# Clinical evaluation of the NaviFast 6D system for intraoperative limb length control in total hip arthroplasty

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## Abstract

**Background and purpose**: Accurate restoration of leg length and femoral offset is critical in total hip arthroplasty (THA), yet intraoperative verification methods remain limited. This clinical study evaluated the accuracy, safety, and feasibility of a novel miniaturized intraoperative measurement arm, NaviFast 6D, in THA.

**Methods**: A prospective two-phase investigation was conducted at four centers. In Phase I, measurements obtained using NaviFast 6D were compared to reference radiographic assessments (via LLDcalc) in 22 cases, and RMS of differences and device measurement error were derived. Phase II (20 analyzable cases) enabled intraoperative adjustment of implant selection based on device data, compared with a control group (n = 30) that was operated using only clinical limb length assessment. Statistical testing included F-ratio comparisons ($v_1 = 29$, $v_2 = 19$). Adverse events, device deficiencies, and procedural deviations were systematically recorded.

**Results**: In the full study sample, the estimated RMS error for NaviFast 6D in LLD measurement was 1.3 mm. The F-statistic for improvement relative to the standard assessment was 5.06 ($p = 0.00026$). No serious device-related complications occurred. Minor adverse events (rim fracture, chipping, screw loosening) were attributed to surgical technique and corrected without lasting effects. The mean absolute postoperative leg length discrepancy (|LLD|) in the study group was 2.5 mm, which was approximately half of that observed in the control group (4.6 mm). The use of the device added ~15 minutes to operative time.

**Conclusion**: NaviFast 6D demonstrated promising accuracy, safety, and intraoperative usability for improving leg length restoration in THA.

# 1 Introduction

## *1.1 Needs Analysis*

Total hip arthroplasty (THA) is among the most common reconstructive surgeries, with U.S. rates increasing from 142 to 257 per 100,000 people between 2000 and 2010 [1]. In 2022, European countries such as Germany, Austria, Denmark, and Belgium reported 282–326 per 100,000, compared to the OECD average of 172. Precise restoration of limb length and hip offset is crucial for maintaining stability, improving gait, enhancing muscle strength, and ensuring patient satisfaction [2, 3]. Inaccurate reconstruction may cause limping, a Trendelenburg gait, lumbar pain, dissatisfaction, and medicolegal issues, and may necessitate revision [4].

Leg length discrepancy (LLD) occurs in 3%–27% of THA cases, averaging 3–17 mm; differences under 10 mm are usually tolerated. Offset errors also impair function—insufficient offset weakens abductors and destabilizes the hip, while excessive offset increases tension and discomfort [5]. Although preoperative templating is essential, its accuracy is limited by radiographic distortion, calibration, and anatomical variability. Digital methods improve prediction but still produce notable outliers [6].

## *1.2 Existing Solutions*

Various intraoperative methods aim to minimize leg length and offset errors in total hip arthroplasty (THA), including clinical assessment, templating, mechanical devices, intraoperative imaging, and computer-assisted systems [7]. Visual or manual assessment is simple and inexpensive but prone to inaccuracies, especially with pelvic tilt or rotation, and often fails to detect discrepancies under 5–10 mm [7]. Analogue and digital templating help

plan implant size and offset but depend on the surgeon's experience, imaging quality, and patient anatomy [7].

Mechanical devices attached to pelvic or femoral landmarks improve reproducibility yet add steps and may shift during surgery [8]. Intraoperative fluoroscopy, particularly with the direct anterior approach, offers real-time visualization of implant position and limb length; however, it increases radiation exposure and procedural complexity [9]. Computer-assisted navigation and robotic systems offer the greatest precision but remain limited by cost and technical demands [10]; registry data show 2-6% usage in the U.S. and Australia. Compact, user-friendly systems, such as the Intellijoint HIP, enable accurate assessment of limb length and offset without major workflow disruption [11].

The aim of this study was to validate the performance of a novel device for intraoperative assessment of limb length change during THA and to test the hypothesis that its use significantly improves postoperative LLD.

# 2. Materials and methods

## 2.1 Description, Intended Use, and Design of the Investigated Device

The clinical study evaluated the NaviFast 6D device (Robotic Medical Solutions Ltd., Łódź, Poland), designed to monitor femoral positional changes during total hip arthroplasty (THA) and verify intraoperative femoral translation and offset variation. The system measures relative, not absolute, differences between baseline and postoperative states, indicating the degree of limb lengthening, shortening, or offset change.

The measuring arm consists of rotationally connected segments; one includes a microprocessor unit with a display that processes sensor data and communicates results to the surgeon. The arm attaches via reusable, sterilizable iliac and femoral mounts (Fig. 1), secured with cannulated stainless-steel screws and positioning pins for reproducibility. After initial measurement, mounts can be detached to avoid procedural interference. A secondary measurement follows cup and trial head placement to guide prosthesis selection.

Previous studies confirm the accuracy and repeatability of NaviFast 6D, supporting its intraoperative utility in THA [12, 13, 14].

## 2.2 Study Design and Methods

The clinical investigation complied with Regulation (EU) 2017/745 on medical devices. The protocol was approved by the Bioethics Committee of the Regional Medical Chamber in Wielkopolska (January 18, 2023; December 13, 2023) and the Polish Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products (April 3, 2023; May 6, 2024), and was registered in Eudamed under number CIV-25-06-053214. The final report received ethical approval on May 21, 2025.

**Study Population**

Eligible participants were adults (20–85 years) scheduled for primary total hip arthroplasty (THA) using standard techniques who provided informed consent. Exclusion criteria included pregnancy, proximal femoral fractures, pseudoarthrosis, severe post-traumatic deformities, bone malignancy, osteomyelitis, and advanced osteoporosis.

**Study Design**

The investigation comprised two phases.

Phase I aimed to verify measurement accuracy and optimize the NaviFast 6D instrumentation. Preoperative anteroposterior (AP) pelvic radiographs supported surgical planning; optional use of LLDcalc software (Lodz University of Technology) allowed automated calculation of leg length and offset discrepancies [15]. Standard THA was performed, with additional intraoperative measurements recorded using NaviFast 6D according to manufacturer instructions. Cannulated screws were inserted into the greater trochanter and supra-acetabular region, and baseline data were collected before component implantation. After prosthesis placement, a second measurement was taken to assess intraoperative limb length and offset changes (Fig. 2). Surgeons were instructed not to alter their intraoperative decisions based on device data. For postoperative verification, AP X-rays of the pelvis were taken again.

**Phase I endpoints** included:

- root mean square (RMS) of differences between NaviFast 6D measurements and radiographic measurements of LLD/LOD changes (ΔLLD/ΔLOD),,
- analysis of operative time impact.

**Phase II** used the finalized device version. Procedures replicated Phase I, except that surgeons could adjust prosthetic components based on NaviFast 6D results and preoperative planning.

**Phase II endpoints** included:

- root mean square (RMS) of differences between NaviFast 6D measurements and radiographic measurements of LLD/LOD changes (ΔLLD/ΔLOD),
- estimated operative time attributable to device use,
- evaluation of limb length and offset restoration (mean and maximal residual differences per operator and overall),

- hypothesis testing: *“NaviFast 6D improves restoration of hip joint anatomy”*, comparing study and control groups.

**Study Sites and Cohort**

The study was conducted at four centers:

- Regional Hospital in Kalisz (n=26; 13 NaviFast, 13 controls),
- Military Clinical Hospital, Lublin (n=49; 32 NaviFast, 17 controls),
- Pabianice Medical Center (n=5; all NaviFast),
- University Orthopedic and Rehabilitation Hospital, Zakopane (n=4; 3 NaviFast, 1 control).

Overall, 84 patients (32 men, 52 women; mean age 62.5 years, range 45–80) were enrolled. The final analysis included 44 patients with complete measurement data. Exclusions comprised 31 controls and 9 cases with protocol deviations, incomplete imaging, or fixation issues (Fig. 3). Phase I ran from April to September 2023 and Phase II from October 2023 to August 2024.

## 2.3 Uncertainty of the Based on AI and Edge Detection in Radiographs Reference Measurement

During the study, the Lodz University of Technology developed LLDcalc (Leg Length Discrepancy Calculator) [15]. The software utilizes AI algorithms to automatically identify anatomical landmarks on pelvic radiographs, normalize femoral adduction angles, detect femoral and ischial tuberosities, and calculate leg length discrepancy (LLD) and offset

discrepancy (LOD) (Fig. 4). Manual correction is possible for atypical anatomy or suboptimal imaging.

Validation was performed on 17 pairs of pelvic radiographs from patients in identical clinical states (no THA between images). As the automated mode is operator-independent, a single operator conducted analyses with minimal manual adjustment. Expected differences in LLD and LOD were assumed to be zero. Statistical analysis included root mean square (RMS) error, maximum absolute error, and mean difference, compared with manual measurements by an experienced orthopedic surgeon.

Automated LLDcalc analysis revealed a markedly lower RMS error for LLD compared with manual measurement (1.91 mm vs. 4.48 mm), but a higher RMS error for LOD (5.54 mm vs. 3.94 mm). An F-test ($\alpha = 0.05$; $v = 17$) confirmed significantly lower variability for LLD using the automated method ($F = 5.53 > 2.58$; $p = 0.0007$) (Table 1).

Reduced reproducibility for LOD was attributed to pelvic rotation variability during imaging, as rotational errors cannot be quantified from standard radiographs.

For subsequent NaviFast 6D accuracy analysis, measurement uncertainty was adopted from LLDcalc results:

- RMS_LLD = 1.91 mm
- RMS_LOD = 5.54 mm

Further details on algorithm design and validation will be presented separately.

## 2.4 Results

### 2.4.1 Phase I Endpoint

For all Phase I and II procedures, reference measurements were obtained using the validated LLDcalc software [15]. Phase I endpoints were analyzed both separately and for the combined cohort (Fig. 5). For Leg Length Discrepancy (LLD) and Leg Offset Discrepancy (LOD), the root mean square (RMS) of the differences (ΔLLD and ΔLOD) between the values measured with the NaviFast 6D system and the corresponding radiographic measurements was calculated (Table 2).

To estimate the RMS error of NaviFast 6D, it was assumed that radiographic and device measurement errors were independent, followed a normal distribution, and had a mean of zero. Accordingly, the total variance of differences equals the sum of both variances:

$$RMS_{\Delta}^{2} = RMS_{NaviFast6D}^{2} + RMS_{X-ray}^{2}$$

From this, the RMS error of NaviFast 6D was derived:

$$RMS_{NaviFast6D} = \sqrt{RMS_{\Delta}^{2} - RMS_{X-ray}^{2}}$$

Inconsistency in LOD measurements was attributed to hip rotation, which markedly affects projected femoral offset on AP radiographs and is difficult to standardize in osteoarthritic hips [16]. Although radiographs were intended to be taken with 15° internal rotation**,** most patients were unable to maintain this position due to limited hip mobility or pain. Consequently, radiographic validation of LOD was unreliable, not implying inaccuracy of NaviFast 6D, but rather limitations of the reference imaging method. Tests on the experimental stand showed that the accuracy of the LLD and LOD measurements using the NaviFast6D is the same [13].

### 2.4.2 Phase II Endpoint

The primary Phase II endpoint was the mean and maximum postoperative differences in leg length and offset between surgeries performed with and without NaviFast 6D.

Only Lublin and Kalisz centers participated in Phase II. In Lublin, 21 surgeries were performed; 19 were analyzed. Two cases were excluded—one due to intentional asymmetry for muscle tension preservation, and one because severe deformity precluded reliable radiographic assessment. In Kalisz, two surgeries were conducted; one was excluded due to incomplete radiographs. Results are presented in Table 3 and in Fig. 6.

The hypothesis that NaviFast 6D intraoperative measurement reduces leg length discrepancy compared to clinical assessment alone was statistically confirmed. With $v_1 = 29$, $v_2 = 19$, and $\alpha = 0.05$, the critical F-value was 2.077, while the observed $F = (6.3^2 / 2.8^2) = 5.06$. The resulting $p = 0.00026$ provides strong evidence that NaviFast 6D significantly improves the accuracy of symmetrical limb length restoration during total hip arthroplasty.

### 2.4.3 Secondary Endpoint

Per protocol, secondary endpoints included comparing operative times between procedures with and without NaviFast 6D. Although attempts were made to record surgeries, video documentation was infeasible due to aseptic constraints and lack of recording equipment. Consequently, analysis relied on surgeons' subjective estimates, indicating that after the learning phase, device use prolonged operations by approximately 15 minutes, primarily due to screw fixation, measurement, and component adjustment steps.

## 2.5 Serious Adverse Events, Device Deficiencies, and Corrective Actions

No serious adverse events occurred during the investigation.

Three medical adverse events were reported: a nondisplaced acetabular rim fracture, minor acetabular roof chipping, and screw loosening during reaming. All were attributed to a technical error—screw placement too close to the rim. The NaviFast 6D arm was withdrawn in these cases, and no adverse clinical outcomes were observed. Such rim or roof injuries are recognized complications related to bone quality and surgical technique [17].

Corrective actions included enforcing a minimum 10 mm safety margin for supra-acetabular screw insertion and advising surgeons to increase this distance or avoid using the device in osteoporotic bone. These measures align with literature recommendations to minimize iatrogenic acetabular injury [54].

During early use, four measurement arms displayed internal start-up errors. These devices were excluded, returned to the manufacturer (Robotic Medical Solutions Ltd), and analyzed. The issue was traced to out-of-tolerance components from one batch. Enhanced inspection and updated assembly procedures were implemented. This conforms with regulatory standards for device deficiency management.

Throughout Phase I, the mechanical properties of the iliac base peg and femoral mount pins were iteratively optimized to prevent bending from nonparallel screw insertion. Two connector damages occurred before final optimization and were not classified as adverse events, as they were part of predefined technical improvements. After modification, the issue

did not recur. Such iterative adjustments reflect good practice for investigational device development.

In two cases, measurements were aborted due to screw loosening in osteoporotic bone, and in three others because of intraoperative bleeding unrelated to device use. These were classified as procedure discontinuations in accordance with investigation standards.

Fixation of the device required additional bone perforations, but no related adverse effects were noted. Similar temporary penetrations (e.g., K-wires) are common in orthopaedics. Although additional holes and prolonged operative time could slightly increase blood loss, literature indicates that standard haemostatic measures effectively mitigate this risk [18].

# 3. Discussion and General Conclusions on Safety and Performance

## 3.1 Conclusions from the Analysis of the Reference Method – Measurement of LLD and LOD on Radiographs

One of the main challenges of the study was the absence of a fully reliable reference measurement method. Conventional radiographic measurements showed high inter-operator variability and inconsistencies even between repeated radiographs of the same patient. The automated method developed and validated during the trial (available at *LLDcalc.com*) reduced the RMS error for LLD more than twofold, achieving 1.91 mm (Table 1). This accuracy was sufficient for evaluating the NaviFast 6D system but still too limited to precisely determine its intrinsic measurement precision (see Section 7.1.2).

Accurate selection of anatomical landmarks was crucial. In most cases, measurements based on the femoral outline were reliable, but discrepancies between limbs occurred due to differences in rotation, altering the visibility of the lesser trochanter and apparent femoral width. Additional causes included post-traumatic deformities or remodeling from long-term prosthesis loading. In such cases, measurements referenced the greater trochanter instead.

Defining a consistent horizontal reference line was also essential. Two methods are described in the literature: the line tangent to the ischial tuberosities and the line connecting the Köhler's teardrop apices, with the latter offering slightly better accuracy. In this study, the ischial tuberosity tangent was preferred due to easier identification. The teardrop landmark was frequently obscured by the acetabular component. When both were visible but the tuberosities were asymmetrical (e.g., from pelvic rotation), the teardrop-based line was used. In two cases, this choice altered the measured LLD by 9–10 mm, and in four by about 2 mm.

In contrast, LOD (leg offset discrepancy) accuracy was substantially lower using both conventional and automated methods, mainly due to its sensitivity to limb rotation. Although radiographs were intended to be taken with 15° internal rotation, this was often unachievable in patients with osteoarthritis or postoperative pain, limiting reliable offset assessment.

## 3.2 Conclusions from Phase I of the Clinical Investigation

According to the clinical investigation plan, the target RMS difference between NaviFast 6D and radiographic reference measurements was < 3 mm. The obtained value for LLD was 2.5 mm, meeting this criterion; a similar result (2.3 mm) was also observed when all Phase I and II data were combined. Based on these results and the known radiographic accuracy, the precision of NaviFast 6D was calculated as RMS = 1.3 mm, corresponding to a 95% confidence accuracy of 2.6 mm.

This precision is sufficient for intraoperative assessment of limb length, enabling accurate implant adjustment. It is smaller than the typical 3 mm increment between femoral head sizes and well below the ≈6 mm threshold considered clinically imperceptible.

For LOD (leg offset discrepancy), the radiographic reference error was approximately twice the target precision for NaviFast 6D, making direct validation impossible. Additionally, the $RMS_{LODcalc}$ = 5.54 mm obtained during control validation (Section 5.3.2) could not be applied to pre- and postoperative radiographs, as most patients were unable to maintain adequate limb rotation due to pain or stiffness.

Consequently, LOD measurement accuracy could not be validated in this study. However, laboratory testing conducted by the sponsor demonstrated comparable precision for LOD (0.5 mm) and LLD (0.7 mm) measurements [13]. The lack of clinical LOD validation suggests that surgeons should not rely exclusively on LOD data for intraoperative decisions. Nonetheless, this limitation has minimal practical significance, as femoral offset is typically adjusted based on muscle tension rather than absolute numerical values. Therefore, LOD results from NaviFast 6D should be considered supplementary and subject to clinical verification.

## 3.3 Conclusions from Phase II of the Clinical Investigation

Phase II of the clinical study confirmed that intraoperative use of the NaviFast 6D arm during total hip arthroplasty improved clinical outcomes in terms of restoring equal limb length. The mean absolute postoperative |LLD| in the study group was 2.5 mm, approximately half the value observed in the control group (4.6 mm). The study protocol anticipated that 90% of measurements would fall below 6 mm; in fact, all cases met this criterion, exceeding expectations.

A statistical test was performed to verify the hypothesis that the intraoperative use of NaviFast 6D results in smaller absolute limb length differences compared to clinical assessment alone. Based on the Phase II experimental data and corresponding degrees of freedom, the calculated p-value was $p = 0.00073$, confirming a highly significant improvement. These findings provide strong evidence that the NaviFast 6D arm enhances the accuracy of anatomic leg length restoration during total hip arthroplasty.

## 3.4 Conclusions on the Secondary Endpoint

The use of the NaviFast 6D device increased operative time by approximately 15 minutes, with a slightly longer duration during the initial learning phase. Given that standard total hip arthroplasty typically takes about 90 minutes [19]**,** this represents only a minor prolongation, clinically negligible from a hospital workflow perspective, as overall throughput depends mainly on preparation and turnover times.

The improvement in LLD correction achieved with NaviFast 6D aligns with meta-analyses showing that navigation or imageless systems enhance accuracy while modestly extending operative duration ($102.6 \pm 35.6$ vs. $91.6 \pm 37.4$ min, $p < 0.001$) [19]. Importantly, no increase in intraoperative bleeding was observed; in cases of unrelated bleeding, early termination of measurements had no adverse effect on surgical outcomes.

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## Author Contributions:

Ireneusz Urbaniak, Jan Blacha, Tomasz Dekert, Tomasz Tuzikiewicz, Wojciech Kącki, and Jakub Kalisz – conduct of clinical investigations;

Michał Panasiuk – study design, preparation of the introduction and conclusions;

Agnieszka Kobierska – statistical analysis, results interpretation, and formulation of conclusions;

Leszek Podsędkowski – preparation of the materials and methods section.

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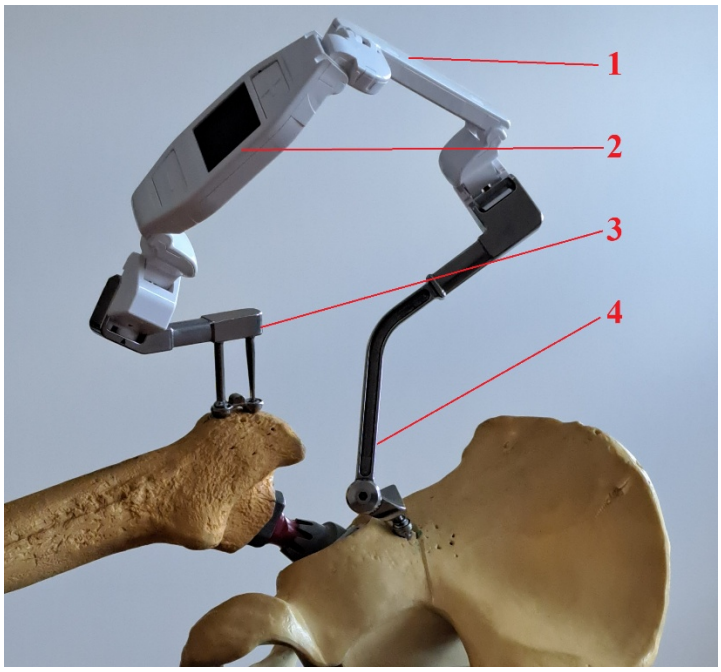



*Fig. 1. NaviFast6D: 1. The measuring arm; 2. Microprocessor unit with display; 3. Femoral mount; 4. Iliac mount*

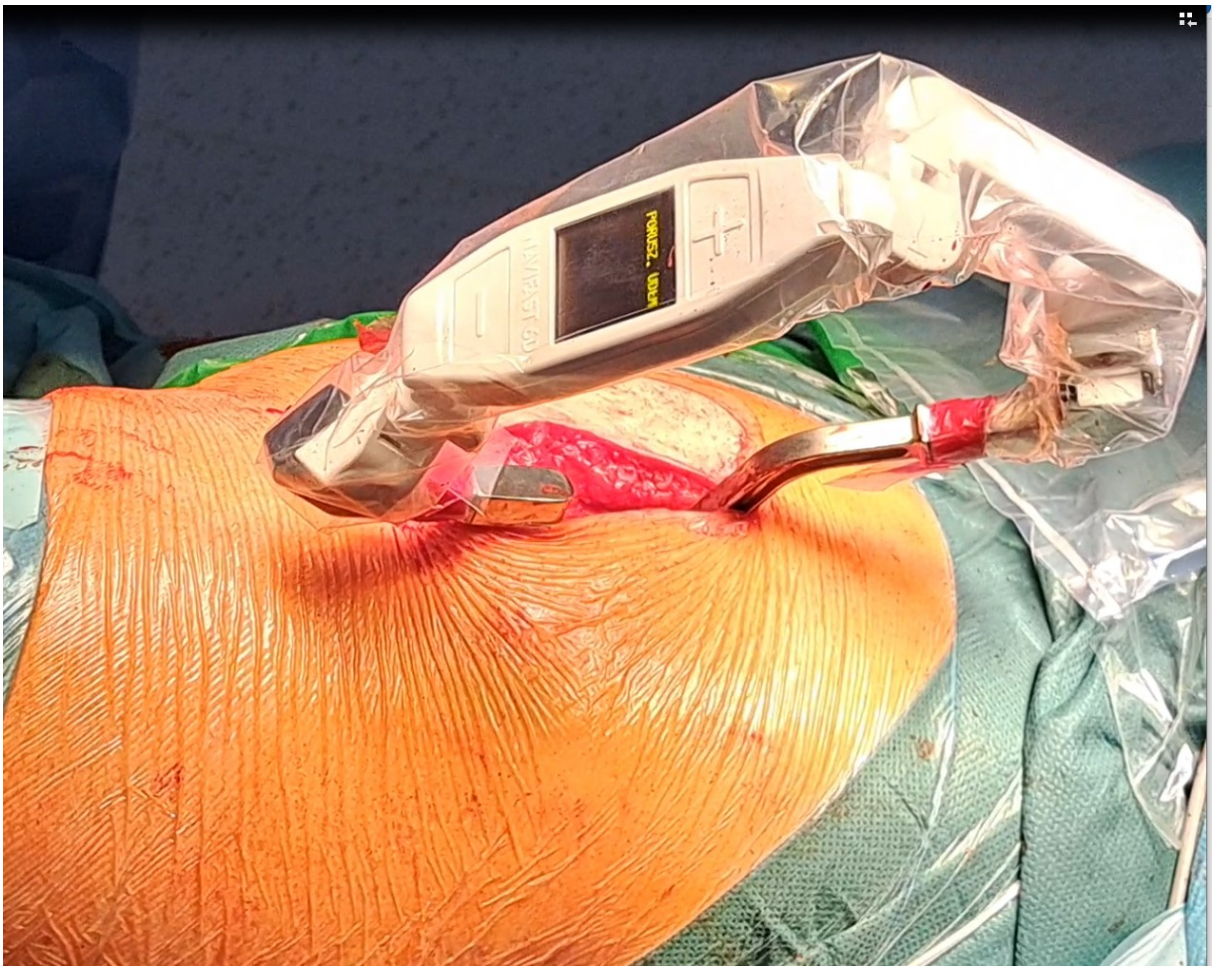


*Fig. 2. NaviFast 6D measurement system during THA surgery*

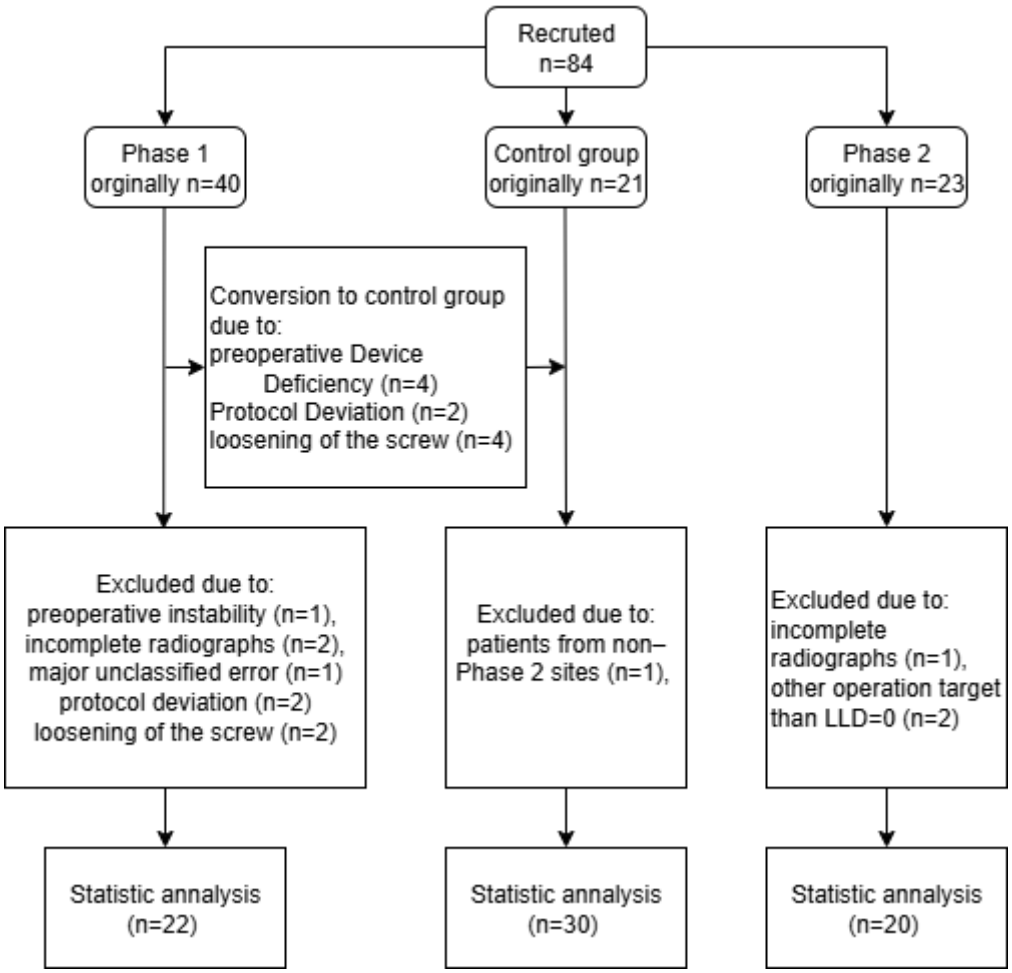



*Fig. 3. Flow chart for inclusion and exclusion of patients*

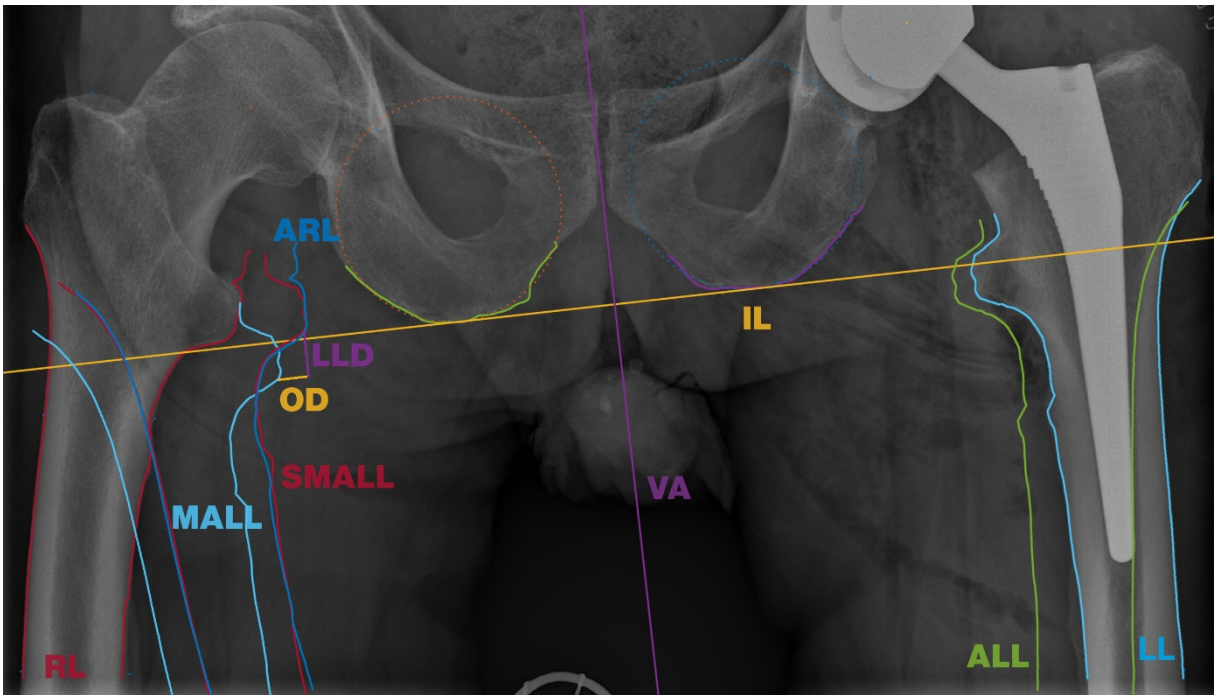
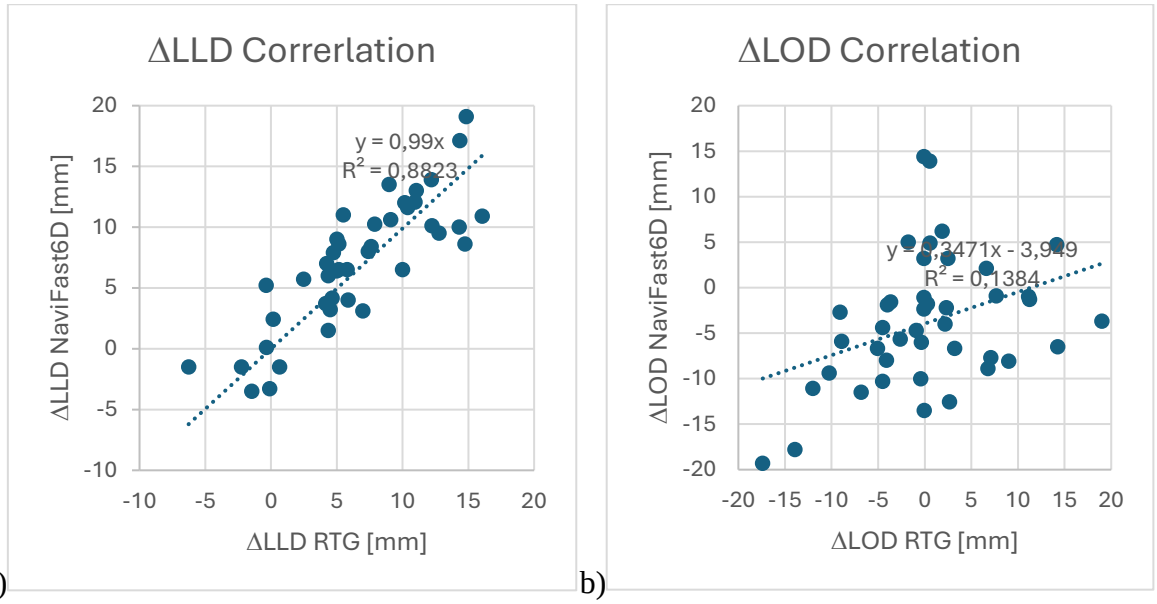



*Fig. 4.* ***Illustration of the Leg Length Discrepancy Calculator (LLDcalc.com) workflow.*** *RL – right leg; ARL – adducted (abducted) right leg; LL – left leg; ALL – adducted (abducted) left leg; MALL – mirror image of ALL; SMALL – shifted MALL to overlap with ARL; LLD – leg length discrepancy; OD – offset difference (LOD); VA – vertical axis; IL – ischial line.*




a) b)

*Fig. 5. Correlation for variables: a) ΔLLD and b) ΔLOD assessed using X-ray imaging and the NaviFast6D system*

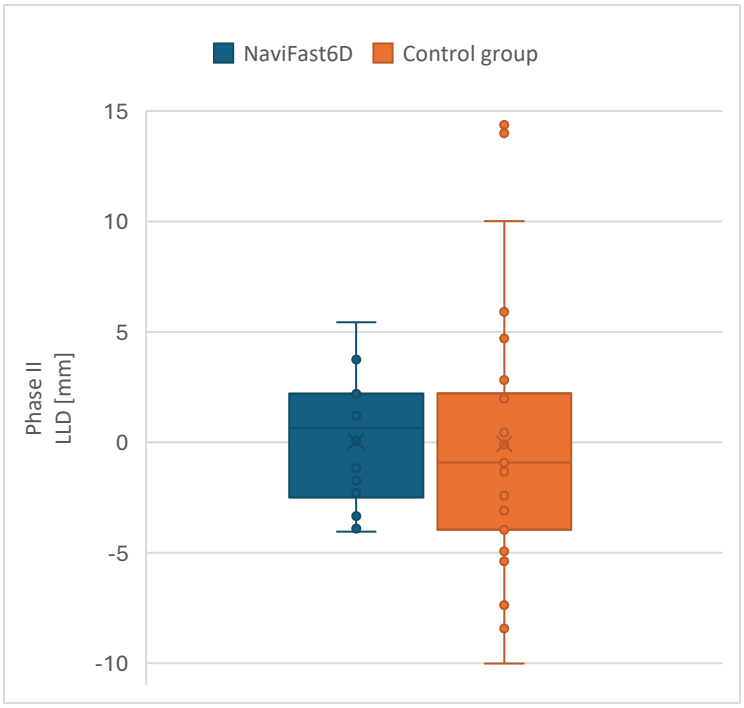



*Fig. 6. LLD Phase II results*

*Table 1. Error analysis of radiographic measurements of LLD and LOD*

| **Method** | **LLD RMS (mm)** | **LLD Max (mm)** | **LLD Mean (mm)** | **LOD RMS (mm)** | **LOD Max (mm)** | **LOD Mean (mm)** |
|---|---|---|---|---|---|---|
| Traditional manual | 4.48 | 9.56 | 0.92 | 3.94 | 7.22 | 0.82 |
| Automated (LLDcalc.com) | 1.91 | 5.09 | 0.09 | 5.54 | 8.21 | –0.42 |

*Table 2. RMS difference values between radiographic and NaviFast 6D measurements*

| | **Phase I study** | | **Entire clinical study** | |
|---|---|---|---|---|
| Number of analyzed cases | 22 | | 44 | |
| | ΔLLD [mm] | ΔLOD [mm] | ΔLLD [mm] | ΔLOD [mm] |
| RMS difference $RMS_{\Delta}$ | 2,5 | 9,1 | 2,3 | 10,4 |
| RMS error of X-ray $RMS_{X-ray}$ | 1,9 | 5,5 | 1,9 | 5,5 |
| RMS error of NaviFast 6D $RMS_{NaviFast6D}$ | 1,7 | 7,2 | 1,3 | 8,9 |
| Compliance with assumptions | Yes | No | Yes | No |

Table 3. Analysis of postoperative leg length discrepancy (LLD) in Phase II

| | Lublin | Kalisz | Total |
|---|---|---|---|
| Number of control cases | 17 | 13 | 30 |

| | | | |
|---|---|---|---|
| Mean postoperative \|LLD\| [mm] | 4.5 | 5.4 | 4.9 |
| RMS postoperative LLD [mm] | 5.7 | 7.0 | 6.3 |
| Max postoperative LLD [mm] | 14.0 | 14.4 | 14.4 |
| % of cases with LLD < 6 mm | 82% | 61% | 73% |
| Number of Phase II cases analyzed | 19 | 1 | 20 |
| Mean postoperative \|LLD\| [mm] | 2.4 | 3.7 | 2.5 |
| RMS postoperative LLD [mm] | 2.7 | 3.7 | 2.8 |
| Max postoperative LLD [mm] | 5.4 | 3.7 | 5.4 |
| % of cases with LLD < 6 mm | 100% | 100% | 100% |

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