UNIVERSITAT DE
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Final Degree Project

Biomedical Engineering Degree

“Robotic-assisted Surgery in Unicompartmental Knee Arthroplasty: Learning Curves and Clinical Outcomes“

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ABSTRACT

Knee osteoarthritis (KOA) significantly impacts patients' quality of life, and when this disease affects only one compartment of the knee, it is effectively treated with Unicompartmental Knee Arthroplasty (UKA). In this surgical technique, the damaged compartment of the knee is replaced with an implant normally made with metal and polyethylene. Nowadays, this procedure can be performed using two approaches: conventional or robotic-assisted surgery.

This project aims to study the impact of the inclusion of the CORI Robotic System in UKA surgeries. The main goal is to analyze the learning curve of the surgeons when adopting this technology in terms of surgical time. The analysis of this curve allows to study if this technological advancement is safe for the patients, even when surgeons are learning how to use the robotic system. Secondary objectives include the comparison of radiological and functional outcomes between conventional and robotic assisted UKA surgeries.

The study has been conducted at the Orthopedics Surgery and Traumatology Department of the Hospital Clínic of Barcelona. All the phases involved, from the selection of patients to participate in the study to the discussion of the results, are detailed in this project

Keywords: Osteoarthritis, Unicompartmental Knee Arthroplasty, Learning Curve, Robotic Surgical Systems, CORI Surgical Robot, CUSUM technique.

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GLOSSARY OF ABREVIATIONS

UKA: Unicompartmental Knee Arthroplasty

ra-UKA: Robotic Assisted Unicompartmental Knee Arthroplasty

c-UKA: Conventional Unicompartmental Knee Arhtroplasty

TKA: Total Knee Arthroplasty

THA: Total Hip Arhtroplasy

CUSUM: Cumulative Sum

ROM: Range of Movement

PROMs: Patient-reported outcome measures

KOA: Knee Osteoarthritis

MB: Mobile Bearing

FB: Fixed Bearing

ORs: Operating Rooms

RMS: Root Mean Square

AI: Artificial Intelligence

AR: Augmented Reality

KOOS-12: Knee injury and Osteoarthritis Outcome Score

NPS: Net Promoter Score

FJS: Forgotten Joint Score

HKA: Hip Knee Ankle

JLH: Joint Line Height

RK: Right Knee

LK: Left Knee

CAGR: Compound Annual Growth Rate

TCA: Tibial Coronal Angle

TSA: Tibial Sagittal Angle

FCA: Femoral Coronal Angle

FSA: Femoral Sagittal Angle

BMI: Body Mass Index

PERT: Program Evaluation and Review Technique

WBS: Work Breakdown Structure

CONTENTS

INTRODUCTION

PROJECT DEFINITION

The main goal of the project is to analyze the learning curve of orthopedic surgeons when incorporating the CORI Surgical System by Smith-Nephew in Unicompartmental Knee Arthroplasty (UKA) surgeries. The analysis is carried out using the technique CUSUM by evaluating the surgical times in consecutive cases. Hypothetically, the first part of the curve represents the learning phase of the surgeons, and the second part the expertise level. As a secondary objective, a comparative statistical analysis is carried out between patients who have been operated in a conventional way and patients operated with robotic-assisted surgery. This comparative study evaluates variables extracted from Patient Reported Outcomes Measures (PROMs) questionnaires regarding functional outcomes and quality of life of the patients after the intervention, and radiological variables. The complete study aims to answer the following questions: With how many surgeries is the robotic assisted UKA learning process established? Are there differences in terms of outcomes and complications during the learning phase compared to the subsequent phase? In other words, is the robot safe even when the surgeon lacks experience? Are there differences in terms of limb alignment and functional outcomes between conventional UKA and r-aUKA?

PROJECT JUSTIFICATION

Knee osteoarthritis (KOA) is a kind of degenerative disease of the knee joint mainly caused by mechanical, metabolic, inflammatory, and immune factors. If this condition is not treated in time, it can cause joint deformity and dysfunction, seriously affecting the patient’s quality of life. Nowadays, Unicompartmental Knee Arthroplasty (UKA) has been proven to be an effective treatment method for isolated medial or lateral compartment KOA in appropriately selected patients (1).

According to the 2019 Annual Report of the National Joint Registry, approximately 10.000 Unicompartmental Knee Arthroplasties (UKAs) are performed yearly in the United Kingdom (2). Furthermore, based on the Third Report of the Catalan Arthroplasty Register, around 384 UKAs are conducted annually in Catalonia (3). The number of Total Knee Arthroplasty (TKA) surgeries performed is known to be higher than that of UKA. However, the increased demand for minimally invasive surgeries has increased the popularity of UKA, which minimizes the release of the soft tissues and preserves the healthy compartments of the knee, leading to a closer mimic of the normal knee kinematics (4).

Studies have shown that the implant survival in medial and lateral UKA exceed 94.6% in the short-to mid-term (<10 years) and 86.6% in the long-term (>10 years) (5). Being this a relatively high survival rate, data from national registries suggest that surgical errors in implant positioning and suboptimal limb alignment are common reasons for implant failure and early revision (6–8). Robotic-assisted technology has been demonstrated to improve the accuracy of bone preparation and implant placement, reduce technical variability and outliers, and enhance reproducibility of limb alignment. Additionally, it is known that the surgical technique for UKA is more demanding and requires more surgical experience than TKA. The outcomes are highly dependent on the surgeon, and theoretically, robotics in UKA helps standardize the process, enabling surgeons with limited UKA experience to achieve good results from the beginning (9). However, implementing ra-UKA requires the understanding and study of the learning curves and their impact on patients to ensure security.

By investigating the learning curve associated with surgeons adopting the CORI robotic system for UKA surgeries, this project aims to address critical questions regarding patient safety, satisfaction, and surgical effectiveness. Additionally, a comparative analysis between conventional UKA (c-UKA) and ra-UKA will offer valuable insights into the respective benefits and limitations of each approach. Specifically, this study aims to assess whether robotic assistance results in better implant alignment, better knee balance, superior functional outcomes, and improved quality of life for patients undergoing UKA surgery.

OBJECTIVES

In this section, the principal objectives of the study are presented. Accomplishing these objectives will facilitate an in-depth analysis, leading to valuable conclusions regarding UKA procedure.

Primary objectives

The principal objective of the project is to analyze the learning curves of surgeons incorporating the CORI robot into UKA, using the CUSUM technique. To achieve this objective, several sub-objectives have been defined:

- Preparation of the robotic-assisted UKAs dataset for the generation of the curve.
- Generation of the learning curve and evaluation of the phases of it: assess the performance of surgeons during the early stages of adopting robotic-assisted techniques in UKA and compare it to the second phase, when surgeons are expected to reach the level of proficiency.
- Measure the surgical proficiency over time: track the progression of the surgeons by analyzing variables such as operating time and implant positioning.

Secondary objectives

The second objective is to compute a comparative statistical analysis between patients who have been operated conventionally and patients operated with robotic-assisted surgery using CORI surgical system. The analysis is made regarding radiological variables (patient-specific measurements) and functional variables (extracted from PROMs questionnaires).

SCOPE OF THE PROJECT

To ensure the project meets its established objectives, it is crucial to define the project scope comprehensively, outlining what the project covers as well as what it does not. By detailing the inclusions and exclusions, the scope ensures that the project stays focused on its intended goals.

- Review of surgical data of surgeons using the CORI surgical system: this involves examining the data collected during surgeries where the robot was used, such as the time taken to perform each operation, as well as other relevant surgical metrics. This data is crucial for generating learning curves, which show how surgeons' performance improves over time with the use of robotic assistance.
- Generation and analysis of learning curves: using the data extracted from the surgeries, the learning curves are generated using the CUSUM technique and later analyzed.
- Review of radiological variables for each patient that underwent either ra-UKA or c-UKA: radiological metrics are used to assess the limb alignment of the patient before and after the surgery. These variables are also included in the comparative analysis.

- Review of clinical and functional data of patients who underwent robotic-assisted surgery: this step involves examining data obtained from patient-reported outcome measures (PROMs) questionnaires for individuals who received robotic-assisted surgery. These questionnaires typically assess factors such as pain, function, and overall quality of life post-surgery.
- Review of clinical or functional data of patients who underwent conventional surgery: similarly, this involves reviewing data from PROMs questionnaires for patients who underwent conventional surgery. By comparing this data with that of patients who received robotic-assisted surgery, we can evaluate the differences in clinical outcomes between the two approaches.
- Provide a detailed description of each variable used in the analysis: for each variable used, a short description of the variable is given. This description indicates how this variable is described, how it is obtained, what is the normal range of values that it takes and whether it is a categorical or continuous variable.
- Performing a comparative statistical analysis of data extracted from conventional surgery versus robotic-assisted surgery: by doing the analysis, the aim is to find significant differences or similarities in surgical outcomes between the two approaches.

STRUCTURE AND METHODOLOGY

This Final Degree Project (TFG) was conducted in the Orthopedic Surgery and Traumatology Department of the Hospital Clínic of Barcelona. The study began in November 2023, when initial contact was established with the department, and at which point the research topic was proposed. The project extended until the end of May 2024 and involved several phases that are detailed in this report.

The first phase consisted of an exhaustive literature review to establish the theoretical framework of the study. The second phase, one of the most extensive and crucial, involved the selection of patients to participate in the analysis. During this stage, the medical records of patients who had undergone Unicompartmental Knee Arthroplasty (UKA) were reviewed. If any unusual characteristics were identified in the surgical report, consultation with the medical team was necessary to determine whether the patient should be included in the study or not. This process aimed to ensure a homogeneous patient database, allowing a fair and accurate comparison of them.

Once the patients were selected, the third phase consisted of performing the statistical analysis, using R-Studio software as the main tool. The fourth phase involved discussion of the results with the medical team, whose clinical vision provided valuable insights for the findings obtained. Subsequently, the final report of the study, which is the present document, was written.

In summary, the study was divided into two main objectives. The first objective (generation of the learning curve) was achieved using a database of 20 patients operated with robotic assistance, all of whom met the inclusion criteria. For the second objective (comparison of ra-UKA and c-UKA), the total database included 33 patients, of whom 15 were operated with conventional techniques and 18 with robotic assistance. Without further ado, all the detailed information on each section is explained extensively in the respective parts of this report.

BACKGROUND

GENERAL CONCEPTS

ANATOMY OF THE KNEE & UKA PROCEDURE OVERVIEW

To properly understand this paper, it is important to know the basic anatomy of the knee. The knee has three compartments: medial, lateral, and patellofemoral. The medial compartment is the articulation between the medial condyle of the femur and the medial aspect of the tibial plateau. The lateral compartment is the articulation between the lateral femoral condyle and the lateral aspect of the tibial plateau. The patellofemoral compartment is the articulation between the patella and the trochlear groove of the femur. A patient can develop osteoarthritis in one, two, or all three of these compartments (10) .

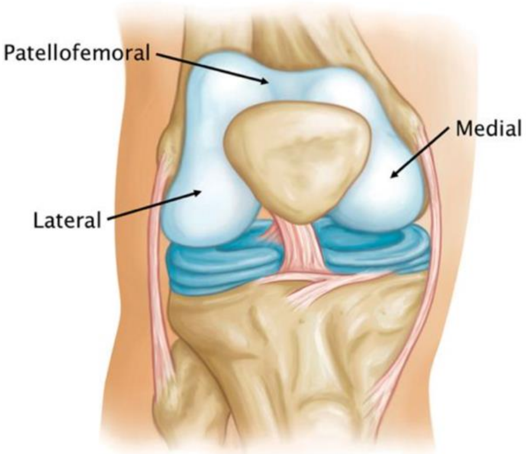


Figure 1. Representation of the three compartments of the knee's anatomy. Adapted from (10).

Unicompartmental Knee Arthroplasty (UKA) is a surgical procedure used for the treatment of osteoarthritis in one compartment of the knee, most commonly in the medial (11). In fact, lateral UKAs are about 5-10% of the total amount of the UKAs (12). In UKAs, the damaged compartment of the knee is replaced with metal and polyethylene components. This way, the part of the bone that is not affected is conserved. In addition, this procedure aims to minimize the release of the soft tissues such as the knee ligaments and tendons. The primary objective of this procedure is to relieve the patient’s pain and improve the knee’s function (11).

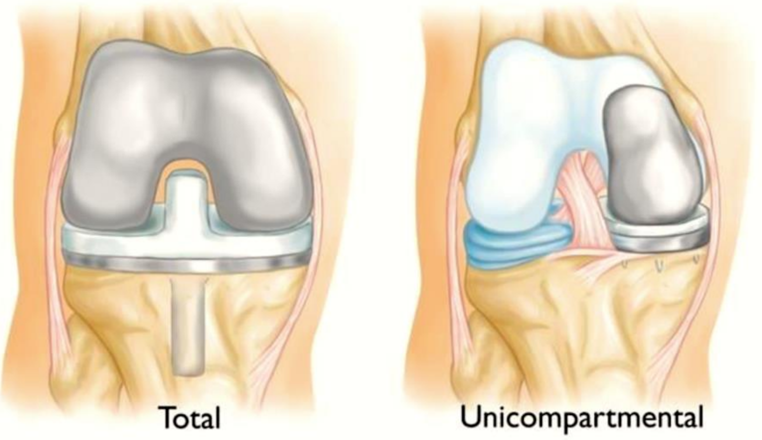


Figure 2. Comparative image between a TKA implant and a UKA implant. Adapted from (10).

While performing this procedure, there are several considerations that must be considered. One of them is whether to use mobile bearing (MB) or fixed bearing (FB) implants. In FB implants, the polyethylene inlay is fixed into the metal tibial plateau. As the distal femoral component is curved and it is sitting on the flat polyethylene, all the forces are focused in a very small contact area, increasing the risk of implant wear. On the other hand, in MB implants the polyethylene inlay is curved and perfectly matches the curve of the femoral component, increasing the contact area and consequently decreasing the risk of wear. MB implants are called "mobile" because the polyethylene inlay is allowed to move freely on top of the metal tibial plateau as the native knee kinematics demands (13). Long-term outcomes in the literature have failed to demonstrate the superiority of one type of bearing over the other concerning implant survival and patient outcomes (14).

To understand how this surgery is performed nowadays and the possibilities and technical aspects of UKA, it is relevant to analyze the historical evolution of this procedure.

ORIGIN OF CONVENTIONAL UKA PROCEDURE

In the early 1950s, Duncan C McKeever speculated that osteoarthritis could be isolated to only one compartment of the knee joint and started to think that the replacement of all the knee joint (TKA) was not always necessary if only one of the knee compartments was affected. Since then, the history of UKA surgery has been characterized by significant milestones. The first attempt was in the early 1950s with an interpositional replacement by MacIntosh and Hunter. The first modular prostheses were developed in the late 1960s and early 1970s by McKeever and other researchers. However, the turning point was in 1982 with the introduction of the Oxford UKA prothesis invented by Goodfellow and O'Connor. This design maximized the contact area between the femoral and tibial component and included an unconstrained high-density polyethylene between them, allowing a full range of motion (ROM). Nowadays, the Oxford prosthesis is the most used and clinically proven in the world. However, other options such as the Persona (from Zimmer Biomet) and Sigma HP partial knees are also gaining popularity (15).

INDICATIONS AND CONTRAINDICATIONS OF THE PROCEDURE

In 1989, Kozinn and Scott provided a framework of indications and contraindications to identify surgical candidates for UKA. The indications included: a diagnosed unicompartmental osteoarthritis or osteonecrosis in either medial or lateral compartment of the knee, a low demand of physical activity, an age superior to 60 years and a weight inferior to 82 kg. At the same time, the patient needed to present minimal pain at rest, a range of motion (ROM) arc superior to 90º with a flexion contracture inferior to 5º and an angular deformity inferior to 15º that could be passively corrected (16).

Traditionally, young, active, patients with an increased body mass index (BMI), patients that suffered patellofemoral joint osteoarthritis and the patients with a deficient anterior cruciate ligament (ACL) were not candidates for UKA. However, considering the improvements in clinical knowledge, the development of new prosthetic models and new available surgical tools, current evidence suggest that these patients may also be good candidates for UKA implantation (16,17).

ADVANTATGES AND DISADVANTATGES OF UKA OVER TKA

It is relevant to mention the advantages of UKA over TKA, since this technique was precisely invented to avoid the replacement of the total knee joint. According to two comparative studies carried out by Laurencin et al (18) and Newman et al (19) the patients operated using UKA had less perioperative morbidity, regained knee motion more rapidly and had better knee function after the surgery.

Additionally, UKA has shorter surgical time, decreased intraoperative blood loss, reduced periarticular soft tissue trauma, better preservation of the native bone, better restoration of native knee kinematics, increased patient satisfaction, better functional outcomes, and higher scores on quality-of-life questionnaires (6–8,20–22)Also, UKA is associated with a shorter hospital stay and a faster return to sports and work activities, leading to a greater profitability and better use of resources compared to the use of TKA (23,24).

Studies suggest that UKA is associated with a lower survival implant rate and so with a higher rate of revisions (25). However, this suggestion remains questionable and is still being studied(15). Data provided by national registers suggest that surgical errors in implant positioning and suboptimal limb alignment are common reasons for implant failure and early revision (6–8). To improve these results, new technologies such as robotic-assisted UKA surgery have been recently implemented.

In this paper, the focus is going to be on the study of robotic-assisted UKA and the analysis of the learning curves when this technology is included. To do so, some research has been done to understand the origin, and the state of the situation of this procedure.

STATE OF THE ART – ROBOTIC UKA

HISTORIC EVOLUTION OF ROBOTIC SYSTEMS IN ORTHOPEDIC SURGERY

Robotic surgery is considered to be the future of surgery by many experts due to the significant advancements and impact over the past two decades (26). Concretely in orthopedic surgery, the first robotic system used was the ROBODOC system in 1992, currently called TSolution-One. It was originally designed to assist the surgeon in cementless total hip arthroplasties (THA) and total knee arthroplasties (TKAs) (27).

Regarding UKA surgeries, the most common complication is early revision and implant failure. These surgical errors can be reduced if the accuracy of bone preparation and implant placement improves, enhancing the reproducibility of limb alignment. Robotic-assisted technology aims to simplify procedures, reduce outliers, and eventually improve clinical outcomes (9).

Nowadays, it is estimated that 20% of the UKA surgeries are being performed with robotic assistance. Consequently, the number of scientific articles and publications related to rUKA has been increasing over the past years (28). To be able to perform this study with a greater perspective. Some of the most relevant publications have been summarized in the following lines.

Robotic Arm-Assisted UKA improves tibial component alignment: a pilot study (29)

This article was published in 2009 by Jess H. Looner, Thomas K. John, and Michael A. Conditt. The key points of the study are summarized in the following way:

- Initial hypothesis: the alignment of the tibial component in UKA will be more precise and less variable when the robotic arm-assisted bone preparation technique is used compared to the conventional approach.
- Methodology: throughout the study period, the researchers assessed the postoperative radiographic alignment of the tibial component against the preoperative plan in 31 patients who had ra-UKA, and in 27 patients who had c-UKA. The goal was to evaluate the differences in bone preparation and the variation associated with each method. The system used in robotic-assisted surgery was the Tactile Guidance System (TGSTM; MAKO Surgical Corp, Ft Lauderdale, FL).
- Studied variables: Root Mean Square (RMS) error and variability in the alignment of the tibial component in the coronal and sagittal planes.
- Statistical test used: unpaired Student's t-tests.
- Results: regarding the RMS error of the tibial slope, a value of 3.1º with the conventional technique was found compared with 1.9º robotically. Additionally, the variance using the conventional approach was 2.6 times greater than the robotic arm-assisted bone preparation method (p-value = 0.02).

It can be concluded that the initial hypothesis of the article is confirmed, as the robotic technique gives more precise results with less variability. However, the study suggests more investigation to determine whether the reduction in these alignment errors ultimately influence implant function or survival.

From this specific article, the type of statistical test carried out between the two groups of patients can be extracted as valuable information, since it is very similar to the type of analysis that is intended to be performed in this project.

Improved accuracy of component positioning with robotic assisted unicompartmental knee arthroplasty: data from a prospective, randomized controlled study (30)

This study was performed between October 2010 and November 2012 by Bell SW, Anthony I, Smith J, Jones B, MacLean A, Rowe P and Blyth M.

- Initial hypothesis: robotic assisted surgery will give increased accuracy of UKA implant positioning compared to conventional surgery.
- Methodology: 120 patients that had osteoarthritis in the medial compartment of the knee were included in the study. Patients were randomized to either conventional (58 patients) or robotic surgery (62 patients). The patients operated using robotic assistance (MAKO RIO System) were implanted with the Restoris MCK FB knee. On the contrary, patients of the conventional group were implanted with the Phase III Oxford MB prothesis. Post-operative CT scans were taken to evaluate the final position of the prosthesis components compared to the preoperative target values.
- Studied variables: sagittal, coronal, and axial alignment of the femoral and tibial components.

- Statistical test used: Fisher's Exact test and the Chi square test were used to compare categorical data. Mann Whitney Test was used to compare continuous variables that were not normally distributed.
- Results: RMS errors were lower in all six component alignment parameters in the robotic assisted group. The level of significance was set with a p-value lower than 0.05 for all the analyses.

This study is very similar to the first one exposed. However, the information that can be extracted is the type of statistical test that they used for non-normally distributed data: Mann Whitney Test.

Most of the studies coincide in the results: using robotic assistance, the risk of postoperative limb alignments outliers decreases. However, they also indicate that more research needs to be done to confirm whether this better alignment is directly related with better functional outcomes and improved patient satisfaction.

It is important to mention that not all studies support robotic assistance. In 2014, Hansen et al. published a comparative study between 32 robotic-assisted UKAs and 32 conventional UKAs (31). The results that they found were the following:

"While both techniques resulted in reproducible and excellent outcomes with low complication rates, the results demonstrate little to no clinical or radiographic difference in outcomes between cohorts" (directly cited from (31)):

The authors emphasized the need for further clinical and economic studies of this new technology, as when a well-trained orthopedic surgeon performs this procedure, no significant differences are observed compared to when it is done by a robotic system. Considering the added cost of robotic techniques, it is necessary to analyze whether the inclusion of this technology in this type of operation is worthwhile (31).

Having done this general research, it is also important to understand the different types of technology that are available and used nowadays for assisted UKAs, including both robotic systems and navigation systems.

PLATFORMS OF THE TECHNOLOGY: NAVIGATING SYSTEMS AND ROBOTIC SYSTEMS

With the increasing incidence of joint replacement surgeries, the demand for precision and reliability in orthopedic surgical procedures has been intensified. Responding to this challenge, the integration of advanced technologies in surgical practice has become essential.

Surgeon-controlled errors in component positioning are the most common reason for implant failure in UKA. Recent studies support the idea that the use of navigation systems in UKA procedures improve the accuracy and decrease the variability in implant placement position and postoperative limb alignment Computer-assisted navigation enables intraoperative dynamic measurement of angles and offers real-time kinematic analysis of the knee, helping to avoid issues like significant residual varus angulation or hyperextension, which can lead to early failure of UKA (32). However, the number of outliers presented using navigation systems, which approaches 15% approximately, is still improvable.

Robotic-assisted systems were introduced to improve the accuracy of implant positioning (29).

Medical robots can be classified according to different aspects. Depending on the level of control the robotic device provides, they are classified in active, semi-active or passive robots. Active systems can perform certain surgical tasks autonomously based on pre-programmed algorithms and defined parameters. They can produce planned femoral and tibial resections. Semi-active systems provide assistance and guidance to the surgeon during the procedure, but the final execution of the operation still depends on the surgeon. They provide immediate intraoperative information to limit the deviation from the initial surgical plan. Passive robotic systems provide recommendations to the surgeon but do not actively participate in the surgical tasks (9).

Table 1. Classification of robotic-assisted surgical systems according to control level. Adapted from (9).

Type of robot	Functionality	Surgeon's role	Example
Active	Autonomous	Supervise procedure and control the "shut-off" switch in emergency cases	RoboDoc system
Semiactive	Adjustable	Perform surgical tasks with the assistance from the system	Mako System
Passive	Orientation and recommendations	Perform surgical procedure	OMNIBotics System

Robotic systems can also be classified depending on their navigation and registration of the patient's anatomy and limb alignment. Image-based systems use plain radiographs, CT or MRI scans of the patient which allow pre-operative planning. These images are later stored in the robotic system to precisely identify and acknowledge the deformities that need to be corrected and set the boundaries of bone removal. On the other hand, image-less systems do not rely on pre-operative imaging data. Instead, they register the knee anatomy intraoperatively after surgical exposure using mapping techniques based on navigation systems. One of the disadvantages of image-based methods is that they involve added costs and radiation exposure due to the need of these preoperative imaging. Referring to the accuracy of both techniques, image-based offers a good accuracy in identifying the depth of bone resection, and in image-less methods the accuracy depends on the precision of inputting data points during registration. The advantage of image-less systems is that they can have a real-time adaptation to the anatomy of the patient and that they can create a virtual model of the patient's knee based on the landmarks identified during surgery (9).

These systems can also be classified in terms of differences in compatibility. Closed robotic systems are designed for the implants of a single manufacturer, while open systems can adapt to the products of different companies (9).

Summing up, all devices aim to assess intraoperatively the flexion and extension spaces of the patient's knee, the soft tissue stability, and limb alignment. With this evaluation, the surgeon can make adjustments in implant positioning, bone resections, and soft tissue release, with the purpose of restoring the knee kinematics and achieving the desired limb alignment and implant positioning (33).

LEARNING CURVES

The main objective of this thesis is to analyze the learning curves of surgeons when including CORI Surgical System in the UKA procedure.

Learning curves generated using the CUSUM technique can be named: CUSUM curves. These curves were described by Page in 1954, being the most widely used in medicine due to their simplicity and easy interpretation. Their advantages include the visual representation of clinical processes progress and the ability to detect changes in trends (34). The use of new technologies in surgical procedures is always associated with a learning curve, as surgeons need to adapt to this new way of operating. In this case study, the learning curves will illustrate how surgeons adapt and improve in the use of CORI Surgical System when performing robotic-assisted UKA surgery, reflecting the transition from novice to expert proficiency. The analysis of these curves allows the identification of the inflection points. These points indicate when the surgeon reach certain level of expertise with the CORI system and, consequently, operating times decrease. This is crucial to evaluate the efficacy and security of the use of this technology in UKA surgeries. The learning curves are going to be evaluated according to the variables 'Surgery Time', which gives the duration of the operation in minutes and 'Date of Intervention'

Understanding and analyzing these learning curves is not only crucial for ensuring safety and efficacy of UKA surgeries, but also provides valuable insights about integrating new technologies in the surgical practice.

STATE OF THE SITUATION

The first robotic assisted UKA at Hospital Clinic was performed on October 2021 (6/10/21), following the introduction of the CORI Surgical System (*Figure 3* illustrates the first robotic intervention in the hospital*)*. The study officially began on November of 2021 (17/11/21), after the project was approved by the ethics committee under the protocol codes HCB/2021/0558 and HCB/2022/0144.

The current study being conducted at the Orthopedic Surgery and Traumatology Department of the hospital is a large-scale prospective cohort study involving patients operated of UKA at the hospital (both conventionally and robotically). Since the large project is a registry, there is no fixed number of patients, instead, all patients undergoing UKA are included. These patients are seen at 'Consultes Externes' of the hospital, and they have been diagnosed with KOA, becoming candidates for UKA if they meet the indications for this surgery. In general terms, the hospital is conducting a comprehensive study including several objectives. The primary goal is to analyze patient satisfaction, functional outcomes, and quality of life 12 months after UKA.

Within this wide study, I was assigned specific objectives for my thesis: to generate and analyze the learning curves of the surgeons when adopting the CORI robotic system in UKA and, as a secondary objective, to compare the functional outcomes and certain radiological variables between ra-UKA and c-UKA patients.

Figure 3. Real image of the first ra-UKA conducted in Hospital Clinic of Barcelona.

MARKET ANALYSIS

The market analysis of this study is mainly focused on the description of the different companies that are dedicated to the manufacture and distribution of surgical material, specifically, surgical robots used in orthopedic surgery. The analysis makes a comparison of the different systems that are available in the market, at a technological level, but also at an economic level.

TARGET SECTOR

In recent years there has been a significant increase in the number of people suffering from osteoarthritis. According to the World Health Organization, in 2019 about 528 million people worldwide suffered from this disease, an increase of 113% since 1990 (35). The knee joint is the most frequently affected, causing severe pain, and consequently reducing patients' quality of life. UKA surgery is one of the procedures that can be performed if osteoarthritis is limited to one of the three knee compartments. In 2017, it was estimated that 10% of knee arthroplasties worldwide were unicompartmental (36). From these UKA surgeries, it is estimated that 20% are being performed with robotic assistance (28).

In consideration of the data provided, it can be said that the target sector of this market analysis is diverse. Firstly, it is directed to the industry dedicated to the manufacturing and distribution of surgical robots, especially those specialized in orthopedic surgeries. Additionally, hospitals seeking to acquire such robotic systems constitute another key target sector. However, it is important to remember that the ultimate goal of all these innovative advancements is to improve the precision of surgical practices, and consequently, enhance the quality of life for patients suffering from these conditions.

ROBOTIC SYSTEMS AVAIABLE FOR UKA SURGERY

Robotic systems merge pre-operative virtual 3D reconstructions with an intraoperative robotic device that actively controls the movements of the surgeon. This integration helps to decrease errors in placing components and aligning limbs during operations (37).

In the realm of orthopedic and traumatological surgery, several companies manufacture surgical robots and navigating systems to assist these procedures. In this section, an exhaustive exploration of these companies, their respective robotic offerings, and a technical comparative between them will be conducted.

CORI – SMITH NEPHEW

Smith-Nephew, a very important medical technology company specialized in orthopedics, offers a diverse portfolio that includes knee implants and robotic-assisted devices. The NAVIO robotic-assisted surgical system was initially launched in Japan in 2019, serving as a semi-active, image-free platform utilized for both TKA and UKA surgeries. Recently, Smith-Nephew introduced the CORI Surgical System, an advancement over the NAVIO system (38)

The CORI system begins by selecting anatomical landmark points on both the femoral and tibial components to generate a 3D model of the patient's knee intraoperatively, eliminating the need for pre-operative CT scans and minimizing radiation exposure. The process of selecting the anatomic landmarks is called ‘Mapping’. Key enhancements of the CORI system include a new camera technology that operates four times faster than the NAVIO one, making faster the patient anatomy registration and virtual mode generation. This virtual model facilitates precise placement of implant components and predicts postoperative range of motion. Once the surgical plan is established, the CORI handpiece utilizes a robust burring system to remove damaged bone areas while preserving healthy tissue for implantation. During the burring process, the surgeon benefits from visual, auditory, and haptic feedback to ensure adherence to the surgical plan, with real-time visual cues displayed on the user interface module. This integrated feedback mechanism simulates the sense of touch by providing force, vibration, and motion feedback, allowing surgeons to feel as if they are interacting with the patient's tissues. This innovative advancement enhances precision and safety in robotic assisted minimally invasive surgeries (39)

In *Figure 4*, a representation of the user interface while the bone is being removed is presented. As it can be seen, different colors are displayed on the screen. Initially, the entire bone surface is covered in pink, and as the surgeon uses the burr to remove bone, the color adapts. The desired color is white; if it turns red, it means the surgeon has exceeded the target bone removal by a few millimeters. The other colors represent intermediate stages. This way, the surgeon can always see and guide themselves with the screen, knowing exactly how many millimeters of bone they are removing.

Figure 4. User interface of the CORI Surgical System. Adapted from (39).

Surgeons can also adjust parameters such as flexion angle, internal rotation angle, and varus/valgus angles virtually, while also managing stress on knee soft tissues like ligaments and tendons. Integration of these technologies enhances implant positioning accuracy, aiming to improve postoperative knee function and range of motion (38,40).

Finally, its compact design and minimal setup time optimize utilization in today's crowded Operating Rooms (ORs). CORI's versatility allows easy transport between different ORs, streamlining workflow management (38,40).

Figure 5. Representation of CORI Surgical System by Smiths Nephew. Adapted from (38).

MAKO SURGICAL SYSTEM - STRYKER

Stryker is one of the world's leading medical technology companies that among other services, provides innovative orthopedic implants and medical and surgical equipment. In 2013, Stryker acquired Mako Surgical Corp. As with the other Surgical Systems available, Mako Robotic-Arm Assisted technology provides a personalized surgical plan based on the anatomy of the patient. In this system, a preoperative CT scan of the knee joint is taken and uploaded in the software. The software created a 3D model of the knee used to pre-plan the surgery. In the OR, the surgeon guides the robotic arm within the pre-defined resection area and the Mako System ensures that the surgeon stays within the defined boundaries. It is important to mention that the pre-surgical plan can be modified during the surgery before starting the bone resection (40).

Stryker reviewed several studies to show evidence of this theoretical improved accuracy in implant positioning when the Mako System is used in UKAs. One of the studies performed was prospective study conducted by Bell et al to assess the accuracy of robotic-assisted UKA using the MAKO system compared to conventional surgery (30). The results showed the percentage of knees with implant components positioned within 2º of the target value. As it can be seen *in Figure 6 (*extracted from a clinical summary conducted by Stryker (41)), according to the study, robotic arm assisted surgeries enabled to place more accurately the femoral and tibial components in a higher percentage of knees.

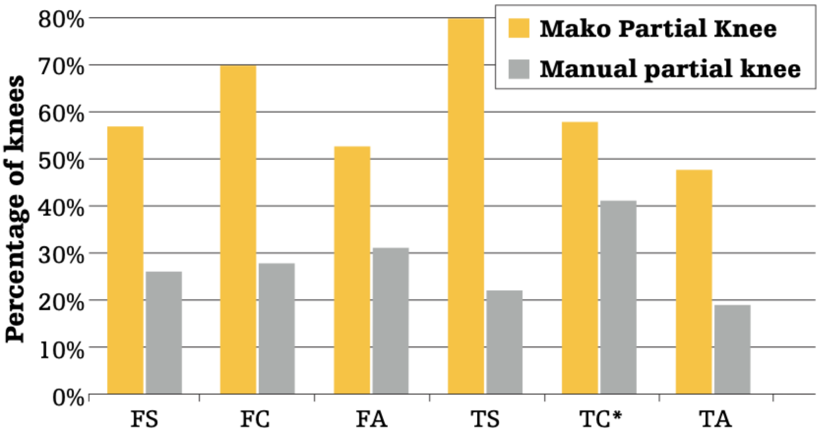


Figure 6. Graph representing a higher percentage of knees with implant components positioned within 2º of the preoperative target value in the knees operated with MAKO Surgical System. The values studied are: Femoral Sagittal (FS), Femoral Coronal (FC), Femoral Axial (FA), Tibial Sagittal (TS), Tibial Coronal (TC) and Tibial Axial (TA). Adapted from (41).

ROSA SURGICAL SYSTEM – ZIMMER BIOMET

Rosa Partial Knee is a robotic system designed to improve the accuracy of implant positioning in UKA surgeries. This innovative system allows surgeons to objectively measure the real-time response in soft tissues of the knee and to perform a virtual simulation of the surgery before doing any bone resection. It utilizes a camera and optical trackers that are secured to the patient's leg to know the exact position of the knee during surgery. The representation of this robotic device can be seen in *Figure 8*. It is composed of two main units:

- Robotic Unit: consists of a compact Robotic Arm and Touchscreen.
- Optical Unit: consists of an optical camera and Touchscreen.

This robot can be used in image-based cases and in imageless cases. In cases based on preoperative X-Rays, a reconstruction of these images is used to create a 3D bone model of the patient's joint. This way, the surgeon can properly prepare for the surgery looking at the specific anatomy of the patient. In cases without preoperative images, the landmarks are placed at the beginning of the surgery to register the points of the patient’s knee needed to acknowledge their specific anatomy (mapping) (42).

Zimmer Biomet company reviewed a cadaveric study perfumed by Lonner JH et al (43). This study included 30 knees per group (robotic-assisted and conventional surgery). The ROSA Partial Knee System was found to give more precise results regarding bone resections for medial UKAs. This was represented according to the level of accuracy achieved when reproducing the intraoperative plan for bone resection angles (see *Figure 7*) (42).

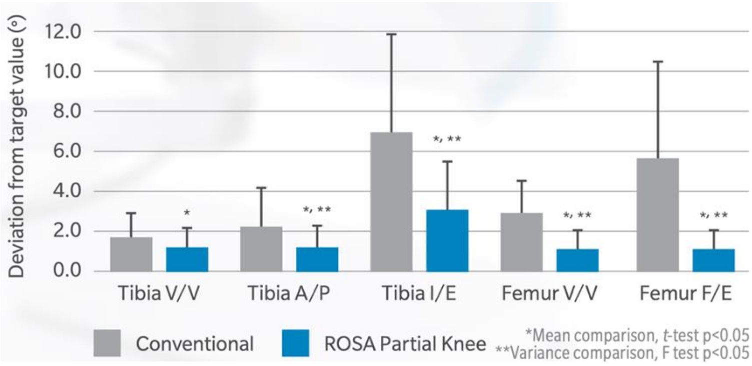


Figure 7. Graphs representing a better accuracy in ROSA Partial Knee assisted surgeries regarding to all bone resections angles in medial UKAs. Image extracted from Rosa Partial Knee System Clinical One Pager from the official website of Zimmer Biomet. Adapted from (42).

Figure 8. Representation of ROSA Surgical System by Zimmer Biomet.

Once the main companies and robots has been studied from a technological point of view, it is interesting to study the differences between them. For this purpose, a comparative table has been adapted from (44):

Table 2. Technological comparison of Surgical Robotic Systems. Adapted from (44).

Variable	CORI	MAKO	ROSA
Type	Semi-Active	Semi-Active	Semi-Active
Base	Imageless (mapping)	CT + mapping	Imageless/XR + mapping
Mapping	Handheld probe	Handheld probe	Handheld probe
Planning	Only intraoperative	Pre-operative	Pre and Intra Operative
Implant	Brand restricted	Brand restricted	Brand restricted

ECONOMIC ANALYSIS

Once the different companies and surgical robots present in the market have been described, it can be concluded that the leading companies in the sector today are SmithNephew, Stryker, and Zimmer Biomet. This subsection aims to conduct an analysis from an economic point of view. It is important to mention that the COVID-19 pandemic had a negative impact on the robotic-assisted surgery market due to the cancellation of surgical procedures during its initial phases. Specifically, the pandemic led to a 60% decline in robotic surgery. However, the market has recovered in the past two years with the restart of the surgeries (45). *Table 3* shows the price of the robotic system offered by each of the mentioned leader companies.

Table 3. Economic comparative table between leading companies in the Orthopedic Surgery Robotic Systems market.

Company name	Robot	Price (€)
Smith&Nephew	CORI	381.461-429.144
Stryker	MAKO	954.000
Zimmer Biomet	ROSA	667.557

The landscape of robotic-assisted surgery for UKA has undergone significant transformation driven by innovation and competition among the different industry leaders. Stryker's MAKO system, introduced after its acquisition in 2013 for $1.65 billion, emerged as a pioneering solution without many competitors enhanced by its advanced capabilities, including precise 3D modeling and haptic feedback (40,45,46). In contrast, Smith & Nephew's recent upgrade from the NAVIO to the CORI Surgical System represents a cheaper option. The difference in price is due to the lower complexity of the CORI system compared to the MAKO one (45). Furthermore, in 2019 Zimmer Biomet incorporated ROSA robotic system, becoming the most important competitor of Stryker due to is innovative robotic bone cutting guide and dual imaging options, offering flexibility and precision in bone cuts and implant positioning (47).

The decision-making process for healthcare institutions contemplating robotic-assisted surgery systems like MAKO, CORI, or ROSA involves careful consideration of specific surgical requirements, budget constraints, and the comparative advantages of each technology.

FUTURE MARKET PERSPECTIVES

The knee replacement market was valued at $10,007 millions in 2022 and is expected to grow at a strong CAGR of around 4.7% during the forecast period (2022-2030) (48). Being more specific, the global unicompartmental knee prosthesis market was valued at $868 millions in 2020 and is expected to reach the value of $1,300 millions by the end of 2031 (49). *Figure 9* represents the knee replacement market by the end – users (48). As it can be seen, there is an expected increase in the demand in this market. While the graph revolves around the knee replacement market at large, these insights can be extrapolated to suggest a parallel growth trajectory for the UKA market.

The main cause of partial knee replacement surgery is osteoarthritis (1). These types of diseases are normally associated with the elderly population, since it is often due to aging, wear and tear of the joint. As it can be expected, the increased life expectancy across the globe is directly associated with the growing prevalence of knee disorders. All these factors are having a direct impact on the growth of the unicompartmental knee prosthesis market. In addition, sports injuries, and the rise in the number of road accidents is expected to affect the market in the upcoming years (49).

The rapid development of technologies and their adoption in the field of medicine promises. In the coming years, robotic technology is destined to undergo significant transformations. Artificial Intelligence (IA), Augmented Reality (AR), and tele-surgery, are some of the technologies that aim to revolutionize robotic surgical systems. Starting with IA, it aims to allow the development of autonomous robots, which can perform tasks independently. Rather than replacing human surgeons, AI will collaborate with them, enhancing precision and reducing fatigue by handling repetitive subtasks like suturing. Augmented Reality will play a crucial role by providing surgeons with enhanced visualization and navigation capabilities during procedures. Additionally, the integration of AR will allow surgeons to access vital patient data like for example, pre-operative scans, without leaving the focus of attention on the patient. Finally, tele-surgery, using wireless networks and robotic technology it will give surgeons the ability to operate on a patient remotely. By operating through a closed-loop system, the surgeon will manipulate the master console, transmitting information to the teleoperator machine and back. Overall, these advancements in robotics technology promise to enhance surgical outcomes, expand access to healthcare, and revolutionize the field of medicine in the coming years (50).

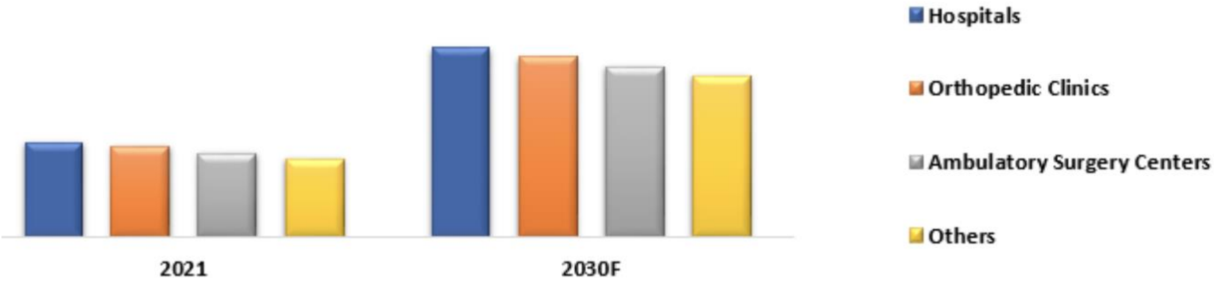


Figure 9. Knee replacement market estimated growth by end-users. Adapted from (48).

CONCEPTION ENGINEERING

Before starting any clinical study, it is essential to explore and consider the different available options. Once a wide range of options has been gathered, several choices must be made to gradually detail the protocol to be followed for the study. This helps in selecting the most suitable solution based on criteria such as efficacy and technical viability. In this particular project, the Conception Engineering section has been divided into different sub-sections, each of them corresponding to a decision that needs to be made.

However, it should be noted that in certain cases, the options may be limited by external factors such as available resources or institutional preferences. For example, this study focuses on the CORI robot, which is the only robotic system available at Hospital Clinic of Barcelona for performing robotic-assisted UKA's.

POSSIBLE SOLUTIONS

This section outlines the various points in the study where decisions need to be made. For each point, the different options available are presented. Subsequently, the chosen option in each case and the reason for its eligibility is discussed.

1. DECISIONS REFERING TO STUDY METHODOLOGY

This first part can be divided into two subsections since the study methodology will have to be decided for each of the objectives of the project. Methodology refers to the general idea of how the analysis will be conducted.

1.1. Principal objective: Learning curve generation

- *Solution 1.1.1:* Generate individual learning curves for each surgeon involved in the study and analyze variations and trends among them.
- *Solution 1.1.2:* Create a collective learning curve and identify overall trends and performance improvements over time.

1.2. Secondary objective: Comparative analysis between ra-UKA and conventional UKA

- *Solution 1.2.1*: Make the comparison of groups taking all conventional cases, regardless of when they were performed.
- *Solution 1.2.2:* Take the conventional ones that match the time when the robotic ones were performed.

2. DECISIONS REFERING TO PATIENT SELECTION

Patient selection in any clinical study is a crucial process that directly influences the validity and representativeness of the results obtained. It is important to note that inclusion criteria must be sufficiently restrictive to ensure that all selected patients are equivalent and can thus be compared with each other. However, a balance must be found to avoid being too restrictive, as variability in results is also desired. This section presents the various inclusion and exclusion criteria that can be chosen.

Inclusion criteria

Solution 2.1.

- Age: over 18 years old.

- Patient exclusively diagnosed with osteoarthrosis of the knee (regardless of whether it is in the medial or lateral compartment of the knee).
- Indication for surgical treatment by means of UKA.
- Patient signs the written informed consent to participate in the study.
- Patients without minimal postoperative follow-up. All patients who underwent surgery at Hospital Clinic are selected, regardless of the date of surgery.

Solution 2.2.

- Age: no age restrictions.
- Patient with a diagnosis of osteoarthrosis of the knee or any other disease that may require partial knee replacement (fractures, etc.).
- Indication for surgical treatment by means of UKA.
- Patient signs the written informed consent to participate in the study.
- Patients with a minimum postoperative follow-up of 12 months.

Solution 2.3.

- Age: patients over 50 years of age.
- Patient whose diagnosis is exclusively osteoarthrosis of the knee (specifically the medial compartment of the knee is affected) or patients with osteonecrosis.
- Indication for surgical treatment by means of UKA.
- Patient signs the written informed consent to participate in the study.
- Patients with a minimum postoperative follow-up of 12 months.

Exclusion criteria

Solution 2.1.

- Patient does not sign the informed consent to participate in the study.
- Patient who undergoes more than one procedure during the surgical procedure, not only UKA.

Solution 2.2.

- Patient does not sign the informed consent to participate in the study.
- Patient who undergoes more than one procedure during the surgical procedure, not only UKA.
- Patients who undergo UKA for a reason other than osteoarthrosis or osteonecrosis.
- Patients with femoropatellar compartment affectations.

3. DECISIONS REFERING TO CASE SELECTION

Once the patients who can potentially participate in the study have been selected, a second stage of case filtering must be performed. This time based on characteristics such as: the surgeons who performed the intervention, the BMI of the patients, etc.

Solution 3.1: filtering of cases according to the BMI of the patients. Consider cases with BMI < 30 kg/m^2.

Solution 3.2: filtering of cases according to the surgeons who performed the intervention:

- *Solution 3.2.1:* select the group of surgeons who performed the most interventions to have a significant sample of each surgeon.
- *Solution 3.2.2:* select all surgeons regardless of the number of operations they have performed.

4. DECISIONS REFERING TO VARIABLES USED FOR THE STUDY

4.1. Principal objective: Learning curve generation and analysis

- *Solution 4.1.1:* Take as variables to study the 'Surgery Time' to observe how time decreases as experience increases and create a variable 'Complication Rate' to track the rate of complications over time to assess if the rate decreases as surgical proficiency increases. Plot the learning curve in chronological order using the variable 'Date of Intervention'.
- *Solution 4.1.2:* Take as variables to study the 'Surgery Time' to observe how time decreases as experience increases and plot the learning curve in chronological order using the variable 'Date of Intervention'

4.2. Secondary objective: Comparative analysis between ra-UKA and conventional UKA

In this objective, several functional and radiological variables can be studied. In each of the solutions, the variables are listed. Look at *Table 4* in the 'Detail Engineering' section for further information about the variables.

- *Solution 4.2.1:* Sex, Age, BMI, Laterality, Type of procedure, NHC, Date of Intervention, Time_IQ, Surgeon, Pain (pre and post-surgery), KOOS12 (pre and post-surgery), FJS (post-surgery), Satisfaction (post-surgery), NPS (post-surgery), HKA (pre and post-surgery), Difference in joint line height (post-surgery).
- *Solution 4.2.2:* All variables of the previous solution and adding: EQ-5D-5L (pre and post-surgery), EQ-NRS (pre and post-surgery), Tibial Coronal Angle (TCA), Tibial Sagittal Angle (TSA), Femoral Coronal Angle (FCA) and Femoral Sagittal Angle (FSA).

5. DECISIONS REFERING TO STATISTICAL ANALYSIS

Regarding the first objective of the project: generation of the learning curve, several solutions are considered. It should be recalled that the generation of the curve is performed using the variables 'Surgical Time' and the case number of surgery.

- *Solution 5.1.1:* Use a linear regression to generate the learning curve, capturing the relation between the number of case and the number of 'Surgical Case'. Expecting that when the number of case increases, the time of surgery decreases, indicating that the surgeons are adapting to the new technology.
- *Solution 5.1.2*: Generate the learning curve using the CUSUM technique.

Regarding the secondary objective of the study: comparison between c-UKA and ra-UKA, the first step before deciding what type of statistical test is going to be used for a particular study, is considering the decisive criteria (51).

- Number of variables
- Type of data: continuous or categorical
- Type of study design: paired (compares observations between groups, for example, before and after surgery variables in the same patient) or unpaired (compares independent samples, for example, comparing two groups whose values of the variables are not related)

Once these aspects are covered, one can decide which is the best option of statistical test for each of the variables studied. In this study, two different and independent groups are considered: the group of patients operated conventionally, and the group of patients operated with robotic assistance. The variables studied are all continuous (numerical values). With this information, the different statistical tests that can be chosen are de following:

- *Solution 5.2.1:* Paired t-test to look for differences between group means in normally distributed data.
- *Solution 5.2.2:* Mann-Whitney test to compare medians between two independent groups when data is not normally distributed.
- *Solution 5.2.3:* Wilcoxon test to compare two independent groups when data is not normally distributed. This test is indicated when working with small samples sizes.
- *Solution 5.2.4:* Fisher's Exact test to determine if there is a significant association between two categorical variables in a contingency table, especially useful for small sample sizes.
- *Solution 5.2.5:* Chi-Squared test used to determine if there is a significant association between two categorical variables in a large sample size contingency table

Depending on the variable studied, different tests will be chosen. Detailed information about the tests used can be consulted in the 'Detail Engineering' section.

6. DECISIONS REFERING TO STATISTICAL SOFTWARE

In the medical research field, a variety of specialized software tools facilitate robust statistical analysis. These programs help to handle processes of collecting, organizing, analyzing, and interpreting statistical data. The most used one used in medical research are listed here (52):

- *Solution 6.1:* STATA
- *Solution 6.2:* MATLAB
- *Solution 6.3:* R-STUDIO
- *Solution 6.4:* IBPM SPSS
- *Solution 6.5:* JMP
- *Solution 6.6:* Statistica
- *Solution 6.7:* Excel

All of them operate similarly, providing functionalities that enable researcher to conduct basic statistical tests effectively.

PROPOSED SOLUTIONS

Once all the possible solutions are exposed, decisions for each point must be made.

1.SOLUTIONS REFERING TO THE STUDY METHODOLOGY:

For the generation of the learning curves: *Solution 1.1.2* has been chosen. The choice is primarily due to the limited size of our database, which does not provide enough surgical cases per surgeon for conducting a comparative analysis between their curves. However, we do have enough cases to construct a collective CUSUM curve.

2.SOLUTION REFERING TO PATIENT SELECTION

Following with the decisions regarding the patient's selection criteria, the inclusion criteria chosen are the ones stated in *Solution 2.3.* The minimum age of the patients participating was set at 50 years old, as most of the patients were above this age and the goal was to have a sample of patients of similar characteristics for the comparison to be fair.

The study was directed specifically to patients who needed the replacement of the medial compartment of the knee, excluding any lateral UKAs from the data base. The decision was driven by the need for equivalence among patients to ensure accuracy in comparisons. Anatomical and biomechanical differences between lateral and medial compartments causes the need for specific implants and surgical techniques for each compartment, which can translate into variations of surgical times or functional outcomes of the patients (12).

Additionally, one of the conditions for the patients to be in this study is that they sign the written informed consent to participate in it. Lastly, the patients included required to have a minimum postoperative follow-up of 12 months. This is because, for the comparative analysis, the results of the PROMs questionnaires (1-year post-operation) were revised.

The exclusion criteria selected are the ones specified in *Solution 2.2.* If the patient did not sign the informed consent to participate in the study, it was directly excluded from it. In some cases, surgeons use the same intervention to, for example, implant two prosthesis in the same knee (bi-compartmental prosthesis). These patients were excluded, as the duration of the surgery is not representative of a simple UKA and because the clinical outcomes of the patients could be different when replacing more than one component of the knee joint. Lastly, only patients who were diagnosed with osteoarthrosis or ostheonecrosis were included in the trial. Patients who, for instance, needed a partial knee replacement for other clinical reasons (for example, fractures) were excluded from the study.

3.SOLUTION REFERING TO CASE SELECTION

In this point, the proposed solution was *Solution 3.2.1.* For the curve to be representative, a relatively large number of cases was needed. However, the surgeries needed to be performed by the same surgeon to be able to track the learning accurately. In this case, as the number of cases available was limited, 2 surgeons were selected for the curve generation. *Solution 3.1* was initially proposed because it is known that, having a BMI > 30 kg/m^2, can lead to interoperative and post-operative complications (53). Nevertheless, this option was soon rejected due to the limited dataset and because 42% of the studied patients had a BMI larger than 30 kg/m^2.

4.SOLUTION REFERING TO VARIABLES USED FOR THE STUDY

Regarding which variables to study, the *Solution 4.1.2* was chosen for the learning curve generation. On the other hand, the *Solution 4.2.1* was selected for the comparative analysis. The decision not to include the additional variables presented in the alternative solution was based on the fact that EQ-5D-5L and EQ-NRS questionnaires evaluate the general health scale of the patient. These scores could not be directly related to the outcomes of the UKA intervention, so they were not considered. The radiological variables (TCA, TSA, FCA, FSA) were not studied because scientific evidence have shown that these angles are not related to the functional outcomes and quality of life of the patients after surgery (54).

5. SOLUTION REFERING TO STATISTICAL ANALYSIS

For the generation of the learning curve, *Solution 5.1.2*. was chosen. CUSUM graphs are the most used for clinical processes monitoring. The main advantages of these curves are their simplicity, their intuitive visual interpretation, and the capacity of detecting trend variations (34). The alternative solution of using lineal regression has been rejected because it does not visually show trend changes as effectively as CUSUM. On the other hand, for the comparative analysis between ra-UKA and c-UKA the solution proposed in most of the cases was the use of Wilcoxon test (*Solution 5.2.3)*. This choice was primarily because in most comparisons conducted, the groups did not meet the conditions required for a t-test. Additionally, the Mann-Whitney test was not chosen because the Wilcoxon test is known to perform better with smaller sample sizes. The Fisher's Exact (*Solution 5.2.4)* test was used to perform comparisons between categorical variables.

6.SOLUTION REFERING TO STATISTICAL SOFTWARE

Lastly, the software used for the analysis was R-Studio (Solution 6.3). The decision was based basically in personal preference, as it is the software that I had used in previous occasions and because it provides an extensive number of tools to conduct the analysis. Moreover, Excel *(Solution 6.7)* was also widely used to generate and modify the data bases aimed to study.

DETAIL ENGINEERING

To conduct this study, several subtasks were completed. This section provides a comprehensive explanation of each phase of the study, covering the following aspects:

- Data selection for the analysis
- Criteria for inclusion and exclusion of cases
- Statistical analysis methods

The study focuses on two main objectives: the generation of learning curves to study the adaptability of surgeons to CORI Surgical System in UKA surgeries, and the comparative analysis between conventional UKA and robotic assisted UKA in terms of functional outcomes and limb alignment. Therefore, this section is divided into two subsections to clearly explain the approach for each objective.

LITERATURE REVIEW

Before undertaking any study, an extensive literature research is essential to understand the state of the situation of the subject aimed to study. In this case the literature reviewed focused on acquiring fundamental knowledge about UKA, robotic-assisted UKA, and articles in which a comparison of both approaches was made. Additionally, studies discussing the generation of learning curves in UKA were searched after. However, this topic is not extensively studied currently, and no articles specifically addressing ra-UKA learning curves were found; most literature discussed learning curves in the context of TKA (Total Knee Arthroplasty). Therefore, some literature on TKA was also utilized, with information extrapolated to our specific case of UKA.

LEARNING CURVES

INITIAL DATA EXPLORATORY ANALYSIS

For the generation of the learning curves, only the robotic-assisted surgeries were considered. The primary objective was to represent the adaptability of the surgeons to a new technology, specifically the CORI Surgical System in UKA surgeries. To achieve this, the initial database was loaded into R software for an initial exploratory analysis. This initial database contained a total of 103 cases, including both conventional and robotic-assisted surgeries.

These 103 possible participants were all those patients operated from the first robotic – assisted UKA performed in the Hospital Clinic (October 2021) until March 2024. Even though UKA's were performed conventionally prior to the adoption of the CORI Surgical System, the decision was made to include only those conventional cases that coincided with the period of robotic surgeries. This decision aimed to limit the comparison to surgeries performed during the same timeframe, thereby ensuring more reliable results.

This initial analysis involved examining the total number of robotic surgeries and dividing the data by individual surgeons to determine the number of robotic procedures each surgeon had performed. The total number of robotic surgeries conducted in the specified period of time was of 42 cases. The aim of this preliminary assessment was to explore the total data available for the analysis, and to make decisions regarding the methodology that was going to be followed during the study to generate the learning curves effectively.

CASES SELECTION FOR THE LEARNING CURVE GENERATION

One of the initial critical decisions in conducting this study was selecting which cases (from the 42 total robotic ones) to include in the analysis. For the generation of learning curves, having a substantial number of cases is essential to ensure the curve is both representative and provides valuable insights. The database included robotic surgeries from 9 different surgeons, from which some where considered and some were not, depending on the number of robotic surgeries they had conducted. The first step was to exclude surgeons who had performed only a limited number of robotic surgeries.

Following this, it was decided to focus on the two surgeons who had conducted the most interventions to generate the learning curve. The number of cases selected summed up a total of 25 surgeries. It is important to note that these two surgeons work together at the Hospital Clinic, and in many cases, they operated on patients together. Therefore, it was decided to represent the learning curve of these surgeons jointly, treating them as a surgical team. This approach is justified by the fact that, since these surgeons frequently operate together their learning can be considered conjunct and cumulative.

It is worth saying that, initially, the option of creating a combined curve for all surgeons, including all 42 cases, was considered. However, it quickly became evident that this approach lacked coherence, as the significant variability among surgeons did not give reliable results. The goal is to represent the cumulative learning of the surgeons. Therefore, by mixing different surgeons, and considering that many of them had only performed 2 or 3 surgeries, the results obtained were not indicative of genuine learning. However, by selecting these two mentioned surgeons, the results made much more sense and were more logical since, as previously stated, they represent the cumulative learning of a team of surgeons who operate together.

REVISION OF PATIENT'S CLINICAL HISTORIES

Once it was decided which cases were going to be analyzed, a revision of the clinical records of these patients was performed. To generate the learning curves, the essential variables required were the 'Date of Intervention' and the 'Surgery Time'. During this phase, it was crucial to ensure that all selected cases were equivalent, meaning they all corresponded exactly to the same procedure and that no complementary procedures were performed during the same surgery. This inspection was necessary as we were evaluating the duration of surgery and comparing surgeries involving, for instance, the implantation of two prostheses, would give inaccurate results due to their longer duration. Specifically, 2 cases involving the implantation of a bicompartmental prosthesis (the unicompartmental implant itself and a patellar prosthesis), were excluded.

Furthermore, the intervention time recorded in the surgical report, the specific document reviewed for each patient, was cross-checked. Additionally, it was important to verify that all selected surgeries were robotic, and correctly recorded in the database. To accomplish this, the post-operative radiographs of each patient were examined. In conventional interventions, only the staples corresponding to the primary incision of the surgery are visible on the postoperative radiograph (*Figure 10)*. In contrast, robotic surgeries show additional staples, typically between two to three on the femur and an equal number on the tibia. These staples, together with visible holes in these bones are seen in the radiographs due to the robot trackers placement during robotic surgery (*Figure 11)*. Thus, the absence of these additional staples in the radiographs indicated that the intervention was conventional, prompting its removal from the robotic surgery group. A total of 2 more cases were excluded after radiographic revision, as they revealed to be conventional rather than robotic surgeries.

Figure 10. Example of post-operative radiography in conventional UKA.

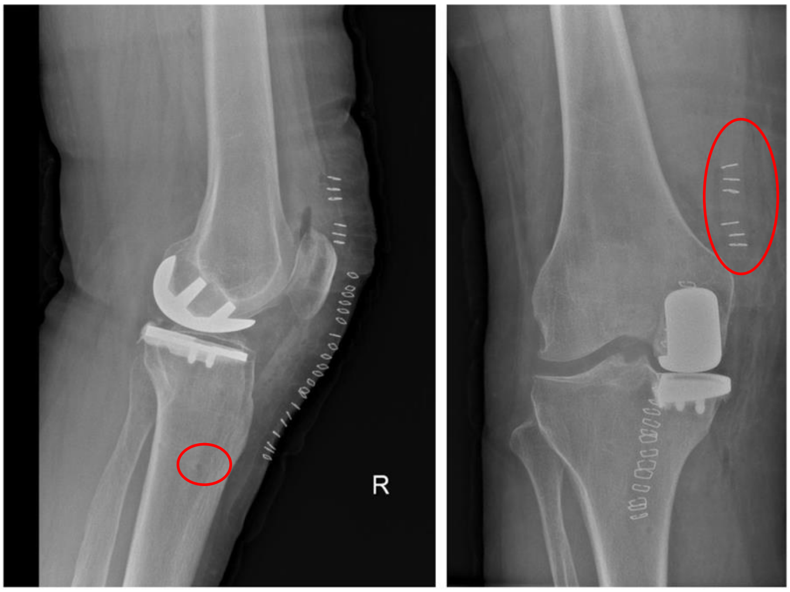


Figure 11. Example of post-operative radiography in robotic-assisted UKA. In the left image, the drilled proximal tibia when collocating the robot's trackers is marked in red. In the right image, additional staples for the accessory wound incision in the femur are marked in red.

Lastly, it was essential to select cases of robotic-assisted UKA in which the medial compartment of the knee was replaced with the prosthesis and to exclude those involving the lateral compartment. This decision was based on the differences in functional outcomes and alignment between medial and lateral UKAs. In fact, lateral UKA is considered a more challenging procedure (12). Therefore, to maintain the study's consistency, the cases of lateral UKAs needed to be excluded. In our particular database, 1 case of lateral UKA's was found and therefore, excluded.

The end of this selection process resulted in a final total of 20 cases for the generation of the learning curve.

LEARNING CURVES GENERATION

Once the case selection was completed, the learning curve for this surgical team was generated using the CUSUM technique. This method, based on cumulative sums, allows the analysis of the surgeon's transition from the learning phase to the expert phase with the new surgical technique (CORI Surgical System). Specifically, the learning curves were generated through the analysis of operative times of each case using the statistical software R-Studio. The process followed for the generation of the curves was essentially as follows.

Before starting the analysis, an Excel table was manually created with the cases to be analyzed and their associated variables. Although the table included demographic values of the patients, for this specific objective, only the variables 'Surgery Time' and 'Date of Intervention' were used. This table was then imported as a CSV file into the R-studio environment. It was essential to ensure that the data were chronologically ordered since the learning curve must be time sequenced. All surgical times were selected, and the mean value was calculated, which served as the standardized value. This standardized value was subtracted from each surgical time. Finally, using the R function $cusum()$, the cumulative sum of these values was calculated and plotted chronologically. It is relevant to mention that the dates were converted into sequential case numbers, so the plot was against these case numbers rather than the date itself. This approach prevented multiple surgeries performed on nearby dates from clustering together and complicating the visual representation of the learning curve.

In *Table 4,* a small fragment of the data table is shown for better understanding.

Table 4. Fragment of the data table used for the generation of the learning curve. Each 'id' corresponds to a specific case and each column to the values of each variable. 'Time_IQ' is represented in minutes. Surgeon 1 or 2 corresponds to the surgeon that performed the surgery.

Id	Date	Time_IQ	Surgeon	Sex	Age
U1	6/10/21	132	1	M	50
U2	25/10/21	128	2	M	65
U3	18/11/21	102	1	H	64

COMPARATIVE ANALYSIS

For this objective, the study also began with an initial database of 103 patients. Unlike the learning curve analysis, where the selection of surgeons was crucial to accurately represent their learning process, this comparative analysis required a broader database to include more cases for comparison. Therefore, the criteria for case selection in this case differed slightly and are outlined in the following sections.

CASES SELECTION FOR THE COMPARATIVE ANALYSIS

The study started with a total of 61 conventionally operated patients and 42 robotically operated patients. From these, the cases to be included in the comparative analysis between c-UKA ra-UKA were selected. In this stage, the decision was made to include surgeries performed by the two surgeons previously selected, as well as two additional surgeons. Thus, the four surgeons who had performed the most UKA surgeries at Hospital Clinic were chosen, regardless of whether the surgeries were conventional or robotic-assisted. This selection resulted in 32 conventional surgeries and 33 robotic surgeries, all performed by these four selected surgeons.

REVISION OF PATIENT'S CLINICAL RECORDS

As with the primary objective discussed earlier, once the potential cases for the comparative analysis were identified the clinical records of these patients were revised to ensure equivalency. From the 33 robotic surgeries, 3 were excluded due to the implantation of bicompartmental prostheses, 3 were excluded because they were lateral UKAs, 4 were excluded for not meeting the minimum follow-up requirement of 12 months, and 3 were excluded after postoperative radiograph review revealed they were conventional rather than robotic surgeries. This process left a total of 20 robotic cases for the comparative analysis.

From the 32 conventional surgeries, 5 were excluded for not meeting the minimum follow-up requirement, and 11 were excluded due to being bicompartmental procedures. This left a total of 16 conventional cases.

By applying these selection criteria, the study ensured that the final set of cases for the comparative analysis was as homogeneous as possible, facilitating a fair and accurate comparison of functional outcomes and limb alignment between conventional and robotic-assisted UKA.

DESCRIPTION OF VARIABLES STUDIED

Before detailing the steps followed to perform the analysis, *Table 5* lists the variables that have been studied. In this table, the name of each variable, their respective units, and a brief description that includes the normal range of values for each variable can be seen.

Table 5. Descriptive table of the studies variables.

	Variable	Units / Values	Definition
General Patient and Intervention Data	Sex	Man/Woman	Patient's gender
	Age	Numeric value (integer)	Patient's age (in years)
	Body Mass Index (BMI)	Kg/m^2	Weight / Height^2
	Laterality	Right knee (RK) / Left knee(LK)	Laterality of the affected knee
	Type of procedure	Robot / Conventional	Approach used to perform intervention
	Case identifier	U_n (n = number of case)	Unique identifier for each case
	Date of Intervention	Day/Month/Year	Surgery date
	Time_IQ	Minutes	Specific duration of the surgery. This time is defined as time from initial surgical incision to final wound closure.
	Surgeon	1 – 4	Numeric value identifying the surgeon that performed the intervention.

Data from PROM questionnaires	Pain	0 -10	Numeric rating scale for pain assessment, at rest and after mobilization (pre and post-surgery).
	Knee injury and Osteoarthritis Outcome Score (KOOS12)	0 - 100	The KOOS-12 contains 12 questions, with each question scored from 0 to 4 points, with 0 representing no knee problems and 4 representing extreme knee problems. The score is calculated as an average of the Pain, Function, and Quality of Life scale scores. 100 is the best possible score. (pre and post-surgery).
	Forgotten Joint Score (FJS)	0 - 100	Questionnaire addressing patient's ability to forget about a joint because of a successful treatment. It consists of 12 questions scored from 1(never) to 5 (mostly) according to the response categories. Thus, the raw scares ranges from 12 to 60. The raw score is linearly transformed to a 0-100 scale, being 100 the best score.
	Satisfaction	0 -10	General satisfaction of the patient with the surgery results.
	Net Promoter Score (NPS)	0 - 10	How likely would the patient recommend the surgery to a family member or friend?
Radiological Data	Hip Knee Ankle (HKA)	Angle (º)	The HKA angle is defined as the angle between the mechanical axes of the femur and tibia in the coronal plane. Literature suggests that the optimal range for this angle is 176º-180º (pre and post-surgery).
	Joint Line Height Difference (JLH)	mm	JLH difference is the vertical distance between the original joint line of the knee (where the femur meets the tibia) and the new joint line after a knee implant is placed. It helps assess how much the knee joint position has changed after surgery. Literature suggests an optimal difference range of 0 mm - 2.5 mm.

REVISION OF PROM'S QUESTIONNAIRES

With the selection of the 16 robotic cases and 20 conventional ones, the next step involved the review of the Patient Reported Outcome Measures (PROMs) questionnaires available in each patient's medical record. These questionnaires were not digitalized, instead, they were uploaded PDF's, manually completed by the patients, this lack of digitalization made the review process slow, as all the information form the questionnaire had to be transferred into an Excel sheet for subsequent analysis. The specific questionnaires reviewed included:

- KOOS12 (preoperative and postoperative)
- Satisfaction (postoperative)
- Pain in motion and at rest (preoperative and postoperative)
- Net Promoter Score (NPS) (postoperative)
- Forgotten Joint Score (FJS) (postoperative)

The formats of these questionnaires can be found on the annexes section of this thesis (Annex 1). It is worth mentioning that while some variables were directly numerically scaled, others required the application of formulas to obtain numerical values. This was the case for the Forgotten Joint Score (FJS) and the KOOS-12 score, for which the formulas are provided below (*Equation 1* (55) and *Equation 2* (56)):

$$FJS\ score\ =\ 100 - \frac{(raw_{score} - 12)}{48} \cdot 100$$

Equation 1. Mathematical formula to compute the FJS score.

$$KOOS12\ score\ =\ \frac{(Average\ item\ score \cdot 100)}{4}$$

Equation 2. Mathematical formula to compute the KOOS-12 score.

STATISTICAL ANALYSIS

1. Radiological variables (HKA and JLH)

The first variables studied between the conventional group and the robotic group were those associated with post-surgery limb alignment. For both variables, the aim was to determine the number of cases that fell outside the range considered correct in the literature. HKA (Hip-Knee-Ankle) angle represents the angle between the mechanical axis of the femur and the tibia in the coronal plane (57). Ideally, this angle is 180º, meaning the axis running through the leg should be perfectly straight. When the angle exceeds 180º, it indicates a valgus deformity of the leg. Conversely, when the angle is less than 180º, it indicates a varus deformity (see *Figure 12).* The literature defines the correct range for this angle as up to 4º of varus, meaning the desired range is [176º - 180º] (58). On the other hand, JLH (Joint Line Height) difference, which is the distance difference between the original knee joint line and the new joint line after the prosthesis is placed was also studied. The optimal range of values for this variable is defined as [0-2.5] mm (59). In this study, any measurement that was outside of the ranges established was considered as 'out of range'. These two radiological variables were studied separately.

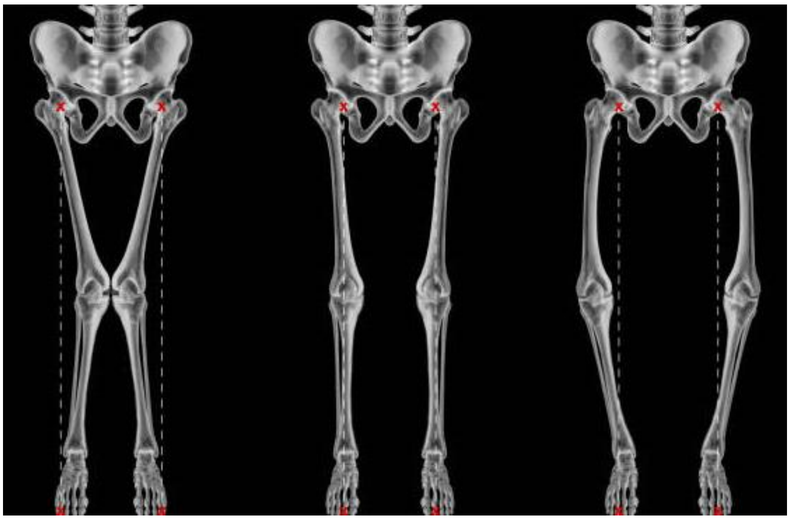


Figure 12. Valgus, normal, and varus knees respectively. Adapted from (60).

Once both the conventional group and the robotic group were divided into 'in range' and 'out of range' categories, a contingency table was created for each approach and for each radiological variable. A Fisher's exact test was then used to compare the groups, as this test is more appropriate for small sample sizes than the chi-squared test.

2. Functional variables (post-operative – pre-operative)

For the variables with both preoperative and postoperative values, a new variable was created: the post-pre difference. These variables were pain during movement *('pain_movement'*), pain at rest *('pain_rest'),* and the KOOS12 score. This analysis aimed to examine the differences in questionnaire scores before and after surgery. The hypothesis was that both pain levels and KOOS12, which measures patient's quality of life, would be better in cases where ra-UKA was performed, instead of c-UKA. Therefore, the goal was to compare the conventional group with the robotic group to determine if there were significant differences in postoperative improvement.

The procedure was as follows for each variable: normality was checked using the Shapiro-Wilk test ***(shapiro.test).*** This test assessed whether the data for the variable followed a normal distribution in both the robotic and conventional surgery groups. If the p-value from the test was greater than 0.05, indicating normality, the homogeneity of variance was evaluated using the F-test (***var.test).*** This test determined whether the variances of between the two groups were homogeneous, with a p-value greater than 0.05 indicating homogeneity. Depending on whether these assumptions were met, either a Student's t-test ***(t.test)*** or a Wilcoxon rank-sum test ***(wilcox.test)*** was performed to compare the means between the groups.

3. Post-operative functional variables

Post-surgery questionnaire variables were evaluated by analyzing the difference in scores between the conventional and robotic groups. The variables studied in this case were: post-operative pain during movement, post-operative pain at rest, KOOS-12 score, patient satisfaction, NPS (Net Promoter Score), and FJS (Forgotten Joint Score). The procedure for comparing mean differences for each variable was as the one explained in the previous section. First, normality and homogeneity of variances were checked. Subsequently, either a t-test or Wilcoxon rank-sum test was selected depending on if the conditions were met or not. In both tests, the arguments of the R function were the variable values from each group.

4. Relation between radiological variables and functional outcomes

Finally, the objective was to assess whether patients with radiological variables categorized as "out of range" showed worse functional outcomes compared to those categorized as "in range". This part consisted of making no distinctions between data from the robotic and conventional group and take all the cases as the initial sample size. This left a sample of 33 patients who underwent UKA. For the HKA radiological variable, each patient was classified as "out of range" or "in range" based on the ranges discussed earlier. Subsequently, differences in functional outcomes between the "in range" and "out of range" groups were analyzed. Then, the exact same was done for the JLH difference radiological variable. Basically, the analysis followed a similar approach as the one detailed in point 2 and 3, but this time it compared groups categorized as 'in range' and 'out of range' for each radiological variable, instead of comparing conventional and robotic groups.

RESULTS

In this section, the results obtained are presented. Again, there is a subdivision corresponding to each specific objective of the study.

LEARNING CURVES

PARTICIPANTS: FLOW DIAGRAM AND GENERAL DATA

As it has been discussed in the 'Detail Engineering' section, for the generation of the learning curves there has been some inclusion and exclusion criteria established. Flowing this criteria, different cases were excluded of the analysis. In *Figure 13,* a flow chart of the included participants is presented.

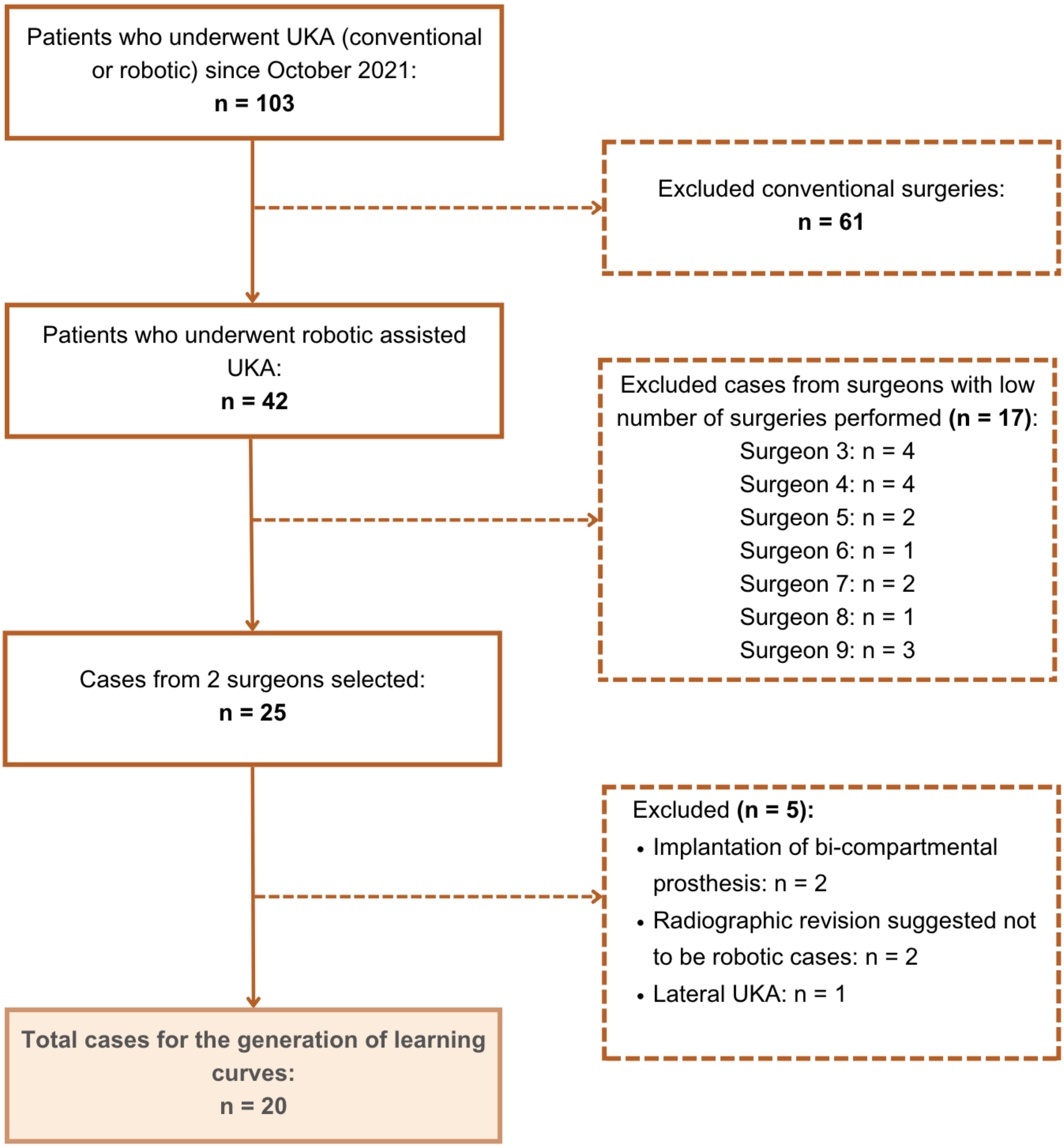


Figure 13. Flow chart of the inclusion process for learning curve generation.

It is also relevant to make a descriptive analysis of the 20 patients selected to acknowledge the sample that is going to be analyzed. General characteristics of the patients are provided in *Table 6.*

Table 6. General characteristics of the patients used for the learning curve generation.

Characteristic	Robotic cases (N= 20)
Age (years)	64.2 ± 7.04 (mean ± SD)
Body Mass Index (BMI)	30.45 ± 4.68 (mean ± SD)
Gender (Male / Female)	M: 25% (n = 5) F: 75% (n = 15)
Laterality (RK/LK)	RK: 60% (n = 12) LK: 40% (n = 8)

Regarding the 20 cases selected, the distribution of cases per surgeon can be seen in the bar chart represented in *Figure 14.*

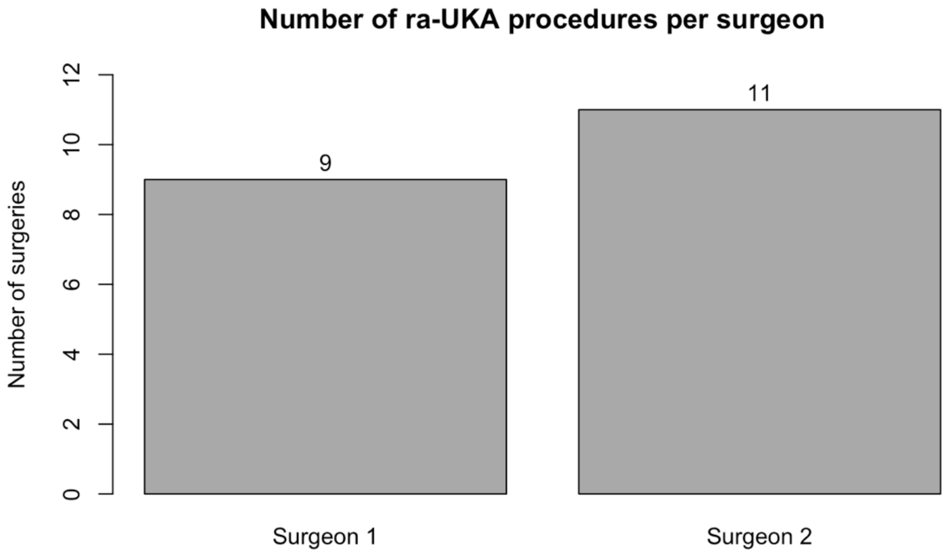


Figure 14. Bar-chart representing the distribution of cases per surgeon for the generation of the learning curve.

OBTAINED LEARNING CURVE

The used variables for the generation of the curve are: '*Date of Intervention*' and '*Surgery Time*' in minutes. The learning curve generated from the data of these two surgeons is shown in *Figure 15*. Notably, the y-axis does not represent the actual surgery times. Instead, it displays the cumulative sum of differences between the surgery durations and a standardized value. It is important to note that these curves are not intended to plot individual surgery times; their primary objective is to detect changes in trends. The following table (*Table 7)* represents the original values of surgical time, the differences when subtracting to these values the standardized value, and lastly, the CUSUM value used to plot the learning curve. The standardized value used in this specific analysis was the mean of all the surgical times: 105 ± 15.56 minutes.

Table 7. Presentation of the values used to plot the learning curve.

Order	Time_IQ (min)	Difference	Cusum Value
1	132	27	27
2	128	23	50
3	102	-3	47
4	88	-17	30
5	118	13	43
6	116	11	54
7	125	20	74
8	88	-17	57
9	99	-6	51
10	96	-9	42
11	94	-11	31
12	97	-8	23
13	103	-2	21
14	93	-12	9
15	85	-20	-11
16	126	21	10
17	87	-18	-8
18	94	-11	-19
19	123	18	-1
20	103	-2	-3

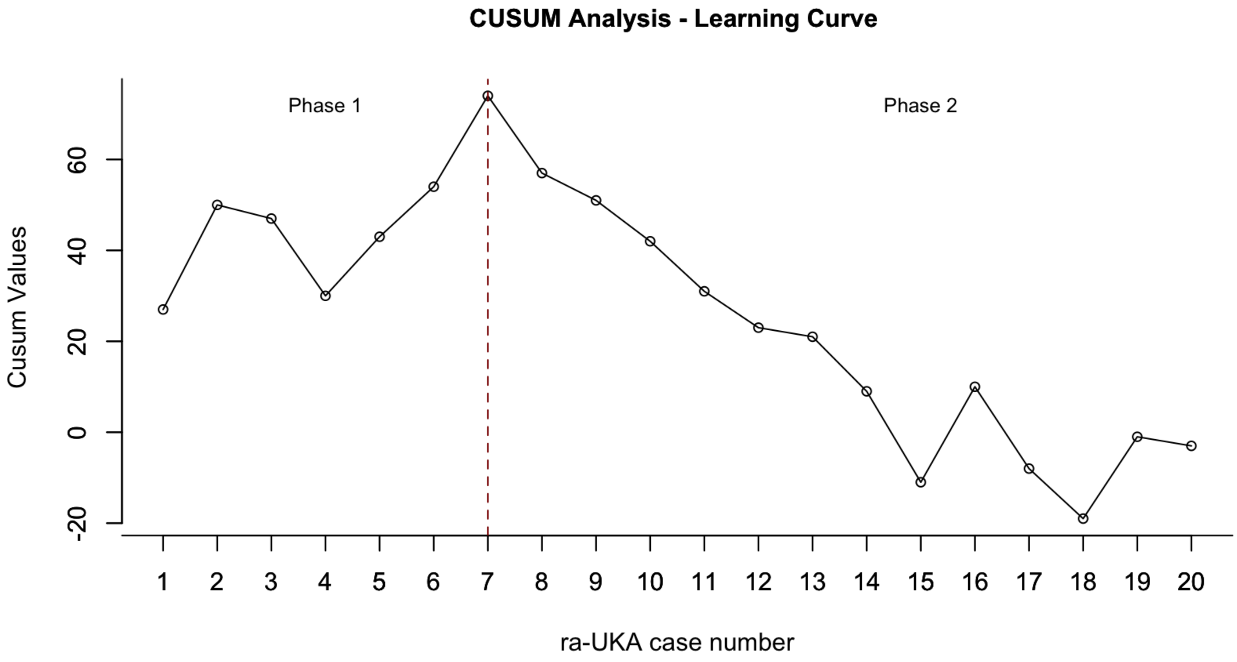


Figure 15. CUSUM analysis showing the learning curve for surgical time in patients undergoing ra-UKA.

In the learning curve, two distinct phases can be observed. Phase 1 corresponds to the initial learning phase, characterized by an increasing trend in the curve. In Phase 2, which can be identified as the proficiency phase, the curve begins to decrease, indicating a reduction in surgery times. This reduction suggests that surgeons have adapted to the new technology and are performing more time efficiently.

These two phases have also been studied separately. The mean surgical times from each phase have been calculated and later compared using the R predefined function $'t.test()'$. The t-test is a statistical technique used to determine if there is a significant difference between the means of two groups of data. It is commonly applied when there are two independent samples, and the aim is to assess whether observed differences between them are statistically significant or could have occurred by chance. For this specific case, the result from the test is exposed in the following table:

Table 8. Results t-test comparing Phase 1 with Phase 2 of the learning curve.

	Mean surgical time $\pm$ SD (min)	Minimum value (min)	Maximum value (min)
Phase 1	116 ± 15.6	88	132
Phase 2	101 ± 13.93	85	126
p-value	0.059		

These two phases have also been studied in terms of the radiological variables to see if there were notable differences in limb alignment between the 'learning phase' and the 'expertise phase'. The standard deviation of the variable '*HKA_post*' in the first phase is of 177.36 ± 2.62, and in the second phase the standard deviation is of 176.69 ± 1.59. On the other hand, standard deviation of the variable 'JLH' in the first phase is of 1.96 ± 0.87, and in the second phase of 2.3 ± 0.85. A Fisher's Exact test comparing each radiological variable between both phases gave a p-value of 0.1521 for HKA and a p-value of 1 for JLH. The percentages of 'Out of range' cases of each phase and of each radiological variable are presented in *Figure 16 and Figure 17.*

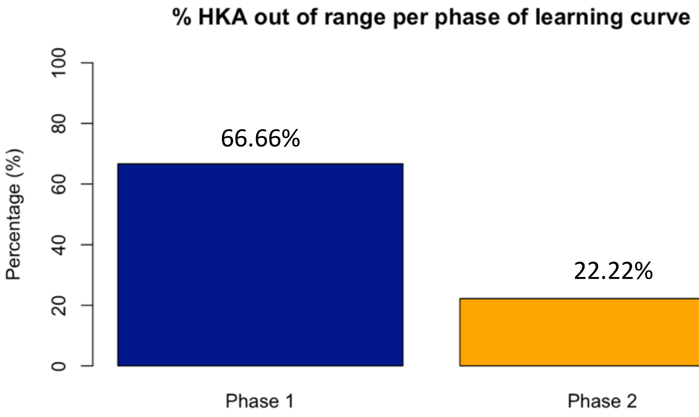


Figure 16. Barplot showing percentage of HKA 'out of range' cases in each phase of the learning curve.

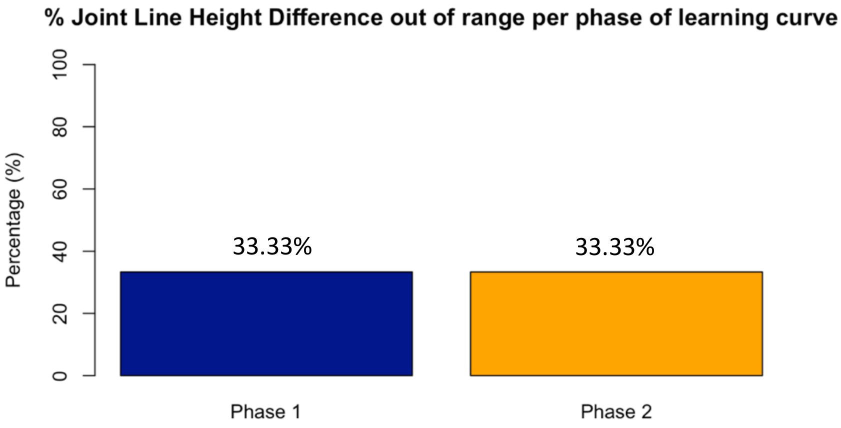


Figure 17. Barplot showing percentages of JLH 'out of range' cases in each phase of the learning curve.

Finally, the differences in functional outcomes between phases have also been studied.

Table 9. Comparison of functional outcomes between Phase 1 and Phase 2 of the learning curve. Variables represent post-operative values

POST variables	Phase 1 (median ± SD)	Phase 2 (median ± SD)	p-value
Resting Pain	0 ± 0.4	0 ± 3.33	0.405
Moving Pain	0.5 ± 2.07	1 ± 3.68	0.75
FJS	100 ± 24.87	62.5 ± 30.26	0.2
Satisfaction	8 ± 0.81	8 ± 1.14	0.14
KOOS-12	98.95 ± 16.3	91.6 ± 15.43	0.067
NPS	10 ± 0.81	10 ± 0.67	0.84

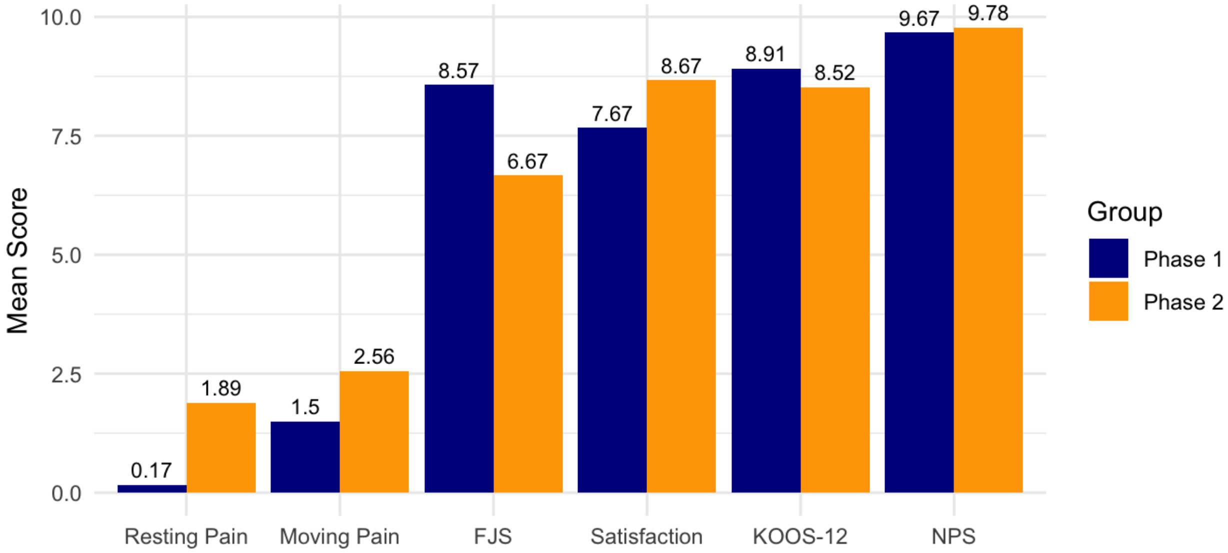


Figure 18. Barplot comparing mean value of each functional variable between Phase 1 and Phase 2 of thelearning curve.

COMPARATIVE ANALYSIS

PARTICIPANTS: FLOW DIAGRAM AND GENERAL DATA

As it has been discussed in the 'Detail Engineering' section, for the comparative analysis the selection of cases varies slightly. Therefore, a new flow chart has been constructed for this secondary objective (*Figure 19*).

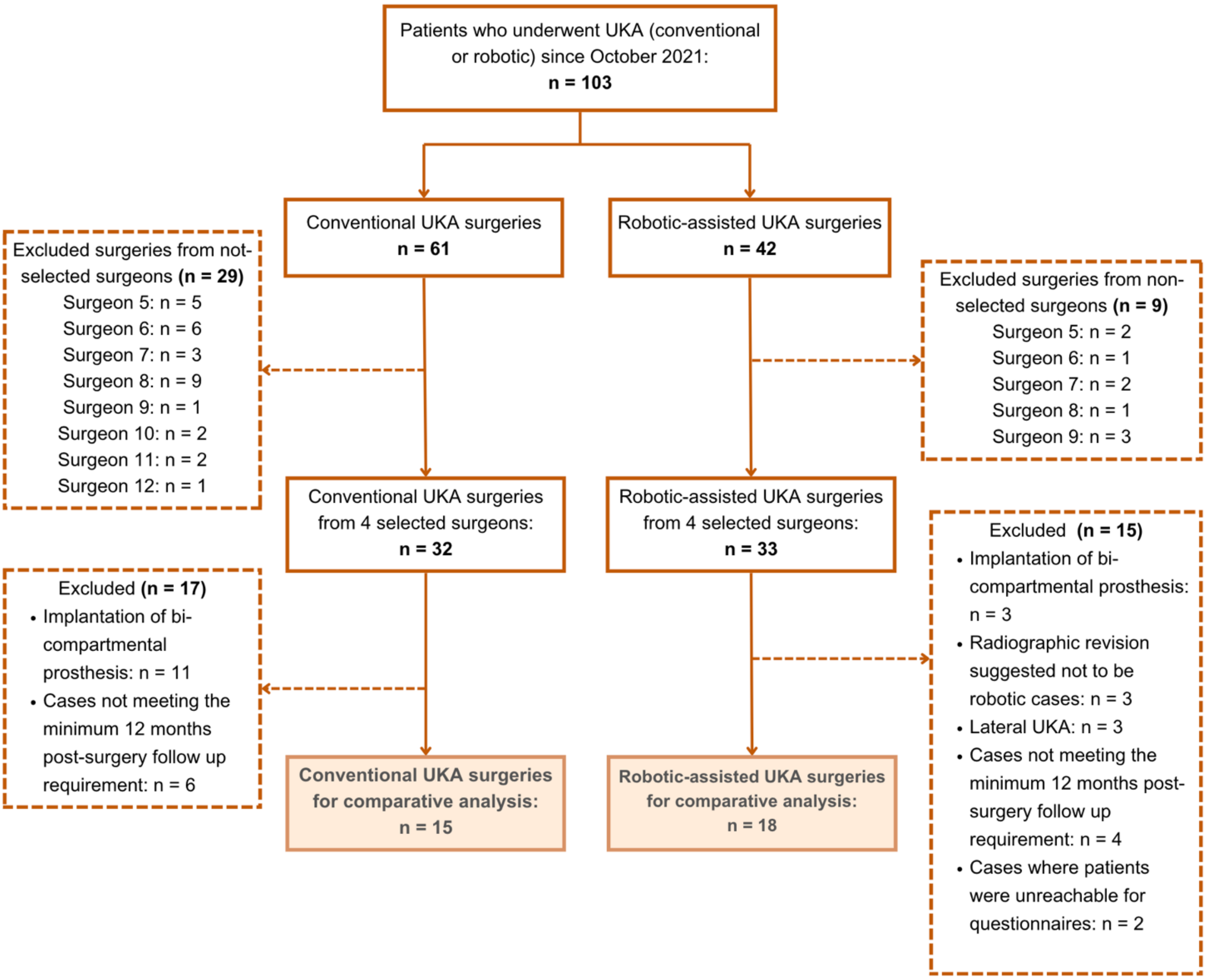


Figure 19. Flow chart of the inclusion process for the comparative analysis between c-UKA and ra-UKA.

Additionally, a descriptive table of the group of patients compared is shown in *Table 10* below.

Table 10. General characteristics of the patients used for comparative analysis.

Characteristic	Conventional UKAs (N = 15)	Robotic assisted UKAs (N = 18)
Age (years)	65.5 ± 14.28 (mean ± SD)	65.6 ± 11.02 (mean ± SD)
Body Mass Index (BMI)	28.16 ± 3.63 (mean ± SD)	30.48 ± 4.4 (mean ± SD)
Gender (Male / Female)	M: 66.66 % (n = 10) F: 33.33 % (n = 5)	M: 33.33 % (n = 6) F: 66.66 % (n = 12)
Laterality (RK/LK)	RK: 33.33 % (n = 5) LK: 66.66 % (n = 10)	RK: 61.1 % (n = 11) LK: 38.9 % (n = 7)

STATISTICAL ANALYSIS RESULTS

1. Radiological variables (HKA and JLH)

Table 11. Distribution of patients categorized as 'In range' and 'Out of range' for HKA angle in both conventional and robotic assisted UKA groups, with the associated p-value for comparison.

HKA	Conventional UKA (n = 15)	Robotic-assisted UKA (n = 18)
In range	66.66 % (n = 10)	66.66 % (n = 12)
Out of range	33.33 % (n = 5)	33.33 % (n = 6)
p - value	1	

Table 12. Distribution of patients categorized as 'In range' and 'Out of range' for JLH distance in both conventional and robotic assisted UKA groups, with the associated p-value for comparison.

JLH	Conventional UKA (n = 15)	Robotic-assisted UKA (n = 18)
In range	86.66 % (n = 13)	66.66 % (n = 12)
Out of range	13.33 % (n = 2)	33.33 % (n = 6)
p - value	0.24	

2. Functional variables (post-operative – pre-operative)

Table 13. Comparison of functional outcomes between conventional and robotic assisted UKA. Variables represent the difference between the post-operative value and the pre-operative value.

	Conventional UKA (median ± SD)	Robotic-assisted UKA (median ± SD)	p-value
Difference Resting Pain	-4 ± 3.11	-5 ± 2.4	0.41
Difference Moving Pain	-4 ± 3.15	-6 ± 2.76	0.3
Difference KOOS-12	50.05 ± 28.66	58.4 ± 13.33	0.19

3. Post-operative functional variables

Table 14. Comparison of functional outcomes between conventional and robotic assisted UKA. Variables represent post-operative values.

POST variables	Conventional UKA (median ± SD)	Robotic-assisted UKA (median ± SD)	p-value
Resting Pain	0 ± 2.56	0 ± 2.47	0.773
Moving Pain	2 ± 3.34	0.5 ± 2.88	0.402
FJS	81.25 ± 34.15	92.7 ± 27.79	0.302
Satisfaction	8 ± 3.08	8 ± 1.17	0.83
KOOS-12	87.5 ± 23.62	94.7 ± 14.65	0.067
NPS	10 ± 2.67	10 ± 0.65	0.0503

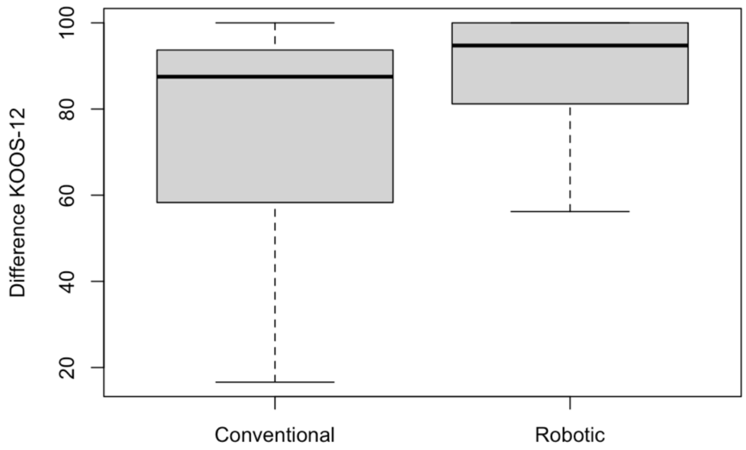


Figure 20. Boxplot showing mean distribution of the KOOS-12 after surgery in the conventional and in the roboticgroup.

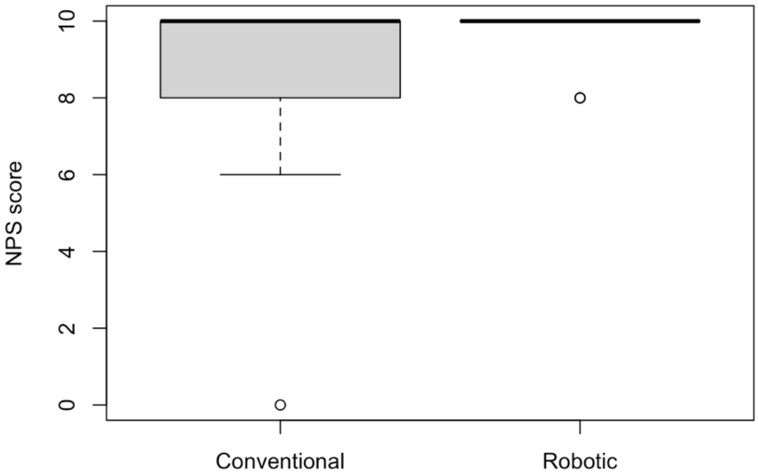


Figure 21. Boxplot showing distribution of the NPS scores after surgery in the conventional and in the robotic group.

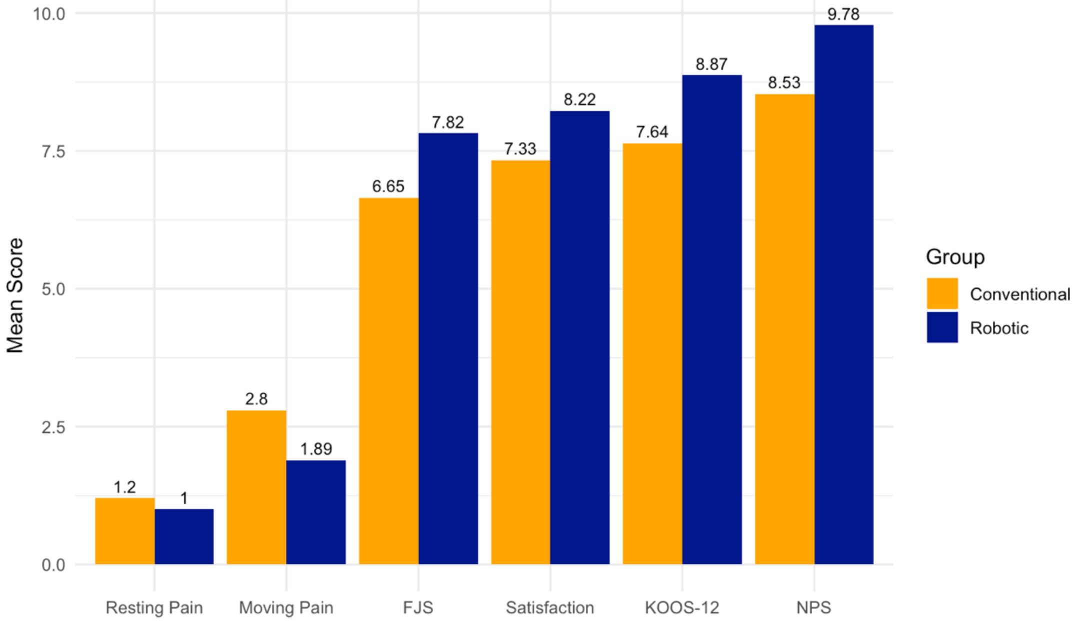


Figure 22. Barplot comparing mean value of each functional variable between conventional and robotic group.

4. Relation between radiological variables and functional outcomes

○ HKA variable

Table 15. Comparison of functional outcomes between 'In range' and 'Out of range' groups for HKA values.

HKA	In range (n = 22)	Out of range (n = 11)	p - value
Difference Resting Pain	-4.6 ± 2.64 (mean±SD)	-4.5 ± 2.84 (mean±SD)	0.92
Difference Moving Pain	-5.1 ± 2.94 (mean±SD)	-4.8 ± 3.08 (mean±SD)	0.801
Difference KOOS-12	58.35 ± 21.97 (median±SD)	52 ± 24.9 (median±SD)	0.3019
Resting Pain POST	5.5 ± 2.95 (median±SD)	6 ± 2.6 (median±SD)	0.94
Moving Pain POST	7 ± 2.06 (median±SD)	7.5 ± 1.66 (median±SD)	0.615
FJS POST	93.7 ± 30.39 (median±SD)	75 ± 31.68 (median±SD)	0.28
Satisfaction POST	8 ± 2.44 (median±SD)	8 ± 1.89(median±SD)	0.59
KOOS-12 POST	92.65 ± 20.62 (median±SD)	72.1 ± 18.35(median±SD)	0.23
NPS POST	10 ± 2.19 (median±SD)	10 ± 1.35(median±SD)	0.78

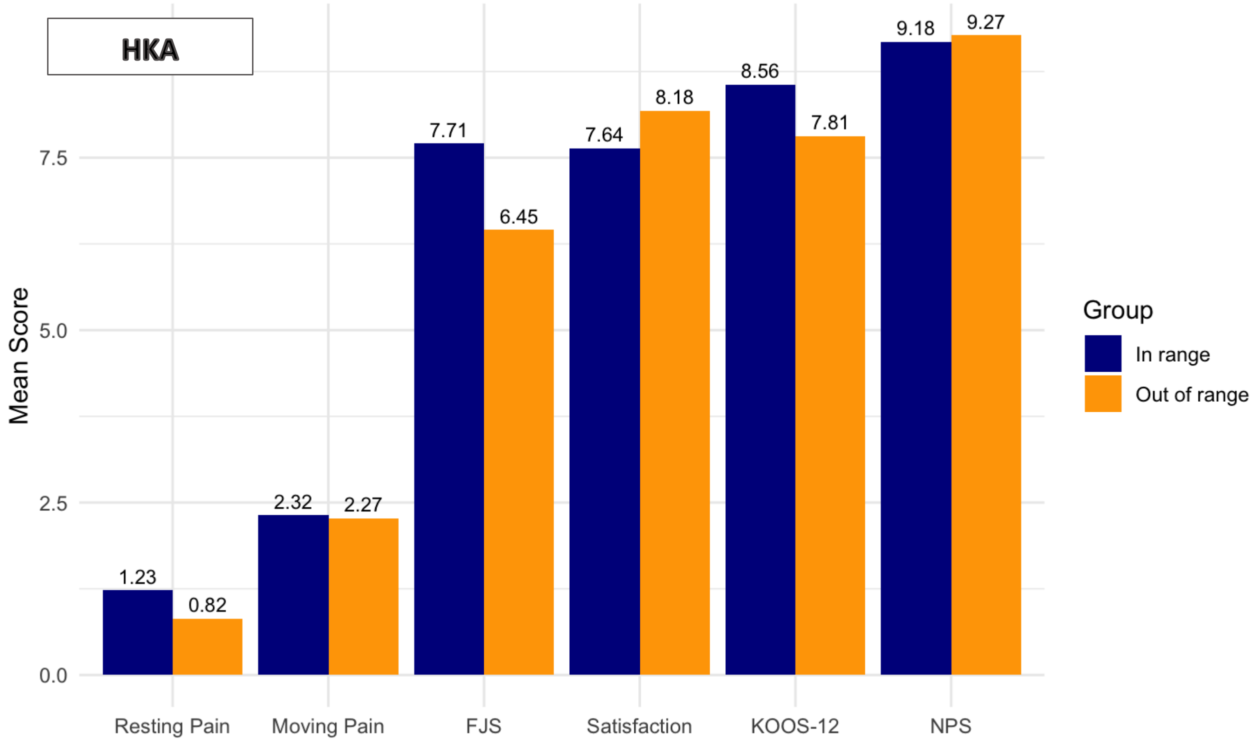


Figure 23. Barplot comparing mean value of each functional variable between 'In range' and 'Out of range' groups for HKA values.

- JLH variable

Table 16. Comparison of functional outcomes between 'In range' and 'Out of range' groups for JLH values.

JLH	In range (n = 25)	Out of range (n = 8)	p - value
Difference Resting Pain	-4.86 ± 2.82 (mean±SD)	-3.75 ± 2.43 (mean±SD)	0.306
Difference Moving Pain	-4.6 ± 3.16 (mean±SD)	-6.13 ± 1.96 (mean±SD)	0.13
Difference KOOS-12	52.1 ± 25.52 (median±SD)	61.45 ± 8.74 (median±SD)	0.26
Resting Pain POST	6.5 ± 2.7 (median±SD)	5 ± 2.8 (median±SD)	0.84
Moving Pain POST	7 ± 2.16 (median±SD)	7 ± 1.07(median±SD)	0.16
FJS POST	81.85 ± 32.7 (median±SD)	100 ± 20.35 (median±SD)	0.0792
Satisfaction POST	8 ± 2.54 (median±SD)	8 ± 1.07(median±SD)	0.72
KOOS-12 POST	87.5 ± 21.04 (median±SD)	97.9 ± 11.97(median±SD)	0.074
NPS POST	10 ± 2.17 (median±SD)	10 ± 0.707(median±SD)	0.37

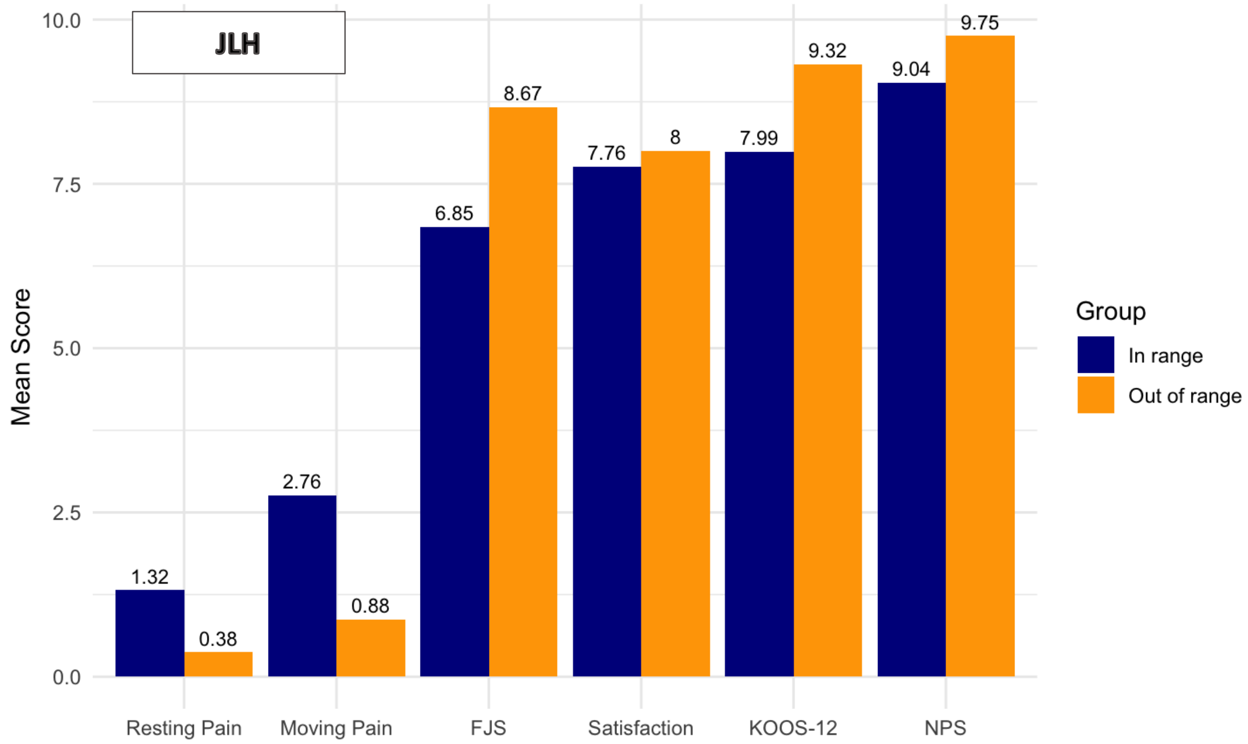


Figure 24. Barplot comparing mean value of each functional variable between 'In range' and 'Out of range' groups for JLH values.

In *Figure 18,22,23 and 24,* the scores for KOOS12 and FJS have been divided by 10 to maintain a consistent scale, resulting in better visual representation of the graph.

DISCUSSION OF RESULTS

LEARNING CURVES

To date, there has been limited research on the learning curves associated with robotic-assisted UKA surgeries. Consequently, there is few existing literature available for comparing results. In contrast, the learning curve for TKA has been more extensively studied. Therefore, most of the comparisons made in this section are based on information from articles discussing learning curves in TKA procedures. It is assumed that this information is applicable to our study of UKA.

IDENTIFICATION OF INFLECTION POINT AND COMPARISON OF PHASES

After generating the learning curve, an inflection point corresponding to case 7 was clearly observed. This point divides the learning curve into two distinct phases: an initial learning phase during which surgeons adapt to the new robotic system, followed by a subsequent phase where proficiency is achieved in terms of surgical times. Kayani et al, conducted a study in which the learning curve of robotic assisted TKA was analyzed (61). They found the inflection point in case number 7, in which the operative times began to decrease. This indicates that our observation is consistent with findings reported in existing literature.

Once these two phases were identified, a comparison between them was performed. Initially, a t-test comparing the mean surgical time of each phase was conducted. Phase one presented a mean time of approximately 116 minutes, whereas phase 2 showed a mean surgical time of 101 minutes. A reduction in surgical duration between phases can be noted. However, the t-test gave a p-value of 0.059, which is slightly above the standard significance thresholds of alpha 0.05. Nevertheless, this result suggests a trend towards statistical relevant differences between the phases. This highlights the need for future research with larger sample sizes to confirm these initial observations.

Besides, both phases were compared regarding radiological variables. The initial hypothesis was that in the initial phase, the limb alignment (measured with the HKA angle and with the Joint Line Height Difference) would be more frequently out of range compared to the second phase where surgeons theoretically have better control of the robotic system. The percentage of 'HKA out of range' values was calculated for each phase. In the first phase 66.66% of the cases were out of range, whereas in the second phase, only 22.22% were out of range. To validate this hypothesis, a Fisher's Exact test was used, and the obtained p-value was of 0.1521, suggesting that the statistical difference between the 'HKA out of range' values of each phase was not statistically significant. Additionally, the standard deviation of the 'HKA_post' variable was larger in the first phase than in the second one. This can suggest that there is bigger variability in the limb alignment in the first phase than in the second one, meaning that once the surgeons adapt to the robotic system, the alignment outcomes improve.

On the other hand, the Joint Line Height was also studied between Phase 1 and Phase 2. The percentage of 'JHL out of range' was of 33.33% for both phases so, in this variable, no differences were found in terms of alignment. Furthermore, the standard deviation of 'JLH_post' was also analyzed in both phases, but there was not a reduction of variability in the second phase.

Finally, a comparison of the functional outcomes between the two phases was conducted. This analysis revealed no significant statistical differences, as all p-values were above the alpha value of 0.05. This indicates that, statistically, there are no significant differences in terms of functional outcomes and patient satisfaction between the phases. Consequently, it can be concluded that the first phase is as safe as the second one, suggesting that the system is safe from the very first case and serves as an important tool for young surgeons starting without experience in UKA procedure.

LIMITATIONS

It is relevant to note that the learning curve for this study was generated using data from two surgeons that had previous experience conducting conventional UKA surgeries, which is not the optimal approach. Ideally, learning curves should be individualized for each surgeon to accurately reflect their personal experience and development, However, this approach was justified because the two surgeons selected for the study operated most of the times together, and it can be considered that their cumulative learning experience was conjunct.

Due to the limited number of robotic surgeries performed by each individual surgeon, it was not possible to generate separate learning curves. We first considered the option of working with censored data to estimate the probability of a surgeon reaching the inflection point before a certain number of cases. However, it was ultimately decided to construct a single learning curve for both surgeons, giving more representative results.

Additionally, it would have been interesting to compare the learning time of these surgeons, who had experience with conventional UKA, with the learning of surgeons who are starting with ra-UKA, without prior experience in c-UKA. Comparing these learning curves, we could have examined whether having prior experience with conventional surgery has positive or negative effected when adopting a new technology, as the CORI surgical robot.

In conclusion, the main limitation for this first objective was the small sample size. Despite this, valuable insights were obtained, such as identifying the inflection point of the curve at case 7, which aligns with findings reported in the literature.

COMPARATIVE ANALYSIS

DISCUSSION

1. Radiological variables (HKA and JLH)

In the initial comparison, which compared cases from robotic and conventional surgery falling within and outside the established range for two radiological variables (HKA, JLH), no statistically significant differences were found as both variables showed p-values exceeding the standard 0.05 threshold. This suggests that surgeons achieve adequate limb alignment as good as the robotic CORI system. However, a study conducted by Yannick Herry et al in 2017 demonstrated that robotic surgery achieved better JLH compared to conventional techniques (62). In this case, ‘better’ is understood as less difference of the joint line height between the preoperative distance and the postoperative distance. Specifically, the robotic-assisted group deviated on average by 1.5 mm from the preoperative value, while the conventional group deviated by 4.5 mm, indicating greater precision with robotic techniques. These findings appear contradictory, and this is possibly influenced by differences in sample size. The study referenced involved 40 patients per group, providing a much larger dataset than ours. Further studies with a larger number of cases would be necessary to validate the hypothesis proposed by Yannick Herry et al.

2. Functional variables (post-operative – pre-operative)

When comparing the postoperative and preoperative differences of the assessed variables, it is notable that the pain values show negative results, this is because the preoperative pain is always higher than the postoperative. Thus, a more negative value signifies greater improvement after the surgical intervention. The values obtained for the robotic group are slightly more negative compared to those of the conventional group. However, the p-value obtained from the Wilcoxon test exceeded the 0.05 threshold in all the variables studied, indicating that the differences in medians are not statistically significant.

3. Post-operative functional variables

The comparison of post-operative functional outcomes between conventional and robotic-assisted UKA show some notable trends. For resting pain, there is no significant difference between the groups (p-value 0.773). Moving pain shows a lower median in the robotic-assisted group, but this difference is not statistically significant (p-value 0.402). The KOOS-12 score is higher in the robotic-assisted group, indicating better knee function, with a p-value of 0.067, suggesting a trend towards statistical significance. Additionally, in the generated boxplot, the conventional group's results show bigger variability and are generally distributed at lower values compared to the robotic group. This visual interpretation suggests that the robotic cases tend to have higher KOOS-12 scores overall. Both groups have the same median NPS score, with a p-value of 0.0503, also indicating a tendency to be statistically significant. This might seem odd because if the medians are equal, one could think that the p-value should be 1, indicating that there is no difference between the samples analyzed. However, the reality is that the Wilcoxon test does not only consider the medians but also looks at the variability of both samples, the sample sizes, among other factors that can give a statistically significant result even if the median values are the same. In this specific case, the p-value obtained could be due to the very different distributions of the samples. As shown in the generated boxplot, most robotic cases have an NPS score of 10, whereas the conventional cases vary between 8 and 10. Specifically, the standard deviation of NPS in the conventional group is 10 ± 2.67, and in the robotic group, it is 10 ± 0.65, making it even clearer that the samples variability is very different. Patient satisfaction scores are similar in both groups (p-value 0.83). Finally, the FJS score is higher in the robotic-assisted group, but the difference is not statistically significant (p-value 0.302). Despite most p-values being above 0.05, the NPS and KOOS-12 scores indicate a trend towards significance, highlighting the potential benefits of robotic-assisted UKA. As observed in the bar plot, the robotic group tends to have slightly better functional outcomes compared to the conventional group. Ahmed Hussein Ghaza et al conducted a Meta-Analysis and found that robotic assisted surgery had better outcomes than the conventional surgery in terms of HKA angle and in terms of Oxford Knee Score (which is a questionnaire that assesses function and pain of the knee after the surgery). However, they did not find statistically significant differences regarding FJS and WOMAC pain score (which measures the pain level) (63). These results suggest further research to investigate the clinical advantages and the impact of robotic technology in UKA.

4. Relation between radiological variables and functional outcomes

Finally, the relation between radiological variables and functional outcomes was studied. No statistically significant differences were found between the 'Out of range' and the 'In range' sub-divisions for each radiological variable. Additionally, the bar plots show better scores of KOOS-12 and FJS for the 'In range' group in the HKA variable. However, regarding the JLH, no better results are found in the 'In range' group. A study conducted in 2023 by Manuel-Paul Sava et al showed that the 176º-180º HKA alignment was reported as an optimal range for the coronal alignment of the knee, resulting in superior functional and clinical outcomes compared to other analyzed intervals (64). Our findings do not align with these results, which may be attributed to the small sample size in our study. Further research with larger sample sizes is needed to validate these findings.

LIMITATIONS

The primary limitation of our study relies in its small sample size, which compromises the robustness of our statistical results. This limitation could explain why our findings did not reach the 0.05 significance threshold in most of the comparisons. Additionally, by including cases from both the first and second phases of the learning curve in our comparison of the c-UKA and ra-UKA approach, there may be significant differences in surgical efficiency and clinical outcomes. With a larger sample size, it would be interesting to explore whether focusing only on the second phase, where surgeons are more proficient with the robotic system, could provide a more accurate comparison and potentially reveal clearer differences between the groups.

TECHNICAL VIABILITY

In this section, the SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis is exposed *(Table 17).* This analysis gives valuable information to evaluate the technical feasibility of the project.

This tool is divided into an internal and an external analysis. The internal analysis involves the Strengths and Weaknesses of the project, and they are aspects that can somehow be controlled. This project stands out for its innovative research focus on the learning curve of orthopedic surgeons using the CORI robot in ra-UKA, which is an area with limited existing literature. A clear inflection point was identified in the learning curve at case 7, distinguishing between the learning and proficiency phases. Conducted at the prestigious Hospital Clínic de Barcelona, the project benefits from strong institutional support, including ethical approval and collaboration from the Orthopedic Surgery and Traumatology Department. Additionally, the high level of guidance and mentorship from the project director and tutor facilitated the progress of the study. Lastly, the possibility of attending surgeries where the CORI robot was used offered a deeper insight into the surgical techniques studied. Regarding the Weaknesses of the project, the small sample size is the biggest limitation, which limits the accuracy of the results and the statistical power of the analysis. Furthermore, the variability and incomplete data in patient clinical records have slowed down the data recollection process notably.

On the other hand, the external analysis involves the Opportunities and Threats of the project, which are external aspects that can impact the project. The project benefits from the increasing research and market interest in the field of robotic assisted surgery, indicating growing opportunities for collaboration and advancements in technology. Potential follow-up studies using the generated R-Code could replicate the analysis with a larger sample size, thereby potentially giving more precise and reliable results. Moreover, this project has a planned publication in a scientific journal, alongside with other analyses conducted in the Orthopedic Surgery Department of the hospital, this way contributing to significative insights in the research of this field. Regarding the threads, the limited available literature on UKA learning curves difficulted the discussion of the results obtained. Lastly, some patients were missing questionnaires in their clinical records, requiring hospital staff to contact them by phone to complete the surveys. However, not all patients could be reached despite these efforts.

Table 17. SWOT analysis.

STRENGTHS	WEAKNESSES
○ Innovative research focus. ○ Strong methodological approach. ○ Clear inflection point identification in the learning curve generated. ○ Institutional support: the project is conducted in the Hospital Clinic of Barcelona, with ethical approval and collaboration from the Orthopedic Surgery and Traumatology Department. ○ High backup from project directors. ○ Possibility of practical experience: attending a surgery where the technology studied (CORI) was used. ○ Clinical significance: the study addresses an important issue in orthopedic surgery.	○ Small sample size. ○ Combined learning curve: using a single learning curve for two surgeons instead of individualized curves. ○ Subjectivity in PROM's questionnaire data. ○ Limited experience using R-Studio software. ○ Variability in patient's clinical records: some clinical records had incomplete data, making the data collection process slower.
OPPORTUNITIES	THREATS
○ Increasing research and market on the studied field. ○ Potential follow-up studies: using the generated R-Code, this study can be repeated with a larger sample size, which probably would give more accurate results. ○ Publication in scientific journals: the project is expected to be published in a scientific journal together with other analysis performed in the Orthopedic Surgery Department of the hospital. ○ Influence on current research on the topic: the results obtained can be useful for the robotic surgery community.	○ Limited available literature on UKA learning curves for later discussion. ○ Patients not answering phone calls to answer the PROM's questionnaires.

ECONOMIC VIABILITY

This section aims to make an analysis regarding the economic aspects of the project. All the costs have been proportionated by the Department of Administrative and Economic Management of ICEMEQ ('Instituto Clinic de Especialidades Médicas y Quirúrgicas'), and they summarize the general cost of the intervention and the corresponding follow up per patient.

First, the amount of money that needs to be paid to Smith-Nephew for their services is the sum of the price of Journey Implant for UKA, and the price of the CORI robot itself. The price for each implant is of approximately 2,240€, and the price of the robot is of 420,000€. If we want to make an estimation of the price of the robot per patient, we can consider the total price and divide it by the years the robot is amortized (approximately 12) and by the number of interventions of ra-UKA per year (approximately 25). This sums up a total of 1,400€ per patient, and summing the cost of the implant, the total amount per patient is of 3640€. The maintenance and consumables of the robot is an added cost that must be considered. Approximately, this cost is of 820€ per intervention.

Next, the cost of the intervention itself must be considered, including the costs associated with the doctors and nurses (1,767€), and the costs associated with the drugs and surgical material used (479€). In this case, considering it all together, gives a total of 2,246€. Additionally, the costs of hospitalizing the patient must be taken into account. In the Hospital Clinic of Barcelona, the reference price per day is of 473.54€ (including salaries of doctors, nurses, and other sanitary professionals). The mean days of hospitalization after a UKA surgery is of 1 day. Therefore, the total cost for all the days sums a total of 473.54€.

It is important to consider the price associated with the pre-operative and post-operative radiographies (XT), as they are crucial for the surgery and for the follow-up. In this hospital, the price for each XR is of 30.66€. However, normally two images are taken summing a total of 61.32€.

The costs of the medicines needed for the patient sums up an average of 23.5€. Finally, it must be said that the cost of doing the research project itself, in this case is of 0€, as it has been done as a Final Degree research Project. Contrarily, the salary of the corresponding researcher must be added to the total cost.

Table 18. Costs associated to the project.

Resource / Service	Cost per patient (€)
Journey UNI implant (Smith-Nephew)	2,240
CORI Robotic System (Smith-Nephew)	1,400
CORI Maintenance and Consumables	820
Surgical Intervention	1,767
Drugs and surgical material	479
Post-Surgery Hospitalization	473.54
XR images (pre- and post-surgery)	61.32
Medicines	23.5
TOTAL	**7264.36**

EXECUTION CHRONOGRAM

WORK BREAKDOWN STRUCTURE (WBS)

The WBS (Work Breakdown Structure) is a hierarchical and visual representation of the project, where the total work is broken into different blocks of work. Each work block contains different individual tasks or activities that must be carried out to achieve the final objectives of the project. By dividing the project into smaller tasks, it is easier to track the process and ensure that all aspects of the project are addressed in a structured manner. As it can be seen in *Figure 25,* the main blocks of this project are the project definition, the previous documentation, the analysis of the data and, finally, the project publication.

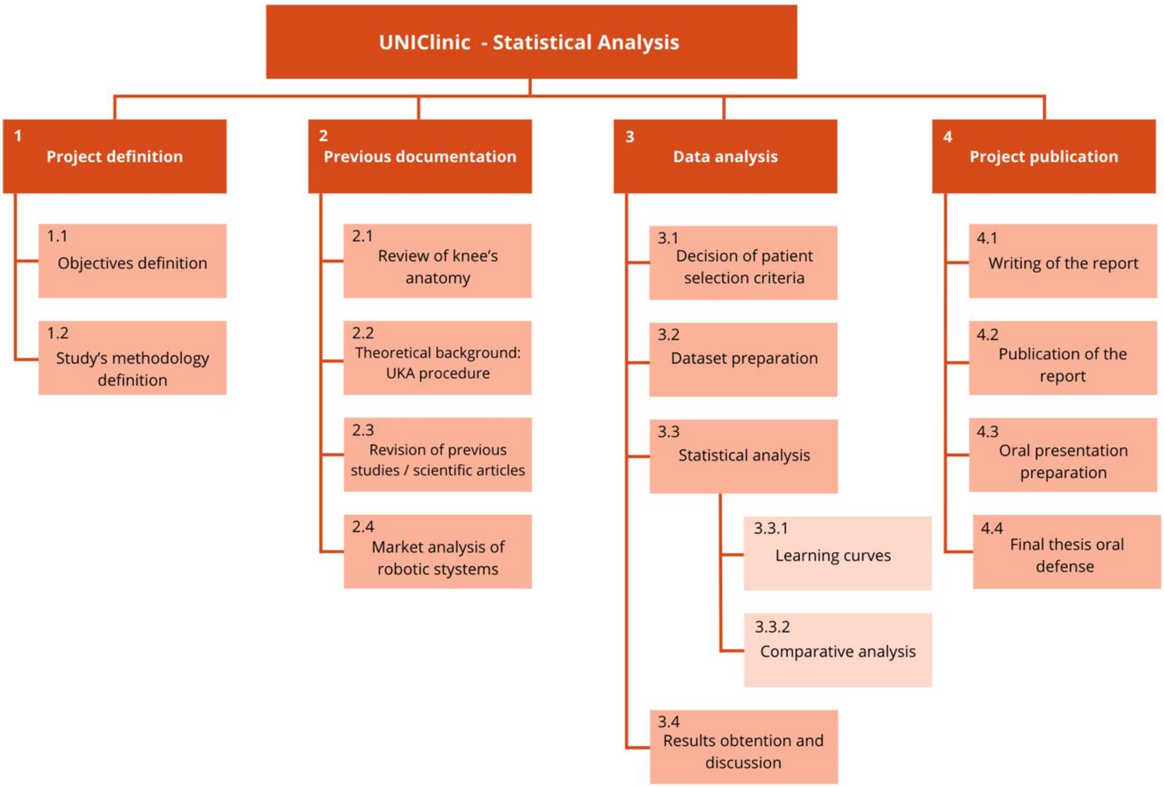


Figure 25. WBS diagram of the project.

The smaller tasks of each block of work are defined in detail in the following WBS dictionary.

Table 19. WBS dictionary of the project.

	Code	Task	Description
Project definition	1.1 (A)	Objectives definition	This task involves clearly defining the principal and secondary objectives of the project. These will act as a guide to establish specific goals and to not lose track of what the project aims to study.
	1.2 (B)	Study's methodology definition	This task describes in detail the methodology with which the study is going to be carried out, from an organization point of view (timings) and from a study design point of view.
Pr	2.1		

	(C)	Review of knee's anatomy	An exhaustive review of the knee anatomy is performed. Knowing the anatomy of the joint is essential to understand the literature of the surgical procedure studied (UKA).
	2.2 (D)	Theoretical background: UKA procedure	This task involves acquiring in-depth knowledge about the UKA procedure. The principles, techniques, indications, and contraindications of this surgical procedure are studied. Not only the conventional technique is studied, but also robotic-assisted UKA.
	2.3 (E)	Revision of previous studies/scientific articles	Exhaustive review of scientific articles and studies published in platforms like Pubmed. This allows the understanding of the current state of the situation and contextualizing the study.
	2.4 (F)	Market analysis of robotic systems	A detailed analysis of the market for robotic systems related to orthopedic surgery, specifically focusing on knee surgery systems, is carried out in this task. This involves examining the features, performance, costs, and market trends.
Data analysis	3.1 (G)	Decision of patient selection criteria	This task involves the creation of specific criteria for selecting patients to participate in the study. These criteria include factors such as age, knee condition, time that have passed since the patient was operated, etc.
	3.2 (H)	Dataset preparation	Preparing the Excel sheets for the different objectives of the project.
	3.3 (I)	Statistical analysis	During this task the statistical analysis of the data will be conducted using the R-Studio software. This includes using different tests and techniques to identify relationships between the data and extract valuable conclusions.
	3.3.1 (J)	Learning curves	Study of the learning process of the surgeons associated with the use of new technologies (robotic surgical system in UKA).
	3.3.2 (K)	Comparative analysis	Comparative test between the two groups of the study: patients who underwent conventional surgery and patients who, on the other side, underwent robotic-assisted surgery.
	3.4 (L)	Results obtention and discussion	Interpretation of the results obtained from the statistical analysis, discussion, and conclusions.
Project publication	4.1 (M)	Writing of the report	Redaction of the written report of the project that will be submitted.
	4.2 (N)	Publication of the report	Deliver the report in the "Campus Virtual" in the established deadline.
	4.3 (O)	Oral presentation preparation	Preparation of a Power Point presentation that highlights the most important aspects and findings of the study.
	4.4 (P)	Final thesis oral defense	Oral presentation and defense of the final degree project.

PERT DIAGRAM

For a project execution to be successful, the correct coordination and planning of it is crucial. PERT is a technique that allows to plan and control the project tasks and activities, as well as their temporal order. This technique enables the identification of the project's critical path and facilitates effective time management. The critical path is the sequence of activities that determines the longest possible duration to complete the entire project. As it can be seen *Table 20*, each task corresponds to a letter and each task has preceded tasks. Additionally, each task has an assigned duration, in this case of days. To estimate this duration in the most accurate way, a probabilistic model is used *(Equation 3).* This model considers the duration of each activity to follow a β distribution. $\mathrm{T}_{\mathrm{PERT}}$ is the estimated time, T_{O} the optimistic time, T_{p} the pessimistic time and T_{n} is the normal time to be invested in a certain task.

$$T_{PERT} = \frac{\mathrm{T}_{\mathrm{O}} + 4\mathrm{T}_{\mathrm{n}} + \mathrm{T}_{\mathrm{p}}}{6}$$

Equation 3. PERT β – distribution equation for time estimation.

Table 20. Ordered tasks required to perform the project, with corresponding precedencies and timings.

WBS code	PERT code	Previous task code	T_{O}	T_{n}	T_{p}	$\mathrm{T}_{\mathrm{PERT}}$	$\mathrm{T}_{\mathrm{PERT\_Round}}$
1.1	A	-	2	5	6	4.66	5
1.2	B	A	3	5	7	5	5
2.1	C	B	2	4	5	3.83	4
2.2	D	C	10	15	18	14.66	15
2.3	E	C	10	15	18	14.66	15
2.4	F	C	5	7	10	7.16	7
3.1	G	B,D,E,F	5	10	15	10	10
3.2	H	G	15	20	23	19.66	20
3.3	I	H	20	25	30	25	25
3.4	J	I	10	12	13	11.83	12
4.1	K	J	30	35	38	34.66	35
4.2	L	K	1	1	2	1.16	1
4.3	M	L	2	5	7	4.83	5
4.4	N	M	1	1	2	1.16	1

It's worth mentioning that the time unit used is days, as it was easier to do the approximation. Additionally, when calculating the estimated time using *Equation 3*, some of the times came out with decimals. Since working with decimals doesn't make much sense in days units, the obtained value has been rounded ($\mathrm{T}_{\mathrm{PERT\_Round}}$). All the information from the table is translated into a PERT diagram represented in Figure *26*, where tasks are chronologically ordered, and a visual outline of the critical path is represented in red.

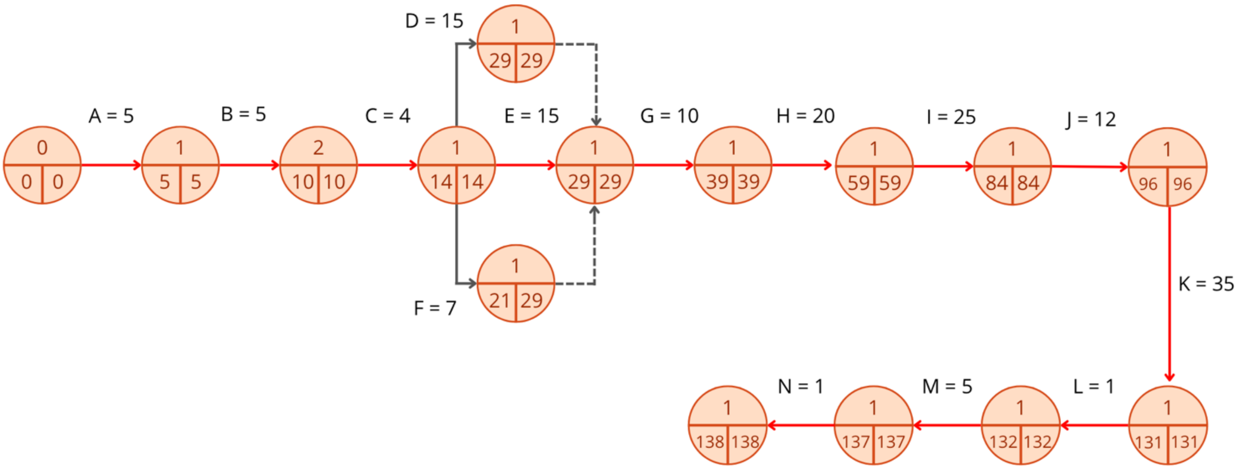
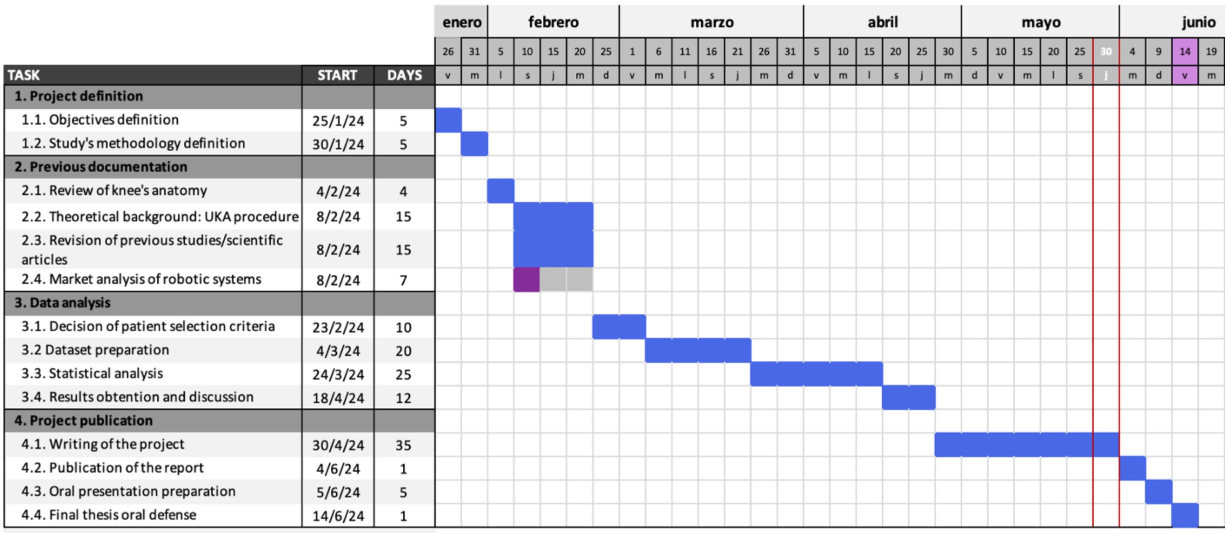


Figure 26. PERT diagram.

GANTT DIAGRAM

The Gantt diagram in *Figure 27* visually represents the workflow for this study. The tasks are divided into blocks, like the Work Breakdown Structure (WBS) diagram, showing their start dates and durations in days. Tasks 2.2, 2.3, and 2.4 occur simultaneously; since they involve literature research, they can be performed concurrently rather than sequentially, which is why they all begin on the same day. The task highlighted in purple is flexible, meaning it needs to be completed within 15 days to ensure it precedes Task 3.1. However, due to its shorter duration, it does not necessarily need to start at the same time as the other two simultaneous tasks. Overall, the total estimated duration of the study, including the writing of the final degree project (TFG) and the preparation for the oral defense is of 138 days.



TASK	START	DAYS
1. Project definition		
1.1. Objectives definition	25/1/24	5
1.2. Study's methodology definition	30/1/24	5
2. Previous documentation		
2.1. Review of knee's anatomy	4/2/24	4
2.2. Theoretical background: UKA procedure	8/2/24	15
2.3. Revision of previous studies/scientific articles	8/2/24	15
2.4. Market analysis of robotic systems	8/2/24	7
3. Data analysis		
3.1. Decision of patient selection criteria	23/2/24	10
3.2 Dataset preparation	4/3/24	20
3.3. Statistical analysis	24/3/24	25
3.4. Results obtention and discussion	18/4/24	12
4. Project publication		
4.1. Writing of the project	30/4/24	35
4.2. Publication of the report	4/6/24	1
4.3. Oral presentation preparation	5/6/24	5
4.4. Final thesis oral defense	14/6/24	1

Figure 27. GANTT diagram.

REGULATIONS AND LEGAL ASPECTS

REGARDING CLINICAL TRIALS

Any research conducted on human subjects to determine or confirm clinical effects is considered a Clinical Trial (CT) and must be regulated accordingly. First, in such a study, it is mandatory that patients sign an informed consent to participate. Once they have agreed, maintaining the confidentiality of patient data is crucial, and only authorized healthcare personnel have access to this data. This is regulated by Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons regarding the processing of personal data and on the free movement of such data, known as GDPR (65).

The GDPR is the EU's legal framework that governs the protection of personal data of citizens living in the European Union. In addition to this regulation, there is national legislation such as Royal Decree 5/2018 of 27 July and the draft Organic Law on Data Protection, which regulates aspects such as the procedure for handling non-compliance and the statute of limitations for sanctions, among other matters (66)

Moreover, the project must be approved by the hospital's ethics committee. In this case, the larger project was already approved by the ethics committee under protocol codes HCB/2021/0558 and HCB/2022/0144.

REGARDING ROBOTIC SURGERY

Robotic surgery is a growing technology nowadays. However, one aspect that is still ambiguous is its legal aspect. There is still a lack of clear laws and legal guidelines on the legal liability of surgeons and manufacturers (67). Surgical robots, including the Cori Surgical System, are categorized as medical devices. FDA device classifications are structured into three classes based on the level of risk associated with their use: Class I, II, and III. According to the FDA, the Cori Surgical System falls under Class II classification, indicating a situation where use of the product may cause temporary or medically reversible adverse health consequences, but the probability of serious adverse health consequences is remote (68). As the device class increases from Class I to Class III, the regulatory controls also escalate. For this specific case, some of the regulations that must be considered are:

- ISO-13485: optimal medical device standard for the medical industry, ensuring that al medical devices comply with appropriate laws and meet customer needs. This certification is a valuable credential that ensures the safety of professionals and customers in clinics, hospitals, and other medical settings (69)

- ISO 17664:2002: specifies the requirements for products that penetrate sterile sites of the human body or contact mucous membranes or damaged skin (70)

- IEC-62304: standard that specifies the process and objectives necessary for safely developing software for medical devices (71)

CONCLUSIONS

The integration of robotic systems in surgical practice represents a significant advancement in modern medicine. There is an enhanced prevalence of minimally invasive surgical techniques such as Unicompartmental Knee Arthroplasty (UKA). When integrating technology like surgical robots into these techniques, studying the safety, precision, and cost-effectiveness becomes crucial.

In this study, the aim was to assess the impact of robotic surgery in unicompartmental knee arthroplasty in terms of radiological variables such as HKA and JLH, as well as functional outcomes derived from patient-reported outcome measures (PROMs)

The learning curve for surgeons adopting this new technology in the operating room was examined. This curve was analyzed in terms of surgical time and divided into two phases. The initial phase shows longer surgical times as surgeons adapt to the technology, while the second phase demonstrates decreased surgical times. Specifically, the learning curve identifies an inflection point at case 7, indicating that surgeons adopt the technology by this point, resulting in reduced surgical times. Furthermore, differences in radiological variables and functional outcomes between these phases were explored. This investigation is critical for understanding the safety implications of integrating new surgical techniques.

Regarding radiological outcomes, a higher percentage of cases outside the range for the HKA variable was observed in the initial phase compared to the second phase. However, in terms of functional outcomes, none of the variables studied showed statistically significant differences between phases. Therefore, it can be concluded that the inclusion of robotic assistance in the operating room is safe and does not negatively impact patients in the early stages of the learning curve

Additionally, conventional techniques were compared with robotic-assisted techniques. Initially hypothesized to be more precise, the study found no significant differences in radiological variables between the two approaches. This suggests that surgeons achieve similar prosthetic placement, resulting in good limb alignment with both approaches (c-UKA and ra-UKA). Furthermore, while there was a trend towards better functional outcomes with ra-UKA, this hypothesis was not statistically supported due to the p-value exceeding significance thresholds. Nonetheless, this observed trend indicates potential benefits that could be further validated with a larger sample size.

In conclusion, this study addresses the initial questions:

- **With how many surgeries is the robotic-assisted UKA learning process established?** The study identifies the learning curve's inflection point at case 7.

- **Are there differences in outcomes and complications during the learning phase compared to the subsequent phase?** Results indicate the system is safe from the first case, delivering comparable outcomes in terms of alignment and functional results over time.

- **Are there differences in limb alignment and functional outcomes between conventional UKA and robotic-assisted UKA?** In the limited sample, no statistically significant differences were found in terms of radiological variables and functional outcomes. However, there was a trend towards better functional outcomes with robotic-assisted UKA.

FUTURE WORK LINES

The main limitation of this study was the small sample size, potentially impacting the detection of significant differences between groups and the generalizability of findings. Therefore, future work should focus on repeating this study with a larger dataset. A larger dataset would enable more robust analyses and allow for answering additional questions. For example, it would be interesting to compare learning curves between surgeons to assess if experienced conventional surgeons adapt faster to robotic techniques, or if surgeons new to both conventional and robotic procedures demonstrate better learning outcomes.

Summing up, this study underscores the importance of continued research into robotic-assisted surgical techniques to optimize patient outcomes and enhance surgical practice.

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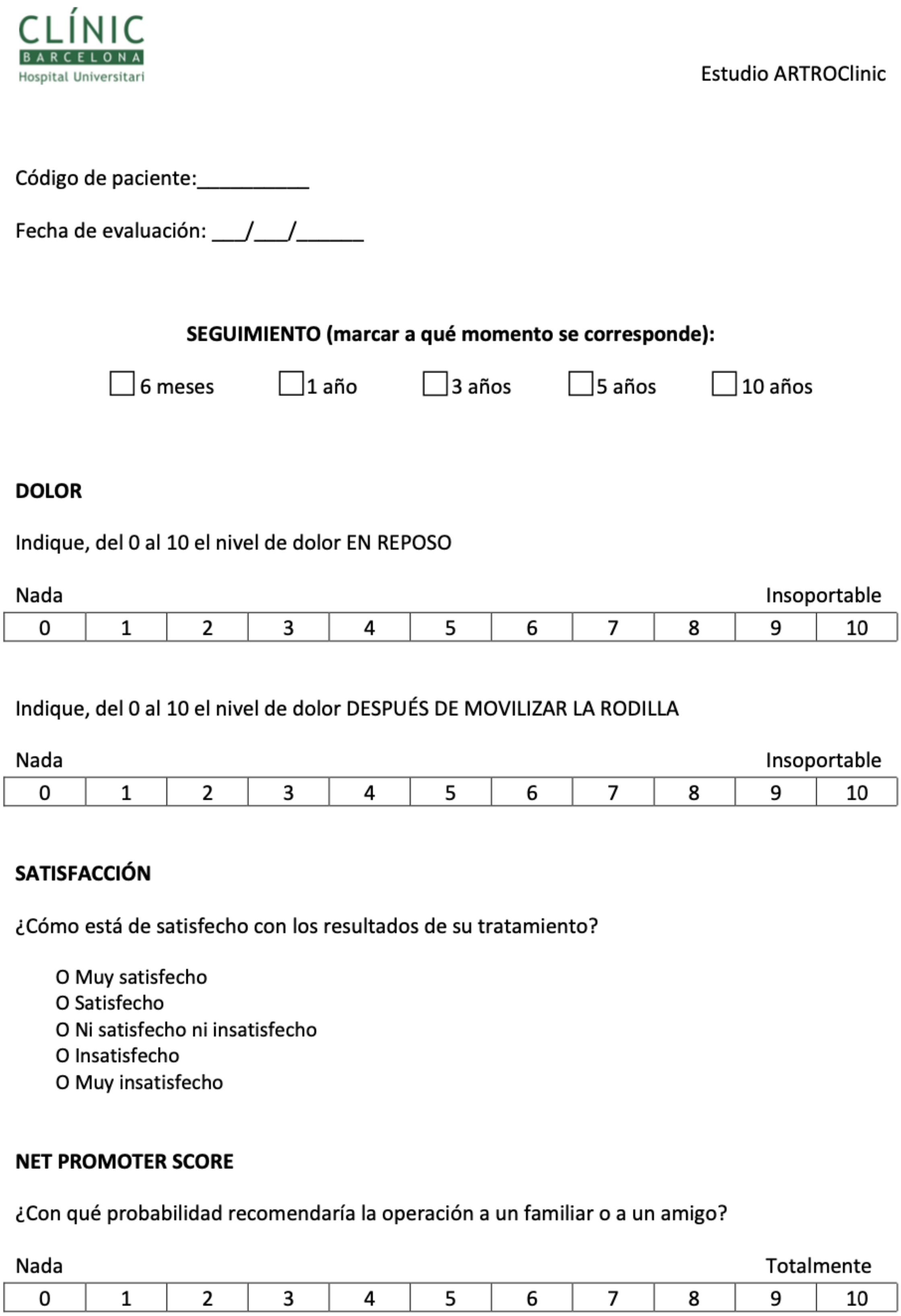
ANNEXES

ANNEX 1 – PROM'S QUESTIONNAIRES



CLÍNIC BARCELONA Hospital Universitari

Estudio ARTROClinic

Código de paciente:__________

Fecha de evaluación: ___/___/______

SEGUIMIENTO (marcar a qué momento se corresponde):

☐ 6 meses ☐ 1 año ☐ 3 años ☐ 5 años ☐ 10 años

DOLOR

Indique, del 0 al 10 el nivel de dolor EN REPOSO

Nada Insoportable

0	1	2	3	4	5	6	7	8	9	10

Indique, del 0 al 10 el nivel de dolor DESPUÉS DE MOVILIZAR LA RODILLA

Nada Insoportable

0	1	2	3	4	5	6	7	8	9	10

SATISFACCIÓN

¿Cómo está de satisfecho con los resultados de su tratamiento?

○ Muy satisfecho
○ Satisfecho
○ Ni satisfecho ni insatisfecho
○ Insatisfecho
○ Muy insatisfecho

NET PROMOTER SCORE

¿Con qué probabilidad recomendaría la operación a un familiar o a un amigo?

Nada Totalmente

0	1	2	3	4	5	6	7	8	9	10

KOOS-12 KNEE SURVEY

Instrucciones: Esta encuesta recoge su opinión sobre su rodilla. Responda a cada pregunta marcando la casilla apropiada y solo una casilla por pregunta. En caso de duda, señale siempre la respuesta que mejor refleja su situación.

DOLOR

1. ¿Con qué frecuencia ha tenido dolor en su rodilla?

Nunca	Mensual	Semanal	Diario	Continuo
☐	☐	☐	☐	☐

¿Cuánto dolor ha tenido en la rodilla en la última semana al realizar las siguientes actividades?

2. Al caminar, sobre una superficie plana

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

3. Al subir o bajar escaleras

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

4. Al estar sentado o recostado

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

ACTIVIDADES COTIDIANAS

Las siguientes preguntas indagan sobre sus actividades físicas, es decir, su capacidad para moverse y valerse por sí mismo. Para cada una de las actividades mencionadas a continuación, indique el grado de dificultad experimentado en la **última semana** a causa de su rodilla.

5. Al levantarse de una silla o sillón

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

6. Al estar de pie

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

7. Al subir o bajar del coche

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

8. Girar o pivotar sobre la rodilla afectada

No tengo	Leve	Moderado	Intenso	Muy intenso
☐	☐	☐	☐	☐

CALIDAD DE VIDA

9. ¿Con qué frecuencia es consciente del problema de su rodilla?

Nunca	Mensualmente	Semanalmente	A diario	Siempre
☐	☐	☐	☐	☐

10. ¿Ha modificado su estilo de vida para evitar actividades que puedan lesionar su rodilla?

No	Levemente	Moderadamente	Drásticamente	Totalmente
☐	☐	☐	☐	☐

11. ¿En qué medida está preocupado por la falta de seguridad en su rodilla?

Nada	Levemente	Moderadamente	Mucho	Excesivamente
☐	☐	☐	☐	☐

12. En general, ¿cuántas dificultades le crea su rodilla?

Ninguna	Algunas	Pocas	Muchas	Todas
☐	☐	☐	☐	☐

Muchas gracias por contestar a todas las preguntas de este cuestionario

Cuestionario sobre la rodilla (Escala de articulación olvidada - 12)

Paciente: ________________ Fecha: ___.___.______

Una articulación sana no es algo de lo que uno sea consciente en la vida diaria. Sin embargo, incluso los problemas más leves pueden aumentar la consciencia que se tiene de ella. Esto significa que usted piensa en su articulación o que le presta atención. Las siguientes preguntas se refieren a **la frecuencia con la que usted es consciente de la articulación de su rodilla afectada en la vida diaria.**

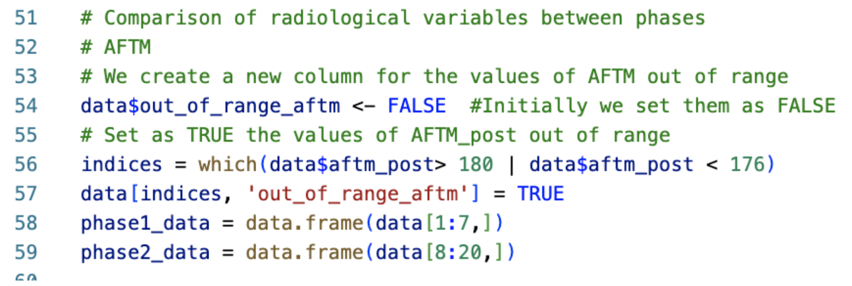
Elija la respuesta más adecuada para cada pregunta.

	¿Es consciente de la articulación de su rodilla…	**Nunca**	**Casi nunca**	**Rara vez**	**A veces**	**Casi siempre**
1.	... en la cama por la noche?	○	○	○	○	○
2.	... cuando permanece sentado/a en una silla durante más de una hora?	○	○	○	○	○
3.	... cuando camina durante más de 15 minutos?	○	○	○	○	○
4.	... cuando se baña/ducha?	○	○	○	○	○
5.	... cuando va en coche?	○	○	○	○	○
6.	... cuando sube un tramo de escaleras?	○	○	○	○	○
7.	... cuando camina sobre un terreno irregular?	○	○	○	○	○
8.	… cuando se levanta de un asiento bajo?	○	○	○	○	○
9.	... cuando está de pie durante largos periodos?	○	○	○	○	○
10.	... cuando hace las tareas del hogar o cuida de su jardín?	○	○	○	○	○
11.	… cuando da un paseo/practica senderismo?	○	○	○	○	○
12.	… cuando practica su deporte favorito?	○	○	○	○	○

ANNEX 2 – R-CODE FOR LEARNING CURVE ANALYSIS

Jsers > mariaguaschizquierdo > Desktop > TFG > Anàlisis de dades > R > CUSUM_entrega.R

```r
#R CODE FOR LEARNING CURVE GENERATION
#set directory
setwd("/Users/mariaguaschizquierdo/Desktop/TFG /Anàlisis de dades/csv")
# import data
data = read.table("cusum_copia.csv",header = T, sep=";")

#Check if data is in chronological order
#Convert Date column to date format:
data$Date <- as.Date(data$Date, format = "%d/%m/%y")
# Order data:
data <- data[order(data$Date), ]

#____________________________________________________CUSUM ROBOTIC SURGERIES_______________________________________________
cases = 1:length(data$Date)
#Standarized value of IQ_Time in robotic UKA
mean_iq_time = mean(data$Time_IQ)
robotic_times = data$Time_IQ
sd(robotic_times) #standard deviation of robotic times

cusum_list = list() #create empty list
#For loop to standarize time values
for (time in robotic_times){
  time_cusum = time - mean_iq_time
  cusum_list = append(cusum_list,time_cusum)
}
#Calculate cumuluative sum of the values
cusum_values = cumsum(cusum_list)

#Plot cusum curve
plot(seq_along(cusum_values),cusum_values, xlab = 'ra-UKA case number', ylab = 'Cusum Values',cex=0.8, frame.plot = FALSE)
axis(1, at = seq(1, length(seq_along(cusum_values))))
axis(1, at = seq(0, 21, by = 1), col.axis = "black", lwd = 1)  # Eje X
axis(2, at = seq(-20, 90, by = 20), col.axis = "black", lwd = 1)  # Eje Y
lines(seq_along(cusum_values), cusum_values, type = "l", col = "black")
abline(v = 7, col = 'darkred', lwd = 1, lty = 2)
text(x = 4, y = 80 * 0.9, labels = "Phase 1", col = "black", cex = 0.8)
text(x = 15, y = 80 * 0.9, labels = "Phase 2", col = "black", cex = 0.8)
title(main = 'CUSUM Analysis - Learning Curve ', cex.main = 1)

#Comparison of the surgery times between the two phases
phase1_times = robotic_times[1:7]
phase2_times = robotic_times[7:20]
#Check normality of data
shapiro.test(phase1_times)
shapiro.test(phase2_times)
#Check variance of data
var.test(phase1_times,phase2_times)
#Conditions of normality of groups and homegeneous variance meet --> t-test
t.test(phase1_times,phase2_times)

```

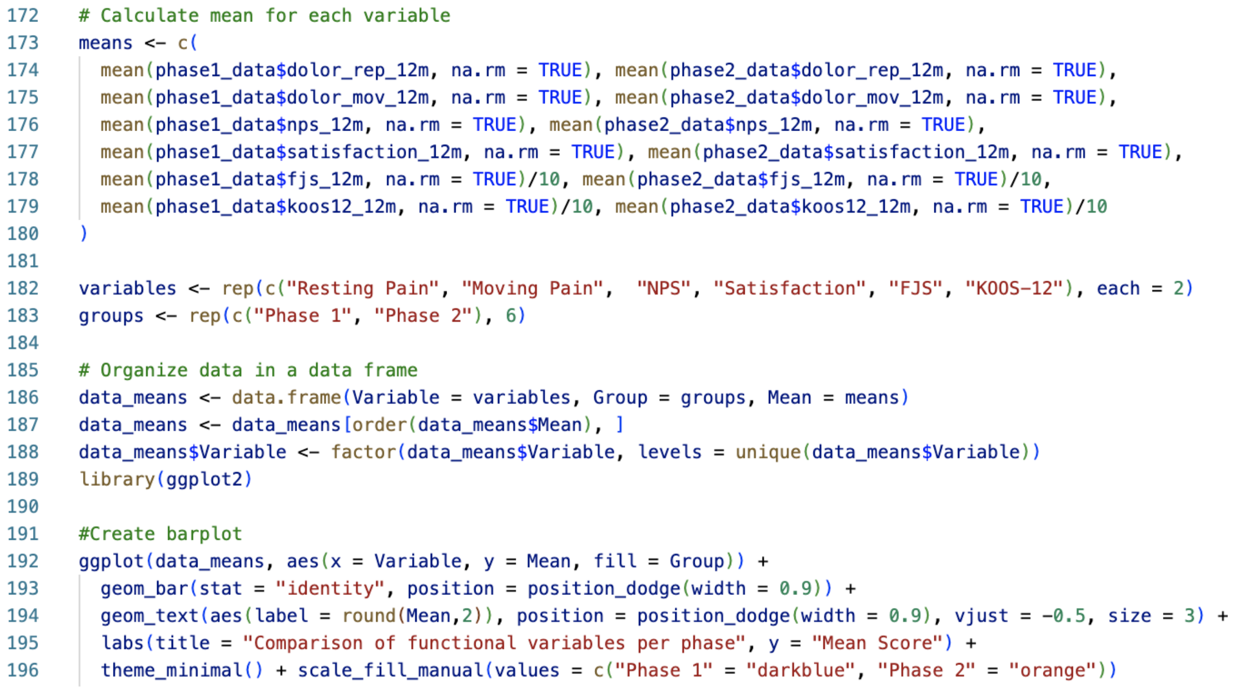


```r
# Comparison of radiological variables between phases
# AFTM
# We create a new column for the values of AFTM out of range
data$out_of_range_aftm <- FALSE  #Initially we set them as FALSE
# Set as TRUE the values of AFTM_post out of range
indices = which(data$aftm_post> 180 | data$aftm_post < 176)
data[indices, 'out_of_range_aftm'] = TRUE
phase1_data = data.frame(data[1:7,])
phase2_data = data.frame(data[8:20,])
```

```r
freq_phase1_aftm = table(phase1_data$out_of_range_aftm)
freq_phase2_aftm = table(phase2_data$out_of_range_aftm)

contingency_table_aftm <- matrix(c(freq_phase1_aftm["TRUE"], freq_phase1_aftm["FALSE"],
                                   freq_phase2_aftm["TRUE"], freq_phase2_aftm["FALSE"]),
                                 nrow = 2,
                                 byrow = TRUE)
rownames(contingency_table_aftm) <- c("Phase 1", "Phase 2")
colnames(contingency_table_aftm) <- c("Out of Range", "Within Range")

# Imprimir la tabla de contingencia
print(contingency_table_aftm)
fisher.test(contingency_table_aftm)

porcentajes_aftm <- c(66.66, 22.22)
fases <- c("Phase 1", "Phase 2")

# Creat bar plot
barplot(porcentajes_aftm, names.arg = fases,col = c("darkblue", "orange"),
ylim = c(0, 100), main = "% HKA out of range per phase of learning curve",
ylab = "Percentage (%)", xlab = "Phase")  # Etiqueta del eje x


# JLH
# We create a new column for the values of distance out of range
data$out_of_range_distance <- FALSE  #Initially we set them as FALSE

# Set as TRUE the values of AFTM_post out of range
indices = which(data$distance> 2.5 | data$distance < 0)
data[indices, 'out_of_range_distance'] = TRUE
phase1_data = data.frame(data[1:7,])
phase2_data = data.frame(data[8:20,])

freq_phase1_jlh = table(phase1_data$out_of_range_distance)
freq_phase2_jlh = table(phase2_data$out_of_range_distance)
```

```r

contingency_table_jlh <- matrix(c(freq_phase1_jlh["TRUE"], freq_phase1_jlh["FALSE"],
                                  freq_phase2_jlh["TRUE"], freq_phase2_jlh["FALSE"]),
                                nrow = 2,
                                byrow = TRUE)

rownames(contingency_table_jlh) <- c("Phase 1", "Phase 2")
colnames(contingency_table_jlh) <- c("Out of Range", "Within Range")

# Imprimir la tabla de contingencia
print(contingency_table_jlh)
fisher.test(contingency_table_jlh)

porcentajes_jlh <- c(33.33, 33.33)
# Crear el gráfico de barras
barplot(porcentajes_jlh, names.arg = fases,col = c("darkblue", "orange"), ylim = c(0, 100),
main = "% JLH out of range per phase of learning curve", ylab = "Percentage (%)", xlab = "Phase")  # Etiqueta del eje x


#____________________________________POST VARIABLES – COMPARISON BETWEEN PHASES_______________________________________
#Resting Pain
#check normallity
shapiro.test(phase1_data$dolor_rep_12m)
shapiro.test(phase2_data$dolor_rep_12m)
#check variability
var.test(phase1_data$dolor_rep_12m,phase2_data$dolor_rep_12m)
#Requirements do not meet
wilcox.test(phase1_data$dolor_rep_12m,phase2_data$dolor_rep_12m)

#Moving pain
#Check normality
shapiro.test(phase1_data$dolor_mov_12m)
shapiro.test(phase2_data$dolor_mov_12m)
```

```r
#Check variability
var.test(phase1_data$dolor_mov_12m,phase2_data$dolor_mov_12m)
#Requirements do not meet
wilcox.test(phase1_data$dolor_mov_12m,phase2_data$dolor_mov_12m)

#KOOS-12
#Check normality
shapiro.test(phase1_data$koos12_12m)
shapiro.test(phase2_data$koos12_12m)
#Check variability
var.test(phase1_data$koos12_12m,phase2_data$koos12_12m)
#Requirements do not meet
wilcox.test(phase1_data$koos12_12m,phase2_data$koos12_12m)

#Satisfaction
#Check normality
shapiro.test(phase1_data$satisfaction_12m)
shapiro.test(phase2_data$satisfaction_12m)
#Check variability
var.test(rob_data$satisfaction_12m,conv_data$satisfaction_12m)
#Requirements do not meet
wilcox.test(phase1_data$satisfaction_12m,phase2_data$satisfaction_12m)

#NPS
#Check normality
shapiro.test(phase1_data$nps_12m)
shapiro.test(phase2_data$nps_12m)
#Check variability
var.test(phase1_data$nps_12m,phase2_data$nps_12m)
#Requirements do not meet
wilcox.test(phase1_data$nps_12m,phase2_data$nps_12m)

#FJS
#Check normality
shapiro.test(phase1_data$fjs_12m)
shapiro.test(phase2_data$fjs_12m)
#Check variability
var.test(phase1_data$fjs_12m,phase2_data$fjs_12m)
# t-test si es compleixen requisits:
t.test(phase1_data$fjs_12m,phase2_data$fjs_12m)
#Requirements do not meet
wilcox.test(phase1_data$fjs_12m,phase2_data$fjs_12m)

```

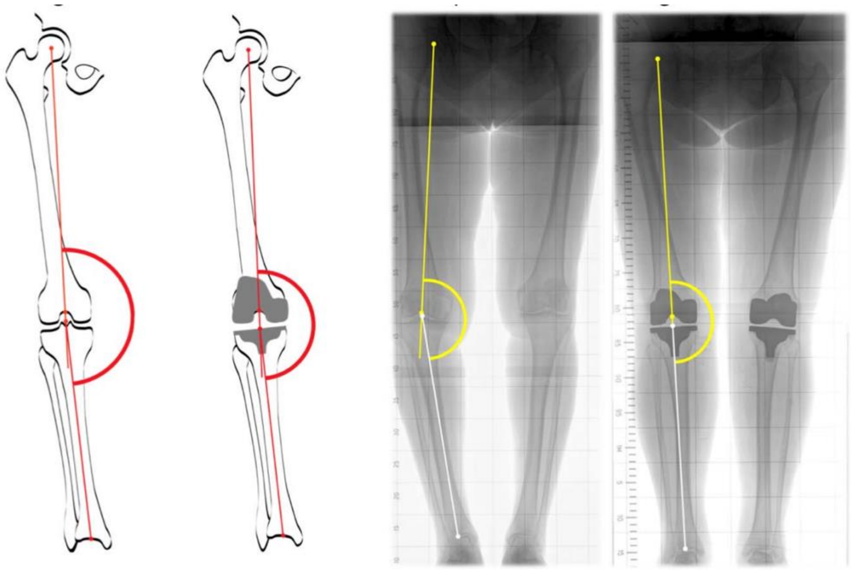


```r
# Calculate mean for each variable
means <- c(
  mean(phase1_data$dolor_rep_12m, na.rm = TRUE), mean(phase2_data$dolor_rep_12m, na.rm = TRUE),
  mean(phase1_data$dolor_mov_12m, na.rm = TRUE), mean(phase2_data$dolor_mov_12m, na.rm = TRUE),
  mean(phase1_data$nps_12m, na.rm = TRUE), mean(phase2_data$nps_12m, na.rm = TRUE),
  mean(phase1_data$satisfaction_12m, na.rm = TRUE), mean(phase2_data$satisfaction_12m, na.rm = TRUE),
  mean(phase1_data$fjs_12m, na.rm = TRUE)/10, mean(phase2_data$fjs_12m, na.rm = TRUE)/10,
  mean(phase1_data$koos12_12m, na.rm = TRUE)/10, mean(phase2_data$koos12_12m, na.rm = TRUE)/10
)

variables <- rep(c("Resting Pain", "Moving Pain",  "NPS", "Satisfaction", "FJS", "KOOS-12"), each = 2)
groups <- rep(c("Phase 1", "Phase 2"), 6)

# Organize data in a data frame
data_means <- data.frame(Variable = variables, Group = groups, Mean = means)
data_means <- data_means[order(data_means$Mean), ]
data_means$Variable <- factor(data_means$Variable, levels = unique(data_means$Variable))
library(ggplot2)

#Create barplot
ggplot(data_means, aes(x = Variable, y = Mean, fill = Group)) +
  geom_bar(stat = "identity", position = position_dodge(width = 0.9)) +
  geom_text(aes(label = round(Mean,2)), position = position_dodge(width = 0.9), vjust = -0.5, size = 3) +
  labs(title = "Comparison of functional variables per phase", y = "Mean Score") +
  theme_minimal() + scale_fill_manual(values = c("Phase 1" = "darkblue", "Phase 2" = "orange"))
```

ANNEX 3 – RADIOLOGICAL VARIABLES EXTRACTION

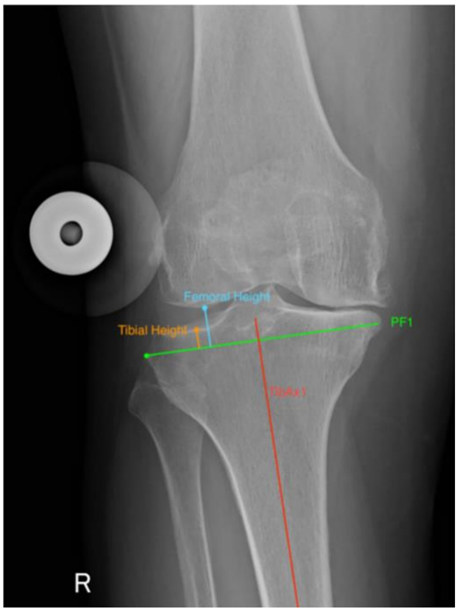
Hip-Knee-Ankle angle (HKA)

El ángulo HKA se obtiene por la intersección del eje mecánico femoral con el eje mecánico tibial.

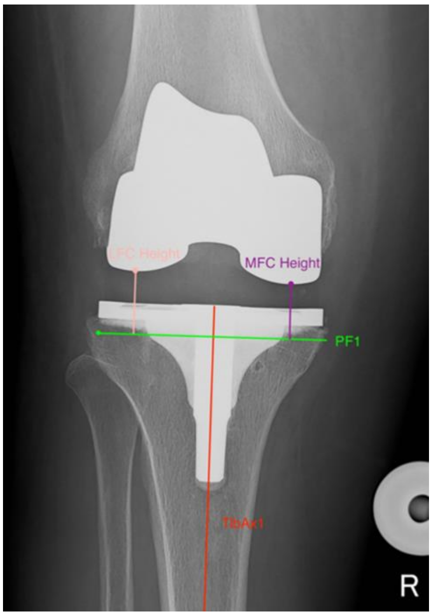


Joint Line Height (JLH)

Medición pre-operatoria



Medición post-operatoria



$$JLH_{PRE} = \frac{Tibial\ Height + Femoral\ Height}{2} \qquad JLH_{POST} = \frac{Medial\ JLH + Lateral\ JLH}{2}$$

$$Change\ in\ JLH\ (mm) = JLH_{POST} - JLH_{PRE}$$