Patient Information Sheet and Informed Consent

Official Title of the Study:

Knee Arthroplasty Surgery: Short-Term Effects of Robotic Assistance (ROSA). Randomized Study.

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Introduction

Total knee arthroplasty (TKA) is a common orthopedic surgical procedure. The survival rate of total knee prostheses is approximately 95% at 10 years and 90% at 15 years. Overall patient satisfaction is estimated at around 80%.

TKA failure is multifactorial, involving patient-related factors, implant design factors, and surgical technique. While patient-related risk factors and infection prevention protocols help reduce complications, current implant materials and designs are not a major cause of failure. Recent clinical series show that instability and malalignment are among the leading causes of early failure, which are primarily surgeon-dependent. Inadequate implant positioning, improper bone resection, or excessive or insufficient soft tissue release can be mitigated by improvements in surgical technique.

The goal of robotic assistance is to eliminate surgical inaccuracies and help execute the preoperative plan with precision. The robot positions and holds the cutting guide in place, assists with distal femoral cuts, determines prosthetic component sizes, and facilitates alignment and soft tissue balancing. The surgeon remains in full control of the saw and performs all bone cuts.

Robotic systems also enable intraoperative assessment of soft tissues, allowing the surgeon to implant the prosthesis in an anatomically adapted position, optimizing alignment and function. This increased precision may enhance early postoperative functional recovery compared to conventional TKA.

The ROSA surgical robot has been approved and commercially available since 2019. At Hospital Universitario Santa Cristina, the ROSA system has been used for TKA procedures since January 2021.

Objectives

Primary Objective:

To compare early functional recovery in patients undergoing TKA with robotic assistance versus conventional manual technique over the first three months after surgery.

Secondary Objectives:

- To analyze length of hospital stay, laboratory parameters, joint range of motion (ROM), and pain in both groups.

- To evaluate mechanical recovery following robotic and manual TKA.
- To compare postoperative long-leg standing radiographs in both groups.

Materials and Methods

Study Design:

Prospective, randomized, controlled study involving two groups of patients undergoing TKA, all operated on by the same experienced surgeon skilled in both conventional and robotic-assisted techniques.

Patients will be selected from those on the hospital surgical waiting list who meet inclusion criteria. Selection is blind and conducted by the hospital's administrative service, independent of the principal investigator. Randomization will follow a parallel 1:1 model, using dice rolls.

Each group will include a minimum of 30 patients, enabling the use of parametric tests supported by the Central Limit Theorem.

Inclusion Criteria

- Patients with primary osteoarthritis indicated for TKA who provide informed consent.
- All patients will receive the same prosthesis model: Persona® (Zimmer Biomet), a posterior-stabilized primary knee prosthesis with patellar resurfacing, approved through public procurement.

Exclusion Criteria

- Previous surgery on the affected knee.
- Presence of other prostheses in the same limb.
- Hip pathology on the same side (e.g., dysplasia, avascular necrosis, arthrodesis, flexion contractures) that limits bone mass or mobility.
- Active infections near the affected knee joint.
- Obesity (BMI > 30).
- Dependent patients.
- Residents of long-term care facilities.
- Anatomical abnormalities, ligament instability, or severe femoral-tibial misalignment requiring alternative prosthesis models.

Surgical Protocol and Randomization

All patients will receive the same implant model: Persona® (Zimmer Biomet, Warsaw, Indiana, USA). Robotic-assisted surgeries will be performed with the ROSA® system (Zimmer Biomet, Warsaw, Indiana, USA).

After preoperative assessment, patients will be added to the surgical schedule. Scheduling occurs 15 days in advance and is managed by the department head. Once scheduled, randomization is performed using dice rolls:

- Even number: Robotic TKA (Group 1)
- Odd number: Manual TKA (Group 2)

Follow-up Schedule

All TKA patients at Hospital Universitario Santa Cristina are followed up weekly in outpatient clinics. First follow-up occurs at 2–3 weeks post-op; subsequent visits are at 2, 3, 6, 9, and 12 months. Annual visits continue for 5 years, then every two years until 10 years.

In this study, patients follow the same clinical follow-up schedule, although the study itself concludes at 3 months.

Variables

Demographic

Age, sex, and comorbidities (diabetes mellitus, hypertension, rheumatoid arthritis, ischemic heart disease, anticoagulation).

Laboratory Parameters

Hemoglobin, hematocrit, ESR, CRP, and D-dimer levels will be recorded preoperatively, on the day of surgery (before and after the procedure), and at hospital discharge. Drain output (mL) during the first 24 hours post-op will also be recorded.

Surgical Parameters

Surgery duration (minutes), intraoperative complications (fracture, ligament or vascular injury), surgeon-performed bone cut corrections, and the difference (mm) between planned and robot-measured resections.

Pain

Assessed daily using a visual analog scale (VAS) during clinical rounds and recorded in the hospital's electronic medical record (HP-HCIS).

Length of Hospital Stay

Number of days from hospital admission for surgery to discharge, obtained from HP-HCIS.

Functional Recovery

Assessed using KOOS and SF-36 questionnaires preoperatively and at 2 and 3 months after surgery.

Joint Range of Motion

Measured daily with a goniometer and recorded in degrees of flexion and extension in the HP-HCIS.

Mechanical Recovery

Evaluated via surface electromyography (EMG) performed before surgery and at 3 months post-op using the Myomed 932 EMG device. Electrodes are placed over target muscle bellies, and both isometric (5-second contractions and rest, 1 minute) and isotonic (5 quick contractions and 5-second rest, 1 minute) protocols are performed. Peak and mean muscle strength are recorded.

Radiology

Preoperative AP/lateral X-rays and long-leg standing radiographs will be performed. Radiologic evaluation includes mechanical and anatomical axis, tibial slope, and osteoarthritis grade (Kellgren-Lawrence). Postoperative AP/lateral X-rays will be taken immediately post-op, at discharge, and at 2 and 3 months.

Data Management and Statistical Analysis

Data will be recorded in a coded database without personal identifiers. A separate confidential file linking study codes to patient identities (name, clinical ID, and national ID) will be kept by the principal investigator.

Patient outcomes will be analyzed over the 3-month period, comparing the evolution of each variable between groups. Descriptive statistics will be used, and group comparisons will be performed using Chi-square tests for binary variables. The CONSORT 2010 guidelines were followed in the preparation of the Methods section.

Ethical Considerations

All potential participants will be informed about the study during the preoperative consultation. An information sheet will be provided, and informed consent will be obtained prior to enrollment.