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Evaluation of Total Knee Arthroplasty with Robotic-Assisted Technology (HUPE/UERJ)

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We are still developing and optimizing this protocol

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Keywords: knee, osteoarthritis, arthroplasty , robotic-assisted surgery, evaluation of total knee arthroplasty, outcomes of total knee arthroplasty, total knee arthroplasty, assisted arthroplasty, arthroplasty at hupe, standardized preoperative planning, robotic assistance, using robotic assistance, first institutional implementation of robotic, standardized preoperative planning with ct imaging, robotic, reduced postoperative pain, assisted technology, postoperative follow, better functional recovery, blind clinical study, tka, postoperative pain, validated functional score

Abstract

This protocol describes a prospective, randomized, double-blind clinical study designed to evaluate the outcomes of total knee arthroplasty (TKA) performed with and without robotic-assisted technology (Mako SmartRobotics®, Stryker) at HUPE/UERJ. It includes standardized preoperative planning with CT imaging, structured data collection using validated functional scores (EVA, KSS, and FJS-12), and a six-month postoperative follow-up.
The expected results are improved precision in component positioning, reduced postoperative pain, and better functional recovery and patient satisfaction when using robotic assistance. This is the first institutional implementation of robotic-assisted arthroplasty at HUPE/UERJ and establishes the methodological foundation for future comparative and multicenter studies.

Attachments

PDF

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191KB

Guidelines

- This protocol must be conducted strictly under the approval of the Research Ethics Committee of the Universidade do Estado do Rio de Janeiro (HUPE/UERJ). All participants must sign a written informed consent (TCLE) before inclusion.
- The study involves human subjects undergoing total knee arthroplasty (TKA) and therefore must comply with the Declaration of Helsinki (2013 revision) and Resolution 466/12 of the Brazilian National Health Council (CNS).
- Only qualified orthopedic surgeons trained in robotic-assisted knee arthroplasty (Mako SmartRobotics, Stryker) are authorized to perform the surgical procedure.
- The preoperative CT scan follows the official Mako Knee CT Scanning Protocol (Stryker, 2022). Radiation exposure is minimal but must be justified and performed according to radiological protection standards.
- Preoperative assessment must include ASA, Ahlbäck, and Kellgren–Lawrence classifications, medical history, and identification of comorbidities that may interfere with anesthesia or rehabilitation.
- All clinical data and images should be anonymized prior to analysis. Patient identification codes must be stored securely in restricted-access systems.
- Adverse events, postoperative complications, or any protocol deviations must be reported to the Ethics Committee within the timeframe established by institutional policy.
- The robotic system and surgical tools must be calibrated and checked before each procedure according to the manufacturer's safety instructions.
- The data collection and analysis must follow Good Clinical Practice (GCP) standards and ensure confidentiality, integrity, and reproducibility of results.

Materials

1. Robotic and Surgical Equipment

- Mako SmartRobotics® System (Stryker, Kalamazoo, MI, USA) — robotic arm and console
- Standard Total Knee Arthroplasty Instrument Set (Stryker® Triathlon system or equivalent)
- Robotic-compatible cutting guides and trackers
- Calibration and registration tools for Mako system
- Sterile surgical drapes and disposable covers for robotic equipment
- Power system and console verification tools

2. Imaging and Planning

- Computed Tomography (CT) scanner capable of following the *Mako Knee CT Scanning Protocol* (Stryker, 2022)
- Planning software integrated with Mako SmartRobotic workstation
- Digital radiography system (RaizX Digital, IRICs) for postoperative alignment evaluation

3. Clinical and Functional Assessment

- Patient Data Collection Form (standardized for this protocol)
- EVA (Visual Analog Scale for pain) — printed or electronic form
- KSS (Knee Society Score) — validated Portuguese version (Silva ALPE et al., 2017)
- FJS-12 (Forgotten Joint Score) — validated Portuguese version (Ferreira MC et al., 2018)
- Goniometer for joint range of motion measurement
- Standard radiographic ruler or alignment gauge

4. Patient Care and Monitoring

- Hospital bed and physiotherapy equipment for early mobilization
- Standard anesthesia and monitoring equipment
- Sterile dressing materials and postoperative care supplies
- Pain management medications as per institutional protocol

5. Data Analysis and Documentation

- Computer with IBM SPSS Statistics v29.0
- Excel or equivalent spreadsheet software for data entry
- Secure data storage (password-protected folder or encrypted cloud drive)
- Institutional Ethics documentation (HUPE/UERJ CEP approval and TCLE forms)

Before start

Before starting this protocol, ensure that:

1. Ethics approval has been obtained from the Research Ethics Committee of the Hospital Universitário Pedro Ernesto (HUPE/UERJ).
2. Written informed consent (TCLE) has been signed by each participant.
3. The robotic system (Mako SmartRobotics, Stryker) and all surgical instruments are properly calibrated, sterilized, and verified according to manufacturer guidelines.
4. The preoperative CT scan has been performed following the official Mako Knee CT Scanning Protocol (Stryker, 2022) and the data are correctly imported into the planning software.
5. The operative team (orthopedic surgeon, anesthesiologist, nursing staff, and radiology technician) has been briefed on the study protocol and their assigned roles.
6. All data collection sheets, including the Patient Data Collection Form and Functional Assessment Protocols (EVA, KSS, FJS-12), are available and pre-labeled with anonymized patient codes.
7. The surgical room and robotic console are configured for safe operation, including power supply check, emergency stop verification, and availability of a backup conventional instrument set.

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