	26.73	30.38	0.88	87.14

AR56	3/11/2021	12.92	0.52	-3.9	88.98	92.75	0.92	0.66	85.32	9.95	29.25	34.77	0.84	88.67
AR58	9/11/2021	18.33	0.91	-1.24	88.46	89.77	1.22	0.77	89.29	9.41	31.39	35.01	0.90	88.95
AR60	12/11/2021	13.13	-0.04	-0.09	87.46	87.23	0.95	0.65	93.74	5.99	31.44	32.92	0.96	89.21
AR65	17/11/2021	12.96	0.69	2.85	90.79	87.88	1.14	0.71	90.79	5.15	31.58	27.61	1.14	88.34
AR67	23/11/2021	12.06	2.8	6.45	91.37	87.39	1.18	0.76	90.43	6.35	24.29	25.04	0.97	89.03

ANNEX 9 – PREOPERATIVE DATA EXTRACTED BY OBSERVER 1

Table 27 - Postoperative data extracted by observer 1

id	Intervention date	JLH (mm)	JLCA (º)	HKA (º)	mLDFA (º)	mMPTA (º)	Altura patellar (Insall-Salvati)	Altura patellar (Caton-Deschamps)	PDFA (º)	Offset anterior (mm)	PCO (mm)	PCO_b (mm)	Ratio PCO	PTTA (º)
AR1	11/12/2020	6.62	-2.2	-1.44	86.19	85.52	1.05	0.75	84.76	6.76	19.42	25.76	0.76	77.89
AR2	18/12/2020	8.33	-2.79	9.99	89.66	80.6	1.22	0.96	89.29	6.32	22.07	24.81	0.89	76.35
AR8	10/2/2021	22.075	9.31	6.92	85.89	87.1	0.90	0.94	87.33	2.86	19.51	37.71	0.52	83.8
AR10	22/2/2021	16.035	4.87	9.48	88.08	83.75	0.90	0.90	83.53	4.84	22	34.87	0.63	80.82
AR11	2/3/2021	0	-	-	-	-	1.03	0.76	83.67	7.21	23.42	36.01	0.65	82.55
AR12	15/3/2021	16.525	0.73	-2.75	83.49	86.36	1.02	0.95	84.01	3.48	19.2	32.25	0.60	85.53
AR14	17/3/2021	14.395	4.2	12.37	93.51	85.56	0.93	0.58	87.39	10.77	26.1	31.98	0.82	79.96
AR16	30/3/2021	9.855	1.63	-1.28	85.89	89.16	1.26	0.95	87.97	7.98	22.66	38.72	0.59	83.03
AR17	14/4/2021	8.435	-0.2	-4.42	84.15	88.53	1.17	0.82	86.63	3.11	16.8	29.26	0.57	83.28
AR24	26/5/2021	19.685	1.03	4.54	85.88	82.73	0.99	0.65	82.93	2.17	17.09	36.13	0.47	88.22
AR26	7/6/2021	16.325	2.35	3.05	88.36	86.94	0.99	0.78	82.21	5.58	19.65	25.88	0.76	87.14
AR30	14/6/2021	13.685	5.27	13.06	89.49	81.52	0.97	0.68	84.55	8.28	21.21	29.9	0.71	83.65
AR36	7/7/2021	13.225	5.43	14.11	89.46	80.59	0.84	0.57	83.94	3.24	22.03	30.57	0.72	84.02
AR35	7/7/2021	14.605	3.47	4.92	88.38	85.92	1.23	0.99	72.47	6.82	21.17	29.96	0.71	80.63
AR41	6/9/2021	16.4	4.15	9.89	90.96	84.64	0.91	0.68	79.77	2.83	26.57	29.52	0.90	76
AR47	13/10/2021	11.49	0.35	5.03	85.64	83.42	1.00	0.81	81.3	3.6	23.17	31.19	0.74	78.65
AR54	2/11/2021	15.65	5.49	13.33	91.7	84.95	1.00	0.89	87.45	3.935	22.3	30.09	0.74	85.13
AR56	3/11/2021	11.38	3.75	4.99	88.84	87.66	0.99	0.97	86.25	2.57	22.98	28.83	0.80	76.67
AR58	9/11/2021	13.095	2.97	-2.22	86.74	90.85	1.02	0.69	80.11	4.36	15.25	30.35	0.50	81.65
AR65	17/11/2021	10.935	7.68	15.61	89.66	81.5	1.10	0.86	80.76	8.48	26.34	27.86	0.95	80.36
AR67	23/11/2021	9.88	4.62	11.52	91.55	86.72	0.99	0.79	86.39	2.89	22.85	25.49	0.90	82.28

ANNEX 10 – EXCEL TABLE PROVIDED BY ROSA KNEE SYSTEM WITH THE INTRAOPERATIVE DATA

Table 28 - Example of intraoperative data provided by ROSA Knee System

SURGEON INFORMATION	
Surgeon Name	XXXXX
Surgery Date	dd/mm/yy
PATIENT INFORMATION	
Case ID	XXXXX
Procedure	Left TKA
Gender	Female
Birth year	XXXXX
TIME BREAKDOWN	
Calibration	00:40:02.688000
Landmark femur	00:02:44.051000
Landmark tibia	00:01:42.102000
Knee State Evaluation	00:35:22.389000
Planning	00:04:35.478000
Surgery (cuts)	00:15:33.972000
INITIAL KNEE STATE	
Minimum Flexion [DEG]	1.4 EXTENSION
Maximum Flexion [DEG],	137.6 FLEXION
Extension: medial laxity [mm]	5.7
Extension: Lateral laxity [mm]	2.3
Extension: Maximum varus [DEG]	1.4 VALGUS
Extension: Maximum valgus [DEG]	13.5 VARUS
30Degree: Maximum varus [DEG]	---
30Degree: Maximum valgus [DEG]	---
45Degree: Maximum varus [DEG]	6.2 VARUS
45Degree: Maximum valgus [DEG]	11.7 VARUS
60Degree: Maximum varus [DEG]	---
60Degree: Maximum valgus [DEG]	---
Flexion: Medial laxity [mm]	0.0
Flexion: Lateral laxity [mm]	0.5
Flexion: Maximum varus [DEG]	4.5 VARUS
Flexion: Maximum valgus [DEG]	9.4 VARUS
120Degree:Maximum varus [DEG]	---
120Degree:Maximum valgus [DEG]	---

FINAL KNEE STATE	
Minimum Flexion/PDFA [DEG]	1.2 EXTENSION
Maximum Flexion/PDFA [DEG]	119.7 FLEXION
Extension: medial laxity [mm]	4.9
Extension: Lateral laxity [mm]	2.5
Extension: Maximum varus [DEG]	0.3 VALGUS
Extension: Maximum valgus [DEG]	5.9 VARUS
30Degree: Maximum varus [DEG]	---
30Degree: Maximum valgus [DEG]	---
45Degree: Maximum varus [DEG]	4.2 VARUS
45Degree: Maximum valgus [DEG]	7.4 VARUS
60Degree: Maximum varus [DEG]	---
60Degree: Maximum valgus [DEG]	---
Flexion: Medial laxity [mm]	3.2
Flexion: Lateral laxity [mm]	2.1
Flexion: Maximum varus [DEG]	2.1 VARUS
Flexion: Maximum valgus [DEG]	8.3 VARUS
120Degree:Maximum varus [DEG]	---
120Degree:Maximum valgus [DEG]	---
FEMUR DISTAL VALIDATION	
Flexion/PDFA [DEG]	N/A
Varus/Valgus/JLCA [DEG]	N/A
Distal medial resection [mm]	-nan(ind)
Distal lateral resection [mm]	-nan(ind)
FEMUR DISTAL CUT PLANNED	
Flexion/PDFA [DEG]	3.0 FLEXION
Varus/Valgus/JLCA [DEG]	1.6 VARUS
Distal medial resection [mm]	7.5
Distal lateral resection [mm]	8.6
Implant type brand	Persona PS Standard
Implant size	7
Planned HKA [DEG]	2.6 VARUS
FEMUR DISTAL VALIDATION	
Flexion [DEG]	2.2 FLEXION
Varus/Valgus [DEG]	1.4 VARUS
Distal medial resection [mm]	8.9
Distal lateral resection [mm]	10.1

FEMUR POSTERIOR VALIDATION	
PCA [DEG]	N/A
TEA [DEG]	N/A
Posterior medial resection [mm]	-nan(ind)
Posterior lateral resection [mm]	-nan(ind)
FEMUR 4IN1 CUT PLANNED	
Rotation from PCA [DEG]	4.4 EXT
Rotation from TEA [DEG]	5.5 EXT
Rotation from Whiteside [DEG]	7.3 EXT
Posterior medial resection [mm]	13.3
Posterior lateral resection [mm]	9.8
Stylus height [mm]	0.4
Implant type brand	Persona PS Standard
Implant size	7
Instrumentation (4-in-1)	Anterior referencing
FEMUR POSTERIOR VALIDATION	
PCA [DEG], N/A	N/A
TEA [DEG], N/A	N/A
Posterior medial resection [mm]	-nan(ind)
Posterior lateral resection [mm]	-nan(ind)
FEMUR 4IN1 CUT PLANNED	
Rotation from PCA [DEG]	4.4 EXT
Rotation from TEA [DEG]	5.5 EXT
Rotation from Whiteside [DEG]	7.3 EXT
Posterior medial resection [mm]	12.8
Posterior lateral resection [mm]	9.3
Stylus height [mm]	-0.1
Implant type brand	Persona PS Standard
Implant size	7
Instrumentation (4-in-1)	Anterior referencing
TIBIA PROXIMAL VALIDATION	
Slope [DEG]	N/A
Varus/Valgus/JLCA [DEG]	N/A
Proximal medial resection [mm]	-nan(ind)
Proximal lateral resection [mm]	-nan(ind)
TIBIAL PROXIMAL CUT PLANNED	
Slope [DEG]	5.0 POSTERIOR

Varus/Valgus/JLCA [DEG]	1.0 VARUS
Rotation [DEG]	0.1 INT
Proximal medial resection [mm]	7.6
Proximal lateral resection [mm]	10.5
Implant type brand	Persona Stemmed Cemented Tibia
Implant size	C
Planned HKA [DEG]	2.6 VARUS
TIBIA PROXIMAL VALIDATION	
Slope [DEG]	4.8 POSTERIOR
Varus/Valgus [DEG]	0.4 VARUS
Proximal medial resection [mm]	7.1
Proximal lateral resection [mm]	10.3
Final Implant Info	
Instrumentation (4-in-1)	Anterior Referencing
Planned HKA [DEG]	2.6 VARUS
Femoral Implant type brand	Persona PS Standard
Femoral Implant size	7
Tibial Implant type brand	Persona Stemmed Cemented Tibia
Tibial Implant size	C
Tibial Insert	10.0

ANNEX 11 – INTRAOPERATIVE DATA EXTRACTED BY ROSA

Table 29 – Summary of intraoperative data

Intervention date	id	HKA	mLDFA	MPTA	PDFA	PPTA	Femoral rotation
11/12/2020	AR1	2	89	89	87	87	5.4
18/12/2020	AR2	2.1	88.9	89	87	87	1.6
10/2/2021	AR8	0	90	90	87	87	6.5
22/2/2021	AR10	2.6	88.4	89	87	87	-0.4
2/3/2021	AR11	-0.2	90.2	90	87	87	-2.4
15/3/2021	AR12	-1	91	90	87	87	-5.5
17/3/2021	AR14	2.9	88.1	89	87	87	-1.5
30/3/2021	AR16	-3	91	92	87	87	3.1
14/4/2021	AR17	-1.6	91.6	90	87.1	87	-8.9
26/5/2021	AR24	2.6	88.4	89	87	87	-2.5
7/6/2021	AR26	1.6	89.4	89	87	87	5.4
8/6/2021	AR29	1.5	89	89.5	87	87	2.6
14/6/2021	AR30	3.1	88.9	88	87	87	-0.5
7/7/2021	AR36	3.4	89.1	87.5	87	87	1.3
7/7/2021	AR35	2	90	88	87	87	4.2
6/9/2021	AR41	2.5	89	88.5	87	87	6.9
13/10/2021	AR47	2.6	88.9	88.5	89	85	2.8
2/11/2021	AR54	4	88	88	87	86	6.7
3/11/2021	AR56	2	89	89	87	86	2.2
9/11/2021	AR58	1.1	89.9	89	87	87	3.7
17/11/2021	AR65	0.4	90.1	89.5	87	85	4.2
23/11/2021	AR67	2.1	88.9	88.25	87	86.925	4.4

ANNEX 12 – ACCURACY TEST TABLE (INTRAOPERATIVE VS POSTOPERATIVE)

Table 30 – Accuracy test table

id	Intervention date	Methodology	HKA	MLDFA	MPTA	PDFA	PTTA	Berger
AR1	11/12/2020	0	2	89	89	87	87	5.4
AR1	11/12/2020	1	0.51	89.3	89.64	81.92	78.64	5.79
AR2	18/12/2020	0	2.1	88.9	89	87	87	1.6
AR2	18/12/2020	1	6.58	87.48	87.54	84.45	89.47	2.02
AR8	10/2/2021	0	0	90	90	87	87	6.5
AR8	10/2/2021	1	3.31	88.55	86.97	88.91	85.72	0.36
AR10	22/2/2021	0	2.6	88.4	89	87	87	-0.4
AR10	22/2/2021	1	2.16	89.53	87.91	89.53	89.32	0.97
AR11	2/3/2021	0	-0.2	90.2	90	87	87	-2.4
AR11	2/3/2021	1	0.98	89.89	89.34	86.27	87.17	4.96
AR12	15/3/2021	0	-1	91	90	87	87	-5.5
AR12	15/3/2021	1	1.21	89.36	86.8	88.5	89.27	3.06
AR14	17/3/2021	0	2.9	88.1	89	87	87	-1.5
AR14	17/3/2021	1	5.35	87.19	85.16	82.77	88.11	0.13
AR16	30/3/2021	0	-3	91	92	87	87	3.1
AR16	30/3/2021	1	2.85	88.28	88.84	85.37	82.35	4.46
AR17	14/4/2021	0	-1.6	91.6	90	87.1	87	-8.9
AR17	14/4/2021	1	1.5	88.1	88	85	86.82	9.82
AR24	26/5/2021	0	2.6	88.4	89	87	87	-2.5
AR24	26/5/2021	1	3.22	89.91	89.21	87.14	89.51	3.02
AR26	7/6/2021	0	1.6	89.4	89	87	87	5.4
AR26	7/6/2021	1	0.71	88.97	89.87	84.84	82.86	7.36
AR30	14/6/2021	0	3.1	88.9	88	87	87	-0.5
AR30	14/6/2021	1	4.72	89.28	87.4	89.13	85.7	0.93
AR35	7/7/2021	0	2	90	88	87	87	4.2

AR35	7/7/2021	1	2.2	89.93	87.24	89.98	85.9	7.65
AR36	7/7/2021	0	3.4	89.1	87.5	87	87	1.3
AR36	7/7/2021	1	7.63	88.82	85.98	80.52	89.5	2.66
AR41	6/9/2021	0	2.5	89	88.5	87	87	6.9
AR41	6/9/2021	1	4.5	88.5	84.1	84.81	88.09	7.1
AR47	13/10/2021	0	2.6	88.9	88.5	89	85	2.8
AR47	13/10/2021	1	0.98	88.71	87.47	86.77	87.87	1.55
AR54	2/11/2021	0	4	88	88	87	86	6.7
AR54	2/11/2021	1	5.31	87.73	88.67	85.93	86.81	0
AR56	3/11/2021	0	2	89	89	87	86	2.2
AR56	3/11/2021	1	1.02	87.4	88.31	87.2	88.15	7.4
AR58	9/11/2021	0	1.1	89.9	89	87	87	3.7
AR58	9/11/2021	1	0.1	87.8	86.83	88.66	88.96	5.01
AR65	17/11/2021	0	0.4	90.1	89.5	87	85	4.2
AR65	17/11/2021	1	4.01	91.8	92.6	89.3	88.47	1.85
AR67	23/11/2021	0	2.1	88.9	88.25	87	86.925	4.4
AR67	23/11/2021	1	4.65	88.1	87.29	89.88	89.39	0.39

ANNEX 13 – INTER-OBSERVER ASSESSTMENT TABLE (OBSERVER 1 VS OBSERVER 2)

Table 31 – Inter-observer assessment table

Intervention date	id	HKA	mLDFA	MPTA	PDFA	PPTA	Femoral rotation
11/12/2020	AR1	2	89	89	87	87	5.4
18/12/2020	AR2	2.1	88.9	89	87	87	1.6
10/2/2021	AR8	0	90	90	87	87	6.5
22/2/2021	AR10	2.6	88.4	89	87	87	-0.4
2/3/2021	AR11	-0.2	90.2	90	87	87	-2.4
15/3/2021	AR12	-1	91	90	87	87	-5.5
17/3/2021	AR14	2.9	88.1	89	87	87	-1.5
30/3/2021	AR16	-3	91	92	87	87	3.1
14/4/2021	AR17	-1.6	91.6	90	87.1	87	-8.9
26/5/2021	AR24	2.6	88.4	89	87	87	-2.5
7/6/2021	AR26	1.6	89.4	89	87	87	5.4
8/6/2021	AR29	1.5	89	89.5	87	87	2.6
14/6/2021	AR30	3.1	88.9	88	87	87	-0.5
7/7/2021	AR36	3.4	89.1	87.5	87	87	1.3
7/7/2021	AR35	2	90	88	87	87	4.2
6/9/2021	AR41	2.5	89	88.5	87	87	6.9
13/10/2021	AR47	2.6	88.9	88.5	89	85	2.8
2/11/2021	AR54	4	88	88	87	86	6.7
3/11/2021	AR56	2	89	89	87	86	2.2
9/11/2021	AR58	1.1	89.9	89	87	87	3.7
17/11/2021	AR65	0.4	90.1	89.5	87	85	4.2
23/11/2021	AR67	2.1	88.9	88.25	87	86.925	4.4

ANNEX 14 – TC VS RX TABLE

Table 32 – TC vs RX table

Intervention date	id	HKA	mLDFA	MPTA	PDFA	PPTA	Femoral rotation
11/12/2020	AR1	2	89	89	87	87	5.4
18/12/2020	AR2	2.1	88.9	89	87	87	1.6
10/2/2021	AR8	0	90	90	87	87	6.5
22/2/2021	AR10	2.6	88.4	89	87	87	-0.4
2/3/2021	AR11	-0.2	90.2	90	87	87	-2.4
15/3/2021	AR12	-1	91	90	87	87	-5.5
17/3/2021	AR14	2.9	88.1	89	87	87	-1.5
30/3/2021	AR16	-3	91	92	87	87	3.1
14/4/2021	AR17	-1.6	91.6	90	87.1	87	-8.9
26/5/2021	AR24	2.6	88.4	89	87	87	-2.5
7/6/2021	AR26	1.6	89.4	89	87	87	5.4
8/6/2021	AR29	1.5	89	89.5	87	87	2.6
14/6/2021	AR30	3.1	88.9	88	87	87	-0.5
7/7/2021	AR36	3.4	89.1	87.5	87	87	1.3
7/7/2021	AR35	2	90	88	87	87	4.2
6/9/2021	AR41	2.5	89	88.5	87	87	6.9
13/10/2021	AR47	2.6	88.9	88.5	89	85	2.8
2/11/2021	AR54	4	88	88	87	86	6.7
3/11/2021	AR56	2	89	89	87	86	2.2
9/11/2021	AR58	1.1	89.9	89	87	87	3.7
17/11/2021	AR65	0.4	90.1	89.5	87	85	4.2
23/11/2021	AR67	2.1	88.9	88.25	87	86.925	4.4

ANNEX 15 – R-STUDIO CODES (STATISTICAL TESTS)

ACCURACY TEST CODE

```
#TFG_Analisi concordanca INTRAOPERATORI vs POSTOPERATORI RX i TM
dades <- read.table("IntraopvsPostop_TC.txt",header=T,sep="\t")
head(dades)

#_____________________EXAMPLE WITH JUST ONE
VARIABLE_____________________________
#_________HKA
#Scatter plot
intra_hka=dades[dades$metode==0,]$HKA
post_hka=dades[dades$metode==1,]$HKA
plot(post_hka~intra_hka,xlab="Intraoperatori",ylab="Postoperatori",yli
m=range(-1,8),xlim=range(-1,8))
abline(0,1)

#Concordanca
library(cccrm)
cccfit_hka=cccvc(dades,"HKA","id","metode")
cccfit_hka

#BlandAltman tolerance limits
diff_hka=post_hka-intra_hka
av_hka=(intra_hka+post_hka)/2
sd_hka=sd(diff_hka)
mean_diff_hka=mean(diff_hka)
uplim_hka=mean_diff_hka+1.96*sd_hka
lowlim_hka=mean_diff_hka-1.96*sd_hka
mean_diff_hka
uplim_hka
lowlim_hka

#BlandAltman plot with tolerance limits
scatter.smooth(av_hka,diff_hka,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(-0.5,5.5),ylim =
range(-3.5,6),main="Bland-Altman plot HKA")
abline(h=c(mean_diff_hka,lowlim_hka,uplim_hka),col=c("#2F5597","#FD940
7","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))
```

```
#_______________MLDFA
#Scatter plot
intra_mldfa=dades[dades$metode==0,]$MLDFA
post_mldfa=dades[dades$metode==1,]$MLDFA
plot(post_mldfa~intra_mldfa,xlab="Intraoperatori",ylab="Postoperatori"
,ylim=range(86,92))
abline(0,1)

#Concordanca
cccfit_mldfa=cccvc(dades,"MLDFA","id","metode")
cccfit_mldfa

#BlandAltman tolerance limits
diff_mldfa=post_mldfa-intra_mldfa
av_mldfa=(intra_mldfa+post_mldfa)/2
sd_mldfa=sd(diff_mldfa)
mean_diff_mldfa=mean(diff_mldfa)
uplim_mldfa=mean_diff_mldfa+1.96*sd_mldfa
lowlim_mldfa=mean_diff_mldfa-1.96*sd_mldfa
mean_diff_mldfa
uplim_mldfa
lowlim_mldfa

#BlandAltman plot with tolerance limits
scatter.smooth(av_mldfa,diff_mldfa,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(87.5,91),ylim =
range(-4,2.25),main="Bland-Altman plot mLDFA")
abline(h=c(mean_diff_mldfa,lowlim_mldfa,uplim_mldfa),col=c("#2F5597","
#FD9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________MPTA
#Scatter plot
intra_mpta=dades[dades$metode==0,]$MPTA
post_mpta=dades[dades$metode==1,]$MPTA
plot(post_mpta~intra_mpta,xlab="Intraoperatori",ylab="Postoperatori",y
lim=range(86,92))
abline(0,1)

#Concordanca
cccfit_mpta=cccvc(dades,"MPTA","id","metode")
cccfit_mpta
```

```
#BlandAltman tolerance limits
diff_mpta=post_mpta-intra_mpta
av_mpta=(intra_mpta+post_mpta)/2
sd_mpta=sd(diff_mpta)
mean_diff_mpta=mean(diff_mpta)
uplim_mpta=mean_diff_mpta+1.96*sd_mpta
lowlim_mpta=mean_diff_mpta-1.96*sd_mpta
mean_diff_mpta
uplim_mpta
lowlim_mpta

#BlandAltman plot with tolerance limits
scatter.smooth(av_mpta,diff_mpta,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(86,91),ylim = range(-
5.5,4),main="Bland-Altman plot mMPTA")
abline(h=c(mean_diff_mpta,lowlim_mpta,uplim_mpta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________PDFA
#Scatter plot
intra_pdfa=dades[dades$metode==0,]$PDFA
post_pdfa=dades[dades$metode==1,]$PDFA
plot(post_pdfa~intra_pdfa,xlab="Intraoperatori",ylab="Postoperatori",y
lim=range(79,91))

abline(0,1)


#BlandAltman tolerance limits -> Descriure
diff_pdfa=post_pdfa-intra_pdfa
av_pdfa=(intra_pdfa+post_pdfa)/2
sd_pdfa=sd(diff_pdfa)
mean_diff_pdfa=mean(diff_pdfa)
uplim_pdfa=mean_diff_pdfa+1.96*sd_pdfa
lowlim_pdfa=mean_diff_pdfa-1.96*sd_pdfa
mean_diff_pdfa
uplim_pdfa
lowlim_pdfa

#Fer boxplot
```

```
boxplot(diff_pdfa,
        main = "Boxplot of the differences PDFA",
        xlab = "Degrees",
        ylab = "Difference between intraop and postop value",
        col = "#FD9407",
        border = "#2F5597",cex.lab=0.65,cex.axis=0.75,cex.main=0.75)

#BlandAltman plot with tolerance limits
scatter.smooth(av_pdfa,diff_pdfa,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,xlim=range(83.5,88.75),ylim = range(-
7,4.75),main="Bland-Altman plot PDFA")
abline(h=c(mean_diff_pdfa,lowlim_pdfa,uplim_pdfa),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))




#_________PTTA
#Scatter plot
intra_ptta=dades[dades$metode==0,]$PTTA
post_ptta=dades[dades$metode==1,]$PTTA
plot(post_ptta~intra_ptta,xlab="Intraoperatori",ylab="Postoperatori",x
lim=range(85,87),ylim=range(85,90))
abline(0,1)

#BlandAltman tolerance limits
diff_ptta=post_ptta-intra_ptta
av_ptta=(intra_ptta+post_ptta)/2
sd_ptta=sd(diff_ptta)
mean_diff_ptta=mean(diff_ptta)
uplim_ptta=mean_diff_ptta+1.96*sd_ptta
lowlim_ptta=mean_diff_ptta-1.96*sd_ptta
mean_diff_ptta
uplim_ptta
lowlim_ptta

#Fer boxplot
boxplot(diff_ptta,
        main = "Boxplot of the differences PTTA",
        xlab = "Degrees",
        ylab = "Difference between intraop and postop value",
        col = "#FD9407",
```

```
        border = "#2F5597",cex.lab=0.65,cex.axis=0.75,cex.main=0.75)

#BlandAltman plot with tolerance limits
scatter.smooth(av_ptta,diff_ptta,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,xlim=range(82.7,88.5),ylim = range(-
9,7),main="Bland-Altman plot PTTA")
abline(h=c(mean_diff_ptta,lowlim_ptta,uplim_ptta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_____________Berger
#Scatter plot
dades_without_outlier=read.table("IntraopvsPostop_TC_senseoutliers.txt
",header=T,sep="\t")

intra_berger=dades_without_outlier[dades_without_outlier$metode==0,]$B
erger
post_berger=dades_without_outlier[dades_without_outlier$metode==1,]$Be
rger
plot(post_berger~intra_berger,xlab="Intraoperatori",ylab="Postoperator
i",xlim=range(-2.5,6.5),ylim=range(-1,8))
abline(0,1)

#Concordanca
cccfit_berger=cccvc(dades_without_outlier,"Berger","id","metode")
cccfit_berger

#BlandAltman tolerance limits
diff_berger=post_berger-intra_berger
av_berger=(intra_berger+post_berger)/2
sd_berger=sd(diff_berger)
mean_diff_berger=mean(diff_berger)
uplim_berger=mean_diff_berger+1.96*sd_berger
lowlim_berger=mean_diff_berger-1.96*sd_berger
mean_diff_berger
uplim_berger
lowlim_berger

#BlandAltman plot with tolerance limits
scatter.smooth(av_berger,diff_berger,pch=16,xlab="Average of intraop
and postop values [degrees]",ylab="Difference between postop and
```

```
intraop value [degrees]",cex.lab=0.75,span=1,xlim=range(-1.5,7),ylim =
range(-9,9),main="Bland-Altman plot Femoral component rotation")
abline(h=c(mean_diff_berger,lowlim_berger,uplim_berger),col=c("#2F5597
","#FD9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))
```

INTER-OBSERVER ASSESSMENT TEST

```
#TFG_Analisi inter-observer assessment
dades <- read.table("RX_ob1vsRX_ob2.txt",header=T,sep="\t")
head(dades)

#_________HKA
#Scatter plot
hka_o1=dades[dades$observer==1,]$HKA
hka_o2=dades[dades$observer==2,]$HKA
plot(hka_o2~hka_o1,xlab="Observer 1",ylab="Observer 2",ylim=range(-
2,8))
abline(0,1)

#Concordanca
library(cccrm)
cccfit_hka=cccvc(dades,"HKA","id","observer")
cccfit_hka

#BlandAltman tolerance limits
diff_hka=hka_o2-hka_o1
av_hka=(hka_o2+hka_o1)/2
sd_hka=sd(diff_hka)
mean_diff_hka=mean(diff_hka)
uplim_hka=mean_diff_hka+1.96*sd_hka
lowlim_hka=mean_diff_hka-1.96*sd_hka
mean_diff_hka
uplim_hka
lowlim_hka

#BlandAltman plot with tolerance limits
scatter.smooth(av_hka,diff_hka,pch=16,xlab="Average of values between
observers [degrees]",ylab="Difference of values between observers
[degrees]",cex.lab=0.75,span=1,xlim=range(-1,7.75),ylim = range(-
3,6),main="Bland-Altman plot HKA (interobserver)")
abline(h=c(mean_diff_hka,lowlim_hka,uplim_hka),col=c("#2F5597","#FD940
7","#FD9407"),lty=2)
```

```
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_____________mLDFA
#Scatter plot
mldfa_o1=dades[dades$observer==1,]$MLDFA
mldfa_o2=dades[dades$observer==2,]$MLDFA
plot(mldfa_o2~mldfa_o1,xlab="Observer 1",ylab="Observer
2",xlim=range(84,96),ylim=range(84,96))
abline(0,1)

#Concordanca
cccfit_mldfa=cccvc(dades,"MLDFA","id","observer")
cccfit_mldfa

#BlandAltman tolerance limits
diff_mldfa=mldfa_o2-mldfa_o1
av_mldfa=(mldfa_o2+mldfa_o1)/2
sd_mldfa=sd(diff_mldfa)
mean_diff_mldfa=mean(diff_mldfa)
uplim_mldfa=mean_diff_mldfa+1.96*sd_mldfa
lowlim_mldfa=mean_diff_mldfa-1.96*sd_mldfa
mean_diff_mldfa
uplim_mldfa
lowlim_mldfa

#BlandAltman plot with tolerance limits
scatter.smooth(av_mldfa,diff_mldfa,pch=16,xlab="Average of values
between observers [degrees]",ylab="Difference of values between
observers [degrees]",cex.lab=0.75,span=1,xlim=range(85.5,95),ylim =
range(-6,6),main="Bland-Altman plot mLDFA (interobserver)")
abline(h=c(mean_diff_mldfa,lowlim_mldfa,uplim_mldfa),col=c("#2F5597","
#FD9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________MPTA
#Scatter plot
mpta_o1=dades[dades$observer==1,]$MPTA
mpta_o2=dades[dades$observer==2,]$MPTA
plot(mpta_o2~mpta_o1,xlab="Observer 1",ylab="Observer
2",xlim=range(84,94),ylim=range(84,94))
abline(0,1)
```

```
#Concordanca
cccfit_mpta=cccvc(dades,"MPTA","id","observer")
cccfit_mpta

#BlandAltman tolerance limits
diff_mpta=mpta_o2-mpta_o1
av_mpta=(mpta_o1+mpta_o2)/2
sd_mpta=sd(diff_mpta)
mean_diff_mpta=mean(diff_mpta)
uplim_mpta=mean_diff_mpta+1.96*sd_mpta
lowlim_mpta=mean_diff_mpta-1.96*sd_mpta
mean_diff_mpta
uplim_mpta
lowlim_mpta

#BlandAltman plot with tolerance limits
scatter.smooth(av_mpta,diff_mpta,pch=16,xlab="Average of values
between observers [degrees]",ylab="Difference of values between
observers [degrees]",cex.lab=0.75,span=1,xlim=range(86,94.5),ylim =
range(-6,6),main="Bland-Altman plot mMPTA (interobserver)")
abline(h=c(mean_diff_mpta,lowlim_mpta,uplim_mpta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________PDFA
#Scatter plot
dades_without_outlier=read.table("RX_ob1vsRX_ob2_without_outlier.txt",
header=T,sep="\t")
pdfa_o1=dades_without_outlier[dades_without_outlier$observer==1,]$PDFA
pdfa_o2=dades_without_outlier[dades_without_outlier$observer==2,]$PDFA
plot(pdfa_o2~pdfa_o1,xlab="Observer 1",ylab="Observer
2",xlim=range(82,96),ylim=range(82,96))
abline(0,1)

#Concordanca
cccfit_pdfa=cccvc(dades_without_outlier,"PDFA","id","observer")
cccfit_pdfa

#BlandAltman tolerance limits
diff_pdfa=pdfa_o2-pdfa_o1
av_pdfa=(pdfa_o1+pdfa_o2)/2
sd_pdfa=sd(diff_pdfa)
```

```
mean_diff_pdfa=mean(diff_pdfa)
uplim_pdfa=mean_diff_pdfa+1.96*sd_pdfa
lowlim_pdfa=mean_diff_pdfa-1.96*sd_pdfa
mean_diff_pdfa
uplim_pdfa
lowlim_pdfa

#BlandAltman plot with tolerance limits
scatter.smooth(av_pdfa,diff_pdfa,pch=16,xlab="Average of values
between observers [degrees]",ylab="Difference of values between
observers [degrees]",cex.lab=0.75,span=1,xlim=range(86,94.5),ylim =
range(-8.5,4),main="Bland-Altman plot PDFA (interobserver)")
abline(h=c(mean_diff_pdfa,lowlim_pdfa,uplim_pdfa),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________PTTA
#Scatter plot
ptta_o1=dades[dades$observer==1,]$PTTA
ptta_o2=dades[dades$observer==2,]$PTTA
plot(ptta_o2~ptta_o1,xlab="Observer 1",ylab="Observer
2",xlim=range(82,95),ylim=range(82,95))
abline(0,1)

#Concordanca
cccfit_ptta=cccvc(dades,"PTTA","id","observer")
cccfit_ptta

#BlandAltman tolerance limits
diff_ptta=ptta_o2-ptta_o1
av_ptta=(ptta_o1+ptta_o2)/2
sd_ptta=sd(diff_ptta)
mean_diff_ptta=mean(diff_ptta)
uplim_ptta=mean_diff_ptta+1.96*sd_ptta
lowlim_ptta=mean_diff_ptta-1.96*sd_ptta
mean_diff_ptta
uplim_ptta
lowlim_ptta

#BlandAltman plot with tolerance limits
scatter.smooth(av_ptta,diff_ptta,pch=16,xlab="Average of values
between observers [degrees]",ylab="Difference of values between
```

```
observers [degrees]",cex.lab=0.75,span=1,xlim=range(85,93),ylim =
range(-8,6.5),main="Bland-Altman plot PTTA (interobserver)")
abline(h=c(mean_diff_ptta,lowlim_ptta,uplim_ptta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________JLCA
#Scatter plot
jlca_o1=dades[dades$observer==1,]$JLCA
jlca_o2=dades[dades$observer==2,]$JLCA
plot(jlca_o2~jlca_o1,xlab="Observer 1",ylab="Observer 2")
abline(0,1)

#Concordanca
cccfit_jlca=cccvc(dades,"JLCA","id","observer")
cccfit_jlca

#BlandAltman tolerance limits
diff_jlca=jlca_o2-jlca_o1
av_jlca=(jlca_o1+jlca_o2)/2
sd_jlca=sd(diff_jlca)
mean_diff_jlca=mean(diff_jlca)
uplim_jlca=mean_diff_jlca+1.96*sd_jlca
lowlim_jlca=mean_diff_jlca-1.96*sd_jlca
mean_diff_jlca
uplim_jlca
lowlim_jlca

#BlandAltman plot with tolerance limits
scatter.smooth(av_jlca,diff_jlca,pch=16,xlab="Average of values
between observers [degrees]",ylab="Difference of values between
observers [degrees]",cex.lab=0.75,span=1,xlim=range(0.1,2.9),ylim =
range(-2,3),main="Bland-Altman plot JLCA (interobserver)")
abline(h=c(mean_diff_jlca,lowlim_jlca,uplim_jlca),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________OFFSET ANTERIOR
#Scatter plot
offan_o1=dades[dades$observer==1,]$ANT_OFFSET
offan_o2=dades[dades$observer==2,]$ANT_OFFSET
```

```
plot(offan_o2~offan_o1,xlab="Observer 1",ylab="Observer 2")
abline(0,1)

#Concordanca
cccfit_offan=cccvc(dades,"ANT_OFFSET","id","observer")
cccfit_offan

#BlandAltman tolerance limits
diff_offan=offan_o2-offan_o1
av_offan=(offan_o1+offan_o2)/2
sd_offan=sd(diff_offan)
mean_diff_offan=mean(diff_offan)
uplim_offan=mean_diff_offan+1.96*sd_offan
lowlim_offan=mean_diff_offan-1.96*sd_offan
mean_diff_offan
uplim_offan
lowlim_offan

#BlandAltman plot with tolerance limits
scatter.smooth(av_offan,diff_offan,pch=16,xlab="Average of values
between observers [mm]",ylab="Difference of values between observers
[mm]",cex.lab=0.75,cex.main=.9,span=1,xlim=range(2,10),ylim = range(-
6,6),main="Bland-Altman plot femoral anterior offset (interobserver)")
abline(h=c(mean_diff_offan,lowlim_offan,uplim_offan),col=c("#2F5597","
#FD9407","#FD9407"),lty=2)
legend("bottomleft",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))



#_________PCO
#Scatter plot
pco_o1=dades[dades$observer==1,]$PCO
pco_o2=dades[dades$observer==2,]$PCO
plot(pco_o2~pco_o1,xlab="Observer 1",ylab="Observer 2")
abline(0,1)

#Concordanca
cccfit_pco=cccvc(dades,"PCO","id","observer")
cccfit_pco

#BlandAltman tolerance limits
diff_pco=pco_o2-pco_o1
av_pco=(pco_o1+pco_o2)/2
sd_pco=sd(diff_pco)
mean_diff_pco=mean(diff_pco)
```

```
uplim_pco=mean_diff_pco+1.96*sd_pco
lowlim_pco=mean_diff_pco-1.96*sd_pco
mean_diff_pco
uplim_pco
lowlim_pco

#BlandAltman plot with tolerance limits
scatter.smooth(av_pco,diff_pco,pch=16,xlab="Average of values between
observers [mm]",ylab="Difference of values between observers
[mm]",cex.lab=0.75,xlim=range(23,37),ylim=range(-
10,10),span=1,main="Bland-Altman plot PCO (interobserver)")
abline(h=c(mean_diff_pco,lowlim_pco,uplim_pco),col=c("#2F5597","#FD940
7","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))
```

TC VS RX CODE

```
#TFG_Analisi TC vs RX
dades <- read.table("TCvsRX_ob1.txt",header=T,sep="\t")
head(dades)


#_____________________EXAMPLE WITH JUST ONE
VARIABLE_____________________________

#_________HKA
#Scatter plot
tc_hka=dades[dades$metode==0,]$HKA
rx_hka=dades[dades$metode==1,]$HKA
plot(rx_hka~tc_hka,xlab="Intraoperatori",ylab="Postoperatori",ylim=ran
ge(-1,8),xlim=range(-1,8))
abline(0,1)

#Concordanca
library(cccrm)
cccfit_hka=cccvc(dades,"HKA","id","metode")
cccfit_hka

#BlandAltman tolerance limits
diff_hka=rx_hka-tc_hka
av_hka=(rx_hka+tc_hka)/2
sd_hka=sd(diff_hka)
mean_diff_hka=mean(diff_hka)
```

```
uplim_hka=mean_diff_hka+1.96*sd_hka
lowlim_hka=mean_diff_hka-1.96*sd_hka
mean_diff_hka
uplim_hka
lowlim_hka

#BlandAltman plot with tolerance limits
scatter.smooth(av_hka,diff_hka,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(-2,6),ylim = range(-
8,5),main="Bland-Altman plot HKA (TC vs RX)")
abline(h=c(mean_diff_hka,lowlim_hka,uplim_hka),col=c("#2F5597","#FD940
7","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_____________MLDFA
#Scatter plot
tc_mldfa=dades[dades$metode==0,]$MLDFA
rx_mldfa=dades[dades$metode==1,]$MLDFA
plot(tc_mldfa~rx_mldfa,xlab="Intraoperatori",ylab="Postoperatori",ylim
=range(86,92))
abline(0,1)

#Concordanca
cccfit_mldfa=cccvc(dades,"MLDFA","id","metode")
cccfit_mldfa

#BlandAltman tolerance limits
diff_mldfa=rx_mldfa-tc_mldfa
av_mldfa=(tc_mldfa+rx_mldfa)/2
sd_mldfa=sd(diff_mldfa)
mean_diff_mldfa=mean(diff_mldfa)
uplim_mldfa=mean_diff_mldfa+1.96*sd_mldfa
lowlim_mldfa=mean_diff_mldfa-1.96*sd_mldfa
mean_diff_mldfa
uplim_mldfa
lowlim_mldfa

#BlandAltman plot with tolerance limits
scatter.smooth(av_mldfa,diff_mldfa,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(87,91.5),ylim =
range(-3.5,6.5),main="Bland-Altman plot mLDFA (TC vs RX)")
```

```
abline(h=c(mean_diff_mldfa,lowlim_mldfa,uplim_mldfa),col=c("#2F5597","
#FD9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________MPTA
#Scatter plot
tc_mpta=dades[dades$metode==0,]$MPTA
rx_mpta=dades[dades$metode==1,]$MPTA
plot(rx_mpta~tc_mpta,xlab="Intraoperatori",ylab="Postoperatori",ylim=r
ange(86,92))
abline(0,1)

#Concordanca
cccfit_mpta=cccvc(dades,"MPTA","id","metode")
cccfit_mpta

#BlandAltman tolerance limits
diff_mpta=rx_mpta-tc_mpta
av_mpta=(tc_mpta+rx_mpta)/2
sd_mpta=sd(diff_mpta)
mean_diff_mpta=mean(diff_mpta)
uplim_mpta=mean_diff_mpta+1.96*sd_mpta
lowlim_mpta=mean_diff_mpta-1.96*sd_mpta
mean_diff_mpta
uplim_mpta
lowlim_mpta

#BlandAltman plot with tolerance limits
scatter.smooth(av_mpta,diff_mpta,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,span=1,xlim=range(84.75,91),ylim =
range(-6,6.5),main="Bland-Altman plot mMPTA (TC vs RX)")
abline(h=c(mean_diff_mpta,lowlim_mpta,uplim_mpta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomleft",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________PDFA
#Scatter plot
tc_pdfa=dades[dades$metode==0,]$PDFA
rx_pdfa=dades[dades$metode==1,]$PDFA
```

```
plot(rx_pdfa~tc_pdfa,xlab="Intraoperatori",ylab="Postoperatori",ylim=r
ange(79,91))
abline(0,1)

#Concordanca
cccfit_pdfa=cccvc(dades,"PDFA","id","metode")
cccfit_pdfa

#BlandAltman tolerance limits -> Descriure
diff_pdfa=rx_pdfa-tc_pdfa
av_pdfa=(tc_pdfa+rx_pdfa)/2
sd_pdfa=sd(diff_pdfa)
mean_diff_pdfa=mean(diff_pdfa)
uplim_pdfa=mean_diff_pdfa+1.96*sd_pdfa
lowlim_pdfa=mean_diff_pdfa-1.96*sd_pdfa
mean_diff_pdfa
uplim_pdfa
lowlim_pdfa

#BlandAltman plot with tolerance limits
scatter.smooth(av_pdfa,diff_pdfa,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",span=1,cex.lab=0.75,xlim=range(85,91.5),ylim =
range(-6,16),main="Bland-Altman plot PDFA (TC vs RX)")
abline(h=c(mean_diff_pdfa,lowlim_pdfa,uplim_pdfa),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))


#_________PTTA
dades_senseoutlier <-
read.table("TCvsRX_ob1_senseoutlier_ptta.txt",header=T,sep="\t")

#Scatter plot
tc_ptta=dades[dades$metode==0,]$PTTA
rx_ptta=dades[dades$metode==1,]$PTTA
plot(rx_ptta~tc_ptta,xlab="Intraoperatori",ylab="Postoperatori",xlim=r
ange(85,87),ylim=range(85,90))
abline(0,1)

#Concordanca
cccfit_ptta=cccvc(dades,"PTTA","id","metode")
cccfit_ptta
```

```
#BlandAltman tolerance limits
diff_ptta=rx_ptta-tc_ptta
av_ptta=(tc_ptta+rx_ptta)/2
sd_ptta=sd(diff_ptta)
mean_diff_ptta=mean(diff_ptta)
uplim_ptta=mean_diff_ptta+1.96*sd_ptta
lowlim_ptta=mean_diff_ptta-1.96*sd_ptta
mean_diff_ptta
uplim_ptta
lowlim_ptta


#BlandAltman plot with tolerance limits
scatter.smooth(av_ptta,diff_ptta,pch=16,xlab="Average of intraop and
postop values [degrees]",ylab="Difference between postop and intraop
value [degrees]",cex.lab=0.75,xlim=range(82.7,90.5),ylim = range(-
6,10),span=1,main="Bland-Altman plot PTTA (TC vs RX)")
abline(h=c(mean_diff_ptta,lowlim_ptta,uplim_ptta),col=c("#2F5597","#FD
9407","#FD9407"),lty=2)
legend("bottomright",legend=c("Mean of the differences","Limits of
agreement"),cex=.5,col=c("#2F5597","#FD9407"),pch=c("-","-"))
```